U.S. SENATE COMMITTEE ON
Finance
SENATOR CHUCK GRASSLEY, OF IOWA - CHAIRMAN
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Floor Statement of U.S. Senator Chuck Grassley of Iowa
Pre-Cloture Vote on Nomination of Dr. Andrew von Eschenbach
to be Commissioner of the Food and Drug Administration
Thursday, December 7, 2006

Thank you Mr. President for the opportunity to speak today on the cloture vote that this body will take later today to bring up the nomination of Dr. Andrew von Eschenbach to be Commissioner of the Food and Drug Administration. I intend to vote against cloture for several reasons.

I have serious concerns about what this cloture vote means for congressional oversight of the executive branch now and in the future and what it means for members like me who placed a hold on this nominee.

I am voting against cloture and I ask my colleagues to join me because I believe we need to send a message to the executive branch that it's not okay to impede congressional investigations. It's not okay to limit the Senate's access to documents, information and employees of the executive branch.

In his book, Congressional Government, Woodrow Wilson wrote in 1885, "Quite as important as lawmaking is vigilant oversight of administration."

Our work as lawmakers does not end with the passage of legislation. This body has a responsibility to the American people to make sure the laws work and they're being implemented effectively, efficiently, and economically. Congressional oversight serves very important goals, and we should not lose sight of them. They include: (1) reviewing actions taken and regulations adopted by executive agencies to make sure the agencies are executing the laws according to the intent of Congress; (2) ensuring that the federal government is not wasting taxpayer dollars. Our oversight work allows us to evaluate the ability of agencies and their managers to carry out program objectives and to improve the efficiency, effectiveness and economy of government programs; (3) ensuring that executive policies reflect the public interest; and (4) protecting the rights and liberties of the American people.

Woodrow Wilson also said in his book, "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 and the voice, and to embody the wisdom and will of its constituents."

Throughout history, Congress has engaged in oversight of the executive branch. For example, the right to Congressional oversight has been asserted in the early days of our republic. As early as 1792, the House of Representatives invoked its authority to conduct oversight when it

appointed a committee to investigate the defeat of General St. Clair and his army by the Indians in the Northwest and empowered it to "call for such persons, papers, and records, as may be necessary for their inquiries."

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 and agencies in their jurisdiction.

Numerous Supreme Court decisions all support the precedent for Congress to oversee all aspects of the federal government. In 1927, in the case of McGrain v. Daugherty, the Supreme Court upheld Congressional authority to conduct oversight in 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 am not getting from the FDA under the leadership of Dr. von Eschenbach. So I take exception to the statement made in support of the cloture motion that "Dr. Andrew von Eschenbach has done a superb job in the position he is currently occupying."

Before you cast your vote in favor of cloture consider what's at stake.

In my interactions with the Department of Health and Human Services and the FDA these last eight months, I have seen a complete and utter disrespect for congressional authority and the law. The Department and the FDA have repeatedly failed to act in good faith in responding to congressional investigations.

Under Dr. von Eschenbach's leadership, the FDA has failed to fully comply with two congressional subpoenas that were issued seven months ago.

Efforts to accommodate the agency's concerns fall on deaf ears and I wonder if I am dealing with "dysfunction by design." Not only has FDA withheld documents that do not appear to be privileged, but it also won't say what has been withheld and why. The subpoenas compel a privilege log, but FDA has not provided one.

What is the agency's explanation? FDA has said that so many documents have been withheld that it is unduly burdensome to provide a privilege log. Even the FDA General Counsel, as recently as Tuesday of this week, could not see why the agency needed to comply with the law and the terms of the subpoenas issued by the Finance Committee.

In denying the Committee access to documents responsive to the subpoenas, the Department and FDA have claimed quote "prosecutorial deliberative process," "confidential communications," and "agency prerogative to determine who will be interviewed or testify before a jurisdictional committee."

This past summer, I asked the Congressional Research Service to look into the Department's policies regarding this matter, and CRS told me that there is "no legal basis" for the Department's executive branch assertions. The legal analysis provided by CRS supports the Committee's position that these executive agency 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 investigation activities and its access to executive branch personnel and documents in carrying out this power.

The Department and FDA says it has been responsive because the agency made available hundreds of thousands, even millions, of pages of documents to the Finance Committee in response to the subpoenas. But the agency can give me all the books and documents housed at the Library of Congress and it won't matter if it's not what I asked for.

