on the Republican side. I ask unanimous consent to hold that remaining time, for me to begin with the Democratic side, and use such time as I shall need.

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

AN INDEPENDENT FDA

Mrs. MURRAY. Mr. President, I rise today to address a matter of extreme importance, women's health, public safety, and the independence and credibility of one of our Nation's most revered Federal agencies, the FDA.

I am very concerned. American women are concerned, and consumers all across this country should be concerned that the FDA is letting politics trump science in the way it approves medicine for American consumers.

I have always supported a strong and independent Food and Drug Administration. It is the only way in which the FDA can truly operate effectively and with the confidence of American consumers and health care providers.

Americans must have faith when they walk into the local grocery store or local pharmacy that the products they purchase are safe, that they are effective, and that their approval has been based on sound science, not on political pressure or pandering to interest groups. By allowing politics to play a role in the decisionmaking, the FDA is now opening a Pandora's box that could have profound consequences in determining the safety and efficacy of the drug approval process.

Unfortunately, recent decisions and delays at the FDA have now called into question the agency's independence and allegiance to science-based decisions, and plan B is exhibit A. But don't take my word for it. Listen to Dr. Susan Wood, the former director of the FDA's Office of Women's Health. In resigning in protest, Dr. Wood wrote:

> I have spent the last 15 years working to ensure that science informs good health policy decisions. I can no longer serve a staff when scientific and clinical evidence fully evaluated and recommended by the professional staff here has been overruled.

In later comments to the Associated Press she said:

> There's fairly widespread concern about FDA's credibility among agency veterans as a result of the Plan B process.

Those are the words of a health care professional who worked for years within the FDA to improve women's health. Her resignation is a huge loss to the agency, to those in Congress who have championed women's health and, most importantly, her resignation is a loss to the millions of American women who rely on the FDA to make choices based on sound science.

Let me take a step back and explain what plan B is and why the FDA's actions are such a threat to the public's health. Plan B is a form of contraception. Plan B contains a specific concentrated dose of ordinary birth control pills that prevent pregnancy. Emergency contraception cannot interrupt or disrupt an established pregnancy. In fact, plan B has the potential to reduce the incidence of abortions, something I think every one of us can agree on. It is an important goal.

Raising the awareness and use of emergency contraceptives such as plan B is an important component to reducing the rate of abortion in the United States. An analysis conducted by the Alan Guttmacher Institute estimates that 51,000 abortions were prevented by emergency contraceptive use in 2000 and that increased use of emergency contraceptives accounted for up to 43 percent of the total decline in abortion rates between 1994 and 2000. Plan B has already been approved by the FDA for prescription use and it is available over the counter in seven States, including my home State of Washington. However, it is not available nationwide.

When it comes to emergency contraceptives, every hour counts. The effectiveness of plan B declines by 50 percent every 12 hours. The longer a woman must wait to see a doctor, get a prescription, and then find a pharmacy that will fill the prescription, the less effective plan B becomes. Even privately insured women with regular access to a health care provider have to overcome significant barriers to obtain a prescription for emergency contraceptives, including finding a pharmacy that stocks plan B within a short timeframe. For many uninsured women and teens, the barriers are often insurmountable.

Back in December of 2003, almost 2 years ago, the FDA's own scientific advisory board overwhelmingly recommended approval of plan B over-the-counter application by a vote of 23 to 4. However, the FDA has not adhered to its own guidelines for drug approval and continues to drag its heels.

In fact, Alastair Wood, who is a member of the advisory panel, told USA Today:

> What's disturbing is that the science was overwhelmingly here, and the FDA is supposed to make decisions on science.

At a HELP Committee hearing in April of this year, I pressed the President's nominee to head the FDA, Dr. Lester Crawford, to answer questions about this long-pending application for nationwide over-the-counter approval of plan B. When Dr. Crawford informed me that he couldn't answer my questions in a public forum, I invited him to my office to discuss the process in a private meeting. My colleagues Senator KENNEDY and Senator CLINTON joined me for a very frustrating meeting in which Dr. Crawford failed to provide any timeline or specific reasons for the FDA's highly unusual foot dragging on the plan B application. It was very clear to me after this disappointing meeting that politics had trumped science, and the public health mission of the FDA had been compromised.

