

**AMENDMENT IN THE NATURE OF A SUBSTITUTE
TO COMMITTEE PRINT
OFFERED BY M . _____**

(CLINICALTRIALS, June 11, 2007)

Strike all after the enacting clause and insert the following:

1 **SEC. 1. EXPANDED CLINICAL TRIAL REGISTRY DATA BANK.**

2 (a) IN GENERAL.—Section 402(i) of the Public
3 Health Service Act (42 U.S.C. 282(i)) is amended to read
4 as follows:

5 “(i) EXPANDED CLINICAL TRIAL REGISTRY DATA
6 BANK.—

7 “(1) DEFINITIONS; REQUIREMENT.—

8 “(A) DEFINITIONS.—In this subsection:

9 “(i) APPLICABLE DEVICE CLINICAL
10 TRIAL.—The term ‘applicable device clin-
11 ical trial’ means—

12 “(I) a prospective study of health
13 outcomes comparing an intervention
14 against a control in human subjects
15 intended to support an application
16 under section 515 or subsections (g)
17 or (m) of section 520, or a report

1 under section 510(k), of the Federal
2 Food, Drug, and Cosmetic Act (other
3 than a limited study to gather essen-
4 tial information used to refine the
5 product or design a pivotal trial and
6 that is not intended to determine safe-
7 ty and effectiveness); and

8 “(II) a pediatric postmarket sur-
9 veillance study as required under sec-
10 tion 522 of the Federal Food, Drug,
11 and Cosmetic Act.

12 “(ii) APPLICABLE DRUG CLINICAL
13 TRIAL.—

14 “(I) IN GENERAL.—The term
15 ‘applicable drug clinical trial’ means a
16 controlled clinical investigation, other
17 than a phase I clinical investigation,
18 of a product subject to section 505 of
19 the Federal Food, Drug, and Cos-
20 metic Act or to section 351 of this
21 Act.

22 “(II) CLINICAL INVESTIGA-
23 TION.—For purposes of subclause (I),
24 the term ‘clinical investigation’ has
25 the meaning given that term in sec-

1 tion 312.3 of title 21, Code of Federal
2 Regulations, or any successor regula-
3 tions.

4 “(III) PHASE I.—The term
5 ‘phase I’ has the meaning given that
6 term in section 312.21 of title 21,
7 Code of Federal Regulations, or any
8 successor regulations.

9 “(iii) CLINICAL TRIAL INFORMA-
10 TION.—The term ‘clinical trial information’
11 means those data elements that are nec-
12 essary to complete an entry in the clinical
13 trial registry data bank under paragraph
14 (2).

15 “(iv) COMPLETION DATE.—The term
16 ‘completion date’ means, with respect to an
17 applicable drug clinical trial or an applica-
18 ble device clinical trial, the date on which
19 there occurs the last medical visit of the
20 clinical trial, regardless of whether the
21 clinical trial concluded according to the
22 prespecified protocol plan or was termi-
23 nated at an earlier date.

24 “(v) RESPONSIBLE PARTY.— The
25 term ‘responsible party’, with respect to an

1 applicable drug clinical trial or applicable
2 device clinical trial, means—

3 “(I) the sponsor of the clinical
4 trial (as defined in section 50.3 of
5 title 21, Code of Federal Regulations
6 or any successor regulations) or the
7 principal investigator of such clinical
8 trial if so designated by such sponsor;
9 or

10 “(II) if no sponsor exists, the
11 grantee, contractor, or awardee for a
12 trial funded by a Federal agency or
13 the principal investigator of such clin-
14 ical trial if so designated by such
15 grantee, contractor, or awardee.

16 “(B) REQUIREMENT.—The Secretary shall
17 develop a mechanism by which—

18 “(i) the responsible party for each ap-
19 plicable drug clinical trial and applicable
20 device clinical trial shall submit the iden-
21 tity and contact information of such re-
22 sponsible party to the Secretary at the
23 time of submission of clinical trial informa-
24 tion under paragraph (2); and

1 “(ii) other Federal agencies may iden-
2 tify the responsible party for an applicable
3 drug clinical trial or applicable device clin-
4 ical trial.

