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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

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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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Fair Access to Clinical Trials Act''.

SEC. 2. REGISTRATION OF CLINICAL TRIALS UNDER PUBLIC HEALTH SERVICE ACT.

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

(1) in section 402, by striking subsection (j); and

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

"SEC. 491A. REGISTRATION OF CLINICAL TRIALS; DATA BANK.

''(a) IN GENERAL.—

''(1) CONDITIONS FOR FINANCIAL AWARDS.—Except as provided in paragraph (2), an entity may not receive an award of a grant, contract, or cooperative agreement under this Act for the conduct of a clinical trial to determine the safety or effectiveness of a use of a drug or device (referred to in this section as a 'product') unless the responsible person for the trial—

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

''(B) agrees to provide to the Secretary information on the results of the trial in accordance with subsection (d)(2);

''(C) agrees to the disclosure to the public of information regarding the trial in accordance with subsection (e); and

''(D) agrees to be subject to audits under subsection (f)(1), and as applicable, to liquidated penalties and the requirement to submit reports under subsection (g)(1).

''(2) EXCEPTION.—Paragraph (1) does not apply to a clinical trial to determine the safety of a use of a drug if the trial is designed solely to detect major toxicities in the drug or to investigate pharmacokinetics, except that such paragraph does apply if the trial is designed solely to investigate pharmacokinetics in a special population or populations.

''(b) DATA BANK.—

''(1) IN GENERAL.— The Secretary, acting through the Director of NIH, shall establish, maintain, and operate a data bank of information provided to the Secretary pursuant to subsection (a), including collecting, cataloging, and storing the information, and disseminating the information in accordance with subsection (e). The activities of the data bank shall be integrated and coordinated with related activities of other agencies of the Department of Health and Human Services, and to the ex-

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

"(2) INFORMATION FROM ELECTIVE SUBMISSIONS.—

"(A) CLINICAL TRIALS REGARDING DRUGS OR DEVICES.—The Secretary may accept for inclusion in the data bank information on clinical trials that are trials to determine the safety or effectiveness of a use of a product but are not subject to requirements under subsection (a). The inclusion of information in the data bank under the preceding sentence is subject to the condition that the responsible person for the clinical trial involved make each of the agreements described in subsection (a)(1).

"(B) OTHER CLINICAL TRIALS.—The Secretary may accept for inclusion in the data bank information on clinical trials that do not involve drugs or devices if the responsible person for the trial involved agrees to such conditions regarding the submission and disclosure of the information as the Secretary determines to be appropriate, taking into account the requirements of this section for clinical trials that do involve drugs or devices.

''(3) CONSULTATION.—The Secretary shall operate the data bank in consultation with the Commissioner of Food and Drugs, the directors of the appropriate agencies of the National Institutes of Health, and the Director of the Centers for Disease Control and Prevention.

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

''(5) ENTRY OF INFORMATION.—Information provided to the Secretary under this section by responsible persons for clinical trials shall be entered in the data bank promptly after the Secretary receives the information, except to the extent that the Secretary determines that the information has not been submitted to the Secretary in accordance with this section, in which case the Secretary shall promptly inform the responsible person involved that corrective actions by the person are necessary to maintain compliance with this section.

''(6) AUTHORITY OF SECRETARY.—

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

as the Secretary determines to be appropriate to assist the public in avoiding misinterpretations of information in the data bank. Statements under the preceding sentence may include statements regarding the data bank in general and statements regarding particular items of information submitted to the data bank. The Secretary may not under the preceding sentence alter any information as submitted.

''(B) FALSE OR MISLEADING INFORMATION.—

''(i) IN GENERAL.—If under subsection (f) the Secretary determines that information presented or cited in the data bank is false or misleading, the Secretary shall, promptly after making such determination, identify in the data bank the information as false or misleading (as applicable), and shall, to the extent practicable, include in the data bank an accurate version of the information. The Secretary shall in addition make appropriate public notification.

