a swimming pool. They can pay their superintendents whatever they want. They can take, not the 5-percent cap we have on administration, they can say we want to use 20 percent for administration.

Also, we have said in the past that these moneys should be used to supplement, not supplant, State efforts. That is taken away. So what can happen is all the money we put out to an area now that normally would go for vocational education or education technology or safe and drug-free schools, all of that money now doesn't have to be used for that, and the State can say, ''OK, we're not going to put the money in, we'll just use the Federal dollars and we'll take our money for roads, bridges'' and whatever else the State wants to do with their money, thus downgrading the amount of funds that actually go into education.

I know it was said by the Senator from Washington, ''Well, not all knowledge resides in Washington; do we know what to do best in local school districts? The answer to that, obviously, is no. Keep in mind this money is not forced on the States. We are just saying this is Federal tax money that we vote to collect. And, yes, we do have a right and an obligation under the Constitution of the United States to decide how that money is to be spent.

We don't have the obligation or the right to decide how States spend their own State tax dollars, but we certainly do have the right and the constitutional obligation to decide how we spend Federal tax dollars. And that's what we said. We want it spent on vocational education. We want it spent on safe and drug-free schools. Those programs have been supported widely on both sides of the aisle.

We have also said we don't want more than 5 percent of that money to go to administrative costs, which has been widely supported on both sides of the aisle. That is all taken away by the Gorton amendment.

Mr. President, I talked with a number of my colleagues on this side of the aisle—certainly not all of them—but a great number of them prior to the vote on final passage. While I voted for final passage of the bill, because there is a lot more good than bad in it, I must state for the record that if, in fact, this provision is not dropped in conference, if we don't have the votes to drop it in conference, if it comes back from conference, as the minority manager on this bill, I am going to vote against it.

I hope that the President will send strong signals that he will veto this bill if this provision remains in the bill because it would do away with years and years of what we have done to focus attention on areas of education, like vocational education, safe and drug-free schools, education technology and others, that we thought were so necessary in order to move this country forward. I just hope this provision will be dropped in conference and that we can come back and support the bill out of conference with the same strong vote that we had here.

Mr. President, I yield the floor.

Mr. LOTT addressed the Chair.

The PRESIDING OFFICER. The majority leader.

## UNANIMOUS-CONSENT AGREEMENT—EXECUTIVE CALENDAR

Mr. LOTT. As in executive session, I ask unanimous consent that at the hour of 2 p.m. today, the Senate proceed to a vote on Executive Calendar No. 234, the nomination of Joseph Bataillon, to be immediately followed by a vote on Calendar No. 236, Christopher Droney, to be immediately followed by a vote on Calendar No. 237, Janet Hall. I ask unanimous consent that there be 2 minutes of debate, equally divided, prior to each of the above votes.

I further ask unanimous consent that immediately following those votes, Calendar Nos. 238, 239, 245 and 247 be confirmed.

I finally ask unanimous consent that following these confirmations, the motions to reconsider be laid upon the table; that any statements relating to the nominations appear at the appropriate place in the RECORD; that the President be immediately notified of the Senate's action; and that the Senate then return to legislative session.

The PRESIDING OFFICER. Without objection, it is so ordered.

## ORDER OF PROCEDURE

Mr. LOTT. Mr. President, for the information then of all Senators, that is three judicial nominations that have been cleared on both sides of the aisle, although recorded votes will be required, and then two U.S. attorneys that have been on the calendar for some time, U.S. Attorney Sharon Zealey of Ohio and U.S. Attorney James Hurd of the Virgin Islands. We also have two nominees for the Corporation for Public Broadcasting that we are able to confirm.

With these nominations moving forward, I think it is very positive for the Senate. I want the Senators to be aware that there will be three back-to-back votes beginning at 2 p.m. today.

Also, I am very pleased we are going to be able to get clearance for all committees to meet during the afternoon hours and the rest of this morning.

I believe, Mr. President, we will momentarily be prepared to go to opening statements with regard to the Food and Drug Administration reform. Senator JEFFORDS and Senator KENNEDY are here ready to proceed.

Mr. President, with regard to the comments made by Senator HARKIN, the fundamental difference in his position and our position with regard to education funds is that we just believe that the people at the local level and people at the State level want good education in their schools. I am a big advocate of vocational education, but I just happen to believe that if the State of Mississippi had more discretion in how those funds are to be used, they probably would put more money in vocational education in our State and less money in some of the programs they are mandated to do by the Federal Government.

We want good vocational education. We want safe schools. The difference is we just think that parents and teachers at the local level would do a better job of deciding how to educate their children than dictates from Washington, DC, and the Federal bureaucracy. It has not worked. We spent billions of dollars on education, and the test scores and the quality of education and the safety of the schools and parental involvement has gone down, down, down, down.

It is time we try something else to really improve education in America. That is what we are trying to do.

I yield the floor, Mr. President.

## FOOD AND DRUG ADMINISTRATION MODERNIZATION AND ACCOUNTABILITY ACT OF 1997

The PRESIDING OFFICER. The clerk will report the bill.

The legislative clerk read as follows:

A bill (S. 830) to amend the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to improve the regulation of food, drugs, devices, and biological products, and for other purposes, which had been reported from to the Committee on Labor and Human Resources, with an amendment to strike all after the enacting clause and inserting in lieu thereof the following:

***SECTION 1. SHORT TITLE.***

*This Act may be cited as the ''Food and Drug Administration Modernization and Accountability Act of 1997''.*

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

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

**SEC. 3. REFERENCES.**

Except as otherwise expressly provided, wherever in this Act an amendment or repeal is expressed in terms of an amendment to, or repeal of, 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. 321 et seq.).

## TITLE I—IMPROVING PATIENT ACCESS

**SEC. 101. MISSION OF THE FOOD AND DRUG ADMINISTRATION.**

Section 903 (21 U.S.C. 393) is amended—

(1) by redesignating subsections (b) and (c) as subsections (c) and (d), respectively; and

(2) by inserting after subsection (a) the following:

''(b) MISSION.—

''(1) IN GENERAL.—The Administration shall protect the public health by ensuring that—

''(A) foods are safe, wholesome, sanitary, and properly labeled;

''(B) human and veterinary drugs are safe and effective;

''(C) there is reasonable assurance of safety and effectiveness of devices intended for human use;

''(D) cosmetics are safe; and

''(E) public health and safety are protected from electronic product radiation.

''(2) SPECIAL RULES.—The Administration shall promptly and efficiently review clinical research and take appropriate action on the marketing of regulated products in a manner that does not unduly impede innovation or product availability. The Administration shall participate with other countries to reduce the burden of regulation, to harmonize regulatory requirements, and to achieve appropriate reciprocal arrangements with other countries.''.

**SEC. 102. EXPEDITED ACCESS TO INVESTIGATIONAL THERAPIES.**

Chapter V (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

''SUBCHAPTER D—UNAPPROVED THERAPIES AND DIAGNOSTICS

**''SEC. 551. EXPANDED ACCESS TO UNAPPROVED THERAPIES AND DIAGNOSTICS.**

''(a) IN GENERAL.—Any person, acting through a physician licensed in accordance with State law, may request from a manufacturer or distributor, and any manufacturer or distributor may provide to a person after compliance with the provisions of this section, an investigational drug (including a biological product) or investigational device for the diagnosis, monitoring, or treatment of a serious disease or condition, or any other disease or condition designated by the Secretary as appropriate for expanded access under this section if—

''(1) the licensed physician determines that the person has no comparable or satisfactory alternative therapy available to diagnose, monitor, or treat the disease or condition involved;

''(2) the licensed physician determines that the risk to the person from the investigational drug or investigational device is not greater than the risk from the disease or condition;

''(3) the Secretary determines that an exemption for the investigational drug or investigational device is in effect under a regulation promulgated pursuant to section 505(i) or 520(g) and the sponsor of the drug or device and investigators comply with such regulation;

''(4) the Secretary determines that the manufacturer of the investigational drug or investigational device is actively pursuing marketing approval with due diligence;

''(5) the Secretary determines that expanded access to the investigational drug or investigational device will not interfere with adequate enrollment of patients by the investigator in the ongoing clinical investigation of the investigational drug or investigational device authorized under section 505(i) or 520(g); and

''(6) the Secretary determines that there is sufficient evidence of safety and effectiveness to support the expanded use of the investigational drug or investigational device in accordance with this section.

''(b) PROTOCOLS.—A manufacturer or distributor may submit to the Secretary 1 or more expanded access protocols covering expanded access use of a drug or device described in subsection (a). The protocols shall be subject to the provisions of section 505(i) or 520(g) and may include any form of use of the drug or device outside a clinical investigation, prior to approval of the drug or device for marketing, including protocols for treatment use, emergency use, or uncontrolled trials, and single patient protocols. If the request for expanded access to an investigational drug or investigational device is intended for a single patient only, the Secretary may waive the requirements of paragraphs (3) and (4) of subsection (a) and accept a submission under section 505(i) or 520(g) for an exemption for the investigational drug or investigational device for the single patient use. In the case of an emergency that does not allow sufficient time for a submission under section 505(i) or 520(g), the Secretary may, prior to the submission, authorize the shipment of the investigational drug or investigational device for a single patient use.

''(c) NOTIFICATION OF AVAILABILITY.—The Secretary shall inform national, State, and local medical associations and societies, voluntary health associations, and other appropriate persons about the availability of an investigational drug or investigational device under expanded access protocols submitted under this section, except that this subsection shall not apply to expanded access protocols for single patient use.

''(d) TERMINATION.—The Secretary may at anytime terminate expanded access provided under subsection (a) for an investigational drug or investigational device if the requirements under this section are no longer met.''.

**SEC. 103. EXPANDED HUMANITARIAN USE OF DEVICES.**

Section 520(m) (21 U.S.C. 360j(m)) is amended—

(1) in paragraph (2), by adding at the end the following flush sentences:

''The request shall be in the form of an application submitted to the Secretary. Not later than 60 days after the date of the receipt of the application, the Secretary shall issue an order approving or denying the application.'';

(2) in paragraph (4)—

(A) in subparagraph (B), by inserting after ''(2)(A)'' the following: '', unless a physician determines that waiting for such an approval from an institutional review committee will cause harm or death to a patient, and makes a good faith effort to obtain the approval, and does not receive a timely response from an institutional review committee on the request of the physician for approval to use the device for such treatment or diagnosis''; and

(B) by adding at the end the following flush sentences:

''In a case in which a physician described in subparagraph (B) uses a device without an approval from an institutional review committee, the physician shall, after the use of the device, notify the chairperson of the institutional review committee of such use. Such notification shall include the identification of the patient involved, the date on which the device was used, and the reason for the use.''; and

(3) by striking paragraph (5) and inserting the following:

''(5) The Secretary may require a person granted an exemption under paragraph (2) to demonstrate continued compliance with the requirements of this subsection if the Secretary believes such demonstration to be necessary to protect the public health or if the Secretary has reason to believe that the criteria for the exemption are no longer met.''.

## TITLE II—INCREASING ACCESS TO EXPERTISE AND RESOURCES

**SEC. 201. INTERAGENCY COLLABORATION.**

Section 903(b) (21 U.S.C. 393(b)), as added by section 101(2), is amended by adding at the end the following:

''(3) INTERAGENCY COLLABORATION.—The Secretary shall implement programs and policies that will foster collaboration between the Administration, the National Institutes of Health, and other science-based Federal agencies, to enhance the scientific and technical expertise available to the Secretary in the conduct of the duties of the Secretary with respect to the development, clinical investigation, evaluation, and postmarket monitoring of emerging medical therapies, including complementary therapies, and advances in nutrition and food science.''.

***SEC. 202. SENSE OF THE COMMITTEE REGARDING MUTUAL RECOGNITION AGREEMENTS AND GLOBAL HARMONIZATION EFFORTS.***

*It is the sense of the Committee on Labor and Human Resources of the Senate that—*

*(1) the Secretary of Health and Human Services should support the Office of the United States Trade Representative, in consultation with the Secretary of Commerce, in efforts to move toward the acceptance of mutual recognition agreements relating to the regulation of drugs, biological products, devices, foods, food additives, and color additives, and the regulation of good manufacturing practices, between the European Union and the United States;*

*(2) the Secretary of Health and Human Services should regularly participate in meetings with representatives of other foreign governments to discuss and reach agreement on methods and approaches to harmonize regulatory requirements; and*

*(3) the Office of International Relations of the Department of Health and Human Services (as established under section 803 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 383)) should have the responsibility of ensuring that the process of harmonizing international regulatory requirements is continuous.*

***SEC. 203. CONTRACTS FOR EXPERT REVIEW.***

*Chapter IX (21 U.S.C. 391 et seq.) is amended by adding at the end the following:*

***''SEC. 906. CONTRACTS FOR EXPERT REVIEW.***

*''(a) IN GENERAL.—*

*''(1) AUTHORITY.—The Secretary may enter into a contract with any organization or any individual (who is not an employee of the Department) with expertise in a relevant discipline, to review, evaluate, and make recommendations to the Secretary on part or all of any application or submission (including a petition, notification, and any other similar form of request) made under this Act for the approval or classification of an article or made under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) with respect to a biological product. Any such contract shall be subject to the requirements of section 708 relating to the confidentiality of information.*

*''(2) INCREASED EFFICIENCY AND EXPERTISE THROUGH CONTRACTS.—The Secretary shall use the authority granted in paragraph (1) whenever the Secretary determines that a contract described in paragraph (1) will improve the timeliness or quality of the review of an application or submission described in paragraph (1). Such improvement may include providing the Secretary increased scientific or technical expertise that is necessary to review or evaluate new therapies and technologies.*

*''(b) REVIEW OF EXPERT REVIEW.—*

*''(1) IN GENERAL.—Subject to paragraph (2), the official of the Food and Drug Administration responsible for any matter for which expert review is used pursuant to subsection (a) shall review the recommendations of the organization or individual who conducted the expert review and shall make a final decision regarding the matter within 60 days after receiving the recommendations.*

*''(2) LIMITATION.—A final decision under paragraph (1) shall be made within the applicable prescribed time period for review of the matter as set forth in this Act or in the Public Health Service Act (42 U.S.C. 201 et seq.).*

*''(3) AUTHORITY OF SECRETARY.—Notwithstanding subsection (a), the Secretary shall retain full authority to make determinations with respect to the approval or disapproval of an article under this Act, the approval or disapproval of a biologics license with respect to a biological product under section 351(a) of the Public Health Service Act, or the classification of an article as a device under section 513(f)(1).''.*

***SEC. 204. ACCREDITED-PARTY REVIEWS.***

*Subchapter A of chapter V (21 U.S.C. 351 et seq.) is amended by adding at the end the following:*

***''SEC. 523. ACCREDITED-PARTY PARTICIPATION.***

*''(a) ACCREDITATION.—*

*''(1) IN GENERAL.—Not later than 1 year after the date of enactment of this section, the Secretary shall accredit entities or individuals who are not employees of the Federal Government, to review reports made to the Secretary under section 510(k) for devices and make recommendations to the Secretary regarding the initial classification of such devices under section 513(f)(1), except that this paragraph shall not apply to reports made to the Secretary under section 510(k) for devices that are—*

*''(A) life-supporting;*

*''(B) life sustaining; or*

*''(C) intended for implantation in the human body for a period of over 1 year.*

*''(2) SPECIAL RULE.—The Secretary shall have the discretion to accredit entities or individuals who are not employees of the Federal Government—*

*''(A) to review reports made to the Secretary under section 510(k) for devices described in subparagraphs (A) through (C) of paragraph (1), and make recommendations of initial classification of such devices; or*

*''(B) to review applications for premarket approval for class III devices under section 515 and make recommendations with respect to the approval or disapproval of such applications.*

*''(b) ACCREDITATION.—Within 180 days after the date of enactment of this section, the Secretary shall adopt methods of accreditation that ensure that entities or individuals who conduct reviews and make recommendations under this section are qualified, properly trained, knowledgeable about handling confidential documents and information, and free of conflicts of interest. The Secretary shall publish the methods of accreditation in the Federal Register on the adoption of the methods.*

*''(c) WITHDRAWAL OF ACCREDITATION.—The Secretary may suspend or withdraw the accreditation of any entity or individual accredited under this section, after providing notice and an opportunity for an informal hearing, if such entity or individual acts in a manner that is substantially not in compliance with the requirements established by the Secretary under subsection (b), including the failure to avoid conflicts of interest, the failure to protect confidentiality of information, or the failure to competently review premarket submissions for devices.*

*''(d) SELECTION AND COMPENSATION.—Subject to subsection (a)(2), a person who intends to make a report described in subsection (a), or to submit an application described in subsection (a), to the Secretary shall have the option to select an accredited entity or individual to review such report or application. Upon the request by a person to have a report or application reviewed by an accredited entity or individual, the Secretary shall identify for the person no less than 2 accredited entities or individuals from whom the selection may be made. Compensation for an accredited entity or individual shall be determined by agreement between the accredited entity or individual and the person who engages the services of the accredited entity or individual and shall be paid by the person who engages such services.*

*''(e) REVIEW BY SECRETARY.—*

*''(1) IN GENERAL.—The Secretary shall require an accredited entity or individual, upon making a recommendation under this section with respect to an initial classification of a device or approval or disapproval of an application for premarket approval, to notify the Secretary in writing of the reasons for such recommendation.*

*''(2) TIME PERIOD FOR REVIEW.—*

*''(A) INITIAL CLASSIFICATION.—Not later than 30 days after the date on which the Secretary is notified under paragraph (1) by an accredited entity or individual with respect to a recommendation of an initial classification of a device, the Secretary shall make a determination with respect to the initial classification.*

*''(B) PREMARKET APPROVAL.—Not later than 60 days after the date on which the Secretary is notified under paragraph (1) by an accredited entity or individual with respect to a recommendation of an approval or disapproval of an application for a device, the Secretary shall make a determination with respect to the approval or disapproval.*

*''(3) SPECIAL RULE.—The Secretary may change the initial classification under section 513(f)(1), or the approval or disapproval of the application under section 515(d), that is recommended by the accredited entity or individual under this section, and in such case shall notify in writing the person making the report or application described in subsection (a) of the detailed reasons for the change.*

*''(f) DURATION.—The authority provided by this section terminates—*

*''(1) 5 years after the date on which the Secretary notifies Congress that at least 2 persons accredited under subsection (b) are available to review devices for each of at least 70 percent of the generic types of devices subject to review under subsection (a); or*

*''(2) 4 years after the date on which the Secretary notifies Congress that at least 35 percent of the devices that are subject to review under subsection (a), and that were the subject of final action by the Secretary in the fiscal year preceding the date of such notification, were reviewed by the Secretary under subsection (e), whichever occurs first.*

*''(g) REPORT.—*

*''(1) IN GENERAL.—Not later than 1 year after the date of enactment of this section, the Secretary shall contract with an independent research organization to prepare and submit to the Secretary a written report examining the use of accredited entities and individuals to conduct reviews under this section. The Secretary shall submit the report to Congress not later than 6 months prior to the conclusion of the applicable period described in subsection (f).*

*''(2) CONTENTS.—The report by the independent research organization described in paragraph (1) shall identify the benefits or detriments to public and patient health of using accredited entities and individuals to conduct such reviews, and shall summarize all relevant data, including data on the review of accredited entities and individuals (including data on the review times, recommendations, and compensation of the entities and individuals), and data on the review of the Secretary (including data on the review times, changes, and reasons for changes of the Secretary).''.*

***SEC. 205. DEVICE PERFORMANCE STANDARDS.***

*(a) ALTERNATIVE PROCEDURE.—Section 514 (21 U.S.C. 360d) is amended by adding at the end the following:*

*''Recognition of a Standard*

*''(c)(1)(A) In addition to establishing performance standards under this section, the Secretary may, by publication in the Federal Register, recognize all or part of a performance standard established by a nationally or internationally recognized standard development organization for which a person may submit a declaration of conformity in order to meet premarket submission requirements or other requirements under this Act to which such standards are applicable.*

*''(B) If a person elects to use a performance standard recognized by the Secretary under subparagraph (A) to meet the requirements described in subparagraph (A), the person shall provide a declaration of conformity to the Secretary that certifies that the device is in conformity with such standard. A person may elect to use data, or information, other than data required by a standard recognized under subparagraph (A) to fulfill or satisfy any requirement under this Act.*

*''(2) The Secretary may withdraw such recognition of a performance standard through publication of a notice in the Federal Register that the Secretary will no longer recognize the*

*standard, if the Secretary determines that the standard is no longer appropriate for meeting the requirements under this Act.*

*''(3)(A) Subject to subparagraph (B), the Secretary shall accept a declaration of conformity that a device is in conformity with a standard recognized under paragraph (1) unless the Secretary finds—*

*''(i) that the data or information submitted to support such declaration does not demonstrate that the device is in conformity with the standard identified in the declaration of conformity; or*

*''(ii) that the standard identified in the declaration of conformity is not applicable to the particular device under review.*

*''(B) The Secretary may request, at any time, the data or information relied on by the person to make a declaration of conformity with respect to a standard recognized under paragraph (1).*

*''(C) A person relying on a declaration of conformity with respect to a standard recognized under paragraph (1) shall maintain the data and information demonstrating conformity of the device to the standard for a period of 2 years after the date of the classification or approval of the device by the Secretary or a period equal to the expected design life of the device, whichever is longer.''.*

*(b) SECTION 301.—Section 301 (21 U.S.C. 331) is amended by adding at the end the following:*

*''(x) The falsification of a declaration of conformity submitted under subsection (c) of section 514 or the failure or refusal to provide data or information requested by the Secretary under section 514(c)(3).''.*

*(c) SECTION 501.—Section 501(e) (21 U.S.C. 351(e)) is amended—*

*(1) by striking ''(e)'' and inserting ''(e)(1)''; and*

*(2) by inserting at the end the following:*

*''(2) If it is, declared to be, purports to be, or is represented as, a device that is in conformity with any performance standard recognized under section 514(c) unless such device is in all respects in conformity with such standard.''.*

## *TITLE III—IMPROVING COLLABORATION AND COMMUNICATION*

### *SEC. 301. COLLABORATIVE DETERMINATIONS OF DEVICE DATA REQUIREMENTS.*

*Section 513(a)(3) (21 U.S.C. 360c(a)(3)) is amended by adding at the end the following:*

*''(C)(i)(I) The Secretary, upon the written request of any person intending to submit an application under section 515, shall meet with such person to determine the type of valid scientific evidence (within the meaning of subparagraphs (A) and (B)) that will be necessary to demonstrate the effectiveness of a device for the conditions of use proposed by such person, to support an approval of an application. The written request shall include a detailed description of the device, a detailed description of the proposed conditions of use of the device, and, if available, information regarding the expected performance from the device. Within 30 days after such meeting, the Secretary shall specify in writing the type of valid scientific evidence that will provide a reasonable assurance that a device is effective under the conditions of use proposed by such person.*

*''(II) Any clinical data, including 1 or more well-controlled investigations, specified in writing by the Secretary for demonstrating a reasonable assurance of device effectiveness shall be specified as a result of a determination by the Secretary—*

*''(aa) that such data are necessary to establish device effectiveness; and*

*''(bb) that no other less burdensome means of evaluating device effectiveness is available that would have a reasonable likelihood of resulting in an approval.*

*''(ii) The determination of the Secretary with respect to the specification of valid scientific evidence under clause (i) shall be binding upon the Secretary, unless—*

*''(I) such determination by the Secretary would be contrary to the public health; or*

