

any requirement for a member of the Armed Forces of the United States to wear indicia or insignia of the United Nations as part of the military uniform of the member; to the Committee on Armed Services.

By Mr. HATCH (for himself, Mr. CRAIG, Mr. BENNETT, and Mr. BURNS):

S. 1371. A bill entitled the "Snowbasin Land Exchange Act of 1995"; to the Committee on Energy and Natural Resources.

By Mr. McCAIN (for himself and Mr. DOLE):

S. 1372. A bill to amend the Social Security Act to increase the earnings limit, and for other purposes; read the first time.

#### SUBMISSION OF CONCURRENT AND SENATE RESOLUTIONS

The following concurrent resolutions and Senate resolutions were read, and referred (or acted upon), as indicated:

By Mr. GRASSLEY (for himself, Mr. BIDEN, Mr. DOLE, Mr. D'AMATO, Mr. MURKOWSKI, Mr. HATCH, Mr. ABRAHAM, Mr. HELMS, Mr. PRESSLER, Mr. BRYAN, Mr. THURMOND, Mrs. FEINSTEIN, Mr. NICKLES, Mr. COVERDELL, and Mr. STEVENS):

S. Res. 189. A resolution to designate Wednesday, November 1, 1995, as "National Drug Awareness Day"; considered and agreed to.

By Mr. WARNER (for himself and Mr. FORD):

S. Res. 190. A resolution to authorize the printing of a revised edition of the Senate Election Law Guidebook; considered and agreed to.

#### STATEMENTS ON INTRODUCED BILLS AND JOINT RESOLUTIONS

By Mr. WELLSTONE:

S. 1369. A bill to amend the Federal Food, Drug, and Cosmetic Act to facilitate the development, approval, and use of medical devices to maintain and improve the public health and quality of life of individuals, and for other purposes; to the Committee on Labor and Human Resource.

#### THE MEDICAL TECHNOLOGY, PUBLIC HEALTH, AND INNOVATION ACT OF 1995

Mr. WELLSTONE. Mr. President, the legislation I am introducing today would take a significant and responsible step toward improving the effectiveness, timeliness, and predictability of the FDA review process for medical devices.

Over the past 9 months, I have met with numerous representatives of Minnesota's medical device industry, patient advocacy groups, clinicians, and officials at the FDA and have concluded that there are indeed steps that Congress should take to make the regulatory process for medical devices more efficient. Minnesotans want the FDA not only to protect public health, but also to promote public health. They want to know not only that new technologies will be safe, but that they will be available to them in a timely manner. Many of Minnesota's medical device manufacturers, researchers, clinicians, and patients in need of new and improved health care technology have become increasingly concerned about the regulatory environment at the FDA.

Two weeks ago I visited SpineTech, which is a perfect example of Minnesota's burgeoning, world-famous medical device industry. It was formed in 1991 with 4 people, funded by venture capital, and it now employs more than 40 people. It manufactures a breakthrough disc replacement technology which has been studied in clinical trials for 3 years. The technology, used for individuals with chronic low-back pain, has been shown to result in shorter hospital stays, less invasive surgery and lower medical costs than the alternative therapy.

SpineTech filed its premarket approval application in January of this year. The application has not yet been accepted by the FDA and thus the premarket approval process has not yet even officially begun. The average total elapsed time for FDA review of PMA applications is now about 823 days. The technology has been available in every other advanced industrialized country for the past 2 years.

The technologies that the FDA regulates are changing rapidly. We cannot afford a regulatory system ill-equipped to speed these advances. As a result, both Congress and the administration are reexamining the paradigms that have governed the FDA. Our challenge will be to define FDA's mission and scope of responsibility, as well as to give guidance on an appropriate balance between the risk and rewards of streamlining all aspects of how FDA does its job—including the approval process for breakthrough products.

The legislation that I will be introducing would begin to address these objectives in three important ways.

First, it would enable the FDA to adopt nationally and internationally recognized performance standards to improve the transparency and effectiveness of the device review process and promote global harmonization and interantional trade. Resource constraints and the time-consuming rule-making process have precluded FDA promulgation of performance standards in the past. This legislation would allow the FDA, when appropriate, to simply adopt consensus standards that are already being used by most of the world and use those standards to assist in determining the safety and effectiveness of class III medical devices. The FDA could require additional data from a manufacturer relevant to an aspect of a device covered by an adopted performance standard if necessary to protect patient safety. Currently, the lack of clear performance standards for class III medical devices is a barrier to the improvement of the quality and timeliness of the premarket approval process.

Second, it would improve communication between the industry and the FDA and the predictability of the review process. I believe that these two factors are so important that I have even included what would usually be management decisions in the legislation. This bill includes provisions for periodic meetings between the applicant and the FDA to ensure that applicants

are promptly informed of any deficiencies in their application, that questions that can be answered easily would be addressed right away, and that applicants would be well-informed about the status of their application. I believe that improving communication between the FDA and industry would result in greater compliance with regulations and that this will ultimately benefit consumers and patients.

Third, the legislation would help the FDA focus its resources more appropriately. PMA supplements or 510(k)s that relate only to changes that can be shown to not adversely affect the safety or effectiveness of the device would not require premarket approval or notification. Manufacturers would instead make information and data supporting the change part of the device master record at the FDA. In addition, the FDA would be able to exempt from premarket notification requirements those class II devices for which such requirements are unnecessary to ensure the public health without first having to go through the time consuming and bureaucratic process of reclassifying them to class I. Enabling the FDA to focus its attention where the real risks are will not only streamline the approval process but also benefit consumers and patients.

