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# Ninth Circuit Deems Company's 'Snappy Slogan' Inadequate Support for Securities Fraud in Light of Additional Disclosures

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On August 20, 2025, the US Court of Appeals for the Ninth Circuit affirmed the district court's dismissal of a securities fraud action in *Sneed v. Talphera*. With this published decision, Cooley secured a complete victory on behalf of its clients – including Talphera (formerly known as AcelRx Pharmaceuticals), a company focused on the development and commercialization of innovative therapies for use in the medically supervised setting. Judge Kenneth Lee, writing for the panel, rejected a theory of securities law liability premised on a pharmaceutical company's "snappy slogan." The Ninth Circuit also highlighted that a Food and Drug Administration (FDA) warning letter is not "dispositive or even necessarily probative" of falsity under the Exchange Act, that a difference of opinion expressed by a former employee is not sufficient to plead a strong inference of scienter, and that relying on "flimsy" falsity allegations "necessarily undermines" a plaintiff's ability to plead scienter.

## Background

This action centers on marketing for an opioid tablet called Dsuvia – pain medication administered sublingually rather than intravenously – that was developed by Talphera. As required by the drug's safety program, known as the Risk Evaluation and Mitigation Strategy (REMS), Dsuvia could only be distributed in medically supervised settings, foreclosing retail pharmacies and at-home usage.

Highlighting the unique, sublingual delivery method of this pain medication, Talphera started using the slogan "Tongue and Done" to market Dsuvia. The slogan appeared (alongside significant caveats) on a tabletop display at medical conferences and in an online banner advertisement. The tabletop display carried more than just the simple slogan, noting: "Please see indication, important Safety Information, including Limitations of Use and BOXED WARNING at this booth." And the banner advertisement flagged that Dsuvia was to be "administered … by a healthcare professional" and was subject to a REMS program. Separately, at a healthcare conference, Talphera's CEO discussed the mechanics of administering Dsuvia, noting that, "ou would simply remove the lock … tilt head back, lift their tongue, inject it under, and you're done. It's basically as simple as that."

The FDA took issue with the "Tongue and Done" promotional materials, claiming in a warning letter that Talphera made "false or misleading claims" for purposes of the Federal Food, Drug, and Cosmetic Act (FDCA) by not providing a balanced description of the "risks and benefits" of the drug. After receiving this warning letter, Talphera stopped using the "Tongue and Done" slogan.

A putative class action lawsuit was then filed, alleging that the slogan was misleading because administering Dsuvia was "more complex" than "Tongue and Done." The plaintiffs claimed that the "Tongue and Done" slogan, as used on the tabletop display and banner advertisement, and the CEO's statements at the healthcare conference, were false or misleading under Section 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5.

After twice dismissing the case with leave to amend, the third time, the district court dismissed the plaintiffs' complaint with prejudice on scienter grounds. On appeal, the Ninth Circuit went even further, holding that the plaintiffs failed to adequately plead both falsity and scienter. Given that this case implicated issues at the intersection of FDA promotional guidelines and securities fraud, the Ninth Circuit's decision provides important clarity regarding the reach of the federal securities laws.

## Ninth Circuit reiterated that statements must be viewed in context

The Ninth Circuit affirmed the district court's dismissal on falsity grounds. Specifically, the court held, " reasonable investor would not blindly accept a slogan without considering other information—in the advertising and the Oppenheimer remarks as well as in SEC disclosures—that clarified the context of 'Tongue and Done.'"

The Ninth Circuit underscored that "context matters" in evaluating whether a statement is false or misleading to a reasonable investor. As the court explained, context is critical because, "we presume that a reasonable investor—who has

money on the line—acts with care and seeks out relevant information." And in this case, the reasonable investor would not "blindly accept" a pithy slogan but would instead take it for what it is: a "catchy phrase[] designed to highlight a desirable or unique product feature."

Because Talphera had disclosed ample clarifying information, the Ninth Circuit held that no reasonable consumer (let alone reasonable investor) would interpret this three-word slogan without critically considering the wealth of other information available to the public, such as materials on the advertisements themselves, content physically available at the booth, and information in the company's Securities and Exchange Commission (SEC) disclosures and online resources.

### Court clarified that an FDA warning letter is 'not dispositive of falsity' in the securities context

For all companies aware of the impact of any potential FDA warning letters, the Ninth Circuit left no doubt that the reasonable investor standard is distinct from that of a medical professional or consumer. The court rejected the plaintiffs' argument that the FDA warning letter objecting to the "Tongue and Done" materials – including the letter's claim that the materials made "false or misleading claims" under the FDCA – was dispositive of falsity claim under the federal securities laws. As the court explained, the securities laws apply a different standard than the FDCA in determining what may be false or misleading – the securities laws approach that question from the perspective of a reasonable **investor**, not a consumer or medical professional. For that reason, the court clarified that any FDA warning letter is "not dispositive or even necessarily probative of falsity" in a securities action.

### Court held 'flimsy' evidence of falsity also necessarily undermined any showing of scienter

The Ninth Circuit also held that the plaintiffs failed to show a strong inference of scienter, explaining that "he flimsy evidence of falsity necessarily undermines the ability to show scienter."

In analyzing statements from former employees, which the plaintiffs relied upon heavily, the Ninth Circuit pointed out that:

1. Few witnesses had sufficient personal knowledge to support scienter.
2. A "good-faith difference of opinion" explained other allegations.
3. The plaintiffs' attempt to plead scienter through the core operations theory failed at the outset because no "fact" existed that would have shown executives that "Tongue and Done" conveyed any sort of "patently false" information.

### Takeaways

This opinion reminds litigants at the crossroads of securities law and advertising that:

- A pithy marketing slogan, when accompanied by robust disclosures, cannot be distorted to support a securities fraud action.
- A company's receipt of an FDA warning letter is "not dispositive or even necessarily probative of falsity."
- A difference of opinion between a former employee and an executive is not sufficient to plead a strong inference of scienter.
- Relying on thin evidence of falsity has ripple effects across a case, "necessarily undermin the ability to plead scienter." If a statement is not clearly false, the likelihood of an "innocent alternative explanation" rises.

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