

110TH CONGRESS
1ST SESSION

H. R. 1561

To amend the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act to improve drug safety and oversight, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MARCH 19, 2007

Mr. WAXMAN (for himself and Mr. MARKEY) 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 to improve drug safety and oversight, 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 “Enhancing Drug Safe-
5 ty and Innovation Act of 2007”.

6 **SEC. 2. TABLE OF CONTENTS.**

7 The table of contents for this Act is as follows:

Sec. 1. Short title.

Sec. 2. Table of contents.

TITLE I—RISK EVALUATION AND MITIGATION STRATEGIES

- Sec. 101. Risk evaluation and mitigation strategies.
- Sec. 102. Enforcement.
- Sec. 103. Regulation of biological products.
- Sec. 104. No effect on withdrawal or suspension of approval.
- Sec. 105. Drugs subject to an abbreviated new drug application.
- Sec. 106. Conforming amendments.
- Sec. 107. Resources.
- Sec. 108. Drug labeling.
- Sec. 109. Factory inspections.
- Sec. 110. Study on integration of expertise of Office of Surveillance and Epidemiology.
- Sec. 111. Benefit-risk assessments.
- Sec. 112. Effective date and applicability.
- Sec. 113. Rule of construction regarding pediatric studies.
- Sec. 114. Authorization of appropriations.

TITLE II—REAGAN-UDALL INSTITUTE FOR APPLIED BIOMEDICAL RESEARCH

- Sec. 201. The Reagan-Udall Institute for Applied Biomedical Research.

TITLE III—CLINICAL TRIALS

- Sec. 301. Clinical trial registry database and clinical trial results database.

TITLE IV—CONFLICTS OF INTEREST

- Sec. 401. Conflicts of interest.

1 **TITLE I—RISK EVALUATION AND**
 2 **MITIGATION STRATEGIES**

3 **SEC. 101. RISK EVALUATION AND MITIGATION STRATEGIES.**

4 Section 505 of the Federal Food, Drug, and Cosmetic
 5 Act (21 U.S.C. 355) is amended by adding at the end the
 6 following:

7 “(o) RISK EVALUATION AND MITIGATION STRAT-
 8 EGY.—

9 “(1) IN GENERAL.—In the case of any drug
 10 subject to subsection (b) or to section 351 of the
 11 Public Health Service Act for which a risk evalua-
 12 tion and mitigation strategy is approved as provided

1 for in this subsection, the applicant shall comply
2 with the requirements of such strategy.

3 “(2) DEFINITIONS.—In this subsection:

4 “(A) ADVERSE DRUG EXPERIENCE.—The
5 term ‘adverse drug experience’ means any ad-
6 verse event associated with the use of a drug in
7 humans, whether or not considered drug re-
8 lated, including—

9 “(i) an adverse event occurring in the
10 course of the use of the drug in profes-
11 sional practice;

12 “(ii) an adverse event occurring from
13 an overdose of the drug, whether acci-
14 dental or intentional;

15 “(iii) an adverse event occurring from
16 abuse of the drug;

17 “(iv) an adverse event occurring from
18 withdrawal of the drug; and

19 “(v) any failure of expected pharma-
20 cological action of the drug.

21 “(B) SERIOUS ADVERSE DRUG EXPERI-
22 ENCE.—The term ‘serious adverse drug experi-
23 ence’ is an adverse event that—

24 “(i) results in—

25 “(I) death;

1 “(II) an adverse drug experience
2 that places the patient at immediate
3 risk of death from the adverse drug
4 experience as it occurred (not includ-
5 ing an adverse drug experience that
6 might have caused death had it oc-
7 curred in a more severe form);

8 “(III) inpatient hospitalization or
9 prolongation of existing hospitaliza-
10 tion;

11 “(IV) a persistent or significant
12 incapacity or substantial disruption of
13 the ability to conduct normal life
14 functions; or

15 “(V) a congenital anomaly or
16 birth defect; or

17 “(ii) based on appropriate medical
18 judgment, may jeopardize the patient and
19 may require a medical or surgical interven-
20 tion to prevent an outcome described under
21 clause (i).

22 “(C) SERIOUS RISK.—The term ‘serious
23 risk’ means a risk of a serious adverse drug ex-
24 perience.

1 “(D) UNEXPECTED SERIOUS RISK.—The
2 term ‘unexpected serious risk’ means a serious
3 adverse drug experience that is not listed in the
4 labeling of a drug, or that may be sympto-
5 matically and pathophysiologically related to an
6 adverse drug experience identified in the label-
7 ing, but differs from such adverse drug experi-
8 ence because of greater severity, specificity, or
9 prevalence.

10 “(E) SIGNAL OF A SERIOUS RISK.—The
11 term ‘signal of a serious risk’ means informa-
12 tion related to a serious adverse drug experi-
13 ence associated with use of a drug and derived
14 from—

15 “(i) a clinical trial;

16 “(ii) adverse event reports;

17 “(iii) a post-approval study, including
18 a study under paragraph (4)(D); or

19 “(iv) peer-reviewed biomedical lit-
20 erature.

21 “(F) NEW SAFETY INFORMATION.—The
22 term ‘new safety information’ with respect to a
23 drug means information about—

24 “(i) a serious risk or an unexpected
25 serious risk associated with use of the drug

1 that the Secretary has become aware of
2 since the last assessment of the approved
3 risk evaluation and mitigation strategy for
4 the drug; or

5 “(ii) the effectiveness of the approved
6 risk evaluation and mitigation strategy for
7 the drug obtained since the last assessment
8 of such strategy.

9 “(3) REQUIRED ELEMENTS OF A RISK EVALUA-
10 TION AND MITIGATION STRATEGY.—The risk evalua-
11 tion and mitigation strategy for a drug shall re-
12 quire—

13 “(A)(i) labeling for the drug for use by
14 health care providers as approved under sub-
15 section (c); and

16 “(ii) for the first 2 years (or for such pe-
17 riod as the Secretary determines on a case-by-
18 case basis to be appropriate) after the drug or
19 a new indication for the drug is approved, inclu-
20 sion in the labeling and any direct-to-consumer
21 advertisements of a unique symbol indicating
22 the newly approved status of the drug or indica-
23 tion;

24 “(B)(i) submission of reports for the drug
25 as required under subsection (k); and

1 “(ii) for a drug that is a vaccine—

2 “(I) analysis of reports to the Vaccine
3 Adverse Event Reporting Systems
4 (VAERS); or

5 “(II) surveillance using the Vaccine
6 Safety Datalink (VSD) or successor data-
7 bases;

8 “(C) a pharmacovigilance statement—

9 “(i) as to whether the reports under
10 subparagraph (B)(i) or, for a vaccine, the
11 analysis and surveillance under subpara-
12 graph (B)(ii), and the periodic assessment
13 under subparagraph (E), are sufficient to
14 assess the serious risks and to identify un-
15 expected serious risks of the drug; and

16 “(ii) if such reports, such analysis and
17 surveillance, and such periodic assessment
18 are not sufficient to assess the serious
19 risks and to identify unexpected serious
20 risks of the drug, that describes what
21 study or studies of the drug are required
22 under paragraph (4)(D) or what clinical
23 trial or trials of the drug are required
24 under paragraph (4)(E);

1 “(D) a justification for the
2 pharmacovigilance statement in subparagraph
3 (C) that takes into consideration—

4 “(i) the estimated size of the treat-
5 ment population for the drug;

6 “(ii) the seriousness of the disease or
7 condition that the drug is used to treat or
8 prevent;

9 “(iii) the expected or actual duration
10 of treatment with the drug;

11 “(iv) the availability and safety of a
12 drug or other treatment, if any, for such
13 disease or condition to which the safety of
14 the drug may be compared; and

15 “(v) the seriousness of the risk at
16 issue and its background incidence in the
17 population; and

18 “(E) a timetable for submission of assess-
19 ments of the strategy, that—

20 “(i) shall be no less frequently than
21 once annually for the first 3 years after
22 the drug is initially approved under sub-
23 section (c) or licensed under section 351 of
24 the Public Health Service Act;

1 “(ii) shall include an assessment in
2 the seventh year after the drug is so ap-
3 proved; and

4 “(iii) subject to clause (ii), for subse-
5 quent years—

6 “(I) shall be at a frequency speci-
7 fied in the strategy;

8 “(II) may be increased or re-
9 duced in frequency as necessary as
10 provided for in paragraph
11 (6)(B)(iv)(VI); and

12 “(III) may be eliminated after
13 the 3-year period described in clause
14 (i) if the Secretary determines that se-
15 rious risks of the drug have been ade-
16 quately identified and assessed and
17 are being adequately managed.

18 “(4) ADDITIONAL POTENTIAL ELEMENTS OF A
19 RISK EVALUATION AND MITIGATION STRATEGY.—

20 “(A) IN GENERAL.—The Secretary may re-
21 quire that the risk evaluation and mitigation
22 strategy for a drug include 1 or more of the ad-
23 ditional elements described in this paragraph,
24 so long as the Secretary makes the determina-

1 tion required with respect to each additional in-
2 cluded element.

3 “(B) MEDGUIDE; PATIENT PACKAGE IN-
4 SERT.—The risk evaluation and mitigation
5 strategy for a drug may require that the appli-
6 cant develop for distribution to each patient
7 when the drug is dispensed—

8 “(i) a Medication Guide, as provided
9 for under part 208 of title 21, Code of
10 Federal Regulations (or any successor reg-
11 ulations); or

12 “(ii) a patient package insert, if the
13 Secretary determines that such insert may
14 help mitigate a serious risk of the drug.

15 “(C) COMMUNICATION PLAN.—The risk
16 evaluation and mitigation strategy for a drug
17 may require that the applicant conduct a com-
18 munication plan to health care providers, if,
19 with respect to such drug, the Secretary deter-
20 mines that such plan may support implementa-
21 tion of an element of the strategy. Such plan
22 may include—

23 “(i) sending letters to health care pro-
24 viders;

1 “(ii) disseminating information about
2 the elements of the risk evaluation and
3 mitigation strategy to encourage implemen-
4 tation by health care providers of compo-
5 nents that apply to such health care pro-
6 viders, or to explain certain safety proto-
7 cols (such as medical monitoring by peri-
8 odic laboratory tests); or

9 “(iii) disseminating information to
10 health care providers through professional
11 societies about any serious risks of the
12 drug and any protocol to assure safe use.

13 “(D) POST-APPROVAL STUDIES.—The risk
14 evaluation and mitigation strategy for a drug
15 may require that the applicant conduct, or pro-
16 vide that the Secretary will conduct, an appro-
17 priate post-approval study, such as a prospec-
18 tive or retrospective observational study (includ-
19 ing through the systematic use of established
20 health care networks and databases), of the
21 drug (with a target schedule for completing the
22 study and reporting the results to the Sec-
23 retary), if the Secretary determines the reports,
24 analysis and surveillance, and periodic assess-

1 ments referred to in paragraph (3)(C) are not
2 sufficient to—

3 “(i) assess evidence of a serious risk
4 related to the safety or effectiveness of the
5 drug; or

6 “(ii) identify unexpected serious risks
7 in domestic populations who use the drug,
8 including populations not included in stud-
9 ies used to approve the drug (such as older
10 people, people with comorbidities, pregnant
11 women, or children).

12 “(E) POST-APPROVAL CLINICAL TRIALS.—
13 The risk evaluation and mitigation strategy for
14 a drug may require that the applicant for a
15 drug for which there is no effective approved
16 application under subsection (j) of this section
17 as of the date that the requirement is first im-
18 posed conduct an appropriate post-approval
19 clinical trial of the drug (with a target schedule
20 for completing the clinical trial and reporting
21 the results to the Secretary) to be included in
22 the clinical trial registry database and clinical
23 trial results database provided for under section
24 402(i) of the Public Health Service Act, if the
25 Secretary determines that a study or studies

1 under subparagraph (D) will likely be inad-
2 equate to assess evidence of a serious risk re-
3 lated to the safety or effectiveness of the drug.

4 “(F) PRECLEARANCE.—

5 “(i) IN GENERAL.—The risk evalua-
6 tion and mitigation strategy for a drug
7 may require that the applicant submit to
8 the Secretary advertisements of the drug
9 for preclearance, if the Secretary deter-
10 mines that such preclearance is necessary
11 to ensure compliance with section 502(n)
12 with respect to the disclosure of informa-
13 tion about a serious risk listed in the label-
14 ing of the drug. The advertisements re-
15 quired to be submitted under the preceding
16 sentence shall be reviewed and cleared by
17 the Secretary within 45 days of submis-
18 sion.

19 “(ii) SPECIFICATION OF ADVERTISE-
20 MENTS.—The Secretary may specify the
21 advertisements required to be submitted
22 under clause (i).

23 “(G) SPECIFIC DISCLOSURES.—

24 “(i) IN GENERAL.—The risk evalua-
25 tion and mitigation strategy for a drug

1 may require that the applicant include in
2 advertisements of the drug a specific dis-
3 closure—

4 “(I) of the date the drug was ap-
5 proved and that the existing informa-
6 tion may not have identified or al-
7 lowed for full assessment of all serious
8 risks of using the drug, if the Sec-
9 retary determines that such disclosure
10 is necessary to protect public health
11 and safety; or

12 “(II) about a serious adverse
13 event listed in the labeling of the drug
14 or a protocol to ensure safe use de-
15 scribed in the labeling of the drug, if
16 the Secretary determines that such
17 advertisements lacking such disclosure
18 would be false or misleading.

19 “(ii) SPECIFICATION OF ADVERTISE-
20 MENTS.—The Secretary may specify the
21 advertisements required to include a spe-
22 cific disclosure under clause (i).

23 “(H) TEMPORARY MORATORIUM.—The
24 risk evaluation and mitigation strategy for a
25 drug may require that for a fixed period after

1 initial approval, not to exceed 3 years, the ap-
2 plicant not issue or cause to be issued direct-
3 to-consumer advertisements of the drug, if the
4 Secretary determines that disclosure under sub-
5 paragraph (G) is inadequate to protect public
6 health and safety, and that such prohibition is
7 necessary to protect public health and safety
8 while additional information about serious risks
9 of the drug is collected, considering—

10 “(i) the number of patients who may
11 be treated with the drug;

12 “(ii) the seriousness of the condition
13 for which the drug will be used;

14 “(iii) the serious adverse events listed
15 in the labeling of the drug;

16 “(iv) the extent to which patients have
17 access to other approved drugs in the
18 pharmacological class of the drug and with
19 the same intended use as the drug; and

20 “(v) the extent to which clinical trials
21 used to approve the drug may not have
22 identified serious risks that might occur
23 among patients expected to be treated with
24 the drug.

1 “(5) RESTRICTIONS ON DISTRIBUTION OR
2 USE.—

3 “(A) IN GENERAL.—If the Secretary deter-
4 mines that a drug shown to be effective can be
5 safely used only if distribution or use of such
6 drug is restricted, the Secretary may require as
7 elements of the risk evaluation and mitigation
8 strategy such restrictions on distribution or use
9 as are needed to ensure safe use of the drug.

