

108TH CONGRESS
2D SESSION

H. R. 5252

To amend the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act with respect to the availability to the public of information on clinical trials to determine the safety and effectiveness of drugs, biological products, and devices, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 7, 2004

Mr. MARKEY (for himself and Mr. WAXMAN) introduced the following bill;
which was referred to the Committee on Energy and Commerce

A BILL

To amend the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act with respect to the availability to the public of information on clinical trials to determine the safety and effectiveness of drugs, biological products, and devices, 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. SHORT TITLE.**

4 This Act may be cited as the “Fair Access to Clinical
5 Trials Act”.

1 **SEC. 2. REGISTRATION OF CLINICAL TRIALS UNDER PUB-**
2 **LIC HEALTH SERVICE ACT.**

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 (j);
6 and

7 (2) by inserting after section 491 the following
8 section:

9 **“SEC. 491A. REGISTRATION OF CLINICAL TRIALS; DATA**
10 **BANK.**

11 “(a) IN GENERAL.—

12 “(1) CONDITIONS FOR FINANCIAL AWARDS.—

13 Except as provided in paragraph (2), an entity may
14 not receive an award of a grant, contract, or cooper-
15 ative agreement under this Act for the conduct of a
16 clinical trial to determine the safety or effectiveness
17 of a use of a drug or device (referred to in this sec-
18 tion as a ‘product’) unless the responsible person for
19 the trial—

20 “(A) agrees to register the trial with the
21 Secretary in accordance with subsection (d)(1);

22 “(B) agrees to provide to the Secretary in-
23 formation on the results of the trial in accord-
24 ance with subsection (d)(2);

1 “(C) agrees to the disclosure to the public
2 of information regarding the trial in accordance
3 with subsection (e); and

4 “(D) agrees to be subject to audits under
5 subsection (f)(1), and as applicable, to liq-
6 uidated penalties and the requirement to submit
7 reports under subsection (g)(1).

8 “(2) EXCEPTION.—Paragraph (1) does not
9 apply to a clinical trial to determine the safety of a
10 use of a drug if the trial is designed solely to detect
11 major toxicities in the drug or to investigate phar-
12 macokinetics, except that such paragraph does apply
13 if the trial is designed solely to investigate phar-
14 macokinetics in a special population or populations.

15 “(b) DATA BANK.—

16 “(1) IN GENERAL.— The Secretary, acting
17 through the Director of NIH, shall establish, main-
18 tain, and operate a data bank of information pro-
19 vided to the Secretary pursuant to subsection (a),
20 including collecting, cataloging, and storing the in-
21 formation, and disseminating the information in ac-
22 cordance with subsection (e). The activities of the
23 data bank shall be integrated and coordinated with
24 related activities of other agencies of the Depart-
25 ment of Health and Human Services, and to the ex-

1 tent practicable, coordinated with other data banks
2 containing similar information.

3 “(2) INFORMATION FROM ELECTIVE SUBMIS-
4 SIONS.—

5 “(A) CLINICAL TRIALS REGARDING DRUGS
6 OR DEVICES.—The Secretary may accept for in-
7 clusion in the data bank information on clinical
8 trials that are trials to determine the safety or
9 effectiveness of a use of a product but are not
10 subject to requirements under subsection (a).
11 The inclusion of information in the data bank
12 under the preceding sentence is subject to the
13 condition that the responsible person for the
14 clinical trial involved make each of the agree-
15 ments described in subsection (a)(1).

16 “(B) OTHER CLINICAL TRIALS.—The Sec-
17 retary may accept for inclusion in the data
18 bank information on clinical trials that do not
19 involve drugs or devices if the responsible per-
20 son for the trial involved agrees to such condi-
21 tions regarding the submission and disclosure of
22 the information as the Secretary determines to
23 be appropriate, taking into account the require-
24 ments of this section for clinical trials that do
25 involve drugs or devices.

1 “(3) CONSULTATION.—The Secretary shall op-
2 erate the data bank in consultation with the Com-
3 missioner of Food and Drugs, the directors of the
4 appropriate agencies of the National Institutes of
5 Health, and the Director of the Centers for Disease
6 Control and Prevention.

7 “(4) NATIONAL LIBRARY OF MEDICINE.—The
8 Director of NIH shall assign to the National Library
9 of Medicine the primary responsibility for carrying
10 out paragraph (1).

11 “(5) ENTRY OF INFORMATION.—Information
12 provided to the Secretary under this section by re-
13 sponsible persons for clinical trials shall be entered
14 in the data bank promptly after the Secretary re-
15 ceives the information, except to the extent that the
16 Secretary determines that the information has not
17 been submitted to the Secretary in accordance with
18 this section, in which case the Secretary shall
19 promptly inform the responsible person involved that
20 corrective actions by the person are necessary to
21 maintain compliance with this section.

22 “(6) AUTHORITY OF SECRETARY.—

23 “(A) INCLUSION OF STATEMENTS TO
24 AVOID MISINTERPRETATIONS.—The Secretary
25 may include in the data bank such statements

1 as the Secretary determines to be appropriate
2 to assist the public in avoiding misinterpreta-
3 tions of information in the data bank. State-
4 ments under the preceding sentence may in-
5 clude statements regarding the data bank in
6 general and statements regarding particular
7 items of information submitted to the data
8 bank. The Secretary may not under the pre-
9 ceding sentence alter any information as sub-
10 mitted.

11 “(B) FALSE OR MISLEADING INFORMA-
12 TION.—

13 “(i) IN GENERAL.—If under sub-
14 section (f) the Secretary determines that
15 information presented or cited in the data
16 bank is false or misleading, the Secretary
17 shall, promptly after making such deter-
18 mination, identify in the data bank the in-
19 formation as false or misleading (as appli-
20 cable), and shall, to the extent practicable,
21 include in the data bank an accurate
22 version of the information. The Secretary
23 shall in addition make appropriate public
24 notification.

1 “(ii) LIMITATION.—Clause (i) does
2 not authorize the disclosure of information
3 if—

4 “(I) the disclosure would con-
5 stitute a clearly unwarranted invasion
6 of personal privacy; or

7 “(II) the information concerns a
8 method or process that is a trade se-
9 cret entitled to protection within the
10 meaning of section 301(j) of the Fed-
11 eral Food, Drug, and Cosmetic Act.

