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Enforcement in Life Sciences Series

Key Cases in 2020 Reflect Emerging DOJ Focus for Pharmaceutical and Medical Device Makers

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About the Enforcement in Life Sciences Series

Recent settlements between the U.S. Department of Justice (DOJ) and a range of FDA-regulated drug and medical device manufacturers provide a snapshot of the DOJ's enforcement focus. These settlements involve new DOJ theories of liability or new ways of evaluating long-standing industry practices and may be harbingers of future DOJ enforcement activity. In this six-part series of client alerts, we take an in-depth look at the facts and legal theories in each case or set of cases, discuss what makes each novel and consider the compliance implications for each. You can find copies of all the client alerts in the series here.

DOJ's Evolving Enforcement Approach to Off-Label Promotion

In three recent settlements, DOJ used the civil False Claims Act to address alleged misconduct involving the content of promotional messaging.[1] A string of judicial decisions since 2012 has recognized First Amendment protections for pharmaceutical manufacturer commercial speech, and these losses have required DOJ and FDA to rethink their approach to investigating company promotional activities. The government has responded by focusing on cases where the facts indicate that promotional messaging is false or misleading, including where promotion encourages the prescribing of products for uses that are not medically necessary.[2] While DOJ has continued to pursue criminal Food, Drug & Cosmetic Act (FDCA) charges in selected cases, the bulk of promotional enforcement since 2015 has been through civil False Claims Act (FCA) cases.

The July 2020 Indivior settlement illustrates this shift. According to DOJ, a portion of the $300 million civil FCA settlement resolved allegations that, from 2010 through 2015, Indivior companies knowingly promoted the sale and use of Suboxone to physicians who were writing prescriptions that were not for a medically accepted indication and lacked a legitimate medical purpose; were issued without any counseling or psychosocial support (as suggested in the label); were for uses that were unsafe, ineffective and

[1] One or more of the cases referenced in this client alert resolved civil False Claims Act liability via settlements that contained a denial of liability by the company. Companies may have a variety of reasons, unrelated to their actual exposure, to resolve such matters without an admission of liability.

[2] See, *e.g.*, our September 28, 2017, client alert on the 2017 Aegerion settlement involving violations of the company's REMS requirements, "Aegerion Settles Criminal and Civil Probe of Promotional Practices, REMS and HIPAA Compliance, and Patient Assistance Programs."

medically unnecessary; and were often diverted.[3] DOJ's focus on causing the submission of claims for medically unnecessary or clinically unsupported uses has been seen in other recent settlements, including:

- Dusa Pharmaceuticals settled a civil FCA investigation that alleged the company caused physicians to submit false claims by knowingly promoting an administration process for a drug that contradicted the product instructions approved by FDA and was unsupported by sufficient clinical evidence.[4]
- Avanir Pharmaceuticals resolved civil FCA allegations that the company implemented a strategy that involved false and misleading promotion of a drug in long-term care facilities for uses that had not been approved by FDA and were not medically accepted indications, as defined by the statutes and regulations governing the federal health care programs.[5]

Although a number of factors can impact how a case is resolved — including the history of the company and the financial impact of the conduct — in our experience the single biggest factor impacting the terms of a settlement is whether there is a patient safety issue at play, particularly when there is a vulnerable patient population involved. Both the Indivior and Avanir settlements involved allegedly vulnerable patient populations, and the Dusa settlement alleged that the company's conduct implicated patient safety.

Compliance Implications

While DOJ's investigative theories relating to company promotional activities are more narrow than the broad criminal off-label theories advanced by the government prior to 2012, companies still face considerable risk in this area. Faced with the conflicting realities of a more permissive judicial view of protected promotional activities juxtaposed against the continued risk that companies are exposed to through sales force activities, companies have varied in their approach. Some companies have continued to impose strict policies prohibiting sales representatives from promoting to HCPs beyond the FDA-approved label, reflecting the perception that the execution risk associated with a more permissive approach is not worth the potential benefit. Other companies, however, take a more nuanced approach and may allow some off-label communications by their sales force, including affirmative dissemination of off-label reprints or closely scripted messaging that is supported by appropriate clinical evidence.

The latter approach can be more resource-intensive to execute as it removes the bright line of the FDA-approved label as the arbiter and instead requires in-house personnel to decide whether proposed messaging is truthful, nonmisleading and consistent with a medically indicated use of the product. This evaluation requires a nuanced and well-informed understanding of both a product's label and the evolving state of medical literature or clinical evidence that may support uses beyond the approved label. Companies considering a more expansive approach should ensure that their review and approval process permits the time and includes the talent resources needed to execute successfully, such as close review by medical professionals. Further, companies should ensure that the documentation of their material review and approval process memorializes the contemporaneous basis for decisions, so that it can be relied on if questions arise in the future.

Companies also should ensure that they are giving appropriate scrutiny to all aspects of their promotional efforts, particularly as many companies' marketing focus has shifted away from printed promotional materials like brochures and towards social media and other electronic means. Consistent with this shift, FDA has focused its promotional oversight activities on social media and other online promotion, including patient-directed advertising; notably, while the Office of Prescription Drug Promotion issued a total of six untitled and warning letters relating to promotional materials in 2020, none of the letters involved traditional printed labeling. Companies should consider reevaluating their material review and approval processes to ensure that they are reviewing the full range of externally focused materials, regardless of medium, and that personnel with the requisite expertise participate in the review process. Companies also may wish to review their social media policies to ensure that they address activities that might be viewed as company promotion.

More fundamentally, it is important for companies to recognize that, while DOJ's approach to promotional activities has narrowed since the heyday of criminal off-label promotion cases in the early 2000s, promotional activities continue to create risk under the FDCA when false or misleading conduct exists and under the FCA, which, although civil, can expose a company to substantial fines and penalties.

[3] DOJ Office of Public Affairs, "Indivior Solutions Pleads Guilty to Felony Charge and Indivior Entities Agree To Pay $600 Million To Resolve Criminal and Civil Investigations as Part of DOJ's Largest Opioid Resolution," July 24, 2020.

[4] DOJ Office of Public Affairs, "DUSA Pharmaceuticals To Pay U.S. $20.75 Million To Settle False Claims Act Allegations Relating to Promotion of Unsupported Drug Administration Process," August 24, 2020.

[5] DOJ Office of Public Affairs, "Pharmaceutical Company Targeting Elderly Victims Admits to Paying Kickbacks, Resolves Related False Claims Act Violations," September 26, 2019.