

110TH CONGRESS
1ST SESSION

S. 484

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 SENATE OF THE UNITED STATES

FEBRUARY 1, 2007

Mr. ENZI (for himself and Mr. KENNEDY) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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”.

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
13 for in this subsection, the applicant shall comply
14 with the requirements of such strategy.

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

16 “(A) ADVERSE DRUG EXPERIENCE.—The
17 term ‘adverse drug experience’ means any ad-
18 verse event associated with the use of a drug in
19 humans, whether or not considered drug re-
20 lated, including—

21 “(i) an adverse event occurring in the
22 course of the use of the drug in profes-
23 sional practice;

1 “(ii) an adverse event occurring from
2 an overdose of the drug, whether acci-
3 dental or intentional;

4 “(iii) an adverse event occurring from
5 abuse of the drug;

6 “(iv) an adverse event occurring from
7 withdrawal of the drug; and

8 “(v) any failure of expected pharma-
9 cological action of the drug.

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

13 “(i) results in—

14 “(I) death;

15 “(II) a adverse drug experience
16 that places the patient at immediate
17 risk of death from the adverse drug
18 experience as it occurred (not includ-
19 ing an adverse drug experience that
20 might have caused death had it oc-
21 curred in a more severe form);

22 “(III) inpatient hospitalization or
23 prolongation of existing hospitaliza-
24 tion;

1 “(IV) a persistent or significant
2 incapacity or substantial disruption of
3 the ability to conduct normal life
4 functions; or

5 “(V) a congenital anomaly or
6 birth defect; or

7 “(ii) based on appropriate medical
8 judgment, may jeopardize the patient and
9 may require a medical or surgical interven-
10 tion to prevent an outcome described under
11 clause (i).

12 “(C) SERIOUS RISK.—The term ‘serious
13 risk’ means a risk of a serious adverse drug ex-
14 perience.

15 “(D) UNEXPECTED SERIOUS RISK.—The
16 term ‘unexpected serious risk’ means a serious
17 adverse drug experience that is not listed in the
18 labeling of a drug, or that may be sympto-
19 matically and pathophysiologically related to an
20 adverse drug experience identified in the label-
21 ing, but differs from such adverse drug experi-
22 ence because of greater severity, specificity, or
23 prevalence.

24 “(E) SIGNAL OF A SERIOUS RISK.—The
25 term ‘signal of a serious risk’ means informa-

1 tion related to a serious adverse drug experi-
2 ence associated with use of a drug and derived
3 from—

4 “(i) a clinical trial;

5 “(ii) adverse event reports;

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

8 “(iv) peer-reviewed biomedical lit-
9 erature.

10 “(F) NEW SAFETY INFORMATION.—The
11 term ‘new safety information’ with respect to a
12 drug means information about—

13 “(i) a serious risk or an unexpected
14 serious risk associated with use of the drug
15 that the Secretary has become aware of
16 since the last assessment of the approved
17 risk evaluation and mitigation strategy for
18 the drug; or

19 “(ii) the effectiveness of the approved
20 risk evaluation and mitigation strategy for
21 the drug obtained since the last assessment
22 of such strategy.

23 “(3) REQUIRED ELEMENTS OF A RISK EVALUA-
24 TION AND MITIGATION STRATEGY.—The risk evalua-

1 tion and mitigation strategy for a drug shall re-
2 quire—

3 “(A) labeling for the drug for use by
4 health care providers as approved under sub-
5 section (c);

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

8 “(ii) for a drug that is a vaccine—

9 “(I) analysis of reports to the Vaccine
10 Adverse Event Reporting Systems
11 (VAERS); or

12 “(II) surveillance using the Vaccine
13 Safety Datalink (VSD) or successor data-
14 bases;

15 “(C) a pharmacovigilance statement—

16 “(i) as to whether the reports under
17 subparagraph (B)(i) or, for a vaccine, the
18 analysis and surveillance under subpara-
19 graph (B)(ii), and the periodic assessment
20 under subparagraph (E), are sufficient to
21 assess the serious risks and to identify un-
22 expected serious risks of the drug; and

23 “(ii) if such reports, such analysis and
24 surveillance, and such periodic assessment
25 are not sufficient to assess the serious

1 risks and to identify unexpected serious
2 risks of the drug, that describes what
3 study or studies of the drug are required
4 under paragraph (4)(D) or what clinical
5 trial or trials of the drug are required
6 under paragraph (4)(E);

7 “(D) a justification for the
8 pharmacovigilance statement in subparagraph
9 (C) that takes into consideration—

10 “(i) the estimated size of the treat-
11 ment population for the drug;

12 “(ii) the seriousness of the disease or
13 condition that the drug is used to treat or
14 prevent;

15 “(iii) the expected or actual duration
16 of treatment with the drug;

17 “(iv) the availability and safety of a
18 drug or other treatment, if any, for such
19 disease or condition to which the safety of
20 the drug may be compared; and

21 “(v) the seriousness of the risk at
22 issue and its background incidence in the
23 population; and

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

1 “(i) shall be no less frequently than
2 once annually for the first 3 years after
3 the drug is initially approved under sub-
4 section (c) or licensed under section 351 of
5 the Public Health Service Act, and at a
6 frequency specified in the strategy for sub-
7 sequent years;

8 “(ii) may be increased or reduced in
9 frequency as necessary as provided for in
10 paragraph (6)(B)(iv)(VI) ; and

11 “(iii) may be eliminated after the first
12 3 years if the Secretary determines that
13 serious risks of the drug have been ade-
14 quately identified and assessed and are
15 being adequately managed.

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

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

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

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

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

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

21 “(i) sending letters to health care pro-
22 viders;

23 “(ii) disseminating information about
24 the elements of the risk evaluation and
25 mitigation strategy to encourage implemen-

1 tation by health care providers of compo-
2 nents that apply to such health care pro-
3 viders, or to explain certain safety proto-
4 cols (such as medical monitoring by peri-
5 odic laboratory tests); or

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

10 “(D) POST-APPROVAL STUDIES.—The risk
11 evaluation and mitigation strategy for a drug
12 may require that the applicant conduct, or pro-
13 vide that the Secretary will conduct, an appro-
14 priate post-approval study, such as a prospec-
15 tive or retrospective observational study (includ-
16 ing through the systematic use of established
17 health care networks and databases), of the
18 drug (with a target schedule for completing the
19 study and reporting the results to the Sec-
20 retary), if the Secretary determines the reports,
21 analysis and surveillance, and periodic assess-
22 ments referred to in paragraph (3)(C) are not
23 sufficient to—

24 “(i) assess a signal of a serious risk
25 with use of the drug; or

1 “(ii) identify unexpected serious risks
2 in domestic populations who use the drug,
3 including populations not included in stud-
4 ies used to approve the drug (such as older
5 people, people with comorbidities, pregnant
6 women, or children).

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

24 “(F) PRECLEARANCE.—

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

15 “(ii) SPECIFICATION OF ADVERTISE-
16 MENTS.—The Secretary may specify the
17 advertisements required to be submitted
18 under clause (i).

19 “(G) SPECIFIC DISCLOSURES.—

20 “(i) IN GENERAL.—The risk evalua-
21 tion and mitigation strategy for a drug
22 may require that the applicant include in
23 advertisements of the drug a specific dis-
24 closure—

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

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

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

20 “(H) TEMPORARY MORATORIUM.—The
21 risk evaluation and mitigation strategy for a
22 drug may require that for a fixed period after
23 initial approval, not to exceed 2 years, the ap-
24 plicant not issue or cause to be issued direct-
25 to-consumer advertisements of the drug, if the

1 Secretary determines that disclosure under sub-
2 paragraph (G) is inadequate to protect public
3 health and safety, and that such prohibition is
4 necessary to protect public health and safety
5 while additional information about serious risks
6 of the drug is collected, considering—

7 “(i) the number of patients who may
8 be treated with the drug;

9 “(ii) the seriousness of the condition
10 for which the drug will be used;

11 “(iii) the serious adverse events listed
12 in the labeling of the drug;

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

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

22 “(5) RESTRICTIONS ON DISTRIBUTION OR
23 USE.—

24 “(A) IN GENERAL.—If the Secretary deter-
25 mines that a drug shown to be effective can be

1 safely used only if distribution or use of such
2 drug is restricted, the Secretary may require as
3 elements of the risk evaluation and mitigation
4 strategy such restrictions on distribution or use
5 as are needed to assure safe use of the drug.

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

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

10 “(ii) not be unduly burdensome on pa-
11 tient access to the drug, particularly for
12 patients with serious or life-threatening
13 diseases or conditions; and

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

19 “(C) ELEMENTS.—The restrictions on dis-
20 tribution or use described under subparagraph
21 (A) shall include 1 or more goals to evaluate or
22 mitigate a serious risk listed in the labeling of
23 the drug and may require that—

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

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

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

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

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

16 “(vi) each patient using the drug be
17 enrolled in a registry.

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

22 “(i) monitor and evaluate implementa-
23 tion of the restrictions by health care pro-
24 viders, pharmacists, patients, and other
25 parties in the health care system who are

1 responsible for implementing the restric-
2 tions;

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

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

12 “(I) who are responsible for im-
13 plementing the restrictions; and

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

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

22 “(A) PROPOSED RISK EVALUATION AND
23 MITIGATION STRATEGY.—

24 “(i) INITIAL APPROVAL.—An appli-
25 cant shall include a proposed risk evalua-

1 tion and mitigation strategy in an applica-
2 tion under subsection (b) or section 351 of
3 the Public Health Service Act for initial
4 approval of the drug.

5 “(ii) APPROVAL OF NEW INDICA-
6 TION.—If no risk evaluation and mitiga-
7 tion strategy for the drug is in effect under
8 this subsection and the drug may not be
9 dispensed without a prescription, the appli-
10 cant shall include a proposed risk evalua-
11 tion and mitigation strategy in an applica-
12 tion, including in a supplemental applica-
13 tion, seeking a new indication for such
14 drug.

15 “(iii) CONTENTS.—A proposed risk
16 evaluation and mitigation strategy—

17 “(I) shall include the minimal
18 elements required under paragraph
19 (3); and

20 “(II) may also include additional
21 elements as provided for under para-
22 graphs (4) and (5).

23 “(B) ASSESSMENT AND MODIFICATION OF
24 A RISK EVALUATION AND MITIGATION STRAT-
25 EGY.—

1 “(i) VOLUNTARY ASSESSMENTS.—The
2 applicant may submit to the Secretary an
3 assessment of, and propose a modification
4 to, the approved risk evaluation and miti-
5 gation strategy for a drug at any time.

6 “(ii) REQUIRED ASSESSMENTS.—The
7 applicant shall submit an assessment of,
8 and may propose a modification to, the ap-
9 proved risk evaluation and mitigation
10 strategy for a drug—

11 “(I) when submitting a supple-
12 mental application for a new indica-
13 tion under subsection (b) or section
14 351 of the Public Health Service Act,
15 unless the drug may be dispensed
16 without a prescription and the risk
17 evaluation and mitigation strategy for
18 the drug includes only the elements
19 under paragraph (3);

20 “(II) when required by the strat-
21 egy, as provided for in the timetable
22 under paragraph (3)(E);

23 “(III) within a time specified by
24 the Secretary, not to be less than 45
25 days, when ordered by the Secretary,

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

6 “(IV) within 90 days when or-
7 dered by the Secretary, if the Sec-
8 retary determines that new safety in-
9 formation indicates that an element
10 under paragraph (5) should be modi-
11 fied or included in the strategy; or

12 “(V) within 15 days when or-
13 dered by the Secretary, if the Sec-
14 retary determines that there may be a
15 cause for action by the Secretary
16 under subsection (e).

