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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, nonpartisan 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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My objective was to revitalize the FDA to give it the regulatory flexibility to effectively regulate the pharmaceutical and medical device industry without jeopardizing timely approval of safe and effective lifesaving drugs and devices. At the same time, I am well aware of the prominent public health role played by the FDA—it is after all, a public health agency, not a drug or device manufacturer. My support for real reforms by no means says that I did not support an aggressive public health agency role for the FDA.

Several weeks ago, I met directly with several biotech companies in the State of Washington. As I sat at the table listening to their concerns I was struck by the amount of experience at the table and level of integrity that many of the companies are known for. I am proud to represent these companies that are on the cutting edge of medical technology and have contributed significantly to improving health care for all Americans. I knew that those companies would not market a dangerous, life threatening drug or device; that none of these companies deliberately act to falsify clinical data or would refuse to complete clinical trials. I knew that these companies were more concerned with getting their lifesaving technologies to patients than simply making a profit. They know the value of one's reputation and are truly proud of the lifesaving work they have done. Sadly, however, not all companies have the same commitment to the patient's health and are allowing stockholders, not scientists, to make decisions. Because of this, I am asking for the Chairman's commitment that the Senate Labor and Human Resources Committee will retain a strong and aggressive oversight role.

We are making some sweeping and some may argue dramatic changes in the way the FDA operates. We need to be sure that these changes are positive and that FDA has the resources and ability to remain an effective public health agency. If we detect future problems or conflicts, I need your commitment and support for swift and thorough hearings. I need to know that we will continue to monitor the FDA, and if legislative revisions are necessary to protect the public health, we will act with great speed. There is probably no other Member more hopeful that some of these reforms will means that patients get access to safe and effective drugs and devices sooner, but I also know that we cannot forget the past. There are certainly many examples of situations where the public health was put into jeopardy by unscrupulous pharmaceutical and medical device manufacturers. I need your assurances that if problems arise we will act to address any potential threat to the public health.

Mr. JEFFORDS. I share the Senator's goal of ensuring a strong FDA and believe the modernization and revitalization provisions included in S. 830 make for a better FDA, not a weaker one. Like you I have had the opportunity to meet with industry groups here in Washington and with consumers, patients, and physicians both here and at home in Vermont. All of these interested parties have made important points about how to modernize the agency while ensuring that its stellar standard for public safety remain as strong as ever. Though Vermont doesn't have any of these large industries regulated by the FDA, all of us use their products. The people and the patient advocates of Vermont have told me that more needs to be done to ensure their timely access to the best therapies available. I believe we have accomplished that with this bill.

I think that the Senator from Washington would agree that it's important to put aside once and for all that consumers, patients, and physicians universally oppose this measure. Vermont patient groups and their members—and I'm sure you have heard from your constituents—have told me that they support this effort to modernize the FDA. The Vermont Epilepsy Association, the Vermont Medical Society, the Vermont Association for the Deaf, the Vermont Board of Pharmacy, the Vermont Alliance for the Mentally Ill, and the Epilepsy Foundation of Vermont have all urged passage of the measure. At the national level we have heard from innumerable groups that support S. 830 and urge its passage. For example, the National Health Council—which includes the Arthritis Foundation, the National Multiple Sclerosis Society, and the Leukemia Society among its over 100 member organizations—took out a full-page advertisement in the Roll Call newspaper urging that the Senate move forward with this legislation.

I agree with my colleague from Washington and you can be assured that if problems do arise, I would act quickly to address any threat to the public health. Simply because we are authorizing PDUFA for 5 years does not mean that we cannot change other sections of the Food, Drug and Cosmetic Act. It could also turn out that some of these reforms, like expanded third party review for medical devices, will become such a success that the FDA will want to extend the program beyond the pilot phase.

Effective and aggressive oversight is one of the most important tools of the Labor and Human Resources Committee for making sure that the FDA can keep pace with the rapid changes in medical technology and still be a public health agency that is the envy of the world. I thank the Senator for her commitment to working toward real reforms that strengthen the FDA and the contributions she has made in crafting this bipartisan measure.

Mrs. MURRAY. I thank the Chairman for his support and commitment to a strong FDA and am grateful for his leadership on this legislation.

