



## A Funny Thing Happened on the Way to the Pharmacists Meeting

Alan G. Minsk

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The Food and Drug Administration's (FDA) Office of Prescription Drug Promotion (OPDP) issued recently a Notice of Violation to a generic drug company for unlawful promotion.<sup>1</sup> While each enforcement letter has its own fact-specific deficiencies, a few items caught our eye. We will note our observations at the end of this Bulletin.

OPDP took exception to the generic drug company's exhibit banner for failing to provide important risk information and omitting material facts. Specifically, the banner made promotional claims but neglected to include any fair balance, such as contraindications, warnings and precautions, or common adverse events. The agency acknowledged that there was a statement at the bottom of the exhibit banner to see a booth representative for the full prescribing information and Important Safety Information. However, according to OPDP, "this statement does not mitigate the misleading omission of risk information." As a result, OPDP claimed the promotion misbranded the drug product.

### AGG Observations

1. The program where the exhibit banner appeared was at the American Society of Health-System Pharmacists meeting. Frequently, FDA objections occur where the promotional message is provided at medical meetings or large scientific conferences. However, as we remind clients, promotional messaging must be compliant wherever it appears.
2. The meeting occurred in Anaheim, California, not exactly the most common or attractive location for medical meetings (no offense to Anaheim). But see point #1. Compliance is compliance, no matter the U.S. location.
3. OPDP rejected the company's attempt to provide fair balance by referring the viewer to another location. As we constantly caution clients, if you provide the good, you must provide the bad. A company cannot draw attention to the positive claims but then direct the user to another place for the less-than-wonderful news without providing at least some negative, balanced information at the same spot as the promotional claim.
4. OPDP noted the exhibit banner was seen by two OPDP officials. **Remember:** anyone approaching a booth can be an FDA official. The individual need not introduce as an FDA official, and one must always be on one's best behavior. And, no, don't ask (as we have been asked by clients), if the individual visiting is from FDA. It doesn't matter. Compliance is compliance.
5. The letter was issued to a generic drug company. While most enforcement letters are sent to innovator companies with new drug applications, as they are more likely to promote, OPDP's jurisdiction applies to any application products.

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<sup>1</sup> The letter can be accessed at [www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/enforcementactivitiesbyfda/warninglettersandnoticeofviolationletterstopharmaceuticalcompanies/ucm447342.pdf](http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/enforcementactivitiesbyfda/warninglettersandnoticeofviolationletterstopharmaceuticalcompanies/ucm447342.pdf).

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