''(ii) LIMITATION.—Clause (i) does not authorize the disclosure of information if—

''(I) the disclosure would constitute a clearly unwarranted invasion of personal privacy; or

''(II) the information concerns a method or process that is a trade secret entitled to protection within the meaning of section 301(j) of the Federal Food, Drug, and Cosmetic Act.

''(c) INSTITUTIONAL REVIEW BOARDS.—For purposes of subsection (a), the Secretary shall amend part 46 of title 45, Code of Federal Regulations, to provide that—

''(1) the functions of institutional review boards under such part include—

''(A) determining whether clinical trials to determine the safety or effectiveness of products are registered under subsection (a)(1)(A); and

''(B) denying the approval of the boards for such trials that are not registered under such subsection;

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

''(3) upon request of an institutional review board for such a trial, the Secretary will provide to the board a copy of the registration for the trial under such subsection (which copy will be the registration as submitted to the Secretary, together with all updates to the registration).

''(d) SUBMISSION OF REQUIRED INFORMATION.—

''(1) SUBMISSION OF REGISTRATION INFORMATION.—

''(A) IN GENERAL.—A registration of a clinical trial under subsection (a)(1)(A) is in accordance with this paragraph if, subject to subparagraph (B), the registration is in such form and is submitted in such manner as the Secretary requires, and the registration contains such information on the design and goals of the trial as the Secretary determines to be important to clinicians or researchers. Such information shall include the following:

''(i) A brief title for the trial, provided in lay language.

"(ii) The disease or condition with which the trial is concerned.

"(iii) The medical intervention or interventions being investigated in the trial.

"(iv) A statement that—

"(I) identifies the product as an unapproved product or as an approved product, as applicable; and

"(II) in addition, in the case of an approved product, identifies the trial as investigating the approved use of the product or an unapproved use of the product, as applicable.

"(v) The purpose of the trial, including a statement of the interventions and comparisons involved.

"(vi) A statement of the hypothesis being tested in the trial.

"(vii) Information on—

"(I) study design;

"(II) methods;

"(III) study phase; and

"(IV) study type.

''(viii) The definition of the primary and secondary outcomes for the trial.

''(ix) The length of time for which data on the primary and secondary outcomes will be collected on each patient.

''(x) Eligibility criteria for participation in the trial.

''(xi) The total number of subjects anticipated to participate in the trial.

''(xii) The anticipated or actual date on which the trial will begin.

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

''(xiv) The identity of each responsible person for the trial.

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

''(xvi) The identity of the principal investigator in the trial.

''(xvii) Contact information for the principal investigator.

''(xviii) A unique protocol number identification number for the trial, which number shall be assigned by the Secretary.

"(xix) After the initial submission of the registration, periodic updates to reflect changes to information provided under this subparagraph and subparagraph (B), which updates—

"(I) are provided not less frequently than once every six months until the results of the trial are submitted under paragraph (2)(A)(i) or a waiver is provided under paragraph (2)(C); and

"(II) identify the dates on which the changes were made.

"(B) SERIOUS OR LIFE-THREATENING DISEASES; TEST OF EFFECTIVENESS.—In the case of a registration under subsection (a)(1)(A) of a clinical trial to test the effectiveness of the use of a product with respect to a serious or life-threatening disease or condition, the registration is in accordance with this paragraph if, in addition to the information described in subparagraph (A), the registration provides the following information:

"(i) A brief summary of the trial, provided in lay language.

"(ii) A description of the location of trial sites.

"(iii) A point of contact for individuals desiring to enroll as subjects in the trial, including a single point of contact for all trial sites.

"(iv) The status of the trial with respect to the enrollment of subjects, stated for the trial in general and for individual trial sites.

"(v) Information that may be available—

"(I) under a treatment investigational new drug application, or a treatment investigational device exemption, that has been submitted to the Secretary under section 561(c) of the Federal Food, Drug, and Cosmetic Act (relating to expanded access protocols); or

"(II) as a Group C cancer drug (as defined by the National Cancer Institute).