For this reason, Senator CLINTON and I joined to place a hold on Dr. Crawford's nomination to head the FDA on June 15, 2005. We placed that hold saying we want a determination on the application. We did not advocate for a particular outcome. All we asked was that the FDA abide by its own rules and regulations. That is a very important point. Senator CLINTON and I did not demand approval. We simply called on the FDA to follow its own procedures. In the end, apparently, even that was asking too much.

The administration and the chairman of the HELP Committee understandably wanted Dr. Crawford confirmed. We began what I consider to be a very productive conversation about restoring integrity to the FDA's process and getting Dr. Crawford confirmed. I thank the chairman for his responsiveness and good-faith efforts. Our discussions culminated in a July 13 letter to the HELP Committee and cochair, to Senator ENZI and to Senator KENNEDY, from Health and Human Services Secretary Michael Leavitt.

This chart shows the letter from Secretary Leavitt:

> I have spoken to the FDA, and based on the feedback I have received, the FDA will act on this application by September 1, 2005.

Based on this letter, based on his personal assurance, Senator CLINTON and I then dropped our hold on Dr. Crawford and subsequently his nomination passed the Senate.

Now, unfortunately for the American people and especially for the integrity of the FDA, Secretary Leavitt and the FDA broke their promise. The FDA had a chance to restore the confidence of American consumers in promoting safe and effective treatments, but it failed in its mission.

A delay is not a decision. For over 6 months, Senator CLINTON and I asked for a simple answer, yes or no. It is a breach of faith to have had this administration give us their word that a decision would be made and have that promise violated. Now the FDA is claiming there are ''unanswered'' questions about plan B's effect on girls under 17. The fact is the pending application does not apply to that group. Today, girls under 17 may only receive this drug with a prescription. That would remain the case if the FDA were to approve plan B's application. The FDA's argument is highly suspect because the Government already regulates products with age restrictions. They do it with tobacco, nicotine gum, and alcohol.

The administration gave us their word, and then they pulled the rug out at the last minute. This continued delay goes against everything the FDA's own advisory panel found nearly 2 years ago, that plan B is safe, it is effective, and it should be available over the counter. There is no credible scientific reason to continue to deny increased access to this safe health care option. In fact, in his statement of further delay, Dr. Crawford acknowledged that the application has scientific merit, but he still refused to approve it.

I can only infer that the FDA and Dr. Crawford, as its head, are continuing to put politics ahead of science. I am not the only one. According to the Washington Post editorial page, August 30:

In recent months, critics have accused the FDA—which is required by law to make decisions exclusively on scientific and legal grounds—of falling victim to outside political agendas.

They have claimed that the Plan B decisions have reflected not sound science and legitimate caution but rather the influence of ''moral'' antiabortion lobbies . . .

By abruptly rejecting an application that had been tailored to meet the FDA's requirements, Mr. Crawford appears to confirm the critics' worst fears.

Whatever the legal arguments taking place, this unexpected delay at this stage of the approval process makes the FDA—long admired around the world for its neutrality and professionalism—look like an easily manipulated political tool.

Here is what Newsday said:

Drugs and politics do not mix.

The current case in point is Plan B, the morning after emergency contraceptive, and the politics of abortion.

Taken together, they are threatening the Food and Drug Administration's credibility as an agency that dispassionately evaluates the safety and effectiveness of drugs.

The FDA said Friday it will delay for 60 days a decision on whether to allow Plan B to be sold to those 16 and older without a prescription.

Officials attributed the foot-dragging to a concern that younger teens would get the drugs and wouldn't use it responsibly.

That rings hollow.

When the FDA rejected an application for over-the-counter sales without age restriction 2 years ago it overruled that staff and an advisory panel, and discounted the experience of six states and 33 countries where such pills are sold without prescription.

The most recent application responsibly included the age restriction.

Here is how the Virginian Pilot put it:

Plan B contraceptives can prevent tens of thousands of abortions and unwanted pregnancies. Restriction on availability to minors is consistent with other national reproductive policies and therefore valid.

A country that can put a man on the moon can surely figure out how to distinguish between younger and older women in selling a pill. If, that is, policymakers care half as much about science in one case as in the other.

And perhaps most succinctly, I quote from the Baltimore Sun:

Dr. Crawford has been forced to adopt many improbable positions in order to keep his job. But now he is at risk of turning the world's most respected drug reviewing agency into a laughingstock.

Nobody wins if that happens.