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

20 “(I) with respect to any goal
21 under paragraph (5), an assessment
22 of how well the restrictions on dis-
23 tribution or use are meeting the goal
24 or whether the goal or such restric-
25 tions should be modified;

1 “(II) with respect to any post-ap-
2 proval study required under para-
3 graph (4)(D), the status of such
4 study, including whether any difficul-
5 ties completing the study have been
6 encountered; and

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

19 “(iv) MODIFICATION.—A modification
20 (whether an enhancement or a reduction)
21 to the approved risk evaluation and mitiga-
22 tion strategy for a drug may include the
23 addition or modification of any element
24 under subparagraph (A), (C), or (D) of
25 paragraph (3) or the addition, modifica-

1 tion, or removal of any element under
2 paragraph (4) or (5), such as—

3 “(I) a labeling change, including
4 the addition of a boxed warning;

5 “(II) adding a post-approval
6 study or clinical trial requirement;

7 “(III) modifying a post-approval
8 study or clinical trial requirement
9 (such as a change in trial design due
10 to legitimate difficulties recruiting
11 participants);

12 “(IV) adding, modifying, or re-
13 moving a restriction on advertising
14 under subparagraph (F), (G), or (H)
15 of paragraph (4);

16 “(V) adding, modifying, or re-
17 moving a restriction on distribution or
18 use under paragraph (5); or

19 “(VI) modifying the timetable for
20 assessments of the strategy under
21 paragraph (3)(E), including to elimi-
22 nate assessments.

23 “(C) REVIEW.—The Secretary shall
24 promptly review the proposed risk evaluation
25 and mitigation strategy for a drug submitted

1 under subparagraph (A), or an assessment of
2 the approved risk evaluation and mitigation
3 strategy for a drug submitted under subpara-
4 graph (B).

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

13 “(i) if the proposed strategy or assess-
14 ment is submitted as part of an application
15 or supplemental application under subpara-
16 graph (A) or (B)(ii)(I), not less than 60
17 days before the action deadline for the ap-
18 plication that has been agreed to by the
19 Secretary and that has been set forth in
20 goals identified in letters of the Secretary
21 (relating to the use of fees collected under
22 section 736 to expedite the drug develop-
23 ment process and the review of human
24 drug applications);

1 “(ii) if the assessment is submitted
2 under subclause (II) or (III) of subpara-
3 graph (B)(ii), not later than 20 days after
4 such submission;

5 “(iii) if the assessment is submitted
6 under subparagraph (B)(i) or under sub-
7 paragraph (B)(ii)(IV), not later than 30
8 days after such submission; or

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

12 “(E) ACTION.—

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

20 “(I) as part of the action letter
21 on the application, when a proposed
22 strategy is submitted under subpara-
23 graph (A) or an assessment of the
24 strategy is submitted under subpara-
25 graph (B)(ii)(I); or

1 “(II) in an order, which shall be
2 made public, issued not later than 50
3 days after the date discussions of such
4 modification begin under subpara-
5 graph (C), when an assessment of the
6 strategy is under subparagraph (B)(i)
7 or under subclause (II), (III), (IV), or
8 (V) of subparagraph (B)(ii).

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

14 “(F) DISPUTE RESOLUTION.—

15 “(i) REQUEST FOR REVIEW.—Not
16 earlier than 15 days, and not later than 35
17 days, after discussions under subparagraph
18 (D) have begun, the applicant may request
19 in writing that a dispute about the strat-
20 egy be reviewed by the Drug Safety Over-
21 sight Board.

22 “(ii) SCHEDULING REVIEW.—If the
23 applicant requests review under clause (i),
24 the Secretary—

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

6 “(II) may convene a special
7 meeting of the Drug Safety Oversight
8 Board to review the matter more
9 promptly, including to meet an action
10 deadline on an application (including
11 a supplemental application).

12 “(iii) AGREEMENT AFTER DISCUSSION
13 OR ADMINISTRATIVE APPEALS.—

14 “(I) FURTHER DISCUSSION OR
15 ADMINISTRATIVE APPEALS.—A re-
16 quest for review under clause (i) shall
17 not preclude further discussions to
18 reach agreement on the risk evalua-
19 tion and mitigation strategy, and such
20 a request shall not preclude the use of
21 administrative appeals within the
22 Food and Drug Administration to
23 reach agreement on the strategy, in-
24 cluding appeals as described in letters
25 of the Secretary (relating to the use of

1 fees collected under section 736 to ex-
2 pedite the drug development process
3 and the review of human drug appli-
4 cations) for procedural or scientific
5 matters involving the review of human
6 drug applications and supplemental
7 applications that cannot be resolved at
8 the divisional level.

9 “(II) AGREEMENT TERMINATES
10 DISPUTE RESOLUTION.—At any time
11 before a decision and order is issued
12 under clause (vi), the Secretary and
13 the applicant may reach an agreement
14 on the risk evaluation and mitigation
15 strategy through further discussion or
16 administrative appeals, terminating
17 the dispute resolution process, and the
18 Secretary shall issue an action letter
19 or order, as appropriate, that de-
20 scribes the strategy.

21 “(iv) MEETING OF THE BOARD.—At
22 the meeting of the Drug Safety Oversight
23 Board described in clause (ii), the Board
24 shall—

25 “(I) hear from both parties; and

1 “(II) review the dispute.

2 “(v) RECOMMENDATION OF THE
3 BOARD.—Not later than 5 days after such
4 meeting of the Drug Safety Oversight
5 Board, the Board shall provide a written
6 recommendation on resolving the dispute
7 to the Secretary.

8 “(vi) ACTION BY THE SECRETARY.—

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

18 “(aa) the action deadline re-
19 ferred to in subparagraph (D)(i);
20 or

21 “(bb) 7 days after receiving
22 the recommendation of the Drug
23 Safety Oversight Board.

24 “(II) ORDER.—With respect to
25 an assessment of the risk evaluation

1 and mitigation strategy under sub-
2 paragraph (B)(i) or under subclause
3 (II), (III), (IV), or (V) of subpara-
4 graph (B)(ii), the Secretary shall
5 issue an order, which shall be made
6 public, that resolves the dispute not
7 later than 7 days after receiving the
8 recommendation of the Drug Safety
9 Oversight Board.

10 “(vii) INACTION.—An approved risk
11 evaluation and mitigation strategy shall re-
12 main in effect until the Secretary acts, if
13 the Secretary fails to act as provided for
14 under clause (vi).

15 “(viii) EFFECT ON ACTION DEAD-
16 LINE.—With respect to the application or
17 supplemental application in which a pro-
18 posed risk evaluation and mitigation strat-
19 egy is submitted under subparagraph (A)
20 or in which an assessment of the strategy
21 is submitted under subparagraph
22 (B)(ii)(I), the Secretary shall be considered
23 to have met the action deadline referred to
24 in subparagraph (D)(i) with respect to
25 such application if the applicant requests

1 the dispute resolution process described in
2 this subparagraph and if the Secretary—

3 “(I) has initiated the discussions
4 described under subparagraph (D) not
5 less than 60 days before such action
6 deadline; and

7 “(II) has complied with the tim-
8 ing requirements of scheduling review
9 by the Drug Safety Oversight Board,
10 providing a written recommendation,
11 and issuing an action letter under
12 clauses (ii), (v), and (vi), respectively.

13 “(ix) DISQUALIFICATION.—No indi-
14 vidual who is an employee of the Food and
15 Drug Administration and who reviews a
16 drug or who participated in an administra-
17 tive appeal under clause (iii)(I) with re-
18 spect to such drug may serve on the Drug
19 Safety Oversight Board at a meeting under
20 clause (iv) to review a dispute about the
21 risk evaluation and mitigation strategy for
22 such drug.

23 “(x) ADDITIONAL EXPERTISE.—The
24 Drug Safety Oversight Board may add
25 members with relevant expertise from the

1 Food and Drug Administration, including
2 the Office of Pediatrics, the Office of
3 Women’s Health, or the Office of Rare
4 Diseases, or from other Federal public
5 health or health care agencies, for a meet-
6 ing under clause (iv) of the Drug Safety
7 Oversight Board.

8 “(G) USE OF ADVISORY COMMITTEES.—
9 The Secretary may convene a meeting of 1 or
10 more advisory committees of the Food and
11 Drug Administration to—

12 “(i) review a concern about the safety
13 of a drug or class of drugs, including be-
14 fore an assessment of the risk evaluation
15 and mitigation strategy or strategies of
16 such drug or drugs is required to be sub-
17 mitted under subclause (II), (III), (IV), or
18 (V) of subparagraph (B)(ii);

19 “(ii) review the risk evaluation and
20 mitigation strategy or strategies of a drug
21 or group of drugs; or

22 “(iii) with the consent of the appli-
23 cant, review a dispute under subparagraph
24 (F).

1 “(H) PROCESS FOR ADDRESSING DRUG
2 CLASS EFFECTS.—

3 “(i) IN GENERAL.—When a concern
4 about a serious risk of a drug may be re-
5 lated to the pharmacological class of the
6 drug, the Secretary may defer assessments
7 of the approved risk evaluation and mitiga-
8 tion strategies for such drugs until the
9 Secretary has convened, after appropriate
10 public notice, 1 or more public meetings to
11 consider possible responses to such con-
12 cern.

13 “(ii) PUBLIC MEETINGS.—Such public
14 meetings may include—

15 “(I) 1 or more meetings of the
16 applicants for such drugs;

17 “(II) 1 or more meetings of 1 or
18 more advisory committees of the Food
19 and Drug Administration, as provided
20 for under subparagraph (G); or

21 “(III) 1 or more workshops of
22 scientific experts and other stake-
23 holders.

1 “(iii) ACTION.—After considering the
2 discussions from any meetings under
3 clause (ii), the Secretary may—

4 “(I) announce in the Federal
5 Register a planned regulatory action,
6 including a modification to each risk
7 evaluation and mitigation strategy, for
8 drugs in the pharmacological class;

9 “(II) seek public comment about
10 such action; and

11 “(III) after seeking such com-
12 ment, issue an order addressing such
13 regulatory action.

14 “(I) INTERNATIONAL COORDINATION.—

15 The Secretary may coordinate the timetable for
16 submission of assessments under paragraph
17 (3)(E), a study under paragraph (4)(D), or a
18 clinical trial under paragraph (4)(E), with ef-
19 forts to identify and assess the serious risks of
20 such drug by the marketing authorities of other
21 countries whose drug approval and risk man-
22 agement processes the Secretary deems com-
23 parable to the drug approval and risk manage-
24 ment processes of the United States.

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

5 “(K) NO EFFECT ON LABELING CHANGES
6 THAT DO NOT REQUIRE PREAPPROVAL.—In the
7 case of a labeling change to which section
8 314.70 of title 21, Code of Federal Regulations
9 (or any successor regulation), applies for which
10 the submission of a supplemental application is
11 not required or for which distribution of the
12 drug involved may commence upon the receipt
13 by the Secretary of a supplemental application
14 for the change, the submission of an assessment
15 of the approved risk evaluation and mitigation
16 strategy for the drug under this subsection is
17 not required.

18 “(7) DRUG SAFETY OVERSIGHT BOARD.—

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

21 “(B) COMPOSITION; MEETINGS.—The
22 Drug Safety Oversight Board shall—

23 “(i) be composed of scientists and
24 health care practitioners who are appointed
25 by the Secretary;

1 “(ii) include representatives from of-
2 fices throughout the Food and Drug Ad-
3 ministration;

4 “(iii) include at least 1 representative
5 from each of the National Institutes of
6 Health, the Department of Health and
7 Human Services (other than the Food and
8 Drug Administration), and the Veterans
9 Health Administration; and

10 “(iv) meet at least monthly to provide
11 oversight and advice to the Secretary on
12 the management of important drug safety
13 issues.”.

