forward with determination but cognizant of her native surroundings and what the benefits will be to everyone.

Mere epitomized the true legacy of an educator, who throughout her lifetime set precedents for Samoan people and especially for Pacific island women, teaching by example. As her island home developed under the guidance of the United States of America for almost a century now, she never forgot her role as an educated Samoan to maintain her indigenous culture.

Judge Betham is survived by her husband of over 40 years, James ''Rusty'' M. Betham, five of her six children, five grandchildren, her 83-year-old mother-in-law, a number of brothers and sisters, and a large extended family in her native Samoa and the world over. She will be missed by all those who knew and loved her.●

THOMAS BROS. GRASS, LTD.

● Mr. FRIST. Mr. President, I rise today to commend Thomas Bros. Grass, Ltd., being named Entrepreneur of the Year by the Dallas Business Journal. Thomas Bros. began in the 1970's, with 10 acres of undeveloped land and a dream. E.A. Thomas and his four sons Ike, Mark, Mike, and Emory, took those 10 acres and started a small business with the desire to produce a wide variety of quality sod for golf courses, athletic fields, and residential properties. Over the years, that small sod farm has blossomed into a successful 2,000-acre family-owned business, with sod operations in three States.

While their headquarters are located in Texas, Thomas Bros. has two sod farms in my home State of Tennessee. The farms in Taft and Nashville have not only strengthened the economies of these communities, they have brought with them the Thomas family spirit of teamwork and community well-being. Not only are they well established as experts in sod production and installation, they have achieved a reputation for quality and efficient service. That reputation makes them standouts in their field, and has earned the family work in major arenas throughout the country, like the Cotton Bowl in Dallas and the Kansas City Chiefs football club.

Mr. President, Thomas Bros.' team approach and home grown commitment to customer satisfaction has certainly benefited the State of Tennessee and is worthy of this recognition as Entrepreneur of the Year. I congratulate them and wish them continued success in future endeavors.●

REAUTHORIZING THE PRESCRIPTION DRUG USER FEE PROGRAM AND CERTAIN FOOD AND DRUG ADMINISTRATION REFORMS

● Mr. WYDEN. Mr. President, I strongly urge my colleagues to support S. 830, the FDA Modernization and Accountability Act.

This bill deserves support for one primary reason. It preserves the FDA's essential mission of validating the safety and effectiveness of new drugs and medical devices, while encouraging innovation and the commercialization of new, life-saving therapies.

This bill is the result of much debate, and tremendous consensus building over the last two Congresses. I'm proud to have played some part in this as a Member of both the House and the Senate, having introduced more than 2 years ago H.R. 1472, the FDA Modernization Act of 1995, which contains several of the key ingredients of the legislation before us today.

From the time we get up in the morning until the time we go to bed at night, we live, work, eat, and drink in a world of products affected by FDA decisionmaking.

Perhaps no other Federal agency has such a broad impact in the daily lives of average Americans.

Food handling and commercial preparation often occurs under the agency's scrutiny. Over-the-counter drugs and nutritional supplements, from vitamins to aspirin, also are certified by the agency.

Life-saving drugs for treatment of cancer, autoimmune deficiency, and other dread diseases are held to its rigorous approval standards.

Medical devices ranging from the simple to the complex, from tongue depressors to computerized diagnostic equipment, must meet FDA quality standards.

These products overseen by the FDA are woven deeply into the fabric of our daily lives, and the agency's twin missions of certifying their safety and effectiveness is supported by the vast majority of Americans.

Yet, balancing those missions against the time and expense required by manufacturers to navigate the FDA approval system has been difficult and controversial. In the last Congress, radical transformation of the agency, even ending the agency as we know it and replacing it with a panel of private-sector, expert entrepreneurs, became a goal of some.

At the very least, reforming the FDA at the beginning of the 104th Congress looked to be an exercise fraught with partisan political turmoil, and destined for gridlock.

But while there was focus on the extreme ends of the argument, those folks arguing for no changes against members demanding wholesale dismemberment of the agency, a broader, bipartisan middle developed.

And with the help of Vice President's GORE's Reinventing Government Program, Members of Congress from both political parties developed practical, bipartisan solutions to the critical process and management problems in the FDA approval process.

I sought to mobilize this bipartisan movement with H.R. 1472 introduced in June 1995. Some in my own party thought I had gone to far, too fast, But I am gratified that many of the elements of that legislation have been retained and strengthened in the legislation and managers amendment we expect to have before us this week.

These include: It streamlines approval systems for biotechnology product manufacturing; it allows approval of important, new breakthrough drugs on the basis of a single, clinically valid trial; it creates a collaborative mechanism allowing applicants to confer constructively with the FDA at critical points in the approval process; it sets reasonable but strict timeframes for approval decisionmaking; it reduces the paperwork and reporting burden now facing manufacturers when they make minor changes in their manufacturing process; it establishes provisions for allowing third-party review of applications at the discretion of the Secretary; and it allows manufacturers to distribute scientifically valid information on uses for approved drugs and devices which may not yet be certified by the FDA.

I am especially pleased that Senators MACK, FRIST, DODD, BOXER, KENNEDY, and I could offer the provisions of this legislation relating to the dissemination of information on off-label uses of approved products.

This provision will allow manufacturers to distribute scientifically and clinically valid information on such uses following a review by the FDA, including a decision by the agency which may require additional balancing material be added to the packet.

Here's why that's important: Manufacturers with an approved drug for ovarian cancer may have important, but not yet conclusive information from new trials that their drug also may reduce brain or breast cancers. That data, while perhaps not yet of a grade to meet supplemental labeling approval, may be important for an end-stage breast cancer patient whose doctor has exhausted all other treatments.

