

**AMENDMENT IN THE NATURE OF A SUBSTITUTE  
TO THE COMMITTEE PRINT  
OFFERED BY \_\_\_\_\_**

**[Clinical Trials Data Banks]**

Strike all after the enacting clause and insert the following:

1 **SECTION 1. CLINICAL TRIAL REGISTRY DATABASE AND**  
2 **CLINICAL TRIAL RESULTS DATABASE.**

3 (a) IN GENERAL.—Title IV of the Public Health  
4 Service Act (42 U.S.C. 281 et seq.) is amended—

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

7 (2) by inserting after section 492B the fol-  
8 lowing new section:

9 **“SEC. 492C. CLINICAL TRIAL REGISTRY DATABASE; CLIN-**  
10 **ICAL TRIAL RESULTS DATABASE.**

11 **“(a) DEFINITIONS.—**In this section:

12 **“(1) APPLICABLE CLINICAL TRIAL.—**The term  
13 ‘applicable clinical trial’—

14 **“(A) means** a clinical trial that is con-  
15 ducted to test the safety or effectiveness (in-  
16 cluding comparative effectiveness) of a drug or  
17 device (irrespective of whether the clinical trial

1 is federally or privately funded, and whether the  
2 clinical trial involves an approved or unap-  
3 proved drug or device);

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

6 “(i) there is an application or pre-  
7 market notification pending before the  
8 Food and Drug Administration for ap-  
9 proval or clearance of the drug or device  
10 involved under section 505, 510(k), or 515  
11 of the Federal Food, Drug, and Cosmetic  
12 Act or section 351 of this Act; or

13 “(ii) the drug or device involved is so  
14 approved or cleared; and

15 “(C) notwithstanding clauses (i) and (ii),  
16 excludes—

17 “(i) a clinical trial to determine the  
18 safety of a use of a drug that is designed  
19 solely to detect major toxicities in the drug  
20 or to investigate pharmacokinetics, unless  
21 the clinical trial is designed to investigate  
22 pharmacokinetics in a special population or  
23 populations; and

24 “(ii) a small clinical trial to determine  
25 the feasibility of a device, or a clinical trial

1 to test prototype devices where the primary  
2 focus is feasibility.

3 “(2) CLINICAL TRIAL INFORMATION.—The term  
4 ‘clinical trial information’ means those data elements  
5 that are necessary to complete an entry in the clin-  
6 ical trial registry database under subsection (b) or  
7 the clinical trial results database under subsection  
8 (c), as applicable.

9 “(3) COMPLETION DATE.—The term ‘comple-  
10 tion date’ means the date of the final collection of  
11 data from subjects in the clinical trial for the pri-  
12 mary and secondary outcomes to be examined in the  
13 trial.

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

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

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

24 “(A) the primary sponsor (as defined in  
25 the International Clinical Trials Registry Plat-

1 form trial registration data set of the World  
2 Health Organization) of the clinical trial; or

3 “(B) the principal investigator of such clin-  
4 ical trial if so designated by such sponsor, so  
5 long as the principal investigator is responsible  
6 for conducting the trial, has access to and con-  
7 trol over the data, has the right to publish the  
8 results of the trial, and has the responsibility to  
9 meet all of the requirements under this section  
10 that are applicable to responsible parties.

11 “(b) CLINICAL TRIALS REGISTRY DATABASE.—

12 “(1) ESTABLISHMENT.—To enhance patient en-  
13 rollment and provide a mechanism to track subse-  
14 quent progress of clinical trials, the Secretary, act-  
15 ing through the Director of NIH, shall establish and  
16 administer a clinical trial registry database in ac-  
17 cordance with this section (referred to in this section  
18 as the ‘registry database’). The Director of NIH  
19 shall ensure that the registry database is made pub-  
20 licly available through the Internet.