14 **SEC. 102. ENFORCEMENT.**

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

18 “(x) If it is a drug subject to an approved risk evalua-
19 tion and mitigation strategy under section 505(o) and the
20 applicant for such drug fails to—

21 “(1) make a labeling change required by such
22 strategy after the Secretary has completed review of,
23 and acted on, an assessment of such strategy under
24 paragraph (6) of such section; or

1 “(2) comply with a requirement of such strat-
2 egy with respect to advertising as provided for under
3 subparagraph (F), (G), or (H) of paragraph (4) of
4 such section.”.

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

8 (1) by redesignating paragraphs (3), (4), and
9 (5) as paragraphs (4), (5), and (6), respectively;

10 (2) by inserting after paragraph (2) the fol-
11 lowing:

12 “(3) An applicant (as such term is used in sec-
13 tion 505(o)) who knowingly fails to comply with a
14 requirement of an approved risk evaluation and miti-
15 gation strategy under such section 505(o) shall be
16 subject to a civil money penalty of not less than
17 \$15,000 and not more than \$250,000 per violation,
18 and not to exceed \$1,000,000 for all such violations
19 adjudicated in a single proceeding.”;

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

22 (4) in paragraph (4), as so redesignated, by
23 striking “paragraph (1) or (2)” each place it ap-
24 pears and inserting “paragraph (1), (2), or (3)”;
25 and

1 (5) in paragraph (6), as so redesignated, by
2 striking “paragraph (4)” each place it appears and
3 inserting “paragraph (5)”.

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

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

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

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

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

18 **SEC. 104. NO EFFECT ON WITHDRAWAL OR SUSPENSION OF**
19 **APPROVAL.**

20 Section 505(e) of the Federal Food, Drug, and Cos-
21 metic Act (21 U.S.C. 355(e)) is amended by adding at
22 the end the following: “The Secretary may withdraw the
23 approval of an application submitted under this section,
24 or suspend the approval of such an application, as pro-
25 vided under this subsection, without first ordering the ap-

1 plicant to submit an assessment of the approved risk eval-
2 uation and mitigation strategy for the drug under sub-
3 section (o)(6)(B)(ii)(V).”.

4 **SEC. 105. DRUGS SUBJECT TO AN ABBREVIATED NEW DRUG**
5 **APPLICATION.**

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

9 “(D) RISK EVALUATION AND MITIGATION STRATEGY
10 REQUIREMENT.—

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

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

19 “(II) Submission of reports, as required
20 under subsection (o)(3)(B)(i) for the applicable
21 listed drug.

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

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

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

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

10 “(VII) Restrictions on distribution or use,
11 if required under subsection (o)(5) for the ap-
12 plicable listed drug, except that such drug may
13 use a different, comparable aspect of such re-
14 strictions on distribution or use as are needed
15 to assure safe use of such drug if —

16 “(aa) the corresponding aspect of the
17 restrictions on distribution or use for the
18 applicable listed drug is claimed by a pat-
19 ent that has not expired or is a method or
20 process that as a trade secret is entitled to
21 protection; and

22 “(bb) the applicant certifies that it
23 has sought a license for use of such aspect
24 of the restrictions on distribution or use
25 for the applicable listed drug.

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

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

7 “(II) shall conduct any post-approval study
8 required under subsection (o)(4)(D) for the ap-
9 plicable listed drug;

10 “(III) shall inform the applicant for a drug
11 approved under this subsection if the risk eval-
12 uation and mitigation strategy for the applica-
13 ble listed drug is modified; and

14 “(IV) in order to minimize the burden on
15 the health care delivery system of different re-
16 strictions on distribution or use for the drug
17 approved under this subsection and the applica-
18 ble listed drug, may seek to negotiate a license
19 under which the applicant for such drug may
20 use an aspect of the restrictions on distribution
21 or use, if required under subsection (o)(5) for
22 the applicable listed drug, that is claimed by a
23 patent that has not expired or is a method or
24 process that as a trade secret is entitled to pro-
25 tection.”.

1 **SEC. 106. CONFORMING AMENDMENTS.**

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

7 (b) CONTENT OF NEW DRUG APPLICATION.—Section
8 505(b)(1) of the Federal Food, Drug, and Cosmetic Act
9 (21 U.S.C. 355(b)) is amended—

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

11 and

12 (2) in subparagraph (G), by striking the period
13 and inserting the following: “, and (H) a proposed
14 risk evaluation and mitigation strategy as described
15 under subsection (o).”.

16 **SEC. 107. RESOURCES.**

17 (a) USER FEES.—Subparagraph (F) of section
18 735(6) of the Federal Food, Drug, and Cosmetic Act (21
19 U.S.C. 379g(6)) is amended to read as follows:

20 “(F) Reviewing and implementing risk
21 evaluation and mitigation strategies, and col-
22 lecting, developing, and reviewing safety infor-
23 mation on drugs, including adverse event re-
24 ports.”.

25 (b) WORKLOAD ADJUSTMENT.—Subparagraph (A) of
26 section 736(c)(2) of the Federal Food, Drug, and Cos-

1 metric Act (21 U.S.C. 379h(c)(2)) is amended to read as
2 follows:

3 “(A) The adjustment shall be determined
4 by the Secretary based on a weighted average
5 of the change in the total number of human
6 drug applications, commercial investigational
7 new drug applications, efficacy supplements,
8 manufacturing supplements, assessments of risk
9 evaluation and mitigation strategies, and uses
10 of dispute resolution under the process for re-
11 viewing and assessing risk evaluation and miti-
12 gation strategies. The Secretary shall publish in
13 the Federal Register the fee revenues and fees
14 resulting from the adjustment and supporting
15 methodologies.”.

16 (c) STRATEGIC PLAN FOR INFORMATION TECH-
17 NOLOGY.—Not later than 1 year after the date of enact-
18 ment of this title, the Secretary of Health and Human
19 Services (referred to in this Act as the “Secretary”) shall
20 submit to the Committee on Health, Education, Labor,
21 and Pensions and the Committee on Appropriations of the
22 Senate and the Committee on Energy and Commerce and
23 the Committee on Appropriations of the House of Rep-
24 resentatives, a strategic plan on information technology
25 that includes—

1 (1) an assessment of the information technology
2 infrastructure, including systems for data collection,
3 access to data in external health care databases,
4 data mining capabilities, personnel, and personnel
5 training programs, needed by the Food and Drug
6 Administration to—

7 (A) comply with the requirements of this
8 title (and the amendments made by this title);

9 (B) achieve interoperability within and
10 among the Centers of the Food and Drug Ad-
11 ministration and between the Food and Drug
12 Administration and product application spon-
13 sors; and

14 (C) utilize electronic health records;

15 (2) an assessment of the extent to which the
16 current information technology assets of the Food
17 and Drug Administration are sufficient to meet the
18 needs assessments under paragraph (1);

19 (3) a plan for enhancing the information tech-
20 nology assets of the Food and Drug Administration
21 toward meeting the needs assessments under para-
22 graph (1); and

23 (4) an assessment of additional resources need-
24 ed to so enhance the information technology assets
25 of the Food and Drug Administration.

1 **SEC. 108. DRUG LABELING.**

2 (a) ACCESSIBLE REPOSITORY OF DRUG LABEL-
3 ING.—Not later than the effective date of this title, the
4 Secretary, through the Commissioner of Food and Drugs,
5 and the Director of the National Institutes of Health, shall
6 establish a searchable repository of structured, electronic
7 product information, including the approved professional
8 labeling and any required patient labeling of each drug
9 approved under section 505 of the Federal Food, Drug,
10 and Cosmetic Act (21 U.S.C. 355) or licensed under sec-
11 tion 351 of the Public Health Service Act (42 U.S.C. 262)
12 in order to improve patient safety through accessible prod-
13 uct information, support initiatives to improve patient care
14 by better management of health care information, and
15 provide standards for drug information. Such repository
16 shall be made publicly accessible on the Internet website
17 of the National Library of Medicine and through a link
18 on the homepage of the Internet website of the Food and
19 Drug Administration.

20 (b) POSTING UPON APPROVAL.—The Secretary shall
21 post in the repository under subsection (a) the approved
22 professional labeling and any required patient labeling of
23 a drug approved under such section 505 or licensed under
24 such section 351 not later than 21 days after the date
25 the drug is approved, including in a supplemental applica-
26 tion with respect to a labeling change.

1 (c) REPORT.—The Secretary shall report annually to
2 the Committee on Health, Education, Labor and Pensions
3 of the Senate and the Committee on Energy and Com-
4 merce of the House of Representatives on the status of
5 the repository under subsection (a), and on progress in
6 posting structured electronic product information, includ-
7 ing posting of information regarding drugs approved prior
8 to the effective date of this title.

9 (d) MEDICATION GUIDES.—Not later than the effec-
10 tive date of this title, the Secretary, through the Commis-
11 sioner of Food and Drugs, shall establish on the Internet
12 website for the repository under subsection (a), a link to
13 a list of each drug, whether approved under such section
14 505 or licensed under such section 351, for which a Medi-
15 cation Guide, as provided for under part 208 of title 21,
16 Code of Federal Regulations (or any successor regula-
17 tions), is required.

18 **SEC. 109. EFFECTIVE DATE AND APPLICABILITY.**

19 (a) EFFECTIVE DATE.—This title shall take effect
20 180 days after the date of enactment of this Act.

21 (b) DRUGS DEEMED TO HAVE RISK EVALUATION
22 AND MITIGATION STRATEGIES.—

23 (1) IN GENERAL.—A drug that was approved
24 before the effective date of this title shall be deemed
25 to have an approved risk evaluation and mitigation

1 strategy under section 505(o) of the Federal Food,
2 Drug, and Cosmetic Act (as added by this title) if
3 there are in effect on the effective date of this title
4 restrictions on distribution or use—

5 (A) required under section 314.520 or sec-
6 tion 601.42 of title 21, Code of Federal Regula-
7 tions; or

8 (B) otherwise agreed to by the applicant
9 and the Secretary for such drug.

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

18 (3) NOTIFICATION.—Not later than 30 days
19 after the effective date of this title, the Secretary
20 shall notify the applicant for each drug described in
21 paragraph (1)—

22 (A) that such drug is deemed to have an
23 approved risk evaluation and mitigation strat-
24 egy pursuant to such paragraph; and

1 (B) of the date, which shall be no earlier
2 than 6 months after the applicant is so notified,
3 by which the applicant shall submit to the Sec-
4 retary an assessment of such approved strategy
5 under paragraph (6)(B) of such section 505(o).

6 (4) ENFORCEMENT ONLY AFTER ASSESSMENT
7 AND REVIEW.—Neither the Secretary nor the Attor-
8 ney General may seek to enforce a requirement of a
9 risk evaluation and mitigation strategy deemed in ef-
10 fect under paragraph (1) before the Secretary has
11 completed review of, and acted on, the first assess-
12 ment of such strategy under such section 505(o).

13 (c) OTHER DRUGS APPROVED BEFORE THE EFFEC-
14 TIVE DATE.—The Secretary, on a case-by-case basis, may
15 require the applicant for a drug approved before the effec-
16 tive date of this title to which subsection (b) does not
17 apply to submit a proposed risk evaluation and mitigation
18 strategy in accordance with the timeframes provided for
19 in subclause (III), (IV), or (V), as applicable, of paragraph
20 (6)(B)(ii) of such section 505(o) if the Secretary deter-
21 mines that—

22 (1) an element described under paragraph
23 (3)(A) of such section 505(o) may require modifica-
24 tion; or

1 (2) a standard for adding an element described
2 in paragraph (4) or (5) of such section 505(o) that
3 is not in effect with respect to such drug may apply
4 to such drug.