Finally, I want to be clear that this legislation is a work in progress. I look forward to working with Senator KASSEBAUM, the chairman of the Labor and Human Resources Committee, and my colleagues on the committee on the concepts included in my proposal. I will work vigorously to ensure they are included in any comprehensive FDA legislation considered by the Senate both this year and in the future. I look forward to continuing to work on these issues with Minnesotans and to pressing ahead next year on whatever we cannot accomplish this year. Clearly there are actions Congress can take to improve the FDA without sacrificing the assurances of safety that all Americans depend on.

Mr. President, I ask unanimous consent that the text of the bill be printed in the RECORD.

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

S. 1369

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

#### SECTION 1. SHORT TITLE AND REFERENCE.

(a) SHORT TITLE.—This Act may be cited as the "Medical Technology, Public Health, and Innovation Act of 1995".

(b) REFERENCE.—Whenever in this Act an amendment or repeal is expressed in terms of an amendment to, or a 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.).

#### SEC. 2. FINDINGS; MISSIONS STATEMENT.

(a) FINDINGS.—The Congress finds the following:

(1) While the United States appropriately puts a top priority on ensuring the safety and efficacy of medical technologies that are introduced into the marketplace the administration of such regulatory effort is causing the United States to lose its leadership role in producing innovative, top-quality medical devices.

(2) One of the key components of the medical device regulatory process that contributes to the United States losing its leadership role in medical device development is the inordinate amount of time it takes for medical technologies to be reviewed by the United States Food and Drug Administration.

(3) The most important result of the United States losing its leadership role is that patients in the United States do not have access to new medical technology in a timely manner.

(4) Delayed patient access to new technology results in lost opportunities to save lives, to reduce hospitalization and recovery time, and to improve the quality of life of patients.

(5) The economic benefits that the United States medical device industry, which is composed principally of smaller companies, has provided through growth in jobs and global trade are threatened by the slow and unpredictable regulatory process at the Food and Drug Administration.

(6) The pace and predictability of the medical device regulatory process, together with a perceived adversarial relationship with the Food and Drug Administration, are in part responsible for the increasing tendency of United States medical device companies to shift research, product development, and manufacturing offshore, at the expense of American jobs, patients, and leading edge clinical research.

(b) **MISSION STATEMENT.**—This legislation seeks to improve the timeliness, effectiveness, and predictability of the medical device approval process for the benefit of United States patients and the United States economy by—

(1) providing for the use of nationally and internationally recognized performance standards to assist the Food and Drug Administration in determining the safety and effectiveness of medical devices;

(2) facilitating communication between medical device companies and the Food and Drug Administration;

(3) redefining clinical testing requirements to reflect the nature of device evolution; and

(4) targeting the use of Food and Drug Administration resources on those devices that are likely to have serious adverse health consequences.

### SEC. 3. PERFORMANCE STANDARDS.

Section 514 (21 U.S.C. 360d) is amended by adding at the end thereof the following new subsection:

#### “ESTABLISHMENT AND ADOPTION OF OTHER STANDARDS

“(c)(1) The Secretary—

“(A) may establish pursuant to subsection (b) performance standards to assist in determining the safety or effectiveness of class III devices under section 515; and

“(B) may amend or revoke the performance standards established under subparagraph (A).

“(2) The Secretary shall, within 365 days of the date of enactment of this subsection, adopt performance standards established by nationally and internationally recognized standard-setting entities and use the standards when applicable to assist in determining the safety and effectiveness of class III devices under section 515.

“(3) The Secretary may not require, as the condition for approving a premarket approval application under section 515, the con-

formity of a class III device with a performance standard established or adopted pursuant to paragraph (1) or (2), respectively, if the applicant submits data other than that required by the performance standard to demonstrate a reasonable assurance of the safety and effectiveness of the device.

“(4) The Secretary, in lieu of requiring data demonstrating the conformity of a class III device with a standard described in paragraph (1) and (2), shall accept certification by the applicant that the device conforms with each standard identified in the application.

“(5) The Secretary may revoke the performance standards adopted under paragraph (2).

“(6) A performance standard established under this subsection for a device—

“(A) shall include provisions to provide reasonable assurance of the safe and effective performance of the device;

“(B) shall, where necessary to provide reasonable assurance of the safe and effective performance of the device, include—

“(i) provisions with respect to the construction, components, ingredients, and properties of the device and the compatibility of the device with power systems and connections to the systems;

“(ii) provisions for the testing (on a sample basis or, if necessary, on an individual basis) of the device or, if it is determined that no other more practicable means are available to the Secretary to assure the conformity of the device to the standard, provisions for the testing (on sample basis or, if necessary, on an individual basis) of the device by the Secretary or by another person at the direction of the Secretary;

“(iii) provisions for the measurement of the performance characteristics of the device;

“(iv) provisions requiring that the results of each or certain of the tests of the device required to be made under clause (ii) demonstrate that the device is in conformity with those portions of the standard for which the test or tests were required; and

“(v) a provision requiring that the sale and distribution of the device be restricted to the extent that the sale and distribution of the device is restricted under a regulation under section 520(e); and

“(C) shall, where appropriate, require the use and prescribe the form and content of labeling for the proper installation, maintenance, operation, and use of the device.”.

