Warning: Newspaper Articles About the Law May Cause Drowsiness

By Reg P. Wydeven October 7, 2006

A few years ago I remember watching television when a commercial for Levitra came on. The ad showed a weary looking middle-aged man slouched over on his back porch. The voiceover explained that Levitra, a new prescription drug, could help you become the man you used to be. Presumably after taking some Levitra, the man was next seen running in his yard with his wife and then he threw a perfectly spiraled football through a swinging tire.

I had just turned 30 at the time, and our Legal Eagles rec-league softball team had just finished a disappointing season. Basketball season was starting soon, and at 30, I had lost whatever miniscule jumping ability and quickness I had in my 20s. Seeing the results the man in the commercial got, I considered taking the announcers advice to call my doctor and ask about Levitra to help become the man I used to be.

Thankfully a few weeks later I saw another Levitra commercial. This ad, however, explained exactly what problems Levitra was designed to straighten out. It turns out that it wasn't prescribed to put spring in your step but rather someplace else. The announcer in the commercial then went on to list many, many potential side effects of Levitra, some of which sounded rather unpleasant.

Feeling relieved that I never called my doctor, I remember later being confused why the pharmaceutical company would pay big bucks for a fancy TV ad only to list a ton of side effects that may scare off customers. The reason is because the federal Food and Drug Administration requires the drug companies to do so.

The FDA regulates prescription drug advertisements and other marketing material. Identified as "promotional labeling," these materials are disseminated by the advertised drug's manufacturer, packer or distributor. The FDA oversees promotional labeling found in printed materials, such as ads in magazines, journals and newspapers, or brochures. It also governs television and radio commercials, infomercials, pharmacy counter displays and billboards.

The FDA has identified three types of drug commercials: "reminder," "product-claim" and "help-seeking" ads. The first Levitra commercial I saw was a reminder ad - one that discloses the name of the product, describes the dosage form (tablet, capsule, or syrup) or price information. The FDA does not allow reminder ads to give the product's indication (use) or make any claims or representations about the product. Reminder ads are so named because they were traditionally used to remind doctors, who are already aware of the drug's name and its use, of its availability.

The second Levitra commercial was a product-claim ad, which includes both the name of a product and its use or a claim of the drug's benefits, such as safety and effectiveness. In exchange, the FDA requires the company to disclose risks and limitations of effectiveness. Known as "fair balance," drug companies can only tout the miraculousness of their drugs if they warn of all the side effects.

"Help-seeking" ads, which discuss a disease or condition and advise the audience to "see your doctor" for possible treatments, are not regulated by the FDA. Because no drug product is mentioned or implied, the ads do not need to include any risk information.

I only wish the FDA required the makers of Levitra to explain how their drug helps you throw a football through a tire.

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