5 **TITLE II—REAGAN-UDALL INSTI-**
6 **TUTE FOR APPLIED BIO-**
7 **MEDICAL RESEARCH**

8 **SEC. 201. THE REAGAN-UDALL INSTITUTE FOR APPLIED**
9 **BIOMEDICAL RESEARCH.**

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

14 **“Subchapter I—Reagan-Udall Institute for**
15 **Applied Biomedical Research**

16 **“SEC. 770. ESTABLISHMENT AND FUNCTIONS OF THE INSTI-**
17 **TUTE.**

18 “(a) IN GENERAL.—The Secretary shall establish a
19 nonprofit corporation to be known as the Reagan-Udall
20 Institute for Applied Biomedical Research (referred to in
21 this subchapter as the ‘Institute’). The Institute shall be
22 headed by an Executive Director, appointed by the mem-
23 bers of the Board of Directors under subsection (e). The
24 Institute shall not be an agency or instrumentality of the
25 United States Government.

1 “(b) PURPOSE OF INSTITUTE.—The purpose of the
2 Institute is to advance the Critical Path Initiative of the
3 Food and Drug Administration to modernize medical
4 product development, accelerate innovation, and enhance
5 product safety.

6 “(c) DUTIES OF THE INSTITUTE.—The Institute
7 shall—

8 “(1) taking into consideration the 2004 report
9 published by the Food and Drug Administration en-
10 titled ‘Innovation or Stagnation? Challenge and Op-
11 portunity on the Critical Path to New Medical Prod-
12 ucts’, identify unmet needs in the sciences of devel-
13 oping, manufacturing, and evaluating the safety and
14 effectiveness of diagnostics, devices, biologics, and
15 drugs, including—

16 “(A) the identification and validation of
17 biomarkers for use in diagnostic, device, bio-
18 logic, and drug development;

19 “(B) the development and validation of
20 animal models for human disease and medical
21 product safety;

22 “(C) pharmacogenomics and inter-indi-
23 vidual variability in drug, biologic, and device
24 response;

1 “(D) the development of data analysis
2 technology and methodology for use in device,
3 biologic, drug, and diagnostic development;

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

6 “(F) toxicological quality assessment tech-
7 nologies;

8 “(G) diagnostic, device, biologic, and drug
9 manufacturing, design, and materials science;

10 “(H) failure mode assessment for medical
11 product development;

12 “(I) improving adverse event reporting and
13 analysis;

14 “(J) bridging engineering data and clinical
15 performance for devices; and

16 “(K) computer modeling;

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

19 “(3) in consultation with the Secretary, assess
20 existing and proposed Federal intramural and extra-
21 mural research and development programs relating
22 to the goals and priorities established under para-
23 graph (2) and facilitate and encourage interagency
24 coordination of such programs;

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

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

9 “(6) release and publish information and data
10 and, to the extent practicable, license, distribute,
11 and release material, reagents, and techniques to
12 maximize, promote, and coordinate the availability of
13 such material, reagents, and techniques for use by
14 the Food and Drug Administration, nonprofit orga-
15 nizations, and academic and industrial researchers
16 to further the goals and priorities established under
17 paragraph (2);

18 “(7) ensure that—

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

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

1 “(C) executed licenses, memoranda of un-
2 derstanding, material transfer agreements, con-
3 tracts, and other such instruments promote, to
4 the maximum extent practicable, the broadest
5 conversion to commercial and noncommercial
6 applications of licensed and patented inventions
7 of the Institute to further the goals and prior-
8 ities established under paragraph (2);

9 “(8) provide objective clinical and scientific in-
10 formation to the Food and Drug Administration
11 and, upon request, to other Federal agencies to as-
12 sist in agency determinations of how to ensure that
13 regulatory policy accommodates scientific advances;

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

16 “(10) carry out such other activities consistent
17 with the purposes of the Institute as the Board de-
18 termines appropriate.

19 “(d) BOARD OF DIRECTORS.—

20 “(1) ESTABLISHMENT.—

21 “(A) IN GENERAL.—The Institute shall
22 have a Board of Directors (referred to in this
23 subchapter as the ‘Board’), which shall be com-
24 posed of ex officio and appointed members in

1 accordance with this subsection. All appointed
2 members of the Board shall be voting members.

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

5 “(i) the immediate past Chair of
6 Board of Directors of the Institute;

7 “(ii) the Commissioner of Food and
8 Drugs;

9 “(iii) the Director of the National In-
10 stitutes of Health;

11 “(iv) the Director of the Centers for
12 Disease Control and Prevention; and

13 “(v) the Director of the Agency for
14 Healthcare Research and Quality.

15 “(C) APPOINTED MEMBERS.—

16 “(i) IN GENERAL.—The ex officio
17 members of the Board under subparagraph
18 (B) shall, by majority vote, appoint to the
19 Board 12 individuals. Of such appointed
20 members—

21 “(I) 4 shall be representatives of
22 the general pharmaceutical, device,
23 and biotechnology industries;

24 “(II) 3 shall be representatives of
25 academic research organizations;

1 “(III) 2 shall be representatives
2 of Government agencies, including the
3 Food and Drug Administration and
4 the National Institutes of Health;

5 “(IV) 2 shall be representatives
6 of patient advocacy organizations; and

7 “(V) 1 shall be a representative
8 of health care providers.

9 “(ii) REQUIREMENT.—The ex officio
10 members shall ensure the Board member-
11 ship includes individuals with expertise in
12 areas including clinical pharmacology, bio-
13 medical informatics, product safety, proc-
14 ess improvement and pharmaceutical
15 sciences, and medical device and bio-
16 medical engineering.

17 “(D) INITIAL MEETING.—

18 “(i) IN GENERAL.—Not later than 30
19 days after the date of the enactment of the
20 Enhancing Drug Safety and Innovation
21 Act of 2007, the Secretary shall convene a
22 meeting of the ex officio members of the
23 Board to—

24 “(I) incorporate the Institute;
25 and

1 “(II) appoint the members of the
2 Board in accordance with subpara-
3 graph (C).

4 “(ii) SERVICE OF EX OFFICIO MEM-
5 BERS.—Upon the appointment of the
6 members of the Board under clause (i)(II),
7 the terms of service of the ex officio mem-
8 bers of the Board as members of the
9 Board shall terminate.

10 “(iii) CHAIR.—The ex officio members
11 of the Board under subparagraph (B) shall
12 designate an appointed member of the
13 Board to serve as the Chair of the Board.

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

15 “(A) establish by-laws for the Institute
16 that—

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

19 “(ii) establish policies for the selection
20 of the officers, employees, agents, and con-
21 tractors of the Institute;

22 “(iii) establish policies, including eth-
23 ical standards, for the acceptance, sollicita-
24 tion, and disposition of donations and

1 grants to the Institution and for the dis-
2 position of the assets of the Institute;

3 “(iv) establish policies whereby any
4 individual who is an officer, employee, or
5 member of the Board of the Institute may
6 not personally or substantially participate
7 in the consideration or determination by
8 the Institute of any matter that would di-
9 rectly or predictably affect any financial
10 interest of the individual or a relative (as
11 such term is defined in section 109(16) of
12 the Ethics in Government Act of 1978) of
13 the individual, of any business organization
14 or other entity, or of which the individual
15 is an officer or employee or is negotiating
16 for employment, or in which the individual
17 has any other financial interest;

18 “(v) establish licensing, distribution,
19 and publication policies that support the
20 widest and least restrictive use by the pub-
21 lic of information and inventions developed
22 by the Institute or with Institute funds to
23 carry out the duties described in para-
24 graphs (6) and (7) of subsection (c);

1 “(vi) specify principles for the review
2 of proposals and awarding of grants and
3 contracts that include peer review and that
4 are substantially consistent with those of
5 the Foundation for the National Institutes
6 of Health;

7 “(vii) specify a process for annual
8 Board review of the operations of the Insti-
9 tute; and

10 “(viii) establish specific duties of the
11 Executive Director;

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

14 “(C) evaluate the performance of the Exec-
15 utive Director; and

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

18 “(3) ADDITIONAL BOARD FUNCTIONS.—The
19 Board may coordinate and collaborate with other en-
20 tities to conduct research, education, and outreach,
21 and to modernize the sciences of developing, manu-
22 facturing, and evaluating the safety and effective-
23 ness of diagnostics, devices, biologics, and drugs.

24 “(4) TERMS AND VACANCIES.—

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

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

9 “(i) shall not affect the power of the
10 remaining members to execute the duties
11 of the Board; and

12 “(ii) shall be filled by appointment by
13 the individuals described in clauses (i)
14 through (v) of paragraph (1)(B) by major-
15 ity vote.

16 “(C) PARTIAL TERM.—If a member of the
17 Board does not serve the full term applicable
18 under subparagraph (A), the individual ap-
19 pointed under subparagraph (B) to fill the re-
20 sulting vacancy shall be appointed for the re-
21 mainder of the term of the predecessor of the
22 individual.

23 “(D) SERVING PAST TERM.—A member of
24 the Board may continue to serve after the expi-

1 ration of the term of the member until a suc-
2 cessor is appointed.

3 “(5) COMPENSATION.—Members of the Board
4 may not receive compensation for service on the
5 Board. Such members may be reimbursed for travel,
6 subsistence, and other necessary expenses incurred
7 in carrying out the duties of the Board, as set forth
8 in the bylaws issued by the Board.

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

12 “(f) NONPROFIT STATUS.—The Institute shall be
13 considered to be a corporation under section 501(c) of the
14 Internal Revenue Code of 1986, and shall be subject to
15 the provisions of such section.

16 “(g) EXECUTIVE DIRECTOR.—

17 “(1) IN GENERAL.—The Board shall appoint an
18 Executive Director who shall serve at the pleasure of
19 the Board. The Executive Director shall be respon-
20 sible for the day-to-day operations of the Institute
21 and shall have such specific duties and responsibil-
22 ities as the Board shall prescribe.

23 “(2) COMPENSATION.—The compensation of
24 the Executive Director shall be fixed by the Board

1 but shall not be greater than the compensation of
2 the Commissioner of Food and Drugs.

3 “(h) ADMINISTRATIVE POWERS.—In carrying out
4 this subchapter, the Board, acting through the Executive
5 Director, may—

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

8 “(2) hire, promote, compensate, and discharge
9 1 or more officers, employees, and agents, as may be
10 necessary, and define their duties;

11 “(3) prescribe the manner in which—

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

14 “(B) general operations of the Institute
15 are to be conducted; and

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

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

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

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

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

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

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

14 “(10) sue and be sued in its corporate name,
15 and complain and defend in courts of competent ju-
16 risdiction;

17 “(11) appoint other groups of advisors as may
18 be determined necessary to carry out the functions
19 of the Institute; and

20 “(12) exercise other powers as set forth in this
21 section, and such other incidental powers as are nec-
22 essary to carry out its powers, duties, and functions
23 in accordance with this subchapter.

24 “(i) ACCEPTANCE OF FUNDS FROM OTHER
25 SOURCES.—The Executive Director may solicit and accept

1 on behalf of the Institute, any funds, gifts, grants, devises,
2 or bequests of real or personal property made to the Insti-
3 tute, including from private entities, for the purposes of
4 carrying out the duties of the Institute.

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

10 “(k) DETAIL OF GOVERNMENT EMPLOYEES.—Fed-
11 eral Government employees may be detailed from Federal
12 agencies with or without reimbursement to those agencies
13 to the Institute at any time, and such detail shall be with-
14 out interruption or loss of civil service status or privilege.
15 Each such employee shall abide by the statutory, regu-
16 latory, ethical, and procedural standards applicable to the
17 employees of the agency from which such employee is de-
18 tailed and those of the Institute.

