

Jeff Susman, MD
Editor-in-Chief



Memo to FDA: Too much information

My daughter Katie recently asked me if a medication could be causing her friend's light-headedness. "Well," I opined, "That certainly wouldn't be a common side effect."

Then I made the mistake of consulting the *PDR* and reviewing the package insert.

I found the usual suspects—nausea, fatigue, and Yes, dizziness—and several oddball side effects, like increased sweating and vision disturbances, that I figured were flukes. And finally, "just a few" other problems to watch for. I gave up counting at 50.

Providing a data dump of every single problem ever reported leads to information overload.

Suffice it to say, this litany of side effects is useless to the average consumer. Providing a data dump of every single problem ever reported in a clinical trial leads to information overload. It's also misleading. While I guess it's a reflection of our litigious society, shouldn't the point of package inserts be to effectively inform patients and give them the guidance they need?

Although package inserts underwent a redesign in 2006, it seems that the FDA commissioners failed to inject some common sense. I have to believe that anyone doing even a modicum of consumer research would find that our current package inserts are worse than no information at all.

How about starting over and developing a schema, such as:

- common side effects which are often related;
- uncommon, but serious side effects; and
- side effects that are occasionally reported but are probably unrelated to medication use.

While we're at it, how about providing an expanded Medication Guide for every prescription drug that's dispensed?

So, Katie, the answer is that light-headedness, increased sweating, vision disturbances, and a whole bunch of other side effects are there in black and white. Tell your friend to talk to her physician and, if possible, to stop taking the medicine and see if the dizziness disappears.

Jeff Susman, MD
jfp@neomed.edu

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EDITORIAL OFFICE
Northeast Ohio Medical University
4209 State Route 44; PO Box 95
Rootstown, OH 44272
Telephone: (330) 325-6254

PUBLISHING OFFICES
Quadrant HealthCom, Inc.
7 Century Drive, Suite 302
Parsippany, NJ 07054
Telephone: (973) 206-3434; Fax: (973) 206-9378