12 “(c) INSTITUTIONAL REVIEW BOARDS.—For pur-
13 poses of subsection (a), the Secretary shall amend part
14 46 of title 45, Code of Federal Regulations, to provide
15 that—

16 “(1) the functions of institutional review boards
17 under such part include—

18 “(A) determining whether clinical trials to
19 determine the safety or effectiveness of prod-
20 ucts are registered under subsection (a)(1)(A);
21 and

22 “(B) denying the approval of the boards
23 for such trials that are not registered under
24 such subsection;

1 “(2) any approval of an institutional review
2 board regarding such a trial is not effective under
3 such part if the trial is not registered under such
4 subsection; and

5 “(3) upon request of an institutional review
6 board for such a trial, the Secretary will provide to
7 the board a copy of the registration for the trial
8 under such subsection (which copy will be the reg-
9 istration as submitted to the Secretary, together
10 with all updates to the registration).

11 “(d) SUBMISSION OF REQUIRED INFORMATION.—

12 “(1) SUBMISSION OF REGISTRATION INFORMA-
13 TION.—

14 “(A) IN GENERAL.—A registration of a
15 clinical trial under subsection (a)(1)(A) is in ac-
16 cordance with this paragraph if, subject to sub-
17 paragraph (B), the registration is in such form
18 and is submitted in such manner as the Sec-
19 retary requires, and the registration contains
20 such information on the design and goals of the
21 trial as the Secretary determines to be impor-
22 tant to clinicians or researchers. Such informa-
23 tion shall include the following:

24 “(i) A brief title for the trial, provided
25 in lay language.

1 “(ii) The disease or condition with
2 which the trial is concerned.

3 “(iii) The medical intervention or
4 interventions being investigated in the
5 trial.

6 “(iv) A statement that—

7 “(I) identifies the product as an
8 unapproved product or as an approved
9 product, as applicable; and

10 “(II) in addition, in the case of
11 an approved product, identifies the
12 trial as investigating the approved use
13 of the product or an unapproved use
14 of the product, as applicable.

15 “(v) The purpose of the trial, includ-
16 ing a statement of the interventions and
17 comparisons involved.

18 “(vi) A statement of the hypothesis
19 being tested in the trial.

20 “(vii) Information on—

21 “(I) study design;

22 “(II) methods;

23 “(III) study phase; and

24 “(IV) study type.

1 “(viii) The definition of the primary
2 and secondary outcomes for the trial.

3 “(ix) The length of time for which
4 data on the primary and secondary out-
5 comes will be collected on each patient.

6 “(x) Eligibility criteria for participa-
7 tion in the trial.

8 “(xi) The total number of subjects an-
9 ticipated to participate in the trial.

10 “(xii) The anticipated or actual date
11 on which the trial will begin.

12 “(xiii) The anticipated or actual date
13 of final data collection from subjects in the
14 trial on the primary outcome.

15 “(xiv) The identity of each responsible
16 person for the trial.

17 “(xv) Sources of funding for the trial
18 in addition to the award under this Act.

19 “(xvi) The identity of the principal in-
20 vestigator in the trial.

21 “(xvii) Contact information for the
22 principal investigator.

23 “(xviii) A unique protocol number
24 identification number for the trial, which
25 number shall be assigned by the Secretary.

1 “(xix) After the initial submission of
2 the registration, periodic updates to reflect
3 changes to information provided under this
4 subparagraph and subparagraph (B),
5 which updates—

6 “(I) are provided not less fre-
7 quently than once every six months
8 until the results of the trial are sub-
9 mitted under paragraph (2)(A)(i) or a
10 waiver is provided under paragraph
11 (2)(C); and

12 “(II) identify the dates on which
13 the changes were made.

14 “(B) SERIOUS OR LIFE-THREATENING DIS-
15 EASES; TEST OF EFFECTIVENESS.—In the case
16 of a registration under subsection (a)(1)(A) of
17 a clinical trial to test the effectiveness of the
18 use of a product with respect to a serious or
19 life-threatening disease or condition, the reg-
20 istration is in accordance with this paragraph
21 if, in addition to the information described in
22 subparagraph (A), the registration provides the
23 following information:

24 “(i) A brief summary of the trial, pro-
25 vided in lay language.

1 “(ii) A description of the location of
2 trial sites.

3 “(iii) A point of contact for individ-
4 uals desiring to enroll as subjects in the
5 trial, including a single point of contact for
6 all trial sites.

7 “(iv) The status of the trial with re-
8 spect to the enrollment of subjects, stated
9 for the trial in general and for individual
10 trial sites.

11 “(v) Information that may be avail-
12 able—

13 “(I) under a treatment investiga-
14 tional new drug application, or a
15 treatment investigational device ex-
16 emption, that has been submitted to
17 the Secretary under section 561(c) of
18 the Federal Food, Drug, and Cos-
19 metic Act (relating to expanded access
20 protocols); or

21 “(II) as a Group C cancer drug
22 (as defined by the National Cancer
23 Institute).

24 “(2) SUBMISSION OF RESULTS OF TRIAL.—

1 “(A) IN GENERAL.—For purposes of sub-
2 section (a)(1)(B), information on the results of
3 a clinical trial is provided in accordance with
4 this paragraph if, subject to subparagraphs (B)
5 and (C), the following conditions are met:

6 “(i) The results are submitted—

7 “(I) not later than 12 months
8 after the earlier of the anticipated
9 date that applies under paragraph
10 (1)(A)(xiii) or the actual date that ap-
11 plies under such paragraph; or

12 “(II) such later date as may
13 apply under an extension under sub-
14 paragraph (B).

15 “(ii) The results are provided in the
16 form of a structured abstract and in such
17 manner as the Secretary may require.

18 “(iii) The results consist of informa-
19 tion determined by the Secretary to be im-
20 portant to clinicians or researchers, in a
21 form that ensures that the information is
22 accurate and not likely to mislead or dis-
23 tort the results of the trial. Such informa-
24 tion shall include the following:

1 “(I) The date on which the trial
2 commenced.

3 “(II) The actual date for the
4 final collection of data from subjects
5 in the trial.

6 “(III) Primary and secondary
7 outcomes, presented succinctly as
8 quantitative data and as tests of
9 hypotheses.

10 “(IV) Basic demographic infor-
11 mation on subjects.

12 “(V) In the group of subjects re-
13 ceiving the product, and in each com-
14 parison group of subjects, the percent-
15 age of individuals who decided to
16 cease participation as subjects and the
17 reasons for ceasing participation.

18 “(VI) Information on significant
19 adverse events in subjects that may be
20 associated with the product involved,
21 including such events for which a
22 causal relationship has not been es-
23 tablished.

24 “(iv) If the trial is investigating an
25 unapproved use of an approved product, a

1 statement is submitted to the data bank
2 that the Food and Drug Administration,
3 as applicable—

4 “(I) is currently reviewing an ap-
5 plication for approval of the unap-
6 proved use;

7 “(II) has disapproved such an
8 application;

9 “(III) has reviewed such an ap-
10 plication, but the application was
11 withdrawn prior to approval or dis-
12 approval; or

13 “(IV) has not reviewed or ap-
14 proved such an application.

15 “(v) After the initial submission of the
16 results, periodic updates are submitted to
17 the data bank to reflect changes in the in-
18 formation submitted under this subpara-
19 graph, which updates—

20 “(I) are provided not less fre-
21 quently than once every six months
22 during the 10-year period beginning
23 on the date on which the results are
24 due under clause (i); and

1 “(II) identify the dates on which
2 the changes were made.

3 “(vi) For each covered article pub-
4 lished in a peer-reviewed scientific or aca-
5 demic journal, the responsible person for
6 the trial submits to the data bank a state-
7 ment that provides a citation to the article.
8 An article published in such a journal is a
9 covered article for purposes of this clause
10 if—

11 “(I) the article discusses the re-
12 sults of the trial;

13 “(II) the responsible person or
14 the principal investigator for the clin-
15 ical trial contributed to the article;
16 and

17 “(III) MEDLINE includes a ci-
18 tation to the article.

19 “(vii) If the due date under clause (i)
20 for the trial is a date that is more than
21 three years after the date on which the
22 trial was registered under subsection
23 (a)(1)(A):

24 “(I) Upon the expiration of such
25 three-year period, the responsible per-

1 son for the trial submits to the data
2 bank a report that describes the
3 progress being made toward submis-
4 sion of the results.

5 “(II) For each two-year period
6 that lapses after the submission of the
7 report under subclause (I), the re-
8 sponsible person submits to the data
9 bank an additional report that de-
10 scribes such progress, except that no
11 report is required under this sub-
12 clause after such due date.

13 “(B) EXTENSIONS.—

14 “(i) IN GENERAL.—The Secretary
15 may provide an extension of the due date
16 under subparagraph (A)(i) for the results
17 of a clinical trial if the responsible person
18 for the trial submits to the Secretary a
19 written request that demonstrates good
20 cause for the extension and provides an es-
21 timate of the date on which the results will
22 be submitted. More than one such exten-
23 sion may be provided by the Secretary for
24 the clinical trial involved.

1 “(ii) EXTENSIONS REGARDING JOUR-
2 NAL PUBLICATION.—

3 “(I) ARTICLE UNDER CONSIDER-
4 ATION FOR PUBLICATION.—The Sec-
5 retary shall under clause (i) provide
6 an extension of 18 months regarding
7 the submission of the results of a clin-
8 ical trial if—

9 “(aa) the request under such
10 clause demonstrates that an arti-
11 cle providing the information de-
12 scribed in subparagraph (A)(iii)
13 has been submitted to a peer-re-
14 viewed scientific or academic
15 journal for which references are
16 included in MEDLINE, and the
17 request demonstrates that the ar-
18 ticle is being considered by the
19 journal for publication; and

20 “(bb) such request is made
21 before the expiration of the 12-
22 month period described in sub-
23 paragraph (A)(i).

24 “(II) ARTICLE ACCEPTED FOR
25 PUBLICATION.—If the responsible per-

1 son for a clinical trial has received an
2 extension under subclause (I) for the
3 trial, the Secretary shall provide an
4 additional extension of six months, be-
5 ginning upon the expiration of such
6 first extension, if the person dem-
7 onstrates to the Secretary, before the
8 expiration of the first extension, that
9 the article involved has been accepted
10 for publication by a journal referred
11 to in such subclause.

12 “(C) WAIVERS REGARDING RESULTS OF
13 TRIAL.—With respect to the requirement under
14 subsection (a)(1)(B) to submit to the Secretary
15 the results of a clinical trial, the Secretary may
16 waive the requirement upon a written request to
17 the Secretary by the responsible person for the
18 trial if the Secretary determines that extraor-
19 dinary circumstances justify the waiver and
20 that providing the waiver is in the public inter-
21 est or consistent with the protection of the pub-
22 lic health. The Secretary shall ensure that in-
23 formation on each such waiver is included in
24 the data bank.

1 “(3) TRACKING OF CHANGES IN INFORMATION
2 SUBMITTED TO DATA BANK.—The Secretary shall
3 ensure that updates to the data bank submitted
4 under paragraphs (1)(A)(xviii) and (2)(A)(v) do not
5 result in the removal from the data bank of the
6 original submissions or of any preceding updates,
7 and that information in the data bank is presented
8 in a manner that enables users to readily access
9 each original submission and to track the changes
10 made by the updates.

11 “(e) PUBLIC DISCLOSURE OF INFORMATION.—

12 “(1) IN GENERAL.—The Secretary shall dis-
13 seminate information in the data bank through in-
14 formation systems in accordance with this sub-
15 section. Information required in this section to be
16 submitted to the data bank shall not be considered
17 confidential commercial information or trade secrets,
18 notwithstanding any other provision of law.

19 “(2) PROHIBITION AGAINST FEES.— The Sec-
20 retary may not impose a fee for providing access to
21 information in the data bank.

