

S. 844. A bill to amend the President John F. Kennedy Assassination Records Collection Act of 1992 to extend the authorization of the Assassination Records Review Board until September 30, 1998; to the Committee on Governmental Affairs.

By Mr. LUGAR (for himself, Mr. HARKIN, Mr. MCCONNELL, Mr. SANTORUM, Mr. ROBERTS, Mr. COCHRAN, Mr. CRAIG, Mr. GRASSLEY, Mr. DASCHLE, Mr. LEAHY, Mr. KERREY, Mr. BAUCUS, Ms. LANDRIEU, Mr. JOHNSON, and Mr. CONRAD):

S. 845. A bill to transfer to the Secretary of Agriculture the authority to conduct the census of agriculture, and for other purposes; to the Committee on Governmental Affairs.

By Mr. AKAKA:

S. 846. A bill to amend the Federal Power Act to remove the jurisdiction of the Federal Energy Regulatory Commission to license projects on fresh waters in the State of Hawaii; to the Committee on Energy and Natural Resources.

By Mr. COATS (for himself, Mr. LIEBERMAN, Mr. BROWNBACK, Mr. ASHCROFT, Mr. COVERDELL, and Mr. GREGG):

S. 847. A bill to provide scholarship assistance for District of Columbia elementary and secondary school students; to the Committee on Governmental Affairs.

By Mr. MURKOWSKI (for himself and Mr. BAUCUS):

S. 848. A bill to direct the Secretary of Health and Human Services, through the Health Care Financing Administration, to expand and strengthen the demonstration project known as the Medicare telemedicine demonstration program; to the Committee on Finance.

#### SUBMISSION OF CONCURRENT AND SENATE RESOLUTIONS

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

By Mr. CRAIG:

S. Res. 96. A resolution proclaiming the week of March 15 through March 21, 1998, as "National Safe Place Week"; to the Committee on the Judiciary.

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

S. Res. 97. A resolution expressing the sense of the Senate that the President should designate the month of June 1997, the fiftieth anniversary of the Marshall Plan, as George C. Marshall month, and for other purposes; considered and agreed to.

By Mr. D'AMATO (for himself, Mr. BOND, Mr. MACK, and Mr. SPECTER):

S. Con. Res. 31. A concurrent resolution concerning the Palestinian Authority and the sale of land to Israelis; to the Committee on Foreign Relations.

#### STATEMENTS ON INTRODUCED BILLS AND JOINT RESOLUTIONS

By Mr. JEFFORDS:

S. 830. A bill 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; to the Committee on Labor and Human Resources.

THE FOOD AND DRUG ADMINISTRATION MODERNIZATION AND ACCOUNTABILITY ACT OF 1997

Mr. JEFFORDS. Mr. President, today I am introducing legislation to modernize the Food and Drug Administra-

tion [FDA] and reauthorize the Prescription Drug User Fee Act for 5 years. This legislation comes as result of over 3 years of consideration by the Congress on steps that could be taken by the agency that would contribute to its mandate to protect the American public while ensuring that life-saving products could be made more readily available.

FDA acknowledges that its mandate also requires it to regulate over one-third of our Nation's products. Within its purview the FDA regulates virtually all of the food and all of the cosmetics, medical devices, and drugs made available to our citizens. I believe, and several members of the Labor Committee share my belief, that in an organization the size of FDA there is always room for improvement and modernization. Our objective, which this legislation achieves, was to identify areas where improvements could be made that will strengthen the agency's ability to approve safe and effective products more expeditiously.

Last year, both the House and the Senate held numerous and extensive hearings on countless proposals for modernizing and reforming the FDA. The Senate Labor and Human Resources Committee successfully reported a bipartisan bill that sought to accomplish many of those reforms. But last year, acrimonious issues remained, time ran out and the bill did not receive floor consideration. This year I have resolved to move forward. I have been committed to addressing last year's most controversial issues. I believe that the legislation I am introducing today addresses virtually all of objections raised last year both in process and in content. This is a better bill and I believe that upon examination, my colleagues will agree that it accomplishes its goal.

I want to comment a moment on the open, consensus-building process we followed in developing this legislation. The Labor Committee held two hearings. During the first the committee received testimony from the principal FDA Deputy Commissioner, Dr. Michael Friedman, and all of the FDA Center Directors. The second hearing included representatives from patient and consumer coalitions and from the food, drug, and medical device sectors regulated by the FDA. Committee members learned from the agency of the administrative reforms and the progress it has already undertaken, areas that remain a challenge, and those areas that require legislative authority to change. The committee listened to consumers' concerns with provisions that were considered last year that they felt would weaken the FDA's ability to protect the public health. Finally, the committee learned of the on-going and needless delays and frustrations facing health care and consumer product sectors of our economy in working with the FDA. The committee learned of the frustrated attempts to work through the bureaucratic lab-

yrinth of needless regulatory delays. Delays that prohibited people from getting access to vitally needed, life saving medical treatments, drugs, and devices.

Since the finish of the committee's hearings we have engaged in an open, collaborative process that has given voice to each party wishing to be heard. For many of these meetings it is worth noting that the agency was a full, cooperating participant and we would not have been able to make the progress made without FDA's collaboration. Several meetings, essentially roundtable discussions, have occurred with bipartisan committee staff, the FDA, and each of the several sectors regulated by the agency. These meetings have given all the participants an opportunity to discuss problems and potential solutions and have been the basis for the consensus bill I am introducing today. Finally, committee staff have had numerous meetings to discuss key provisions in the bill with a wide range of consumer groups including, among others, the Patient Coalition, Public Citizen, the Centers for Science in the Public Interest, the Pediatric AIDS Foundation, and the National Organization for Rare Diseases. It should be clear that no person or group was excluded from this deliberative process.

Let me turn to the content of this measure and the steps we have taken to respond to the controversies raised last year. Five key objections were raised against the FDA reform bill that had been reported on a strong bipartisan vote from the Labor and Human Resources Committee during the last Congress. In that vein, we have sought to and have accomplished addressing each of the substantive concerns raised by the minority.

Last year's measure was criticized by some for the number of mandatory, but shortened, product review time frames that critics said would overburden the FDA and for the hammers that would have required FDA to contract out some product reviews or to give priority to products approved abroad. Today's legislation eliminates most of the mandatory time frames and retains only those necessary to ensure collaborative, more efficient reviews or to facilitate quick reviews of low risk products. The contracting out and European review hammers that would have forced FDA actions have been eliminated.

Last year's provision allowing for third party, outside expert review were criticized for turning central regulatory authority decisions over to private industry, creating conflicts of interest, and depriving FDA of resources and expertise. Today's legislation adopts FDA's current system for accrediting and selecting third-party review organizations. The bill expands FDA's current pilot third-party review program beyond just the lowest risk devices and FDA retains final approval for all devices. Devices that are life-