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

1           “(A) conforms to the International Clinical  
2           Trials Registry Platform trial registration data  
3           set of the World Health Organization;

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

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

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

12          “(E) if the drug is not approved under sec-  
13          tion 505 of the Federal Food, Drug, and Cos-  
14          metic Act or licensed under section 351 of this  
15          Act, or the device is not cleared under section  
16          510(k) or approved under section 515 of the  
17          Federal Food, Drug, and Cosmetic Act, speci-  
18          fies whether or not there is expanded access to  
19          the drug or device under section 561 of the  
20          Federal Food, Drug, and Cosmetic Act for  
21          those who do not qualify for enrollment in the  
22          clinical trial and how to obtain information  
23          about such access;

24          “(F) includes, with respect to any indi-  
25          vidual who is not an employee of the responsible

1 party for the clinical trial or of the manufac-  
2 turer of the drug or device involved, information  
3 on whether the responsible party or manufac-  
4 turer has entered into any agreement with such  
5 individual that restricts in any manner the abil-  
6 ity of the individual—

7 “(i) to discuss the results of the trial  
8 at a scientific meeting or any other public  
9 or private forum; or

10 “(ii) to publish the results of the trial,  
11 or a description or discussion of the results  
12 of the trial, in a scientific or academic  
13 journal; and

14 “(G) requires the inclusion of such other  
15 data elements to the registry database as ap-  
16 propriate.

17 “(3) FORMAT AND STRUCTURE.—

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

22 “(i) The indication being studied in  
23 the clinical trial, using Medical Subject  
24 Headers (MeSH) descriptors.

1                   “(ii) The safety issue being studied in  
2                   the clinical trial.

3                   “(iii) The enrollment status of the  
4                   clinical trial.

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

6                   “(B) FORMAT.—The Director of the NIH  
7                   shall ensure that the registry database is easily  
8                   used by patients, and that entries are easily  
9                   compared.

10                  “(4) DATA SUBMISSION.—The responsible party  
11                  for an applicable clinical trial shall submit to the Di-  
12                  rector of NIH for inclusion in the registry database  
13                  the clinical trial information described in paragraph  
14                  (2).

15                  “(5) TRUTHFUL CLINICAL TRIAL INFORMA-  
16                  TION.—

17                         “(A) IN GENERAL.—The clinical trial in-  
18                         formation submitted by a responsible party  
19                         under this subsection shall not be false or mis-  
20                         leading.

21                         “(B) EFFECT.—Subparagraph (A) shall  
22                         not have the effect of requiring clinical trial in-  
23                         formation to include information from any  
24                         source other than the clinical trial involved.

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

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

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

16                 “(B) shall include identification of the  
17                 dates of any such changes;

18                 “(C) not later than 30 days after the en-  
19                 rollment status of such clinical trial changes,  
20                 shall include an update of the enrollment sta-  
21                 tus; and

22                 “(D) not later than 30 days after the com-  
23                 pletion date of the clinical trial, shall include a  
24                 report to the Director that such clinical trial is  
25                 complete.

1           “(8) APPLICABILITY OF DEVICE TRIALS.—Ap-  
2           plicability of device trials shall be delayed until after  
3           approval.

4           “(c) CLINICAL TRIALS RESULTS DATABASE.—

5           “(1) ESTABLISHMENT.—To ensure that results  
6           of clinical trials are made public and that patients  
7           and providers have current information regarding  
8           the results of clinical trials, the Secretary, acting  
9           through the Director of NIH, shall establish and ad-  
10          minister a clinical trial results database in accord-  
11          ance with this section (referred to in this section as  
12          the ‘results database’). The Director of NIH shall  
13          ensure that the results database is made publicly  
14          available through the Internet.

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

19                 “(A) The indication studied in the clinical  
20                 trial, using Medical Subject Headers (MeSH)  
21                 descriptors.

22                 “(B) The safety issue studied in the clin-  
23                 ical trial.

1           “(C) Whether an application for the tested  
2 indication is approved, pending approval, with-  
3 drawn, or not submitted.

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

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

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

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

11           “(ii) Each financial sponsor of the  
12 clinical trial.

