

109TH CONGRESS  
2D SESSION

# S. 3807

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.

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## IN THE SENATE OF THE UNITED STATES

AUGUST 3, 2006

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

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## 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 2006”.

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 (j) or 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, which—

15 “(A) shall require the elements under  
16 paragraph (3); and

17 “(B) may require one or more additional  
18 elements under paragraph (4) or (5), so long as  
19 the Secretary makes the determination required  
20 with respect to each such element.

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

22 “(A) SERIOUS RISK.—The term ‘serious  
23 risk’ means a risk of a serious adverse drug ex-  
24 perience as defined in section 314.80 of title 21,

1 Code of Federal Regulations (or any successor  
2 regulation).

3 “(B) UNEXPECTED SERIOUS RISK.—The  
4 term ‘unexpected serious risk’ means a serious  
5 adverse drug experience as defined in section  
6 314.80 of title 21, Code of Federal Regulations  
7 (or any successor regulation) that is not listed  
8 in the labeling of a drug, or that may be symp-  
9 tomatically and pathophysiologically related to  
10 an adverse drug experience identified in the la-  
11 beling, but differs from such adverse drug expe-  
12 rience because of greater severity or specificity.

13 “(C) EMPIRICAL SIGNAL OF A SERIOUS  
14 RISK.—The term ‘empirical signal of a serious  
15 risk’ means information related to a serious ad-  
16 verse drug experience as defined in section  
17 314.80 of title 21, Code of Federal Regulations  
18 (or any successor regulation) associated with  
19 use of a drug and derived from—

20 “(i) a clinical trial;

21 “(ii) adverse event reports;

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

24 “(iv) peer-reviewed biomedical lit-  
25 erature.

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

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

“(ii) the effectiveness of the approved risk evaluation and mitigation strategy for the drug.

“(E) DRUG SAFETY OVERSIGHT BOARD.—The term ‘Drug Safety Oversight Board’ means a body of scientists who have been appointed to serve from offices throughout the Food and Drug Administration and other Federal agencies to provide oversight and advice to the Secretary through the Director of the Center for Drug Evaluation and Research of the Food and Drug Administration on the management of important drug safety issues and which meets monthly.

“(3) REQUIRED ELEMENTS OF A RISK EVALUATION 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 by the Secretary of re-  
10       ports to the Vaccine Adverse Event Re-  
11       porting Systems (VAERS); or

12                      “(II) surveillance by the Secretary  
13       using the Vaccine Safety Datalink (VSD)  
14       or successor databases;

15               “(C) a pharmacovigilance statement as to  
16       whether—

17                      “(i) the reports under subparagraph  
18       (B)(i) or, for a vaccine, the analysis and  
19       surveillance under subparagraph (B)(ii),  
20       and the periodic assessment under sub-  
21       paragraph (E), are sufficient to assess the  
22       serious risks and to identify unexpected se-  
23       rious risks of the drug; or

24                      “(ii) studies under paragraph (4)(D)  
25       or clinical trials under paragraph (4)(E)

1 are needed to assess the serious risks and  
2 identify unexpected serious risks of the  
3 drug;

4 “(D) a justification for the  
5 pharmacovigilance statement in subparagraph  
6 (C) that takes into consideration—

7 “(i) the estimated size of the treat-  
8 ment population for the drug;

9 “(ii) the seriousness of the disease or  
10 condition that the drug is used to treat;

11 “(iii) the expected or actual duration  
12 of treatment with the drug;

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

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

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

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

the Public Health Service Act, and at a frequency determined by the Secretary for subsequent years;

“(ii) may be increased or reduced by the Secretary in frequency as necessary; and

“(iii) may be eliminated after the first 3 years if the Secretary determines that serious risks of the drug have been adequately identified and assessed and are being adequately managed.

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

“(A) IN GENERAL.—The risk evaluation and mitigation strategy for a drug may require one or more of the additional elements described in this paragraph, so long as the Secretary makes the determination required with respect to each such element.

“(B) MEDGUIDE.—The risk evaluation and mitigation strategy for a drug may require that the applicant develop for distribution to each patient when the drug is dispensed—

“(i) a Medication Guide, as provided for under part 208 of title 21, Code of

1 Federal Regulations (or any successor reg-  
2 ulations); or

3 “(ii) a patient package insert, if the  
4 Secretary determines that such insert may  
5 help minimize a serious risk of the drug.

6 “(C) COMMUNICATION PLAN.—The risk  
7 evaluation and mitigation strategy for a drug  
8 may require that the applicant conduct a com-  
9 munication plan to health care providers, if,  
10 with respect to such drug, the Secretary deter-  
11 mines that such plan may support implementa-  
12 tion of an element of the strategy under sub-  
13 paragraph (D) or (E) or under paragraph (5),  
14 which may include—

15 “(i) sending letters to health care pro-  
16 viders;

17 “(ii) disseminating information about  
18 the elements of the risk evaluation and  
19 mitigation strategy to encourage compli-  
20 ance by health care providers with compo-  
21 nents that apply to such health care pro-  
22 viders, or to explain certain safety proto-  
23 cols (such as medical monitoring by peri-  
24 odic laboratory tests); or

1                   “(iii) disseminating information to  
2                   health care providers through professional  
3                   societies about any serious risks of the  
4                   drug and how to prescribe and use the  
5                   drug safely.

6                   “(D) POST-APPROVAL STUDIES.—The risk  
7                   evaluation and mitigation strategy for a drug  
8                   may require that the applicant or the Secretary  
9                   conduct an appropriate post-approval study of  
10                  the drug (with target commencement and com-  
11                  pletion dates), if the Secretary determines the  
12                  study is necessary to assess an empirical signal  
13                  of a serious risk with use of the drug or to  
14                  identify unexpected serious risks in domestic  
15                  populations who use the drug but were not in-  
16                  cluded in studies used to approve the drug  
17                  (such as older people, people with comorbidities,  
18                  pregnant women, or children), such as a pro-  
19                  spective or retrospective observational study.

20                  “(E) POST-APPROVAL CLINICAL TRIALS.—  
21                  The risk evaluation and mitigation strategy for  
22                  a drug may require that the applicant for a  
23                  drug for which there is no effective approved  
24                  application under subsection (j) as of the date  
25                  that the requirement is first imposed conduct

1 an appropriate post-approval clinical trial of the  
2 drug (with target commencement and comple-  
3 tion dates), to be included in the clinical trial  
4 registry database and clinical trial results data-  
5 base provided for under section 402(j) of the  
6 Public Health Service Act, if the Secretary de-  
7 termines that the clinical trial is necessary, and  
8 that a study under subparagraph (D) will likely  
9 be inadequate, to assess an empirical signal of  
10 a serious risk with use of the drug;

11 “(F) PRECLEARANCE.—The risk evalua-  
12 tion and mitigation strategy for a drug may re-  
13 quire that the applicant submit to the Secretary  
14 advertisements of the drug for preclearance, if  
15 the Secretary determines that such preclearance  
16 is necessary to ensure compliance with section  
17 502(n) with respect to the disclosure of infor-  
18 mation about a serious risk listed in the label-  
19 ing of the drug, so long as advertisements re-  
20 quired to be submitted under this subparagraph  
21 are reviewed and cleared within 30 days by the  
22 Secretary.

23 “(G) SPECIFIC DISCLOSURES.—The risk  
24 evaluation and mitigation strategy for a drug  
25 may require that the applicant include a spe-

1           cific disclosure in advertisements of the drug, if  
2           the Secretary determines that advertisements  
3           lacking such disclosure would be false or mis-  
4           leading or that such disclosure is necessary to  
5           protect public health and safety—

6                   “(i) of the date the drug was ap-  
7                   proved and that the existing information  
8                   may not have identified or fully assessed  
9                   all serious risks of using the drug;

10                   “(ii) about a serious adverse event  
11                   listed in the labeling of the drug; or

12                   “(iii) about a protocol to ensure safe  
13                   use described in the labeling of the drug;  
14                   or

15           “(H) TEMPORARY MORATORIUM.—The  
16           risk evaluation and mitigation strategy for a  
17           drug may require that for a fixed period after  
18           initial approval, not to exceed 2 years, the ap-  
19           plicant not issue or cause to be issued direct-  
20           to-consumer advertisements of the drug, if the  
21           Secretary determines that disclosure under sub-  
22           paragraph (G) is inadequate to protect public  
23           health and safety, and that such prohibition is  
24           necessary to protect public health and safety

1 while additional information about serious risks  
2 of the drug is collected, considering—

3 “(i) the number of patients who may  
4 be treated with the drug;

5 “(ii) the seriousness of the condition  
6 for which the drug will be used;

7 “(iii) the serious adverse events listed  
8 in the labeling of the drug;

9 “(iv) the extent to which patients have  
10 access to other approved drugs in the  
11 pharmacological class of the drug and with  
12 the same intended use as the drug; and

13 “(v) the extent to which studies used  
14 to approve the drug may not have identi-  
15 fied serious risks that might occur among  
16 patients expected to be treated with the  
17 drug.

18 “(5) RESTRICTIONS ON DISTRIBUTION AND  
19 USE.—

20 “(A) IN GENERAL.—If the Secretary deter-  
21 mines that a drug presents a significant risk to  
22 public health, and provides significant benefits  
23 to patients, the risk evaluation and mitigation  
24 strategy may require restrictions on distribution  
25 and use to address such risk of the drug, so

1 long as application of elements under paragraph  
2 (4) are insufficient to manage such risk.

3 “(B) LIMITS ON RESTRICTIONS.—Such re-  
4 strictions under subparagraph (A) shall be—

5 “(i) commensurate with the risk;

6 “(ii) necessary to ensure safe use of  
7 the drug given the risk; and

8 “(iii) not unduly burdensome on pa-  
9 tient access to the drug, particularly for  
10 patients with serious or life-threatening  
11 diseases or conditions.

12 “(C) ELEMENTS.—The restrictions on dis-  
13 tribution and use described under subparagraph  
14 (A) shall include one or more goals to evaluate  
15 or mitigate a serious risk listed in the labeling  
16 of the drug and may require that—

17 “(i) health care providers that pre-  
18 scribe the drug have particular training or  
19 experience, or elect to be specially certified;

20 “(ii) pharmacies, practitioners, or  
21 health care settings that dispense the drug  
22 elect to be specially certified;

23 “(iii) the drug be dispensed to pa-  
24 tients only in certain health care settings,  
25 such as hospitals;

1           “(iv) the drug be dispensed to pa-  
2           tients with evidence or other documenta-  
3           tion of safe-use conditions, such as labora-  
4           tory test results;

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

7           “(vi) each patient using the drug be  
8           enrolled in a registry.