10 “(B) LIMITS ON RESTRICTIONS.—Such re-
11 strictions under subparagraph (A) shall—

12 “(i) be commensurate with the spe-
13 cific risk presented by the drug;

14 “(ii) not be unduly burdensome on pa-
15 tient access to the drug, particularly for
16 patients with serious or life-threatening
17 diseases or conditions; and

18 “(iii) to the extent practicable, con-
19 form with restrictions on distribution or
20 use for other drugs with similar risks, so
21 as to minimize the burden on the health
22 care delivery system.

23 “(C) ELEMENTS.—The restrictions on dis-
24 tribution or use described in subparagraph (A)
25 shall include 1 or more goals to evaluate or

1 mitigate a serious risk listed in the labeling of
2 the drug and may require that—

3 “(i) health care providers that pre-
4 scribe the drug have special training or ex-
5 perience, or are specially certified;

6 “(ii) pharmacies, practitioners, or
7 health care settings that dispense the drug
8 are specially certified;

9 “(iii) the drug be dispensed to pa-
10 tients only in certain health care settings,
11 such as hospitals;

12 “(iv) the drug be dispensed to pa-
13 tients with evidence or other documenta-
14 tion of safe-use conditions, such as labora-
15 tory test results;

16 “(v) each patient using the drug be
17 subject to certain monitoring; or

18 “(vi) each patient using the drug be
19 enrolled in a registry.

20 “(D) IMPLEMENTATION SYSTEM.—The re-
21 strictions on distribution or use described in
22 subparagraph (A) may require a system
23 through which the applicant is able to—

24 “(i) monitor and evaluate implementa-
25 tion of the restrictions by health care pro-

1 viders, pharmacists, patients, and other
2 parties in the health care system who are
3 responsible for implementing the restric-
4 tions;

5 “(ii) work to improve implementation
6 of the restrictions by health care providers,
7 pharmacists, patients, and other parties in
8 the health care system who are responsible
9 for implementing the restrictions; and

10 “(iii) stop distribution of the drug to
11 those health care providers, pharmacists,
12 and other parties in the health care sys-
13 tem—

14 “(I) who are responsible for im-
15 plementing the restrictions; and

16 “(II) whom the applicant knows
17 have failed to meet their responsibil-
18 ities for implementing the restrictions,
19 after the applicant has informed such
20 party of such failure and such party
21 has not remedied such failure.

22 “(E) PATENTS.—The Secretary shall not
23 approve a risk evaluation and mitigation strat-
24 egy for a drug, or any modification to the strat-
25 egy, under paragraph (6) if—

1 “(i) the strategy includes a restriction
2 on distribution or use described in sub-
3 paragraph (A) that is protected by a pat-
4 ent;

5 “(ii) such patent was issued after the
6 date of the enactment of this subsection;
7 and

8 “(iii) such patent would prohibit or
9 impair the application of such restriction
10 under section 505(j)(2)(E)(i)(VII) to a
11 drug that is the subject of an abbreviated
12 new drug application.

13 “(6) SUBMISSION AND REVIEW OF RISK EVAL-
14 UATION AND MITIGATION STRATEGY.—

15 “(A) PROPOSED RISK EVALUATION AND
16 MITIGATION STRATEGY.—

17 “(i) INITIAL APPROVAL.—An appli-
18 cant shall include a proposed risk evalua-
19 tion and mitigation strategy in an applica-
20 tion under subsection (b) or section 351 of
21 the Public Health Service Act for initial
22 approval of the drug.

23 “(ii) APPROVAL OF NEW INDICA-
24 TION.—If no risk evaluation and mitiga-
25 tion strategy for the drug is in effect under

1 this subsection and the drug may not be
2 dispensed without a prescription, the appli-
3 cant shall include a proposed risk evalua-
4 tion and mitigation strategy in an applica-
5 tion, including in a supplemental applica-
6 tion, seeking a new indication for such
7 drug.

8 “(iii) CONTENTS.—A proposed risk
9 evaluation and mitigation strategy—

10 “(I) shall include the minimal
11 elements required under paragraph
12 (3); and

13 “(II) may also include additional
14 elements as provided for under para-
15 graphs (4) and (5).

16 “(B) ASSESSMENT AND MODIFICATION OF
17 A RISK EVALUATION AND MITIGATION STRAT-
18 EGY.—

19 “(i) VOLUNTARY ASSESSMENTS.—The
20 applicant may submit to the Secretary an
21 assessment of, and propose a modification
22 to, the approved risk evaluation and miti-
23 gation strategy for a drug at any time.

24 “(ii) REQUIRED ASSESSMENTS.—The
25 applicant shall submit an assessment of,

1 and may propose a modification to, the ap-
2 proved risk evaluation and mitigation
3 strategy for a drug—

4 “(I) when submitting a supple-
5 mental application for a new indica-
6 tion under subsection (b) or section
7 351 of the Public Health Service Act,
8 unless the drug may be dispensed
9 without a prescription and the risk
10 evaluation and mitigation strategy for
11 the drug includes only the elements
12 under paragraph (3);

13 “(II) when required by the strat-
14 egy, as provided for in the timetable
15 under paragraph (3)(E);

16 “(III) within a time specified by
17 the Secretary, not to be less than 45
18 days, when ordered by the Secretary,
19 if the Secretary determines that new
20 safety or effectiveness information in-
21 dicates that an element under para-
22 graph (3) or (4) should be modified or
23 included in the strategy;

24 “(IV) within 90 days when or-
25 dered by the Secretary, if the Sec-

1 retary determines that new safety or
2 effectiveness information indicates
3 that an element under paragraph (5)
4 should be modified or included in the
5 strategy; or

6 “(V) within 15 days when or-
7 dered by the Secretary, if the Sec-
8 retary determines that there may be a
9 cause for action by the Secretary
10 under subsection (e).

11 “(iii) ASSESSMENT.—An assessment
12 of the approved risk evaluation and mitiga-
13 tion strategy for a drug shall include—

14 “(I) with respect to any goal
15 under paragraph (5), an assessment
16 of how well the restrictions on dis-
17 tribution or use are meeting the goal
18 or whether the goal or such restric-
19 tions should be modified;

20 “(II) with respect to any post-ap-
21 proval study required under para-
22 graph (4)(D), the status of such
23 study, including whether any difficul-
24 ties completing the study have been
25 encountered; and

1 “(III) with respect to any post-
2 approval clinical trial required under
3 paragraph (4)(E), the status of such
4 clinical trial, including whether enroll-
5 ment has begun, the number of par-
6 ticipants enrolled, the expected com-
7 pletion date, whether any difficulties
8 completing the clinical trial have been
9 encountered, and registration informa-
10 tion with respect to requirements
11 under section 402(i) of the Public
12 Health Service Act.

13 “(iv) MODIFICATION.—A modification
14 (whether an enhancement or a reduction)
15 to the approved risk evaluation and mitiga-
16 tion strategy for a drug may include the
17 addition or modification of any element
18 under subparagraph (A), (C), or (D) of
19 paragraph (3) or the addition, modifica-
20 tion, or removal of any element under
21 paragraph (4) or (5), such as—

22 “(I) a labeling change, including
23 the addition of a boxed warning;

24 “(II) adding a post-approval
25 study or clinical trial requirement;

1 “(III) modifying a post-approval
2 study or clinical trial requirement
3 (such as a change in trial design due
4 to legitimate difficulties recruiting
5 participants);

6 “(IV) adding, modifying, or re-
7 moving a restriction on advertising
8 under subparagraph (F), (G), and
9 (H) of paragraph (4);

10 “(V) adding, modifying, or re-
11 moving a restriction on distribution or
12 use under paragraph (5); or

13 “(VI) modifying the timetable for
14 assessments of the strategy under
15 paragraph (3)(E), including to elimi-
16 nate assessments.

17 “(C) REVIEW.—

18 “(i) IN GENERAL.—The Secretary
19 shall promptly review the proposed risk
20 evaluation and mitigation strategy for a
21 drug submitted under subparagraph (A),
22 or an assessment of the approved risk eval-
23 uation and mitigation strategy for a drug
24 submitted under subparagraph (B).

1 “(ii) **MARKETING PLAN.**—As part of a
2 review conducted under this subparagraph,
3 the Secretary may require the applicant to
4 submit its marketing plan for the drug, so
5 as to allow the Secretary to determine
6 whether any of the proposed or ongoing
7 marketing activities undermine any of the
8 requirements of the risk evaluation and
9 mitigation strategy.

10 “(D) **DISCUSSION.**—The Secretary shall
11 initiate discussions of the proposed risk evalua-
12 tion and mitigation strategy for a drug sub-
13 mitted under subparagraph (A), or of an as-
14 sessment of the approved risk evaluation and
15 mitigation strategy for a drug submitted under
16 subparagraph (B), with the applicant to deter-
17 mine a strategy—

18 “(i) if the proposed strategy or assess-
19 ment is submitted as part of an application
20 or supplemental application under subpara-
21 graph (A) or (B)(ii)(I), not less than 60
22 days before the action deadline for the ap-
23 plication that has been agreed to by the
24 Secretary and that has been set forth in
25 goals identified in letters of the Secretary

1 (relating to the use of fees collected under
2 section 736 to expedite the drug develop-
3 ment process and the review of human
4 drug applications);

5 “(ii) if the assessment is submitted
6 under subclause (II) or (III) of subpara-
7 graph (B)(ii), not later than 20 days after
8 such submission;

9 “(iii) if the assessment is submitted
10 under subparagraph (B)(i) or under sub-
11 paragraph (B)(ii)(IV), not later than 30
12 days after such submission; or

13 “(iv) if the assessment is submitted
14 under subparagraph (B)(ii)(V), not later
15 than 10 days after such submission.

16 “(E) ACTION.—

17 “(i) IN GENERAL.—Unless the appli-
18 cant requests the dispute resolution proc-
19 ess described under subparagraph (F), the
20 Secretary shall approve and describe the
21 risk evaluation and mitigation strategy for
22 a drug, or any modification to the strat-
23 egy—

24 “(I) as part of the action letter
25 on the application, when a proposed

1 strategy is submitted under subpara-
2 graph (A) or an assessment of the
3 strategy is submitted under subpara-
4 graph (B)(ii)(I); or

5 “(II) in an order issued not later
6 than 50 days after the date discus-
7 sions of such modification begin under
8 subparagraph (C), when an assess-
9 ment of the strategy is under sub-
10 paragraph (B)(i) or under subclause
11 (II), (III), (IV), or (V) of subpara-
12 graph (B)(ii).

13 “(ii) INACTION.—An approved risk
14 evaluation and mitigation strategy shall re-
15 main in effect until the Secretary acts, if
16 the Secretary fails to act as provided under
17 clause (i).

18 “(iii) PUBLIC AVAILABILITY.—Any ac-
19 tion letter described in clause (i)(I) or
20 order described in clause (i)(II) shall be
21 made publicly available.

22 “(F) DISPUTE RESOLUTION.—

23 “(i) REQUEST FOR REVIEW.—Not
24 earlier than 15 days, and not later than 35
25 days, after discussions under subparagraph

1 (D) have begun, the applicant may request
2 in writing that a dispute about the strat-
3 egy be reviewed by the Drug Safety Over-
4 sight Board. Upon receipt of such a re-
5 quest, the Secretary shall schedule the dis-
6 pute for review under clause (ii) and, not
7 later than 5 business days of scheduling
8 the dispute for review, shall publish by
9 posting on the Internet or otherwise a no-
10 tice that the dispute will be reviewed by
11 the Drug Safety Oversight Board.

12 “(ii) SCHEDULING REVIEW.—If the
13 applicant requests review under clause (i),
14 the Secretary—

15 “(I) shall schedule the dispute
16 for review at 1 of the next 2 regular
17 meetings of the Drug Safety Over-
18 sight Board, whichever meeting date
19 is more practicable; or

20 “(II) may convene a special
21 meeting of the Drug Safety Oversight
22 Board to review the matter more
23 promptly, including to meet an action
24 deadline on an application (including
25 a supplemental application).

1 “(iii) AGREEMENT AFTER DISCUSSION
2 OR ADMINISTRATIVE APPEALS.—

3 “(I) FURTHER DISCUSSION OR
4 ADMINISTRATIVE APPEALS.—A re-
5 quest for review under clause (i) shall
6 not preclude further discussions to
7 reach agreement on the risk evalua-
8 tion and mitigation strategy, and such
9 a request shall not preclude the use of
10 administrative appeals within the
11 Food and Drug Administration to
12 reach agreement on the strategy, in-
13 cluding appeals as described in letters
14 of the Secretary (relating to the use of
15 fees collected under section 736 to ex-
16 pedite the drug development process
17 and the review of human drug appli-
18 cations) for procedural or scientific
19 matters involving the review of human
20 drug applications and supplemental
21 applications that cannot be resolved at
22 the divisional level.

23 “(II) AGREEMENT TERMINATES
24 DISPUTE RESOLUTION.—At any time
25 before a decision and order is issued

1 under clause (vii), the Secretary and
2 the applicant may reach an agreement
3 on the risk evaluation and mitigation
4 strategy through further discussion or
5 administrative appeals, terminating
6 the dispute resolution process, and the
7 Secretary shall issue an action letter
8 or order, as appropriate, that de-
9 scribes the strategy.

10 “(iv) MEETING OF THE BOARD.—At
11 the meeting of the Drug Safety Oversight
12 Board described in clause (ii), the Board
13 shall—

14 “(I) hear from both parties; and

15 “(II) review the dispute.

16 “(v) RECORD OF PROCEEDINGS.—The
17 Secretary shall ensure that the proceedings
18 of any such meeting are recorded, tran-
19 scribed, and made public within 30 days of
20 the meeting. The Secretary shall redact the
21 transcript to protect any trade secrets or
22 other confidential information described in
23 section 552(b)(4) of title 5, United States
24 Code.

1 “(vi) RECOMMENDATION OF THE
2 BOARD.—Not later than 5 days after any
3 such meeting, the Drug Safety Oversight
4 Board shall provide a written recommenda-
5 tion on resolving the dispute to the Sec-
6 retary. Not later than 5 days after the
7 Board provides such written recommenda-
8 tion to the Secretary, the Secretary shall
9 make the recommendation available to the
10 public.

11 “(vii) ACTION BY THE SECRETARY.—

12 “(I) ACTION LETTER.—With re-
13 spect to a proposed risk evaluation
14 and mitigation strategy submitted
15 under subparagraph (A) or to an as-
16 sessment of the strategy submitted
17 under subparagraph (B)(ii)(I), the
18 Secretary shall issue an action letter
19 that resolves the dispute not later
20 than the later of—

21 “(aa) the action deadline re-
22 ferred to in subparagraph (D)(i);
23 or

1 “(bb) 7 days after receiving
2 the recommendation of the Drug
3 Safety Oversight Board.

4 “(II) ORDER.—With respect to
5 an assessment of the risk evaluation
6 and mitigation strategy under sub-
7 paragraph (B)(i) or under subclause
8 (II), (III), (IV), or (V) of subpara-
9 graph (B)(ii), the Secretary shall
10 issue an order, which shall be made
11 public, that resolves the dispute not
12 later than 7 days after receiving the
13 recommendation of the Drug Safety
14 Oversight Board.

