

**[Committee Print]**110<sup>TH</sup> CONGRESS  
1<sup>ST</sup> SESSION**H. R.** \_\_\_\_\_

To amend the Public Health Service Act to provide for the establishment of a clinical trial registry database and a clinical trial results database, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

M\_\_\_\_. \_\_\_\_\_ introduced the following bill; which was referred to the  
Committee on \_\_\_\_\_

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**A BILL**

To amend the Public Health Service Act to provide for the establishment of a clinical trial registry database and a clinical trial results database, and for other purposes.

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. CLINICAL TRIAL REGISTRY DATABASE AND**  
4 **CLINICAL TRIAL RESULTS DATABASE.**

5 (a) IN GENERAL.—Subsection (i) of section 402 of  
6 the Public Health Service Act (42 U.S.C. 282), as amend-  
7 ed by Public Law 109–482, is amended to read as follows:

1           “(i) CLINICAL TRIAL REGISTRY DATABASE; CLIN-  
2 ICAL TRIAL RESULTS DATABASE.—

3           “(1) DEFINITIONS.—In this subsection:

4           “(A) APPLICABLE CLINICAL TRIAL.—The  
5 term ‘applicable clinical trial’—

6           “(i) means a clinical trial that is con-  
7 ducted to test the safety or effectiveness  
8 (including comparative effectiveness) of a  
9 drug or device (irrespective of whether the  
10 clinical trial is federally or privately fund-  
11 ed, and whether the clinical trial involves  
12 an approved or unapproved drug or de-  
13 vice);

14           “(ii) includes such a clinical trial that  
15 is conducted outside of the United States  
16 if—

17           “(I) there is an application or  
18 premarket notification pending before  
19 the Food and Drug Administration  
20 for approval or clearance of the drug  
21 or device involved under section 505,  
22 510(k), or 515 of the Federal Food,  
23 Drug, and Cosmetic Act or section  
24 351 of this Act; or

1 “(II) the drug or device involved  
2 is so approved or cleared; and

3 “(iii) notwithstanding subclauses (I)  
4 and (II), excludes—

5 “(I) a clinical trial to determine  
6 the safety of a use of a drug that is  
7 designed solely to detect major  
8 toxicities in the drug or to investigate  
9 pharmacokinetics, unless the clinical  
10 trial is designed to investigate phar-  
11 macokinetics in a special population  
12 or populations; and

13 “(II) a small clinical trial to de-  
14 termine the feasibility of a device, or  
15 a clinical trial to test prototype de-  
16 vices where the primary focus is feasi-  
17 bility.

18 “(B) CLINICAL TRIAL INFORMATION.—The  
19 term ‘clinical trial information’ means those  
20 data elements that are necessary to complete an  
21 entry in the clinical trial registry database  
22 under paragraph (2) or the clinical trial results  
23 database under paragraph (3), as applicable.

24 “(C) COMPLETION DATE.—The term ‘com-  
25 pletion date’ means the date of the final collec-

1           tion of data from subjects in the clinical trial  
2           for the primary and secondary outcomes to be  
3           examined in the trial.

4           “(D) DEVICE.—The term ‘device’ has the  
5           meaning given to that term in section 201(h) of  
6           the Federal Food, Drug, and Cosmetic Act.

7           “(E) DRUG.—The term ‘drug’ means a  
8           drug as defined in section 201(g) of the Federal  
9           Food, Drug, and Cosmetic Act or a biological  
10          product as defined in section 351 of this Act.

11          “(F) RESPONSIBLE PARTY.—The term ‘re-  
12          sponsible party’, with respect to an applicable  
13          clinical trial, means—

14                 “(i) the primary sponsor (as defined  
15                 in the International Clinical Trials Reg-  
16                 istry Platform trial registration data set of  
17                 the World Health Organization) of the  
18                 clinical trial; or

19                 “(ii) the principal investigator of such  
20                 clinical trial if so designated by such spon-  
21                 sor, so long as the principal investigator is  
22                 responsible for conducting the trial, has ac-  
23                 cess to and control over the data, has the  
24                 right to publish the results of the trial, and  
25                 has the responsibility to meet all of the re-

1            requirements under this section that are ap-  
2            plicable to responsible parties.

3            “(2) CLINICAL TRIALS REGISTRY DATABASE.—

4                  “(A) ESTABLISHMENT.—To enhance pa-  
5                  tient enrollment and provide a mechanism to  
6                  track subsequent progress of clinical trials, the  
7                  Secretary, acting through the Director of NIH,  
8                  shall establish and administer a clinical trial  
9                  registry database in accordance with this sub-  
10                 section (referred to in this subsection as the  
11                 ‘registry database’). The Director of NIH shall  
12                 ensure that the registry database is made pub-  
13                 licly available through the Internet.

14                  “(B) CONTENT.—The Secretary shall pro-  
15                  mulgate regulations for the submission to the  
16                  registry database of clinical trial information  
17                  that—

18                          “(i) conforms to the International  
19                          Clinical Trials Registry Platform trial reg-  
20                          istration data set of the World Health Or-  
21                          ganization;

22                          “(ii) includes the city, State, and zip  
23                          code for each clinical trial location;

24                          “(iii) includes a statement of the esti-  
25                          mated completion date for the clinical trial;

1                   “(iv) includes the identity and contact  
2 information of the responsible party;

3                   “(v) if the drug is not approved under  
4 section 505 of the Federal Food, Drug,  
5 and Cosmetic Act or licensed under section  
6 351 of this Act, or the device is not cleared  
7 under section 510(k) or approved under  
8 section 515 of the Federal Food, Drug,  
9 and Cosmetic Act, specifies whether or not  
10 there is expanded access to the drug or de-  
11 vice under section 561 of the Federal  
12 Food, Drug, and Cosmetic Act for those  
13 who do not qualify for enrollment in the  
14 clinical trial and how to obtain information  
15 about such access;

16                   “(vi) includes, with respect to any in-  
17 dividual who is not an employee of the re-  
18 sponsible party for the clinical trial or of  
19 the manufacturer of the drug or device in-  
20 volved, information on any agreement that  
21 the responsible party or manufacturer has  
22 entered into with such individual that re-  
23 stricts in any manner the ability of the in-  
24 dividual—

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

4                   “(II) to publish the results of the  
5                   trial, or a description or discussion of  
6                   the results of the trial, in a scientific  
7                   or academic journal; and

8                   “(vii) requires the inclusion of such  
9                   other data elements to the registry data-  
10                  base as appropriate.