9           “(D) COMPLIANCE SYSTEM.—The restric-  
10          tions on distribution and use described under  
11          subparagraph (A) may require a compliance  
12          system through which the applicant is able to—

13           “(i) monitor and evaluate compliance  
14           with the restrictions by health care pro-  
15           viders, pharmacists, patients, and other  
16           parties in the health care system who are  
17           responsible for implementing the restric-  
18           tions;

19           “(ii) work to improve implementation  
20           of the restrictions by health care providers,  
21           pharmacists, patients, and other parties in  
22           the health care system who are responsible  
23           for implementing the restrictions; and

1 “(iii) limit participation by those  
2 health care providers, pharmacists, and  
3 other parties in the health care system—

4 “(I) who are responsible for im-  
5 plementing the restrictions; and

6 “(II) whom the applicant knows  
7 have failed to meet their responsibil-  
8 ities for implementing the restrictions,  
9 after the applicant has informed such  
10 party of such failure and such party  
11 has not remedied such failure.

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

14 “(A) PROPOSED RISK EVALUATION AND  
15 MITIGATION STRATEGY.—An applicant shall in-  
16 clude in an application under subsection (b) or  
17 section 351 of the Public Health Service Act  
18 (including in a supplemental application seeking  
19 a new indication if no risk evaluation and miti-  
20 gation strategy for the drug is in effect under  
21 this subsection) a proposed risk evaluation and  
22 mitigation strategy, which—

23 “(i) shall include the minimal ele-  
24 ments required under paragraph (3); and

1 “(ii) may also include additional ele-  
2 ments as provided for under paragraphs  
3 (4) and (5).

4 “(B) ASSESSMENT AND MODIFICATION OF  
5 A RISK EVALUATION AND MITIGATION STRAT-  
6 EGY.—

7 “(i) IN GENERAL.—The applicant may  
8 submit to the Secretary an assessment of,  
9 and propose a modification to, the ap-  
10 proved risk evaluation and mitigation  
11 strategy for a drug at any time, and shall  
12 submit such an assessment, which may  
13 propose such a modification—

14 “(I) when submitting a supple-  
15 mental application for a new indica-  
16 tion under subsection (b) or section  
17 351 of the Public Health Service Act;

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

21 “(III) within a time specified by  
22 the Secretary, not to be less than 45  
23 days, when ordered by the Secretary if  
24 the Secretary determines that new  
25 safety information indicates that an

1 element under paragraph (3) or (4)  
2 should be modified or included in the  
3 strategy;

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

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

15 “(ii) ASSESSMENT.—An assessment of  
16 the performance and adequacy of the ap-  
17 proved risk evaluation and mitigation  
18 strategy for a drug shall include—

19 “(I) with respect to any goal  
20 under paragraph (5), an assessment  
21 of whether the restrictions on dis-  
22 tribution and use are meeting the goal  
23 or whether the goal or such restric-  
24 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, the expected completion date,  
5 and whether any difficulties com-  
6 pleting the study have been encoun-  
7 tered; and

8 “(III) with respect to any post-  
9 approval clinical trial required under  
10 paragraph (4)(E), whether enrollment  
11 has begun, the number of participants  
12 enrolled, the expected completion date,  
13 and whether any difficulties com-  
14 pleting the clinical trial have been en-  
15 countered.

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

1 “(I) a labeling change, including  
2 the addition of a boxed warning;

3 “(II) adding a post-approval  
4 study or clinical trial requirement;

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

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

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

17 “(VI) modifying the timetable for  
18 assessments of the strategy under  
19 paragraph (3)(E).

20 “(C) REVIEW.—The Secretary shall  
21 promptly review the proposed risk evaluation  
22 and mitigation strategy for a drug submitted  
23 under paragraph (A), or an assessment of the  
24 approved risk evaluation and mitigation strat-

egy for a drug submitted under subparagraph  
(B).

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

“(i) when submitted as part of an ap-  
plication or supplemental application under  
subparagraph (A) or (B)(i)(I), not less  
than 60 days before the action deadline for  
the application that has been agreed to by  
the Secretary and that has been set forth  
in goals identified in letters of the Sec-  
retary (relating to the use of fees collected  
under section 736 to expedite the drug de-  
velopment process and the review of  
human drug applications);

“(ii) when submitted under subpara-  
graph (B)(i)(II) or (III), not later than 20  
days after such submission;

1 “(iii) when submitted voluntarily by  
2 the applicant or under subparagraph  
3 (B)(i)(IV), not later than 30 days after  
4 such submission; or

5 “(iv) when submitted under subpara-  
6 graph (B)(i)(V), not later than 10 days  
7 after such submission.

8 “(E) ACTION.—

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

16 “(I) as part of the action letter  
17 on the application, when a proposed  
18 strategy is submitted under subpara-  
19 graph (A) or an assessment of the  
20 strategy is submitted under subpara-  
21 graph (B)(i)(I); or

22 “(II) in an order, which shall be  
23 made public, issued not later than 50  
24 days after the date discussions of such  
25 modification begin under subpara-

graph (C), when an assessment of the strategy is submitted voluntarily by the applicant or under subclause (II), (III), (IV), or (V) of subparagraph (B)(i).

“(ii) INACTION.—An approved risk evaluation and mitigation strategy shall remain in effect until the Secretary acts, if the Secretary fails to act as provided under clause (i).

“(F) DISPUTE RESOLUTION.—

“(i) REQUEST FOR REVIEW.—Not earlier than 15 days, and not later than 35 days, after discussions under subparagraph (D) have begun to determine a mutually agreeable risk evaluation and mitigation strategy, the applicant may request in writing that a dispute about the strategy be reviewed by the Drug Safety Oversight Board.

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

“(I) shall schedule the dispute for review at 1 of the next 2 regular

1 meetings of the Drug Safety Over-  
2 sight Board, whichever meeting date  
3 is more practicable; or

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

10 “(iii) AGREEMENT TERMINATES DIS-  
11 PUTE RESOLUTION.—At any time before a  
12 decision and order is issued under clause  
13 (vi), the Secretary and the applicant may  
14 reach an agreement on the risk evaluation  
15 and mitigation strategy, terminating the  
16 dispute resolution process, and the Sec-  
17 retary shall issue an action letter or order,  
18 as appropriate, that describes the mutually  
19 agreeable strategy.

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

24 “(I) hear from both parties; and

25 “(II) review the dispute.

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

7                   “(vi) ACTION BY THE SECRETARY.—

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

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

19 or

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

23                   “(II) ORDER.—With respect to  
24 an assessment of the risk evaluation  
25 and mitigation strategy submitted vol-

1                   untarily by the applicant or under  
2                   subclause (II), (III), (IV), or (V) of  
3                   subparagraph (B)(i), the Secretary  
4                   shall issue an order, which shall be  
5                   made public, that resolves the dispute  
6                   not later than 7 days after receiving  
7                   the recommendation of the Drug Safe-  
8                   ty Oversight Board.

9                   “(vii) 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 for  
13                  under clause (vi).

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

pute resolution process described in this subparagraph and if the Secretary—

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

“(II) has complied with the timing requirements of scheduling review, providing a written recommendation, and issuing an action letter under clauses (ii), (v), and (vi), respectively.

“(ix) OTHER DISPUTE RESOLUTION.—Procedural or scientific matters involving the review of human drug applications and supplements that cannot be resolved at the divisional level may in addition be appealed as described in letters of the Secretary (relating to the use of fees collected under section 736 to expedite the drug development process and the review of human drug applications).

“(x) DISQUALIFICATION.—No individual who is an employee of the Food and Drug Administration and who reviews the application for a drug or who participated

1 in other dispute resolution under clause  
2 (ix) with respect to such drug may serve  
3 on the Drug Safety Oversight Board at a  
4 meeting under clause (iv) to review a dis-  
5 pute about the risk evaluation and mitiga-  
6 tion strategy for such drug.

7 “(xi) ADDITIONAL EXPERTISE.—The  
8 Drug Safety Oversight Board may add  
9 members from offices within the Food and  
10 Drug Administration with relevant exper-  
11 tise, including the Office of Pediatrics, the  
12 Office of Women’s Health, or the Office of  
13 Rare Diseases, for a meeting under clause  
14 (iv) of the Drug Safety Oversight Board.

15 “(G) PROCESS FOR ADDRESSING DRUG  
16 CLASS EFFECTS.—

17 “(i) IN GENERAL.—When a concern  
18 about a serious risk of a drug may be re-  
19 lated to the pharmacological class of the  
20 drug, the Secretary may defer assessments  
21 of the approved risk evaluation and mitiga-  
22 tion strategies for such drugs until the  
23 Secretary has convened, after appropriate  
24 public notice, one or more public meetings

1 to consider possible responses to such con-  
2 cern.

3 “(ii) PUBLIC MEETINGS.—Such public  
4 meetings may include—

5 “(I) one or more meetings of the  
6 applicants for such drugs;

7 “(II) one or more meetings of an  
8 appropriate advisory committee of the  
9 Food and Drug Administration; or

10 “(III) one or more workshops of  
11 scientific experts and other stake-  
12 holders.

13 “(iii) ACTION.—After considering the  
14 discussions from any meetings under  
15 clause (ii), the Secretary may—

16 “(I) announce in the Federal  
17 Register a planned regulatory action,  
18 including a modification to each risk  
19 evaluation and mitigation strategy, for  
20 drugs in the pharmacological class;

21 “(II) seek public comment about  
22 such action; and

23 “(III) after seeking such com-  
24 ment, issue an order addressing such  
25 regulatory action.

1           “(H) INTERNATIONAL COORDINATION.—

2           To the extent practicable, the Secretary shall  
3           coordinate elements of the risk evaluation and  
4           mitigation strategy for a drug, such as the  
5           timetable for submission of assessments under  
6           paragraph (3)(E), a study under paragraph  
7           (4)(D), or a clinical trial under paragraph  
8           (4)(E), with efforts to manage the serious risks  
9           of such drug by the marketing authorities of  
10          other countries whose drug approval and risk  
11          management processes the Secretary deems  
12          comparable to the drug approval and risk man-  
13          agement processes of the United States.

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

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

1 by the Secretary of a supplemental application  
2 for the change, the submission of an assessment  
3 of the approved risk evaluation and mitigation  
4 strategy for the drug under this subsection is  
5 not required.”.

