Influencers Take Note: OPDP Issues Untitled Letter Regarding an Interview with a Brand Spokesperson

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On June 14, 2019, FDA's Office of Prescription Drug Promotion (OPDP) issued an Untitled Letter[1] regarding a direct-to-consumer video of an interview featuring a paid company spokesperson. Among other violations, OPDP noted that the video does not present balanced risk and benefit information and that it makes false or misleading claims or representations about the risks and efficacy of the promoted product. The Untitled Letter directs the product sponsor to cease distribution of the video. Below, we briefly describe the letter and lessons for companies that use paid or unpaid "influencers" (e.g., health care providers, social media personalities, or other "influencers") in their marketing.

Product

The product discussed in the video is a prescription-only topical solution indicated for dermatologic use. The product labeling includes a number of warnings and precautions, including potential blindness.

Video

The direct-to-consumer video featured an interview originally broadcast on ABC's "The View," on September 19, 2018. During the interview, cast of "The View" discussed the product with a physician who was also a paid company spokesperson. The video could be accessed through the company's social media channels on its Facebook® and LinkedIn® pages. The video was also available on the Internet via YouTube.® The product sponsor submitted a copy of the video and corresponding script to OPDP under cover of Form FDA 2253.[2]

The video included a discussion of the potential benefits of the product for patients with a specific skin condition, as well as a limited description of some product risks, and superimposed text ("Supers") with additional information. However, as discussed in more detail below, OPDP determined that the video failed to include prominent, balancing risk information and made false and misleading claims about the efficacy associated with the product.

Previous FDA Input

OPDP notes that the company previously sought and received advisory comments on draft presentations with certain similarities to the video, and that agency staff had raised a number of concerns. In particular, OPDP notes that, in advisory comments issued in March 2018, agency staff recommended that the company revise the proposed presentations so that they would not omit material information regarding the risks associated with the product or otherwise misrepresent important risk information. Agency staff also recommended that the company revise the proposed presentation so as not to overstate the efficacy for the product.

1 FDA may issue an Untitled Letter for violations that are under the threshold of regulatory significance for a Warning Letter. An Untitled Letter provides an opportunity for the notified person or entity to take voluntary action to correct the violation before the agency initiates an enforcement action. FDA does not make all Untitled Letters public, but does so under certain conditions (e.g., if the Letter may provide useful notice of issues that may be relevant to multiple regulated entities). Recent public Untitled Letters issued by FDA's Center for Drug Evaluation and Research (CDER), including this Untitled Letter, are available at: https://www.fda.gov/drugs/warning-letters-and-notice-violation-letters-pharmaceutical-companies/warning-letters-2019.

2 FDA Form 2253, T*ransmittal of Advertisements and Promotional Labeling for Drugs and Biologics for Human Use*, is a form developed by the agency to accompany the notification of promotional material required under 21 CFR § 314.81(b)(3)(i).

Violations Cited in Untitled Letter

The Untitled Letter sets forth OPDP's determination that the video makes false or misleading claims and/or representations about the risks associated with and the efficacy of the product, and that the video thus misbrands the product.[3] The Untitled Letter notes that distribution of the video is violative, and requests that the sponsor cease distribution of the video.

Among other FDA concerns, the Untitled Letter states that:

- The video did not provide a balanced presentation of risks and benefits.
- The agency is concerned that the company is promoting the product in a manner that fails to adequately present the serious risks of the drug or describe the efficacy of the drug in a truthful and non-misleading manner, despite previous direction from OPDP.
- The video is concerning to FDA from a public health perspective because it fails to include information regarding serious risks associated with [the product], which bears warnings and precautions related to the risks of serious eye disorders (such as permanent eye injury including blindness) and severe skin reactions.

With regard to risk, OPDP find the materials to be misleading, in that they omit material balancing risk information. In particular:

- The video features a discussion with a physician who is a paid spokesperson, in which there are claims and representations about the benefits of the product. However, the video fails to include prominent, balancing risk information.
    - First, the video fails to reveal serious risks that are reflected in the warnings and precautions for the drug and are intended to be communicated to patients as described in the prescribing information (PI) and Patient Information (PPI).
        - OPDP acknowledges that, in addition to the spokesperson referring consumers to the product website for more information, the video includes Supers listing the drug's most common side effects and directing consumers to the website for full safety and PI.
        - However, OPDP states that this does not mitigate the video's omission of the serious risk information regarding the warnings and precautions about serious eye disorders and severe local skin reactions. The agency notes that, by omitting these warnings and precautions, the video fails to provide material information about the consequences that may result from the use of the drug and creates a misleading impression about the drug's safety.
    - Second, OPDP notes that the claims and presentations in the video with respect to the drug's common adverse reactions create misleading impressions regarding treatment with the product and its safety profile.
        - The spokesperson makes a claim that the typically, in one or two treatments, skin lesions go away and that is the end of it. The claims are followed by presentations of side-by-side visual images that contain photographs of two patients depicting treatment of skin lesions with the product before treatment, at three weeks, and at "final result."
            - While these images are presented, the spokesperson notes one of the most common adverse reactions (stinging), but does not present any of the other most common local adverse reactions, many of which also occurred immediately after treatment.
            - OPDP finds it misleading for the spokesperson to state that patients can experience stinging upon application, without disclosing the other most common immediate local adverse reactions.
            - The agency further notes that many patients experience local adverse reactions at a longer interval after product application as well (up to 15 weeks after treatment), and thus, it is misleading for the spokesperson to suggest that typically after one or two treatments, "that's the end of it."