11                  “(C) FORMAT AND STRUCTURE.—

12                  “(i) SEARCHABLE CATEGORIES.—The  
13                  Director of NIH shall ensure that the pub-  
14                  lic may search the entries in the registry  
15                  database by 1 or more of the following cri-  
16                  teria:

17                         “(I) The indication being studied  
18                         in the clinical trial, using Medical  
19                         Subject Headers (MeSH) descriptors.

20                         “(II) The safety issue being stud-  
21                         ied in the clinical trial.

22                         “(III) The enrollment status of  
23                         the clinical trial.

24                         “(IV) The sponsor of the clinical  
25                         trial.

1                   “(ii) FORMAT.—The Director of the  
2                   NIH shall ensure that the registry data-  
3                   base is easily used by patients, and that  
4                   entries are easily compared.

5                   “(D) DATA SUBMISSION.—The responsible  
6                   party for an applicable clinical trial shall submit  
7                   to the Director of NIH for inclusion in the reg-  
8                   istry database the clinical trial information de-  
9                   scribed in subparagraph (B).

10                  “(E) TRUTHFUL CLINICAL TRIAL INFOR-  
11                  MATION.—

12                   “(i) IN GENERAL.—The clinical trial  
13                   information submitted by a responsible  
14                   party under this paragraph shall not be  
15                   false or misleading in any particular.

16                   “(ii) EFFECT.—Clause (i) shall not  
17                   have the effect of requiring clinical trial in-  
18                   formation to include information from any  
19                   source other than the clinical trial involved.

20                  “(F) TIMING OF SUBMISSION.—Except as  
21                  provided in subparagraph (G), the clinical trial  
22                  information for a clinical trial required to be  
23                  submitted under this paragraph shall be sub-  
24                  mitted not later than 14 days after the first pa-  
25                  tient is enrolled in such clinical trial.

1           “(G) UPDATES.—The responsible party for  
2           an applicable clinical trial shall submit to the  
3           Director of NIH for inclusion in the registry  
4           database periodic updates to reflect changes to  
5           the clinical trial information submitted under  
6           this paragraph. Such updates—

7                   “(i) shall be provided not less than  
8                   once every six months until information on  
9                   the results of the trial is submitted under  
10                  paragraph (3);

11                  “(ii) shall include identification of the  
12                  dates of any such changes;

13                  “(iii) not later than 30 days after the  
14                  enrollment status of such clinical trial  
15                  changes, shall include an update of the en-  
16                  rollment status; and

17                  “(iv) not later than 30 days after the  
18                  completion date of the clinical trial, shall  
19                  include a report to the Director that such  
20                  clinical trial is complete.

21           “(3) CLINICAL TRIALS RESULTS DATABASE.—

22                   “(A) ESTABLISHMENT.—To ensure that  
23                   results of clinical trials are made public and  
24                   that patients and providers have current infor-  
25                   mation regarding the results of clinical trials,

1 the Secretary, acting through the Director of  
2 NIH, shall establish and administer a clinical  
3 trial results database in accordance with this  
4 subsection (referred to in this subsection as the  
5 ‘results database’). The Director of NIH shall  
6 ensure that the results database is made pub-  
7 licly available through the Internet.

8 “(B) SEARCHABLE CATEGORIES.—The Di-  
9 rector of NIH shall ensure that the public may  
10 search the entries in the results database by 1  
11 or more of the following:

12 “(i) The indication studied in the clin-  
13 ical trial, using Medical Subject Headers  
14 (MeSH) descriptors.

15 “(ii) The safety issue studied in the  
16 clinical trial.

17 “(iii) Whether an application for the  
18 tested indication is approved, pending ap-  
19 proval, withdrawn, or not submitted.

20 “(iv) The phase of the clinical trial.

21 “(v) The name of the drug or device  
22 that is the subject of the clinical trial.

23 “(vi) Within the documents described  
24 in subclauses (II) and (III) of subpara-

1 graph (C)(ii), the following information, as  
2 applicable:

3 “(I) The sponsor of the clinical  
4 trial.

5 “(II) Each financial sponsor of  
6 the clinical trial.

7 “(C) CONTENTS.—

8 “(i) IN GENERAL.—The responsible  
9 party for an applicable clinical trial shall  
10 submit to the Director of NIH for inclu-  
11 sion in the results database the clinical  
12 trial information described in clause (ii).

13 “(ii) REQUIRED ELEMENTS.—In sub-  
14 mitting clinical trial information for a clin-  
15 ical trial to the Director of NIH for inclu-  
16 sion in the results database, the respon-  
17 sible party shall include, with respect to  
18 such clinical trial, the following informa-  
19 tion:

20 “(I) The information described in  
21 clauses (i) through (v) of subpara-  
22 graph (B).

23 “(II) A non-promotional sum-  
24 mary document that is written in non-

1 technical, understandable language for  
2 patients that includes the following:

3 “(aa) The purpose of the  
4 clinical trial.

5 “(bb) The sponsor of the  
6 clinical trial.

7 “(cc) A point of contact for  
8 information about the clinical  
9 trial.

10 “(dd) A description of the  
11 patient population tested in the  
12 clinical trial.

