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Ninth Circuit says improper drug marketing slogan does not suffice to plead Exchange Act claim

August 26, 2025 | Client Update | 4-minute read

On August 20, 2025, a Ninth Circuit panel affirmed the dismissal of a putative securities class action against a pharmaceutical company. It found that while the Food and Drug Administration concluded that the company's marketing was not fair and balanced, the improper marketing did not suffice to establish either falsity or scienter for a federal securities claim.

In March 2019, pharmaceutical manufacturer Talphera, Inc. began using the slogan "Tongue and Done" on marketing materials used at investor conferences to refer to its development of DSUVIA—a powerful opioid tablet that can be administered sublingually—i.e., under the tongue. To minimize the risk of abuse, only healthcare professionals could administer the product, which they would do by placing an applicator in the patient's mouth to deliver the pill under the patient's tongue. During one of these conferences, Talphera's CEO described the process as a simple one. (Op. at 8.)

In February 2021, the Food and Drug Administration (FDA) issued a warning letter to Talphera. The FDA objected to the "Tongue and Done" slogan and claimed that Talphera made false and misleading claims within the meaning of the Federal Food, Drug, and Cosmetic Act by not providing a balanced description of the risks and benefits of DSUVIA. After receiving the FDA warning letter, Talphera stopped using the "Tongue and Done" slogan.

Several shareholders sued Talphera and its officers for alleged violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and SEC Rule 10b-5. The plaintiffs claimed that Talphera's use of its marketing slogan misled investors about the drug's administration complexity and market potential. The district court dismissed the complaint with prejudice based on the plaintiffs' failure to adequately plead facts indicating a strong inference of scienter (i.e., intentional deception). Appealing to the Ninth Circuit, the plaintiffs argued that Talphera misled investors by omitting material information about DSUVIA, including information about dosing, administration, and limitations of use. They also challenged the "Tongue and Done" slogan as itself being false and misleading.

Writing for the panel, Circuit Judge Kenneth K. Lee affirmed the district court's dismissal. In analyzing the falsity of the challenged statements, the panel began by asking, "[c]an a snappy slogan for a potent pharmaceutical be deceptive and lead to liability under our securities laws?" The panel's answer was no, not "where the company provided additional disclosures alongside the slogan in materials intended for investors." (Op. at 3).

The panel determined that a reasonable investor "would not blindly accept a marketing slogan by itself" without considering other information. In the panel's view, even a reasonable consumer would understand the limits of a slogan and, for example, look beyond the slogan on the front of a bag of potato chips in order to find the nutritional information on the back.

The panel found that Talphera provided copious clarifying information next to its use of the "Tongue and Done" slogan on its tabletop and banner ads displayed at investor conferences, including disclosures on limitations of use and warnings that DSUVIA must be administered by a healthcare professional in a healthcare setting. It also found that reasonable investors would have read Talphera's SEC disclosures and warnings, which provided further context on DSUVIA's potential market. The panel therefore found that Talphera's use of its slogan would not, in context, mislead a reasonable

investor.

The panel also concluded that the FDA's warning letter was not dispositive of falsity. It noted that, in determining the sufficiency of pleadings under the Exchange Act, courts must adopt the perspective of the reasonable investor, while the Food, Drug, and Cosmetic Act imposes different legal requirements and is focused on the perspective of patients and "prescribers of drugs." The panel reasoned that just because the FDA requires disclosure of specific instructions to healthcare providers does not make the omission of that information relevant to a reasonable investor. (Op. at 16.)

With regard to scienter, the panel found that plaintiffs' use of statements from confidential witnesses did not establish scienter in part because the confidential witnesses never interacted with the individual Talphera executives named as defendants. The panel also rejected plaintiffs' attempt to show scienter through a "core operations" theory, which allows courts in certain circumstances to infer that facts critical to a business's core operations must be known to the company's key officers. The panel found that the "core operations" doctrine was not applicable because it could not identify any alleged fact that would have led Talphera's officers to know the "Tongue and Done" slogan conveyed patently false information. The panel concluded that the most plausible inference is that Talphera used the "Tongue and Done" slogan in good faith to market DSUVIA's biggest selling point—that patients can receive the drug orally instead of intravenously. (Op. at 17.)

The decision is a reminder that in assessing whether a plaintiff has satisfied the Private Securities Litigation Reform Act's heightened pleading requirements at the motion to dismiss stage, courts must look at the full context surrounding a challenged statement and presume that a reasonable investor will act with care and seek out relevant information. The decision also highlights the distinction between the requirements of the Exchange Act and the Food, Drug, and Cosmetic Act, recognizing that FDA warning letters are not dispositive or even necessarily probative of falsity under the Exchange Act.

If you have any questions regarding the matters covered in this publication, please reach out to any of the lawyers listed below or your usual Davis Polk contact.

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