5 “(2) EXPANSION OF CLINICAL TRIAL REGISTRY
6 DATA BANK WITH RESPECT TO CLINICAL TRIAL IN-
7 FORMATION.—

8 “(A) IN GENERAL.—

9 “(i) EXPANSION OF DATA BANK.—To
10 enhance patient enrollment and provide a
11 mechanism to track subsequent progress of
12 clinical trials, the Secretary shall expand,
13 in accordance with this subsection, the
14 clinical trials registry of the data bank
15 (‘registry databank’) provided for under
16 subsection (i)(3)(A), as such subsection
17 and such registry data bank existed imme-
18 diately prior to enactment of the [new bill
19 name]. The Secretary shall ensure that
20 the registry data bank, as so expanded, is
21 made publicly available through the Inter-
22 net.

23 “(ii) CONTENT OF EXPANDED
24 DATABANK.—Not later than 18 months
25 after the date of enactment of the [bill

1 name], and after notice and comment, the
2 Secretary shall promulgate regulations to
3 require the submission to the registry data
4 bank (as expanded under this paragraph)
5 of clinical trial information for applicable
6 drug clinical trials and applicable device
7 clinical trials that—

8 “(I) considers the International
9 Clinical Trials Registry Platform trial
10 registration data set of the World
11 Health Organization;

12 “(II) includes the city, State, and
13 zip code for each clinical trial location,
14 or (or the city and country for loca-
15 tions outside the United States) and,
16 if available, a toll free number
17 through which additional information
18 may be accessed;

19 “(III) if the product is not ap-
20 proved under section 505 of the Fed-
21 eral Food, Drug, and Cosmetic Act or
22 licensed under section 351 of this Act,
23 specifies whether or not there is ex-
24 panded access to the product under
25 section 561 of the Federal Food,

1 Drug, and Cosmetic Act for those who
2 do not qualify for enrollment in the
3 clinical trial and how to obtain infor-
4 mation about such access;

5 “(IV) requires the inclusion of
6 such other data elements to the reg-
7 istry data bank as appropriate; and

8 “(V) becomes effective 90 days
9 after issuance of the final rule.

10 “(B) FORMAT AND STRUCTURE.—

11 “(i) SEARCHABLE CATEGORIES.—The
12 Secretary shall ensure that the public may
13 search the entries in the registry data bank
14 by 1 or more of the following criteria:

15 “(I) The disease or condition
16 being studied in the clinical trial,
17 using Medical Subject Headers
18 (MeSH) descriptors.

19 “(II) The intervention being
20 studied in the clinical trial.

21 “(III) The location of the clinical
22 trial.

23 “(IV) The age group studied in
24 the clinical trial, including pediatric
25 subpopulations.

1 “(V) In the case of an applicable
2 drug clinical trial, the study phase of
3 the clinical trial.

4 “(VI) The recruitment status of
5 the clinical trial.

6 “(VII) The National Clinical
7 Trial number or other study identi-
8 fication for the clinical trial.

9 “(ii) FORMAT.—The Secretary shall
10 ensure that the registry data bank is easily
11 used by the public, and that entries are
12 easily compared.

13 “(C) DATA SUBMISSION.—The responsible
14 party for an applicable drug clinical trial or ap-
15 plicable device clinical trial shall submit to the
16 Secretary for inclusion in the registry data
17 bank the clinical trial information described in
18 subparagraph (A)(ii).

19 “(D) TRUTHFUL CLINICAL TRIAL INFOR-
20 MATION.—

21 “(i) IN GENERAL.— The clinical trial
22 information submitted by a responsible
23 party under this paragraph shall not be
24 false or misleading in any particular.

1 “(ii) EFFECT.—Clause (i) shall not
2 have the effect of requiring clinical trial in-
3 formation with respect to an applicable
4 drug clinical trial or an applicable device
5 clinical trial to include information from
6 any source other than such clinical trial in-
7 volved.

8 “(E) CHANGES IN CLINICAL TRIAL STA-
9 TUS.—

10 “(i) ENROLLMENT.—The responsible
11 party for an applicable drug clinical trial
12 or an applicable device clinical trial shall
13 update the enrollment status not later than
14 30 days after the enrollment status of such
15 clinical trial changes.

16 “(ii) COMPLETION.—The responsible
17 party for an applicable drug clinical trial
18 or applicable device clinical trial shall re-
19 port to the Secretary that such clinical
20 trial is complete not later than 30 days
21 after the completion date of the clinical
22 trial.

