



GIBSON DUNN

Life Sciences Securities Litigation Insights

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## Even Marketing Materials Can Subject Issuers to Securities Fraud Claim

[\*Sneed v. AcelRx Pharms., Inc.\*](#), No. 21-CV-04353-BLF, 2024 WL 2059121 (N.D. Cal. May 7, 2024).

### Case Highlights

On May 7, 2024, a federal district court dismissed securities fraud claims brought against a pharmaceutical company related to a marketing slogan used to promote the company's drug. At issue in *Sneed v. AcelRx Pharms., Inc.* ("*Sneed*")<sup>[1]</sup>, was AcelRx Pharmaceuticals, Inc.'s ("AcelRx") marketing slogan, "Tongue and Done," used to promote its FDA-approved drug DSUVIA, an opioid painkiller. AcelRx had presented the "Tongue and Done" slogan on its website, among other places, to highlight the ease of administering DSUVIA (*i.e.*, sublingually) compared to other opioid painkillers, which are administered either orally (which requires a patient's ability to swallow) or via intravenous injection.

In February 2021, AcelRx received a warning letter from the FDA stating that the "Tongue and Done" slogan contained "false or misleading claims and representations about the risks and efficacy of DSUVIA" and thus violated the Federal Food, Drug, and Cosmetic Act (FDCA). After AcelRx disclosed the warning letter, the company's stock dropped about 9%. The plaintiff then sued under federal securities laws alleging that, in using the slogan, the company made a misleading statement to investors because it omitted material information regarding DSUVIA's safety, including information about dosing, administration, and limitations on its use. The plaintiff claimed that the allegedly misleading slogan subjected AcelRX to a foreseeable and increased risk of regulatory investigations or enforcement actions for misbranding violations under the

FDCA.

In response, the defendants argued, among other things, that AcelRx specifically disclosed information about DSUVIA's safety and dosing information, as well as the risk of a receiving an FDA warning letter in its SEC filings. The defendants further argued that the slogan was targeted at medical professionals, not investors, and, as such, no reasonable investor would have relied on the slogan when making their investment decision. Despite acknowledging that the company's disclosures "weaken" plaintiff's allegations, the court found that the plaintiff could allege the statement was misleading. However, the court granted defendants' motion to dismiss the complaint because it found that plaintiff did not plead that the statement was made with fraudulent intent.

### Key Takeaways

*Sneed* highlights the risk that even marketing materials—or any other kind of publicly-available material, even if not specifically targeted at investors—may form the basis of a warning letter and ultimately, a securities fraud claim. *Sneed* also illustrates the interplay between federal securities laws and other regulatory regimes, highlighting the risk that alleged violations of *other* statutes may be levered by plaintiffs' lawyers to plead securities law violations, particularly where the alleged violations involve statements to non-investor market constituents. Pharmaceutical and biotechnology companies, thus, would benefit from involving securities litigation counsel when developing marketing materials or other public disclosures, even if not directed to investors, to minimize legal exposure under the federal securities laws.

*\*Update: On August 20, 2025, the Ninth Circuit affirmed the district court's dismissal of a securities fraud action against AcelRx, holding that plaintiff failed to allege both that the challenged statement was false and that it was made with fraudulent intent. See Sneed v. Talphera, 147 F.4th 1123 (9th Cir. 2025). Relevant here, the Ninth Circuit observed that "[a] reasonable investor would not blindly accept a slogan without considering other information—in the advertising and the speech as well as in SEC disclosures—that clarified the context of 'Tongue and Done'" and held that the FDA warning letter objecting to the slogan "[did] not mean the slogan [was] necessarily deceptive" given that what may be considered "misleading" is different for a reasonable investor than for a medical professional.*

[1] *Sneed v. AcelRx Pharms., Inc.*, No. 21-CV-04353-BLF, 2024 WL 2059121 (N.D. Cal. May 7, 2024).

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