15 “(viii) INACTION.—An approved risk
16 evaluation and mitigation strategy shall re-
17 main in effect until the Secretary acts, if
18 the Secretary fails to act as provided for
19 under clause (vii).

20 “(ix) EFFECT ON ACTION DEAD-
21 LINE.—With respect to the application or
22 supplemental application in which a pro-
23 posed risk evaluation and mitigation strat-
24 egy is submitted under subparagraph (A)
25 or in which an assessment of the strategy

1 is submitted under subparagraph
2 (B)(ii)(I), the Secretary shall be considered
3 to have met the action deadline referred to
4 in subparagraph (D)(i) with respect to
5 such application if the applicant requests
6 the dispute resolution process described in
7 this subparagraph and if the Secretary—

8 “(I) has initiated the discussions
9 described under subparagraph (D) not
10 less than 60 days before such action
11 deadline; and

12 “(II) has complied with the tim-
13 ing requirements of scheduling review
14 by the Drug Safety Oversight Board,
15 providing a written recommendation,
16 and issuing an action letter under
17 clauses (ii), (vi), and (vii), respec-
18 tively.

19 “(x) DISQUALIFICATION.—No indi-
20 vidual who is an employee of the Food and
21 Drug Administration and who reviews a
22 drug or who participated in an administra-
23 tive appeal under clause (iii)(I) with re-
24 spect to such drug may serve on the Drug
25 Safety Oversight Board at a meeting under

1 clause (iv) to review a dispute about the
2 risk evaluation and mitigation strategy for
3 such drug.

4 “(xi) ADDITIONAL EXPERTISE.—The
5 Drug Safety Oversight Board may add
6 members with relevant expertise from the
7 Food and Drug Administration, including
8 the Office of Pediatrics, the Office of
9 Women’s Health, or the Office of Rare
10 Diseases, or from other Federal public
11 health or health care agencies, for a meet-
12 ing under clause (iv) of the Drug Safety
13 Oversight Board.

14 “(G) USE OF ADVISORY COMMITTEES.—
15 The Secretary may convene a meeting of 1 or
16 more advisory committees of the Food and
17 Drug Administration to—

18 “(i) review a concern about the safety
19 of a drug or class of drugs, including be-
20 fore an assessment of the risk evaluation
21 and mitigation strategy or strategies of
22 such drug or drugs is required to be sub-
23 mitted under subclause (II), (III), (IV), or
24 (V) of subparagraph (B)(ii);

1 “(ii) review the risk evaluation and
2 mitigation strategy or strategies of a drug
3 or group of drugs; or

4 “(iii) review a dispute under subpara-
5 graph (F).

6 “(H) PROCESS FOR ADDRESSING DRUG
7 CLASS EFFECTS.—

8 “(i) IN GENERAL.—When a concern
9 about a serious risk of a drug may be re-
10 lated to the pharmacological class of the
11 drug, the Secretary may defer assessments
12 of the approved risk evaluation and mitiga-
13 tion strategies for such drugs until the
14 Secretary has convened 1 or more public
15 meetings to consider possible responses to
16 such concern. If the Secretary defers an
17 assessment under this clause, the Sec-
18 retary shall give notice to the public of the
19 deferral not later than 5 days of the defer-
20 ral.

21 “(ii) PUBLIC MEETINGS.—Such public
22 meetings may include—

23 “(I) 1 or more meetings of the
24 applicants for such drugs;

1 “(II) 1 or more meetings of 1 or
2 more advisory committees of the Food
3 and Drug Administration, as provided
4 for under subparagraph (G); or

5 “(III) 1 or more workshops of
6 scientific experts and other stake-
7 holders.

8 “(iii) ACTION.—After considering the
9 discussions from any meetings under
10 clause (ii), the Secretary may—

11 “(I) announce in the Federal
12 Register a planned regulatory action,
13 including a modification to each risk
14 evaluation and mitigation strategy, for
15 drugs in the pharmacological class;

16 “(II) seek public comment about
17 such action; and

18 “(III) after seeking such com-
19 ment, issue an order addressing such
20 regulatory action.

21 “(I) INTERNATIONAL COORDINATION.—
22 The Secretary may coordinate the timetable for
23 submission of assessments under paragraph
24 (3)(E), a study under paragraph (4)(D), or a
25 clinical trial under paragraph (4)(E), with ef-

1 forts to identify and assess the serious risks of
2 such drug by the marketing authorities of other
3 countries whose drug approval and risk man-
4 agement processes the Secretary deems com-
5 parable to the drug approval and risk manage-
6 ment processes of the United States. If the Sec-
7 retary takes action to coordinate such time-
8 table, the Secretary shall give notice to the pub-
9 lic of the action not later than 5 days after the
10 action.

11 “(J) EFFECT.—Use of the processes de-
12 scribed in subparagraphs (H) and (I) shall not
13 delay action on an application or a supplement
14 to an application for a drug.

15 “(K) NO EFFECT ON LABELING CHANGES
16 THAT DO NOT REQUIRE PREAPPROVAL.—In the
17 case of a labeling change to which section
18 314.70 of title 21, Code of Federal Regulations
19 (or any successor regulation), applies for which
20 the submission of a supplemental application is
21 not required or for which distribution of the
22 drug involved may commence upon the receipt
23 by the Secretary of a supplemental application
24 for the change, the submission of an assessment
25 of the approved risk evaluation and mitigation

1 strategy for the drug under this subsection is
2 not required.

3 “(7) DRUG SAFETY OVERSIGHT BOARD.—

4 “(A) IN GENERAL.—There is established a
5 Drug Safety Oversight Board.

6 “(B) COMPOSITION; MEETINGS.—The
7 Drug Safety Oversight Board shall—

8 “(i) be composed of scientists and
9 health care practitioners appointed by the
10 Secretary, each of whom is an employee of
11 the Federal Government;

12 “(ii) include representatives from of-
13 fices throughout the Food and Drug Ad-
14 ministration;

15 “(iii) include at least 1 representative
16 from each of the National Institutes of
17 Health, the Department of Health and
18 Human Services (other than the Food and
19 Drug Administration), and the Veterans
20 Health Administration; and

21 “(iv) meet at least monthly to provide
22 oversight and advice to the Secretary on
23 the management of important drug safety
24 issues.”.

1 **SEC. 102. ENFORCEMENT.**

2 (a) MISBRANDING.—Section 502 of the Federal
3 Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amend-
4 ed by adding at the end the following:

5 “(y) If it is a drug subject to an approved risk evalua-
6 tion and mitigation strategy under section 505(o) and the
7 applicant for such drug fails to—

8 “(1) make a labeling change required by such
9 strategy after the Secretary has completed review of,
10 and acted on, an assessment of such strategy under
11 paragraph (6) of such section; or

12 “(2) comply with a requirement of such strat-
13 egy provided for under paragraph (3), (4), or (5) of
14 such section.

15 “(z) Failure to conduct a postmarket study required
16 under section 506 (or any regulation thereunder).”.

17 (b) CIVIL PENALTIES.—Section 303(f) of the Federal
18 Food, Drug, and Cosmetic Act (21 U.S.C. 333(f)) is
19 amended—

20 (1) by redesignating paragraphs (3), (4), and
21 (5) as paragraphs (4), (5), and (6), respectively;

22 (2) by inserting after paragraph (2) the fol-
23 lowing:

24 “(3) Any person who violates a requirement of this
25 Act which relates to drugs shall be liable to the United
26 States for a civil penalty in an amount not less than

1 \$50,000 for each such violation and, for all such violations
2 adjudicated in a single proceeding, in an amount not to
3 exceed the following:

4 “(A) For drugs on the market for at least one year,
5 10 percent of the annual United States sales revenue dur-
6 ing the year prior to which the person is subject to the
7 civil penalty, based upon data from IMS Health Inc.’s Re-
8 tail and Provider Prospective Combined Purchases on the
9 United States sales revenue of the drug or, in the event
10 IMS data is not available, based upon any comparable
11 data.

12 “(B) For drugs on the market for less than one year,
13 \$1,000,000.”;

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

16 (4) in paragraph (4), as so redesignated, by
17 striking “paragraph (1) or (2)” each place it ap-
18 pears and inserting “paragraph (1), (2), or (3)”;
19 and

20 (5) in paragraph (6), as so redesignated, by
21 striking “paragraph (4)” each place it appears and
22 inserting “paragraph (5)”.

23 **SEC. 103. REGULATION OF BIOLOGICAL PRODUCTS.**

24 Section 351 of the Public Health Service Act (42
25 U.S.C. 262) is amended—

1 (1) in subsection (a)(2), by adding at the end
2 the following:

3 “(D) RISK EVALUATION AND MITIGATION STRAT-
4 EGY.—A person that submits an application for a license
5 under this paragraph shall submit to the Secretary as part
6 of the application a proposed risk evaluation and mitiga-
7 tion strategy as described under section 505(o) of the Fed-
8 eral Food, Drug, and Cosmetic Act.”; and

9 (2) in subsection (j), by inserting “, including
10 the requirements under section 505(o) of such Act,”
11 after “, and Cosmetic Act”.

12 **SEC. 104. NO EFFECT ON WITHDRAWAL OR SUSPENSION OF**
13 **APPROVAL.**

14 Section 505(e) of the Federal Food, Drug, and Cos-
15 metic Act (21 U.S.C. 355(e)) is amended by adding at
16 the end the following: “The Secretary may withdraw the
17 approval of an application submitted under this section,
18 or suspend the approval of such an application, as pro-
19 vided under this subsection, without first ordering the ap-
20 plicant to submit an assessment of the approved risk eval-
21 uation and mitigation strategy for the drug under sub-
22 section (o)(6)(B)(ii)(V).”.

1 **SEC. 105. DRUGS SUBJECT TO AN ABBREVIATED NEW DRUG**
2 **APPLICATION.**

3 Section 505(j)(2) of the Federal Food, Drug, and
4 Cosmetic Act (21 U.S.C. 355(j)(2)) is amended by adding
5 at the end the following:

6 “(E) RISK EVALUATION AND MITIGATION STRATEGY
7 REQUIREMENT.—

8 “(i) IN GENERAL.—A drug that is the subject
9 of an abbreviated new drug application under this
10 subsection shall be subject to only the following ele-
11 ments of the risk evaluation and mitigation strategy
12 required under subsection (o) for the applicable list-
13 ed drug:

14 “(I) Labeling, as required under subsection
15 (o)(3)(A) for the applicable listed drug.

16 “(II) Submission of reports, as required
17 under subsection (o)(3)(B)(i) for the applicable
18 listed drug.

19 “(III) A Medication Guide or patient pack-
20 age insert, if required under subsection
21 (o)(4)(B) for the applicable listed drug.

22 “(IV) Preclearance of advertising, if re-
23 quired under subsection (o)(4)(F) for the appli-
24 cable listed drug.

1 “(V) Specific disclosures in advertising, if
2 required under subsection (o)(4)(G) for the ap-
3 plicable listed drug.

4 “(VI) A temporary moratorium on direct-
5 to-consumer advertising, if required under sub-
6 section (o)(4)(H) for the applicable listed drug.

7 “(VII) Restrictions on distribution or use,
8 if required under subsection (o)(5) for the listed
9 drug. A drug that is the subject of an abbrevi-
10 ated new drug application and the listed drug
11 shall use a single, shared system under sub-
12 section (o)(5)(D). The Secretary may waive the
13 requirement under the preceding sentence for a
14 drug that is the subject of an abbreviated new
15 drug application if the Secretary determines
16 that (aa) it is not practical for the drug to use
17 such single, shared system or (bb) the burden
18 of using the single, shared system outweighs
19 the benefit of using the single system.

20 “(ii) ACTION BY SECRETARY.—For an applica-
21 ble listed drug for which a drug is approved under
22 this subsection, the Secretary—

23 “(I) shall undertake any communication
24 plan to health care providers required under
25 section (o)(4)(C) for the applicable listed drug;

1 “(II) shall conduct any post-approval study
2 required under subsection (o)(4)(D) for the ap-
3 plicable listed drug; and

4 “(III) shall inform the applicant for a drug
5 approved under this subsection if the risk eval-
6 uation and mitigation strategy for the applica-
7 ble listed drug is modified.”.

8 **SEC. 106. CONFORMING AMENDMENTS.**

9 (a) PRECLEARANCE OF ADVERTISEMENTS.—Section
10 502(n)(3)(A) of the Federal Food, Drug, and Cosmetic
11 Act (21 U.S.C. 352(n)(3)(A)) is amended by inserting
12 “(or when required under section 505(o)(4)(F))” after
13 “except in extraordinary circumstances”.

14 (b) CONTENT OF NEW DRUG APPLICATION.—Section
15 505(b)(1) of the Federal Food, Drug, and Cosmetic Act
16 (21 U.S.C. 355(b)) is amended—

17 (1) in subparagraph (F), by striking “and”;
18 and

19 (2) in subparagraph (G), by striking the period
20 and inserting the following: “, and (H) a proposed
21 risk evaluation and mitigation strategy as described
22 under subsection (o).”.

1 **SEC. 107. RESOURCES.**

2 (a) **USER FEES.**—Subparagraph (F) of section
3 735(6) of the Federal Food, Drug, and Cosmetic Act (21
4 U.S.C. 379g(6)) is amended to read as follows:

5 “(F) Reviewing and implementing risk
6 evaluation and mitigation strategies, and col-
7 lecting, developing, and reviewing safety or ef-
8 fectiveness information on drugs, including ad-
9 verse event reports.”.

10 (b) **WORKLOAD ADJUSTMENT.**—Subparagraph (A) of
11 section 736(c)(2) of the Federal Food, Drug, and Cos-
12 metic Act (21 U.S.C. 379h(c)(2)) is amended to read as
13 follows:

14 “(A) The adjustment shall be determined
15 by the Secretary based on a weighted average
16 of the change in the total number of human
17 drug applications; commercial investigational
18 new drug applications; efficacy supplements;
19 manufacturing supplements; implementation,
20 assessment, review, and enforcement activities
21 for risk evaluation and mitigation strategies;
22 and uses of dispute resolution under the process
23 for reviewing and assessing risk evaluation and
24 mitigation strategies. The Secretary shall pub-
25 lish in the Federal Register the fee revenues

1 and fees resulting from the adjustment and
2 supporting methodologies.”.

3 (c) STRATEGIC PLAN FOR INFORMATION TECH-
4 NOLOGY.—Not later than 1 year after the date of enact-
5 ment of this title, the Secretary of Health and Human
6 Services (referred to in this Act as the “Secretary”) shall
7 submit to the Committee on Health, Education, Labor,
8 and Pensions and the Committee on Appropriations of the
9 Senate and the Committee on Energy and Commerce and
10 the Committee on Appropriations of the House of Rep-
11 resentatives, a strategic plan on information technology
12 that includes—

13 (1) an assessment of the information technology
14 infrastructure, including systems for data collection,
15 access to data in external health care databases (in-
16 cluding databases of the Centers for Medicare &
17 Medicaid Services and the Department of Veterans
18 Affairs), data mining capabilities, personnel, and
19 personnel training programs, needed by the Food
20 and Drug Administration to—

21 (A) comply with the requirements of this
22 title (and the amendments made by this title);

23 (B) achieve interoperability within and
24 among the Centers of the Food and Drug Ad-
25 ministration and between the Food and Drug

1 Administration and product application spon-
2 sors; and

3 (C) utilize electronic health records;

4 (2) an assessment of the extent to which the
5 current information technology assets of the Food
6 and Drug Administration are sufficient to meet the
7 needs assessments under paragraph (1);

8 (3) a plan for enhancing the information tech-
9 nology assets of the Food and Drug Administration
10 toward meeting the needs assessments under para-
11 graph (1); and

12 (4) an assessment of additional resources need-
13 ed to so enhance the information technology assets
14 of the Food and Drug Administration.

15 **SEC. 108. DRUG LABELING.**

16 (a) ACCESSIBLE REPOSITORY OF DRUG LABEL-
17 ING.—Not later than the effective date of this title, the
18 Secretary, through the Commissioner of Food and Drugs,
19 and the Director of the National Institutes of Health, shall
20 establish a searchable repository of structured, electronic
21 product information (including health warnings, Dear
22 Doctor letters, and the approved professional labeling and
23 any required patient labeling of each drug approved under
24 section 505 of the Federal Food, Drug, and Cosmetic Act
25 (21 U.S.C. 355) or licensed under section 351 of the Pub-

1 lic Health Service Act (42 U.S.C. 262)) in order to im-
2 prove patient safety through accessible product informa-
3 tion, support initiatives to improve patient care by better
4 management of health care information, and provide
5 standards for drug information. Such repository shall be
6 made publicly accessible on the Internet website of the Na-
7 tional Library of Medicine and through a link on the
8 homepage of the Internet website of the Food and Drug
9 Administration.

10 (b) POSTING UPON APPROVAL.—The Secretary shall
11 post in the repository under subsection (a) the approved
12 professional labeling and any required patient labeling of
13 a drug approved under such section 505 or licensed under
14 such section 351 not later than 21 days after the date
15 the drug is approved, including in a supplemental applica-
16 tion with respect to a labeling change.

17 (c) REPORT.—The Secretary shall report annually to
18 the Committee on Health, Education, Labor and Pensions
19 of the Senate and the Committee on Energy and Com-
20 merce of the House of Representatives on the status of
21 the repository under subsection (a), and on progress in
22 posting structured electronic product information, includ-
23 ing posting of information regarding drugs approved prior
24 to the effective date of this title.

1 (d) MEDICATION GUIDES.—Not later than the effec-
2 tive date of this title, the Secretary, through the Commis-
3 sioner of Food and Drugs, shall establish on the Internet
4 website for the repository under subsection (a), a link to
5 a list of each drug, whether approved under such section
6 505 or licensed under such section 351, for which a Medi-
7 cation Guide, as provided for under part 208 of title 21,
8 Code of Federal Regulations (or any successor regula-
9 tions), is required.

10 **SEC. 109. FACTORY INSPECTIONS.**

11 Paragraph (1) of section 704(a) of the Federal Food,
12 Drug, and Cosmetic Act (21 U.S.C. 374(a)) is amended
13 by inserting “or marketing data” after “No inspection au-
14 thorized by the preceding sentence or by paragraph (3)
15 shall extend to financial data, sales data other than ship-
16 ment data”.

17 **SEC. 110. STUDY ON INTEGRATION OF EXPERTISE OF OF-**

18 **FICE OF SURVEILLANCE AND EPIDEMI-**

19 **LOGY.**

20 Not later than 1 year after the date of the enactment
21 of this Act, the Commissioner of Food and Drugs shall
22 submit a report to the Congress on the Commissioner’s
23 efforts to integrate the expertise of the Office of Surveil-
24 lance and Epidemiology into the Food and Drug Adminis-

1 tration’s approval, labeling, and post-approval safety deci-
2 sions.

3 **SEC. 111. BENEFIT-RISK ASSESSMENTS.**

4 Not later than 1 year after the date of the enactment
5 of this Act, the Commissioner of Food and Drugs shall
6 submit to the Congress a report on how best to commu-
7 nicate to the public the risks and benefits of new drugs
8 and the role of the risk evaluation and mitigation strategy
9 in assessing such risks and benefits.

10 **SEC. 112. EFFECTIVE DATE AND APPLICABILITY.**

11 (a) **EFFECTIVE DATE.**—This title shall take effect
12 180 days after the date of enactment of this Act.

13 (b) **DRUGS DEEMED TO HAVE RISK EVALUATION**
14 **AND MITIGATION STRATEGIES.**—

15 (1) **IN GENERAL.**—A drug that was approved
16 before the effective date of this title shall be deemed
17 to have an approved risk evaluation and mitigation
18 strategy under section 505(o) of the Federal Food,
19 Drug, and Cosmetic Act (as added by this title) if
20 there are in effect on the effective date of this title
21 restrictions on distribution or use—

22 (A) required under section 314.520 or sec-
23 tion 601.42 of title 21, Code of Federal Regula-
24 tions; or

1 (B) otherwise agreed to by the applicant
2 and the Secretary for such drug.

3 (2) RISK EVALUATION AND MITIGATION STRAT-
4 EGY.—The approved risk evaluation and mitigation
5 strategy deemed in effect for a drug under para-
6 graph (1) shall consist of the elements described in
7 subparagraphs (A) and (B) of paragraph (3) of such
8 section 505(o) and any other additional elements
9 under paragraphs (4) and (5) in effect for such drug
10 on the effective date of this title.

11 (3) NOTIFICATION.—Not later than 30 days
12 after the effective date of this title, the Secretary
13 shall notify the applicant for each drug described in
14 paragraph (1)—

15 (A) that such drug is deemed to have an
16 approved risk evaluation and mitigation strat-
17 egy pursuant to such paragraph; and

18 (B) of the date, which shall be no earlier
19 than 6 months after the applicant is so notified,
20 by which the applicant shall submit to the Sec-
21 retary an assessment of such approved strategy
22 under paragraph (6)(B) of such section 505(o).

23 (c) OTHER DRUGS APPROVED BEFORE THE EFFEC-
24 TIVE DATE.—The Secretary, on a case-by-case basis, may
25 require the applicant for a drug approved before the effec-

1 tive date of this title to which subsection (b) does not
2 apply to submit a proposed risk evaluation and mitigation
3 strategy in accordance with the timeframes provided for
4 in subclause (III), (IV), or (V), as applicable, of paragraph
5 (6)(B)(ii) of such section 505(o) if the Secretary deter-
6 mines (with respect to such drug or with respect to the
7 group of drugs to which such drug belongs) that—

8 (1) an element described under paragraph
9 (3)(A) of such section 505(o) may require modifica-
10 tion; or

11 (2) a standard for adding an element described
12 in paragraph (4) or (5) of such section 505(o) that
13 is not in effect with respect to such drug or class of
14 drugs may apply.

15 (d) USE OF ADVISORY COMMITTEES; PROCESS FOR
16 ADDRESSING DRUG CLASS EFFECTS.—In imposing a re-
17 quirement under subsection (c), the Secretary—

18 (1) may convene a meeting of 1 or more advi-
19 sory committees of the Food and Drug Administra-
20 tion in accordance with paragraph (6)(G) of such
21 section 505(o); and

22 (2) may use the process described in paragraph
23 (6)(H) of such section 505(o) (relating to addressing
24 drug class effects).

1 **SEC. 113. RULE OF CONSTRUCTION REGARDING PEDIATRIC**
2 **STUDIES.**

3 Nothing in this Act or the amendments made by this
4 Act shall be construed to affect the authority of the Sec-
5 retary or the Commissioner of Food and Drugs to require
6 pediatric studies under section 505A of the Federal Food,
7 Drug, and Cosmetic Act (21 U.S.C. 355a).

8 **SEC. 114. AUTHORIZATION OF APPROPRIATIONS.**

9 (a) IN GENERAL.—For carrying out this title and the
10 amendments made by this title, there is authorized to be
11 appropriated \$25,000,000 for each of fiscal years 2008
12 through 2012.

13 (b) RELATION TO OTHER FUNDING.—The authoriza-
14 tion of appropriations under subsection (a) is in addition
15 to any other funds available for carrying out this title and
16 the amendments made by this title.

17 **TITLE II—REAGAN-UDALL INSTI-**
18 **TUTE FOR APPLIED BIO-**
19 **MEDICAL RESEARCH**

20 **SEC. 201. THE REAGAN-UDALL INSTITUTE FOR APPLIED**
21 **BIOMEDICAL RESEARCH.**

22 (a) IN GENERAL.—Chapter VII of the Federal Food,
23 Drug, and Cosmetic Act (21 U.S.C. 371 et seq.), as
24 amended by Public Law 109–462, is amended by adding
25 at the end the following:

1 **“Subchapter I—Reagan-Udall Institute for**
2 **Applied Biomedical Research**

3 **“SEC. 770. ESTABLISHMENT AND FUNCTIONS OF THE INSTI-**
4 **TUTE.**

5 “(a) IN GENERAL.—The Secretary shall establish a
6 nonprofit corporation to be known as the Reagan-Udall
7 Institute for Applied Biomedical Research (referred to in
8 this subchapter as the ‘Institute’). The Institute shall be
9 headed by an Executive Director, appointed by the mem-
10 bers of the Board of Directors under subsection (e). The
11 Institute shall not be an agency or instrumentality of the
12 United States Government.

13 “(b) PURPOSE OF INSTITUTE.—The purpose of the
14 Institute is to advance the Critical Path Initiative of the
15 Food and Drug Administration to modernize medical
16 product development, accelerate innovation, and enhance
17 product safety.

18 “(c) DUTIES OF THE INSTITUTE.—The Institute
19 shall—

20 “(1) taking into consideration the 2004 report
21 published by the Food and Drug Administration en-
22 titled ‘Innovation or Stagnation? Challenge and Op-
23 portunity on the Critical Path to New Medical Prod-
24 ucts’, identify unmet needs in the sciences of devel-
25 oping, manufacturing, and evaluating the safety and

1 effectiveness of diagnostics, devices, biologics, and
2 drugs, including—

3 “(A) the identification and validation of
4 biomarkers for use in diagnostic, device, bio-
5 logic, and drug development;

6 “(B) the development and validation of
7 animal models for human disease and medical
8 product safety;

9 “(C) pharmacogenomics and inter-indi-
10 vidual variability in drug, biologic, and device
11 response;

12 “(D) the development of data analysis
13 technology and methodology for use in device,
14 biologic, drug, and diagnostic development;

15 “(E) advancing improvements to the de-
16 sign and conduct of clinical trials;

17 “(F) toxicological quality assessment tech-
18 nologies;

19 “(G) diagnostic, device, biologic, and drug
20 manufacturing, design, and materials science;

21 “(H) failure mode assessment for medical
22 product development;

23 “(I) improving adverse event reporting and
24 analysis;

1 “(J) bridging engineering data and clinical
2 performance for devices; and

3 “(K) computer modeling;

4 “(2) establish goals and priorities in order to
5 meet the unmet needs identified in paragraph (1);

6 “(3) in consultation with the Secretary, assess
7 existing and proposed Federal intramural and extra-
8 mural research and development programs relating
9 to the goals and priorities established under para-
10 graph (2) and facilitate and encourage interagency
11 coordination of such programs;

12 “(4) award grants to, or enter into contracts or
13 cooperative agreements with, scientists and entities
14 to advance the goals and priorities established under
15 paragraph (2);

16 “(5) recruit meeting participants and hold or
17 sponsor (in whole or in part) meetings as appro-
18 priate to further the goals and priorities established
19 under paragraph (2);

20 “(6) release and publish information and data
21 and, to the extent practicable, license, distribute,
22 and release material, reagents, and techniques to
23 maximize, promote, and coordinate the availability of
24 such material, reagents, and techniques for use by
25 the Food and Drug Administration, nonprofit orga-

1 nizations, and academic and industrial researchers
2 to further the goals and priorities established under
3 paragraph (2);

4 “(7) ensure that—

5 “(A) action is taken as necessary to obtain
6 patents for inventions developed by the Insti-
7 tute or with funds from the Institute;

8 “(B) action is taken as necessary to enable
9 the licensing of inventions developed by the In-
10 stitute or with funds from the Institute; and

11 “(C) executed licenses, memoranda of un-
12 derstanding, material transfer agreements, con-
13 tracts, and other such instruments promote, to
14 the maximum extent practicable, the broadest
15 conversion to commercial and noncommercial
16 applications of licensed and patented inventions
17 of the Institute to further the goals and prior-
18 ities established under paragraph (2);

19 “(8) provide objective clinical and scientific in-
20 formation to the Food and Drug Administration
21 and, upon request, to other Federal agencies to as-
22 sist in agency determinations of how to ensure that
23 regulatory policy accommodates scientific advances;

24 “(9) conduct annual assessments of the unmet
25 needs identified in paragraph (1); and

1 “(10) carry out such other activities consistent
2 with the purposes of the Institute as the Board de-
3 termines appropriate.

4 “(d) BOARD OF DIRECTORS.—

5 “(1) ESTABLISHMENT.—

6 “(A) IN GENERAL.—The Institute shall
7 have a Board of Directors (referred to in this
8 subchapter as the ‘Board’), which shall be com-
9 posed of ex officio and appointed members in
10 accordance with this subsection. All appointed
11 members of the Board shall be voting members.

12 “(B) EX OFFICIO MEMBERS.—The ex offi-
13 cio members of the Board shall be—

14 “(i) the immediate past Chair of the
15 Board of Directors of the Institute;

16 “(ii) the Commissioner of Food and
17 Drugs;

18 “(iii) the Director of the National In-
19 stitutes of Health;

20 “(iv) the Director of the Centers for
21 Disease Control and Prevention; and

22 “(v) the Director of the Agency for
23 Healthcare Research and Quality.

24 “(C) APPOINTED MEMBERS.—

1 “(i) IN GENERAL.—The ex officio
2 members of the Board under subparagraph
3 (B) shall, by majority vote, appoint to the
4 Board 12 individuals. Of such appointed
5 members—

6 “(I) 3 shall be representatives of
7 the general pharmaceutical, device,
8 and biotechnology industries;

9 “(II) 3 shall be representatives of
10 academic research organizations;

11 “(III) 2 shall be representatives
12 of Government agencies, including the
13 Food and Drug Administration and
14 the National Institutes of Health;

15 “(IV) 3 shall be representatives
16 of patient advocacy and consumer or-
17 ganizations; and

18 “(V) 1 shall be a representative
19 of health care providers.

20 “(ii) REQUIREMENT.—The ex officio
21 members shall ensure the Board member-
22 ship includes individuals with expertise in
23 areas including clinical pharmacology, bio-
24 medical informatics, product safety, proc-
25 ess improvement and pharmaceutical

1 sciences, and medical device and bio-
2 medical engineering.