"(2) SUBMISSION OF RESULTS OF TRIAL.—

"(A) IN GENERAL.—For purposes of subsection (a)(1)(B), information on the results of a clinical trial is provided in accordance with this paragraph if, subject to subparagraphs (B) and (C), the following conditions are met:

"(i) The results are submitted—

"(I) not later than 12 months after the earlier of the anticipated date that applies under paragraph (1)(A)(xiii) or the actual date that applies under such paragraph; or

"(II) such later date as may apply under an extension under subparagraph (B).

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

"(iii) The results consist of information determined by the Secretary to be important to clinicians or researchers, in a form that ensures that the information is accurate and not likely to mislead or distort the results of the trial. Such information shall include the following:

''(I) The date on which the trial commenced.

''(II) The actual date for the final collection of data from subjects in the trial.

''(III) Primary and secondary outcomes, presented succinctly as quantitative data and as tests of hypotheses.

''(IV) Basic demographic information on subjects.

''(V) In the group of subjects receiving the product, and in each comparison group of subjects, the percentage of individuals who decided to cease participation as subjects and the reasons for ceasing participation.

''(VI) Information on significant adverse events in subjects that may be associated with the product involved, including such events for which a causal relationship has not been established.

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

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

"(I) is currently reviewing an application for approval of the unapproved use;

"(II) has disapproved such an application;

"(III) has reviewed such an application, but the application was withdrawn prior to approval or disapproval; or

"(IV) has not reviewed or approved such an application.

"(v) After the initial submission of the results, periodic updates are submitted to the data bank to reflect changes in the information submitted under this subparagraph, which updates—

"(I) are provided not less frequently than once every six months during the 10-year period beginning on the date on which the results are due under clause (i); and

''(II) identify the dates on which the changes were made.

''(vi) For each covered article published in a peer-reviewed scientific or academic journal, the responsible person for the trial submits to the data bank a statement that provides a citation to the article. An article published in such a journal is a covered article for purposes of this clause if—

''(I) the article discusses the results of the trial;

''(II) the responsible person or the principal investigator for the clinical trial contributed to the article; and

''(III) MEDLINE includes a citation to the article.

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

''(I) Upon the expiration of such three-year period, the responsible per-

son for the trial submits to the data bank a report that describes the progress being made toward submission of the results.

"(II) For each two-year period that lapses after the submission of the report under subclause (I), the responsible person submits to the data bank an additional report that describes such progress, except that no report is required under this subclause after such due date.

"(B) EXTENSIONS.—

"(i) IN GENERAL.—The Secretary may provide an extension of the due date under subparagraph (A)(i) for the results of a clinical trial if the responsible person for the trial submits to the Secretary a written request that demonstrates good cause for the extension and provides an estimate of the date on which the results will be submitted. More than one such extension may be provided by the Secretary for the clinical trial involved.

"(ii) EXTENSIONS REGARDING JOURNAL PUBLICATION.—

"(I) ARTICLE UNDER CONSIDERATION FOR PUBLICATION.—The Secretary shall under clause (i) provide an extension of 18 months regarding the submission of the results of a clinical trial if—

"(aa) the request under such clause demonstrates that an article providing the information described in subparagraph (A)(iii) has been submitted to a peer-reviewed scientific or academic journal for which references are included in MEDLINE, and the request demonstrates that the article is being considered by the journal for publication; and

"(bb) such request is made before the expiration of the 12-month period described in subparagraph (A)(i).

"(II) ARTICLE ACCEPTED FOR PUBLICATION.—If the responsible per-

son for a clinical trial has received an extension under subclause (I) for the trial, the Secretary shall provide an additional extension of six months, beginning upon the expiration of such first extension, if the person demonstrates to the Secretary, before the expiration of the first extension, that the article involved has been accepted for publication by a journal referred to in such subclause.