13           “(3) CONTENTS.—

14           “(A) IN GENERAL.—The responsible party  
15 for an applicable clinical trial shall submit to  
16 the Director of NIH for inclusion in the results  
17 database the clinical trial information described  
18 in subparagraph (B).

19           “(B) REQUIRED ELEMENTS.—In submit-  
20 ting clinical trial information for a clinical trial  
21 to the Director of NIH for inclusion in the re-  
22 sults database, the responsible party shall in-  
23 clude, with respect to such clinical trial, the fol-  
24 lowing information:

1                   “(i) The information described in sub-  
2 paragraphs (A) through (E) of subsection  
3 (b)(2).

4                   “(ii) A summary that is written in  
5 non-technical, understandable language for  
6 patients that includes the following:

7                               “(I) The purpose of the clinical  
8 trial.

9                               “(II) The sponsor of the clinical  
10 trial.

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

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

15                               “(V) A general description of the  
16 clinical trial and results, including a  
17 description of and the reasons for any  
18 changes in the clinical trial design  
19 that occurred since the date of sub-  
20 mission of clinical trial information  
21 for inclusion in the registry database  
22 established under subsection (b) and a  
23 description of any significant safety  
24 information.

1 “(iii) A summary that is technical in  
2 nature that includes the following:

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

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

7 “(III) Each financial sponsor of  
8 the clinical trial.

9 “(IV) A point of contact for sci-  
10 entific information about the clinical  
11 trial.

12 “(V) A description of the patient  
13 population tested in the clinical trial.

14 “(VI) A general description of  
15 the clinical trial and results, including  
16 a description of and the reasons for  
17 any changes in the clinical trial design  
18 that occurred since the date of sub-  
19 mission of clinical trial information  
20 for the clinical trial in the registry  
21 database established under subsection  
22 (b).

23 “(VII) Summary data describing  
24 the results, including—

1                   “(aa) whether the primary  
2 endpoint was achieved, including  
3 relevant statistics;

4                   “(bb) an assessment of any  
5 secondary endpoints, if applica-  
6 ble, including relevant statistics;  
7 and

8                   “(cc) any significant safety  
9 information, including a sum-  
10 mary of the incidence of serious  
11 adverse events observed in the  
12 clinical trial and a summary of  
13 the most common adverse events  
14 observed in the clinical trial and  
15 the frequencies of such events.

16                   “(iv) With respect to the group of  
17 subjects receiving the drug or device in-  
18 volved, and each comparison group of sub-  
19 jects, the percentage of individuals who  
20 ceased participation as subjects and the  
21 reasons for ceasing participation.

22                   “(v) With respect to an individual who  
23 is not an employee of the responsible party  
24 for the clinical trial or of the manufacturer  
25 of the drug or device involved, information

1 (to the extent not submitted under sub-  
2 section (b)(2)(F)) on any agreement that  
3 the responsible party or manufacturer has  
4 entered into with such individual that re-  
5 stricts in any manner the ability of the in-  
6 dividual—

7 “(I) to discuss the results of the  
8 trial at a scientific meeting or any  
9 other public or private forum; or

10 “(II) to publish the results of the  
11 trial, or a description or discussion of  
12 the results of the trial, in a scientific  
13 or academic journal.

14 “(vi) A link to available peer-reviewed  
15 publications based on the results of the  
16 clinical trial.

17 “(vii) The completion date of the clin-  
18 ical trial.

19 “(viii) A link to the Internet web post-  
20 ing of any adverse regulatory actions taken  
21 by the Food and Drug Administration,  
22 such as a warning letter, that was sub-  
23 stantively based on the clinical trial design,  
24 outcome, or representation made by the

1 applicant about the design or outcome of  
2 the clinical trial.

