are going to vote them up or down and finish the bill. I yield the floor.

Mr. MCCONNELL. Mr. President, let me add, we will finish the bill tomorrow for certain. It will be, obviously, easier on the membership if we do it earlier in the day.

I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The legislative clerk proceeded to call the roll.

Mr. ENZI. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

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

EXECUTIVE SESSION

NOMINATION OF LESTER M. CRAWFORD TO BE COMMISSIONER OF FOOD AND DRUGS, DEPARTMENT OF HEALTH AND HUMAN SERVICES

The PRESIDING OFFICER. Under the previous order, the Senate will now proceed to executive session to consider Executive Calendar No. 172, which the clerk will report.

The legislative clerk read the nomination of Lester M. Crawford, of Maryland, to be Commissioner of Food and Drugs, Department of Health and Human Services.

The PRESIDING OFFICER. There will now be 30 minutes of debate equally divided prior to the vote.

The Senator from Wyoming.

Mr. ENZI. Mr. President, I yield myself 5 minutes.

I rise to discuss the pending nomination of Dr. Lester Crawford to be the Commissioner of Food and Drugs. I particularly thank all of the people who have been involved in this nomination process. It has been a great bipartisan effort. It has been thoroughly explored and we finally are at a point where we can have an actual FDA Commissioner approved. It will be a tremendous relief to me and to the Nation, I am sure.

I particularly want to thank Senator KENNEDY for his efforts in proceeding through the different hearings that we have had and all of the other work that we have had to do. The Food and Drug Administration is tasked with the broad and critical mission of protecting public health. The FDA Commissioner is in charge of an agency that regulates $1 trillion worth of products a year.

The agency ensures the safety and effectiveness of all drugs and biological products like vaccines, medical devices, and animal drugs and feed. It also oversees the safety of a vast variety of food products as well as medical and consumer products, including cosmetics.

In addition, the Commissioner is responsible for advancing the public health by helping to speed innovations in its mission areas and by helping the public get accurate, science-based information on medicines and foods. The FDA has been without a confirmed Commissioner for more than a year.

In January of this year, 17 members of the Senate Committee on Health, Education, Labor and Pensions sent a bipartisan letter to the President urging him to nominate a Commissioner to provide the agency with greater clarity and certainty in its mission to protect our food and drug supplies. Recent breakthroughs in medical science and technology show how quickly science and technology are changing our lives each and every day.

The FDA is at a critical point in its history. The potential benefits from our medical research are staggering. A fully confirmed FDA Commissioner is essential to ensuring that these medical breakthroughs can be brought to the market safely and effectively. Consumers deserve to have a fully functional FDA that can oversee the industry with confidence and authority and harness the technical achievements that can improve and save lives.

I believe the President's nominee, Dr. Lester Crawford, has the right qualifications to lead the FDA and to bring about the necessary reforms to maintain consumer confidence in our Nation's drug safety. Clearly we need someone at the helm of the FDA who can direct the agency and work with Congress to find the answers to these and many other difficult issues that will continue to come before us.

Dr. Crawford has been Acting Commissioner of FDA since March of 2004. He has a long and distinguished career in private and public service. He worked at the FDA in other capabilities before joining the agency again in 2002.

The show of support for Dr. Crawford's nomination has been strong. In the runup to Dr. Crawford's confirmation hearing in March, my committee received letters of support from more than 100 individuals and organizations. It is high time we had this debate and this vote. We waited many months for President Bush to send us a qualified nominee for the post.

In response to our bipartisan letter to the President, the President nominated Dr. Crawford. We have waited long enough. I think we can all agree that we need a strong leader at the FDA right now and one who has a mandate to act. We must be forward looking. There are many items before the FDA that require the immediate attention of an FDA Commissioner vested with full authority.

The authority flows directly from the act of Senate confirmation. Without a Senate-confirmed leader, we cannot expect the FDA to be as effective as we need it to be.

Dr. Crawford's nomination was reported favorably out of the Committee on Health, Education, Labor and Pensions on June 15. So I am pleased that we are now ready to confirm Dr. Crawford so that he can take charge, take action, and take responsibility for leading the FDA in the best interests of the public health.

I yield the floor and reserve the remainder of my time.

The PRESIDING OFFICER. The Senator from Massachusetts.

Mr. KENNEDY. Mr. President, I congratulate my friend and chairman of the Committee on Health, Education, Labor, and Pensions for his leadership in ensuring that the Senate will have an opportunity to vote on Dr. Crawford and, hopefully, approve his nomination.

During one time or another during 3 of the last 4 years we have not had a head of the Food and Drug Administration. As Chairman ENZI has pointed out, this agency has enormous power, influence, and say-so on many of the different issues that affect every family in this country. It regulates food, cosmetics, drugs, medical devices, even televisions and cell phones a full quarter of every dollar consumers spend. And FDA really sets the standard for the rest of the world in how it regulates these products. The rest of the world looks to our Food and Drug Administration as the gold standard, and, as Chairman ENZI pointed out, we have not had a permanent Commissioner for 3 of the last 4 years. I think we have suffered because of it.