13 “(ee) A general description  
14 of the clinical trial and results,  
15 including a description of and the  
16 reasons for any changes in the  
17 clinical trial design that occurred  
18 since the date of submission of  
19 clinical trial information for in-  
20 clusion in the registry database  
21 established under paragraph (2)  
22 and a description of any signifi-  
23 cant safety information.

1                   “(III) A non-promotional sum-  
2                   mary document that is technical in  
3                   nature that includes the following:

4                               “(aa) The purpose of the  
5                               clinical trial.

6                               “(bb) The sponsor of the  
7                               clinical trial.

8                               “(cc) Each financial sponsor  
9                               of the clinical trial.

10                              “(dd) A point of contact for  
11                              scientific information about the  
12                              clinical trial.

13                              “(ee) A description of the  
14                              patient population tested in the  
15                              clinical trial.

16                              “(ff) A general description  
17                              of the clinical trial and results,  
18                              including a description of and the  
19                              reasons for any changes in the  
20                              clinical trial design that occurred  
21                              since the date of submission of  
22                              clinical trial information for the  
23                              clinical trial in the registry data-  
24                              base established under paragraph  
25                              (2).

1                   “(gg) Summary data de-  
2                   scribing the results, including—

3                   “(AA) whether the pri-  
4                   mary endpoint was achieved,  
5                   including relevant statistics;

6                   “(BB) an assessment of  
7                   any secondary endpoints, if  
8                   applicable, including relevant  
9                   statistics; and

10                  “(CC) any significant  
11                  safety information, including  
12                  a summary of the incidence  
13                  of serious adverse events ob-  
14                  served in the clinical trial  
15                  and a summary of the most  
16                  common adverse events ob-  
17                  served in the clinical trial  
18                  and the frequencies of such  
19                  events.

20                  “(IV) With respect to the group  
21                  of subjects receiving the drug or de-  
22                  vice involved, and each comparison  
23                  group of subjects, the percentage of  
24                  individuals who ceased participation

1 as subjects and their reasons for ceas-  
2 ing participation.

3 “(V) With respect to an indi-  
4 vidual who is not an employee of the  
5 responsible party for the clinical trial  
6 or of the manufacturer of the drug or  
7 device involved, information (to the  
8 extent not submitted under paragraph  
9 (2)(B)(vi)) on any agreement that the  
10 responsible party or manufacturer has  
11 entered into with such individual that  
12 restricts in any manner the ability of  
13 the individual—

14 “(aa) to discuss the results  
15 of the trial at a scientific meeting  
16 or any other public or private  
17 forum; or

18 “(bb) to publish the results  
19 of the trial, or a description or  
20 discussion of the results of the  
21 trial, in a scientific or academic  
22 journal.

23 “(VI) A link to available peer-re-  
24 viewed publications based on the re-  
25 sults of the clinical trial.

1                   “(VII) The completion date of  
2                   the clinical trial.

3                   “(VIII) A link to the Internet  
4                   web posting of any adverse regulatory  
5                   actions taken by the Food and Drug  
6                   Administration, such as a warning let-  
7                   ter, that was substantively based on  
8                   the clinical trial design, outcome, or  
9                   representation made by the applicant  
10                  about the design or outcome of the  
11                  clinical trial.

12                  “(D) TIMING.—

13                  “(i) IN GENERAL.—Except as pro-  
14                  vided in clauses (ii) and (iii), a responsible  
15                  party shall submit to the Director of NIH  
16                  for inclusion in the results database clin-  
17                  ical trial information for an applicable clin-  
18                  ical trial not later than 1 year after the  
19                  earlier of—

20                  “(I) the estimated completion  
21                  date of the trial, as submitted under  
22                  paragraph (2)(B); or

23                  “(II) the actual date of the com-  
24                  pletion, or termination before comple-  
25                  tion, of the trial, as applicable.

1                   “(ii) EXTENSIONS.—The Director of  
2                   NIH may provide an extension of the  
3                   deadline for submission of clinical trial in-  
4                   formation under clause (i) if the respon-  
5                   sible party for the trial submits to the Di-  
6                   rector a written request that demonstrates  
7                   good cause for the extension and provides  
8                   an estimate of the date on which the infor-  
9                   mation will be submitted. The Director of  
10                  NIH may grant more than one such exten-  
11                  sion for the clinical trial involved.

12                  “(iii) UPDATES.—The responsible  
13                  party for an applicable clinical trial shall  
14                  submit to the Director of NIH for inclu-  
15                  sion in the results database periodic up-  
16                  dates to reflect changes in the clinical trial  
17                  information submitted under this para-  
18                  graph. Such updates—

19                         “(I) shall be provided not less  
20                         frequently than once every six months  
21                         during the 10-year period beginning  
22                         on the date on which information is  
23                         due under clause (i); and

24                         “(II) shall identify the dates on  
25                         which the changes were made; and

1                   “(III) shall include, not later  
2                   than 30 days after any change in the  
3                   regulatory status of the drug or device  
4                   involved, an update informing the Di-  
5                   rector of NIH of such change.

6                   “(E) TRUTHFUL CLINICAL TRIAL INFOR-  
7                   MATION.—

8                   “(i) IN GENERAL.—The clinical trial  
9                   information submitted by a responsible  
10                  party under this paragraph shall not be  
11                  false or misleading in any particular.

12                  “(ii) EFFECT.—Clause (i) shall not  
13                  have the effect of requiring clinical trial in-  
14                  formation with respect to a clinical trial to  
15                  include information from any source other  
16                  than such clinical trial.