6 **SEC. 102. ENFORCEMENT.**

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

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

13 “(1) make a labeling change required by such  
14 strategy after the Secretary has completed review of,  
15 and acted on, an assessment of such strategy under  
16 paragraph (6) of such section; or

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

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

24 (1) by redesignating paragraphs (3), (4), and  
25 (5) as paragraphs (4), (5), and (6), respectively;

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

3           “(3) An applicant (as such term is used in sec-  
 4       tion 505(o)) who knowingly fails to comply with a  
 5       requirement of an approved risk evaluation and miti-  
 6       gation strategy under such section 505(o) shall be  
 7       subject to a civil money penalty of not less than  
 8       \$15,000 and not more than \$250,000 per violation,  
 9       and not to exceed \$1,000,000 for all such violations  
 10      adjudicated in a single proceeding.”;

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

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

17          (5) in paragraph (6), as so redesignated, by  
 18      striking “paragraph (4)” each place it appears and  
 19      inserting “paragraph (5)”.

20   **SEC. 103. CONFORMING AMENDMENTS.**

21          (a) REGULATION OF BIOLOGICAL PRODUCTS.—Sec-  
 22      tion 351 of the Public Health Service Act (42 U.S.C. 262)  
 23      is amended—

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

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

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

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

15       (c) CONTENT OF A NEW DRUG APPLICATION.—Sec-  
 16 tion 505(b)(1) of the Federal Food, Drug, and Cosmetic  
 17 Act (21 U.S.C. 355(b)) is amended—

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

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

24       (d) WITHDRAWAL OR SUSPENSION OF APPROVAL.—  
 25 Section 505(e) of the Federal Food, Drug, and Cosmetic

1 Act (21 U.S.C. 355(e)) is amended by adding at the end  
 2 the following: “The Secretary may withdraw the approval  
 3 of an application submitted under subsection (b) or (j),  
 4 or suspend the approval of such an application, as pro-  
 5 vided under this subsection, without first ordering the ap-  
 6 plicant to submit an assessment of the approved risk eval-  
 7 uation and mitigation strategy for the drug under sub-  
 8 section (o)(6)(B)(i)(V).”.

9 (e) DRUGS SUBJECT TO AN ABBREVIATED NEW  
 10 DRUG APPLICATION.—Section 505(j)(2) of the Federal  
 11 Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(2)) is  
 12 amended by adding at the end the following:

13 “(D) RISK EVALUATION AND MITIGATION STRATEGY  
 14 REQUIREMENT.—A drug that is the subject of an abbre-  
 15 viated new drug application under this subsection shall be  
 16 subject to each element of the risk evaluation and mitiga-  
 17 tion strategy required under subsection (o) for the applica-  
 18 ble listed drug, except for any post-approval clinical trial  
 19 requirement described under paragraph (4)(E) of such  
 20 subsection.”.

21 **SEC. 104. RESOURCES.**

22 (a) USER FEES.—Subparagraph (F) of section  
 23 735(6) of the Federal Food, Drug, and Cosmetic Act (21  
 24 U.S.C. 379g(6)) is amended to read as follows:

1           “(F) Reviewing and implementing risk  
2           evaluation and mitigation strategies, and col-  
3           lecting, developing, and reviewing safety infor-  
4           mation on drugs, including adverse event re-  
5           ports.”.

6           (b) PUBLIC ACCOUNTABILITY.—Section 505(a) of  
7           the Prescription Drug User Fee Amendments of 2002  
8           (Subtitle A of title V of the Public Health Security and  
9           Bioterrorism Preparedness and Response Act of 2002  
10          (Public Law 107-188)) is amended by adding at the end  
11          the following:

12           “(3) DRUG SAFETY.—The recommendations  
13          under paragraph (1) shall include estimates of the  
14          amounts by which the fee revenue amounts for fiscal  
15          years 2008 through 2012 should be increased to re-  
16          view and implement risk evaluation and mitigation  
17          strategies, and to collect, develop, and review safety  
18          information on drugs, including adverse event re-  
19          ports.”.

20          (c) STRATEGIC PLAN FOR INFORMATION TECH-  
21          NOLOGY.—Not later than 1 year after the date of enact-  
22          ment of this title, the Secretary of Health and Human  
23          Services (referred to in this Act as the “Secretary”) shall  
24          submit to the Committee on Health, Education, Labor,  
25          and Pensions and the Committee on Appropriations of the

1 Senate and the Committee on Energy and Commerce and  
 2 the Committee on Appropriations of the House of Rep-  
 3 resentatives, a strategic plan on information technology  
 4 that includes—

5           (1) an assessment of the information technology  
 6 infrastructure, including data collection and data  
 7 mining systems, needed by the Food and Drug Ad-  
 8 ministration to comply with the requirements of this  
 9 title (and the amendments made by this title), to es-  
 10 tablish standards to achieve interoperability, and to  
 11 move toward electronic health records;

12           (2) an assessment of the extent to which the  
 13 current information technology assets of the Food  
 14 and Drug Administration are sufficient to meet the  
 15 needs assessment under paragraph (1);

16           (3) a plan for enhancing the information tech-  
 17 nology assets of the Food and Drug Administration  
 18 toward meeting the needs assessment under para-  
 19 graph (1); and

20           (4) an assessment of additional resources need-  
 21 ed to so enhance the information technology assets  
 22 of the Food and Drug Administration.

23 **SEC. 105. DRUG LABELING.**

24           (a) ACCESSIBLE REPOSITORY OF DRUG LABEL-  
 25 ING.—Not later than the effective date of this title, the

1 Secretary, through the Commissioner of Food and Drugs,  
2 and the Director of the National Institutes of Health, shall  
3 establish a searchable repository of structured, electronic  
4 product information, including the approved professional  
5 labeling and any required patient labeling of each drug  
6 approved under section 505 of the Federal Food, Drug,  
7 and Cosmetic Act (21 U.S.C. 355) or licensed under sec-  
8 tion 351 of the Public Health Service Act (42 U.S.C. 262)  
9 in order to improve patient safety through accessible prod-  
10 uct information, support initiatives to improve patient care  
11 by better management of health care information, and  
12 provide standards for drug information. Such repository  
13 shall be made publicly accessible on the Internet website  
14 of the National Library of Medicine and through a link  
15 on the homepage of the Internet website of the Food and  
16 Drug Administration.

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

24 (c) REPORT.—The Secretary shall report annually to  
25 the Committee on Energy and Commerce of the House

1 of Representatives and the Committee on Health, Edu-  
 2 cation, Labor and Pensions of the Senate on the status  
 3 of the repository under subsection (a), and on progress  
 4 in posting structured electronic product information, in-  
 5 cluding posting of information regarding drugs approved  
 6 prior to the effective date of this title.

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

16 **SEC. 106. EFFECTIVE DATE AND APPLICABILITY.**

17 (a) EFFECTIVE DATE.—This title shall take effect  
 18 180 days after the date of enactment of this Act.

19 (b) DRUGS DEEMED TO HAVE RISK EVALUATION  
 20 AND MITIGATION STRATEGIES.—

21 (1) IN GENERAL.—A drug that was approved  
 22 before the effective date of this title and for which  
 23 there are in effect on the effective date of this title  
 24 restrictions on distribution and use required under  
 25 section 314.520 or section 600.42 of title 21, Code

1 of Federal Regulations, or otherwise agreed to by  
2 the applicant and the Secretary for such drug, shall  
3 be deemed to have an approved risk evaluation and  
4 mitigation strategy under such section 505(o) of the  
5 Federal Food, Drug, and Cosmetic Act (as added by  
6 this title).

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

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

19 (A) that such drug is deemed to have an  
20 approved risk evaluation and mitigation strat-  
21 egy pursuant to such paragraph; and

22 (B) of the date, which shall be no earlier  
23 than 6 months after the applicant is so notified,  
24 by which the applicant shall submit to the Sec-

1           retary an assessment of such approved strategy  
2           under paragraph (6)(B) of such section 505(o).

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

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

19               (1) an element described under paragraph  
20               (3)(A) of such section 505(o) may require modifica-  
21               tion; or

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

1 **TITLE II—REAGAN-UDALL INSTI-**  
2 **TUTE FOR APPLIED BIO-**  
3 **MEDICAL RESEARCH**

4 **SEC. 201. THE REAGAN-UDALL INSTITUTE FOR APPLIED**  
5 **BIOMEDICAL RESEARCH.**

6 (a) IN GENERAL.—Chapter VII of the Federal Food,  
7 Drug, and Cosmetic Act (21 U.S.C. 371 et seq.) is amend-  
8 ed by adding at the end the following:

9 **“Subchapter H—Establishment of Reagan-**  
10 **Udall Institute for Applied Biomedical**  
11 **Research**

12 **“SEC. 760. ESTABLISHMENT AND FUNCTIONS OF THE INSTI-**  
13 **TUTE.**

14 “(a) IN GENERAL.—There is established within the  
15 Food and Drug Administration an Institute to be known  
16 as the Reagan-Udall Institute for Applied Biomedical Re-  
17 search (referred to in this subchapter as the ‘Institute’).  
18 The Institute shall be headed by an Executive Director,  
19 appointed by the members of the Board of Directors under  
20 subsection (e).

21 “(b) PURPOSE OF INSTITUTE.—The purpose of the  
22 Institute is to advance the Critical Path Initiative of the  
23 Food and Drug Administration to modernize medical  
24 product development, accelerate innovation, and enhance  
25 product safety by—

1           “(1) initiating, sponsoring, and organizing col-  
2           laborative and multidisciplinary research in the  
3           sciences of developing, manufacturing, and evalu-  
4           ating the safety and effectiveness of diagnostics, de-  
5           vices, biologics, and drugs;

6           “(2) ensuring the broad participation of aca-  
7           demic, government, and industrial researchers in the  
8           work of the Institute; and

9           “(3) ensuring the maximum distribution and  
10          utilization of the outcomes of such research, includ-  
11          ing through publication of research results and dis-  
12          semination of intellectual property generated by the  
13          Institute.

