Your heavenly grace, and give them courage to face perils with trust in You. Give them a sense of Your abiding presence, wherever they may be.

We pray in Your sovereign Name. Amen.

PLEDGE OF ALLEGIANCE

The PRESIDENT pro tempore led the Pledge of Allegiance, as follows:

I pledge allegiance to the Flag of the United States of America, and to the Republic for which it stands, one nation under God, indivisible, with liberty and justice for all.

RESERVATION OF LEADER TIME

The PRESIDENT pro tempore. Under the previous order, the leadership time is reserved.

EXECUTIVE SESSION

NOMINATION OF ANDREW VON ESCHENBACH TO BE COMMISSIONER OF FOOD AND DRUGS, DEPARTMENT OF HEALTH AND HUMAN SERVICES

The PRESIDENT pro tempore. Under the previous order, the Senate will proceed to executive session to consider the nomination of Andrew von Eschenbach, of Texas, which the clerk will report.

The legislative clerk read the nomination of Andrew von Eschenbach to be Commissioner of Food and Drugs, Department of Health and Human Services.

RECOGNITION OF THE MAJORITY LEADER

The PRESIDENT pro tempore. The majority leader is recognized.

SCHEDULE

Mr. FRIST. Mr. President, this morning the Senate will vote on the motion to invoke cloture on the nomination of the FDA Commissioner, Andrew von Eschenbach. Senators can expect to have this vote around 10:30 to 10:45 this morning, following the 1 hour for debate. As Senator Enzi yesterday made, this is a very important position, and to have this confirmation finally being accomplished will be a great achievement for this Congress.

Once cloture is invoked, we will try to schedule that vote on confirmation early in the day. There are several critical items the Senate must act on before we adjourn sine die, and therefore Senators should adjust their travel plans to be here voting over the coming days.

I will be working with colleagues on both sides of the aisle to wrap up our business for the Congress, and I appreciate Senators’ willingness to work together on a number of legislative and executive matters.

RECOGNITION OF THE MINORITY LEADER

The PRESIDENT pro tempore. The minority leader is recognized.

MOVING THE LEGISLATIVE AGENDA

Mr. REID. Mr. President, Andrew von Eschenbach is cleared on this side, so as far as we are concerned there is no need for a cloture vote. We look forward to working with the distinguished majority leader today, maybe tomorrow, maybe Saturday, to try to get as much cooperation out of Senators as possible. I know the leadership has worked long and hard to try to come up with something that is very important for the country. We will continue to monitor that and do everything we can as we try to move this legislative agenda along.

PROTECTING AMERICAN VALUES

Mr. FRIST. Mr. President, I will be very brief. I want to speak on another matter. I know we want to get to the hour of pre-vote time here shortly. That will also mark, once we adjourn, this official change in leadership and change in the Senate agenda. I know many of my colleagues and many of my conservative allies view this change with a bit of trepidation, but change is good, change is constructive. It can be difficult, it can be hectic, and it can be messy, but change forces us all to reexamine who we are, where we are, and where we want to go; what we know, what we believe.

I believe that with the responsibility to protect traditional, commonsense American values, I believe when we give the American people the freedom to invest their money as they choose, they will take control, they will grow, and the economy is going to flourish. It is going to have more freedom to grow.

At the end of the day, I believe good leaders don’t talk about principles—they talk about them—but good leaders lead on principle. They act, and they act with solutions, even if they don’t know that the outcome is going to be 100-per cent successful every time a bill is taken to the floor.

I think that is one of the things that at least I tried to do, is not say let’s only take to the floor what will nec- essarily pass but what is the right thing to do, on principle; what is the right thing for us to be considering.

During my tenure in public office, it is what I tried to do, to lead on prin ciple and act with solutions. It does come from that surgical approach of fixing things, of operating, of action.

For example . . . for 10 years, we grappled with the issue of Internet gambling. We watched the industry mushroom from a $30 million industry in 1996 to a $12 billion industry today. We watched an addiction undermine families, dash dreams, and fray the fabric of a moral society.

So we acted with a solution . . . by passing the Internet Gambling Prohi bition and Enforcement Act to provide new enforcement tools to prosecute illegal Internet gambling.

Let me give you a few more recent examples of how we have led on prin ciple, and acted with solutions.

We passed the Adam Walsh Child Protection and Safety Act . . . which creates a national sex offender registry, strengthens measures to prevent child pornography, and reinforces laws against child porn.

