

## FDA to Study Designs of Direct-to-Consumer Drug Ads

By Emily P. Walker, Washington Correspondent, MedPage Today  
Published: December 30, 2008

WASHINGTON, Dec. 30 -- The FDA is planning a major study to determine whether the side-effect information required in television ads for prescription drugs is getting through to consumers.

The results of the study, plans for which were disclosed today in a Federal Register notice, may change how manufacturers can advertise prescription products to consumers.

For the study, FDA researchers will develop a series of mock TV ads for a fictitious blood pressure medication and show them to some 2,400 people over the age of 40.

While an announcer is reading the drug's risk information, the ads will show images that range from being very consistent with the risk information or very inconsistent with the risk information -- such as a couple walking on the beach.

Participants will be asked to recall risk and benefit information of the ads so researchers can gauge which versions of the ad promoted the most and least risk recall.

Current FDA rules require that prescription drugs include a "fair balance" of the risks and benefits of a drug. The so-called "major statement" of an ad must be presented in a "clear, conspicuous, and neutral manner." But determining whether the risk and benefits are given fair play is difficult, the FDA said in its Federal Register notice.

"Ads can present information in ways that can optimize or skew the relative balance of risks and benefits," the notice said.

"Do images of people frolicking on a beach counteract the risk information being presented?" said Allan Coukell, policy director at the Prescription Project, a drug-safety advocacy group.

Healthcare providers, Congress, and advocacy groups, such as the Prescription Project, have expressed concern with consumer ads' presentation of side effects.

"The concern is that every ad ends with the litany of risks; you sort of discount it," Coukell said.

According to the notice, visual images can influence processing risk-related information by distracting consumers and causing them to recall the benefits of a drug, while forgetting or ignoring the risk information.

The FDA also expressed concern that consumers' strong positive feelings for well-known brands -- giving the Advil brand of ibuprofen as an example -- may trump their ability to grasp the products' potential harmful effects.

The study would also evaluate the effectiveness of text in commercials to determine whether putting risk information in writing in addition to a voice-over might make the risks more memorable.

Similar studies have already shown that people are much better at recalling the benefits of a drug than its risks, according to Ruth Day, Ph.D., director of the Medical Cognition Laboratory at Duke University.

Participants in past studies, on average, can correctly recall 80% of the benefits presented in a drug ad, and only 20% of the risks, Dr. Day testified in a congressional hearing last May.

"Overall, side effects and other risks are disadvantaged relative to benefits," said Dr. Day.

A number of drug ads have come under congressional scrutiny in 2008, including ads for atorvastatin (Lipitor), epoetin alfa (Procrit), ezetimibe (Zetia), and the ezetimibe-simvastatin combination product (Vytorin). (See: [AMA Backs FDA Pre-Screening of Direct-to-Consumer TV Drug Ads](#))

The same issues have been raised about consumer ads for medical devices. (See: [Medical Device Direct-to-Consumer Ads Said to Need More FDA Oversight](#))

The Institute of Medicine recently recommended a two-year delay in direct-to-consumer advertising of new drugs following FDA approval, to allow time for unexpected side effects to be recognized.

Rep. Henry Waxman (D-Calif.), the incoming chairman of the House Energy and Commerce Committee, which oversees health and consumer protection issues, has said he supports giving authority to the FDA to block direct-to-consumer ads for new drugs on a case-by-case basis.

The FDA originally proposed the study in August 2007. It altered the design somewhat in response to public comments.

The public may submit comments on the revised proposal through Jan. 29, 2009.