Now we have the opportunity, with Dr. Crawford, to fill that job, and I will explain in just a few moments why I think he is eminently qualified.

I agree with those who believe that we are in the life science century. We have seen a commitment to the promise of the this century by the Congress and by administrations in recent times when we effectively doubled the NIH budget. We have seen the sequencing of the gene, the progress that we have made with DNA, the real possibility of breakthrough drugs, and the debates we are having on stem cell research. This is truly the life science century.

Quite frankly, the most important position in this life science century is who is heads the Food and Drug Administration, because we will want to have these breakthrough drugs and other treatments available to people at the earliest possible time, and that is FDA's job. We want to make sure these treatments are safe and effective. That is going to be an enormous responsibility, but I believe the possibilities and the meaning for families will be breathtaking.

So that is why this position, and the FDA, is so important. There are many things that we do in this body, and many people who are directly involved say this or that thing is the most important thing that we are going to do in the session. Well, this might not be the most important thing that is done in this session, but having a responsible, informed, enlightened, future-looking, tough-minded administrator at the Food and Drug Administration is enormously important for all Americans. That is what this debate and discussion is about.

It has also been about the importance of following science. This is enormously important, and I will say an additional word about that. It is important for the FDA to have the confidence of the American people that the FDA is calling the important decisions it makes as the science reveals that ideology and politics have not become involved.

I rise in support of Dr. Crawford to be the Commissioner of the Food and Drug Administration. Modern drugs, vaccines, and medical devices can work miracles but only if FDA does its job to see that they are safe and effective. We use food and food products from around the world and we count on the FDA to see that they are not contaminated.

FDA touches the lives of every American every day. As I said before, a full quarter of consumer products are regulated by the FDA. That is why it is so important the FDA have a full-fledged Commissioner. I fully support Dr. Crawford's nomination for the position.

His impressive record and clear commitment to public health will serve the agency well. He has dedicated his life to public service and to public health. He is trained as both a veterinarian and a pharmacologist and has many years of experience in government, industry, and the academic world.

His leadership experience at FDA dates back to 1978 when he headed the Center for Veterinary Medicine. Over the years since then, he has led the Food Safety and Inspection Service at the Department of Agriculture, headed a major association on veterinary medical education, and most recently served as Deputy Commissioner and Acting Commissioner of the Food and Drug Administration itself.

Under Dr. Crawford's leadership at FDA, we have seen stepped up efforts to monitor drug safety and to inform patients and doctors about the risks of drugs. We have recently seen increased scrutiny of drug advertising. FDA also made Herculean efforts to seek and permit the use of flu vaccines from other sources after the vaccine shortage last year, and I am hopeful that these efforts will pay off this year and in the following years in new manufacturers of flu vaccine for the U.S. market.

Clearly, more must be done. With a Commissioner in place, we can work much more effectively on the key issues facing the agency, from how FDA monitors drug safety to ways to address the flu vaccine shortage, to how it handles the conflicts of interest on its advisory committees and how it has acted on Plan B.

I intend to work with Chairman ENZI and the other members of our HELP Committee to see that these issues are addressed, to help Dr. Crawford make any changes at the agency that are needed, and to help craft legislation that will allow FDA to do its vital job more effectively.

On drug safety, FDA can only request drug companies to take action to protect the public. It is obvious that companies often have conflicts of interest and the FDA needs the authority to require better labels and insist on clinical trials of drugs already on the market, not just request them.

We need to improve the post-market monitoring of drug safety. Clinical trials before approval can and do detect many safety problems, but they should not end FDA's responsibility for the safety of drugs already on the market. When needed, new clinical trials should be required.

I just mention at this time that we intend to report out information technology legislation from the HELP Committee, hopefully this week. With information technology, we will be able to better monitor how drugs are used and the adverse reactions to those drugs, and hopefully have those reports promptly so that we will be able to provide greater protection to the public. That legislation will hopefully come out of our committee with a strong bipartisan commitment and with new leadership, and the opportunities that are out at the FDA with these new breakthrough drugs, it can make an enormous difference in terms of the quality of health care and the safety of treatments for the American people.

Above all, FDA needs enough resources to do its job effectively. The Office of Drug Safety does not even have computer systems capable of analyzing data as thoroughly as possible, and it cannot always purchase access to drug usage databases that could identify safety problems. It inspects less than 2 percent of imported food, and this much only because of a large increase in funds to FDA for that purpose after 9/11.

I note my friend and colleague, the Senator from Utah, Mr. HATCH, when he was chairman of the Health and Human Resources Committee, we worked together to try to help make sure the FDA would get the kind of resources to modernize itself and develop the kinds of technology to deal with a number of these issues.

I know of Dr. Crawford's concern for these problems and look forward to working with him to address them. I also commend Senator MURRAY and Senator CLINTON for their leadership in addressing the FDA's refusal to act on Plan B. Thanks to their leadership, the FDA has committed to making a decision on this application by September 1. I commend Secretary Leavitt and Dr. Crawford for this commitment.