23 “(F) TIMING OF SUBMISSION.—The clin-
24 ical trial information for an applicable drug
25 clinical trial or an applicable device clinical trial

1 required to be submitted under this paragraph
2 shall be submitted not later than—

3 “(i) prior to the enrollment of the
4 first patient in such clinical trial; or

5 “(ii) such earlier date as may be re-
6 quired by another provision of this sub-
7 section.

8 “(G) POSTING OF DATA.—The Secretary
9 shall ensure that clinical trial information for
10 applicable drug clinical trials and applicable de-
11 vice clinical trials submitted in accordance with
12 this paragraph is posted publicly within 30 days
13 of such submission. The Secretary may provide
14 by regulation for a longer time period for such
15 posting if appropriate.

16 “(H) VOLUNTARY SUBMISSIONS.—A re-
17 sponsible party for a clinical trial that is not an
18 applicable drug clinical trial or an applicable de-
19 vice clinical trial may submit clinical trial infor-
20 mation to the registry data bank in accordance
21 with this subsection.

22 “(3) EXPANSION OF REGISTRY DATA BANK TO
23 INCLUDE RESULTS OF CLINICAL TRIALS.—

24 “(A) LINKING REGISTRY DATA BANK TO
25 EXISTING RESULTS.—

1 “(i) IN GENERAL.—Beginning not
2 later than 90 days after the date of enact-
3 ment of the **[bill name]**, the Secretary
4 shall ensure that the registry data bank in-
5 cludes links to results information (includ-
6 ing, as applicable, information specified in
7 clause (ii)) for applicable drug clinical
8 trials and applicable device clinical trials,
9 not later than 30 days after such informa-
10 tion becomes publicly available.

11 “(ii) REQUIRED INFORMATION.—

12 “(I) INFORMATION.—The Sec-
13 retary shall ensure that the registry
14 data bank includes links to the fol-
15 lowing information:

16 “(aa) If an advisory com-
17 mittee considered at a meeting
18 an applicable drug clinical trial
19 or an applicable device clinical
20 trial, any posted Food and Drug
21 Administration summary docu-
22 ment regarding such applicable
23 drug clinical trial or applicable
24 device clinical trial.

1 “(bb) If an applicable drug
2 clinical trial was conducted in re-
3 sponse to a written request
4 issued pursuant to section 505A
5 of the Federal Food, Drug, and
6 Cosmetic Act, or is cited in sup-
7 port of an assessment submitted
8 pursuant to section 505B of such
9 Act, a link to the summary or as-
10 sessment of the results of such
11 trial as posted on the website of
12 the Food and Drug Administra-
13 tion.

14 “(cc) Food and Drug Ad-
15 ministration public health
16 advisories and notifications re-
17 garding the product that is the
18 subject of the applicable drug
19 clinical trial or applicable device
20 clinical trial, respectively, if any.

21 “(dd) For an applicable
22 drug clinical trial, the Food and
23 Drug Administration action
24 package for approval document
25 required under section 505(l)(2)

1 of the Federal Food, Drug, and
2 Cosmetic Act.

3 “(ee) For an applicable de-
4 vice clinical trial, in the case of a
5 premarket application under
6 paragraph (1) or (2) of section
7 515(c) of the Federal Food,
8 Drug, and Cosmetic Act, the de-
9 tailed summary of information
10 respecting the safety and effec-
11 tiveness required under section
12 520(h)(1) of such Act, or, in the
13 case of a report under section
14 510(k) of such Act, the section
15 510(k) summary of safety and ef-
16 fectiveness data required under
17 section 807.95(d) of title 21,
18 Code of Federal Regulations (or
19 any successor regulations).

20 “(II) INFORMATION.—The Sec-
21 retary shall ensure that the registry
22 data bank includes links to the fol-
23 lowing information:

24 “(aa) Medline citations to
25 publications reporting results

1 from each applicable drug clinical
2 trial and applicable device clinical
3 trial.

4 “(bb) The entry for the
5 product that is the subject of an
6 applicable drug clinical trial in
7 the National Library of Medicine
8 database of structured product
9 labels, if available.

10 “(iii) RESULTS FOR EXISTING DATA
11 BANK ENTRIES.—The Secretary may in-
12 clude the links described in clause (ii) for
13 data bank entries for clinical trials sub-
14 mitted to the data bank prior to enactment
15 of the [bill name], as available.

