

**[COMMITTEE PRINT]**

[SHOWING TEXT OF COMMITTEE PRINT AS APPROVED BY SUBCOMMITTEE ON HEALTH ON JUNE 19, 2007]

110TH CONGRESS  
1ST 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.—Title IV of the Public Health  
6 Service Act (42 U.S.C. 281 et seq.) is amended—

1 (1) in section 402, by striking subsection (i);

2 and

3 (2) by inserting after section 492B the fol-

4 lowing new section:

5 **“SEC. 492C. CLINICAL TRIAL REGISTRY DATABASE; CLIN-**  
6 **ICAL TRIAL RESULTS DATABASE.**

7 “(a) DEFINITIONS.—In this section:

8 “(1) APPLICABLE CLINICAL TRIAL.—The term  
9 ‘applicable clinical trial’—

10 “(A) means a clinical trial that is con-  
11 ducted to test the safety or effectiveness (in-  
12 cluding comparative effectiveness) of a drug or  
13 device (irrespective of whether the clinical trial  
14 is federally or privately funded, and whether the  
15 clinical trial involves an approved or unap-  
16 proved drug or device);

17 “(B) includes such a clinical trial that is  
18 conducted outside of the United States if—

19 “(i) there is an application or pre-  
20 market notification pending before the  
21 Food and Drug Administration for ap-  
22 proval or clearance of the drug or device  
23 involved under section 505, 510(k), or 515  
24 of the Federal Food, Drug, and Cosmetic  
25 Act or section 351 of this Act; or

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

3                   “(C) notwithstanding clauses (i) and (ii),  
4                   excludes—

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

12                  “(ii) a small clinical trial to determine  
13                  the feasibility of a device, or a clinical trial  
14                  to test prototype devices where the primary  
15                  focus is feasibility.

16                  “(2) CLINICAL TRIAL INFORMATION.—The term  
17                  ‘clinical trial information’ means those data elements  
18                  that are necessary to complete an entry in the clin-  
19                  ical trial registry database under subsection (b) or  
20                  the clinical trial results database under subsection  
21                  (c), as applicable.

22                  “(3) COMPLETION DATE.—The term ‘comple-  
23                  tion date’ means the date of the final collection of  
24                  data from subjects in the clinical trial for the pri-

1       mary and secondary outcomes to be examined in the  
2       trial.

3               “(4) DEVICE.—The term ‘device’ has the mean-  
4       ing given to that term in section 201(h) of the Fed-  
5       eral Food, Drug, and Cosmetic Act.

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

10              “(6) RESPONSIBLE PARTY.—The term ‘respon-  
11       sible party’, with respect to an applicable clinical  
12       trial, means—

13                      “(A) the primary sponsor (as defined in  
14       the International Clinical Trials Registry Plat-  
15       form trial registration data set of the World  
16       Health Organization) of the clinical trial; or

17                      “(B) the principal investigator of such clin-  
18       ical trial if so designated by such sponsor, so  
19       long as the principal investigator is responsible  
20       for conducting the trial, has access to and con-  
21       trol over the data, has the right to publish the  
22       results of the trial, and has the responsibility to  
23       meet all of the requirements under this section  
24       that are applicable to responsible parties.

25              “(b) CLINICAL TRIALS REGISTRY DATABASE.—

1           “(1) ESTABLISHMENT.—To enhance patient en-  
2           rollment and provide a mechanism to track subse-  
3           quent progress of clinical trials, the Secretary, act-  
4           ing through the Director of NIH, shall establish and  
5           administer a clinical trial registry database in ac-  
6           cordance with this section (referred to in this section  
7           as the ‘registry database’). The Director of NIH  
8           shall ensure that the registry database is made pub-  
9           licly available through the Internet.

10           “(2) CONTENT.—The Secretary shall promul-  
11           gate regulations for the submission to the registry  
12           database of clinical trial information that—

13                   “(A) conforms to the International Clinical  
14                   Trials Registry Platform trial registration data  
15                   set of the World Health Organization;

16                   “(B) includes the city, State, and zip code  
17                   for each clinical trial location or a toll free  
18                   number through which such location informa-  
19                   tion may be accessed;

20                   “(C) includes a statement of the estimated  
21                   completion date for the clinical trial;

22                   “(D) includes the identity and contact in-  
23                   formation of the responsible party;

24                   “(E) if the drug is not approved under sec-  
25                   tion 505 of the Federal Food, Drug, and Cos-

1           metic Act or licensed under section 351 of this  
2           Act, or the device is not cleared under section  
3           510(k) or approved under section 515 of the  
4           Federal Food, Drug, and Cosmetic Act, speci-  
5           fies whether or not there is expanded access to  
6           the drug or device under section 561 of the  
7           Federal Food, Drug, and Cosmetic Act for  
8           those who do not qualify for enrollment in the  
9           clinical trial and how to obtain information  
10          about such access;

11                 “(F) includes, with respect to any indi-  
12           vidual who is not an employee of the responsible  
13           party for the clinical trial or of the manufac-  
14           turer of the drug or device involved, information  
15           on whether the responsible party or manufac-  
16           turer has entered into any agreement with such  
17           individual that restricts in any manner the abil-  
18           ity of the individual—

19                         “(i) to discuss the results of the trial  
20                         at a scientific meeting or any other public  
21                         or private forum; or

22                         “(ii) to publish the results of the trial,  
23                         or a description or discussion of the results  
24                         of the trial, in a scientific or academic  
25                         journal; and

1           “(G) requires the inclusion of such other  
2 data elements to the registry database as ap-  
3 propriate.