19 “(l) ANNUAL REPORTS.—

20 “(1) REPORTS TO INSTITUTE.—Any recipient of
21 a grant, contract, or cooperative agreement from the
22 Institute under this section shall submit to the Insti-
23 tute a report on an annual basis for the duration of
24 such grant, contract, or cooperative agreement, that

1 describes the activities carried out under such grant,
2 contract, or cooperative agreement.

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

6 “(A) details the progress of the Institute in
7 furthering the goals and priorities established
8 under subsection (c)(2); and

9 “(B) provides recommendations for incor-
10 porating such progress into regulatory and
11 product review activities of the Food and Drug
12 Administration.

13 “(3) REPORT TO CONGRESS.—Beginning with
14 fiscal year 2009, the Executive Director shall submit
15 to the Committee on Health, Education, Labor, and
16 Pensions and the Committee on Appropriations of
17 the Senate and the Committee on Energy and Com-
18 merce and the Committee on Appropriations of the
19 House of Representatives an annual report that—

20 “(A) describes the activities of the Insti-
21 tute and of the recipients of a grant, contract,
22 or cooperative agreement under this section, in-
23 cluding the practical impact of the Institute on
24 medical product development;

1 “(B) provides a specific accounting of the
2 source of all funds used by the Institute to
3 carry out such activities; and

4 “(C) describes how such funds were used
5 by the Institute.

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

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

14 (b) OTHER INSTITUTE PROVISIONS.—Chapter VII
15 (21 U.S.C. 371 et seq.) (as amended by subsection (a))
16 is amended by adding at the end the following:

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

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

21 “(b) USE OF SPACE.—The Secretary shall consult
22 with the Administrator of General Services to ensure the
23 most cost-efficient arrangement for the leasing or pur-
24 chase of real property for adequate facilities which, if
25 practicable, shall be located at the Food and Drug Admin-

1 istration, to meet the needs of the Institute in carrying
2 out this subchapter.

3 **“SEC. 772. ACTIVITIES OF THE FOOD AND DRUG ADMINIS-**
4 **TRATION.**

5 “(a) IN GENERAL.—The Commissioner shall receive
6 and assess the report submitted to the Commissioner by
7 the Executive Director of the Institute under section
8 770(1)(2).

9 “(b) REPORT TO CONGRESS.—The Commissioner
10 shall submit to the Committee on Health, Education,
11 Labor, and Pensions and the Committee on Appropria-
12 tions of the Senate and the Committee on Energy and
13 Commerce and the Committee on Appropriations of the
14 House of Representatives an annual report that describes
15 the implementation of any recommendations included in
16 the report described under subsection (a).”.

17 **TITLE III—CLINICAL TRIALS**

18 **SEC. 301. CLINICAL TRIAL REGISTRY DATABASE AND CLIN-**
19 **ICAL TRIAL RESULTS DATABASE.**

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

23 “(i) CLINICAL TRIAL REGISTRY DATABASE; CLIN-
24 ICAL TRIAL RESULTS DATABASE.—

25 “(1) DEFINITIONS; REQUIREMENT.—

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

2 “(i) CLINICAL TRIAL INFORMATION.—

3 The term ‘clinical trial information’ means
4 those data elements that are necessary to
5 complete an entry in the clinical trial reg-
6 istry database under paragraph (2) or the
7 clinical trial results database under para-
8 graph (3), as applicable.

9 “(ii) COMPLETION DATE.—The term
10 ‘completion date’ means, with respect to a
11 clinical trial, the date on which the last pa-
12 tient enrolled in the clinical trial has com-
13 pleted his or her last medical visit of the
14 clinical trial, whether the clinical trial con-
15 cluded according to the prespecified pro-
16 tocol plan or was terminated.

17 “(iii) DRUG.—The term ‘drug’ means
18 a drug as defined in section 201(g) of the
19 Federal Food, Drug, and Cosmetic Act or
20 a biological product as defined in section
21 351 of this Act.

22 “(iv) RESPONSIBLE PARTY.—The
23 term ‘responsible party’, with respect to a
24 clinical trial of a drug, means the sponsor
25 of the clinical trial or the principal investi-

1 gator of such clinical trial if so designated
2 by such sponsor.

3 “(B) REQUIREMENT.—The Secretary shall
4 develop a mechanism by which—

5 “(i) the responsible party for each ap-
6 plicable clinical trial shall submit the iden-
7 tity and contact information of such re-
8 sponsible party to the Secretary at the
9 time of submission of clinical trial informa-
10 tion under paragraph (2); and

11 “(ii) other Federal agencies may iden-
12 tify the responsible party for an applicable
13 clinical trial.

14 “(2) CLINICAL TRIAL REGISTRY DATABASE.—

15 “(A) APPLICABLE CLINICAL TRIAL.—

16 “(i) IN GENERAL.—For purposes of
17 this paragraph the term ‘applicable clinical
18 trial’ means—

19 “(I) a therapeutic or chemo-
20 preventive clinical trial to verify the
21 efficacy and establish appropriate
22 doses for the drug conducted before
23 the drug is approved under section
24 505 of the Federal Food, Drug, and

1 Cosmetic Act or licensed under section
2 351 of this Act;

3 “(II) a therapeutic or chemo-
4 preventive confirmatory clinical trial;

5 “(III) a clinical trial conducted
6 after the drug is approved under such
7 section 505 or licensed under such
8 section 351; or

9 “(IV) a pharmacokinetic study to
10 support a pediatric indication for the
11 drug.

12 “(ii) EXCEPTIONS.—

13 “(I) CERTAIN EXPLORATORY
14 TRIALS.—A clinical trial under clause
15 (i)(I) does not include an exploratory
16 clinical trial that is intended solely to
17 assess safety, solely to evaluate phar-
18 macokinetics, or solely to verify effi-
19 cacy.

20 “(II) OBSERVATIONAL STUD-
21 IES.—A clinical trial under clause (i)
22 does not include an observational
23 study.

24 “(B) ESTABLISHMENT.—

1 “(i) IN GENERAL.—To enhance pa-
2 tient enrollment and provide a mechanism
3 to track subsequent progress of clinical
4 trials, the Secretary, acting through the
5 Director of NIH, shall establish and ad-
6 minister a clinical trial registry database in
7 accordance with this subsection (referred
8 to in this subsection as the ‘registry data-
9 base’). The Director of NIH shall ensure
10 that the registry database is made publicly
11 available through the Internet.

12 “(ii) CONTENT.—The Secretary shall
13 promulgate regulations for the submission
14 to the registry database of clinical trial in-
15 formation that—

16 “(I) conforms to the Inter-
17 national Clinical Trials Registry Plat-
18 form trial registration data set of the
19 World Health Organization;

20 “(II) includes the city, State, and
21 zip code for each clinical trial location;

22 “(III) if the drug is not approved
23 under section 505 of the Federal
24 Food, Drug, and Cosmetic Act or li-
25 censed under section 351 of this Act,

1 specifies whether or not there is ex-
2 panded access to the drug under sec-
3 tion 561 of the Federal Food, Drug,
4 and Cosmetic Act for those who do
5 not qualify for enrollment in the clin-
6 ical trial and how to obtain informa-
7 tion about such access; and

8 “(IV) requires the inclusion of
9 such other data elements to the reg-
10 istry database as appropriate.

11 “(C) FORMAT AND STRUCTURE.—

12 “(i) SEARCHABLE CATEGORIES.—The
13 Director of NIH shall ensure that the pub-
14 lic may search the entries in the registry
15 database by 1 or more of the following cri-
16 teria:

17 “(I) The indication being studied
18 in the clinical trial, using Medical
19 Subject Headers (MeSH) descriptors.

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

22 “(III) The enrollment status of
23 the clinical trial.

24 “(IV) The sponsor of the clinical
25 trial.

1 “(ii) **FORMAT.**—The Director of the
2 NIH shall ensure that the registry data-
3 base is easily used by patients, and that
4 entries are easily compared.

5 “(D) **DATA SUBMISSION.**—The responsible
6 party for an applicable clinical trial shall submit
7 to the Director of NIH for inclusion in the reg-
8 istry database the clinical trial information de-
9 scribed in subparagraph (B)(ii).

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 an applicable
19 clinical trial to include information from
20 any source other than such clinical trial.

21 “(F) **CHANGES IN CLINICAL TRIAL STA-**
22 **TUS.**—

23 “(i) **ENROLLMENT.**—The responsible
24 party for an applicable clinical trial shall
25 update the enrollment status not later than

1 30 days after the enrollment status of such
2 clinical trial changes.

3 “(ii) COMPLETION.—The responsible
4 party for an applicable clinical trial shall
5 report to the Director of NIH that such
6 clinical trial is complete not later than 30
7 days after the completion date of the clin-
8 ical trial.

9 “(G) TIMING OF SUBMISSION.—The clin-
10 ical trial information for an applicable clinical
11 trial required to be submitted under this para-
12 graph shall be submitted not later than 14 days
13 after the first patient is enrolled in such clinical
14 trial.

15 “(3) CLINICAL TRIALS RESULTS DATABASE.—

16 “(A) APPLICABLE CLINICAL TRIAL.—

17 “(i) IN GENERAL.—For purposes of
18 this paragraph, the term ‘applicable clin-
19 ical trial’ means—

20 “(I) a clinical trial conducted be-
21 fore the drug is approved under sec-
22 tion 505 of the Federal Food, Drug,
23 and Cosmetic Act or licensed under
24 section 351 of this Act that is—

1 “(aa) a therapeutic or
2 chemopreventive confirmatory
3 clinical trial;

4 “(bb) a clinical trial for a
5 drug approved as a fast-track
6 product under section 506 of the
7 Federal Food, Drug, and Cos-
8 metic Act, if such clinical trial is
9 used to form the primary basis of
10 an efficacy claim for such drug;
11 or

12 “(cc) if required by the Sec-
13 retary under subparagraph
14 (G)(i), a clinical trial described in
15 paragraph (2)(A)(i)(I);

16 “(II) a clinical trial completed
17 after the drug is approved under such
18 section 505 or licensed under such
19 section 351; or

20 “(III) a pharmacokinetic study to
21 support a pediatric indication for the
22 drug.

23 “(ii) EXCEPTIONS.—

24 “(I) CERTAIN EXPLORATORY
25 TRIALS.—A clinical trial under clause

1 (i)(I) does not include an exploratory
2 clinical trial that is intended solely to
3 assess safety, solely to evaluate phar-
4 macokinetics, or solely to verify effi-
5 cacy.

6 “(II) OBSERVATION STUDIES.—A
7 clinical trial under clause (i) does not
8 include an observational study.

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

18 “(C) SEARCHABLE CATEGORIES.—The Di-
19 rector of NIH shall ensure that the public may
20 search the entries in the results database by 1
21 or more of the following:

22 “(i) The indication studied in the clin-
23 ical trial, using Medical Subject Headers
24 (MeSH) descriptors.

1 “(ii) The safety issue studied in the
2 clinical trial.

3 “(iii) Whether an application for the
4 tested indication is approved, pending ap-
5 proval, withdrawn, or not submitted.

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

7 “(v) The name of the drug that is the
8 subject of the clinical trial.

9 “(vi) Within the documents described
10 in subclauses (II) and (III) of subpara-
11 graph (D)(ii), the following information, as
12 applicable:

13 “(I) The sponsor of the clinical
14 trial.

15 “(II) Each financial sponsor of
16 the clinical trial.

17 “(D) CONTENTS.—

18 “(i) IN GENERAL.—The responsible
19 party for an applicable clinical trial shall
20 submit to the Director of NIH for inclu-
21 sion in the results database the clinical
22 trial information described in clause (ii).

23 “(ii) REQUIRED ELEMENTS.—In sub-
24 mitting clinical trial information for an ap-
25 plicable clinical trial to the Director of

1 NIH for inclusion in the results database,
2 the responsible party shall include, with re-
3 spect to such clinical trial, the following in-
4 formation:

5 “(I) The information described in
6 clauses (i) through (v) of subpara-
7 graph (C).

