U.S. SENATE COMMITTEE ON
Finance
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Floor Statement of U.S. Senator Chuck Grassley of Iowa
Nomination of Dr. Lester Crawford to Commissioner of the Food and Drug Administration
Monday, July 18, 2005

I rise to address the nomination of Dr. Lester Crawford to be Commissioner of the Food and Drug Administration. I have considered Dr. Crawford's experience and performance on the job for well over a year now. In fact, Dr. Crawford has been the man in charge at FDA since I began taking a hard look at the FDA. It has been a long year for the FDA, and I have taken a long look at Dr. Crawford's efforts to address FDA's problems.

I know Dr. Crawford is intimately familiar with how the FDA operates. He has twice served as acting Commissioner, most recently since March 2004, and his lengthy service at the FDA is commendable. Dr. Crawford and I have met on a couple occasions. He seems to have the best of intentions. He told me personally that he understands there are problems at the FDA that need to be fixed. I believed at one point that he was capable of fixing those problems. However, as the saying goes, "the proof is in the pudding." Today, I am here to say that I cannot vote for Dr. Crawford to be the next Commissioner of the FDA.

During the last 18 months, this country's confidence in the FDA has been shaken. It has been shaken not because of one isolated incident or one isolated whistleblower. It has been shaken because multiple drug safety concerns have been exposed by more than one courageous whistleblower. My oversight of the FDA leads me to the conclusion that there are cultural and systemic problems at the FDA. Unfortunately, Dr. Crawford has long been part of that same culture and system. The evidence is overwhelming that the FDA must change to better protect the American people. Dr. Crawford does not appear willing to be the man to change the FDA. During Dr. Crawford's tenure, I have witnessed the suppression of the scientific process and the muzzling of scientific dissent. First, with Dr. Mosholder finding a link between anti-depressants, children and suicide. And second with Dr. Graham's allegations regarding the FDA, Vioxx and post-marketing safety generally. Dr. Graham's testimony before the Finance Committee suggests that the problems are systemic. Oversight of the FDA exposed the cozy relationship that exists between the FDA and the drug industry. It revealed that the FDA negotiated for almost two years with Merck about how to change the Vioxx label so people would know about the risk of heart attacks.

But the problems are not isolated to the Center for Drug Evaluation and Research. My staff continues to interview FDA staff across the agency, employees who are doing important work on drugs, devices, and biologics. It is becoming more and more obvious to me that FDA is plagued by structural, personnel, cultural, and scientific problems. Those problems should be equally obvious to Dr. Crawford. But under the leadership of Dr. Crawford, the FDA appears to be in a state of denial. Over the past 18 months, Dr. Crawford has not stepped up to the plate. I

have seen no recognition of the depth and breadth of the problems at the FDA. I have only seen a few short-term band-aids.

The systemic problems at the FDA demand visionary leadership. Dr. Crawford has not shown me that he is the leader to fix the FDA.