3 “(4) TIMING.—

4 “(A) IN GENERAL.—Except as provided in  
5 subparagraphs (B) and (C), a responsible party  
6 shall submit to the Director of NIH for inclu-  
7 sion in the results database clinical trial infor-  
8 mation for an applicable clinical trial not later  
9 than 1 year after the earlier of—

10 “(i) the estimated completion date of  
11 the trial, as submitted under subsection  
12 (b)(2); or

13 “(ii) the actual date of the completion,  
14 or termination before completion, of the  
15 trial, as applicable.

16 “(B) EXTENSIONS.—The Director of NIH  
17 may provide an extension of the deadline for  
18 submission of clinical trial information under  
19 subparagraph (A) if the responsible party for  
20 the trial submits to the Director a written re-  
21 quest that demonstrates good cause for the ex-  
22 tension and provides an estimate of the date on  
23 which the information will be submitted. The  
24 Director of NIH may grant more than one such  
25 extension for the clinical trial involved.

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

7                   “(i) shall be provided not less fre-  
8                   quently than once every 6 months during  
9                   the 10-year period beginning on the date  
10                  on which information is due under sub-  
11                  paragraph (A); and

12                  “(ii) shall identify the dates on which  
13                  the changes were made; and

14                  “(iii) shall include, not later than 30  
15                  days after any change in the regulatory  
16                  status of the drug or device involved, an  
17                  update informing the Director of NIH of  
18                  such change.

19           “(5) TRUTHFUL CLINICAL TRIAL INFORMA-  
20           TION.—

21                  “(A) IN GENERAL.—The clinical trial in-  
22                  formation submitted by a responsible party  
23                  under this subsection shall not be false or mis-  
24                  leading in any particular.

1           “(B) EFFECT.—Subparagraph (A) shall  
2 not have the effect of requiring clinical trial in-  
3 formation with respect to a clinical trial to in-  
4 clude information from any source other than  
5 such clinical trial.

6           “(6) PUBLIC AVAILABILITY OF RESULTS.—

7           “(A) PRE-APPROVAL STUDIES.—Except as  
8 provided in subparagraph (E), with respect to  
9 an applicable clinical trial that is completed be-  
10 fore the drug is initially approved under section  
11 505 of the Federal Food, Drug, and Cosmetic  
12 Act or initially licensed under section 351 of  
13 this Act, or the device is initially cleared under  
14 section 510(k) or approved under section 515 of  
15 the Federal Food, Drug, and Cosmetic Act, the  
16 Director of NIH shall make publicly available  
17 on the results database the clinical trial infor-  
18 mation submitted for such clinical trial not  
19 later than 30 days after—

20           “(i) the drug or device is approved  
21 under such section 505, licensed under  
22 such section 351, cleared under such sec-  
23 tion 510(k), or approved under such sec-  
24 tion 515, as applicable; or

1                   “(ii) the Secretary issues a not ap-  
2                   provable letter or a not substantially equiv-  
3                   alent letter for the drug or device under  
4                   such section 505, 351, 510(k), or 515, as  
5                   applicable.

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

16                  “(C) POST-APPROVAL STUDIES.—Except  
17                  as provided in subparagraphs (D) and (E), with  
18                  respect to an applicable clinical trial that is  
19                  completed after the drug is initially approved  
20                  under such section 505 or licensed under such  
21                  section 351, or the device is initially cleared  
22                  under such section 510(k) or approved under  
23                  such section 515, the Director of NIH shall  
24                  make publicly available on the results database  
25                  the clinical trial information submitted for such

1 clinical trial not later than 30 days after the  
2 date of such submission.

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

5 “(i) IN GENERAL.—If the manufac-  
6 turer of the drug or device is the sponsor  
7 or a financial sponsor of an applicable clin-  
8 ical trial, and such manufacturer certifies  
9 to the Director of NIH that such manufac-  
10 turer has filed, or will file within 1 year,  
11 an application seeking approval under such  
12 section 505, licensing under such section  
13 351, clearance under such section 510(k),  
14 or approval under such section 515 for the  
15 use studied in such clinical trial (which use  
16 is not included in the labeling of the ap-  
17 proved drug or device), then the Director  
18 of NIH shall make publicly available on  
19 the results database the clinical trial infor-  
20 mation submitted for such clinical trial on  
21 the earlier of the date that is 30 days after  
22 the date—