"(C) WAIVERS REGARDING RESULTS OF TRIAL.—With respect to the requirement under subsection (a)(1)(B) to submit to the Secretary the results of a clinical trial, the Secretary may waive the requirement upon a written request to the Secretary by the responsible person for the trial if the Secretary determines that extraordinary circumstances justify the waiver and that providing the waiver is in the public interest or consistent with the protection of the public health. The Secretary shall ensure that information on each such waiver is included in the data bank.

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

''(e) PUBLIC DISCLOSURE OF INFORMATION.—

''(1) IN GENERAL.—The Secretary shall disseminate information in the data bank through information systems in accordance with this subsection. Information required in this section to be submitted to the data bank shall not be considered confidential commercial information or trade secrets, notwithstanding any other provision of law.

''(2) PROHIBITION AGAINST FEES.— The Secretary may not impose a fee for providing access to information in the data bank.

''(3) INTERNET SITES.—

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

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

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

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

"(B) RELATION TO CERTAIN INTERNET SITE.—The Secretary shall ensure that the Internet site or portion thereof operated under subparagraph (A)(ii) includes information of the type that was available on ClinicalTrials.gov as of the day before the date of the enactment of the Fair Access to Clinical Trials Act (relating to serious or life-threatening diseases). This section may not be construed as requiring the Secretary to terminate or alter ClinicalTrials.gov, or as prohibiting the Secretary from terminating or altering such site.

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

quired in paragraph (5) to be disclosed, all disclosures shall be made through an Internet site or sites under paragraph (3) and any other means determined appropriate by the Secretary, except that in the case of information of the type referred to in paragraph (3)(B) and intended for patients seeking to enroll as subjects in clinical trials, the means of disclosure shall include toll-free telephone communications.

''(5) REQUIRED DISCLOSURES; AUTHORITY OF SECRETARY FOR EXCLUSIONS.—

''(A) CLINICIANS AND RESEARCHERS.—With respect to means of disclosure under this subsection that are intended for clinicians and researchers, the Secretary shall through such means disclose all information in the data bank, except that the Secretary may exclude information contained in the data bank pursuant to subsection (d)(1)(B) if the Secretary determines that such information is not useful to clinicians and researchers.

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

as subjects in clinical trials, the Secretary shall through such means disclose all information in the data bank, except that the Secretary may exclude any information that the Secretary determines is not useful to such patients. The Secretary may not under the preceding sentence exclude information of the type referred to in paragraph (3)(B).

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

''(A) All such disclosures shall begin promptly after the registration involved is submitted to the Secretary, other than disclosure of the definitions of the primary and secondary outcomes.

''(B) Disclosure of the definition of the primary and secondary outcomes shall begin at the same time as disclosure of the results of the trial begin under paragraph (7)(A).

''(7) RESULTS OF TRIAL; DATE OF DISCLOSURE.—

''(A) IN GENERAL.—In the case of information regarding a clinical trial that is contained in the data bank pursuant to subsection (d)(2), disclosures required in paragraph (5) shall begin promptly after the information is submitted to the Secretary, subject to subparagraph (B).

''(B) WAIVER REGARDING RESULTS OF TRIAL.—In the case of information contained in the data bank on waivers under subsection (d)(2)(C), disclosures required in paragraph (5) shall begin promptly after the waiver is provided.

''(f) DETERMINATION OF VIOLATIONS.—

''(1) COMPLIANCE AUDITS.—

''(A) IN GENERAL.—The Secretary shall conduct periodic audits of responsible persons for clinical trials receiving awards described in subsection (a)(1) in order to determine whether the persons 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 responsible persons for clinical trials who have at any time been included on the list under subsection (g)(1)(A)(i), taking into account the number and severity of the violations involved.

"(2) NOTICE TO RESPONSIBLE PERSONS.—Promptly after determining that a responsible person for a clinical trial is in violation of a requirement under subparagraph (A) or (B) of subsection (a)(1), the Secretary shall notify the person in writing of the violation.