### SEC. 4. PREMARKET APPROVAL.

(a) **APPLICATION.**—Section 515(c) (21 U.S.C. 360e(c)) is amended—

(1) in paragraph (1)—

(A) by striking subparagraph (D); and

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

(2) by adding at the end thereof the following new paragraphs:

“(3)(A) An applicant—

“(i) shall include in an application described in paragraph (1) an identifying reference to any applicable performance standard established or adopted under paragraph (1) or (2) of section 514(c), respectively; and

“(ii) shall include in the application—

“(I) a certification by the applicant as described in section 514(c)(4), that the device complies with the applicable performance standard; or

“(II) data to support the safety or effectiveness of the device.

“(B)(i) Except as provided in clause (ii), the Secretary may not require an applicant who submits an application for premarket approval for a class III device under paragraph (1) to submit preclinical data and information regarding the device relevant to a performance standard established or adopted under paragraph (1) or (2) of section 514(c),

respectively, if such standard defines performance or other specifications for the device, and the applicant certifies that the device conforms to the standard.

“(ii) The Secretary may require an applicant described in clause (i) to submit preclinical data and information regarding a class III device if additional information or data are necessary to protect patient safety.

“(C) The Secretary shall require an applicant who certifies that a device conforms to an applicable performance standard established or adopted under paragraph (1) or (2) of section 514(c), respectively to maintain data demonstrating such conformance for a period of time that is equal to the period of time for the design and expected life of the device and to make the data available to the Secretary upon request.

“(D) The Secretary may deny, withdraw, or temporarily suspend approval of a premarket approval application for a class III device if—

“(i) the Secretary determines that the device does not conform to an applicable performance standard (on which the applicant relied) established or adopted under paragraph (1) or (2) of section 514(c), respectively; and

“(ii) such conformance is considered by the Secretary to be material in approving the device.

“(4) The Secretary shall accept retrospective or historical clinical data as a control or for use in determining whether there is a reasonable assurance of device safety and effectiveness if the data are available and the effects of the device on disease progression are clearly defined and well understood.

“(5) The Secretary may not require the sponsor of an application to conduct clinical trials for a device using randomized controls unless—

“(A)(i) such controls are scientifically and ethically feasible;

“(ii) the effects of the device on disease progression are not clearly defined and well understood as determined by the Secretary; and

“(iii) retrospective or historical data are not available that meet the standards of the Secretary for quality and completeness; or

“(B) such controls are necessary to support specific marketing claims.

“(6) The Secretary may not require in a supplement to a premarket approval application data from randomized clinical trials for a modification to a device if—

“(A) the modification does not substantially and adversely affect safety or effectiveness; and

“(B) the modified device has the same intended use and is intended for similar patient populations as the approved device.”.

(b) **ACTION ON APPLICATION.**—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 (6)”;

(2) by redesignating paragraphs (2) and (3) as paragraphs (6) and (7), respectively; and

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

“(2) Each premarket approval application and supplement received by the Secretary under subsection (c) shall be reviewed in the following manner to achieve final action on the application within 180 days of the receipt of the application:

“(A) The Secretary shall make a determination within 30 days of the receipt of an application filed under subsection (c) of whether the application satisfies the content requirements of paragraphs (1) and (3) of subsection (c) and applicable regulations, and

the Secretary shall notify the applicant of the determination and whether the application has been accepted or has not been accepted for review for premarket approval. If the Secretary fails to notify the applicant within the 30-day period that the application is not sufficiently complete to permit a substantive review, the application shall be considered as filed by the Secretary.

“(B) The Secretary shall, within 45 days after the date of the acceptance of an application for review under subparagraph (A)—

“(i) provide the applicant the opportunity for a meeting (or teleconference) with the Secretary to—

“(I) inform the applicant of the general progress and status of the application;

“(II) advise the applicant of deficiencies in the application that have not been communicated to the applicant.

The applicant shall have the right to be informed in writing with respect to the information communicated to the applicant during the meeting or teleconference under subclauses (I) and (II).

“(ii) determine whether an advisory panel should be convened by the Secretary to review the application or to consider an issue related to the application.

“(C) The Secretary shall, within 90 days after the date of the acceptance of an application for review under subparagraph (A) provide an applicant the opportunity for a meeting (or teleconference) with the Secretary to—

“(i) inform the applicant of the general progress and status of the application;

“(ii) review actions taken by the applicant to correct deficiencies identified at the 45-day meeting described in subparagraph (B);

“(iii) advise the applicant of the deficiencies in the application that have not been communicated to the applicant; and

“(iv) review the proposed labeling for the device.

The applicant shall have the right to be informed in writing with respect to the information communicated to the applicant during the meeting or teleconference under clauses (i) through (iv).

“(D)(i) When an advisory panel is convened under subparagraph (B)(ii) to review an application or to consider an issue related to the application, the Secretary shall within 15 days after the close of the advisory panel meeting provide the applicant the opportunity for a meeting (or teleconference) with the Secretary to identify any remaining issues with respect to the approval of the application.

“(ii) If an advisory panel is not convened under subparagraph (B)(ii), the Secretary shall, within 120 days after the date of the acceptance of an application for review under subparagraph (A), provide the applicant the opportunity for a meeting (or teleconference) with the Secretary to—

“(I) inform the applicant of the general progress and status of the application;

“(II) review the actions taken to correct deficiencies identified in the application at the 90-day meeting described in subparagraph (C); and

“(III) advise the applicant of the deficiencies in the application that have not been communicated to the applicant.

“(iii) The applicant shall have the right to be informed in writing with respect to the information communicated to the applicant during the meeting or teleconference under clauses (i) and (ii).

