Congress of the United States
House of Representatives
Washington, D.C. 20515

October 12, 2005

Honorable Michael O. Leavitt
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue
Washington, D.C. 20201

Dear Mr. Secretary:

We are writing to express concern about the decision to permit Dr. Andrew von Eschenbach to lead the Food and Drug Administration (FDA) while remaining the director of the National Cancer Institute (NCI) at the National Institutes of Health. This dual responsibility – which exists despite Dr. von Eschenbach's pledge to give up his "day to day" duties at NCI – opens the door to unacceptable conflicts of interest.

FDA and NCI each have critical and independent roles in the drug safety system. In order to conduct a study on an experimental drug in human subjects, NCI must demonstrate to FDA that the drug is reasonably safe for initial testing in humans. Later in the drug development process, FDA is responsible for approving the same drugs that were tested at NCI.

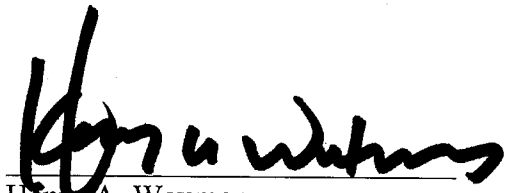
Having the same person at the helm of the NCI and the FDA violates the independent safeguards built into this system. There is no justification for merging these distinct roles.

Unfortunately, Dr. von Eschenbach's responses to this conflict have been inadequate. For instance, he stated that, at FDA, he will refrain from participating in "approval applications affecting drugs, devices, and biologics submitted by NCI or where an NCI employee was a Principal Investigator." There may be occasions in which NCI employees invented or were involved in the early development of a particular drug compound that was then transferred to a commercial enterprise for additional development. Although that commercial enterprise would ultimately be responsible for seeking FDA drug approval, in this instance, NCI clearly would have played a significant role in the drug's development. Dr. von Eschenbach's prior involvement with this drug at NCI would still represent a conflict of interest.

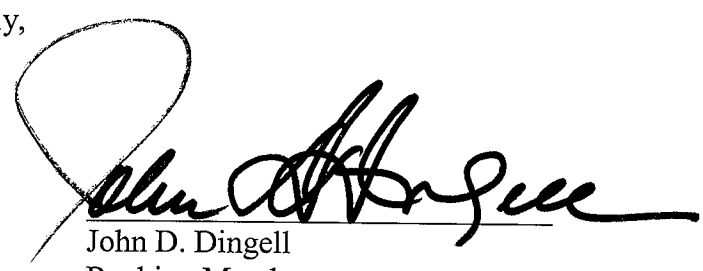
We are also concerned that the administration has explicitly reserved the ability to involve Dr. von Eschenbach in FDA matters in which NCI is a party on a "case-by-case basis." This provision negates Dr. von Eschenbach's promise to abstain from such matters. There is also no process by which the public can access information on the administration's handling of Dr. von Eschenbach's conflicts of interest as they arise.

At a time when public confidence in the FDA has been severely undermined by a series of controversies, appointing a commissioner who faces a variety of potential conflicts of interest is a misguided choice that will seriously weaken both agencies. We urge you to insist on the appointment of an acting commissioner who is free from conflicts of interest and unencumbered by the demands of a second, equally vital role in protecting our nation's public health. Further, we urge you to nominate a permanent full-time FDA commissioner at the earliest possible moment.

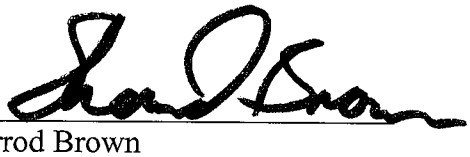
Sincerely,



Henry A. Waxman
Ranking Member
Committee on Government Reform



John D. Dingell
Ranking Member
Committee on Energy and Commerce



Sherrod Brown
Ranking Member
Subcommittee on Health
Committee on Energy and Commerce