Getting Drug Ads to Add Up: The FDA Thinks Less Is More

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How many of us have been blissfully paging through our favorite magazine, only to come upon a jarring page of eye-numbing type concerning the risks and side effects of a prescription drug? No one really reads those “ads,” so why are they there?

Well, don’t blame the manufacturers. They are simply doing, more or less, what the U.S. Food and Drug Administration (FDA) has instructed them to do. All print ads for prescription drugs must contain a “true statement of information in brief summary relating to side effects, contraindications . . . and effectiveness.” “Brief,” according to the FDA, means detailed information on all specific side effects and contraindications.

Companies fulfill their responsibility to include this “brief summary” (a true oxymoron) by reprinting the product-specific risk portions of the professional labeling. They take the information from the folded insert in the product carton and toss it onto the printed page, word for word. This is not a requirement, but companies have been doing this simply to stay on the right side of the FDA’s enforcement office.

Thankfully, the FDA is finally agreeing that those eye-fogging pages of verbose summaries regarding risks are flunking the test of usefulness. That is why the agency published proposed changes in its February 2004 draft guidance on direct-to-consumer (DTC) drug advertising. Comments are coming in, and final guidelines will be issued later this year.

It should be noted that the FDA is concerned about more than just the opaque-ness of the brief summary information. The agency now realizes, according to testing results over the past few years, that drug advertisements, both in print and on television—whether they mention a specific drug or whether they are nonspecific “help-seeking” or “disease awareness” ads alerting readers and television viewers to general chronic conditions for which drugs are available—send consumers heading to their physicians.

Here is an interesting statistic: Of all patients who visited their doctors because of a drug ad they saw and who mentioned that prescription drug by brand name, 87% actually had the condition that the drug was intended to treat. For this reason, the FDA wants to encourage drug companies to handle their direct-to-consumer advertising appropriately.

As for the draft guidance documents, the FDA is considering whether to redefine the required brief summary to include elements of the patient labeling (as distinct from the FDA-approved professional labeling) incorporated into a drug package. The labeling for patients does not address each specific risk that is mentioned in the professional labeling. It simply contains the most important information that patients need in order to use the product appropriately, and it focuses on the most serious risks associated with the product and its less serious, but most commonly occurring, adverse reactions.

Another option might be to allow drug companies to reprint the “Highlights” section of the professional labeling, which was part of a proposed rule that was issued by the FDA in 2000. This section, which appears near the top of the professional labeling, was supposed to include key warnings and information about potential risks. Although the proposed rule has not been finalized, the FDA might let drug companies substitute the information that would be in the Highlights section for the current risk information as long as it is written in plain English.

The FDA is considering an even more radical option: deleting the separate page containing the risk information and condensing this material into bullet points in a “risk information window” within the body of a regular advertisement, with pictures and color.

As long as the FDA is trying to encourage responsible consumer analysis of drug claims, why not be truly innovative? Why stop at risk information? Perhaps the FDA might ask drug companies to simplify the drug effectiveness data in the professional labeling, with particular emphasis on the outcomes of clinical trials.

I once took the time to read this information for an expensive allergy drug that my physician had prescribed for me. Frankly, I was astonished by what I considered to be very ambiguous results. Not surprisingly, the nasal spray did nothing for me. At another time, after arthroscopic knee surgery, my orthopedist prescribed rofecoxib (Vioxx® Merck). I had been seeing all sorts of television ads for this new wonder drug. Vioxx®, however, did not work for me. I switched to generic Naprosyn® (naproxen), which worked much better.

Maybe the FDA ought to expand the proposed guidelines to cover drug effectiveness. Advertisements could contain language like the following: “This drug works well for everyone all the time”; or, conversely: “This pills work better for some than others, so don’t get your hopes up.”