3 “(D) INITIAL MEETING.—

4 “(i) IN GENERAL.—Not later than 30
5 days after the date of the enactment of the
6 Enhancing Drug Safety and Innovation
7 Act of 2007, the Secretary shall convene a
8 meeting of the ex officio members of the
9 Board to—

10 “(I) incorporate the Institute;

11 and

12 “(II) appoint the members of the
13 Board in accordance with subpara-
14 graph (C).

15 “(ii) SERVICE OF EX OFFICIO MEM-
16 BERS.—Upon the appointment of the
17 members of the Board under clause (i)(II),
18 the terms of service of the ex officio mem-
19 bers of the Board as members of the
20 Board shall terminate.

21 “(iii) CHAIR.—The ex officio members
22 of the Board under subparagraph (B) shall
23 designate an appointed member of the
24 Board to serve as the Chair of the Board.

25 “(2) DUTIES OF BOARD.—The Board shall—

1 “(A) establish bylaws for the Institute
2 that—

3 “(i) are published in the Federal Reg-
4 ister and available for public comment;

5 “(ii) establish policies for the selection
6 of the officers, employees, agents, and con-
7 tractors of the Institute;

8 “(iii) establish policies, including eth-
9 ical standards, for the acceptance, sollicita-
10 tion, and disposition of donations and
11 grants to the Institution and for the dis-
12 position of the assets of the Institute;

13 “(iv) establish policies whereby any
14 individual who is an officer, employee, or
15 member of the Board of the Institute may
16 not personally or substantially participate
17 in the consideration or determination by
18 the Institute of any matter that would di-
19 rectly or predictably affect any financial
20 interest of the individual or a relative (as
21 such term is defined in section 109(16) of
22 the Ethics in Government Act of 1978) of
23 the individual, of any business organization
24 or other entity, or of which the individual
25 is an officer or employee or is negotiating

1 for employment, or in which the individual
2 has any other financial interest;

3 “(v) establish licensing, distribution,
4 and publication policies that support the
5 widest and least restrictive use by the pub-
6 lic of information and inventions developed
7 by the Institute or with Institute funds to
8 carry out the duties described in para-
9 graphs (6) and (7) of subsection (c);

10 “(vi) specify principles for the review
11 of proposals and awarding of grants and
12 contracts that include peer review and that
13 are substantially consistent with those of
14 the Foundation for the National Institutes
15 of Health;

16 “(vii) specify a process for annual
17 Board review of the operations of the Insti-
18 tute; and

19 “(viii) establish specific duties of the
20 Executive Director;

21 “(B) prioritize and provide overall direc-
22 tion to the activities of the Institute;

23 “(C) evaluate the performance of the Exec-
24 utive Director; and

1 “(D) carry out any other necessary activi-
2 ties regarding the functioning of the Institute.

3 “(3) ADDITIONAL BOARD FUNCTIONS.—The
4 Board may coordinate and collaborate with other en-
5 tities to conduct research, education, and outreach,
6 and to modernize the sciences of developing, manu-
7 facturing, and evaluating the safety and effective-
8 ness of diagnostics, devices, biologics, and drugs.

9 “(4) TERMS AND VACANCIES.—

10 “(A) TERM.—The term of office of each
11 member of the Board appointed under para-
12 graph (1)(C) shall be 4 years, except that the
13 terms of offices for the initial appointed mem-
14 bers of the Board shall expire on a staggered
15 basis as determined by the ex officio members.

16 “(B) VACANCY.—Any vacancy in the mem-
17 bership of the Board—

18 “(i) shall not affect the power of the
19 remaining members to execute the duties
20 of the Board; and

21 “(ii) shall be filled by appointment by
22 the individuals described in clauses (i)
23 through (v) of paragraph (1)(B) by major-
24 ity vote.

1 “(C) PARTIAL TERM.—If a member of the
2 Board does not serve the full term applicable
3 under subparagraph (A), the individual ap-
4 pointed under subparagraph (B) to fill the re-
5 sulting vacancy shall be appointed for the re-
6 mainder of the term of the predecessor of the
7 individual.

8 “(D) SERVING PAST TERM.—A member of
9 the Board may continue to serve after the expi-
10 ration of the term of the member until a suc-
11 cessor is appointed.

12 “(5) COMPENSATION.—Members of the Board
13 may not receive compensation for service on the
14 Board. Such members may be reimbursed for travel,
15 subsistence, and other necessary expenses incurred
16 in carrying out the duties of the Board, as set forth
17 in the bylaws issued by the Board.

18 “(e) INCORPORATION.—The ex officio members of the
19 Board shall serve as incorporators and shall take whatever
20 actions necessary to incorporate the Institute.

21 “(f) NONPROFIT STATUS.—The Institute shall be
22 considered to be a corporation under section 501(c) of the
23 Internal Revenue Code of 1986, and shall be subject to
24 the provisions of such section.

25 “(g) EXECUTIVE DIRECTOR.—

1 “(1) IN GENERAL.—The Board shall appoint an
2 Executive Director who shall serve at the pleasure of
3 the Board. The Executive Director shall be respon-
4 sible for the day-to-day operations of the Institute
5 and shall have such specific duties and responsibil-
6 ities as the Board shall prescribe.

7 “(2) COMPENSATION.—The compensation of
8 the Executive Director shall be fixed by the Board
9 but shall not be greater than the compensation of
10 the Commissioner of Food and Drugs.

11 “(h) ADMINISTRATIVE POWERS.—In carrying out
12 this subchapter, the Board, acting through the Executive
13 Director, may—

14 “(1) adopt, alter, and use a corporate seal,
15 which shall be judicially noticed;

16 “(2) hire, promote, compensate, and discharge
17 1 or more officers, employees, and agents, as may be
18 necessary, and define their duties;

19 “(3) prescribe the manner in which—

20 “(A) real or personal property of the Insti-
21 tute is acquired, held, and transferred;

22 “(B) general operations of the Institute
23 are to be conducted; and

24 “(C) the privileges granted to the Board
25 by law are exercised and enjoyed;

1 “(4) with the consent of the applicable executive
2 department or independent agency, use the informa-
3 tion, services, and facilities of such department or
4 agencies in carrying out this section;

5 “(5) enter into contracts with public and pri-
6 vate organizations for the writing, editing, printing,
7 and publishing of books and other material;

8 “(6) hold, administer, invest, and spend any
9 gift, devise, or bequest of real or personal property
10 made to the Institute under subsection (i);

11 “(7) enter into such other contracts, leases, co-
12 operative agreements, and other transactions as the
13 Board considers appropriate to conduct the activities
14 of the Institute;

15 “(8) modify or consent to the modification of
16 any contract or agreement to which it is a party or
17 in which it has an interest under this subchapter;

18 “(9) take such action as may be necessary to
19 obtain patents and licenses for devices and proce-
20 dures developed by the Institute and its employees;

21 “(10) sue and be sued in its corporate name,
22 and complain and defend in courts of competent ju-
23 risdiction;

1 “(11) appoint other groups of advisors as may
2 be determined necessary to carry out the functions
3 of the Institute; and

4 “(12) exercise other powers as set forth in this
5 section, and such other incidental powers as are nec-
6 essary to carry out its powers, duties, and functions
7 in accordance with this subchapter.

8 “(i) ACCEPTANCE OF FUNDS FROM OTHER
9 SOURCES.—The Executive Director may solicit and accept
10 on behalf of the Institute, any funds, gifts, grants, devises,
11 or bequests of real or personal property made to the Insti-
12 tute, including from private entities, for the purposes of
13 carrying out the duties of the Institute.

14 “(j) SERVICE OF FEDERAL EMPLOYEES.—Federal
15 Government employees may serve on committees advisory
16 to the Institute and otherwise cooperate with and assist
17 the Institute in carrying out its functions, so long as such
18 employees do not direct or control Institute activities.

19 “(k) DETAIL OF GOVERNMENT EMPLOYEES.—Fed-
20 eral Government employees may be detailed from Federal
21 agencies with or without reimbursement to those agencies
22 to the Institute at any time, and such detail shall be with-
23 out interruption or loss of civil service status or privilege.
24 Each such employee shall abide by the statutory, regu-
25 latory, ethical, and procedural standards applicable to the

1 employees of the agency from which such employee is de-
2 tailed and those of the Institute.

3 “(1) ANNUAL REPORTS.—

4 “(1) REPORTS TO INSTITUTE.—Any recipient of
5 a grant, contract, or cooperative agreement from the
6 Institute under this section shall submit to the Insti-
7 tute a report on an annual basis for the duration of
8 such grant, contract, or cooperative agreement, that
9 describes the activities carried out under such grant,
10 contract, or cooperative agreement.

11 “(2) REPORT TO FDA.—Beginning with fiscal
12 year 2009, the Executive Director shall submit to
13 the Commissioner an annual report that—

14 “(A) details the progress of the Institute in
15 furthering the goals and priorities established
16 under subsection (c)(2); and

17 “(B) provides recommendations for incor-
18 porating such progress into regulatory and
19 product review activities of the Food and Drug
20 Administration.

21 “(3) REPORT TO CONGRESS.—Beginning with
22 fiscal year 2009, the Executive Director shall submit
23 to the Committee on Health, Education, Labor, and
24 Pensions and the Committee on Appropriations of
25 the Senate and the Committee on Energy and Com-

1 merce and the Committee on Appropriations of the
2 House of Representatives an annual report that—

3 “(A) describes the activities of the Insti-
4 tute and of the recipients of a grant, contract,
5 or cooperative agreement under this section, in-
6 cluding the practical impact of the Institute on
7 medical product development;

8 “(B) provides a specific accounting of the
9 source of all funds used by the Institute to
10 carry out such activities; and

11 “(C) describes how such funds were used
12 by the Institute.

13 “(m) SEPARATION OF FUNDS.—The Executive Di-
14 rector shall ensure that the funds received from the Treas-
15 ury are held in separate accounts from funds received
16 from entities under subsection (i).

17 “(n) AUTHORIZATION OF APPROPRIATIONS.—There
18 are authorized to be appropriated such sums as may be
19 necessary for each of fiscal years 2008 through 2013 to
20 carry out subsections (a), (b), and (d) through (m).”.

21 (b) OTHER INSTITUTE PROVISIONS.—Chapter VII
22 (21 U.S.C. 371 et seq.) (as amended by subsection (a))
23 is amended by adding at the end the following:

1 **“SEC. 771. LOCATION OF INSTITUTE.**

2 “(a) IN GENERAL.—The Institute shall, if prac-
3 ticable, be located not more than 20 miles from the Dis-
4 trict of Columbia.

5 “(b) USE OF SPACE.—The Secretary shall consult
6 with the Administrator of General Services to ensure the
7 most cost-efficient arrangement for the leasing or pur-
8 chase of real property for adequate facilities which, if
9 practicable, shall be located at the Food and Drug Admin-
10 istration, to meet the needs of the Institute in carrying
11 out this subchapter.

12 **“SEC. 772. ACTIVITIES OF THE FOOD AND DRUG ADMINIS-**
13 **TRATION.**

14 “(a) IN GENERAL.—The Commissioner shall receive
15 and assess the report submitted to the Commissioner by
16 the Executive Director of the Institute under section
17 770(1)(2).

18 “(b) REPORT TO CONGRESS.—The Commissioner
19 shall submit to the Committee on Health, Education,
20 Labor, and Pensions and the Committee on Appropria-
21 tions of the Senate and the Committee on Energy and
22 Commerce and the Committee on Appropriations of the
23 House of Representatives an annual report that describes
24 the implementation of any recommendations included in
25 the report described under subsection (a).”.

1 **TITLE III—CLINICAL TRIALS**

2 **SEC. 301. CLINICAL TRIAL REGISTRY DATABASE AND CLIN-**
3 **ICAL TRIAL RESULTS DATABASE.**

4 (a) IN GENERAL.—Subsection (i) of section 402 of
5 the Public Health Service Act (42 U.S.C. 282), as amend-
6 ed by Public Law 109–482, is amended to read as follows:

7 “(i) CLINICAL TRIAL REGISTRY DATABASE; CLIN-
8 ICAL TRIAL RESULTS DATABASE.—

9 “(1) DEFINITIONS.—In this subsection:

10 “(A) APPLICABLE CLINICAL TRIAL.—The
11 term ‘applicable clinical trial’—

12 “(i) means a clinical trial that is con-
13 ducted to test the safety or effectiveness
14 (including comparative effectiveness) of a
15 drug or device (irrespective of whether the
16 clinical trial is federally or privately fund-
17 ed, and whether the clinical trial involves
18 an approved or unapproved drug or de-
19 vice);

20 “(ii) includes such a clinical trial that
21 is conducted outside of the United States
22 if—

23 “(I) there is an application or
24 premarket notification pending before
25 the Food and Drug Administration

1 for approval or clearance of the drug
2 or device involved under section 505,
3 510(k), or 515 of the Federal Food,
4 Drug, and Cosmetic Act or section
5 351 of this Act; or

6 “(II) the drug or device involved
7 is so approved or cleared; and

8 “(iii) notwithstanding subclauses (I)
9 and (II), excludes—

10 “(I) a clinical trial to determine
11 the safety of a use of a drug that is
12 designed solely to detect major
13 toxicities in the drug or to investigate
14 pharmacokinetics, unless the clinical
15 trial is designed to investigate phar-
16 macokinetics in a special population
17 or populations; and

18 “(II) a small clinical trial to de-
19 termine the feasibility of a device, or
20 a clinical trial to test prototype de-
21 vices where the primary focus is feasi-
22 bility.

23 “(B) CLINICAL TRIAL INFORMATION.—The
24 term ‘clinical trial information’ means those
25 data elements that are necessary to complete an

1 entry in the clinical trial registry database
2 under paragraph (2) or the clinical trial results
3 database under paragraph (3), as applicable.

4 “(C) COMPLETION DATE.—The term ‘com-
5 pletion date’ means the date of the final collec-
6 tion of data from subjects in the clinical trial
7 for the primary and secondary outcomes to be
8 examined in the trial.

9 “(D) DEVICE.—The term ‘device’ has the
10 meaning given to that term in section 201(h) of
11 the Federal Food, Drug, and Cosmetic Act.

12 “(E) DRUG.—The term ‘drug’ means a
13 drug as defined in section 201(g) of the Federal
14 Food, Drug, and Cosmetic Act or a biological
15 product as defined in section 351 of this Act.

16 “(F) RESPONSIBLE PARTY.—The term ‘re-
17 sponsible party’, with respect to an applicable
18 clinical trial, means—

19 “(i) the primary sponsor (as defined
20 in the International Clinical Trials Reg-
21 istry Platform trial registration data set of
22 the World Health Organization) of the
23 clinical trial; or

24 “(ii) the principal investigator of such
25 clinical trial if so designated by such spon-

1 sor, so long as the principal investigator is
2 responsible for conducting the trial, has ac-
3 cess to and control over the data, has the
4 right to publish the results of the trial, and
5 has the responsibility to meet all of the re-
6 quirements under this section that are ap-
7 plicable to responsible parties.

