The following named captain in the line of the United States Navy for promotion to the permanent grade of rear admiral (lower half), pursuant to Title 10, United States Code, Section 624, subject to qualifications, therefore, as provided by law:

UNRESTRICTED LINE OFFICER

To be rear admiral (lower half)

Capt. John B. Padgett III, 000–00–0000, United States Navy.

The following named officer for appointment in the United States Air Force to the grade of major general under the provisions of title 10, United States Code, section 624:

To be major general

Brig. Gen. John B. Hall, Jr., 000–00–0000, Regular Air Force.

The following named officer for appointment to the grade of lieutenant general while assigned to a position of importance and responsibility under Title 10, United States Code, section 601:

To be lieutenant general

Maj. Gen. Brett M. Dula, 000–00–0000, United States Air Force.

The following named officer for appointment to the grade of lieutenant general while assigned to a position of importance and responsibility under title 10, United States Code, section 601:

To be lieutenant general

Maj. Gen. Nicholas B. Kehoe, III, 000–00–0000, United States Air Force.

The following named officer for appointment to the grade of lieutenant general on the retired list pursuant to the provisions of Title 10, United States Code, section 1370:

To be lieutenant general

Lt. Gen. Thad A. Wolfe, 000–00–0000, United States Air Force.

The following named officer for appointment to the grade of lieutenant general while assigned to a position of importance and responsibility under Title 10, United States Code, section 601:

To be lieutenant general

Maj. Gen. James F. Record, 000–00–0000, United States Air Force.

The following named Medical Corps Competitive Category officers for appointment in the Regular Army of the United States to the grade of brigadier general under the provisions of title 10, U.S.C., sections 611(a) and 624(c):

To be brigadier general

Col. George J. Brown, 000–00–0000, United States Army.

Col. Robert F. Griffin, 000–00–0000, United States Army.

The following named officer for promotion in the Regular Army of the United States to the grade indicated under title 10, U.S.C., sections 611(a) and 624(c):

To be brigadier general

Col. Bettye H. Simmons, 000–00–0000, United States Army.

The following named officers for promotion in the Regular Army of the United States to the grade indicated, under the provisions of title 10, United States Code, Sections 611(a) and 624:

To be permanent major general

Brig. Gen. Robert W. Roper, Jr., 000–00–0000.
Brig. Gen. Edward L. Andrews, 000–00–0000.
Brig. Gen. David K. Heebner, 000–00–0000.
Brig. Gen. Morris J. Boyd, 000–00–0000.
Brig. Gen. Robert R. Hicks, Jr., 000–00–0000.
Brig. Gen. Stewart W. Wallace, 000–00–0000.
Brig. Gen. James M. Wright, 000–00–0000.
Brig. Gen. Charles W. Thomas, 000–00–0000.
Brig. Gen. George H. Harmeyer, 000–00–0000.
Brig. Gen. John F. Michitsch, 000–00–0000.
Brig. Gen. Lon E. Maggart, 000–00–0000.
Brig. Gen. Henry T. Glisson, 000–00–0000.
Brig. Gen. Thomas N. Burnette, Jr., 000–00–0000.
Brig. Gen. David H. Ohle, 000–00–0000.
Brig. Gen. Milton Hunter, 000–00–0000.
Brig. Gen. James T. Hill, 000–00–0000.
Brig. Gen. Greg L. Gile, 000–00–0000.
Brig. Gen. James C. Riley, 000–00–0000.
Brig. Gen. Randall L. Rigby, 000–00–0000.
Brig. Gen. Daniel J. Petrosky, 000–00–0000.
Brig. Gen. Michael B. Sherfield, 000–00–0000.
Brig. Gen. James C. King, 000–00–0000.
Brig. Gen. Joseph G. Garrett, III, 000–00–0000.
Brig. Gen. Leroy R. Goff, III, 000–00–0000.
Brig. Gen. Daniel G. Brown, 000–00–0000.
Brig. Gen. William P. Tangney, 000–00–0000.
Brig. Gen. Charles S. Mahan, Jr., 000–00–0000.
Brig. Gen. John J. Maher, III, 000–00–0000.
Brig. Gen. Leon J. LaPorte, 000–00–0000.
Brig. Gen. Claudia J. Kennedy, 000–00–0000.

(The above nominations were reported with the recommendation that they be confirmed.)