16 “(B) FEASIBILITY STUDY.—

17 “(i) The Director of NIH shall con-
18 duct a study to determine the best, vali-
19 dated methods of making the results of
20 clinical trials publicly available after the
21 approval of the product that is the subject
22 of an applicable drug clinical trial or the
23 approval or clearance of a product that is
24 the subject of an applicable device clinical
25 trial.

1 “(ii) Not later than 18 months after
2 initiating such study, the Director of NIH
3 shall submit to the Secretary a report
4 based on any findings of such study.

5 “(iii) The Secretary shall review the
6 report submitted by the Director of NIH
7 and issue a final report within 90 days,
8 which shall be made publicly available
9 through posting on the website of the De-
10 partment of Health and Human Services,
11 including posting on the website of the
12 NIH. .

13 “(C) RULEMAKING.—

14 “(i) IN GENERAL.—If the Secretary
15 determines, after considering the findings
16 of the feasibility study under subparagraph
17 (B), that including clinical trial results in
18 the registry data bank is the best method
19 of making such results publicly available
20 and the Secretary determines that such in-
21 clusion is appropriate, the Secretary shall
22 promulgate regulations, to determine, for
23 applicable drug clinical trials and applica-
24 ble device clinical trials—

1 “(I) how to ensure valid and reli-
2 able methods of expanding the reg-
3 istry data bank to include results in-
4 formation for such clinical trials;

5 “(II) the clinical trials of which
6 the results information is appropriate
7 for adding to the expanded registry
8 data bank; and

9 “(III) the appropriate timing of
10 the posting of such results informa-
11 tion.

12 “(ii) TIME REQUIREMENT.—If the
13 Secretary promulgates regulations under
14 clause (i), the Secretary shall ensure that
15 a final rule is promulgated not later than
16 30 months after the date the Secretary is
17 required to make publicly available the
18 final report specified under subparagraph
19 (B)(iii).

20 “(iii) CONTENT OF REGULATIONS.—
21 The regulations promulgated pursuant to
22 clause (i) shall establish—

23 “(I) definitions to determine
24 which clinical trials results informa-
25 tion data elements shall be included in

1 the registry data bank, taking into ac-
2 count the needs of different popu-
3 lations of users of the registry data
4 bank;

5 “(II) a standard format for the
6 submission of clinical trials results to
7 the registry data bank;

8 “(III) a standard procedure for
9 the submission of clinical trial results
10 information, including the timing of
11 submission and the timing of posting
12 of results information, to the registry
13 data bank, taking into account the
14 possible impacts on publication of
15 manuscripts based on the clinical
16 trial; and

17 “(IV) an implementation plan for
18 the prompt inclusion of clinical trials
19 results information in the registry
20 data bank.

21 “(D) CONSIDERATION OF WORLD HEALTH
22 ORGANIZATION DATA SET.—The Secretary shall
23 consider the status of the consensus data ele-
24 ments set for reporting clinical trial results of

1 the World Health Organization if promulgating
2 the regulations under subparagraph (C)).

3 “(E) TRUTHFUL CLINICAL TRIAL INFOR-
4 MATION.—

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

9 “(ii) EFFECT.—Clause (i) shall not
10 have the effect of requiring clinical trial in-
11 formation with respect to an applicable
12 drug clinical trial or an applicable device
13 clinical trial to include information from
14 any source other than such clinical trial in-
15 volved.

16 “(4) COORDINATION AND COMPLIANCE.—

17 “(A) CLINICAL TRIALS SUPPORTED BY
18 GRANTS OR COOPERATIVE AGREEMENTS FROM
19 THE SECRETARY.—

20 “(i) IN GENERAL.—Subject to clause
21 (iv), the Secretary may not initially release
22 funds under a research grant or research
23 award to the recipient of a grant or coop-
24 erative agreement, with respect to the ap-
25 plicable drug clinical trial or applicable de-

1 vice clinical trial for which such person is
2 the responsible party and which such funds
3 would support, if such recipient has not
4 complied with the requirement of clause
5 (ii)

6 “(ii) REQUIREMENT FOR RECIPIENTS
7 OF GRANTS OR COOPERATIVE AGREE-
8 MENTS.—If an applicable drug clinical trial
9 or applicable device clinical trial is funded
10 in whole or in part by a grant or coopera-
11 tive agreement from the Secretary to con-
12 duct research , any progress report forms
13 required under such grant or cooperative
14 agreement shall include provision for a cer-
15 tification by such recipient that the respon-
16 sible party has made all required submis-
17 sions to the Secretary under paragraph
18 (2).