4           “(3) FORMAT AND STRUCTURE.—

5           “(A) SEARCHABLE CATEGORIES.—The Di-  
6 rector of NIH shall ensure that the public may  
7 search the entries in the registry database by 1  
8 or more of the following criteria:

9           “(i) The indication being studied in  
10 the clinical trial, using Medical Subject  
11 Headers (MeSH) descriptors.

12           “(ii) The safety issue being studied in  
13 the clinical trial.

14           “(iii) The enrollment status of the  
15 clinical trial.

16           “(iv) The sponsor of the clinical trial.

17           “(B) FORMAT.—The Director of the NIH  
18 shall ensure that the registry database is easily  
19 used by patients, and that entries are easily  
20 compared.

21           “(4) DATA SUBMISSION.—The responsible party  
22 for an applicable clinical trial shall submit to the Di-  
23 rector of NIH for inclusion in the registry database  
24 the clinical trial information described in paragraph  
25 (2).

1           “(5) TRUTHFUL CLINICAL TRIAL INFORMA-  
2           TION.—

3           “(A) IN GENERAL.—The clinical trial in-  
4           formation submitted by a responsible party  
5           under this subsection shall not be false or mis-  
6           leading.

7           “(B) EFFECT.—Subparagraph (A) shall  
8           not have the effect of requiring clinical trial in-  
9           formation to include information from any  
10          source other than the clinical trial involved.

11          “(6) TIMING OF SUBMISSION.—Except as pro-  
12          vided in paragraph (7), the clinical trial information  
13          for a clinical trial required to be submitted under  
14          this subsection shall be submitted not later than 14  
15          days after the first patient is enrolled in such clin-  
16          ical trial.

17          “(7) UPDATES.—The responsible party for an  
18          applicable clinical trial shall submit to the Director  
19          of NIH for inclusion in the registry database peri-  
20          odic updates to reflect changes to the clinical trial  
21          information submitted under this subsection. Such  
22          updates—

23                 “(A) shall be provided not less than once  
24                 every 6 months until information on the results  
25                 of the trial is submitted under subsection (c);

1           “(B) shall include identification of the  
2           dates of any such changes;

3           “(C) not later than 30 days after the en-  
4           rollment status of such clinical trial changes,  
5           shall include an update of the enrollment sta-  
6           tus; and

7           “(D) not later than 30 days after the com-  
8           pletion date of the clinical trial, shall include a  
9           report to the Director that such clinical trial is  
10          complete.

11          “(8) APPLICABILITY OF DEVICE TRIALS.—Ap-  
12          plicability of device trials shall be delayed until after  
13          approval.

14          “(c) CLINICAL TRIALS RESULTS DATABASE.—

15           “(1) ESTABLISHMENT.—To ensure that results  
16           of clinical trials are made public and that patients  
17           and providers have current information regarding  
18           the results of clinical trials, the Secretary, acting  
19           through the Director of NIH, shall establish and ad-  
20           minister a clinical trial results database in accord-  
21           ance with this section (referred to in this section as  
22           the ‘results database’). The Director of NIH shall  
23           ensure that the results database is made publicly  
24           available through the Internet.

1           “(2) SEARCHABLE CATEGORIES.—The Director  
2 of NIH shall ensure that the public may search the  
3 entries in the results database by 1 or more of the  
4 following:

5           “(A) The indication studied in the clinical  
6 trial, using Medical Subject Headers (MeSH)  
7 descriptors.

8           “(B) The safety issue studied in the clin-  
9 ical trial.

10           “(C) Whether an application for the tested  
11 indication is approved, pending approval, with-  
12 drawn, or not submitted.

13           “(D) The phase of the clinical trial.

14           “(E) The name of the drug or device that  
15 is the subject of the clinical trial.

16           “(F) Within the documents described in  
17 clauses (i) and (ii) of paragraph (3)(B), the fol-  
18 lowing information, as applicable:

19           “(i) The sponsor of the clinical trial.

20           “(ii) Each financial sponsor of the  
21 clinical trial.

22           “(3) CONTENTS.—

23           “(A) IN GENERAL.—The responsible party  
24 for an applicable clinical trial shall submit to  
25 the Director of NIH for inclusion in the results

1 database the clinical trial information described  
2 in subparagraph (B).

3 “(B) REQUIRED ELEMENTS.—In submit-  
4 ting clinical trial information for a clinical trial  
5 to the Director of NIH for inclusion in the re-  
6 sults database, the responsible party shall in-  
7 clude, with respect to such clinical trial, the fol-  
8 lowing information:

9 “(i) The information described in sub-  
10 paragraphs (A) through (E) of subsection  
11 (b)(2).

12 “(ii) A summary that is written in  
13 non-technical, understandable language for  
14 patients that includes the following:

15 “(I) The purpose of the clinical  
16 trial.