“(E) The Secretary shall, within 150 days after the date of the acceptance of an application for review under subparagraph (A), notify the applicant of the decision of the Secretary to approve or disapprove the application.

“(F) The Secretary shall exclude the time that an applicant takes to respond to the Secretary's requests for additional data or

information in determining when the 45-day, 90-day, 120-day and 150-day periods described in subparagraphs (B), (C), (D), and (E) expire.

“(3) To permit better treatment or better diagnoses of life-threatening or irreversibly debilitating diseases or conditions, the Secretary shall expedite the review for devices—

“(A) representing breakthrough technologies;

“(B) offering significant advantages over existing approved alternatives; or

“(C) for which accelerated availability is in the best interest of the public health.

“(4)(A) The Secretary shall annually publish a status report on the premarket clearance or approval of applications and other device submissions.

“(B) The report described in subparagraph (A) shall include—

“(i) a specific statement from the Secretary concerning the performance of the Food and Drug Administration in reducing the backlog in the reviewing of applications for premarket clearance or approval for a device and meeting statutory time limitations applicable to the review of the applications;

“(ii) with respect to devices, data (which shall be provided by the Center for Devices and Radiological Health and each division of the Office of Device Evaluation of the Center for Devices and Radiological Health) on—

“(I) the number of premarket approval applications, supplements, premarket notifications, and applications for investigational device exemptions, not accepted for filing by the Secretary;

“(II) the total time (beginning on the date of the filing of an application and ending on the date of the clearance or approval of the application) required to review the premarket approval applications, supplements, premarket notifications, and applications for investigational device exemptions;

“(III) the total time (excluding the time periods permitted for an applicant to prepare and submit to the Secretary responses or additional information or data requested by the Secretary) as calculated by the Food and Drug Administration to complete the review of each premarket approval application, supplement, premarket notification, and application for investigational device exemption;

“(IV) the number of adverse decisions made with respect to the applications and supplements described in subclause (II);

“(V) the number of nonapprovable letters for device submissions;

“(VI) the number of deficiency letters for device submissions;

“(VII) the number of times applicants are required to supply information during the review of an application or supplement described in subclause (II); and

“(VIII) the performance of the actions described in paragraph (2), including performance information with respect to the number of premarket approval applications that were or were not reviewed within the time limitations described in such paragraph and the time necessary to carry out each of the actions; and

“(iii) baseline data for the data described in subclauses (I) through (VII) of clause (ii) for the preceding year.

“(5) The Secretary shall complete the review of all premarket approval supplements that do not contain clinical data within 90 days of the receipt of a supplement that has been accepted for filing.”

(c) ELIMINATION OF PREMARKET APPROVAL OF SUPPLEMENTS.—The Secretary of Health and Human Services shall eliminate premarket approval of supplements that relate to manufacturing and product changes of a device that can be demonstrated through appropriate protocols or other methods to not affect adversely the safety or effectiveness of a device. The Secretary of Health and Human Services shall require the manufac-

turer of a device to submit to the Secretary of Health and Human Services any information relied upon to support a device-related change that is not subject to premarket approval of a supplement to an application approved under section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e). The information shall be made a part of the device master record. The information shall be maintained for a period of time equal to the period of time for the design and expected life of the device, but not less than 2 years after the date of release of the device for commercial distribution by the manufacturer.

## SEC. 5. PREMARKET NOTIFICATION REQUIREMENTS.

(a) EXEMPTION FOR CLASS I AND II DEVICES.—Section 510 (21 U.S.C. 360) is amended by adding at the end thereof the following new subsection:

“(l) Within 365 days of the date of enactment of this section, the Secretary shall exempt from the notification requirement under subsection (k) class I and II devices that should not be subject to the notification requirement because such notification is not necessary to provide a reasonable assurance of the safety and effectiveness of the devices. Prior to making such determination, the Secretary shall provide an opportunity for notice and comment with respect to the appropriateness of the exemption for the class I and II devices.”

### (b) LIMITATION ON NOTIFICATION.—

(1) IN GENERAL.—The Secretary of Health and Human Services shall not enforce the requirement for additional notifications under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)) for a change or modification to a device initially classified under section 513(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)) that—

(A) is other than a major change or a major modification in the intended use;

(B) is supported by nonclinical data or information, when appropriate; and

(C) can be shown to not adversely affect the safety and effectiveness of the device.

(2) MAINTENANCE OF NOTIFICATION DATA.—The Secretary of Health and Human Services shall require the manufacturer of a device to submit to the Secretary of Health and Human Services all data and information relied upon to document that a change or modification of a device described in paragraph (1) does not require an additional notification under section 510(k). The data and information shall be made a part of the device master record. The data and information shall be maintained for a period of time equal to the period of time for the design and expected life of the device, but not less than 2 years after the date of release of the device for commercial distribution by the manufacturer.

## SEC. 6. INVESTIGATIONAL DEVICE EXEMPTION.

(a) REGULATIONS.—Section 520(g) (21 U.S.C. 360j(g)) is amended—

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

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

“(4) The Secretary shall, within 120 days of the date of enactment of this paragraph, by regulation amending the content of part 812 of title 21 of the Code of Federal Regulations, amend the procedures with respect to the approval of studies under this subsection as follows:

“(A) The regulation shall include provisions that require the Secretary to permit

the sponsor to meet with the Secretary prior to the submission of an application to develop a protocol for a study subject to the regulation, that require that the protocol shall be agreed upon in writing by the sponsor and the Secretary, and that set forth a time limitation for the sponsor to conduct a followup of a study.