8 “(2) CLINICAL TRIALS REGISTRY DATABASE.—

9 “(A) ESTABLISHMENT.—To enhance pa-
10 tient enrollment and provide a mechanism to
11 track subsequent progress of clinical trials, the
12 Secretary, acting through the Director of NIH,
13 shall establish and administer a clinical trial
14 registry database in accordance with this sub-
15 section (referred to in this subsection as the
16 ‘registry database’). The Director of NIH shall
17 ensure that the registry database is made pub-
18 licly available through the Internet.

19 “(B) CONTENT.—The Secretary shall pro-
20 mulgate regulations for the submission to the
21 registry database of clinical trial information
22 that—

23 “(i) conforms to the International
24 Clinical Trials Registry Platform trial reg-

1 istration data set of the World Health Or-
2 ganization;

3 “ (ii) includes the city, State, and zip
4 code for each clinical trial location;

5 “ (iii) includes a statement of the esti-
6 mated completion date for the clinical trial;

7 “ (iv) includes the identity and contact
8 information of the responsible party;

9 “ (v) if the drug is not approved under
10 section 505 of the Federal Food, Drug,
11 and Cosmetic Act or licensed under section
12 351 of this Act, or the device is not cleared
13 under section 510(k) or approved under
14 section 515 of the Federal Food, Drug,
15 and Cosmetic Act, specifies whether or not
16 there is expanded access to the drug or de-
17 vice under section 561 of the Federal
18 Food, Drug, and Cosmetic Act for those
19 who do not qualify for enrollment in the
20 clinical trial and how to obtain information
21 about such access;

22 “ (vi) includes, with respect to any in-
23 dividual who is not an employee of the re-
24 sponsible party for the clinical trial or of
25 the manufacturer of the drug or device in-

1 involved, information on any agreement that
2 the responsible party or manufacturer has
3 entered into with such individual that re-
4 stricts in any manner the ability of the in-
5 dividual—

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

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

13 “(vii) requires the inclusion of such
14 other data elements to the registry data-
15 base as appropriate.

16 “(C) FORMAT AND STRUCTURE.—

17 “(i) SEARCHABLE CATEGORIES.—The
18 Director of NIH shall ensure that the pub-
19 lic may search the entries in the registry
20 database by 1 or more of the following cri-
21 teria:

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

1 “(II) The safety issue being stud-
2 ied in the clinical trial.

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

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

7 “(ii) **FORMAT.**—The Director of the
8 NIH shall ensure that the registry data-
9 base is easily used by patients, and that
10 entries are easily compared.

11 “(D) **DATA SUBMISSION.**—The responsible
12 party for an applicable clinical trial shall submit
13 to the Director of NIH for inclusion in the reg-
14 istry database the clinical trial information de-
15 scribed in subparagraph (B).

16 “(E) **TRUTHFUL CLINICAL TRIAL INFOR-**
17 **MATION.**—

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

22 “(ii) **EFFECT.**—Clause (i) shall not
23 have the effect of requiring clinical trial in-
24 formation to include information from any
25 source other than the clinical trial involved.

1 “(F) TIMING OF SUBMISSION.—Except as
2 provided in subparagraph (G), the clinical trial
3 information for a clinical trial required to be
4 submitted under this paragraph shall be sub-
5 mitted not later than 14 days after the first pa-
6 tient is enrolled in such clinical trial.

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

13 “(i) shall be provided not less than
14 once every six months until information on
15 the results of the trial is submitted under
16 paragraph (3);

17 “(ii) shall include identification of the
18 dates of any such changes;

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

23 “(iv) not later than 30 days after the
24 completion date of the clinical trial, shall

1 include a report to the Director that such
2 clinical trial is complete.

3 “(3) CLINICAL TRIALS RESULTS DATABASE.—

4 “(A) ESTABLISHMENT.—To ensure that
5 results of clinical trials are made public and
6 that patients and providers have current infor-
7 mation regarding the results of clinical trials,
8 the Secretary, acting through the Director of
9 NIH, shall establish and administer a clinical
10 trial results database in accordance with this
11 subsection (referred to in this subsection as the
12 ‘results database’).

13 “(B) SEARCHABLE CATEGORIES.—The Di-
14 rector of NIH shall ensure that the public may
15 search the entries in the results database by 1
16 or more of the following:

17 “(i) The indication studied in the clin-
18 ical trial, using Medical Subject Headers
19 (MeSH) descriptors.

20 “(ii) The safety issue studied in the
21 clinical trial.

22 “(iii) Whether an application for the
23 tested indication is approved, pending ap-
24 proval, withdrawn, or not submitted.

25 “(iv) The phase of the clinical trial.

1 “(v) The name of the drug or device
2 that is the subject of the clinical trial.

3 “(vi) Within the documents described
4 in subclauses (II) and (III) of subpara-
5 graph (C)(ii), the following information, as
6 applicable:

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

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

11 “(C) CONTENTS.—

12 “(i) IN GENERAL.—The responsible
13 party for an applicable clinical trial shall
14 submit to the Director of NIH for inclu-
15 sion in the results database the clinical
16 trial information described in clause (ii).

17 “(ii) REQUIRED ELEMENTS.—In sub-
18 mitting clinical trial information for a clin-
19 ical trial to the Director of NIH for inclu-
20 sion in the results database, the respon-
21 sible party shall include, with respect to
22 such clinical trial, the following informa-
23 tion:

1 “(I) The information described in
2 clauses (i) through (v) of subpara-
3 graph (B).

4 “(II) A non-promotional sum-
5 mary document that is written in non-
6 technical, understandable language for
7 patients that includes the following:

8 “(aa) The purpose of the
9 clinical trial.

10 “(bb) The sponsor of the
11 clinical trial.

12 “(cc) A point of contact for
13 information about the clinical
14 trial.

15 “(dd) A description of the
16 patient population tested in the
17 clinical trial.

18 “(ee) A general description
19 of the clinical trial and results,
20 including a description of and the
21 reasons for any changes in the
22 clinical trial design that occurred
23 since the date of submission of
24 clinical trial information for in-
25 clusion in the registry database

1 established under paragraph (2)
2 and a description of any signifi-
3 cant safety information.

4 “(III) A non-promotional sum-
5 mary document that is technical in
6 nature that includes the following:

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

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

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

13 “(dd) A point of contact for
14 scientific information about the
15 clinical trial.

16 “(ee) A description of the
17 patient population tested in the
18 clinical trial.

19 “(ff) A general description
20 of the clinical trial and results,
21 including a description of and the
22 reasons for any changes in the
23 clinical trial design that occurred
24 since the date of submission of
25 clinical trial information for the

1 clinical trial in the registry data-
2 base established under paragraph
3 (2).

4 “(gg) Summary data de-
5 scribing the results, including—

6 “(AA) whether the pri-
7 mary endpoint was achieved,
8 including relevant statistics;

9 “(BB) an assessment of
10 any secondary endpoints, if
11 applicable, including relevant
12 statistics; and

13 “(CC) any significant
14 safety information, including
15 a summary of the incidence
16 of serious adverse events ob-
17 served in the clinical trial
18 and a summary of the most
19 common adverse events ob-
20 served in the clinical trial
21 and the frequencies of such
22 events.

23 “(IV) With respect to the group
24 of subjects receiving the drug or de-
25 vice involved, and each comparison

1 group of subjects, the percentage of
2 individuals who ceased participation
3 as subjects and their reasons for ceas-
4 ing participation.

5 “(V) With respect to an indi-
6 vidual who is not an employee of the
7 responsible party for the clinical trial
8 or of the manufacturer of the drug or
9 device involved, information (to the
10 extent not submitted under paragraph
11 (2)(B)(vi)) on any agreement that the
12 responsible party or manufacturer has
13 entered into with such individual that
14 restricts in any manner the ability of
15 the individual—

16 “(aa) to discuss the results
17 of the trial at a scientific meeting
18 or any other public or private
19 forum; or

20 “(bb) to publish the results
21 of the trial, or a description or
22 discussion of the results of the
23 trial, in a scientific or academic
24 journal.

1 “(VI) A link to available peer-re-
2 viewed publications based on the re-
3 sults of the clinical trial.

4 “(VII) The completion date of
5 the clinical trial.

6 “(VIII) A link to the Internet
7 web posting of any adverse regulatory
8 actions taken by the Food and Drug
9 Administration, such as a warning let-
10 ter, that was substantively based on
11 the clinical trial design, outcome, or
12 representation made by the applicant
13 about the design or outcome of the
14 clinical trial.

15 “(D) TIMING.—

16 “(i) IN GENERAL.—Except as pro-
17 vided in clauses (ii) and (iii), a responsible
18 party shall submit to the Director of NIH
19 for inclusion in the results database clin-
20 ical trial information for an applicable clin-
21 ical trial not later than 1 year after the
22 earlier of—

23 “(I) the estimated completion
24 date of the trial, as submitted under
25 paragraph (2)(B); or

1 “(II) the actual date of the com-
2 pletion, or termination before comple-
3 tion, of the trial, as applicable.

4 “(ii) EXTENSIONS.—The Director of
5 NIH may provide an extension of the
6 deadline for submission of clinical trial in-
7 formation under clause (i) if the respon-
8 sible party for the trial submits to the Di-
9 rector a written request that demonstrates
10 good cause for the extension and provides
11 an estimate of the date on which the infor-
12 mation will be submitted. The Director of
13 NIH may grant more than one such exten-
14 sion for the clinical trial involved.

15 “(iii) UPDATES.—The responsible
16 party for an applicable clinical trial shall
17 submit to the Director of NIH for inclu-
18 sion in the results database periodic up-
19 dates to reflect changes in the clinical trial
20 information submitted under this para-
21 graph. Such updates—

22 “(I) shall be provided not less
23 frequently than once every six months
24 during the 10-year period beginning

1 on the date on which information is
2 due under clause (i); and

3 “(II) shall identify the dates on
4 which the changes were made; and

5 “(III) shall include, not later
6 than 30 days after any change in the
7 regulatory status of the drug or device
8 involved, an update informing the Di-
9 rector of NIH of such change.

10 “(E) TRUTHFUL CLINICAL TRIAL INFOR-
11 MATION.—

12 “(i) IN GENERAL.—The clinical trial
13 information submitted by a responsible
14 party under this paragraph shall not be
15 false or misleading in any particular.

16 “(ii) EFFECT.—Clause (i) shall not
17 have the effect of requiring clinical trial in-
18 formation with respect to a clinical trial to
19 include information from any source other
20 than such clinical trial.

21 “(F) PUBLIC AVAILABILITY OF RE-
22 SULTS.—

23 “(i) PRE-APPROVAL STUDIES.—Ex-
24 cept as provided in clause (v), with respect
25 to an applicable clinical trial that is com-

1 pleted before the drug is initially approved
2 under section 505 of the Federal Food,
3 Drug, and Cosmetic Act or initially li-
4 censed under section 351 of this Act, or
5 the device is initially cleared under section
6 510(k) or approved under section 515 of
7 the Federal Food, Drug, and Cosmetic
8 Act, the Director of NIH shall make pub-
9 licly available on the results database the
10 clinical trial information submitted for
11 such clinical trial not later than 30 days
12 after—

13 “(I) the drug or device is ap-
14 proved under such section 505, li-
15 censed under such section 351,
16 cleared under such section 510(k), or
17 approved under such section 515, as
18 applicable; or

19 “(II) the Secretary issues a not
20 approvable letter or a not substan-
21 tially equivalent letter for the drug or
22 device under such section 505, 351,
23 510(k), or 515, as applicable.

24 “(ii) MEDICAL AND CLINICAL PHAR-
25 MACOLOGY REVIEWS OF PRE-APPROVAL

1 STUDIES.—Not later than 90 days after
2 the date applicable under subclause (I) or
3 (II) of clause (i) with respect to an appli-
4 cable clinical trial, the Director of NIH
5 shall make publicly available on the results
6 database a summary of the available med-
7 ical and clinical pharmacology reviews con-
8 ducted by the Food and Drug Administra-
9 tion for such trial.

10 “(iii) POST-APPROVAL STUDIES.—EX-
11 cept as provided in clauses (iv) and (v),
12 with respect to an applicable clinical trial
13 that is completed after the drug is initially
14 approved under such section 505 or li-
15 censed under such section 351, or the de-
16 vice is initially cleared under such section
17 510(k) or approved under such section
18 515, the Director of NIH shall make pub-
19 licly available on the results database the
20 clinical trial information submitted for
21 such clinical trial not later than 30 days
22 after the date of such submission.

23 “(iv) SEEKING APPROVAL OF A NEW
24 USE FOR THE DRUG OR DEVICE.—

1 “(I) IN GENERAL.—If the manu-
2 facturer of the drug or device is the
3 sponsor or a financial sponsor of an
4 applicable clinical trial, and such man-
5 ufacturer certifies to the Director of
6 NIH that such manufacturer has
7 filed, or will file within 1 year, an ap-
8 plication seeking approval under such
9 section 505, licensing under such sec-
10 tion 351, clearance under such section
11 510(k), or approval under such sec-
12 tion 515 for the use studied in such
13 clinical trial (which use is not included
14 in the labeling of the approved drug
15 or device), then the Director of NIH
16 shall make publicly available on the
17 results database the clinical trial in-
18 formation submitted for such clinical
19 trial on the earlier of the date that is
20 30 days after the date—

21 “(aa) the new use of the
22 drug or device is approved under
23 such section 505, licensed under
24 such section 351, cleared under

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

3 “(bb) the Secretary issues a
4 not approvable letter or a not
5 substantially equivalent letter for
6 the new use of the drug or device
7 under such section 505, 351,
8 510(k), or 515; or

9 “(cc) the application or pre-
10 market notification under such
11 section 505, 351, 510(k), or 515
12 is withdrawn.

13 “(II) LIMITATION ON CERTIFI-
14 CATION.—If a manufacturer makes a
15 certification under subclause (I) with
16 respect to a clinical trial, the manu-
17 facturer shall make such a certifi-
18 cation with respect to each applicable
19 clinical trial that is required to be
20 submitted in an application for ap-
21 proval of the use studied in the clin-
22 ical trial.

23 “(III) 2-YEAR LIMITATION.—The
24 clinical trial information subject to
25 subclause (I) shall be made publicly

1 available on the results database on
2 the date that is 2 years after the date
3 the certification referred to in sub-
4 clause (I) was made to the Director of
5 NIH, if a regulatory action referred to
6 in item (aa), (bb), or (cc) of subclause
7 (I) has not occurred by such date.

8 “(IV) MEDICAL AND CLINICAL
9 PHARMACOLOGY REVIEWS.—Not later
10 than 90 days after the date applicable
11 under item (aa), (bb), or (cc) of sub-
12 clause (I) or subclause (III) with re-
13 spect to an applicable clinical trial,
14 the Director of NIH shall make pub-
15 licly available on the results database
16 a summary of the available medical
17 and clinical pharmacology reviews
18 conducted by the Food and Drug Ad-
19 ministration for such trial.

