making ourselves easily seduced by arguments of drill, drill, drill, with oil companies having record profits and with, of course, the people, our folks, all of us, having to endure $3 a gallon gasoline.

In an ideal world, you could say that you could do both—yes, in an ideal world. But this isn’t an ideal world. This is a world in which the policy has always been drill, drill, drill. We have to break that policy. We have to start on things just like this proposal which is another part of the drill strategy of this administration. Only then are we going to protect our national security and only then are we going to protect our national economy by shifting to other fuels and to vehicles of which we easily have the technology now to get 40 miles per gallon on the fleet average instead of 27 miles per gallon on the fleet average.

You can imagine, if we can do that, instead of relying on a plan to drill for more oil that is not going to become available for another 10 years—if we will change the policy right now, which will have an immediate effect, starting tomorrow, on our consumption of oil—then, only then, will America start to move on a path truly toward energy independence.

Madam President, I yield the floor.

CONCLUSION OF MORNING BUSINESS

The PRESIDING OFFICER. Morning business is now closed.

PRESCRIPTION DRUG USER FEE AMENDMENTS OF 2007

The PRESIDING OFFICER. Under the previous order, the Senate will proceed to the consideration of S. 1082, which was ordered reported by the Senate Committee on Health, Education, Labor, and Pensions.

The assistant legislative clerk read the report as follows:

A bill (S. 1082) to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes.

The Senate proceeded to consider the bill, which had been reported from the Committee on Health, Education, Labor, and Pensions, with an amendment to strike all after the enacting clause and insert in lieu thereof the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the “Food and Drug Administration Revitalization Act”.

TITLES I—PRESCRIPTION DRUG USER FEES

SEC. 101. SHORT TITLE; REFERENCES IN TITLE.

(a) Short Title.—This title may be cited as the “Prescription Drug User Fee Amendments of 2007”.

(b) References in Title.—Except as otherwise specified, wherever in this title an amendment is expressed in terms of an amendment to a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

SEC. 102. DRUG FEES.

Section 735 (21 U.S.C. 379g) is amended—

(1) by striking the section designation and all that follows through “For purposes of this subchapter:” and inserting the following:

“SEC. 735. DRUG FEES.

(a) Purpose.—It is the purpose of this part that the fees imposed under this part be dedicated toward expediting the drug development process, the process for the review of human drug applications, and postmarket drug safety, and that fees set forth in this part be used to fund the goals identified in paragraph (1) of this section. Towards this purpose, this part in the letters from the Secretary to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record.

(b) REPORT.

(1) PERFORMANCE REPORT.—For fiscal years 2008 through 2012, not later than 120 days after the end of each fiscal year during which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in subsection (a) during such fiscal year and the future plans of the Food and Drug Administration for reporting to the Congress the goals. The report for a fiscal year shall include information on all previous cohorts for which the Secretary has not given a complete response on all human drug applications and supplements in the cohort.

(2) FISCAL REPORT.—For fiscal years 2008 through 2012, not later than 120 days after the end of each fiscal year during which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected during such fiscal year for which the report is made.

(3) PUBLIC AVAILABILITY.—The Secretary shall make the reports required under paragraphs (1) and (2) available to the public on the Internet website of the Food and Drug Administration.

(c) REAUTHORIZATION.

(1) CONSULTATION.—In developing recommendations to present to Congress with respect to the goals, and plans for meeting the goals, for the process for the review of human drug applications for the first 5 fiscal years after fiscal year 2012, and for the reauthorization of this part for fiscal years 2013 through 2017, the Secretary shall consult with—

(A) the Committee on Energy and Commerce of the House of Representatives;

(B) the Committee on Health, Education, Labor, and Pensions of the Senate;

(C) scientific and academic experts;

(D) health care professionals;

(E) representatives of patient and consumer advocacy groups; and

(F) the regulated industry.

(2) PUBLIC REVIEW OF RECOMMENDATIONS.—After negotiating with the regulated industry, the Secretary shall—

(A) present the recommendations developed under paragraph (1) to the Congressional committees specified in subparagraph (A) of subsection (a) of this section;

(B) publish such recommendations in the Federal Register;

(C) provide for a period of 30 days for the public to provide written comments on such recommendations;

(D) hold a meeting at which the public may present its views on such recommendations; and

(E) assess the public views and comments, revise such recommendations as necessary.

(2) TRANSMITTAL OF RECOMMENDATIONS.—Not later than January 15, 2013, the Secretary shall transmit to Congress the revised recommendations under paragraph (1), a summary of the views and comments received under such paragraph, and any changes made to the recommendations in response to such views and comments.

DEFINITIONS.—For purposes of this part:—

(2) in subsection (d)—

(A) in paragraph (1)—

(i) by striking “505(b)(1),” and inserting “505(b)(1), or”;

(ii) by striking subparagraph (B); and

(B) in paragraph (3)(C), by—

(i) striking “the list” and inserting “the list (not including the discontinued section of such list)”;

(ii) striking “a list” and inserting “a list (not including the discontinued section of such a list)”;

(C) in paragraph (4), by inserting before the period at the end of the following: “(such as capsules, tablets, and lyophilized products before reinstatement)”;

(D) by amending paragraph (6)(F) to read as follows:

“(F) In the case of drugs approved under human drug applications or supplements, premarket safety activities, including—

(i) collecting, developing, and reviewing safety information on approved drugs (including adverse event reports);

(ii) developing and using improved adverse event data collection systems (including information technology systems); and

(iii) developing and using improved analytical tools to assess potential safety problems (including by accessing external data bases).”;-

(E) in paragraph (8)—

(i) by striking “April of the preceding fiscal year” and inserting “October of the preceding fiscal year”; and

(ii) by striking “April 1997” and inserting “October 1996”;

(F) by redesigning paragraph (9) as paragraph (10); and

(G) by inserting after paragraph (6)(F) the following:

(9) The term ‘person’ includes an affiliate of such person.”.

SEC. 103. AUTHORITY TO AUTHORIZE AND USE DRUG FEES.

(a) TYPES OF FEES.—Section 736(a) (21 U.S.C. 379h(a)) is amended—

(1) in the matter preceding paragraph (1), by striking “1993” and inserting “2008”;

(2) in paragraph (1)—

(A) in subparagraph (D)—

(i) by striking “or withdrawn without a waiver before filing”;

(B) by redesigning subparagraphs (E) and (F) as subparagraphs (D) and (E), respectively; and

(C) by inserting after subparagraph (D) the following:

“(E) Fee for application previously refused for filing or withdrawn before filing.—An application or supplement that has been refused for filing or that was withdrawn before filing, if filed under protest or resubmitted, shall be subject to the fee under subparagraph (A) (unless an exception under subparagraph (C) or (F) applies or the fee is waived or reduced under subsection (d)), without regard to previous payment of such a fee and the refund of 75 percent of that fee under subparagraph (D),”;

and

SEC. 104. AUTHORITY TO REASSIGN FEES.

(a) GENERAL AUTHORITY.—Section 736(d) (21 U.S.C. 379h(d)) is amended—

(1) in paragraph (1)—

(A) by striking “April 1997” and inserting “October 1996”;

(B) by redesigning paragraph (2) as paragraph (1); and

(C) by striking “October 1996”;

(2) in subsection (a)—

(A) by redesigning paragraph (3) as paragraph (2); and

(B) by redesigning paragraph (4) as paragraph (3);

and

SEC. 105. AUTHORITY TO COLLECT FEES.

(a) AUTHORITY.—Section 736(b) (21 U.S.C. 379h(b)) is amended—

(1) in paragraph (1)—

(A) by striking “April 1997” and inserting “October 1996”; and

(B) by redesigning paragraph (2) as paragraph (1);

and

SEC. 106. AUTHORITY TO USE FEES.

(a) AUTHORITY.—Section 736(c) (21 U.S.C. 379h(c)) is amended—

(1) in paragraph (1)—

(A) by striking “April 1997” and inserting “October 1996”;

(B) by redesigning paragraph (2) as paragraph (1);

and

FUSED FOR FILING OR WITHDRAWN BEFORE FILING ” after “REFUND OF FEE IF APPLICATION REFUSED FOR FILING”.

(2) in paragraph (2)—

(A) by redesigning paragraphs (2) and (3) as paragraphs (1) and (2); and

(B) by redesigning paragraphs (4) and (5) as paragraphs (3) and (4), respectively.

(3) in paragraph (3)—

(A) by redesigning paragraphs (3) and (4) as paragraphs (2) and (3); and

(B) by redesigning paragraphs (5) and (6) as paragraphs (4) and (5), respectively.

(4) in paragraph (4)—

(A) by redesigning paragraphs (4) and (5) as paragraphs (3) and (4); and

(B) by redesigning paragraphs (6) and (7) as paragraphs (5) and (6), respectively.
(3) in paragraph (2)—
(A) in subparagraph (A), by striking “subparagraph (B)” and inserting “subparagraphs (B) and (C)”; and
(B) by striking at the end the following:
“(C) SPECIAL RULES FOR COMPOUNDED
POSITRON EMISSION TOMOGRAPHY DRUGS.—
“(1) IN GENERAL.—Except as provided in
clause (2), the Food and Drug Administration shall be authorized to be assessed a fee under subsection (A) to one
quarter of the costs paid for rent and rent-related expenses are
less than $11,721,000. The reductions made under subparagraph (A) shall be credited to the appropriation ac-
count of the Food and Drug Administration as a credit be
collected under this section pursuant to appropriation Acts for
fiscal year 2012.”
(4) FEE WAIVER OR REDUCTION.—Section

376A. PROGRAM TO ASSESS AND USE FEES FOR THE ADVISORY REVIEW OF PRESCRIPTION DRUG ADVERTISING

SEC. 104. AUTHORITY TO ASSESS AND USE PRESCRIPTION DRUG ADVERTISING FEES.

Chapter VII, subchapter C, part 2 (21 U.S.C. 379g et seq.) is amended by adding after section 735 the following new section:

SEC. 735A. AUTHORIZATION OF APPROPRIATIONS—

1. AUTHORIZATION OF APPROPRIATIONS.—
Section 736(g)(3) (21 U.S.C. 379h(g)(3)) is amended to read as follows:
“(a) Authorization of Appropriations.—

(1) AUTHORIZATION OF APPROPRIATIONS.—
Section 736(g)(3) (21 U.S.C. 379h(g)(3)) is amended to read as follows:
“(1) AUTHORIZATION OF APPROPRIATIONS.—

(1) ADVISORY REVIEW FEE.—
(A) IN GENERAL.—Except as provided in sub-
paragraph (B), each person who on or after October 1, 2007, submits a proposal for direct-to-con-
sumer television advertisement shall not be assessed a fee unless the sponsor designates it as a substitution
for advisory review.
(B) PAYMENT.—The fee required by subpara-
graph (A) shall be due not later than October 1 of the fiscal year in which the direct-to-con-
sumer television advertisement shall be submitted to the Secretary for advisory review.
(C) MODIFICATION OF ADVISORY REVIEW FEES.

(1) LATE PAYMENT.—If, on or before November
1 of the fiscal year in which the fees are due, a person has not paid all fees that were due for the previous fiscal year, the Secretary shall charge and collect fees in accordance with this section.

(2) EXCEPTION FOR REQUIRED SUBMISSIONS.—
(A) IN GENERAL.—Except as provided in sub-
section (c)(3), the fee required to be submitted to the Secretary prior to its initial public dissemination shall not be assessed a fee unless the sponsor designates it as a substitution for advisory review.
(B) PAYMENT.—The fee required by subpara-
graph (A) shall be due not later than October 1 of the fiscal year in which the direct-to-con-
sumer television advertisement shall be submitted to the Secretary for advisory review.

(3) CREDITING AND AVAILABILITY OF FEES.—

(4) OFFSET.—If the cumulative amount of fees assessed during fiscal years 2009 and 2010, plus the amount estimated to be collected for fiscal year 2011, exceeds the amount of fees specified in paragraph (1), the Secretary shall be authorized to be collected under this section pursuant to appropriation Acts for fiscal year 2012.”

(5) ADJUSTMENT FOR WORKLOAD.—After review of the recommendations by the independent accounting firm, the Secretary shall make appropriate changes to the workload adjustment methodology in setting fees for fiscal years 2010 through 2012. If the study is not conducted, no adjustment for changes in review activities shall be made after fiscal year 2009.

(6) WORKLOAD ADJUSTMENT.—Section 736(c)(2) (21 U.S.C. 379h(c)(2)) is amended—

(A) in subparagraph (A), by striking “2002” and inserting “2013”;
(B) in paragraph (2), by striking “subsection (c)(4)” and inserting “subsection (c)(5)”; and
(C) in paragraph (3), by striking “subsection (c)(4)” and inserting “subsection (c)(5)”.
advertisements for advisory review that are in excess of the number identified by that person in response to the Federal Register notice described in subsection (c)(3)(A), that person must pay a fee for each direct-to-consumer television advertisement that is for a fiscal year after October 1, 2007, is assessed an advisory review fee. The Secretary shall establish under subsection (f) fees paid under this paragraph shall be submitted by each person to the Secretary for advisory review.

(2) LIMITS.—

(i) IN GENERAL.—The payment of a fee under this paragraph for a fiscal year entitles the person that has paid the fee to an advisory review by the Secretary of 1 direct-to-consumer television advertisement and acceptance of 1 submission for advisory review of the same advertisement. The submission shall be submitted in the fiscal year for which the fee was assessed, except that a person may carry over no more than 1 paid advisory review submission to the next fiscal year. Resubmissions may be submitted without regard to the fiscal year of the initial advisory review submission.

(ii) NO REFUND.—Except as provided by subsection (c)(2), fees paid under this paragraph shall not be refunded.

(iii) NO WAIVER, EXEMPTION, OR REDUCTION.—The Secretary shall not grant a waiver, exemption, or reduction of any fees due or payable under this section.

(iv) NON-TRANSFERABILITY.—The right to an advisory review is not transferable, except to a successor in interest.

(2) OPERATING RESERVE FEES.—

(A) IN GENERAL.—Each person that, on or after October 1, 2007, is assessed an advisory review fee under paragraph (1) shall be subject to an operating reserve fee established under subsection (d)(2) only in the first fiscal year in which the fee is assessed, and to operate the program for the period for which the fee is assessed. Such fees shall be due 20 days before the submission of proposed direct-to-consumer television advertisements for advisory review prior to initial broadcast. The Secretary, in its determination of the operating reserve fee, shall, if necessary, consult with the Federal Communications Commission.

(B) PAYMENT.—Except as provided in sub-paragraph (C), the fee required by subparagraph (A) shall be due no later than October 1 of the first fiscal year in which the person is required to pay an advisory review fee under paragraph (1).

(C) LATE NOTICE OF SUBMISSION.—If, in the first fiscal year of a person’s participation in the Program, that person submits any direct-to-consumer television advertisement for advisory review that are in excess of the number identified by that person in response to the Federal Register notice described in subsection (c)(3)(A), that person must pay an operating reserve fee for each of those advertisements exceeding the number identified by the Federal Register notice. Such fees shall be due 20 days before the submission of the advertisements for advisory review.

(D) DETERMINATION OF WORKLOAD ADJUSTMENT.—

(1) IN GENERAL.—Beginning with fiscal year 2009, after the fee revenues established in sub-section (b) of this section are adjusted for a fiscal year for inflation in accordance with paragraph (1), the fee revenues shall be adjusted further for such fiscal year to reflect changes in the workload of the Secretary with respect to the submission of proposed direct-to-consumer television advertisements for advisory review prior to initial broadcast.

(2) DETERMINATION OF WORKLOAD ADJUSTMENT.—

(A) IN GENERAL.—Beginning with fiscal year 2009, after the fee revenues established in sub-section (b) of this section are adjusted for a fiscal year for inflation in accordance with paragraph (1), the fee revenues shall be adjusted further for such fiscal year to reflect changes in the workload of the Secretary with respect to the submission of proposed direct-to-consumer television advertisements for advisory review prior to initial broadcast.

(B) DETERMINATION OF WORKLOAD ADJUSTMENT.—

(i) IN GENERAL.—The Secretary shall establish the operating reserve fee under subsection (c)(2)(A) for each person required to pay the fee under subsection (c)(2)(A) that person pursuant to subsection (c)(3)(A) by the advisory review fee established pursuant to subsection (c)(2)(A).

(ii) INFLATION ADJUSTMENT.—Beginning with fiscal year 2009, after the fee revenues established in subsection (b) and the fee revenue amount established under subsection (b) are adjusted for inflation in accordance with paragraph (1), the fee revenue amount established in subsection (b) shall be adjusted by the Secretary under this subsection only to the extent necessary in the operating reserve for the process for the advisory review of prescription drug advertising.

(iii) NON-TRANSFERABILITY.—The right to an advisory review is not transferable, except to a successor in interest.

(3) ANNUAL FEE SETTING.—

(A) NUMBER OF ADVERTISEMENTS.—The Secretary shall, 60 days before the start of each fiscal year, publish in the Federal Register a notice requesting any person to notify the Secretary within 30 days of the number of direct-to-consumer television advertisements the person intends to submit for advisory review in the Secretary in the next fiscal year. Notification to the Secretary of the number of advertisements a person intends to submit for advisory review shall be subject to the Secretary’s review prior to initial broadcast and the Secretary’s equalizing binding by that person to pay the annual advisory review fee for that number of submissions on or before October 1 of the fiscal year in which the number is intended to be submitted. A person shall at the same time also notify the Secretary if such person intends to use a paid submission from the previous fiscal year under subsection (c)(1) and fees resulting from the adjustment made under this paragraph and the supporting methodologies. Under no circumstances shall the adjustment made under this paragraph result in fee revenues for a fiscal year that are less than the fee revenues established for the prior fiscal year.

(B) DETERMINATION OF WORKLOAD ADJUSTMENT.—

(i) IN GENERAL.—The Secretary shall publish in the Federal Register, as part of the notice described in paragraph (1), a notice determining the fee revenues to be generated from the workload of the Secretary in the next fiscal year. Notification to the Secretary under this subsection only to the extent necessary in the operating reserve for the process for the advisory review of prescription drug advertising.

(ii) INFLATION ADJUSTMENT.—Beginning with fiscal year 2009, after the fee revenues established in subsection (b) and the fee revenue amount established under subsection (b) are adjusted for inflation in accordance with paragraph (1), the fee revenue amount established in subsection (b) shall be adjusted by the Secretary under this subsection only to the extent necessary in the operating reserve for the process for the advisory review of prescription drug advertising.

(iii) NON-TRANSFERABILITY.—The right to an advisory review is not transferable, except to a successor in interest.

(3) USE OF OPERATING RESERVE.—The Secretary may use funds from the revenues under subsection (c)(2)(A) for any pro rata basis to operate the Program in the event the fees collected in any fiscal year to make up the difference between the fee revenue amount established for that fiscal year under subsection (b) and the amount of fees collected for that fiscal year pursuant to subsection (a), or to pay costs of ending the Program if it is terminated pursuant to subsection (f) or if it is not reauthorized after fiscal year 2012.

(4) REFUND OF OPERATING RESERVES.—Within 20 days of the end of each fiscal year, the Secretary shall refund the entire amount of operating reserve fees paid by such person under this section.

(5) EFFECT OF FAILURE TO PAY FEES.—Notwithstanding any other law or regulation of the Secretary, a submission for advisory review of a direct-to-consumer television advertisement sub- mitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted for review by the Secretary unless all fees owed by such person under this section have been paid.

(6) EFFECT OF INADEQUATE FUNDING OF PROGRAM.—

(A) IN GENERAL.—If on November 1, 2007, or 120 days after enactment of the Prescription Drug User Fee Amendments of 2007, whichever is later, the Secretary has received fees from the Prescription Drug User Fee Amendments of 2007, less than the amount of fees collected in any fiscal year to make up the difference between the fee revenue amount established for that fiscal year under subsection (b) and the amount of fees collected for that fiscal year pursuant to subsection (a)(2), or $120 million, the Secretary shall provide notice that it is not able to accept any submission for advisory review for which fees are owed by such person under this section.
SEC. 201. RISK EVALUATION.

(a) IN GENERAL.—Subsection (k) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended by adding at the end the following:

"(3) RISK IDENTIFICATION AND ASSESSMENT.—

"(A) IN GENERAL.—The Secretary shall facilitate a public-private partnership to—

"(i) implement a routine active monitoring system for postmarket drug safety; and

"(ii) focus postmarket studies under subsection (o)(4)(B) and postapproval clinical trials under subsection (o)(4)(C) more effectively on cases for which reports under paragraph (1) and other safety signal detection is not sufficient to resolve whether there is an elevated risk of a serious adverse event associated with use of a drug.

(b) PUBLIC-PRIVATE PARTNERSHIP.—The public-private partnership described in subparagraph (A) shall—

"(i) develop a mechanism for the pooling of relevant data from Federal and private electronic health care population databases that—

"(I) includes, in aggregate—

"(aa) at least 25,000,000 patients by January 1, 2009; and

"(bb) at least 100,000,000 patients by January 1, 2012;

"(II) allows access to full-text medical records, where available;

"(III) takes into consideration the need for data completeness, coding, cleansing, and trans-
“(i) priority drug safety questions; and
“(ii) mechanisms for answering such questions, including through—
“(I) active adverse drug experience monitoring; and
“(II) when such monitoring is not sufficient, postmarket studies under subsection (o)(4)(B) and postapproval clinical trials under subsection (o)(4)(C).

“(E) ANALYSIS OF DRUG SAFETY DATA.—The Secretary shall engage independent private research groups, including through the Centers for Excellence in Federal and Research on Therapeutics provided for under section 905 of the Public Health Service Act, to conduct analyses of data relating to priority drug safety questions.

“(F) CONTRACT REQUIREMENTS.—The Secretary shall provide the analyses described under subparagraph (E), including the methods and results of such analyses, to the appropriate health care providers, available to the public for review and comment.

“(G) PUBLIC AVAILABILITY OF ANALYSES.—The Secretary shall make the analyses described under subparagraph (E), including the methods and results of such analyses, available to the public for review and comment.

“(H) QUALIFIED ENTITIES.—The Secretary shall enter into contracts with a sufficient number of qualified entities to develop and provide information to the Secretary in a timely manner.

“(I) ENROLLMENT AND RETENTION.—The Secretary shall enter into a contract with an entity under clause (i) only if the Secretary determines that the entity has the research capacity and expertise to conduct and complete the activities under this paragraph.

“(J) IN AN INFORMATION TECHNOLOGY INFRASTRUCTURE.—These activities shall be conducted within an information technology infrastructure to support adverse event surveillance and data and operational standards to provide security for such data; and

“(K) EFFECTIVE USE.—The qualified entity shall ensure that the data provided by the Secretary in a manner that violates—

“(I) the Federal regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (concerning the privacy of individually-identifiable beneficiary health information); or

“(II) sections 552 or 552a of title 5, United States Code, with regard to the privacy of individually-identifiable beneficiary health information.

“(L) COMPONENT OF ANOTHER ORGANIZATION.—If a qualified entity is a component of another organization—

“(I) the qualified entity shall maintain the data related to the activities carried out under this paragraph separate from the other components of the organization and establish appropriate security measures to maintain the confidentiality and privacy of such data; and

“(II) the entity shall not make an unauthorized disclosure of the data; or

“(M) NONRENEWAL.—If a contract under this paragraph is terminated or not renewed, the following requirements shall apply.

“(I) CONFIDENTIALITY AND PRIVACY REGULATIONS.—The entity shall continue to comply with the confidentiality and privacy requirements under this paragraph with respect to all data disclosed by the Secretary.

“(II) DISPOSITION OF DATA.—The entity shall return to the Secretary all data disclosed to the entity, or, if returning the data is not practicable, destroy the data.

“(J) COMPETITIVE PROCEDURES.—The Secretary shall use competitive procedures (as defined in section 106(c) of the Federal Acquisition Policy Act) to enter into contracts under subparagraph (H).