22 “(3) INTERNET SITES.—

23 “(A) IN GENERAL.—The Secretary shall
24 operate one or more searchable Internet sites
25 for purposes of presenting to clinicians and re-

1 searchers, and to patients seeking to enroll as
2 subjects in clinical trials, information in the
3 data bank that is required in paragraph (5) to
4 be disclosed. The Secretary shall ensure that—

5 “(i) such a site, or a portion of a site,
6 is designed specifically for use by clinicians
7 and researchers; and

8 “(ii) such a site, or a portion of a site,
9 is designed specifically for use by patients
10 seeking to enroll as subjects in clinical
11 trials.

12 “(B) RELATION TO CERTAIN INTERNET
13 SITE.—The Secretary shall ensure that the
14 Internet site or portion thereof operated under
15 subparagraph (A)(ii) includes information of
16 the type that was available on ClinicalTrials.gov
17 as of the day before the date of the enactment
18 of the Fair Access to Clinical Trials Act (relat-
19 ing to serious or life-threatening diseases). This
20 section may not be construed as requiring the
21 Secretary to terminate or alter
22 ClinicalTrials.gov, or as prohibiting the Sec-
23 retary from terminating or altering such site.

24 “(4) SPECIFIC MEANS OF DISCLOSURE.—With
25 respect to information in the data bank that is re-

1 quired in paragraph (5) to be disclosed, all disclo-
2 sures shall be made through an Internet site or sites
3 under paragraph (3) and any other means deter-
4 mined appropriate by the Secretary, except that in
5 the case of information of the type referred to in
6 paragraph (3)(B) and intended for patients seeking
7 to enroll as subjects in clinical trials, the means of
8 disclosure shall include toll-free telephone commu-
9 nications.

10 “(5) REQUIRED DISCLOSURES; AUTHORITY OF
11 SECRETARY FOR EXCLUSIONS.—

12 “(A) CLINICIANS AND RESEARCHERS.—

13 With respect to means of disclosure under this
14 subsection that are intended for clinicians and
15 researchers, the Secretary shall through such
16 means disclose all information in the data bank,
17 except that the Secretary may exclude informa-
18 tion contained in the data bank pursuant to
19 subsection (d)(1)(B) if the Secretary determines
20 that such information is not useful to clinicians
21 and researchers.

22 “(B) PATIENTS SEEKING ENROLLMENT AS
23 SUBJECTS IN CLINICAL TRIALS.—With respect
24 to means of disclosure under this subsection
25 that are intended for patients seeking to enroll

1 as subjects in clinical trials, the Secretary shall
2 through such means disclose all information in
3 the data bank, except that the Secretary may
4 exclude any information that the Secretary de-
5 termines is not useful to such patients. The
6 Secretary may not under the preceding sentence
7 exclude information of the type referred to in
8 paragraph (3)(B).

9 “(6) REGISTRATION INFORMATION; DATE OF
10 DISCLOSURE.—In the case of information regarding
11 a clinical trial that is contained in the data bank
12 pursuant to subparagraph (A) or (B) of subsection
13 (d)(1), disclosures required in paragraph (5) shall
14 begin in accordance with the following:

15 “(A) All such disclosures shall begin
16 promptly after the registration involved is sub-
17 mitted to the Secretary, other than disclosure of
18 the definitions of the primary and secondary
19 outcomes.

20 “(B) Disclosure of the definition of the pri-
21 mary and secondary outcomes shall begin at the
22 same time as disclosure of the results of the
23 trial begin under paragraph (7)(A).

24 “(7) RESULTS OF TRIAL; DATE OF DISCLO-
25 SURE.—

1 “(A) IN GENERAL.—In the case of infor-
2 mation regarding a clinical trial that is con-
3 tained in the data bank pursuant to subsection
4 (d)(2), disclosures required in paragraph (5)
5 shall begin promptly after the information is
6 submitted to the Secretary, subject to subpara-
7 graph (B).

8 “(B) WAIVER REGARDING RESULTS OF
9 TRIAL.—In the case of information contained in
10 the data bank on waivers under subsection
11 (d)(2)(C), disclosures required in paragraph (5)
12 shall begin promptly after the waiver is pro-
13 vided.

14 “(f) DETERMINATION OF VIOLATIONS.—

15 “(1) COMPLIANCE AUDITS.—

16 “(A) IN GENERAL.—The Secretary shall
17 conduct periodic audits of responsible persons
18 for clinical trials receiving awards described in
19 subsection (a)(1) in order to determine whether
20 the persons have submitted information as re-
21 quired under agreements under subparagraphs
22 (A) and (B) of such subsection, including deter-
23 mining whether any of the information is false
24 or misleading.

1 “(B) PRIORITY.—In conducting audits
2 under subparagraph (A), the Secretary shall
3 give priority to responsible persons for clinical
4 trials who have at any time been included on
5 the list under subsection (g)(1)(A)(i), taking
6 into account the number and severity of the vio-
7 lations involved.

8 “(2) NOTICE TO RESPONSIBLE PERSONS.—
9 Promptly after determining that a responsible per-
10 son for a clinical trial is in violation of a require-
11 ment under subparagraph (A) or (B) of subsection
12 (a)(1), the Secretary shall notify the person in writ-
13 ing of the violation.

14 “(g) ACTIONS OF SECRETARY REGARDING VIOLA-
15 TIONS.—

16 “(1) IN GENERAL.—If a responsible person for
17 a clinical trial is in violation of an agreement under
18 subparagraph (A) or (B) of subsection (a)(1) (in-
19 cluding submitting information under such a sub-
20 paragraph that is false or misleading), the following
21 applies, subject to paragraph (4) of this subsection:

22 “(A) In any case in which the violation is
23 not corrected within 30 days after the Secretary
24 provides to the responsible person a notice
25 under subsection (f)(2) regarding the violation:

1 “(i) Through Internet sites under sub-
2 section (e)(3) and such other means as the
3 Secretary determines to be appropriate, the
4 Secretary shall announce to the public that
5 the responsible person is in violation of
6 this section. For purposes of the preceding
7 sentence, the Secretary shall maintain a
8 list of responsible persons in violation that
9 is available to the public.

