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**Provision of bill attached

REMARKS OF SENATOR EDWARD M. KENNEDY ON AVANDIA SAFETY CONCERNS

(As prepared for delivery)

Too often, it takes a crisis to move Congress to act on an urgent national need. We have already had crisis after crisis on drug safety, and yesterday we learned of another. A report published in the New England Journal of Medicine shows that the diabetes drug Avandia may increase the risk of heart attacks and death. If further evidence were needed that improving drug safety is an urgent national priority, this latest report puts the issue beyond any doubt.

Two weeks ago, by an overwhelming vote of 93 to 1, the Senate approved strong and comprehensive legislation to enable the Food and Drug Administration to do what needs to be done to improve drug safety, and we're working now with our colleagues in the House to see that this legislation is signed into law as soon as possible.

Yesterday's report was based on an analysis of 42 clinical trials. The report concluded that use of Avandia could raise the risk of heart disease. I commend the authors for their skill and persistence – but we must ask this basic question -- why did the American public have to wait more than 8 years and depend on a group of independent scientists to conduct this study, before we learn of a major safety concern with this drug? Why wasn't the FDA doing this kind of analysis? Why aren't companies required to undertake additional safety tests if there are unanswered questions about their products?

The answer is that the FDA does not have the resources and the information technology to conduct these analyses itself, and it doesn't have the authority needed to require companies to perform them. The legislation the Senate recently approved corrects both of these major flaws.

The FDA Revitalization Act passed by the Senate establishes a strong new system of active surveillance for drug safety problems after a drug is on the market. Today, the FDA has ample authority to require pre-market studies to ensure that drugs going on the market are safe and effective. But the FDA has no such authority to require adequate oversight of drug use after marketing begins.

Instead, FDA relies on a sporadic and ineffective system of passive reporting of adverse events. Our legislation changes that by requiring the FDA to link electronic health care databases to answer questions about the safety of drugs on the market.

Tens of millions of patients will be included in this oversight. It will mean better and faster identification and assessment of drug risks. We need to make certain that any unforeseen risks associated with any drug are detected as quickly as possible, so that effective protections can be implemented before lives are needlessly put at risk. Our legislation provides the resources needed to make this happen by adding to the fees that drug companies are required to pay, and by devoting the additional funds to drug safety.

Some critics of the FDA have called for an end to user fees. They seem to think that, without the user fees, millions of dollars in additional resources will magically appear to aid the FDA in its work. Sadly, wishing won't make it so. No magic will replace the resources that would be lost if the user fees are allowed to lapse. The right choice for drug safety is to do what our bill does – renew the user fees and make sure they are used for drug safety, not just drug reviews.

Our legislation gives FDA the authority to require a drug company to conduct any post-approval study necessary to answer a question that the FDA's own surveillance system won't answer. This power is essential. The New England Journal authors noted the limitations of their own analysis and suggested that a large prospective trial might be the best way to get the answers we need about Avandia.

Some of the clinical trials used in the New England Journal report were found in a registry of clinical trial results that Glaxo voluntarily maintains. That's better than some companies have done, but a set of scattered registries are often of little use to patients and health care professionals. The Senate bill requires the results of clinical trials to be made available to the public in a single easily accessible database. That will help patients get information about the medicines they take – and it will help scientists identify drug safety problems faster.

Information alone is not enough to protect the public health. The FDA also needs the authority to take action where needed. The bill does more than merely give the FDA the tools it needs to identify and assess the risks of drugs. When new information requires new labeling information or a medication guide, the FDA is given the authority to order it.

Right now, all FDA can do after approval is request a labeling change or request a medication guide or request patient labeling or request a review of drug advertising. Safeguarding the lives of American patients shouldn't have to depend on requests. The bill gives FDA the authority to require those measures, and impose civil money penalties to enforce them.

Our legislation also gives the FDA broad discretion to require safety information to be included in advertising for any drug. It ensures that this information will be presented in a clear, conspicuous and neutral manner. No longer will advertisers be able to gloss over basic safety information by distracting viewers with pretty scenes in the background. Safety information will have to be presented in the manner appropriate to what it is – potentially life-saving information.

We don't know yet the right action to take on Avandia. Perhaps the drug should be withdrawn. Perhaps the best course is a strong warning for doctors and patients, with significant new safety information required in advertising. But whatever the right actions are, the FDA will have the authority to require them, once the legislation is enacted.

Our legislation will help make the FDA once again the gold standard for protecting the public health. It should not take a new crisis to persuade Congress to act. I look forward to working with our colleagues in the House to see that this needed legislation is signed into law without delay.

**The Kennedy-Enzi bill would help to ensure that a similar situation does not occur. The provision that is directly related is below:

Subtitle C--Clinical Trials

SEC. 231. EXPANDED CLINICAL TRIAL REGISTRY DATA BANK.

(a) In General- Section 402 of the Public Health Service Act (42 U.S.C. 282) is amended by--
(1) redesignating subsections (j) and (k) as subsections (k) and (l), respectively; and

(2) inserting after subsection (i) the following:

^ (j) Expanded Clinical Trial Registry Data Bank-

^ (1) DEFINITIONS; REQUIREMENT-

^ (A) DEFINITIONS- In this subsection:

` (i) APPLICABLE DEVICE CLINICAL TRIAL- The term `applicable device clinical trial' means—

` (I) a prospective study of health outcomes comparing an intervention against a control in human subjects intended to support an application under section 515 or 520(m), or a report under section 510(k), of the Federal Food, Drug, and Cosmetic Act (other than a limited study to gather essential information used to refine the device or design a pivotal trial and that is not intended to determine safety and effectiveness of a device); and

` (II) a pediatric postmarket surveillance as required under section 522 of the Federal Food, Drug, and Cosmetic Act.

` (ii) APPLICABLE DRUG CLINICAL TRIAL-

` (I) IN GENERAL- The term `applicable drug clinical trial' means a controlled clinical investigation, other than a phase I clinical investigation, of a product subject to section 505 of the Federal Food, Drug, and Cosmetic Act or to section 351 of this Act.

` (II) CLINICAL INVESTIGATION- For purposes of subclause (I), the term `clinical investigation' has the meaning given that term in section 312.3 of title 21, Code of Federal Regulations.

` (III) PHASE I- The term `phase I' has the meaning given that term in section 312.21 of title 21, Code of Federal Regulations.

` (iii) CLINICAL TRIAL INFORMATION- The term `clinical trial information' means those data elements that are necessary to complete an entry in the clinical trial registry data bank under paragraph (2).

` (iv) COMPLETION DATE- The term `completion date' means, with respect to an applicable drug clinical trial or an applicable device clinical trial, the date on which the last patient enrolled in the clinical trial has completed his or her last medical visit of the clinical trial, whether the clinical trial concluded according to the prespecified protocol plan or was terminated.

` (v) DEVICE- The term `device' means a device as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act.

` (vi) DRUG- The term `drug' means a drug as defined in section 201(g) of the Federal Food, Drug, and Cosmetic Act or a biological product as defined in section 351 of this Act.

` (vii) RESPONSIBLE PARTY- The term `responsible party', with respect to a clinical trial of a drug or device, means—

` (I) the sponsor of the clinical trial (as defined in section 50.3 of title 21, Code of Federal Regulations (or any successor regulations)) or the principal investigator of such clinical trial if so designated by such sponsor; or

` (II) if no sponsor exists, the grantee, contractor, or awardee for a trial funded by a Federal agency or the principal investigator of such clinical trial if so designated by such grantee, contractor, or awardee.

` (B) REQUIREMENT- The Secretary shall develop a mechanism by which—

` (i) the responsible party for each applicable drug clinical trial and applicable device clinical trial shall submit the identity and contact information of such responsible party to the Secretary at the time of submission of clinical trial information under paragraph

(2); and

^ (ii) other Federal agencies may identify the responsible party for an applicable drug clinical trial or applicable device clinical trial.