*''(II) based on new information (other than the information reviewed by the Secretary in making such determination) obtained by the Secretary prior to the approval of an application for an investigational device exemption under section 520(g), the Secretary finds that such determination is scientifically inappropriate.''.*

### *SEC. 302. COLLABORATIVE REVIEW PROCESS.*

*Section 515(d) (21 U.S.C. 360e(d)) is amended—*

*(1) in paragraph (1)(A), by striking ''paragraph (2) of this subsection'' each place it appears and inserting ''paragraph (4)'';*

*(2) by redesignating paragraphs (2) and (3) as paragraphs (4) and (5), respectively; and*

*(3) by inserting after paragraph (1) the following:*

*''(2)(A)(i) The Secretary shall, upon the written request of the applicant involved, meet with the applicant not later than 100 days after the receipt of an application, from the applicant, that has been filed as complete under subsection (c), to discuss the review status of the application.*

*''(ii) If the application does not appear in a form that would require an approval under this subsection, the Secretary shall in writing, and prior to the meeting, provide to the applicant a description of any deficiencies in the application identified by the Secretary and identify the information (other than information the Secretary needs to make a finding under paragraph (4)(C)) that is required to bring the application into an approvable form.*

*''(iii) The Secretary and the applicant may, by mutual consent, establish a different schedule for a meeting required under this paragraph.*

*''(B) The Secretary shall notify the applicant immediately of any deficiency identified in the application that was not described as a deficiency in the written description provided by the Secretary under subparagraph (A).''.*

## *TITLE IV—IMPROVING CERTAINTY AND CLARITY OF RULES*

### *SEC. 401. POLICY STATEMENTS.*

*Section 701(a) (21 U.S.C. 371(a)) is amended—*

*(1) by striking ''(a) The'' and inserting ''(a)(1) The''; and*

*(2) by adding at the end the following:*

*''(2) Not later than February 27, 1999, the Secretary, after evaluating the effectiveness of the Good Guidance Practices document published in the Federal Register at 62 Fed. Reg. 8961, shall promulgate a regulation specifying the policies and procedures of the Food and Drug Administration for the development, issuance, and use of guidance documents.''.*

### *SEC. 402. PRODUCT CLASSIFICATION.*

*Chapter VII (21 U.S.C. 371 et seq.) is amended by adding at the end the following:*

*''SUBCHAPTER D—CLASSIFICATION OF PRODUCTS AND ENVIRONMENTAL IMPACT REVIEWS*

### *''SEC. 741. CLASSIFICATION OF PRODUCTS.*

*''(a) REQUEST.—A person who submits an application or submission (including a petition, notification, and any other similar form of request) under this Act, may submit a request to the Secretary respecting the classification of an article (including an article that is a combination product subject to section 503(g)) as a drug, biological product, or device, or respecting the component of the Food and Drug Administration that will regulate the article. In submitting the request, the person shall recommend a classification for the article, or a component to regulate the article, as appropriate.*

*''(b) STATEMENT.—Not later than 60 days after the receipt of the request described in subsection (a), the Secretary shall determine the classification of the article or the component of the Food and Drug Administration that will regulate the article and shall provide to the person a written statement that identifies the classification of the article or the component of the Food and Drug Administration that will regulate the article and the reasons for such determination. The Secretary may not modify such statement except with the written consent of the person or for public health reasons.*

*''(c) INACTION OF SECRETARY.—If the Secretary does not provide the statement within the 60-day period described in subsection (b), the recommendation made by the person under subsection (a) shall be considered to be a final determination by the Secretary of the classification of the article or the component of the Food and Drug Administration that will regulate the article and may not be modified by the Secretary except with the written consent of the person or for public health reasons.''.*

### *SEC. 403. USE OF DATA RELATING TO PREMARKET APPROVAL.*

*(a) IN GENERAL.—Section 520(h)(4) (21 U.S.C. 360j(h)(4)) is amended to read as follows:*

*''(4)(A) Any information contained in an application for premarket approval filed with the Secretary pursuant to section 515(c) (including information from clinical and preclinical tests or studies that demonstrate the safety and effectiveness of a device, but excluding descriptions of methods of manufacture and product composition) shall be available, 6 years after the application has been approved by the Secretary, for use by the Secretary in—*

*''(i) approving another device;*

*''(ii) determining whether a product development protocol has been completed, under section 515 for another device;*

*''(iii) establishing a performance standard or special control under this Act; or*

*''(iv) classifying or reclassifying another device under section 513 and subsection (l)(2).*

*''(B) The publicly available detailed summaries of information respecting the safety and effectiveness of devices required by paragraph (1)(A) shall be available for use by the Secretary as the evidentiary basis for the agency action described in subparagraph (A).''.*

*(b) CONFORMING AMENDMENT.—Section 517(a) (21 U.S.C. 360g(a)) is amended—*

*(1) in paragraph (8), by adding ''or'' at the end;*

*(2) in paragraph (9), by striking '', or'' and inserting a comma; and*

*(3) by striking paragraph (10).*

### *SEC. 404. CONSIDERATION OF LABELING CLAIMS FOR PRODUCT REVIEW.*

*(a) PREMARKET APPROVAL.—Section 515(d)(1)(A) (21 U.S.C. 360e(d)(1)(A)) is amended by adding at the end the following flush sentences:*

*''In making the determination whether to approve or deny the application, the Secretary shall rely on the conditions of use included in the proposed labeling as the basis for determining whether or not there is a reasonable assurance of safety and effectiveness, if the proposed labeling is neither false nor misleading. In determining whether or not such labeling is false or misleading, the Secretary shall fairly evaluate all material facts pertinent to the proposed labeling.''.*

*(b) PREMARKET NOTIFICATION.—Section 513(i)(1) (21 U.S.C. 360c(i)(1)) is amended by adding at the end the following:*

*''(C) Whenever the Secretary requests information to demonstrate that the devices with differing technological characteristics are substantially equivalent, the Secretary shall only request information that is necessary to make a substantial equivalence determination. In making such a request, the Secretary shall consider the least burdensome means of demonstrating substantial equivalence and shall request information accordingly.*

*''(D) The determinations of the Secretary under this section and section 513(f)(1) with respect to the intended use of a device shall be based on the intended use included in proposed labeling of the device submitted in a report under section 510(k).''.*

**SEC. 405. DEFINITION OF A DAY FOR PURPOSES OF PRODUCT REVIEW.**

Section 201 (21 U.S.C. 321) is amended by adding at the end the following:

''(ii) In any provision relating to a review of any application or submission (including a petition, notification, and any other similar form of request), made under this Act with respect to an article that is a new drug, device, biological product, new animal drug, an animal feed bearing or containing a new animal drug, color additive, or food additive, that is submitted to the Secretary to obtain marketing approval, to obtain classification of a device under section 513(f)(1), or to establish or clarify the regulatory status of the article—

''(1) the term 'day' means a calendar day in which the Secretary has responsibility to review such an application or submission; and

''(2) a reference to a date relating to the receipt of such an application or submission by the Secretary shall be deemed to be a reference to the date on which the Secretary receives a complete application or submission within the meaning of this Act and the regulations promulgated under this Act.''.

**SEC. 406. CERTAINTY OF REVIEW TIMEFRAMES.**

(a) CLARIFICATION ON THE 90-DAY TIMEFRAME FOR PREMARKET NOTIFICATION REVIEWS.—Section 510(k) (21 U.S.C. 360) is amended by adding at the end the following flush sentence:

''The Secretary shall review the notification required by this subsection and make a determination under section 513(f)(1) not later than 90 days after receiving the notification.''.

(b) CERTAINTY OF 180-DAY REVIEW TIMEFRAME.—Section 515(d) (21 U.S.C. 360e(d)), as amended by section 302, is amended by inserting after paragraph (2) the following:

''(3) Except as provided in paragraph (1), the period for the review of an application by the Secretary under this subsection shall be not more than 180 days. Such period may not be restarted or extended even if the application is amended.''.

**SEC. 407. LIMITATIONS ON INITIAL CLASSIFICATION DETERMINATIONS.**

Section 510 (21 U.S.C. 360) is amended by adding at the end the following:

''(m) The Secretary may not withhold a determination of the initial classification of a device under section 513(f)(1) because of a failure to comply with any provision of this Act that is unrelated to a substantial equivalence decision, including a failure to comply with the requirements relating to good manufacturing practices under section 520(f).''.

**SEC. 408. CLARIFICATION WITH RESPECT TO A GENERAL USE AND SPECIFIC USE OF A DEVICE.**

Not later than 270 days after the date of enactment of this section, the Secretary of Health and Human Services shall promulgate a final regulation specifying the general principles that the Secretary of Health and Human Services will consider in determining when a specific intended use of a device is not reasonably included within a general use of such device for purposes of a determination of substantial equivalence under section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(1)).

**SEC. 409. CLARIFICATION OF THE NUMBER OF REQUIRED CLINICAL INVESTIGATIONS FOR APPROVAL.**

(a) DEVICE CLASSES.—Section 513(a)(3)(A) (21 U.S.C. 360c(a)(3)(A)) is amended by striking ''clinical investigations'' and inserting ''1 or more clinical investigations''.

(b) NEW DRUGS.—Section 505(d) (21 U.S.C. 355(d)) is amended by adding at the end the following: ''Substantial evidence may, as appropriate, consist of data from 1 adequate and well-controlled clinical investigation and confirmatory evidence (obtained prior to or after such investigation), if the Secretary determines, based on relevant science, that such data and evidence are sufficient to establish effectiveness.''.

**SEC. 410. PROHIBITED ACTS.**

Section 301(l) (21 U.S.C. 331(l)) is repealed.

## TITLE V—IMPROVING ACCOUNTABILITY

**SEC. 501. AGENCY PLAN FOR STATUTORY COMPLIANCE AND ANNUAL REPORT.**

Section 903(b) (21 U.S.C. 393(b)), as amended by section 201, is further amended by adding at the end the following:

''(4) AGENCY PLAN FOR STATUTORY COMPLIANCE.—

''(A) IN GENERAL.—Not later than 180 days after the date of enactment of this paragraph, the Secretary, after consultation with relevant experts, health care professionals, representatives of patient and consumer advocacy groups, and the regulated industry, shall develop and publish in the Federal Register a plan bringing the Secretary into compliance with each of the obligations of the Secretary under this Act and other relevant statutes. The Secretary shall biannually review the plan and shall revise the plan as necessary, in consultation with such persons.

''(B) OBJECTIVES OF AGENCY PLAN.—The plan required by subparagraph (A) shall establish objectives, and mechanisms to be used by the Secretary, acting through the Commissioner, including objectives and mechanisms that—

''(i) minimize deaths of, and harm to, persons who use or may use an article regulated under this Act;

''(ii) maximize the clarity of, and the availability of information about, the process for review of applications and submissions (including petitions, notifications, and any other similar forms of request) made under this Act, including information for potential consumers and patients concerning new products;

''(iii) implement all inspection and postmarket monitoring provisions of this Act by July 1, 1999;

''(iv) ensure access to the scientific and technical expertise necessary to ensure compliance by the Secretary with the statutory obligations described in subparagraph (A);

''(v) establish a schedule to bring the Administration into full compliance by July 1, 1999, with the time periods specified in this Act for the review of all applications and submissions described in clause (ii) and submitted after the date of enactment of this paragraph; and

''(vi) reduce backlogs in the review of all applications and submissions described in clause (ii) for any article with the objective of eliminating all backlogs in the review of the applications and submissions by January 1, 2000.

''(5) ANNUAL REPORT.—

''(A) CONTENTS.—The Secretary shall prepare and publish in the Federal Register and solicit public comment on an annual report that—

''(i) provides detailed statistical information on the performance of the Secretary under the plan described in paragraph (4);

''(ii) compares such performance of the Secretary with the objectives of the plan and with the statutory obligations of the Secretary;

''(iii) analyzes any failure of the Secretary to achieve any objective of the plan or to meet any statutory obligation;

''(iv) identifies any regulatory policy that has a significant impact on compliance with any objective of the plan or any statutory obligation; and

''(v) sets forth any proposed revision to any such regulatory policy, or objective of the plan that has not been met.

''(B) STATISTICAL INFORMATION.—The statistical information described in subparagraph (A)(i) shall include a full statistical presentation relating to all applications and submissions (including petitions, notifications, and any other similar forms of request) made under this Act and approved or subject to final action by the Secretary during the year covered by the report. In preparing the statistical presentation, the Secretary shall take into account the date of—

''(i) the submission of any investigational application;

''(ii) the application of any clinical hold;

''(iii) the submission of any application or submission (including a petition, notification, and any other similar form of request) made under this Act for approval or clearance;

''(iv) the acceptance for filing of any application or submission described in clause (iii) for approval or clearance;

''(v) the occurrence of any unapprovable action;

''(vi) the occurrence of any approvable action; and

''(vii) the approval or clearance of any application or submission described in clause (iii).''.

## TITLE VI—BETTER ALLOCATION OF RESOURCES BY SETTING PRIORITIES

**SEC. 601. MINOR MODIFICATIONS.**

(a) ACTION ON INVESTIGATIONAL DEVICE EXEMPTIONS.—Section 520(g) (21 U.S.C. 360j(g)) is amended by adding at the end the following:

''(6)(A) The Secretary shall, not later than 120 days after the date of enactment of this paragraph, by regulation modify parts 812 and 813 of title 21, Code of Federal Regulations to update the procedures and conditions under which a device intended for human use may, upon application by the sponsor of the device, be granted an exemption from the requirements of this Act.

''(B) The regulation shall permit developmental changes in a device (including manufacturing changes) in response to information collected during an investigation without requiring an additional approval of an application for an investigational device exemption or the approval of a supplement to such application, if the sponsor of the investigation determines, based on credible information, prior to making any such changes, that the changes—

''(i) do not affect the scientific soundness of an investigational plan submitted under paragraph (3)(A) or the rights, safety, or welfare of the human subjects involved in the investigation; and

''(ii) do not constitute a significant change in design, or a significant change in basic principles of operation, of the device.''.

(b) ACTION ON APPLICATION.—Section 515(d)(1)(B) (21 U.S.C. 360e(d)(1)(B)) is amended by adding at the end the following:

''(iii) The Secretary shall accept and review data and any other information from investigations conducted under the authority of regulations required by section 520(g), to make a determination of whether there is a reasonable assurance of safety and effectiveness of a device subject to a pending application under this section if—

''(I) the data or information is derived from investigations of an earlier version of the device, the device has been modified during or after the investigations (but prior to submission of an application under subsection (c)) and such a modification of the device does not constitute a significant change in the design or in the basic principles of operation of the device that would invalidate the data or information; or

''(II) the data or information relates to a device approved under this section, is available for use under this Act, and is relevant to the design and intended use of the device for which the application is pending.''.

(c) ACTION ON SUPPLEMENTS.—Section 515(d) (21 U.S.C. 360e(d)), as amended by section 302, is further amended by adding at the end the following:

''(6)(A)(i) A supplemental application shall be required for any change to a device subject to an approved application under this subsection that affects safety or effectiveness, unless such change is a modification in a manufacturing procedure or method of manufacturing and the holder of the approved application submits a written notice to the Secretary that describes in detail the change, summarizes the data or information supporting the change, and informs the Secretary that the change has been made under the requirements of section 520(f).

''(ii) The holder of an approved application who submits a notice under clause (i) with respect to a manufacturing change of a device shall not distribute the device for a period of 14 days after the date on which the Secretary receives the notice.

''(B)(i) Subject to clause (ii), in reviewing a supplement to an approved application, for an incremental change to the design of a device that affects safety or effectiveness, the Secretary shall approve such supplement if—

''(I) nonclinical data demonstrate that the design modification creates the intended additional capacity, function, or performance of the device; and

''(II) clinical data from the approved application and any supplement to the approved application provide a reasonable assurance of safety and effectiveness for the changed device.

''(ii) The Secretary may require, when necessary, additional clinical data to evaluate the design modification to provide a reasonable assurance of safety and effectiveness.''.

**SEC. 602. ENVIRONMENTAL IMPACT REVIEW.**

Chapter VII (21 U.S.C. 371 et seq.), as amended by section 402, is further amended by adding at the end the following:

**''SEC. 742. ENVIRONMENTAL IMPACT REVIEW.**

''Notwithstanding any other provision of law, no action by the Secretary pursuant to this Act shall be subject to an environmental assessment, an environmental impact statement, or other environmental consideration unless the Secretary demonstrates, in writing—

''(1) that there is a reasonable probability that the environmental impact of the action is sufficiently substantial and within the factors that the Secretary is authorized to consider under this Act; and

''(2) that consideration of the environmental impact will directly affect the decision on the action.''.

**SEC. 603. EXEMPTION OF CERTAIN CLASSES OF DEVICES FROM PREMARKET NOTIFICATION REQUIREMENT.**

(a) CLASS I AND CLASS II DEVICES.—Section 510(k) (21 U.S.C. 360(k)) is amended by striking ''intended for human use'' and inserting ''intended for human use (except a device that is classified into class I under section 513 or 520 unless the Secretary determines such device is intended for a use that is of substantial importance in preventing impairment of human health or such device presents a potential unreasonable risk of illness or injury, or a device that is classified into class II under section 513 or 520 and is exempt from the requirements of this subsection under subsection (l))''.

(b) PUBLICATION OF EXEMPTION.—Section 510 (21 U.S.C. 360) is amended by inserting after subsection (k) the following:

''(l)(1) Not later than 30 days after the date of enactment of this subsection, the Secretary shall publish in the Federal Register a list of each type of class II device that does not require a notification under subsection (k) to provide reasonable assurance of safety and effectiveness. Each type of class II device identified by the Secretary not to require the notification shall be exempt from the requirement to provide notification under subsection (k) as of the date of the publication of the list in the Federal Register.

''(2) Beginning on the date that is 1 day after the date of the publication of a list under this subsection, the Secretary may exempt a class II device from the notification requirement of subsection (k), upon the Secretary's own initiative or a petition of an interested person, if the Secretary determines that such notification is not necessary to assure the safety and effectiveness of the device. The Secretary shall publish in the Federal Register notice of the intent of the Secretary to exempt the device, or of the petition, and provide a 30-day comment period for public comment. Within 120 days after the issuance of the notice in the Federal Register, the Secretary shall publish an order in the Federal Register that sets forth the final determination of the Secretary regarding the exemption of the device that was the subject of the notice.''.

**SEC. 604. EVALUATION OF AUTOMATIC CLASS III DESIGNATION.**

Section 513(f) (21 U.S.C. 360c(f)) is amended—

(1) in paragraph (1)—

(A) in subparagraph (B), by striking ''paragraph (2)'' and inserting ''paragraph (3)''; and

(B) in the last sentence, by striking ''paragraph (2)'' and inserting ''paragraph (2) or (3)'';

(2) by redesignating paragraphs (2) and (3) as paragraphs (3) and (4), respectively; and

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

''(2)(A) Any person who submits a report under section 510(k) for a type of device that has not been previously classified under this Act, and that is classified into class III under paragraph (1), may request, within 30 days after receiving written notice of such a classification, the Secretary to classify the device into class I or II under the criteria set forth in subparagraphs (A) through (C) subsection (a)(1). The person may, in the request, recommend to the Secretary a classification for the device. The request shall describe the device and provide detailed information and reasons for the recommended classification.

''(B)(i) Not later than 60 days after the date of the submission of the request under subparagraph (A) for classification of a device under the criteria set forth in subparagraphs (A) through (C) of subsection (a)(1), the Secretary shall by written order classify the device. Such classification shall be the initial classification of the device for purposes of paragraph (1) and any device classified under this paragraph into class I or II shall be a predicate device for determining substantial equivalence under paragraph (1).

''(ii) A device that remains in class III under this subparagraph shall be deemed to be adulterated within the meaning of section 501(f)(1)(B) until approved under section 515 or exempted from such approval under section 520(g).

''(C) Within 30 days after the issuance of an order classifying a device under this paragraph, the Secretary shall publish a notice in the Federal Register announcing such classification.''.

**SEC. 605. SECRETARY'S DISCRETION TO TRACK DEVICES.**

(a) RELEASE OF INFORMATION.—Section 519(e) (21 U.S.C. 360i(e)) is amended by adding at the end the following flush sentence:

''Any patient receiving a device subject to tracking under this section may refuse to release, or refuse permission to release, the patient's name, address, social security number, or other identifying information for the purpose of tracking.''.

(b) PUBLICATION OF CERTAIN DEVICES.—Not later than 180 days after the date of enactment of this Act, the Secretary of Health and Human Services shall develop and publish in the Federal Register a list that identifies each type of device subject to tracking under section 519(e)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i(e)(1)). Each device not identified by the Secretary of Health and Human Services under this subsection or designated by the Secretary under section 519(e)(2) shall be deemed to be exempt from the mandatory tracking requirement under section 519 of such Act. The Secretary of Health and Human Services shall have authority to modify the list of devices exempted from the mandatory tracking requirements.

**SEC. 606. SECRETARY'S DISCRETION TO CONDUCT POSTMARKET SURVEILLANCE.**

(a) IN GENERAL.—Section 522 (21 U.S.C. 360l) is amended by striking ''SEC. 522.'' and all that follows through ''(2) DISCRETIONARY SURVEILLANCE.—The'' and inserting the following:

''SEC. 522. (a) DISCRETIONARY SURVEILLANCE.—The''.

(b) SURVEILLANCE APPROVAL.—Section 522(b) (21 U.S.C. 360l(b)) is amended to read as follows:

''(b) SURVEILLANCE APPROVAL.—

''(1) IN GENERAL.—Each manufacturer that receives notice from the Secretary that the manufacturer is required to conduct surveillance of a device under subsection (a) shall, not later than 30 days after receiving the notice, submit for the approval of the Secretary, a plan for the required surveillance.

''(2) DETERMINATION.—Not later than 60 days after the receipt of the plan, the Secretary shall determine if a person proposed in the plan to conduct the surveillance has sufficient qualifications and experience to conduct the surveillance and if the plan will result in the collection of useful data that can reveal unforeseen adverse events or other information necessary to protect the public health and to provide safety and effectiveness information for the device.

''(3) LIMITATION ON PLAN APPROVAL.—The Secretary may not approve the plan until the plan has been reviewed by a qualified scientific and technical review committee established by the Secretary.''.

(c) DURATION OF SURVEILLANCE.—Section 522 (21 U.S.C. 360l), as amended by subsection (b), is further amended by adding at the end the following:

''(c) DURATION OF SURVEILLANCE.—

''(1) IN GENERAL.—Each manufacturer required to conduct surveillance of a device under subsection (a) shall be required to conduct such surveillance for not longer than 24 months.

''(2) EXTENSION OF THE PERIOD OF SURVEILLANCE.—If the Secretary determines that additional surveillance is needed to identify the incidence of adverse events documented during the initial period of surveillance that were not foreseen at the time of approval or classification of the device, the Secretary may extend the period of surveillance for such time as may be necessary after providing the person required to conduct such surveillance an opportunity for an informal hearing to determine whether or not additional surveillance is appropriate and to determine the appropriate period, if any, for such surveillance.''.

**SEC. 607. REPORTING.**

(a) REPORTS.—Section 519 (21 U.S.C. 360i) is amended—

(1) in subsection (a)—

(A) in the first sentence by striking ''make such reports, and provide such information,'' and inserting ''and submit such samples and components of devices (as required by paragraph (10)),''; and

(B) by inserting after the first sentence the following: ''Every person who is a manufacturer or importer of a device intended for human use shall make reports, and provide such information, as the Secretary may by regulation reasonably require to assure that such device is not adulterated or misbranded and to assure the safety and effectiveness of such device.'';

(C) in the last sentence by striking ''sentence'' and inserting ''sentences'';

(D) in paragraph (8), by striking ''; and'' and inserting a semicolon; and

(E) by striking paragraph (9) and inserting the following:

''(9) shall require distributors to keep records and make such records available to the Secretary upon request; and'';

(2) by striking subsection (d); and

(3) in subsection (f), by striking '', importer, or distributor'' each place it appears and inserting ''or importer''.