“(K) REVIEW OF CONTRACT IN THE EVENT OF A MERGER OR ACQUISITION.—The Secretary shall review the contract with a qualified entity under this paragraph in the event of a merger or acquisition of the entity in order to ensure that the requirements under this paragraph will continue to be met.

“(L) AUTHORIZATION OF APPROPRIATIONS.—There are appropriated to carry out this section $30,000,000 for each of fiscal years 2008 through 2012.

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

“SECT. 202. RISK EVALUATION AND MITIGATION STRATEGIES.—

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

“SECT. 505A. RISK EVALUATION AND MITIGATION STRATEGIES.—

"(A) RISK EVALUATION.—If a risk evaluation and mitigation strategy for a drug is required, such strategy shall include—

"(i) the labeling for the drug for use by health care providers as approved under subsection (c);

"(ii) a timetable for submission of assessments of the strategy that—

"(I) new drug (including any ester or salt of the active ingredient) of which has been approved or listed in any other application under this section or section 351 of the Public Health Service Act; and

"(iii) shall be no less frequently than 18 months and 3 years after the drug is initially approved and at a frequency specified in the strategy for subsequent years; and

"(II) 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.

"(iii) for a drug other than a drug described under clause (i), shall occur at a frequency determined by the Secretary; and

"(iv) may be increased or reduced in frequency as necessary as provided for in paragraph (2)."
and there is no effective approved application for the drug under subsection (i) as of the date that the requirement is first imposed, the risk evaluation and mitigation strategy for the drug may require that the applicant conduct a specific disclosure about a serious risk listed in the labeling of the drug, or that an applicant conduct an appropriate postapproval clinical trial of the drug (which shall include a timeframe specified by the Secretary for completing the clinical trial and reporting to the Secretary the results of the trial) to be included in the clinical trial registry data bank provided for under subsections (i) and (j) of section 407 of the Public Health Service Act.

(5) ADDITIONAL POTENTIAL COMMUNICATION ELEMENTS OF A RISK EVALUATION AND MITIGATION STRATEGY.—

(a) GENERAL.—(I) IN GENERAL.—If the Secretary determines that disclosure under subparagraph (i)(iii) is inadequate to protect public health and safety, and that a risk evaluation and mitigation strategy for the drug (which shall include a timeframe specified by the Secretary for completing the strategy and reporting to the Secretary and the public on the results of the strategy) to be included in the strategy for the drug, such as to provide a description of serious risks that might occur among patients expected to be treated with the drug, and to mitigate such risk, may require that the applicant include in advertisements lacking a specific disclosure about a serious risk listed in the labeling of the drug.

(ii) Required Proposal.—An applicant may include a proposed risk evaluation and mitigation strategy for a drug in an application, including in a supplemental application, under subsection (b) or section 351 of the Public Health Service Act for the drug.

(1) SPECIFIC DISCLOSURES.—The Secretary may specify the advertisements required to be submitted under clause (i).

(ii) Specific Disclosures.—If the Secretary determines that preapproval of advertisements is necessary to ensure the inclusion of a true statement in each advertisement of serious risks that might occur among patients expected to be treated with the drug, the risk evaluation and mitigation strategy for the drug may require that the applicant submit to the Secretary advertisements of the drug not later than 45 days before dissemination of the advertisement.

(iii) Specification of Advertisements.—The Secretary may specify the advertisements required to be submitted under clause (i).

(E) SPECIFIC DISCLOSURES.—(I) SERIOUS RISK; SAFETY PROTOCOL.—If the Secretary determines that advertisements lacking a specific disclosure about a serious risk listed in the labeling of a drug or about a protocol to ensure safe use described in the labeling of the drug, the drug, or a protocol to conduct an evaluation and mitigation strategy for the drug may require that the applicant include in advertisements of the drug such disclosure.

(ii) DATE OF APPROVAL.—If the Secretary determines that advertisements lacking a specific disclosure of the date a drug was approved and that the drug is subject to more serious risks of the drug is necessary to protect public health and safety, and that a risk evaluation and mitigation strategy for the drug may require that the applicant include in advertisements of the drug such disclosure.

(iii) SPECIFICATION OF ADVERTISEMENTS.—The Secretary may require as elements of the strategy for the drug that advertisements required to include a specific disclosure under clause (i) or (ii).

(F) TEMPORARY MORATORIUM.—To the extent consistent with the Constitution, if the Secretary determines that disclosure under subparagraph (ii)(iii) is inadequate to protect public health and safety, and that a risk evaluation and mitigation strategy for the drug (which shall include a timeframe specified by the Secretary for completing the trial and reporting to the Secretary the results of the trial) to be included in the clinical trial registry data bank provided for under subsections (i) and (j) of section 407 of the Public Health Service Act.

(6) RESTRICTIONS ON DISTRIBUTION OR USE OF DRUGS WITH KNOWN UNUSUAL, SERIOUS RISKS.—

(A) IN GENERAL.—When a risk evaluation and mitigation strategy for a drug is required, and considering the adequacy of the labeling of the drug and other communication elements under paragraph (5) to mitigate a specific serious risk listed in the labeling of the drug, if the Secretary determines that the drug, which has been shown to be effective, can be safely used only if distribution or use of such drug is restricted, the Secretary may require as elements of such strategy such restrictions on distribution or use as are needed to assure safe use of the drug.

(B) LIMITS ON RESTRICTIONS TO ASSURE ACCESS AND MINIMIZE BURDEN.—Such restrictions under subparagraph (A) shall—

(i) be commensurate with the specific serious risk presented by the drug;

(ii) not unduly burdensome on patient access to the drug, considering in particular—

(1) patients who have difficulty accessing health care; and

(2) patients who have particular training or experience, or who have difficulty accessing health care; and

(iii) the extent to which clinical trials used to approve the drug may have identified serious risks that might occur among patients expected to be treated with the drug;

(7) RESTRICTIONS ON DISTRIBUTION OR USE FOR DRUGS WITH KNOWN UNUSUAL, SERIOUS RISKS.—

(A) IN GENERAL.—When a risk evaluation and mitigation strategy for a drug is required, and considering the adequacy of the labeling of the drug and other communication elements under paragraph (5) to mitigate a specific serious risk listed in the labeling of the drug, if the Secretary determines that the drug, which has been shown to be effective, can be safely used only if distribution or use of such drug is restricted, the Secretary may require as elements of such strategy such restrictions on distribution or use as are needed to assure safe use of the drug.

(B) LIMITS ON RESTRICTIONS TO ASSURE ACCESS AND MINIMIZE BURDEN.—Such restrictions under subparagraph (A) shall—

(i) be commensurate with the specific serious risk presented by the drug;

(ii) not unduly burdensome on patient access to the drug, considering in particular—

(1) patients who have difficulty accessing health care; and

(2) patients who have particular training or experience, or who have difficulty accessing health care; and

(iii) the extent to which clinical trials used to approve the drug may have identified serious risks that might occur among patients expected to be treated with the drug;

(iii) the seriousness of the condition for which the drug will be used;

(III) whether and how the labeling of the drug is to be changed and what elements of the risk evaluation and mitigation strategy—

(iv) the drug be dispensable to patients only in certain health care settings, such as hospitals;

(v) the drug be dispensed to patients with evidence or other documentation of safe-use conditions, and what results

(vi) each patient using the drug be subject to certain monitoring; or

(vii) each patient using the drug be enrolled in a strategy.

(11) RESTRICTION ON DISTRIBUTION OR USE FOR DRUGS WITH KNOWN UNUSUAL, SERIOUS RISKS.—

(A) IN GENERAL.—When a risk evaluation and mitigation strategy for a drug is required, and considering the adequacy of the labeling of the drug and other communication elements under paragraph (5) to mitigate a specific serious risk listed in the labeling of the drug, if the Secretary determines that disclosure under subparagraph (i)(iii) is inadequate to protect public health and safety, and that a risk evaluation and mitigation strategy for the drug (which shall include a timeframe specified by the Secretary for completing the strategy and reporting to the Secretary and the public on the results of the strategy) to be included in the strategy for the drug, such as to provide a description of serious risks that might occur among patients expected to be treated with the drug, and to mitigate such risk, may require that the applicant include in advertisements lacking a specific disclosure about a serious risk listed in the labeling of the drug.

(12) RESTRICTIONS ON DISTRIBUTION OR USE FOR DRUGS WITH KNOWN UNUSUAL, SERIOUS RISKS.—

(A) IN GENERAL.—When a risk evaluation and mitigation strategy for a drug is required, and considering the adequacy of the labeling of the drug and other communication elements under paragraph (5) to mitigate a specific serious risk listed in the labeling of the drug, if the Secretary determines that disclosure under subparagraph (i)(iii) is inadequate to protect public health and safety, and that a risk evaluation and mitigation strategy for the drug (which shall include a timeframe specified by the Secretary for completing the strategy and reporting to the Secretary and the public on the results of the strategy) to be included in the strategy for the drug, such as to provide a description of serious risks that might occur among patients expected to be treated with the drug, and to mitigate such risk, may require that the applicant include in advertisements lacking a specific disclosure about a serious risk listed in the labeling of the drug.

(ii) medguide; patient package insert .—

(iii) the drug be dispensed to patients only in certain health care settings, such as hospitals;

(iv) the drug be dispensed to patients with evidence or other documentation of safe-use conditions, and what results

(v) the drug be dispensed to patients only in certain health care settings, such as hospitals;

(vi) the drug be dispensed to patients with evidence or other documentation of safe-use conditions, and what results

(vii) each patient using the drug be subject to certain monitoring; or

(viii) each patient using the drug be enrolled in a strategy.

(13) RESTRICTIONS ON DISTRIBUTION OR USE FOR DRUGS WITH KNOWN UNUSUAL, SERIOUS RISKS.—

(A) IN GENERAL.—When a risk evaluation and mitigation strategy for a drug is required, and considering the adequacy of the labeling of the drug and other communication elements under paragraph (5) to mitigate a specific serious risk listed in the labeling of the drug, if the Secretary determines that disclosure under subparagraph (i)(iii) is inadequate to protect public health and safety, and that a risk evaluation and mitigation strategy for the drug (which shall include a timeframe specified by the Secretary for completing the strategy and reporting to the Secretary and the public on the results of the strategy) to be included in the strategy for the drug, such as to provide a description of serious risks that might occur among patients expected to be treated with the drug, and to mitigate such risk, may require that the applicant include in advertisements lacking a specific disclosure about a serious risk listed in the labeling of the drug.

(ii) medguide; patient package insert .—

(iii) the drug be dispensed to patients only in certain health care settings, such as hospitals;

(iv) the drug be dispensed to patients with evidence or other documentation of safe-use conditions, and what results

(v) the drug be dispensed to patients only in certain health care settings, such as hospitals;

(vi) the drug be dispensed to patients with evidence or other documentation of safe-use conditions, and what results

(vii) each patient using the drug be subject to certain monitoring; or

(viii) each patient using the drug be enrolled in a strategy.

(14) RESTRICTIONS ON DISTRIBUTION OR USE FOR DRUGS WITH KNOWN UNUSUAL, SERIOUS RISKS.—

(A) IN GENERAL.—When a risk evaluation and mitigation strategy for a drug is required, and considering the adequacy of the labeling of the drug and other communication elements under paragraph (5) to mitigate a specific serious risk listed in the labeling of the drug, if the Secretary determines that disclosure under subparagraph (i)(iii) is inadequate to protect public health and safety, and that a risk evaluation and mitigation strategy for the drug (which shall include a timeframe specified by the Secretary for completing the strategy and reporting to the Secretary and the public on the results of the strategy) to be included in the strategy for the drug, such as to provide a description of serious risks that might occur among patients expected to be treated with the drug, and to mitigate such risk, may require that the applicant include in advertisements lacking a specific disclosure about a serious risk listed in the labeling of the drug.

(2) RESTRICTIONS ON DISTRIBUTION OR USE FOR DRUGS WITH KNOWN UNUSUAL, SERIOUS RISKS.—

(A) IN GENERAL.—When a risk evaluation and mitigation strategy for a drug is required, and considering the adequacy of the labeling of the drug and other communication elements under paragraph (5) to mitigate a specific serious risk listed in the labeling of the drug, if the Secretary determines that disclosure under subparagraph (i)(iii) is inadequate to protect public health and safety, and that a risk evaluation and mitigation strategy for the drug (which shall include a timeframe specified by the Secretary for completing the strategy and reporting to the Secretary and the public on the results of the strategy) to be included in the strategy for the drug, such as to provide a description of serious risks that might occur among patients expected to be treated with the drug, and to mitigate such risk, may require that the applicant include in advertisements lacking a specific disclosure about a serious risk listed in the labeling of the drug.

(ii) medguide; patient package insert .—

(iii) the drug be dispensed to patients only in certain health care settings, such as hospitals;

(iv) the drug be dispensed to patients with evidence or other documentation of safe-use conditions, and what results

(v) the drug be dispensed to patients only in certain health care settings, such as hospitals;

(vi) the drug be dispensed to patients with evidence or other documentation of safe-use conditions, and what results

(vii) each patient using the drug be subject to certain monitoring; or

(viii) each patient using the drug be enrolled in a strategy.
“(III) within a timeframe specified by the Secretary, not to be less than 45 days, when ordered by the Secretary (acting through the offices described in subparagraph (A)(ii)(I)), if the Secretary determines that there may be a cause for disapproval of the drug and there is a dispute about the strategy, including the major elements described in section 735(a).

(4) A request for review under clause (i), the Secretary—

(a) that the drug is to be discussed by the Drug Safety Oversight Board; and

(b) the date on which the Drug Safety Oversight Board shall discuss such drug; and

(5) shall apply section 355(j), section 502 of title 21, and section 1906 of title 18, United States Code, to any request for information about such review.

(III) AGREEMENT AFTER DISPUTE OR ADMINISTRATIVE APPEALS.—

(A) FURTHER DISCUSSION OR ADMINISTRATIVE APPEALS.—A request for review under clause (i) shall not preclude—

(aa) further discussions to reach agreement on the risk evaluation and mitigation strategy; or

(bb) the use of administrative appeals within the Food and Drug Administration to reach agreement on the strategy, including the major elements described in section 735(a).

(B) DISPUTE RESOLUTION.—If a proposed risk evaluation and mitigation strategy for a drug submitted under clause (ii), the Board shall—

(I) REQUEST FOR REVIEW.—In any case other than a submission under subparagraph (A)(i) in which the Secretary for initial approval of a drug if there is a dispute about the strategy, not earlier than 15 days, and not later than 30 days, after discussions under subparagraph (D) have begun, the applicant shall request in writing that the dispute be reviewed by the Drug Safety Oversight Board.

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

(aa) shall schedule the dispute for review at 1 of the next 2 regular meetings of the Drug Safety Oversight Board, whenever meeting date is more practicable; or

(bb) may convene a special meeting of the Drug Safety Oversight Board to review the matter more promptly, including to meet an action deadline on an application (including a supplemental application).

(III) ALL ADVISANCE NOTICE TO THE PUBLIC.—The Secretary shall give notice to the public through the Federal Register and on the Internet website of the Food and Drug Administration—

(aa) that the drug is to be discussed by the Drug Safety Oversight Board; and

(bb) the date on which the Drug Safety Oversight Board shall discuss such drug; and

(iii) if the application requests review under clause (i), the Secretary—

(aa) shall issue an action letter or order, as appropriate, that describes the strategy.

(iv) MEETING OF THE BOARD.—At the meeting of the Drug Safety Oversight Board described in clause (i), the Board shall—

(I) hear from both parties; and

(II) review the dispute.

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

(vi) ACTION BY THE SECRETARY.—

(A) ACTION LETTER.—With respect to a proposed risk evaluation and mitigation strategy submitted under subparagraph (A)(ii) or an assessment of a risk evaluation and mitigation strategy submitted under subparagraph (B)(ii) or subparagraph (C)(ii), the Secretary shall issue an action letter that resolves the dispute not later than the later of—

(aa) the action deadline for the action letter on the application; or

(bb) the Secretary accepting the recommendation of the Drug Safety Oversight Board.

(B) ORDER.—With respect to a proposed risk evaluation and mitigation strategy submitted under subparagraph (A)(ii) or an assessment of the risk evaluation and mitigation strategy submitted under subparagraph (B)(ii) or under subparagraph (C)(ii), the Secretary—

(I) if the application requests review under clause (i), the Secretary—

(aa) shall schedule the dispute for review at 1 of the next 2 regular meetings of the Drug Safety Oversight Board, whenever meeting date is more practicable; or

(bb) may convene a special meeting of the Drug Safety Oversight Board to review the matter more promptly, including to meet an action deadline on an application (including a supplemental application);

(II) if the application requests review under clause (i), the Secretary—

(aa) shall issue an action letter or order, as appropriate, that describes the strategy.

(III) ALL ADVISANCE NOTICE TO THE PUBLIC.—The Secretary shall give notice to the public through the Federal Register and on the Internet website of the Food and Drug Administration—

(aa) that the drug is to be discussed by the Drug Safety Oversight Board; and

(bb) the date on which the Drug Safety Oversight Board shall discuss such drug; and

(I) ACTION LETTER.—With respect to a proposed risk evaluation and mitigation strategy submitted under subparagraph (A)(ii) or an assessment of a risk evaluation and mitigation strategy submitted under subparagraph (B)(ii) or subparagraph (C)(ii), the Secretary shall issue an action letter that resolves the dispute not later than the later of—

(aa) the action deadline for the action letter on the application; or

(bb) the Secretary accepting the recommendation of the Drug Safety Oversight Board.

(II) ORDER.—With respect to a proposed risk evaluation and mitigation strategy submitted under subparagraph (A)(ii) or an assessment of the risk evaluation and mitigation strategy submitted under subparagraph (B)(ii) or under subparagraph (C)(ii), the Secretary—

(I) if the application requests review under clause (i), the Secretary—

(aa) shall schedule the dispute for review at 1 of the next 2 regular meetings of the Drug Safety Oversight Board, whenever meeting date is more practicable; or

(bb) may convene a special meeting of the Drug Safety Oversight Board to review the matter more promptly, including to meet an action deadline on an application (including a supplemental application);

(II) if the application requests review under clause (i), the Secretary—

(aa) shall issue an action letter or order, as appropriate, that describes the strategy.
the dispute not later than 7 days after receiving the recommendation of the Drug Safety Oversight Board.

''(viii) EFFECT ON ACTION DEADLINE.—With respect to a supplemental application in which a proposed risk evaluation and mitigation strategy is submitted under subparagraph (B)(i)(I) or in which an assessment of the strategy submitted under subparagraph (B)(i)(I), the Secretary shall be considered to have met the action deadline for the action letter under clause (ii), the Secretary may: (I) announce in the Federal Register a supplemental application for the drug under subsection (o)(7)(B)(ii)(V).''.

SEC. 205. NO EFFECT ON WITHDRAWAL OR SUSPENSION OF APPROVAL.

Section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) is amended by adding at the end the following: "(2) in subsection (i), by inserting "including the requirements under section 505(o) of such Act," after "(ii)".

SEC. 206. DRUGS SUBJECT TO AN ABBREVIATED NEW DRUG APPLICATION.

Section 505(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(2)) is amended by adding at the end the following: "(B) IN GENERAL.—A drug that is the subject of an abbreviated new drug application under this subsection shall be subject to the following: (I) DRUG SAFETY OVERSIGHT BOARD.—(1) IN GENERAL.—There is established a Drug Safety Oversight Board.

SEC. 207. ENFORCEMENT.

Section 505(e)(l) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(l)) is amended by adding at the end the following: "(2) in the heading of such section, by striking "prescription drug" and inserting "drug, including a nondrug product that is intended for direct-to-consumer advertising as provided for in subsection (d)(3)(G)";".

SEC. 208. PROHIBITION ON USE OF FEDERAL FUNDS.

Section 360(e)(4)(A)(i) of the Social Security Act (42 U.S.C. 1395xv(e)(4)(A)(i)) is amended by striking "for the applicable listed drug" and inserting "for the applicable listed drug, and with the consent of the applicable listed drug holder, to a health care provider who is not otherwise entitled to payment for such drug under section 1862(a) of the Social Security Act (42 U.S.C. 1395f(a)) for services furnished to an individual who is not otherwise entitled to payment for such drug under such section.".

$1,000,000 for all such violations adjudicated in a single proceeding.";''

(3) in paragraph (2)(C), by striking "paragraph (3)(A)", and inserting paragraph (3)(A)";''

(4) in paragraph (4), as so redesignated, by striking "paragraph (1) or (2)" each place it appears and inserting "paragraph (1), (2), or (3)";''

(5) in paragraph (6), as so redesignated, by striking "paragraph (4)" each place it appears and inserting "paragraph (5)".

SEC. 204. REGULATION OF DRUGS THAT ARE BIOLOGICAL PRODUCTS.

Section 351 of the Public Health Service Act (42 U.S.C. 262) is amended—(1) in subsection (a)(2), by adding at the end the following:

(2) in subsection (i), by inserting "including the requirements under section 505(o) of such Act," after "(ii)".

SEC. 205. NO EFFECT ON WITHDRAWAL OR SUSPENSION OF APPROVAL.

Section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) is amended by adding at the end the following: "(2) in subsection (i), by inserting "including the requirements under section 505(o) of such Act," after "(ii)".

SEC. 206. DRUGS SUBJECT TO AN ABBREVIATED NEW DRUG APPLICATION.

Section 505(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(2)) is amended by adding at the end the following: "(B) IN GENERAL.—A drug that is the subject of an abbreviated new drug application under this subsection shall be subject to the following: (I) DRUG SAFETY OVERSIGHT BOARD.—(1) IN GENERAL.—There is established a Drug Safety Oversight Board.

SEC. 207. ENFORCEMENT.

Section 505(e)(l) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(l)) is amended by adding at the end the following: "(2) in the heading of such section, by striking "prescription drug" and inserting "drug, including a nondrug product that is intended for direct-to-consumer advertising as provided for in subsection (d)(3)(G)";".

SEC. 208. PROHIBITION ON USE OF FEDERAL FUNDS.

Section 360(e)(4)(A)(i) of the Social Security Act (42 U.S.C. 1395xv(e)(4)(A)(i)) is amended by striking "for the applicable listed drug" and inserting "for the applicable listed drug, and with the consent of the applicable listed drug holder, to a health care provider who is not otherwise entitled to payment for such drug under section 1862(a) of the Social Security Act (42 U.S.C. 1395f(a)) for services furnished to an individual who is not otherwise entitled to payment for such drug under such section.".

$1,000,000 for all such violations adjudicated in a single proceeding.";''

(3) in paragraph (2)(C), by striking "paragraph (3)(A)", and inserting paragraph (3)(A)";''

(4) in paragraph (4), as so redesignated, by striking "paragraph (1) or (2)" each place it appears and inserting "paragraph (1), (2), or (3)";''

(5) in paragraph (6), as so redesignated, by striking "paragraph (4)" each place it appears and inserting "paragraph (5)".

SEC. 204. REGULATION OF DRUGS THAT ARE BIOLOGICAL PRODUCTS.

Section 351 of the Public Health Service Act (42 U.S.C. 262) is amended—(1) in subsection (a)(2), by adding at the end the following:

(2) in subsection (i), by inserting "including the requirements under section 505(o) of such Act," after "(ii)".

SEC. 205. NO EFFECT ON WITHDRAWAL OR SUSPENSION OF APPROVAL.

Section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) is amended by adding at the end the following: "(2) in subsection (i), by inserting "including the requirements under section 505(o) of such Act," after "(ii)".

SEC. 206. DRUGS SUBJECT TO AN ABBREVIATED NEW DRUG APPLICATION.