17                  “(F) PUBLIC AVAILABILITY OF RE-  
18                  SULTS.—

19                  “(i) PRE-APPROVAL STUDIES.—Ex-  
20                  cept as provided in clause (v), with respect  
21                  to an applicable clinical trial that is com-  
22                  pleted before the drug is initially approved  
23                  under section 505 of the Federal Food,  
24                  Drug, and Cosmetic Act or initially li-  
25                  censed under section 351 of this Act, or

1 the device is initially cleared under section  
2 510(k) or approved under section 515 of  
3 the Federal Food, Drug, and Cosmetic  
4 Act, the Director of NIH shall make pub-  
5 licly available on the results database the  
6 clinical trial information submitted for  
7 such clinical trial not later than 30 days  
8 after—

9 “(I) the drug or device is ap-  
10 proved under such section 505, li-  
11 censed under such section 351,  
12 cleared under such section 510(k), or  
13 approved under such section 515, as  
14 applicable; or

15 “(II) the Secretary issues a not  
16 approvable letter or a not substan-  
17 tially equivalent letter for the drug or  
18 device under such section 505, 351,  
19 510(k), or 515, as applicable.

20 “(ii) MEDICAL AND CLINICAL PHAR-  
21 MACOLOGY REVIEWS OF PRE-APPROVAL  
22 STUDIES.—Not later than 90 days after  
23 the date applicable under subclause (I) or  
24 (II) of clause (i) with respect to an appli-  
25 cable clinical trial, the Director of NIH

1 shall make publicly available on the results  
2 database a summary of the available med-  
3 ical and clinical pharmacology reviews con-  
4 ducted by the Food and Drug Administra-  
5 tion for such trial.

6 “(iii) POST-APPROVAL STUDIES.—Ex-  
7 cept as provided in clauses (iv) and (v),  
8 with respect to an applicable clinical trial  
9 that is completed after the drug is initially  
10 approved under such section 505 or li-  
11 censed under such section 351, or the de-  
12 vice is initially cleared under such section  
13 510(k) or approved under such section  
14 515, the Director of NIH shall make pub-  
15 licly available on the results database the  
16 clinical trial information submitted for  
17 such clinical trial not later than 30 days  
18 after the date of such submission.

19 “(iv) SEEKING APPROVAL OF A NEW  
20 USE FOR THE DRUG OR DEVICE.—

21 “(I) IN GENERAL.—If the manu-  
22 facturer of the drug or device is the  
23 sponsor or a financial sponsor of an  
24 applicable clinical trial, and such man-  
25 ufacturer certifies to the Director of

1 NIH that such manufacturer has  
2 filed, or will file within 1 year, an ap-  
3 plication seeking approval under such  
4 section 505, licensing under such sec-  
5 tion 351, clearance under such section  
6 510(k), or approval under such sec-  
7 tion 515 for the use studied in such  
8 clinical trial (which use is not included  
9 in the labeling of the approved drug  
10 or device), then the Director of NIH  
11 shall make publicly available on the  
12 results database the clinical trial in-  
13 formation submitted for such clinical  
14 trial on the earlier of the date that is  
15 30 days after the date—

16 “(aa) the new use of the  
17 drug or device is approved under  
18 such section 505, licensed under  
19 such section 351, cleared under  
20 such section 510(k), or approved  
21 under such section 515;

22 “(bb) the Secretary issues a  
23 not approvable letter or a not  
24 substantially equivalent letter for  
25 the new use of the drug or device

1 under such section 505, 351,  
2 510(k), or 515; or

3 “(cc) the application or pre-  
4 market notification under such  
5 section 505, 351, 510(k), or 515  
6 is withdrawn.

7 “(II) LIMITATION ON CERTIFI-  
8 CATION.—If a manufacturer makes a  
9 certification under subclause (I) with  
10 respect to a clinical trial, the manu-  
11 facturer shall make such a certifi-  
12 cation with respect to each applicable  
13 clinical trial that is required to be  
14 submitted in an application for ap-  
15 proval of the use studied in the clin-  
16 ical trial.

17 “(III) 2-YEAR LIMITATION.—The  
18 clinical trial information subject to  
19 subclause (I) shall be made publicly  
20 available on the results database on  
21 the date that is 2 years after the date  
22 the certification referred to in sub-  
23 clause (I) was made to the Director of  
24 NIH, if a regulatory action referred to

1 in item (aa), (bb), or (cc) of subclause  
2 (I) has not occurred by such date.

3 “(IV) MEDICAL AND CLINICAL  
4 PHARMACOLOGY REVIEWS.—Not later  
5 than 90 days after the date applicable  
6 under item (aa), (bb), or (cc) of sub-  
7 clause (I) or subclause (III) with re-  
8 spect to an applicable clinical trial,  
9 the Director of NIH shall make pub-  
10 licly available on the results database  
11 a summary of the available medical  
12 and clinical pharmacology reviews  
13 conducted by the Food and Drug Ad-  
14 ministration for such trial.

15 “(V) SEEKING PUBLICATION.—

16 “(I) IN GENERAL.—If the prin-  
17 cipal investigator of an applicable clin-  
18 ical trial is seeking publication in a  
19 peer-reviewed biomedical journal of a  
20 manuscript based on the results of the  
21 clinical trial and the responsible party  
22 so certifies to the Director of NIH—

23 “(aa) the responsible party  
24 shall notify the Director of NIH  
25 of the publication date of such

1 manuscript not later than 15  
2 days after such date; and

3 “(bb) the Director of NIH  
4 shall make publicly available on  
5 the results database the clinical  
6 trial information submitted for  
7 such clinical trial on the date  
8 that is 30 days after the publica-  
9 tion date of such manuscript.

10 “(II) LIMITATIONS.—The clinical  
11 trial information subject to subclause  
12 (I)—

13 “(aa) shall be made publicly  
14 available on the results database  
15 on the date that is 2 years after  
16 the date that the clinical trial in-  
17 formation was required to be  
18 submitted to the Director of NIH  
19 if the manuscript referred to in  
20 such subclause has not been pub-  
21 lished by such date; and

22 “(bb) shall not be required  
23 to be made publicly available  
24 under section 552 of title 5,  
25 United States Code (commonly

1 known as the ‘Freedom of Infor-  
2 mation Act’), prior to the date  
3 applicable to such clinical trial  
4 information under this clause.