17 “(II) The sponsor of the clinical  
18 trial.

19 “(III) A point of contact for in-  
20 formation about the clinical trial.

21 “(IV) A description of the patient  
22 population tested in the clinical trial.

23 “(V) A general description of the  
24 clinical trial and results, including a  
25 description of and the reasons for any

1 changes in the clinical trial design  
2 that occurred since the date of sub-  
3 mission of clinical trial information  
4 for inclusion in the registry database  
5 established under subsection (b) and a  
6 description of any significant safety  
7 information.

8 “(iii) A summary that is technical in  
9 nature that includes the following:

10 “(I) The purpose of the clinical  
11 trial.

12 “(II) The sponsor of the clinical  
13 trial.

14 “(III) Each financial sponsor of  
15 the clinical trial.

16 “(IV) A point of contact for sci-  
17 entific information about the clinical  
18 trial.

19 “(V) A description of the patient  
20 population tested in the clinical trial.

21 “(VI) A general description of  
22 the clinical trial and results, including  
23 a description of and the reasons for  
24 any changes in the clinical trial design  
25 that occurred since the date of sub-

1 mission of clinical trial information  
2 for the clinical trial in the registry  
3 database established under subsection  
4 (b).

5 “(VII) Summary data describing  
6 the results, including—

7 “(aa) whether the primary  
8 endpoint was achieved, including  
9 relevant statistics;

10 “(bb) an assessment of any  
11 secondary endpoints, if applica-  
12 ble, including relevant statistics;  
13 and

14 “(cc) any significant safety  
15 information, including a sum-  
16 mary of the incidence of serious  
17 adverse events observed in the  
18 clinical trial and a summary of  
19 the most common adverse events  
20 observed in the clinical trial and  
21 the frequencies of such events.

22 “(iv) With respect to the group of  
23 subjects receiving the drug or device in-  
24 volved, and each comparison group of sub-  
25 jects, the percentage of individuals who

1           ceased participation as subjects and the  
2           reasons for ceasing participation.

3                   “(v) With respect to an individual who  
4           is not an employee of the responsible party  
5           for the clinical trial or of the manufacturer  
6           of the drug or device involved, information  
7           (to the extent not submitted under sub-  
8           section (b)(2)(F)) on any agreement that  
9           the responsible party or manufacturer has  
10          entered into with such individual that re-  
11          stricts in any manner the ability of the in-  
12          dividual—

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

16                   “(II) to publish the results of the  
17          trial, or a description or discussion of  
18          the results of the trial, in a scientific  
19          or academic journal.

20                   “(vi) A link to available peer-reviewed  
21          publications based on the results of the  
22          clinical trial.

23                   “(vii) The completion date of the clin-  
24          ical trial.

1                   “(viii) A link to the Internet web post-  
2                   ing of any adverse regulatory actions taken  
3                   by the Food and Drug Administration,  
4                   such as a warning letter, that was sub-  
5                   stantively based on the clinical trial design,  
6                   outcome, or representation made by the  
7                   applicant about the design or outcome of  
8                   the clinical trial.

9                   “(4) TIMING.—

10                   “(A) IN GENERAL.—Except as provided in  
11                   subparagraphs (B) and (C), a responsible party  
12                   shall submit to the Director of NIH for inclu-  
13                   sion in the results database clinical trial infor-  
14                   mation for an applicable clinical trial not later  
15                   than 1 year after the earlier of—

16                   “(i) the estimated completion date of  
17                   the trial, as submitted under subsection  
18                   (b)(2); or

19                   “(ii) the actual date of the completion,  
20                   or termination before completion, of the  
21                   trial, as applicable.

22                   “(B) EXTENSIONS.—The Director of NIH  
23                   may provide an extension of the deadline for  
24                   submission of clinical trial information under  
25                   subparagraph (A) if the responsible party for

1 the trial submits to the Director a written re-  
2 quest that demonstrates good cause for the ex-  
3 tension and provides an estimate of the date on  
4 which the information will be submitted. The  
5 Director of NIH may grant more than one such  
6 extension for the clinical trial involved.

7 “(C) UPDATES.—The responsible party for  
8 an applicable clinical trial shall submit to the  
9 Director of NIH for inclusion in the results  
10 database periodic updates to reflect changes in  
11 the clinical trial information submitted under  
12 this subsection. Such updates—

13 “(i) shall be provided not less fre-  
14 quently than once every 6 months during  
15 the 10-year period beginning on the date  
16 on which information is due under sub-  
17 paragraph (A); and

18 “(ii) shall identify the dates on which  
19 the changes were made; and

20 “(iii) shall include, not later than 30  
21 days after any change in the regulatory  
22 status of the drug or device involved, an  
23 update informing the Director of NIH of  
24 such change.

1           “(5) TRUTHFUL CLINICAL TRIAL INFORMA-  
2           TION.—

3           “(A) IN GENERAL.—The clinical trial in-  
4           formation submitted by a responsible party  
5           under this subsection shall not be false or mis-  
6           leading in any particular.

