

Bad Ad Program: 2010-2011 Year End Report

Background

On May 11, 2010, FDA's Center for Drug Evaluation and Research (CDER) launched the *Bad Ad* outreach program with the goal of encouraging health care professionals (HCPs) to recognize and report suspected untruthful or misleading drug promotion.

Led by CDER's Division of Drug Marketing Advertising and Communications (DDMAC), this effort was primarily designed to inform HCPs about what constitutes misleading promotion —from both a legal and clinical perspective — and provide them an easy process for reporting suspected violations to FDA.

Below are key highlights of the program's activities during its first year of operation.

- FDA Commissioner Hamburg kicked off the Bad Ad Program with a [letter](#) to more than 33,000 physicians, announcing FDA's efforts to “collaborate with health care professionals to address misleading promotion, wherever it occurs.”
- Concurrently, FDA released a [press announcement](#) marking the program's launch.
- DDMAC created an [informational video](#) about *Bad Ad*, citing examples of untruthful and misleading promotions. And how to report suspected violations.
- DDMAC created a *Bad Ad* [brochure](#) designed to educate HCPs about prescription drug promotion.
- Throughout the year, DDMAC representatives staffed exhibits at 15 medical conferences across the country, speaking with HCPs about how they can help stop misleading drug promotion. DDMAC representatives also conducted extended presentations at two U.S. teaching hospitals.
- On April 28, 2011, FDA hosted a live [Bad Ad webinar](#) for medical and pharmacy professionals with more than 400 attendees.

All of these efforts were intended to raise awareness in the medical community that HCPs can play a valuable role in helping FDA prevent untruthful and misleading prescription drug promotion.

Year One Data

Of the 328 reports of potentially untruthful or misleading promotion, 188 were submitted by HCPs, 116 were submitted by consumers, and 24 were submitted by representatives of regulated industry. Historically, prior to the *Bad Ad* launch, FDA received an average of about 104 reports per year. This number and diversity of reports received after the *Bad Ad*

program was launched indicates to FDA that the program was successful in raising awareness of untruthful and misleading promotion.

Of the 188 reports submitted by HCPs, 87 were identified for a comprehensive review, demonstrating a relatively strong level of knowledge in the medical community about what constitutes misleading promotion. Of the 116 reports submitted by consumers, 24 were identified for a comprehensive review. Of the 24 reports submitted by industry, 14 were identified for a comprehensive review. Many of the other reports helped to focus FDA's surveillance efforts in other ways or were referred to other FDA Centers (i.e., potentially misleading ads for dietary supplements sent to the Center for Food, potentially misleading ads for devices sent to the Center for Devices and Radiological health, etc.).

During the *Bad Ad* program's first year, FDA heard some criticisms of anonymous reporting. It was noted by some that anonymous reports could unjustly accuse some promotions of being misleading when in fact they may be appropriately aligned with regulations. For this reason it is noteworthy to mention that of all reports of potentially untruthful or misleading promotion during the first year of the *Bad Ad* program, only 4% were submitted anonymously.

Although FDA is encouraged by the significant increase in the number of reports of potentially untruthful or misleading drug promotion, the Agency does not view the total number of reports, or number of enforcement actions taken as the primary measures for program success. Instead, FDA's most important measure of success for this program is the heightened sense of awareness of misleading promotion among HCPs throughout the health care community and the likely useful deterrent this awareness has on drug promoters who might run afoul of regulation absent of such messaging.

Future plans

Based on the overwhelmingly positive feedback and response from the medical community, FDA expects to continue and expand its *Bad Ad* efforts in the coming years. Expansion includes the development of a web-based continuing education program. Aligned with the program's primary goal of educating HCPs, FDA will focus additional efforts on students and early career HCPs. FDA will also be actively seeking opportunities to collaborate with the nation's medical, pharmacy, and nursing schools to enhance student education and

will continue conducting presentations at U.S. teaching hospitals. Future activities will also include continued attendance of DDMAC representatives at trade shows across the country, including those of the:

- American Academy of Physician Assistants
- American Academy of Nurse Practitioners
- American Academy of Family Physicians
- American Academy of Pediatrics
- American College of Gastroenterology
- American Society of Health System Pharmacists

Highlights of Bad Ad Enforcement Actions

- [Derma-Smoothe Warning Letter issued 12/03/2010](#). The first action resulting from a Bad Ad complaint was on a particularly egregious website promoting a product for use in a vulnerable population.
- [Infergen Warning Letter issued 03/21/2011](#). A [promotional piece](#) was mailed directly to a clinical pharmacist who was concerned that the information overstated the effectiveness of the promoted product.
- [Savella Notice of Violation issued 04/28/2011](#). This Bad Ad complaint is representative of the types of promotion we hope to curtail in field-based settings. This regulatory action was supported by a signed statement from a physician outlining violative oral statements that were similar to statements made directly to DDMAC reviewers during the same time period.
- [Atelvia Notice of Violation issued 05/05/2011](#). This video footage of a violative product detail that occurred in a physician's office was posted to YouTube.com. Of note, is that this violation was reported to Bad Ad when the posted video had less than 20 views. As a result of this early reporting, DDMAC was able to prevent the violative video from being viewed by a much larger audience.
- [Vyvanse Warning Letter issued 05/06/2011](#). This Bad Ad report came from an astute nurse, who noticed that a promotional piece that was likely viewed everyday by the office's HCPs was misleading in that it was designed to hide the important risk information from plain view.

Thank You

Finally, FDA would like to thank each and every person who took the time to send a report to the *Bad Ad* Program. The majority of the reports to this program came from HCPs whose contributions have helped ensure the accuracy of the drug information that both HCPs and their patients use to make treatment decisions.