We passed the Trafficking Victims Protection Reauthorization Act, which will reinforce the first federal law to strengthen prosecution efforts against human traffickers.

We passed legislation securing the right to pray in U.S.

We passed legislation protecting the Mount Soledad Memorial Cross.

We passed the Broadcast Decency En forcement Act, which allows for the 10-fold increase of FCC fines for indecency violations.

We passed Cord blood legislation that harnesses the power of stem cells in cord blood to develop new cures for life-threatening diseases.

We passed the Fetus Farming Prohibition Act, which prohibits the gestation of fetal tissue in order to use it for research.

And perhaps most notably . . . we confirmed John Roberts Chief Justice of the Supreme Court . . . and Samuel Alito as an associate Justice of the Supreme Court.

We confirmed 18 Circuit court nomi nees and 87 District court judges, including six previously obstructed nomi nees. America needs judges who are fair, independent, and committed to equal justice under the law . . . and we made sure that’s what America got.

Over the past 12 years, what Republicans have done has changed our economy, our country, and our way of life for the better.

Our record of success, combined with the lessons of November’s election, en sures that our party will re dedicate itself to serving the interests of America, both here at home and around the world.

That vision—optimistic, forward looking, hopeful—will be grounded in the fundamentals of commonsense conserv ative values best found on Main Street and in families with whom we have the privilege of interacting all across the country.

The PRESIDENT pro tempore. Under the previous order, there will be 60 minutes for debate, prior to the cloture vote, with time divided as follows: the Senator from Wyoming, Mr. Enzi, or his designee, 30 minutes; the Senator from Iowa, Mr. Grassley, 20 minutes; the Senator from Louisiana, Mr. Vitter, 10 minutes.

Who yields time? The Senator from Wyoming is recognized.

Mr. ENZI. Mr. President, I rise to discuss the pending nomination of Dr. Andrew von Eschenbach to be the Commission of Food and Drugs. The FDA has a very broad and critical mission in protecting our public health. The Commissioner of Food and Drugs is in
charge of an agency that regulates $1 trillion worth of products a year. The FDA ensures the safety and effectiveness of all drugs, biological products such as vaccines, medical devices, and animal drugs and feed. Let me repeat that: all drugs, all biological products such as vaccines, medical devices, 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.

As Commissioner of Food and Drugs, Dr. von Eschenbach would be 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 food. Dr. von Eschenbach has a strong record. He is an accomplished scientist, a proven manager, and a man with a vision. He is also a cancer survivor, and he has brought that perspective, and the compassion that comes with it, to his government service. He gave up a job he loved, a challenging but rewarding post directing the National Cancer Institute, to offer his service for what I believe is a much more challenging and definitely thankless job of leading the FDA.

The FDA has been without a confirmed Commissioner for all but 18 months of the last 5½ years. Have you ever seen a business that can run for 5½ years without a boss except for 18 months? And that was a tenuous 18 months. I believe we can all agree that we need a strong leader at the FDA now, and one who has a mandate to act. He needs full authority to bring back the morale of the Department and get the job done. 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. But that authority flows directly from the act of Senate confirmation. Without a Senate-confirmed leader, we can’t expect the FDA to be as effective as we need it to be. I urge my colleagues to consider this.

I know some of my colleagues on and off the committee are not completely satisfied with their interactions with the FDA during Dr. von Eschenbach’s tenure. Some would urge that the Food and Drug Administration move quickly on congressional oversight by the FDA and its Commissioner over decisions made involving one product or one issue or something extraneous, even, to the Food and Drug Administration. It would be an especially dangerous precedent at this point.

We have a mandate with respect to the FDA during the 110th Congress. We have to reauthorize both the drug and device user fee programs, address two expiring pediatric programs, and improve our drug safety system.

The FDA needs a leader with the backing and mandate that Senate confirmation provides in order to be our partner in these efforts. Dr. von Eschenbach has received significant support from the HELP Committee. His nomination was supported in many different ways, and has offered to serve them by running this critically important agency. I am talking about a doctor with cancer expertise, management expertise, and vision, who has agreed to run this agency because he wants to give back to his country.

I urge my colleagues who are not on our committee to give Dr. von Eschenbach a chance to effectively run the FDA with full statutory authority, so I urge my colleagues to accept the President’s nominee, Dr. Andrew von Eschenbach, and vote to confirm him as the next Commissioner of Food and Drugs. Voting yes on this cloture vote will be the first step voting on a permanent head to oversee our Nation’s food and drug system.