14          “(c) DUTIES OF THE INSTITUTE.—The Institute  
15          shall—

16               “(1) establish goals and priorities relating to  
17               the sciences of developing, manufacturing, and eval-  
18               uating the safety and effectiveness of diagnostics,  
19               devices, biologics, and drugs;

20               “(2) identify unmet needs in the sciences of de-  
21               veloping, manufacturing, and evaluating the safety  
22               and effectiveness of diagnostics, devices, biologics,  
23               and drugs;

24               “(3) in consultation with the National Insti-  
25               tutes of Health, assess existing and proposed Fed-

1       eral intramural and extramural research and devel-  
2       opment programs relating to such sciences, facilitate  
3       and encourage interagency coordination of such pro-  
4       grams, and participate in such programs relating to  
5       such sciences, including—

6               “(A) the identification and validation of  
7               biomarkers for use in diagnostic, device, bio-  
8               logic, and drug development;

9               “(B) the development and validation of  
10              animal models for human disease;

11              “(C) pharmacogenomics and inter-indi-  
12              vidual variability in drug and biologic response;

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

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

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

20              “(G) device manufacturing, design and  
21              materials science;

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

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

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

3                   “(K) computer modeling;

4                   “(4) award grants to, or enter into contracts or  
5                   cooperative agreements with, scientists and entities  
6                   to advance the purposes of the Institute pursuant to  
7                   the processes established in the by-laws under sub-  
8                   section (d)(2)(A);

9                   “(5) 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                  “(6) ensure that—

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

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

23                         “(C) executed licenses, memoranda of un-  
24                         derstanding, material transfer agreements, con-  
25                         tracts, and other such instruments promote, to

1           the maximum extent practicable, the broadest  
2           conversion to commercial and noncommercial  
3           applications of licensed and patented inventions  
4           of the Institute consistent with subsection  
5           (b)(3);

6           “(7) recruit scientists and hold or sponsor (in  
7           whole or in part) meetings as appropriate to further  
8           the purposes of the Institute;

9           “(8) provide objective clinical and scientific in-  
10          formation to the Food and Drug Administration  
11          and, upon request, to other Federal agencies regard-  
12          ing how to ensure that regulatory policy accommo-  
13          dates scientific advances;

14          “(9) conduct annual evaluations of research ac-  
15          tivities that are supported by the Institute; 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; and

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

11 “(C) APPOINTED MEMBERS.—

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

17 “(I) 4 shall be representatives of  
18 the general pharmaceutical, device,  
19 and biotechnology industries;

20 “(II) 3 shall be representatives of  
21 academic research organizations;

22 “(III) 2 shall be representatives  
23 of Government agencies, including the  
24 Food and Drug Administration and  
25 the National Institutes of Health;

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

3 “(V) 1 shall be a representative  
4 of health care providers.

5 “(ii) REQUIREMENT.—The ex officio  
6 members shall ensure the Board member-  
7 ship includes individuals with expertise in  
8 clinical pharmacology, biomedical  
9 informatics, information management,  
10 product safety, process improvement and  
11 pharmaceutical sciences, and medical de-  
12 vice and biomedical engineering.

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

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

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

18 “(ii) 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 (5) and (6) of subsection (c);

1 “(iii) specify criteria and processes for  
 2 the review of proposals and awarding of  
 3 grants and contracts that include peer re-  
 4 view and that are substantially consistent  
 5 with those established by other government  
 6 organizations, such as the National Insti-  
 7 tutes of Health and the National Science  
 8 Foundation;

9 “(iv) specify a process for annual  
 10 Board review of the operations of the Insti-  
 11 tute; and

12 “(v) establish specific duties of the  
 13 Executive Director;

14 “(B) identify and prioritize the scientific  
 15 needs that may be effectively and uniquely ad-  
 16 dressed by the Institute;

17 “(C) prioritize and provide overall direction  
 18 to the research activities of the Institute;

19 “(D) evaluate the performance of the Ex-  
 20 ecutive Director; and

21 “(E) carry out any other necessary activi-  
 22 ties regarding the functioning of the Institute.

23 “(3) ADDITIONAL BOARD FUNCTIONS.—

24 “(A) IN GENERAL.—The Board may estab-  
 25 lish 1 or more Critical Path Institutes to con-

duct multidisciplinary and collaborative research, education, and outreach, and to modernize the sciences of developing, manufacturing, and evaluating the safety and effectiveness of diagnostics, devices, biologics, and drugs.

“(B) ELIGIBILITY.—To be eligible to host a Critical Path Institute described in subparagraph (A), an entity shall—

“(i) be a State or local government, institution of higher education, or non-profit entity with demonstrated ability, personnel, and clinical and other technical expertise to undertake the duties consistent with the activities in subparagraph (A); and

“(ii) submit to the Board an application at such time, in such manner, and containing such information as the Board may require.

“(4) CHAIR.—The ex officio members of the Board under paragraph (1)(B) shall designate an appointed member of the Board to serve as the Chair of the Board.

“(5) 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 ex officio members of the Board in the  
 14           manner described under paragraph  
 15           (1)(C)(i).

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 by the ex officio members of the Board  
 20           in the manner described under paragraph  
 21           (1)(C)(i) to fill the resulting vacancy shall be  
 22           appointed for the remainder of the term of the  
 23           predecessor of the individual.

24           “(D) SERVING PAST TERM.—A member of  
 25           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           “(6) 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) EXECUTIVE DIRECTOR.—

10           “(1) IN GENERAL.—The Board shall appoint an  
11           Executive Director who shall serve at the pleasure of  
12           the Board. The Executive Director shall be respon-  
13           sible for the day-to-day operations of the Institute  
14           and shall have such specific duties and responsibil-  
15           ities as the Board shall prescribe.

16           “(2) COMPENSATION.—The compensation of  
17           the Executive Director shall be fixed by the Board  
18           but shall not be greater than the compensation of  
19           the Commissioner of Food and Drugs.

20           “(f) ADMINISTRATIVE POWERS.—In carrying out this  
21           subchapter, the Board, acting through the Executive Di-  
22           rector, may—

23           “(1) hire, promote, compensate, and discharge  
24           1 or more officers, employees, and agents, as may be  
25           necessary, and define their duties;

1 “(2) prescribe the manner in which—

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

4 “(B) general operations of the Institute  
5 are to be conducted; and

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

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

12 “(4) enter into contracts with public and pri-  
13 vate organizations for the writing, editing, printing,  
14 and publishing of books and other material;

15 “(5) hold, administer, invest, and spend any  
16 gift, devise, or bequest of real or personal property  
17 made to the Institute under subsection (g);

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

22 “(7) appoint other groups of advisors as may be  
23 determined necessary to carry out the functions of  
24 the Institute; and

1           “(8) exercise other powers as set forth in this  
 2           section, and such other incidental powers as are nec-  
 3           essary to carry out its powers, duties, and functions  
 4           in accordance with this subchapter.

5           “(g) ACCEPTANCE OF FUNDS FROM OTHER  
 6 SOURCES.—The Executive Director may accept on behalf  
 7 of the Institute, any funds, gifts, devises, or bequests of  
 8 real or personal property made to the Institute from  
 9 sources outside the Food and Drug Administration, in-  
 10 cluding private entities, for the purposes of carrying out  
 11 the duties of the Institute.

12          “(h) ANNUAL REPORTS.—

13           “(1) REPORTS TO INSTITUTE.—Any recipient of  
 14           a grant, contract, or cooperative agreement from the  
 15           Institute under this section shall submit to the Insti-  
 16           tute a report on an annual basis for the duration of  
 17           such grant, contract, or cooperative agreement, that  
 18           describes the activities carried out under such grant,  
 19           contract, or cooperative agreement.

20           “(2) REPORT TO CONGRESS.—Beginning with  
 21           fiscal year 2008, the Executive Director shall submit  
 22           to the Committee on Health, Education, Labor, and  
 23           Pensions and the Committee on Appropriations of  
 24           the Senate and the Committee on Energy and Com-

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

3 “(A) describes the activities of the Insti-  
4 tute and of the recipients of a grant, contract,  
5 or cooperative agreement under this section, in-  
6 cluding the practical impact of the Institute on  
7 medical product development, with emphasis on  
8 progress made by the Food and Drug Adminis-  
9 tration in incorporating Critical Path priorities  
10 to modernize medical product development, ac-  
11 celerate innovation, and enhance product safety;

12 “(B) provides a specific accounting of the  
13 source of all funds used by the Institute to  
14 carry out such activities; and

15 “(C) describes how such funds were used  
16 by the Institute.

17 “(i) SEPARATION OF FUNDS.—The Executive Direc-  
18 tor shall ensure that the funds received from the Treasury  
19 are held in separate accounts from funds received from  
20 private entities under subsection (g).

21 “(j) AUTHORIZATION OF APPROPRIATIONS.—

22 “(1) IN GENERAL.—There are authorized to be  
23 appropriated \$20,000,000 for each of fiscal years  
24 2008 through 2013 to carry out this section, section  
25 761, and section 762.

1           “(2) LIMITATION.—From amounts appro-  
 2           priated for a fiscal year under subparagraph (A),  
 3           the Secretary shall use not less than \$1,200,000 to  
 4           carry out subsections (a), (b), and (d) through (i).”.

5           (b) EMPLOYEES FROM OTHER FEDERAL AGEN-  
 6           CIES.—Chapter VII (21 U.S.C. 380 et seq.) (as amended  
 7           by subsection (a)) is amended by adding at the end the  
 8           following:

9           **“SEC. 761. ACCEPTING EMPLOYEES FROM OTHER FEDERAL**  
 10           **AGENCIES.**

11           “(a) COLLABORATION WITH OTHER AGENCIES.—To  
 12           carry out the purposes of the Institute, the Secretary, act-  
 13           ing through the Commissioner of Food and Drugs and in  
 14           consultation with the Executive Director of the Institute,  
 15           may collaborate with other Federal agencies and accept  
 16           the services of employees from those agencies without re-  
 17           imbursement to those agencies.

18           “(b) DETAIL OF GOVERNMENT EMPLOYEES.—Not  
 19           more than 5 Federal Government employees may be de-  
 20           tailed to the Institute at any time for a period not to ex-  
 21           ceed 6 years for each such employee, and such detail shall  
 22           be without civil service status or privilege. Such employees  
 23           shall abide by the statutory, regulatory, ethical, and proce-  
 24           dural standards applicable to employees of the Food and  
 25           Drug Administration.

1       “(c) PROCUREMENT OF TEMPORARY AND INTERMIT-  
 2 TENT SERVICES.—The Executive Director may procure  
 3 temporary and intermittent services under section 3109(b)  
 4 of title 5, United States Code, at rates for individuals  
 5 which do not exceed the daily equivalent of the annual rate  
 6 of basic pay prescribed for level V of the Executive Sched-  
 7 ule under section 5316 of such title.

8       “(d) NO ADDITIONAL LIABILITY.—Nothing in this  
 9 section adds to any liability that the United States may  
 10 have under chapter 171 of title 28, United States Code  
 11 (commonly known as the Federal Tort Claims Act).”.

