

Service study has helped catalyze a growing recognition that the Harbor Islands deserve protection, as a unique resource that can greatly expand recreational opportunities for families in the Boston area and for visitors from across the country. Already, more than 25 million tourists visit Massachusetts each year, with 10 million visiting the Boston area annually. Fulfilling the potential of the Harbor Islands will strengthen tourism and significantly benefit the local economy, as well as enhance the experience of visitors to the area.

As recommended by the Park Service study, to fulfill that potential, we must improve public access to the islands and adopt a coordinated approach to their management. This legislation calls on the National Park Service to work closely with State and local governments and nonprofit organizations to preserve the natural and cultural resources of the islands and make them more accessible to the public through the use of a public water transportation system. The bill establishes a partnership among the various levels of government, and requires a commitment of non-Federal funds on at least a three-to-one matching basis with Federal funds. It does not involve any substantial purchase of land by the Federal Government; instead, it authorizes the Park Service to develop cooperative agreements with the State, local and private owners of the islands to ensure their protection and expanded public use.

The Boston Harbor Islands will be an exceptional addition to the National Park System. Their natural beauty and historical significance eminently merit this protection and preservation. The partnership approach will keep Federal costs to a minimum and assure the success of this effort for generations to come. I urge my colleagues to support this important legislation.

By Mrs. KASSEBAUM:

S. 1477. 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 PERFORMANCE AND ACCOUNTABILITY ACT OF 1995

• Mrs. KASSEBAUM. Mr. President, I introduce the Food and Drug Administration Performance and Accountability Act of 1995. This comprehensive reform bill is designed to ensure that Americans continue to enjoy and our Nation continues to lead the world in the development of new, life-saving and life-enhancing pharmaceuticals and medical devices and wholesome, abundant, and affordable foods by reforming the role of the Food and Drug Administration in the testing and review of new products.

Over the years, the FDA's requirements for clinical testing and its premarket reviews of new products have

grown increasingly complex, time-consuming, and expensive. From the 1960's to the 1990's, for example, the time required to complete clinical trials for new drugs has grown from 2½ years to nearly 6 years. From the beginning of the process to the end, it takes an average of 12 years and costs \$359 million to bring a new drug to market. By law, the FDA is required to review and act on applications to market new drugs and devices within 180 days. Today, however, it takes the agency on average 649 days to complete its review of new devices and 570 days to complete its review of most new drugs.

These increasing FDA demands on new product development and delays in new product reviews are reducing incentives for research and development, encouraging American companies to locate abroad, delaying Americans' access to new pharmaceuticals and medical devices, and costing American jobs.

The legislation I am introducing today is designed to correct these problems. First, the bill makes clear that a prime mission of the FDA is facilitating the rapid and efficient development and availability of safe and effective products that will benefit the public. It puts the agency on notice that Congress and the American people expect it to allocate its time, energy, and resources accordingly.

Second, the bill puts teeth into statutory deadlines for agency action. The FDA commissioner is required, in consultation with patient advocacy groups and the regulated industries, to establish and meet yearly performance standards that will bring the agency into compliance and keep it in compliance with statutory deadlines for action on premarket approval applications. The commissioner will be required to report yearly on the agency's performance and, if the agency is out of compliance, to contract with outside experts for product reviews.

Third, to ensure that desperately ill and suffering patients have access to promising new therapies, the bill will expand access to investigational new pharmaceuticals and medical devices. To ensure that physicians are as fully informed as possible about these new therapies and about new uses for already approved therapies, the bill will ease the agency's current severe restrictions on the dissemination of information about them.

Fourth, the bill establishes a collaborative clinical testing and review process. It requires the agency to meet with companies in the early stage of the clinical testing to establish the parameters for testing and avoid last-minute changes in protocol designs once testing is underway. Once testing has been completed and the agency receives an application for product approval, the agency would again be required to meet with companies to better ensure the smooth and timely review of the application.

Fifth, the bill provides the agency with the statutory flexibility it needs

to make changes in its clinical testing policies and product review procedures. For example, it modifies current law, which appears now to require two or more clinical studies, to permit the agency to base its approval on one well-designed clinical study when appropriate. As further examples, the bill updates outmoded statutory requirements for the regulation of biological products, reduces the number of medical devices that the agency is required to review, and makes it easier for the agency to use national and internationally recognized performance standards in evaluating the safety and effectiveness of devices.