^ (2) EXPANSION OF CLINICAL TRIAL REGISTRY DATA BANK WITH RESPECT TO CLINICAL TRIAL INFORMATION-

^ (A) IN GENERAL-

^ (i) EXPANSION OF DATA BANK- To enhance patient enrollment and provide a mechanism to track subsequent progress of clinical trials, the Secretary, acting through the Director of NIH, shall expand, in accordance with this subsection, the clinical trials registry of the data bank described under subsection (i)(3)(A) (referred to in this subsection as the 'registry data bank'). The Director of NIH shall ensure that the registry data bank is made publicly available through the Internet.

^ (ii) CONTENT- Not later than 18 months after the date of enactment of the Enhancing Drug Safety and Innovation Act of 2007, and after notice and comment, the Secretary shall promulgate regulations to expand the registry data bank to require the submission to the registry data bank of clinical trial information for applicable drug clinical trials and applicable device clinical trials that—

^ (I) conforms to the International Clinical Trials Registry Platform trial registration data set of the World Health Organization;

^ (II) includes the city, State, and zip code for each clinical trial location, or a toll-free number through which such location information may be accessed;

^ (III) if the drug is not approved under section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of this Act, specifies whether or not there is expanded access to the drug under section 561 of the Federal Food, Drug, and Cosmetic Act for those who do not qualify for enrollment in the clinical trial and how to obtain information about such access;

^ (IV) requires the inclusion of such other data elements to the registry data bank as appropriate; and

^ (V) becomes effective 90 days after issuance of the final rule.

^ (B) FORMAT AND STRUCTURE-

^ (i) SEARCHABLE CATEGORIES- The Director of NIH shall ensure that the public may search the entries in the registry data bank by 1 or more of the following criteria:

^ (I) The disease or condition being studied in the clinical trial, using Medical Subject Headers (MeSH) descriptors.

^ (II) The treatment being studied in the clinical trial.

^ (III) The location of the clinical trial.

^ (IV) The age group studied in the clinical trial, including pediatric subpopulations.

^ (V) The study phase of the clinical trial.

^ (VI) The source of support for the clinical trial, which may be the National Institutes of Health or other Federal agency, a private industry source, or a university or other organization.

^ (VII) The recruitment status of the clinical trial.

^ (VIII) The National Clinical Trial number or other study identification for the clinical trial.

ˆ (ii) FORMAT- The Director of the NIH shall ensure that the registry data bank is easily used by the public, and that entries are easily compared.

ˆ (C) DATA SUBMISSION- The responsible party for an applicable drug clinical trial shall submit to the Director of NIH for inclusion in the registry data bank the clinical trial information described in subparagraph (A)(ii).

ˆ (D) TRUTHFUL CLINICAL TRIAL INFORMATION-

ˆ (i) IN GENERAL- The clinical trial information submitted by a responsible party under this paragraph shall not be false or misleading in any particular.

ˆ (ii) EFFECT- Clause (i) shall not have the effect of requiring clinical trial information with respect to an applicable drug clinical trial or an applicable device clinical trial to include information from any source other than such clinical trial involved.

ˆ (E) CHANGES IN CLINICAL TRIAL STATUS-

ˆ (i) ENROLLMENT- The responsible party for an applicable drug clinical trial or an applicable device clinical trial shall update the enrollment status not later than 30 days after the enrollment status of such clinical trial changes.

ˆ (ii) COMPLETION- The responsible party for an applicable drug clinical trial or applicable device clinical trial shall report to the Director of NIH that such clinical trial is complete not later than 30 days after the completion date of the clinical trial.

ˆ (F) TIMING OF SUBMISSION- The clinical trial information for an applicable drug clinical trial or an applicable device clinical trial required to be submitted under this paragraph shall be submitted not later than 21 days after the first patient is enrolled in such clinical trial.

ˆ (G) POSTING OF DATA-

ˆ (i) APPLICABLE DRUG CLINICAL TRIAL- The Director of NIH shall ensure that clinical trial information for an applicable drug clinical trial submitted in accordance with this paragraph is posted publicly within 30 days of such submission.

