PATIENT SAFETY BLOG

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Drug Ads Flout FDA Rules in Medical Journals

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Anyone who watches TV has been bewildered/amused/confused/annoyed by pharmaceutical ads that begin by explaining how your life can be perfect if you take this drug, and end with a rushed recitation of all the things that can go wrong if in fact you do take the drug.

Drug companies, of course, are obliged by the FDA to include potential side effects when they're trying to sell you their products. But as proved by a recent study in PLoS ONE (a journal for peer-reviewed scientific and medical research), Big Pharma pretty much thumbs its nose at the FDA when it advertises in medical journals, where it's trying to sell its wares to doctors.

Among the nine publications reviewed by researchers were such mainstream journals as Annals of Internal Medicine, New England Journal of Medicine and Journal of the American Medical Association. About half of the ads reviewed violated at least one FDA rule, and about one-third were "possibly" out of compliance because of missing information. More than half of the drug ads failed to quantify serious risks. Fewer than 1 in 5 adhered to all FDA guidelines.

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As explained by MedPage Today, the pharmaceutical industry spends $58 billion on marketing; the FDA's division of marketing and advertising has $9 million. So what are the chances a miscreant marketer will get caught?

To help bridge the budget gap, the FDA recently implemented the "Bad Ad" program, asking physicians to report nonadherent or misleading ads. But that's like asking the playground monitor to report bad behavior – what's bad to one monitor is just kids being kids to another. As the researchers noted, the guidelines are difficult to enforce, don't emphasize transparency and ignore basic information relevant to prescribing.

The most common breaches or possible breaches of rules were:

- misused references to the scientific literature;
- misleading use of graphics;
- failure to cite references;
- overrepresentation of the experience with the drug.

By medical specialty, at least one FDA rule was broken by ads for:

- 6 in 10 hematology/oncology products;
- 5 in 10 cardiovascular and diabetes products;
- more than 4 in 10 psychiatric products.

As the researchers wrote, "Advertisements do a poor job of conveying basic information necessary for safe prescribing, with the majority failing to quantify serious risks."

Despite their concerns, they said that "most advertisements we reviewed satisfied the majority of FDA guidelines." It makes you wonder, though, about the squishy nature of the guidelines – the

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researchers also noted that an ad that makes no specific claim about efficacy and does not quantify drug safety is still in compliance.

The study recommends that the FDA update and simplify ad regulations, and require ads to explain risks clearly, offer information on absolute benefits and verifiable references and identify the appropriate population for the drug's use.

All of that seems like a no-brainer. And another reason why, when your doctor prescribes a drug, you should ask what are the potential side effects and risks, and why he or she has chosen it over others. Read the patient information that's included in the drug packaging.

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