I reserve the remainder of my time.

The President pro tempore. The Senator from Iowa.

Mr. GRASSLEY. Mr. President, my opposition to the cloture motion is as much about whether we are going to be able to fulfill our constitutional responsibilities of oversight of the administrative branch of Government as it is about the particular qualifications of the nominee. I intend to vote against cloture and I hope that Democrats who are listening—particularly those Democrats in the last election who were bellyaching because there wasn’t any oversight on the part of Republicans toward the executive branch of Government—would pay attention to the fact that there is something to do with and is an illustration of the lack of cooperation on the part of the executive branch, failure to cooperate with Congress on the issue of congressional oversight.

I have a couple of questions about what this cloture vote means, then, to congressional oversight of the executive branch now and in the future, and what it means for Members such as me, who placed a hold on this nominee. This was not a secret hold. I made this hold public.

I am voting against cloture and ask my colleagues to join me because I believe we need to send a message to the executive branch that it is not OK to impede congressional investigations. It is not OK to limit the Senate’s access to documents, information, and employees of the executive branch. In his book on congressional government, Woodrow Wilson, before he was President, when he was a professor at Princeton, wrote, in 1885: “Quite as important as lawmaking is vigilant oversight of the administration.”

Our work as lawmakers does not end with the passage of a bill. This body has a responsibility to the American people to make sure that laws work and that they are being implemented effectively, efficiently, and economically. Congressional oversight serves very important goals, and we should not lose sight. They include reviewing actions taken and regulations adopted by executive agencies to make sure that the agencies are executing law according to the intent of Congress, and, therefore, ensuring that the Government is not wasting taxpayers’ dollars. Oversight work allows us to evaluate the ability of agencies and managers to carry out program objectives and improve the efficiency, effectiveness, and economy of Government programs; next, ensuring that executive policies reflect the public interest and that public interest is expressed in the laws of Congress; and, lastly, protecting the rights and liberties of the American people.

Woodrow Wilson also said in his book that:

It is the proper duty of a representative body to look diligently into every affair of Government and to talk much about what it sees. It is meant to be the eyes, the voice and embody the wisdom and the will of its constituents.

In America, with our Government, the public’s business ought to be public. But when you have coverups and the lack of information from Congress, as demonstrated by this request for documents, and when we get a document back with practically 57 pages removed, what is in those 57 pages that we ought to have access to? That is just one example of lack of information and the lack of cooperation from this agency.

Throughout history, Congress has engaged in oversight of the executive branch. The right to congressional oversight has been asserted from the earliest days of our Republic. In 1792, the House invoked its authority to conduct oversight when it appointed a committee to investigate the defeat of General St. Clair and his Army by Indians in the Northwest and empowered the “call for such persons, papers, and records as may be necessary” for that inquiry.

In fact, the Constitution grants Congress extensive authority to oversee and investigate executive branch activities.

Congressional oversight was also recognized explicitly in the passage of the Legislative Reorganization Act of 1946.
which required the standing committees of Congress to exercise continuous watchfulness over programs of agencies in their jurisdiction. Numerous Supreme Court decisions will support all the precedents for Congress to see all aspects of the Federal Government.

In 1997, in McGrain v. Daugherty, the Supreme Court upheld congressional authority to conduct oversight of the Teapot Dome scandal. Justice Van Devanter writing for the unanimous Court stated:

We are of the opinion that the power of inquiry with the process to enforce it is an essential and appropriate auxiliary to the legislative function.

To do oversight, Congress needs access to information and people in the executive branch. And that is what I did not, and still may not, be getting from the FDA under the leadership of Dr. Von Eschenbach—as an example, 47 pages removed; another example, 43 pages removed.

How are you going to conduct oversight when you get answers such as that from the Food and Drug Administration?

I take exception to the statement made in support of the clout motion. People ought to be ashamed of saying Dr. Andrew von Eschenbach has done a superb job in the position he is currently occupying with answers such as that to the Congress of the United States. That is an insult. Before you cast your vote in favor of clout, consider what is at stake—and particularly Members on the other side of the aisle who, during the campaign, in campaign commercial after campaign commercial after campaign commercial, said Congress is not doing its job of oversight, implying that Republicans were covering up wrongdoing by the administration. If you want to preserve your access to information and do the oversight that you think you are going to do, when you are in the majority and you get answers such as that, do you think you are going to be able to do oversight?