8 “(II) A non-promotional sum-
9 mary document that is written in non-
10 technical, understandable language for
11 patients that includes the following:

12 “(aa) The purpose of the
13 clinical trial.

14 “(bb) The sponsor of the
15 clinical trial.

16 “(cc) A point of contact for
17 information about the clinical
18 trial.

19 “(dd) A description of the
20 patient population tested in the
21 clinical trial.

22 “(ee) A general description
23 of the clinical trial and results,
24 including a description of and the
25 reasons for any changes in the

1 clinical trial design that occurred
2 since the date of submission of
3 clinical trial information for in-
4 clusion in the registry database
5 established under paragraph (2)
6 and a description of any signifi-
7 cant safety information.

8 “(III) A non-promotional sum-
9 mary document that is technical in
10 nature that includes the following:

11 “(aa) The purpose of the
12 clinical trial.

13 “(bb) The sponsor of the
14 clinical trial.

15 “(cc) Each financial sponsor
16 of the clinical trial.

17 “(dd) A point of contact for
18 scientific information about the
19 clinical trial.

20 “(ee) A description of the
21 patient population tested in the
22 clinical trial.

23 “(ff) A general description
24 of the clinical trial and results,
25 including a description of and the

1 reasons for any changes in the
2 clinical trial design that occurred
3 since the date of submission of
4 clinical trial information for the
5 clinical trial in the registry data-
6 base established under paragraph
7 (2).

8 “(gg) Summary data de-
9 scribing the results, including—

10 “(AA) whether the pri-
11 mary endpoint was achieved,
12 including relevant statistics;

13 “(BB) an assessment of
14 any secondary endpoints, if
15 applicable, including relevant
16 statistics; and

17 “(CC) any significant
18 safety information, including
19 a summary of the incidence
20 of serious adverse events ob-
21 served in the clinical trial
22 and a summary of the most
23 common adverse events ob-
24 served in the clinical trial

1 and the frequencies of such
2 events.

3 “(IV) A link to available peer-re-
4 viewed publications based on the re-
5 sults of the clinical trial.

6 “(V) The completion date of the
7 clinical trial.

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

17 “(E) TIMING.—A responsible party shall
18 submit to the Director of NIH for inclusion in
19 the results database clinical trial information
20 for an applicable clinical trial not later than 1
21 year after the completion date of the clinical
22 trial as reported under paragraph (2)(F)(ii).

23 “(F) TRUTHFUL CLINICAL TRIAL INFOR-
24 MATION.—

1 “(i) IN GENERAL.—The clinical trial
2 information submitted by a responsible
3 party under this paragraph shall not be
4 false or misleading in any particular.

5 “(ii) EFFECT.—Clause (i) shall not
6 have the effect of requiring clinical trial in-
7 formation with respect to an applicable
8 clinical trial to include information from
9 any source other than such clinical trial.

10 “(G) INCLUSION OF EARLIER-STAGE CLIN-
11 ICAL TRIALS.—

12 “(i) IN GENERAL.—The Secretary
13 may, subject to clause (ii), require through
14 rulemaking the submission of clinical trial
15 information for the clinical trials described
16 in paragraph (2)(A)(i)(I) to the Director of
17 NIH for inclusion in the results database.

18 “(ii) CONDITIONS FOR REQUIRING IN-
19 CLUSION OF EARLIER-STAGE TRIALS.—The
20 Secretary may promulgate regulations pur-
21 suant to clause (i) if—

22 “(I) the Comptroller General of
23 the United States has submitted to
24 the Secretary the report described
25 under clause (iii); and

1 “(II) such report recommends
2 the inclusion in the results database
3 of clinical trial information for the
4 clinical trials described under para-
5 graph (2)(A)(i)(I).

6 “(iii) STUDY BY GAO.—Not earlier
7 than 2 years after the results database has
8 been established, the Comptroller General
9 of the United States shall initiate a report
10 that—

11 “(I) evaluates the operation of
12 the database, including with respect to
13 cost, burden on drug sponsors and
14 agencies, and the value to patients
15 and health care providers of inclusion
16 in the results database of clinical trial
17 information with respect to clinical
18 trials described in paragraph
19 (2)(A)(i)(I);

20 “(II) recommends whether or not
21 clinical trial information for such clin-
22 ical trials should be included in the re-
23 sults database;

24 “(III) if the recommendation
25 under subclause (II) is to include the

1 clinical trial information for such clin-
2 ical trials in the results database, rec-
3 ommends whether such information
4 should be included in the same format
5 as the clinical trial information of
6 other applicable clinical trials, or if
7 modifications are necessary;

8 “(IV) provides recommendations
9 for any modifications described under
10 subclause (III); and

11 “(V) is submitted to the Com-
12 mittee on Health, Education, Labor,
13 and Pensions of the Senate, the Com-
14 mittee on Energy and Commerce of
15 the House of Representatives, and the
16 Secretary.

17 “(H) CHANGE IN REGULATORY STATUS.—
18 The responsible party for an applicable clinical
19 trial shall inform the Director of NIH of a
20 change in the regulatory status submitted
21 under subparagraph (C)(ii) of a drug that is
22 the subject of an applicable clinical trial within
23 30 days of such change, so that the Director
24 can update the results database accordingly.

25 “(I) PUBLIC AVAILABILITY OF RESULTS.—

1 “(i) PRE-APPROVAL STUDIES.—EX-
2 cept as provided in clause (iv), with respect
3 to an applicable clinical trial that is com-
4 pleted before the drug is initially approved
5 under section 505 of the Federal Food,
6 Drug, and Cosmetic Act or initially li-
7 censed under section 351 of this Act, the
8 Director of NIH shall make publicly avail-
9 able on the results database the clinical
10 trial information submitted for such clin-
11 ical trial not later than 30 days after—

12 “(I) the drug is approved under
13 such section 505 or licensed under
14 such section 351; or

15 “(II) the Secretary issues a not
16 approvable letter for the drug under
17 such section 505 or such section 351.

18 “(ii) POST-APPROVAL STUDIES.—EX-
19 cept as provided in clauses (iii) and (iv),
20 with respect to an applicable clinical trial
21 that is completed after the drug is initially
22 approved under such section 505 or ini-
23 tially licensed under such section 351, the
24 Director of NIH shall make publicly avail-
25 able on the results database the clinical

1 trial information submitted for such clin-
2 ical trial not later than 30 days after the
3 date of such submission.

4 “(iii) SEEKING APPROVAL OF A NEW
5 USE FOR THE DRUG.—

6 “(I) IN GENERAL.—If the manu-
7 facturer of the drug is the sponsor or
8 a financial sponsor of the applicable
9 clinical trial, and such manufacturer
10 certifies to the Director of NIH that
11 such manufacturer has filed, or will
12 file within 1 year, an application seek-
13 ing approval under such section 505
14 or licensing under such section 351
15 for the use studied in such clinical
16 trial (which use is not included in the
17 labeling of the approved drug), then
18 the Director of NIH shall make pub-
19 licly available on the results database
20 the clinical trial information sub-
21 mitted for such clinical trial on the
22 earlier of the date that is 30 days
23 after the date—

1 “(aa) the application is ap-
2 proved under such section 505 or
3 licensed such section 351;

4 “(bb) the Secretary issues a
5 not approvable letter for the ap-
6 plication under such section 505
7 or such section 351; or

8 “(cc) the application under
9 such section 505 or such section
10 351 is withdrawn.

11 “(II) LIMITATION ON CERTIFI-
12 CATION.—A manufacturer shall not
13 make a certification under subclause
14 (I) with respect to an applicable clin-
15 ical trial unless the manufacturer
16 makes such a certification with re-
17 spect to each applicable clinical trial
18 that is required to be submitted in an
19 application for approval of the use
20 studied in the clinical trial involved.

21 “(III) 2-YEAR LIMITATION.—The
22 clinical trial information subject to
23 subclause (I) shall be made publicly
24 available on the results database on
25 the date that is 2 years after the date

1 the certification referred to in sub-
2 clause (I) was made to the Director of
3 NIH, if a regulatory action referred to
4 in item (aa), (bb), or (cc) of subclause
5 (I) has not occurred by such date.

6 “(iv) SEEKING PUBLICATION.—

7 “(I) IN GENERAL.—If the prin-
8 cipal investigator of the applicable
9 clinical trial is seeking publication in
10 a peer-reviewed biomedical journal of
11 a manuscript based on the results of
12 the clinical trial and the responsible
13 party so certifies to the Director of
14 NIH—

15 “(aa) the responsible party
16 shall notify the Director of NIH
17 of the publication date of such
18 manuscript not later than 15
19 days after such date; and

20 “(bb) the Director of NIH
21 shall make publicly available on
22 the results database the clinical
23 trial information submitted for
24 such clinical trial on the date

1 that is 30 days after the publica-
2 tion date of such manuscript.

3 “(II) LIMITATION.—The clinical
4 trial information subject to subclause
5 (I) shall be made publicly available on
6 the results database on the date that
7 is 2 years after the date that the clin-
8 ical trial information was required to
9 be submitted to the Director of NIH
10 if the manuscript referred to in such
11 subclause has not been published by
12 such date.

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

25 “(4) COORDINATION AND COMPLIANCE.—

1 “(A) CLINICAL TRIALS SUPPORTED BY
2 GRANTS FROM FEDERAL AGENCIES.—

3 “(i) IN GENERAL.—No Federal agen-
4 cy may release funds under a research
5 grant to a person who has not complied
6 with paragraphs (2) and (3) for any appli-
7 cable clinical trial for which such person is
8 the responsible party.

9 “(ii) GRANTS FROM CERTAIN FED-
10 ERAL AGENCIES.—If an applicable clinical
11 trial is funded in whole or in part by a
12 grant from the National Institutes of
13 Health, the Agency for Healthcare Re-
14 search and Quality, or the Department of
15 Veterans Affairs, any grant or progress re-
16 port forms required under such grant shall
17 include a certification that the responsible
18 party has made all required submissions to
19 the Director of NIH under paragraphs (2)
20 and (3).

21 “(iii) VERIFICATION BY FEDERAL
22 AGENCIES.—The heads of the agencies re-
23 ferred to in clause (ii), as applicable, shall
24 verify that the clinical trial information for
25 each applicable clinical trial for which a

1 grantee is the responsible party has been
2 submitted under paragraph (2) and (3), as
3 applicable, before releasing funding for a
4 grant to such grantee.

5 “(iv) NOTICE AND OPPORTUNITY TO
6 REMEDY.—If the head of an agency re-
7 ferred to in clause (ii), as applicable,
8 verifies that a grantee has not submitted
9 clinical trial information as described in
10 clause (iii), such agency head shall provide
11 notice to such grantee of such non-compli-
12 ance and allow such grantee 30 days to
13 correct such non-compliance and submit
14 the required clinical trial information.

15 “(v) CONSULTATION WITH OTHER
16 FEDERAL AGENCIES.—The Secretary
17 shall—

18 “(I) consult with other agencies
19 that conduct human studies in accord-
20 ance with part 46 of title 45, Code of
21 Federal Regulations (or any successor
22 regulations), to determine if any such
23 studies are applicable clinical trials
24 under paragraph (2) or (3); and

1 “(II) develop with such agencies
2 procedures comparable to those de-
3 scribed in clauses (ii), (iii), and (iv) to
4 ensure that clinical trial information
5 for such applicable clinical trials is
6 submitted under paragraphs (2) and
7 (3).

8 “(B) COORDINATION OF REGISTRY DATA-
9 BASE AND RESULTS DATABASE.—

10 “(i) IN GENERAL.—Each entry in the
11 registry database under paragraph (2)
12 shall include a link to the corresponding
13 entry in the results database under para-
14 graph (3).

