

For Immediate Release
Monday, March 12, 2007

Grassley says FDA problems need sunshine, calls on Commissioner to reverse chill factor

WASHINGTON — Sen. Chuck Grassley said that statements by the Commissioner of the Food and Drug Administration discourage agency employees and scientists from speaking up about problems with the way the FDA monitors drug safety in the United States and raise questions about what the FDA might be trying to hide.

In a letter sent Friday to Commissioner Andrew C. von Eschenbach, Grassley asked about a February comment of the Commissioner reported in The (NJ) Star-Ledger, where the Commissioner expressed his unwillingness to tolerate whistleblowers who go outside the agency just because they disagree with a final outcome.

“The danger is that FDA employees interpret this to mean they can’t talk with Congress if they want to about problems inside the agency and, as a result, those problems are less likely to see the light of day and be fixed,” Grassley said. “The latest news report isn’t the first time we’ve heard about Dr. von Eschenbach attempting to chill dissenting points of view and scare FDA employees into silence. His statements are of growing concern to me.”

Von Eschenbach is scheduled to testify on Wednesday before the Senate Health, Education, Labor, and Pensions Committee.

Grassley has been conducting oversight of the FDA since 2004 and has urged the drug safety agency to act with greater independence and transparency. He has demonstrated how the FDA’s relationship with the drug industry is “too cozy” and sought accountability when agency leaders have acted to suppress scientific dissent regarding agency actions and drug-safety recommendations.

In January, Grassley reintroduced FDA-reform legislation with Sen. Christopher Dodd. Their bills would revamp and prioritize the post-market surveillance process within the Food and Drug Administration (S.468) and greatly expand public access to information about clinical trials regardless of the outcome of those trials through a clinical trials registry and results database (S.467). The senators authored nearly identical bills in the last Congress in the aftermath of Vioxx and the revelation of suicide risks with the pediatric use of antidepressants.

The text of Grassley’s March 9, 2007 letter follows here.

March 9, 2007

Andrew C. von Eschenbach, M.D.
Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Commissioner von Eschenbach:

As a senior member of the United States Senate and as Ranking Member of the Committee on Finance (Committee), it is my duty under the Constitution to conduct oversight into the actions of the executive branch, including the activities of the Food and Drug Administration (FDA). The Committee has exclusive jurisdiction over the Medicare and Medicaid programs. Accordingly, the Committee has a responsibility to protect the safety and well-being of the more than 80 million Americans who receive health care coverage under Medicare and Medicaid to ensure that the drugs they receive through these programs are safe and effective. Careful Congressional oversight of the FDA is especially important to ensure that FDA upholds its responsibility to the public's safety by properly regulating the nation's drug supply. The proper role of an agency leader is to cooperate with legitimate Congressional oversight activities, not to impede Congressional inquiries or conceal information from Congress. Interfering with Congressional oversight hurts not only the agency, but ultimately the American public. It is also important that an agency leader assure his employees that it is both acceptable and within their rights to speak to Congress should they feel compelled to do so.

I was extremely troubled by the statements that The Star-Ledger reported you made on February 21, 2007 at a conference sponsored by the Center for Medicine and the Public Interest. The Star-Ledger reported that you expressed your unwillingness to tolerate whistleblowers who go outside the agency just because they disagree with a final outcome. You are further quoted as saying, "the people have to understand to go outside that process is not constructive. It is actually destructive."

Several individuals, both inside and outside of FDA, brought this matter to my attention shortly after the article appeared. The commonly expressed concern was that your statements are being interpreted to prohibit FDA employees from talking to Congress and threaten FDA employees who choose not to abide by your decree. I fear that, if not rescinded or clarified, your statements would have a chilling effect on FDA employees' sharing with Congress the information we need to do our jobs. Often employees and other internal sources have crucial information to share and courageous whistleblowers, including FDA employees, have played important roles in Congressional inquiries in the past. Perhaps most importantly is the fact that had your statement been made at an earlier time the many concerns regarding the internal operation of the FDA, its cozy relationships with industry, and the severe cultural divisiveness that is rampant within the FDA would still be "secret." Some may think that keeping such matters "secret" is in the best interest of the American public. However, I disagree vehemently.

I am also troubled by accounts of some of your past statements to agency personnel. For example, I have been informed that you ordered a meeting with all FDA staff involved with the approval of the antibiotic, Ketek. This meeting was held after the press reported information that was critical of how the FDA handled safety issues with Ketek. As I understand it, and as FDA employees reported, you sent a clear message at this meeting. I understand that you told the assembled staff that it was important to be "a team player" and that if someone disagreed with the coach, they should keep their opinions and concerns "inside the locker room." You also said, according to those present, that anyone who spoke "outside the locker room" might find

themselves "kicked off the team." Some suggest that your intent was simply to boost morale. But some long-time FDA employees took your words more literally and I don't blame them. They took your message to mean that their career is in jeopardy if they speak to Congress or outside the agency. To me, it demonstrates poor judgment and intolerance for dissenting opinions and an aversion to transparency.