(b) REGISTRATION.—Section 510(g) (21 U.S.C. 360(g)) is amended—

(1) by redesignating paragraph (4) as paragraph (5);

(2) by inserting after paragraph (3), the following:

''(4) any distributor who acts as a wholesale distributor of devices, and who does not manufacture, repackage, process, or relabel a device; or''; and

(3) by adding at the end the following flush sentence:

''In this subsection, the term 'wholesale distributor' means any person who distributes a device from the original place of manufacture to the person who makes the final delivery or sale of the device to the ultimate consumer or user.''.

**SEC. 608. PILOT AND SMALL-SCALE MANUFACTURE.**

Section 505(c) (21 U.S.C. 355(c)) is amended by adding at the end the following:

''(4) A new drug manufactured in a pilot or other small facility may be used to demonstrate the safety and effectiveness of the new drug and to obtain approval of the new drug prior to scaling up to a larger facility, unless the Secretary determines that a full scale production facility is necessary to ensure the safety or effectiveness of the new drug.''.

**SEC. 609. REQUIREMENTS FOR RADIOPHARMACEUTICALS.**

(a) REQUIREMENTS.—

(1) REGULATIONS.—

(A) PROPOSED REGULATIONS.—Not later than 180 days after the date of enactment of this Act, the Secretary of Health and Human Services, after consultation with patient advocacy groups, associations, physicians licensed to use radiopharmaceuticals, and the regulated industry, shall issue proposed regulations governing the approval of radiopharmaceuticals designed for diagnosis and monitoring of diseases and conditions. The regulations shall provide that the determination of the safety and effectiveness of such a radiopharmaceutical under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or section 351 of the Public Health Service Act (42 U.S.C. 262) shall include (but not be limited to) consideration of the proposed use of the radiopharmaceutical in the practice of medicine, the pharmacological and toxicological activity of the radiopharmaceutical (including any carrier or ligand component of the radiopharmaceutical), and the estimated absorbed radiation dose of the radiopharmaceutical.

(B) FINAL REGULATIONS.—Not later than 18 months after the date of enactment of this Act, the Secretary shall promulgate final regulations governing the approval of the radiopharmaceuticals.

(2) SPECIAL RULE.—In the case of a radiopharmaceutical intended to be used for diagnostic or monitoring purposes, the indications for which such radiopharmaceutical is approved for marketing may, in appropriate cases, refer to manifestations of disease (such as biochemical, physiological, anatomic, or pathological processes) common to, or present in, 1 or more disease states.

(b) DEFINITION.—In this section, the term ''radiopharmaceutical'' means—

(1) an article—

(A) that is intended for use in the diagnosis or monitoring of a disease or a manifestation of a disease in humans; and

(B) that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons; or

(2) any nonradioactive reagent kit or nuclide generator that is intended to be used in the preparation of any such article.

**SEC. 610. MODERNIZATION OF REGULATION OF BIOLOGICAL PRODUCTS.**

(a) LICENSES.—

(1) IN GENERAL.—Section 351(a) of the Public Health Service (42 U.S.C. 262(a)) is amended to read as follows:

''(a)(1) Except as provided in paragraph (4), no person shall introduce or deliver for introduction into interstate commerce any biological product unless—

''(A) a biologics license is in effect for the biological product; and

''(B) each package of the biological product is plainly marked with—

''(i) the proper name of the biological product contained in the package;

''(ii) the name, address, and applicable license number of the manufacturer of the biological product; and

''(iii) the expiration date of the biological product.

''(2)(A) The Secretary shall establish, by regulation, requirements for the approval, suspension, and revocation of biologics licenses.

''(B) The Secretary shall approve a biologics license application on the basis of a demonstration that—

''(i) the biological product that is the subject of the application is safe, pure, and potent; and

''(ii) the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent.

''(3) A biologics license application shall be approved only if the applicant (or other appropriate person) consents to the inspection of the facility that is the subject of the application, in accordance with subsection (c).

''(4) The Secretary shall prescribe requirements under which a biological product undergoing investigation shall be exempt from the requirements of paragraph (1).''.

(2) ELIMINATION OF EXISTING LICENSE REQUIREMENT.—Section 351(d) of the Public Health Service Act (42 U.S.C. 262(d)) is amended—

(A) by striking ''(d)(1)'' and all that follows through ''of this section.'';

(B) in paragraph (2)—

(i) by striking ''(2)(A) Upon'' and inserting ''(d)(1) Upon;'' and

(ii) by redesignating subparagraph (B) as paragraph (2); and

(C) in paragraph (2) (as so redesignated by subparagraph (B)(ii))—

(i) by striking ''subparagraph (A)'' and inserting ''paragraph (1)''; and

(ii) by striking ''this subparagraph'' each place it appears and inserting ''this paragraph''.

(b) LABELING.—Section 351(b) of the Public Health Service Act (42 U.S.C. 262(b)) is amended to read as follows:

''(b) No person shall falsely label or mark any package or container of any biological product or alter any label or mark on the package or container of the biological product so as to falsify the label or mark.''.

(c) INSPECTION.—Section 351(c) of the Public Health Service Act (42 U.S.C. 262(c)) is amended by striking ''virus, serum,'' and all that follows and inserting ''biological product.''.

(d) DEFINITION; APPLICATION.—Section 351 of the Public Health Service Act (42 U.S.C. 262) is amended by adding at the end the following:

''(i) In this section, the term 'biological product' means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.''.

(e) CONFORMING AMENDMENT.—Section 503(g)(4) (21 U.S.C. 353(g)(4)) is amended—

(1) in subparagraph (A)—

(A) by striking ''section 351(a)'' and inserting ''section 351(i)''; and

(B) by striking ''262(a)'' and inserting ''262(i)''; and

(2) in subparagraph (B)(iii), by striking ''product or establishment license under subsection (a) or (d)'' and inserting ''biologics license application under subsection (a)''.

(f) SPECIAL RULE.—The Secretary of Health and Human Services shall take measures to minimize differences in the review and approval of products required to have approved biologics license applications under section 351 of the Public Health Service Act (42 U.S.C. 262) and products required to have approved full new drug applications under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(1)).

**SEC. 611. APPROVAL OF SUPPLEMENTAL APPLICATIONS FOR APPROVED PRODUCTS.**

(a) PERFORMANCE STANDARDS.—Not later than 180 days after the date of enactment of this section, the Secretary of Health and Human Services shall publish in the Federal Register performance standards for the prompt review of supplemental applications submitted for approved articles under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.).

(b) GUIDANCE TO INDUSTRY.—Not later than 180 days after the date of enactment of this section, the Secretary of Health and Human Services shall issue final guidances to clarify the requirements for, and facilitate the submission of data to support, the approval of supplemental applications for the approved articles described in subsection (a). The guidances shall—

(1) clarify circumstances in which published matter may be the basis for approval of a supplemental application;

(2) specify data requirements that will avoid duplication of previously submitted data by recognizing the availability of data previously submitted in support of an original application; and

(3) define supplemental applications that are eligible for priority review.

(c) RESPONSIBILITIES OF CENTERS.—The Secretary of Health and Human Services shall designate an individual in each center within the Food and Drug Administration (except the Center for Food Safety and Applied Nutrition) to be responsible for—

(1) encouraging the prompt review of supplemental applications for approved articles; and

(2) working with sponsors to facilitate the development and submission of data to support supplemental applications.

(d) COLLABORATION.—The Secretary of Health and Human Services shall implement programs and policies that will foster collaboration between the Food and Drug Administration, the National Institutes of Health, professional medical and scientific societies, and other persons, to identify published and unpublished studies that may support a supplemental application, and to encourage sponsors to make supplemental applications or conduct further research in support of a supplemental application based, in whole or in part, on such studies.

**SEC. 612. HEALTH CARE ECONOMIC INFORMATION.**

Section 502 (21 U.S.C. 352) is amended by adding at the end the following:

''(u) In the case of a health care economic statement that is included in labeling or advertising provided to a formulary committee, managed care organization, or similar entity with responsibility for drug selection decisions (other than the label or approved physician package insert) relating to an indication approved under section 505 or 351 of the Public Health Service Act (42 U.S.C. 262), if the health care economic statement is not based on competent and reliable scientific evidence. The only requirements applicable to any such statement under this Act shall be the requirements of this paragraph. In this paragraph, the term 'health care economic statement' means any statement that identifies, measures, or compares the costs (direct, indirect, and intangible) and health care consequences of a drug to another drug, to another health care intervention for the same indication, or to no intervention, where the primary endpoint is an economic outcome.''.

**SEC. 613. EXPEDITING STUDY AND APPROVAL OF FAST TRACK DRUGS.**

(a) IN GENERAL.—Chapter V (21 U.S.C. 351 et seq.), as amended by section 102, is further amended by adding at the end the following:

''SUBCHAPTER E—FAST TRACK DRUGS

**''SEC. 561. FAST TRACK DRUGS.**

''(a) DESIGNATION OF DRUG AS A FAST TRACK DRUG.—

''(1) IN GENERAL.—The Secretary shall facilitate development, and expedite review and approval of new drugs and biological products

*that are intended for the treatment of serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs for such conditions. In this Act, such products shall be known as 'fast track drugs'.*

*''(2) REQUEST FOR DESIGNATION.—The sponsor of a drug (including a biological product) may request the Secretary to designate the drug as a fast track drug. A request for the designation may be made concurrently with, or at any time after, submission of an application for the investigation of the drug under section 505(i) or section 351(a)(4) of the Public Health Service Act.*

*''(3) DESIGNATION.—Within 30 calendar days after the receipt of a request under paragraph (2), the Secretary shall determine whether the drug that is the subject of the request meets the criteria described in paragraph (1). If the Secretary finds that the drug meets the criteria, the Secretary shall designate the drug as a fast track drug and shall take such actions as are appropriate to expedite the development and review of the drug.*

*''(b) APPROVAL OF APPLICATION FOR A FAST TRACK DRUG.—*

*''(1) IN GENERAL.—The Secretary may approve an application for approval of a fast track drug under section 505(b) or section 351 of the Public Health Service Act (21 U.S.C. 262) upon a determination that the drug has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit.*

*''(2) LIMITATION.—Approval of a fast track drug under this subsection may be subject to the requirements—*

*''(A) that the sponsor conduct appropriate post-approval studies to validate the surrogate endpoint or otherwise confirm the clinical benefit of the drug; and*

*''(B) that the sponsor submit copies of all promotional materials related to the fast track drug during the preapproval review period and following approval, at least 30 days prior to dissemination of the materials for such period of time as the Secretary deems appropriate.*

*''(3) EXPEDITED WITHDRAWAL OF APPROVAL.—The Secretary may withdraw approval of a fast track drug using expedited procedures (as prescribed by the Secretary in regulations) including a procedure that provides an opportunity for an informal hearing, if—*

*''(A) the sponsor fails to conduct any required post-approval study of the fast track drug with due diligence;*

*''(B) a post-approval study of the fast track drug fails to verify clinical benefit of the fast track drug;*

*''(C) other evidence demonstrates that the fast track drug is not safe or effective under conditions of use of the drug; or*

*''(D) the sponsor disseminates false or misleading promotional materials with respect to the fast track drug.*

*''(c) REVIEW OF INCOMPLETE APPLICATIONS FOR APPROVAL OF A FAST TRACK DRUG.—*

*''(1) IN GENERAL.—If preliminary evaluation by the Secretary of clinical efficacy data for a fast track drug under investigation shows evidence of effectiveness, the Secretary shall evaluate for filing, and may commence review of portions, of an application for the approval of the drug if the applicant provides a schedule for submission of information necessary to make the application complete and any fee that may be required under section 736.*

*''(2) EXCEPTION.—Any time period for review of human drug applications that has been agreed to by the Secretary and that has been set forth in goals identified in letters of the Secretary (relating to the use of fees collected under section 736 to expedite the drug development process and the review of human drug applications) shall not apply to an application submitted under paragraph (1) until the date on which the application is complete.*

*''(d) AWARENESS EFFORTS.—The Secretary shall—*

*''(1) develop and widely disseminate to physicians, patient organizations, pharmaceutical and biotechnology companies, and other appropriate persons a comprehensive description of the provisions applicable to fast track drugs established under this section; and*

*''(2) establish an ongoing program to encourage the development of surrogate endpoints that are reasonably likely to predict clinical benefit for serious or life-threatening conditions for which there exist significant unmet medical needs.''.*

*(b) GUIDANCE.—Within 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall issue guidance for fast track drugs that describes the policies and procedures that pertain to section 561 of the Federal Food, Drug, and Cosmetic Act.*

***SEC. 614. MANUFACTURING CHANGES FOR DRUGS AND BIOLOGICS.***

*(a) IN GENERAL.—Chapter VII (21 U.S.C. 371 et seq.), as amended by section 602, is further amended by adding at the end the following:*

*''SUBCHAPTER E—MANUFACTURING CHANGES*

***''SEC. 751. MANUFACTURING CHANGES.***

*''(a) IN GENERAL.—A change in the manufacture of a new drug, including a biological product, may be made in accordance with this section.*

*''(b) CHANGES.—*

*''(1) VALIDATION.—Before distributing a drug made after a change in the manufacture of the drug from the manufacturing process established in the approved new drug application under section 505, or license application under section 351 of the Public Health Service Act, the applicant shall validate the effect of the change on the identity, strength, quality, purity, and potency of the drug as the identity, strength, quality, purity, and potency may relate to the safety or effectiveness of the drug.*

*''(2) REPORTS.—The applicant shall report the change described in paragraph (1) to the Secretary and may distribute a drug made after the change as follows:*

*''(A) MAJOR MANUFACTURING CHANGES.*

*''(i) IN GENERAL.—Major manufacturing changes, which are of a type determined by the Secretary to have substantial potential to adversely affect the identity, strength, quality, purity, or potency of the drug as the identity, strength, quality, purity, and potency may relate to the safety or effectiveness of a drug, shall be submitted to the Secretary in a supplemental application and drugs made after such changes may not be distributed until the Secretary approves the supplemental application.*

*''(ii) DEFINITION.—In this subparagraph, the term 'major manufacturing changes' means—*

*''(I) changes in the qualitative or quantitative formulation of a drug or the specifications in the approved marketing application for the drug (unless exempted by the Secretary from the requirements of this subparagraph);*

*''(II) changes that the Secretary determines by regulation or issuance of guidance require completion of an appropriate human study demonstrating equivalence of the drug to the drug manufactured before such changes; and*

*''(III) other changes that the Secretary determines by regulation or issuance of guidance have a substantial potential to adversely affect the safety or effectiveness of the drug.*

*''(B) OTHER MANUFACTURING CHANGES.—*

*''(i) IN GENERAL.—As determined by the Secretary, manufacturing changes other than major manufacturing changes shall—*

*''(I) be made at any time and reported annually to the Secretary, with supporting data; or*

*''(II) be reported to the Secretary in a supplemental application.*

*''(ii) DISTRIBUTION OF THE DRUG.—In the case of changes reported in accordance with clause (i)(II)—*

*''(I) the applicant may distribute the drug 30 days after the Secretary receives the supplemental application unless the Secretary notifies the applicant within such 30-day period that prior approval of such supplemental application is required; and*

*''(II) the Secretary shall, after making the notification to the applicant under subclause (I), approve or disapprove each such supplemental application.*

*''(iii) SPECIAL RULE.—The Secretary may determine types of manufacturing changes after which distribution of a drug may commence at the time of submission of such supplemental application.''.*

*(b) EXISTING LAW.—The requirements of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.) and the Public Health Service Act (42 U.S.C. 201 et seq.) that are in effect on the date of enactment of this Act with respect to manufacturing changes shall remain in effect—*

*(1) for a period of 24 months after the date of enactment of this Act; or*

*(2) until the effective date of regulations promulgated by the Secretary of Health and Human Services implementing section 751 of the Federal Food, Drug, and Cosmetic Act,*

*whichever is sooner.*

***SEC. 615. DATA REQUIREMENTS FOR DRUGS AND BIOLOGICS.***

*Within 12 months after the date of enactment of this Act, the Secretary of the Health and Human Services, acting through the Commissioner of Food and Drugs, shall issue guidance that describes when abbreviated study reports may be submitted, in lieu of full reports, with a new drug application under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) and with a biologics license application under section 351 of the Public Health Service Act (42 U.S.C. 262) for certain types of studies. Such guidance shall describe the kinds of studies for which abbreviated reports are appropriate and the appropriate abbreviated report formats.*

***SEC. 616. FOOD CONTACT SUBSTANCES.***

*(a) FOOD CONTACT SUBSTANCES.—Section 409(a) (21 U.S.C. 348(a)) is amended—*

*(1) in paragraph (1)—*

*(A) by striking ''subsection (i)'' and inserting ''subsection (j)''; and*

*(B) by striking at the end ''or'';*

*(2) by striking the period at the end of paragraph (2) and inserting ''; or'';*

*(3) by inserting after paragraph (2) the following:*

*''(3) in the case of a food additive as defined in this Act that is a food contact substance, there is—*

*''(A) in effect, and such substance and the use of such substance are in conformity with, a regulation issued under this section prescribing the conditions under which such additive may be safely used; or*

*''(B) a notification submitted under subsection (h) that is effective.''; and*

*(4) by striking the matter following paragraph (3) (as added by paragraph (2)) and inserting the following flush sentence:*

*''While such a regulation relating to a food additive, or such a notification under subsection (h) relating to a food additive that is a food contact substance, is in effect, and has not been revoked pursuant to subsection (i), a food shall not, by reason of bearing or containing such a food additive in accordance with the regulation or notification, be considered adulterated under section 402(a)(1).''.*

*(b) NOTIFICATION FOR FOOD CONTACT SUBSTANCES.—Section 409 (21 U.S.C. 348), as amended by subsection (a), is further amended—*

*(1) by redesignating subsections (h) and (i), as subsections (i) and (j), respectively;*

*(2) by inserting after subsection (g) the following:*

*''Notification Relating to a Food Contact Substance*

*''(h)(1) Subject to such regulations as may be promulgated under paragraph (3), a manufacturer or supplier of a food contact substance may, at least 120 days prior to the introduction or delivery for introduction into interstate commerce of the food contact substance, notify the*

Secretary of the identity and intended use of the food contact substance, and of the determination of the manufacturer or supplier that the intended use of such food contact substance is safe under the standard described in subsection (c)(3)(A). The notification shall contain the information that forms the basis of the determination, the fee required under paragraph (5), and all information required to be submitted by regulations promulgated by the Secretary.

''(2)(A) A notification submitted under paragraph (1) shall become effective 120 days after the date of receipt by the Secretary and the food contact substance may be introduced or delivered for introduction into interstate commerce, unless the Secretary makes a determination within the 120-day period that, based on the data and information before the Secretary, such use of the food contact substance has not been shown to be safe under the standard described in subsection (c)(3)(A), and informs the manufacturer or supplier of such determination.

''(B) A decision by the Secretary to object to a notification shall constitute final agency action subject to judicial review.

''(C) In this paragraph, the term 'food contact substance' means the substance that is the subject of a notification submitted under paragraph (1), and does not include a similar or identical substance manufactured or prepared by a person other than the manufacturer identified in the notification.

''(3)(A) The process in this subsection shall be utilized for authorizing the marketing of a food contact substance except where the Secretary determines that submission and review of a petition under subsection (b) is necessary to provide adequate assurance of safety, or where the Secretary and any manufacturer or supplier agree that such manufacturer or supplier may submit a petition under subsection (b).

''(B) The Secretary is authorized to promulgate regulations to identify the circumstances in which a petition shall be filed under subsection (b), and shall consider criteria such as the probable consumption of such food contact substance and potential toxicity of the food contact substance in determining the circumstances in which a petition shall be filed under subsection (b).

''(4) The Secretary shall keep confidential any information provided in a notification under paragraph (1) for 120 days after receipt by the Secretary of the notification. After the expiration of such 120 days, the information shall be available to any interested party except for any matter in the notification that is a trade secret or confidential commercial information.

''(5)(A) Each person that submits a notification regarding a food contact substance under this section shall be subject to the payment of a reasonable fee. The fee shall be based on the resources required to process the notification including reasonable administrative costs for such processing.

''(B) The Secretary shall conduct a study of the costs of administering the notification program established under this section and, on the basis of the results of such study, shall, within 18 months after the date of enactment of the Food and Drug Administration Modernization and Accountability Act of 1997, promulgate regulations establishing the fee required by subparagraph (A).

''(C) A notification submitted without the appropriate fee is not complete and shall not become effective for the purposes of subsection (a)(3) until the appropriate fee is paid.

''(D) Fees collected pursuant to this subsection—

''(i) shall not be deposited as an offsetting collection to the appropriations for the Department of Health and Human Services;

''(ii) shall be credited to the appropriate account of the Food and Drug Administration; and

''(iii) shall be available in accordance with appropriation Acts until expended, without fiscal year limitation.

''(6) In this section, the term 'food contact substance' means any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food.'';

(3) in subsection (i), as so redesignated by paragraph (1), by adding at the end the following: ''The Secretary shall by regulation prescribe the procedure by which the Secretary may deem a notification under subsection (h) to no longer be effective.''; and

(4) in subsection (j), as so redesignated by paragraph (1), by striking ''subsections (b) to (h)'' and inserting ''subsections (b) to (i)''.

(c) EFFECTIVE DATE.—Notifications under section 409(h) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (b), may be submitted beginning 18 months after the date of enactment of this Act.

**SEC. 617. HEALTH CLAIMS FOR FOOD PRODUCTS.**

Section 403(r)(3) (21 U.S.C. 343(r)(3)) is amended by adding at the end the following:

''(C) Notwithstanding the provisions of clauses (A)(i) and (B), a claim of the type described in subparagraph (1)(B) that is not authorized by the Secretary in a regulation promulgated in accordance with clause (B) shall be authorized and may be made if—

''(i) an authoritative scientific body of the Federal Government with official responsibility for public health protection or research directly relating to human nutrition (such as the National Institutes of Health or the Centers for Disease Control and Prevention), the National Academy of Sciences, or a subdivision of the scientific body or the National Academy of Sciences, has published an authoritative statement, which is currently in effect, about the relationship between a nutrient and a disease or health-related condition to which the claim refers;

''(ii) a person has submitted to the Secretary at least 90 days before the first introduction of a food into interstate commerce a notice of the claim, including a concise description of the basis upon which such person relied for determining that the requirements of subclause (i) have been satisfied;

''(iii) the claim and the food for which the claim is made are in compliance with clause (A)(ii), and are otherwise in compliance with paragraph (a) and section 201(n); and

''(iv) the claim is stated in a manner so that the claim is an accurate representation of the authoritative statement referred to in subclause (i) and so that the claim enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet.

For purposes of this paragraph, a statement shall be regarded as an authoritative statement of such a scientific body described in subclause (i) only if the statement is published by the scientific body and shall not include a statement of an employee of the scientific body made in the individual capacity of the employee.

''(D) A claim meeting the requirements of clause (C) may be made until—

''(i) such time as the Secretary issues a final regulation under clause (B) prohibiting or modifying the claim, and the regulation has become effective; or

''(ii) a district court of the United States in an enforcement proceeding under chapter III has determined that the requirements of clause (C) have not been met.''.