I commend Chairman ENZI of the HELP Committee, who both in committee and on the floor has been even handed yet persistent in pursuing Dr. Crawford's nomination to be Commissioner. Once again, he has shown the leadership that will serve our committee well. I look forward to working with him to assist Dr. Crawford and the agency in its important public health work.

Dr. Crawford is well qualified to be Commissioner. He deserves to have full authority as Commissioner. It is time for the Senate to give him the title as well as the responsibility. I support his confirmation. I urge my colleagues to do so as well and I look forward to working with him in the years ahead.

The PRESIDING OFFICER. Who yields time?

Mr. ENZI. Mr. President, I yield 5 minutes to the Senator from Utah, Mr. HATCH, a former chairman of the committee that handles this. He has handled these confirmations before.

The PRESIDING OFFICER. The Senator from Utah.

Mr. HATCH. Mr. President, I rise in strong support of the nomination of Dr. Lester Crawford for the Commissioner of Food and Drugs.

I am pleased that the Senate is finally considering Dr. Crawford's nomination and urge my colleagues to support his nomination.

I want to stress that tonight's vote is extremely important—not only for the FDA—but for all Americans.

FDA needs a permanent Commissioner—in fact, the agency has not had a Commissioner since May 2004.

The FDA needs someone to lead on important matters where the agency has oversight—such as drug safety, food safety, approval for drugs and medical devices, and counteracting biological attacks.

Dr. Crawford is that man.

Since Dr. Crawford has been the Acting Commissioner of the FDA, he has had many accomplishments of considerable note.

Under his leadership, the FDA has undergone the most significant consolidation of FDA expertise in history with the physical facility moves to the Harvey Wiley building—the FDA's Center for Food Safety & Applied Nutrition near University of Maryland—and the White Oak campus.

As a result of Dr. Crawford's personal intervention and involvement, the most at-risk Americans were able to receive a safe and effective flu vaccine last year during the shortage crisis.

Dr. Crawford steered the FDA through one of the most difficult times in its history with the various drug safety issues of last year resulting in the creation of a new Drug Safety Oversight Board and Drug Watch internet page for consumers. This is a landmark milestone in drug safety and a paradigm shift for the FDA to one of openness and transparency.

Dr. Crawford has led the FDA on a series of important decisions that have transformed the regulation of food in the United States.

Under his leadership, the FDA fully implemented the Bioterrorism Act of 2002 a law that helps make our food supply safe on a daily basis. We have much more work to do and I am pleased to say you are helping to lead in that regard, Mr. President, and I am very appreciative of that.

Dr. Crawford implemented a risk management plan for the shell eggs industry that reduces dramatically the probability of salmonella.

Dr. Crawford is personally responsible for the complete overhaul and reform of good manufacturing practices for drugs, foods, and dietary supplements. When all of these major regulations are fully implemented, Dr. Crawford will be successful in creating the best quality control system in the world for regulating these consumer products.

Most recently, he assured me that the agency's final action on dietary supplement GMPs will be forthcoming in the near future. I welcomed his decision and the finality he has promised to this long overdue process.

Dr. Crawford has overseen user fee programs for both medical devices and veterinary drugs.

Dr. Crawford has led the agency in the development of the ''critical path'' that promotes a plan for bringing novel discoveries to market through the FDA system to fight such diseases as cancer.

I am convinced that Dr. Crawford is the best person for the job and the sooner we get him confirmed, the better.

On a personal note, I have known Dr. Crawford for many years.

He is a man of integrity.

He is a strong leader.

He is accessible.

He is someone who understands both science and public policy.

I believe that Dr. Crawford has all the qualities necessary to be the best Commissioner the FDA has ever had.

I urge my colleagues to vote in favor of Dr. Crawford today, a vote so long overdue.

I yield the remainder of my time to the distinguished chairman.

The PRESIDING OFFICER. Who yields time?

Mr. ENZI. Mr. President, I yield 2 minutes to the Senator from Iowa, Mr. GRASSLEY.

The PRESIDING OFFICER. The Senator from Iowa is recognized for 2 minutes.

Mr. GRASSLEY. Mr. President, I have considered Dr. Crawford's experience and performance on the job for well over a year now. In fact, Dr. Crawford has been the man in charge at FDA since I began taking a hard look at the FDA. It has been a long year for the FDA and I have taken a long look at Dr. Crawford's efforts to address FDA's problems.

I know Dr. Crawford is intimately familiar with how the FDA operates. He has twice served as acting Commissioner, most recently since March 2004, and his lengthy service at the FDA is commendable. Dr. Crawford and I have met on a couple occasions. He is a gentleman and seems to have the best of intentions. He told me personally that he understands there are problems at the FDA that need to be fixed. I believed at one point that he was capable of fixing those problems. However, as the saying goes, ''the proof is in the pudding.'' Today, I am here to say that I cannot vote for Dr. Crawford to be the next Commissioner of the FDA.

