



## FDA program targets false or misleading prescription drug promotion

February 1, 2024

from the Food and Drug Administration

Article type: [FDA Update](#)

Topics: [Pharmacology](#), [Therapeutics](#)



The pharmaceutical industry spends billions of dollars each year promoting prescription drugs, with most of the money going toward marketing products directly to health care providers (HCPs).

Prescription drug promotion can provide HCPs with valuable information, but it is important to recognize if it's false or misleading.

The Food and Drug Administration's (FDA's) [Bad Ad Program](#) seeks to raise awareness in the medical community of potentially false or misleading prescription drug promotion and help HCPs learn how to evaluate promotional messages. If HCPs believe promotion is false or misleading, they can report it to the FDA by emailing [BadAd@FDA.gov](mailto:BadAd@FDA.gov) or calling 855-RX-BADAD.

As of October 2023, HCPs have submitted 2,932 reports of potentially false or misleading promotion to the Bad Ad Program, including for products that are indicated for pediatric patients. All of the reports have been or are being reviewed and investigated. If the promotion meets the criteria for further action, the FDA moves forward with a risk-based compliance strategy to stop the promotion. Even in cases where the report did not lead to a compliance action, it still served to inform the FDA where to focus ongoing surveillance activities.

The FDA's compliance action for false or misleading prescription drug promotion typically involves issuance of an Untitled or Warning letter to the pharmaceutical company. These letters serve to notify the company of the alleged violation and give it an opportunity to make prompt, voluntary corrections. In 2023, the FDA issued [five such letters](#).

Common issues identified by the FDA in prescription drug promotion include:

- omitting or downplaying risk information,
- overstating the drug's effectiveness,
- failing to present a fair balance of risk and benefit information,
- making unsupported claims about a drug,
- making misleading drug comparisons and
- promoting a drug that still is under investigation or is not FDA approved.

An example of a misleading claim is an ad that states a new antibiotic works in as little as three days, but the FDA-approved labeling states the primary endpoint in the clinical trial was 10 days and no data support a shorter treatment duration.

“Prescribers should be vigilant for these types of common issues when reviewing pharmaceutical companies’ materials,” said Catherine “Katie” Gray, Pharm.D., director of the FDA Office of Prescription Drug Promotion. “The FDA-approved product labeling is a great resource to check” (see <https://www.accessdata.fda.gov/scripts/cder/daf/>).

### **Common persuasive techniques**

The 2022 AAP technical report [Health Care Clinicians and Product Promotion by Industry](#) acknowledges that products made by the pharmaceutical industry are essential to provide high-quality care to children. The report also states that HCPs “have an ethical duty to recognize situations and marketing strategies that are designed to influence their choice of diagnostic and therapeutic options for their patients. At a minimum, health care clinicians should be aware of the techniques used to attempt to alter their behavior and guard against them.”

The table below summarizes techniques that have been shown to influence behavior change and decision-making.

Principles of influence	Examples
<b>Authority</b> People are more likely to take advice from experts.	Pharmaceutical companies sponsor key opinion leaders or experts to speak at medical meetings about their drug product.
<b>Reciprocity</b> People feel obligated to return a favor or repay in-kind when they are given something.	HCPs prescribe a drug after receiving drug samples.
<b>Commitment and consistency</b> People want to be consistent with their prior choices or commitments.	Recommending a drug once causes HCPs to continue recommending it in the future.
<b>Liking</b> People more often comply with requests made by people they know and like.	Friendly, outgoing or attractive pharmaceutical representatives with similar clinical backgrounds connect with HCPs to influence prescribing behaviors.
<b>Social proof</b> People tend to follow the lead of others who are in a similar situation.	If peers prescribe a certain medication, HCPs assume it's the "right" drug to prescribe.

“Providers can appreciate the science of persuasion and influence,” Dr. Gray said. “We are encouraged by the response we are seeing from providers alerting us when they identify promotion they think is concerning.”

*The FDA Office of Pediatric Therapeutics, Office of New Drug's Division of Pediatrics and Maternal Health, and Office of Prescription Drug Promotion contributed to this article.*

### Resources

- To report potentially false or misleading prescription drug promotion, email [BadAd@FDA.gov](mailto:BadAd@FDA.gov) or call 855-RX-BADAD.
- [Information on the FDA's Bad Ad Program](#)