**SEC. 618. PEDIATRIC STUDIES MARKETING EXCLUSIVITY.**

Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 505 the following:

**''SEC. 505A. PEDIATRIC STUDIES OF DRUGS.**

''(a) MARKET EXCLUSIVITY FOR NEW DRUGS.—If, prior to approval of an application that is submitted under section 505(b)(1) the Secretary determines that information relating to the use of a drug in the pediatric population may produce health benefits in that population, the Secretary makes a written request for pediatric studies (which may include a timeframe for completing such studies), and such studies are completed within any such timeframe and the reports thereof submitted in accordance with subsection (d)(2) or completed within any such timeframe and the reports thereof are accepted in accordance with subsection (d)(3)—

''(1)(A) the period during which an application may not be submitted under subsections (c)(3)(D)(ii) and (j)(4)(D)(ii) of section 505 shall be five years and six months rather than five years, and the references in subsections (c)(3)(D)(ii) and (j)(4)(D)(ii) of section 505 to four years, to forty-eight months, and to seven and one-half years shall be deemed to be four and one-half years, fifty-four months, and eight years, respectively; or

''(B) the period of market exclusivity under subsections (c)(3)(D) (iii) and (iv) and (j)(4)(D) (iii) and (iv) of section 505 shall be three years and six months rather than three years; and

''(2)(A) if the drug is the subject of—

''(i) a listed patent for which a certification has been submitted under section 505(b)(2)(A)(ii) or section (j)(2)(A)(vii)(II) and for which pediatric studies were submitted prior to the expiration of the patent (including any patent extensions); or

''(ii) a listed patent for which a certification has been submitted under section 505(b)(2)(A)(iii) or section 505(j)(2)(A)(vii)(III),

the period during which an application may not be approved under section 505(c)(3) or section 505(j)(4)(B) shall be extended by a period of six months after the date the patent expires (including any patent extensions); or

''(B) if the drug is the subject of a listed patent for which a certification has been submitted under section 505(b)(2)(A)(iv) or section 505(j)(2)(A)(vii)(IV), and in the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed, the period during which an application may not be approved under section 505(c)(3) or section 505(j)(4)(B) shall be extended by a period of six months after the date the patent expires (including any patent extensions).

''(b) SECRETARY TO DEVELOP LIST OF DRUGS FOR WHICH ADDITIONAL PEDIATRIC INFORMATION MAY BE BENEFICIAL.—Not later than 180 days after the date of enactment of this section, the Secretary, after consultation with experts in pediatric research (such as the American Academy of Pediatrics, the Pediatric Pharmacology Research Unit Network, and the United States Pharmacopoeia) shall develop, prioritize, and publish an initial list of approved drugs for which additional pediatric information may produce health benefits in the pediatric population. The Secretary shall annually update the list.

''(c) MARKET EXCLUSIVITY FOR ALREADY-MARKETED DRUGS.—If the Secretary makes a written request for pediatric studies (which may include a timeframe for completing such studies) concerning a drug identified in the list described in subsection (b) to the holder of an approved application under section 505(b)(1) for the drug, the holder agrees to the request, and the studies are completed within any such timeframe and the reports thereof submitted in accordance with subsection (d)(2) or completed within any such timeframe and the reports thereof accepted in accordance with subsection (d)(3)—

''(1)(A) the period during which an application may not be submitted under subsections (c)(3)(D)(ii) and (j)(4)(D)(ii) of section 505 shall be five years and six months rather than five years, and the references in subsections (c)(3)(D)(ii) and (j)(4)(D)(ii) of section 505 to four years, to forty-eight months, and to seven and one-half years shall be deemed to be four

*and one-half years, fifty-four months, and eight years, respectively; or*

*''(B) the period of market exclusivity under subsections (c)(3)(D) (iii) and (iv) and (j)(4)(D) (iii) and (iv) of section 505 shall be three years and six months rather than three years; and*

*''(2)(A) if the drug is the subject of—*

*''(i) a listed patent for which a certification has been submitted under section 505(b)(2)(A)(ii) or (j)(2)(A)(vii)(II) and for which pediatric studies were submitted prior to the expiration of the patent (including any patent extensions); or*

*''(ii) a listed patent for which a certification has been submitted under section 505(b)(2)(A)(iii) or section 505(j)(2)(A)(vii)(III),*

*the period during which an application may not be approved under section 505(c)(3) or section 505(j)(4)(B) shall be extended by a period of six months after the date the patent expires (including any patent extensions); or*

*''(B) if the drug is the subject of a listed patent for which a certification has been submitted under section 505(b)(2)(A)(iv) or section 505(j)(2)(A)(vii)(IV), and in the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed, the period during which an application may not be approved under section 505(c)(3) or section 505(j)(4)(B) shall be extended by a period of six months after the date the patent expires (including any patent extensions).*

*''(d) CONDUCT OF PEDIATRIC STUDIES.—*

*''(1) AGREEMENT FOR STUDIES.—The Secretary may, pursuant to a written request for studies, after consultation with—*

*''(A) the sponsor of an application for an investigational new drug under section 505(i);*

*''(B) the sponsor of an application for a drug under section 505(b)(1); or*

*''(C) the holder of an approved application for a drug under section 505(b)(1),*

*agree with the sponsor or holder for the conduct of pediatric studies for such drug.*

*''(2) WRITTEN PROTOCOLS TO MEET THE STUDIES REQUIREMENT.—If the sponsor or holder and the Secretary agree upon written protocols for the studies, the studies requirement of subsection (a) or (c) is satisfied upon the completion of the studies and submission of the reports thereof in accordance with the original written request and the written agreement referred to in paragraph (1). Not later than 60 days after the submission of the report of the studies, the Secretary shall determine if such studies were or were not conducted in accordance with the original written request and the written agreement and reported in accordance with the requirements of the Secretary for filing and so notify the sponsor or holder.*

*''(3) OTHER METHODS TO MEET THE STUDIES REQUIREMENT.—If the sponsor or holder and the Secretary have not agreed in writing on the protocols for the studies, the studies requirement of subsection (a) or (c) is satisfied when such studies have been completed and the reports accepted by the Secretary. Not later than 90 days after the submission of the reports of the studies, the Secretary shall accept or reject such reports and so notify the sponsor or holder. The Secretary's only responsibility in accepting or rejecting the reports shall be to determine, within the 90 days, whether the studies fairly respond to the written request, whether such studies have been conducted in accordance with commonly accepted scientific principles and protocols, and whether such studies have been reported in accordance with the requirements of the Secretary for filing.*

*''(e) DELAY OF EFFECTIVE DATE FOR CERTAIN APPLICATIONS; PERIOD OF MARKET EXCLUSIVITY.—If the Secretary determines that the acceptance or approval of an application under section 505(b)(2) or 505(j) for a drug may occur after submission of reports of pediatric studies under this section, which were submitted prior to the expiration of the patent (including any patent extension) or market exclusivity protection, but before the Secretary has determined whether the requirements of subsection (d) have been satisfied, the Secretary shall delay the acceptance or approval under section 505(b)(2) or 505(j), respectively, until the determination under subsection (d) is made, but such delay shall not exceed 90 days. In the event that requirements of this section are satisfied, the applicable period of market exclusivity referred to in subsection (a) or (c) shall be deemed to have been running during the period of delay.*

*''(f) NOTICE OF DETERMINATIONS ON STUDIES REQUIREMENT.—The Secretary shall publish a notice of any determination that the requirements of subsection (d) have been met and that submissions and approvals under section 505(b)(2) or (j) for a drug will be subject to the provisions of this section.*

*''(g) DEFINITIONS.—As used in this section, the term 'pediatric studies' or 'studies' means at least 1 clinical investigation (that, at the Secretary's discretion, may include pharmacokinetic studies) in pediatric age-groups in which a drug is anticipated to be used.*

*''(h) LIMITATION.—The holder of an approved application for a new drug that has already received six months of market exclusivity under subsection (a) or (c) may, if otherwise eligible, obtain six months of market exclusivity under subsection (c)(1)(B) for a supplemental application, except that the holder is not eligible for exclusivity under subsection (c)(2).*

*''(i) SUNSET.—No period of market exclusivity shall be granted under this section based on studies commenced after January 1, 2004. The Secretary shall conduct a study and report to Congress not later than January 1, 2003 based on the experience under the program. The study and report shall examine all relevant issues, including—*

*''(1) the effectiveness of the program in improving information about important pediatric uses for approved drugs;*

*''(2) the adequacy of the incentive provided under this section;*

*''(3) the economic impact of the program; and*

*''(4) any suggestions for modification that the Secretary deems appropriate.''.*

***SEC. 619. POSITRON EMISSION TOMOGRAPHY.***

*(a) REGULATION OF COMPOUNDED POSITRON EMISSION TOMOGRAPHY DRUGS UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.—*

*(1) DEFINITION.—Section 201 (21 U.S.C. 321), as amended by section 405, is further amended by adding at the end the following:*

*''(jj) The term 'compounded positron emission tomography drug' means a drug that—*

*''(1) exhibits spontaneous disintegration of unstable nuclei, including the emission of positrons;*

*''(2) includes any nonradioactive reagent, reagent kit, ingredient, nuclide generator, accelerator, target material, electronic synthesizer, or other apparatus or computer program to be used in the preparation of any such drug; and*

*''(3)(A) has been compounded in a State in accordance with State law for a patient or for research, teaching, or quality control by or on the order of a practitioner licensed by that State to compound or order such a drug; or*

*''(B) has been compounded in a Federal facility in a State in accordance with the law of the State in which the facility is located.''.*

*(b) REGULATION AS A DRUG.—Section 501(a)(2) (21 U.S.C. 351(a)(2)) is amended by striking ''; or (3)'' and inserting the following: ''; or (C) if it is a compounded positron emission tomography drug and the methods used in, or the facilities and controls used for, its compounding, processing, packing, or holding do not conform to or are not operated or administered in conformity with the positron emission tomography compounding standards and the official monographs of the United States Pharmacopoeia to assure that such drug meets the requirements of this Act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess; or (3)''.*

*(c) REGULATION AS A NEW DRUG.—Section 505 (21 U.S.C. 355) is amended by adding at the end the following:*

*''(n) The provisions of subsections (a) and (j) shall not apply to the preparation of a compounded positron emission tomography drug.''.*

*(d) REVOCATION OF CERTAIN INCONSISTENT DOCUMENTS.—Not later than 30 days after the date of enactment of this Act, the Secretary of Health and Human Services shall publish in the Federal Register a notice revoking—*

*(1) a notice entitled ''Regulation of Positron Emission Tomographic Drug Products: Guidance; Public Workshop'', published in the Federal Register of February 27, 1995;*

*(2) a notice entitled ''Guidance for Industry: Current Good Manufacturing Practices for Positron Emission Tomographic (PET) Drug Products'', published in the Federal Register of April 22, 1997; and*

*(3) a final rule entitled ''Current Good Manufacturing Practice for Finished Pharmaceuticals; Positron Emission Tomography'', published in the Federal Register of April 22, 1997.*

## *TITLE VII—FEES RELATING TO DRUGS*

***SEC. 701. SHORT TITLE.***

*This title may be cited as the ''Prescription Drug User Fee Reauthorization Act of 1997''.*

***SEC. 702. FINDINGS.***

*Congress finds that—*

*(1) prompt approval of safe and effective new drugs and other therapies is critical to the improvement of the public health so that patients may enjoy the benefits provided by these therapies to treat and prevent illness and disease;*

*(2) the public health will be served by making additional funds available for the purpose of augmenting the resources of the Food and Drug Administration that are devoted to the process for review of human drug applications;*

*(3) the provisions added by the Prescription Drug User Fee Act of 1992 have been successful in substantially reducing review times for human drug applications and should be—*

*(A) reauthorized for an additional 5 years, with certain technical improvements; and*

*(B) carried out by the Food and Drug Administration with new commitments to implement more ambitious and comprehensive improvements in regulatory processes of the Food and Drug Administration; and*

*(4) the fees authorized by amendments made in this title will be dedicated toward expediting the drug development process and the review of human drug applications as set forth in the goals identified in the letters of _____, and _____, from the Secretary of Health and Human Services to the chairman of the Committee on Commerce of the House of Representatives and the chairman of the Committee on Labor and Human Resources of the Senate, as set forth at ___ Cong. Rec. _____ (daily ed. _____, 1997).*

***SEC. 703. DEFINITIONS.***

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

*(1) in the second sentence of paragraph (1)—*

*(A) by striking ''Service Act, and'' and inserting ''Service Act,''; and*

*(B) by striking ''September 1, 1992.'' and inserting the following: ''September 1, 1992, does not include an application for a licensure of a biological product for further manufacturing use only, and does not include an application or supplement submitted by a State or Federal Government entity for a drug or biological product that is not distributed commercially. Such term does include an application for licensure, as described in subparagraph (D), of a large volume biological product intended for single dose injection for intravenous use or infusion.'';*

*(2) in the second sentence of paragraph (3)—*

*(A) by striking ''Service Act, and'' and inserting ''Service Act,''; and*

*(B) by striking ''September 1, 1992.'' and inserting the following: ''September 1, 1992, does not include a biological product that is licensed*

for further manufacturing use only, and does not include a drug or biological product that is not distributed commercially and is the subject of an application or supplement submitted by a State or Federal Government entity. Such term does include a large volume biological product intended for single dose injection for intravenous use or infusion.'';

(3) in paragraph (4), by striking ''without'' and inserting ''without substantial'';

(4) in paragraph (7)(A)—

(A) by striking ''employees under contract'' and all that follows through ''Administration,'' and inserting ''contractors of the Food and Drug Administration,''; and

(B) by striking ''and committees,'' and inserting ''and committees and to contracts with such contractors,'';

(5) in paragraph (8)—

(A) in subparagraph (A)—

(i) by striking ''August of'' and inserting ''April of''; and

(ii) by striking ''August 1992'' and inserting ''April 1997'';

(B) by striking subparagraph (B) and inserting the following:

''(B) 1 plus the total percentage increase for such fiscal year since fiscal year 1997 in basic pay under the General Schedule in accordance with section 5332 of title 5, United States Code, as adjusted by any locality-based comparability payment pursuant to section 5304 of such title for Federal employees stationed in the District of Columbia.''; and

(C) by striking the second sentence; and

(6) by adding at the end the following:

''(9) The term 'affiliate' means a business entity that has a relationship with a second business entity if, directly or indirectly—

''(A) 1 business entity controls, or has the power to control, the other business entity; or

''(B) a third party controls, or has power to control both of the business entities.''.

***SEC. 704. AUTHORITY TO ASSESS AND USE DRUG FEES.***

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

(1) by striking ''Beginning in fiscal year 1993'' and inserting ''Beginning in fiscal year 1998'';

(2) in paragraph (1)—

(A) by striking subparagraph (B) and inserting the following:

''(B) PAYMENT.—The fee required by subparagraph (A) shall be due upon submission of the application or supplement.'';

(B) in subparagraph (D)—

(i) in the subparagraph heading, by striking ''NOT ACCEPTED'' and inserting ''REFUSED'';

(ii) by striking ''50 percent'' and inserting ''75 percent'';

(iii) by striking ''subparagraph (B)(i)'' and inserting ''subparagraph (B)''; and

(iv) by striking ''not accepted'' and inserting ''refused''; and

(C) by adding at the end the following:

''(E) EXCEPTION FOR DESIGNATED ORPHAN DRUG OR INDICATION.—A person that submits a human drug application for a prescription drug product that has been designated as a drug for a rare disease or condition pursuant to section 526, or a supplement proposing to include a new indication for a rare disease or condition pursuant to section 526, shall not be assessed a fee under subparagraph (A), unless the human drug application includes indications for other than rare diseases or conditions.

''(F) EXCEPTION FOR APPLICATIONS AND SUPPLEMENTS FOR PEDIATRIC INDICATIONS.—A person that submits a human drug application or supplement that includes an indication for use in pediatric populations shall be assessed a fee under subparagraph (A) only if—

''(i) the application is for initial approval for use in a pediatric population; or

''(ii) the application or supplement is for approval for use in pediatric and non-pediatric populations.

''(G) REFUND OF FEE IF APPLICATION WITHDRAWN.—If an application or supplement is withdrawn after the application or supplement is filed, the Secretary may waive and refund the fee or a portion of the fee if no substantial work was performed on the application or supplement after the application or supplement was filed. The Secretary shall have the sole discretion to waive and refund a fee or a portion of the fee under this subparagraph. A determination by the Secretary concerning a waiver or refund under this paragraph shall not be reviewable.'';

(3) in paragraph (2)(A), by striking ''505(j), and'' and inserting the following: ''505(j) or under an abbreviated new drug application pursuant to regulations in effect prior to the implementation of the Drug Price Competition and Patent Term Restoration Act of 1984, or a product approved under an application filed under section 507 that is abbreviated, and''; and

(4) in paragraph (3)—

(A) in subparagraph (A)—

(i) in clause (i), by striking ''is listed'' and inserting ''has been submitted for listing''; and

(ii) by striking ''Such fee shall be payable'' and all that follows through ''section 510.'' and inserting the following: ''Such fee shall be payable for the fiscal year in which the product is first submitted for listing under section 510, or for relisting under section 510 if the product has been withdrawn from listing and relisted. After such fee is paid for that fiscal year, such fee shall be payable on or before January 31 of each year. Such fee shall be paid only once for each product for a fiscal year in which the fee is payable.''; and

(B) in subparagraph (B), by striking ''505(j).'' and inserting the following: ''505(j), or under an abbreviated new drug application pursuant to regulations in effect prior to the implementation of the Drug Price Competition and Patent Term Restoration Act of 1984, or is a product approved under an application filed under section 507 that is abbreviated.''.

(b) FEE AMOUNTS.—Section 736(b) (21 U.S.C. 379h(b)) is amended to read as follows:

''(b) FEE AMOUNTS.—Except as provided in subsections (c), (d), (f), and (g), the fees required under subsection (a) shall be determined and assessed as follows:

''(1) APPLICATION AND SUPPLEMENT FEES.—

''(A) FULL FEES.—The application fee under subsection (a)(1)(A)(i) shall be $250,704 in fiscal year 1998, $256,338 in each of fiscal years 1999 and 2000, $267,606 in fiscal year 2001, and $258,451 in fiscal year 2002.

''(B) OTHER FEES.—The fee under subsection (a)(1)(A)(ii) shall be $125,352 in fiscal year 1998, $128,169 in each of fiscal years 1999 and 2000, $133,803 in fiscal year 2001, and $129,226 in fiscal year 2002.

''(2) FEE REVENUES FOR ESTABLISHMENT FEES.—The total fee revenues to be collected in establishment fees under subsection (a)(2) shall be $35,600,000 in fiscal year 1998, $36,400,000 in each of fiscal years 1999 and 2000, $38,000,000 in fiscal year 2001, and $36,700,000 in fiscal year 2002.

''(3) TOTAL FEE REVENUES FOR PRODUCT FEES.—The total fee revenues to be collected in product fees under subsection (a)(3) in a fiscal year shall be equal to the total fee revenues collected in establishment fees under subsection (a)(2) in that fiscal year.''.

(c) INCREASES AND ADJUSTMENTS.—Section 736(c) (21 U.S.C. 379h(c)) is amended—

(1) in the subsection heading, by striking ''INCREASES AND'';

(2) in paragraph (1)—

(A) by striking ''(1) REVENUE'' and all that follows through ''increased by the Secretary'' and inserting the following: ''(1) INFLATION ADJUSTMENT.—The fees and total fee revenues established in subsection (b) shall be adjusted by the Secretary'';

(B) in subparagraph (A), by striking ''increase'' and inserting ''change'';

(C) in subparagraph (B), by striking ''increase'' and inserting ''change''; and

(D) by adding at the end the following flush sentence:

''The adjustment made each fiscal year by this subsection will be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 1997 under this subsection.'';

(3) in paragraph (2), by striking ''October 1, 1992,'' and all that follows through ''such schedule.'' and inserting the following: ''September 30, 1997, adjust the establishment and product fees described in subsection (b) for the fiscal year in which the adjustment occurs so that the revenues collected from each of the categories of fees described in paragraphs (2) and (3) of subsection (b) shall be set to be equal to the revenues collected during the past fiscal year from the category of application and supplement fees described in paragraph (1) of subsection (b).''; and

(4) in paragraph (3), by striking ''paragraph (2)'' and inserting ''this subsection''.

(d) FEE WAIVER OR REDUCTION.—Section 736(d) (21 U.S.C. 379h(d)) is amended—

(1) by redesignating paragraphs (1), (2), (3), and (4) as subparagraphs (A), (B), (C), and (D), respectively and indenting appropriately;

(2) by striking ''The Secretary shall grant a'' and all that follows through ''finds that—'' and inserting the following:

''(1) IN GENERAL.—The Secretary shall grant a waiver from or a reduction of 1 or more fees assessed under subsection (a) where the Secretary finds

that—'';

(3) in subparagraph (C) (as so redesignated by paragraph (1)), by striking '', or'' and inserting a comma;

(4) in subparagraph (D) (as so redesignated by paragraph (1)), by striking the period and inserting '', or'';

(5) by inserting after subparagraph (D) (as so redesignated by paragraph (1)) the following:

''(E) the applicant is a small business submitting its first human drug application to the Secretary for review.''; and

(6) by striking ''In making the finding in paragraph (3),'' and all that follows through ''standard costs.'' and inserting the following:

''(2) USE OF STANDARD COSTS.—In making the finding in paragraph (1)(C), the Secretary may use standard costs.

''(3) RULES RELATING TO SMALL BUSINESSES.—

''(A) DEFINITION.—In paragraph (1)(E), the term 'small business' means an entity that has fewer than 500 employees, including employees of affiliates.

''(B) WAIVER OF APPLICATION FEE.—The Secretary shall waive under paragraph (1)(E) the application fee for the first human drug application that a small business or its affiliate submits to the Secretary for review. After a small business or its affiliate is granted such a waiver, the small business or its affiliate shall pay—

''(i) application fees for all subsequent human drug applications submitted to the Secretary for review in the same manner as an entity that does not qualify as a small business; and

''(ii) all supplement fees for all supplements to human drug applications submitted to the Secretary for review in the same manner as an entity that does not qualify as a small business.''.

(e) ASSESSMENT OF FEES.—Section 736(f)(1) (21 U.S.C. 379h(f)(1)) is amended—

(1) by striking ''fiscal year 1993'' and inserting ''fiscal year 1997''; and

(2) by striking ''fiscal year 1992'' and inserting ''fiscal year 1997 (excluding the amount of fees appropriated for such fiscal year)''.

(f) CREDITING AND AVAILABILITY OF FEES.—Section 736(g) (21 U.S.C. 379h(g)) is amended—

(1) in paragraph (1), by adding at the end the following: ''Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for the process for the review of human drug applications within the meaning of section 735(6).'';

(2) in paragraph (2)—

(A) in subparagraph (A), by striking ''Acts'' and inserting ''Acts, or otherwise made available for obligation,''; and

(B) in subparagraph (B), by striking ''over such costs for fiscal year 1992'' and inserting ''over such costs, excluding costs paid from fees collected under this section, for fiscal year 1997''; and

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

''(3) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated for fees under this section—

''(A) $106,800,000 for fiscal year 1998;

''(B) $109,200,000 for fiscal year 1999;

''(C) $109,200,000 for fiscal year 2000;

''(D) $114,000,000 for fiscal year 2001; and

''(E) $110,100,000 for fiscal year 2002,

as adjusted to reflect adjustments in the total fee revenues made under this section and changes in the total amounts collected by application, supplement, establishment, and product fees.