In these and in a number of other ways, the FDA Performance and Accountability Act of 1995 will transform the FDA from a growing barrier to innovation into an active partner in innovation. •

#### ADDITIONAL COSPONSORS

S. 581

At the request of Mr. FAIRCLOTH, the name of the Senator from Iowa [Mr. GRASSLEY] was added as a cosponsor of S. 581, a bill to amend the National Labor Relations Act and the Railway Labor Act to repeal those provisions of Federal law that require employees to pay union dues or fees as a condition of employment, and for other purposes.

S. 981

At the request of Mr. EXON, the name of the Senator from California [Mrs. BOXER] was added as a cosponsor of S. 981, a bill entitled "Truck Safety and Congressional Partnership Act".

S. 1030

At the request of Mr. REID, the name of the Senator from Maine [Ms. SNOWE] was added as a cosponsor of S. 1030, a bill entitled the "Federal Prohibition of Female Genital Mutilation Act of 1995."

S. 1212

At the request of Mr. COATS, the name of the Senator from New Jersey [Mr. BRADLEY] was added as a cosponsor of S. 1212, a bill to provide for the establishment of demonstration projects designed to determine the social, civic, psychological, and economic effects of providing to individuals and families with limited means an opportunity to accumulate assets, and to determine the extent to which an asset-based welfare policy may be used to enable individuals and families with low income to achieve economic self-sufficiency.

S. 1392

At the request of Mr. BAUCUS, the name of the Senator from Maine [Mr. COHEN] was added as a cosponsor of S. 1392, a bill to impose temporarily a 25 percent duty on imports of certain Canadian wood and lumber products, to require the administering authority to initiate an investigation under title VII of the Tariff Act of 1930 with respect to such products, and for other purposes.

S. 1419

At the request of Mrs. KASSEBAUM, the name of the Senator from Maine [Ms. SNOWE] was added as a cosponsor of S. 1419, a bill to impose sanctions against Nigeria.

S. 1470

At the request of Mr. MCCAIN, the names of the Senator from Delaware [Mr. BIDEN] and the Senator from Virginia [Mr. WARNER] were added as cosponsors of S. 1470, a bill to amend title II of the Social Security Act to provide for increases in the amounts of allowable earnings under the Social Security earnings limit for individuals who have attained retirement age, and for other purposes.

## SENATE JOINT RESOLUTION 43

At the request of Mr. SANTORUM, his name was added as a cosponsor of Senate Joint Resolution 43, a joint resolution expressing the sense of Congress regarding Wei Jingsheng; Gedhun Choekyi Nyima, the next Panchen Lama of Tibet; and the human rights practices of the Government of the People's Republic of China.

## SENATE CONCURRENT RESOLUTION 35—RELATIVE TO BOSNIA

Mrs. HUTCHISON (for herself, Mr. INHOFE, Mr. CRAIG, Mr. NICKLES, Mr. KYL, Mr. LOTT, Mr. BENNETT, Mr. BROWN, Mr. BURNS, Mr. CAMPBELL, Mr. COATS, Mr. D'AMATO, Mr. DOMENICI, Mr. FAIRCLOTH, Mr. FRIST, Mr. GRAMS, Mr. HATCH, Mr. HELMS, Mr. KEMPTHORNE, Mr. MURKOWSKI, Mr. PRESSLER, Mr. SANTORUM, Mr. SHELBY, Mr. SIMPSON, Mr. SMITH, Mr. STEVENS, Mr. THOMAS, Mr. THOMPSON, and Mr. THURMOND) submitted the following concurrent resolution; which was considered and not agreed to:

S. CON. RES. 35

*Resolved by the Senate (the House of Representatives concurring),*

## SECTION 1. EXPRESSING OPPOSITION TO THE DEPLOYMENT DECISION.

The Congress opposes President Clinton's decision to deploy United States military ground forces into the Republic of Bosnia and Herzegovina to implement the General Framework Agreement for Peace in Bosnia and Herzegovina and its associated annexes.

## SEC. 2 EXPRESSING SUPPORT FOR UNITED STATES MILITARY PERSONNEL WHO ARE DEPLOYED.

The Congress strongly supports the United States military personnel who may be ordered by the President to implement the General Framework Agreement for Peace in Bosnia and Herzegovina and its associated annexes.

## SEC. 3. TRANSMITTAL OF RESOLUTION.

The Secretary of the Senate shall transmit a copy of this concurrent resolution to the President.

## SENATE CONCURRENT RESOLUTION 36—DIRECTING THE SECRETARY OF THE SENATE

Mr. LEVIN submitted the following concurrent resolution; which was considered and agreed to:

S. CON. RES. 36

*Resolved by the Senate (the House of Representatives concurring),* That in the enroll-

ment of the bill S. 1060, to provide for the disclosure of lobbying activities to influence the Federal Government, and for other purposes, the Secretary of the Senate shall make the following corrections:

(1) In section 6(8), strike "6" and insert "7".

