When prescription drugs go OTC, ads talk less of harms: study

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Two different federal agencies monitor each, researcher explains.

(HealthDay)—When prescription drugs become available over-the-counter, advertisements for the medications are far less likely to tell consumers about the potential harms and side effects, new research finds.

The reason for it, experts say, likely has to do with which federal agency regulates the marketing materials for each type of drug. The U.S. Food and Drug Administration (FDA) regulates ads for prescription drugs, while ads for over-the-counter drugs are regulated by the U.S. Federal Trade Commission (FTC).

The FTC has much less stringent standards than the FDA for what manufacturers have to reveal about products in their marketing

materials, the researchers noted.

The FDA requires prescription drug advertising to provide consumers with a "fair balance" of risks and benefits— for drug ads, that often means rattling off a lengthy list of potential side effects.

The FTC, on the other hand, holds drug advertisements to the same standards as other consumer products, requiring a "reasonable" standard of truthfulness.

The looser requirements mean that information about potential side effects and harm aren't included in most over-the-counter drug ads, said study author Dr. Jeremy Greene, an associate professor in the history of medicine department and the department of medicine at Johns Hopkins University.

"One of the FDA's guiding principles for regulating direct-to-consumer ads for prescription drugs is there needs to be a fair presentation of the risks and benefits," Greene explained. "The FTC has fewer requirements or specific regulations for how risks and benefits should be presented. The FTC is interested in making sure there are no fraudulent statements being made, and there is no active deception."

The findings are published in the Sept. 12 issue of the Journal of the American Medical Association.

Greene and his colleagues analyzed print and broadcast advertisements for four commonly used drugs that were heavily marketed to consumers as prescription drugs and then approved for sale over-the-counter.

The drugs included loratadine (brand name: Claritin, sold over-the-counter since 2002), omeprazole (brand name: Prilosec, went over-the-counter in 2004), orlistat (brand name: Alli, Xenical, sold over-the-

counter since 2007), and cetirizine (brand name: Zyrtec, sold over-the-counter since 2008).

When the drugs were available only by prescription, 70 percent of the ads mentioned potential harms. After the drugs were available over-the-counter, only 11 percent did, the investigators found.

After drugs became available over-the-counter, only about half of print and broadcast advertisements mentioned a drug's generic name, compared to 94 percent of ads when drugs were prescription-only. Knowing a drug's generic name can help consumers make sure they're not taking more than one medication that has it as a component, risking overdose, Greene explained.

To give consumers the information they need to better understand risk, the FDA should be given authority to regulate marketing of over-the-counter drugs, or perhaps the FTC should adopt guidelines similar to what the FDA requires, according to Greene.

That said, few think even the FDA's "fair balance" guidelines are sufficient enough to really inform, he added.

Drug company advertising often includes a laundry list of potential side effects. That offers consumers little way to determine which risks they should pay the most attention to, or which risks should impact their decision-making about taking the drug, said Diane Pinakiewicz, president of the National Patient Safety Foundation.

"That is fulfilling the fair balance requirements, but the real purpose should be education of the consumer on the benefits and the risks of a drug in language people can understand, and fair balance doesn't do that effectively at all," Pinakiewicz said.

With consumers getting even less information about the risks of over-the-counter drugs, she suggests people consult with their physicians or their pharmacist about any medications they're taking.

Overdoses on acetaminophen (Tylenol) or ibuprofen (Advil) have become all too common, Greene added, highlighting that even the most commonplace drugs can have a downside.

"Once a drug becomes over-the-counter, it can still be quite dangerous and possibly fatal," Greene said.

More information: The Consumer Healthcare Products Association has more on over-the-counter drug safety.