19 “(iii) NOTICE AND OPPORTUNITY TO
20 REMEDY.—If the Secretary verifies that
21 such responsible party has not submitted
22 clinical trial information as described in
23 clause (ii), the Secretary shall provide no-
24 tice to such recipient of such non compli-
25 ance and allow such recipient 30 days to

1 correct such non compliance and submit
2 the required clinical trial information. The
3 Secretary may extend the 30 day time pe-
4 riod upon public notification.

5 “(iv) WAIVER.— For purposes of
6 clause (i), the Secretary may waive appli-
7 cation of the requirement under clause (ii)
8 under such circumstances, and with re-
9 spect to such recipients, as the Secretary
10 determines appropriate.

11 “(v) CONSULTATION WITH OTHER
12 FEDERAL AGENCIES.—The Secretary
13 shall—

14 “(I) consult with other agencies
15 that conduct research involving
16 human subjects in accordance with
17 any section of part 46 of title 45,
18 Code of Federal Regulations (or any
19 successor regulations), to determine if
20 any such research is an applicable
21 drug clinical trial or an applicable de-
22 vice clinical trial under paragraph (1);
23 and

24 “(II) consult with such agencies
25 in the development by such of agen-

1 cies procedures comparable to those
2 described in clauses (i) through (iv) to
3 ensure that clinical trial information
4 for such applicable drug clinical trials
5 and applicable device clinical trial is
6 submitted under paragraph (2).

7 “(B) CERTIFICATION.—At the time of sub-
8 mission of an application under section 505 of
9 the Federal Food, Drug, and Cosmetic Act, sec-
10 tion 515 of such Act, subsections (g) or (m) of
11 section 520 of such Act, or section 351 of this
12 Act, or submission of a report under section
13 510(k) of the Federal Food, Drug, and Cos-
14 metic Act, such application or report shall be
15 accompanied by a certification, under penalties
16 of perjury, that to the best of the applicant’s or
17 submitter’s knowledge, that all applicable re-
18 quirements of this subsection have been met. If
19 the application or submission pertains to a
20 product with respect to which there is or has
21 been an applicable drug clinical trial or an ap-
22 plicable device clinical trial, the certification
23 shall include the appropriate National Clinical
24 Trial Control number for each such trial.

1 “(5) LIMITATION ON DISCLOSURE OF CLINICAL
2 TRIAL INFORMATION.—

3 “(A) IN GENERAL.—Nothing in this sub-
4 section (or under section 552 of title 5, United
5 States Code) shall require the Secretary to pub-
6 licly disclose, from any record or source other
7 than the registry data bank expanded under
8 this subsection, information described in sub-
9 paragraph (B).

10 “(B) INFORMATION DESCRIBED.—Infor-
11 mation described in this subparagraph is—

12 “(i) information submitted to the Sec-
13 retary under this subsection, or informa-
14 tion of the same general nature as (or inte-
15 grally associated with) the information so
16 submitted; and

17 “(ii) not otherwise publicly available,
18 including because it is protected from dis-
19 closure under section 552 of title 5, United
20 States Code.

21 “(6) WAIVERS REGARDING CERTAIN CLINICAL
22 TRIALS.—The Secretary may waive, in whole or in
23 part, with or without conditions, any applicable re-
24 quirements of this subsection with respect to an ap-
25 plicable drug clinical trial or an applicable device

1 clinical trial if the Secretary determines that ex-
2 traordinary circumstances justify the waiver and
3 that providing the waiver is in the public interest,
4 consistent with the protection of public health, or in
5 the interest of national security. Not later than 60
6 days after any part of a waiver is granted, the Sec-
7 retary shall notify, in writing, the appropriate com-
8 mittees of Congress of the waiver and provide an ex-
9 planation for why the waiver was granted.

10 “(7) AUTHORIZATION OF APPROPRIATIONS.—

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

13 (b) CONFORMING AMENDMENTS.—

14 (1) PROHIBITED ACTS.—Section 301 of the
15 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
16 331) is amended by adding at the end the following:

17 “(jj)(1) The failure to submit the certification re-
18 quired by section 402(i)(4)(B) of the Public Health Serv-
19 ice Act, or knowingly submitting a false certification under
20 such section.

21 “(2) The submission of clinical trial information
22 under section 402(i) of the Public Health Service Act that
23 is promotional or false or misleading in any particular
24 under paragraph (2) or (3) of such subsection (i).”.