12       (c) OTHER INSTITUTE PROVISIONS.—Chapter VII  
 13 (21 U.S.C. 371 et seq.) (as amended by subsection (b))  
 14 is amended by adding at the end the following:

15       **“SEC. 762. LOCATION OF INSTITUTE.**

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

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

1 (d) RECOVERY AND RETENTION OF FEES FOR FOIA  
 2 REQUESTS.—Chapter VII of the Federal Food, Drug, and  
 3 Cosmetic Act (21 U.S.C. 371 et seq.) (as amended by sub-  
 4 section (c)) is amended by adding at the end the following:

5 **“SEC. 763. RECOVERY AND RETENTION OF FEES FOR FREE-**  
 6 **DOM OF INFORMATION REQUESTS TO THE IN-**  
 7 **STITUTE.**

8 “(a) IN GENERAL.—The Secretary, acting through  
 9 the Commissioner of Food and Drugs, may—

10 “(1) set and charge fees, in accordance with  
 11 section 552(a)(4)(A) of title 5, United States Code,  
 12 to recover all reasonable costs incurred in processing  
 13 requests made under section 552 of title 5, United  
 14 States Code, for records obtained or created by the  
 15 Institute under this Act or any other Federal law for  
 16 which responsibility for administration has been del-  
 17 egated to the Institute by the Secretary;

18 “(2) retain all fees charged for such requests;  
 19 and

20 “(3) establish an accounting system and proce-  
 21 dures to control receipts and expenditures of fees re-  
 22 ceived under this section.

23 “(b) USE OF FEES.—The Secretary and the Commis-  
 24 sioner of Food and Drugs shall not use fees received under  
 25 this section for any purpose other than funding the proc-

1 essing of requests described in subsection (a)(1). Such fees  
 2 shall not be used to reduce the amount of funds made  
 3 available to carry out other provisions of this Act.

4 “(c) WAIVER OF FEES.—Nothing in this section shall  
 5 supersede the right of a requester to obtain a waiver of  
 6 fees pursuant to section 552(a)(4)(A) of title 5, United  
 7 States Code.”.

## 8 **TITLE III—CLINICAL TRIALS**

### 9 **SEC. 301. CLINICAL TRIAL REGISTRY DATABASE AND CLIN-** 10 **ICAL TRIAL RESULTS DATABASE.**

11 (a) IN GENERAL.—Section 402(j) of the Public  
 12 Health Service Act (42 U.S.C. 282(j)) is amended to read  
 13 as follows:

14 “(j) CLINICAL TRIAL REGISTRY DATABASE; CLIN-  
 15 ICAL TRIAL RESULTS DATABASE.—

16 “(1) DEFINITIONS; REQUIREMENT.—

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

18 “(i) CLINICAL TRIAL INFORMATION.—

19 The term ‘clinical trial information’ means  
 20 those data elements that are necessary to  
 21 complete an entry in the clinical trial reg-  
 22 istry database under paragraph (2) or the  
 23 clinical trial results database under para-  
 24 graph (3), as applicable.

1           “(ii) COMPLETION DATE.—The term  
2           ‘completion date’ means, with respect to a  
3           clinical trial, the date on which the last pa-  
4           tient enrolled in the clinical trial has com-  
5           pleted his or her last medical visit of the  
6           clinical trial (known as last patient last  
7           visit), whether the clinical trial concluded  
8           according to the prespecified protocol plan  
9           or was terminated.

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

15           “(iv) RESPONSIBLE PARTY.—The  
16           term ‘responsible party’, with respect to a  
17           clinical trial of a drug, means the sponsor  
18           of the clinical trial or the principal investi-  
19           gator of such clinical trial if so designated  
20           by such sponsor.

21           “(B) REQUIREMENT.—The Secretary shall  
22           develop a mechanism by which—

23           “(i) the responsible party for each ap-  
24           plicable clinical trial shall submit the iden-  
25           tity and contact information of such re-

1           sponsible party to the Secretary at the  
2           time of submission of clinical trial informa-  
3           tion under paragraph (2); and

4           “(ii) other Federal agencies may iden-  
5           tify the responsible party for an applicable  
6           clinical trial.

7           “(2) CLINICAL TRIAL REGISTRY DATABASE.—

8           “(A) APPLICABLE CLINICAL TRIAL.—

9           “(i) IN GENERAL.—For purposes of  
10          this paragraph the term ‘applicable clinical  
11          trial’ means—

12           “(I) an interventional clinical  
13           trial conducted before the drug is ap-  
14           proved under section 505 of the Fed-  
15           eral Food, Drug, and Cosmetic Act or  
16           licensed under section 351 of this Act  
17           that is—

18           “(aa) a therapeutic or  
19           chemopreventive exploratory clin-  
20           ical trial to verify the efficacy  
21           and establish appropriate doses  
22           for the drug; or

23           “(bb) a therapeutic or  
24           chemopreventive confirmatory  
25           clinical trial;

1 “(II) a clinical trial conducted  
2 after the drug is approved under such  
3 section 505 or licensed under such  
4 section 351; or

5 “(III) a pharmacokinetic study to  
6 support a pediatric indication for the  
7 drug.

8 “(ii) EXCEPTION.—A clinical trial  
9 under clause (i)(I)(aa) does not include—

10 “(I) an exploratory clinical trial  
11 that is intended solely to assess safety  
12 or solely to evaluate pharmacokinetics;  
13 or

14 “(II) an observational study.

15 “(B) ESTABLISHMENT.—

16 “(i) IN GENERAL.—To enhance pa-  
17 tient enrollment and provide a mechanism  
18 to track subsequent progress of clinical  
19 trials, the Secretary, acting through the  
20 Director of NIH, shall establish and ad-  
21 minister a clinical trial registry database in  
22 accordance with this subsection (referred  
23 to in this subsection as the ‘registry data-  
24 base’). The Director of NIH shall ensure

1 that the registry database is made publicly  
2 available through the Internet.

3 “(ii) CONTENT.—The Secretary shall  
4 promulgate regulations for the submission  
5 to the registry database of clinical trial in-  
6 formation that—

7 “(I) conforms to the Inter-  
8 national Clinical Trials Registry Plat-  
9 form trial registration data set of the  
10 World Health Organization;

11 “(II) if the drug is not approved  
12 under section 505 of the Federal  
13 Food, Drug, and Cosmetic Act or li-  
14 censed under section 351 of this Act,  
15 specifies whether or not there is a  
16 mechanism to access the drug outside  
17 of the clinical trial for those who do  
18 not qualify for enrollment in the clin-  
19 ical trial and how to obtain informa-  
20 tion about such a mechanism; and

21 “(III) requires the inclusion of  
22 such other data elements to the reg-  
23 istry database as appropriate.

24 “(C) FORMAT AND STRUCTURE.—

1 “(i) SEARCHABLE CATEGORIES.—The  
2 Director of NIH shall ensure that the pub-  
3 lic may search the entries in the registry  
4 database by—

5 “(I)(aa) the indication being  
6 studied in the clinical trial, using  
7 Medical Subject Headers (MeSH)  
8 descriptors; or

9 “(bb) the safety issue being stud-  
10 ied in the clinical trial;

11 “(II) enrollment status of the  
12 clinical trial; and

13 “(III) the sponsor of the clinical  
14 trial.

15 “(ii) FORMAT.—The Director of the  
16 NIH shall ensure that the registry data-  
17 base is easily used by patients, and that  
18 entries are easily compared.

19 “(D) DATA SUBMISSION.—The responsible  
20 party for an applicable clinical trial shall submit  
21 to the Director of NIH for inclusion in the reg-  
22 istry database the clinical trial information de-  
23 scribed in subparagraph (B)(ii).

24 “(E) TRUTHFUL CLINICAL TRIAL INFOR-  
25 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                  “(F) CHANGES IN CLINICAL TRIAL STA-  
11                  TUS.—

12                   “(i) ENROLLMENT.—The responsible  
13                   party for an applicable clinical trial shall  
14                   update the enrollment status not later than  
15                   30 days after the enrollment status of such  
16                   clinical trial changes.

17                   “(ii) COMPLETION.—The responsible  
18                   party for an applicable clinical trial shall  
19                   report to the Director of NIH that such  
20                   clinical trial is complete not later than 30  
21                   days after the completion date of the clin-  
22                   ical trial.

23                   “(G) TIMING OF SUBMISSION.—The clin-  
24                   ical trial information for an applicable clinical  
25                   trial required to be submitted under this para-

graph shall be submitted not later than 14 days after the first patient is enrolled in such clinical trial.

“(3) CLINICAL TRIALS RESULTS DATABASE.—

“(A) APPLICABLE CLINICAL TRIAL.—

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

“(I) an interventional clinical trial conducted before the drug is approved under section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of this Act that is—

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

“(bb) a clinical trial for a drug approved as a fast-track product under section 506 of the Federal Food, Drug, and Cosmetic Act, if such clinical trial is used to form the primary basis of an efficacy claim for such drug; or

1 “(cc) if required by the Sec-  
2 retary under subparagraph  
3 (G)(i), a clinical trial described in  
4 paragraph (2)(A)(i)(I)(aa);

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

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

12 “(ii) EXCEPTION.—A clinical trial  
13 under clause (i) does not include—

14 “(I) an exploratory clinical trial  
15 that is intended solely to assess safety  
16 or solely to evaluate pharmacokinetics;  
17 or

18 “(II) an observational study.

19 “(B) ESTABLISHMENT.—To ensure that  
20 results of clinical trials are made public and  
21 that patients and providers have current infor-  
22 mation regarding the results of clinical trials,  
23 the Secretary, acting through the Director of  
24 NIH, shall establish and administer a clinical  
25 trial results database in accordance with this

subsection (referred to in this subsection as the  
‘results database’).

“(C) SEARCHABLE CATEGORIES.—The Director of NIH shall ensure that the public may search the entries in the results database by—

“(i)(I) the indication studied in the clinical trial, using Medical Subject Headers (MeSH) descriptors; or

“(II) the safety issue studied in the clinical trial;

“(ii) whether an application for the tested indication is approved, pending approval, withdrawn, or not submitted;

“(iii) the phase of the clinical trial;

“(iv) the name of the drug that is the subject of the clinical trial; and

“(v) within the documents described in subclauses (II) and (III) of subparagraph (D)(ii)—

“(I) the sponsor of the clinical trial; and

“(II) each financial sponsor of the clinical trial.