5 “(G) VERIFICATION OF SUBMISSION PRIOR  
6 TO PUBLIC AVAILABILITY.—In the case of clin-  
7 ical trial information that is submitted under  
8 this paragraph, but is not made publicly avail-  
9 able pending either regulatory action or publica-  
10 tion under clause (iv) or (v) of subparagraph  
11 (F), as applicable, the Director of NIH shall re-  
12 spond to inquiries from other Federal agencies  
13 and peer-reviewed journals to confirm that such  
14 clinical trial information has been submitted  
15 but has not yet been made publicly available on  
16 the results database.

17 “(4) UPDATES; TRACKING OF CHANGES IN SUB-  
18 MITTED INFORMATION.—The Director of NIH shall  
19 ensure that updates submitted to the Director under  
20 paragraphs (2)(G) and (3)(D) do not result in the  
21 removal from the registry database or the results  
22 database of the original submissions or of any pre-  
23 ceding updates, and that information in such data-  
24 bases is presented in a manner that enables users to

1 readily access each original submission and to track  
2 the changes made by the updates.

3 “(5) COORDINATION AND COMPLIANCE.—

4 “(A) CLINICAL TRIALS SUPPORTED BY  
5 GRANTS FROM FEDERAL AGENCIES.—

6 “(i) IN GENERAL.—No Federal agen-  
7 cy may release funds under a research  
8 grant to a person who has not complied  
9 with paragraphs (2) and (3) for any appli-  
10 cable clinical trial for which such person is  
11 the responsible party.

12 “(ii) GRANTS FROM CERTAIN FED-  
13 ERAL AGENCIES.—If an applicable clinical  
14 trial is funded in whole or in part by a  
15 grant from the National Institutes of  
16 Health or the Agency for Healthcare Re-  
17 search and Quality, any grant or progress  
18 report forms required under such grant  
19 shall include a certification that the re-  
20 sponsible party has made all required sub-  
21 missions to the Director of NIH under  
22 paragraphs (2) and (3).

23 “(iii) VERIFICATION BY FEDERAL  
24 AGENCIES.—The heads of the agencies re-  
25 ferred to in clause (ii), as applicable, shall

1           verify that the clinical trial information for  
2           each applicable clinical trial for which a  
3           grantee is the responsible party has been  
4           submitted under paragraph (2) and (3), as  
5           applicable, before releasing funding for a  
6           grant to such grantee.

7           “(iv) NOTICE AND OPPORTUNITY TO  
8           REMEDY.—If the head of an agency re-  
9           ferred to in clause (ii), as applicable,  
10          verifies that a grantee has not submitted  
11          clinical trial information as described in  
12          clause (iii), such agency head shall provide  
13          notice to such grantee of such noncompli-  
14          ance and allow such grantee 30 days to  
15          correct such noncompliance and submit the  
16          required clinical trial information.

17          “(v) CONSULTATION WITH OTHER  
18          FEDERAL AGENCIES.—The Secretary  
19          shall—

20                 “(I) consult with other agencies  
21                 that conduct human studies in accord-  
22                 ance with part 46 of title 45, Code of  
23                 Federal Regulations (or any successor  
24                 regulations), to determine if any such

1 studies are applicable clinical trials;  
2 and

3 “(II) develop with such agencies  
4 procedures comparable to those de-  
5 scribed in clauses (ii), (iii), and (iv) to  
6 ensure that clinical trial information  
7 for such applicable clinical trials is  
8 submitted under paragraphs (2) and  
9 (3).

10 “(B) COORDINATION OF REGISTRY DATA-  
11 BASE AND RESULTS DATABASE.—

12 “(i) IN GENERAL.—Each entry in the  
13 registry database under paragraph (2) or  
14 the results database under paragraph (3)  
15 shall include a link to the corresponding  
16 entry in the results database or the reg-  
17 istry database, respectively.

18 “(ii) MISSING ENTRIES.—

19 “(I) IN GENERAL.—If, based on  
20 a review of the entries in the registry  
21 database under paragraph (2), the Di-  
22 rector of NIH determines that a re-  
23 sponsible party has failed to submit  
24 required clinical trial information to  
25 the results database under paragraph

1 (3), the Director of NIH shall inform  
2 the responsible party involved of such  
3 failure and permit the responsible  
4 party to correct the failure within 30  
5 days.

6 “(II) FAILURE TO CORRECT.—If  
7 the responsible party does not correct  
8 a failure to submit required clinical  
9 trial information within the 30-day  
10 period described under subclause (I),  
11 the Director of NIH shall report such  
12 noncompliance to the scientific peer  
13 review committees of the Federal re-  
14 search agencies and to the Office of  
15 Human Research Protections.

16 “(III) PUBLIC NOTICE OF FAIL-  
17 URE TO CORRECT.—The Director of  
18 NIH shall include in the clinical trial  
19 registry database entry and the clin-  
20 ical trial results database entry for  
21 each applicable clinical trial a notice  
22 of any uncorrected failure to submit  
23 required clinical trial information and  
24 shall provide that the public may eas-  
25 ily search for such entries.

1 “(C) ACTION ON APPLICATIONS.—

2 “(i) VERIFICATION PRIOR TO FIL-  
3 ING.—The Secretary, acting through the  
4 Commissioner of Food and Drugs, shall  
5 verify that the clinical trial information re-  
6 quired under paragraphs (2) and (3) for  
7 an applicable clinical trial is submitted  
8 pursuant to such paragraphs, as applica-  
9 ble—

10 “(I) when considering a drug or  
11 device for an exemption under section  
12 505(i) or section 520(g) of the Fed-  
13 eral Food, Drug, and Cosmetic Act;  
14 and

15 “(II) prior to filing an applica-  
16 tion or premarket notification under  
17 section 505, 510(k), or 515 of the  
18 Federal Food, Drug, and Cosmetic  
19 Act or section 351 of this Act, that  
20 includes information from such clin-  
21 ical trial.