PHARMACY COMPOUNDING

Mr. KENNEDY. Madam President, I would like to engage my colleagues, Senator JEFFORDS, the distinguished chairman of the Labor and Resources Committee, and Senator HUTCHINSON, the distinguished Senator from Arkansas, regarding a provision in S. 830 pertaining to the practice of pharmacy compounding.

Mr. JEFFORDS. I would be pleased to enter into such a colloquy with the distinguished Senators from Massachusetts and Arkansas.

Mr. KENNEDY. First, I want to commend my colleagues and their staffs for their efforts in the difficult task of drawing the line between drug manufacturing and pharmacy compounding. Ordinary pharmacy compounding has been traditionally regulated by the States, but drug manufacturing, even when conducted by State-licensed pharmacists, is regulated under Federal law. Under current law, the Federal Food, Drug, and Cosmetic Act specifically exempts from the inspection and registration provisions of the act pharmacies that compound drugs for sale in the regular course of dispensing or selling drugs at retail. However, FDA and the courts that have addressed the matter interpret the act as not providing any general exemption from the new drug, adulteration, and misbranding provisions for drugs compounded by pharmacists. It is my understanding that section 809 of S. 830 would bring the legal status of compounding in line with FDA's longstanding enforcement policy of regulating only drug manufacturing, not ordinary pharmacy compounding. This legislation would, as I understand it, exempt drugs compounded in pharmacies from the new drug, and certain other, provisions of the act, but the exemption would not create a loophole that would allow unregulated drug manufacturing to occur under the guise of pharmacy compounding.

Mr. HUTCHINSON. As the sponsor of the amendment that became section 809 of S. 830, I concur with the distinguished ranking minority member of the Labor and Human Resources Committee that this legislation would ensure patient access to individualized drug therapy, and prevent unnecessary FDA regulation of health professional practice. This legislation would exempt pharmacy compounding from several regulatory requirements but would not exempt drug manufacturing from the act's requirements. The legislation also sets forth a number of conditions that would have to be met in order to qualify for the exemption from the act's requirements. I would note that the conditions established by section 809 should be used by the State boards of pharmacy and medicine for proper regulation of pharmacy compounding in addition to State-specific regulations. When a State board determines that certain compounding activities are outside the parameters established in section 809, that State board should refer the practitioners in question to the FDA for review.

Mr. KENNEDY. I thank the distinguished Senator from Arkansas for describing the reasons why this section is so important to patients and to the health professions. I want to especially commend his staff for working with mine to develop this legislation that exempts from Federal law the activities that are appropriately regulated by the States.

It is my understanding that some of the conditions are intended to ensure that the volume of compounding does not approach that ordinarily associated with drug manufacturing. Other conditions appear to be intended to ensure that the compounded drugs that qualify for the exemption have appropriate assurances of quality and safety since these compounded drugs would not be subject to the more comprehensive regulatory requirements that apply to manufactured drug products.

Mr. JEFFORDS. I believe the Senator is correct in his understanding.

Mr. DOMENICI. Madam President, I rise in support of S. 830, the FDA Modernization Act. This bill provides comprehensive—and long overdue reform to the FDA.

The primary focus of S. 830 is to streamline and strengthen the FDA's review and approval of lifesaving drugs and medical devices. One important mechanism for doing this is the Prescription Drug User Fee Act [PDUFA]. PDUFA authorizes the FDA to use fees collected from prescription drug manufacturers to expedite the FDA's review of drugs. The fees collected go to hiring new employees to increase the FDA's resources for reviewing new drugs.

With all of the advances in science and medicine, we must ensure the swift review of new drugs for life-threatening diseases. When there are backlogs and delays in drug approval, American lives can be lost. For example:

The 7-year delay in the FDA's eventual approval of beta blocker heart medicines cost the lives of 119,000 Americans; and

The FDA's 3½-year delay in approving the new drug Interleukin-2 (IL-2) cost 25,000 Americans to die of kidney cancer, even though the drug already had been approved for use in nine other countries.

This bill is good because it will give Americans access to lifesaving medication, without needless delay.

I would like to share with you the story of one man from my home State of New Mexico who would benefit from this bill.

Leonard Alderete is 39 years old and has lived in Albuquerque, NM all of his life. In 1987, Leonard was diagnosed HIV positive. Five years later, Leonard sought medical intervention because his condition worsened and he feared his life would end. Leonard began taking the standard AZT. In 1996, Leonard's health again took a downturn. Blood tests revealed that the virus had spread at an alarming rate through his system. In order to slow the spread of the virus, Leonard needed an aggressive treatment.