''(4) OFFSET.—Any amount of fees collected for a fiscal year which exceeds the amount of fees specified in appropriation Acts for such fiscal year, shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under appropriation Acts for a subsequent fiscal year.''.

(g) REQUIREMENT FOR WRITTEN REQUESTS FOR WAIVERS, REDUCTIONS, AND FEES.—Section 736 (21 U.S.C. 379h) is amended—

(1) by redesignating subsection (i) as subsection (j); and

(2) by inserting after subsection (h) the following:

''(i) WRITTEN REQUESTS FOR WAIVERS, REDUCTIONS, AND REFUNDS.—To qualify for consideration for a waiver or reduction under subsection (d), or for a refund, of any fee collected in accordance with subsection (a), a person shall submit to the Secretary a written request for such waiver, reduction, or refund not later than 180 days after such fee is due.''.

(h) SPECIAL RULE FOR WAIVER, REFUNDS, AND EXCEPTIONS.—Any requests for waivers, refunds, or exceptions for fees paid prior to the date of enactment of this Act shall be submitted in writing to the Secretary of Health and Human Services within 1 year after the date of enactment of this Act.

**SEC. 705. ANNUAL REPORTS.**

(a) FIRST REPORT.—Beginning with fiscal year 1998, not later than 60 days after the end of each fiscal year during which fees are collected under part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g et seq.), the Secretary of Health and Human Services shall prepare and submit to the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letter described in section 702(4) during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals.

(b) SECOND REPORT.—Beginning with fiscal year 1998, not later than 120 days after the end of each fiscal year during which fees are collected under the part described in subsection (a), the Secretary of Health and Human Services shall prepare and submit to the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate 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.

**SEC. 706. EFFECTIVE DATE.**

The amendments made by this title shall take effect October 1, 1997.

**SEC. 707. TERMINATION OF EFFECTIVENESS.**

The amendments made by sections 703 and 704 cease to be effective October 1, 2002 and section 705 ceases to be effective 120 days after such date.

## TITLE VIII—MISCELLANEOUS

**SEC. 801. REGISTRATION OF FOREIGN ESTABLISHMENTS.**

Section 510(i) (21 U.S.C. 360(i)) is amended to read as follows:

''(i)(1) Any establishment within any foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or a device that is imported or offered for import into the United States shall register with the Secretary the name and place of business of the establishment and the name of the United States agent for the establishment.

''(2) The establishment shall also provide the information required by subsection (j).

''(3) The Secretary is authorized to enter into cooperative arrangements with foreign countries to ensure that adequate and effective means are available for purposes of determining, from time to time, whether drugs or devices manufactured, prepared, propagated, compounded, or processed by an establishment described in paragraph (1), if imported or offered for import into the United States, shall be refused admission on any of the grounds set forth in section 801(a).''.

**SEC. 802. ELIMINATION OF CERTAIN LABELING REQUIREMENTS.**

(a) PRESCRIPTION DRUGS.—Section 503(b)(4) (21 U.S.C. 353(b)(4)) is amended to read as follows:

''(4)(A) A drug that is subject to paragraph (1) shall be deemed to be misbranded if at any time prior to dispensing the label of the drug fails to bear, at a minimum, the symbol 'Rx only'.

''(B) A drug to which paragraph (1) does not apply shall be deemed to be misbranded if at any time prior to dispensing the label of the drug bears the symbol described in subparagraph (A).''.

(b) MISBRANDED DRUG.—Section 502(d) (21 U.S.C. 352(d)) is repealed.

(c) CONFORMING AMENDMENTS.—

(1) Section 503(b)(1) (21 U.S.C. 353(b)(1)) is amended—

(A) by striking subparagraph (A); and

(B) by redesignating subparagraphs (B) and (C) as subparagraphs (A) and (B), respectively.

(2) Section 503(b)(3) (21 U.S.C. 353(b)(3)) is amended by striking ''section 502(d) and''.

(3) Section 102(9)(A) of the Controlled Substances Act (21 U.S.C. 802(9)(A)) is amended—

(A) in clause (i), by striking ''(i)''; and

(B) by striking ''(ii)'' and all that follows.

**SEC. 803. CLARIFICATION OF SEIZURE AUTHORITY.**

Section 304(d)(1) (21 U.S.C. 334(d)(1)) is amended—

(1) in paragraph (1), in the fifth sentence, by striking ''paragraphs (1) and (2) of section 801(e)'' and inserting ''subparagraphs (A) and (B) of section 801(e)(1)''; and

(2) by inserting after the fifth sentence the following: ''Any person seeking to export an imported article pursuant to any of the provisions of this subsection shall establish that the article was intended for export at the time the article entered commerce.''.

**SEC. 804. INTRAMURAL RESEARCH TRAINING AWARD PROGRAM.**

Chapter IX (21 U.S.C. 391 et seq.), as amended by section 203, is further amended by adding at the end the following:

**''SEC. 907. INTRAMURAL RESEARCH TRAINING AWARD PROGRAM.**

''(a) IN GENERAL.—The Secretary, acting through the Commissioner of Food and Drugs, may, directly or through grants, contracts, or cooperative agreements, conduct and support intramural research training in regulatory scientific programs by predoctoral and postdoctoral scientists and physicians, including the support through the use of fellowships.

''(b) LIMITATION ON PARTICIPATION.—A recipient of a fellowship under subsection (a) may not be an employee of the Federal Government.

''(c) SPECIAL RULE.—The Secretary, acting through the Commissioner of Food and Drugs, may support the provision of assistance for fellowships described in subsection (a) through a Cooperative Research and Development Agreement.''.

**SEC. 805. DEVICE SAMPLES.**

(a) RECALL AUTHORITY.—

(1) IN GENERAL.—Section 518(e)(2) (21 U.S.C. 360h(e)(2)) is amended by adding at the end the following:

''(C) If the Secretary issues an amended order under subparagraph (A), the Secretary may require the person subject to the order to submit such samples of the device and of components of the device as the Secretary may reasonably require. If the submission of such samples is impracticable or unduly burdensome, the requirement of this subparagraph may be met by the submission of complete information concerning the location of 1 or more such devices readily available for examination and testing.''.

(2) TECHNICAL AMENDMENT.—Section 518(e)(2)(A) (21 U.S.C. 360h(e)(2)(A)) is amended by striking ''subparagraphs (B) and (C)'' and inserting ''subparagraph (B)''.

(b) RECORDS AND REPORTS ON DEVICES.—Section 519(a) (21 U.S.C. 360i(a)) is amended by inserting after paragraph (9) the following:

''(10) may reasonably require a manufacturer, importer, or distributor to submit samples of a device and of components of the device that may have caused or contributed to a death or serious injury, except that if the submission of such samples is impracticable or unduly burdensome, the requirement of this paragraph may be met by the submission of complete information concerning the location of 1 or more such devices readily available for examination and testing.''.

**SEC. 806. INTERSTATE COMMERCE.**

Section 709 (21 U.S.C. 379a) is amended by striking ''a device'' and inserting ''a device, food, drug, or cosmetic''.

**SEC. 807. NATIONAL UNIFORMITY FOR NONPRESCRIPTION DRUGS AND COSMETICS.**

Chapter VII (21 U.S.C. 371 et seq.), as amended by section 614, is further amended by adding at the end the following:

''SUBCHAPTER F—NATIONAL UNIFORMITY FOR NONPRESCRIPTION DRUGS FOR HUMAN USE AND COSMETICS

**''SEC. 761. NATIONAL UNIFORMITY FOR NONPRESCRIPTION DRUGS AND COSMETICS.**

''(a) IN GENERAL.—Except as provided in subsection (b), (c)(1), or (d), no State or political subdivision of a State may establish or continue in effect any requirement—

''(1) that relates to the regulation of a drug intended for human use that is not subject to the requirements of section 503(b)(1) or a cosmetic; and

''(2) that is different from or in addition to, or that is otherwise not identical with, a requirement of this Act, the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.), or the Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq.).

''(b) EXEMPTION.—Upon application of a State, the Secretary may by regulation, after notice and opportunity for written and oral presentation of views, exempt from subsection (a), under such condition as may be prescribed in such regulation, a State requirement that—

''(1) protects an important public interest that would otherwise be unprotected;

''(2) would not cause any drug or cosmetic to be in violation of any applicable requirement or prohibition under Federal law; and

''(3) would not unduly burden interstate commerce.

''(c) SCOPE.—For purposes of subsection (a), a requirement that relates to the regulation of a drug or cosmetic—

''(1) shall not include any requirement that relates to the practice of pharmacy or any requirement that a drug be dispensed only upon the prescription of a practitioner licensed by law to administer such drug; and

''(2) shall be deemed to include any requirement relating to public information or any other form of public communication relating to the safety or effectiveness of a drug or cosmetic.

''(d) NO EFFECT ON PRODUCT LIABILITY LAW.—Nothing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State.''.

**SEC. 808. INFORMATION PROGRAM ON CLINICAL TRIALS FOR SERIOUS OR LIFE-THREATENING DISEASES.**

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

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

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

''(j)(1) The Secretary, acting through the Director of the National Institutes of Health and subject to the availability of appropriations, shall establish, maintain, and operate a program with respect to information on research relating to the treatment, detection, and prevention of serious or life-threatening diseases and conditions. The program shall, with respect to the agencies of the Department of Health and Human Services, be integrated and coordinated, and, to the extent practicable, coordinated with other data banks containing similar information.

''(2)(A) After consultation with the Commissioner of Food and Drugs, the directors of the appropriate agencies of the National Institutes of Health (including the National Library of Medicine), and the Director of the Centers for Disease Control and Prevention, the Secretary shall, in carrying out paragraph (1), establish a data bank of information on clinical trials for drugs, and biologicals, for serious or life-threatening diseases and conditions.

''(B) In carrying out subparagraph (A), the Secretary shall collect, catalog, store and disseminate the information described in such subparagraph. The Secretary shall disseminate such information through information systems, which shall include toll-free telephone communications, available to individuals with serious or life-threatening diseases and conditions, to other members of the public, to health care providers, and to researchers.

''(3) The Data Bank shall include the following:

''(A) A registry of clinical trials (whether federally or privately funded) of experimental treatments for serious or life-threatening diseases and conditions under regulations promulgated pursuant to sections 505 and 520 of the Federal Food, Drug, and Cosmetic Act that provides a description of the purpose of each experimental drug or biological protocol, either with the consent of the protocol sponsor, or when a trial to test efficacy begins. Information provided shall consist of eligibility criteria, a description of the location of trial sites, and a point of contact for those wanting to enroll in the trial, and shall be in a form that can be readily understood by members of the public. Such information must be forwarded to the Data Bank by the sponsor of the trial not later than 21 days after the approval by the Food and Drug Administration.

''(B) Information pertaining to experimental treatments for serious or life-threatening diseases and conditions that may be available—

''(i) under a treatment investigational new drug application that has been submitted to the Food and Drug Administration pursuant to part 312 of title 21, Code of Federal Regulations; or

''(ii) as a Group C cancer drug.

The Data Bank may also include information pertaining to the results of clinical trials of such treatments, with the consent of the sponsor, including information concerning potential toxicities or adverse effects associated with the use or administration of such experimental treatments.

''(4) The Data Bank shall not include information relating to an investigation if the sponsor has certified to the Secretary that disclosure of such information would substantially interfere with the timely enrollment of subjects in the investigation.

''(5) For the purpose of carrying out this subsection, there are authorized to be appropriated such sums as may be necessary. Fees collected under section 736 of the Federal Food, Drug, and Cosmetic (21 U.S.C. 379h) shall not be authorized or appropriated for use in carrying out this subsection.''.

(b) COLLABORATION AND REPORT.—

(1) IN GENERAL.—The Secretary of Health and Human Services, the Director of the National Institutes of Health, and the Commissioner of Food and Drugs shall collaborate to determine the feasibility of including device investigations within the scope of the registry requirements set forth in subsection (j) of section 402 of the Public Health Service Act.

(2) REPORT.—Not later than 2 years after the date of enactment of this section, the Secretary of Health and Human Services shall prepare and submit to the Committee on Labor and Human Resources of the Senate and the Committee on Commerce of the House of Representatives a report that shall consider, among other things—

(A) the public health need, if any, for inclusion of device investigations within the scope of the registry requirements set forth in subsection (j) of section 402 of the Public Health Service Act; and

(B) the adverse impact, if any, on device innovation and research in the United States if information relating to such device investigations is required to be publicly disclosed.

**SEC. 809. APPLICATION OF FEDERAL LAW TO THE PRACTICE OF PHARMACY COMPOUNDING.**

Section 503 (21 U.S.C. 353) is amended by adding at the end the following:

''(h)(1) Sections 501(a)(2)(B), 502(f)(1), 502(l), 505, and 507 shall not apply to a drug product if—

''(A) the drug product is compounded for an identified individual patient, based on a medical need for a compounded product—

''(i) by a licensed pharmacist in a State licensed pharmacy or a Federal facility, or a licensed physician, on the prescription order of a licensed physician or other licensed practitioner authorized by State law to prescribe drugs; or

''(ii) by a licensed pharmacist or licensed physician in limited quantities, prior to the receipt of a valid prescription order for the identified individual patient, and is compounded based on a history of the licensed pharmacist or licensed physician receiving valid prescription orders for the compounding of the drug product that have been generated solely within an established relationship between the licensed pharmacist, or licensed physician, and—

''(I) the individual patient for whom the prescription order will be provided; or

''(II) the physician or other licensed practitioner who will write such prescription order; and

''(B) the licensed pharmacist or licensed physician—

''(i) compounds the drug product using bulk drug substances—

''(I) that—

''(aa) comply with the standards of an applicable United States Pharmacopeia monograph; or

''(bb) in a case in which such a monograph does not exist, are drug substances that are covered by regulations issued by the Secretary under paragraph (3);

''(II) that are manufactured by an establishment that is registered under section 510 (including a foreign establishment that is registered under section 510(i)); and

''(III) that are accompanied by valid certificates of analysis for each bulk drug substance;

''(ii) compounds the drug product using ingredients (other than bulk drug substances) that comply with the standards of an applicable United States Pharmacopeia monograph and the United States Pharmacopeia chapter on pharmacy compounding;

''(iii) only advertises or promotes the compounding service provided by the licensed pharmacist or licensed physician and does not advertise or promote the compounding of any particular drug, class of drug, or type of drug;

''(iv) does not compound a drug product that appears on a list published by the Secretary in the Federal Register of drug products that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective;

''(v) does not compound a drug product that is identified by the Secretary in regulation as presenting demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of that drug product; and

''(vi) does not distribute compounded drugs outside of the State in which the drugs are compounded, unless the principal State agency of jurisdiction that regulates the practice of pharmacy in such State has entered into a memorandum of understanding with the Secretary (based on the adequate regulation of compounding performed in the State) that provides for appropriate investigation by the State agency of complaints relating to compounded products distributed outside of the State.

''(2)(A) The Secretary shall, after consultation with the National Association of Boards of Pharmacy, develop a standard memorandum of understanding for use by States in complying with paragraph (1)(B)(vi).

''(B) Paragraph (1)(B)(vi) shall not apply to a licensed pharmacist or licensed physician, who does not distribute inordinate amounts of compounded products outside of the State, until—

''(i) the date that is 180 days after the development of the standard memorandum of understanding; or

''(ii) the date on which the State agency enters into a memorandum of understanding under paragraph (1)(B)(vi),

whichever occurs first.

''(3) The Secretary, after consultation with the United States Pharmacopeia Convention Incorporated, shall promulgate regulations limiting compounding under paragraph (1)(B)(i)(I)(bb) to drug substances that are components of drug products approved by the Secretary and to other drug substances as the Secretary may identify.

''(4) The provisions of paragraph (1) shall not apply—

''(A) to compounded positron emission tomography drugs as defined in section 202(jj); or

''(B) to radiopharmaceuticals.''.

The Senate proceeded to consider the bill.

Mr. JEFFORDS addressed the Chair.

The PRESIDING OFFICER. The Senator from Vermont.

AMENDMENT NO. 1130

(Purpose: To provide a complete substitute)

Mr. JEFFORDS. Mr. President, I send a modification of the committee amendment to the desk.

The PRESIDING OFFICER. The clerk will report the amendment.

The legislative clerk read as follows:

The Senator from Vermont [Mr. JEFFORDS] proposes an amendment numbered 1130.

Mr. JEFFORDS. Mr. President, I ask unanimous consent that further reading of the amendment be dispensed with.

The PRESIDING OFFICER. Without objection, it is so ordered.

(The text of the amendment is printed in today's RECORD under ''Amendments Submitted.'')

Mr. LOTT addressed the Chair.

The PRESIDING OFFICER. The majority leader.

Mr. LOTT. Will the Senator yield?

Mr. JEFFORDS. I certainly yield to the majority leader.

Mr. LOTT. Mr. President, this will be just very brief. I know you have your statements. Senator KENNEDY has another event at 3 or 4 that he may attend. I have a conflict with other events, too.

CLOTURE MOTION

Mr. LOTT. Mr. President, I send a cloture motion to the desk and ask the clerk to report.

The PRESIDING OFFICER. The cloture motion having been presented under rule XXII, the Chair directs the clerk to read the motion.

The legislative clerk read as follows:

CLOTURE MOTION

We the undersigned Senators, in accordance with the provisions of rule XXII of the Standing Rules of the Senate, do hereby move to bring to a close debate on the substitute amendment to Calendar No. 105, S. 830, the FDA reform bill:

Trent Lott, James M. Jeffords, Pat Roberts, Kay Bailey Hutchison, Tim Hutchinson, Conrad Burns, Chuck Hagel, Jon Kyl, Rod Grams, Pete Domenici, Ted Stevens, Christopher S. Bond, Strom Thurmond, Judd Gregg, Don Nickles, and Paul Coverdell.

Mr. JEFFORDS addressed the Chair.

The PRESIDING OFFICER. The Senator from Vermont.

Mr. JEFFORDS. Mr. President, the amendment that I sent to the desk is a modification of the committee amendment, and it is the amendment we desire to move forward on.

The PRESIDING OFFICER. Amendment No. 1130 is a modification of the committee substitute, and cloture has been filed on that amendment.

Mr. JEFFORDS. Thank you, Mr. President.

First, filing a cloture motion sort of indicates a serious situation which requires its action. I am pleased to report that I am more optimistic now than I have been at any time that a vote will not be necessary to have cloture and that we are all working very long and hard upon resolving the remaining questions. The most difficult one that we were facing appears to be resolved. So it is my firm belief that by the time we come before this body again, other than today's debate, we will have an opportunity to expeditiously pass an FDA bill for the Food and Drug Administration to ensure that we have it passed in time to prevent the problems which might occur by failing to do so.

Legislation to reform and modernize the Food and Drug Administration has been under consideration by Congress for over 3 years. At least six hearings have been held over the past 2 years in the Senate.

Last year, our measure was reported out of committee but never reached the floor for full consideration. This year, we have held hearings and worked through months of negotiations with my colleague from Massachusetts and with the administration.

S. 830 passed out of the Labor Committee on a vote of 14–4, a strong statement as to the bipartisan support this moderate measure enjoys. Last week we had a vote on the motion to proceed, and the vote was 89–5 that we begin consideration of this measure. We are here today to do that. The Senate spoke loud and clear last week: ''Let's move on the bill. Let's consider amendments. And let us vote.'' We have now had over 15 hours of debate on this measure stretching back to before the August recess.

Most recently, we spent a good part of Friday and Monday debating essentially 6 pages out of the 152-page bill. The time to move forward on this measure is now. I urge Senators to examine this measure, and I believe they will agree with me that it provides moderate, incremental but important improvements to the FDA while continuing the agency's ''gold standard'' of public safety.

I have never worked harder on a bill, and I say the same for the members of the committee, than we have on this one. The number of hours that have been spent bringing about consensus is incredible. I thank my ranking member and our staff for their cooperation and for placing us in a position where I believe we can expeditiously pass this next week without the necessity of having to invoke cloture.

So at this point, Mr. President, I yield the floor.

Mr. KENNEDY addressed the Chair.

The PRESIDING OFFICER. The Senator from Massachusetts.

Mr. KENNEDY. Mr. President, as I have on other occasions, I pay tribute to my friend and colleague from Vermont, Senator JEFFORDS, who has been shepherding this very complicated but enormously important health policy issue through the Senate. As he has correctly stated, there has been broad agreement on a number of the very important aspects of the bill that relate to the drug and medical device provisions.

We have made considerable progress on one other aspect of the legislation, and that deals with an amendment which was added by the Senator from New Hampshire, which I will address momentarily. There are still some very important issues that are still being considered by Members. All of us are hopeful that we will have a positive outcome, but we are not quite there yet.

Mr. President, just on another item, I want to identify myself with the excellent remarks of my friend and colleague from Iowa, Senator HARKIN, on the vote that was taken just an hour or so ago about the block granting of various education programs.

I think all of us have understood that the role of the Federal Government is very limited in terms of its help and assistance to local communities in terms of education. We have a much more profound responsibility in the areas of higher education. But our responsibilities in the elementary and secondary education respects that education is a local function but also an important State responsibility.

That is why for every dollar that is expended, only about 6 cents of that dollar really comes from the Federal Government. The targeting of those programs has been in the areas where there has been, as he pointed out and others have recognized, general recognition nationwide of very important national objectives, and that is with the most disadvantaged students, primarily in the areas of basic skills—basic skills—math and science programs in the title I programs across this country, the neediest children in the most disadvantaged areas. It is a very important program. It has been evaluated, has had broad support. That is one of the very important areas.

There have been adjustments about what programs will be in and what programs will be out, but you cannot get away from the fact that these programs that have been included are targeted and by and large go to local communities where there is wide discretion. If you take the Goals 2000, 90 percent of that fund is spent at the local level. You can't get any more in terms of local control than what we have at the present time.

You find that there is 2 percent administrative costs by the Department of Education in the overall programming, 6 percent at the State level of all of these various programs. A great percent of that 6 percent is technical assistance, goes to local communities that are trying to deal perhaps with special-needs children. Maybe it is a small community that has two or three members of a class that have special needs. They do not develop a whole program, but there are other schools, other school districts that have similar kinds of needs.

This technical assistance helps and assists those local communities: the School to Work Program has had strong bipartisan support—we still remember the strong Republican support to try to help young people move from school into the employment programs and into employment—the drug-free schools to try to do something about the problems of drug addiction and violence in our various school districts.

Now, we do not know. There is no accountability in this particular program. There is no requirement for reporting on how the money is expended. It bypassed even the States, so the States will not have an understanding of how these resources are going to be spent. We do not know which States

are going to be advantaged, which disadvantaged or communities advantaged or disadvantaged.

So I join in expressing strong reservations. I want to say very clearly that if this comes back, this particular provision, we are going to take some time on the floor of the U.S. Senate to really make sure that not only every Member of this body understands it but all Americans understand it. If the local States want to expend additional resources, let them go out and tax their local communities to do so. If they want it, let them do it. But if we are going to commit ourselves to trying to raise resources to meet targeted needs for the neediest children in this country, we ought to be able to do it. If you are going to take that and block grant it and send it back to the States and just use the Federal tax system to raise these funds, that ought to be done in a different forum. We will have a longer time to debate it if it comes back. But we should not permit a vote in support of the general appropriations to go by without some comment.