(2) In section 9(7), insert "and" after the semicolon, in section 9(8), strike "; and" and insert a period, and strike paragraph (9) of section 9.

(3) In section 12(c), strike "7" and insert "6".

(4) In section 15(a)(2), strike "8" and insert "7".

(5) In section 15(b)(1), strike ", 5(a)(2)," and in section 15(b)(2), strike "8" and insert "7".

(6) In section 24(b), strike "13, 14, 15, and 16" and insert "9, 10, 11, and 12".

(7) In section 12(b)(1), strike "7" and insert in lieu thereof "6".

## AMENDMENTS SUBMITTED

TECHNICAL CORRECTIONS  
CONCURRENT RESOLUTION

## SIMPSON (AND CRAIG)

## AMENDMENT NO. 3098

Mr. BROWN (for Mr. SIMPSON, for himself and Mr. CRAIG) proposed an amendment to the concurrent resolution (H. Con. Res. 116) directing the Secretary of the Senate to make technical corrections in the enrollment of S. 1060; as follows:

On page 2, after line 10 insert the following: (7) In section 18, strike "contract, loan, or any other form" and insert "or loan".

(8) In section 12(b)(1), strike "7" and insert "6".

THE AU PAIR PROGRAMS  
EXTENSION ACTHELMS (AND DODD) AMENDMENT  
NO. 3099

Mr. BROWN (for Mr. HELMS, for himself and Mr. DODD) proposed an amendment to the bill (S. 1465) to extend au pair programs; as follows:

On line 9 strike "1999" and replace with "1997".

On line 10, strike "1998" and replace with "1996".

AUTHORITY FOR COMMITTEES TO  
MEET

## COMMITTEE ON ARMED SERVICES

Mr. HATCH. Mr. President, I ask unanimous consent that the Committee on Armed Services be authorized to meet on Wednesday, December 13, 1995, at 10 a.m. in open session, to consider the nomination of Mr. H. Martin Lancaster for appointment as Assistant Secretary of the Army for Civil Works.

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

COMMITTEE ON ENVIRONMENT AND PUBLIC  
WORKS

Mr. HATCH. Mr. President, I ask unanimous consent that the full Committee on Environment and Public

Works be granted permission to conduct a hearing Wednesday, December 13, at 9:30 a.m., Hearing Room (SD-406), with respect to the reauthorization of the Clean Water Act on municipal issues.

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

## SELECT COMMITTEE ON INTELLIGENCE

Mr. HATCH. Mr. President, I ask unanimous consent that the Select Committee on Intelligence be authorized to meet during the session of the Senate on Wednesday, December 13, 1995 at 2 p.m. to hold a closed hearing regarding intelligence matters.

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

SUBCOMMITTEE ON FORESTS AND PUBLIC LAND  
MANAGEMENT

Mr. HATCH. Mr. President, I ask unanimous consent that the Subcommittee on Forests and Public Land Management of the Committee on Energy and Natural Resources be granted permission to meet during the session of the Senate on Wednesday, December 13, 1995, for purposes of conducting a subcommittee hearing which is scheduled to begin at 2:30 p.m. The purpose of this hearing is to consider S. 901, the Water Recycling Projects; S. 1013, the Garrison Diversion Unit Project; S. 1154, the Fort Peck Rural County Water Supply System Act of 1995; S. 1169, the McCall Area Wastewater Reclamation and Reuse Project, and S. 1186, the Flathead Irrigation and Power Project.

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

## ADDITIONAL STATEMENTS

## ILLICIT DRUGS

• Mr. D'AMATO. Mr. President, I rise today to discuss a vital, bicameral effort to combat drugs in this country. The Task Force on National Drug Policy, of which I am a proud member, was announced today to work to solve a serious problem: narcotics.

Despite efforts by Congress to curtail the flow of drugs into this country and its use by Americans, it seems as though the results have been lost with this administration. The intent of this task force is to focus the White House on a problem that is far from being resolved, and where much attention needs to be paid.

This is particularly important in light of recent studies that have indicated a growing trend in illicit drug use among teenagers. Studies indicate that, despite a decline in drug use among teens during the 1980's, drug use has risen sharply in the past few years. Cocaine use by high school students increased 36 percent since 1991-92, which was the period of lowest use. Marijuana use increased as well. Between the 1990-92 school year and 1994, marijuana use among junior high school students rose 111 percent and rose 67 percent in high schools. Now, one in three high