7           “(B) EFFECT.—Subparagraph (A) shall  
8           not have the effect of requiring clinical trial in-  
9           formation with respect to a clinical trial to in-  
10          clude information from any source other than  
11          such clinical trial.

12          “(6) PUBLIC AVAILABILITY OF RESULTS.—

13          “(A) PRE-APPROVAL STUDIES.—Except as  
14          provided in subparagraph (E), with respect to  
15          an applicable clinical trial that is completed be-  
16          fore the drug is initially approved under section  
17          505 of the Federal Food, Drug, and Cosmetic  
18          Act or initially licensed under section 351 of  
19          this Act, or the device is initially cleared under  
20          section 510(k) or approved under section 515 of  
21          the Federal Food, Drug, and Cosmetic Act, the  
22          Director of NIH shall make publicly available  
23          on the results database the clinical trial infor-  
24          mation submitted for such clinical trial not  
25          later than 30 days after—

1           “(i) the drug or device is approved  
2           under such section 505, licensed under  
3           such section 351, cleared under such sec-  
4           tion 510(k), or approved under such sec-  
5           tion 515, as applicable; or

6           “(ii) the Secretary issues a not ap-  
7           provable letter or a not substantially equiv-  
8           alent letter for the drug or device under  
9           such section 505, 351, 510(k), or 515, as  
10          applicable.

11          “(B) MEDICAL AND CLINICAL PHARMA-  
12          COLOGY REVIEWS OF PRE-APPROVAL STUD-  
13          IES.—Not later than 90 days after the date ap-  
14          plicable under clause (i) or (ii) of subparagraph  
15          (A) with respect to an applicable clinical trial,  
16          the Director of NIH shall make publicly avail-  
17          able on the results database a summary of the  
18          available medical and clinical pharmacology re-  
19          views conducted by the Food and Drug Admin-  
20          istration for such trial.

21          “(C) POST-APPROVAL STUDIES.—Except  
22          as provided in subparagraphs (D) and (E), with  
23          respect to an applicable clinical trial that is  
24          completed after the drug is initially approved  
25          under such section 505 or licensed under such

1 section 351, or the device is initially cleared  
2 under such section 510(k) or approved under  
3 such section 515, the Director of NIH shall  
4 make publicly available on the results database  
5 the clinical trial information submitted for such  
6 clinical trial not later than 30 days after the  
7 date of such submission.

8 “(D) SEEKING APPROVAL OF A NEW USE  
9 FOR THE DRUG OR DEVICE.—

10 “(i) IN GENERAL.—If the manufac-  
11 turer of the drug or device is the sponsor  
12 or a financial sponsor of an applicable clin-  
13 ical trial, and such manufacturer certifies  
14 to the Director of NIH that such manufac-  
15 turer has filed, or will file within 1 year,  
16 an application seeking approval under such  
17 section 505, licensing under such section  
18 351, clearance under such section 510(k),  
19 or approval under such section 515 for the  
20 use studied in such clinical trial (which use  
21 is not included in the labeling of the ap-  
22 proved drug or device), then the Director  
23 of NIH shall make publicly available on  
24 the results database the clinical trial infor-  
25 mation submitted for such clinical trial on

1 the earlier of the date that is 30 days after  
2 the date—

3 “(I) the new use of the drug or  
4 device is approved under such section  
5 505, licensed under such section 351,  
6 cleared under such section 510(k), or  
7 approved under such section 515;

8 “(II) the Secretary issues a not  
9 approvable letter or a not substan-  
10 tially equivalent letter for the new use  
11 of the drug or device under such sec-  
12 tion 505, 351, 510(k), or 515; or

13 “(III) the application or pre-  
14 market notification under such section  
15 505, 351, 510(k), or 515 is with-  
16 drawn.

17 “(ii) LIMITATION ON CERTIFI-  
18 CATION.—If a manufacturer makes a cer-  
19 tification under clause (i) with respect to a  
20 clinical trial, the manufacturer shall make  
21 such a certification with respect to each  
22 applicable clinical trial that is required to  
23 be submitted in an application for approval  
24 of the use studied in the clinical trial.

1                   “(iii) 2-YEAR LIMITATION.—The clin-  
2                   ical trial information subject to clause (i)  
3                   shall be made publicly available on the re-  
4                   sults database on the date that is 2 years  
5                   after the date the certification referred to  
6                   in clause (i) was made to the Director of  
7                   NIH, if a regulatory action referred to in  
8                   subclause (I), (II), or (III) of clause (i) has  
9                   not occurred by such date.

10                   “(iv) MEDICAL AND CLINICAL PHAR-  
11                   MACOLOGY REVIEWS.—Not later than 90  
12                   days after the date applicable under sub-  
13                   clause (I), (II), or (III) of clause (i) or  
14                   clause (iii) with respect to an applicable  
15                   clinical trial, the Director of NIH shall  
16                   make publicly available on the results data-  
17                   base a summary of the available medical  
18                   and clinical pharmacology reviews con-  
19                   ducted by the Food and Drug Administra-  
20                   tion for such trial.