As you should know, interfering with a Congressional inquiry is against the law. I have attached a copy of 18 U.S.C. § 1505 to this letter for your reference. That law states:

Whoever corruptly, or by threats or force, or by any threatening letter or communication influences, obstructs, or impedes or endeavors to influence, obstruct, or impede the due and proper administration of the law under which any pending proceeding is being had before any department or agency of the United States, or the due and proper exercise of the power of inquiry under which any inquiry or investigation is being had by either House, or any committee of either House or any joint committee of the Congress--

Shall be fined under this title, imprisoned not more than 5 years or, if the offense involves international or domestic terrorism (as defined in section 2331), imprisoned not more than 8 years, or both.

Additionally, denying or interfering with employees' rights to furnish information to Congress is also against the law. I have attached a copy of 5 U.S.C. § 7211 to this letter for your reference. That law states:

The right of employees, individually or collectively, to petition Congress or a Member of Congress, or to furnish information to either House of Congress, or to a committee or Member thereof, may not be interfered with or denied.

Finally, and as you should also know, Federal officials who deny or interfere with employees' rights to furnish information to Congress are not entitled to have their salary paid by taxpayers' dollars. I have attached a copy of P.L. 109-115 § 818 to this letter for your reference. As enacted by continuing resolution (H.J. Res 20, P.L.110-5) P.L. 109-115 § 818 continues in effect. P.L. 109-115 § 818 states:

No part of any appropriation contained in this or any other Act shall be available for the payment of the salary of any officer or employee of the Federal Government, who -

(1) prohibits or prevents, or attempts or threatens to prohibit or prevent, any other officer or employee of the Federal Government from having any direct oral or written communication or contact with any Member, committee, or subcommittee of the Congress in connection with any matter pertaining to the employment of such other officer or employee or pertaining to the department or agency of such other officer or employee in any way, irrespective of whether such communication or contact is at the initiative of such other officer or employee or in response to the request or inquiry of such Member, committee, or subcommittee; or

(2) removes, suspends from duty without pay, demotes, reduces in rank, seniority, status, pay, or

performance of efficiency rating, denies promotion to, relocates, reassigns, transfers, disciplines, or discriminates in regard to any employment right, entitlement, or benefit, or any term or condition of employment of, any other officer or employee of the Federal Government, or attempts or threatens to commit any of the foregoing actions with respect to such other officer or employee, by reason of any communication or contact of such other officer or employee with any Member, committee, or subcommittee of the Congress as described in paragraph (1).

FDA employees, like employees at any other government agency, have the right to talk to Congress. If FDA employees have concerns to share, it is not anyone's place to forbid them from doing so. Many of your employees are sophisticated enough to realize that sweeping problems under the rug is not an effective long term solution. It is better to admit the problems and strive to solve them. In fact, I am eager to help solve the many problems plaguing the FDA, and as I have said before, I am happy to work with you to accomplish this important effort-Americans expect no less.

Your actions to discourage FDA employees from talking to Congressional investigators or otherwise "going outside the agency" or "talking outside the locker room" make me wonder what it is FDA is trying to hide. Sunshine is the best disinfectant. If there are problems at FDA, I assure you concealing them is not the solution. It does a disservice to your employees, and ultimately to the public who entrust their well-being to your agency's assessment of the safety and efficacy of the drugs in their medicine cabinets.

I do not know if your statements were intended to prohibit FDA employees from talking to Congress and threaten them if, despite your warnings, they exercised their right to do so, but that is exactly how your statements were interpreted by some FDA employees and others who heard your vigorous and repeated admonishments against employees talking outside of FDA. If discouraging FDA employees from talking to Congress was not your intent - you need to correct the misconceptions your statements have caused and you need to correct that perception now. After all, it is well known that what people perceive is often their reality.

Accordingly, if the perceptions are correct and discouraging FDA employees from talking to Congress was your intent - I propose that you tell FDA employees you have seen the error in such a policy. This can best be accomplished by notifying all FDA employees that they are free to talk to Congress and you do not intend to interfere with their right to come forward and share information with Congress. If your intent was indeed to prohibit FDA employees from bringing their concerns to Congress then please articulate that position in writing also.

I am also providing a copy of this letter to Chairman Kennedy and Ranking Member Enzi, as well as to Chairmen Dingell and Stupak, and Ranking Members Barton and Whitfield in light of the fact that you will be appearing before them in the near term. Perhaps you can take that opportunity to clarify your position before Congress, the American people and most importantly for FDA employees.

Thank you for your prompt attention to this matter.

Sincerely,

Charles E. Grassley
Ranking Member

Enclosures:

Statutory text 18 U.S.C. § 1505

Statutory text 5 U.S.C. § 7211

Statutory text P.L. 109-115 § 818