ˆ (ii) APPLICABLE DEVICE CLINICAL TRIAL- The Director of NIH shall ensure that clinical trial information for an applicable device clinical trial submitted in accordance with this paragraph is posted publicly within 30 days of clearance under section 510(k) of the Federal Food, Drug, and Cosmetic Act, or approval under section 515 or section 520(m) of such Act, as applicable.

ˆ (H) VOLUNTARY SUBMISSIONS- A responsible party for a clinical trial that is not an applicable drug clinical trial or an applicable device clinical trial may submit clinical trial information to the registry data bank in accordance with this subsection.

ˆ (3) EXPANSION OF REGISTRY DATA BANK TO INCLUDE RESULTS OF CLINICAL TRIALS-

ˆ (A) LINKING REGISTRY DATA BANK TO EXISTING RESULTS-

ˆ (i) IN GENERAL- Beginning not later than 90 days after the date of enactment of the Enhancing Drug Safety and Innovation Act of 2007, for those clinical trials that form the primary basis of an efficacy claim or are conducted after the drug involved is approved or after the device involved is cleared or approved, the Secretary shall ensure that the registry data bank includes links to results information for such clinical trial—

ˆ (I) not earlier than 30 days after the date of the approval of the drug involved or clearance or approval of the device involved; or

` (II) not later than 30 days after such information becomes publicly available, as applicable.

` (ii) REQUIRED INFORMATION-

` (I) FDA INFORMATION- The Secretary shall ensure that the registry data bank includes links to the following information:

` (aa) If an advisory committee considered at a meeting an applicable drug clinical trial or an applicable device clinical trial, any posted Food and Drug Administration summary document regarding such applicable drug clinical trial or applicable clinical device trial.

` (bb) If an applicable drug clinical trial was conducted under section 505A or 505B of the Federal Food, Drug, and Cosmetic Act, a link to the posted Food and Drug Administration assessment of the results of such trial.

` (cc) Food and Drug Administration public health advisories regarding the drug or device that is the subject of the applicable drug clinical trial or applicable device clinical trial, respectively, if any.

` (dd) For an applicable drug clinical trial, the Food and Drug Administration action package for approval document required under section 505(l)(2) of the Food Drug and Cosmetic Act.

` (ee) For an applicable device clinical trial, in the case of a premarket application, the detailed summary of information respecting the safety and effectiveness of the device required under section 520(h)(1) of the Federal Food, Drug, and Cosmetic Act, or, in the case of a report under section 510(k) of such Act, the section 510(k) summary of the safety and effectiveness data required under section 807.95(d) of title 21, Code of Federal Regulations (or any successor regulations).

` (II) NIH INFORMATION- The Secretary shall ensure that the registry data bank includes links to the following information:

` (aa) Medline citations to any publications regarding each applicable drug clinical trial and applicable device clinical trial.

` (bb) The entry for the drug that is the subject of an applicable drug clinical trial in the National Library of Medicine database of structured product labels, if available.

` (iii) RESULTS FOR EXISTING DATA BANK ENTRIES- The Secretary may include the links described in clause (ii) for data bank entries for clinical trials submitted to the data bank prior to enactment of the Enhancing Drug Safety and Innovation Act of 2007, as available.

` (B) FEASIBILITY STUDY- The Director of NIH shall--

` (i) conduct a study to determine the best, validated methods of making the results of clinical trials publicly available after the approval of the drug that is the subject of an applicable drug clinical trial; and

` (ii) not later than 18 months after initiating such study, submit to the Secretary any findings and recommendations of such study.

` (C) NEGOTIATED RULEMAKING-

` (i) IN GENERAL- The Secretary shall establish a negotiated rulemaking process pursuant to subchapter IV of chapter 5 of title 5, United States Code, to determine, for applicable drug clinical trials—

` (I) how to ensure quality and validate methods of expanding the registry data bank to include clinical trial results information for trials not within the scope of this Act;