23 “(I) the new use of the drug or  
24 device is approved under such section  
25 505, licensed under such section 351,

1 cleared under such section 510(k), or  
2 approved under such section 515;

3 “(II) the Secretary issues a not  
4 approvable letter or a not substan-  
5 tially equivalent letter for the new use  
6 of the drug or device under such sec-  
7 tion 505, 351, 510(k), or 515; or

8 “(III) the application or pre-  
9 market notification under such section  
10 505, 351, 510(k), or 515 is with-  
11 drawn.

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

20 “(iii) 2-YEAR LIMITATION.—The clin-  
21 ical trial information subject to clause (i)  
22 shall be made publicly available on the re-  
23 sults database on the date that is 2 years  
24 after the date the certification referred to  
25 in clause (i) was made to the Director of

1 NIH, if a regulatory action referred to in  
2 subclause (I), (II), or (III) of clause (i) has  
3 not occurred by such date.

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

15 “(E) SEEKING PUBLICATION.—

16 “(i) IN GENERAL.—If the principal in-  
17 vestigator of an applicable clinical trial is  
18 seeking publication in a peer-reviewed bio-  
19 medical journal of a manuscript based on  
20 the results of the clinical trial and the re-  
21 sponsible party so certifies to the Director  
22 of NIH—

23 “(I) the responsible party shall  
24 notify the Director of NIH of the pub-  
25 lication date of such manuscript not

1 later than 15 days after such date;  
2 and

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

9 “(ii) LIMITATIONS.—The clinical trial  
10 information subject to clause (i)—

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

19 “(II) shall not be required to be  
20 made publicly available under section  
21 552 of title 5, United States Code  
22 (commonly known as the ‘Freedom of  
23 Information Act’), prior to the date  
24 applicable to such clinical trial infor-  
25 mation under this subparagraph.

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

12           “(d) UPDATES; TRACKING OF CHANGES IN SUB-  
13 MITTED INFORMATION.—The Director of NIH shall en-  
14 sure that updates submitted to the Director under sub-  
15 sections (b)(7) and (c)(4) do not result in the removal  
16 from the registry database or the results database of the  
17 original submissions or of any preceding updates, and that  
18 information in such databases is presented in a manner  
19 that enables users to readily access each original submis-  
20 sion and to track the changes made by the updates.

21           “(e) COORDINATION AND COMPLIANCE.—

22           “(1) CONSULTATION WITH OTHER FEDERAL  
23 AGENCIES.—The Secretary shall—

24           “(A) consult with other agencies that con-  
25 duct human studies in accordance with part 46

1 of title 45, Code of Federal Regulations (or any  
2 successor regulations), to determine if any such  
3 studies are applicable clinical trials; and

4 “(B) develop with such agencies appro-  
5 priate procedures to ensure that clinical trial in-  
6 formation for such applicable clinical trials is  
7 submitted under subsection (b) and (c).

8 “(2) COORDINATION OF REGISTRY DATABASE  
9 AND RESULTS DATABASE.—

10 “(A) IN GENERAL.—Each entry in the reg-  
11 istry database under subsection (b) or the re-  
12 sults database under subsection (c) shall in-  
13 clude a link to the corresponding entry in the  
14 results database or the registry database, re-  
15 spectively.

16 “(B) MISSING ENTRIES.—

17 “(i) IN GENERAL.—If, based on a re-  
18 view of the entries in the registry database  
19 under subsection (b), the Director of NIH  
20 determines that a responsible party has  
21 failed to submit required clinical trial in-  
22 formation to the results database under  
23 subsection (c), the Director of NIH shall  
24 inform the responsible party involved of

1 such failure and permit the responsible  
2 party to correct the failure within 30 days.