10 “(ii) The responsible person is, pursu-
11 ant to subsection (a)(1)(D), subject to a
12 liquidated penalty of not more than a total
13 of \$15,000 for all violations adjudicated in
14 a single proceeding in the case of an indi-
15 vidual, and \$10,000 per day until the vio-
16 lation is corrected in the case of any other
17 person, except that if the person is a non-
18 profit entity the penalty may not exceed a
19 total of \$15,000 for all violations adju-
20 dicated in a single proceeding. Paragraphs
21 (3) through (5) of section 303(f) of the
22 Federal Food, Drug, and Cosmetic Act
23 apply to the imposition of such a penalty
24 to the same extent and in the same man-
25 ner as such paragraphs apply to a penalty

1 imposed under paragraph (1) or (2) of
2 such section.

3 “(B) In any case in which the violation is
4 a significant violation and is not corrected with-
5 in 60 days after the Secretary provides to the
6 responsible person a notice under subsection
7 (f)(2) regarding the violation, the Secretary
8 shall, after notice and an opportunity for a
9 hearing, consider the person to be ineligible for
10 any future awards described in subsection
11 (a)(1) until the violation is corrected, except
12 that notice and an opportunity for a hearing
13 are not required if a hearing regarding such
14 violation was held pursuant to subparagraph
15 (A)(ii).

16 “(C) In any case in which the violation is
17 a failure to submit to the data bank the results
18 of the trial by the due date under subsection
19 (d)(2)(A)(i), the Secretary shall order the re-
20 sponsible person to submit to the data bank
21 periodic reports on the progress being made to-
22 ward submission of the results, which reports
23 shall be submitted not less frequently than once
24 every two years until the results are submitted
25 to the data bank.

1 “(2) RELATION TO RELATED REQUIRE-
2 MENTS.—If a responsible person for a clinical trial
3 is ineligible for purposes of section 565(f)(1)(B) or
4 566(a)(2) of the Federal Food, Drug, and Cosmetic
5 Act, the person is ineligible for any award described
6 in subsection (a)(1) during the period of such ineli-
7 gibility, without regard to whether the person is in-
8 eligible under paragraph (1)(B) of this subsection.

9 “(3) FALSE OR MISLEADING INFORMATION.—If
10 the Secretary determines that the responsible person
11 for a clinical trial has submitted to the data bank
12 information that is false or misleading, and if on
13 such basis a civil money has been imposed under
14 paragraph (1)(A)(ii) on such person or the person
15 has becomes ineligible within the meaning of para-
16 graph (1)(B) or (2), the Secretary shall remove the
17 information from the data bank, subject to any judi-
18 cial review of such action or actions of the Secretary.

19 “(4) WAIVER REGARDING INELIGIBILITY FOR
20 FUNDING.—With respect to a responsible person
21 who is ineligible for purposes of paragraph (1)(B) or
22 (2), the Secretary may waive the applicability of
23 such paragraph in order to provide for a clinical
24 trial if the Secretary determines that providing the
25 waiver is in the public interest or consistent with the

1 protection of the public health. Each such deter-
2 mination of the Secretary shall be published in the
3 Federal Register.

4 “(5) FUNDING OF COMPARATIVE STUDIES.—
5 Penalties collected by the Secretary under paragraph
6 (1)(A)(ii) shall be used by the Secretary to make
7 awards of grants, contracts, or cooperative agree-
8 ments for the conduct of comparative clinical trials
9 to determine the safety or relative effectiveness of
10 products.

11 “(h) CRITERIA.—The Secretary shall establish cri-
12 teria regarding compliance with this section.

13 “(i) AWARD FOR CONDUCT OF CLINICAL TRIAL;
14 COMPLIANCE COSTS AS DIRECT COSTS.—In admin-
15 istering an award of a grant, contract, or cooperative
16 agreement that is subject to subsection (a)(1), the Sec-
17 retary shall consider the costs of complying with require-
18 ments under such subsection as part of the direct costs
19 of conducting the clinical trial involved.

20 “(j) DEFINITIONS.—For purposes of this section:

21 “(1) The term ‘approved product’ means a
22 product that is approved, licensed, or cleared for
23 commercial distribution under section 505, 510(k),
24 or 515 of the Federal Food, Drug, and Cosmetic Act
25 or under section 351 of this Act.

1 “(2) The term ‘approved use’, with respect to
2 an approved product, means a use that is an ap-
3 proved, licensed, or cleared use of the product under
4 a provision of law referred to in paragraph (1).

5 “(3) The term ‘clinical trial’, with respect to a
6 product, means a clinical investigation within the
7 meaning of section 505(i) of the Federal Food,
8 Drug, and Cosmetic Act (in the case of drug), or
9 within the meaning of section 520(g) of such Act (in
10 the case of a device), as applicable, except that such
11 term does not include such an investigation that
12 does not prospectively assign human subjects to
13 intervention or comparison groups to study the caus-
14 al relationship between a medical intervention and
15 an outcome.

16 “(4) The term ‘data bank’ means the data bank
17 under subsection (b).

18 “(5) The term ‘device’ has the meaning given
19 such term in section 201(h) of the Federal Food,
20 Drug, and Cosmetic Act.

21 “(6) The term ‘drug’ has the meaning given
22 such term in section 201(g)(1) of the Federal Food,
23 Drug, and Cosmetic Act. Such term includes a bio-
24 logical product.

1 “(7) The term ‘MEDLINE’ means the biblio-
2 graphic electronic data base of references to journal-
3 published articles that is operated by the National
4 Library of Medicine and is designated by such Li-
5 brary as the Medical Literature, Analysis, and Re-
6 trieval System Online.

7 “(8) The term ‘product’ has the meaning indi-
8 cated for such term in subsection (a)(1).

9 “(9) The term ‘researchers’ means individuals
10 who conduct research on drugs or devices.

11 “(10) The term ‘responsible person’, with re-
12 spect to a clinical trial to determine the safety or ef-
13 fectiveness of a use of a product, has the following
14 meaning, as applicable:

15 “(A) In any case in which an application
16 has been submitted for an exemption under sec-
17 tion 505(i) or 520(g)(2)(A) with respect to the
18 trial, such term means the entity who, within
19 the meaning of such section, is the sponsor of
20 the trial.