If this is the type of cooperation I am getting from the FDA under Dr. von Eschenbach, I am very concerned about the cooperation, if any, we will have once he becomes the permanent Commissioner. And every Member of Congress should be equally concerned if they take their constitutional duty of conducting oversight of the executive branch seriously.

I cannot emphasize this enough-but a vote for cloture today is a vote against oversight and that is not what this Senate should be doing and 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 by as instances of fraud, waste and abuse continue to endanger the health and safety of the American people. This Senate needs to make it clear to the executive branch that Congress takes its oversight responsibilities seriously and vote against cloture.

Floor Statement of U.S. Senator Chuck Grassley of Iowa
Post-Cloture Vote on the Nomination of Dr. Andrew von Eschenbach
to be Commissioner of the Food and Drug Administration
Thursday, December 7, 2006

Mr. President, I rise again to raise issues with the nomination of Dr. Andrew von Eschenbach. I placed a hold on this nominee and voted against cloture because I take my constitutional duty to conduct oversight very seriously.

I spend a great deal of my time in the Senate trying to make government work. I charge my staff to conduct oversight rigorously and to investigate any areas where the federal government is failing to be transparent, accountable and effective. In other words, if it fails the sniff test, I'll blow the whistle on it.

Today, I'm blowing the whistle on this nominee. In good conscience, I placed a hold on this nomination and I will not vote in favor of him today. A vote for this nominee would be an endorsement of the stonewalling and disrespect he has shown for Congressional oversight. I can say this not only because of his actions but because his words are on the record.

In response to a nomination question, I asked this nominee if he would cooperate with Congressional oversight and Dr. von Eschenbach identified a number of "executive branch interests" as a basis for not complying with Congressional requests, including "matters pending before the Agency," "pre-decisional, deliberative process information" and "open investigation information."

Dr. von Eschenbach was not well-served by whomever counseled him on these matters. He should know that during my years in the Senate, my investigators have obtained access to every single one of these categories of so-called confidential information.

His answer is at odds with my belief that Congressional oversight is one of the best ways to shake things up at a government agency and expose the truth. I say this is not just about the FDA, it's true of any government agency.

If an agency is not doing the right thing, typically behind it there's an effort to keep information suppressed. An effort to keep people from doing what they think ought to be done. An effort to keep people from doing what their job requires them to do and to not let that information out.

The muzzling of dissent and information is too common throughout our government. Things that should be transparent in government just aren't. And under Dr. von Eschenbach, the FDA has not only avoided transparency but it also has threatened those who are trying desperately to expose the truth.

I met with this nominee after the White House sent his nomination to the Senate last March. I hoped he would provide the kind of strong, permanent leadership the FDA needs. Over the next nine months, this nominee showed me that he is unlikely to provide that kind of leadership.

My belief is what you see is what you get. I fear what we will get from this nominee is what we got from him as Acting Commissioner. Let me tell you why with a few examples.

First, the doctor failed to live up to his word. In our meeting, he said he respected and understood the important role Congress plays as an equal branch of government. It didn't take long after that meeting before the first red flags appeared.

In April the Committee began its investigation of the FDA's approval and post-market surveillance of Ketek. Ketek is an antibiotic that came under renewed scrutiny last January. It looks like it is another drug where the FDA was caught flat-footed again. The Finance Committee issued two subpoenas in May after the FDA refused to provide documents related to Ketek.

During this time, the FDA also refused access to some FDA officials. The Finance

Committee was forced to issue a subpoena to a special agent in the FDA's Office of Criminal Investigations. The FDA refused to allow my staff to speak to this federal employee, citing a policy against providing access to line agents.

Yet only months before, my staff interviewed two line agents from FDA in another case. Apparently, the policy abruptly changed. I've seen it change over the years with other investigations. This "policy" is not law and it is typically enforced when the stakes are at their highest and there's something to hide.

I took this matter seriously enough that I went myself to the Department of Health and Human Services to meet with this agent. I was told that if this agent wanted to speak to me he would have to assert his status as a whistleblower under federal law.

I ask you today what I asked that day: Why does this government employee have to become a whistleblower to talk to me or anyone in Congress? Is that acceptable to the Members of this Senate?

Also, this government employee's supervisors put him in a no-win situation, and because of that, he risks being in contempt of Congress. This is an agent who put a doctor in jail for fraud in a Ketek study, he did the right thing, it's a closed case, we want to talk to him about a closed case, and FDA says no -- what does the FDA have to hide or cover up?