That doctor, and her patient, has the absolute right to that information.

This legislation will save lives, not sacrifice them.

It will mean that more doctors and their patients will have meaningful access to life-saving information about drugs that treat dread diseases like AIDS and cancer.

It will mean that biologic products will have a swifter passage through an approval process which no longer will require unnecessarily difficult demands with regard to the size of a start-up manufacturing process.

It will mean that break-through drugs which offer relief from, or curses of deadly disease for which there is no approved therapy will get into the marketplace earlier, on the basis of a special expedited approval system.

But legislation, indeed laws, are only words on paper.

Mr. President, we must also have a new FDA Commissioner who is as committed to these changes as former Commissioner David Kessler was committed to the war on teenage smoking.

The pharmaceutical industry is a robust, risk-taking, technology-driven

business. But by measure of total U.S. employment growth in this industry is stalling out. While sales by U.S.-based concerns continue to increase, more of the industry's manufacturing—its jobs—is migrating overseas. Part of the reason is rising domestic development costs. According to Tufts University, the average development time for a new drug is now up to 7 years. And the cost of such developments now figures out at something close to $360 million per product. We shouldn't kid ourselves about who foots the bill for these high development and approval costs—it's the consumer, and it comes via the extraordinary high prices we pay on drugs which can spell the literal difference between life and death.

S. 830 significantly reforms that regime, recognizing that we all—government, industry, and consumers—have a real stake in cutting the explosive costs of bringing new medical products to the marketplace, and in making available break-through, life-saving therapies more quickly, and at a lower price.

Along with these important reforms, S. 380 also reauthorizes for 5 years the Prescription Drug User Fee Act, a very successful program that has helped swiftly approve scores of new life-saving therapies.

Let me also point out that while this bill makes substantial and far-reaching improvements, it distinctly moderates last year's reform effort.

So-called hammers that would have caused the agency to lose jurisdiction over the approval process if tight decision-making deadlines were not met have been eliminated.

Also missing is last year's provision requiring the agency to approve products previously approved in Europe.

My colleagues should understand that this bill is the result of efforts to reach a true common ground on many tough issues. Many more issues were gray, than they were black or white. Extremists on neither side of the debate can claim an advantage, or a victory.

The real victory, I believe, will be realized by the American consumer.●

ORDERS FOR TUESDAY, JULY 29, 1997

Mr. SHELBY. Mr. President, I ask unanimous consent that when the Senate completes its business today, it stand in adjournment until the hour of 10 a.m. on Tuesday, July 29.

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

Mr. SHELBY. I further ask that on Tuesday, immediately following the prayer, the routine requests through the morning hour be granted and the Senate immediately proceed to a period for the transaction of morning business until the hour of 11:30 a.m. with Senators permitted to speak for up to 5 minutes, with the following exceptions: Senator LOTT or his designee, 45 minutes; Senator DASCHLE or his designee, 45 minutes.

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

Mr. SHELBY. Mr. President, I also ask unanimous consent that at 11:30 a.m. the Senate resume consideration of S. 1022, the Commerce, Justice, State appropriations bill, with Senator WELLSTONE being recognized as permitted under the order.

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

Mr. SHELBY. I further ask unanimous consent that from 12:30 p.m. to 2:15 p.m. the Senate recess for the weekly policy luncheons to meet.

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

Mr. SHELBY. I ask unanimous consent that the votes relative to S. 1022 scheduled to begin at 9:30 a.m. now begin at 2:15 p.m.

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

PROGRAM

Mr. SHELBY. For the information of all Senators, tomorrow the Senate will be in a period of morning business until the hour of 11:30 a.m. By previous order, at 11:30 a.m., the Senate will resume consideration of S. 1022, the Commerce, Justice, State appropriations bill. Under the order, Senator WELLSTONE will be recognized to debate these two amendments to the bill. Also, as under the previous order, at 2:15 p.m., following the weekly policy luncheons, the Senate will proceed to a series of votes on the remaining amendments in order to S. 1022, the State, Justice, Commerce appropriations bill, including final passage.

Also, by previous consent, following those votes at 2:15 p.m., the Senate will resume the Transportation appropriations bill. Therefore, additional votes could occur.

ADJOURNMENT UNTIL 10 A.M. TOMORROW

Mr. SHELBY. If there is no further business to come before the Senate, I now ask unanimous consent that the Senate stand in adjournment under the previous order.

There being no objection, the Senate, at 7:01 p.m., adjourned until Tuesday, July 29, 1997, at 10 a.m.

NOMINATIONS

Executive nominations received by the Senate July 28, 1997:

DEPARTMENT OF ENERGY

JOHN C. ANGELL, OF MARYLAND, TO BE AN ASSISTANT SECRETARY OF ENERGY (CONGRESSIONAL AND INTERGOVERNMENTAL AFFAIRS), VICE DERRICK L. FORRISTER, RESIGNED.

DEPARTMENT OF EDUCATION

MARSHALL S. SMITH, OF CALIFORNIA, TO BE DEPUTY SECRETARY OF EDUCATION, VICE MADELEINE KUNIN.

WITHDRAWAL

Executive message transmitted by the President to the Senate on July 28, 1997, withdrawing from further Senate consideration the following nomination:

NATIONAL INSTITUTE OF BUILDING SCIENCES

NIRANJAN S. SHAH, OF ILLINOIS, TO BE A MEMBER OF THE BOARD OF DIRECTORS OF THE NATIONAL INSTITUTE OF BUILDING SCIENCES FOR A TERM EXPIRING SEPTEMBER 7, 1998, VICE JOHN H. MILLER, TERM EXPIRED, WHICH WAS SENT TO THE SENATE ON JANUARY 9, 1997.