In my interactions with the Department of Health and Human Services and the FDA these last 8 months, I have seen a complete and utter disrespect for congressional authority and the law. The department and the FDA administration have claimed “prosecutorial deliberative process” or “confidential communications” or “agency prerogatives” to determine who will be provided access to documents and why the agency needed to comply with a subpoena before a jurisdictional committee, when those on the other side of the aisle get answers such as that when you are going to be in the majority, what are you going to do about it? Are you going to keep your commitment to the American people for the majority? And are you going to be able to do the oversight when you get rationales such as “prosecutorial deliberative process” or “confidential communications” or “agency prerogatives”?

I could not talk to line agent named West because you can’t talk to line agents when 3 months before I talked to line agents? There was someone from the Justice Department before the Judiciary Committee, when Senator Kennedy said, “I want access to line agents,” unrelated to what I am talking about: Line Agent West, whom I wanted to talk to and I was told I couldn’t talk to because you can’t talk to line agents, the official at the Justice Department said to Senator Kennedy:

You can talk to line agents. We will get them for you.

I do not know whether that ever happened. But that was the answer.

When I went around doing my questioning of Justice Department officials, I said: What about my ability to talk to Line Agent West? It just seemed as if I was going to be able to talk to Line Agent West. But yet this very day the administration is advising the Secretary of the Interior that we can’t talk to Line Agent West, which is key to whether some of these investigations are allowing dangerous drugs on the market. In Cedar Rapids, IA, I have a family that lost an 18-year-old because of a drug that was on the market then and which is not on the market now.

It seems to me that if you are concerned about the safety of drugs, this information is important, and if you haven’t had it covered up in the FDA, you aren’t protecting the public. If Congress knows about it, you are not doing your job of oversight.

This past summer I asked the Congressional Research Service to look into the department’s policies regarding this matter. And the Congressional Research Service told me that there is “no legal basis” for the department’s executive branch assertion. This analysis provided by Congressional Research Service supports the committee’s position that these executive agencies’ claims have been consistently rejected and compliance with congressional requests in the past has been forthcoming. CRS cites numerous court cases which establish and support Congress’s power to engage in oversight and investigate activities and its access to executive branch personnel and documents in carrying out our powers of oversight.

The Department of Health and Human Services, the FDA within Health and Human Services, says it has been responsive because the agency made available hundreds of thousands of pages of documents to the Finance Committee in response to its subpoena. But the agency can give me all of the books and all the documents housed at the Library of Congress and it won’t matter if it is not what I have asked for and the pages are removed.

It is this type of cooperation that I am getting under this Director that you are now going to confirm. I am very concerned about the cooperation, if any, that the FDA has with the Department commissioner. Every Member of Congress should be equally concerned if they take their constitutional duty of conducting oversight of the executive branch seriously, and most importantly to the new majority when you are going to carry out your campaign promises to make sure that there is proper oversight, checks and balances against an executive branch of Government you think is exceeding authority. Every Member should be concerned we cannot enough.

A vote for clout today is a vote against oversight, and that is not what this Senate should be doing. It is not what the American people sent us here to do. We need to step up congressional oversight to protect our Nation’s system of checks and balances and not reward those who seek to impede our constitutional authority.

This body should not walk hand in hand with the executive branch and sit idly while instances of abuse and fraud continue to endanger the health and safety of American people. This Senate needs to make it clear to the executive branch that Congress takes its oversight responsibilities seriously and to vote against clout. If we do have clout, I will have other remarks during postcloture debate.

The PRESIDING OFFICER (Ms. Murkowski). The Senator from Wyoming.

Mr. ENZI. Madam President, I want to briefly comment.

I understand the frustration. I have been working with him trying to get documents, trying to get the interview
with Mr. West. I want you to put yourself in Dr. Von Eschenbach’s position. He has not been confirmed. He does not have the full authority to run that department. So what he has to do is rely on the Department of Justice, as the Senator mentioned. The Department of Justice is not as involved in this as you might want it to be. I don’t think he has authority to go beyond what the Department of Justice says.

The Senator is one of the most diligent Members to hold oversight hearings for anybody that I know. I appreciate the depth that you go to for individuals as well as groups. I know it is what you are doing on this one. Unless we give him full authority, he has to rely on the Justice Department. The way one has to take on the Department of Justice is through the Judiciary Committee and bring them to task for giving him that kind of advice. I think he is just following the advice he has gotten from those who he has to rely on until he has authority. It will be different when he has full authority. I yield 2 minutes to the Senator from Alaska.