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

12 “(iii) PUBLIC NOTICE OF FAILURE TO  
13 CORRECT.—The Director of NIH shall in-  
14 clude in the clinical trial registry database  
15 entry and the clinical trial results database  
16 entry for each applicable clinical trial a no-  
17 tice of any uncorrected failure to submit  
18 required clinical trial information and shall  
19 provide that the public may easily search  
20 for such entries.

21 “(3) ACTION ON APPLICATIONS.—

22 “(A) VERIFICATION PRIOR TO FILING.—  
23 The Secretary, acting through the Commis-  
24 sioner of Food and Drugs, shall verify that the  
25 clinical trial information required under sub-

1 sections (b) and (c) for an applicable clinical  
2 trial is submitted pursuant to such subsections,  
3 as applicable—

4 “(i) when considering a drug or device  
5 for an exemption under section 505(i) or  
6 section 520(g) of the Federal Food, Drug,  
7 and Cosmetic Act; and

8 “(ii) prior to filing an application or  
9 premarket notification under section 505,  
10 510(k), or 515 of the Federal Food, Drug,  
11 and Cosmetic Act or section 351 of this  
12 Act, that includes information from such  
13 clinical trial.

14 “(B) NOTIFICATION.—If the Secretary de-  
15 termines under subparagraph (A) that clinical  
16 trial information has not been submitted as re-  
17 quired by subsection (b) or (c), the Secretary  
18 shall notify the applicant and the responsible  
19 party of such noncompliance and require sub-  
20 mission of such information within 30 days.

21 “(C) REFUSAL TO FILE.—If the respon-  
22 sible party does not remedy such noncompliance  
23 within 30 days of receipt of notification under  
24 subparagraph (B), the Secretary shall refuse to

1 file, approve, or clear such application or pre-  
2 market notification.

3 “(4) CONTENT REVIEW.—

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

12 “(i) acting through the Commissioner  
13 of Food and Drugs to examine the results  
14 data for such clinical trials submitted to  
15 Secretary when such data are submitted—

16 “(I) for review as part of an ap-  
17 plication under section 505 or 515 of  
18 the Federal Food, Drug, and Cos-  
19 metic Act or under section 351 of this  
20 Act or a premarket notification under  
21 section 510(k) of the Federal Food,  
22 Drug, and Cosmetic Act; or

23 “(II) in an annual status report  
24 on the drug or device under such ap-  
25 plication;

1                   “(ii) acting with the Federal agency  
2                   that funds such clinical trial in whole or in  
3                   part by a grant to examine the results data  
4                   for such clinical trials; and

5                   “(iii) acting through inspections under  
6                   section 704 of the Federal Food, Drug,  
7                   and Cosmetic Act to examine results data  
8                   for such clinical trials not described in  
9                   clause (i) or (ii).

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

19                  “(f) PENALTIES FOR NONCOMPLIANCE.—

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

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

24                         “(B) The submission of clinical trial infor-  
25                         mation under this section that is false or mis-

1 leading in any particular in violation of sub-  
2 section (b)(5) or (c)(5).

3 “(2) CERTAIN PENALTIES.—Section 303(a) of  
4 the Federal Food, Drug, and Cosmetic Act applies  
5 with respect to a violation of paragraph (1) to the  
6 same extent and in the same manner as such section  
7 303(a) applies with respect to a violation of section  
8 301 of such Act.

9 “(3) CONSIDERATIONS.—In determining wheth-  
10 er to apply a penalty under paragraph (2) or under  
11 paragraph (4) for a violation described in paragraph  
12 (1), the Secretary, acting through the Commissioner  
13 of Food and Drugs, shall consider—

14 “(A) whether the responsible party  
15 promptly corrects the noncompliance when pro-  
16 vided notice;

17 “(B) whether the responsible party has en-  
18 gaged in a pattern or practice of noncompli-  
19 ance; and

20 “(C) the extent to which the noncompli-  
21 ance involved may have significantly misled  
22 health care providers or patients concerning the  
23 safety or effectiveness of the drug involved.

