

What's needed on prescription labels

WHEN VIOXX was pulled from the market, it was predictable that other drugs in its class of Cox-2 inhibitors might follow. The drug's manufacturer, Merck, stopped selling its top painkiller after studies showed that Vioxx doubled heart attack and stroke risk. Now the Food and Drug Administration has ordered Pfizer to remove the painkiller Bextra, leaving only one Cox-2 drug on the market, Celebrex.

The FDA also announced that "black box" warnings must be added to many other painkillers, including household names like Motrin. These warnings might increase consumer awareness of drug risks, but they are not enough. That's because risks must be interpreted in the context of benefits. With big benefits and no good alternatives, people might accept substantial drug risks. But with small benefits, or safer alternatives, people may not accept any extra risk. You need balanced information about benefit and risk to decide whether drugs are worth taking.

Instead, consumers get billions of dollars of advertising remarkably light on facts. Risk information is typically buried in fine print. And benefit information is even harder to find: The most basic information of how well drugs work is hardly ever provided. Instead, ads use vague promises like "Zyrtec works" and Crestor for cholesterol lowering "when diet and exercise aren't enough" – rather than telling

consumers how well Zyrtec works or whether cholesterol lowering with Crestor translates into fewer heart attacks or deaths.

Drug companies do this because the FDA lets them. The more heavily advertised a drug, the more patients ask their doctors for prescriptions. Nearly one-quarter of Americans incorrectly believe that only "extremely effective" drugs can be advertised. Consumers would be surprised to learn how small the benefits of many drugs are particularly compared with older, possibly safer alternatives.

But drug ads don't have to be so uninformative. Imagine a prescription drug facts box, modeled after the nutrition facts box you see on packaged foods. Instead of calorie counts and daily requirements, the prescription drug facts box would convey crucial information about benefit and risk in a form people could understand.

The box would contain information

Prescription Drug Facts: Benefit of Vioxx			
In a study, people with arthritis either took Vioxx or Ibuprofen Here are the percents of people who said the following after 6 weeks			
Patient's rating of the medication on their arthritis symptoms	Given Ibuprofen	Given Vioxx	Effect of Vioxx
Excellent effect	9 %	9 %	Same
Good effect	43 %	50 %	More
Fair, poor or no effect	48 %	41 %	Fewer

on the experience of people who did or did not take the drug. How their experience was measured would depend on the drug's purpose. For medications treating symptoms, the measure would tell how many people felt better; for drugs preventing disease, how many got sick; for drugs that save lives, how many died. The box would present drug risks and prioritize them by presenting life-threatening ones plus the most common bothersome ones. Where would this information come from? It already exists – buried in FDA approval documents.

Consider what a prescription drug facts box might have said about the benefit of Vioxx. A 60-year-old with knee or hip pain could expect a 9 percent chance of an "excellent response" to Vioxx, a 50 percent chance of a "good response," and a 41 percent chance of a "fair, poor, or no response." Almost identical to people's response to good old Ibuprofen. Consumers knowing Vioxx provided no extra

benefit over an older and presumably safer drug might not have accepted any added risk; including the risk inherent in all new drugs: that we simply don't know how its safety record will hold up over time.

Last year we tested consumer reactions to the benefit part of a Vioxx prescription drug facts box. Before seeing the box, fewer than 20 percent of people believed that Motrin was as effective as Vioxx for arthritis pain. After seeing the box, this proportion almost tripled. The 200 consumers in our study found the box easy to understand, and more than 90 percent preferred ads with a box rather than the standard version without it.

If FDA wants consumers to have the information needed to make good choices, it should think outside "black box" warnings. If drug companies are allowed to continue direct-to-consumer advertising (the United States is one of two countries allowing it), they should have to provide a prescription drug facts box to tell consumers how much help they can expect from this drug and how big the benefit (or risk) is compared to others with more-established safety records.

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