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December 8, 2004

Dr. Lester Crawford
Acting Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Dr. Crawford:

I am writing to express my deep concern regarding recent reports of intimidation of and retaliation against FDA employees who share their unvarnished, scientific opinions with Members and Committees of Congress that oversee the FDA. In particular, I am troubled by allegations that FDA managers sought to discredit and intimidate Dr. David Graham prior to his testimony before the Senate Finance Committee in late November. I understand that Senator Charles Grassley, Chairman of the Senate Committee on Finance, has expressed similar concerns and has requested that the Office of Inspector General, Department of Health and Human Services, investigate this matter. I fully support Chairman Grassley's request.

I have also been made aware of new reports that FDA managers are suppressing FDA scientists who raise safety concerns that may interfere with a new product's licensure approval process. These reports appear to be part of a larger, dangerous pattern that has come to light in the past year in which FDA censors scientists who raise safety concerns that may negatively impact a new or existing FDA-approved product. The muzzling of Dr. Andrew Mosholder, who detected problems with antidepressants, and Dr. Graham, who discovered severe problems with Vioxx and other prescription drugs, are two prime examples of this troubling trend.

FDA's core mission is safety. Sanctioning FDA scientists who raise safety concerns is antithetical to this mission. These dangerous practices must end. I am confident that many of my colleagues on the House Appropriations Committee share my concerns. Therefore, I urge you, as the acting head of the agency, to inform all FDA employees immediately that they have the right and the obligation to raise safety concerns, assure them that they will not suffer retribution in any way for doing so, and that their concerns will be seriously addressed.

Thank you for your attention to this matter. I look forward to your prompt response.

Sincerely,

Maurice D. Hinchey

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