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Senate

The Senate met at 11 a.m., and was called to order by the President pro tempore [Mr. THURMOND].

PRAYER

The Chaplain, Dr. Lloyd John Ogilvie, offered the following prayer:

''If we pray, we will believe;

''If we believe, we will love;

''If we love, we will serve.''

These words of the late Mother Teresa of Calcutta call us to prayer.

Almighty God who cares profoundly for the lost, the lonely, the sick, and the suffering, we express our gratitude for one who has allowed her heart to be broken by what breaks Your heart. We thank You for the life of Your loyal servant, Mother Teresa.

Lord, You have told us that what we do for the least, we do for You. We thank You for the way You came to her in the poor and suffering and they were cared for as if ministering to You.

Like Jesus, she did not seek to be served but to serve. She has shown us the value of every person You love. The spirit of love pulsated through her. She was a riverbed for the flow of Your grace for the castoffs of society. Her own prayer expresses our desires:

''Make us worthy, Lord to serve our fellow men throughout the world who live and die in poverty and hunger. Give them, through our hands, this day their daily bread; and by our understanding love, give peace and joy.''

As we have seen what You can do through a person totally committed to You, and unreservedly dedicated to love as You love, we are moved to rededicate our own lives to sacrificial service and receive supernatural power to give ourselves to those who hurt and need hope, who suffer and long for strength. One life to live; t'will soon be past; only what's done for You will last. In the name of our Lord and Saviour. Amen.

RECOGNITION OF THE MAJORITY LEADER

The PRESIDENT pro tempore. The able majority leader, Senator LOTT of Mississippi, is recognized

Mr. LOTT. Thank you, Mr. President.

SCHEDULE

Mr. LOTT. Mr. President, today, the Senate will resume debate on the motion to proceed to S. 830, the Food and Drug Administration reform bill. Under the previous order, there are 4 hours of debate remaining on the motion to proceed equally divided between Senator JEFFORDS and Senator KENNEDY. I believe Senator JEFFORDS is on the floor ready to use his share of the time.

Following the expiration or yielding back of time, the Senate will resume consideration of S. 1061, which is the Labor-Health and Human Services appropriations bill. Also under the order that was agreed to, a vote on an amendment relating to S. 1061 is expected around 5 p.m. today. In addition, Members are reminded that under the consent, all amendments remaining in order to the Labor-HHS appropriations bill must be offered by the close of business today.

Any further votes ordered on amendments to the bill, S. 1061, or other votes, will be stacked to occur on Tuesday at a time to be determined. And we will consult with the Democratic leader about what those amendments will be or other votes and what time they will actually occur.

In addition, under the previous order, the Senate will begin consideration of the FDA reform bill following the disposition of S. 1061, but not before 4 p.m. on Tuesday, although it is my hope that certainly by 5 o'clock on Tuesday we will be working on the substance of the FDA bill.

Members can expect then that the Senate will complete the Labor-HHS bill, the FDA reform bill, and we will begin then with the Interior appropriations bill this week. Whether we will be able to finish that, how late we will have to go on Wednesday night or Thursday night or whether or not we will have votes on Friday will depend on what kind of progress we make during the day Tuesday, Wednesday, and Thursday.

The next rollcall vote then will be at 5 o'clock today on an amendment related to the Labor-HHS appropriations bill or other vote that we may get worked out.

TRIBUTE TO MOTHER TERESA

Mr. LOTT. Mr. President, like the Chaplain, and on behalf of the Senate, I would like to pay tribute today to Mother Teresa. I know that I am speaking for every Member of the Senate in expressing our sorrow in the loss of Mother Teresa, this wonderful lady.

At the same time, we realize that if ever there was a life well lived, it was hers. Her passing helps us understand the psalm's comfort for those who mourn, that ''precious in the eyes of the Lord is the death of His faithful ones.''

Only 3 months ago, Mother Teresa came here to the Capitol. She joined us as we gave to her the Congressional Gold Medal in support of her work for the poorest of the world's poor. Even then, everyone present understood that it would only be a matter of time before her work, never finished, would rest in other hands.

But what an honor it was for us to meet her. The leaders were there, and the Members of the House and the Senate. That was a special occasion. We all felt touched by this elderly lady, who at once was so frail and at the same time so tough and so unconcerned about anything except the suffering of others.

This was a lady who, on an earlier visit to Washington, when she was being escorted to a White House car

● This ''bullet'' symbol identifies statements or insertions which are not spoken by a Member of the Senate on the floor.

waiting to take her to the airport, inquired about how her companions would get to the airport. When she was told they would go in a different vehicle, she declared everyone must stay together and take the bus.

To put it mildly, fame, and accolades were not important to her. What was important to her—what shaped her life from the Balkan village where she was born to the places of power where she was honored—was a devotion to the most vulnerable members of the human family, especially children, both before and after their birth.

When she first visited the Capitol back in 1981, one of our colleagues, then Senator James Buckley of New York, remarked, ''There is no telling what may be started by someone like her, who plays with fire by striking sparks off the flinty heart.''

Today, 16 years later, it is magnificently clear what she did start, literally around the world. Out of her poverty, she enriched mankind. Out of her loneliness, she showed us the heights of the human spirit. From the perspective of this century's end, we have a better understanding of what true greatness really is.