21 “(B) In any case in which such an applica-
22 tion has not been submitted, such term means
23 the entity who is or will be providing the largest
24 share of the monetary support for the trial

1 (without regard to any in-kind support for the
2 trial), subject to the following:

3 “(i) If the Federal Government or a
4 State is or will be providing the largest
5 share, such term means the principal in-
6 vestigator for the trial.

7 “(ii) If a nonprofit private entity is or
8 will be providing the largest share, such
9 term means the principal investigator for
10 the trial in any case in which such entity
11 and investigator have jointly certified to
12 the Secretary that the investigator will be
13 the responsible person for purposes of this
14 section.

15 “(iii) If two or more entities provide
16 equal monetary support for the trial and
17 no other entity provides a greater amount
18 of monetary support, such term means
19 each of the entities providing such equal
20 support, other than the Federal Govern-
21 ment or a State.

22 “(iv) Notwithstanding clauses (i)
23 through (iii), if an entity submits to the
24 Secretary a written request to be the re-
25 sponsible person for purposes of this sec-

1 tion, such term means that entity in any
2 case in which the Secretary determines
3 that the entity is or will be providing mon-
4 etary support for the trial and is respon-
5 sible for conducting the trial.

6 “(11) The term ‘unapproved product’ means a
7 product that is not an approved product.

8 “(12) The term ‘unapproved use’, with respect
9 to an approved product, means a use that is not an
10 approved use.

11 “(k) AUTHORIZATION OF APPROPRIATIONS.—For the
12 purpose of carrying out this section, there are authorized
13 to be appropriated such sums as may be necessary for fis-
14 cal year 2004 and each subsequent fiscal year. Fees col-
15 lected under section 736 or 738 of the Federal Food,
16 Drug, and Cosmetic Act shall not be used in carrying out
17 this section.”.

18 (b) CLINICAL INVESTIGATIONS IN PROGRESS.—With
19 respect to a clinical investigation to determine the safety
20 or effectiveness of a use of a drug, biological product, or
21 device, if the final data collection from subjects in the trial
22 on the primary outcome has not been completed as of the
23 date of the enactment of this Act, and if the investigation
24 is being conducted with an award of a grant, contract,
25 or cooperative agreement under the Public Health Service

1 Act, the investigation becomes subject to section 491A of
2 such Act (as added by subsection (a) of this section) upon
3 the expiration of 30 days after the date of the enactment
4 of this Act, except that registration information required
5 pursuant to subsection (d)(1) of such section 491A is due
6 upon the expiration of such 30 days. For purposes of the
7 preceding sentence, the term “clinical investigation” has
8 the meaning that applies for purposes of subsection (j)(3)
9 of such section 491A.

10 (c) RULE OF CONSTRUCTION REGARDING PRIOR
11 PROVISION.—With respect to the data bank program
12 under section 402(j) of the Public Health Service Act as
13 in effect on the day before the date of the enactment of
14 this Act:

15 (1) Subsection (a) shall be construed as a
16 transfer and modification of the program, and not as
17 the termination of the program and the establish-
18 ment of a different program.

19 (2) All information contained in the data bank
20 on such day shall continue to be contained in the
21 data bank, subject to section 491A of the Public
22 Health Service Act (as added by subsection (a) of
23 this section) or other applicable provisions of law.

1 **SEC. 3. OTHER CONDITIONS REGARDING DATA BANK ON**
2 **CLINICAL TRIALS.**

3 (a) INVESTIGATIONAL DRUGS AND DEVICES.—

4 (1) IN GENERAL.—Subchapter E of chapter V
5 of the Federal Food, Drug, and Cosmetic Act (21
6 U.S.C. 360bbb et seq.) is amended by adding at the
7 end the following section:

8 **“SEC. 565. INVESTIGATIONAL DRUGS AND DEVICES; CONDI-**
9 **TIONS REGARDING DATA BANK ON CLINICAL**
10 **TRIALS.**

11 “(a) IN GENERAL.—

12 “(1) CONDITIONS FOR EXEMPTIONS.—Except
13 as provided in paragraph (2), an exemption under
14 section 505(i) or 520(g)(2)(A) for an investigation
15 to determine the safety or effectiveness of the use of
16 a drug or device (referred to in this section as a
17 ‘product’) may not be considered to be in effect un-
18 less—

19 “(A) the sponsor of the investigation
20 agrees to register the investigation with the
21 Secretary;

22 “(B) the sponsor of the investigation
23 agrees to provide to the Secretary information
24 on the results of the investigation; and

1 “(C) the sponsor of the investigation
2 agrees to the disclosure to the public of infor-
3 mation regarding the investigation.

4 “(2) EXCEPTION.—Paragraph (1) does not
5 apply to an investigation to determine the safety of
6 a use of a drug if the trial is designed solely to de-
7 tect major toxicities in the drug or to investigate
8 pharmacokinetics, except that such paragraph does
9 apply if the trial is designed solely to investigate
10 pharmacokinetics in a special population or popu-
11 lations.

12 “(b) INSTITUTIONAL REVIEW BOARDS.—For pur-
13 poses of subsection (a), the Secretary shall amend parts
14 50, 56, and 812 of title 21, Code of Federal Regulations,
15 to provide that—

16 “(1) the functions of institutional review boards
17 under such parts include—

18 “(A) determining whether investigations
19 are registered under subsection (a)(1)(A); and

20 “(B) denying the approval of the boards
21 for investigations that are not registered under
22 such subsection;

23 “(2) any approval of an institutional review
24 board regarding an investigation is not effective

1 under such parts if the investigation is not reg-
2 istered under such subsection; and

3 “(3) upon request of an institutional review
4 board for such an investigation, the Secretary will
5 provide to the board a copy of the registration for
6 the investigation under such subsection (which copy
7 will be the registration as submitted to the Sec-
8 retary, together with all updates to the registration).

9 “(c) CERTAIN EXEMPTIONS.—The reference in sub-
10 section (a) to an exemption under section 505(i) includes
11 an exemption described in section 312.2(b) of title 21,
12 Code of Federal Regulations. The reference in such sub-
13 section to an exemption under section 520(g)(2)(A) in-
14 cludes an exemption described in section 812.2(b) of such
15 title 21.