“(B) The regulation shall require the Secretary to permit developmental changes in devices subject to the regulation in response to information gathered during the course of an investigation without requiring an additional approval of an application for an investigational device exemption, or the approval of a supplement to the application, if the changes meet the following requirements:

“(i) The changes do not constitute a significant change in the design of the product or a significant change in basic principles of operation.

“(ii) The changes do not adversely affect patient safety.

The regulation shall require that such a change be documented in records the applicant is required to maintain with respect to the investigational device exemption.

“(C) The regulation shall provide for the use of an investigational device for diagnosis or treatment use under a protocol or investigational device exemption if the following requirements are met:

“(i) The device is intended to treat or diagnose a serious or immediately life-threatening disease.

“(ii) There is no comparable or satisfactory device or other therapy available to treat or diagnose that disease in the intended patient population.

“(iii) The device is under investigation in a controlled clinical trial under an investigational device exemption in effect for the trial or all clinical trials for the device have been completed.

“(iv) The sponsor of the controlled clinical trial is actively pursuing marketing approval of the investigational device with due diligence.

“(D) The regulation shall require the Secretary to consult with advisory panels, which have the appropriate expertise, with respect to the establishment of an appropriate time limitation for the conduct of a followup study by the sponsor of the study.

(b) CONFORMING AMENDMENTS.—Section 517(a)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360g(a)(7)) is amended—

(1) by striking “section 520(g)(4)” and inserting “section 520(g)(5)”; and

(2) by striking “section 520(g)(5)” and inserting “section 520(g)(6)”.

#### SEC. 7. ESTABLISHMENT OF A POLICY AND PERFORMANCE REVIEW PANEL.

Chapter IX of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 901 et seq.) is amended by adding at the end thereof the following new section:

#### “SEC. 906. POLICY AND PERFORMANCE REVIEW PANEL.

“(a) ESTABLISHMENT.—There is established a panel to be known as the Food and Drug Policy and Performance Review Panel (hereafter referred to in this section as the ‘Panel’).

“(b) MEMBERSHIP.—The members of the Panel shall be appointed by the Secretary in accordance with subsection (d)(1) and shall include—

“(1) individuals with expertise in medical, scientific, and health policy and regulatory issues;

“(2) representatives of industry, voluntary health associations, and patient advocacy groups; and

“(3) representatives of the Food and Drug Administration.

“(c) TERMS.—

“(1) IN GENERAL.—Each member of the Panel shall serve for a term of not more than

3 years and the terms of office of such members shall be staggered.

“(2) REAPPOINTMENT.—Each member of the Panel may be reappointed, but may not serve more than 3 consecutive terms.

“(3) VACANCIES.—Any vacancy in the Panel shall not affect the powers of the Panel and shall be filled in the same manner as the original appointment.

“(d) ORGANIZATIONAL STRUCTURE.—

“(1) IN GENERAL.—The Chairperson of the Panel shall organize the Panel in a manner that will ensure that there is a portion of the membership of the Panel monitoring the activities of each Center within the Food and Drug Administration. The membership of the Panel shall be composed of individuals with expertise necessary to ensure appropriate review of the performance of each Center.

“(2) DEFINITION.—For the purposes of this section, the term ‘Center’ means the Center for Devices and Radiological Health, Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research, Center for Food Safety and Applied Nutrition, Center for Veterinary Medicine, and Center for Toxicological Research.

“(e) CHAIRPERSON AND VICE CHAIRPERSON.—The Secretary shall select a Chairperson and Vice Chairperson from among the members of the Panel.

“(f) INITIAL MEETING.—Not later than 30 days after the date on which all members of the Panel have been appointed, the Panel shall hold its first meeting.

“(g) MEETINGS.—The Panel shall meet at the call of the Chairperson.

“(h) QUORUM.—A majority of the members of the Panel shall constitute a quorum, but a lesser number of members may hold hearings.

“(i) DUTIES.—The Panel shall—

“(1) monitor the activities carried out by the Secretary through the Commissioner of Food and Drugs;

“(2) review the performance of the Food and Drug Administration to determine if the Food and Drug Administration is carrying out its mission to protect and promote the public health and is developing appropriate policy and effective regulations to carry out its mission;

“(3) review the performance of each Center in accordance with subsection (d)(1);

“(4) meet at least twice annually with appropriate management officials of the Food and Drug Administration and representatives of each Center;

“(5) participate in the development of agency guidelines; and

“(6) seek to facilitate the international harmonization of regulatory requirements, while ensuring that a product that is subject to the provisions of this Act, and that is marketed in the United States, is safe and effective.

“(j) REPORT.—The Panel shall annually 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 that evaluates the performance of the Food and Drug Administration (including a description of the activities that the Food and Drug Administration has successfully or unsuccessfully carried out) and includes a recommendation on the administrative modifications needed to improve such performance.

“(k) HEARINGS.—The Panel may hold such hearings, sit and act at such times and places, take such testimony, and receive such evidence as the Panel considers advisable to carry out the purposes of this Act.

“(l) INFORMATION FROM FEDERAL AGENCIES.—The Panel may secure directly from any Federal department or agency such information as the Panel considers necessary to carry out the provisions of this Act. Upon request of the Chairperson of the Panel, the

head of such department or agency shall furnish such information to the Panel.

“(m) POSTAL SERVICES.—The Panel may use the United States mails in the same manner and under the same conditions as other departments and agencies of the Federal Government.

