

# Study finds majority of pharmaceutical ads do not adhere to FDA guidelines

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A study led by Mount Sinai School of Medicine researchers of 192 pharmaceutical advertisements in biomedical journals found that only 18 percent were compliant with Food and Drug Administration (FDA) guidelines, and over half failed to quantify serious risks including death. The study, is published online today in the journal *Public Library of Science (PLoS) One*.

"Marketing research has consistently shown that journal advertising is the most profitable form of drug marketing, with an estimated return on investment of five dollars for every dollar spent," said Dr. Deborah Korenstein, lead author of the study and Associate Professor of Medicine at Mount Sinai School of Medicine. "Our study, the first in nearly 20 years to provide a systematic assessment of the adherence of US advertisements to FDA guidance, shows that the current system is not in the best interest of the health of the public."

Researchers performed a cross-sectional analysis of prescription pharmaceutical advertisements published in nine journals in November 2008. They evaluated adherence to FDA standards and the presence of content that is important for physicians to use when safely prescribing the drugs. Of the 192 advertisements for 82 unique products, only 15 fully adhered to all 20 FDA Prescription Drug Advertising Guidelines. In addition, 57.8 percent of the advertisements did not quantify serious risks, 48.2 percent lacked verifiable references, and 28.9 percent failed to present adequate efficacy quantification.

"The limited resources of the FDA's Division of Drug Marketing and Advertising are a major barrier to successful regulation of the pharmaceutical industry's multi-billion dollar marketing budget," said Dr. Korenstein. "We are hopeful that an update in FDA regulations, with increased emphasis on the transparent presentation of basic safety and efficacy information, might improve the quality of information provided in physician-directed pharmaceutical advertisements."

Provided by The Mount Sinai Hospital

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