- ˘ (II) the clinical trials of which the results information is appropriate for adding to the expanded registry data bank; and
- ˘ (III) the appropriate timing of the posting of such results information.
- ˘ (ii) TIME REQUIREMENT- The process described in paragraph (1) shall be conducted in a timely manner to ensure that—
 - ˘ (I) any recommendation for a proposed rule—
 - ˘ (aa) is provided to the Secretary not later than 21 months after the date of the enactment of the Enhancing Drug Safety and Innovation Act of 2007; and
 - ˘ (bb) includes an assessment of the benefits and costs of the recommendation; and
 - ˘ (II) a final rule is promulgated not later than 30 months after the date of the enactment of the Enhancing Drug Safety and Innovation Act of 2007, taking into account the recommendations under subclause (I) and the results of the feasibility study conducted under subparagraph (B).
 - ˘ (iii) REPRESENTATION ON NEGOTIATED RULEMAKING COMMITTEE- The negotiated rulemaking committee established by the Secretary pursuant to clause (i) shall include members representing—
 - ˘ (I) the Food and Drug Administration;
 - ˘ (II) the National Institutes of Health;
 - ˘ (III) other Federal agencies as the Secretary determines appropriate;
 - ˘ (IV) patient advocacy and health care provider groups;
 - ˘ (V) the pharmaceutical industry;
 - ˘ (VI) contract clinical research organizations;
 - ˘ (VII) the International Committee of Medical Journal Editors; and
 - ˘ (VIII) other interested parties, including experts in privacy protection, pediatrics, health information technology, health literacy, communication, clinical trial design and implementation, and health care ethics.
 - ˘ (iv) CONTENT OF REGULATIONS- The regulations promulgated pursuant to clause (i) shall establish--
 - ˘ (I) procedures to determine which clinical trials results information data elements shall be included in the registry data bank, taking into account the needs of different populations of users of the registry data bank;
 - ˘ (II) a standard format for the submission of clinical trials results to the registry data bank;
 - ˘ (III) a standard procedure for the submission of clinical trial results information, including the timing of submission and the timing of posting of results information, to the registry data bank, taking into account the possible impacts on publication of manuscripts based on the clinical trial;
 - ˘ (IV) a standard procedure for the verification of clinical trial results information, including ensuring that free text data elements are non-promotional; and

^ (V) an implementation plan for the prompt inclusion of clinical trials results information in the registry data bank.

^ (D) CONSIDERATION OF WORLD HEALTH ORGANIZATION DATA SET- The Secretary shall consider the status of the consensus data elements set for reporting clinical trial results of the World Health Organization when promulgating the regulations under subparagraph (C).

^ (E) TRUTHFUL CLINICAL TRIAL INFORMATION-

^ (i) IN GENERAL- The clinical trial information submitted by a responsible party under this paragraph shall not be false or misleading in any particular.

^ (ii) EFFECT- Clause (i) shall not have the effect of requiring clinical trial information with respect to an applicable drug clinical trial or an applicable device clinical trial to include information from any source other than such clinical trial involved.

^ (F) WAIVERS REGARDING CERTAIN CLINICAL TRIAL RESULTS- The Secretary may waive any applicable requirements of this paragraph for an applicable drug clinical trial or an applicable device clinical trial, upon a written request from the responsible person, if the Secretary determines that extraordinary circumstances justify the waiver and that providing the waiver is in the public interest, consistent with the protection of public health, or in the interest of national security. Not later than 30 days after any part of a waiver is granted, the Secretary shall notify, in writing, the appropriate committees of Congress of the waiver and provide an explanation for why the waiver was granted.

^ (4) COORDINATION AND COMPLIANCE-

^ (A) CLINICAL TRIALS SUPPORTED BY GRANTS FROM FEDERAL AGENCIES-

^ (i) IN GENERAL- No Federal agency may release funds under a research grant to an awardee who has not complied with paragraph (2) for any applicable drug clinical trial or applicable device clinical trial for which such person is the responsible party.

^ (ii) GRANTS FROM CERTAIN FEDERAL AGENCIES- If an applicable drug clinical trial or applicable device clinical trial is funded in whole or in part by a grant from the Food and Drug Administration, National Institutes of Health, the Agency for Healthcare Research and Quality, or the Department of Veterans Affairs, any grant or progress report forms required under such grant shall include a certification that the responsible party has made all required submissions to the Director of NIH under paragraph (2).