1 (2) CIVIL MONEY PENALTIES.—Section 303(f)
2 of the Federal Food, Drug, and Cosmetic Act (21
3 U.S.C. 333(f)), as amended by section 203, is fur-
4 ther amended by—

5 (A) redesignating paragraphs (4), (5), and
6 (6) as paragraphs (5), (6), and (7), respec-
7 tively;

8 (B) inserting after paragraph (3) the fol-
9 lowing:

10 “(4) Any person who violates section 301(jj)
11 shall be subject to a civil monetary penalty of not
12 more than \$10,000 for the first violation, and not
13 more than \$20,000 for each subsequent violation.”.

14 (C) in paragraph (2)(C), by striking
15 “paragraph (4)(A)” and inserting “paragraph
16 (5)(A)”;

17 (D) in paragraph (5), as so redesignated,
18 by striking “paragraph (1), (2), or (3)” each
19 place it appears and inserting “paragraph (1),
20 (2), (3), or (4)”;

21 (E) in paragraph (7), as so redesignated,
22 by striking “paragraph (5)” each place it ap-
23 pears and inserting “paragraph (6)”.

24 (3) ADDITION OF CERTIFICATION REQUIRE-
25 MENTS.—

1 (A) INVESTIGATIONAL NEW DRUGS.—Sec-
2 tion 505(i) of the Federal Food, Drug, and
3 Cosmetic Act (21 U.S.C. 355(i)) is amended—

4 (i) in paragraph (2)—

5 (I) in subparagraph (A), by strik-
6 ing “and” at the end;

7 (II) in subparagraph (B), by
8 striking the period and inserting “;
9 and”; and

10 (III) by adding at the end the
11 following new subparagraph:

12 “(C) the certification required under sec-
13 tion 402(i)(4)(B) of the Public Health Service
14 Act.”; and

15 (ii) in paragraph (4), by adding at the
16 end the following: “The Secretary shall up-
17 date such regulations to require inclusion
18 in the informed consent form a statement
19 that clinical trial information for such clin-
20 ical investigation has been or will be sub-
21 mitted for inclusion in the registry data
22 bank pursuant to section 402(i) of the
23 Public Health Service Act.”.

24 (B) NEW DRUG APPLICATIONS.—Section
25 505(b) of the Federal, Food, Drug, and Cos-

1 metec Act (21 U.S.C. 355(b)) is amended by
2 adding at the end the following:

3 “(6) An application submitted under this sub-
4 section shall be accompanied by the certification re-
5 quired under section 402(i)(4)(B) of the Public
6 Health Service Act. Such certification shall not be
7 considered an element of such application.”.

8 (C) ABBREVIATED NEW DRUG APPLICA-
9 TIONS.—Section 505(j)(2) of the Federal Food,
10 Drug, and Cosmetic Act (21 U.S.C. 355(j)(2))
11 is amended by adding at the end the following
12 new subparagraph:

13 “(E) An application submitted under this
14 subsection shall be accompanied by the certifi-
15 cation required under section 402(i)(4)(B) of
16 the Public Health Service Act. Such certifi-
17 cation shall not be considered an element of
18 such application.”.

19 (D) BIOLOGICS LICENSE APPLICATIONS.—
20 Section 351(a)(2) of the Public Health Service
21 Act (42 U.S.C. 262(a)(2)) is amended by add-
22 ing at the end the following new subparagraph:

23 “(D) A person that submits an application
24 for a license under this paragraph shall submit
25 to the Secretary, as an accompaniment to such

1 application, the certification required under sec-
2 tion 402(i)(4)(B). Such certification shall not
3 be considered part of such application.”.

4 (E) REPORTS UNDER SECTION 510(k).—
5 Section 510(k) of the Federal Food, Drug, and
6 Cosmetic Act (21 U.S.C. 360(k)) is amended by
7 adding at the end the following:

8 “A notification submitted under this subsection that
9 contains clinical trial data for an applicable device clinical
10 trial (as defined in section 402(i)(1) of the Public Health
11 Service Act) shall be accompanied by the certification re-
12 quired under section 402(i)(4)(B) of such Act. Such cer-
13 tification shall not be considered an element of such notifi-
14 cation.”.