22 “(ii) NOTIFICATION.—If the Secretary  
23 determines under clause (i) that clinical  
24 trial information has not been submitted  
25 as required by paragraph (2) or (3), the

1 Secretary shall notify the applicant and the  
2 responsible party of such noncompliance  
3 and require submission of such information  
4 within 30 days.

5 “(iii) REFUSAL TO FILE.—If the re-  
6 sponsible party does not remedy such non-  
7 compliance within 30 days of receipt of no-  
8 tification under clause (ii), the Secretary  
9 shall refuse to file, approve, or clear such  
10 application or premarket notification.

11 “(D) CONTENT REVIEW.—

12 “(i) IN GENERAL.—To ensure that  
13 the summary documents described in para-  
14 graph (3)(C) are non-promotional, and are  
15 not false or misleading in any particular  
16 under paragraph (3)(E), the Secretary  
17 shall compare such documents to the re-  
18 sults data of the clinical trial for a rep-  
19 resentative sample of applicable clinical  
20 trials by—

21 “(I) acting through the Commis-  
22 sioner of Food and Drugs to examine  
23 the results data for such clinical trials  
24 submitted to Secretary when such  
25 data are submitted—

1                   “(aa) for review as part of  
2                   an application under section 505  
3                   or 515 of the Federal Food,  
4                   Drug, and Cosmetic Act or under  
5                   section 351 of this Act or a pre-  
6                   market notification under section  
7                   510(k) of the Federal Food,  
8                   Drug, and Cosmetic Act; or

9                   “(bb) in an annual status  
10                  report on the drug or device  
11                  under such application;

12                  “(II) acting with the Federal  
13                  agency that funds such clinical trial in  
14                  whole or in part by a grant to exam-  
15                  ine the results data for such clinical  
16                  trials; and

17                  “(III) acting through inspections  
18                  under section 704 of the Federal  
19                  Food, Drug, and Cosmetic Act to ex-  
20                  amine results data for such clinical  
21                  trials not described in subclause (I) or  
22                  (II).

23                  “(ii) NOTICE OF NONCOMPLIANCE.—  
24                  If the Secretary determines that the clin-  
25                  ical trial information submitted in such a

1 summary document is promotional, or false  
2 or misleading in any particular, the Sec-  
3 retary shall notify the responsible party  
4 and give such party an opportunity to rem-  
5 edy such noncompliance by submitting the  
6 required revised clinical trial information  
7 within 30 days of such notification.

8 “(6) PENALTIES FOR NONCOMPLIANCE.—

9 “(A) IN GENERAL.—The following acts  
10 and the causing thereof are unlawful:

11 “(i) The failure to submit clinical trial  
12 information as required by this section.

13 “(ii) The submission of clinical trial  
14 information under this section that is pro-  
15 motional or false or misleading in any par-  
16 ticular in violation of paragraph (2)(E) or  
17 (3)(E).

18 “(B) CERTAIN PENALTIES.—Section  
19 303(a) of the Federal Food, Drug, and Cos-  
20 metic Act applies with respect to a violation of  
21 subparagraph (A) to the same extent and in the  
22 same manner as such section 303(a) applies  
23 with respect to a violation of section 301 of  
24 such Act.

1           “(C) CONSIDERATIONS.—In determining  
2 whether to apply a penalty under subparagraph  
3 (B) or subparagraph (D) of this paragraph for  
4 a violation described in subparagraph (A), the  
5 Secretary, acting through the Commissioner of  
6 Food and Drugs, shall consider—

7           “(i) whether the responsible party  
8 promptly corrects the noncompliance when  
9 provided notice;

10           “(ii) whether the responsible party  
11 has engaged in a pattern or practice of  
12 noncompliance; and

13           “(iii) the extent to which the non-  
14 compliance involved may have significantly  
15 misled health care providers or patients  
16 concerning the safety or effectiveness of  
17 the drug involved.

18           “(D) CIVIL PENALTIES.—

19           “(i) IN GENERAL.—A person is sub-  
20 ject to a civil penalty in accordance with  
21 this subparagraph if the person commits a  
22 violation described in subparagraph (A)  
23 and fails to correct the violation by the end  
24 of the 30-day period described in clause  
25 (ii).

1           “(ii) NOTIFICATION.—If a person is  
2           in violation of subparagraph (A), the Sec-  
3           retary shall notify the person of such non-  
4           compliance and give the person a 30-day  
5           period to correct such violation before im-  
6           posing a civil penalty under this subpara-  
7           graph.

8           “(iii) AMOUNT OF PENALTY.—The  
9           amount of a civil penalty under this para-  
10          graph shall be not more than a total of  
11          \$15,000 for all violations adjudicated in a  
12          single proceeding in the case of an indi-  
13          vidual, and not more than \$10,000 per day  
14          until the violation is corrected in the case  
15          of any other person, except that if the per-  
16          son is a nonprofit entity the penalty may  
17          not exceed a total of \$15,000 for all viola-  
18          tions adjudicated in a single proceeding.

19          “(iv) PROCEDURES.—The provisions  
20          of paragraphs (4) through (6) of section  
21          303(f) of the Federal Food, Drug, and  
22          Cosmetic Act apply to the imposition of a  
23          penalty under this paragraph to the same  
24          extent and in the same manner as such

1 provisions apply to a penalty imposed  
2 under such section 303(f).