During the last 18 months, this country's confidence in the FDA has been shaken. It has been shaken not because of one isolated incident or one isolated whistleblower. It has been shaken because multiple drug safety concerns have been exposed by more than one courageous whistleblower. My oversight of the FDA leads me to the conclusion that there are cultural and systemic problems at the FDA. Unfortunately, Dr. Crawford has long been part of that same culture and system. The evidence is overwhelming that the FDA must change to better protect the American people. Dr. Crawford does not appear willing to be the man to change the FDA.

During Dr. Crawford's tenure, I have witnessed the suppression of the scientific process and the muzzling of scientific dissent. First, with Dr. Mosholder finding a link between antidepressants, children and suicide. And second with Dr. Graham's allegations regarding the FDA, Vioxx and postmarketing safety generally. Dr. Graham's testimony before the Finance Committee suggests that the problems are systemic. Oversight of the FDA exposed the cozy relationship that exists between the FDA and the drug industry. It revealed that the FDA negotiated for almost 2 years with Merck about how to change the Vioxx label so people would know about the risk of heart attacks.

But the problems are not isolated to the Center for Drug Evaluation and Research. My staff continues to interview FDA staff across the agency, employees who are doing important work on drugs, devices, and biologics. It is becoming more and more obvious to me that FDA is plagued by structural, personnel, cultural, and scientific problems. Those problems should be equally obvious to Dr. Crawford. But under the leadership of Dr. Crawford, the FDA appears to be in a state of denial. Over the past 18 months, Dr. Crawford has not stepped up to the plate. I have seen no recognition of the depth and breadth of the problems at the FDA. I have only seen a few short-term bandaids.

The systemic problems at the FDA demand visionary leadership. Dr. Crawford has not shown me that he is the leader to fix the FDA.

Mr. HARKIN. Mr. President, I rise in favor of the nomination of Dr. Lester Crawford to be the Commissioner of the Food and Drug Administration. I do this because I believe it is important for the FDA to have stable, permanent leadership at this critical time in its history. Dr. Crawford has valuable experience both in and out of government and has a background that makes him qualified for this position.

I want to highlight several issues where I would like to work with Dr. Crawford in the future. First, Congress passed the Dietary Supplement Health and Education Act, DSHEA, in 1994 to ensure the availability and safety of dietary supplements that millions of Americans rely on. Under the leadership of Dr. Crawford as Acting Commissioner, FDA has made significant progress in implementing and enforcing it. There is still work to be done on this issue, and I look forward to continuing to work with FDA to fully implement DSHEA, and to make sure that U.S. consumers have access to safe, effective, and affordable dietary supplements. ,

Second, given the Nation's obesity epidemic, I appreciate the efforts Dr. Crawford and the agency are making to improve consumer education and information regarding nutrition choices. I urge Dr. Crawford to follow-up and implement recommendations contained in the FDA report on obesity, ''Calories Count.'' In particular, Dr. Crawford should direct the entire restaurant industry to follow the recommendation to develop a nationwide and point-of-sale nutrition information campaign for consumers to include information on calories.

However, I am also voting in favor of Dr. Crawford's nomination in full support of the efforts of my colleagues, Senators MURRAY and CLINTON, to obtain a commitment from Dr. Crawford prior to his confirmation that the FDA will act promptly and in a scientifically appropriate manner on the sale of emergency contraception. I understand they have secured that commitment. I share Senator MURRAY's and Senator CLINTON's concern about the FDA's handling of the application for over-the-counter sale of emergency contraception, or the ''morning after'' , pill. There is absolutely no dispute that emergency contraception is safe and effective. The FDA's own advisory panel concluded unanimously in December 2004 that emergency contraception was both safe and effective. I strongly disagree with the FDA's decision last year to deny over the counter status to emergency contraception. Over the counter sale is about prevention. The morning after pill prevents the need for abortions, a goal that every Member of this body supports.

I am voting in favor of Dr. Crawford today. However, with this vote, I urge the FDA to address some fundamental challenges facing it in the future. The FDA must continue to take action to address post-market safety of the drugs it approves. In several high profile cases, the public's trust in the agency has been eroded. I look forward to working with Dr. Crawford on safety issues in the future.

Mr. KOHL. Mr. President, I rise in support of the nomination of Lester Crawford to serve as Commissioner of the Food and Drug Administration, FDA. The FDA has been without a permanent director for too long. I believe Lester Crawford is qualified to head the FDA and hope the establishment of permanent leadership can put to rest some of the uncertainty and delayed decisions that have been plaguing the agency for the last year.

While I remain concerned about resistance by the FDA to allow the reimportation of prescription drugs to ensure that our seniors have access to affordable prescription drugs, I have expressed my concerns to Dr. Crawford. The reality is that drug importation is already happening. It's time to stop defending the status quo and setting up new roadblocks, and I am hopeful that Dr. Crawford will work with Congress to give Americans the price relief and safety assurances they need.