Mr. THURMOND. Mr. President, from the Committee on Armed Services, I report favorably the attached listing of nominations.

Those identified with a single asterisk (*) are to be placed on the Executive Calendar. Those identified with a double asterisk (**) are to lie on the Secretary's desk for the information of any Senator since these names have already appeared in the RECORDS of March 8, April 24, September 5, 8, 19, October 10, 11, and 19, 1995, and to save the expense of printing again.

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

(The nominations ordered to lie on the Secretary's desk were printed in the RECORDS of March 8, April 24, September 5, 8, 19, October 10, 11, and 19, 1995 at the end of the Senate proceedings.)

*In the Navy there are 23 promotions to the grade of rear admiral (lower half) (list begins with Stephen Hall Baker) (Reference No. 234–1)

**In the Naval Reserve there are 332 promotions to the grade of captain (list begins with John M. Abernathy III) (Reference No. 257–1)

*Captain John B. Padgett, III, USN to be rear admiral (lower half) (Reference No. 275)

**In the Navy there is 1 promotion to the grade of lieutenant commander (Robert W. Ernst) (Reference No. 343–1)

*Brigadier General John B. Hall, Jr., USAF to be major general (Reference No. 426)

*In the Army there are 30 promotions to the grade of major general (list begins with Robert W. Roper, Jr.) (Reference No. 533)

**In the Navy there are 1,240 promotions to the grade of lieutenant commander (list begins with Timothy A. Adams) (Reference No. 623–1)

**In the Navy there are 741 appointments to the grade of commander and below (list begins with Albert M. Carden) (Reference No. 628–1)

Total: 2,369.

* Rear Admiral Dennis C. Blair, USN to be vice admiral (Reference No. 472)

** In the Air Force there are 2,360 promotions to the grade of major (list begins with Tarek C. Abboushi) (Reference No. 611)

* Major General Brett M. Dula, USAF to be lieutenant general (Reference No. 639)

* Major General James F. Record, USAF to be lieutenant general (Reference No. 640)

* Lieutenant General Thad A. Wolfe, USAF to be placed on the retired list in the grade of lieutenant general (Reference No. 641)

* Colonel Bettye H. Simmons, USA to be brigadier general (Reference No. 643)

* In the Army there are 2 appointments to the grade of brigadier general (list begins with George J. Brown) (Reference No. 644)

** In the Army there are 71 promotions to the grade of colonel (list begins with Anthony C. Aiken) (Reference No. 645)

** In the Navy there are 844 promotions to the grade of lieutenant commander (list begins with William D. Agerton) (Reference No. 647)

* Major General Nicholas B. Kehoe, III, USAF to be lieutenant general (Reference No. 668)

** In the Air Force Reserve there are 20 promotions to the grade of lieutenant colonel (list begins with Julian Andrews) (Reference No. 669)

** In the Army there is 1 promotion to the grade of major (Amy M. Autry) (Reference No. 670)

** In the Army there are 2 promotions to the grade of colonel and below (list begins with Michael B. Neveu) (Reference No. 671)

** In the Army there is 1 promotion to the grade of major (Duane A. Belote) (Reference No. 672)

** In the Marine Corps there are 66 appointments to the grade of captain (list begins with Thurmond Bell) (Reference No. 673)

** In the Air Force Reserve there are 714 promotions to the grade of lieutenant colonel (list begins with Laraine L. Acosta) (Reference No. 674)

** In the Air Force there are 28 promotions to the grade of colonel and below (list begins with Larry E. Freeman) (Reference No. 683)

** In the Army there is 1 promotion to the grade of lieutenant colonel (Derek J. Harvey) (Reference No. 684)

** In the Army Reserve there are 16 promotions to the grade of colonel (list begins with Barbara Hasbargen) (Reference No. 685)

** In the Army Reserve there are 567 promotions to the grade of lieutenant colonel (list begins with Mary B. Alexander) (Reference No. 686)

Total: 4,699.

INTRODUCTION OF BILLS AND JOINT RESOLUTIONS

The following bills and joint resolutions were introduced, read the first and second time by unanimous consent, and referred as indicated:

By Mr. LIEBERMAN:

S. 1368. 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 Armed Services and the Committee on Commerce, Science, and Transportation.

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 Resources.

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.

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 manufacturers 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 rulemaking 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 betwen 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 scarificing 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: