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July 21, 2006

Honorable Michael O. Leavitt
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Mr. Secretary:

I am writing to draw to your attention a survey of FDA scientists that was conducted by the Union of Concerned Scientists (UCS) and Public Employees for Environmental Responsibility (PEER). The survey reveals that hundreds of agency scientists are concerned about inappropriate political interference that is compromising the agency's public health mission.

Last month I released a report prepared by the minority staff of the House Committee on Government Reform that revealed a significant decline in enforcement actions taken by FDA during the Bush Administration. According to the report, officials in FDA headquarters have routinely rejected the enforcement recommendations of career field staff.[1] The new survey of FDA scientists, which was sent to more than 5,900 scientists and includes responses from nearly 1,000, provides additional indications of turmoil within the ranks of the agency.

The survey finds that a large number of FDA scientists have experienced improper interference from agency superiors. One hundred forty-five FDA scientists (18%) report in the survey that they "have been asked, for non-scientific reasons, to inappropriately exclude or alter technical information or … conclusions in an FDA scientific document." According to one scientist at the Center for Drug Evaluation and Research, "management's overruling of competent science results in inappropriate drug development."

The survey also shows that many FDA scientists have been inappropriately censored or ordered to distort their research. One hundred sixty-three of the scientists (20%) said they "have

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[1] Minority Staff, Special Investigations Division, House Committee on Government Reform, *Prescription for Harm: The Decline in FDA Enforcement Activity* (June 26, 2006).

been asked explicitly by FDA decision makers to provide incomplete, inaccurate, or misleading information to the public, regulated industry, medial, or elected/senior government officials."

The survey indicates that many FDA scientists feel the agency is unable to adequately meet its public health responsibilities. Six hundred eighty-six scientists (70%) felt that FDA does not have sufficient resources to achieve its mission of "protecting the public health … and helping the public get the accurate, science based information they need to use medicines and foods to improve their health." Furthermore, the survey suggests that FDA's effectiveness is in decline. Four hundred sixty-six of the scientists (47%) said their center was less effective than it was five years ago, while only 273 (27%) said their center was more effective.

According to the survey, morale among FDA scientists is also declining. Three hundred ninety-five FDA scientists (40%) rated their morale as "poor" or worse. And 507 scientists (52%) indicated that "over the past few years [their] personal job satisfaction has decreased." One respondent commented that "[m]orale has declined so much in the last three years in our office that experienced people that would have continued working after reaching retirement age are now counting the days until they can leave."

The results of the survey show that there is internal turmoil at FDA. I urge you to make restoring the scientific integrity and independence of FDA a public health priority. Steps must be taken to halt inappropriate political intrusion into FDA decision making and reverse the decline in FDA's morale and effectiveness.

I ask that you provide me with your plan to address this serious problem by August 25, 2006.

Sincerely,

Henry A. Waxman
Ranking Minority Member

Enclosure