I am also hopeful that the appointment of Dr. Crawford will help restore the agency's focus on ensuring that safe and effective drugs reach the market in a timely manner, and that recent issues that have plagued the FDA, such as questions regarding drug safety, advisory committee conflicts of interest and drug advertisements, to name only a few, will be addressed.

Mrs. CLINTON. Mr. President, I rise today to oppose the nomination of Lester Crawford to be Commissioner of the Food and Drug Administration.

The FDA is a vitally important agency, charged with ensuring that the products we rely on for our health and well-being are safe and effective. Having a strong leader at the helm is essential to a well-functioning agency.

Ultimately, after weighing the facts and considering the events that have occurred under Dr. Crawford's watch as Acting Commissioner, I came to the conclusion that I cannot support this nominee.

As I said during Dr. Crawford's confirmation hearing and during the HELP Committee's consideration of his nomination, Dr. Crawford's tenure at the FDA has been marked by controversy. The agency has faced scrutiny over its response to various crises: the failure to adequately warn us of the possibility of an influenza vaccine shortage, the failure to heed concerns about drug safety raised by both agency employees and outside scientists, and the failure to adequately separate science from what is viewed as ideology-driven decisionmaking.

As a result, public confidence in the ability of the FDA to ensure the safety and efficacy of drugs is failing. The dedicated scientists and civil servants who work at the agency are losing morale. They have clearly identified the need for reform, for change, and for improvements at the agency.

In December 2004, the Office of the Inspector General of the Department of Health and Human Services released the results of a survey that found two-thirds of FDA scientists do not believe the agency adequately monitors the safety of prescription drugs.

In March 2005, Dr. Sandra Kweder, Deputy Director of the Office of New Drugs at the FDA, testified that it ''would be helpful'' to change FDA authority, and give them the power to require changes in drug labels, rather than have to negotiate such changes in a lengthy back-and-forth process with manufacturers.

And just last week, Dr. Janet Woodcock, Deputy Commissioner of Operations at the agency, told an Institute of Medicine panel:

> This system has obviously broken down to some extent, as far as the fully informed provider and the fully informed patient.

But Dr. Crawford's response to these concerns has been less than adequate. He has maintained that the agency ''is fully capable of carrying out its mission under its current regulatory and statutory authority,'' despite statements and evidence to the contrary from both those inside and outside the agency.

His attempts to address the clear issues faced by the agency have been inadequate to the task. For example, despite his November 2004 announcement that the FDA would fill the position of Director of Office of Drug Safety, this position is still vacant—at a time when concerns over drug safety have been at the forefront of news about the FDA.

At a time when the FDA needs a strong leader to restore its reputation, Dr. Crawford represents an unacceptable status quo. I fear that his record demonstrates that he lacks the vision and the drive necessary to ensure that the FDA is the gold standard of drug regulation. He has failed to address the concerns raised by his own employees about the needs of the agency. And he cannot provide assurances that the FDA will place science, not ideology or other interests, as the cornerstone of its decisionmaking.

In addition, I am deeply concerned about the interference of personal beliefs over science in the decisionmaking process surrounding emergency contraception. By now, the details are all too familiar: the FDA's scientific advisory committees voted 23 to 4 in favor of the drug being made available over the counter. More than 70 organizations, including the American Academy of Physicians, American Associations of Family Physicians, American College of Obstetrics and Gynecologists, and the American Medical Association, submitted testimony in support of Plan B being made available over the counter.

Press reports later revealed that internal FDA memos indicated that career professionals at the agency had recommended unconditional approval of the application. And according to a May 8, 2004, article in the New York Times, several former FDA officials said they ''could not remember another instance in which Dr. Galson, a career officer in the public health service or any of his predecessors had overruled both an advisory committee and staff recommendations.''

In May, both The Nation and the Washington Post reported that Dr. Hager, a member of the Reproductive Health Advisory Committee, had stated, on videotape that he was asked to write a minority report arguing that Plan B should not be made available over the counter.

And the result, up until Friday, was foot dragging by the FDA. That is why my colleague, Senator MURRAY, and I felt it necessary to hold up Dr. Crawford's nomination. We wanted to send a strong message that the FDA needed to act on this application, which it has had for more than 2 years. We believed, and still do, that the American people have a right to an answer.

On Friday, we received a letter stating that the FDA would make a decision on Barr Laboratory's application to move Plan B to over-the-counter status by September 1, 2005. This is a giant step forward, but it does not erase the missteps under Dr. Crawford's watch.

That is why I cannot in good faith support Dr. Crawford to be Commissioner of the FDA. Like so many Members of this body, I want the FDA to have a permanent Commissioner, and I think it is high time for that. But that Commissioner must be someone who can restore the drug approval and safety processes to the gold standard that the New Yorkers who I represent and the Americans who rely on this process for their health and, even their lives, deserve.

I vote ''nay'' and I urge my colleagues to do the same.

Ms. MIKULSKI. Mr. President, I rise before you today to discuss the nomination of Lester Crawford as Commissioner of the FDA.