No amount of semantics or politicking can change the fact that the HHS Secretary and the FDA performed a bait and switch with the Senate and, more importantly, to the American people. Today, the Bush administration has its FDA Commissioner, but the American public still does not have an answer on plan B. Unfortunately, the FDA, which has long been known as the gold standard in drug approval, is now at risk of becoming known for a double standard.

The health and well-being of the American people should not blow with the political winds. Caring for our residents is an American issue, and part of that goal is ensuring that our residents have access to safe, effective medicines in a timely fashion. As a new member of the Senate HELP Committee back in 1997 I faced the daunting task of working to help reform the FDA. I, along with my colleagues, was dedicated to making the Food and Drug Modernization Act work.

The intent of this landmark legislation was to introduce a new culture at the FDA, one which would expedite the drug approval process by eliminating unnecessary bureaucratic delays while ensuring product safety.

This new partnership was intended to open the lines of communication and ensure that manufacturers had a clear understanding of what would be required in our drug approval process. The FDA has broken those lines of communication and has now called into question the future of drug approval within the agency.

I believe strongly in a strong and independent FDA, but I believe this agency has made a mockery of Congress and of its own procedures and its own protocols. They have abused the trust of Congress and of the American people in the way they have played around with plan B. It is far past time to return credibility to the FDA. The FDA needs to return to the gold standard, not continue to create a double standard that puts politics ahead of the health and safety of the American public.

This is not the last word on this issue. The problem with politics subverting the FDA's adherence to science and its integrity is so profound and so urgent that I intend to use every tool available to me as a Senator to make sure this discussion about our priorities and our future is not lost.

Mr. President, I yield the floor.

The PRESIDING OFFICER. The Senator from Vermont is recognized.

Mr. LEAHY. Mr. President, I ask unanimous consent that I may speak for up to 20 minutes.

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

Mr. LEAHY. I thank the distinguished Presiding Officer.

NOMINATION OF JOHN ROBERTS

Mr. LEAHY. Mr. President, this week, as we celebrate our Constitution's 218th anniversary, we are nearing the exercise of one of the Senate's most solemn constitutional requirements and responsibilities. Few decisions the Senate faces are as consequential and enduring as when the Senate decides whether to confirm, by giving its consent, the nomination of a justice—of course, even more so when the nomination is for Chief Justice of the United States.

The Supreme Court is different from the lower courts. The Supreme Court is the only Federal court required by the Constitution itself. Actually, the Chief Justice is the only member of the Court expressly named in the Constitution. All other courts are bound by the decisions of the Supreme Court. Its decisions are final. They are unappealable. Only the Supreme Court can modify or overrule its precedents. Its power is enormous. The role of the Chief Justice is to lead not only that all-powerful Court but the entire third branch of Government. We have had 43 Presidents in this country, but we have had only 16 Chief Justices—all appointed for life.

The distinguished senior Senator from West Virginia, Mr. BYRD, whose passionate advocacy established our Constitution Day commemoration, describes the Constitution very accurately as the soul of our Nation. The Senate's advice and consent responsibilities are at the core of this body's vital role in our Republic.

This week, we commemorate our Constitution in a time of great challenges, and we are reminded again how resilient our Constitution is in empowering our Nation to meet each era's challenges. The carefully calibrated checks and balances within our Constitution are essential to that. No branch of Government is intended to be the rubberstamp of another branch.

Each day, Americans are fighting and dying in Iraq. Hundreds of thousands of Americans have been displaced by disasters here at home. Four years after 9/11, with public confidence shattered, we have to embark on a review of why we are still not prepared to respond to a terrorist attack or foreseen natural disasters.

The cost of energy—gas and home heating fuels—continues to climb to all-time highs, adding to the cost of other goods. The administration is suspending environmental and worker protections. Poverty and the disparities of opportunity between races and classes continue their insidious rise each year. After having seen recent years of budget surpluses, now the country's budget deficits are at previously unheard of levels—between $300 billion and $400 billion a year. Our national debt is at $8 trillion—8,000 billion dollars—that is a profligate amount. It can only be paid off by our children and our grandchildren.

So Americans need to know their constitutional rights will be protected, that their Government is on their side, and that the courts will be a place of refuge, stability, independence, and justice.

The nomination of Judge John Roberts to be Chief Justice of the United States presents a close question and one that each Senator must carefully weigh and decide. This is a question that holds serious consequences for all Americans today and for generations to come. I have approached this nomination with an open mind, as I do all judicial nominations. There is no entitlement to confirmation for lifetime