15 (F) PREMARKET APPROVAL APPLICA-
16 TION.—Section 515(c) of the Federal Food,
17 Drug, and Cosmetic Act (21 U.S.C. 360e(c)) is
18 amended—

19 (i) in paragraph (1)—

20 (I) in subparagraph (F), by strik-
21 ing “; and” and inserting a semicolon;

22 (II) by redesignating subpara-
23 graph (G) as subparagraph (H); and

24 (III) by inserting after subpara-
25 graph (F) the following:

1 “(G) the certification required under sec-
2 tion 402(i)(4)(B) of the Public Health Service
3 Act (which shall not be considered an element
4 of such application); and”

5 (ii) in paragraph (2)(A), by adding at
6 the end the following:

7 “(xiii) the certification required under
8 section 402(i)(4)(B) of the Public Health
9 Service Act (which shall not be considered
10 an element of such report).”; and

11 (G) HUMANITARIAN DEVICE EXEMP-
12 TION.—Section 520(m)(2) of the Federal Food,
13 Drug, and Cosmetic Act (21 U.S.C. 360e(c)) is
14 amended in the first sentence in the matter fol-
15 lowing subparagraph (C), by inserting at the
16 end before the period “and such application
17 shall include the certification required under
18 section 402(i)(4)(B) of the Public Health Serv-
19 ice Act (which shall not be considered an ele-
20 ment of such application)”.

21 (H) INVESTIGATIONAL DEVICE EXEMPTION
22 APPLICATION.—Section 520(g)(2)(b) of the
23 Federal Food, Drug, and Cosmetic Act (21
24 U.S.C. 360j(g)(2)(b)) is amended—

1 (i) in clause (i), by inserting, before
2 the period, the following: “and include the
3 certification required under section
4 402(i)(4)(B) of the Public Health Service
5 Act (which shall not be considered an ele-
6 ment of such application)”;

7 (ii) by redesignating clause (iii) as
8 clause (iv); and

9 (iii) by inserting after clause (ii) the
10 following clause:

11 “(iii) A requirement that the informed
12 consent form pursuant to paragraph
13 (3)(D) shall include a statement that clin-
14 ical trial information for such clinical in-
15 vestigation has been or will be submitted
16 for inclusion in the registry data bank pur-
17 suant to section 402(i) of the Public
18 Health Service Act.”.

19 (c) **RULE OF CONSTRUCTION.**—The fact of submis-
20 sion of clinical trial information, if submitted in compli-
21 ance with section 402(i) of the Public Health Service Act
22 (as amended by this section), that relates to a use of a
23 product not included in the labeling of the product as ap-
24 proved or cleared shall not be construed by the Secretary
25 or in any administrative or judicial proceeding, as evidence

1 of a new intended use of the product that is different from
2 the intended use of the product set forth in the labeling
3 of the product as approved or cleared. The availability of
4 clinical trial information through the data bank under
5 such subsection (i), if submitted in compliance with such
6 subsections, shall not be considered as labeling, adultera-
7 tion, or misbranding of the product under the Federal
8 Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

9 (d) TRANSITION RULE; EFFECTIVE DATE OF FUND-
10 ING RESTRICTIONS.—

11 (1) TRANSITION RULE FOR CLINICAL TRIALS
12 INITIATED PRIOR TO EXPANSION OF REGISTRY DATA
13 BANK.—The responsible party (as defined in para-
14 graph (1) of section 402(i) of the Public Health
15 Service Act (as added by this section)) for an appli-
16 cable drug clinical trial or applicable device clinical
17 trial (as defined under such paragraph (1)) that is
18 initiated after the date of enactment of this subtitle
19 and before the effective date of the regulations pro-
20 mulgated under paragraph (2) of such section
21 402(i), shall submit required clinical trial informa-
22 tion under such section not later than 120 days
23 after such effective date.

24 (2) FUNDING RESTRICTIONS.—Subparagraph
25 (A) of paragraph (4) of such section 402(i) shall

1 take effect 210 days after the effective date of the
2 regulations promulgated under paragraph (2) of
3 such section 402(i).

4 (e) EFFECTIVE DATE.—Beginning 90 days after the
5 date of enactment of this title, the responsible party for
6 an applicable drug clinical trial or an applicable device
7 clinical trial (as such terms are defined in such section
8 402(i)) that is initiated after the date of enactment of this
9 title and before the effective date of the regulations issued
10 under subparagraph (A) of paragraph (2) of such sub-
11 section, shall submit clinical trial information under such
12 paragraph (2).