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06 Nov 2023 | **Analysis**

Rx Ad/Promo Practices Should Be Part Of Acquisition Due Diligence, DoJ Official Says

by Sue Sutter

Recent revision to DoJ's self-disclosure policy includes safe harbor for a company that timely discloses and remediates an acquired entity's promotional violations. Experts expect continued enforcement around evidence of an off-label, intended use and say FDA is looking at the fuzzy line between unbranded and branded ads.

The due diligence inquiry for an acquisition should include the drug advertising and promotional practices of the target company, a senior Department of Justice official said.

Speaking at the Food and Drug Law Institute's medical products advertising and promotion conference, Arun Rao, deputy assistant attorney general for DOJ's Consumer Protection Branch, described how acquiring companies that discover an acquiree's promotional misconduct after the fact can still reap the benefits of the department's self-disclosure policy under a recent policy modification.

Separately, experts predicted several areas of enforcement focus in the coming year, including continued scrutiny of claims for an intended but unapproved use, inappropriate sharing of personal data, and the sometimes fuzzy line between unbranded disease awareness and branded prescription drug ads.

Self-Disclosure Policy As A Carrot

In a September 2022 memo, Deputy Attorney General Lisa Monaco announced that DoJ will not seek a guilty plea where a corporation has voluntarily self-disclosed, fully cooperated and remediated the criminal conduct. It also will not require the imposition of an independent compliance monitor for a cooperating corporation that voluntarily discloses conduct and has implemented an effective compliance program. (Also see "*Corporations Can Avoid Guilty Pleas, Compliance Monitors Under New DOJ Policies*" - Pink Sheet, 17 Jan, 2023.)

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The Department of Justice is "sometimes fond to have sticks, but we're trying to broaden our engagement by providing some incentives." – DoJ's Arun Rao

"The idea here was to set nationwide, consistent incentives for voluntary corporate disclosures," Rao said of the Monaco memo. "The goal of the policy is to try to incentivize corporate self-disclosure coming forward to the government when a company determines internally there may have been some misconduct. And we're trying to set forth standardized transparent criteria for that reporting that, if it's met, can actually result in some concrete real-world rewards for the company."

Rao called it a carrot, not a stick, approach. "I think [at] the department we're sometimes fond to have sticks, but we're trying to broaden our engagement by providing some incentives."

Following release of the Monaco memo, DoJ's various components issued their own policies for how they will evaluate self-disclosure, with the Consumer Protection Branch publishing its policy in February. (Also see "*DOJ Enforcement: Talking With US FDA Is Not Enough To Get Credit For Self-Disclosure*" - Pink Sheet, 31 May, 2023.)

"The branch looked at its unique mission ... related to health and safety and consumer fraud in developing the policy," Rao said. Although it is broadly similar to what other department components have put together, CPB's policy is intended to apply to, among other things, disclosures related to marketing of products that are regulated by the Food and Drug Administration, and conduct under the jurisdiction of the Federal Trade Commission.

The CPB policy governs self-disclosure if a company uncovers misconduct in advertising or promotion of a medical product or dietary supplement, although self-disclosure merely to the FTC or the FDA is not enough, Rao said.

"You can't come to the DOJ later and say, 'Look, we've made a disclosure to the FTC,'" Rao said. "We're looking actually for the disclosure to come to the department itself. And if that happens, the benefits are pretty substantial," as outlined in the September 2022 Monaco memo.

Absent aggravating factors that are defined as placing consumers at significant risk of death or serious bodily injury, "if a company voluntary self discloses, timely and fully cooperates and fully remediates, they're not going to have to plead guilty," Rao said.

“And in terms of remediation, what we're talking about is responding by trying to remedy any harm caused by the criminal conduct, and then also acting to prevent future criminal conduct. That can include making modifications to a company's corporate compliance policy.” If a company does all this, they will not be subject to an independent compliance monitor, he said.

Safe Harbor For Acquisitions

DoJ is constantly working to refine this self-disclosure policy, Rao said, pointing to a new mergers and acquisitions safe harbor *policy* announced in October.

If an acquiring company uncovers misconduct, including any related to advertising or promotion, by an acquired company and reports that misconduct within six months of closing of the deal, and then remediates within a year, it will receive a presumption that DoJ will decline to prosecute with respect to the acquired company’s conduct.

“The presence of aggravating factors at the acquired company is not in any way going to impact the acquiring company's ability to issue a declination,” Rao said. “This is, again, intended to be a pretty juicy carrot.”

“I guess the other takeaway here is that it's worth making sure that your due diligence policies and procedures cover advertising and promotion risks in this area if they don't already do so,” Rao said.

Data-Sharing Cases A Focus

During a separate panel discussion on enforcement trends, Gabriel Scannapieco, CBP assistant director, described the types of cases his office is seeing right now, as well as issues he expects will see the spotlight in the coming year.

“We continue to address potential off-label claims to the extent they relate to an unapproved, intended use,” Scannapieco said. “There’s been some change over time over the last few years that you don’t see actions being taken necessarily just because somebody says something that is true but off-label. But there have been a number of actions even recently in which both statements that have been made, along with other evidence about how a company intended a product to be used, are combined to demonstrate violation of the Food, Drug and Cosmetic Act.”

He cited two recent cases involving medical devices that were intended to be used to treat migraine pain, but 510(k) notifications for that use had not been submitted. (Also see "*News We’re Watching – 13 January*" - Medtech Insight, 13 Jan, 2023.)

“These cases have become a little bit more complicated over the last few years, but the department continues to hear about them, we continue to investigate them and prosecute them,” Scannapieco said.

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He described another bucket of cases as those in which entities are making unapproved new drug claims on the internet and social media for various types of products.

"I think that we'll continue to see a number of actions come through our office that really are coming through these newer channels of promotion that relate to social media," he said.

Further, Scannapieco predicted there would be more enforcement cases related to how personal data are being used in the promotional space and potential sharing of that data by companies.

"I wouldn't be surprised that there would be more and more cases like" the GoodRx case, in which the prescription drug discount provider was fined $1.5m by the FTC for sharing consumer information with third-party advertisers without consent.

Unbranded Vs. Branded Ads

Alan Minsk, a partner at Arnall, Golden and Gregory in Atlanta, flagged the line between unbranded disease awareness and branded ads on social media as an area that could face closer FDA scrutiny.

Unbranded disease awareness ads may be readily viewed as ads for a specific branded drug when there is only one company or drug in a therapeutic space, or the unbranded ad uses the same colors as the branded product, Minsk said.

"I think FDA will be careful because they don't want to get sued or lose a lawsuit, but I do think that there is going to be a little bit more peeling of the onion, or at least 'who you fooling?'"