20 “(v) SEEKING PUBLICATION.—

21 “(I) IN GENERAL.—If the prin-
22 cipal investigator of an applicable clin-
23 ical trial is seeking publication in a
24 peer-reviewed biomedical journal of a
25 manuscript based on the results of the

1 clinical trial and the responsible party
2 so certifies to the Director of NIH—

3 “(aa) the responsible party
4 shall notify the Director of NIH
5 of the publication date of such
6 manuscript not later than 15
7 days after such date; and

8 “(bb) the Director of NIH
9 shall make publicly available on
10 the results database the clinical
11 trial information submitted for
12 such clinical trial on the date
13 that is 30 days after the publica-
14 tion date of such manuscript.

15 “(II) LIMITATIONS.—The clinical
16 trial information subject to subclause
17 (I)—

18 “(aa) shall be made publicly
19 available on the results database
20 on the date that is 2 years after
21 the date that the clinical trial in-
22 formation was required to be
23 submitted to the Director of NIH
24 if the manuscript referred to in

1 such subclause has not been pub-
2 lished by such date; and

3 “(bb) shall not be required
4 to be made publicly available
5 under section 552 of title 5,
6 United States Code (commonly
7 known as the ‘Freedom of Infor-
8 mation Act’), prior to the date
9 applicable to such clinical trial
10 information under this clause.

11 “(G) VERIFICATION OF SUBMISSION PRIOR
12 TO PUBLIC AVAILABILITY.—In the case of clin-
13 ical trial information that is submitted under
14 this paragraph, but is not made publicly avail-
15 able pending either regulatory action or publica-
16 tion under clause (iv) or (v) of subparagraph
17 (F), as applicable, the Director of NIH shall re-
18 spond to inquiries from other Federal agencies
19 and peer-reviewed journals to confirm that such
20 clinical trial information has been submitted
21 but has not yet been made publicly available on
22 the results database.

23 “(4) UPDATES; TRACKING OF CHANGES IN SUB-
24 MITTED INFORMATION.—The Director of NIH shall
25 ensure that updates submitted to the Director under

1 paragraphs (2)(G) and (3)(D) do not result in the
2 removal from the registry database or the results
3 database of the original submissions or of any pre-
4 ceding updates, and that information in such data-
5 bases is presented in a manner that enables users to
6 readily access each original submission and to track
7 the changes made by the updates.

8 “(5) COORDINATION AND COMPLIANCE.—

9 “(A) CLINICAL TRIALS SUPPORTED BY
10 GRANTS FROM FEDERAL AGENCIES.—

11 “(i) IN GENERAL.—No Federal agen-
12 cy may release funds under a research
13 grant to a person who has not complied
14 with paragraphs (2) and (3) for any appli-
15 cable clinical trial for which such person is
16 the responsible party.

17 “(ii) GRANTS FROM CERTAIN FED-
18 ERAL AGENCIES.—If an applicable clinical
19 trial is funded in whole or in part by a
20 grant from the National Institutes of
21 Health, the Agency for Healthcare Re-
22 search and Quality, or the Department of
23 Veterans Affairs, any grant or progress re-
24 port forms required under such grant shall
25 include a certification that the responsible

1 party has made all required submissions to
2 the Director of NIH under paragraphs (2)
3 and (3).

4 “(iii) VERIFICATION BY FEDERAL
5 AGENCIES.—The heads of the agencies re-
6 ferred to in clause (ii), as applicable, shall
7 verify that the clinical trial information for
8 each applicable clinical trial for which a
9 grantee is the responsible party has been
10 submitted under paragraph (2) and (3), as
11 applicable, before releasing funding for a
12 grant to such grantee.

13 “(iv) NOTICE AND OPPORTUNITY TO
14 REMEDY.—If the head of an agency re-
15 ferred to in clause (ii), as applicable,
16 verifies that a grantee has not submitted
17 clinical trial information as described in
18 clause (iii), such agency head shall provide
19 notice to such grantee of such noncompli-
20 ance and allow such grantee 30 days to
21 correct such noncompliance and submit the
22 required clinical trial information.

23 “(v) CONSULTATION WITH OTHER
24 FEDERAL AGENCIES.—The Secretary
25 shall—

1 “(I) consult with other agencies
2 that conduct human studies in accord-
3 ance with part 46 of title 45, Code of
4 Federal Regulations (or any successor
5 regulations), to determine if any such
6 studies are applicable clinical trials;
7 and

8 “(II) develop with such agencies
9 procedures comparable to those de-
10 scribed in clauses (ii), (iii), and (iv) to
11 ensure that clinical trial information
12 for such applicable clinical trials is
13 submitted under paragraphs (2) and
14 (3).

15 “(B) COORDINATION OF REGISTRY DATA-
16 BASE AND RESULTS DATABASE.—

17 “(i) IN GENERAL.—Each entry in the
18 registry database under paragraph (2) or
19 the results database under paragraph (3)
20 shall include a link to the corresponding
21 entry in the results database or the reg-
22 istry database, respectively.

23 “(ii) MISSING ENTRIES.—

24 “(I) IN GENERAL.—If, based on
25 a review of the entries in the registry

1 database under paragraph (2), the Di-
2 rector of NIH determines that a re-
3 sponsible party has failed to submit
4 required clinical trial information to
5 the results database under paragraph
6 (3), the Director of NIH shall inform
7 the responsible party involved of such
8 failure and permit the responsible
9 party to correct the failure within 30
10 days.

11 “(II) FAILURE TO CORRECT.—If
12 the responsible party does not correct
13 a failure to submit required clinical
14 trial information within the 30-day
15 period described under subclause (I),
16 the Director of NIH shall report such
17 noncompliance to the scientific peer
18 review committees of the Federal re-
19 search agencies and to the Office of
20 Human Research Protections.

21 “(III) PUBLIC NOTICE OF FAIL-
22 URE TO CORRECT.—The Director of
23 NIH shall include in the clinical trial
24 registry database entry and the clin-
25 ical trial results database entry for

1 each applicable clinical trial a notice
2 of any uncorrected failure to submit
3 required clinical trial information and
4 shall provide that the public may eas-
5 ily search for such entries.

6 “(C) ACTION ON APPLICATIONS.—

7 “(i) VERIFICATION PRIOR TO FIL-
8 ING.—The Secretary, acting through the
9 Commissioner of Food and Drugs, shall
10 verify that the clinical trial information re-
11 quired under paragraphs (2) and (3) for
12 an applicable clinical trial is submitted
13 pursuant to such paragraphs, as applica-
14 ble—

15 “(I) when considering a drug or
16 device for an exemption under section
17 505(i) or section 520(g) of the Fed-
18 eral Food, Drug, and Cosmetic Act;
19 and

20 “(II) prior to filing an applica-
21 tion or premarket notification under
22 section 505, 510(k), or 515 of the
23 Federal Food, Drug, and Cosmetic
24 Act or section 351 of this Act, that

1 includes information from such clin-
2 ical trial.

3 “(ii) NOTIFICATION.—If the Secretary
4 determines under clause (i) that clinical
5 trial information has not been submitted
6 as required by paragraph (2) or (3), the
7 Secretary shall notify the applicant and the
8 responsible party of such noncompliance
9 and require submission of such information
10 within 30 days.

11 “(iii) REFUSAL TO FILE.—If the re-
12 sponsible party does not remedy such non-
13 compliance within 30 days of receipt of no-
14 tification under clause (ii), the Secretary
15 shall refuse to file, approve, or clear such
16 application or premarket notification.

17 “(D) CONTENT REVIEW.—

18 “(i) IN GENERAL.—To ensure that
19 the summary documents described in para-
20 graph (3)(C) are non-promotional, and are
21 not false or misleading in any particular
22 under paragraph (3)(E), the Secretary
23 shall compare such documents to the re-
24 sults data of the clinical trial for a rep-

1 representative sample of applicable clinical
2 trials by—

3 “(I) acting through the Commis-
4 sioner of Food and Drugs to examine
5 the results data for such clinical trials
6 submitted to Secretary when such
7 data are submitted—

8 “(aa) for review as part of
9 an application under section 505
10 or 515 of the Federal Food,
11 Drug, and Cosmetic Act or under
12 section 351 of this Act or a pre-
13 market notification under section
14 510(k) of the Federal Food,
15 Drug, and Cosmetic Act; or

16 “(bb) in an annual status
17 report on the drug or device
18 under such application;

19 “(II) acting with the Federal
20 agency that funds such clinical trial in
21 whole or in part by a grant to exam-
22 ine the results data for such clinical
23 trials; and

24 “(III) acting through inspections
25 under section 704 of the Federal

1 Food, Drug, and Cosmetic Act to ex-
2 amine results data for such clinical
3 trials not described in subclause (I) or
4 (II).

5 “(ii) NOTICE OF NONCOMPLIANCE.—

6 If the Secretary determines that the clin-
7 ical trial information submitted in such a
8 summary document is promotional, or false
9 or misleading in any particular, the Sec-
10 retary shall notify the responsible party
11 and give such party an opportunity to rem-
12 edy such noncompliance by submitting the
13 required revised clinical trial information
14 within 30 days of such notification.

15 “(6) PENALTIES FOR NONCOMPLIANCE.—

16 “(A) IN GENERAL.—The following acts
17 and the causing thereof are deemed to be pro-
18 hibited by section 301 of the Federal Food,
19 Drug, and Cosmetic Act:

20 “(i) The failure to submit clinical trial
21 information as required by this section.

22 “(ii) The submission of clinical trial
23 information under this section that is pro-
24 motional or false or misleading in any par-

1 particular in violation of paragraph (2)(E) or
2 (3)(E).

3 “(B) CONSIDERATIONS.—In determining
4 whether to apply a penalty under the Federal
5 Food, Drug, and Cosmetic Act or under sub-
6 paragraph (C) of this paragraph for a violation
7 described in subparagraph (A), the Secretary,
8 acting through the Commissioner of Food and
9 Drugs, shall consider—

10 “(i) whether the responsible party
11 promptly corrects the noncompliance when
12 provided notice;

13 “(ii) whether the responsible party
14 has engaged in a pattern or practice of
15 noncompliance; and

16 “(iii) the extent to which the non-
17 compliance involved may have significantly
18 misled health care providers or patients
19 concerning the safety or effectiveness of
20 the drug involved.

21 “(C) CIVIL PENALTIES.—

22 “(i) IN GENERAL.—A person is sub-
23 ject to a civil penalty in accordance with
24 this subparagraph if the person commits a
25 violation described in subparagraph (A)

1 and fails to correct the violation by the end
2 of the 30-day period described in clause
3 (ii).

4 “(ii) NOTIFICATION.—If a person is
5 in violation of subparagraph (A), the Sec-
6 retary shall notify the person of such non-
7 compliance and give the person a 30-day
8 period to correct such violation before im-
9 posing a civil penalty under this subpara-
10 graph.

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

22 “(iv) PROCEDURES.—The provisions
23 of paragraphs (4) through (6) of section
24 303(f) of the Federal Food, Drug, and
25 Cosmetic Act apply to the imposition of a

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

5 “(7) AUTHORIZATION OF APPROPRIATIONS.—

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

8 (b) CONFORMING AMENDMENTS.—

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

12 (A) in paragraph (1)—

13 (i) in subparagraph (C), by striking

14 “and” after the semicolon;

15 (ii) in subparagraph (D)—

16 (I) by aligning the indentation of

17 such subparagraph with the indenta-

18 tion of subparagraphs (A), (B), and

19 (C); and

20 (II) by striking the period at the

21 end and inserting “; and”; and

22 (iii) by adding at the end the fol-

23 lowing:

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

1 at issue required under section 402(i) of the Public
2 Health Service Act for inclusion in the registry data-
3 base and the results database described in such sec-
4 tion.”;

5 (B) in paragraph (3)(B)—

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

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

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

12 “(iii) clinical trial information for the clinical
13 investigation at issue was not submitted in compli-
14 ance with section 402(i) of the Public Health Service
15 Act.”; and

16 (C) in paragraph (4), by adding at the end
17 the following: “The Secretary shall update such
18 regulations to require inclusion in the informed
19 consent form a statement that clinical trial in-
20 formation for such clinical investigation will be
21 submitted for inclusion in the registry database
22 and results database, as applicable, described in
23 section 402(i) of the Public Health Service
24 Act.”.

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

4 (A) in the first sentence, by inserting after
5 “or any particular;” the following: “or (8) the
6 applicant failed to submit the clinical trial in-
7 formation for any applicable clinical trial as re-
8 quired by section 402(i) of the Public Health
9 Service Act;”; and

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

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

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

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

21 “(iii) A requirement that the person
22 applying for an exemption for a device as-
23 sure that such person is in compliance with
24 the requirements of section 402(i) of the
25 Public Health Service Act for the submis-

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

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

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

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

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

13 “(3) action taken by such person to comply
14 with requirements under section 402(i) of the Public
15 Health Service Act for the submission of clinical
16 trial information for inclusion in the registry data-
17 base and the results database described in such sec-
18 tion.”.

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

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

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

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

4 “(F) the applicant is in violation of the re-
5 quirements under section 402(i) of the Public
6 Health Service Act for the submission of clin-
7 ical trial information for inclusion in the reg-
8 istry database or the results database described
9 in such section.”.

10 (c) GUIDANCE.—Not later than 180 days after the
11 date of enactment of this Act, the Commissioner of Food
12 and Drugs, in consultation with the Director of the Na-
13 tional Institutes of Health, shall issue guidance to clarify
14 which clinical trials are applicable clinical trials (as de-
15 fined in section 402(i)(2) of the Public Health Service Act,
16 as amended by this section) and required to be submitted
17 for inclusion in the clinical trial registry database de-
18 scribed in such section.

19 (d) PREEMPTION.—

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

1 (2) RULE OF CONSTRUCTION.—The fact of sub-
2 mission of clinical trial information, if submitted in
3 compliance with section 402(i) of the Public Health
4 Service Act (as amended by this section), that re-
5 lates to a use of a drug or device not included in the
6 official labeling of the approved drug or device shall
7 not be construed by the Secretary or in any adminis-
8 trative or judicial proceeding, as evidence of a new
9 intended use of the drug or device that is different
10 from the intended use of the drug or device set forth
11 in the official labeling of the drug or device. The
12 availability of clinical trial information through the
13 databases under paragraphs (2) and (3) of such sec-
14 tion 402(i), if submitted in compliance with such
15 section 402(i), shall not be considered as labeling,
16 adulteration, or misbranding of the drug or device
17 under the Federal Food, Drug, and Cosmetic Act
18 (21 U.S.C. 301 et seq.).

19 (e) EFFECTIVE DATES.—

20 (1) ESTABLISHMENT OF REGISTRY DATABASE
21 AND RESULTS DATABASE.—Not later than 1 year
22 after the date of enactment of this Act, the Director
23 of NIH shall establish the registry database and the
24 results database of clinical trials of drugs and de-

1 vices in accordance with section 402(i) of the Public
2 Health Service Act (as amended by subsection (a)).

