PATIENT SAFETY BLOG

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Murky Research: The New Era of Prescription Drug Safety

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Time was when the Food and Drug Administration would give a new drug the go-ahead for marketing based on a handful of studies involving no more than a few thousand patients. Then millions of prescriptions would be written over the next few years, and the drug would finally have its real test of safety on the open market, with the American consumer as the guinea pig. If the drug flunked the real-world test, it would be taken off the market, with a flurry of product liability lawsuits and calls for regulatory reform. This script is familiar from fen-Phen to Vioxx.

Now with the FDA's decision to split the baby in half with the diabetes drug Avandia, many are saying a new and different era of prescription drug safety is upon us. Instead of the old Up-Or-Down, and

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sometimes later Out, the FDA is setting up what one drug industry commentator, Gooznews, calls Permission Slip Medicine.

To get a prescription filled for Avandia -- and presumably other controversial drugs down the road -- a patient will have to hand the pharmacist a signed slip of paper acknowledging that he or she has discussed the medication with the doctor and both have decided together that they really, really want to have this drug, despite the availability of other alternatives like Actos which doesn't seem to carry the risk of heart attack and stroke that Avandia apparently has.

I say "apparently has" for Avandia, because the drug agency says it's not really sure. Part of its decision to punt on Avandia, keeping it available but harder to get, included posting on the FDA website a series of memos from top level agency staffers showing how very sophisticated drug reviewers could read the same studies and come to opposite conclusions on safety and the need for more research. Click here to see the memos. Note the contrast between the memo by FDA firebrand David Graham, who wanted Avandia yanked completely from pharmacy shelves, as has happened in Europe, and more conciliatory memos by long-time agency officials like Robert Temple.

In the old days, the other option for an in-between drug like Avandia would have been to add a dire statement to the official product labeling about the newly discovered risk. This has already happened for Avandia. These warnings are often called black box warnings because they appear in bold face at the very beginning of the columns of dense prose of the official language published in the Physicians Desk Reference and various online sources.

But who reads the black box warnings? Certainly lawyers like me do, when a client comes calling with a serious injury or death and it turns out the drug culprit didn't have such a black box warning, or their doctor didn't mention it to them. But if my experience is any measure, many doctors pay little attention to the official label. That's part of the long-running scandal of prescription drug education in the United

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States, which is dominated by the legions of drug salespersons who regularly trundle their briefcases of free samples and glossy handouts down the back hallways of doctor offices.

The new FDA action is intended to force doctor and patient to sit down quietly together and make a reasoned decision about whether this drug is right for this patient, despite the bad stuff that has happened to other people. That may be a good thing.

Avandia is one of the growing class of drugs that once you're on it, you swallow the pill every day for the rest of your life. The goal for Avandia is to lower blood sugar in diabetics, and that can prevent other bad long-term issues like diabetic blindness (retinopathy) and kidney disease. So the good intent is there.

But with a safer alternative apparently out there, what's the point of loading extra risk onto the patient? That's a dialogue that the FDA has now shifted from its officials onto the desks of individual doctors.

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