Section 505(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(2)) is amended by adding at the end the following: "(B) IN GENERAL.—A drug that is the subject of an abbreviated new drug application under this subsection shall be subject to the following: (I) DRUG SAFETY OVERSIGHT BOARD.—(1) IN GENERAL.—There is established a Drug Safety Oversight Board.

SEC. 207. ENFORCEMENT.

Section 505(e)(l) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(l)) is amended by adding at the end the following: "(2) in the heading of such section, by striking "prescription drug" and inserting "drug, including a nondrug product that is intended for direct-to-consumer advertising as provided for in subsection (d)(3)(G)";".

SEC. 208. PROHIBITION ON USE OF FEDERAL FUNDS.

Section 360(e)(4)(A)(i) of the Social Security Act (42 U.S.C. 1395xv(e)(4)(A)(i)) is amended by striking "for the applicable listed drug" and inserting "for the applicable listed drug, and with the consent of the applicable listed drug holder, to a health care provider who is not otherwise entitled to payment for such drug under section 1862(a) of the Social Security Act (42 U.S.C. 1395f(a)) for services furnished to an individual who is not otherwise entitled to payment for such drug under such section.".
"(D) STRATEGIC PLAN FOR INFORMATION TECHNOLOGY.—Not later than 1 year after the date of enactment of this title, the Secretary of Health and Human Services (referred to in this title as "Secretary") shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on the Budget of the House of Representatives, a strategic plan on information technology that includes—

(1) an assessment of the information technology needed to support the appropriate data collection, access to data in external health care databases, data mining capabilities, personnel, and personnel training programs, needed by the Federal Government to support the drug development process and to publish drug labeling necessary to protect public health.

(2) the inclusion of strategies for meeting the needs assessments toward meeting the needs assessments

SEC. 297. RESOURCES.

(a) USER FEES.—Subparagraph (F) of section 733(d)(6) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 373(d)(6)), as amended by section 103, is amended—

(1) in clause (ii), by striking "systems; and" and inserting "systems; and"

(2) in clause (iii), by striking "bases; and" and inserting "bases; and"

(b) WORKLOAD ADJUSTMENT.—Subparagraph (A) of section 736(c)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 376(c)(2)), in the first sentence by striking "and manufacturing changes submitted to the Secretary, and" and inserting "and manufacturing changes, and assessments of risk evaluation and mitigation strategies submitted to the Secretary, uses of disease resolution under the process for reviewing and assessing risk evaluation and mitigation strategies, and"

(c) ADDITIONAL FEE REVENUES FOR DRUG SAFETY.—Section 736 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 376), as amended by section 103, is amended by—

(1) striking the subsection designation and all that follows through "—Except" and inserting the following:

"(b) FEE REVENUE AMOUNTS.—

(1) IN GENERAL.—Except; and"

(2) adding at the end the following:

"(i) $392,783,000; plus

(2) AMOUNT DETERMINED.—For any fiscal year 2012 through 2013, the amount determined under this subparagraph is the sum of—

"(i) $392,783,000; plus

(ii) the amount equal to—

"(i) $50,000,000, minus

(iii) an amount equal to one-fifth of the amount by which the appropriations for salaries and expenses of the Food and Drug Administration for such fiscal year exceed the amount of appropriations for the salaries and expenses of the Food and Drug Administration for the fiscal year 2009, adjusted as provided under subsection (c)(1).

In making the adjustment under subsection (1)(i) for any fiscal year 2012, subsection (c)(1)(i) shall be applied by substituting "2009" for "2008".

(c) LIMITATION.—This paragraph shall not apply for any fiscal year if the amount described under subparagraph (B)(i) is less than 0%.

"(D) SAFETY LABELING CHANGES.—

(1) NOTIFICATION.—The holder of an approved application under section 505 of this Act or a license under section 351 of the Public Health Service Act (referred to in this title as a "holder") shall promptly notify the Secretary if the holder becomes aware of new safety information that the holder believes should be included in the labeling of the drug. The Secretary shall promptly notify the holder if the Secretary becomes aware of new safety information that the Secretary believes should be included in the labeling of the drug.

(2) DISCUSSION REGARDING LABELING CHANGES.—Following notification pursuant to paragraph (1), the Secretary and holder shall discuss the new safety information in order to reach agreement on whether the labeling for the drug should be modified to reflect the new safety information and, if so, on the contents of such changes.

(3) SUPPLEMENT.—If the Secretary determines that there is reasonable scientific evidence that an adverse event is associated with use of the drug, the Secretary may request the holder to submit a supplement to an application under section 505 of this Act or to a license under section 351 of the Public Health Service Act (referred to in this section as a "supplement") proposing changes to the approved labeling to reflect the new safety information, including changes to boxed warnings, contraindications, warnings, precautions, and adverse reactions (referred to in this section as a "safety labeling change"). If the Secretary determines that no safety labeling change is necessary or appropriate based upon the new safety information or

(ii) notify the holder in writing that the Secretary or does not agree with the Secretary's determination that no labeling change is necessary or appropriate, the Secretary (on his or her own initiative or upon request by the holder) shall refer the matter for expedited review to the Drug Safety Oversight Board.

(4) ACTION BY THE DRUG SAFETY OVERSIGHT BOARD.—Not later than 45 days after receiving a request under paragraph (3)(B), the Drug Safety Oversight Board shall—

(A) review the new safety information;
(B) review all written material submitted by the Secretary and the holder;

(C) convene a meeting to hear oral presentations and arguments from the Secretary and the holder;

(D) make a written recommendation to the Secretary—

(i) concerning appropriate safety labeling changes, if any, and after not later than 20 days after receiving the recommendation—

(ii) stating that no safety labeling changes are necessary or appropriate based upon the new safety information.

(5) ASSESSMENT OF RECOMMENDATIONS.—

(A) ACTION BY THE SECRETARY.—The Secretary shall consider the recommendation of the Drug Safety Oversight Board made under paragraph (4) after not later than 20 days after receiving the recommendation—

(i) issue an order requiring the holder to make any safety labeling change that the Secretary determines to be necessary and appropriate; or

(ii) if the Secretary determines that no safety labeling change is necessary or appropriate, the Secretary shall notify the holder of this determination in writing.

(B) FAILURE TO ACT.—If the Secretary fails to act by not later than 20 days after receiving the recommendation of the Drug Safety Oversight Board, the written recommendation of the Drug Safety Oversight Board shall be considered the order of the Secretary under this paragraph.

(C) NONDELEGATION.—The Secretary's authority under this paragraph shall not be delegated to any individual below the level of the Director of the Center for Drug Evaluation and Research, or the Director of the Center for Biologics Evaluation and Research, of the Food and Drug Administration.

(6) IMMEDIATE PUBLICATION.—If the holder, not later than 10 days after receiving an order under subparagraph (A) or (B) of paragraph (5), does not agree to make a safety labeling change ordered by the Secretary, the Secretary may deem the drug that is the subject of the request to be misbranded.

(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to change the standards in existence on the date of enactment of this section for determining whether safety labeling changes are necessary or appropriate.

(2) REVIEW COMMITTEE.—Section 202 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352 et seq.), as amended by section 203, is further amended by adding at the end the following:

SEC. 210. ACTION PACKAGE FOR APPROVAL.

Section 505(l) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or licensed under section 351 of the Public Health Service Act (42 U.S.C. 262) in any other application under section 505 or licensed under section 351 for which a Medication Guide, as provided for under part 206 of title 21, Code of Federal Regulations (or any successor regulations), is required.

SEC. 211. RISK COMMUNICATION.

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

SEC. 566. ADVISORY COMMITTEE ON RISK COMMUNICATION.

(a) In General.—The Secretary shall establish an advisory committee to be known as the ‘‘Advisory Committee on Risk Communication’’ (referred to in this section as the ‘‘Committee’’).

(b) Duties.—The Secretary shall advise the Commissioner on methods to effectively communicate risks associated with the products regulated by the Food and Drug Administration.

(c) MEMBERS.—The Secretary shall ensure that the Committee is composed of experts on risk communication, experts on the risks described in paragraph (b), and representatives of patient, consumer, and health professional organizations.

(d) PERMANENCE OF COMMITTEE.—Section 14 of the Federal Advisory Committee Act shall not apply to the Committee established under this section.

SEC. 212. REFERRAL TO ADVISORY COMMITTEE.

Section 505 of the Federal Food, Drug, and Cosmetic Act, as amended by this section 202, is further amended by adding at the end the following:

SEC. 213. RESPONSE TO THE INSTITUTE OF MEDICINE.

(a) IN GENERAL.—Not later than 1 year after the date of enactment of this title, the Secretary shall issue a report responding to the 2006 report of the Institute of Medicine entitled ‘‘The Future of Drug Safety—Promoting and Protecting the Health of the Public’’.

(b) CONTENT OF REPORT.—The report issued by the Secretary under subsection (a) shall include—

(1) an update on the implementation by the Food and Drug Administration of its plan to respond to the Institute of Medicine report described in paragraph (a); and

(2) an assessment of how the Food and Drug Administration has implemented—

"(D) DISAGREEMENT.—A scientific review of an application is considered the work of the reviewer and shall not be altered by management or the reviewer once final. Disagreements by reviewers, division directors, and other members of the FDA management may be raised with the Associate Commissioner for Policy and Planning if any or all of the major conclusions of a reviewer shall be documented in a separate review or in an addendum to the review.

(E) MEMBERS.—The Secretary shall ensure that the Committee is composed of experts on risk communication, experts on the risks described in paragraph (b), and representatives of patient, consumer, and health professional organizations.

(F) PERMANENCE OF COMMITTEE.—Section 14 of the Federal Advisory Committee Act shall not apply to the Committee established under this section.

SEC. 212. REFERRAL TO ADVISORY COMMITTEE.

Section 505 of the Federal Food, Drug, and Cosmetic Act, as amended by this section 202, is further amended by adding at the end the following:

"(G) REFERRAL TO ADVISORY COMMITTEE.—

(1) IN GENERAL.—Prior to the approval of a drug no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under the Public Health Service Act, the Secretary shall refer such drug to a Food and Drug Administration advisory committee for review at a meeting of such advisory committee.

(2) EXCEPTION.—Notwithstanding paragraph (1), an advisory committee review of a drug described in paragraph (b) shall not occur within 1 year after approval of such a drug if—

(A) the clinical trial that formed the primary basis of the safety and efficacy determination was halted by a drug safety monitoring board or an Institutional Review Board before its scheduled completion due to early unanticipated therapeutic results; or

(B) the Secretary determines that it would be beneficial to the public health.

SEC. 213. RESPONSE TO THE INSTITUTE OF MEDICINE.

(a) IN GENERAL.—Not later than 1 year after the date of enactment of this title, the Secretary shall issue a report responding to the 2006 report of the Institute of Medicine entitled ‘‘The Future of Drug Safety—Promoting and Protecting the Health of the Public’’.

(b) CONTENT OF REPORT.—The report issued by the Secretary under subsection (a) shall include—

(1) an update on the implementation by the Food and Drug Administration of its plan to respond to the Institute of Medicine report described in paragraph (a); and

(2) an assessment of how the Food and Drug Administration has implemented—

"(D) DISAGREEMENT.—A scientific review of an application is considered the work of the reviewer and shall not be altered by management or the reviewer once final. Disagreements by reviewers, division directors, and other members of the FDA management may be raised with the Associate Commissioner for Policy and Planning if any or all of the major conclusions of a reviewer shall be documented in a separate review or in an addendum to the review.

(E) MEMBERS.—The Secretary shall ensure that the Committee is composed of experts on risk communication, experts on the risks described in paragraph (b), and representatives of patient, consumer, and health professional organizations.

(F) PERMANENCE OF COMMITTEE.—Section 14 of the Federal Advisory Committee Act shall not apply to the Committee established under this section.

SEC. 212. REFERRAL TO ADVISORY COMMITTEE.

Section 505 of the Federal Food, Drug, and Cosmetic Act, as amended by this section 202, is further amended by adding at the end the following:

"(G) REFERRAL TO ADVISORY COMMITTEE.—

(1) IN GENERAL.—Prior to the approval of a drug no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under the Public Health Service Act, the Secretary shall refer such drug to a Food and Drug Administration advisory committee for review at a meeting of such advisory committee.

(2) EXCEPTION.—Notwithstanding paragraph (1), an advisory committee review of a drug described in paragraph (b) shall not occur within 1 year after approval of such a drug if—

(A) the clinical trial that formed the primary basis of the safety and efficacy determination was halted by a drug safety monitoring board or an Institutional Review Board before its scheduled completion due to early unanticipated therapeutic results; or

(B) the Secretary determines that it would be beneficial to the public health.

"(D) DISAGREEMENT.—A scientific review of an application is considered the work of the reviewer and shall not be altered by management or the reviewer once final. Disagreements by reviewers, division directors, and other members of the FDA management may be raised with the Associate Commissioner for Policy and Planning if any or all of the major conclusions of a reviewer shall be documented in a separate review or in an addendum to the review.

(E) MEMBERS.—The Secretary shall ensure that the Committee is composed of experts on risk communication, experts on the risks described in paragraph (b), and representatives of patient, consumer, and health professional organizations.

(F) PERMANENCE OF COMMITTEE.—Section 14 of the Federal Advisory Committee Act shall not apply to the Committee established under this section.

SEC. 212. REFERRAL TO ADVISORY COMMITTEE.

Section 505 of the Federal Food, Drug, and Cosmetic Act, as amended by this section 202, is further amended by adding at the end the following:

"(G) REFERRAL TO ADVISORY COMMITTEE.—

(1) IN GENERAL.—Prior to the approval of a drug no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under the Public Health Service Act, the Secretary shall refer such drug to a Food and Drug Administration advisory committee for review at a meeting of such advisory committee.

(2) EXCEPTION.—Notwithstanding paragraph (1), an advisory committee review of a drug described in paragraph (b) shall not occur within 1 year after approval of such a drug if—

(A) the clinical trial that formed the primary basis of the safety and efficacy determination was halted by a drug safety monitoring board or an Institutional Review Board before its scheduled completion due to early unanticipated therapeutic results; or

(B) the Secretary determines that it would be beneficial to the public health.
(A) the recommendations described in such Institute of Medicine report; and
(B) the requirement under paragraph (7) of section 505(o) of the Federal Food, Drug, and Cosmetic Act (as added by this title), that the appropriate office responsible for reviewing a drug and the office responsible for postapproval safety with respect to the drug act together to assess, implement, and ensure compliance with the requirements of such section 505(o).

SEC. 214. EFFECTIVE DATE AND APPLICABILITY.

(a) EFFECTIVE DATES.—

(1) IN GENERAL.—A drug that was approved before the effective date of this subtitle shall be deemed to have been approved in accordance with the Federal Food, Drug, and Cosmetic Act (as added by this subtitle) that the Secretary has completed review of, and that the application contains such additional elements under paragraphs (4), (5), and (6) in effect for such drug on the effective date of this subtitle.

(2) EFFECTIVE DATE.—Not later than 30 days after the date of enactment of this title, the Secretary shall notify the applicant for each drug described in paragraph (1) that the Secretary has completed review of, and that the application contains such additional elements under paragraphs (4), (5), and (6) in effect for such drug on the effective date of this subtitle.

(b) EFFECTIVE DATE OF STRATEGIES.—Not later than 30 days after the effective date of this subtitle, the Secretary shall notify the applicant for each drug described in paragraph (1) that the Secretary has completed review of, and that the application contains such additional elements under paragraphs (4), (5), and (6) in effect for such drug on the effective date of this subtitle.

(2) EFFECTIVE DATE OF STRATEGIES.—Not later than 30 days after the effective date of this subtitle, the Secretary shall notify the applicant for each drug described in paragraph (1) that the Secretary has completed review of, and that the application contains such additional elements under paragraphs (4), (5), and (6) in effect for such drug on the effective date of this subtitle.

(3) IN GENERAL.—A drug that was approved before the effective date of this subtitle shall be deemed to have been approved in accordance with the Federal Food, Drug, and Cosmetic Act (as added by this subtitle) that the Secretary has completed review of, and that the application contains such additional elements under paragraphs (4), (5), and (6) in effect for such drug on the effective date of this subtitle.

(c) EFFECTIVE DATE OF STRATEGIES.—Not later than 30 days after the effective date of this subtitle, the Secretary shall notify the applicant for each drug described in paragraph (1) that the Secretary has completed review of, and that the application contains such additional elements under paragraphs (4), (5), and (6) in effect for such drug on the effective date of this subtitle.

(d) EFFECTIVE DATE OF STRATEGIES.—Not later than 30 days after the effective date of this subtitle, the Secretary shall notify the applicant for each drug described in paragraph (1) that the Secretary has completed review of, and that the application contains such additional elements under paragraphs (4), (5), and (6) in effect for such drug on the effective date of this subtitle.

Subtitle B—Reagan-Udall Foundation for the Food and Drug Administration

SEC. 221. THE REAGAN-UDALL FOUNDATION FOR THE FOOD AND DRUG ADMINISTRATION.

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

"Subchapter I—Reagan-Udall Foundation for the Food and Drug Administration"

"(a) [Existing provision]"

"(b) PURPOSE OF FOUNDATION.—The purpose of the Foundation is to advance the mission of the Food and Drug Administration to modernize medical, veterinary, food, food ingredient, and cosmetic product development, accelerate innovation, and enhance product safety.

"(c) BOARD OF DIRECTORS.—The Foundation shall—

(1) taking into consideration the Critical Path reports and priorities published by the Food and Drug Administration, identify unmet needs in the development, manufacture, and evaluation of the safety and effectiveness, including postapproval, of drugs, including diagnostics, biologics, and, and the safety of food, food ingredients, and cosmetics;

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

(3) in consultation with the Secretary, identify existing and proposed Federal intramural and extramural research and development programs relating to the goals and priorities established under paragraph (2), coordinate Foundation activities with such programs, and minimize Foundation duplication of existing efforts;

(4) award grants to, or enter into contracts, memoranda of understanding, or cooperative agreements with, scientists and entities, which may include the Food and Drug Administration, university consortia, public-private partnerships, institutions of higher education, entities described in section 501(c)(3) of the Internal Revenue Code (and exempt from tax under section 501(a) of such Code), and industry, to efficiently and effectively advance the goals and priorities established under paragraph (2);

(5) recruit meeting participants and hold or sponsor (in whole or in part) meetings as appropriate to further the goals and priorities established under paragraph (2);

(6) release data on information and data and, to the extent practicable, license, distribute, and release material, reagents, and techniques to maximize, promote, and coordinate the development, validation, and use of scientific data, protocols, and techniques for use by the Food and Drug Administration, nonprofit organizations, and academic and industrial researchers to further the goals and priorities established under paragraph (2);

(7) ensure that—

(A) action is taken as necessary to obtain patents for inventions developed by the Foundation or with funds from the Foundation;

(B) action is taken as necessary to enable the licensing of inventions developed by the Foundation or with funds from the Foundation;

(C) executed licenses, memoranda of understanding, material transfer agreements, contracts, and other such instruments, promote, to the maximum extent practicable, the broadest conversion to commercial and noncommercial applications of licensed and patented inventions of the Foundation to further the goals and priorities established under paragraph (2);

(8) provide objective clinical and scientific information to the Food and Drug Administration and, upon request, to other Federal agencies to assist in agency determinations of how to meet regulatory policy accommodates scientific advances and meets the agency’s public health mission;

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

(10) carry out such other activities consistent with the purposes of the Foundation as the Board determines appropriate.

(2) BOARD OF DIRECTORS.—

(A) Establishment.—

(1) IN GENERAL.—The Foundation shall have a Board of Directors (referred to in this subsection as the ‘Board’) to provide strategic and, in coordination with those of the Foundation for the National Institutes of Health, to the extent determined practicable and appropriate by the Board, to carry out its purpose.

(B) EX OFFICIO MEMBERS.—The ex officio members of the Board shall be representatives of patient or consumer advocacy organizations; and

(C) APPOINTED MEMBERS.—

(i) IN GENERAL.—The ex officio members of the Board under subparagraph (B) shall, by majority vote, appoint to the Board 12 individuals, from a list of candidates provided by the National Academy of Sciences. Of such appointed members—

(1) 4 shall be representatives of the general public, including medical, device, food, cosmetic, and biotechnology industries;

(2) 3 shall be representatives of academic research organizations;

(3) 2 shall be representatives of consumer advocacy organizations; and

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

(ii) REQUIREMENT.—The ex officio members shall ensure the Board membership includes individuals with expertise in areas including the science of developing and evaluating the safety and effectiveness of devices, including diagnostics, biologics, and drugs, and the safety of food, food ingredients, and cosmetics.

(iii) INITIAL MEETING.—

(I) IN GENERAL.—Not later than 30 days after the date of the enactment of the Enhancing Drug Safety and Innovation Act of 2007, the Secretary shall convene a meeting of the ex officio members of the Board to—

(A) incorporate the Foundation; and

(B) appoint the members of the Board in accordance with subparagraph (C).

(II) REQUIREMENT.—Not later than 30 days after the date of the enactment of the Enhancing Drug Safety and Innovation Act of 2007, the Secretary shall convene a meeting of the ex officio members of the Board to—

(A) incorporate the Foundation; and

(B) appoint the members of the Board in accordance with subparagraph (C).

(iv) SERVICE OF EX OFFICIO MEMBERS.—Upon the appointment of the members of the Board under clause (i)(II), the terms of service of the ex officio members of the Board as members of the Board shall terminate.

(C) APPOINTED MEMBERS.—The ex officio members of the Board under subparagraph (B) shall designate an appointed member of the Board to serve as Chair of the Board.

(2) DUTIES OF BOARD.—The Board shall—

(A) establish bylaws for the Foundation that—

(i) are published in the Federal Register and available for public comment;

(ii) establish policies for the selection of the officers, employees, agents, and contractors of the Foundation;

(iii) establish policies, including ethical standards, for the acceptance, solicitation, and disposition of donations and grants to the Foundation and for the disposition of the assets of the Foundation, including strict limits on the ability of donors to include stipulations or restrictions on the use of donated funds;

(iv) establish policies that would subject all employees, fellows, and trainees of the Foundation to the conflict of interest standards under section 208 of title 18, United States Code; and

(v) establish policies that would subject all employees, fellows, and trainees of the Foundation to the conflict of interest standards under section 208 of title 18, United States Code.

(iv) SERVICE OF EX OFFICIO MEMBERS.—Upon the appointment of the members of the Board under clause (i)(II), the terms of service of the ex officio members of the Board as members of the Board shall terminate.

(C) APPOINTED MEMBERS.—The ex officio members of the Board under subparagraph (B) shall designate an appointed member of the Board to serve as Chair of the Board.

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(iv) establish policies that would subject all employees, fellows, and trainees of the Foundation to the conflict of interest standards under section 208 of title 18, United States Code; and

(v) establish policies that would subject all employees, fellows, and trainees of the Foundation to the conflict of interest standards under section 208 of title 18, United States Code.
“(viii) establish policies for the execution of memoranda of understanding and cooperative agreements between the Foundation and other entities, including the Food and Drug Administration.

“(ix) establish policies for funding training fellowships, whether at the Foundation, academic or scientific institutions, or the Food and Drug Administration, for scientists, doctors, and other professionals who are not employees of regulated industry, to foster greater understanding of and expertise in new scientific tools, diagnostic, manufacturing techniques, and potential barriers to translating basic research into clinical and regulatory practice;

“(x) specify a process for annual Board review of the Foundation; and

“(xi) establish specific duties of the Executive Director;

“(xii) prioritize and provide overall direction to the activities of the Foundation:

“(C) shall be 4 years, except that the terms of offices for the initial appointed members of the Board shall expire on a staggered basis as determined by the Office of the Executive Director.

“(B) VACANCY.—Any vacancy in the membership of the Board—

“(ii) shall not affect the power of the remaining members to execute the duties of the Board; and

“(iii) shall be filled by appointment by the appointed members described in paragraph (1)(C) by majority vote.