15 “(ii) MISSING ENTRIES.—

16 “(I) IN GENERAL.—If, based on
17 a review of the entries in the registry
18 database under paragraph (2), the Di-
19 rector of NIH determines that a re-
20 sponsible party has failed to submit
21 required clinical trial information to
22 the results database under paragraph
23 (3), the Director of NIH shall inform
24 the responsible party involved of such
25 failure and permit the responsible

1 party to correct the failure within 30
2 days.

3 “(II) FAILURE TO CORRECT.—If
4 the responsible party does not correct
5 a failure to submit required clinical
6 trial information within the 30-day
7 period described under subclause (I),
8 the Director of NIH shall report such
9 non-compliance to the scientific peer
10 review committees of the Federal re-
11 search agencies and to the Office of
12 Human Research Protections.

13 “(III) PUBLIC NOTICE OF FAIL-
14 URE TO CORRECT.—The Director of
15 NIH shall include in the clinical trial
16 registry database entry and the clin-
17 ical trial results database entry for
18 each such clinical trial a notice of any
19 uncorrected failure to submit required
20 clinical trial information and shall
21 provide that the public may easily
22 search for such entries.

23 “(C) ACTION ON APPLICATIONS.—

24 “(i) VERIFICATION PRIOR TO FIL-
25 ING.—The Secretary, acting through the

1 Commissioner of Food and Drugs, shall
2 verify that the clinical trial information re-
3 quired under paragraphs (2) and (3) for
4 an applicable clinical trial is submitted
5 pursuant to such applicable paragraph—

6 “(I) when considering a drug for
7 an exemption under section 505(i) of
8 the Federal Food, Drug, and Cos-
9 metic Act, including as the drug pro-
10 gresses through the clinical trials de-
11 scribed under paragraph (2)(A)(i);
12 and

13 “(II) prior to filing an applica-
14 tion under section 505 of the Federal
15 Food, Drug, and Cosmetic Act or
16 under section 351 of this Act that in-
17 cludes information from such clinical
18 trial.

19 “(ii) NOTIFICATION.—If the respon-
20 sible party has not submitted such clinical
21 trial information, the Secretary shall notify
22 the applicant and the responsible party of
23 such non-compliance and require submis-
24 sion of such results within 30 days.

1 “(iii) REFUSAL TO FILE.—If the re-
2 sponsible party does not remedy such non-
3 compliance within 30 days of receipt of no-
4 tification under clause (ii), the Secretary
5 shall refuse to file such application.

6 “(D) CONTENT REVIEW.—

7 “(i) IN GENERAL.—To assure that the
8 summary documents described in para-
9 graph (3)(D) are non-promotional, and are
10 not false or misleading in any particular
11 under paragraph (3)(F), the Secretary
12 shall compare such documents to the re-
13 sults data of the clinical trial for a rep-
14 resentative sample of applicable clinical
15 trials by—

16 “(I) acting through the Commis-
17 sioner of Food and Drugs to examine
18 the results data for such clinical trials
19 submitted to Secretary when such
20 data are submitted—

21 “(aa) for review as part of
22 an application under section 505
23 of the Federal Food, Drug, and
24 Cosmetic Act or under section
25 351 of this Act; or

1 “(bb) in an annual status
2 report on the drug under such
3 application;

4 “(II) acting with the Federal
5 agency that funds such clinical trial in
6 whole or in part by a grant to exam-
7 ine the results data for such clinical
8 trials; and

9 “(III) acting through inspections
10 under section 704 of the Federal
11 Food, Drug, and Cosmetic Act to ex-
12 amine results data for such clinical
13 trials not described in subclause (I) or
14 (II).

15 “(ii) NOTICE OF NON-COMPLIANCE.—
16 If the Secretary determines that the clin-
17 ical trial information submitted in such a
18 summary document is promotional, or false
19 or misleading in any particular, the Sec-
20 retary shall notify the responsible party
21 and give such party an opportunity to rem-
22 edy such non-compliance by submitting the
23 required revised clinical trial information
24 within 30 days of such notification.

1 “(E) PENALTY FOR NON-COMPLIANCE.—In
2 determining whether to apply a penalty under
3 section 301(jj) of the Federal Food, Drug, and
4 Cosmetic Act, the Secretary, acting through the
5 Commissioner of Food and Drugs, shall con-
6 sider—

7 “(i) whether the responsible party
8 promptly corrects the non-compliance when
9 provided notice;

10 “(ii) whether the responsible party
11 has engaged in a pattern or practice of
12 non-compliance; and

13 “(iii) the extent to which the non-
14 compliance involved may have significantly
15 misled healthcare providers or patients
16 concerning the safety or effectiveness of
17 the drug involved.

18 “(5) LIMITATION ON DISCLOSURE OF CLINICAL
19 TRIAL INFORMATION.—Disclosure to the public of
20 clinical trial information submitted to the Director
21 of NIH under this subsection and requested under
22 section 552 of title 5, United States Code (com-
23 monly known as the Freedom of Information Act)
24 shall be made only as provided for under paragraphs
25 (2) and (3).

1 “(6) AUTHORIZATION OF APPROPRIATIONS.—

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

4 (b) CONFORMING AMENDMENTS.—

5 (1) PROHIBITED ACTS.—Section 301 of the
6 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
7 331), as amended by Public Law 109–462, is
8 amended by adding at the end the following:

9 “(jj)(1) The failure to submit clinical trial informa-
10 tion as required by section 402(i) of the Public Health
11 Service Act.

12 “(2) The submission of clinical trial information
13 under section 402(i) of the Public Health Service Act that
14 is promotional or false or misleading in any particular
15 under paragraph (2)(E) or (3)(F) of such section 402(i).”.

16 (2) NEW DRUGS.—

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

20 (i) in paragraph (1)—

21 (I) in subparagraph (C), by strik-
22 ing “and” after the semicolon;

23 (II) in subparagraph (D), by
24 striking the period at the end and in-
25 serting “; and”; and

1 (III) by adding at the end the
2 following:

3 “(E) the submission to the Director of NIH of
4 clinical trial information for the clinical investigation
5 at issue required under section 402(i) of the Public
6 Health Service Act for inclusion in the registry data-
7 base and the results database described in such sec-
8 tion.”;

9 (ii) in paragraph (3)(B)—

10 (I) in clause (i), by striking “or”
11 after the semicolon;

12 (II) in clause (ii), by striking the
13 period at the end and inserting “; or”;
14 and

15 (III) by adding at the end the
16 following:

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

21 (iii) in paragraph (4), by adding at
22 the end the following: “The Secretary shall
23 update such regulations to require inclu-
24 sion in the informed consent form a state-
25 ment that clinical trial information for

1 such clinical investigation will be submitted
2 for inclusion in the registry database and
3 results database, as applicable, described
4 in section 402(i) of the Public Health
5 Service Act.”.

6 (B) REFUSAL TO APPROVE APPLICA-
7 TION.—Section 505(d) of the Federal Food,
8 Drug, and Cosmetic Act (21 U.S.C. 355(d)) is
9 amended—

10 (i) in the first sentence, by inserting
11 after “or any particular;” the following:
12 “or (8) the applicant failed to submit the
13 clinical trial information for any applicable
14 clinical trial submitted as part of the appli-
15 cation to the Director of the National In-
16 stitutes of Health in compliance with sec-
17 tion 402(i) of the Public Health Service
18 Act;”; and

19 (ii) in the second sentence, by striking
20 “clauses (1) through (6)” and inserting
21 “paragraphs (1) through (8)”.

22 (c) GUIDANCE.—Not later than 180 days after the
23 date of enactment of this Act, the Commissioner of Food
24 and Drugs, in consultation with the Director of the Na-
25 tional Institutes of Health, shall issue guidance to clarify

1 which clinical trials are applicable clinical trials (as de-
2 fined in section 402(i)(2) of the Public Health Service Act,
3 as amended by this section) and are required to be sub-
4 mitted for inclusion in the clinical trial registry database
5 described in such section 402(i)(2).

6 (d) PREEMPTION.—

7 (1) IN GENERAL.—No State or political subdivi-
8 sion of a State may establish or continue in effect
9 any requirement for the registration of clinical trials
10 or for the inclusion of information relating to the re-
11 sults of clinical trials in a database.

12 (2) RULE OF CONSTRUCTION.—The fact of sub-
13 mission of clinical trial information, if submitted in
14 compliance with section 402(i) of the Public Health
15 Service Act (as amended by this section), that re-
16 lates to a use of a drug not included in the official
17 labeling of the approved drug shall not be construed
18 by the Secretary or in any administrative or judicial
19 proceeding, as evidence of a new intended use of the
20 drug that is different from the intended use of the
21 drug set forth in the official labeling of the drug.
22 The availability of clinical trial information through
23 the databases under paragraphs (2) and (3) of such
24 section 402(i), if submitted in compliance with such
25 section 402(i), shall not be considered as labeling,

1 adulteration, or misbranding of the drug under the
2 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
3 301 et seq.).

4 (e) EFFECTIVE DATES.—

5 (1) ESTABLISHMENT OF REGISTRY DATABASE
6 AND RESULTS DATABASE.—Not later than 1 year
7 after the date of enactment of this Act, the Director
8 of NIH shall establish the registry database and the
9 results database of clinical trials of drugs in accord-
10 ance with section 402(i) of the Public Health Service
11 Act (as amended by subsection (a)).

12 (2) CLINICAL TRIALS INITIATED PRIOR TO OP-
13 ERATION OF REGISTRY DATABASE.—The responsible
14 party (as defined in such section 402(i)) for an ap-
15 plicable clinical trial under paragraph (2) of such
16 section 402(i) that is initiated after the date of en-
17 actment of this Act and before the date such reg-
18 istry database is established under paragraph (1) of
19 this subsection, shall submit required clinical trial
20 information not later than 120 days after the date
21 such registry database is established.

22 (3) CLINICAL TRIALS INITIATED AFTER OPER-
23 ATION OF REGISTRY DATABASE.—The responsible
24 party (as defined in such section 402(i)) for an ap-
25 plicable clinical trial under paragraph (2) of such

1 section 402(i) that is initiated after the date such
2 registry database is established under paragraph (1)
3 of this subsection shall submit required clinical trial
4 information in accordance with such paragraph (2).

5 (4) TRIALS COMPLETED BEFORE OPERATION
6 OF RESULTS DATABASE.—

7 (A) IN GENERAL.—Paragraph (3) of such
8 section 402(i) shall take effect 90 days after
9 the date the results database is established
10 under paragraph (1) of this subsection with re-
11 spect to any applicable clinical trial (as defined
12 in such section 402(i)(3)) that—

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

15 (ii) is completed between the date of
16 enactment of this section and such date of
17 establishment under paragraph (1) of this
18 subsection.

19 (B) OTHER TRIALS.—Except as provided
20 in subparagraph (A), paragraph (3) of such
21 section 402(i) shall take effect 180 days after
22 the date that the results database is established
23 under paragraph (1) of this subsection with re-
24 spect to any applicable clinical trial (as defined
25 in such section 402(i)(3)) that is completed be-

1 tween the date of enactment of this Act and
2 such date of establishment under paragraph
3 (1).

4 (C) TRIALS SUBMITTED IN AN APPLICA-
5 TION.—Except as provided in subparagraph
6 (A), paragraph (3) of such section 402(i) shall
7 take effect for any clinical trial if—

8 (i) data from such clinical trial is sub-
9 mitted in an application or supplement to
10 an application under section 505 of the
11 Food, Drug, and Cosmetic Act or under
12 section 351 of the Public Health Service
13 Act that—

14 (I) is submitted 180 days or
15 more after the date that the results
16 database is established under para-
17 graph (1) of this subsection; and

18 (II) contains data from an appli-
19 cable clinical trial; and

20 (ii) such clinical trial would otherwise
21 be an applicable clinical trial under such
22 paragraph (3) except for its date of com-
23 pletion.