24 “(4) CIVIL PENALTIES.—

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

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

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

23           “(D) PROCEDURES.—The provisions of  
24 paragraphs (4) through (6) of section 303(f) of  
25 the Federal Food, Drug, and Cosmetic Act

1           apply to the imposition of a penalty under this  
2           subsection to the same extent and in the same  
3           manner as such provisions apply to a penalty  
4           imposed under such section 303(f).

5           “(g) AUTHORIZATION OF APPROPRIATIONS.—There  
6           are authorized to be appropriated to carry out this section  
7           \$10,000,000 for each fiscal year.”.

8           (b) CONFORMING AMENDMENTS.—

9           (1) INVESTIGATIONAL NEW DRUGS.—Section  
10          505(i) of the Federal Food, Drug, and Cosmetic Act  
11          (21 U.S.C. 355(i)) is amended—

12                   (A) in paragraph (1)—

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

15                           (ii) in subparagraph (D)—

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

20                                   (II) by striking the period at the  
21                                   end and inserting “; and”; and

22                                   (iii) by adding at the end the fol-  
23                                   lowing:

24                                   “(E) the submission to the Director of NIH of  
25                                   clinical trial information for the clinical investigation

1 at issue required under section 492C of the Public  
2 Health Service Act for inclusion in the registry data-  
3 base and the results database described in such sec-  
4 tion.”;

5 (B) in paragraph (3)(B)—

6 (i) in clause (i), by striking “or” after  
7 the semicolon;

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

10 (iii) by adding at the end the fol-  
11 lowing:

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

16 (C) in paragraph (4), by adding at the end  
17 the following: “The Secretary shall update such  
18 regulations to require inclusion in the informed  
19 consent form a statement that clinical trial in-  
20 formation for such clinical investigation will be  
21 submitted for inclusion in the registry database  
22 and results database, as applicable, described in  
23 section 492C of the Public Health Service  
24 Act.”.

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

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

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

13           (3) INVESTIGATIONAL NEW DEVICES.—Sub-  
14           paragraph (B) of section 520(g)(2) of the Federal  
15           Food, Drug, and Cosmetic Act (21 U.S.C.  
16           360j(g)(2)) is amended—

17                   (A) by redesignating clause (iii) as clause  
18                   (iv); and

19                   (B) by inserting after clause (ii) the fol-  
20                   lowing:

21                           “(iii) A requirement that the person  
22                           applying for an exemption for a device as-  
23                           sure that such person is in compliance with  
24                           the requirements of section 492C of the  
25                           Public Health Service Act for the submis-

1                   sion of clinical trial information for inclu-  
2                   sion in the registry database and the re-  
3                   sults database described in such section.”.

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

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

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

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

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

19                  (5) REFUSAL TO APPROVE NEW DEVICE APPLI-  
20                  CATION.—Paragraph (2) of section 515(d) of the  
21                  Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
22                  360e(d)) is amended—

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

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

3 (C) by inserting after subparagraph (E)  
4 the following:

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

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

20 (d) PREEMPTION.—

21 (1) IN GENERAL.—No State or political subdivi-  
22 sion of a State may establish or continue in effect  
23 any requirement for the registration of clinical trials  
24 or any requirement for the inclusion of information  
25 relating to the results of clinical trials in a database.

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

19          (e) EFFECTIVE DATES.—

20                 (1) ESTABLISHMENT OF REGISTRY DATABASE  
21                 AND RESULTS DATABASE.—Not later than 1 year  
22                 after the date of the enactment of this Act, the Di-  
23                 rector of NIH shall establish the registry database  
24                 and the results database of clinical trials of drugs  
25                 and devices in accordance with section 492C of the

1 Public Health Service Act (as amended by sub-  
2 section (a)).

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

13 (3) CLINICAL TRIALS INITIATED AFTER OPER-  
14 ATION OF REGISTRY DATABASE.—The responsible  
15 party (as defined in such section 492C) for an appli-  
16 cable clinical trial (as defined in such section 492C)  
17 that is initiated after the date such registry database  
18 is established under paragraph (1) of this subsection  
19 shall submit required clinical trial information in ac-  
20 cordance with subsection (b) of such section 492C.

