OPDP 2023 ENFORCEMENT HEATS UP WITH TWO NEW LETTERS ISSUED IN THE MONTH OF AUGUST

After no enforcement actions for the first six months of 2023, enforcement from the Food and Drug Administration's ("FDA") Office of Prescription Drug Promotion ("OPDP") is heating up with two new letters issued in the month of August. The first was a Warning Letter issued on August 4, 2023, to a pharmaceutical manufacturer for making "misleading" claims about efficacy in a professional sales aid directed to health care professionals for a drug approved for maintenance treatment of patients with chronic obstructive pulmonary disease ("COPD"). The second was an Untitled Letter issued on August 11, 2023, to another pharmaceutical manufacturer for making false and misleading claims in a social media post about its progestin-only birth control pill.

Below is a summary of key takeaways from the letters.

False or Misleading Claims About Efficacy

OPDP continues to scrutinize the presentation of study data to support claims in promotional materials. According to OPDP, the drug manufacturer in the Warning Letter presented misleading claims about efficacy when it referred to "an observed relative difference" in all-cause mortality ("ACM") for COPD patients. However, the study cited by the manufacturer failed to show statistically significant results on ACM and as such did not allow for conclusions to be drawn regarding ACM. Additionally, the cited study was designed in such a way that the abrupt removal of the patients from inhaled corticosteroids prior to entering a treatment arm could have acted as a confounding factor when determining a positive effect on ACM. OPDP also took issue with the drug's sales aid which made claims that the product " was the ONLY triple therapy vs ICS/LABA to show a significant reduction in severe exacerbations." According to the FDA, the cited study did not support this claim because the data did not show a statistically significant reduction for patients treated with the drug relative to comparator groups. While a cautionary statement was present in the sales aid, the statement was insufficient to "mitigate the misleading impression" created by the presentation of data.

In the Untitled Letter, OPDP found that the manufacturer created misleading claims about efficacy when it claimed, "Offer your patients estrogen-free birth control with periods on a schedule." However, studies showed that 81.2% of patients had scheduled bleeding in Cycle 1 but this percentage decreased to 26.4% after 13 cycles of treatment. In another study of the drug, scheduled bleeding also decreased over time from 98.0% in Cycle 1 to 28.4% in Cycle 13. Thus, the cited studies indicated that the majority of patients did not experience periods on a schedule despite the manufacturer's claims. Furthermore, the use of the product was associated with bleeding irregularities and amenorrhea with 40.3% and 52.2% in Studies CF111/303 and CF111/304, respectively experiencing unscheduled bleeding.

False or Misleading Risk Information

In the Untitled Letter, OPDP found that the pharmaceutical manufacturer failed to provide any risk information in its post about its drug, despite the fact that the drug presented multiple risks including but not limited to hyperkalemia, thromboembolic disorders, bone loss and cervical cancer. Due to the absence of risk information, OPDP found that there was a misleading impression about the drug's safety.

Failure to Submit Under Form FDA-2253

OPDP also noted that the manufacturer of the drug in the Untitled Letter failed to submit the social media post under Form FDA-2253, which is required per 21 C.F.R. § 314.81 (b)(3)(i) prior to the initial dissemination of any labeling or advertisement for a prescription drug product.

PRACTICAL TAKEAWAYS

- While OPDP was relatively quiet for most of 2023, with the current pace of enforcement actions, the agency is on track to surpass the number of enforcement actions for 2022 (As we reported here, OPDP issued a total of four letters in 2022 including three Untitled Letters and one Warning Letter).
- The presentation of study data continues to be a major focus for OPDP. Companies should avoid overstating the efficacy of the drug or creating a misleading impression when presenting study data, and carefully determine whether claims that may appear to be

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"consistent with label;" are too far-reaching.

- Companies should ensure that all promotional materials are submitted to FDA under FDA Form 2253. While submission does not eliminate the risk of FDA enforcement, it creates another opportunity for conducting an internal review of the material before it is disseminated.
- Companies should continue to have strong processes for the review of promotional materials and carefully review past enforcement actions to minimize the risk of OPDP enforcement. As we have noted before, a company's promotional review process is key to minimizing the chances of receiving an Untitled or Warning Letter from OPDP.

If you have any questions or would like help with the advertising and promotion of drugs, biologics, or medical devices, please contact:

- Carolina Wirth at (202) 780-2989 or cwirth@hallrender.com; or
- Your primary Hall Render contact.

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