“(n) DETAIL OF GOVERNMENT EMPLOYEES.—Any Federal Government employee may be detailed to the Panel without reimbursement, and such detail shall be without interruption or loss of civil service status or privilege.

“(o) PROCUREMENT OF TEMPORARY AND INTERMITTENT SERVICES.—The Chairperson of the Panel may procure temporary and intermittent services under section 3109(b) of title 5, United States Code, at rates for individuals which do not exceed the daily equivalent of the annual rate of basic pay prescribed for level V of the Executive Schedule under section 5316 of such title.

“(p) TERMINATION OF THE PANEL.—The termination provisions of section 14 of the Federal Advisory Committee Act (5 U.S.C. App.) shall not apply to the Panel.”

By Mr. CRAIG (for himself, Mr. DOLE, Mr. LOTT, Mr. BROWN, Mr. BURNS, Mr. CAMPBELL, Mr. FAIRCLOTH, Mr. FRIST, Mr. GRAMS, Mr. GRASSLEY, Mr. GREGG, Mr. HELMS, Mr. INHOFE, Mr. KEMPTHORNE, Mr. MURKOWSKI, Mr. PRESSLER, Mr. SANTORUM, Mr. SHELBY, Mr. SIMPSON, Mr. SMITH, Mr. STEVENS, and Mr. THOMAS):

S. 1370. A bill to amend title 10, United States Code, to prohibit the imposition of any requirement for a member of the Armed Forces of the United States to wear indicia or insignia of the United Nations as part of the military uniform of the member; to the Committee on Armed Services.

#### MILITARY UNIFORM LEGISLATION

Mr. CRAIG. Mr. President, I am pleased to be joining my colleague from the House of Representatives, Majority Whip TOM DELAY, in introducing legislation that will prohibit the requirement that members of the United States Armed Forces wear United Nations uniform items.

Mr. President, we have all been watching the reports as U.S. Army Specialist Michael New has become a casualty of the debate over American troops participating in U.N. operations.

In violating a lawful order issued through the U.S. Chain of Command, he will be held accountable under the standards set by the U.S. Code of Military Justice for refusing to wear a United Nations cap and shoulder patch.

Specialist New was to have been deployed to participate in operation Able Sentry in Macedonia, the stated purpose of which is to observe the border and discourage, by its presence, the spread of hostilities into Macedonia.

The operations in Macedonia in which the American forces are participating are conducted under the auspices of the United Nations. A

Norwegian general officer currently exercises operations control over the American task force Able Sentry.

While a U.N. commander has operational control, it is my understanding that the command of the U.S. task force remains under the U.S. chain of command.

Mr. President, on October 10, Army Specialist Michael New reported for duty without wearing the United Nations shoulder patch and beret he and his unit were issued to wear as part of their uniform while deployed in Macedonia. On October 17, Specialist New was charged for failure to obey a lawful order in violation of article 92, Uniform Code of Military Justice.

Mr. President, I would also note that Michael New will have legal representation and receive due process under these standards, as is extended to any military member who stands accused of violating military rules. The Army has indicated to me that care will be taken to ensure military standards of justice and fairness prevail.

The situation that has resulted from Specialist New's actions has caused me great concern. As one who feels very strongly about this Nation's sovereignty and responsibilities placed on our Armed Forces to protect and defend this Nation, I find myself very frustrated with what has happened.

Mr. President, my sympathy with his decision to refuse to wear the U.N. patch and hat does not change the fact that we must abide by the standards set by the Military Code of Conduct if we are to assure order and fairness in the military. Our military must rely on strict chain of command and order. That is without a doubt.

However, the men and women who have chosen to serve this Nation and the American people should not be put in a position which forces them to bear allegiance to any nation or organization other than the United States of America. Michael New made the decision to serve in the Armed Forces in order to defend the United States, not the United Nations. Therefore, in order to resolve this situation, I am introducing legislation that prevents any member of the U.S. Armed Forces from being required to wear, as part of their military uniform, any insignia of the United Nations.

Mr. President, there is still another, broader issue that must be addressed, and that is the use of U.S. forces under U.N. command.

It is my understanding that except for some expertise that was provided by a limited number of American advisors, until the past 2 or 3 years, no American troops had served in U.N. peacekeeping forces. In my view, the United States should not assume responsibility for resolving every conflict that develops around the world.

American combat troops are not, and should not be used as "world policemen."

Mr. President, I supported Senator NICKLES' amendment to the fiscal year 1994 defense appropriations legislation which would have required congres-

sional approval before American troops could serve under foreign command, except when the President certifies it is an emergency or that our national security is at risk.

Unfortunately, the amendment was defeated on a 33 to 65 vote.

This issue remains unresolved. Therefore I also support hearings in the Senate Armed Services Committee aimed at reviewing Specialist New's case and the proper role U.S. troops should play in international military operations.

Mr. President, I would just urge my colleagues to review the bill that I am introducing today in the greater context of this situation. We must not lose sight of the fact that the men and women who volunteered to serve in our Armed Forces, volunteered to defend the United States of America, not the United Nations.

Mr. President, I ask unanimous consent that the text of the bill be printed in the RECORD.

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

S. 1370

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

**SECTION 1. PROHIBITION ON REQUIREMENT FOR MEMBERS OF THE ARMED FORCES TO WEAR UNIFORM ITEMS OF THE UNITED NATIONS.**

(a) IN GENERAL.—Chapter 45 of title 10, United States Code, is amended by adding at the end the following:

(a) IN GENERAL.—Chapter 45 of title 10, United States Code, is amended by adding at the end the following:

**“§ 777. Insignia of United Nations: prohibition on requirement for wearing**

“No member of the armed forces may be required to wear as part of the uniform any badge, symbol, helmet, headgear, or other visible indicia or insignia which indicates (or tends to indicate) an allegiance or affiliation to or with the United Nations.”.