“(C) PARTIAL TERM.—If a member of the Board does not serve the full term applicable under paragraph (1)(C), the individual appointed under subparagraph (B) to fill the resulting vacancy shall be appointed for the remainder of the term of the predecessor of the individual.

“(D) SERVING PAST TERM.—A member of the Board may continue to serve after the expiration of the term of the member until a successor is appointed.

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

“(F) INCORPORATION.—The ex officio members of the Board shall serve as incorporators and shall take whatever actions necessary to incorporate the Foundation.

“(i) NONPROFIT STATUS.—The Foundation shall be considered to be a corporation under section 501(c) of the Internal Revenue Code of 1986, and shall be subject to the provisions of such section.

“(g) EXECUTIVE DIRECTOR.—

“(1) IN GENERAL.—The Board shall appoint and execute a Director of the Foundation who shall serve as the Director of the Board. The Executive Director shall be responsible for the day-to-day operations of the Foundation and shall have such specific duties and responsibilities as the Board shall prescribe.

“(2) COMPENSATION.—The compensation of the Executive Director shall be fixed by the Board but shall not be greater than the compensation of the Commissioner.

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

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

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

“(3) prescribe the manner in which—

“(A) real or personal property of the Foundation is acquired, held, and transferred;

“(B) general operations of the Foundation are to be conducted; and

“(C) the provisions of this subchapter are to be interpreted and administered.

“(i) DETAIL OF GOVERNMENT EMPLOYEES; FELLOWSHIPS.—

“(1) DETAIL FROM FEDERAL AGENCIES.—Federal Government employees may serve on committees advisory to the Foundation and otherwise cooperate with and assist the Foundation in carrying out its functions, so long as such employees do not direct or control Foundation activities.

“(2) DETAIL FROM FEDERAL AGENCIES.—Federal Government employees may be detailed from Federal agencies with or without reimbursement to those agencies at any time, and such detail shall be without interruption or loss of civil service status or privilege. Each such employee shall abide by the statutory, regulatory, ethical, and procedural standards applicable to the employees of the agency from which such employees are detailed and those of the Foundation.

“(j) VOLUNTARY SERVICE; ACCEPTANCE OF FEDERAL EMPLOYEES.—

“(1) Foundation.—The Executive Director of the Foundation may accept the services of employees detailed from Federal agencies with or without reimbursement to those agencies.

“(2) FOOD AND DRUG ADMINISTRATION.—The Commissioner may accept the uncompensated services of Foundation fellows or trainees.

“(k) DETAIL FROM FEDERAL AGENCIES; MEMORANDA OF UNDERSTANDING; COOPERATIVE AGREEMENTS; OTHER AGREEMENTS.—

“(1) DETAIL FROM FEDERAL AGENCIES; MEMORANDA OF UNDERSTANDING; COOPERATIVE AGREEMENTS; OTHER AGREEMENTS.—The Commissioner may accept the uncompensated services of Foundation fellows or trainees. Such services shall be considered to be undertaking an activity under contract with the Secretary as described in section 708.

“(l) ANNUAL REPORTS.—

“(1) REPORT TO FOUNDATION.—Any recipient of a grant, contract, fellowship, memorandum of understanding, or cooperative agreement from the Foundation under this section shall submit to the Foundation, at the end of each year, a report on the status, including the practical barriers to translating basic research into clinical and regulatory practice; and define their duties;

“(3) prescribe the manner in which—

“(A) real or personal property of the Foundation is acquired, held, and transferred;

“(B) general operations of the Foundation are to be conducted; and

“(C) the provisions of this subchapter are to be interpreted and administered.

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“(2) DETAIL FROM FEDERAL AGENCIES.—Federal Government employees may be detailed from Federal agencies with or without reimbursement to those agencies at any time, and such detail shall be without interruption or loss of civil service status or privilege. Each such employee shall abide by the statutory, regulatory, ethical, and procedural standards applicable to the employees of the agency from which such employees are detailed and those of the Foundation.

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“(l) ANNUAL REPORTS.—

“(1) REPORT TO FOUNDATION.—Any recipient of a grant, contract, fellowship, memorandum of understanding, or cooperative agreement from the Foundation under this section shall submit to the Foundation, at the end of each year, a report on the status, including the practical barriers to translating basic research into clinical and regulatory practice; and define their duties;

“(3) prescribe the manner in which—

“(A) real or personal property of the Foundation is acquired, held, and transferred;

“(B) general operations of the Foundation are to be conducted; and

“(C) the provisions of this subchapter are to be interpreted and administered.

“(i) DETAIL OF GOVERNMENT EMPLOYEES; FELLOWSHIPS.—

“(1) DETAIL FROM FEDERAL AGENCIES.—Federal Government employees may serve on committees advisory to the Foundation and otherwise cooperate with and assist the Foundation in carrying out its functions, so long as such employees do not direct or control Foundation activities.

“(2) DETAIL FROM FEDERAL AGENCIES.—Federal Government employees may be detailed from Federal agencies with or without reimbursement to those agencies at any time, and such detail shall be without interruption or loss of civil service status or privilege. Each such employee shall abide by the statutory, regulatory, ethical, and procedural standards applicable to the employees of the agency from which such employees are detailed and those of the Foundation.

“(j) VOLUNTARY SERVICE; ACCEPTANCE OF FEDERAL EMPLOYEES.—

“(1) Foundation.—The Executive Director of the Foundation may accept the services of employees detailed from Federal agencies with or without reimbursement to those agencies.

“(2) FOOD AND DRUG ADMINISTRATION.—The Commissioner may accept the uncompensated services of Foundation fellows or trainees.

“(k) DETAIL FROM FEDERAL AGENCIES; MEMORANDA OF UNDERSTANDING; COOPERATIVE AGREEMENTS; OTHER AGREEMENTS.—

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“(l) ANNUAL REPORTS.—

“(1) REPORT TO FOUNDATION.—Any recipient of a grant, contract, fellowship, memorandum of understanding, or cooperative agreement from the Foundation under this section shall submit to the Foundation, at the end of each year, a report on the status, including the practical barriers to translating basic research into clinical and regulatory practice; and define their duties;

“(3) prescribe the manner in which—

“(A) real or personal property of the Foundation is acquired, held, and transferred;

“(B) general operations of the Foundation are to be conducted; and

“(C) the provisions of this subchapter are to be interpreted and administered.

“(i) DETAIL OF GOVERNMENT EMPLOYEES; FELLOWSHIPS.—

“(1) DETAIL FROM FEDERAL AGENCIES.—Federal Government employees may serve on committees advisory to the Foundation and otherwise cooperate with and assist the Foundation in carrying out its functions, so long as such employees do not direct or control Foundation activities.

“(2) DETAIL FROM FEDERAL AGENCIES.—Federal Government employees may be detailed from Federal agencies with or without reimbursement to those agencies at any time, and such detail shall be without interruption or loss of civil service status or privilege. Each such employee shall abide by the statutory, regulatory, ethical, and procedural standards applicable to the employees of the agency from which such employees are detailed and those of the Foundation.

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“(1) DETAIL FROM FEDERAL AGENCIES; MEMORANDA OF UNDERSTANDING; COOPERATIVE AGREEMENTS; OTHER AGREEMENTS.—The Commissioner may accept the uncompensated services of Foundation fellows or trainees. Such services shall be considered to be undertaking an activity under contract with the Secretary as described in section 708.

“(l) ANNUAL REPORTS.—

“(1) REPORT TO FOUNDATION.—Any recipient of a grant, contract, fellowship, memorandum of understanding, or cooperative agreement from the Foundation under this section shall submit to the Foundation, at the end of each year, a report on the status, including the practical barriers to translating basic research into clinical and regulatory practice; and define their duties;

“(3) prescribe the manner in which—

“(A) real or personal property of the Foundation is acquired, held, and transferred;

“(B) general operations of the Foundation are to be conducted; and

“(C) the provisions of this subchapter are to be interpreted and administered.
SEC. 231. EXPANDED CLINICAL TRIAL REGISTRY DATA BANK. 

(a) In general.—Section 302 of the Public Health Service Act (42 U.S.C. 262) is amended by—

(1) redesignating subsections (i) and (k) as subsections (k) and (l), respectively; and

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

(1) EXPANDED CLINICAL TRIAL REGISTRY DATA BANK. 

(A) Definitions; requirement.—

(i) DEFINITIONS.—In this subsection:

(I) APPLICABLE DEVICE CLINICAL TRIAL.—The term ‘applicable device clinical trial’ means—

(II) a pediatric postmarket surveillance as defined in section 201(g) of the Federal Food, Drug, and Cosmetic Act or a biological product defined in section 351 of this Act, which may be the National Institutes of Health Clinical Center, or approved, a clinical trial prescribed under the jurisdiction of the Secretary, acting through the Director of NIH, to evaluate the safety and effectiveness of medical devices when such clinical trial, including pediatric subpopulations.

(ii) COMPLETION.—The responsible party for a clinical trial that is not an applicable drug clinical trial or applicable device clinical trial shall update the enrollment status to ‘complete’ not later than 30 days after the completion date of the clinical trial.

(iii) SEARCHABLE CATEGORIES.—The Director of NIH shall ensure that the registry data bank includes links to results information for such clinical trial.

(B) FORMAT AND STRUCTURE.—

(i) IN GENERAL.—Beginning not later than 90 days after the date of enactment of the Food and Drug Administration Safety and Innovation Act of 2007, and after notice and comment, the Secretary shall promulgate regulations to expand the registry data bank to include information for an applicable device clinical trial and applicable device clinical trial.

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

(c) Data submission.—The responsible party for an applicable drug clinical trial or an applicable device clinical trial shall update the enrollment status not later than 30 days after the enrollment status of such clinical trial.

(d) Posting of data.—The Director of NIH shall ensure that clinical trial information for an applicable drug clinical trial submitted in accordance with this paragraph is posted publicly within 30 days of such submission.

(e) Access.—The Director of NIH shall ensure that clinical trial information becomes publicly available, as applicable.

(f) Voluntary submissions.—A responsible party for a clinical trial that is not an applicable drug clinical trial or applicable device clinical trial may submit clinical trial information to the registry data bank in accordance with this subsection.

(g) Expansion of registry data bank to include results of clinical trials.—

(1) Linking registry data bank to existing results.—

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

(i) Requirement.—The Secretary shall ensure that the registry data bank includes links to the following information:

(ii) Final report.—The Secretary shall ensure that the registry data bank includes links to the following information:
“(aa) If an advisory committee considered at a meeting an applicable drug clinical trial or an applicable device clinical trial, any posted Food and Drug Administration summary document regarding the safety and effectiveness of the applicable drug clinical trial or applicable device clinical trial.

“(bb) If an applicable drug clinical trial was conducted under section 505A or 505B of the Federal Food, Drug, and Cosmetic Act, and any applicable device clinical trial, and in the case of a premarket application, the detailed summary of information respecting the safety and effectiveness of the device required under section 520(h)(1) of the Federal Food, Drug, and Cosmetic Act, or, in the case of a report under section 510(k) of such Act, the section 510(k) summary of the safety and effectiveness data required under section 807.85(d) of title 21, Code of Federal Regulations (or any successor regulations).

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

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

“(ee) For an applicable device clinical trial, in the case of a premarket application, the detailed summary of information respecting the safety and effectiveness of the device required under section 520(h)(1) of the Federal Food, Drug, and Cosmetic Act, or, in the case of a report under section 510(k) of such Act, the section 510(k) summary of the safety and effectiveness data required under section 807.85(d) of title 21, Code of Federal Regulations (or any successor regulations).

“(1) NIH INFORMATION.—The Secretary shall ensure that the registry data bank includes links to the following information:

“(aa) Medline citations to any publications regarding the clinical trial, drug, or device.

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

“(cc) RESULTS FOR EXISTING DATA BANK ENTRIES.—The Secretary may include the links described in subparagraph (bb), and any applicable clinical trial or applicable device clinical trial.

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

“(ee) For an applicable device clinical trial, in the case of a premarket application, the detailed summary of information respecting the safety and effectiveness of the device required under section 520(h)(1) of the Federal Food, Drug, and Cosmetic Act, or, in the case of a report under section 510(k) of such Act, the section 510(k) summary of the safety and effectiveness data required under section 807.85(d) of title 21, Code of Federal Regulations (or any successor regulations).

“(2) FEASIBILITY STUDY.—The Director of NIH shall—

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

“(ii) applicable 6 months after initiating such study, submit to the Secretary any findings and recommendations of such study.

“(C) NEGOTIATED RULEMAKING.—

“(1) NEGOTIATED RULEMAKING.—The Secretary shall establish a negotiated rulemaking process pursuant to subchapter IV of chapter 5 of title 5, United States Code, to determine, for applicable drug clinical trials—

“(I) how to ensure quality and validate methods of expanding the registry data bank to include clinical trial results information for trials not yet approved; and

“(II) the clinical trials of which the results information is appropriate for adding to the expanded registry data bank; and

“(III) the appropriate timing of the posting of such results information.

“(II) TIME REQUIREMENT.—The process described in paragraph (1) shall be conducted in a timely manner to ensure that—

“(I) any recommendation for a proposed rule—

“(aa) is provided to the Secretary not later than 21 months after the date of the enactment of the Enhancing Drug Safety and Innovation Act of 2007; and

“(bb) encompasses an assessment of the benefits and costs of the recommendation; and

“(II) a final rule is promulgated not later than 30 months after the date of the enactment of the Enhancing Drug Safety and Innovation Act of 2007, taking into account the recommendations under subclause (I) and the results of the feasibility study conducted under subparagraph (B).

“(III) REPRESENTATION ON NEGOTIATED RULEMAKING COMMITTEE.—The negotiated rulemaking committee established by the Secretary pursuant to clause (I) shall include members representing—

“(I) the Food and Drug Administration; (II) the National Institutes of Health; (III) other Federal agencies as the Secretary determines appropriate; (IV) patient advocacy and health care provider groups; (V) the pharmaceutical industry; (VI) contract research organizations; (VII) the International Committee of Medical Journal Editors; and

“(VIII) other interested parties, including experts in privacy protection, pediatrics, health information technology, health literacy, communication, clinical trial design and implementation, and health care ethics.

“(IV) CONTEXT OF REGULATIONS.—The regulations promulgated pursuant to clause (I) shall establish—

“(I) procedures to determine which clinical trials results information data elements shall be included in the registry data bank, including in such results information the needs of different populations of users of the registry data bank;

“(II) a standard procedure for the submission of clinical trials results to the registry data bank;

“(III) a standard procedure for the submission of clinical trials results information, to the registry data bank, taking into account the possible impacts on publication of manuscripts based on the clinical trial;

“(IV) a standard procedure for the verification of clinical trials results information, including ensuring that free text data elements are non-promotional, if the Secretary determines that extraordinary circumstances justify the waiver and that providing the waiver is in the public interest, consistent with the protection of public health, or in the interest of national security. Not later than 30 days after any part of a waiver is granted, the Secretary shall notify, in writing, the appropriate committees of Congress of the reasons for providing an explanation for why the waiver was granted.

“(V) COORDINATION AND COMPLIANCE.—

“(A) CLINICAL TRIALS SUPPORTED BY GRANTS TO NIGMS.—The Secretary may waive any applicable requirements of this paragraph for an applicable drug clinical trial or an applicable device clinical trial, upon a written request from the responsible institution and a determination that extraordinary circumstances justify the waiver and that the waiver is in the public interest, consistent with the protection of public health, or in the interest of national security. Not later than 30 days after any part of a waiver is granted, the Secretary shall notify, in writing, the appropriate committees of Congress of the reasons for providing an explanation for why the waiver was granted.

“(B) CERTIFICATION TO ACCOMPANY DRUG, BIOLOGICAL PRODUCT, AND DEVICE SUBMISSIONS.—At the time of submission of an application under section 505 of the Federal Food, Drug, and Cosmetic Act, section 515 of such Act, section 520(m) of such Act, or section 531 of such Act, or submission of a report under section 510(k) of such Act, such application or submission shall be accompanied by a certification that verifiable requirements set forth in this subsection have been met. Where available, such certification shall include the appropriate National Clinical Trial control numbers.

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

“(D) LIMITATION ON DISCLOSURE OF CLINICAL TRIAL INFORMATION.—

“(I) IN GENERAL.—Nothing in this subsection (or under section 552 of title 5, United States Code) shall require the Secretary to publicly disclose, from any record or source other than the registry data bank, any information that is not public information as defined by section 552 of title 5, United States Code.

“(ii) if any applicable device clinical trial for which such person is the responsible party.
out this subsection $10,000,000 for each fiscal year.’’.

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

‘‘(2) The submission of clinical trial information under subsection (i) or (j) of section 402 of the Public Health Service Act that is pro-

motional or false or misleading in any par-

ticular or paragraph (2) or (3) of such sub-

section.’’.

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

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

(B) inserting after paragraph (3) the follow-

ing:

‘‘(d) Any person who violates section 301(i)(j) shall be subject to a civil monetary penalty of not more than $10,000 for the first violation, and not more than $20,000 for each subsequent viola-

tion.’’

(3) NEW DRUGS AND DEVICES.—(A) Paragraphs (1), (2), (4), (5), (6), and (7) of section 301(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333(i)) are amended in paragraph (4), by adding at the end the following: ‘‘The Secretary shall revise such regulations to re-

quire inclusion in the informed consent form a statement that clinical trial information for such clinical investigation has been or will be submitted for inclusion in the registry data bank pursuant to subsections (i) and (j) of section 402 of the Public Health Service Act.’’.

(B) Section 305(b) of the Federal, Food, Drug, and Cosmetic Act (21 U.S.C. 335(b)) is amended by adding at the end the following:

‘‘(6) A notice submitted under this subsection shall be accompanied by the certification required under section 402(k)(4)(B) of the Public Health Service Act. Such certification shall not be considered an element of such certification required under section 402(k)(4)(B) of the Public Health Service Act (which shall not be considered an element of such certification required under section 402(k)(4)(B) of the Public Health Service Act) shall be accompanied by the certification required under such section.''

(2) Device Premarket Approval Application.—Section 315(c) of the Federal, Food, Drug, and Cosmetic Act (21 U.S.C. 335(c)) is amended—

(i) in subparagraph (F), by striking ‘‘and’’ and inserting semicolon;

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

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

‘‘(G) the certification required under section 402(k)(4)(B) of the Public Health Service Act (which shall not be considered an element of such certification required under section 402(k)(4)(B) of the Public Health Service Act).’’

(3) HUMANITARIAN DEVICE EXEMPTION.—Section 520(m)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(e)(2)) is amended in the first sentence in the matter following subparagraph (C), by inserting at the end before the period ‘‘and such application shall include a statement that the submission of clinical trial information is necessary to determine the most effective informational and recruitment activities. The Secretary shall also take into ac-

count the advice of advisory committees with the greatest number of vacancies.’’

(3) CONFLICTS OF INTEREST.—The conflicts of interest provisions of title XVII of the Public Health Service Act (42 U.S.C. 200d et seq.) are amended—

(A) redesignating paragraphs (1), (2), and (3) of section 200d as paragraphs (2), (3), and (4), respectively;

(B) inserting after paragraph (3) the fol-

lowing:

‘‘(4) LIMITATION.—The Secretary may not grant a waiver under paragraph (3) for a member of an advisory committee if the member’s own scientific work is involved.’’

(4) DISCLOSURE OF WAIVER.—Notwithstanding section 377(a)(2) of the Ethics in Government Act (5 U.S.C. App.), the following shall apply:

(A) 15 OR MORE DAYS IN ADVANCE.—As soon as practicable, but in no case later than 15 days prior to a meeting of an advisory committee at which a written determination as referred to in section 208(b)(1) of the United States Code, a written certification as referred to in section 208(b)(3) of the United States Code, or a waiver as referred to in paragraph (3) applies, the Secretary shall disclose (other than information exempted from disclosure under section 552 CONGRESSIONAL RECORD — SENATE April 30, 2007
of title 5, United States Code, and section 552a of title 5, United States Code (popularly known as the Freedom of Information Act and the Privacy Act of 1974, respectively)) on the Internet website of the Food and Drug Administration.

(ii) the type, nature, and magnitude of the financial interests of the advisory committee member to which such determination, certification, or waiver applies; and

(iii) the reasons of the Secretary for such determination, certification, or waiver.

(bb) PUBLIC RECORD.—In the case of a financial interest that becomes known to the Secretary less than 30 days prior to a meeting of an advisory committee to which a written certification referred to in section 200(b)(2) of title 18, United States Code, a written certification as referred to in section 200(b)(3) of title 18, United States Code, or a waiver as referred to in paragraph (3) applies, the Secretary shall disclose (other than information exempted from disclosure under section 552 of title 5, United States Code, and section 52a of title 5, United States Code) on the Internet website of the Food and Drug Administration, the information described in clauses (i) and (ii) of subparagraph (A) as soon as practicable after the Secretary makes such determination, certification, or waiver, but in no case later than the date of such meeting.

(bb) PUBLIC RECORD.—The Secretary shall ensure that the public record and transcript of each meeting of an advisory committee includes the disclosure required under subsection (c)(5) (other than information exempted from disclosure under title 5, United States Code, and section 52a of title 5, United States Code).

(c) ANNUAL REPORT.—Not later than February 1 of each year, the Secretary shall submit to the Inspector General of the Department of Health and Human Services, the Committee on Appropriations and the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Appropriations and the Committee on Energy and Commerce of the House of Representatives, a report that describes

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

(2) with respect to such year, the aggregate number of disclosures required under subsection (c)(5) for each meeting of an advisory committee and the percentage of individuals to whom such disclosures did not apply as compared to the number of members of such committee for each such meeting;

(3) with respect to such year, the number of times the disclosures required under subsection (c)(5) occurred under subparagraph (B) of such section; and

(4) how the Secretary plans to reduce the number of vacancies reported under paragraph (1) during the fiscal year following such year, and mechanisms to encourage the nomination of individuals for service on an advisory committee, including those who are classified by the Food and Drug Administration as academicians or practitioners.

(f) PERIODIC REVIEW OF GUIDANCE.—Not less than once every 5 years, the Secretary shall review and update such guidance as necessary.

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

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


SEC. 251. DATABASE FOR AUTHORIZED GENERIC DRUGS.

Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), as amended by this title, is further amended by adding at the end the following:

'(q) DATABASE FOR AUTHORIZED GENERIC DRUGS—

'(1) IN GENERAL.—

'(A) PUBLICATION.—The Commissioner shall—

(i) not later than 9 months after the date of enactment of the Food and Drug and Innovation Act of 2007, publish a complete list on the Internet website of the Food and Drug Administration of all authorized generic drugs (including the name of the company manufacturer, and the date the authorized generic drug entered the market); and

(ii) update the list quarterly to include each authorized generic drug included in an annual report submitted to the Secretary by the sponsor of a listed drug during the preceding 3-month period.

'(B) NOTIFICATION.—The Commissioner shall notify relevant Federal agencies, including the Centers for Medicare & Medicaid Services and the Federal Trade Commission, any time the Commissioner receives the information described in subparagraph (A).

'(2) INCLUSION.—The Commissioner shall include in the list submitted under subparagraph (A) each authorized generic drug included in an annual report submitted to the Secretary by the sponsor of a listed drug after January 1, 1999.

'(3) AUTOMATIC EXCLUSION.—In this section, the term ‘authorized generic drug’ means a listed drug (as that term is used in subsection (j)) that—

'(A) has been approved under subsection (c); and

'(B) is marketed, sold, or distributed directly or indirectly to retail class of trade under a different labeling, packaging (other than repackaging), or trade mark than the listed drug.

SEC. 252. MEDICAL MARIJUANA.

The Secretary shall require that State-legalized medical marijuana be subject to the full regulatory requirements of the Food and Drug Administration, including a risk evaluation and mitigation strategy and all other requirements and penalties of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) regarding safe and effective reviews, approval, sale, marketing, and use of pharmaceuticals.