16 “(d) RELATIONSHIP TO SIMILAR REQUIREMENTS.—
17 For purposes of subsection (a):

18 “(1) The responsibilities of a sponsor of an in-
19 vestigation, and of the Secretary, are the same as
20 apply under section 491A of the Public Health Serv-
21 ice Act with respect to responsible persons, except to
22 the extent of taking into account that this section
23 concerns conditions for exemptions referred to in
24 subsection (a)(1) and section 491A of such Act con-

cerns conditions for the receipt of an award under such Act.

“(2) The Secretary shall administer the program under this section and the program under section 491A of such Act as substantially a single program, shall not require duplicative registrations, and shall otherwise avoid duplicative activities.

“(e) DETERMINATION OF VIOLATIONS.—

“(1) COMPLIANCE AUDITS.—

“(A) IN GENERAL.—The Secretary shall conduct periodic audits of sponsors of investigations for which exemptions referred to in subsection (a)(1) are in effect in order to determine whether the sponsors have submitted information as required under agreements under subparagraphs (A) and (B) of such subsection, including determining whether any of the information is false or misleading.

“(B) PRIORITY.—In conducting audits under subparagraph (A), the Secretary shall give priority to sponsors of investigations who have at any time been included on the list under subsection (f)(1)(A)(i), taking into account the number and severity of the violations involved.

1 “(2) NOTICE TO SPONSORS.—Promptly after
2 determining that a sponsor of an investigation is in
3 violation of a requirement under subparagraph (A)
4 or (B) of subsection (a)(1), the Secretary shall no-
5 tify the sponsor in writing of the violation.

6 “(f) ACTIONS OF SECRETARY REGARDING VIOLA-
7 TIONS.—

8 “(1) IN GENERAL.—If a sponsor of an inves-
9 tigation is in violation of an agreement under sub-
10 paragraph (A) or (B) of subsection (a)(1) (including
11 submitting information under such a subparagraph
12 that is false or misleading), the following applies,
13 subject to paragraph (2) of this subsection:

14 “(A) In any case in which the violation is
15 not corrected within 30 days after the Secretary
16 provides to the sponsor a notice under sub-
17 section (e)(2) regarding the violation:

18 “(i) Through Internet sites operated
19 pursuant to subsection (d) and such other
20 means as the Secretary determines to be
21 appropriate, the Secretary shall announce
22 to the public that the sponsor is in viola-
23 tion of this section. For purposes of the
24 preceding sentence, the Secretary shall

1 maintain a list of sponsors in violation that
2 is available to the public.

3 “(ii) The sponsor is subject to a civil
4 penalty of not more than a total of
5 \$15,000 for all violations adjudicated in a
6 single proceeding in the case of an indi-
7 vidual, and \$10,000 per day until the vio-
8 lation is corrected in the case of any other
9 person, except that if the person is a non-
10 profit entity the penalty may not exceed a
11 total of \$15,000 for all violations adju-
12 dicated in a single proceeding. Paragraphs
13 (3) through (5) of section 303(f) apply to
14 the imposition of such a penalty to the
15 same extent and in the same manner as
16 such paragraphs apply to a penalty im-
17 posed under paragraph (1) or (2) of such
18 section.

19 “(B) In any case in which the violation is
20 a significant violation and is not corrected with-
21 in 60 days after the Secretary provides to the
22 sponsor a notice under subsection (e)(2) regard-
23 ing the violation, the Secretary may, after no-
24 tice and an opportunity for a hearing, consider
25 the sponsor to be ineligible for any future ex-

1 emptions referred to in subsection (a)(1) for
2 any investigation until the violation is corrected,
3 except that notice and an opportunity for a
4 hearing are not required if a hearing regarding
5 such violation was held pursuant to subpara-
6 graph (A)(ii).

7 “(C) In any case in which the violation is
8 a failure to submit to the data bank the results
9 of the investigation by the due date that applies
10 pursuant to subsection (d), the Secretary shall
11 order the sponsor of the investigation to submit
12 to the data bank periodic reports on the
13 progress being made toward submission of the
14 results, which reports shall be submitted not
15 less frequently than once every two years until
16 the results are submitted to the data bank.

17 “(2) FALSE OR MISLEADING INFORMATION.—If
18 the Secretary determines that the sponsor of an in-
19 vestigation has submitted to the data bank informa-
20 tion that is false or misleading, and if on such basis
21 a civil money has been imposed under paragraph
22 (1)(A)(ii) on the sponsor or the sponsor has become
23 ineligible within the meaning of paragraph (1)(B),
24 the Secretary shall remove the information from the

1 data bank, subject to any judicial review of such ac-
2 tion or actions of the Secretary.

3 “(3) WAIVER REGARDING INELIGIBILITY FOR
4 EXEMPTIONS.—With respect to a sponsor who is in-
5 eligible for purposes of paragraph (1)(B), the Sec-
6 retary may waive the applicability of such paragraph
7 in order to provide for an investigation if the Sec-
8 retary determines that providing the waiver is in the
9 public interest or consistent with the protection of
10 the public health. Each such determination of the
11 Secretary shall be published in the Federal Register.

12 “(4) FUNDING OF COMPARATIVE STUDIES.—
13 Penalties collected by the Secretary under paragraph
14 (1)(A)(ii) shall be used by the Secretary to make
15 awards of grants or contracts for the conduct of
16 comparative investigations to determine the safety or
17 relative effectiveness of products.

18 “(g) DEFINITIONS.—

19 “(1) IN GENERAL.—Definitions under section
20 491A(j) of the Public Health Service Act apply for
21 purposes of this section, subject to paragraph (2).

22 “(2) INVESTIGATION.—For purposes of this
23 section, the term ‘investigation’ means a clinical in-
24 vestigation within the meaning of section 505(i) (in
25 the case of drug), or within the meaning of section

1 520(g) (in the case of a device), as applicable, except
2 that such term does not include such an investiga-
3 tion that does not prospectively assign human sub-
4 jects to intervention or comparison groups to study
5 the causal relationship between a medical interven-
6 tion and an outcome.”.