(b) CLERICAL AMENDMENT.—The table of sections at the beginning of such chapter is amended by adding at the end the following:

“777. Insignia of United Nations: prohibition on requirement for wearing.”.

By Mr. HATCH (for himself, Mr. CRAIG, Mr. BENNETT, and Mr. BURNS):

S. 1371. A bill entitled the “Snowbasin Land Exchange Act of 1995”; to the Committee on Energy and Natural Resources.

THE SNOWBASIN LAND EXCHANGE ACT OF 1995

Mr. HATCH. Mr. President, I rise today to introduce legislation to effectuate a land exchange at the Snowbasin Ski Resort located east of Ogden, Utah. Senators CRAIG, BENNETT, and BURNS are cosponsoring this legislation.

Basically, the intent of this legislation is simple. It directs the Secretary of Agriculture to exchange 1,320 acres of federally owned land within Utah's Cache National Forest for lands of approximately equal value owned by the Sun Valley Company, which owns the Snowbasin Ski Resort. Snowbasin is located 30 miles north of Salt Lake City

and has been open for skiing since the early 1940s. It is one of the world's greatest areas for snow and winter sports as evidenced by the recent decision by the International Olympic Committee (IOC) to have Salt Lake City host the 2002 Winter Olympic Games. It is precisely because of the IOC's decision that this legislation is necessary.

In 1985, a year after it purchased financially plagued Snowbasin, the Sun Valley Company, recognized as an environmentally sensitive manager of its recreational lands, asked the Forest Service to exchange 2,500 acres of land to improve the resort's base facilities and infrastructure. This request was initially reduced to 1,320. Five years later, after conducting an environmental impact statement and extensive studies and public reviews, the Forest Service decided to exchange approximately 700 acres. At the same time, the Forest Service reached the conclusions that the future success of Snowbasin requires private ownership of lands at the base of the ski area and that a land exchange was consistent with the priorities established in the 1985 Wasatch-Cache Land and Reserve Management Plan.

Unfortunately, since 1990 and despite the diligent efforts of both the Forest Service and the Sun Valley Company, little progress has occurred toward the exchange. I will not take the time to detail these difficulties. However, my colleagues should know that the land exchange process has been long, tedious, and very costly to all parties, particularly to Snowbasin.

Last June, Salt Lake City was selected as the site for the 2002 Winter Olympic Games. Due to its rugged mountain terrain, gradient and technical difficulty, Snowbasin has been identified as the venue for all Downhill, Combined Downhill, and Super G events for men and women. These highly popular races traditionally attract some of the largest Olympic audiences. The snail's pace with which the exchange process has been moving has many people associated with Snowbasin and the Salt Lake City Olympic Organizing Committee, including myself, worried that Snowbasin will not be sufficiently prepared to handle the Olympic skiing events and their accompanying crowds.

I am sure my colleagues can appreciate what it requires for a community to prepare a venue to host any Olympic event. In the case of Snowbasin, these pre-2002 activities include the installation of chairlifts, construction of a connector road, fencing and safety netting, additional ski runs, maintenance buildings, new spectator and service areas, parking lot expansion, restrooms and other items identified in Phase 1 of the Sun Valley Company's Master Plan for Snowbasin. These activities must be done in the near future and can be

more effectively and environmentally accomplished if done on private property.

In exchange for the forested acreage, the Sun Valley Company will convey four major parcels to the Forest Service that have been previously identified by the Forest Service as desirable for acquisition. These parcels are specifically listed in our legislation, and their combined acreage exceeds 4,000 acres. Obviously, this land possesses outstanding recreational, wildlife, mountain, and access values for public use and enjoyment. The values of the Federal and non-federal lands involved in this exchange will be determined by utilizing nationally recognized appraisal standards.

Mr. President, we in Utah are overjoyed that the eyes of the world will be upon us, upon our mountains, and upon the "Greatest Snow on Earth." At the same time, there is serious concern whether the facilities to support the Olympics can be constructed, tested for safety, and become fully operational by 2002, especially when considering it will take three summer seasons to complete the development of Phase 1 of the Snowbasin Master Plan. Pursuit of a land exchange at Snowbasin through the administrative process, and possibly the courts, does not alleviate this concern and only exacerbates the problems of timing and uncertainty. Legislative action on Snowbasin places control of this matter with the Congress, rather than the courts, and will ensure that all aspects of the 2002 Winter Olympic Games are in their proper place once the world focuses on Salt Lake City.

I urge my colleagues to carefully review this legislation and the reasons why it is crucial that this proposal be adopted during the 104th Congress. I look forward to working with them to achieve this goal.

Mr. BENNETT. Mr. President, as Utah prepares to host the 2002 Winter Olympics, I am pleased today to join my colleague Senator HATCH in introducing the Snowbasin Land Exchange Act of 1995. Snowbasin Ski Resort, which is owned by Sun Valley Company, will host both the men's and women's downhill ski events. This land exchange will direct the Secretary to exchange 1,320 acres of Forest Service Lands within the Cache National Forest for lands of approximate and equal value owned by Sun Valley Co. This legislation is fundamental to the success of the 2002 Winter Olympics. It is a win-win situation for all parties involved and I encourage my colleagues to support this bill.