Mr. VITTER. Madam President, during my time of almost 7 years as chairman of the Appropriations Committee, I have met with Dr. Von Eschenbach quite often. We had many requests for documents. I can’t remember one that he refused. But beyond that, I came to the floor today to say that I have gotten to know Dr. Von Eschenbach personally, and I can’t think of a more qualified man at this time to be confirmed to this position. I hope the Senate will vote cloture and we will confirm Dr. Andrew von Eschenbach as requested by the President. I thank the Chair.

Mrs. HUTCHISON. Madam President, I thank Senator Enzi for working together to bring this nomination to the Senate. We should have a bipartisan vote in confirming Dr. Andrew von Eschenbach.

Mr. VITTER. Madam President, I rise today to speak against the cloture motion to confirm Dr. Andrew von Eschenbach as Commissioner of the FDA. I have had a public hold on this nomination and have been very upfront about it. Because my serious concerns have not been addressed in any significant way, I will vote against cloture. If cloture is invoked, I will vote against the nomination.

Mr. STEVENS. Madam President, I yield the floor.

Mrs. HUTCHISON. Madam President, I thank Senator Enzi for working together to bring this nomination to the Senate. We should have a bipartisan vote in confirming Dr. Andrew von Eschenbach.

Mr. ENZI. Madam President, I yield 10 minutes to the Senator from Texas.

Mr. VITTER. Madam President, I rise to speak against the cloture motion to confirm Dr. Andrew von Eschenbach as Commissioner of the FDA. I have had a public hold on this nomination and have been very upfront about it. Because my serious concerns have not been addressed in any significant way, I will vote against cloture. If cloture is invoked, I will vote against the nomination.

In doing so, I want to be clear I have nothing against Dr. Von Eschenbach’s technical credentials or professional experience. They are very impressive in many ways. I strongly object to this nomination because the FDA and Dr. Von Eschenbach, acting on orders from the administration, has had a complete and utter lack of action creating a reasonable, safe system for reimportation of prescription drugs from Canada and elsewhere.

Clearly, this nomination making him the permanent head of the FDA will only further delay that reasonable implementation of an importation policy. In fact, at my extensive meeting with Dr. Von Eschenbach, my discussion with him made that perfectly clear. I give him credit. I suppose, for being very direct about that, although I am not sure he fully understands the advantages of a reimportation policy. It is for this reason I will vote against cloture. If cloture is invoked, I will vote against the nomination.
The FDA is completely capable of setting up a reimportation system, one that is safe and effective. The FDA can do this. It is not a matter of technical ability. We have great technical and other resources in this country. It is a matter of political will. At any time, the FDA can come up with a plan in this area. It is completely feasible.

My hold on this nomination, as I said, was very public, upfront, and clear. I made it clear I would lift it, contingent on a very simple request to implement even the most modern prescription drug reimportation plan—perhaps beginning with personal reimportation from Canada, including Internet and mail order sales. The FDA could do this. It is fully capable of doing this. It simply will not because of lack of political will.

The need for this is very obvious to me. Every time I talk to consumers in Louisiana, particularly seniors, it becomes more obvious. The need is obvious and as important is the growing support for this—not just out in the country where that support has always been strong but in the Congress, in the Senate, in the House.

The need to pass comprehensive drug reimportation language in 2003. It passed it by an overwhelming majority. More recently, the Senate passed my amendment coauthored by Senator BILL NELSON of Florida by a vote of 68 to 32. This past July, that was a significant breakthrough because it was the first time we had a meaningful, straight up-or-down vote on a reimportation issue in the Senate. Again, the vote was clear. It was overwhelming. That important amendment passed 68 to 32.

All this shows that the majority of Americans strongly support allowing all Americans to purchase safe, cheaper prescription drugs from Canada and elsewhere. Americans are clearly tired of hearing the government refuse to budge. Not only does the administration refuse to budge, it even went so far as to quietly implement a new policy last year at U.S. Customs and Border Protection to go after individual American citizens crossing back into the United States from other countries—mostly Canada—with medicine, actually seizing their packages containing legal medication at those border checkpoints. That is a very high-handed policy, when these citizens are doing nothing but trying to get absolutely necessary prescription drugs at a reasonable cost.

Coupled with the FDA and the administration's stubborn reluctance to implement even the most modern program that would lift this hold, that no change would be made with the confirmation of this nominee.