Now, Mr. President, I am pleased that we have achieved an important compromise on one of the most important issues in the FDA reform legislation, the issue of Federal preemption of State regulation of over-the-counter drugs and cosmetics.

I compliment Senator GREGG, Secretary Shalala, and others involved in working out this responsible agreement. It will assure that States have the ability to step in to protect consumers from cosmetics when necessary while also providing companies reasonable guarantees that when the FDA has acted effectively to protect consumers, they will not be subjected to conflicting and potentially duplicative labeling requirements.

Under the agreement, the Federal Government will not preempt State regulation of the safety of a cosmetic. This is appropriate. If a State feels strongly enough about a particular ingredient or a product to ban it or to take similar actions, it should be free to do so. States virtually never use this authority. But even though it is rarely used, it should be preserved.

In the critical realm of packaging and labeling where States have been most active in ensuring consumers receive the information they need to protect themselves, this amendment strikes a fair balance. The reason preserving States' ability to act is so important is that FDA regulation has been weak. Under this agreement, States would continue to have the ability to act to protect their consumers except in those cases where the FDA has already taken appropriate action in a specific area.

The compromise reached in section 762, which relates to the preemption of the State regulation for the packaging and labeling of cosmetics, will assure that the States retain full authority to regulate cosmetics in those circumstances when the FDA has not acted. As you know, I think it is essential for the States to be able to regulate the labeling and packaging of cosmetics whenever the FDA has not acted. This is especially important because there is so little FDA regulation in the area of cosmetics.

Section 762 would preempt a State labeling and packaging requirement only when FDA has specifically acted on the same aspect of the labeling or packaging of that cosmetic. Thus, if FDA issues a regulation that requires cosmetic manufacturers to include a specific warning about an aspect of an ingredient in a cosmetic, a State cannot require a different warning about the same aspect of that ingredient.

For example, if the FDA required a warning label for a particular product regarding its use by pregnant women, the State would be prohibited from requiring a different warning label for the same hazard and product. On the other hand, where the FDA has not taken action, the States would be free to fill the gap. So, if we are going to breathe new life into the FDA to take on more and more kinds of responsibilities to assure the public in terms of some of these health hazards, as a result of the debates we have had in the past days, they are free to do so.

On the other hand, if a State wants to require a warning on a cosmetic and FDA has not acted, the State can require that warning. For example, Minnesota has required a caution statement on flammable products. This provision would not preempt that requirement because FDA has not acted.

Similarly, if FDA requires a warning about a specific ingredient contained in a cosmetic, ingredient A, and a State wants to require a warning about another ingredient in the same cosmetic, ingredient B, the State would not be preempted. Likewise, if FDA requires a warning about a certain aspect of an ingredient for example, ingredient A causes cancer, a State can require a warning about a different aspect of the same ingredient for example, ingredient A causes birth defects. The bottom line is that the States are preempted only when FDA has acted on the same ingredient and the same health concern.

Finally, this provision does not in any way affect the State's ability to regulate the safety of cosmetics. Thus, if FDA has a specific labeling requirement for a cosmetic ingredient about a particular concern, the State may take additional steps, such as a ban on the ingredient, to protect the public health, although the State cannot require additional labeling about the concern for that ingredient.

This may very well be an invitation to give the FDA the authority and the resources to adequately regulate cosmetics, but if they do not do it, which is the condition today, we are not going to be interfering with the States. That is very, very important.

The debate on this issue has highlighted the potential hazards that cosmetics pose to consumers, especially women, which are too often underestimated.

A study by the respected, nonpartisan General Accounting Office reported that more than 125 ingredients available for use in cosmetics are suspected in causing cancer. Other cosmetics may cause adverse effects on the nervous system, including convulsions. Still other ingredients are suspected of causing birth defects. And a carefully controlled study found that 1 in 60 users suffered a cosmetic-related injury identified by a physician.

The fact is, Mr. President, there are enormous numbers of new compounds, an enormous expansion of the use of various products, including toxic products, that are being utilized in cosmetics. We want to make sure that the States, through their own public health agencies or through various studies or through their research, are going to be able to raise health concerns necessary to protect their consumers.

Mr. President, we have outlined at other times on the floor various items which raise some important concerns—alpha-hydroxy acid, feminine hygiene products, and talcum powder. We have heard from Dr. Wallinga, a physician at the Natural Resource Defense Council. He points out the dangers of these products citing studies in prestigious medical journals.

We have in this compromise preserved the right of the States to protect the public.

We have seen recently the impact of State laws on public health. In California, for example, action has been taken against Grecian Formula and toluene in nail polish.

We also know of other States that have introduced legislation aimed at further regulation of cosmetics. New York, for example, is pursuing expiration dating of certain cosmetics. Ohio and Texas are also considering additional regulation of cosmetics. My own State of Massachusetts is pursuing a consumer right-to-know law similar to that in California.

Nothing in this legislation will infringe upon these or similar activities by the States to protect the public.

The agreement we have reached today is a very reasonable one. I commend Senator GREGG for his hard work in making it a reality. The fact is neither the Food and Drug Administration nor the States are doing enough to protect women from the dangers posed by cosmetics. This issue deserves to be a high priority. I intend to see that it is.

Mr. President, regarding remaining issues in the legislation, I hope we can have the same hard work and accommodation in addressing these issues before we turn to the legislation. They deal with important questions about the procedures of the Food and Drug Administration in reviewing medical devices. We want to make sure that the medical devices that are going to be used on the American public are safe

and effective. We want to make sure that FDA reviewers look at data on the use of a medical device that is clearly indicated by the technical design of the device—whether or not it is on the label. Under the current language, FDA would be unable to make a complete review of the device. The public would be deprived of assurances they have today that devices are truly safe and effective. We talked about this previously on the floor of the U.S. Senate. We will have further opportunity to address this issue. It is an extremely important one.

A second item we hope to address is ensuring that FDA can consider certain manufacturing practices that produce an unsafe product in clearing a medical device for marketing. The language requires FDA to allow a new device on the market even if the manufacturer is producing defective devices. This provision endangers the public health by putting unsafe products on the market. It also requires the Food and Drug Administration to spend its resources chasing after unsafe medical devices already on the market rather than simply requiring that the device be produced safely in the first place.

These are important items and in my full statement, to a considerable degree, I expand on them.

There are environment considerations, the effective removal of the environmental impact statements under NEPA. I do not remember considering this provision as part of our hearings on this legislation. I do not feel that we should start taking various agencies and exempting them from considering the environmental impact of their actions. I think this is an issue that we should address.

My colleagues have raised other questions in terms of the ethical issues that surround the payment of third party reviewers. These individuals are going to be reviewing products that are manufactured by the same companies that are paying them. This raises important ethical issues. I will have an opportunity to debate and take action on some of those.

I thank very much, Mr. President, the chairman of the committee, for his continued cooperation, and the other Members for their help and assistance. I am particularly grateful to Senator GREGG for his cooperation in helping us work out a satisfactory resolution of the amendment on cosmetics.

Consumers have suffered painful, permanent injuries from hair treatment products that have caught fire. They have suffered serious urinary tract infections from bubble bath. They have suffered life-threatening allergic reactions to hair dyes, and severe chemical burns from skin creams and sun tan lotions. The GAO concluded that ''cosmetics are being marketed in the United States which may pose a serious hazard to the public.''

And these are only the acute injuries that require immediate medical care. The poisons in cosmetics can also cause long-term injuries and illnesses that do not develop for years after exposure.

Three specific products highlight the risks consumers face. Alpha-hydroxy acid is one of the hottest selling cosmetic products on the market, with sales of roughly a billion dollars a year. It is sold to erase fine lines and tighten the skin. FDA has received numerous complaints of adverse effects from the use of these products. Alpha-hydroxy acids have been linked to severe redness, burning, blistering, bleeding, rash, itching, and skin discoloration. Most troubling, there is concern that alpha-hydroxy may promote skin cancer by increasing sensitivity to sun exposure. Yet these products are in the marketplace—with no warning labels and no limits on the concentrations that may be sold. Under this bill, every State would be prohibited from requiring these sensible warnings.

I ask unanimous consent that I may put a fact sheet laying the issues on alpha-hydroxy in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

WHO WILL ACT TO PROTECT THE PUBLIC FROM HAZARDOUS PRODUCTS IN COSMETICS IF S. 830 PASSES? NO ONE WILL!

(Statement of David Wallinga, MD, MPA, Senior Scientist, Public Health Program, Natural Resources Defense Council, September 10, 1997)

People often assume that government is there to protect them. They figure that if a consumer product is sold at the corner drug or department store, it must some passed some sort of regulatory scrutiny. People would especially like to believe that cosmetics—the products they put on their hair, lips, faces and underarms each day—have been adequately tested and found to be safe.

They couldn't be more wrong. As a physician, I couldn't believe it when it first learned how powerless the Food and Drug Administration is to regulate cosmetics in a way that ensures their safety. FDA's lack of regulatory authority is based on a law from 1938—a time when scientists knew very little about the potential health effects of the chemicals found in cosmetics. This law only lets FDA act if a cosmetic has been adulterated or misbranded. What's even more amazing is that the law has absolutely no requirement that cosmetic products be tested for safety.

That means the thousands of chemicals currently found in cosmetics: Do not have to be tested to see if they are absorbed through the skin and in the blood; do not have to be tested to see if the cause cancer; do not have to be tested to see if they cause allergies or infections; do not have to be tested for effects on the brain or nervous system; do not have to be tested to see if they affect fertility or the reproductive organs; and do not have to be tested for their effects on infants and children, who can be more susceptible to the toxic effects of certain chemicals.

It is outrageous that products which people put on their faces, their underarms and other parts of their body each day are not even adequately tested for safety. Testing of the pesticide in your dog's flea collar is more extensive than that for cosmetics. This, despite the fact that cosmetics are often used by pregnant women, and women of reproductive age. Since many chemicals in cosmetics are fat-soluble, or are organic solvents, it means they can penetrate the skin—and possibly enter the fetus where they may cause reproductive harm.

It gets worse. The Senate is now proposing to strip the states of much of their regulatory authority over cosmetics as well. In particular, the Senate would limit the states ability to provide consumers with product warnings and other information, including adequate labeling. This will extend FDA's ignorance about potentially-toxic cosmetic products to consumers. It will also strip consumers of their only conceivable protection against these products. In this regulatory magic act, science will have been frozen solid. FDA is already frozen into the science of the 1930s; now, we are freezing out states from acting on any new scientific information. This might be great news for a $20 billion dollar-a-year industry, but its pretty lousy news for public health.

Each year, around 1000 new cosmetic products enter the consumer market. In perfumes and fragrances alone, there are at least 1500 different chemicals. How many of these are safe? No one knows. But because of the FDA's impotence, it is certain that the vast majority have not been broadly tested for health effects, and are not well understood from a scientific standpoint.

There are some cosmetics, however, whose safety we already have good reason to question. Skin-peeling creams, for example, are extremely popular. But they contain alpa-hydroxyacids which have been shown to greatly increase the skin's susceptibility to ultraviolent light. Someone who has used one of these creams recently would want to be careful about sun exposure, to prevent sunburn and avoid the increased risk of skin cancer. How will the consumer know to use sun screen or avoid sun exposure after using these creams? The short answer is, they won't.

FDA not only lacks the authority to require safety testing, it also has very weak authority to require product labels that reflect health and safety concerns about cosmetics. Even worse, the proposed bill would deny individual states the authority to require such labels. It doesn't seem like much to ask: a label that would tell people to avoid sun or use sunscreen. It's not a product ban, it's not changing the formulation . . . it's just an advisory label. But it will be forbidden by this law. We will instead just have to hope that industry voluntarily labels its products so that people use them correctly.

There's more. In medicine we know about a disease called ''talcosis'' which occurs from inhaling talcum powder. Mostly, that's a problem in talc workers. But what about a recent study from Yale University, a study that confirmed earlier research finding an association between the use of talcum powder on the genital region and ovarian cancer in women? Scientists have shown that talc particles can enter the body and accumulate in ovarian tissue. There, they are associated with a 40% increased risk of ovarian cancer. Ovarian cancer is hard to diagnose, hard to treat effectively, and is often fatal. It is something which is much better to prevent than to try and treat once it occurs. Yet if a state wanted to notify women that talcum powder should not be used regularly in the genital region, that would be illegal under this new law.

These are only two examples of the many, many potential hazards from the thousands of chemicals in cosmetic products. There are more: hair dyes and shampoos which contain coal tars which are known to cause cancer; feminine hygiene products associated with infertility, ectopic pregnancy, and an increased risk of pelvic inflammatory disease; lipstick and hair dyes which contain lead,

used by pregnant women, and particularly dangerous for fetuses; and numerous products which contain immune system sensitizers, such as cinnamates, which can cause severe allergic reactions, skin rashes, or asthma.

Currently, we have an empty law regulating these cosmetics, a law directing the FDA into empty regulation. Until we have a better system in place at the federal level, we should certainly not interfere with the right of states to act on these hazards, and to protect the health of their citizens, independently. Our best hope as consumers, as patients, and as health care professionals, is to let states fill this regulatory gap.

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FACT SHEET: FDA REFORM BILL AND PREEMPTION OF COSMETIC REGULATION BY THE STATES

The regulation of health and safety has traditionally rested in the hands of the States.

Cosmetics pose substantial threats to the health and safety of consumers.

There is no substantial Federal regulatory presence in cosmetics (see below), but proposed cosmetic preemption would completely bar the States from exercising their traditional regulation of cosmetic labeling, packaging and consumer information and would severely limit states ability to regulate these products in other ways.

BACKGROUND

Traditionally, preemption only takes place in areas where the Federal government has a strong presence, or has ''occupied that field.''

FDA currently employs less than 30 people to regulate the $20 billion cosmetics industry. Only 2 employees actually regulate cosmetic packaging and labeling.

FDA has no authority to approve cosmetic products or review ingredients, require companies to register, or to even report cosmetic-related injuries.

Nor can FDA require products be tested for safety or the results of safety testing be made available to the FDA or the public. It has no legal access to manufacturers' records. Nor can it require a product recall—cosmetic recalls are voluntary.

The basic Federal law regulating cosmetics has not been amended since 1938.

A 1978 General Accounting Office (GAO) study found that more than 125 cosmetic ingredients were suspected of causing cancer. Twenty ingredients were believed to cause central nervous system disorders, ranging from headaches and drowsiness to convulsions. Twenty-five were believed to cause birth defects The industry adds approximately 1,000 new chemicals annually, with no requirement to show that these chemicals are safe.

The GAO concluded that ''cosmetics are being marketed in the United States which may pose a serious hazard to the public'' and recommended that additional Federal authorities be granted to FDA to protect the public.

S. 830 AND STATE PREEMPTION

There is no public record, hearings, testimony, studies or otherwise, from the 104th or 105th Congresses which substantively addresses the issue of cosmetic preemption.

The cosmetics preemption provision was not in the Chairman's original mark, nor was it subject to hearings.

States will be completely barred from regulating cosmetic labeling and packaging under S. 830. States will also be barred from establishing any requirements for communicating the safety and effectiveness of a drug or cosmetic to the public.

States will also be barred from other forms of safety regulation if the Federal government has acted in that area, even if the Federal regulation is outdated, narrow, or vague.

The industry cannot cite one example of a burdensome state regulation that this law preempts.

OTHERS OPPOSED TO S. 830 PREEMPTION PROVISION

The Administration position states, ''if the bill were maintained in its present form, and the outstanding issues were not addressed, I would be forced to recommend to the President that he veto this legislation.''

A broad coalition of state officials, women's organizations, environmental advocates, and others concerned about public health opposes this provision (see attached letters)

EXAMPLES OF COSMETIC INJURIES

A six year old girl in Oakland, California had her mother apply a hair product to her head, which resulted in second degree burns to the child's ears and neck.

A 59-year old California woman almost died from an allergic reaction to hair dye.

A 47-year old woman had her cornea destroyed by a mascara wand.

Still another woman's hair caught fire as the result of an inflammable hair treatment gel.

In fact, a carefully controlled three month study found that one in 60 users of cosmetics experienced adverse reactions.

DANGERS OF WIDELY USED PRODUCTS

The attached fact sheets highlight possible dangers from three widely used cosmetic products: skin creams containing alpha-hydroxy products—skin irritation and burns, long-term risk of skin cancer associated with greater sun sensitivity; feminine hygiene products—pelvic inflammatory disease, ectopic pregnancy, and infertility; and talc and talcum powder—ovarian cancer.

INTERNATIONAL STANDARDS

The European Union requires full ingredient listing on packaging, documentary proof of good manufacturing practice and similar proof that extensive testing has been carried out.

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FACT SHEET: HAZARDS OF SKIN CARE PRODUCTS CONTAINING ALPHA-HYDROXY

WHAT ARE ALPHA-HYDROXY ACIDS?

Alpha-hydroxy acids are naturally occurring acids that have recently been included in skin care products. Alpha-hydroxy products promise to erase wrinkles and acne, restore skin elasticity and firmness, and produce younger-looking, smoother skin. They are used both in skin creams intended for daily use and ''skin peels'' that are sometimes described as chemical face lifts.

Products containing alpha-hydroxy acids working by penetrating the upper-layer of skin, breaking apart the bonds that hold the skin cells together. The skin then sloughs off these cells.

Alpha-hydroxy products include Avon Anew Face Cream, Ponds' Age Defying Complex, Alpha Hydrox Face Cream, Murad, and MDForte.

Products containing alpha-hydroxy acids are among the hottest-selling cosmetics, used by millions of women, with sales of roughly a billion dollars a year.

WHAT ARE THE CONCERNS ABOUT COSMETICS CONTAINING ALPHA-HYDROXY ACIDS?

There is very little data on the effects of alpha-hydroxy acids. Researcher suggests that they can cause skin irritation and increased sensitivity to UV radiation, with the potential for increasing risk of skin cancer. There have been no long-term studies of the safety of the product.

FDA reported that between 1989 and 1996, there were likely ''many thousands'' of complaints associated with alpha-hydroxy acids, including ''severe redness, swelling (especially in the area of the eyes), burning, blistering, bleeding, rash, itching, and skin discoloration. Many of the products involved are the lower concentration, mass market products.'' (February 23, 1996 letter from Dr. John E. Bailey (Acting Director, Office of Cosmetics and Colors, FDA) to Dr. F. Alan Andersen (Scientific Coordinator and Director, Cosmetic Ingredient Review). At least one major manufacturer has discontinued one of its alpha-hydroxy products because of the high volume of complaints.

In fact, FDA was sufficiently concerned about alpha-hydroxy acids that it designated them as their highest priority for review by the National Toxicology Program—a rare occurrence for a cosmetic.

A June 1997 report sponsored by the cosmetics industry found that more study is needed to determine if the use of alpha-hydroxy acids to remove the epidermis causes the skin to be more UV sensitive and increasingly susceptible to skin cancer. In the meantime, the report noted that ''some steps should be taken to minimize the potential that use a alpha-hydroxy acid ingredients would result in increased sun sensitivity. Accordingly, the Expert Panel admonished producers of leave-on cosmetics containing alpha-hydroxy acid ingredients to either formulate to avoid increasing sun sensitivity or to provide directions for use that include the daily use of sun protection.'' (Final Report: June 6, 1997 Cosmetic Ingredient Review, pg. 131). The report also made safety recommendations regarding maximum acceptable levels for alpha-hydroxy acids in both products for daily use and products used for skin peels by cosmeticians or health professionals.

There are no binding requirements assuring that manufacturers abide by the safety recommendations of the advisory committee with regard to tolerance levels or provide any safety information on the product. Manufacturers' packaging typically includes no warnings on the need to use sunscreen in conjunction with use of the product, no warning on the potential danger of skin cancer from use of the product, no information on risks of skin damage or irritation. Nor are the manufacturers required to list on the package the concentration of alpha-hydroxy acids in the product, or inform users if the other ingredients strengthen or weaken its effectiveness.

Under S. 830, States would be prohibited from requiring warning labels or other consumer information about alpha-hydroxy acids.

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FACT SHEET: ADVERSE HEALTH EFFECTS OF FEMININE HYGIENE PRODUCTS

Over one third of all women regularly use feminine hygiene products—generating roughly $100 million a year in sales.

These products have been shown to cause upper reproductive tract infections, pelvic inflammatory disease, ectopic pregnancies and infertility in women.[1]

Analyses has shown that use of these products increased the overall risk of pelvic inflammatory disease by 73% and the risk of ectopic pregnancy by 76%.[2]

The current literature also suggests an increased risk in cervical cancer.[3]

Researchers at University of Washington, Brigham and Women's Hospital, Harvard Medical School, Mount Sinai School of Medicine and Centers for Disease Control and Prevention have all published data regarding the adverse effects of feminine hygiene products.[4]

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[1] Footnotes at end of factsheet.

The National Women's Health Network testified that the FDA needs to do more to educate women and recommended that feminine hygiene product labeling information on their severe adverse effects.[5]

Under S. 830, States would be prohibited from requiring warning labels or other consumer information on feminine hygiene products.

FOOTNOTES

1. J Zhang, AG Thomas, and E Leybovich. ''Vaginal douching and adverse health effects: a meta-analysis.'' *American Journal of Public Health*. 1997 Jul; 87(7): 1207–1211.

2. Ibid.

3. Gardner JW, KL Shuman, ML Slattery, JS Sanborn, TM Abbott, and JC Overall Jr. ''Is vaginal douching related to cervical carcinoma?'' *American Journal of Epidemiology*. 1991 Feb; 133(4): 368–375.

4. Baird DD, CR Weinberg, LF Voight and JR Daling. ''Vaginal douching and reduced fertility'' *American Journal of Public Health* 1996 June: 86(6):844–850. Kendrick JS, HK Atrash, LT Strauss, PM Garguiullo and YW Ahn. ''Vaginal Douching and the risk of ectopic pregnancy among black women.'' *American Journal of Obstetrics and Gynecology*. 1997 May; 176(5):991–997. Onderdonk AB, ML Delaney, PL Hinkson and Am DuBois. ''Quantitative and qualitative effects of douche preparations on vaginal microflora.'' *Obstetrics and Gynecology*. 1992 Sept; 803 Pt 1):333–8.; Phillips RS, RE Tuomala, PJ Feldblum, J Schachter, MJ Rosenberg, and MD Aronson, ''The effects of cigarette smoking, Chlamydia trachomatis infection, and vaginal douching on ectopic pregnancy.'' *Obstetrics and Gynecology*. 1992 Jan; 79(1): 85–90, and Zhang J, p 1207–1211.

5. Cox, Lisa. National Women's Health Network testimony before FDA Nonprescription Drugs Advisory Committee hearing, 15 Apr 1997.

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FACT SHEET: TALC MAY POSE A RISK OF OVARIAN CANCER

Talc, or talcum powder, is widely used in popular bath and cosmetic products, and is applied directly to the body, typically after bathing. Common products with talc include baby powders and sanitary napkins.

A relationship between talc exposure and ovarian cancer has been investigated by a number of prominent epidemiologists and physicians for years.

A recent study by the Yale School of Public Health confirmed that talc exposure may lead to an increased risk of developing ovarian cancer.[1]

Dr. Harvey Risch in the Yale study, states that, ''Several lines of evidence support the argument for an association between talc usage and ovarian carcinoma.''[2]

In the United States, approximately 26,000 women develop ovarian cancer annually.[3]

Due to its chemical similarity to asbestos, talc has long been suspected as a lung and ovarian carcinogen.[4]

A technique used to extract ovarian tumor material found talc particles in approximately 75% of ovarian tumors examined. Subsequent evaluations have appeared to support the contention of an association between talc exposure and ovarian carcinoma.[5]

The Cancer Prevention Coalition has submitted a citizen's petition to FDA expressing their concern about the possible health risks posed by talc and requested the agency establish regulations to require carcinogen warning labels on cosmetics containing talc as an ingredient.