By Mr. LIEBERMAN:

S. 1373. A bill to provide for state regulation of prices charged for services provided by, and routes of service of, motor vehicles that provide tow or wrecker services, and for other purposes; to the Committee on Commerce, Science, and Transportation.

THE TOWING TECHNICAL CORRECTION ACT

• Mr. LIEBERMAN. Mr. President, I introduce an Intrastate Towing Tech-

nical Corrections Act. This legislation will clarify that it is not Congress' intent to preempt state or local regulations dealing with the operation of tow trucks. I would like to recognize the junior Senator from Washington who introduced similar legislation in the 103d Congress, which, unfortunately, was not acted upon prior to adjournment.

Last year Congress passed the Federal Aviation Administration Authorization Act of 1994. The act included a provision in section 601 which effectively preempts state and local intrastate trucking regulations pertaining to prices, routes, and service. However, it was not Congress' intention to legislate on towing issues; and it has opened up myriad problems for the consumer, leading to higher towing rates.

In Connecticut, towing rates have been deregulated; and tow operators are free to charge as much as they want. Now, some may say that the market should determine prices—and I agree—but in the towing market the consumer has no other recourse, more times than not, than to pay the tow truck operator after the vehicle has been towed. Safety concerns abound also. Especially when considering large tractor trailers that break down on interstate highways.

I have heard from many constituents that deregulation is causing exorbitant price increases in their towing rates. Again, this was not our intention when we passed the Federal Aviation Administration Authorization Act of 1994. This bill will keep towing charges in line with market prices.

Plain and simple, Mr. President, deregulation is leading to overcharging. My bill would let the States set towing rates. It would be beneficial for the consumer and beneficial for States.

I ask unanimous consent to place in the RECORD excerpts from an article in the Hartford Courant by Tom Condon, which addresses this problem.

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

[From the Hartford Courant, Aug. 22, 1995]

DEREGULATING TOWING HAS LEFT PUBLIC ON HOOK

(By Tom Condon)

On Aug. 8, a tractor-trailer driver for Dick Harris Trucking Co. of Lynchburg, Va., pulled his rig off I-95 at Exit 34 in Milford. He didn't hit the narrow exit ramp just right, and the tractor and box gently rolled over.

Police called Robert's Service Center of Milford to clear the ramp. The trailer was full of pallets of rolled steel. Robert's crew winched the cargo out of the truck, righted it, then towed everything away.

What the owners of the truck aren't happy with is the towing bill, which is for \$10,400.

"It's excessive, that's the problem I have with it," said Bud Holt, vice president of the trucking company. Holt, who said he is a former state trooper and insurance claims adjuster, said Robert's billed some of the workers at \$60 an hour, which "is too much."

It doesn't matter, Holt. Welcome to Connecticut, where towing rates have been deregulated, and tow operators can charge as much as they want.

There is another side to the Milford case. Robert Bruno, owner of the service center, says this was a very complicated operation for which he had to rent expensive equipment. He said he had to winch the heavy pallets out of the truck with a rented low motor, then load them on rented flatbeds. Then he righted the tractor and trailer without damaging them.

Bruno said he brought the cargo back to his yard and unloaded it. Then, at the direction of the trucking company, he reloaded it on the flatbeds and took it to a freight yard with a loading dock, so it could be loaded back on the trailer.

He said he got the call at 11:30 a.m., and the last of his crew didn't finish until midnight. He said his real cost was almost \$14,000, but he decided to give the trucking company a break, hoping for future business. Holt said he understood the job took 10 hours, and said he thought \$1,000 an hour excessive.

Not so, said Bruno. He said some operators would have gouged the trucking company and charged \$20,000 for the job, but said he didn't. Bruno has released the trailer, but is still holding the tractor, until the dispute is resolved. Both sides have lawyers.

If this doesn't make the case that deregulation is leading to overcharging, let's go back to old reliable, a guy we can always count on to hose the public, Bob Spillane of Walnut Street Service Inc. of Hartford.

On May 10, an ironworker named Pete Toner of Langdon, N.H., parked his Bronco in a private parking lot—never do that—at the corner of Ashley and Garden streets and visited the Ashley Cafe. When he came out, the car was gone. He then walked to the police lockup at Morgan Street, finally learned the car had been towed, called Spillane and got no answer.

When he got the Bronco the next day, the bill was \$139. He said Spillane didn't answer his phone, then charged him for storage. The tow from the bar to Spillane's garage is one block. This is an outrage, but at the moment motor vehicles officials say there's nothing they can do about it (not that they ever did much about it in the past).

On Jan. 1, a federal law went into effect that prevents states or cities from regulating "price, route or service of any motor carrier . . . or any motor carrier with respect to the transportation of property." State officials have interpreted this to mean they can't regulate towing rates.

If a conservative is a liberal who's been mugged, an opponent of deregulation is someone who's had to pay \$139 after his car was towed one block. If this idiotic law isn't changed, government is going to have to get back into the towing business to keep the public from getting fleeced. We don't want that. ●

#### ADDITIONAL COSPONSORS

S. 324

At the request of Mr. WARNER, the name of the Senator from Tennessee [Mr. THOMPSON] was added as a cosponsor of S. 324, a bill to amend the Fair Labor Standards Act of 1938 to exclude from the definition of employee firefighters and rescue squad workers who perform volunteer services and to prevent employers from requiring employees who are firefighters or rescue squad workers to perform volunteer services,