^ (iii) VERIFICATION BY FEDERAL AGENCIES- The heads of the agencies referred to in clause (ii), as applicable, shall verify that the clinical trial information for each applicable drug clinical trial or applicable device clinical trial for which a grantee is the responsible party has been submitted under paragraph (2) before releasing any remaining funding for a grant or funding for a future grant to such grantee.

^ (iv) NOTICE AND OPPORTUNITY TO REMEDY- If the head of an agency referred to in clause (ii), as applicable, verifies that a grantee has not submitted clinical trial information as described in clause (iii), such agency head shall provide notice to such grantee of such non-compliance and allow such grantee 30 days to correct such non-compliance and submit the required clinical trial information.

^ (v) CONSULTATION WITH OTHER FEDERAL AGENCIES- The Secretary shall--

^ (I) consult with other agencies that conduct research involving human subjects in accordance with any section of part 46 of title 45, Code of Federal Regulations (or any successor regulations), to determine if any such research is an applicable drug clinical trial or an applicable device clinical trial under paragraph (1); and

^ (II) develop with such agencies procedures comparable to those described in clauses (ii), (iii), and (iv) to ensure that clinical trial information for such applicable drug clinical trials and

applicable device clinical trial is submitted under paragraph (2).

“(B) CERTIFICATION TO ACCOMPANY DRUG, BIOLOGICAL PRODUCT, AND DEVICE

SUBMISSIONS- At the time of submission of an application under section 505 of the Federal Food, Drug, and Cosmetic Act, section 515 of such Act, section 520(m) of such Act, or section 351 of this Act, or submission of a report under section 510(k) of such Act, such application or submission shall be accompanied by a certification that all applicable requirements of this subsection have been met. Where available, such certification shall include the appropriate National Clinical Trial control numbers.

“(C) VERIFICATION OF SUBMISSION PRIOR TO POSTING- In the case of clinical trial information that is submitted under paragraph (2), but is not made publicly available pending regulatory approval or clearance, as applicable, the Director of NIH shall respond to inquiries from other Federal agencies and peer-reviewed scientific journals to confirm that such clinical trial information has been submitted but has not yet been posted.

“(5) LIMITATION ON DISCLOSURE OF CLINICAL TRIAL INFORMATION-

“(A) IN GENERAL- Nothing in this subsection (or under section 552 of title 5, United States Code) shall require the Secretary to publicly disclose, from any record or source other than the registry data bank expanded under this subsection, information described in subparagraph (B).

“(B) INFORMATION DESCRIBED- Information described in this subparagraph is--

“(i) information submitted to the Director of NIH under this subsection, or information of the same general nature as (or integrally associated with) the information so submitted; and

“(ii) not otherwise publicly available, including because it is protected from disclosure under section 552 of title 5, United States Code.

“(6) AUTHORIZATION OF APPROPRIATIONS- There are authorized to be appropriated to carry out this subsection \$10,000,000 for each fiscal year.’.

(b) Conforming Amendments-

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

(2)

“(jj)(1) The failure to submit the certification required by section 402(j)(4)(B) of the Public Health Service Act, or knowingly submitting a false certification under such section.

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

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

(A) redesignating paragraphs (4), (5), and (6) as paragraphs (5), (6), and (7), respectively;

(B) inserting after paragraph (3) the following:

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

(C) in paragraph (2)(C), by striking ‘paragraph (4)(A)’ and inserting ‘paragraph (5)(A)’;

(D) in paragraph (5), as so redesignated, by striking ‘paragraph (1), (2), or (3)’ each place it appears and inserting ‘paragraph (1), (2), (3), or (4)’; and

(E) in paragraph (7), as so redesignated, by striking ‘paragraph (5)’ each place it appears

and inserting ` paragraph (6)'.

(3) NEW DRUGS AND DEVICES-

(A) INVESTIGATIONAL NEW DRUGS- Section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) is amended in paragraph (4), by adding at the end the following: ` The Secretary shall update such regulations to require inclusion in the informed consent form a statement that clinical trial information for such clinical investigation has been or will be submitted for inclusion in the registry data bank pursuant to subsections (i) and (j) of section 402 of the Public Health Service Act.'.

