Alive and Kicking: FDA Issues Notices of Violation for Promoting Investigational Products as Safe and Effective

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The Food and Drug Administration's Office of Prescription Drug Promotion didn't take the summer off, despite the uncertainty surrounding any new enforcement action relating to off-label promotion. Specifically, OPDP recently issued two Notice of Violation letters to drug companies for promoting investigational new drugs as safe and effective. In the first notice, the company provided information about the product's use and efficacy in the main exhibit hall of the American Society for Clinical Oncology's (ASCO) annual meeting in June, next to displays of approved drugs.[1] OPDP took issue with three aspects of the displayed information that, together, it found to constitute unlawful promotional activity, making the investigational product "misbranded":

1. Use of the trade name without making it clear that the drug was investigational
2. Conclusory statements about the drug's benefits, when it had not been approved for any use
3. Claims of improved survival rate, but citing only animal trials and non-human studies; again, the investigational product was not approved

OPDP issued a second Notice of Violation letter to two companies, who are co-developing a product, for promoting the investigational new drug on their websites.[2] One company had a designated webpage with extensive product information on an investigational drug, including information on its use and potential benefits. Overall, OPDP found the webpage to be an attempt to shape public impression of the drug before it is approved. Some of the promotional activities flagged by OPDP are similar to those mentioned in the previous letter:

1. Use of a trade name without disclosing that the drug is investigational is misleading
2. Statements about the use of an unapproved product that are phrased as established facts suggest that the drug is safe and/or effective for those uses
3. A hard-to-find disclaimer that indirectly says a drug is not yet approved is insufficient to mitigate promotional claims made on the website

AGG Observations

1. FDA's regulations permit the scientific exchange of information on investigational drugs; however, FDA does not permit promotion of an investigational new drug as safe and effective. Companies should avoid conclusory and subjective statements and should provide objective and balanced data, period.
2. Audience perception and placement of information at medical meetings matters. In this case, FDA objected to the placement of information about an investigational product near information about approved products. In our experience, companies should have separate booths to distinguish between investigational and commercial products or, at a minimum, separate them within the booth. The blurring of lines can give the wrong impression that an investigational drug is approved if materials are in close proximity to commercial materials, without clear separation or delineation.

1 http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCcompanies/UCM518986.pdf.

2 http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM520687.pdf.

3. Related to Observation 2, if a company uses the trade name for an investigational product, it should make clear that the product is not approved and the trade name is pending FDA review. There is nothing inherently illegal by using a trade name in a prior-approval setting, but an unqualified trade name may convey approval, which is false and misleading. In addition, companies should remember that the agency can reject the proposed trade name before the application's approval.
4. OPDP has been relatively quiet with enforcement letters, particularly as it determines how it will address off-label promotion. However, in both of these cases, off-label promotion wasn't an issue. The product was investigational: there was no label. The letters focused on promoting an investigational new drug.
5. FDA often attends medical meetings, particularly national conferences. Agency representatives are not required to identify themselves and, if they see unlawful messaging, they do not need to wait for a competitor trade complaint. In this case, OPDP issued its Notice of Violation less than three months from the meeting date. While the enforcement letter did not mention the officials' presence at the ASCO meeting, it seems reasonable to expect they were there. Be careful. Be very careful.
6. The general impression given by a website is important. If information on an investigational drug is going to be shared on a company's website, it should be explicitly clear that the drug has not yet been approved as safe and effective. A disclaimer hidden in a sub-page that a visitor to the website would not easily be able to find is likely insufficient.

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