21                   “(E) SEEKING PUBLICATION.—

22                   “(i) IN GENERAL.—If the principal in-  
23                   vestigator of an applicable clinical trial is  
24                   seeking publication in a peer-reviewed bio-  
25                   medical journal of a manuscript based on

1 the results of the clinical trial and the re-  
2 sponsible party so certifies to the Director  
3 of NIH—

4 “(I) the responsible party shall  
5 notify the Director of NIH of the pub-  
6 lication date of such manuscript not  
7 later than 15 days after such date;  
8 and

9 “(II) the Director of NIH shall  
10 make publicly available on the results  
11 database the clinical trial information  
12 submitted for such clinical trial on the  
13 date that is 30 days after the publica-  
14 tion date of such manuscript.

15 “(ii) LIMITATIONS.—The clinical trial  
16 information subject to clause (i)—

17 “(I) shall be made publicly avail-  
18 able on the results database on the  
19 date that is 2 years after the date  
20 that the clinical trial information was  
21 required to be submitted to the Direc-  
22 tor of NIH if the manuscript referred  
23 to in such clause has not been pub-  
24 lished by such date; and

1                   “(II) shall not be required to be  
2                   made publicly available under section  
3                   552 of title 5, United States Code  
4                   (commonly known as the ‘Freedom of  
5                   Information Act’), prior to the date  
6                   applicable to such clinical trial infor-  
7                   mation under this subparagraph.

8                   “(7) VERIFICATION OF SUBMISSION PRIOR TO  
9                   PUBLIC AVAILABILITY.—In the case of clinical trial  
10                  information that is submitted under this subsection,  
11                  but is not made publicly available pending either  
12                  regulatory action or publication under subparagraph  
13                  (D) or (E) of paragraph (6), as applicable, the Di-  
14                  rector of NIH shall respond to inquiries from other  
15                  Federal agencies and peer-reviewed journals to con-  
16                  firm that such clinical trial information has been  
17                  submitted but has not yet been made publicly avail-  
18                  able on the results database.

19                  “(d) UPDATES; TRACKING OF CHANGES IN SUB-  
20                  MITTED INFORMATION.—The Director of NIH shall en-  
21                  sure that updates submitted to the Director under sub-  
22                  sections (b)(7) and (c)(4) do not result in the removal  
23                  from the registry database or the results database of the  
24                  original submissions or of any preceding updates, and that  
25                  information in such databases is presented in a manner

1 that enables users to readily access each original submis-  
2 sion and to track the changes made by the updates.

3 “(e) COORDINATION AND COMPLIANCE.—

4 “(1) CONSULTATION WITH OTHER FEDERAL  
5 AGENCIES.—The Secretary shall—

6 “(A) consult with other agencies that con-  
7 duct human studies in accordance with part 46  
8 of title 45, Code of Federal Regulations (or any  
9 successor regulations), to determine if any such  
10 studies are applicable clinical trials; and

11 “(B) develop with such agencies appro-  
12 priate procedures to ensure that clinical trial in-  
13 formation for such applicable clinical trials is  
14 submitted under subsection (b) and (c).

15 “(2) COORDINATION OF REGISTRY DATABASE  
16 AND RESULTS DATABASE.—

17 “(A) IN GENERAL.—Each entry in the reg-  
18 istry database under subsection (b) or the re-  
19 sults database under subsection (c) shall in-  
20 clude a link to the corresponding entry in the  
21 results database or the registry database, re-  
22 spectively.

23 “(B) MISSING ENTRIES.—

24 “(i) IN GENERAL.—If, based on a re-  
25 view of the entries in the registry database

1 under subsection (b), the Director of NIH  
2 determines that a responsible party has  
3 failed to submit required clinical trial in-  
4 formation to the results database under  
5 subsection (c), the Director of NIH shall  
6 inform the responsible party involved of  
7 such failure and permit the responsible  
8 party to correct the failure within 30 days.

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

18 “(iii) PUBLIC NOTICE OF FAILURE TO  
19 CORRECT.—The Director of NIH shall in-  
20 clude in the clinical trial registry database  
21 entry and the clinical trial results database  
22 entry for each applicable clinical trial a no-  
23 tice of any uncorrected failure to submit  
24 required clinical trial information and shall

1           provide that the public may easily search  
2           for such entries.

3           “(3) ACTION ON APPLICATIONS.—

4           “(A) VERIFICATION PRIOR TO FILING.—

5           The Secretary, acting through the Commis-  
6           sioner of Food and Drugs, shall verify that the  
7           clinical trial information required under sub-  
8           sections (b) and (c) for an applicable clinical  
9           trial is submitted pursuant to such subsections,  
10          as applicable—

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

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

21           “(B) NOTIFICATION.—If the Secretary de-  
22           termines under subparagraph (A) that clinical  
23           trial information has not been submitted as re-  
24           quired by subsection (b) or (c), the Secretary  
25           shall notify the applicant and the responsible

1 party of such noncompliance and require sub-  
2 mission of such information within 30 days.

3 “(C) REFUSAL TO FILE.—If the respon-  
4 sible party does not remedy such noncompliance  
5 within 30 days of receipt of notification under  
6 subparagraph (B), the Secretary shall refuse to  
7 file, approve, or clear such application or pre-  
8 market notification.

