



Getting Credit for Being An Informant: FDA's Bad Ad Campaign Receives CME Certification

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Apparently, in line with whistleblower inducements that often surface in Medicare fraud and abuse cases, the Food and Drug Administration (FDA) has decided to expand its efforts to encourage physicians to turn in drug companies that engage in questionable promotional efforts.

We have written about the FDA's Truthful Prescription Drug Advertising and Promotion campaign, known as the "Bad Ad" campaign, by which FDA, specifically FDA's Center for Drug Evaluation and Research's (CDER) Office of Prescription Drug Promotion (OPDP), has encouraged physicians to inform OPDP of potential illegal promotional activity. While not all complaints have triggered agency enforcement, OPDP has issued letters to drug companies for unlawful promotional activity citing the Bad Ad campaign. Recently, the campaign received a boost for visibility when an e-learning course, based on the program, received Continuing Medical Education certification. Here are some highlights of this new development:

- The training course is one hour and has been certified by different accreditation groups, such as the Accreditation Council for Continuing Medical Education, the American Nurses Credentialing Center, the Accreditation Council for Pharmacy Education, the American Association of Nurse Practitioner, and the American Academy of Physicians Assistants.
- The course includes videos, case study reports, and Q&A sessions.
- There are a number of categories or modules, which include:
 - The basics of the Bad Ad program;
 - FDA's history;
 - Prescription drug promotion requirements;
 - A message from the CDER Director, Dr. Janet Woodcock; and
 - Examples of proper and improper ads, using mock-up promotions for a fictional product.

It is difficult to predict whether there will be more Bad Ad-related complaints, although one might expect an uptick in volume. In addition, it is too soon to know whether there will be increased OPDP enforcement due to the CME-certified course. However, at a minimum, OPDP will increase awareness of its program.

Getting CME credit for learning how to inform on an industry that is your partner in curing disease? While we can accept OPDP's goal and intent to discourage unlawful promotional conduct, can Distinguished Informant Medals be far behind?

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