Under S. 830, States would be prohibited from requiring warning labels or other consumer information about the possible hazards of talc.

FOOTNOTES

1. Chang, Stella and Risch, Harvey. ''Perineal Talc Exposure and Risk of Ovarian Carcinoma,'' *Cancer*. Vol. 79, No. 12, June 15, 1997.

2. Ibid.

3. Ibid.

4. Herbst AL. ''The Epidemiology of Ovarian Carcinoma and the Current Status of Tumor Markers to Detect Disease,'' *American Journal of Obstetrics and Gynecology*. Vol. 170, 1994.

5. Hederson, WJ, et al. ''Talc and Carcinoma of the Ovary and Cervix,'' *Journal of Obstetrics and Gynecology for the British Commonwealth*. Vol. 78, 1971.

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[1] Footnotes at end of factsheet.

Mr. KENNEDY. Mr. President, a critical point is that an industry-appointed panel itself set out safety tolerance levels for use of the product with regard to short-term effects and warned that the product should not be used without sunscreen. Yet, there is absolutely no binding requirement that manufacturers follow these recommendations—and virtually none of the products carry the information or warnings developed by the industry's own committee that would enable consumers to help protect their own safety. And, in point of fact, there has been no truly independent evaluation of the work of the industry panel. In fact, the FDA is so concerned about the safety of alpha-hydroxy acid that it has chosen it has its top priority for review by the prestigious National Toxicology Program.

A second example is feminine hygiene products, which have sales of $100 million a year. More than one-third of women use them—but they pose serious health hazards. They have been shown to cause upper reproductive tract infections, pelvic inflammatory disease, ectopic pregnancies, and infertility. They may place women at additional hazard for cervical cancer. Women using these products should have the right to warning labels informing them of these hazards. But the FDA has done little to protect or warn women against these dangers.

There are a substantial number of studies on the safety of these products. The evidence that they are dangerous seems incontrovertible—but this legislation would prevent States from acting to simply warn women of the dangers. How outrageous it is that women should face illness and sterility without being warned of the danger of a seemingly harmless and beneficial product.

A third example is talc, or talcum powder is widely used in popular bath and cosmetic products. But it is chemically similar to asbestos, and it has long been suspected of causing cancer. A number of studies have suggested the possibility of a link to ovarian cancer, which afflicts 26,000 women annually—but there are no warning labels on these products. American women deserve better protection from their Government.

These three issues have been carefully analyzed by Dr. David Wallinga, a physician and the senior scientist at the Natural Resources Defense Council. He points out the dangers of each of these three products based on studies in prestigious medical journals from researchers at institutions like Yale and the Mount Sinai Hospital in New York. I ask unanimous consent to enter his comments in the RECORD, along with the articles analyzing these issues.

Federal oversight of this $20 billion industry today is extremely limited. The basic Federal law regulating cosmetics has not been updated since 1938. The FDA has less than 30 employees overseeing this huge industry—and only two employees dealing with the critical issues of packaging, labeling, and consumer warnings. The FDA has no authority to require manufacturers to register their plants and products. It cannot require manufacturers to file data on the ingredients in their products. It cannot compel manufacturers to file reports on cosmetic-related injuries. It cannot require that products be tested for safety or that the results of safety testing be made available to the agency. It does not have the right of access to manufacturers' records. It cannot require recall of a product.

In the Federal Food, Drug and Cosmetic Act there are 126 pages devoted to the regulation of drugs and devices; 55 pages are devoted to foods regulation. A full eight pages of the act is dedicated to definitions. But less than two pages are devoted to cosmetic regulation.

In 1938, there was no requirement that industry show safety of drugs, medical devices, food additives, or cosmetics before they were marketed. Today, the public demands higher standards of protection, and they have been established for drugs, for medical devices, and for food additives—but not for cosmetics.

The agreement we have reached today is a highly reasonable one. I especially commend Senator GREGG for his hard work to make it a reality. But the fact is that neither the FDA and the States are doing enough to protect women from these dangers. This is an issue that deserves a higher priority, and I intend to do all I can to see that it gets it.

There are important remaining issues in this legislation, and I hope that with the same hard work and spirit of accommodation we can reach agreement on these issues before we return to consideration of this legislation on Tuesday.

Two changes in the regulation of devices in particular put consumers at unacceptable and unnecessary risk. They should be removed in this bill before it goes forward—and the administration has made it clear that they put the whole bill at risk of a veto.

A great deal of negotiation has taken place on the medical device provisions of this bill, and I compliment Senator JEFFORDS, Senator COATS, and my other colleagues on the committee for resolving most of the device provisions in a way that is consistent with protection of the public health. But there are at least two medical device provisions in the bill which still raise substantial concerns. They could be corrected very simply and with negligible effect to the basic purpose and intent of this bill. Yet these corrections have not been made and my colleagues deserve a clear description of the hazards they pose.

A brief explanation of how the FDA regulates and clears medical devices for marketing may first be in order. Under current law, manufacturers of

new class I and class II devices can get their products onto the market by showing that they are substantially equivalent to devices already on the market. For example, the manufacturer of a new laser can get that laser onto the market if it can show FDA that the laser is substantially equivalent to a laser that is already on the market.

Similarly, the manufacturer of a new biopsy needle can get that biopsy needle onto the market by showing that it is substantially equivalent to a biopsy needle already on the market. And the manufacturer of new patient examination gloves can get those gloves onto the market by showing that they are substantially equivalent to patent gloves already on the market.

Mr. President, these manufacturers are obliged to demonstrate substantial equivalence to the FDA by showing that the new product has the same intended use as the old product and that the new product has the same technological characteristics as the old product. If the new product has different technological characteristics, these characteristics must not raise new types of safety and effectiveness questions in order for the product to still be substantially equivalent to the older product.

The logic of this process for bringing medical devices onto market is quite simple: if a product is very much like an existing product, it can get to market quickly. If it raises new safety or effectiveness questions, those questions should be answered before the product can be marketed.

This process for getting new medical devices on the market, commonly known as the 510(k) process, is considered by most to be the easier route to the market. Devices that are not substantially equivalent to a class I or class II device already on the market must go through a full premarket review. Thus, device manufacturers have an incentive to get new products on the market through the 510(k) process. And in fact, well over 90 percent of all new devices get on the market through the submission of a 510(k) application.

This legislation seriously compromises the FDA's ability to protect the public health through its regulation of medical devices that are marketed through the 510(k) process. Of the dozens of provisions that we have negotiated and discussed which affect medical devices in this bill, these two still raise fundamental public health problems. Although few in number, these provisions raise substantial risks to the public health which simply cannot be ignored.

The first problem raised by this bill relating to medical devices is its prohibition on the FDA from considering how a new device will be used if the manufacturer has not included that use in its proposed labeling.

You may think that this approach makes sense—why should the Agency consider the use of a device if the manufacturer has not specified that use on the label? I'll tell you why—because that proposed label may be false or misleading. How would the FDA know that? Because the design of the new device may make it perfectly clear that the new device is intended for a different use.

Let me provide my colleagues with a few examples. Let's talk about the biopsy needle I mentioned before, which is used on breast lesions. Most biopsy needles for breast lesions currently on the market take a tissue sample that is about the size of the tip of pencil lead. Let's assume the manufacturer of a new biopsy needle comes to the FDA with a 510(k) submission. But this new biopsy needle takes a tissue sample that is 50 times as big—the size of a 1-inch piece of a hot dog.

The manufacturer of this new needle has proposed labeling that says that the needle will be used like the old, marketed needles to biopsy breast lesions. But FDA knows that the chunk of tissue being biopsied will usually exceed the size of the lesion. This makes it clear to FDA—and to any impartial observer—that the new needle will in most cases be used to remove the lesion.

Under these circumstances the FDA should be able to ask the manufacturer to provide information on this new use. Is it safe to remove lesions? Does it really work? The bill, however, categorically bars FDA from asking these essential questions. This means that the FDA would be unable to make a complete review of the device and the public would be deprived of existing assurances that devices are truly safe and effective.

The proponents of this provision have argued that the FDA could simply say that the change in device design or technology—such as the change in size of the biopsy needle—renders the new product unequivalent to the old product. But that is not always true. The manufacturer could argue that there are no new questions of safety or effectiveness for the purpose claimed on the label. In the case of the biopsy needle, Mr. President, there are times where a large sample is needed—a sample larger than a pencil tip.

So long as the larger needle is safe and effective for removing a sample, FDA would still be barred from obtaining data about the new use of removing lesions—and to the extent the needle is used for the new use, women could be put at risk for an effective or unsafe treatment of breast cancer.

Another good example is surgical lasers. Lasers have been used for decades to remove tissue. Several years ago, a manufacturer added a side-firing mechanism to their laser to improve its use in prostate patients. While the manufacturer did not include this specific use in its proposed labeling, it was transparently clear that the new side-firing design was intended solely for this purpose of treating prostate patients.

As a result, FDA required the manufacturer to submit data demonstrating the laser's safety and effectiveness in treating prostate patients. This is precisely how the device review process should work. Manufacturers must prove their devices live up to their claims, while patients and doctors receive all of the information needed to make the best possible treatment choices.

But under this bill, FDA would be prohibited from getting adequate safety data on the laser's use on prostate patients—even though that would be the product's primary use. This defies common sense yet this is the result of one troubling and indefensible provision.

Other examples in the way that this provision could allow unsafe and ineffective devices abound. A stent designed to open the bile duct for gallstones could be modified in a way that clearly was designed to make it a treatment for blockages of the carotid artery.

Without adequate testing, it could put patients at risk of stroke or death. But under this bill, the FDA would be prohibited from looking behind the label to the actual intended use of the device. A laser to use to excise warts could have its power raised so that it was also possible to use it in smoothing facial wrinkles. But without FDA's ability to assure adequate testing, the use of the laser for this purpose could lead to irreversible scarring.

Most companies, of course, will not try to bypass the process in this way. But some bad actors will. And this legislation should not force the FDA to fight those bad actors with one hand tied behind it. This provision is like asking a policeman to accept a known armed robber's assurance that the only reason he is wearing a mask and carrying a gun is that he is going to a costume party.

The second way this bill undercuts the FDA's ability to protect the public health and adequately regulate medical devices is the way it forces the FDA to clear a new device for marketing even if the Agency knows that the manufacturer cannot manufacture a safe device.

Let me repeat that statement. It sounds frankly preposterous but it is true. One of the bill's provisions actually requires the FDA to allow a new device onto the market even if the manufacturer is producing defective devices. Surprisingly, the proponents of this provision freely admit that this is true.

Under current law, let's assume that a maker of new examination gloves submits a 510(k) to the FDA and claims that the new gloves are substantially equivalent to gloves already on the market. If the FDA knows for a fact from its inspectors that the company uses a manufacturing process that often results in these gloves having holes, FDA would simply not clear the gloves for marketing. FDA would find

that these gloves are not substantially equivalent to gloves on the market because gloves on the market don't have holes. That's common sense, and fortunately, that's also the law.

In contrast, this bill would force FDA to clear the gloves for marketing. At this point, these defective gloves would be sold to hospitals, clinics, and HMO's, where they will be used routinely by doctors, nurses, paramedics, and other health professionals every single day. Every single glove would expose these professionals needlessly to the risk of fatal blood-borne diseases like AIDS and hepatitis.

Here is the response of the provision's supporters. They argue that once these defective gloves are in the market and being used by health professionals, FDA can simply institute an enforcement action to remove them from the market. But when hundreds or thousands of defective devices have been distributed, and when dozens or hundreds of facilities may be using these devices, an enforcement action entails far more than blowing a whistle or picking up the phone to place a simple call.

In reality, the FDA must coordinate with the U.S. Attorney's office, the U.S. Marshal's Service and persuade the court of jurisdiction to issue the appropriate papers. As any attorney or law enforcement professional can tell you that this takes precious time. And in the case of a defective device which is exposing people to unnecessary risks, time is absolutely critical. The sooner a defective glove is pulled from the market, the sooner the public is protected.

But all this makes absolutely no sense when the FDA today can prevent this situation from ever arising. If this provision becomes law, the debater's point distinguishing between different forms of FDA authority will ultimately be paid for in the health and safety of American consumers placed at needless risk of death and injury. In fact, even the regulated industry is willing to compromise on this provision, because they recognize that it is so unreasonable.

So I hope we can continue to work to compromise these important devices issues over the weekend. We have been successful on so many other issues in this bill. These should be resolvable as well.

The last unacceptable element of this bill is an assault on basic environmental protections contained in the National Environmental Protection Act. The National Environmental Protection Act of 1969 is a key Federal environmental statute which regulates the Government's own actions through environmental impact statements. Under NEPA, Federal agencies must undertake a comprehensive environmental planning process for every major action they take. This law is a crucial statutory assurance that the work of the Government and the actions of regulated industries are consistent with the guiding principle of environmental protection.

Section 602 of the bill broadly exempts the FDA's activities from environmental impact assessments under NEPA. In fact, the provision even precludes the FDA from taking environmental considerations into account in its work. The administration unequivocally opposes this provision. This week, I spoke with the Vice President, who expressed his serious personal concerns about this provision. In just a few sentences, this bill opens the door to weakening our environmental protections and lays a welcome mat down for future exemptions and future attacks on an effective and essential environmental statute.

This is a terrible precedent, but it also directly affects the environment. The FDA regulates products which constitute a quarter of our gross domestic product. When it makes decisions on food containers, or manufacturing plant approvals, or handling and disposal of medical supplies, it can have an immense impact on the environment.

Ironically, this antienvironmental extremism is not even demanded by the regulated industry, which regards the reforms of the NEPA process recently announced by the Clinton administration as fair and balanced.

We all agree on the importance of FDA reform. The reauthorization of the Prescription Drug User Fee Program is tremendously important to assure that the FDA will have adequate resources to review new drugs and biological products quickly and effectively. This legislation contains many significant reforms that can streamline the regulatory process and codify improvements that FDA has already taken administratively. I compliment Senator JEFFORDS, the chairman of our committee, and many other colleagues who have worked hard on this bill and have been willing to work together to eliminate many other troublesome provisions in the bill as originally introduced. Let us now move to complete this work by fixing the remaining contentious issues included in this legislation.

The PRESIDING OFFICER. The Senator from Vermont is recognized.

Mr. JEFFORDS. Mr. President, this legislation is the result of a well-considered process to consult with all points of view and to benefit from the expertise needed to craft legislation on this complex matter. The substitute before us today stands on the shoulders of four hearings and a committee markup of a comprehensive Food and Drug Administration reform bill in the 104th Congress.

This year we held two more hearings, taking testimony from Food and Drug Administration, industry experts, physicians, and consumer groups—and I emphasize ''and consumer groups.'' Staff held dozens of meetings with Food and Drug Administration, experts and patient groups, discussing in detail every issue of this bill. The negotiation process with Food and Drug Administration, and the minority started in the drafting phase of the bill and continued up to and right through the markup, and has continued right up to this moment. This has been a process marked by openness and consultation.

The philosophy of this bill is to codify recent efforts of the self-reform of the Food and Drug Administration, and a great deal of that is self-reform which we are codifying, and to provide the Food and Drug Administration with the tools to do even better in certain areas.

We recognize that Congress cannot micromanage an agency like the Food and Drug Administration, nor do we want to. But we must set realistic performance goals to ensure the public is protected and well served and that the industry is fairly treated. In an era of flat or declining resources, we must give the Food and Drug Administration the management tools it needs to manage an increasing workload without the expectation of ever-increasing appropriations to assist them.

The first title of S. 830 establishes in statute that the mission of the Food and Drug Administration is to protect the public health, promptly and efficiently review clinical research, and take appropriate action on the marketing of regulated products in a manner that does not unduly impede innovation or product availability.

From the 1906 Food and Drugs Act through the 1990 Safe Medical Devices Act, food and drug law has emphasized the duty of the Food and Drug Administration is to protect the public against unsafe or ineffective products. This legislation, as reflected in the mission statement, strengthens protection of the public from unsafe or ineffective products and provides a better balance in the law by ensuring timely access to safe and effective products. It is simple: Safe and effective products can be made available more quickly—and they should be. That is what this bill does.

The legislation reauthorizes the Prescription Drug User Fee Act of 1992, commonly referred to as PDUFA, to allow the continued collection of user fees from prescription drug manufacturers for 5 additional years. PDUFA I represented a consensus among the Food and Drug Administration, the prescription drug industry, and Congress that the industry would pay user fees to augment the resources of the Food and Drug Administration devoted to the review of human drug applications. PDUFA I has succeeded in substantially reducing review times for human drug applications, bringing those drugs to the market sooner than before.

At some point in the debate I would like to engage a colloquy with Senator MIKULSKI, a cosponsor of S. 830, to discuss the importance of the performance enhancements that PDUFA will bring to the drug review process. We have all

benefited from Senator MIKULSKI's determination to bring the Food and Drug Administration into the 21st century for the benefit of her own constituents who work at the FDA, for the betterment of the burgeoning biotechnology sector in Maryland, and for the parties throughout America who are served by the technologies developed by those companies.

Title VII of S. 830, or PDUFA II, would build on the original legislation by codifying new commitments from FDA to implement more ambitious and comprehensive improvements in the regulatory process. PDUFA I focused on reducing the length of time taken by FDA in reviewing an application. The committee commends FDA for successfully meeting, and at times exceeding, the performance goals established at PDUFA I. However, while review times for submitted applications have improved, the period of time taken to get the drug through the drug development phase has recently increased from 5 to 7 years. Appropriately, PDUFA II will focus on shortening overall development time.

It will streamline interaction with the FDA during the highly regulated drug development phase and also establish new performance levels and procedures for FDA that are designed to reduce the time required to show that a drug is ready for FDA review.

The bill provides improved access to new treatments and important information needed by patients. Section 102 establishes a statutory right for any person, acting through a physician, to request an investigational drug, biological product, or device for diagnosis of a serious disease or condition. This provision builds upon current FDA programs that have proved so successful for aids and cancer drugs, and this is an area that is critical to all of us.

This section of the bill includes modifications urged by the FDA and patient groups, that codify important patient protections. These provide patient access under their physician's supervision, to unapproved therapies, under the existing emergency use, and investigational device and drug treatment exemption programs.

Another important provision advocated by the patient groups as one of their top priorities is section 808, which establishes a registry of clinical trials, both publicly or privately funded, of experimental drugs and biological or serious life-threatening medical conditions.

Registry information must be understandable to the general public and include the purpose of experimental protocol, trial eligibility criteria, and sites and contact points for people wishing to enroll in a clinical trial. It is critical that those people who are suffering from the diseases of this nature be able to find out how they can get involved and be able to take part in a program which is designed to bring them back to health. Patients, health care providers, researchers, and the public would access the registry through toll-free telephone communications and other informational systems. This provision was included in the bill as an amendment offered by Senator DODD, based on legislation introduced by Senator SNOWE and Senator FEINSTEIN. We are all grateful for their leadership in this area. I should add that Senator DODD, who is a cosponsor of S. 830, must be recognized for his early and unflagging support for enacting broad-based reform this year. He has worked incredibly hard and has been one of the most steadfast leaders in bringing forth a bipartisan bill.

Yet another provision designed to speed new drugs to patients who need them is section 613. The FDA currently has a number of mechanisms aimed at streamlining the development and approval process for new therapies for serious and life-threatening conditions. Section 613 establishes a statutory mechanism for identifying breakthrough drugs early in the product development phase. It provides sponsors of such drugs a reasonable opportunity for early interaction with the agency to further help streamline the development and approval process for such drugs.

This provision is intended to clarify and to coordinate some of FDA's mechanisms for new drugs and biological products that are intended for the treatment of serious and life-threatening conditions and that demonstrate the potential to address unmet medical needs for such conditions. It defines and clarifies a process pursuant to which sponsors of these drugs may interact with the FDA, and includes provisions that will ensure that these processes are well known and well understood.

I want to mention other changes made in the substitute that have been the subject of discussion between the committee markup and floor consideration.

I want to make sure that everyone has an opportunity to know what we will be voting on and that they will have an opportunity to review this and, hopefully, fully understand it. Certainly, my staff, and I am sure Senator KENNEDY's staff is available to enlighten them if they have questions. I urge all members to take a look at the bill that is now before the Senate.

The third-party review provision has undergone substantial revision since its was first debated in the 104th Congress. This provision has been developed under the leadership of Senator COATS, who has played an important role in advancing FDA modernization throughout this process. This year, he has played a special role in the development of S. 830 from its inception and provided wise counsel on how to achieve the best possible reform at the FDA. The third-party review pilot in this bill moves important expansion to the current FDA third-party review program for medical devices.

I should mention that two amendments to the provision on third-party review for medical devices offered by Senator HARKIN in committee, which were not agreed to, did form the basis for subsequent compromise reflected in the substitute now before the Senate. To meet the Senator's concerns and the concerns of others, the bill sponsors have agreed to statutory language establishing the right of FDA to review records related to compensation arrangements, and excluding from third-party review class III products, products that are implanted for more than 1 year, products that are life sustaining or life supporting, and products that are of substantial importance in the prevention of impairment to human health.

This was an important provision which brought peace of mind to many and allowed us to come forward with the bill in the form we have now. These changes in scope and the additional safeguards to protect against conflict of interest broaden public confidence in this pilot and provide FDA with a needed tool to manage an increasing workload of medical device reviews.

Two other critical provisions to improve the medical device review program will make the review process more efficient and collaborative for high-technology products—those which offer the greatest benefit for patients and which also experience the longest review times at FDA. Senator WELLSTONE is the sponsor of legislation to reform the medical device approval process that includes these two provisions and others in S. 830, and I applaud his leadership on these issues. Section 301 creates the opportunity for a manufacturer to meet with FDA to establish the type of scientific evidence necessary to demonstrate effectiveness for a device. FDA had earlier concerns about binding determinations of device data requirements needed to show efficacy. In response to the FDA, the provision has been modified to ensure that the agency will receive sufficient information to make such a determination and is provided authority to modify the determination where appropriate.

Manufacturers should not have to spend months wondering if their application is still on track in the review process. Section 302 requires the agency to meet with manufacturers 100 days after a premarket approval application is submitted to discuss deficiencies and any additional information required for approval. This provision, too, was modified to address FDA's concerns that the agency only be required to identify deficiencies known at the time of the 100-day meetings. And FDA would only be required to identify information needed to correct those deficiencies.

In recognition that the mandatory postmarket surveillance authority established in the 1990 Safe Medical Devices Act was overbroad and inconsistently applied, S. 830 made the current mandatory postmarketing surveillance discretionary and limited surveillance to a 24-month period, unless FDA

showed that longer time is needed to track device after marketing.

Concerns of the FDA and patient group are further addressed in the substitute by striking the portions of the provision establishing new duration and scope limitations on postmarket surveillance—under the agreement the only change to the existing surveillance authority is to make it discretionary, allowing FDA the flexibility to impose surveillance requirements as appropriate without leaving itself or companies in technical violation of the law.

Another area of disagreement prior to markup was the manner in which S. 830 proposed to handle certain types of manufacturing changes for medical devices. Senate bill 830 proposed to allow these changes to proceed on the basis of a notification rather than a full supplemental application.