“(D) CONTENTS.—

1           “(i) IN GENERAL.—The responsible  
2           party for an applicable clinical trial shall  
3           submit to the Director of NIH for inclu-  
4           sion in the results database the clinical  
5           trial information described in clause (ii).

6           “(ii) REQUIRED ELEMENTS.—In sub-  
7           mitting clinical trial information for an ap-  
8           plicable clinical trial to the Director of  
9           NIH for inclusion in the results database,  
10          the responsible party shall include, with re-  
11          spect to such clinical trial, the following in-  
12          formation:

13               “(I) The information described in  
14               clauses (i) through (iv) of subpara-  
15               graph (C).

16               “(II) A non-promotional sum-  
17               mary document that is written in non-  
18               technical, understandable language for  
19               patients that includes the following:

20                   “(aa) The purpose of the  
21                   clinical trial.

22                   “(bb) The sponsor of the  
23                   clinical trial.

1                   “(cc) A point of contact for  
2 information about the clinical  
3 trial.

4                   “(dd) A description of the  
5 patient population tested in the  
6 clinical trial.

7                   “(ee) A general description  
8 of the clinical trial and results,  
9 including a description of and the  
10 reasons for any changes in the  
11 clinical trial design that occurred  
12 since the date of submission of  
13 clinical trial information for in-  
14 clusion in the registry database  
15 established under paragraph (2)  
16 and a description of any signifi-  
17 cant safety information.

18                   “(III) A non-promotional sum-  
19 mary document that is technical in  
20 nature that includes the following:

21                   “(aa) The purpose of the  
22 clinical trial.

23                   “(bb) The sponsor of the  
24 clinical trial.

1           “(cc) Each financial sponsor  
2 of the clinical trial.

3           “(dd) A point of contact for  
4 scientific information about the  
5 clinical trial.

6           “(ee) A description of the  
7 patient population tested in the  
8 clinical trial.

9           “(ff) A general description  
10 of the clinical trial and results,  
11 including a description of and the  
12 reasons for any changes in the  
13 clinical trial design that occurred  
14 since the date of submission of  
15 clinical trial information for the  
16 clinical trial in the registry data-  
17 base established under paragraph  
18 (2).

19           “(gg) Summary data de-  
20 scribing the results, including—

21                   “(AA) whether the pri-  
22 mary endpoint was achieved,  
23 including relevant statistics;

24                   “(BB) an assessment of  
25 any secondary endpoints, if

1 applicable, including relevant  
2 statistics; and

3 “(CC) any significant  
4 safety information, including  
5 a summary of the incidence  
6 of serious adverse events ob-  
7 served in the clinical trial  
8 and a summary of the most  
9 common adverse events ob-  
10 served in the clinical trial  
11 and the frequencies of such  
12 events.

13 “(IV) A link to available peer-re-  
14 viewed publications based on the re-  
15 sults of the clinical trial, if any.

16 “(V) The completion date of the  
17 clinical trial.

18 “(VI) A link to the Internet web  
19 posting of any adverse regulatory ac-  
20 tions taken by the Food and Drug  
21 Administration, such as a warning let-  
22 ter, that was substantively based on  
23 the clinical trial design, outcome, or  
24 representation made by the applicant

1                   about the design or outcome of the  
2                   clinical trial.

3                   “(E) TIMING.—A responsible party shall  
4                   submit to the Director of NIH for inclusion in  
5                   the results database clinical trial information  
6                   for an applicable clinical trial not later than 1  
7                   year after the completion date of the clinical  
8                   trial as reported under paragraph (2)(F)(ii).

9                   “(F) TRUTHFUL CLINICAL TRIAL INFOR-  
10                  MATION.—

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

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

20                  “(G) INCLUSION OF EARLIER CLINICAL  
21                  TRIALS.—

22                  “(i) IN GENERAL.—The Secretary  
23                  may, subject to clause (ii), require through  
24                  rulemaking the submission of clinical trial  
25                  information for the clinical trials described

1 in paragraph (2)(A)(i)(I)(aa) to the Direc-  
2 tor of NIH for inclusion in the results  
3 database.

4 “(ii) CONDITIONS FOR REQUIRING IN-  
5 CLUSION OF EARLIER TRIALS.—The Sec-  
6 retary may promulgate regulations pursu-  
7 ant to clause (i) if—

8 “(I) the Comptroller General of  
9 the United States has submitted to  
10 the Secretary the report described  
11 under clause (iii); and

12 “(II) such report recommends  
13 the inclusion in the results database  
14 of clinical trial information for the  
15 clinical trials described under para-  
16 graph (2)(A)(i)(I)(aa).

17 “(iii) STUDY BY GAO.—Not earlier  
18 than 2 years after the results database has  
19 been established, the Comptroller General  
20 of the United States shall initiate a report  
21 that—

22 “(I) evaluates the operation of  
23 the database, including with respect to  
24 cost, burden on drug sponsors and  
25 agencies, and the value to patients

1 and health care providers of inclusion  
2 in the results database of clinical trial  
3 information with respect to clinical  
4 trials described in paragraph  
5 (2)(A)(i)(I)(aa);

6 “(II) recommends whether or not  
7 clinical trial information for such clin-  
8 ical trials should be included in the re-  
9 sults database;

10 “(III) if the recommendation  
11 under subclause (II) is to include the  
12 clinical trial information for such clin-  
13 ical trials in the results database, rec-  
14 ommends whether such information  
15 should be included in the same format  
16 as the clinical trial information of  
17 other applicable clinical trials, or if  
18 modifications are necessary;

19 “(IV) provides recommendations  
20 for any modifications described under  
21 subclause (III); and

22 “(V) is submitted to the Com-  
23 mittee on Health, Education, Labor,  
24 and Pensions of the Senate, the Com-  
25 mittee on Energy and Commerce of

1 the House of Representatives, and the  
2 Secretary.

3 “(H) CHANGE IN REGULATORY STATUS.—

4 The responsible party for an applicable clinical  
5 trial shall update the regulatory status sub-  
6 mitted under subparagraph (C)(ii) of a drug  
7 that is the subject of an applicable clinical trial  
8 within 30 days of a change in such status.

9 “(I) PUBLIC AVAILABILITY OF RESULTS.—

10 “(i) PRE-APPROVAL STUDIES.—Ex-  
11 cept as provided in clause (iv), with respect  
12 to an applicable clinical trial that is com-  
13 pleted before the drug is initially approved  
14 under section 505 of the Federal Food,  
15 Drug, and Cosmetic Act or initially li-  
16 censed under section 351 of this Act, the  
17 Director of NIH shall make publicly avail-  
18 able on the results database the clinical  
19 trial information submitted for such clin-  
20 ical trial not later than 30 days after—

21 “(I) the drug is approved under  
22 such section 505 or licensed under  
23 such section 351; or

1                   “(II) the Secretary issues a not  
2                   approvable letter for the drug under  
3                   such section 505 or such section 351.

4                   “(ii) POST-APPROVAL STUDIES.—Ex-  
5                   cept as provided in clauses (iii) and (iv),  
6                   with respect to an applicable clinical trial  
7                   that is completed after the drug is initially  
8                   approved under such section 505 or ini-  
9                   tially licensed under such section 351, the  
10                  Director of NIH shall make publicly avail-  
11                  able on the results database the clinical  
12                  trial information submitted for such clin-  
13                  ical trial not later than 30 days after the  
14                  date of such submission.

15                  “(iii) SEEKING APPROVAL OF A NEW  
16                  USE FOR THE DRUG.—

17                  “(I) IN GENERAL.—If the manu-  
18                  facturer of the drug is the sponsor or  
19                  a financial sponsor of the applicable  
20                  clinical trial, and such manufacturer  
21                  certifies to the Director of NIH that  
22                  such manufacturer has filed, or will  
23                  file within 1 year, an application seek-  
24                  ing approval under such section 505  
25                  or licensing under such section 351

1 for the use studied in such clinical  
2 trial (which use is not included in the  
3 labeling of the approved drug), then  
4 the Director of NIH shall make pub-  
5 licly available on the results database  
6 the clinical trial information sub-  
7 mitted for such clinical trial on the  
8 earlier of the date that is 30 days  
9 after the date—

10 “(aa) the application is ap-  
11 proved under such section 505 or  
12 licensed such section 351;

13 “(bb) the Secretary issues a  
14 not approvable letter for the ap-  
15 plication under such section 505  
16 or such section 351; or

17 “(cc) the application under  
18 such section 505 or such section  
19 351 is withdrawn.

20 “(II) LIMITATION ON CERTIFI-  
21 CATION.—A manufacturer shall not  
22 make a certification under subclause  
23 (I) with respect to an applicable clin-  
24 ical trial unless the manufacturer  
25 makes such a certification with re-

1 spect to each applicable clinical trial  
2 that is required to be submitted in an  
3 application for approval of the use  
4 studied in the clinical trial involved.

5 “(III) 2 YEAR LIMITATION.—The  
6 clinical trial information subject to  
7 subclause (I) shall be made publicly  
8 available on the results database on  
9 the date that is 2 years after the date  
10 that the clinical trial information was  
11 required to be submitted to the Direc-  
12 tor of NIH if a regulatory action re-  
13 ferred to in item (aa), (bb), or (cc) of  
14 subclause (I) has not occurred by  
15 such date.

16 “(iv) SEEKING PUBLICATION.—

17 “(I) IN GENERAL.—If the prin-  
18 cipal investigator of the applicable  
19 clinical trial is seeking publication in  
20 a peer-reviewed biomedical journal of  
21 a manuscript based on the results of  
22 the clinical trial and the responsible  
23 party so certifies to the Director of  
24 NIH—

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

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

13          “(II) LIMITATION.—The clinical  
14          trial information subject to subclause  
15          (I) shall be made publicly available on  
16          the results database on the date that  
17          is 2 years after the date that the clin-  
18          ical trial information was required to  
19          be submitted to the Director of NIH  
20          if the manuscript referred to in such  
21          subclause has not been published by  
22          such date.

23          “(J) VERIFICATION OF SUBMISSION PRIOR  
24          TO PUBLIC AVAILABILITY.—In the case of clin-  
25          ical trial information that is submitted under

1 this paragraph, but is not made publicly avail-  
2 able pending either regulatory action or publica-  
3 tion under clause (iii) or (iv) of subparagraph  
4 (I), as applicable, the Director of NIH shall re-  
5 spond to inquiries from other Federal agencies  
6 and peer-reviewed journals to confirm that such  
7 clinical trial information has been submitted  
8 but has not yet been made publicly available on  
9 the results database.

