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United States Senate

COMMITTEE ON FINANCE

WASHINGTON, DC 20510-6200

KOLAN DAVIS, STAFF DIRECTOR AND CHIEF COUNSEL
RUSSELL SULLIVAN, DEMOCRATIC STAFF DIRECTOR

May 16, 2006

Via Electronic Transmission

Andrew C. von Eschenbach, M.D.
Acting Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. von Eschenbach:

The Senate Committee on Finance (Committee) has jurisdiction over the Medicare and Medicaid programs and, accordingly, a responsibility to the more than 80 million Americans who receive health care coverage, including prescription drugs, under those programs.

The Committee continues to investigate extremely troubling allegations related to, among other things, the approval and post-market surveillance of telithromycin (Ketek) by the Food and Drug Administration (FDA). One of the most troubling allegations is that the FDA approved Ketek with full knowledge that some of the clinical safety data supporting its approval was beset by systemic data integrity problems. While the FDA takes its time negotiating with Sanofi-Aventis to decide what drug risk information the public should know, it is completely mystifying why a fraudulent clinical trial is referenced in safety information on the FDA's website. The American people deserve better. When will the FDA do the right thing and correct this information?

As Chairman of the Committee, I also respectfully request that your staff make immediate arrangements for my Committee staff to interview Special Agent _____, who successfully investigated and participated in the prosecution and sentencing of Dr. Maria Anne Kirkman Campbell to nearly five years in prison for her fraud in Ketek Study 3014. In addition, provide a copy of all documents and communications related to Ketek and Study 3014 in the possession of Special Agent _____, including, but not limited to, all emails related to Ketek and/or the Committee's investigation of Ketek. Given the gravity of the Ketek allegations, I respectfully request that your staff contact my staff by no later than Thursday, May 18, 2006, to make arrangements for this interview and for the Committee to obtain the requested documents from Special Agent _____ by no later than May 24, 2006. If you anticipate any difficulty in complying with this deadline, please immediately contact my Committee staff.

As you know, I requested that all FDA employees involved directly or indirectly with Ketek be immediately provided with a copy of my letter, dated April 27, 2006, to inform them of their right to speak and to cooperate with Congress. I also requested that

all FDA employees should be informed that no documents, records, data or information related, directly or indirectly, to Ketek shall be destroyed, modified, removed or otherwise made inaccessible to the Committee. Further, if any FDA employee believes that he or she has been subject to retaliation for meeting with Committee staff and/or for anything associated with the Committee's ongoing investigation of Ketek, the employee should contact the Committee immediately. Thank you for forwarding a copy of this letter to employees within the Center for Drug Evaluation and Research, however, I understand that it was not forwarded to the Office of Criminal Investigations, among others.

Accordingly, please advise Special Agent [redacted] and all FDA employees within the Office of Criminal Investigations that they have the right to speak directly and independently to Congress, or to a Committee of Congress, without interference from the FDA if they wish, in accordance with 5 U.S.C. § 7211. Retaliation against these individuals, or any other FDA employees, who communicate with the Committee in reference to Ketek will not be tolerated. Such conduct is further punishable by 18 U.S.C. § 1505 and false statements and perjury are likewise punishable pursuant to 18 U.S.C. § 1001. Further, under 5 U.S.C. § 2302(b)(8), a federal employee authorized to take, direct others to take, recommend or approve any personnel action may not take, fail to take, or threaten to take any personnel action against an employee because of protected whistleblowing. Protected whistleblowing is defined as disclosing information which the discloser reasonably believes evidences: a violation of law, rule, or regulation; gross mismanagement; gross waste of funds; an abuse of authority; or a substantial and specific danger to public health or safety.

Please also note that P.L. 109-115 enunciates a government-wide prohibition on the use of appropriated funds to pay the salary of any federal official who prohibits or prevents or threatens to prevent or prohibit a federal officer or employee from contacting Congress, and "any punishment or threat of punishment because of any contact or communication by an officer or employee with a Member, committee or subcommittee."

Thank you in advance for your assistance.

Sincerely,



Charles E. Grassley
Chairman