I first want to say that I love the FDA. FDA is in my home State of Maryland. It employs over 10,000 of my constituents. It is right down the road from the NIH. I am proud to have all that research at NIH, and then have FDA in Maryland standing up for the food safety of the American people, looking out to make sure that the drugs and the technologies that we use are safe.

Over the years I have fought for the right facilities, the right resources, and now the right leadership at the FDA. But I tell you, today is a very sad day for me because I cannot bring myself to support Lester Crawford as the Commissioner, and it is because I am so enthusiastic about FDA.

While I agree the agency has needed someone in charge, Dr. Crawford has not been in charge. His stewardship of the agency going back to 2002 has been both tepid and passive.

For example, under Dr. Crawford's leadership, the drug Vioxx was found to have increased risk of heart attacks long before FDA took any action. FDA was slow to reveal the knowledge of increased rates of suicides among teenagers taking antidepressants. There was delay. There is the politicizing of science as exemplified by the endless dispute over emergency contraception. And then there has been a ''just say no'' attitude to imported drugs.

And all of those people looking at homeland security tell us that our food supply is vulnerable to terrorist attacks. And what do we get from the FDA? We get passivity.

I am particularly concerned about the issue of drug safety. The FDA has been and must remain the gold standard in maintaining drug safety. Yet today there is a crisis of confidence over drug safety in the public's mind. At Dr. Crawford's nomination hearing in the HELP Committee earlier this year, he suggested that the newly formed Drug Safety Board within the FDA will be a way to guarantee this safety. I asked him how he could guarantee this board—which will exist within the FDA—will be able to provide independent review.

He gave me the bureaucratic answer and bureaucratic structure. I asked if he would be in charge of this important guarantee. He said ''no,'' he was going to delegate that to an Assistant Commissioner. I asked ''Why?'' He said: ''Because I would have to be involved in personnel and budgets.'' Well—that is his job, isn't it? That is exactly the kind of answer we are talking about. You cannot preside over FDA. You have to run FDA.

The nations of the world that cannot afford it look to our FDA to be the gold standard. Physicians and other allied health people who are prescribing drugs or using technologies need to know that they have an FDA that they can count on. And also we, the patients of the United States of America, need to know that we can count on the FDA. And the pharmaceutical industry has to have an FDA that provides even-handed regulatory authority. That is why I cannot support Lester Crawford as Commissioner.

It is with great reluctance that I have come to this decision, but it is because I love FDA and its mission, and know that the people of America are counting on it. Whether you are a doctor, or whether you are a patient, we need the FDA, and we need strong leadership. Therefore, regretfully, and reluctantly, and sadly, I am going to vote ''nay''.

The PRESIDING OFFICER. The Senator from Wyoming.

Mr. ENZI. Mr. President, I yield myself 2 minutes.

I thank everybody who has made comments today. I wish to address the last few comments that were made because our committee has oversight over the Food and Drug Administration. We are concerned about any situation that would give people less than full confidence in the medicines they are taking.

What we have been faced with for the last 18 months, which has been mentioned, is kind of giving a person a job. We have not given him the job, we have kind of given him the job. Anybody who has read transcripts from previous confirmation hearings would know that this is an extremely difficult position to ever get confirmed from. There are a lot of viewpoints from both sides. We have to have somebody in charge who has full authority, who has the right to look at the science and make decisions, who has full authority to make structural changes. I would say that Senator KENNEDY and I have been looking at that, doing the oversight.

With respect to drug safety, I want my colleagues to know that I take the recent drug safety concerns seriously. Senator KENNEDY and I are working together with our fellow committee members to develop comprehensive FDA drug safety legislation in this Congress and to bring that bill before the Senate so there can be those changes.

We will act, but we will act in a way that is mindful of the importance of weighing the risks of drugs and the benefits of the drugs on the same scale. Every drug has risks, and we would do the American people a grave disservice if we overreact to recent controversies.

The PRESIDING OFFICER. Who yields time? The Senator from Massachusetts.

Mr. KENNEDY I yield myself 2 minutes.

Mr. President, I agree with the Senator from Iowa that the Vioxx incident was an important failure for FDA. But that was not the failure of Dr. Crawford or even of FDA. The main problem is the FDA does not have the resources necessary to do the kind of work that is required. It happens to be the case. The main problem at FDA is one of resources. The FDA does not have the money it needs to address drug safety, to do the monitoring of drugs, the post-approval surveillance that it should. The Office of Drug Safety needs better computers and better access to the databases that are out there that can tell us about how drugs are being used and what happens when they are used. Congress needs to give the FDA more resources to do this.

With respect to the antidepressants, the FDA quite legitimately worked to better understand the issue before it required the label change. With respect to the Vioxx label change, the Senator is correct that it took too long, but that is because we in Congress have not given FDA the authority to require label changes. We need to change that.

The FDA does not have all of the kinds of authority it needs to regulate drugs after they are approved. I will be glad to work with the Senator from Iowa because, as one who has been interested since I have been in the Senate about strengthening the FDA, we have not given them the authority and the power to be able to do that kind of job.

Mr. HATCH. Will the Senator yield on that point?