9 “(4) CONTENT REVIEW.—

10 “(A) IN GENERAL.—To ensure that the  
11 summary documents described in subsection  
12 (c)(3) are non-promotional, and are not false or  
13 misleading in any particular under subsection  
14 (c)(5), the Secretary shall compare such docu-  
15 ments to the results data of the clinical trial for  
16 a representative sample of applicable clinical  
17 trials by—

18 “(i) acting through the Commissioner  
19 of Food and Drugs to examine the results  
20 data for such clinical trials submitted to  
21 Secretary when such data are submitted—

22 “(I) for review as part of an ap-  
23 plication under section 505 or 515 of  
24 the Federal Food, Drug, and Cos-  
25 metic Act or under section 351 of this

1 Act or a premarket notification under  
2 section 510(k) of the Federal Food,  
3 Drug, and Cosmetic Act; or

4 “(II) in an annual status report  
5 on the drug or device under such ap-  
6 plication;

7 “(ii) acting with the Federal agency  
8 that funds such clinical trial in whole or in  
9 part by a grant to examine the results data  
10 for such clinical trials; and

11 “(iii) acting through inspections under  
12 section 704 of the Federal Food, Drug,  
13 and Cosmetic Act to examine results data  
14 for such clinical trials not described in  
15 clause (i) or (ii).

16 “(B) NOTICE OF NONCOMPLIANCE.—If the  
17 Secretary determines that the clinical trial in-  
18 formation submitted in such a summary docu-  
19 ment is promotional, false or misleading in any  
20 particular, the Secretary shall notify the re-  
21 sponsible party and give such party an oppor-  
22 tunity to remedy such noncompliance by sub-  
23 mitting the required revised clinical trial infor-  
24 mation within 30 days of such notification.

25 “(f) PENALTIES FOR NONCOMPLIANCE.—

1           “(1) IN GENERAL.—The following acts and the  
2 causing thereof are unlawful:

3           “(A) The failure to submit clinical trial in-  
4 formation as required by this section.

5           “(B) The submission of clinical trial infor-  
6 mation under this section that is false or mis-  
7 leading in any particular in violation of sub-  
8 section (b)(5) or (c)(5).

9           “(2) CERTAIN PENALTIES.—Section 303(a) of  
10 the Federal Food, Drug, and Cosmetic Act applies  
11 with respect to a violation of paragraph (1) to the  
12 same extent and in the same manner as such section  
13 303(a) applies with respect to a violation of section  
14 301 of such Act.

15           “(3) CONSIDERATIONS.—In determining wheth-  
16 er to apply a penalty under paragraph (2) or under  
17 paragraph (4) for a violation described in paragraph  
18 (1), the Secretary, acting through the Commissioner  
19 of Food and Drugs, shall consider—

20           “(A) whether the responsible party  
21 promptly corrects the noncompliance when pro-  
22 vided notice;

23           “(B) whether the responsible party has en-  
24 gaged in a pattern or practice of noncompli-  
25 ance; and

1           “(C) the extent to which the noncompli-  
2           ance involved may have significantly misled  
3           health care providers or patients concerning the  
4           safety or effectiveness of the drug involved.

5           “(4) CIVIL PENALTIES.—

6           “(A) IN GENERAL.—A person is subject to  
7           a civil penalty in accordance with this para-  
8           graph if the person commits a violation de-  
9           scribed in paragraph (1) and fails to correct the  
10          violation by the end of the 30-day period de-  
11          scribed in subparagraph (B).

12          “(B) NOTIFICATION.—If a person is in vio-  
13          lation of paragraph (1), the Secretary shall no-  
14          tify the person of such noncompliance and give  
15          the person a 30-day period to correct such vio-  
16          lation before imposing a civil penalty under this  
17          paragraph.

18          “(C) AMOUNT OF PENALTY.—The amount  
19          of a civil penalty under this subsection shall be  
20          not more than a total of \$15,000 for all viola-  
21          tions adjudicated in a single proceeding in the  
22          case of an individual, and not more than  
23          \$10,000 per day until the violation is corrected  
24          in the case of any other person, except that if  
25          the person is a nonprofit entity the penalty may

1 not exceed a total of \$15,000 for all violations  
2 adjudicated in a single proceeding.

3 “(D) PROCEDURES.—The provisions of  
4 paragraphs (4) through (6) of section 303(f) of  
5 the Federal Food, Drug, and Cosmetic Act  
6 apply to the imposition of a penalty under this  
7 subsection to the same extent and in the same  
8 manner as such provisions apply to a penalty  
9 imposed under such section 303(f).

10 “(g) AUTHORIZATION OF APPROPRIATIONS.—There  
11 are authorized to be appropriated to carry out this section  
12 \$10,000,000 for each fiscal year.”.