"(g) ACTIONS OF SECRETARY REGARDING VIOLATIONS.—

"(1) IN GENERAL.—If a responsible person for a clinical trial is in violation of an agreement under subparagraph (A) or (B) of subsection (a)(1) (including submitting information under such a subparagraph that is false or misleading), the following applies, subject to paragraph (4) of this subsection:

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

''(i) Through Internet sites under subsection (e)(3) and such other means as the Secretary determines to be appropriate, the Secretary shall announce to the public that the responsible person is in violation of this section. For purposes of the preceding sentence, the Secretary shall maintain a list of responsible persons in violation that is available to the public.

''(ii) The responsible person is, pursuant to subsection (a)(1)(D), subject to a liquidated penalty of not more than a total of $15,000 for all violations adjudicated in a single proceeding in the case of an individual, and $10,000 per day until the violation is corrected in the case of any other person, except that if the person is a nonprofit entity the penalty may not exceed a total of $15,000 for all violations adjudicated in a single proceeding. Paragraphs (3) through (5) of section 303(f) of the Federal Food, Drug, and Cosmetic Act apply to the imposition of such a penalty to the same extent and in the same manner as such paragraphs apply to a penalty

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

''(B) In any case in which the violation is a significant violation and is not corrected within 60 days after the Secretary provides to the responsible person a notice under subsection (f)(2) regarding the violation, the Secretary shall, after notice and an opportunity for a hearing, consider the person to be ineligible for any future awards described in subsection (a)(1) until the violation is corrected, except that notice and an opportunity for a hearing are not required if a hearing regarding such violation was held pursuant to subparagraph (A)(ii).

''(C) In any case in which the violation is a failure to submit to the data bank the results of the trial by the due date under subsection (d)(2)(A)(i), the Secretary shall order the responsible person to submit to the data bank periodic reports on the progress being made toward submission of the results, which reports shall be submitted not less frequently that once every two years until the results are submitted to the data bank.

''(2) RELATION TO RELATED REQUIREMENTS.—If a responsible person for a clinical trial is ineligible for purposes of section 565(f)(1)(B) or 566(a)(2) of the Federal Food, Drug, and Cosmetic Act, the person is ineligible for any award described in subsection (a)(1) during the period of such ineligibility, without regard to whether the person is ineligible under paragraph (1)(B) of this subsection.

''(3) FALSE OR MISLEADING INFORMATION.—If the Secretary determines that the responsible person for a clinical trial has submitted to the data bank information that is false or misleading, and if on such basis a civil money has been imposed under paragraph (1)(A)(ii) on such person or the person has becomes ineligible within the meaning of paragraph (1)(B) or (2), the Secretary shall remove the information from the data bank, subject to any judicial review of such action or actions of the Secretary.

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

protection of the public health. Each such determination of the Secretary shall be published in the Federal Register.

''(5) FUNDING OF COMPARATIVE STUDIES.—Penalties collected by the Secretary under paragraph (1)(A)(ii) shall be used by the Secretary to make awards of grants, contracts, or cooperative agreements for the conduct of comparative clinical trials to determine the safety or relative effectiveness of products.

''(h) CRITERIA.—The Secretary shall establish criteria regarding compliance with this section.

''(i) AWARD FOR CONDUCT OF CLINICAL TRIAL; COMPLIANCE COSTS AS DIRECT COSTS.—In administering an award of a grant, contract, or cooperative agreement that is subject to subsection (a)(1), the Secretary shall consider the costs of complying with requirements under such subsection as part of the direct costs of conducting the clinical trial involved.

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

''(1) The term 'approved product' means a product that is approved, licensed, or cleared for commercial distribution under section 505, 510(k), or 515 of the Federal Food, Drug, and Cosmetic Act or under section 351 of this Act.

''(2) The term 'approved use', with respect to an approved product, means a use that is an approved, licensed, or cleared use of the product under a provision of law referred to in paragraph (1).

