



Consumer Federation of America



U.S. Public Interest Research Group

March 15, 2005

The Honorable Senate Member
Committee on Health, Education,
Labor and Pensions
United States Senate
Washington, D.C. 20510

Dear Senator:

This Thursday, the Senate Committee on Health, Education, Labor and Pensions will consider the nomination of Dr. Lester Crawford to be the Commissioner of the Food and Drug Administration.

Before voting on his nomination, we urge you to ask, and get answers to, important questions about Dr. Crawford's record at FDA and his plans to achieve meaningful drug safety reform as Commissioner.

Dr. Crawford has served at the helm of FDA, as either Deputy or Acting Commissioner, for the last three years. During that time, the agency's high profile missteps and failure to take timely action to protect consumers from unreasonable drug safety risks have raised serious questions about his leadership, his ability to manage interagency conflicts and willingness to act in the best interest of consumers.

Dr. Crawford and Secretary of Health and Human Services Michael Leavitt recently announced the creation of an independent drug safety oversight board at FDA. Unfortunately the move offers no true substantive reform and bears little resemblance to the "emboldened new vision" it is supposed to represent. The Drug Safety Board does nothing to improve the agency's weak regulatory capacity or to address the inherent internal conflicts of interest that prevent FDA from identifying unreasonable safety risks and taking timely action to protect the public from them.

The agency's recent high-profile failings on the safety of widely used painkillers and antidepressants are symptoms of a larger problem that can only be resolved with critically needed new laws. First, FDA lacks authority to require drug companies to conduct safety studies once a drug is approved and to require timely protective action when unreasonable risks arise.

Second, the organizational structure of the FDA suffers from inherent conflicts of interest by allowing reviewers in the Office of New Drugs to make important determinations about the post-market safety of drugs they approve. In 2004, these conflicts discouraged public release of findings by reviewers in the Office of Drug Safety, who have no authority to take action on their own, nor even the right to ensure that FDA advisory committees, doctors and patients have access to their findings.

And third, patients and doctors don't have access to all clinical trial results, both good and bad, for widely prescribed medications. Meanwhile, drug makers are free to publish the positive results in medical journals, while downplaying less favorable findings.

In the face of widely publicized regulatory shortcomings at FDA, Dr. Crawford has not acknowledged the need for substantive changes to increase the FDA's ability to protect consumers.

Though he claims to have a bold vision for the FDA, the question is whether or not Dr. Crawford is committed to achieving substantive rather than symbolic drug safety reform. Such reforms must include full public disclosure of all clinical trial results, greater independence for the Office of Drug Safety, stronger authority to require additional studies on the safety of approved drugs, and increased capacity to take action to mitigate unreasonable risks when they arise.

Before the Senate HELP Committee reports his nomination, we urge you to compel Dr. Crawford to enumerate steps he will take to change the agency's culture and achieve meaningful administrative and legislative reforms to FDA's drug safety system.

Sincerely,

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