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

23 (A) IN GENERAL.—Subsection (c) of such  
24 section 492C shall take effect 90 days after the  
25 date the results database is established under

1 paragraph (1) of this subsection with respect to  
2 any applicable clinical trial (as defined in such  
3 section 492C) that—

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

6 (ii) is completed between the date of  
7 the enactment of this Act and such date of  
8 establishment under paragraph (1) of this  
9 subsection.

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

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

25 (6) RETROACTIVITY OF DATABASE.—

1 (A) VOLUNTARY SUBMISSIONS.—The Sec-  
2 retary of Health and Human Services (referred  
3 to in this paragraph as the “Secretary”) shall  
4 establish procedures and mechanisms to allow  
5 for the voluntary submission to the Secretary—

6 (i) of clinical trial information for in-  
7 clusion in the registry database (as defined  
8 in such section 492C) on applicable clinical  
9 trials (as defined in such section 492C)  
10 initiated before the date of the enactment  
11 of this Act; and

12 (ii) of clinical trial information for in-  
13 clusion in the results database (as defined  
14 in such section 492C) on applicable clinical  
15 trials (as defined in such section 492C)  
16 completed before the date of the enactment  
17 of this Act.

18 (B) REQUIRED SUBMISSIONS.—Notwith-  
19 standing the preceding paragraphs of this sub-  
20 section, in any case in which the Secretary de-  
21 termines that submission of clinical trial infor-  
22 mation for an applicable clinical trial (as de-  
23 fined in such section 492C) described in clause  
24 (i) or (ii) of subparagraph (A) is in the interest  
25 of the public health—

1 (i) the Secretary may require that  
2 such information be submitted to the Sec-  
3 retary in accordance with such section  
4 492C; and

5 (ii) failure to comply with such a re-  
6 quirement shall be treated as a violation of  
7 the corresponding requirement of such sec-  
8 tion 492C.

9 (7) FUNDING RESTRICTIONS.—Paragraph (1)  
10 of subsection (e) of such section 492C shall take ef-  
11 fect 210 days after the date that the clinical trial  
12 registry database and the clinical trial results data-  
13 base are established under paragraph (1) of this  
14 subsection.

15 (8) STATUS OF CLINICALTRIALS.GOV  
16 WEBSITE.—

17 (A) IN GENERAL.—After receiving public  
18 comment and not later than 90 days after the  
19 date of the enactment of this Act, the Secretary  
20 shall publish in the Federal Register a notice  
21 determining the more efficient approach to es-  
22 tablishing the registry database described in  
23 subsection (b) of such section 492C and wheth-  
24 er such approach is—

1 (i) that such registry database should  
2 expand and build upon the data bank de-  
3 scribed in section 402(i) of the Public  
4 Health Service Act (as in effect on the day  
5 before the date of the enactment of this  
6 Act); or

7 (ii) that such registry database should  
8 supplant the data bank described in such  
9 section 402(i) (as in effect on the day be-  
10 fore the date of the enactment of this Act).

11 (B) CLINICALTRIALS.GOV SUPPLANTED.—

12 If the Secretary determines to apply the ap-  
13 proach described under subparagraph (A)(ii),  
14 the Secretary shall maintain an archive of the  
15 data bank described in such section 402(i) (as  
16 in effect on the day before the date of the en-  
17 actment of this Act) on the Internet website of  
18 the National Library of Medicine.

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

20 (a) IN GENERAL.—The Comptroller General of the  
21 United States shall conduct a study to determine whether  
22 information on the trials registry and database is consid-  
23 ered promotional and to evaluate the implementation of  
24 this database.

1           (b) REPORT.—Not later than one year after the date  
2 of the enactment of this Act, the Comptroller General shall  
3 complete the study under subsection (a) and submit to the  
4 Congress a report on the results of such study.