10 “(4) COORDINATION AND COMPLIANCE.—

11 “(A) CLINICAL TRIALS SUPPORTED BY  
12 GRANTS FROM FEDERAL AGENCIES.—

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

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

1 port forms required under such grant shall  
2 include a certification that the responsible  
3 party has made all required submissions to  
4 the Director of NIH under paragraphs (2)  
5 and (3).

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

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

1                   “(v) CONSULTATION WITH OTHER  
2                   FEDERAL AGENCIES.—The Secretary  
3                   shall—

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

11                  “(II) develop with such agencies  
12                  procedures comparable to those de-  
13                  scribed in clauses (ii), (iii), and (iv) to  
14                  ensure that clinical trial information  
15                  for such applicable clinical trials is  
16                  submitted under paragraphs (2) and  
17                  (3).

18                  “(B) COORDINATION OF REGISTRY DATA-  
19                  BASE AND RESULTS DATABASE.—

20                  “(i) IN GENERAL.—Each entry in the  
21                  registry database under paragraph (2)  
22                  shall include a link to the corresponding  
23                  entry in the results database under para-  
24                  graph (3).

25                  “(ii) MISSING ENTRIES.—

1           “(I) IN GENERAL.—If, based on  
2           a review of the entries in the registry  
3           database under paragraph (2), the Di-  
4           rector of NIH determines that a re-  
5           sponsible party has failed to submit  
6           required clinical trial information to  
7           the results database under paragraph  
8           (3), the Director of NIH shall inform  
9           the responsible party involved of such  
10          failure and permit the responsible  
11          party to correct the failure within 30  
12          days.

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

23          “(III) PUBLIC NOTICE OF FAIL-  
24          URE TO CORRECT.—The Director of  
25          NIH shall include in the clinical trial

1 registry database entry and the clin-  
2 ical trial results database entry for  
3 each such clinical trial a notice of any  
4 uncorrected failure to submit required  
5 clinical trial information and shall  
6 provide that the public may easily  
7 search for such entries.

8 “(C) ACTION ON APPLICATIONS.—

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

16 “(I) when considering a drug for  
17 an exemption under section 505(i) of  
18 the Federal Food, Drug, and Cos-  
19 metic Act, including as the drug pro-  
20 gresses through the clinical trials de-  
21 scribed under paragraph (2)(A)(i);  
22 and

23 “(II) prior to filing an applica-  
24 tion under section 505 of the Federal  
25 Food, Drug, and Cosmetic Act or

1 under section 351 of this Act that in-  
2 cludes information from such clinical  
3 trial.

4 “(ii) NOTIFICATION.—If the respon-  
5 sible party has not submitted such clinical  
6 trial information, the Secretary shall notify  
7 the applicant and the responsible party of  
8 such non-compliance and require submis-  
9 sion of such results within 30 days.

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

15 “(D) CONTENT REVIEW.—

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

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

6 “(aa) for review as part of  
7 an application under section 505  
8 of the Federal Food, Drug, and  
9 Cosmetic Act or under section  
10 351 of this Act; or

11 “(bb) in an annual status  
12 report on the drug under such  
13 application;

14 “(II) acting through the Inspec-  
15 tor General of the Department of  
16 Health and Human Services and with  
17 the Federal agency that funds such  
18 clinical trial in whole or in part by a  
19 grant to examine the results data for  
20 such clinical trials; and

21 “(III) acting through inspections  
22 under section 704 of the Federal  
23 Food, Drug, and Cosmetic Act to ex-  
24 amine results data for such clinical

1 trials not described in subclause (I) or  
2 (II).

3 “(ii) NOTICE OF NON-COMPLIANCE.—

4 If the Secretary or Inspector General of  
5 the Department of Health and Human  
6 Services determines that the clinical trial  
7 information submitted in such a summary  
8 document is promotional, or false or mis-  
9 leading in any particular, the Secretary  
10 shall notify the responsible party and give  
11 such party an opportunity to remedy such  
12 non-compliance by submitting the required  
13 revised clinical trial information within 30  
14 days of such notification.

15 “(E) PENALTY FOR NON-COMPLIANCE.—In  
16 determining whether to apply a penalty under  
17 section 301(ii) of the Federal Food, Drug, and  
18 Cosmetic Act, the Secretary, acting through the  
19 Commissioner of Food and Drugs, shall con-  
20 sider—

21 “(i) whether the responsible party  
22 promptly corrects the non-compliance when  
23 provided notice;

1                   “(ii) whether the responsible party  
2                   has engaged in a pattern or practice of  
3                   non-compliance; and

4                   “(iii) the extent to which the non-  
5                   compliance involved may have significantly  
6                   misled healthcare providers or patients  
7                   concerning the safety or effectiveness of  
8                   the drug involved.

9                   “(5) LIMITATION ON DISCLOSURE OF CLINICAL  
10                  TRIAL INFORMATION.—Disclosure to the public of  
11                  clinical trial information submitted to the Director  
12                  of NIH under this subsection and requested under  
13                  section 552 of title 5, United States Code (com-  
14                  monly known as the Freedom of Information Act)  
15                  shall be made only as provided for under paragraphs  
16                  (2) and (3).

17                  “(6) AUTHORIZATION OF APPROPRIATIONS.—  
18                  There are authorized to be appropriated to carry out  
19                  this subsection such sums as may be necessary.”.

20                  (b) CONFORMING AMENDMENTS.—

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

1       “(ii)(1) The failure to submit clinical trial informa-  
 2       tion as required by section 402(j) of the Public Health  
 3       Service Act.

4       “(2) The submission of clinical trial information  
 5       under section 402(j) of the Public Health Service Act that  
 6       is promotional or false or misleading in any particular  
 7       under paragraph (2)(E) or (3)(F) of such section 402(j).”.

8               (2) NEW DRUGS.—

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

12                      (i) in paragraph (1)—

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

15                              (II) in subparagraph (D), by  
 16                              striking the period at the end and in-  
 17                              serting “; and”; and

18                              (III) by adding at the end the  
 19                              following:

20                      “(E) the submission to the Director of NIH of  
 21              clinical trial information for the clinical investigation  
 22              at issue required under section 402(j) of the Public  
 23              Health Service Act for inclusion in the registry data-  
 24              base and the results database described in such sec-  
 25              tion.”;

1 (ii) in paragraph (3)(B)—

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

4 (II) in clause (ii), by striking the  
5 period at the end and inserting “; or”;  
6 and

7 (III) by adding at the end the  
8 following:

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

13 (iii) in paragraph (4), by adding at  
14 the end the following: “The Secretary shall  
15 update such regulations to require inclu-  
16 sion in the informed consent form a state-  
17 ment that clinical trial information for  
18 such clinical investigation will be submitted  
19 for inclusion in the registry database and  
20 results database, as applicable, described  
21 in section 402(j) of the Public Health  
22 Service Act.”.

23 (B) REFUSAL TO APPROVE APPLICA-  
24 TION.—Section 505(d) of the Federal Food,

1 Drug, and Cosmetic Act (21 U.S.C. 355(d)) is  
2 amended—

3 (i) in the first sentence, by inserting  
4 after “or any particular;” the following:  
5 “or (8) the applicant failed to submit the  
6 clinical trial information for any applicable  
7 clinical trial submitted as part of the appli-  
8 cation to the Director of the National In-  
9 stitutes of Health in compliance with sec-  
10 tion 402(j) of the Public Health Service  
11 Act;”; and

12 (ii) in the second sentence, by striking  
13 “clauses (1) through (6)” and inserting  
14 “(1) through (8)”.

15 (c) GUIDANCE.—Not later than 180 days after the  
16 date of enactment of this Act, the Commissioner of Food  
17 and Drugs, in consultation with the Director of the Na-  
18 tional Institutes of Health, shall issue guidance to clarify  
19 which clinical trials are applicable clinical trials (as de-  
20 fined in section 402(j)(2) of the Public Health Service Act,  
21 as amended by this section) (42 U.S.C. 282(j)(2)) and are  
22 required to be submitted for inclusion in the clinical trial  
23 registry database described in such section 402(j)(2).

24 (d) PREEMPTION.—

1           (1) IN GENERAL.—No State or political subdivi-  
2           sion of a State may establish or continue in effect  
3           any requirement for the registration of clinical trials  
4           or for the inclusion of information relating to the re-  
5           sults of clinical trials in a database.

6           (2) RULE OF CONSTRUCTION.—The fact of sub-  
7           mission of clinical trial information, if submitted in  
8           compliance with section 402(j) of the Public Health  
9           Service Act (as amended by this section) (42 U.S.C.  
10          282(j)), that relates to a use of a drug not included  
11          in the labeling of the approved drug shall not be  
12          construed by the Secretary or in any administrative  
13          or judicial proceeding, as evidence of a new intended  
14          use of the drug that is different from the intended  
15          use of the drug set forth in the official labeling of  
16          the drug. The availability of clinical trial information  
17          through the databases under paragraphs (2) and (3)  
18          of such section 402(j), if submitted in compliance  
19          with such section 402(j), shall not be considered as  
20          labeling, adulteration, or misbranding of the drug  
21          under the Federal Food, Drug, and Cosmetic Act  
22          (21 U.S.C. 301 et seq.).

23          (e) EFFECTIVE DATES.—

24                (1) ESTABLISHMENT OF REGISTRY DATABASE  
25                AND RESULTS DATABASE.—Not later than 1 year

1 after the date of enactment of this Act, the Director  
2 of NIH shall establish the registry database and the  
3 results database of clinical trials of drugs in accord-  
4 ance with section 402(j) of the Public Health Service  
5 Act (42 U.S.C. 282(j)) (as amended by subsection  
6 (a)).

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

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

1           (4) TRIALS COMPLETED BEFORE OPERATION  
2       OF RESULTS DATABASE.—

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

9           (i) involves a drug to treat a serious  
10       and life-threatening condition; and

11          (ii) is completed between the date of  
12       enactment of this section and such date of  
13       establishment under paragraph (1) of this  
14       subsection.

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

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

5 (i) such clinical trial would otherwise  
6 be an applicable clinical trial under para-  
7 graph (3) except for its date of completion;  
8 and

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

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

19 (II) contains data from an appli-  
20 cable clinical trial.

21 (5) TRIALS COMPLETED AFTER ESTABLISH-  
22 MENT OF RESULTS DATABASE.—Paragraph (3) of  
23 such section 402(j) shall apply to any applicable  
24 clinical trial that is completed after the date that the

1 results database is established under paragraph (1)  
2 of this subsection.