TITLE III—MEDICAL DEVICES

SEC. 301. SHORT TITLE; REFERENCES.

(a) SHORT TITLE.—This title may be cited as the ‘Medical Device User Fee Amendments of 2007’.

(b) REFERENCES.—Except as otherwise specified, whenever in this title an amendment is expressed in terms of an amendment to a section or other provision, the reference shall be considered to be made to a section or other provision of the Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355 et seq.) of the Centers for Medicare & Medicaid Services and the Federal Trade Commission, any time the Commissioner receives the information described in subparagraph (A).

Subtitle A—Device User Fees

SEC. 302. DEVICE FEES.

Section 727 (21 U.S.C. 379h) is amended—

(1) by striking the section designation and all that follows through ‘‘For purposes of this subchapter’’ and inserting the following:

‘‘SEC. 727. DEVICE FEES.

'(a) PURPOSE.—It is the purpose of this part that the fees authorized under this part be dedicated to improving the process for the review of device applications and for assuring the safety and effectiveness of devices, as set forth in the goals identified for purposes of this part in the letter from the Chair- man of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Com- mercial Activities of the Senate, as set forth in the Congres- sional Record.

(1) CONGRESSIONAL RECORD.—For fiscal years 2008 through 2012, not later than 120 days after the end of each fiscal year during which fees are collected under this part, the Secretary shall present in Congress a report to the Committees on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report con- cerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in subsection (a) during such fiscal year and the future plans of the Food and Drug Administration in meeting the goals. The report for a fiscal year shall include information on all previous cohorts for which the Secretary has not given a complete response on all device market application, supplements, and premarket notifications in the co-

(2) FISCAL REPORT.—For fiscal years 2008 through 2012, not later than 120 days after the end of each fiscal year during which fees are collected under this part, the Secretary shall provide in Congress a report to the Committees on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report on the number of device applications filed during such fiscal year and the future plans of the Food and Drug Administration, of the fees collected during such fiscal year for which the report is made.

(3) PUBLIC AVAILABILITY.—The Secretary shall make the reports required under paragraph (1) and (2) available to the public on the Internet website of the Food and Drug Administration.

(4) REAUTHORIZATION.—

(1) CONSULTATION.—In developing recommenda-

(tion to present recommendations to Congress with respect to the goals, and plans for meeting the goals, for the process for the review of device applications for the first 5 fiscal years after fiscal year 2012, and for the reauthorization of this part for such fiscal years, the Secretary shall consult with—

(A) the Committee on Energy and Commerce of the House of Representatives;

(B) the Committee on Health, Education, Labor, and Pensions of the Senate;

(C) scientific and academic experts;

(D) health care professionals;

(E) representatives of patient and consumer advocacy groups; and

(F) the regulated industry.

(2) PUBLIC REVIEW OF RECOMMENDATIONS.—After negotiations with the regulated industry, the Secretary shall—

(A) present the recommendations developed under paragraph (1) to the Congressional committees specified in such paragraph;

(B) publish such recommendations in the Federal Register;

(C) provide for a period of 30 days for the public to provide written comments on such recommendations;

(D) hold a meeting at which the public may present its views on such recommendations; and

(E) after consideration of such public views and comments, revise such recommendations as necessary.

(3) TRANSMITTAL OF RECOMMENDATIONS.—Not later than January 15, 2012, the Secretary shall submit to Congress the revised recommendations under paragraph (2), a summary of the views and comments received under such paragraph, and any changes made to the re-

(d) DEFINITIONS.—For purposes of this part—

(1) by redesignating paragraphs (5), (6), (7), and (8) as paragraphs (7), (8), (9), and (11), respec-

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(3) in subsection (c)—
(A) in the heading, by striking “Annual Fee Setting”; and
(B) in paragraph (1), by striking the second sentence;
(C) by redesigning paragraphs (2) and (3) as paragraphs (3) and (4), respectively;
(D) by inserting after paragraph (1) the following:

“(2) ADJUSTMENT OF ANNUAL ESTABLISHMENT REGISTRATION FEE.—
(A) IN GENERAL.—When setting the fees for fiscal years 2009 and 2010, the Secretary may increase the establishment registration fee specified in subsection (b) only if the Secretary estimates that the number of establishments submitting fees for fiscal year 2009 is less than 12,530, but in no case shall the percent increase be more than 8.5 percent over the amount for such fee specified in subsection (b) for fiscal year 2010. If the Secretary makes any adjustment to the establishment registration fee for fiscal year 2010, then the establishment registration fee for fiscal years 2011 and 2012 under subsection (b) shall be adjusted as follows: the fee for fiscal year 2011 shall be equal to the adjusted fee for fiscal year 2010, increased by 8.5 percent, and the fee for fiscal year 2012 shall be equal to the adjusted fee for fiscal year 2011, increased by 8.5 percent.
(B) PUBLICATION IN THE FEDERAL REGISTER.—The Secretary shall publish any determination with respect to any establishment registration fee adjustment made under subparagraph (A), and the rationale for such determination, in the Federal Register.”; and
(E) in paragraph (2)(A), as so redesignated—
(i) by striking “For fiscal years 2006 and 2007,” and inserting “The”;
(ii) by striking “of fiscal year 2008” and inserting “of the next fiscal year”;
(IV) by redesignating clauses (ii) and (iii) as clauses (i) and (ii), respectively;
(V) by inserting after clause (c) the following:

“(v) SOLE DISCRETION TO REFUND.—The Secretary shall have sole discretion to refund a fee or portion of the fee under this subparagraph. A determination by the Secretary concerning a refund under this paragraph shall not be reviewable.”; and

(B) by striking at the end the following:

“(3) ANNUAL ESTABLISHMENT REGISTRATION FEE.—
(A) IN GENERAL.—Except as provided in subparagraph (B), each establishment subject to a registration fee shall be subject to a fee for each initial or annual registration beginning with its registration for fiscal year 2008.
(B) EXCEPTION FOR FEDERAL OR STATE GOVERNMENT ESTABLISHMENT.—No fee shall be required under subparagraph (A) for an establishment operated by a Federal or State Government entity unless a device manufactured by the establishment is to be distributed commercially.
(C) PAYMENT.—The annual establishment registration fee shall be due once each fiscal year, upon the initial registration of the establishment or upon the annual registration under section 710; and

(2) by striking subsection (b) and inserting the following:

“FEE AMOUNTS.—Except as provided in subsections (c), (d), and (e), the fees under subsection (a) shall be based on the following fee amounts:

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Fee Type</th>
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<tbody>
<tr>
<td>2008</td>
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<tr>
<td>2012</td>
<td>$256,384</td>
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(3) in subsection (c)—
(A) by striking “following:

(1) by striking “ Annual Fee Setting ”; and
(B) in paragraph (1), by striking the second sentence;
(C) by redesigning paragraphs (2) and (3) as paragraphs (3) and (4), respectively;
(D) by inserting after paragraph (1) the following:

“(2) ADJUSTMENT OF ANNUAL ESTABLISHMENT REGISTRATION FEE.—
(A) IN GENERAL.—When setting the fees for fiscal years 2009 and 2010, the Secretary may increase the establishment registration fee specified in subsection (b) only if the Secretary estimates that the number of establishments submitting fees for fiscal year 2009 is less than 12,530, but in no case shall the percent increase be more than 8.5 percent over the amount for such fee specified in subsection (b) for fiscal year 2010. If the Secretary makes any adjustment to the establishment registration fee for fiscal year 2010, then the establishment registration fee for fiscal years 2011 and 2012 under subsection (b) shall be adjusted as follows: the fee for fiscal year 2011 shall be equal to the adjusted fee for fiscal year 2010, increased by 8.5 percent, and the fee for fiscal year 2012 shall be equal to the adjusted fee for fiscal year 2011, increased by 8.5 percent.
(B) PUBLICATION IN THE FEDERAL REGISTER.—The Secretary shall publish any determination with respect to any establishment registration fee adjustment made under subparagraph (A), and the rationale for such determination, in the Federal Register.”; and
(E) in paragraph (2)(A), as so redesignated—
(i) by striking “For fiscal years 2006 and 2007,” and inserting “The”;
(ii) by striking “of fiscal year 2008” and inserting “of the next fiscal year”;
(IV) by redesignating clauses (ii) and (iii) as clauses (i) and (ii), respectively;
(V) by inserting after clause (c) the following:

“(v) SOLE DISCRETION TO REFUND.—The Secretary shall have sole discretion to refund a fee or portion of the fee under this subparagraph. A determination by the Secretary concerning a refund under this paragraph shall not be reviewable.”; and

(B) by striking at the end the following:

“(3) ANNUAL ESTABLISHMENT REGISTRATION FEE.—
(A) IN GENERAL.—Except as provided in subparagraph (B), each establishment subject to a registration fee shall be subject to a fee for each initial or annual registration beginning with its registration for fiscal year 2008.
(B) EXCEPTION FOR FEDERAL OR STATE GOVERNMENT ESTABLISHMENT.—No fee shall be required under subparagraph (A) for an establishment operated by a Federal or State Government entity unless a device manufactured by the establishment is to be distributed commercially.
(C) PAYMENT.—The annual establishment registration fee shall be due once each fiscal year, upon the initial registration of the establishment or upon the annual registration under section 710; and

(2) by striking subsection (b) and inserting the following:

“FEE AMOUNTS.—Except as provided in subsections (c), (d), and (e), the fees under subsection (a) shall be based on the following fee amounts:

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(III) Firms not submitting tax returns to the United States Internal Revenue Service.—The applicant shall support its claim that it meets the definition under subparagraph (A) by submitting the criteria for a small business.

(I) A signed certification, in such form as the Secretary may direct through a notice published in the Federal Register, that the applicant meets the criteria for a small business.

(II) A certification, in English, from the national taxing authority of the country in which it is headquartered, that the applicant has submitted certifications for all of its affiliates, or that it has no affiliates, whichever is applicable.

(iii) by striking subparagraph (C) and inserting the following:

(E) Such person shall notify the Secretary of any withdrawal, suspension, restriction, or expiration of certification of conformance with the quality systems standard referred to in paragraph (7) for any manufacturer that such person inspects under this subsection not later than 30 days after such withdrawal, suspension, restriction, or expiration.

(iv) by striking subparagraph (C) and inserting the following:

(IV) A statement signed by the head of the applicant or its chief financial officer that it has submitted certifications for all of its affiliates, or that it has no affiliates, whichever is applicable.

(ii) by striking paragraph (4) and inserting paragraph (4) as follows:

(A) by amending subparagraph (A) to read as follows:

(f) EFFECT OF FAILURE TO PAY FEES.—

(1) In general.—

(i) the owner or operator of the establishment submits to the Secretary a notice indicating the intent to use such a person to conduct the inspection, and the date on which the inspection is scheduled to begin; and

(7) fees were not assessed under subsection (a) for the fiscal year, and the Secretary continues to be in effect with respect to premarket applications, premarket reports, premarket notification submissions, and supplemental premarket notifications submitted by the applicant, the Secretary shall continue to be in effect with respect to premarket applications, premarket reports, premarket notification submissions, and supplemental premarket notifications submitted by the applicant, the Secretary shall continue to be in effect with respect to premarket applications, premarket reports, premarket notification submissions, and supplemental premarket notifications submitted by the applicant, the Secretary shall continue to be in effect with respect to premarket applications, premarket reports, premarket notification submissions, and supplemental premarket notifications submitted by the applicant, the Secretary shall continue to be in effect with respect to premarket applications, premarket 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shall continue to be in effect with respect to premarket applications, premarket reports, premarket notice to the purpose of setting risk-based inspectional priorities.

SUBTITLE B—AMENDMENTS REGARDING REGULATION OF MEDICAL DEVICES

SEC. 311. INSPECTIONS BY ACCREDITED PERSONS.

Section 730(q) (21 U.S.C. 374(q)) is amended—

in paragraph (1) by striking “not later than the date after the date of enactment of this subtitle,”

in paragraph (2) by inserting “The Secretary”;

and

in paragraph (3) by adding at the end the following:

(F) Such person may conduct audits to establish conformance with the quality systems standard referred to in paragraph (7); and

(G) Such person may conduct inspections by persons accredited under paragraph (2) if the following conditions are met:

(A) with respect to inspections to be conducted by an accredited person—

(i) the owner or operator of the establishment submits to the Secretary a notice indicating the intent to use such a person to conduct the inspection, and the date on which the inspection is scheduled to begin; and

(ii) the accredited person whom the establishment selects to conduct the inspection is listed on the Internet site of the Food and Drug Administration referred to in paragraph (4).

(B) as requested by the Secretary, the establishment requests the accredited person specified in the notice under subparagraph (A) provides information concerning the relationship between the establishment and such accredited person; and

in paragraph (4) by adding subparagraph (A) to read as follows:

(A) Persons accredited under paragraph (2) to conduct inspections shall record in writing the inspection observations and shall present the observations to the device establishment’s designated representative and describe each observation. Additionally, such accredited person shall prepare an inspection report in a form and manner designated by the Secretary, taking into consideration the goals of international harmonization of quality systems standards. Any observations recorded by such inspection shall be determined by the Secretary; and

in paragraph (5) by adding the following:

under this section pursuant to appropriation for fiscal year 2012.”.

SEC. 304. SALES AND MARKETING OF MEDICAL DEVICES

Public Law 107-250, and notwithstanding the amendments made by this subtitle, part 3 of chapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, as in effect on the date of enactment of this subtitle, shall continue to be in effect with respect to premarket applications, premarket reports, premarket notification submissions, and supplemental premarket notification submissions made in a fiscal year prior to fiscal year 2008.

SEC. 305. EFFECTIVE DATE.

The amendments made by this subtitle shall take effect on the date of the enactment of this subtitle.
SEC. 312. EXTENSION OF AUTHORITY FOR THIRD PARTY REVIEW OF PREMARKET NOTIFICATION.

Section 526(c) (21 U.S.C. 360m(c)) is amended by striking "2007" and inserting "2012".

SEC. 313. REGISTRATION.

(a) ANNUAL REGISTRATION OF PRODUCERS OF DRUGS AND DEVICES.—Section 510(b) (21 U.S.C. 359(b)) is amended—

(1) by striking "(b) On or before" and inserting "(b)(1) On or before";

(2) in paragraph (1), by striking "or a device or devices"; and

(3) by adding at the end the following new paragraph:

"(2) Between October 1 and December 31 of each year every person who owns or operates any establishment within any State engaged in the manufacture, preparation, propagation, compounding, or processing of any drug or device shall register with the Secretary his name, places of business, and all such establishments."

(b) REGISTRATION OF FOREIGN ESTABLISHMENTS.—Section 510(h)(1) (21 U.S.C. 359(h)(1)) is amended—

(1) by striking "(1) On or before" and inserting "(A) On or before";

(2) in subparagraph (A)—

(A) by striking "processing of a drug or a device that is imported" and inserting "processing of a drug that is imported";

(B) by striking "or device" each place it appears; and

(3) by adding after such subparagraph (A) the following new subparagraph:

"(B) Between October 1 and December 31 of each year, any establishment within any foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a device that is imported or offered for import into the United States shall, through electronic means in accordance with the criteria established by the Secretary, register with the Secretary the name and place of business of the establishment, the name of the United States agent for the establishment, the name of each importer of such device in the United States that is known to the establishment, and the name of each person who imports or offers for import such device to the United States for purposes of importation.".

SEC. 314. FILING OF LISTS OF DRUGS AND DEVICES MANUFACTURED, PREPARED, PROPAGATED, AND COMPOUNDED BY REGISTRIERS; ACCOMPANYING DISCLOSURES.

Section 510(h)(2) (21 U.S.C. 359(h)(2)) is amended—

(a) in the matter preceding subparagraph (A), to read as follows:

"(2) Each person who registers with the Secretary under this section shall report to the Secretary, with respect to any drug or device, once during the month of June of each year and once during the month of December of each year, and (ii) with regard to devices, once each year between October 1 and December 31, the following information:

(1) in subparagraph (A), by striking "both places it appears and inserting "(E)";

(2) in paragraph (1)(A)(ii), by striking "(D)" and inserting "(E)";

(3) by striking "((ii) the" and inserting "(II) the";

(4) by striking "(B) if the drug is the subject" and inserting "(II) if the drug is the subject";

(5) by striking "(I) and inserting "(I) and (II)";

(6) by striking "(ii) a listed patent" and inserting "(ii) a listed patent";

(7) by striking "(II) a listed patent" and inserting "(II) a listed patent";

(b) REQUEST FOR PEDICAT STUDIES.—

SEC. 315. ELECTRONIC REGISTRATION AND LISTING.

Section 510(p)(2) (21 U.S.C. 359(p)) is amended to read as follows:

"(p)(1) With regard to any establishment engaged in the manufacture, preparation, propagation, compounding, or processing of a device, the registration and listing information required by this section shall be submitted to the Secretary by electronic means, unless the Secretary grants a waiver because electronic registration and listing is not reasonable for the person requesting such waiver.

"(2) With regard to any establishment engaged in the manufacture, preparation, propagation, compounding, or processing of a device, the registration and listing information required by this section shall be submitted to the Secretary by electronic means, unless the Secretary grants a waiver because electronic registration and listing is not reasonable for the person requesting such waiver.

"(3) TITLE IV—PEDIATRIC MEDICAL PRODUCTS

Subtitle A—Best Pharmaceuticals for Children

SEC. 315. SHORT TITLE.

This subtitle shall be cited as the "Best Pharmaceuticals for Children Amendments of 2007."
sponsoring appropriating committees. The Secretary’s only responsibility in accepting or rejecting the reports shall be to determine, within the 180 days, whether the studies fairly respond to the written request, have been conducted in accordance with commonly accepted scientific principles and protocols, and have been reported in accordance with the requirements of the Secretary for filing.

(b) In general.—Nothing in this subsection alters or amends section 301(1) of this Act or section 552 of title 5, United States Code.

(c) By striking subsections (e) and (j) and inserting the following:

(e) NOTICE OF DETERMINATIONS ON STUDIES REQUIRED.—

‘‘(1) IN GENERAL.—The Secretary shall publish a notice of any determination made on or after the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007, in a manner consistent with section 653, to supplement, not supplant, other requirements that govern the publication of such notices. Such notice identified by such notice identifying any drug for which, on or after the date of enactment of this Act, a pediatric formulation was developed, studied, and found to be safe and effective in the pediatric population (or specified subpopulation) if the pediatric formulation for such drug is not introduced onto the market within a reasonable time after the date such formulation becomes available. Each such notice shall be published not later than 30 days after the date of the Secretary’s determination regarding market exclusivity and shall include a copy of the initial written request made under subsection (b) or (c).

(2) IDENTIFICATION OF CERTAIN DRUGS.—The Secretary shall require the publication of a notice identifying any drug for which, on or after the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007, a pediatric formulation was developed, studied, and found to be safe and effective in the pediatric population (or specified subpopulation) if the pediatric formulation for such drug is not introduced onto the market within a reasonable time after the date such formulation becomes available. Each such notice shall be published not later than 30 days after the date of the Secretary’s determination regarding market exclusivity and shall include a copy of the initial written request made under subsection (b) or (c).

(3) REVIEW OF PEDIATRIC STUDIES.—The committee established under paragraph (1) shall review all studies conducted under this section, including obtaining any recommendation of such Office pursuant to subsection (d)(2), then each period of market exclusivity deemed or extended under subsection (b) or (c) shall be reduced by 3 months for each study that the Secretary determines that a pediatric study conducted under this section does or does not demonstrate that the drug is the subject of the market exclusivity is safe and effective, including whether such study results are inconclusive, in pediatric populations or subpopulations, the Secretary shall order the labeling of such product to include information about the results of the study and a statement of the Secretary’s determination.

(ii) in subsection (k), as redesignated by paragraph (9), (A) in paragraph (1)—

(i) by striking ‘‘(c)(1)(A)(ii)’’ and inserting ‘‘(c)(1)(A)’’; and

(ii) by striking ‘‘(B)’’ and inserting ‘‘(B)(2)’’; and

(B) in paragraph (2), by striking ‘‘(c)(1)(B)’’ and inserting ‘‘(c)(1)(B)(ii)’’

(C) by redesignating paragraph (2) as paragraph (3); and

(D) by inserting after paragraph (1) the following:

‘‘(2) DISSEMINATION OF INFORMATION REGARDING LABELING CHANGES.—Beginning on the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007, the Secretary shall disseminate information concerning labeling changes in any way the Secretary determines is appropriate, to include, at a minimum, a notice of the availability of information concerning labeling changes and information about the products and indications that are subject to such changes. As part of such dissemination, the Secretary shall, in the annual summary developed pursuant to subsection (i), the Secretary shall ensure that all adverse event reports that have been received for such drug (regardless of when such report was received) are referred to the Office of Pediatric Therapeutics established under section 6 of the Best Pharmaceuticals for Children Act (Public Law 107-199). In considering such reports, the Director of such Office shall provide for the review of the report by the Pediatric Advisory Committee, including obtaining any recommendations of such Committee regarding whether the Secretary should take action under this section in response to such reports.

(3) REPORTING IN SUBSEQUENT YEARS.—Follow ing the 1-year period described in paragraph (1), the Secretary shall, as appropriate, refer to the Office of Pediatric Therapeutics all pediatric adverse event reports for a drug for which a pediatric study was conducted under this section. In considering such reports, the Director of such Office may provide for the review of such reports by the Pediatric Advisory Committee, including obtaining any recommendations of such Committee regarding whether the Secretary should take action in response to such reports.

(E) by inserting after paragraph (5) the following:

‘‘(5) OTHER LABELING CHANGES.—If, on or after the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007, the Secretary determines that a pediatric study conducted under this section does or does not demonstrate that the drug is the subject of the market exclusivity is safe and effective, including whether such study results are inconclusive, in pediatric populations or subpopulations, the Secretary shall order the labeling of such product to include information about the results of the study and a statement of the Secretary’s determination.

’’

(9) In section 552 of title 5, United States Code, as redesignated by the Best Pharmaceuticals for Children Amendments of 2007, in subsection (k), as redesignated by paragraph (9), (A) in paragraph (2)—

(i) by striking ‘‘(c)(1)(B)’’ and inserting ‘‘(c)(1)(B)(ii)’’

(ii) by striking ‘‘(B)’’ and inserting ‘‘(B)(2)’’; and

(B) in paragraph (2), by striking ‘‘(c)(1)(B)’’ and inserting ‘‘(c)(1)(B)(ii)’’
SEC. 403. PROGRAM FOR PEDIATRIC STUDIES OF DRUGS.

Section 409I of the Public Health Service Act (42 U.S.C. 284m) is amended—

(A) by inserting subsection (m), as redesignated by paragraph (9), the following:

"(n) REFERRAL IF PEDIATRIC STUDIES NOT COMPLETE—

(1) IN GENERAL.—Beginning on the date of enactment of the Best Pharmaceuticals for Children Amendments of 2007, if pediatric studies of a drug, completed under section 409H of the Public Health Service Act, have not been completed—

(A) by striking the last sentence of paragraph (c), and inserting the following:

"(A) a decision under paragraph (1)(A) is not made within 3 years of the date of enactment of this section;";

(B) by striking paragraph (3), and inserting the following:

"(3) EFFECT OF SUBSECTION.—Nothing in this subsection alters or amends section 301(j) of this title.

(2) in subsection (d), by striking the last sentence of that subsection, and inserting the following:

"(D) the Secretary shall refer the drug for inclusion on the list established under section 409H of the Public Health Service Act for the conduct of studies.

(3) PUBLIC NOTICE.—The Secretary shall give the public notice of—

(A) a decision under paragraph (1)(A) not to require an assessment under section 505B and the basis for such decision; and

(B) any referral under paragraph (1)(B) of a drug for inclusion on the list established under section 409H of the Public Health Service Act, on or before the date of enactment of this subsection.