Mr. KENNEDY. Yes.

Mr. HATCH. Isn't it true we passed the FDA revitalization bill back in 1989 to create this central campus where we could have the best state-of-the-art equipment? We had 48 different locations where FDA was located all over the greater Washington area; is that true?

Mr. KENNEDY. The Senator is correct.

Mr. HATCH. We have treated the FDA like a wicked stepsister instead of giving it the money it needs. It handles more than 25 percent of all consumer products in America, right?

Mr. KENNEDY. The Senator is correct.

Mr. HATCH. No matter who is FDA Commissioner, under those circumstances it is very difficult to get a handle on everything that needs to be addressed by the FDA.

Mr. KENNEDY. The Senator is correct. I look forward to the opportunity of working with the Senator from Utah, the Senator from Wyoming, and the Senator from Iowa. We ought to give this agency the authority, the power and the responsibility, as well as the resources to use it effectively. I know under Chairman ENZI we will have the oversight to make sure the agency is doing what it should.

But I do believe this nominee deserves to be the Commissioner. I think it is about time we have a Commissioner. Then let's all work together to make sure he and the agency meet his and its responsibilities.

The PRESIDING OFFICER. The time of the Senator has expired. Who yields time?

Mr. ENZI. Mr. President, as we move to a vote on the nomination of Dr. Lester Crawford to serve as Commissioner of Food and Drugs, I want to remind my colleagues of the important role the Food and Drug Administration plays in protecting and promoting the public health.

The FDA's mission is broad. The FDA regulates food, drugs, biologics, medical devices, animal feed, and cosmetics. The FDA regulates everything from cellular phones to cell tissue and gene therapies. In fact, Americans spend more than 25 cents of every dollar on products regulated by the FDA.

And as science progresses, the challenges of regulation grow. For instance, the FDA regulates a host of new products that blur the FDA's traditional boundaries. Today, the FDA is charged with regulating drug-delivery devices, such as coronary stents coated with drugs that contribute to keeping arteries open. Then there are next-generation orthopedic implants with biologic products built into them to stimulate tissue growth.

All of these new innovations require a nimble and responsive agency to regulate them, and they require resources to match. Today, in fact, Senator KENNEDY and I are introducing legislation to protect and strengthen a critical user-fee program. This program provides FDA with a stable stream of revenues to support the agency's mission to review and approve new medical devices. Without our action, that program would expire at the end of this fiscal year.

I believe that is just one expression of bipartisan support for FDA. Is FDA perfect? Of course not. FDA is staffed by human beings, and from time to time they make mistakes—as do we all.

But the FDA plays a critical role in our Nation's public health, and an important agency such as FDA needs to

have a strong leader with the power vested in him by Presidential nomination and Senate confirmation.

So I urge my colleagues to accept the President's nominee, Dr. Lester Crawford, and to vote to confirm him as the next Commissioner of Food and Drugs.

Mr. KENNEDY. Will the Senator yield another minute? Am I right, we have until a quarter of?

The PRESIDING OFFICER. The Senator from Wyoming has a minute 20 seconds remaining, the Senator from Massachusetts has 2 minutes 40 seconds.

Mr. KENNEDY. May I ask the Senator for a minute?

Mr. ENZI. Yes.

Mr. KENNEDY. Seeing who is in the chair, does the Senator not agree with me that one of the additional important responsibilities of the FDA is going to be bioterrorism? We are going to need a Commissioner at the FDA to lead this important work to prepare us against a bioterrorist attack. That is going to be enormously important. The HELP Committee has had our recent briefings on this issue, and bioterrorism is certainly an important area on which we will need the leadership of the FDA. I know the Senator from Wyoming is concerned about this bioterrorism, and the BioShield legislation, to make sure we have the vaccines and other medical products on line to respond to the dangers of bioterrorism. Bioterrorism is a pressing area in which we are going to have to work, and we need a leader at FDA to help us.

Mr. ENZI. The Senator is absolutely correct. The Presiding Officer is chairing that subcommittee and holding extensive hearings on that and bringing together some great experts to help us resolve that.

Mr. HATCH. Will the Senator yield also for just a moment? We introduced the bioshield II, the Lieberman-Hatch bill that has gone a long way to resolving this matter, and I intend to work with the Senator from North Carolina and the distinguished chairman and ranking member to see if we can bring this to a conclusion that works.

I thank the chairman.

Mr. ENZI. Mr. President, I yield any remaining time we have. I ask for the yeas and nays.

The PRESIDING OFFICER. Is there a sufficient second? There is a sufficient second. The question is, Will the Senate advise and consent to the nomination of Lester M. Crawford, of Maryland, to be Commissioner of Food and Drugs, Department of Health and Human Services. On this question, the yeas and nays have been ordered. The clerk will call the roll.

The legislative clerk called the roll.

Mr. MCCONNELL. The following Senators are necessarily absent: the Senator from Oklahoma (Mr. COBURN), the Senator from Arizona (Mr. MCCAIN), and the Senator from Alaska (Ms. MURKOWSKI).