Again, this is an issue of utmost importance to every American family and, of course, it particularly impacts seniors. I talk to affected families and affected seniors in Louisiana about this all the time. They tell me, at a time when pharmaceutical companies are making record profits, the costs of prescription drugs are still skyrocketing and the very same medicines usually manufactured by the very same companies are sold at a fraction of the costs a few miles north of the border in Canada or in other countries around the world. And they tell me they are very skeptical. They should be. I share that attitude. I share that skepticism.

Opposing the right of an American to buy prescription drugs, FDA-approved medicines to use for themselves, is a wrong policy. We pay the highest prices in the world for prescription drugs in America. Our prices subsidize not only rock-bottom prices in almost every other country but also sky-high and escalating profits of the pharmaceutical companies. That is not fair. That should not be allowed to continue. That is why we need to pass this important policy of reimportation.

Many of my colleagues have spoken about this significant issue in the Senate. In September, my colleague from Michigan spoke eloquently about the need to allow the reimportation of safe drugs as a way to pressure U.S. pharmaceutical companies to lower prices here. That is the key, not just offering this option of cheaper drugs from another source but breaking up the present system that allows companies to charge dramatically different prices for the same drug around the world. And, in addition, as we see in the United States, that system will fall with reimportation. That system will fall with reimportation.

So that is why I continue this fight. That is why it is so important. Although certainly this nominee may very well be confirmed by the Senate today, I am very optimistic that, as we make progress on this issue, we march forward with the reimportation regime. That is why I continue this fight.

So as I oppose cloture, as I oppose this nomination, I do so in that spirit and with real optimism that we are not only making progress, but we will, in fact, move forward on this issue in the future. Next year, I expect my bill to be fully debated. In this Congress, that bill is S. 109, the Pharmaceutical Market Access Act. I believe it will reach the floor and will get a full debate with a full-blown reimportation plan to be here on the floor of the Senate for a full debate and a fair vote.

So as I oppose cloture, as I oppose this nomination, I do so in that spirit and with real optimism that we are not only making progress, but we will, in fact, move forward on this issue in the future. Next year, I expect my bill to be fully debated. In this Congress, that bill is S. 109, the Pharmaceutical Market Access Act. I believe it will reach the floor and will get a full debate with a full-blown reimportation plan to be here on the floor of the Senate for a full debate and a fair vote.
So under present law, that is possible, and that is what I was referring to. But I respect the Senator’s point of view.

Mr. ENZI. I appreciate that comment. If you were a person who was in a catch-22 position, a very qualified doctor who was wanted to do a good job with FDA and you knew that half the people or a third of the people or even 10 percent of the people did not want drug importation and you were the guy in charge of maybe making this determination for the first time—ever 18 years ago when Congress had opposite opinions on it—I do not think you would want to put yourself in that position.

He has just had a number of catch-22 positions where he can irritate half or more of us by making a decision, and nobody is going to make a decision in their confirmation process that way.

It is actually the Health and Human Services Secretary who has to certify under the new law as well.

So I get him confirmed and then do the kind of oversight we need to do to make sure he does everything that is possible to make sure we have safe food and drugs.

Mr. President. I yield up to 10 minutes of additional time from Senator Bennett.

The PRESIDING OFFICER. The Senator from Utah.

Mr. BENNETT. Mr. President, I did not plan to talk about drug reimportation, but coming on the heels of this conversation, I simply want to make this one observation: The key statement made by the Senator from Louisiana was safe drug reimportation. And the key problem here is certifying that the drugs coming across the border—are they coming in that way that they can be traced back, that there is a system, in fact, of the drugs, they are, in fact, safe.

The Congress has said the drugs can be reimported back into the United States as soon as the Secretary can certify that they are safe. No matter how many times we have seen the sample runs, if you will, that have been made on this issue. They have found again and again that a certain percentage of the drugs coming back are, in fact, not drugs manufactured in the United States. They have been manufactured elsewhere, packaged in Canada or Mexico or wherever, and then sent back to the United States fraudulently, as if they were, in fact, the original drugs.

Not all of them have yet killed anybody that I know of. They are not so unsafe that they have, in fact, poisoned anybody. Overwhelmingly, the history has been that the dosage in the drugs is simply not the same as advertised in the drugs manufactured in the United States. They have traces of whatever the drug might be in the fraudulent packages, but the dose control is not the same, and it is dangerous to the individual taking the drug if he or she assumes they are getting a certain dosage and in fact, they are getting a different dosage.