3 “(7) AUTHORIZATION OF APPROPRIATIONS.—

4 There are authorized to be appropriated to carry out  
5 this subsection \$10,000,000 for each fiscal year.”.

6 (b) CONFORMING AMENDMENTS.—

7 (1) INVESTIGATIONAL NEW DRUGS.—Section  
8 505(i) of the Federal Food, Drug, and Cosmetic Act  
9 (21 U.S.C. 355(i)) is amended—

10 (A) in paragraph (1)—

11 (i) in subparagraph (C), by striking  
12 “and” after the semicolon;

13 (ii) in subparagraph (D)—

14 (I) by aligning the indentation of  
15 such subparagraph with the indenta-  
16 tion of subparagraphs (A), (B), and  
17 (C); and

18 (II) by striking the period at the  
19 end and inserting “; and”; and

20 (iii) by adding at the end the fol-  
21 lowing:

22 “(E) the submission to the Director of NIH of  
23 clinical trial information for the clinical investigation  
24 at issue required under section 402(i) of the Public  
25 Health Service Act for inclusion in the registry data-

1 base and the results database described in such sec-  
2 tion.”;

3 (B) in paragraph (3)(B)—

4 (i) in clause (i), by striking “or” after  
5 the semicolon;

6 (ii) in clause (ii), by striking the pe-  
7 riod at the end and inserting “; or”; and

8 (iii) by adding at the end the fol-  
9 lowing:

10 “(iii) clinical trial information for the clinical  
11 investigation at issue was not submitted in compli-  
12 ance with section 402(i) of the Public Health Service  
13 Act.”; and

14 (C) in paragraph (4), by adding at the end  
15 the following: “The Secretary shall update such  
16 regulations to require inclusion in the informed  
17 consent form a statement that clinical trial in-  
18 formation for such clinical investigation will be  
19 submitted for inclusion in the registry database  
20 and results database, as applicable, described in  
21 section 402(i) of the Public Health Service  
22 Act.”.

23 (2) REFUSAL TO APPROVE NEW DRUG APPLICA-  
24 TION.—Section 505(d) of the Federal Food, Drug,  
25 and Cosmetic Act (21 U.S.C. 355(d)) is amended—

1 (A) in the first sentence, by inserting after  
2 “or any particular;” the following: “or (8) the  
3 applicant failed to submit the clinical trial in-  
4 formation for any applicable clinical trial as re-  
5 quired by section 402(i) of the Public Health  
6 Service Act;”; and

7 (B) in the second sentence, by striking  
8 “clauses (1) through (6)” and inserting “para-  
9 graphs (1) through (8)”.

10 (3) INVESTIGATIONAL NEW DEVICES.—Sub-  
11 paragraph (B) of section 520(g)(2) of the Federal  
12 Food, Drug, and Cosmetic Act (21 U.S.C.  
13 360j(g)(2)) is amended—

14 (A) by redesignating clause (iii) as clause  
15 (iv); and

16 (B) by inserting after clause (ii) the fol-  
17 lowing:

18 “(iii) A requirement that the person  
19 applying for an exemption for a device as-  
20 sure that such person is in compliance with  
21 the requirements of section 402(i) of the  
22 Public Health Service Act for the submis-  
23 sion of clinical trial information for inclu-  
24 sion in the registry database and the re-  
25 sults database described in such section.”.

1           (4) REFUSAL TO CLEAR NEW DEVICE PRE-  
2 MARKET NOTIFICATION REPORT.—Subsection (k) of  
3 section 510 of the Federal Food, Drug, and Cos-  
4 metic Act (21 U.S.C. 360) is amended—

5           (A) in paragraph (1), by striking “and” at  
6 the end; and

7           (B) in paragraph (2), by striking the pe-  
8 riod at the end and inserting “, and”; and

9           (C) by adding at the end the following:

10          “(3) action taken by such person to comply  
11 with requirements under section 402(i) of the Public  
12 Health Service Act for the submission of clinical  
13 trial information for inclusion in the registry data-  
14 base and the results database described in such sec-  
15 tion.”.

16          (5) REFUSAL TO APPROVE NEW DEVICE APPLI-  
17 CATION.—Paragraph (2) of section 515(d) of the  
18 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
19 360e(d)) is amended—

20          (A) in subparagraph (D), by striking “or”  
21 at the end;

22          (B) in subparagraph (E), by striking the  
23 period at the end and inserting “; or”; and

24          (C) by adding at the end the following:

1           “(F) the applicant is in violation of the re-  
2           quirements under section 402(i) of the Public  
3           Health Service Act for the submission of clin-  
4           ical trial information for inclusion in the reg-  
5           istry database or the results database described  
6           in such section.”.

7           (c) GUIDANCE.—Not later than 180 days after the  
8           date of enactment of this Act, the Commissioner of Food  
9           and Drugs, in consultation with the Director of the Na-  
10          tional Institutes of Health, shall issue guidance to clarify  
11          which clinical trials are applicable clinical trials (as de-  
12          fined in section 402(i)(2) of the Public Health Service Act,  
13          as amended by this section) and required to be submitted  
14          for inclusion in the clinical trial registry database de-  
15          scribed in such section.

16          (d) PREEMPTION.—

17           (1) IN GENERAL.—No State or political subdivi-  
18          sion of a State may establish or continue in effect  
19          any requirement for the registration of clinical trials  
20          or for the inclusion of information relating to the re-  
21          sults of clinical trials in a database.

22           (2) RULE OF CONSTRUCTION.—The fact of sub-  
23          mission of clinical trial information, if submitted in  
24          compliance with section 402(i) of the Public Health  
25          Service Act (as amended by this section), that re-

1       lates to a use of a drug or device not included in the  
2       official labeling of the approved drug or device shall  
3       not be construed by the Secretary or in any adminis-  
4       trative or judicial proceeding, as evidence of a new  
5       intended use of the drug or device that is different  
6       from the intended use of the drug or device set forth  
7       in the official labeling of the drug or device. The  
8       availability of clinical trial information through the  
9       databases under paragraphs (2) and (3) of such sec-  
10      tion 402(i), if submitted in compliance with such  
11      section 402(i), shall not be considered as labeling,  
12      adulteration, or misbranding of the drug or device  
13      under the Federal Food, Drug, and Cosmetic Act  
14      (21 U.S.C. 301 et seq.).