Under this Acting Commissioner, the FDA has also attempted to hide and cover-up documents.

The Finance Committee has received hundreds of pages that say, "57 pages removed," or "43 pages removed."

Other documents have whole pages, paragraphs or sentences redacted with no explanation as to why. Sometimes documents are marked redacted; other times they are not marked, even when it is evident that information is missing.

There is no explanation for what documents have been withheld or redacted. It is incomprehensible and looks like the work of the Keystone cops rather than an agency responsible for drugs and devices.

One of the FDA's most incompetent and absurd moments was when it sent one of my own request letters back to me with information redacted out of it. On top of such nonsense, the FDA has produced versions of the same document redacted different ways.

Recently, I wrote Secretary Leavitt and Attorney General Gonzales to explain the basis for some redactions. Again, two copies of the same document were redacted differently. It called into question the good faith basis for the redaction altogether. I could go on and on with examples showing the stonewalling and withholding of information from legitimate Congressional requests.

What it boils down to is that this nominee has demonstrated that he doesn't understand

that government truly is the people's business. He doesn't seem to understand that the people who finance it have a right to know what their government is doing and how it is spending their money.

I will give you one final example. I have long been a champion of whistleblowers. I was the lead Senate sponsor of the 1986 whistleblower amendments to the False Claims Act. Back then we were interested in dismantling a too cozy relationship between defense contractors and the Pentagon. Today, whistleblowers are once again the key to dismantling the cozy relationship between some drug companies and the Food and Drug Administration.

In June Dr. von Eschenbach held a meeting with FDA staff involved with Ketek. FDA employees present say he used a lot of sports metaphors regarding being "team players" and keeping opinions "inside the locker room." Basically he said to not criticize the FDA "outside the locker room." Apparently, he stated that anyone who spoke outside the locker room might find themselves "off the team."

This nominee held this meeting in the midst of an ongoing congressional investigation of Ketek. He called the meeting after a number of critical reports in the media about the FDA's handling of Ketek.

A number of FDA employees interviewed by the Committee were offended by his comments, found them highly questionable, inappropriate, and potentially threatening. I agree with them.

The leader of an agency should not hold a meeting to suggest that dissenters will be kicked off the team. This is the type of action that shows the true stripes of this nominee. He broke his word that he respected whistleblowers and would not raise even the appearance of retaliation.

When it comes to health care and public safety, we need to empower whistleblowers more than ever. They demonstrate extraordinary courage in the face of extraordinary adversity. It's extremely difficult to be a whistleblower. As I like to say, they are about as welcome as a skunk at a picnic. Yet, it is whistleblowers in government who put their job security on the line to come forward and expose fraud or wrongdoing for the public good.

My Finance Committee staff has been investigating serious allegations raised by whistleblowers at FDA for more than three years. Many of these allegations are very serious and call into question whether the FDA is fulfilling its mission to protect the health and safety of Americans.

The way the FDA under this nominee has handled the investigation of Ketek shows the agency would like to keep its business secret. It doesn't want these issues made public or subjected to the scrutiny. The culture at FDA has been we will let the public know what we think they need to know.

The American people don't want the government making decisions about what's good for them behind closed doors.

The goal of the Finance Committee's oversight has been straightforward. As chairman, I wanted to bring out in the open the decisions made by the FDA. For too long the agency has been making its decisions behind closed doors.

This nominee is not likely to serve well because he just doesn't seem to get it. He has placed media relations over the mission of FDA. First and foremost, he is supposed to do the right thing on behalf of Americans. Dr. von Eschenbach has other interests to serve and they are not always the interests of John Q. Public.

Now I hear from time to time from other agencies that particular documents are especially sensitive, or that the release of certain documents could jeopardize a criminal investigation - I understand that. But in those circumstances, I have reached accommodations. Unfortunately, in this case, my efforts to work with Dr. von Eschenbach and his subordinates have been all but summarily dismissed.

In closing, I intend to keep pressing the FDA for greater transparency and openness. As I continue with my Constitutional duties to conduct oversight, I look forward to working with my colleagues to ensure transparency, accountability, and effective governance by the executive branch. The bottom line is that Congress needs to stay committed to oversight of the executive branch. The public depends on Congress to fulfill its duty and hold executive agency leadership accountable.