

Chairman Dingell, Subcommittee on Health hearing entitled "Assessing the Safety of Our Nation's Drug Supply"

Statement of Congressman John D. Dingell, Chairman
Committee on Energy and Commerce

SUBCOMMITTEE ON HEALTH
HEARING ENTITLED "ASSESSING THE SAFETY OF OUR NATION'S DRUG SUPPLY"
May 9, 2007

Mr. Chairman, thank you for holding this important hearing. We are here to discuss the safety of our nation's drug supply.

What does it mean to say that a drug is FDA approved? Good government would say that the Food and Drug Administration approval should be the "gold standard" throughout the world that the drugs approved provide needed therapies for consumers without causing further medical complications or, worse, death. Unfortunately, FDA approval of pharmaceuticals as the "gold standard" has been called into question. Incidents highlighted by the recall of the arthritis drug, Vioxx, have created a crisis of confidence in the Food and Drug Administration.

I have publicly expressed my dissatisfaction with the way in which FDA has handled the important issue of drug safety. FDA's lack of transparency and recent recalls have greatly contributed to the loss of public confidence. The agency must aggressively monitor and assess safety and efficacy throughout the entire lifecycle of a product. Simply stated, FDA must ensure that just as much time, resources, and energy are invested in aggressive post-market observation as is spent in pre-market trials, consultation and meetings with industry.

A recent Institute of Medicine report concluded that FDA and the pharmaceutical industry do not consistently communicate safety concerns in a timely and effective fashion. In addition to insisting on structural and resources changes within the agency, we must also continue to push for cultural change at FDA. Public health policy is ultimately a human enterprise, and all facets of FDA's drug programs must work in a coordinated fashion for a common purpose; namely, assuring consumers that the drugs they take are safe and effective.

FDA has taken steps to boost consumer confidence. In 2004, they introduced a new drug safety initiative that promised to promote a culture of openness and enhanced oversight within the Agency and have included additional drug safety provisions in its recent PDUFA proposal. The agency also asked the Institute of Medicine to evaluate its current system of drug safety and make recommendations for improvement.

The Government Accountability Office (GAO) has also weighed in, and in 2006 released a report on FDA's ability to ensure a safe drug supply. That report included a number of recommendations. I am pleased that a representative from GAO is here to discuss this report. While we appreciate these efforts, it is not clear whether they are sufficient. We are here today to see what additional steps the Congress may need to take so that U.S. citizens are protected and confidence in the Agency is restored.

I appreciate this hearing and look forward to the testimony of our witnesses and the input of our Members as we discuss the safety of the U.S. drug supply.

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Prepared by the Committee on Energy and Commerce
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