Leonard's doctor prescribed the drug regiment of 3TC, AZT, and Crixivan, which is also known as a triple cocktail. A key drug in this mixture is the protease inhibitor, Crixivan. Through PDUFA, Crixivan was made available to consumers within 3 months of its submission to the FDA. Shortly thereafter, Leonard began taking Crixivan.

Thanks to the "triple cocktail," the virus is now below detectable levels. Although this is not a cure, it does provide Leonard hope—a more long-term hope for the future.

Leonard is a member of the Governor's task force on HIV/AIDS. He is the only member who has HIV. As a member of the Task Force, he advocates for the rights of those who are HIV infected—as well as those in the community who are affected.

Leonard has written, called, and even traveled to my office in Washington, DC two times this year to urge my support for this bill. Leonard provides testimonial for the importance of FDA reform, and especially PDUFA.

Fortunately, patients afflicted with AIDS as well as other life threatening diseases have a "Leonard" advocating for them. There are many other Leonards both silent and vocal all across the country who will benefit from this bill. It is on their behalf that I urge my colleagues to support S. 830.

Ms. MOSELEY-BRAUN. Madam President, I support S. 830, the Food and Drug Administration Modernization and Accountability Act of 1997. I also want to commend Senators JEFFORDS and KENNEDY for their hard work on this legislation, and the compromises that will ultimately improve the FDA and improve the public's access to cutting edge medical technology.

Despite recent improvements, I am concerned that the length of time and amount of paperwork required for FDA approval of new products may still be excessive. For many companies desiring to market new products, application to the FDA is a formidable obstacle. In some cases, the length and complexity of the process can deter companies from even applying. This is a particularly troubling prospect given the increasing globalization of markets for health care products and food.

The FDA cannot continue to protect the public health through its traditional methods. Most industrialized and emerging nations participate in multilateral trade agreements that aim to reduce trade barriers. These agreements will continue to bring pressure on the FDA to harmonize its regulatory policies with other international safety and performance standards. The policies that have made the United States the "gold standard" in public health protection must be reformed to function properly in this global economy. This does not mean that we cannot continue to be the gold standard. It simply means that market forces will bring pressure on the FDA to implement policies that encourage the launching of new products in this country, as opposed to Europe, and ensures that the United States maintains its technical and scientific leadership in health disciplines.

As stewards of this generation, we must move to strike the balance between protecting the public health, fostering global trade under multilateral agreements, ensuring swift access to new health technology for Americans, and strengthening the U.S. technical and scientific leadership. S. 830 is a very good effort to balance those sometimes competing goals.

First, the bill reauthorizes the Prescription Drug User Fee Act [PDUFA] for an additional 5 years. PDUFA has been one the most successful pieces of governmental reform legislation. During the 5 years since we first passed PDUFA, the average approval time for pharmaceutical products has dropped over 40 percent. There is still more room for improvement. Many product reviews remain cumbersome, and applicants at times do not have a clear indication of the type of information necessary for FDA review.

S. 830 also makes considerable progress in expediting patients access to important new therapies and potentially life-saving experimental treatments. Just a few months ago, one of my constituents encountered considerable bureaucratic red-tape in her effort to access a potentially life-saving treatment for Hodgkin's disease. Only after countless appeals by my office and hundreds of my constituents did the FDA acquiesce. The troubling part of this incident was that the FDA had approved the same treatment for other patients several years prior. This is not to say that the people who work at the FDA were not following their current guidelines. They were probably following the guidelines to the letter. But the spirit of the FDA's mission was utterly lost in the process. S. 830 makes the much needed reforms.

Along the same lines, the bill also establishes a national registry of clinical trials. The primary impediment to patients access to potentially life-saving treatment is not the FDA but actually a lack of knowledge about ongoing research. A national database, which patients can access, will greatly assist people across the Nation who are searching for hope for their illnesses. This important reform is long overdue and absolutely necessary to continue providing Americans the best in medical treatment and technology.

Finally, the bill strikes an appropriate balance between protecting the public interests and allowing manufacturers to share important off-label use information with providers. It would have been a grave mistake to either prevent the distribution of off-label use information or not allow the FDA to play a vital role in ensuring the adequacy of information being distributed by manufacturers. I know that a lot of work went into the compromise