CLIENT ALERT

A Hashtag Away from a Warning Letter? Kim Kardashian's Instagram Post Triggers FDA Warning Letter that Sends a Strong Message to Drug Makers

August 2015

Kim Kardashian's use of social media to praise a morning sickness drug landed the drug maker in hot water when the FDA determined that her Instagram post caused the drug to be misbranded under the federal Food, Drug, and Cosmetic Act (FDCA). After receiving a tip through the FDA's "Bad Ad" Program, the Office of Prescription Drug Promotion (OPDP) reviewed her post and concluded that, by omitting risks and use limitations, it misleadingly made the drug, DICLEGIS, seem safer than it actually was. As a result, on August 7, the FDA issued a warning letter to the drug maker.

The social media post included a photo of the reality star holding a bottle of the drug and the following message, including the disclosure that she was "partnering" with the drug maker:

> OMG. Have you heard about this? As you guys know my #morningsickness has been pretty bad. I tried changing things about my lifestyle, like my diet, but nothing helped, so I talked to my doctor. He prescribed me #Diclegis, and I felt a lot better and most importantly, it's been studied and there was no increased risk to the baby. I'm so excited and happy with my results that I'm partnering with Duchesnay USA to raise awareness about treating morning sickness. If you have morning sickness, be safe and sure to ask your doctor about the pill with the pregnant woman on it and find out more www.diclegis.com; www.DiclegisImportantSafetyInfo.com.

Omission of Risk Information

According to the FDA, an advertisement is false or misleading "[i]f the ad states that the drug is more effective or has fewer or less severe effects than has been demonstrated … [the agency] also pay[s] careful attention to balance, making sure the risks are displayed prominently so that they can be read, heard, and understood easily." OPDP contended that the social media post was misleading because it touted the benefits of the drug, yet failed to communicate any of the associated risks. While the post included the link to websites whereby consumers could receive additional information about the product, the FDA noted that it "does not mitigate the misleading omission of risk information." The FDA further explained: "[b]y omitting the risks associated with [the drug] the social media post misleadingly fails to provide material information about the consequences that may result from the use of the drug and suggests that it is safer than has been demonstrated." The warning letter indicated that this was the second time the drug maker had omitted risk information and limitations on use.

The First Amendment

Pharmaceutical advertising has historically received heightened First Amendment protections. The Supreme Court expanded on this notion in 2011 in *Sorrell v. IMS Health Inc.*, 131 S.Ct. 2653 (2011). At issue was Vermont's Prescription Confidentiality Law, which restricted the sale, disclosure, and use of pharmacy records that revealed the prescribing practices of individual doctors. In particular, the statute prohibited "detailers," employed by pharmaceutical manufacturers, from using "prescriber-identifying

information" received by pharmacies to generate reports. The reports were then used by pharmaceutical companies to increase sales to doctors. In striking down the Vermont law, the court applied heightened judicial scrutiny because the statute "imposes a burden based on the content of speech and the identity of the speaker." In addition, the court explained that "the State may not seek to remove a popular but disfavored product from the marketplace by prohibiting truthful, [non-misleading] advertisements that contain impressive endorsements or catchy jingles. That the State finds expression too persuasive does not permit it to quiet the speech or to burden its messengers."

Shortly after *Sorrell* was decided, these First Amendment protections were underscored in *Amarin Pharma, Inc. et al. v. Food and Drug Administration et. al.*, No. 15 Civ. 3588, 2015 WL 4720039 (S.D.N.Y. Aug. 7, 2015), involving off-label marketing. In this case, the court granted a motion for preliminary injunction against the FDA and, notably, held that it was a drug maker's constitutional right to communicate "truthful and non-misleading" statements regarding uses of its drug that had not been approved by the FDA. *See* "FDA Loses Battle to Limit Truthful, Non-Misleading Off-Label Promotion of Approved Drugs."

Thus, the FDA's push to regulate and reduce the amount of truthful—albeit incomplete—pharmaceutical endorsements appearing on social media may rest on constitutionally shaky grounds.

Conclusion

Say what you want about Kim Kardashian, but there is one thing that is undeniable—she is influential. With over 43 million followers on Instagram, it is not difficult to grasp why companies would be attracted to the reality star's social media accounts. Yet, regulating this platform is not easy. In 2013, the FDA admitted that the internet and social media has complicated its job, noting that "[it] has increased the volume and extent of materials and speeded the delivery of those materials. Websites can have hundreds of pages and can change daily. It is important to know that although we closely monitor what companies say, we generally do not have authority over statements made by independent organizations or persons … unless they are acting on behalf of a company." However, the FDA's warning letter sends the clear message that, when partnering with public figures, drug makers must adhere to the requirements of the FDCA even if the promotion is coming from an Instagram account rather than the drug maker's own mouth.

Other Articles in This Month's Edition:

For more information, please contact the professional(s) listed below, or your regular Crowell & Moring contact.

John Fuson
Partner – Washington, D.C.
Phone: +1 202.624.2910
Email: jfuson@crowell.com

Chalana Netasha Damron
Counsel – Washington, D.C.
Phone: +1 202.624.2566
Email: cdamron@crowell.com