13 (b) CONFORMING AMENDMENTS.—

14 (1) INVESTIGATIONAL NEW DRUGS.—Section  
15 505(i) of the Federal Food, Drug, and Cosmetic Act  
16 (21 U.S.C. 355(i)) is amended—

17 (A) in paragraph (1)—

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

20 (ii) in subparagraph (D)—

21 (I) by aligning the indentation of  
22 such subparagraph with the indenta-  
23 tion of subparagraphs (A), (B), and  
24 (C); and

1 (II) by striking the period at the  
2 end and inserting “; and”; and

3 (iii) by adding at the end the fol-  
4 lowing:

5 “(E) the submission to the Director of NIH of  
6 clinical trial information for the clinical investigation  
7 at issue required under section 492C of the Public  
8 Health Service Act for inclusion in the registry data-  
9 base and the results database described in such sec-  
10 tion.”;

11 (B) in paragraph (3)(B)—

12 (i) in clause (i), by striking “or” after  
13 the semicolon;

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

16 (iii) by adding at the end the fol-  
17 lowing:

18 “(iii) clinical trial information for the clinical  
19 investigation at issue was not submitted in compli-  
20 ance with section 492C of the Public Health Service  
21 Act.”; and

22 (C) in paragraph (4), by adding at the end  
23 the following: “The Secretary shall update such  
24 regulations to require inclusion in the informed  
25 consent form a statement that clinical trial in-

1           formation for such clinical investigation will be  
2           submitted for inclusion in the registry database  
3           and results database, as applicable, described in  
4           section 492C of the Public Health Service  
5           Act.”.

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

9                   (A) in the first sentence, by inserting after  
10                  “in any particular;” the following: “or (8) the  
11                  applicant failed to submit the clinical trial in-  
12                  formation for any applicable clinical trial as re-  
13                  quired by section 492C of the Public Health  
14                  Service Act;”; and

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

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

22                   (A) by redesignating clause (iii) as clause  
23                  (iv); and

24                   (B) by inserting after clause (ii) the fol-  
25                  lowing:

1                   “(iii) A requirement that the person  
2                   applying for an exemption for a device as-  
3                   sure that such person is in compliance with  
4                   the requirements of section 492C of the  
5                   Public Health Service Act for the submis-  
6                   sion of clinical trial information for inclu-  
7                   sion in the registry database and the re-  
8                   sults database described in such section.”.

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

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

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

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

18                  “(3) action taken by such person to comply  
19                  with requirements under section 492C of the Public  
20                  Health Service Act for the submission of clinical  
21                  trial information for inclusion in the registry data-  
22                  base and the results database described in such sec-  
23                  tion.”.

24                  (5) REFUSAL TO APPROVE NEW DEVICE APPLI-  
25                  CATION.—Paragraph (2) of section 515(d) of the

1 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
2 360e(d)) is amended—

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

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

7 (C) by inserting after subparagraph (E)  
8 the following:

9 “(F) the applicant is in violation of the re-  
10 quirements under section 492C of the Public  
11 Health Service Act for the submission of clin-  
12 ical trial information for inclusion in the reg-  
13 istry database or the results database described  
14 in such section.”.

15 (c) GUIDANCE.—Not later than 180 days after the  
16 date of the enactment of this Act, the Commissioner of  
17 Food and Drugs, in consultation with the Director of the  
18 National Institutes of Health, shall issue guidance to clar-  
19 ify which clinical trials are applicable clinical trials (as de-  
20 fined in section 492C of the Public Health Service Act,  
21 as amended by this section) and required to be submitted  
22 for inclusion in the clinical trial registry database de-  
23 scribed in such section.

24 (d) PREEMPTION.—

1           (1) IN GENERAL.—No State or political subdivi-  
2           sion of a State may establish or continue in effect  
3           any requirement for the registration of clinical trials  
4           or any requirement for the inclusion of information  
5           relating to the results of clinical trials in a database.

6           (2) RULE OF CONSTRUCTION.—The fact of sub-  
7           mission of clinical trial information, if submitted in  
8           compliance with section 492C of the Public Health  
9           Service Act (as amended by this section), that re-  
10          lates to a use of a drug or device not included in the  
11          official labeling of the approved drug or device shall  
12          not be construed by the Secretary or in any adminis-  
13          trative or judicial proceeding, as evidence of a new  
14          intended use of the drug or device that is different  
15          from the intended use of the drug or device set forth  
16          in the official labeling of the drug or device. The  
17          availability of clinical trial information through the  
18          databases under subsections (b) and (c) of such sec-  
19          tion 492C, if submitted in compliance with such sec-  
20          tion 492C, shall not be considered as labeling, adul-  
21          teration, or misbranding of the drug or device under  
22          the Federal Food, Drug, and Cosmetic Act (21  
23          U.S.C. 301 et seq.).

24          (e) EFFECTIVE DATES.—

1           (1) ESTABLISHMENT OF REGISTRY DATABASE  
2           AND RESULTS DATABASE.—Not later than 1 year  
3           after the date of the enactment of this Act, the Di-  
4           rector of NIH shall establish the registry database  
5           and the results database of clinical trials of drugs  
6           and devices in accordance with section 492C of the  
7           Public Health Service Act (as amended by sub-  
8           section (a)).

9           (2) CLINICAL TRIALS INITIATED PRIOR TO OP-  
10          ERATION OF REGISTRY DATABASE.—The responsible  
11          party (as defined in such section 492C) for an appli-  
12          cable clinical trial (as defined in such section 492C)  
13          that is initiated after the date of the enactment of  
14          this Act and before the date such registry database  
15          is established under paragraph (1) of this sub-  
16          section, shall submit required clinical trial informa-  
17          tion not later than 120 days after the date such reg-  
18          istry database is established.