Mr. DURBIN. I announce that the Senator from New Jersey (Mr. CORZINE), the Senator from Connecticut (Mr. DODD), and the Senator from Arkansas (Mrs. LINCOLN) are necessarily absent.

The PRESIDING OFFICER (Mr. CORNYN). Are there any other Senators in the Chamber desiring to vote?

The result was announced—yeas 78, nays 16, as follows:

[Rollcall Vote No. 190 Ex.]

YEAS—78

Akaka	Dole	Lott
Alexander	Domenici	Lugar
Allard	Ensign	Martinez
Allen	Enzi	McConnell
Bayh	Feingold	Nelson (FL)
Bennett	Feinstein	Nelson (NE)
Biden	Frist	Pryor
Bingaman	Graham	Reed
Bond	Gregg	Reid
Brownback	Hagel	Roberts
Bunning	Harkin	Rockefeller
Burns	Hatch	Salazar
Burr	Hutchison	Santorum
Byrd	Inhofe	Sarbanes
Carper	Inouye	Sessions
Chafee	Isakson	Shelby
Chambliss	Jeffords	Smith
Cochran	Johnson	Specter
Coleman	Kennedy	Stevens
Collins	Kerry	Sununu
Conrad	Kohl	Talent
Cornyn	Kyl	Thomas
Craig	Landrieu	Thune
Crapo	Leahy	Voinovich
DeMint	Levin	Warner
DeWine	Lieberman	Wyden

NAYS—16

Baucus	Durbin	Schumer
Boxer	Grassley	Snowe
Cantwell	Lautenberg	Stabenow
Clinton	Mikulski	Vitter
Dayton	Murray	
Dorgan	Obama	

NOT VOTING—6

Coburn	Dodd	McCain
Corzine	Lincoln	Murkowski

The nomination was confirmed.

The PRESIDING OFFICER. The President will be notified of the Senate's action.

LEGISLATIVE SESSION

The PRESIDING OFFICER. Under the previous order, the Senate will return to legislative session.

DEPARTMENT OF STATE, FOREIGN OPERATIONS, AND RELATED PROGRAMS APPROPRIATIONS ACT, 2006—Continued

The PRESIDING OFFICER. The Senator from Iowa.

Mr. GRASSLEY. Mr. President, I ask unanimous consent to set aside the pending amendment for the purpose of offering an amendment.

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

AMENDMENT NO. 1250

Mr. GRASSLEY. Mr. President, I am going to offer an amendment. Before I send it to the desk, I want to speak to the amendment.

In March of 2004, the Export-Import Bank approved the issuance of $9.87 million in taxpayer-guaranteed credit insurance to help Angostura Holdings Limited, of Trinidad and Tobago, to finance the construction of an ethanol dehydration plant in Trinidad. The purpose of this credit insurance was to enable Angostura to purchase equipment to be used to dehydrate up to 100 million gallons of Brazilian ethanol annually. Angostura would then reexport the resulting dehydrated ethanol to the United States duty free under the current Caribbean Basin Initiative Trade Preference Program.

The credit insurance approval, however, had one major flaw. It appeared to violate the Export-Import Bank's authorizing statute. I want to explain that statute.

Section 635(e) of the Export-Import Bank's authorizing statute—that is the Export-Import Bank Act of 1945—states that the bank is not to provide credit or financial guarantees to expand production of commodities for export to the United States if the resulting production capacity is expected to compete with U.S. production of the same commodity and the extension of such credit will cause substantial injury—I emphasize ''substantial injury''—to U.S. producers of the same commodity.

The statute goes on to provide that ''the extension of any credit or guarantee by the Bank will cause substantial injury if the amount of the capacity for production established, or the amount of the increase in such capacity expanded, by such credit or guarantee equals or exceeds 1 percent of United States production,'' with emphasis upon exceeding 1 percent of United States production.

I want to go back to last year then. As of last year, when the credit guarantees for Angostura were approved, the total 100 million gallon capacity of the Angostura facility was nearly 4 percent of U.S. production. This amount clearly then exceeds the 1 percent threshold for causing substantial injury to the U.S. ethanol industry as spelled out in the Export-Import Bank's authorizing statute.

I want to make clear, we are not talking about changing existing policy. We are talking about not letting somebody use subterfuge to get around existing law. It appeared to me that the approval of credit guarantees for Angostura by the Export-Import Bank violated the bank's authorizing statute. Moreover, as the amount financed by the Export-Import Bank was less than $10 million—remember, we are talking about $9.87 million—there was no detailed economic impact analysis conducted by the bank. So it seems to me they were conveniently under the $10 million threshold as a way of muddying the waters, camouflaging this transaction, not drawing attention, not even taking their official look at the requirements of the statute by being about $130,000 under the $10 million threshold, hoping that somehow this would get by without our finding out about it.

In the Consolidated Appropriations Act of 2005, Congress asked the Export-Import Bank for an explanation of the credit guarantees for Angostura. Specifically, the 2005 Act required the Export-Import Bank to submit a report to