7 (2) CONFORMING AMENDMENTS.—Chapter V of
8 the Federal Food, Drug, and Cosmetic Act (21
9 U.S.C. 351 et seq.) is amended—

10 (A) in section 505(i), by adding at the end
11 the following paragraph:

12 “(5) The provision of an exemption under paragraph
13 (1) is subject to section 565 (relating to information on
14 investigations).”; and

15 (B) in section 520(g), by adding at the end
16 the following paragraph:

17 “(8) The provision of an exemption under paragraph
18 (2)(A) is subject to section 565 (relating to information
19 on investigations).”.

20 (b) PREMARKET APPLICATION OR REPORT; LABEL-
21 ING AND ADVERTISING.—Subchapter E of chapter V of
22 the Federal Food, Drug, and Cosmetic Act, as amended
23 by subsection (a) of this section, is amended by adding
24 at the end the following section:

1 **“SEC. 566. PREMARKET APPLICATION OR REPORT; LABEL-**
2 **ING AND ADVERTISING; RELATION TO DATA**
3 **BANK ON CLINICAL TRIALS.**

4 “(a) PREMARKET APPLICATION OR REPORT.—If a
5 person submits to the Secretary an application under sec-
6 tion 505(b) or 515 or a report under section 510(k), and
7 one or more of the investigations presented to the Sec-
8 retary by the person for purposes of the application or
9 report are investigations that are not subject to require-
10 ments under section 565 or under section 491A of the
11 Public Health Service, and if the person was the principal
12 investigator or the responsible person for the investigation
13 involved, the following applies:

14 “(1) The person is subject to a civil penalty—

15 “(A) in any case in which information on
16 the investigation has not, as of the date on
17 which the application or report is submitted to
18 the Secretary, been submitted to the data bank
19 described in such section 491A to the same ex-
20 tent as would have been required as of such
21 date if the investigation had been subject to
22 such requirements (without regard to time-
23 frames for the submission of information that
24 would have applied before such date under such
25 section); and

1 “(B) in any case in which, after such date,
2 information on the investigation is not sub-
3 mitted to the data bank to the same extent as
4 would be required if the investigation were sub-
5 ject to such requirements.

6 “(2) If the person is subject to a civil penalty
7 under paragraph (1), the Secretary, in addition to
8 such penalty, may, after notice and an opportunity
9 for a hearing, consider the person to be ineligible for
10 any future exemptions under section 505(i) or
11 520(g)(2)(A) for any investigation until the informa-
12 tion involved is submitted to the data bank as de-
13 scribed in paragraph (1), except that notice and an
14 opportunity for a hearing are not required if a hear-
15 ing regarding such violation was held pursuant to
16 paragraph (1).

17 “(b) LABELING AND ADVERTISEMENTS.—If a person
18 disseminates labeling, or an advertisement or other de-
19 scriptive printed matter, for a drug or device for human
20 use and the labeling, advertisement, or other matter refers
21 to an investigation that is not subject to requirements
22 under section 565 or under section 491A of the Public
23 Health Service, and if the person was the principal investi-
24 gator or the responsible person for the investigation, the
25 person is subject to a civil penalty—

1 “(1) in any case in which information on the in-
2 vestigation has not, as of the date on which the la-
3 beling, advertisement, or other matter enters the
4 market, been submitted to the data bank described
5 in such section 491A to the same extent as would
6 have been required as of such date if the investiga-
7 tion had been subject to such requirements (without
8 regard to timeframes for the submission of informa-
9 tion that would have applied before such date under
10 such section); and

11 “(2) in any case in which, after such date, in-
12 formation on the investigation is not submitted to
13 the data bank to the same extent as would be re-
14 quired if the investigation were subject to such re-
15 quirements.

16 “(c) AMOUNT OF CIVIL PENALTY; PROCEDURE.—A
17 civil penalty under subsection (a)(1) or (b) shall be not
18 more than a total of \$15,000 for all violations adjudicated
19 in a single proceeding in the case of an individual, and
20 \$10,000 per day until the violation is corrected in the case
21 of any other person, except that if the person is a non-
22 profit entity the penalty may not exceed a total of \$15,000
23 for all violations adjudicated in a single proceeding. Para-
24 graphs (3) through (5) of section 303(f) apply to the im-
25 position of such a penalty to the same extent and in the

1 same manner as such paragraphs apply to a penalty im-
2 posed under paragraph (1) or (2) of such section.

3 “(d) BIOLOGICS LICENSE APPLICATION.—Sub-
4 sections (a) and (c) apply with respect to a biologics li-
5 cense application under section 351 of the Public Health
6 Service Act to the same extent and in the same manner
7 as such subsections apply with respect to an application
8 or report referred to in subsection (a).

9 “(e) DEFINITIONS.—For purposes of this section:

10 “(1) The term ‘investigation’ has the meaning
11 given such term in section 565(g).

12 “(2) The term ‘responsible person’ has the
13 meaning given such term in section 491A(j) of the
14 Public Health Service Act. ”.

15 (c) CLINICAL INVESTIGATIONS IN PROGRESS.—With
16 respect to a clinical investigation to determine the safety
17 or effectiveness of a use of a drug, biological product, or
18 device, if the final data collection from subjects in the in-
19 vestigation on the primary outcome has not been com-
20 pleted as of the date of the enactment of this Act, and
21 if the investigation is one for which an exemption under
22 section 505(i) or 520(g)(2)(A) of the Federal Food, Drug,
23 and Cosmetic Act is in effect, the investigation becomes
24 subject to section 565 of such Act (as added by subsection
25 (a) of this section) upon the expiration of 30 days after

1 the date of the enactment of this Act, except that registra-
2 tion information required pursuant to subsection (d) of
3 such section 565 is due upon the expiration of such 30
4 days. For purposes of the preceding sentence, the term
5 “clinical investigation” has the meaning given such term
6 in subsection (g)(2) of such section 565.

7 **SEC. 4. RULE OF CONSTRUCTION REGARDING AUTHORITY**
8 **OF SECRETARY FOR PUBLIC DISCLOSURE OF**
9 **INFORMATION ON CLINICAL TRIALS.**

10 This Act and the amendments made by this Act may
11 not be construed as limiting the authority of the Secretary
12 of Health and Human Services to disclose to the public
13 information on clinical trials to determine the safety or
14 effectiveness of the use of drugs, which authority was in
15 effect as of the day before the date of the enactment of
16 this Act.

○