19          (3) CLINICAL TRIALS INITIATED AFTER OPER-  
20          ATION OF REGISTRY DATABASE.—The responsible  
21          party (as defined in such section 492C) for an appli-  
22          cable clinical trial (as defined in such section 492C)  
23          that is initiated after the date such registry database  
24          is established under paragraph (1) of this subsection

1 shall submit required clinical trial information in ac-  
2 cordance with subsection (b) of such section 492C.

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

5 (A) IN GENERAL.—Subsection (c) of such  
6 section 492C shall take effect 90 days after the  
7 date the results database is established under  
8 paragraph (1) of this subsection with respect to  
9 any applicable clinical trial (as defined in such  
10 section 492C) that—

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

13 (ii) is completed between the date of  
14 the enactment of this Act and such date of  
15 establishment under paragraph (1) of this  
16 subsection.

17 (B) OTHER TRIALS.—Except as provided  
18 in subparagraph (A), subsection (c) of such sec-  
19 tion 492C shall take effect 180 days after the  
20 date that the results database is established  
21 under paragraph (1) of this subsection with re-  
22 spect to any applicable clinical trial that is com-  
23 pleted between the date of the enactment of this  
24 Act and such date of establishment under para-  
25 graph (1).

1           (5) TRIALS COMPLETED AFTER ESTABLISH-  
2           MENT OF RESULTS DATABASE.—Subsection (c) of  
3           such section 492C shall apply to any clinical trial  
4           that is completed after the date that the results  
5           database is established under paragraph (1) of this  
6           subsection.

7           (6) RETROACTIVITY OF DATABASE.—

8                   (A) VOLUNTARY SUBMISSIONS.—The Sec-  
9                   retary of Health and Human Services (referred  
10                   to in this paragraph as the “Secretary”) shall  
11                   establish procedures and mechanisms to allow  
12                   for the voluntary submission to the Secretary—

13                           (i) of clinical trial information for in-  
14                           clusion in the registry database (as defined  
15                           in such section 492C) on applicable clinical  
16                           trials (as defined in such section 492C)  
17                           initiated before the date of the enactment  
18                           of this Act; and

19                           (ii) of clinical trial information for in-  
20                           clusion in the results database (as defined  
21                           in such section 492C) on applicable clinical  
22                           trials (as defined in such section 492C)  
23                           completed before the date of the enactment  
24                           of this Act.

1 (B) REQUIRED SUBMISSIONS.—Notwith-  
2 standing the preceding paragraphs of this sub-  
3 section, in any case in which the Secretary de-  
4 termines that submission of clinical trial infor-  
5 mation for an applicable clinical trial (as de-  
6 fined in such section 492C) described in clause  
7 (i) or (ii) of subparagraph (A) is in the interest  
8 of the public health—

9 (i) the Secretary may require that  
10 such information be submitted to the Sec-  
11 retary in accordance with such section  
12 492C; and

13 (ii) failure to comply with such a re-  
14 quirement shall be treated as a violation of  
15 the corresponding requirement of such sec-  
16 tion 492C.

17 (7) FUNDING RESTRICTIONS.—Paragraph (1)  
18 of subsection (e) of such section 492C shall take ef-  
19 fect 210 days after the date that the clinical trial  
20 registry database and the clinical trial results data-  
21 base are established under paragraph (1) of this  
22 subsection.

23 (8) STATUS OF CLINICALTRIALS.GOV  
24 WEBSITE.—

1 (A) IN GENERAL.—After receiving public  
2 comment and not later than 90 days after the  
3 date of the enactment of this Act, the Secretary  
4 shall publish in the Federal Register a notice  
5 determining the more efficient approach to es-  
6 tablishing the registry database described in  
7 subsection (b) of such section 492C and wheth-  
8 er such approach is—

9 (i) that such registry database should  
10 expand and build upon the data bank de-  
11 scribed in section 402(i) of the Public  
12 Health Service Act (as in effect on the day  
13 before the date of the enactment of this  
14 Act); or

15 (ii) that such registry database should  
16 supplant the data bank described in such  
17 section 402(i) (as in effect on the day be-  
18 fore the date of the enactment of this Act).

19 (B) CLINICALTRIALS.GOV SUPPLANTED.—  
20 If the Secretary determines to apply the ap-  
21 proach described under subparagraph (A)(ii),  
22 the Secretary shall maintain an archive of the  
23 data bank described in such section 402(i) (as  
24 in effect on the day before the date of the en-

1           actment of this Act) on the Internet website of  
2           the National Library of Medicine.

3 **SEC. 2. STUDY BY GOVERNMENT ACCOUNTABILITY OFFICE.**

4           (a) **IN GENERAL.**—The Comptroller General of the  
5 United States shall conduct a study to determine whether  
6 information on the trials registry and database is consid-  
7 ered promotional and to evaluate the implementation of  
8 this database.

9           (b) **REPORT.**—Not later than one year after the date  
10 of the enactment of this Act, the Comptroller General shall  
11 complete the study under subsection (a) and submit to the  
12 Congress a report on the results of such study.