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Statement of Rep. Henry A. Waxman
For the Hearing, "The Roles of FDA and Pharmaceutical Companies in Ensuring the Safety of Approved Drugs, Like Vioxx."

May 5, 2005

Thank you, Chairman Davis, for holding this hearing today. I also would like to thank you and your staff for leading this investigation into drug safety in the United States. You have asked tough questions and requested the information that the Committee needs to perform its essential oversight function.

On the subject of Vioxx, there are many tough questions. Today's hearing focuses on one of the most important: Why did so many doctors prescribe so much Vioxx for so long?

Vioxx was approved in May 1999. Less than a year later, Merck announced that in a major clinical trial, Vioxx was associated with four to five times more heart attacks than naproxen, another anti-inflammatory drug. Over the next year and half, additional concerns were raised by an FDA advisory committee and by articles in the *New York Times* and the *Journal of the American Medical Association*.

Yet sales continued to surge. Vioxx reached $2 billion in sales faster than any drug in Merck's history. At the time of its withdrawal, after the cardiovascular risks were confirmed in another major study, over 100 million Vioxx prescriptions in the United States had been filled.

We now know that many of these prescriptions were dangerous and unnecessary.

Overprescription of a dangerous drug can be a public health disaster. In the case of Vioxx, experts have estimated that as many as 140,000 Americans may have suffered unnecessary heart attacks, strokes, and other serious medical complications from the drug.

It is critical to understand what went wrong. Why did doctors write so many Vioxx prescriptions even as evidence of harm mounted?

An important issue is whether FDA reacted too slowly to evidence of Vioxx's dangers. It took FDA over two years to add a discussion of cardiovascular risks to the Vioxx label. FDA

took nearly three years to conduct its own epidemiological study of Vioxx's safety. And the agency never forced Merck to conduct a study specifically to address cardiovascular safety.

My conclusion is that FDA should have done more to understand the risk and protect the public. The question we all need to ask is how we can prevent this from happening in the future. Congress needs to give the agency new authorities and additional resources to ensure the safety of drugs after they are approved and marketed.

Today, we will also discuss Merck's actions. Let me start by saying that Merck deserves credit for conducting important research on Vioxx's safety, presenting this research at major medical meetings, and publishing the studies in leading medical journals.

But a company's responsibility does not end with publishing its research. What Merck said about its research findings to doctors and consumers — and what Merck failed to say — has critical importance.

One part of this equation is well known: Merck's direct-to-consumer advertisements. Merck spent over $300 million dollars on consumer advertisements for Vioxx. Probably everyone in this room saw Dorothy Hamill on television skating in circles on behalf of Vioxx.

Today, we will focus on the hidden side of pharmaceutical promotion: how Merck communicated about Vioxx to physicians.

Merck employed more than 3,000 sales representatives to promote Vioxx to doctors and hospitals. These Merck representatives were extraordinarily well trained. Our Committee has examined more than 20,000 pages of documents. These documents show that Merck trained their sales force to exploit virtually every interaction with physicians.

Merck and the drug industry say that the role of drug representatives is to educate doctors about new products and new medical research. But the documents tell a different story.

The goal was sales, not education. Merck representatives were instructed to use subtle gestures to subconsciously gain the trust of physicians. They were permitted to discuss only "approved" journal articles, defined by Merck as articles that "provide solid evidence as to why [doctors] should prescribe Merck products." And health risks were viewed as "obstacles" that the sales force was instructed to surmount.

The first evidence of Vioxx's health risks were disclosed in March 2000, when Merck published the VIGOR study. This study showed that Vioxx had five times greater cardiovascular risks than naproxen.

Doctors naturally asked Merck's representatives about the implications of Merck's study. In response, Merck gave its representatives a "Cardiovascular Card" that indicated that Vioxx was actually eight to eleven times <u>safer</u> than anti-inflammatory drugs like naproxen.

As we now know, this Cardiovascular Card was inaccurate and misleading. The data it cited did not support Merck's conclusions. During a staff briefing earlier this week, an FDA official said that the relevance of the studies presented in the card to the cardiovascular safety of Vioxx was "nonexistent." According to the official, it would be "ridiculous" and "scientifically inappropriate" to use the data in the way Merck did.

Eleven months after the VIGOR study, an FDA advisory committee met to consider the study's implications. The committee concluded that doctors should be advised about the risks that Merck had found.

But here's how Merck responded: the very day after the FDA advisory committee said that doctors should be informed about the VIGOR study, Merck sent a bulletin to its sales representatives that stated: "DO NOT INITIATE DISCUSSIONS ON THE FDA ADVISORY COMMITTEE ... OR THE RESULTS OF THE ...VIGOR STUDY."

The same thing happened in May 2001 after a *New York Times* expose highlighted the dangers of Vioxx. Merck sent a bulletin to its field representatives that stated: "DO NOT INITIATE DISCUSSIONS ON THE RESULTS OF THE ... VIGOR STUDY OR ANY OF THE RECENT ARTICLES IN THE PRESS ON VIOXX."

Instead of informing doctors about the risks of Vioxx, Merck told its representatives to continue to rely on the highly questionable Cardiovascular Card. In fact, Merck gave its sales force a specific script to use with doctors when showing them the card, telling them to say to doctors that the cardiovascular mortality of Vioxx was eight times lower than other drugs.

A few months later, *JAMA* published a critical article about Vioxx's safety risks. Merck's response was to launch "Project Offense" to overcome the cardiovascular "obstacle." Its sales team was told to "quickly and effectively address all physician obstacles and return to the core messages for VIOXX."

The Merck documents are complex and the details are important, so my staff prepared a detailed briefing memo that summarizes the key documents and places them in perspective. I will make this document available to members and the witnesses.

When I step back and look for the big picture, here's what I see. Merck says the mission of its 3,000-person sales force is to educate doctors. This sales force is given extraordinary training so that it can capitalize on virtually every interaction with doctors. Yet when it comes to the one thing doctors most needed to know about Vioxx — its health risks — Merck's answer seems to be disinformation and censorship.

Merck's sales representatives were trained to sell as if lives depended upon it. But ultimately, their message may have cost lives instead.

This is not an easy hearing for me. I have worked with Merck for decades, and I know that Merck usually has high standards for corporate conduct and has produced many life-saving drugs.

But the purpose of oversight is to ask the hard questions. And the case of Vioxx reveals a side of pharmaceutical marketing that is rarely exposed. It is essential for the public, medical professionals, and FDA to be aware of what happened here, so that we can prevent unnecessary injuries to patients in the future.

I thank the witnesses for coming and look forward to their testimony today.