(4) IN GENERAL.—Not later than 1 year after the date of enactment of this section, the Secretary shall complete the pediatric studies and reports required under section 409I of the Public Health Service Act, for the conduct of studies.

(5) PUBLICATION.—Not later than 1 year after the date of enactment of this section, the Secretary shall publish—

(A) a list of priority issues in pediatric pharmacology, pharmacogenetic determinants of drug response, metabolism of drugs and biologics in children, and pediatric clinical trials;

(B) particular pediatric diseases, disorders or conditions, evidence-based knowledge and testing of therapeutics, including drugs and biologics, may be beneficial in pediatric populations; and

(C) the adequacy of necessary infrastructure to conduct pediatric pharmacological research, including research networks and trained pediatric investigators.

(6) PEDIATRIC STUDIES AND RESEARCH.—The Secretary, acting through the National Institutes of Health, shall award funds to entities that have proposed to conduct pediatric clinical trials or other research (including qualified universities, hospitals, laboratories, contract research organizations, practice groups, federally funded programs such as pediatric pharmacology research units, other public or private institutions, or individuals) to enable the entities to conduct the drug studies or other research on the issues described in subsection (a). The Secretary may use contracts, grants, or other appropriate funding mechanisms to award funds under this subsection.

(7) IN GENERAL.—The Secretary shall designate which drug is subject to the requirements contained in this section.

(8) EFFECTIVE DATE.—This section shall take effect not later than 1 year after the date of enactment of this section.

(9) AUTHORIZATION OF APPROPRIATIONS.—

(1) IN GENERAL.—There are authorized to be appropriated to the Secretary of Health and Human Services, for the fiscal year ending September 30, 2008, to carry out this section, $200,000,000.

(2) IMPROVEMENTS.—Any amounts appropriated to the Secretary under this section are authorized to remain available until September 30, 2008.
(B) the results of those efforts, including ef- forts made to encourage the conduct of appro- priate studies in neonates by companies with products that have sufficient safety and other information to enable the conduct of the studies ethical and safe.

(b) IOM STUDY.—Not later than 3 years after the date of enactment of this subtitle, the Sec- retary of Health and Human Services shall enter into a contract with the Institute of Medicine to conduct a study and report to Congress regarding the written requests made and the studies conducted pursuant to section 953A of the Fed- eral Food, Drug, and Cosmetic Act. The Insti- tute of Medicine may devise an appropriate mechanism to review a representative sample of requests made for studies conducted pursuant to such section in order to conduct such study. Such study shall—

(1) review such representative written requests issued by the Secretary since 1997 under sub- sections (b) and (c) of such section 505A;

(2) review and assess such representative pedi- atric studies conducted under such subsections (b) and (c) since 1997 and labeling changes made as a result of such studies; and

(3) review the use of extrapolation for pedi- atric populations and the use of alternative endpoints in pediatric populations, clinical assessment tools, and ethical issues in pediatric clinical trials.

SEC. 405. TRAINING OF PEDIATRIC PHAR- MACOLOGISTS.

(a) INVESTMENT IN TOMORROW’S PEDIATRIC RESEARCHERS.—Section 452G(2) of the Public Health Service Act (42 U.S.C. 285g-16(2)) is amended by adding before the period at the end the following: “, including pediatric pharmaco- logical research”;

(b) PEDIATRIC RESEARCH LOAN REPAYMENT PROGRAM.—Section 487A(1) of the Public Health Service Act (42 U.S.C. 288-6a(1)) is amended by inserting “including pediatric pharmaco- logical research,” after “pediatric research.”

SEC. 406. FOUNDATION FOR THE NATIONAL IN- STITUTES OF HEALTH.

Section 499(c)(1)(C) of the Public Health Service Act (42 U.S.C. 290b(c)(1)(C)) is amended by striking “and studies listed by the Secretary pursuant to section 499(a)(1)(A) of the Act and referred under section 505A(d)(4)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a(d)(4)(C))” and inserting “and studies for which the Secretary issues a certification under section 505A(n)(1)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a(n)(1)(A))”.

SEC. 407. CONTINUATION OF OPERATION OF COM- MITTEE.

Section 14 of the Best Pharmaceuticals for Children Act (21 U.S.C. 355a note) is amended by adding at the end the following:

“(d) CONTINUATION OF OPERATION OF COMMITTEE.—Notwithstanding section 14 of the Fed- eral Advisory Committee Act (5 U.S.C. App.), the advisory committee shall continue to operate during the 5-year period beginning on the date of enactment of the Best Pharmaceuticals for Children Act of 2007.”

SEC. 408. PEDIATRIC SUBCOMMITTEE OF THE ON- COLOGIC DRUGS ADVISORY COM- MITTEE.

Section 15 of the Best Pharmaceuticals for Children Act (42 U.S.C. 284m note) is amended by adding at the end the following:

“(D) PROVIDES RECOMMENDATIONS TO THE INTERNAL REVIEW COMMITTEE.—Notwithstanding section 505A(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a(j)) regarding the implementation of amendments to sections 505A and 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a and 355c) with respect to the treat- ment of pediatric cancers.”; and

“(B) by adding at the end the following:

“(3) CONTINUATION OF OPERATION OF SUB- COMMITTEE.—Notwithstanding section 14 of the Federal Advisory Committee Act (5 U.S.C. App.), the Subcommittee shall continue to operate dur- ing the 5-year period beginning on the date of enactment of the Best Pharmaceuticals for Chil- dren Amendments of 2007.”; and

“(2) in subsection (d), by striking “2003” and inserting “2009”.

SEC. 409. EFFECTIVE DATE AND LIMITATION FOR RULE RELATING TO TOLL-FREE NUM- BER FOR ADVERSE EVENTS ON LA- BELING FOR HUMAN DRUG PROD- UCTS.

(a) IN GENERAL.—Notwithstanding subsection II of chapter 5, and chapter 7, of title 5, United States Code (commonly known as the “Adminis- trative Procedure Act’) and any other provision of law, the proposed rule issued by the Commis- sioner of Food and Drugs entitled “Toll-Free Number for Reporting Adverse Events on Label- ing for Human Drug Products”, 69 Fed. Reg. 21776, (April 22, 2004) shall take effect on Janu- ary 1, 2008, unless such Commissioner issues the final rule before such date.

(b) LIMITATION.—The proposed rule that takes effect under subsection (a), or the final rule de- scribed under subsection (a), shall, notwith- standing section 409I of the Best Pharma- ceuticals for Children Act (21 U.S.C. 355b(a)), not apply to a drug—

(1) for which an application is approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355);

(2) that is not described under section 503(b)(1) of such Act (21 U.S.C. 333(b)(1)); and

(3) in the packaging of which includes a toll-free num- ber through which consumers can report complaints to the manufacturer or distributor of the drug.

Subtitle B—Pediatric Research Improvement

SEC. 411. SHORT TITLE.

This subtitle may be cited as the “Pediatric Research Improvement Act”.

SEC. 412. PEDIATRIC FORMULATIONS, EXTRAPO- LATIONS, AND DEFERRALS.

Section 505Ba(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c(b)) is amend- ed—

(1) by striking paragraph (1) and inserting the follow- ing:

“(1) n GENERAL.—After providing notice in the form of a letter, or a written request under section 505A that was declined by the sponsor or holder, and an opportunity for written response and a meeting, which may include an advisory committee meeting, the Secretary may (by order in the form of a letter) require the sponsor or holder of an approved application for a drug or biological product under section 505 or the holder of a license for a biological product under section 351 of the Public Health Service Act (42 U.S.C. 262) to submit by a specified date the assessments described in subsection (a)(2) and the written request, as appropriate, if the Secretary finds that—

“(A) the drug or biological product is used for a substantial number of pediatric patients for unlabelled indications; and

“(B) adequate pediatric labeling could confer a benefit on pediatric patients.

“(2) IN GENERAL.—Nothing in this section shall be construed to mean that the drug or biological product would represent a meaningful therapeutic benefit over existing therapies for pediatric patients for 1 or more of the claimed indications; or

“(C) the absence of adequate pediatric label- ing could pose a risk to pediatric patients.”;

(2) in paragraph (2)(B), by adding at the end the follow- ing:

“(2) DEFERRAL.—

“(A) IN GENERAL.—On the initiative of the Sec- retary or at the request of the applicant, the Secretary may defer submission of some or all assessments required under paragraph (1) until a specified date after approval of the drug or issuance of the license for a biological product if—

“(i) the Secretary finds that—

“(I) the drug or biological product is ready for approval for use in adults before pediatric stud- ies are complete;

“(II) pediatric studies should be delayed until additional safety or effectiveness data have been collected; or

“(III) there is another appropriate reason for deferral; and

“(ii) the applicant submits to the Secretary—

“(I) certification of the grounds for deferring the assessments;

“(II) a description of the planned or ongoing studies;

“(III) evidence that the studies are being con- ducted or will be conducted with due diligence and at the earliest possible time; and

“(IV) a timeline for the completion of such studies.

“(B) ANNUAL REVIEW.—

“(1) IN GENERAL.—On an annual basis fol- lowing the approval of a sub- paragraph (A), the applicant shall submit to the Secretary the following information:

“(I) Information detailing the progress made in conducting pediatric studies;

“(II) If no progress has been made in con- ducting such studies, evidence and documenta- tion that such studies will be conducted with due diligence and at the earliest possible time.

“(III) PUBLIC AVAILABILITY.—The informa- tion submitted through the annual review under clause (i) shall promptly be made available to the public in an easily accessible manner, in- cluding through the website of the Food and Drug Administration.”.

SEC. 413. IMPROVING AVAILABILITY OF PEDI- ATRIC DATA FOR ALREADY MAR- KTED PRODUCTS.

Section 505B(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c(b)) is amend- ed—

(1) by striking paragraph (1) and inserting the follow- ing:

“(1) IN GENERAL.—After providing notice in the form of a letter, or a written request under section 505A that was declined by the sponsor or holder, and an opportunity for written response and a meeting, which may include an advisory committee meeting, the Secretary may (by order in the form of a letter) require the sponsor or holder of an approved application for a drug or biological product under section 505 or the holder of a license for a biological product under section 351 of the Public Health Service Act (42 U.S.C. 262) to submit by a specified date the assessments described in subsection (a)(2) and the written request, as appropriate, if the Secretary finds that—

“(A) the drug or biological product is used for a substantial number of pediatric patients for unlabelled indications; and

“(B) adequate pediatric labeling could confer a benefit on pediatric patients.

“(2) IN GENERAL.—Nothing in this section shall be construed to mean that the drug or biological product would represent a meaningful therapeutic benefit over existing therapies for pediatric patients for 1 or more of the claimed indications; or

“(C) the absence of adequate pediatric label- ing could pose a risk to pediatric patients.”;

(2) in paragraph (2)(B), by adding at the end the follow- ing:

“(2) DEFERRAL.—

“(3) EFFECT OF SUBSECTION.—Nothing in this subsection alters or amends section 301(i) of this Act or section 552 of title 5 or section 1905 of title 18, United States Code.”.

SEC. 414. SUNSET; REVIEW OF PEDIATRIC ASSESS- MENTS; LABELING CHANGES; AND PEDI- ATRIC ASSURANCE.

Section 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c) is amend- ed—

(1) redesignating subsection (h) as subsection (k);

(2) in subsection (j), as so redesignated, by striking “505A(n)” and inserting “505A(p)”;
(1) by redesignating subsection (f) as subsection (k);
(2) by redesignating subsection (g) as subsection (l); and
(3) by inserting after subsection (e) the following:

"(i) REVIEW OF PEDIATRIC ASSESSMENT REQUESTS, PEDIATRIC ASSESSMENTS, DEFEASALS, AND WAIVERS.—

"(A) REVIEW.—The Secretary shall create an internal committee to review all pediatric assessment requests received under this section, all pediatric assessments conducted under this section, and all deferral and waiver requests made pursuant to this section. Such internal committee shall be composed of individuals, each of whom is an employee of the Food and Drug Administration, with the following expertise:

(a) Pediatrics.
(b) Biopharmacology.
(c) Statistics.
(d) Drugs and drug formulations.
(e) Pediatric ethics.
(f) Legal issues.
(g) Appropriate expertise pertaining to the pediatric product under review.

"(B) Final determination.—The Secretary shall issue a final determination with respect to each request for deferral or waiver received under this section. The decision of the Secretary shall be rendered within 90 days of receipt.

"(2) DISPUTE RESOLUTION.—

(A) REQUEST FOR LABELING CHANGE AND FAILURE TO AGREE.—If the Commissioner determines that a sponsor and the Commissioner disagree on appropriate changes to labeling for the drug that is the subject of the application or supplement, not later than 180 days after the date of the submission of the application or supplement, the Commissioner shall request that the sponsor make any labeling change that the Commissioner determines to be appropriate; and

(B) ACTION BY THE PEDIATRIC ADVISORY COMMITTEE.—Not later than 90 days after receiving such a request, the Pediatric Advisory Committee shall review the labeling changes recommended by the Commissioner and approve or disapprove the labeling changes recommended by the Commissioner.

"(3) EFFECT OF SUBSECTION.—Nothing in this section shall alter or amend section 301(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343l(j)).

"(4) EFFECT.—The requirements of this subsection shall supplement, not supplant, other requirements of this Act or section 552 of title 5, United States Code.

"(B) GAO REPORT.—Not later than September 30, 2007, the Comptroller General of the United States, in consultation with the Secretary of Health and Human Services, shall submit to Congress a report on the effectiveness of section 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355l) since 1997 and labeling changes made as a result of such studies and their impact on clinical trials.

"(5) REPRESENTATIVE SAMPLE.—The Institute of Medicine shall select and devise an approach to review a representative sample of studies conducted pursuant to section 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355l) to determine whether the processes and productivity of the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research in order to make the required assessment.

"(6) GAO REPORT.—Not later than September 1, 2010, the Comptroller General of the United States, in consultation with the Secretary of Health and Human Services, shall submit to Congress a report on the effectiveness of section 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355l) in ensuring that medicines used by children are tested and properly labeled, including—

(A) the number and importance of drugs for children that are being tested as a result of this provision and the importance for children, health care providers, parents, and others of labeling changes made as a result of such testing;

(B) the number and importance of drugs for children that are not being tested for their use with pediatric labeling; and

(C) the number of drugs for which testing is being done and for which labeling changes are required, including the date labeling changes were made and which labeling changes required the use of the
dispute resolution process established under such section 505B, together with a description of the outcomes of such process, including a description of the disputes and the recommendations of the Pediatric Advisory Committee.

SEC. 417. TECHNICAL CORRECTIONS.


Subtitle C—Pediatric Medical Devices

SEC. 421. SHORT TITLE.

This subtitle may be cited as the ‘‘Pediatric Medical Device Safety and Improvement Act of 2007’’.

SEC. 422. TRACKING PEDIATRIC DEVICE APPROVALS.

Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 351 the following:

**SEC. 351A. PEDIATRIC USES OF DEVICES.**

‘‘(a) NEW DEVICES.—

‘‘(1) IN GENERAL.—A person that submits to the Secretary an application under section 520(m), or an application (or supplement to an application) or a product development protocol under section 315, shall include in the application a protocol the information described in paragraph (2).

‘‘(2) REQUIRED INFORMATION.—The application or protocol described in paragraph (1) shall include in a description of any pediatric subpopulation that suffers from the disease or condition that the device is intended to treat, diagnose, or cure; and

‘‘(B) the number of affected pediatric patients.

‘‘(3) ANNUAL REPORT.—Not later than 18 months after the date of enactment of this section, and annually thereafter, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that includes—

‘‘(A) the number of devices approved in the year preceding the year in which the report is submitted, for which there is a pediatric subpopulation that suffers from the disease or condition that the device is intended to treat, diagnose, or cure; and

‘‘(B) the number of devices approved in the year preceding the year in which the report is submitted, labeled for use in pediatric patients.

‘‘(4) DETERMINATION OF PEDIATRIC EFFECTIVENESS BASED ON SIMILAR COURSE OF DISEASE OR SIMILAR EFFECT OF DEVICE ON ADULTS.—

‘‘(1) IN GENERAL.—If the course of the disease or condition and the effects of the device are sufficiently similar in adults and pediatric patients, the Secretary may conclude that adult data may be used to support a determination of a reasonable assurance of effectiveness in pediatric populations, as appropriate.

‘‘(2) EXTRAPOLATION BETWEEN SUBPOPULATIONS.—A study may not be needed in each pediatric subpopulation if data from one subpopulation can be extrapolated to another subpopulation.

‘‘(c) PEDIATRIC SUBPOPULATION.—In this section, the term ‘pediatric subpopulation’ has the meaning given the term in section 520(m)(6)(E)(ii).’’.

SEC. 423. MODIFICATION TO HUMANITARIAN DEVICE EXEMPTION:

(a) IN GENERAL—Section 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(m)) is amended—

(1) in paragraph (3), by striking ‘‘No’’ and inserting ‘‘Except as provided in paragraph (6), no’’;

(2) in paragraph (4)—

(A) by inserting ‘‘, if the Secretary has reason to believe that the requirements of paragraph (6) are no longer met,’’ after ‘‘public health’’; and

(B) by inserting the end the following:

‘‘(i) The device with respect to which the exemption is granted is intended for the treatment or diagnosis of a disease or condition that occurs in pediatric patients or in a pediatric subpopulation, and such device is labeled for use in pediatric patients or in a pediatric subpopulation in which the disease or condition occurs.

(ii) The device was not previously approved under this subsection for the pediatric patients or in a pediatric subpopulation for which the exemption is granted.

(iii) Such person immediately notifies the Secretary an application under section 352(m)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(m)(2)) with respect to a device to profit from such device pursuant to section 520(m)(6) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(m)(6)) (as amended by subsection (a)), including—

(1) an assessment of whether such device was amended by subsection (a) has increased the availability of pediatric devices for conditions that occur in small numbers of children, including any increase or decrease in the number of—

(A) exemptions granted under such section 520(m)(2) for pediatric devices; and

(B) applications approved under section 515 of such Act (21 U.S.C. 355(c)) for devices intended to treat, diagnose, or cure conditions that occur in pediatric patients or for devices labeled for use in a pediatric population;

(2) the conditions or diseases the pediatric devices were intended to treat or diagnose and the estimated size of the pediatric patient population for each condition or disease;

(3) the costs of the pediatric devices, based on a survey of children's hospitals;

(4) the extent to which the costs of such devices are covered by health insurance;

(5) the impact, if any, of allowing profit on access to such devices for patients;

(6) the profits made by manufacturers for each device that receives an exemption under such section 520(m)(2); and

(7) an estimate of the extent of the use of the pediatric devices by both adults and pediatric populations for a condition or disease other than the condition or disease on the label of such devices; and

(b) REPORT.—Not later than January 1, 2012, the Comptroller General of the United States regarding the effectiveness of such section 520(m)(6) (as amended by subsection (a)) and whether any modifications to such section 520(m)(6) (as amended by subsection (a)) should be made.

(c) GIZATION.—Not later than 180 days after the date of enactment of this subtitle, the Commissioner of Food and Drugs shall issue guidelines to institutional review boards on how to evaluate requests for approval for devices for which a humanitarian device exemption under
section 520(m)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360l)(m)(2) has been granted.

SEC. 424. CONTACT POINT FOR AVAILABLE FUNDING.

Section 402(b) of the Public Health Service Act (42 U.S.C. 282(b)) is amended—

(1) in paragraph (21), by striking “and” after the semicolon at the end of paragraph (20) and inserting “;”;

(2) in paragraph (22), by striking the period at the end and inserting “; and”;

and (3) by inserting after paragraph (22) the following—

“(22) shall designate a contact point or office to help innovators and physicians identify sources of funding available for pediatric medical device development.”.

SEC. 425. DEMONSTRATION GRANTS FOR IMPROVING PEDIATRIC DEVICE AVAILABILITY.

(a) IN GENERAL.—

(1) REQUEST FOR PROPOSALS.—Not later than 90 days after the date of enactment of this subtitple, the Secretary of Health and Human Services shall issue a request for proposals for 1 or more grants or contracts to nonprofit consortia for demonstration projects to promote pediatric device development.

(2) DETERMINATION ON GRANTS OR CONTRACTS.—Not later than 180 days after the date the Secretary of Health and Human Services issues a request for proposals under paragraph (1), the Secretary shall make a determination on the granting or contracting under this section.

(b) APPLICATION.—A nonprofit consortium that desires to receive a grant or contract under this section shall submit an application to the Secretary of Health and Human Services at such time, in such manner, and containing such information as the Secretary may require.

(c) USE OF FUNDS.—A nonprofit consortium that receives a grant or contract under this section shall submit an application to the Secretary of Health and Human Services to facilitate the application for approval or clearance of devices labeled for pediatric use.

(d) COORDINATION.

(1) NATIONAL INSTITUTES OF HEALTH.—In making such grants or contracts, the Secretary, in consultation with the Director of the National Institutes of Health, the small business Administration, the National Science Foundation, the Department of Energy, the Department of Education, the Department of Veterans Affairs, the Agency for Healthcare Research and Quality, and the National Institutes of Standards and Technology; (2) HEALTHCARE RESEARCH AND QUALITY.—The plans under subparagraph (A) shall include—

(i) the current status of federally funded pediatric medical device research;

(ii) any gaps in such research, which may include a survey of pediatric medical providers regarding unmet pediatric medical device needs, as needed; and

(iii) a research agenda for improving pediatric medical device development and Food and Drug Administration clearance or approval of pediatric medical devices, and for evaluative measures of short- and long-term safety and effectiveness of pediatric medical devices.

(b) PEDIATRIC ADVISORY COMMITTEE.—Section 14 of the Best Pharmaceuticals for Children Act (42 U.S.C. 284m note) is amended—

(1) in subsection (a), by inserting “including drugs and biological products” and medical devices” after “therapeutics”; and

(2) in subsection (b)—

(A) in paragraph (1), by inserting “including drugs and biological products” and medical devices” after “therapeutics”;

and (B) in paragraph (2)—

(i) in subparagraph (A), by striking “and 505B” and inserting “505B, 510(k), 515, and 520(m)”; and

(ii) by striking subparagraph (B) and insert-

the following—

“(B) identification of research priorities related to therapeutics (including drugs and biological products) and medical devices for pediatric populations and the need for additional diagnostics and treatments for specific pediatric diseases or conditions; and”; and

(iii) in subparagraph (C), by inserting “(including drugs and biological products) and medical devices” after “therapeutics”.

SEC. 427. SURVEILLANCES.

(a) POSTMARKET SURVEILLANCES.—Section 522 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356) is amended—

(1) by striking subsection (a) and inserting the following—

“(a) POSTMARKET SURVEILLANCE.—

“(1) IN GENERAL.—

“(A) CONDUCT.—The Secretary may by order require a manufacturer to conduct postmarket surveillances of any device of the manufacturer that is a class II or class III device if the failure of which would be reasonably likely to have serious adverse health consequences;

“(ii) that is expected to have significant use in pediatric populations; or

“(iii) that is intended to be implanted in the human body for more than 1 year, or a life sustaining or life supporting device used outside a device user facility.

“(B) CONDITION.—The Secretary may order a postmarket surveillance of any device under paragraph (A) as a condition to approval of an application (or a supplement to an application) or a product development protocol under section 515 or as a condition to clearance of a premarket notification under section 510(k) only for a device described in subparagraph (A)(ii).

“(2) RULE OF CONSTRUCTION.—The provisions of paragraph (1) shall have no effect on authorities otherwise provided under the Act or regulations issued under this Act.”; and

(2) in subsection (b)—

(A) by striking “(b) SURVEILLANCE APPROVAL.—Each” and inserting the following—

“(b) SURVEILLANCE APPROVAL.—

“(1) IN GENERAL.—

“(A) by striking “The Secretary, in consulta-

“tion” and inserting “Except as provided in paragraph (2), the Secretary, in consultation”;

“(B) by striking “any determination” and in-

serting “Except as provided in paragraph (2), any determination”; and

(D) by adding at the end the following—

“(2) LONGER SURVEILLANCES FOR PEDIATRIC DEVICES.—The Secretary may by order require a postmarket surveillance of any device of more than 36 months with respect to a device that is expected to have significant use in pediatric populations if such period of more than 36 months is necessary in order to assess the impact of the device on growth and development, or the effects of growth, development, activity level, or other factors on the safety of the device.”.