The substitute modifies the provision in the manufacturing changes section so that FDA may in some cases still require the submission of a supplement for a manufacturing change, and such supplement must be approved prior to implementation of the change. These manufacturing change supplements shall be reviewed in 135 days. This compromise will still allow many, if not most, manufacturing changes to proceed under a streamlined process.

Senator GREGG, who worked very, very hard on this bill, has been certainly one of those who deserves a great deal of credit for bringing it to the body in the form it is in, which I believe is most satisfactory. He is to be also commended for his proposals to streamline the FDA process for the consideration of health claims based on Federal research and his amendments to establish uniformity for over-the-counter [OTC] drugs and cosmetics.

He has modified this provision to exempt California's proposition 65 and allow States to regulate cosmetic labeling and packaging issues where FDA has not acted. Senate bill 830 authorizes truthful, nonmisleading health claims for food products that are based on published authoritative statements of scientific bodies of the U.S. Government such as the National Institutes of Health. FDA expressed concern regarding the length of time the agency had to assess these proposed claims and the mechanism by which they might prevent a particular claim from going forward. Agreement with FDA was reached on the basis that FDA is given 30 additional days to review a health claim under the provision, for a total of 120 days to review a health claim. FDA is able to prevent the claim from being used in the marketplace by issuing an interim final regulation. FDA may also block a claim from going forward, if the conditions established under the provision governing claims are not met. Again, I thank the Senator for his excellent work in crafting this provision and reaching agreement with the FDA.

The committee adopted an amendment by Senator FRIST which conforms the statute with FDA's current practice and today's science with regard to the quality of data required to show drug efficacy. I am especially grateful to Dr. FRIST, a cosponsor of the S. 830, whose medical expertise has lent credibility to the decisions we have made in the complex area of medical technology regulation.

Senator DEWINE, joined by Senator DODD, offered an important amendment to establish incentives for the conduct of research into pediatric uses for existing and new drugs.

The bill was improved by Senator HUTCHINSON's amendment, to establish a rational framework for pharmacy compounding, which respects the State regulation of pharmacy while allowing an appropriate role for FDA. I look forward to participating in a colloquy with the Senator and the ranking minority member on this topic.

The ranking minority member, Senator KENNEDY, has played a vital role in bringing this compromise to the floor. In markup, he offered two important amendments adopted by the committee. One amendment, developed in consultation with Senator GREGG, improved a provision from last year's legislation governing the regulation of radiopharmaceuticals. The second improved the bill's provision setting forth a streamlined process for the review of supplemental applications for new uses of approved drugs.

I commend the Senator for his hard work and willingness to compromise on a number of issues which threatened to hold up proceeding on the bill. We reached agreement on the distribution of health care economic information. This data is the essential information ingredient in the drug selection process in the growing managed care sector of the health insurance marketplace. We agreed to require pharmaceutical companies to report annually on their efforts to comply with postapproval studies. This is essential information needed to provide the assurance that these studies will in fact be completed. Again, I thank the Senator for his willingness to work out these and other compromises.

Finally, I would like to comment on the involvement of patient and consumer groups: They testified at one of our committee hearings. Also, our staff met a dozen times with representatives of these groups to discuss their proposals, share our ideas and drafts, and debate policy issues. Representatives of these groups were in key meetings with industry, FDA, and bipartisan staff to discuss the resolution of issues they identified as critical—pharmacoeconomics and the requirement of drug companies to comply with postapproval, or phase four, study requirements are examples of where we relied heavily on their advice and were pleased to have their information.

The bill reflects changes to address their concerns: Companies must report on their compliance with phase four studies; FDA is given express authority to inspect compensation records of third-party reviewers; patients will have access to a registry of clinical trials information; and additional safeguards were built into the provision allowing expanded access to products under clinical investigation. It is clear that these groups have played an active and important role in drafting this bill.

Mr. President, I stand before the body today with a sense of relief because, for the first time, I feel we are really, without any further delays, coming toward completion. It is also still my purpose and my goal to ensure that all Members will still have an opportunity to express themselves, and that when we come back next time, I hope that we will have an agreement or unanimous consent that we can proceed without the necessity of invoking cloture, and have amendments established to be considered in reasonable lengths of time, so that this bill can move forward. Certainly, I ask those who are desiring to propose amendments, when we come back here next week, to get in touch with us today, tomorrow, and during the weekend and the first of the week so we can try to accommodate all Members who desire to have amendments that they desire to have expeditiously considered.

I urge all of the body to recognize that this is an important piece of legislation. It has to be acted upon yet by the House. They are anxiously awaiting us to move, so hopefully the bills can be as close together as possible, so that we can have the bill signed into law expeditiously, within a month.

With that, Mr. President, I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

Mr. HARKIN. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

The PRESIDING OFFICER. Without objection, it is so ordered.

Mr. HARKIN. Mr. President, I yield 10 minutes to the Senator from Minnesota.

The PRESIDING OFFICER (Mr. ALLARD). The Senator from Minnesota.

Mr. WELLSTONE. Mr. President, I come to the floor to speak about S. 830, the FDA Modernization Reform Act of 1997.

I guess there are a couple of things I would like to say about this piece of legislation.

First of all, I would like to thank my colleagues who have worked very hard on this. Senator JEFFORDS, Senator KENNEDY, Senator COATS, Senator GREGG, Senator HARKIN, and many others as well.

I also would like to thank Linda Degutis, who is going to be on the floor with me who has been a fellow with our office. These fellow programs are wonderful programs. I think many of us are always looking for additional support and expertise. She has done a marvelous job.

This bill has traveled an interesting journey. It was in committee markup about maybe a year ago, or thereabouts. I voted against it then. That was a difficult vote for me because it never really came to the floor. But I said then that there was much in this bill that I approved. I wanted to see some changes. But I thought the bill went too far.

It was frustrating because on the medical device part of this bill our office had put much work into it. We spent about a year and a half, and I think other Senators know what this is like—writing a lot of the provisions. But I thought the legislation went too far.

There were a number of things in it that are technical sounding. I will not go into all of it. But it was an overreach. It went too far trying to privatize FDA. The one thing you don't want to do is throw the baby out with the bathwater. I really have to keep the consumer protection part. It is quite one thing to say that you want more predictability and more timeliness and more focus in the regulatory process. I am all for that. It is one thing to say that we have to get these products to the market in a timely fashion. I am all for that. But they have to be safe and effective.

Then we came back to committee. The second time around it was close again because there were some provisions in the bill that I did not agree with. I voted for it. I have tried to work real hard with lots of different people here. I don't think I need to talk about myself because that is not important. I think this has been a pretty darned important collaborative effort.

We are almost there. I thank Senator GREGG for his cooperation. I think the provisions dealing with cosmetics and preemption of State standards, which would have affected my State in a very negative way, was a mistake. I think that has been worked out. We still may have some work to do yet with NEPA in terms of how this affects environmental impact statements. I believe that will be worked out. There are a couple of other problems that I think we are working on right now.

But, Mr. President, let me just say that it is my belief that we can do better—that we can provide medical products to consumers in a more timely manner through the provisions in this bill while retaining significant consumer protection. It is my belief as a Senator that this legislation would improve the predictability and the timeliness and the focus of the regulatory process for medical products.

Mr. President, next week when we bring this bill up, I am going to talk about what all of this means in specifics because this has been about 2½ years of work for me as a Senator from Minnesota. But as long as we are just kind of setting the stage here, if you will, I think the mood here in the Senate is very positive.

I say to Senator JEFFORDS again, Senator JEFFORDS has done a really fine job of bringing people together. I actually think that we brought together not only Democrats and Republicans but others, a lot of people who have been involved with this. I will give full credit to a lot of the consumer organizations who have not agreed with everything in the bill, and they have been fighting hard and they continue to fight hard. They certainly have let me know when they have not agreed with positions I have taken, but they have done it with class, and they have been tough. They should be tough, and they should be critical. And they have been.

By the same token, I want to make it clear that I think the business community, the industry has been very responsible. At one point in time when the Congress first started talking about FDA reform, I think there were some—this now goes back probably 2 years or so—who really looked at this as an opportunity to privatize FDA, roll back the really important consumer protection provisions.

I think that is over. It is over for a lot of different reasons. It is over because I think people now in the Congress hopefully understand that people in the country are not interested in not having strong consumer protection. They view FDA as extremely important to them and the regulation that FDA does as being very important to their lives and to their children's lives.

I also think people have pulled back from that because the of industry—and I want to give a lot of credit to the industry. There are a lot of people in the industry—and I know more about the medical device industry—who have basically every step along the way made it clear that, no, this goes too far; we are willing to compete with the gold standard; we are just asking to get our products to the market in a more timely fashion, but we don't want to give any ground. These products have to be safe and effective.

To say that there ought to be more predictability, to say that when you have a protocol and you have waited for a year or you have waited more than a year and then all of a sudden you are told the protocol is no good, you had a right to learn about that earlier, you would like to at least have conversation with the agency, is very reasonable.

Now, we had some provisions in the bill, including when I voted for it in the committee, that I thought still needed to be worked on, changes needed to be made. Again, Senator JEFFORDS, Senator KENNEDY, and a number of people worked very hard and I think we have really worked very diligently, and a lot of those problems I think we have dealt with.

So what we have here, Mr. President, I think is an important piece of legislation. We will undoubtedly have that, when we bring this bill to the floor—I say to my colleague, Tuesday, probably, is that correct?

Mr. JEFFORDS. That is correct.

Mr. WELLSTONE. There will be discussion. Some of us are still working on improvements. But overall what this piece of legislation does, I will summarize—and I will talk about it in specifics later. I will talk about it in a fairly technical way next week. But if I had to summarize, I do believe now after tough negotiation, after a lot of people in the country being involved with this on all sides, after Democrats and Republicans I think pulled together on this, with Senator JEFFORDS—and I am not just saying this because he is in the Chamber—really providing key leadership, Senator KENNEDY being in there fighting, with Senator COATS as well, being willing to negotiate; I am proud of our office's roll and other people as well, what we have is a piece of legislation which says essentially, look, there will be more predictability, there will be more timeliness, more focus on FDA's regulatory action, we can get products to the market in a timely fashion, which is important to families and consumers, but we can do it in such a way that we do not sacrifice consumer protection.

We are almost there, and I think this is going to be a very important reform bill, and I am very proud to be a part of it.

I thank my colleague for his work.

Mr. JEFFORDS. Mr. President, I will yield on my time. I thank the Senator for all the work he has put into this bill. I know he is probably one of the strongest consumer advocates this Senate has ever seen. I would like to chat with the Senator just a bit because there is some concern of consumer advocates in my State who say how come we are getting all these editorials? And I would have to say in fairness to this committee they are based upon information which may have been true a month or 2 months or 3 months ago, but we have gone out of our way to put on the web pages—in fact, the most recent agreement which we have reached on cosmetics is now, or will be this afternoon, on the web pages so that all they have to do is tune in and they can see the exact wording.

So I urge those who are still nervous about what is in the bill to find out. It is available. In the modern age of being able to have information available, it is available instantly around the country. I hope that we would continue to work on the basis of what the bill is instead of what it used to be.

I acknowledge the Senator's contribution to this effort entirely. The Senator has been instrumental in proposing innovative ideas and finding solutions. He has done an outstanding job in helping myself and Senator KENNEDY bring this bill to where it is. The Senator is looked upon by many as a person they can trust to protect the interests of the consumer. So I thank the Senator for his very active participation in this bill.

Mr. WELLSTONE. Mr. President, I thank my colleague, and I think he is right about the time lag on information that has gotten to people. We have

continued to be in tough negotiations and a good number of these problems have been resolved. I guess my style would be to say to the strong consumer organizations, keep on pushing hard to the very end. I think this is emerging as a real solid piece of work, and I am proud to be a part of it.

I thank the Senator very much for the very gracious remarks. Linda Degutis, again, I thank very much for her help. She has been helpful in this in a big way.

I thank the Chair.

Mr. DODD. Mr. President, I want to begin by thanking my colleagues for their overwhelming support last week for cloture on the motion to proceed with this bill. Some 89 Senators very loudly and very clearly told us last week that they were ready to move forward to reauthorize PDUFA and to begin debating the other critical reforms this bill contains.

There is no Federal agency with a more direct and significant impact on the lives of the American people than the Food and Drug Administration. The foods we serve our family, the medicines we take when we're sick, even the drugs we give our pets, are all approved and monitored by the FDA.

We must not lose the opportunity that we have before us now to enact legislation that ensures the FDA has the authorities it needs to bring safe and effective products to the American people quickly and efficiently.

I would like to again thank both Senator JEFFORDS and Senator KENNEDY for their perseverance on this issue. Time after time they have been willing to return to the bargaining table after many others would have just walked away. With open minds and in good faith, they've extensively negotiated this bill, line by line.

We have come to a point where issues on which Members were previously completely polarized—third party review of medical devices, off-label dissemination of information, health claims for food products, the number of clinical trials needed for drug approval, and just today national uniformity of cosmetics—we've now reached agreement.

I don't know that any of us would have thought unanimity possible on these provisions even 2 months ago—yet here we are with full agreement on all but a handful of issues.

I know we have a better bill for all of the arduous negotiations that have occurred.

Just as an example of how far we've come, let's talk about third party review of medical devices. The bill would expand the pilot program currently administered by the FDA.

This is a program, I should note, that is supported by the FDA as a way to make more efficient use of its resources.

In last years debate, which many of you will remember as being much more acrimonious, we were told this provision was a nonstarter, no room to compromise, subject closed.

This year, I am pleased to say, a spirit of bipartisanship and compromise prevailed. Senator HARKIN, Senator KENNEDY, and Senator COATS worked diligently to draft language that ensures that higher risk devices aren't inappropriately included in this pilot program and that strong conflict of interest protections are in place.

And just last night, again on an issue that appeared unresolvable—national uniformity for cosmetics, we have reached agreement. Senator GREGG has offered what I think is a very reasonable compromise. In the area of safety requirements, States can continue to regulate where the FDA has not acted.

Conflicting State requirements that could confuse consumers will be removed. But where the FDA has not chosen to act, where it does not have either the manpower or the authority to protect the public, States can contain to play their historic role in regulating cosmetics.

This is the kind of effort made over and over again on this bill—some 30 times just since markup 2 months ago we have made improvements to this bill. A great many of us take pride in the product that has been created—a bill that will speed lifesaving drugs and devices to patients and that clearly retains the FDA as the undisputed arbiter of the safety effectiveness of these products.

Mr. President, I would like to speak for a moment about some of the positive reforms contained in this bill.

At the heart of this bill is the 5-year reauthorization of PDUFA, the Prescription Drug User Fee Act—a piece of legislation remarkable for the fact that there is unanimous agreement that it really works.

PDUFA has set up a system of user fees which drug companies pay to the FDA. These fees have enabled the Agency to hire more staff. As a result, drug approval times have been cut almost in half, getting new and life-saving therapies to patients more quickly.

In addition, by improving the certainty and clarity of the product review process, S. 830 encourages U.S. companies to continue to develop and manufacture their products in the United States. The legislation emphasizes collaboration early on between the FDA and industry during the product development and product approval phases. This will prevent misunderstandings about Agency expectations and should result in even quicker development and approval times.

In addition, S. 830 establishes or expands upon several mechanisms to provide patients and other consumers with greater access to information and to life-saving products.

For example, S. 830 will give individuals with life-threatening illness greater access to information about the location of on-going clinical trials of drugs.

Based on a bill originally championed by Senators SNOWE and FEINSTEIN. I offered an amendment in committee, which I was pleased to see adopted, to expand an existing aids database to include trials for all serious or life-threatening diseases.

Experimental trials offer hope for patients who have not benefited from treatments currently on the market. Currently, patients' ability to access experimental treatments is dependent upon their spending large amounts of time and energy contacting individual drug manufacturers just to discover the existence of trials.

This is not a burden that we should place on individuals already struggling with chronic and debilitating diseases. This database will provide ''one-stop-shopping'' for patients seeking information on the location of and eligibility criteria for studies of promising treatments.

Mr. President, I am particularly pleased that this bill incorporates the Better Pharmaceuticals for Children Act, legislation originally introduced by our former colleague from Kansas, Senator Kassebaum, and now cosponsored by myself and Senator DEWINE, along with Senators KENNEDY, MIKULSKI, HUTCHINSON, COLLINS, and COCHRAN.

This provision addresses the problem of the lack of information about how drugs work on children, a problem that just last month President Clinton recognized publicly as a national crisis.

According to the American Academy of Pediatrics, only one-fifth of all drugs on the market have been tested for their safety and effectiveness in children. This legislation provides a fair and reasonable market incentive for drug companies to make the extra effort needed to test their products for use by children. It gives the Secretary of Health and Human Services the authority to request pediatric clinical trials for new drug applications and for drugs currently on the market. If the manufacturer successfully conducts the additional research, 6 extra months of market exclusivity would be given.

I recognize that there are few matters still unresolved on this bill despite the best efforts of all involved. And those we will need to simply address though the traditional process of holding votes on the issues.

One issue, which I plan to discuss further when we debate the bill on Tuesday involves section 404 of the bill, which relates to the FDA's review of medical devices. This provision, the so-called labeling claims provision clarifies current law by stating that when reviewing a device for approval, FDA should look at safety and efficacy issues raised by the use for which the product was developed and for which it will be marketed.

Again, this is current law. Unfortunately, in a few instances, the FDA has inappropriately expanded the scope of its review by requiring manufacturers to submit data on potential uses of product.

Some have raised concerns that under this provision a manufacturer

could propose a very narrowly worded label for a device and that the FDA would be barred from asking for information on other obvious uses.

This is simply not the case. The FDA retains its current authority to not approve a device if based on a fair evaluation of all material facts, the labeling is false or misleading. Clearly, if a bad actor device manufacturer attempted to get a misleading label past the FDA, the Agency would have full authority to disapprove the product.

I was pleased to join Senator JEFFORDS as the first Democratic cosponsor of this bill. I would thank him again for the hard work and long hours that he and his staff, as well, as Senator KENNEDY, Senator MIKULSKI, Senator WELLSTONE, Senator COATS, Senator GREGG, and others, have contributed.

I look forward to further debate on and to joining my colleague next week in enacting this legislation.

Mr. JEFFORDS. Mr. President, I make a point of order that a quorum is not present and ask unanimous consent that it be evenly divided between the minority and majority.

The PRESIDING OFFICER. Without objection, it is so ordered. The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

Mr. JEFFORDS. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

The PRESIDING OFFICER. Without objection, it is so ordered.

Mr. JEFFORDS. The minority representative and myself are sitting here. There is some time left. However, we also want to move the calendar forward as best we can. I just want to alert all Members, minority and majority, if we do not receive a communication from a Member or staff within 10 minutes, it is our intention to yield back the remainder of our time in order that we may move the process of the Senate forward. I just let everyone know that. We will be sitting here, awaiting the news.

I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

Mr. JEFFORDS. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

The PRESIDING OFFICER. Without objection, it is so ordered.

Mr. JEFFORDS. Mr. President, speaking on behalf of the leader, I ask unanimous consent that the cloture vote with respect to FDA occur at 10 a.m. on Tuesday, September 16, the mandatory quorum call under rule XXII be waived, and the time between 9:30 and 10 a.m. be equally divided for debate, prior to the vote.

The PRESIDING OFFICER. Without objection, it is so ordered.

Mr. JEFFORDS. Therefore, under rule XXII, all first-degree amendments must be filed at the desk by 1 p.m. on Monday, September 15. I ask unanimous consent that all second-degree amendments may be filed up to the time of the vote on Tuesday.

The PRESIDING OFFICER. Without objection, it is so ordered.

Mr. JEFFORDS. Mr. President, at this time, and I have the permission of the minority, I will yield back the remainder of our time, both minority and majority time; and I so do.

The PRESIDING OFFICER. All time is yielded back.

Mr. JEFFORDS. Mr. President, I make a point of order a quorum is not present.

The PRESIDING OFFICER. The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

Mr. INHOFE. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

The PRESIDING OFFICER. Without objection, it is so ordered.

Mr. INHOFE. I ask unanimous consent that I be recognized for 5 minutes as if in morning business.

The PRESIDING OFFICER. Without objection, it is so ordered.

## IN MEMORY OF MOTHER TERESA

Mr. INHOFE. Mr. President, Mother Teresa, truly a saint, died last week at age 87. I think we have all talked about her and the fact she dedicated her life to helping the poor and the sick, the dying around the world, particularly in India. But I remember so well a morning on February 3, 1994. It was a National Prayer Breakfast. We had invited Mother Teresa to come and be our speaker. She did not reject. She just said, well, if the Lord is willing, I will be there. And we said, do you think he will be willing? And she wasn't too sure.

Nonetheless, she did show up and we had an audience of 3,000 people in the hotel, including the President and his wife, and the Vice President and Mrs. Gore, and congressional leaders, people from all over the Hill and from all over America. Every State was represented, almost every country was represented, and, of course, in addition to that there was a television audience of millions.

Mother Teresa gave really an extraordinary speech. It was referred to by columnist Cal Thomas as ''the most startling and bold proclamation of truth to power I have heard in my more than 30 professional years in Washington.''

I think a lot of us know Peggy Noonan. She was the speech writer for Ronald Reagan. She called it ''a breathtaking act of courage.''

In describing it she said Mother Teresa was introduced and spoke of God and love and families. She said, ''We must love one another and care for one another.'' And she described it that there were ''great purrs of agreement'' from the audience. And I remember that so well because I was one who was purring.

But the speech became more pointed at that moment.

Mother Teresa—and I am quoting now, Mr. President—said:

> I feel that the greatest destroyer of peace today is abortion, because it is a war against the child, a direct killing of the innocent child, murder by the mother herself. And if we accept that a mother can kill her own child, how can we tell people not to kill one another?

She said:

> By abortion, the mother does not learn to love but kills even her own child to solve her problems. And, by abortion, the father is told that he does not have to take any responsibility at all for the child he has brought into the world. That father is likely to put other women into the same trouble. So abortion just leads to more abortion.

Then she said:

> Any country that accepts abortion is not teaching its people to love, but to use any violence to get what they want. This is why the greatest destroyer of love and peace is abortion.

Mrs. Noonan described the scene:

> For about 1.3 seconds there was complete silence, then applause built up and swept across the room. But not everyone: the President and the First Lady, the Vice President and Mrs. Gore looked like seated statues at Madame Tussaud's, glistening in the lights and moving not a muscle.

I remember when Mother Teresa then looked over at President and Mrs. Clinton and she said:

> Please don't kill the child. I want the child. Please give me the child. I am willing to accept any child who would be aborted and to give that child a married couple who will love the child and be loved by the child.
>
> From here, a sign of care for the weakest of weak—the unborn child—must go out to the world. If you become a burning light of justice and peace in the world, then really you will be truest to what the founders of this country stood for.

Mr. President, we must revere Mother Teresa for what she was, the saint that she was, and we must remember her. But I think most of all we must listen to her. I repeat: ''Any country that accepts abortion is not teaching its people to love but to use any violence to get what they want. This is why the greatest destroyer of love and peace is abortion.''

I suggest the absence of a quorum.

The PRESIDING OFFICER (Mr. HAGEL). The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

Mr. DORGAN. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

The PRESIDING OFFICER. Without objection, it is so ordered.

Mr. DORGAN. Mr. President, I ask unanimous consent to speak for 10 minutes as in morning business.

The PRESIDING OFFICER. Without objection, it is so ordered.

## FAST-TRACK TRADE AUTHORITY

Mr. DORGAN. Mr. President, the President has sent to the Congress a determination that he would like Congress to provide what is called fast-track trade authority with which he could negotiate additional and new