

COMMITTEE ON GOVERNMENT REFORM
CONGRESSMAN TOM DAVIS, CHAIRMAN



NEWS RELEASE

For Immediate Release
October 8, 2004

Contact: David Marin
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Davis Questions FDA on Vioxx News Reports

Washington, D.C. - House Government Reform Committee Chairman Tom Davis (R-VA) wrote today to Dr. Lester Crawford, Acting Commissioner of the Food and Drug Administration, seeking an official response to press reports today that an FDA official was kept from presenting data to the public. Today's letter follows one sent two days ago by Davis to Crawford, seeking information related to FDA's post-approval surveillance of medications in light of the worldwide recall of Vioxx, an arthritis medication produced by Merck & Co. The company decided to withdraw the drug from the marketplace after it inadvertently discovered that the drug's use may increase the risk of heart attack and stroke.

A copy of today's letter follows. The October 6 letter can be found on the Committee's web site, www.reform.house.gov.

October 8, 2004

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

Dear Acting Commissioner Crawford:

Press reports today raise questions about whether a Food and Drug Administration (FDA) official tasked with evaluating the data of Kaiser Permanente patients on COX-2 inhibitor drugs, was prevented from presenting his findings and conclusions to the public. Today's *Washington Post* article, entitled "FDA Official

Alleges Pressure to Suppress Vioxx Findings,” reported that Dr. David Graham, Associate Science Director of the Office of Drug Safety, believed he was subjected to “veiled threats” when he attempted to release his findings from the Kaiser Permanente study on the increased risks of heart attacks and strokes of patients taking Vioxx. The article further stated that a senior FDA official recommended “watering down” his report.

These allegations of suppressing the release of data showing a serious health risk for patients are extremely troubling. In conjunction with the Committee’s current review of FDA’s surveillance of the safety of drugs on the market, specifically with regard to its oversight of Vioxx, the Committee seeks information to determine whether Dr. Graham was prevented, in any manner, from presenting his findings on the harmful effects of Vioxx, and if so, why. Therefore, please produce the following documents by October 15, 2004:

1. All records relating to the study investigating the cardiovascular risk of COX-2 inhibitor drugs by data from Kaiser Permanente patients, including, but not limited to, all draft or final reports or memorandums, internal correspondence, emails, and notes between and among the participants of the research team, including FDA, Kaiser Permanente and Vanderbilt University School of Medicine.
2. All records of communication between FDA and Merck & Co., Inc. relating to the study investigating the cardiovascular risk of COX-2 inhibitor drugs by data from Kaiser Permanente patients.
3. All records of Dr. David Graham relating to the safety and efficacy of COX-2 inhibitor drugs, including, but not limited to, internal correspondence and emails.

Finally, we request that FDA provide to Committee staff by October 20, 2004, a briefing covering the details of FDA’s surveillance of Vioxx, and the allegations raised by Dr. David Graham. Following the briefing, we expect to interview other FDA officials with relevant information.

Sincerely,

Tom Davis
Chairman

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