The monsters of our era—Mao, Stalin, Hitler, and the rest—they and their ideologies are in the trash heap of history. But what Mother Teresa launched, with bare hands and with an open heart, is going to last far longer than anyone can imagine.

Sad as our loss of her may be, we should not forget that her passing would not be viewed by her as a tragedy, but as a triumph. She had that assurance from the person to whom she gave her life, who surely has said to her, ''I was hungry, and you gave me to eat. I was thirsty, and you gave me to drink.''

So as we celebrate her life, let us now celebrate her joy.

Mr. President, I yield the floor.

FOOD AND DRUG ADMINISTRATION MODERNIZATION AND ACCOUNTABILITY ACT OF 1997—MOTION TO PROCEED

The PRESIDING OFFICER (Mr. DEWINE). The clerk will report.

The assistant legislative clerk read as follows:

A bill (S. 830) 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.

The Senate resumed the consideration of the motion to proceed.

Mr. JEFFORDS addressed the Chair.

The PRESIDING OFFICER. The Senator from Vermont is recognized.

Mr. JEFFORDS. First, I want to thank the majority leader for, I think very aptly and appropriately and eloquently, expressing our thoughts about Mother Teresa. All of us were moved by her life, and all feel similarly as to his feelings about what she did for all the people of the world.

Mr. President, today, we move forward again on the motion to proceed with respect to the reform of the FDA bill, S. 830.

Under the Federal Food, Drug, and Cosmetic Act, Food and Drug Administration commonly known as FDA, has two important functions: First, the review and approval of important new products that can improve the public health, such as lifesaving drugs, biological products, and medical devices; and second, the prevention of harm to the public from marketed products that are unsafe or ineffective. Since 1938, the Federal Food, Drug, and Cosmetic Act has been amended numerous times to expand the FDA's mission to ensure that only safe or ineffective products are marketed.

But the act has been changed only once, by the Prescription Drug User Fee Act of 1992, commonly called PDUFA, to strengthen the FDA's ability to review and approve expeditiously important new products that can improve the public health.

Food and Drug Administration Modernization and Accountability Act of 1997, S. 830, is designed to ensure the timely availability of safe and effective new products that will benefit the public and to ensure that our Nation continues to lead the world in new product innovation and development.

The legislation accomplishes three major objectives: It builds upon recent administrative reforms that both streamline FDA's procedures and strengthen the agency's ability to accomplish its mandate in an era of limited Federal resources; it requires a greater degree of accountability from the agency in how it pursues its mandate; and third, it provides for the reauthorization of PDUFA.

The FDA acknowledges that its mandate requires it to regulate over one-third of our Nation's products. Within its purview the FDA regulates nearly all of the food and all of the cosmetics, medical devices, and drugs made available to our citizens.

This legislation identifies areas where improvements can be made that will strengthen the agency's ability to approve safe and effective products more expeditiously. It builds upon the numerous investigations by Congress, the FDA, the General Accounting Office, and other organizations that have identified problems with the current FDA product approval system and have recommended reasonable reforms to streamline and strengthen that system. The major provisions of S. 830 accomplishes, among others, the following purposes. The legislation:

First, establishes a clearly defined, balanced mission for the FDA;

Second, it improves patient access to needed therapies and provides expedited humanitarian access to medical devices;

Third, creates new incentives for determining better pharmaceuticals for children;

Fourth, gives patients access to new therapies more quickly through a new fast-track drug approval process;

Fifth, increases access to information by health professionals and patients;

Next, increases agency access to expertise and resources;

Also, improves the certainty and clarity of rules;

And further, improves agency accountability and provides for better resources allocation by setting priorities;

It also, simplifies the approval process for indirect food contact substances and provides a more reasonable standard for some health claims; and,

The legislation reauthorizes the PDUFA Program thus ensuring additional resource availability for the agency to conform with its necessary missions.

Mr. President, let us explore these objectives in greater detail. First, the legislation establishes a clearly defined, balanced mission for the FDA. Congress has never established a mission statement for the FDA. This bill does.

The FDA in March 1993 adopted a formal statement declaring that the agency ''is a team of dedicated professionals working to protect and promote the health of the American people.'' Although this statement defines the agency's mission in terms of ensuring that the products it regulates comply with the law, there is no reference to the importance of approving new products that benefit the public.

The legislation amends the Food Drug and Cosmetic Act by adding an agency mission statement focused on: First, protecting the public health by ensuring that the products it regulates meet the appropriate FDA regulatory standards; second, promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a manner which does not unduly impede innovation or product availability; and, third, participating with other countries to reduce regulatory burdens, harmonize regulatory requirements, and achieve appropriate reciprocal arrangements with other countries.

The legislation improves patient access to needed therapies and provides expedited humanitarian access to medical devices. The FDA has no cross-cutting program that ensures access by patients with serious or life-threatening diseases to drugs or devices in clinical trials—even when that unapproved therapy may be the only way to save the patient's life.

The legislation would create new law whereby manufacturers may provide, under strictly controlled circumstances and in response to a patient's request, an investigational product for those patients needing treatment for a serious or life-threatening disease. The legislation also improves the existing program for the humanitarian use of medical devices for patient populations of fewer than 4,000.