

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: