

COMMITTEE ON GOVERNMENT REFORM
CONGRESSMAN TOM DAVIS, CHAIRMAN



NEWS RELEASE

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Davis Questions FDA's Drug Monitoring Program

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 (FDA), seeking information relating 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.

Concerns about the drug's safety have been around since 2000, one year after FDA approved Vioxx. Subsequent studies further raised questions as to the safety of the drug. In 2002, FDA requested additional warning labels for the medication following an Arthritis Advisory Committee meeting. Despite the mounting evidence that Vioxx increases the risk of cardiovascular problems, FDA recently approved the drug for use by children.

"Given the amount of information circulating in regards to the potentially harmful effects of Vioxx, why hasn't FDA, the agency that is supposed to protect the public, been more active in this area? This recall combined with the news stories about antidepressant drugs increasing the risk of suicides among teenagers raises troubling concerns as to the adequacy of FDA's drug safety monitoring program," said Chairman Davis.

A copy of the letter follows:

October 5, 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:

On September 30, 2004, Merck & Co., Inc. (Merck) announced the voluntary worldwide withdrawal of Vioxx, an arthritis and acute pain medication taken by more than two million people worldwide. This decision was based on a clinical trial study that suggested Vioxx might increase the risk of heart attack and stroke. The study was designed to determine whether Vioxx protects against the reoccurrence of colon polyps, not to assess the drug's efficacy and safety.

Several recent news reports have suggested that concerns regarding Vioxx first surfaced in 2000, just one year after Vioxx received the Food and Drug Administration's (FDA) approval. A study that compared Vioxx to naproxen, an aspirin-like drug, showed patients on Vioxx suffered from a slightly increased risk of cardiovascular problems. Subsequent studies indicated the use of Vioxx led to heightened cardiac and stroke risks. In 2002, following Arthritis Advisory Committee meeting, the FDA required an additional warning on the drug's label. Despite the mounting evidence that continual use of Vioxx poses increased health risks, the drug was recently approved by the FDA for the relief of symptoms from juvenile rheumatoid arthritis in children 2 years and older.

In light of Merck's withdrawal of Vioxx from the market and other recent news stories examining FDA's review of the safety and efficacy of anti-depressant drug use by children, I am concerned whether FDA has been sufficiently aggressive in monitoring drug safety. To better understand FDA's post-approval surveillance on the safety of medication, please respond to the following questions and provide the necessary records and documents by October 19, 2004:

1. Describe the adverse event reporting mechanisms FDA has in place to learn of any potential warning signs or harmful side effects of drugs?
 - a. Are pharmaceutical companies required to collect adverse event reports and provide that data to FDA? If so, provide the dates and means of communication that Merck used to notify FDA about Vioxx.
 - b. How many reports from patients did FDA's MedWatch receive regarding Vioxx or other COX-2 inhibitor drugs over the past five years? What action, if any, did FDA take in response to these reports?
 - c. Is FDA aware of any deaths that can be attributed directly or indirectly to the use of Vioxx or other COX-2 inhibitor drugs?
2. When did Merck first alert FDA of their data linking Vioxx to an increase in heart risk? Provide the date, the information received, and what action, if any, FDA took in response.

3. FDA required additional labeling for Vioxx in 2002 to alert the public to an increased risk of heart problems following the recommendations of the Arthritis Advisory Committee.
 - a. What additional oversight or review of Vioxx did FDA take after the warning label was required in 2002?
 - b. Does FDA require companies to perform safety studies and report those findings to FDA? If so, how often are the studies required and who within FDA is responsible to review them?
 - c. Please provide a copy of the warning label for Vioxx implemented in 2002.
 - d. Please provide the documents, analysis, and studies submitted by the Arthritis Advisory Committee to FDA that led to the additional warning for Vioxx.

4. According to press accounts, when Merck voluntarily withdrew the drug from the market, FDA was in the process of reviewing additional reports showing the increased risk of cardiac attack and stroke with the use of Vioxx.
 - a. How long had FDA been reviewing this data and who in FDA was responsible for reviewing it?
 - b. How many studies has FDA conducted on the safety and efficacy of Vioxx following its approval in 1999?
 - c. Why did FDA not order a stricter second warning on the drug's label following an August 2004 FDA statistical study of patients from the Kaiser Permanente Health System?
 - d. Did FDA plan to initiate a study involving individuals after the Kaiser Permanente statistical study showed an increase in heart and stroke risk?

5. Does FDA plan to examine potential harmful side effects in other COX-2 inhibitor drugs on the market such as Celebrex and Bextra?
 - a. What are the parameters of the study and when will it begin?
 - b. Does FDA plan to request more safety data from Merck regarding Arcoxia, their second-generation version of Vioxx, which is currently under review for FDA approval?

Sincerely,

Tom Davis
Chairman

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