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## Senate

The Senate met at 12 noon, and was called to order by the President pro tempore [Mr. THURMOND].

### PRAYER

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

Thank You, dear God, for the anchor of hope in You that we have for the storms of life. When we lower our anchor, we know it will hold solid in the bedrock of Your faithfulness in spite of the billows of adversity and blasts of conflict. We are able to ride out the storms of difficulty and discouragement because we know You will sustain us. We share the psalmist's confidence, "I wait for the Lord, my soul waits, and in His word I do hope."—Psalm 130:5.

Our hope is not in the supposed reliability of people, the presumed predictability of circumstances, nor the imagined security of human power. Our hope is in Your grace and truth. We know You will never leave us nor forsake us.

Keep us anchored today so we won't drift from our commitment to serving You. We claim Your destiny for our life. And throughout this day, may we feel the tug of the anchor and know that we are indeed secure. In the name of our Lord and Saviour. Amen.

### RECOGNITION OF THE ACTING MAJORITY LEADER

The PRESIDENT pro tempore. The able acting majority leader, the senior Senator from Vermont, is recognized.

Mr. JEFFORDS. Thank you, Mr. President.

### SCHEDULE

Mr. JEFFORDS. Mr. President, today the Senate is resuming consideration of S. 830, the FDA reform legislation. Under the consent agreement, there will be 4 hours of debate prior to a vote on final passage of the bill. Some of

that debate time may be yielded back. Therefore, Senators can expect a rollcall vote on passage of S. 830 between 3:45 and 4 o'clock this afternoon.

Following that vote, the Senate may begin consideration of the D.C. appropriations bill. Additional rollcall votes may occur throughout the day as the Senate considers the last of the appropriations bills. The Senate may also consider any of the available appropriations conference reports.

I thank my colleagues for their attention.

### FOOD AND DRUG ADMINISTRATION MODERNIZATION AND ACCOUNTABILITY ACT OF 1997

The PRESIDING OFFICER (Mr. SMITH of Oregon). Under the previous order, the Senate will now resume consideration of S. 830, which the clerk will report.

The 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 foods, drugs, devices and biological products, and for other purposes.

The Senate resumed consideration of the bill.

The PRESIDING OFFICER. Under the previous order, there will now be 4 hours of debate to be equally divided between the chairman and the ranking member.

Mr. JEFFORDS. Mr. President, this is, hopefully, the final moments of debate on the FDA reform bill. There is no Senator who has been of more help and assistance, not only to the committee but to her constituents, than the Senator from Maryland. Thus, I am pleased that the one who will be opening the debate today is that Senator. So I yield her such time as she may consume; and may she consume a lot of time.

The PRESIDING OFFICER. The Senator from Maryland is recognized.

Ms. MIKULSKI. Mr. President, thank you.

Mr. President, in a few hours we will be voting on the final passage of the FDA Modernization and Accountability Act.

I am so pleased that this day has finally arrived. I thank the chairman of the Labor Committee, Mr. JEFFORDS, for all of his incredible patience, persistence, dedication, and attention to really lead the mission to move FDA into the 21st century. I thank him for his heartfelt devotion to accomplishing this mission and for never giving up. I also want to thank his staff for their hard work and for the bipartisan, non-partisan way in which they worked.

Let me also acknowledge the tremendous contribution of the ranking member, Senator KENNEDY. There is no doubt that this is a better bill and FDA will be in better shape because of his efforts.

Mr. President, I have worked on FDA reform for a number of years. When I was a Member of the House of Representatives, we embarked, on a bipartisan basis, to ensure consumer protection, to prevent dumping of drugs that did not meet our standards into Third World countries.

Then coming to the Senate, I joined with my colleague from Massachusetts, Senator KENNEDY, and with the Senator from Utah, Mr. HATCH, in fashioning something called the Prescription Drug User Fee Act, otherwise nicknamed PDUFA. What PDUFA did is provide, through a user fee mechanism, the ability to hire 600 more people at FDA to analyze the safety and efficacy of pharmaceuticals to move them to the marketplace.

Because of PDUFA and the great legislative idea of Kennedy-Hatch, FDA was able to hire more people to examine products that were being presented for evaluation and get them to clinical practice more quickly.

The leadership of Kennedy-Hatch on PDUFA has not only stood the test of time, but it has shown that we can expedite the drug approval process while maintaining safety and efficacy.

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



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