3 OPDP notes that the product is misbranded within the meaning of the Federal Food, Drug and Cosmetic Act (FD&C Act); see 21 U.S.C. 352(a), (n), 321(n), and 331(a); see also 21 CFR 202.1(e)(3)(iii) and (e)(5).

- OPDP acknowledges that common side effects are listed in a Super simultaneously with the images depicting two patients and in a separate Super following the visuals.
  - However, the agency notes that the first Super contains unrelated efficacy information and that both Supers are presented in conjunction with compelling and attention-grabbing photographs of patients before and after treatment and the spokesperson statements. OPDP notes that a large amount of unrelated information is presented at a fast pace over approximately 10 seconds and all competes for the consumer's attention.
  - As a result, it is difficult for consumers to adequately process, and the information in the "Supers" is not sufficient to mitigate the misleading impression created by the video claims and visual presentations.
- OPDP concludes that, as a whole, the claims and presentations, the omission of the warnings and precautions, and the lack of prominent, balancing risk information create a misleading impression regarding product treatment and minimize the risks of the product.

With regard to efficacy, OPDP finds the materials to be misleading, in that they suggest greater efficacy than the product actually provides, and provide confusing information about efficacy. In particular:

- In the video, the spokesperson makes a number of claims, including that, typically, in one or two treatments, skin lesions go away and that is the end of it. The claims are followed by presentations of side-by-side, before and after, visual images that contain before and after photographs of two patients depicting treatment of skin lesions with the product.
  - OPDP states that the claims and presentations misleadingly represent that the typical patient treated with the product will experience similar results, while the clinical studies section of the PI suggests that a much lower percentage of patients (figures under 10%) will have this result.
    - The agency notes that, while the images for these two patients may be an accurate reflection of their own experiences, the personal experience of these two patients does not adequately support the suggestion that patients treated with the product will typically achieve complete clearance of their skin lesions.
    - OPDP acknowledges that the Super presented in conjunction with the claims and visual presentations includes the proportion of who achieved clearance, and discloses that individual results may vary.
      - However, agency staff note that this Super is the same one that also presents the most common side effects of the product in addition to the efficacy information and is presented in conjunction with compelling and attention-grabbing before-and-after photographs and spokesperson statements. Also, as in the case of the risk information, a large amount of unrelated information is presented at a fast pace over approximately 10 seconds and competes for the consumer's attention.
      - OPDP notes that, as a result, it is difficult for consumers to adequately process and comprehend this contextual information.
  - OPDP concludes that, as a whole, the Supers are not sufficient to mitigate the misleading impression that typical patients treated with the product will achieve complete clearance of all skin lesions. Moreover, the claims and visual presentations are misleading because they suggest that more patients will achieve complete clearance of their skin lesions than has been demonstrated.

Next steps for the company

The Untitled Letter requests that the company immediately cease violating the FD&C Act, and explain the company's plan to discontinue use of violative materials. OPDP notes that, if the company believes that the products are not in violation of the FD&C Act, the company may submit its reasoning and any supporting information for the agency's consideration. If the company does not comply with the requests, FDA may initiate enforcement action.

AGG Observations:

- FDA is aware of and observes both mass media and social media marketing.
  - Although FDA does not monitor every ad or promotion, the agency does pay attention to these spaces.
  - In addition to FDA, your competitors may be watching and could send a complaint. Health care providers or consumers may also report promotions they think may be illegal to FDA (or to FTC for that matter).
- If OPDP provides advisory comments on a draft presentation, it would be wise to make the recommended changes.
  - In this case, despite previous FDA feedback on similar presentations, it appears that the company failed to adequately incorporate the changes recommended by the agency. These included presentation of serious risks of the drug and appropriate description of product efficacy.
  - The process of seeking FDA advisory review requires time and staff resources both for the sponsor (in preparing and submitting the draft materials) and for FDA (in reviewing the materials and providing comment). If a company and FDA have made this investment of resources, it would make sense to revise the submitted or similar materials to address the OPDP recommendations.
- Supers or other disclaimers alone are not enough to mitigate incomplete or misleading promotional statements or visual presentations regarding safety, efficacy, and typical course of treatment.
  - While the company included Supers in the video to provide additional information, and the spokesperson referred consumers to the product website, OPDP did not find these Supers and statement to be adequate to balance to the claims and visual presentations in the video.
  - Companies should ensure that promotional materials adequately balance benefit statements and claims with corresponding risk information.
  - Companies should ensure that efficacy information is presented in a clear and complete manner.

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