24 (5) TRIALS COMPLETED AFTER ESTABLISH-
25 MENT OF RESULTS DATABASE.—Paragraph (3) of

1 such section 402(i) shall apply to any applicable
2 clinical trial that is completed after the date that the
3 results database is established under paragraph (1)
4 of this subsection.

5 (6) FUNDING RESTRICTIONS.—Subparagraph
6 (A) of paragraph (4) of such section 402(i) shall
7 take effect 210 days after the date that the clinical
8 trial registry database and the clinical trial results
9 database are established under paragraph (1) of this
10 subsection.

11 (7) STATUS OF CLINICALTRIALS.GOV
12 WEBSITE.—

13 (A) IN GENERAL.—After receiving public
14 comment and not later than 90 days after the
15 date of enactment of this Act, the Secretary
16 shall publish in the Federal Register a notice
17 determining the more efficient approach to es-
18 tablishing the registry database described in
19 paragraph (2) of such section 402(i) and
20 whether such approach is—

21 (i) that such registry database should
22 expand and build upon the database de-
23 scribed in section 402(i) of the Public
24 Health Service Act (as in effect on the day

1 before the date of enactment of this Act);

2 or

3 (ii) that such registry database should
4 supplant the database described in such
5 section 402(i) (as in effect on the day be-
6 fore the date of enactment of this Act).

7 (B) CLINICALTRIALS.GOV SUPPLANTED.—

8 If the Secretary determines to apply the ap-
9 proach described under subparagraph (A)(ii),
10 the Secretary shall maintain an archive of the
11 database described in such section 402(i) (as in
12 effect on the day before the date of enactment
13 of this Act) on the Internet website of the Na-
14 tional Library of Medicine.

15 **TITLE IV—CONFLICTS OF** 16 **INTEREST**

17 **SEC. 401. CONFLICTS OF INTEREST.**

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

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

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

23 “(1) ADVISORY COMMITTEE.—The term ‘advi-
24 sory committee’ means an advisory committee under
25 the Federal Advisory Committee Act that provides

1 advice or recommendations to the Secretary regard-
2 ing activities of the Food and Drug Administration.

3 “(2) FINANCIAL INTEREST.—The term ‘finan-
4 cial interest’ means a financial interest under section
5 208(a) of title 18, United States Code.

6 “(3) INDUSTRY FINANCIAL INTEREST.—The
7 term ‘industry financial interest’, with respect to ap-
8 pointment for a term to an advisory committee,
9 means an interest in a company that is a member
10 of the relevant industry that would be a financial in-
11 terest were an advisory committee to consider a par-
12 ticular matter involving such company.

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

15 “(A) with respect to an advisory committee
16 that advises the Secretary on human drugs, bio-
17 logics, or devices, the pharmaceutical, bio-
18 technology, and device industries;

19 “(B) with respect to an advisory committee
20 that advises the Secretary on animal drugs or
21 devices, the animal drug and the animal device
22 industries; and

23 “(C) with respect to an advisory committee
24 that advises the Secretary on foods, the food in-
25 dustry.

1 “(b) APPOINTMENTS TO ADVISORY COMMITTEES.—

2 “(1) DISCLOSURE OF INDUSTRY FINANCIAL IN-
3 TERESTS.—Each individual under consideration for
4 a term appointment to an advisory committee shall
5 disclose to the Secretary all industry financial inter-
6 ests.

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

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

13 “(A) shall review the expertise and the in-
14 dustry financial interests, as disclosed under
15 paragraph (1), of each individual under consid-
16 eration for the appointment, so as to appoint
17 the individuals, from among those individuals
18 under consideration for appointment, who are
19 the most qualified relative to their industry fi-
20 nancial interests that could require a written
21 determination as referred to in section
22 208(b)(1) of title 18, United States Code, a
23 written certification as referred to in section
24 208(b)(3) of title 18, United States Code, or a
25 waiver as referred to in subsection (c)(3) for

1 service on the committee at a meeting of the
2 committee; and

3 “(B) may appoint 2 or more qualified indi-
4 viduals with similar expertise and whose indus-
5 try financial interests are nonoverlapping or
6 minimally overlapping, so as to minimize the
7 likelihood that an advisory committee will need
8 the expertise of an appointed individual who re-
9 quires a written determination as referred to in
10 section 208(b)(1) of title 18, United States
11 Code, a written certification as referred to in
12 section 208(b)(3) of title 18, United States
13 Code, or a waiver as referred to in subsection
14 (c)(3) for service on the committee at a meeting
15 of the committee.

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

17 “(1) IN GENERAL.—Not later than 45 days be-
18 fore a meeting of an advisory committee, each mem-
19 ber of the committee shall disclose to the Secretary
20 all financial interests in accordance with section
21 208(b) of title 18, United States Code.

22 “(2) FINANCIAL GAIN OF ADVISORY COMMITTEE
23 MEMBER OR FAMILY MEMBER.—No member of an
24 advisory committee may vote with respect to any
25 matter considered by the advisory committee if such

1 member or an immediate family member of such
2 member could gain financially from the advice given
3 to the Secretary with respect to such matter.

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

9 “(4) LIMITATION.—In no case may the Sec-
10 retary grant a waiver under paragraph (3) for a
11 member of an advisory committee if the scientific
12 work of such member is under consideration by the
13 committee.

14 “(5) DISCLOSURE OF WAIVER.—

15 “(A) MORE THAN 15 DAYS IN ADVANCE.—

16 As soon as practicable, but in no case later
17 than 15 days prior to a meeting of an advisory
18 committee to which a written determination as
19 referred to in section 208(b)(1) of title 18,
20 United States Code, a written certification as
21 referred to in section 208(b)(3) of title 18,
22 United States Code, or a waiver as referred to
23 in paragraph (3) applies, the Secretary shall
24 disclose (other than information exempted from
25 disclosure under section 552 of title 5, United

1 States Code, and section 552a of title 5, United
2 States Code (popularly known as the Freedom
3 of Information Act and the Privacy Act of
4 1974, respectively)) on the Internet website of
5 the Food and Drug Administration—

6 “(i) the financial interests of the advi-
7 sory committee member to which such de-
8 termination, certification, or waiver ap-
9 plies; and

10 “(ii) the reasons of the Secretary for
11 such determination, certification, or waiv-
12 er.

13 “(B) LESS THAN 15 DAYS IN ADVANCE.—

14 In the case of a financial interest that becomes
15 known to the Secretary less than 30 days prior
16 to a meeting of an advisory committee to which
17 a written determination as referred to in section
18 208(b)(1) of title 18, United States Code, a
19 written certification as referred to in section
20 208(b)(3) of title 18, United States Code, or a
21 waiver as referred to in paragraph (3) applies,
22 the Secretary shall disclose (other than infor-
23 mation exempted from disclosure under section
24 552 of title 5, United States Code, and section
25 552a of title 5, United States Code) on the

1 Internet website of the Food and Drug Admin-
2 istration, the information described in clauses
3 (i) and (ii) of subparagraph (A) as soon as the
4 Secretary makes such determination, certifi-
5 cation, or waiver, but in no event later than the
6 date of such meeting.

7 “(d) PUBLIC RECORD.—The Secretary shall ensure
8 that the public record and transcript of each meeting of
9 an advisory committee includes the disclosure required
10 under subsection (c)(5) (other than information exempted
11 from disclosure under section 552 of title 5, United States
12 Code, and section 552a of title 5, United States Code).

13 “(e) ANNUAL REPORT.—Not later than January 15
14 of each year, the Secretary shall submit a report to the
15 Inspector General of the Department of Health and
16 Human Services, the Committee on Appropriations and
17 the Committee on Health, Education, Labor, and Pen-
18 sions of the Senate, and the Committee on Appropriations
19 and the Committee on Energy and Commerce of the
20 House of Representatives—

21 “(1) with respect to the fiscal year that ended
22 on September 30 of the previous year, the number
23 of vacancies on each advisory committee, the number
24 of nominees received for each committee, and the
25 number of such nominees willing to serve;

1 “(2) with respect to such year, the aggregate
2 number of disclosures required under subsection
3 (c)(5) for each meeting of each advisory committee
4 and the percentage of individuals to whom such dis-
5 closures did not apply who served on such committee
6 for each such meeting;

7 “(3) with respect to such year, the number of
8 times the disclosures required under subsection
9 (c)(5) occurred under subparagraph (B) of such sub-
10 section; and

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

14 (b) GUIDANCE.—

15 (1) NOMINATIONS.—Not later than 270 days
16 after the date of enactment of this Act, and after
17 seeking input from professional medical and sci-
18 entific societies, the Secretary shall publish in the
19 Federal Register for public comment a proposed
20 mechanism for encouraging the nomination of indi-
21 viduals who are classified by the Food and Drug Ad-
22 ministration as academicians or practitioners for
23 service on an advisory committee.

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

4 (A) that clarifies the circumstances in
5 which the Secretary may make a written deter-
6 mination as referred to in section 208(b)(1) of
7 title 18, United States Code, make a written
8 certification as referred to in section 208(b)(3)
9 of title 18, United States Code, or grant a waiv-
10 er as referred to section 712(c)(3) of the Fed-
11 eral Food, Drug, and Cosmetic Act (as added
12 by this section), including those circumstances
13 that—

14 (i) favor the inclusion of an individual
15 on an advisory committee;

16 (ii) favor making such a determina-
17 tion, certification, or waiver for an indi-
18 vidual on an advisory committee;

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

23 (iv) disfavor the inclusion of an indi-
24 vidual on an advisory committee;

1 (B) that defines how financial interests im-
2 puted to an individual bear upon his or her eli-
3 gibility for service on an advisory committee or
4 for service at a meeting of an advisory com-
5 mittee; and

6 (C) to ensure consistency within and
7 among the centers of the Food and Drug Ad-
8 ministration in applying section 208(b) of title
9 18, United States Code, and such section
10 712(c)(3).

11 (3) PERIODIC REVIEW.—At least once every 5
12 years, the Secretary shall review the guidance de-
13 scribed under paragraph (2) and update such guid-
14 ance as necessary.

15 (c) REVIEW BY INSPECTOR GENERAL.—

16 (1) IN GENERAL.—The Inspector General of
17 the Department of Health and Human Services shall
18 conduct a review, which may include surveys of past
19 or current members of advisory committees, of the
20 processes of the Food and Drug Administration
21 for—

22 (A) evaluating the financial interests of a
23 member of such an advisory committee while
24 the member serves on such a committee and

1 after the member has served on such a com-
2 mittee; and

3 (B) assuring the completeness and accu-
4 racy of information contained in the disclosures
5 described in subsections (b)(1) and (c)(1) of
6 such section 712 of the Federal Food, Drug,
7 and Cosmetic Act (as added by this section).

8 (2) SUBMISSION OF REPORT.—Not later than
9 18 months after the effective date of this section,
10 the Inspector General of the Department of Health
11 and Human Services shall submit to Congress a re-
12 port based on the review required under paragraph
13 (1), and include any recommendations for the im-
14 provement of such processes.

15 (d) DEFINITIONS.—For purposes of this section, the
16 terms “advisory committee” and “financial interest” have
17 the meaning given such terms in section 712 of the Fed-
18 eral Food, Drug, and Cosmetic Act (as added by this sec-
19 tion).

20 (e) CONFORMING AMENDMENT.—Section 505(n) of
21 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
22 355(n)) is amended by—

23 (1) striking paragraph (4); and

24 (2) redesignating paragraphs (5), (6), (7), and

25 (8) as paragraphs (4), (5), (6), and (7), respectively.

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

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