Words Are Very Unnecessary: FDA Issues Letter for Unlawful Video Interview

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In its 1990 hit, "Enjoy The Silence," Depeche Mode sings, "Words are very unnecessary, they can only do harm." The Food and Drug Administration's Office of Prescription Drug Promotion (OPDP) issued its second Untitled Letter in 2018 (also referred to as a Notice of Violation), informing a drug company that the statements made in a direct-to-consumer (DTC) video of an interview that featured paid and trained company spokespeople (here, a physician and the physician's patient) were unlawful.[1]

Background

- The DTC video made false and misleading claims about the prescription product's efficacy and risks, which included a boxed warning, and FDA expressed concern that the video failed to include any risk information. FDA found the omission especially problematic given the product's boxed warning.
- In the video, the physician spokesperson referred viewers to a non-branded link that redirected to a branded site and to their respective doctor for additional safety information. However, the agency said, "[T]his does not mitigate the omission of the risk information from the video."
- The patient spokesperson was asked about side effects, and she replied she did not experience any. FDA noted:

  > While the Patient Spokesperson's statements may be an accurate reflection of her own experience … these statements misleadingly suggest that patients using [product] will have similar results and will not experience side effects, further exacerbating the misleading impression created by the omission of risk information. The personal experience [of an individual treated with the product] … such as this spokesperson does not constitute support for the suggestion that other patients will not experience adverse events after starting [product] therapy and does not obviate the requirement to present risk information.

- At the end of the video interview, when there was an opportunity for the paid physician spokesperson to provide risk information, the physician failed to do so.
- The video also contained misleading claims about the product's efficacy. Specifically, the patient spokesperson said she experienced instant relief but, again, FDA noted that, while it might have been her personal experience, there was no evidence or data provided by the company to support this was a typical patient experience.

AGG Observations

- OPDP has not gone away and will take action when it believes promotional messaging is unlawful. While FDA has recently issued guidance on dissemination of off-label information, and we have written on the agency's (lack of) enforcement in this area, the Untitled Letter focused on false and misleading information.
- In the Untitled Letter, FDA reminds industry that risk information must be provided at the

1 www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCcompanies/ucm612143.pdf (last accessed July 16, 2018)

same time that claims of safety and efficacy are made. It is insufficient to direct the viewer to another location, such as a website, to see this information.

- It is important for a drug company to train third parties on FDA requirements, because they are agents for the company. At the end of the day, spokespeople are no different than company officials and, if they do not follow FDA rules and company policies (which, hopefully, comply with FDA rules), they need to be retrained, disciplined (if appropriate) and terminated (if there is a constant pattern of non-compliance). If a company wants the benefits of third-party statements, it must accept the risks as well.
- It is important that companies' Promotional Review Committees (PRCs) (or similarly-named groups) review the video scripts before the videos are produced. We serve as the legal representatives on many PRCs and, frequently, the videos are produced and then brought to PRC for signoff. If objections are raised, the response is often, "It's too late (or expensive) to redo the video." While we recognize that interviews cannot be scripted and conversations must have some spontaneity, reviewing a script or storyboard in advance (and seeing the video before it is distributed) can help mitigate potential regulatory risks.
- We often see the use of patient testimonials in promotional materials, such as social media. Personal experiences can have an impact. However, a sample size of one is subjective and is not scientifically sound. If the experience is not supported by evidence or data, atypical or otherwise overstates benefits (or understates risks), it can be misleading.
- Words, indeed, can be necessary and, in fact, may do no harm. But, be careful. FDA is listening.

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