(b) PEDIATRIC ADVISORY COMMITTEE.—Section 14 of the Best Pharmaceuticals for Children Act (42 U.S.C. 284m note) is amended—

(1) in subsection (a), by inserting “including drugs and biological products” and medical devices” after “therapeutics”; and

(2) in subsection (b)—

(A) in paragraph (1), by inserting “including drugs and biological products” and medical devices” after “therapeutics”;

and (B) in paragraph (2)—

(i) in subparagraph (A), by striking “and 505B” and inserting “505B, 510(k), 515, and 520(m)”; and

(ii) by striking subparagraph (B) and insert-

the following—

“(B) identification of research priorities related to therapeutics (including drugs and biological products) and medical devices for pediatric populations and the need for additional diagnostics and treatments for specific pediatric diseases or conditions; and”; and

(iii) in subparagraph (C), by inserting “(including drugs and biological products) and medical devices” after “therapeutics”.

SEC. 428. SEVERABILITY CLAUSE.

If any provision of this Act, an amendment made by this Act, or the application of such provision or amendment to any person or circumstance is held to be unconstitutional, the remainder of this Act, the amendments made by this Act, or the application of such provision or amendment to any person or circumstance shall not be affected thereby.

The PRESIDING OFFICER. The Senator from Massachusetts is recognized.

Mr. KENNEDY. Madam President, this week the Senate has the opportunity to set a new and better direction for the safety and the prescription drugs and medical devices that make such a profound difference in the lives of our people.

Every day, families across America rely on the Food and Drug Administration in ways they barely realize. When you put dimer on the table, they are counting on the FDA to see that the food is free from contamination. They trust the FDA to make sure that the drugs they take are safe and effective. From prescription drugs, to pacemakers, to chemotherapy, to the food we eat, the FDA impacts the health of hundreds of millions of Americans and monitors products that account for a quarter of the Nation’s economy.
The FDA should be the “gold standard” for safety, but its luster has been tarnished in recent years for failure to protect the American people from unsafe drugs. The public was shocked that the arthritis drug Vioxx was able to stay on the market for years, even though it nearly doubled the risk of heart attack and stroke. Antidepressants used by millions were found to increase the risk of suicide in adolescents. Millions of Americans have needlessly been put at risk, and they have done nothing to reform and strengthen the agency.

We are responding now with bipartisan legislation, that is the product of months of work in our committee. I commend my colleague and friend in this effort, Senator Enzi, for his work on this proposal that will improve the way FDA oversees the safety of drugs. Almost half of all Americans take at least one pill a day, so this legislation will make a difference in the lives of every American family. Our proposals were strengthened by our colleague from New Hampshire, Senator Gregg.

Safety is at the core. Our legislation was guided by the recommendations of the impressive report by the Institute of Medicine on the “Future of Drug Safety.” Its major recommendations for reform are included in this legislation.

This chart I have in the Chamber gives an overview of how the Food and Drug Administration: Build the internal epidemiology and informatics capacity in order to improve the postmarket assessment of drugs, have postclinical trial results in a public database, have regularly analyzed postmarket study results. This aspect about postmarketing surveillance is a key in terms of drug safety. We have included their recommendations. Another is: Give the FDA better enforcement tools. I am going to refer to that a moment. Another is Conduct regular evaluation of new drug safety profiles. We have included that. I will expand on that point in a few moments. Another is: Substantially increase drug safety resources available to the FDA. We have also included those.

So those were recommendations from the Institute of Medicine. We have reviewed the same subject matter. We evaluated those very carefully and we have taken the major recommendations in terms of safety and included them in this legislation.

A small number of health systems in America—or now referring to postmarketing surveillance and the use of electronic records—effectively links the surveillance of various kinds of prescription drugs to safety databases. These systems—Kaiser Permanente, Mayo Clinic, Veterans’ Administration—have the means to examine whether Vioxx and other drugs were being used effectively. They found that these drugs were being prescribed inappropriately, and they took steps to curb their overuse. As a result, they approved the use of these medications only for patients who had no other options. Overuse went down and safety improved.

The use of these databases should not be limited to the few health systems that already do that when research shows there is a need to make use of every aspect of modern health care technology to safeguard the public’s health. Mark McClellan, the former FDA Commissioner, calls these kinds of systems health IT for drug safety. Our proposal includes his recommendations.

Surveillance is essential, but effective action is needed when a safety problem is detected. Each drug has unique risks and benefits. There can be no one-size-fits-all approach to drug safety. That is why our legislation includes a flexible but effective program for safety. We call it a risk evaluation and management system. It can be tailored to the unique characteristics of each drug. It gives the FDA the authority to act when action is needed to protect public health, but it also contains safeguards to prevent such action from being imposed when there is no reason to do so.

For some drugs, it is essential to require postmarket studies. Yet FDA today lacks the basic authority to require such trials to be conducted. FDA can request them but it cannot require them, and has few ways to see they are completed. As a result, companies routinely promise to conduct studies that are never even started, much less completed.

This chart I have in the Chamber shows how, under current law, postmarket studies are not completed. These are the studies that have been requested by the FDA because they are for sound safety reasons. Yet 71 percent of them were not even started. Our legislation says when they are required and recommended by the company, they must move ahead.

In its recent report on drug safety, GAO pointed out the failure of the current system. Its report states:

In the absence of specific authority, FDA often relies on drug sponsors voluntarily agreeing to conduct such postmarketing studies. But the postmarketing studies that drug sponsors agree to conduct have not consistently been completed. The FDA has little leverage to ensure that the studies are carried out by imposing administrative penalties.

Our legislation solves this problem. It gives the FDA clear authority to require the conduct of the postmarketing studies when there is a public health need to do so, and it gives the FDA the ability to assess fines on those who ignore their responsibilities.

Data mining and postmarketing studies help detect problems, but the FDA needs the ability to take other action to protect the public health. Here, too, the current law is inadequate. FDA lacks clear authority to require measures to prevent their use effectively. The result is that lives are on the line, doctors are making the critical decisions. But because FDA’s authority is so unclear, it must first call the lawyers for their opinion as to whether the agency can act. The Institute of Medicine identified this major weakness of current law and called on Congress to give FDA the authority to require risk management plans and postmarket studies to protect the public health. These programs can be as simple as new information on a drug label or an advisory notice to doctors or as sophisticated as special monitoring of programs for patients who use a particular drug. The legislation does not mandate what these measures should be, but it does give the FDA the authority to make the right choice for the public health. This authority has been lacking in the past.

For Vioxx, it took 14 months to change the drug’s label to warn doctors and patients of the danger. Because FDA had weak authority, it had to ask the manufacturer to change the label voluntarily and very reluctantly. The manufacturer stalled and stalled. When patients are in danger, FDA should not have to wait to get legal opinions to decide how to protect health. It should be able to act immediately, and our bill gives them that authority.

In many cases, companies have hidden evidence of safety problems. Our bill addresses this abuse by including a public database of all clinical trials and their results. Listen to that: all clinical trials and their results. A company will no longer be able to hide the results if they do not show what the company wanted.

Some would say any increase in drug safety will inevitably decrease access to needed drugs, but that is a false argument. Consider the situation now. When the FDA is confronted with a new drug that may impose safety risks, or where additional study may be required, with little expectations that those risks will be mitigated by a voluntarist approach, the authority to ensure that the studies are going to be conducted—FDA might reasonably conclude the risks of approving the drug are too great and, therefore, not approved.

Under our legislation, the calculation is reversed. With this bill in place, FDA could allow patients to have access to the drug, secure in the knowledge that effective safety measures were in place. The only way to do that is we call on Congress to give FDA the authority to require risk management plans and postmarket studies to protect the public health. This authority has been lacking in the past.

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That is support from the organization that has been put together that is protecting safety for the consumers. That is the balance our legislation strikes: greater safety, hand in hand with better access.

As our debate continues, I will discuss additional aspects of the legislation, especially its new ideas for accelerating drug development, its renewal of our commitment to safe and effective drugs for children, and its provisions to improve drug science, and increased transparency of the FDA.

We are also working with our colleagues from Iowa and Kansas, Senator HARKIN and Senator ROBERTS, on ways to refine our provisions on direct-to-consumer advertising, to make certain they are consistent with the Constitution. We are working with Senator DURBIN and other colleagues on the committee on proposals for food safety on pet food. These bipartisan proposals are being readied for floor action shortly. I look forward to further discussions on them.

Our committee will continue to work to improve the ways FDA can monitor and improve food safety. In this new era of life sciences, medical advances will continue to bring immense benefit for our citizens. To fulfill the potential of that bright future, we need not only brilliant researchers to develop the drugs of tomorrow but also strong and vigilant watchdogs for public health to guarantee that new drugs and medical devices are safe and beneficial, and that they actually reach the patients who urgently need them.

Congress has ample power to restore the luster the FDA has lost in recent years. The legislation we are now considering represents a bipartisan consensus on the best way to get the job done.

I want to mention a few additional items. I am quoting now from the FDA’s report brief on 2006:

The Food and Drug Administration’s authorities must be clarified and strengthened to empower the agency to take rapid, decisive action when necessary and appropriate. FDA lacks the clear, unambiguous authority needed to enforce sponsor compliance with regulatory requirements and, instead, relies on the process of productive negotiations with the industry.

We have taken that. That is their No. 1 statement.

Included in that we have—this is the IOM committee.

The committee recommends that the FDA ensure that the FDA has the ability to require postmarketing risk assessment and to monitor and ensure the safe use of drugs.

We have done it.

These conditions may be imposed both before and after approval of a new drug, a new indication or a new dosage.

We have incorporated those concepts, as well as the identification of some new contraindications or patterns of adverse effects.

It talks about the distribution, conditioned on compliance, with agency-initiated changes and drug labels. We have achieved that. Conditioned on specific warnings, proposal materials, distribution conditioned on a moratorium, on direct consumer advertising. We have at least addressed that.

It also includes distribution of restrictions for special training, if need be, for physicians. It also has distribution conditions on the performance of specific medical procedures. It talks about clinical trials. FDA needs increased enforcement authority, better enforcement tools directly related to devices which should include fines and injunctions and withdrawal of drug approval.

We haven’t taken every one of these recommendations—not every one precisely—but we have taken the essence of these recommendations, and we have included those that are as a result of our extensive hearings. I could go on with this, and will later on, perhaps, but I won’t today. I wish to mention, finally, the various groups.

We mentioned the Alliance for Drug Safety and Access. I will include these letters of support. This is to Senators KENNEDY and ENZI:

On behalf of the Alliance for Drug Safety and Access, we write today to express our support for the goals of titles I and II of S. 1082, the Food and Drug Administration Reauthorization Act.

It will continue the timely access of patients to new therapies and will improve the ability of the Food and Drug Administration to ensure safety of drugs already on the market.

S. 1082 takes a life-cycle approach to the risk-benefit assessment of drugs and biologics—

This is so, though we have not included biologics in this proposal with regard to drugs as endorsed by the Alliance and recommended by the Institute.

We are pleased that this legislation gives the FDA the ability to continue to study the safety of drugs after approval, flexible enforcement tools to ensure compliance with the new safety protections, and additional funding to support these new activities.

It allows the FDA to approve drugs more quickly, knowing it will have the ability to respond to the patients if safety concerns appear afterwards.

This represents a group of at least 30 different health organizations that have followed this most closely.

We have a letter that has been sent to Senator Enzi and Senator HARKIN, talking about how this legislation impacts children and giving special recognition, as they should, to our colleagues and friends, Senator Dodd, who has been such a leader in this area, and Senator CLINTON as well, who has been so thoughtful in this area.

It points out the Pediatric Medical Device Safety Improvement Act of 2000 provides a comprehensive approach to ensure that children are not left behind in cutting-edge research and revolutionary technologies for medical devices. It talks about swift action and passage.

The American Psychiatric Association talks about how the provisions of this bill will ensure the Food and Drug Administration is equipped with the necessary tools to enhance its consistency, transparency, and accountability in ensuring the safety of drugs post-approval.

The American Psychiatric Association advocates for patient safety and supports further postmarket research of medications to ensure the safety and efficacy of medications, especially for mental illnesses. The letter says:

We look forward to working with you to rebuild the Administration’s reputation and creating a universal drug safety monitoring system that is reliable and dependable.

They indicate their strong support for the legislation.

Again, another letter of support from the American College of Pharmacy, and it talks about the particular emphasis. Right now, they have achieving science knowledge, which improves their decisionmaking regulatory oversight. Science knowledge grows on a daily basis. We know we are in the life science century. That agency, the FDA, to have the best efforts of science and science knowledge, and we have included special provisions to enhance that particular effort, and this association has recognized that.

We also have a letter from the Consumers Union, and they talk about their strong support for this legislation. They oppose any weakening amendments of this important legislation. It also has some reference to section 302 of the recent polls who point out that 96 percent of Americans agree that Government should have the power to require warning labels if safety problems are identified, with 80 percent of those strongly agreeing to that philosophy. Right now, the FDA has to negotiate safety warnings.

It also talks about the strong support the American people have for the FDA, which doesn’t have the authority to conduct studies to be performed once the drug is on the market. The American people are way ahead of us. They also show strong support to make public the clinical trial studies. This bill does that. Sixty-eight percent of the American people strongly agree the drug studies should be made public.

Eighty-four percent of the American people believe advertising for prescription drugs with safety concerns should be prohibited. Then it continues: The survey shows that drug ads lead to overprescribing, with 38 percent strongly agreeing and 59 percent agreeing that the Government should restrict advertising by pharmaceutical companies altogether. We have done that. Eighty-four percent of the American people strongly agree the drug studies should be made public.

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in the RECORD and the references to some of the editorials from across the county—I am not going to ask that they all be printed, but I will ask that selected ones be printed in the RECORD and that other newspapers be referenced and supported.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

THE ALLIANCE FOR DRUG SAFETY AND ACCESS,
April 17, 2007.

Hon. Edward M. Kennedy, Chairman, Senate Health, Education, Labor, and Pension Committee, U.S. Senate, Washington, DC.
Hon. Michael B. Enzi, Ranking Member, Senate Health, Education, Labor, and Pension Committee, U.S. Senate, Washington, DC.

Dear Senators Kennedy and Enzi:

On behalf of the Alliance for Drug Safety and Access (ADSA), we write today to express our support for the goals of Titles I and II of S. 1082, the “Food and Drug Administration Revitalization Act.” We appreciate your leadership in this bipartisan legislation, which will both continue the timely access of patients to new therapies and improve the Food and Drug Administration (FDA) to ensure the safety of drugs already on the market. While we would appreciate the opportunity to continue to work with you in strengthening this legislation as it moves forward, we urge the Committee on Health, Education, Labor and Pensions to report out this legislation for consideration by the full Senate.

ADSA members advocate on behalf of over 31 million patients, including those suffering from spinal cord injuries, paralysis, multiple sclerosis, leukodystrophies, Tourette Syndrome, and over 6,000 known rare diseases. Our members also represent over 100,000 providers of care to pediatric patients and individuals with mental illnesses.

S. 1082 takes a life-cycle approach to the risk-benefit assessment of drugs and biologicals, as endorsed by ADSA and recommended by the Institute of Medicine. We see this legislation giving the FDA the ability to continue to study the safety of drugs after approval, flexible enforcement tools necessary to ensure compliance with safety and efficacy protections, and additional funding to support these new activities. Allowing the agency to act on clear safety signals could actually allow the FDA to approve drugs more quickly, knowing it will have the ability to respond on behalf of patients if safety concerns appear post-market.

We know that you share our interest in both speeding life-saving drugs to patients while also protecting the integrity of the post-market. And, we believe that with sufficient resources both goals are achievable through the legislation you have authored. ADSA is working with you to move forward these goals and toward strengthening provisions of your legislation related to patient access to clinical trial information and the FDA’s relationship with patient communities.

Thank you again for your leadership on this critical issue and the opportunity to share our views.

AIDS Treatment Access Coalition
American Academy of Pediatrics
American Academy of Child and Adolescent Psychiatry
American Psychiatric Association
Christian Women’s在家 Foundation
Elizabeth Glaser Pediatric AIDS Foundation
National Multiple Sclerosis Society
National Organization for Rare Disorders (NORD)

PARKINSON’S ACTION NETWORK TURINTE SYNDROME ASSOCIATION.

April 17, 2007.

Hon. Edward Kennedy, U.S. Senate, Washington, DC.
Hon. Michael B. Enzi, Ranking Member, Senate Health, Education, Labor, and Pension Committees, U.S. Senate, Washington, DC.
Hon. Christopher J. Dodd, U.S. Senate, Washington, DC.
Hon. Hillary Rodham Clinton, U.S. Senate, Washington, DC.

Dear Senators Kennedy, Enzi, Dodd and Clinton:

As organizations working to ensure better health care for the nation’s children, we write to extend our support for the commitment to children’s health and to express our support for legislation to reauthorize the Pediatric Research Equity Act (PREA) and the Pediatric Research Equity Act (PREEA) to improve children’s access to safe medical devices. We are very pleased that PREA and PREEA reauthorization language and S. 830, the Pediatric Medical Device Safety and Improvement Act, have been included in the Chairman’s mark of S. 1082, the “Food and Drug Administration Revitalization Act,” for consideration by the Senate Health, Education, Labor, and Pensions Committee.

Over the past decade, Congress has enacted bipartisan legislation that has dramatically increased the number of drugs tested and labeled for children. The PREA requirements are extraordinary—over 336 requests have been generated for over 760 pediatric studies, resulting in over 387 drug labeling changes for children. Sen. Dodd’s BPCA reauthorization language strengthens this very successful existing program in several important ways, including ensuring prompt label changes, requiring that all study protocols and results be made public, improving adverse events reporting for children, and identifying and addressing unmet medical needs and treatments for children’s diseases. In addition, the BPCA language includes a reasoned approach to address the small percentage of drugs for which the exclusivity provision has far exceeded the incentive it was intended to provide pharmaceutical companies.

S. 965, the Pediatric Research Improvement Act (PRIA), introduced by Sen. Clinton and included in the Chairman’s mark, reauthorizes the Pediatric Research Equity Act of 2003 (PREA), which requires drug manufacturers to test their products for use in children. This law ensures that children are not a therapeutic afterthought and that has generated impressive and invaluable safety and dosing information for children. Since the 2003 passage of PREA, 55 drugs have new or improved labels for children. These drugs range from treatment of ear infections to the prevention of rejection of organ transplants. S. 965 places children on equal therapeutic footing with adults by creating the presumption that medicines coming onto the market for illnesses and conditions that occur in children will be labeled for pediatric use and be available in formulations (e.g., liquids, chewable tablets) that children can take.

The recent passage of the BPCA and Improvement Act of 2007 provides a comprehensive approach to ensuring that children are not left behind as cutting-edge research and innovation move forward. The Pediatric Research Equity Act (PREA) is the largest and most comprehensive piece of legislation ever to address the lack of medications as a matter of fact, not chance. We are grateful for your long-standing leadership and commitment to improving the health of our nation’s children and look forward to working with you to pass this critical legislation and support for the goals of Titles I and II of S. 1082, the “Food and Drug Administration Revitalization Act.”

American Academy of Pediatrics
Elizabeth Glaser Pediatric AIDS Foundation
AIDS Alliance for Children, Youth & Families
American Academy of Child and Adolescent Psychiatry
American Cancer Society
American Psychiatric Association
American Public Health Association
Arthritis Foundation
Association of School Medical Pediatric Association
Children’s Cause for Cancer Advocacy
National Association of Children’s Hospitals (N.A.C.H.)
National Organization for Rare Disorders
National Research Center for Women and Families

Society for Pediatric Research

AMERICAN PSYCHIATRIC

The American Psychiatric Association (APA) would like to thank Senators Edward Kennedy and Mike Enzi for their introduction of the bipartisan bill, “Enhancing Drug Safety and Innovation Act of 2007” (S.484). The provisions of the bill will help ensure that the Food and Drug Administration is equipped with the necessary tools to enhance its consistency, transparency and accountability in assuring the safety of drugs post approval.

The APA is the national medical specialty society representing more than 37,000 psychiatric physicians nationwide. We specialize in the diagnosis and treatment of mental and emotional illnesses and substance use disorders. APA advocates for patients’ safety and supports post-market research of medications to ensure the safety and efficacy of medications used to treat mental illnesses.

The APA thanks you again for your dedication and commitment to enhancing the nation’s drug safety monitoring system. We look forward to working with you to rebuild the Administration’s reputation and creating a universal drug safety monitoring system that is reliable and dependable in order to make wise decisions. As your staff move forward with further action on legislation, Lizbeth Burch, Deputy Director, Government Relations for the APA or Chitrani Birbal, Federal Legislative Coordinator.

Sincerely,

James H. Scully, Jr., M.D., Sc.D.
CEO and Medical Director,
American Psychiatric Association
For full access to this document, please visit the source link below:

The Society for Cardiovascular Angiography and Interventions is a professional association representing 3,700 invasive and interventional cardiologists. SCAI supports excellence in cardiovascular catheterization, angiography, and interventional cardiology through physician education and representation, and quality initiatives to enhance patient safety.

Fortunately, cardiovascular disease is far less common in the pediatric population than in the adult population. The bad fortune does however frequently lead to unique challenges for the pediatric interventional cardiological who treats these patients. The ED's of cardiac centers are clinical and we are more frequently solving those problems, saving children's lives and avoiding the trauma of surgery. Other challenges, and perhaps the most frustrating ones are related to obtaining the safe medical devices necessary to treat these patients. Devices that are available to our colleagues in Europe are not available in America. We support the FDA's efforts to ensure that only safe and effective medical devices are used on patients in our country, but when the entry barriers into the American markets are so high that manufacturers refuse to enter—some patients suffer and die needlessly. Required is an appropriate balance between mutually exclusive goals of safety and availability.

We are especially pleased that your legislation will require the FDA to issue guidance to investigational device committees (IDCs) on how to appropriately consider the use of the humanitarian device exemption (HDE) at their institution. When HDE devices are not part of an ongoing trial, IDC's (which focus on reviewing the care of patients in trials) are sometimes confused.

We believe that the FDA explicit statutory authority to extrapolate from adult to pediatric patients in appropriate situations could help FDA officials expedite their review of some pediatric medical devices.

We applaud the provision that allows companies to make a profit on HDE devices designed for children. This change will encourage the development of more devices by providing an opportunity for profit and also by reducing concerns about audits, specifically those assumptions which could determine a profit was made when a manufacturer calculated their financial situation differently. We note that the 4,000 cap is arbitrary and far below the patient limit that is placed on orphan drugs. We believe that more devices will be available to pediatric patients and those with congenital heart disease if that cap is raised. We encourage you to consider such an increase either as a part of this legislation or broader FDA reform legislation.

We look forward to working with you and your staff to support passage of this legislation and thank you once again for your efforts. Our contact person for this effort is Wayne Fisher and may be reached at (202) 375-6341 or wpowell@scai.org.

Sincerely,

GREGORY J. DEEMER, M.D., FSCAI, President


Hon. EDWARD KENNEDY, Chairman, Senate Committee on Health, Education, Labor, and Pensions.

Hon. MIKE ENZI, Ranking Member, Senate Committee on Health, Education, Labor, and Pensions.

Mr. ENZI. Madam President, I wish to thank the Senator from Massachusetts, Senator Kennedy, for his outstanding presentation on what is in the bill.