''(3) The term 'clinical trial', with respect to a product, means a clinical investigation within the meaning of section 505(i) of the Federal Food, Drug, and Cosmetic Act (in the case of drug), or within the meaning of section 520(g) of such Act (in the case of a device), as applicable, except that such term does not include such an investigation that does not prospectively assign human subjects to intervention or comparison groups to study the causal relationship between a medical intervention and an outcome.

''(4) The term 'data bank' means the data bank under subsection (b).

''(5) The term 'device' has the meaning given such term in section 201(h) of the Federal Food, Drug, and Cosmetic Act.

''(6) The term 'drug' has the meaning given such term in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act. Such term includes a biological product.

"(7) The term 'MEDLINE' means the bibliographic electronic data base of references to journal-published articles that is operated by the National Library of Medicine and is designated by such Library as the Medical Literature, Analysis, and Retrieval System Online.

"(8) The term 'product' has the meaning indicated for such term in subsection (a)(1).

"(9) The term 'researchers' means individuals who conduct research on drugs or devices.

"(10) The term 'responsible person', with respect to a clinical trial to determine the safety or effectiveness of a use of a product, has the following meaning, as applicable:

"(A) In any case in which an application has been submitted for an exemption under section 505(i) or 520(g)(2)(A) with respect to the trial, such term means the entity who, within the meaning of such section, is the sponsor of the trial.

"(B) In any case in which such an application has not been submitted, such term means the entity who is or will be providing the largest share of the monetary support for the trial

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

''(i) If the Federal Government or a State is or will be providing the largest share, such term means the principal investigator for the trial.

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

''(iii) If two or more entities provide equal monetary support for the trial and no other entity provides a greater amount of monetary support, such term means each of the entities providing such equal support, other than the Federal Government or a State.

''(iv) Notwithstanding clauses (i) through (iii), if an entity submits to the Secretary a written request to be the responsible person for purposes of this sec-

tion, such term means that entity in any case in which the Secretary determines that the entity is or will be providing monetary support for the trial and is responsible for conducting the trial.

''(11) The term 'unapproved product' means a product that is not an approved product.

''(12) The term 'unapproved use', with respect to an approved product, means a use that is not an approved use.

''(k) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for fiscal year 2004 and each subsequent fiscal year. Fees collected under section 736 or 738 of the Federal Food, Drug, and Cosmetic Act shall not be used in carrying out this section.''.

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

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

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

(1) Subsection (a) shall be construed as a transfer and modification of the program, and not as the termination of the program and the establishment of a different program.

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

SEC. 3. OTHER CONDITIONS REGARDING DATA BANK ON CLINICAL TRIALS.

(a) INVESTIGATIONAL DRUGS AND DEVICES.—

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

"SEC. 565. INVESTIGATIONAL DRUGS AND DEVICES; CONDITIONS REGARDING DATA BANK ON CLINICAL TRIALS.

''(a) IN GENERAL.—

''(1) CONDITIONS FOR EXEMPTIONS.—Except as provided in paragraph (2), an exemption under section 505(i) or 520(g)(2)(A) for an investigation to determine the safety or effectiveness of the use of a drug or device (referred to in this section as a 'product') may not be considered to be in effect unless—

''(A) the sponsor of the investigation agrees to register the investigation with the Secretary;

''(B) the sponsor of the investigation agrees to provide to the Secretary information on the results of the investigation; and

''(C) the sponsor of the investigation agrees to the disclosure to the public of information regarding the investigation.

''(2) EXCEPTION.—Paragraph (1) does not apply to an investigation to determine the safety of a use of a drug if the trial is designed solely to detect major toxicities in the drug or to investigate pharmacokinetics, except that such paragraph does apply if the trial is designed solely to investigate pharmacokinetics in a special population or populations.