That has been the challenge. That has been the problem. And until the Secretary of HHS, be it Donna Shalala or Michael Leavitt, can come forward and certify that all of these are, in fact, as advertised, it is the law that they cannot be brought into the United States. I think that is an appropriate law protecting people in the United States.

I agree with the Senator from Wyoming that it really is not appropriate to hold up Dr. Von Eschenbach’s confirmation on this issue because it has to be decided by the scientists and those who are doing the sampling of the shipments rather than the head of the FDA.

I have gotten to know Dr. Von Eschenbach as the chairman of the Agriculture Appropriations Subcommittee. You usually think of agricultural appropriations in terms of crop supports and USDA activities. But for whatever reason, in its wisdom, Congress at one point put jurisdiction over the Food and Drug Administration into that subcommittee. So, if you would think of him in the position of dealing with this man as he has come begging.

As we are in the Appropriations subcommittees, everybody who has responsibility over which we have control, when they come asking for things, they come outlining their position, and they come describing what they will do with the money. All of us who have been on the Appropriations Committee have had this experience with a wide variety of people from the executive branch. I have never seen anyone who has come before our subcommittee better prepared, with a better understanding of how the money will be spent, and with more vision as to where the money ought to be spent to take the agency into the future than Dr. Von Eschenbach.

We have not just sat and discussed budget issues; we have not just sat and talked about dollars and cents—what are you going to spend here and what are you going to spend there—he has outlined for me in our conversations where he thinks the FDA of the future ought to be and what it will cost to get it there.

I have been very struck and impressed by his vision for the FDA. This is not a man who is content to simply superintend what he has on his plate. This is a man who has the capacity to look to the horizon, and maybe even beyond the horizon, to see where America ought to be.

In the practice of medicine right now, drug therapy is the cutting edge. Yes, we are developing new operations. We are developing new surgical procedures to try to push the envelope out further as far as health care is concerned. But the major breakthroughs are coming through drug therapy. There are all kinds of situations now where it can be handled with drug therapy that obviates the need for an operation and is less of a medical intrusion. The implications of that are huge, and the role of the FDA in that kind of medical revolution of the future is paramount. We absolutely have to have at the head of the FDA, in that kind of revolution, a man who is visionary, a man who looks to the future, and a man who understands the potential that lies in the area which he superin-
are safe and effective, that the cosmetics, dietary supplements, and over-the-counter medications we count on are sold safely, with truthful and non-misleading claims. This agency regulates animal drugs and radiological devices and so much more. Yet, time after time, it does without a confirmed commissioner. And this is the absolutely wrong time for that to happen.

Think about the key FDA issues we are facing: the safety of the food supply, how to improve drug safety, instituting a system of mandatory adverse event reporting for serious events associated with the use of dietary supplements and nonprescription drugs, extending the user fee programs for drugs and devices, and the incentives for pediatric drug testing—and I have named only a few of the issues. We are facing all these pressing public policy issues, and yet we expect the agency to do its job without a confirmed commissioner. That is not right. It is simply not right.

The President has nominated a well-qualified, more-than-capable medical doctor to the position of Commissioner of Food and Drugs. I know Dr. Von Eschenbach well. He is a man of integrity. He is a good manager. He is a good listener. He knows the importance of working well with Congress, and I believe he will work well with us.

I urge my colleagues—to do what is right and vote yes on this nomination. It is what Dr. Von Eschenbach deserves. It is what the agency deserves. And it is what the American people deserve.

The PRESIDING OFFICER. The Senator from Wyoming.

Mr. ENZI. Mr. President, I thank the Senator from Utah for his delightful comments. He speaks so clearly and explains things so well. I know of his contacts with Dr. Von Eschenbach. I hope people will follow his advice and vote for cloture.

Dr. Von Eschenbach's qualifications are excellent. He is supported by many organizations. We had received a number of letters in support of his nomination prior to his confirmation hearing. Those were duly entered in the hearing record. However, since then we have received additional letters of support.

I ask unanimous consent that those letters be printed in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

OMERIS,
Columbus, OH, August 2, 2006.
Hon. Michael B. Enzi, Chairman, Committee on Health, Education, Labor and Pensions, Dirksen Senate Office Building, Washington, DC.

Dear Chairman Enzi: Omeris, Ohio's bioscience membership and development organization, and our member companies, are writing in support of the nomination of Dr. Andrew von Eschenbach to be Commissioner of the Food and Drug Administration.