3 (2) CLINICAL TRIALS INITIATED PRIOR TO OP-
4 ERATION OF REGISTRY DATABASE.—The responsible
5 party (as defined in such section 402(i)) for an ap-
6 plicable clinical trial (as defined in such section
7 402(i)) that is initiated after the date of enactment
8 of this Act and before the date such registry data-
9 base is established under paragraph (1) of this sub-
10 section, shall submit required clinical trial informa-
11 tion not later than 120 days after the date such reg-
12 istry database is established.

13 (3) CLINICAL TRIALS INITIATED AFTER OPER-
14 ATION OF REGISTRY DATABASE.—The responsible
15 party (as defined in such section 402(i)) for an ap-
16 plicable clinical trial (as defined in such section
17 402(i)) that is initiated after the date such registry
18 database is established under paragraph (1) of this
19 subsection shall submit required clinical trial infor-
20 mation in accordance with paragraph (2) of such
21 section 402(i).

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

24 (A) IN GENERAL.—Paragraph (3) of such
25 section 402(i) shall take effect 90 days after

1 the date the results database is established
2 under paragraph (1) of this subsection with re-
3 spect to any applicable clinical trial (as defined
4 in such section 402(i)) that—

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

7 (ii) is completed between the date of
8 enactment of this Act and such date of es-
9 tablishment under paragraph (1) of this
10 subsection.

11 (B) OTHER TRIALS.—Except as provided
12 in subparagraph (A), paragraph (3) of such
13 section 402(i) shall take effect 180 days after
14 the date that the results database is established
15 under paragraph (1) of this subsection with re-
16 spect to any applicable clinical trial that is com-
17 pleted between the date of enactment of this
18 Act and such date of establishment under para-
19 graph (1).

20 (5) TRIALS COMPLETED AFTER ESTABLISH-
21 MENT OF RESULTS DATABASE.—Paragraph (3) of
22 such section 402(i) shall apply to any clinical trial
23 that is completed after the date that the results
24 database is established under paragraph (1) of this
25 subsection.

1 (6) RETROACTIVITY OF DATABASE.—

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

7 (i) of clinical trial information for in-
8 clusion in the registry database (as defined
9 in such section 402(i)) on applicable clin-
10 ical trials (as defined in such section
11 402(i)) initiated before the date of the en-
12 actment of this Act; and

13 (ii) of clinical trial information for in-
14 clusion in the results database (as defined
15 in such section 402(i)) on applicable clin-
16 ical trials (as defined in such section
17 402(i)) completed before the date of the
18 enactment of this Act.

19 (B) REQUIRED SUBMISSIONS.—Notwith-
20 standing the preceding paragraphs of this sub-
21 section, in any case in which the Secretary de-
22 termines that submission of clinical trial infor-
23 mation for an applicable clinical trial (as de-
24 fined in such section 402(i)) described in clause

1 (i) or (ii) of subparagraph (A) is in the interest
2 of the public health—

3 (i) the Secretary may require that
4 such information be submitted to the Sec-
5 retary in accordance with such section
6 402(i); and

7 (ii) failure to comply with such a re-
8 quirement shall be treated as a violation of
9 the corresponding requirement of such sec-
10 tion 402(i).

11 (7) FUNDING RESTRICTIONS.—Subparagraph
12 (A) of paragraph (5) of such section 402(i) shall
13 take effect 210 days after the date that the clinical
14 trial registry database and the clinical trial results
15 database are established under paragraph (1) of this
16 subsection.

17 (8) STATUS OF CLINICALTRIALS.GOV
18 WEBSITE.—

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

1 paragraph (2) of such section 402(i) and
2 whether such approach is—

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

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

13 (B) CLINICALTRIALS.GOV SUPPLANTED.—
14 If the Secretary determines to apply the ap-
15 proach described under subparagraph (A)(ii),
16 the Secretary shall maintain an archive of the
17 database described in such section 402(i) (as in
18 effect on the day before the date of enactment
19 of this Act) on the Internet website of the Na-
20 tional Library of Medicine.

1 **TITLE IV—CONFLICTS OF**
2 **INTEREST**

3 **SEC. 401. CONFLICTS OF INTEREST.**

4 (a) IN GENERAL.—Subchapter A of chapter VII of
5 the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371
6 et seq.) is amended by inserting at the end the following:

7 **“SEC. 712. CONFLICTS OF INTEREST.**

8 “(a) DEFINITIONS.—For purposes of this section:

9 “(1) ADVISORY COMMITTEE.—The term ‘advi-
10 sory committee’ means an advisory committee under
11 the Federal Advisory Committee Act that provides
12 advice or recommendations to the Secretary regard-
13 ing activities of the Food and Drug Administration.

14 “(2) FINANCIAL INTEREST.—The term ‘finan-
15 cial interest’ means a financial interest under section
16 208(a) of title 18, United States Code.

17 “(3) INDUSTRY FINANCIAL INTEREST.—The
18 term ‘industry financial interest’, with respect to ap-
19 pointment for a term to an advisory committee,
20 means an interest in a company that is a member
21 of the relevant industry that would be a financial in-
22 terest were an advisory committee to consider a par-
23 ticular matter involving such company.

24 “(4) RELEVANT INDUSTRY.—The term ‘rel-
25 evant industry’ means—

1 “(A) with respect to an advisory committee
2 that advises the Secretary on human drugs, bio-
3 logics, or devices, the pharmaceutical, bio-
4 technology, and device industries;

5 “(B) with respect to an advisory committee
6 that advises the Secretary on animal drugs or
7 devices, the animal drug and the animal device
8 industries; and

9 “(C) with respect to an advisory committee
10 that advises the Secretary on foods, the food in-
11 dustry.

12 “(b) APPOINTMENTS TO ADVISORY COMMITTEES.—

13 “(1) DISCLOSURE OF INDUSTRY FINANCIAL IN-
14 TERESTS.—Each individual under consideration for
15 a term appointment to an advisory committee shall
16 disclose to the Secretary all industry financial inter-
17 ests.

18 “(2) DISCLOSURES NOT PUBLICLY AVAIL-
19 ABLE.—No disclosure required under paragraph (1)
20 shall be made available to the public.

21 “(3) EVALUATION AND CRITERIA.—When con-
22 sidering a term appointment to an advisory com-
23 mittee, the Secretary—

24 “(A) shall review the expertise and the in-
25 dustry financial interests, as disclosed under

1 paragraph (1), of each individual under consid-
2 eration for the appointment, so as to appoint
3 the individuals, from among those individuals
4 under consideration for appointment, who are
5 the most qualified relative to their industry fi-
6 nancial interests that could require a written
7 determination as referred to in section
8 208(b)(1) of title 18, United States Code, a
9 written certification as referred to in section
10 208(b)(3) of title 18, United States Code, or a
11 waiver as referred to in subsection (c)(3) for
12 service on the committee at a meeting of the
13 committee; and

14 “(B) may appoint 2 or more qualified indi-
15 viduals with similar expertise and whose indus-
16 try financial interests are nonoverlapping or
17 minimally overlapping, so as to minimize the
18 likelihood that an advisory committee will need
19 the expertise of an appointed individual who re-
20 quires a written determination as referred to in
21 section 208(b)(1) of title 18, United States
22 Code, a written certification as referred to in
23 section 208(b)(3) of title 18, United States
24 Code, or a waiver as referred to in subsection

1 (c)(3) for service on the committee at a meeting
2 of the committee.

3 “(c) GRANTING AND DISCLOSURE OF WAIVERS.—

4 “(1) IN GENERAL.—Not later than 45 days be-
5 fore a meeting of an advisory committee, each mem-
6 ber of the committee shall disclose to the Secretary
7 all financial interests in accordance with section
8 208(b) of title 18, United States Code.

9 “(2) FINANCIAL GAIN OF ADVISORY COMMITTEE
10 MEMBER OR FAMILY MEMBER.—No member of an
11 advisory committee may vote with respect to any
12 matter considered by the advisory committee if such
13 member or an immediate family member of such
14 member could gain financially from the advice given
15 to the Secretary with respect to such matter.

16 “(3) WAIVER.—In addition to considerations
17 under section 208(b) of title 18, United States Code,
18 the Secretary may grant a waiver of a conflict of in-
19 terest requirement if such waiver is necessary to af-
20 ford the advisory committee essential expertise.

21 “(4) LIMITATION.—In no case may the Sec-
22 retary grant a waiver under paragraph (3) for a
23 member of an advisory committee if the scientific
24 work of such member is under consideration by the
25 committee.

1 “(5) DISCLOSURE OF WAIVER.—

2 “(A) MORE THAN 15 DAYS IN ADVANCE.—

3 As soon as practicable, but in no case later
4 than 15 days prior to a meeting of an advisory
5 committee to which a written determination as
6 referred to in section 208(b)(1) of title 18,
7 United States Code, a written certification as
8 referred to in section 208(b)(3) of title 18,
9 United States Code, or a waiver as referred to
10 in paragraph (3) applies, the Secretary shall
11 disclose (other than information exempted from
12 disclosure under section 552 of title 5, United
13 States Code, and section 552a of title 5, United
14 States Code (popularly known as the Freedom
15 of Information Act and the Privacy Act of
16 1974, respectively)) on the Internet website of
17 the Food and Drug Administration—

18 “(i) the financial interests of the advi-
19 sory committee member to which such de-
20 termination, certification, or waiver ap-
21 plies; and

22 “(ii) the reasons of the Secretary for
23 such determination, certification, or waiv-
24 er.

1 “(B) LESS THAN 15 DAYS IN ADVANCE.—

2 In the case of a financial interest that becomes
3 known to the Secretary less than 30 days prior
4 to a meeting of an advisory committee to which
5 a written determination as referred to in section
6 208(b)(1) of title 18, United States Code, a
7 written certification as referred to in section
8 208(b)(3) of title 18, United States Code, or a
9 waiver as referred to in paragraph (3) applies,
10 the Secretary shall disclose (other than infor-
11 mation exempted from disclosure under section
12 552 of title 5, United States Code, and section
13 552a of title 5, United States Code) on the
14 Internet website of the Food and Drug Admin-
15 istration, the information described in clauses
16 (i) and (ii) of subparagraph (A) as soon as the
17 Secretary makes such determination, certifi-
18 cation, or waiver, but in no event later than the
19 date of such meeting.

20 “(d) PUBLIC RECORD.—The Secretary shall ensure
21 that the public record and transcript of each meeting of
22 an advisory committee includes the disclosure required
23 under subsection (c)(5) (other than information exempted
24 from disclosure under section 552 of title 5, United States
25 Code, and section 552a of title 5, United States Code).

1 “(e) ANNUAL REPORT.—Not later than January 15
2 of each year, the Secretary shall submit a report to the
3 Inspector General of the Department of Health and
4 Human Services, the Committee on Appropriations and
5 the Committee on Health, Education, Labor, and Pen-
6 sions of the Senate, and the Committee on Appropriations
7 and the Committee on Energy and Commerce of the
8 House of Representatives—

9 “(1) with respect to the fiscal year that ended
10 on September 30 of the previous year, the number
11 of vacancies on each advisory committee, the number
12 of nominees received for each committee, and the
13 number of such nominees willing to serve;

14 “(2) with respect to such year, the aggregate
15 number of disclosures required under subsection
16 (c)(5) for each meeting of each advisory committee
17 and the percentage of individuals to whom such dis-
18 closures did not apply who served on such committee
19 for each such meeting;

20 “(3) with respect to such year, the number of
21 times the disclosures required under subsection
22 (c)(5) occurred under subparagraph (B) of such sub-
23 section; and

1 “(4) how the Secretary plans to reduce the
2 number of vacancies reported under paragraph (1)
3 during the fiscal year following such year.”.

4 (b) GUIDANCE.—

5 (1) NOMINATIONS.—Not later than 270 days
6 after the date of enactment of this Act, and after
7 seeking input from professional medical and sci-
8 entific societies, the Secretary shall publish in the
9 Federal Register for public comment a proposed
10 mechanism for encouraging the nomination of indi-
11 viduals who are classified by the Food and Drug Ad-
12 ministration as academicians or practitioners for
13 service on an advisory committee.

14 (2) WAIVER DETERMINATIONS.—Not later than
15 270 days after the date of enactment of this Act the
16 Secretary shall issue or revise guidance—

17 (A) that clarifies the circumstances in
18 which the Secretary may make a written deter-
19 mination as referred to in section 208(b)(1) of
20 title 18, United States Code, make a written
21 certification as referred to in section 208(b)(3)
22 of title 18, United States Code, or grant a waiv-
23 er as referred to section 712(c)(3) of the Fed-
24 eral Food, Drug, and Cosmetic Act (as added

1 by this section), including those circumstances
2 that—

3 (i) favor the inclusion of an individual
4 on an advisory committee;

5 (ii) favor making such a determina-
6 tion, certification, or waiver for an indi-
7 vidual on an advisory committee;

8 (iii) favor limitations on an individ-
9 ual's ability to act when making such a de-
10 termination, certification, or waiver for the
11 individual on an advisory committee; and

12 (iv) disfavor the inclusion of an indi-
13 vidual on an advisory committee;

14 (B) that defines how financial interests im-
15 puted to an individual bear upon his or her eli-
16 gibility for service on an advisory committee or
17 for service at a meeting of an advisory com-
18 mittee; and

19 (C) to ensure consistency within and
20 among the centers of the Food and Drug Ad-
21 ministration in applying section 208(b) of title
22 18, United States Code, and such section
23 712(c)(3).

24 (3) PERIODIC REVIEW.—At least once every 5
25 years, the Secretary shall review the guidance de-

1 scribed under paragraph (2) and update such guid-
2 ance as necessary.

3 (c) REVIEW BY INSPECTOR GENERAL.—

4 (1) IN GENERAL.—The Inspector General of
5 the Department of Health and Human Services shall
6 conduct a review, which may include surveys of past
7 or current members of advisory committees, of the
8 processes of the Food and Drug Administration
9 for—

10 (A) evaluating the financial interests of a
11 member of such an advisory committee while
12 the member serves on such a committee and
13 after the member has served on such a com-
14 mittee; and

15 (B) assuring the completeness and accu-
16 racy of information contained in the disclosures
17 described in subsections (b)(1) and (c)(1) of
18 such section 712 of the Federal Food, Drug,
19 and Cosmetic Act (as added by this section).

20 (2) SUBMISSION OF REPORT.—Not later than
21 18 months after the effective date of this section,
22 the Inspector General of the Department of Health
23 and Human Services shall submit to Congress a re-
24 port based on the review required under paragraph

1 (1), and include any recommendations for the im-
2 provement of such processes.

3 (d) DEFINITIONS.—For purposes of this section, the
4 terms “advisory committee” and “financial interest” have
5 the meaning given such terms in section 712 of the Fed-
6 eral Food, Drug, and Cosmetic Act (as added by this sec-
7 tion).

8 (e) CONFORMING AMENDMENT.—Section 505(n) of
9 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
10 355(n)) is amended by—

11 (1) striking paragraph (4); and

12 (2) redesignating paragraphs (5), (6), (7), and
13 (8) as paragraphs (4), (5), (6), and (7), respectively.

14 (f) EFFECTIVE DATE.—The amendments made by
15 this section shall take effect on October 1, 2007.

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