''(b) INSTITUTIONAL REVIEW BOARDS.—For purposes of subsection (a), the Secretary shall amend parts 50, 56, and 812 of title 21, Code of Federal Regulations, to provide that—

''(1) the functions of institutional review boards under such parts include—

''(A) determining whether investigations are registered under subsection (a)(1)(A); and

''(B) denying the approval of the boards for investigations that are not registered under such subsection;

''(2) any approval of an institutional review board regarding an investigation is not effective

under such parts if the investigation is not registered under such subsection; and

''(3) upon request of an institutional review board for such an investigation, the Secretary will provide to the board a copy of the registration for the investigation under such subsection (which copy will be the registration as submitted to the Secretary, together with all updates to the registration).

''(c) CERTAIN EXEMPTIONS.—The reference in subsection (a) to an exemption under section 505(i) includes an exemption described in section 312.2(b) of title 21, Code of Federal Regulations. The reference in such subsection to an exemption under section 520(g)(2)(A) includes an exemption described in section 812.2(b) of such title 21.

''(d) RELATIONSHIP TO SIMILAR REQUIREMENTS.—For purposes of subsection (a):

''(1) The responsibilities of a sponsor of an investigation, and of the Secretary, are the same as apply under section 491A of the Public Health Service Act with respect to responsible persons, except to the extent of taking into account that this section concerns conditions for exemptions referred to in 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.

''(2) NOTICE TO SPONSORS.—Promptly after determining that a sponsor of an investigation is in violation of a requirement under subparagraph (A) or (B) of subsection (a)(1), the Secretary shall notify the sponsor in writing of the violation.

''(f) ACTIONS OF SECRETARY REGARDING VIOLATIONS.—

''(1) IN GENERAL.—If a sponsor of an investigation is in violation of an agreement under subparagraph (A) or (B) of subsection (a)(1) (including submitting information under such a subparagraph that is false or misleading), the following applies, subject to paragraph (2) of this subsection:

''(A) In any case in which the violation is not corrected within 30 days after the Secretary provides to the sponsor a notice under subsection (e)(2) regarding the violation:

''(i) Through Internet sites operated pursuant to subsection (d) and such other means as the Secretary determines to be appropriate, the Secretary shall announce to the public that the sponsor is in violation of this section. For purposes of the preceding sentence, the Secretary shall

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

''(ii) The sponsor is subject to a civil penalty of not more than a total of $15,000 for all violations adjudicated in a single proceeding in the case of an individual, and $10,000 per day until the violation is corrected in the case of any other person, except that if the person is a nonprofit entity the penalty may not exceed a total of $15,000 for all violations adjudicated in a single proceeding. Paragraphs (3) through (5) of section 303(f) apply to the imposition of such a penalty to the same extent and in the same manner as such paragraphs apply to a penalty imposed under paragraph (1) or (2) of such section.

''(B) In any case in which the violation is a significant violation and is not corrected within 60 days after the Secretary provides to the sponsor a notice under subsection (e)(2) regarding the violation, the Secretary may, after notice and an opportunity for a hearing, consider the sponsor to be ineligible for any future ex-

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

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

''(2) FALSE OR MISLEADING INFORMATION.—If the Secretary determines that the sponsor of an investigation has submitted to the data bank information that is false or misleading, and if on such basis a civil money has been imposed under paragraph (1)(A)(ii) on the sponsor or the sponsor has becomes ineligible within the meaning of paragraph (1)(B), the Secretary shall remove the information from the

data bank, subject to any judicial review of such action or actions of the Secretary.

''(3) WAIVER REGARDING INELIGIBILITY FOR EXEMPTIONS.—With respect to a sponsor who is ineligible for purposes of paragraph (1)(B), the Secretary may waive the applicability of such paragraph in order to provide for an investigation if the Secretary determines that providing the waiver is in the public interest or consistent with the protection of the public health. Each such determination of the Secretary shall be published in the Federal Register.

