Committee On Finance
Max Baucus, Ranking Member

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Statement of U.S. Senator Max Baucus
"FDA, Merck and Vioxx: Putting Patient Safety First?"

Thank you, Mr. Chairman, for holding this hearing. The withdrawal of the pain-killer Vioxx from the market has raised serious questions.

Two million patients were taking Vioxx in late September when Merck pulled it due to concerns about the increased risk of heart attacks and strokes. While we do not know the true extent of the risk, tens of thousands of patients potentially could have suffered a heart attack or stroke as a result of the drug.

This hearing is an opportunity to take a hard look at what happened with Vioxx. But this hearing goes beyond Merck and Vioxx. We must think critically about the way we test and evaluate drugs to ensure their safety.

In the weeks since Merck withdrew Vioxx, many questions have been raised. Questions like:

- When did Merck know about the potential dangers of Vioxx?
- And should the company have acted sooner to withdraw the drug?
- Why didn't the FDA detect the risks associated with Vioxx during the initial approval process, or even in the 5 years since approval?
- Does the FDA have sufficient resources, authority and independence to ensure that the drugs it approves are safe?
- And should we be doing more to monitor drug safety after a drug has been approved?

These questions, and many others, must be answered so that medications do not pose a risk to Americans' health. These issues are critical to Medicare and Medicaid beneficiaries. In the 5 years that Vioxx was on the market, Medicaid spent more than $1 billion on the drug. And Medicaid bears the cost of any additional medical care necessary when drugs cause injury.

Furthermore, in just over a year, Medicare will begin covering prescription drugs through the optional Part D benefit. We need to be certain that beneficiaries of the new program are not exposed to potentially harmful medications.

I am concerned that what happened with Vioxx may have been due, in part, to insufficient emphasis on complete, rigorous, and expansive clinical trials. Clinical trials focused on drug safety should not stop when the FDA approves a drug. We need to continue testing drugs to thoroughly evaluate the potential risks, not just the benefits.

Clinical trial results should be more transparent. The conduct and reporting of clinical trials is critical to approving a new drug. And we must continue to evaluate and monitor drugs even after they are approved to ensure their safety and effectiveness.

In addition, I have encouraged drug manufacturers to expand the number of patients who participate in clinical trials, including patients in rural areas such as Montana.

I also support greater use of studies that test the comparative effectiveness and safety of drugs in similar therapeutic classes. The Medicare bill that passed last year designated $50 million for these studies. And I have supported raising the level of funding to $75 million. But the current Senate appropriations bill only includes $15 million. We should do more.

Finally, the Vioxx situation raises serious concerns about the broad implications of the medical malpractice reform bill currently being considered by the Congress.

Liability restrictions in this bill apply not just to doctors and hospitals. They also include pharmaceutical and medical product manufacturers, such as Merck. And the legislation creates new protections for products approved by the FDA, like Vioxx.

Given the events we are discussing today, I think the Congress and the public need to take a hard look at this legislation. I hope that today's hearing will shed light on recent events. And I look forward to hearing from our witnesses. Thank you, Mr. Chairman.

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