15      (e) EFFECTIVE DATES.—

16           (1) ESTABLISHMENT OF REGISTRY DATABASE  
17      AND RESULTS DATABASE.—Not later than 1 year  
18      after the date of enactment of this Act, the Director  
19      of NIH shall establish the registry database and the  
20      results database of clinical trials of drugs and de-  
21      vices in accordance with section 402(i) of the Public  
22      Health Service Act (as amended by subsection (a)).

23           (2) CLINICAL TRIALS INITIATED PRIOR TO OP-  
24      ERATION OF REGISTRY DATABASE.—The responsible  
25      party (as defined in such section 402(i)) for an ap-

1 applicable clinical trial (as defined in such section  
2 402(i)) that is initiated after the date of enactment  
3 of this Act and before the date such registry data-  
4 base is established under paragraph (1) of this sub-  
5 section, shall submit required clinical trial informa-  
6 tion not later than 120 days after the date such reg-  
7 istry database is established.

8 (3) CLINICAL TRIALS INITIATED AFTER OPER-  
9 ATION OF REGISTRY DATABASE.—The responsible  
10 party (as defined in such section 402(i)) for an ap-  
11 plicable clinical trial (as defined in such section  
12 402(i)) that is initiated after the date such registry  
13 database is established under paragraph (1) of this  
14 subsection shall submit required clinical trial infor-  
15 mation in accordance with paragraph (2) of such  
16 section 402(i).

17 (4) TRIALS COMPLETED BEFORE OPERATION  
18 OF RESULTS DATABASE.—

19 (A) IN GENERAL.—Paragraph (3) of such  
20 section 402(i) shall take effect 90 days after  
21 the date the results database is established  
22 under paragraph (1) of this subsection with re-  
23 spect to any applicable clinical trial (as defined  
24 in such section 402(i)) that—

1 (i) involves a drug to treat a serious  
2 or life-threatening condition; and

3 (ii) is completed between the date of  
4 enactment of this Act and such date of es-  
5 tablishment under paragraph (1) of this  
6 subsection.

7 (B) OTHER TRIALS.—Except as provided  
8 in subparagraph (A), paragraph (3) of such  
9 section 402(i) shall take effect 180 days after  
10 the date that the results database is established  
11 under paragraph (1) of this subsection with re-  
12 spect to any applicable clinical trial that is com-  
13 pleted between the date of enactment of this  
14 Act and such date of establishment under para-  
15 graph (1).

16 (5) TRIALS COMPLETED AFTER ESTABLISH-  
17 MENT OF RESULTS DATABASE.—Paragraph (3) of  
18 such section 402(i) shall apply to any clinical trial  
19 that is completed after the date that the results  
20 database is established under paragraph (1) of this  
21 subsection.

22 (6) RETROACTIVITY OF DATABASE.—

23 (A) VOLUNTARY SUBMISSIONS.—The Sec-  
24 retary of Health and Human Services (referred  
25 to in this paragraph as the “Secretary”) shall

1 establish procedures and mechanisms to allow  
2 for the voluntary submission to the Secretary—

3 (i) of clinical trial information for in-  
4 clusion in the registry database (as defined  
5 in such section 402(i)) on applicable clin-  
6 ical trials (as defined in such section  
7 402(i)) initiated before the date of the en-  
8 actment of this Act; and

9 (ii) of clinical trial information for in-  
10 clusion in the results database (as defined  
11 in such section 402(i)) on applicable clin-  
12 ical trials (as defined in such section  
13 402(i)) completed before the date of the  
14 enactment of this Act.

15 (B) REQUIRED SUBMISSIONS.—Notwith-  
16 standing the preceding paragraphs of this sub-  
17 section, in any case in which the Secretary de-  
18 termines that submission of clinical trial infor-  
19 mation for an applicable clinical trial (as de-  
20 fined in such section 402(i)) described in clause  
21 (i) or (ii) of subparagraph (A) is in the interest  
22 of the public health—

23 (i) the Secretary may require that  
24 such information be submitted to the Sec-

1           retary in accordance with such section  
2           402(i); and

3                   (ii) failure to comply with such a re-  
4           quirement shall be treated as a violation of  
5           the corresponding requirement of such sec-  
6           tion 402(i).

7           (7) FUNDING RESTRICTIONS.—Subparagraph  
8           (A) of paragraph (5) of such section 402(i) shall  
9           take effect 210 days after the date that the clinical  
10          trial registry database and the clinical trial results  
11          database are established under paragraph (1) of this  
12          subsection.

13          (8) STATUS OF CLINICALTRIALS.GOV  
14          WEBSITE.—

15                  (A) IN GENERAL.—After receiving public  
16          comment and not later than 90 days after the  
17          date of enactment of this Act, the Secretary  
18          shall publish in the Federal Register a notice  
19          determining the more efficient approach to es-  
20          tablishing the registry database described in  
21          paragraph (2) of such section 402(i) and  
22          whether such approach is—

23                          (i) that such registry database should  
24                  expand and build upon the database de-  
25                  scribed in section 402(i) of the Public

1 Health Service Act (as in effect on the day  
2 before the date of enactment of this Act);

3 or

4 (ii) that such registry database should  
5 supplant the database described in such  
6 section 402(i) (as in effect on the day be-  
7 fore the date of enactment of this Act).

8 (B) CLINICALTRIALS.GOV SUPPLANTED.—

9 If the Secretary determines to apply the ap-  
10 proach described under subparagraph (A)(ii),  
11 the Secretary shall maintain an archive of the  
12 database described in such section 402(i) (as in  
13 effect on the day before the date of enactment  
14 of this Act) on the Internet website of the Na-  
15 tional Library of Medicine.

16 **SEC. 2. RULE OF CONSTRUCTION REGARDING FEDERAL**  
17 **PREEMPTION.**

18 Nothing in this Act or the amendments made by this  
19 Act may be construed as having any legal effect on any  
20 cause of action for damages under the law of any State  
21 (including statutes, regulations, and common law).