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

''(g) DEFINITIONS.—

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

''(2) INVESTIGATION.—For purposes of this section, the term 'investigation' means a clinical investigation within the meaning of section 505(i) (in the case of drug), or within the meaning of section

520(g) (in the case of a device), as applicable, except that such term does not include such an investigation that does not prospectively assign human subjects to intervention or comparison groups to study the causal relationship between a medical intervention and an outcome.''.

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

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

''(5) The provision of an exemption under paragraph (1) is subject to section 565 (relating to information on investigations).''; and

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

''(8) The provision of an exemption under paragraph (2)(A) is subject to section 565 (relating to information on investigations).''.

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

"SEC. 566. PREMARKET APPLICATION OR REPORT; LABELING AND ADVERTISING; RELATION TO DATA BANK ON CLINICAL TRIALS.

"(a) PREMARKET APPLICATION OR REPORT.—If a person submits to the Secretary an application under section 505(b) or 515 or a report under section 510(k), and one or more of the investigations presented to the Secretary by the person for purposes of the application or report are investigations that are not subject to requirements under section 565 or under section 491A of the Public Health Service, and if the person was the principal investigator or the responsible person for the investigation involved, the following applies:

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

"(A) in any case in which information on the investigation has not, as of the date on which the application or report is submitted to the Secretary, been submitted to the data bank described in such section 491A to the same extent as would have been required as of such date if the investigation had been subject to such requirements (without regard to timeframes for the submission of information that would have applied before such date under such section); and

"(B) in any case in which, after such date, information on the investigation is not submitted to the data bank to the same extent as would be required if the investigation were subject to such requirements.

"(2) If the person is subject to a civil penalty under paragraph (1), the Secretary, in addition to such penalty, may, after notice and an opportunity for a hearing, consider the person to be ineligible for any future exemptions under section 505(i) or 520(g)(2)(A) for any investigation until the information involved is submitted to the data bank as described in paragraph (1), except that notice and an opportunity for a hearing are not required if a hearing regarding such violation was held pursuant to paragraph (1).

"(b) LABELING AND ADVERTISEMENTS.—If a person disseminates labeling, or an advertisement or other descriptive printed matter, for a drug or device for human use and the labeling, advertisement, or other matter refers to an investigation that is not subject to requirements under section 565 or under section 491A of the Public Health Service, and if the person was the principal investigator or the responsible person for the investigation, the person is subject to a civil penalty—

''(1) in any case in which information on the investigation has not, as of the date on which the labeling, advertisement, or other matter enters the market, been submitted to the data bank described in such section 491A to the same extent as would have been required as of such date if the investigation had been subject to such requirements (without regard to timeframes for the submission of information that would have applied before such date under such section); and

''(2) in any case in which, after such date, information on the investigation is not submitted to the data bank to the same extent as would be required if the investigation were subject to such requirements.

''(c) AMOUNT OF CIVIL PENALTY; PROCEDURE.—A civil penalty under subsection (a)(1) or (b) shall be not more than a total of $15,000 for all violations adjudicated in a single proceeding in the case of an individual, and $10,000 per day until the violation is corrected in the case of any other person, except that if the person is a nonprofit entity the penalty may not exceed a total of $15,000 for all violations adjudicated in a single proceeding. Paragraphs (3) through (5) of section 303(f) apply to the imposition of such a penalty to the same extent and in the

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

''(d) BIOLOGICS LICENSE APPLICATION.—Subsections (a) and (c) apply with respect to a biologics license application under section 351 of the Public Health Service Act to the same extent and in the same manner as such subsections apply with respect to an application or report referred to in subsection (a).

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

''(1) The term 'investigation' has the meaning given such term in section 565(g).

''(2) The term 'responsible person' has the meaning given such term in section 491A(j) of the Public Health Service Act. ''.

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

the date of the enactment of this Act, except that registration information required pursuant to subsection (d) of such section 565 is due upon the expiration of such 30 days. For purposes of the preceding sentence, the term ''clinical investigation'' has the meaning given such term in subsection (g)(2) of such section 565.

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

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

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