(B) NEW DRUG APPLICATIONS- Section 505(b) of the Federal, Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) is amended by adding at the end the following:

` (6) An application submitted under this subsection shall be accompanied by the certification required under section 402(j)(4)(B) of the Public Health Service Act. Such certification shall not be considered an element of such application.'.

(C) DEVICE REPORTS UNDER SECTION 510(k)- Section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)) is amended by adding at the end the following:

` A notification submitted under this subsection that contains clinical trial data for an applicable device clinical trial (as defined in section 402(j)(1) of the Public Health Service Act) shall be accompanied by the certification required under section 402(j)(4)(B) of such Act. Such certification shall not be considered an element of such notification.'.

(D) DEVICE PREMARKET APPROVAL APPLICATION- Section 515(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(c)) is amended—

(i) in subparagraph (F), by striking ` ; and' and inserting a semicolon;

(ii) by redesignating subparagraph (G) as subparagraph (H); and

(iii) by inserting after subparagraph (F) the following:

` (G) the certification required under section 402(j)(4)(B) of the Public Health Service Act (which shall not be considered an element of such application); and'.

(E) HUMANITARIAN DEVICE EXEMPTION- Section 520(m)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(c)) is amended in the first sentence in the matter following subparagraph (C), by inserting at the end before the period ` and such application shall include the certification required under section 402(j)(4)(B) of the Public Health Service Act (which shall not be considered an element of such application)'.

(c) Preemption-

(1) IN GENERAL- No State or political subdivision of a State may establish or continue in effect any requirement for the registration of clinical trials or for the inclusion of information relating to the results of clinical trials in a database.

(2) RULE OF CONSTRUCTION- The fact of submission of clinical trial information, if submitted in compliance with subsection (i) and (j) of section 402 of the Public Health Service Act (as amended by this section), that relates to a use of a drug or device not included in the official labeling of the approved drug or device shall not be construed by the Secretary or in any administrative or judicial proceeding, as evidence of a new intended use of the drug or device that is different from the intended use of the drug or device set forth in the official labeling of the drug or device. The availability of clinical trial information through the data bank under such subsections (i) and (j), if submitted in compliance with such subsections, shall not be considered as labeling, adulteration, or misbranding of the drug or device under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

(d) Transition Rule; Effective Date of Funding Restrictions-

(1) TRANSITION RULE FOR CLINICAL TRIALS INITIATED PRIOR TO EXPANSION OF REGISTRY DATA BANK- The responsible party (as defined in paragraph (1) of section 402(j) of the Public Health Service Act (as added by this section)) for an applicable drug clinical trial or applicable device clinical trial (as defined under such paragraph (1)) that is initiated after the date of enactment of this subtitle and before the effective date of the regulations promulgated under paragraph (2) of such section 402(j), shall submit required clinical trial information under such section not later than 120 days after such effective date.

(2) FUNDING RESTRICTIONS- Subparagraph (A) of paragraph (4) of such section 402(j) shall take effect 210 days after the effective date of the regulations promulgated under paragraph (2) of such section 402(j).

(e) Effective Date-

(1) IN GENERAL- Beginning 90 days after the date of enactment of this title, the responsible party for an applicable drug clinical trial or an applicable device clinical trial (as that term is defined in such section 402(j)) that is initiated after the date of enactment of this title and before the effective date of the regulations issued under subparagraph (A) of paragraph (2) of such subsection, shall submit clinical trial information under such paragraph (2).

(2) RULEMAKING-

(A) IN GENERAL- Except as provided in subparagraph (B), subsection (c)(1) shall become effective on the date on which the regulation promulgated pursuant to section 402(j)(3)(C)(i) of the Public Health Service Act, as added by this section, becomes effective.

(B) EXCEPTION- Subsection (c)(1) shall apply with respect to any clinical trial for which the registry data bank includes links to results information, as provided for under section 402(j)(3)(A) of such Act, as added by this section.