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

9 (7) STATUS OF CLINICALTRIALS.GOV  
10 WEBSITE.—

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

19 (i) that such registry database should  
20 expand and build upon the database de-  
21 scribed in section 402(j) of the Public  
22 Health Service Act (as in effect on the day  
23 before the date of enactment of this Act);  
24 or

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

5 (B) CLINICALTRIALS.GOV SUPPLANTED.—

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

## 13 **TITLE IV—CONFLICTS OF** 14 **INTEREST**

### 15 **SEC. 401. CONFLICTS OF INTEREST.**

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

#### 19 **“SEC. 712. CONFLICTS OF INTEREST.**

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

21 “(1) INVOLVEMENT.—The term ‘involvement’  
 22 means any financial interest in—

23 “(A) a product that is under consideration  
 24 by a panel;

1                   “(B) a competing product of such a prod-  
2                   uct;

3                   “(C) the sponsor of such product; or

4                   “(D) the sponsor of such a competing  
5                   product.

6                   “(2) PANEL.—The term ‘panel’ means any  
7                   committee, board, commission, council, conference,  
8                   panel, task force, or other similar group, or any sub-  
9                   committee or other subgroup thereof, that is estab-  
10                  lished by statute or by the Secretary to provide ad-  
11                  vice or recommendations to the Secretary regarding  
12                  activities of the Food and Drug Administration.

13                  “(3) PRODUCT.—The term ‘product’ means a  
14                  food, drug, biological product, device, or electronic  
15                  product that is regulated by the Food and Drug Ad-  
16                  ministration.

17                  “(b) APPOINTMENTS TO PANELS.—

18                  “(1) DISCLOSURE.—Prior to appointment to a  
19                  panel, each candidate member of a panel shall dis-  
20                  close to the Secretary all involvements that such  
21                  candidate may have with the work likely to be un-  
22                  dertaken by the panel during the term of the ap-  
23                  pointment for which the candidate is under consider-  
24                  ation.

1           “(2) EVALUATION AND CRITERIA.—When con-  
2           sidering an appointment to a panel, the Secretary—

3                   “(A) shall review the expertise and poten-  
4                   tial involvements of the candidate for appoint-  
5                   ment relative to the scope of work likely to be  
6                   undertaken by the panel during the term of the  
7                   appointment for which the candidate is under  
8                   consideration, so as to—

9                           “(i) maximize to the extent prac-  
10                           ticable the appointment of qualified indi-  
11                           viduals with no involvements, or only po-  
12                           tential involvements of low magnitude, with  
13                           such work; and

14                           “(ii) minimize to the extent prac-  
15                           ticable the appointment of individuals with  
16                           potential involvements of high magnitude  
17                           with such work; and

18                   “(B) may appoint 2 or more qualified indi-  
19                   viduals with similar expertise and non-overlap-  
20                   ping or minimally overlapping potential involve-  
21                   ments, so as to minimize the likelihood that a  
22                   panel will need the expertise of an appointed in-  
23                   dividual who requires a waiver for service on  
24                   the panel at a meeting of such panel.

25           “(c) DISCLOSURE BY PANEL MEMBER.—

1           “(1) IN GENERAL.—Prior to a meeting of a  
2           panel, each member of such panel shall disclose to  
3           the Secretary all involvements that such member  
4           may have with the work to be undertaken by such  
5           panel at such meeting.

6           “(2) DETERMINATION BY SECRETARY WITH RE-  
7           SPECT TO PANEL MEETINGS.—

8           “(A) IN GENERAL.—The Secretary shall  
9           make a determination with respect to each  
10          panel member based on the expertise of such  
11          panel member and the disclosure under para-  
12          graph (1). Such a determination shall be in one  
13          of the following categories:

14          “(i) APPROVAL FOR SERVICE.—The  
15          Secretary shall make the determination of  
16          approval for service for a panel member if  
17          there are no involvements or if the involve-  
18          ments of the panel member are of low  
19          magnitude.

20          “(ii) APPROVAL FOR SERVICE WITH A  
21          WAIVER OR LIMITED WAIVER.—The Sec-  
22          retary shall make the determination of ap-  
23          proval for service with a waiver or limited  
24          waiver for a panel member if the involve-  
25          ments of the panel member are of medium

1 or high magnitude and the Secretary cer-  
2 tifies in writing that—

3 “(I) such waiver is necessary to  
4 provide the panel with essential exper-  
5 tise; or

6 “(II) the need for the individual’s  
7 service outweighs the potential for a  
8 conflict of interest created by the dis-  
9 closed involvements.

10 “(iii) RECUSAL.—The Secretary shall  
11 make the determination of recusal for a  
12 panel member if the involvements of the  
13 panel member are of medium or high mag-  
14 nitude but a waiver or limited waiver could  
15 not be granted under clause (ii) because  
16 the criteria for certification by the Sec-  
17 retary under such clause were not met.

18 “(B) NOTICE OF DETERMINATION.—

19 “(i) MORE THAN 15 DAYS IN AD-  
20 VANCE.—A soon as practicable, but in no  
21 case later than 15 days prior to a meeting  
22 of a panel to which a determination for a  
23 panel member under clause (ii) or (iii) of  
24 subparagraph (A) applies, the Secretary  
25 shall disclose (other than information ex-

1           empted from disclosure under section 552  
2           of title 5, United States Code (popularly  
3           known as the Freedom of Information  
4           Act)) on the Internet website of the Food  
5           and Drug Administration—

6                       “(I) the type of the involvements;

7                       “(II) the nature of the involve-  
8                       ments;

9                       “(III) the magnitude of the in-  
10                      volvements; and

11                     “(IV) the reasons for any deter-  
12                     mination of the Secretary under such  
13                     clause (ii).

14                     “(ii) LESS THAN 15 DAYS IN AD-  
15                     VANCE.—In the case of a conflict of inter-  
16                     est that becomes known to the Secretary  
17                     less than 15 days prior to a meeting to  
18                     which the determination under clause (ii)  
19                     or (iii) of subparagraph (A) applies, the  
20                     Secretary shall disclose (other than infor-  
21                     mation exempted from disclosure under  
22                     section 552 of title 5, United States Code  
23                     (popularly known as the Freedom of Infor-  
24                     mation Act)) on the Internet website of the  
25                     Food and Drug Administration, the infor-

1                   mation described in subclauses (I) through  
 2                   (IV) of clause (i) of this subparagraph as  
 3                   soon as practicable, but in no event later  
 4                   than the date of such meeting.

5           “(d) LIMITATIONS.—In no case—

6                   “(1) may the Secretary grant a waiver under  
 7                   subsection (c)(2) for a panel member if the scientific  
 8                   work of such member is under consideration by the  
 9                   panel; or

10                   “(2) may a panel member vote with respect to  
 11                   any matter considered by the panel if such panel  
 12                   member or an immediate family member of such  
 13                   panel member could gain financially from the advice  
 14                   given to the Secretary with respect to such matter.

15           “(e) PUBLIC RECORD.—The Secretary shall ensure  
 16           that the public record of each meeting of a panel includes  
 17           a description of any determination of the Secretary made  
 18           under subsection (c)(2), including the category of such de-  
 19           termination and the involvements of each panel member  
 20           (other than information exempted from disclosure under  
 21           section 552 of title 5, United States Code (popularly  
 22           known as the Freedom of Information Act)).”.

23           (b) GUIDANCE.—

24                   (1) NOMINATIONS.—Not later than 270 days  
 25                   after the date of enactment of this Act the Secretary

1 shall publish in the Federal Register for public com-  
2 ment a proposed mechanism for encouraging the  
3 nomination of individuals who are classified by the  
4 Food and Drug Administration as academicians or  
5 practitioners for service on a panel (as defined in  
6 section 712 of the Federal Food, Drug, and Cos-  
7 metic Act (as added by this section)).

8 (2) CONFLICT OF INTEREST DETERMINA-  
9 TIONS.—Not later than 270 days after the date of  
10 enactment of this Act the Secretary shall issue or re-  
11 vise guidance—

12 (A) that defines the circumstances that,  
13 taking into consideration the categories of de-  
14 termination under subsection (c) of section 712  
15 of the Federal Food, Drug, and Cosmetic Act  
16 (as added by this section)—

17 (i) favor the inclusion of an individual  
18 on a panel;

19 (ii) favor a waiver of a conflict of in-  
20 terest requirement for an individual on a  
21 panel;

22 (iii) favor a limited waiver of a con-  
23 flict of interest requirement for an indi-  
24 vidual on a panel; and

1 (iv) disfavor the inclusion of an indi-  
2 vidual on a panel;

3 (B) that gives greater priority to consider-  
4 ation of an individual's net worth over consider-  
5 ation of absolute dollar value of an involvement  
6 in evaluating the magnitude of an involvement  
7 for purposes of making a determination under  
8 such subsection (c);

9 (C) that defines how financial interests im-  
10 puted to an individual bear upon his or her eli-  
11 gibility for service on a panel or for service at  
12 a meeting of a panel;

13 (D) that clarifies and improves the proc-  
14 esses to ensure disclosure of, and to verify the  
15 accuracy of, financial interests imputed to an  
16 individual; and

17 (E) to ensure consistency within and  
18 among the centers of the Food and Drug Ad-  
19 ministration in the issuance of determinations  
20 under such subsection (c).

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

25 (c) REVIEW BY INSPECTOR GENERAL.—

1           (1) IN GENERAL.—The Inspector General of  
2       the Department of Health and Human Services  
3       shall, on a periodic basis, conduct a review of the  
4       current financial interests, which shall be disclosed  
5       to the Inspector General in the same format and  
6       manner as under subsection (c) of section 712 of the  
7       Federal Food, Drug, and Cosmetic Act (as added by  
8       this section), of a representative sample of individ-  
9       uals who have completed service on such a panel (as  
10      defined in such section 712).

11          (2) SUBMISSION OF REPORT.—As part of the  
12      semiannual report required under section 5 of the  
13      Inspector General Act of 1978 (5 U.S.C. App.), the  
14      Inspector General of the Department of Health and  
15      Human Services shall include any findings with re-  
16      spect to an individual being rewarded or otherwise  
17      compensated by a sponsor of a product or a sponsor  
18      of a competing product in exchange for the individ-  
19      ual's vote as a member of a panel of the Food and  
20      Drug Administration which considered the product  
21      or a competing product (as such terms are used in  
22      such section 712), or the absence of any such find-  
23      ings.

1       (d) CONFORMING AMENDMENT.—Section 505(n) of  
2 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
3 355(n)) is amended by—

4           (1) striking paragraph (4); and

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

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

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