[ERRATA]
RISK AND RESPONSIBILITY: THE ROLES OF FDA AND PHARMACEUTICAL COMPANIES IN ENSURING THE SAFETY OF APPROVED DRUGS, LIKE VIOXX

HEARING

BEFORE THE

COMMITTEE ON GOVERNMENT REFORM

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ERRATA

The prepared statement of Hon. Charles W. Dent was not included in the hearing record and appears below.

[The prepared statement of Hon. Charles W. Dent follows:]

Statement for FDA/Vioxx Hearing from Congressman Dent:

Thank you, Chairman Davis, for holding this very important hearing on the roles of the FDA and pharmaceutical companies in ensuring the safety of approved drugs.

It is extremely important that prescription drugs are safe and effective. I am encouraged by the FDA's drug safety initiative of the creation of the Drug Safety Oversight Board (DSB). The DSB will provide oversight and advice to the Director of FDA's Center for Drug Evaluation and Research (CDER) on the management of important drug safety issues and will manage the flow of emerging safety information through FDA's recently proposed Drug Watch Web site to health care professionals and patients.

While I am concerned about the possible underestimation of the risks involved in the long-term use of any and all drugs, I applaud Merck's voluntary withdraw, independent of FDA input, of the drug Vioxx from the market, in September 2004. While the subsequent studies of the drugs Bextra and Celebrex were also found to have links to cardiovascular risks, earlier this year (February 2005) the FDA Advisory Committee endorsed the continued marketing of Bextra, Celebrex, and Vioxx, finding the benefits of the drugs outweighed the risks, in that Vioxx is considered safer for the stomach than aspirin and other anti-inflammatory drugs. Several months later, in April 2005, upon FDA review of the Advisory Committee's recommendations, the FDA asked to withdraw Bextra from the market and requested the inclusion of a "black box" warning regarding cardiovascular risks on Celebrex labeling. However, it made no official ruling regarding Vioxx because of Merck's voluntary removal.

It is important that we work to restore confidence in our nation's drug supply. The FDA must facilitate early and accurate information regarding the risks and benefits of prescription drugs to health care practitioners and patients. The FDA must communicate to the public the latest information regarding prescription drugs so that the patient, along with his or her physician, can make the best possible treatment decisions. We must also be sure that drug companies are not burying information about a drug's safety or effectiveness.