I rise to speak about S. 1082 as well. It is a comprehensive bill to enhance drug safety and provide key resources to the Food and Drug Administration—the FDA—for the review of new drugs, for the review of medical devices, and to ensure that drugs and devices for children are safe and effective. It has been a long and careful road for this bill.

The Senate Committee on Health, Education, Labor and Pensions embarked on a top-to-bottom review of the FDA's drug safety and approval process over 2 years ago. This bill is the culmination of our review and the input of hundreds of stakeholders. I will speak for a moment discussing why the drug safety components and the changes that are being made are so critical to restoring the
peace of mind to Americans who want to be assured the drugs they purchase to address illnesses and chronic medical conditions can be relied on and trusted.

“Bipartisan” is a word that is kind of thrown around in this Chamber a lot, and sometimes it means that one person from one party joins several people from the other party. For Senator KENNEDY and me, bipartisan means you actually work together to find out what the problem is, what the potential solutions are, and how you can meet those needs. I mentioned it has been a long process—over 2 years—and it is still a work in progress—and we are making progress.

We held hearings on the FDA. A lot of those hearings were held in the heat of the moment, when certain drugs were having problems, and we recognize that is a problem. One of the problems with Congress is we usually see that if it is worth reacting to, it is worth overreacting to. We have always taken a very careful view in our committee to make sure that was not the case.

Other committees held hearings on the FDA, even though the FDA is under the jurisdiction of our committee, and we have no problem with that. We have taken the suggestions we have gotten through those hearings and considered them for this legislation. We have put together a list of principles, and we took that to the stakeholders to see what all the people involved thought about the principles we had. Then we did the tough part. We drafted the details. It is easy to sell concepts, but details are tough. Until you have those details put down in writing and have people look at every word that is in them, you can’t tell whether you have a bill. But we went through that process. We took it back to the stakeholders. We redrafted. We filed that back, more work. This year, we have had more hearings on FDA, and we have had a markup. That is when all the Committee Members are offered a chance to request or suggest amendments to the bill.

We probably had about 50 amendments and worked on the 12 major categories of amendments. Some of those were worked into the bill as part of the markup. Some of them have been put into the manager’s amendment. This is a work in progress. We are still looking at some of those, figuring out what is needed and how to get there. I appreciate the cooperation we have had from the Members with their suggestions and the staff of the Members with their suggestions, because throughout the last weekend, there were hours and hours and hours spent by Senator KENNEDY’s staff and my staff and the interested Senators and their staffs to arrive at the best bill possible. We are not there yet. We are close. That is the way we work on bills—a long process with decisions being made up to the last possible moment so that we can have the best possible solution for the people of this country. That is bipartisan.

It was mentioned there have been some hearings on food safety. Recently, there has been some real criticism of the FDA. We held hearings on food safety. I don’t want the people of this country to think it is all bad. In fact, I was amazed that three Federal agencies have to work together on a food problem. The CDC, the Department of Agriculture, and the Food and Drug Administration have to work together because each of them has a role in discovering whether there is a problem. I was amazed to find out that with as few as 50 cases spread out across the whole United States, they can diagnose and determine there is a problem and get products off the market. If you are not amazed with that, you are not paying attention. We have agencies that work together, and they work together in critical ways for the people of America. They can notice, with a real small sampling—when you consider the millions of people in this country, the millions of people who are being fed every day—they can recognize a supply shortage and get the harmful product off the market. It would be nice if they could prevent that. They are working on that.

But when you consider the number of producers in this country and other countries, they have a tremendous job, and we have to be sure they have the tools to do that job as well. But that is a job that is in addition to the drug approvals. This bill concentrates on the drug approvals.

Vioxx was one of the triggers of these discussions. As we saw with Vioxx, the FDA doesn’t have enough tools to deal with newly identified risks when those risks become evident after a drug has been on the market for a long time. Most of the FDA’s current authority is based on information and plans available at the time of approval. They have a massive job determining if a drug is ready to go to market. What is amazing is that once they have given that approval, their options are very limited. Now, that creates a little bit of a dilemma for them. They don’t know everything that will happen with that drug. Yes, it has been through clinical trials. What is a clinical trial? It is a controlled study of people taking the drug, and sometimes people who are not taking the drug—a controlled study. Once that drug is approved, it goes out to the whole market—not controlled people, not people that we know what other drugs they are taking or what other kinds of things they are doing. That can have a different result than under a controlled situation.

The FDA’s choice has been to take the information and approve the drug and then monitor the drug, but have relatively few tools after that point. What can be the result of that? The FDA can say let’s really be careful before we approve this because we will have expended our toolbox. They have said: If you will give us a bigger toolbox for after the approval, we can approve the drugs quicker. We can have some assurance that because of the labeling, things will be fine. But we won’t have expended as much about preapproval because we will have tools after approval—tools for quick recognition of additional problems as it goes out to the major markets.

We need to have that happen if we are going to have safe drugs in this country. We have always relied on that, and we expect that. The FDA, for the most part, has delivered.

So much more needs to be done to be able to clarify the FDA’s authority, to give them the bigger toolbox so that FDA can proactively react to additional safety information whenever that safety information is discovered. That is the purpose of this underlying legislation. The FDA does have the authority to manage the risks of drugs—for drugs such as novel cancer therapies approved under subpart H for accelerated approval. Is that faster approval? The FDA has the authority to apply restrictions on distribution for those drugs at the time of approval to provide further safeguards against misuse and adverse reactions. However, if such a risk is determined after the drug is on the market, the only option the FDA has now is to pull the drug from the market, disrupting patient care.

Some of the people who have that drug are deriving a tremendous benefit from it and are not having the adverse reaction and would feel hurt if it is pulled away from them as the only option that the FDA has. The FDA does not want to disrupt patient care. Those who need the protection they want to help, those who don’t need the protection won’t be hurt. We don’t want to disrupt patient care.

The option now, I repeat, is to pull the drug from everyone. Then, of course, they can pull it back on the market so it can apply those special risk management tools. We have chosen to give the FDA in this bill the authority to impose those restrictions after a drug comes on the market, too, so there is no disruption in patient care.

The bill also makes several key improvements to get their information through advertising and labeling. The changes ensure that patients get access to new and changing information in a timely manner. As Vioxx made clear, FDA has very little authority to require labeling changes postmarket. Those changes are primarily negotiated and they don’t have any time limits on the two parties coming to an agreement to the labeling change.

Now we have included provisions that ensure that those discussions between the FDA and a drug manufacturer come to a close, rather than relying on the FDA’s “nuclear option.”
which is pulling the drug from the market. It hurts a lot of patients and disrupts their care.

Imagine a system that gives the FDA, through sound science and remarkable innovation, the tools to get drugs to the market quickly and confidently, especially when lives are on the line and people need new drugs and therapies. Imagine a system that gives the FDA new authority to take swift, appropriate, and decisive action to ensure patient safety and protect consumers when new information comes to light to expose unexpected risks. We can make this a reality with the passage of this bill.

FDA doesn’t have a current mechanism for active, routine surveillance of potential safety problems. Thus, it cannot as readily detect safety problems after a drug has been put on the market—short of a catastrophe. FDA has minimal authority to require additional observational studies or clinical trials before a drug is already on the market. FDA cannot even make companies finish studies they have agreed to pursue concerning safety impacts on patients.

Given the current FDA limitations, I strongly felt it was necessary to correct those problems and ensure that FDA has the right tools and toolbox to address drug safety after the drug is on the market. That is why this bill creates the risk evaluation and mitigation strategy, or REMS. The REMS gives FDA a full toolbox of options for dealing with potential safety problems, even if they are discovered after a drug is first marketed. I hope you are noticing a trend.

With this new toolbox, FDA has the ability to identify side effects after the drug is marketed through active surveillance. FDA also has the authority to request a separate study or clinical trial to learn more about a particular potential safety problem. FDA can also obtain timely label changes for the first time under the new REMS system.

How does this all work together? A house cannot be built without a foundation. Routine, active safety monitoring using large linked databases—what I like to call “health IT for drug safety”—is the foundation. Risk evaluation and mitigation strategy, or REMS, is the house.

I thank the Senator from New Hampshire for all of his work on health IT for drug safety and his emphasis on being able to have the right surveillance and the right trigger to be able to put these things into place at an appropriate time. In designing that house, you can have a small, simple house, or you can have a big fancy house. The size and complexity of your house should match your needs. The REMS is customizable, buildable to address whatever risks are present for the drug in question. The REMS allows you to build for your house as your family grows, for example. You can also move into a smaller home if you find you don’t need so much space.

Let’s talk about how this would work. Let’s say drug A treats high blood pressure, has very few side effects. Therefore, the label and use of routine, active safety monitoring will be enough to manage the risk. Drug A doesn’t need a REMS. However, drug B, which also treats high blood pressure, has serious side effects, including occasional liver failure. The label and use of routine, active safety monitoring is not enough to manage the risk. Therefore, drug B needs a REMS.

The REMS will include extra warnings on the label, perhaps periodic letters to doctors to remind them of the risks, and require testing and a system to test patients for liver enzyme levels before they are allowed to fill a prescription. As I said, not every drug needs a REMS. However, every drug will need a very active FDA with all of the necessary tools to identify and quickly manage additional risks.

Like everyone who purchases a product for myself, my children, or my grandchildren, I want the assurance that the product is safe and beneficial. This bill gives the FDA the necessary resources and tools so that moms and dads are able to trust that product at the pharmacy counter and know that it is safe and effective.

As I mentioned, this bill is still a work in progress. There are a dozen amendments to several of which have been in the managers’ amendment, and several are still being worked on. We do want faster drug approval, but we want assurances that as the whole population becomes a clinical trial, connection can be made quickly to any problems without the need to pull the drug off the market and away from those who could benefit. I will have more to say about other potential things that will not be in this bill that I may wish to withdraw the bill or maybe be adverse to what we are trying to do in the bill, and some of them that have not had enough study yet. I will comment on those as they come up, if they come up at this point. I yield the floor.

The PRESIDING OFFICER. The Senator from Ohio is recognized.

Mr. BROWN. Madam President, I appreciate the words of my colleague, the Senator from Wyoming, Mr. Enzi. S. 1082 is a major piece of legislation that aims to—and will—achieve a profoundly important goal. It will improve the public health.

When it is riskier to take a drug than to skip it, the public health is compromised. When a lifesaving prescription drug or medical device languishes at the FDA because of backlogs in the approval process, the public health is compromised. When pediatricians are forced to fly by the seat of their pants because there is no data to guide the use of a drug or medical device in children specifically, the public health is compromised. When FDA has the responsibility but lacks the tools to assess the safety or effectiveness of a new drug or device, the public health is compromised.

S. 1082 tackles each of these problems. It gives FDA more authority and drugmakers a greater incentive to assure the safety of medicines before and after drug approval.

It reauthorizes user fees, an additional source of funding that enables FDA to speed up the approval of new prescription drugs and medical devices.

It reauthorizes financial incentives to encourage drugmakers to test their products for use in children, and it establishes similar incentives for medical device manufacturers.

At the same time, it puts more teeth in FDA’s authority to require studies when the health or safety of children is clearly at risk.

S. 1082 creates a new institute charged with developing up-to-date methods of assessing the safety and effectiveness of cutting-edge medical interventions.

You are no doubt going to hear complaints about this bill. Some Members will tell you that it is overly bureaucratic. Coincidentally, that is exactly what the brand-name drug industry says about it.

Nobody can accuse the drugmakers of intransigency. They consistently place their own self-interest ahead of health care safety, access, and affordability.

The drug industry doesn’t want FDA to take additional steps to prevent prescription-drug-related injury or death, although the drug industry is open to being shielded when those tragedies happen. When Members of this body stand up and claim this bill is too bureaucratic, don’t buy into it.

This is a carefully crafted bipartisan bill. It is less stringent than consumer groups want and more stringent than the drug industry wants. In other words, it is a compromise—a compromise that will improve the public health. There will be amendments to this bill. As Members on both sides of the aisle review them, I urge them to remember this: Amendments that improve drug safety will benefit consumers and reduce health care costs. Amendments that increase price competition in the prescription drug market will benefit consumers and reduce health care costs. And amendments that weaken this bill or block price competition in the marketplace will benefit—who else—the brand-name drug industry.

The drug industry has more than 3,000 lobbyists here and in the House of Representatives. Last year alone, the drug industry spent more than $150 million lobbying at the Federal level. That is quite a home court advantage. As one might imagine, anybody who has lost loved ones to unsafe drugs and people who cannot afford to fill their prescriptions don’t have quite as deep pockets as the drug industry. Still, this is a drug safety bill, this is a drug access bill, this is not a drug industry bill.

I hope every Member will consider the bill and every amendment in that
I thank all of us are reassured we are on the right track, not only as a result of the extensive hearings we held but the very extensive review the Institute of Medicine gave, a highly regarded, distinguished, respected agency. During the course of the hearings, we had very good attendance and exchange of the representatives of the Institute of Medicine, and we have worked with them subsequently in terms of the language and refinements.

As we said, we didn’t just copy everything, but the essential aspect of the safety provisions in our legislation is, quite frankly, preferable. I think it is working closely with Senator Enzi as well on the other areas of public policy in terms of food safety and the follow-on biologics which are very much involved in as well.

I thank the Senator from Ohio for his comments. We know him for being someone who has spent a great deal of time making sure safe drugs are going to get to people who need them. There are many dimensions to this debate. He has certainly been one whom, over the course of time, on the Health Committee in the House of Representatives, I have had an opportunity to work with on a number of health issues. He has been very active and involved with this issue on our committee and also on making sure we are going to have not only safe drugs but also have access to them.

I will take a moment, because I think it is probably worthwhile in the opening presentation, to go through one of the many safety crises we had with prescription drugs and look at what existing authority was there and then how that could have been handled under that legislation.

People will look through this legislation—it is not all that long, but it is complex. The results are enormously important and very basic and very fundamental. I use Vioxx as a point of illustration, which I think most Americans remember the circumstances where hundreds of thousands of Americans with heart needs were put at risk.

This was really the question—this is the FDA Reauthorization Act—how we could have averted the Vioxx disaster. I think people are beginning to study this legislation, and also our colleagues who are reviewing the record ask about how this legislation can make a difference on a particular drug. This chart is very useful in understanding that point.

Can the FDA quickly detect safety problems with a drug? Vioxx, no. Under our legislation, the answer is yes. Senator Enzi gave an excellent presentation on how we can do that using the most modern technology, using the greatest availability of public and private collections of adverse reactions, and bringing those together within the agency. We know all of that is going to gradually expand in the future, so that agency will have the best of science. They will be able to protect safety. The answer with this legislation is yes.

Can the FDA require label changes to warn of safety problems? The answer with Vioxx was no. They spent 14 months trying to negotiate the issue of the labels. Under our legislation, they would be able to do that.

I mention that as one of the things they will be able to do. They can either take the pharmaceutical—they have the power to do it. It is not done because you don’t want to take the chance that there may be some people in the public, given the health risks, who are justified in taking that particular medication—they have the power to do it. It is not done because you don’t want to take the chance that there may be some people in the public, given the health risks, who are justified in taking that particular medication, they might not be. Can we put label changes on? They would be able to do it very quickly.

Are companies stopped from hiding safety problems? This comes back to what both Senator Enzi and I referenced in making public clinical trials. That is enormously important. Senator Mikulski has been very involved in the transparency parts of this legislation. I hope those in the Senate who are interested and concerned about the issues of transparency might take a moment and talk with Senator Mikulski. Hopefully, she will speak on these issues because she has made a very important contribution.

Part of this transparency is that these clinical trials will be available, to understand the significance of any safety problems, which hasn’t been the case, but they will also be available to people who may want to enroll in a clinical trial for a particular illness, a particular disease and know there is a particular trial that is going to take place and say: I think I want to enroll in that particular trial because it is taking place. People don’t know that now. That is enormously important and valuable to people. Whoever becomes part of a clinical trial and finds out a particular drug can be lifesaving, it is of enormous importance and consequence.

We have knowledge of the clinical trial in terms of safety but also in terms of the opportunities that are coming up, particularly in this period of life sciences, with these extraordinary breakthroughs we are seeing now—the mapping of the human genome, sequencing of the gene, and I think before long in stem cell research we are going to see incredible possibilities, and people are going to want to become part of clinical trials.

But with regard to responding to this—are companies stopped from hiding safety problems, yes; does FDA have flexible tools to enforce safety decisions—it was expressed very well by Senator Enzi. He wanted that the big toolbox. That is the way we should look at it. There is a variety of tools in that toolbox. He explained that. There are a number of different ways that those who are committed to safety can utilize these different tools to ensure safety. Some may require a heavier hand than others. What we want, obviously, is to do enough to provide protection but not enough to discourage use where it is necessary.

Finally, is FDA the gold standard for protecting public health and assuring access? We are strongly committed to making sure it is. We believe that with the safety protections we have put in the bill and also the inclusions, working with the pharmaceutical industry in terms of PDUFA and MDMFA to try to always find ways of expediting the consideration of these lifesaving drugs—that was one of the very important purposes, giving emphasis for example for many of the health issues that are of such concern to the American people: cancer, cardiovascular issues, Parkinson’s disease, Alzheimer’s disease, juvenile diabetes disease, the AIDS virus, and many others—we can try to move toward a better relationship between the companies and FDA, in the sense that we can move this process, move more quickly, but do it more safely. That is what we are attempting to do, to ensure, in this life science century, that these breakthroughs do to be available and also do it in a way that will be safe. This is an example of one of the challenges the country has been facing recently, between the old and the new.

We have tried this afternoon to describe in greater detail the various provisions of the legislation. We have not spent a great deal of time on the provisions which were supported by the Senator from Wyoming and myself with regard to children, so-called biologics. We recognize, through the good work of Senator Dodd and Senator Clinton, the fact that children are not just little grownups; they are children. Many of these substances have different reactions, different impacts in terms of their development. It has taken special kinds of focus and attention to try to be more responsive to those needs. Our committee has done that. As a result, we see strong support from the American Pediatric Society and others for the changes we have made, as well as other provisions and modernized provisions to encourage greater research but also to protect the interests of children. We have
strong support from the various groups that have spent their lifetime speaking for children.

We will probably have an opportunity to get into some greater detail in discussion of those provisions. As I mentioned in our comments, we have recognized the importance of developing and upgrading the science function in this agency. We think the FDA—at a time we are having breakthroughs in knowledge, in science, in medicine—we want to make sure that the FDA is out there on the cutting edge with respect to these breakthroughs and know where they are going. We have paid particular attention to those as well.

Then the Udall-Reagan Foundation is to try to look longer term at ways in which the agency functions and take a longer look to make recommendations to the private sector and to the public sector about how it can be more effective generally. That kind of idea has not been in the past. I think very well be enormously valuable and helpful to legislators in the future.

We have tried to get legislation that will provide the protection presently, help and assist breakthrough technologies, and provide a faster track for the American people in the future, but to do it with greater safety protections for all families, and to recognize we are at a time of breakthrough science, which that agency has to have, and there are going to be breakthroughs in different modalities that agency working in the future. We have tried to build into this an agency that can give us advice so we can be more effective in the future.

I hope we will be able to move ahead. I know we have gone through, in careful detail, the administration's positions over the weekend. We certainly respect those. We have had a good exchange with the administration. For those who are interested, if they read through the letter they sent to Senator Enzi and myself, and then if they look at the recommendation of the Institute of Medicine, they will find we are much closer to the recommendations of the Institute of Medicine. We may face some amendments in those areas. We look forward to having a good discussion and debate and the opportunity to expand some of the points we have made this evening.

Mr. KENNEDY. I thank particularly Secretary Leavitt and those people on his staff. We had discussions over the weekend. They had some suggestions for changes. We asked for more detail on those changes. We also asked for them to be prioritized. I was pleased they were delivered within a matter of a very short period of time. That shows people in Government can work together and that they do work on the weekends to get those things done. A lot of people think when we go into recess, all work stops. We here stops. But there are dedicated staff who put their best effort into getting together and working together, sometimes in very tense situations and long hours, mostly through the night—last night. Then they have to draft what has actually been decided. It is a very difficult process. We owe them a great deal of credit. I want the American people to know that, too.

I yield the floor.

The PRESIDING OFFICER. The Senator from Massachusetts is recognized.

Mr. KENNEDY. Madam President, we have the legislation before us. We hope those who have an interest and have some amendments, will be in touch with Senator Enzi and ourselves through this late afternoon, early evening, or first thing in the morning. We want to try to address those amendments early in the day, as early as we can. We understand both parties have their lunches and have important matters to discuss, and I am sure this will be among them. But we are ready for any of the amendments, as I underlined what Senator Enzi has said. We will give great participation in our markup with the members of our committee. As he mentioned as well, we have had enormous involvement of our committee members and many others over the period since the legislation was reported out of our committee until now.

We are still in the process of trying to do business because we think this legislation is so important. We hope those who do have amendments will be in touch with us at the earliest possible time.

MORNING BUSINESS

Mr. KENNEDY. I ask unanimous consent we now go into a period of morning business, with Senators permitted to speak therein.

The PRESIDING OFFICER (Mr. WHITEHOUSE). Without objection, it is so ordered.

IN RECOGNITION OF CIMARRON-MEMORIAL HIGH SCHOOL

Mr. REID. Mr. President, it is my privilege to congratulate the High Rollers team of Cimarron-Memorial High School in Las Vegas. This team recently won a championship victory at the FIRST Robotics Competition at the Georgia Dome in Atlanta.

The FIRST Robotics Competition, otherwise known as the "Superbowl of Smarts," is designed to inspire young people to pursue opportunities in science and technology careers. The competition challenges teams of high school students and their mentors to construct robots over the course of 6 weeks while adhering to competition guidelines and design specifications.

Founded in 1989 through the vision of inventor Dean Kamen, FIRST is a not-for-profit whose acronym means "For Inspiration and Recognition of Science and Technology." As a result of Mr. Kamen's leadership, FIRST has grown into one of the leading robotics competitions in the entire country. Students from more than 1,300 high schools and 23 countries participated in this year's event.

The High Rollers team from Cimarron paired with a coalition of two high school teams from South Windsor, CT, and Worcester, MA, to win the national championship title with a thrilling 59 to 54 victory in the final round. In honor of their victory, the students will meet with President Bush and attend a congressional reception where they will demonstrate their robots and share their achievements with Members of Congress.

The Cimarron team has a long tradition of success that is reflective of their hard work, dedication, and creativity as well as Cimarron-Memorial High School's strong commitment to academic excellence. They were among the top participants at the FIRST Las Vegas Regional held in March on the campus of the University of Nevada, Las Vegas and were named the Las Vegas Regional champions in 2005 and 2006. I know that every Member of the Senate joins me in honoring the extraordinary accomplishments of Cimarron-Memorial High School and its FIRST Robotics National Championship team.

HONORING MARGARET BLACKSHERE

Mr. DURBIN. Mr. President, I rise today to honor Margaret Blacksheere, a woman for whom I have great respect and admiration.

Margaret Blackshere has been involved in the labor movement for more than 40 years and remains deeply committed to helping the working families of Illinois. Until February, she served as president of the 1-million-member strong Illinois AFL-CIO, the third-largest state labor body in the country. Over the years, she has never been afraid to roll up her sleeves and join the picket line or to lead the march.

Margaret always arrived first and left last. She knows that America's working men and women—those who perform some of the most demanding yet vital tasks in our society—are the real heroes. For her, her service has been a privilege an opportunity to fight for rights she believes should be guaranteed.

Margaret didn't start out to be a labor leader; she began her career as a kindergarten teacher in Madison, IL. She became involved in the labor movement almost by accident, after she and her fellow teachers were repeatedly passed over for raises they had earned. In response, she and her colleagues mobilized to pass a referendum that would raise their wages. It wasn't just about the money. It was about having a voice.

This early effort led to a job with the local Illinois Federation of Teachers affiliate in Madison. Through hard work, Margaret rose to become state-wide vice president of the IFT.