Dr. von Eschenbach is an excellent choice to head the FDA. He has an outstanding career as a physician, researcher, and administrator in both the public and the private sectors. As a physician, he has treated cancer patients, and as a researcher, he has published more than 200 articles and books and was the founding director of M.D. Anderson's Prostate Cancer Research Program. As an administrator, he has served as the president-elect to the American Cancer Society.

It is critically important to our industry and to the nation that the position of the FDA Commissioner be filled. Strong leadership is essential if the FDA is to be most effectively fulfill its mission of assuring the food Americans eat is safe and healthful, that the drugs they take are safe and effective, and that the medical devices they rely on for cures and treatments are safe and effective and represent the latest and best that our industry can offer. Experience has shown that a permanent director continued by the Senate is necessary to assure that the agency has the authoritative leadership it needs to respond promptly and effectively to all the challenges it faces.

Prompt confirmation of Dr. von Eschenbach is especially important in view of the issues that are currently facing the FDA. Next year, both the medical device and drug user fee programs will be renewed by Congress, and the agreements between industry and the FDA that will be the starting point for the reauthorization are being negotiated right now. The Critical Path Initiative, which offers so much potential for speeding the development and approval of safe and effective products is just getting off the ground and needs a strong advocate. The challenge of determining how FDA can most effectively conduct postmarket surveillance to assure the safety and effectiveness of approved products is an issue that needs strong leadership from the top. The continuing challenges of food safety and preparation for a pandemic or bioterrorist attack need a strong FDA voice.

Omeris, members, Ohio's bioscience companies, help revitalize our state's economy while developing, commercializing and technologies that benefit the world. Omeris is a focal point for the bioscience and biotechnology community, providing networking and technical events, continuing developing web-based resources, addressing public policy, and analyzing resource and funding issues.

We respectfully urge you to support Dr. von Eschenbach's prompt confirmation. Thank you for considering this request.

Sincerely,
ANTHONY J. DENNIS, President & CEO,
OMERIS,
To: Senate Health, Education, Labor and Pensions Committee.
From: Dr. Edwin A. Mirand, Secretary-Treasurer, NYSCPA.
Subject: Nomination of Dr. Andrew von Eschenbach as Permanent Commissioner of Food and Drug Administration.

The New York State Cancer Program Association, Inc. supports the nomination by President & CEO Dr. Andrew von Eschenbach.

Dr. Von Eschenbach's experience as a researcher will be a tremendous asset to the Agency and to the nation to the full Senate.

Dr. von Eschenbach would provide the vital leadership that is needed at the FDA. Moreover, his diverse background as a physician, educator, and advocate will be a tremendous asset to the Agency and to the nation for he can view the Agency's mission from many different perspectives and help to foster the collaboration that is so important to advancing medical science and quality health care.

The ALS Association is pleased to offer our strong support for this nomination and again urge the Committee and the Senate to support Dr. von Eschenbach as the next Commissioner of the Food and Drug Administration.

Sincerely,
STEVE GIBSON, Vice President, Government Relations and Public Affairs.

CANCER CURR COALITION,
Senator Michael B. Enzi, Chairman, U.S. Senate Committee on Health, Education, Labor and Pensions, Washington, DC.

Dear Senator Enzi: The Cancer Cure Coalition supports the nomination of Dr. Andrew VonEschenbach for the position of Commissioner of the Food and Drug Administration (FDA). Dr. Andrew VonEschenbach brings to the FDA with a better focus to confront the challenges and new opportunities facing the agency. Dr. von Eschenbach will lead the agency and strengthen the credibility of its decision-making process.

EDWIN A. MIRAND, Secretary.
The yeas and nays are mandatory under the rule. The clerk will call the roll.

The assistant legislative clerk called the roll. Mr. McCONNELL. The following Senators were necessarily absent: the Senator from Utah (Mr. HATCH) and the Senator from Alabama (Mr. SHELBY).

Mr. DURBIN. I announce that the Senator from Delaware (Mr. BIDEN), the Senator from Vermont (Mr. JEFORDS), and the Senator from Massachusetts (Mr. KENNEDY) are necessarily absent.

I further announce that, if present and voting, the Senator from Massachusetts (Mr. KENNEDY) would vote "yea."

The PRESIDING OFFICER (Mr. ENZI). Are there any other Senators in the Chamber desiring to vote? The yeas and nays resulted—yeas 89, nays 6, as follows:

YEAES—89