You Can Pay Now or You Will Pay Later: FDA Issues a Warning Letter to a Pharmaceutical Company for a Misleading Patient Co-Pay Assistance Voucher

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On March 29, 2016, the Food and Drug Administration's Office of Prescription Drug Promotion (OPDP) issued a Warning Letter to a pharmaceutical company for a patient co-pay assistance voucher that failed to include risk information, omitted material facts by not providing the full indication, and was not submitted on a Form FDA-2253.[1] Despite the uncertainty surrounding the agency's enforcement of off-label promotional activities, particularly in light of recent court cases, OPDP is not sitting idly. This is the second enforcement letter that OPDP has issued for unlawful prescription drug promotion in 2016.[2]

While the Warning Letter is fact-specific, here are some key points expressed by FDA. We will also offer our own observations.

Background

The co-pay assistance voucher provided the prescription drug's indication and made representations and suggestions about the product's efficacy without communicating any risk information. For example, it said that the product was "the #1 prescribed branded Rx treatment for head lice," and it "should be used as part of an overall head lice management program." The voucher referred patients to the product website and the package insert (PI) for additional information, but OPDP said these statements "do not mitigate the omission of risk information."

- The voucher failed to include a Limitation of Use, included in the Indications and Usage section of the package insert, and did not "adequately communicate" that the product was approved only for patients 6 months of age and older. OPDP acknowledged the company placed a statement about the age group on the bottom of the back page, but its placement and prominence were not sufficient.

- The company failed to include the promotional labeling to OPDP on a Form FDA-2253.

- OPDP required the company to take corrective action, including remedial messaging "using the same media, and generally for the same duration of time and with the same frequency that the violative promotional material was disseminated."

1 The Warning Letter can be accessed at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM493790.pdf (last accessed April 11, 2016).

2 OPDP's first Untitled Letter of 2016 is available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM482464.pdf (last accessed April 11, 2016).

AGG Observations

- Once again, OPDP is making clear that a company cannot provide the indication and positive, promotional messages and then direct the reader or user to another location for risk information. Any labeling or advertising material must include fair balance at the same time. So, while the company in this case referred the user to a product website and the PI, fair balance needed to be provided on the piece itself. The failure to provide any risk information while only providing positive, promotional messages, particularly in a piece directed to consumers, was likely a factor in the issuance of a Warning Letter, rather than a Notice of Violation.

- A company cannot truncate an indication in a labeling piece. The indication is the approved use and, in some cases, such as this one, might include a limitation of use. While, understandably, companies might not want to highlight a limitation of a product, particularly if there are space limitations with the promotional forum or venue, the indication is what it is. If there is a limitation, it must be prominently communicated in the material, not omitted or buried in text. We sit on a number of Promotional Review Committees for clients, and this is an area that we continue to see potential disclosure issues. We expect that we will see more OPDP enforcement in this specific limitation of use space.

- Qualifications, disclaimers, or more descriptive messages must be clear and prominent. In the Warning Letter example, the company offered information about the age group indicated for the product. However, it was placed at the bottom of the back page of a wordy, small-type voucher. Simply providing explanatory information in a promotional piece is not sufficient; it must be easily visible to, in OPDP's words, "mitigate the misleading impression" of the product's broader application.

- While we cannot recall OPDP issuing an enforcement letter against a company merely for failing to submit a 2253 form alone, it will enforce the requirement, described in 21 C.F.R. § 314.81, that labeling or advertising must be submitted to OPDP at the time of initial dissemination of the labeling or initial publication of the advertisement for the prescription drug product. Therefore, companies must ensure that all such promotional materials are submitted as required.

- Some in the industry have speculated that, in light of recent court decisions relating to off-label promotion, OPDP would not take action against unlawful promotion anytime soon. We have never held such a view that OPDP would, essentially, abdicate its compliance authority. While OPDP might be more cautious about when it decides to take enforcement action, it is reminding the industry that it is not going away anytime soon. Companies, particularly through their internal Promotional Review Committee process, must continue to be vigilant in reviewing materials to maximize regulatory compliance.

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