

Securities Law Alert

KEY DEVELOPMENT IN SHAREHOLDER LITIGATION

Ninth Circuit: “Snappy” Opioid Slogan Not Deceptive Where Additional Disclosures Clarified Its Context

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On August 20, 2025, the Ninth Circuit affirmed the dismissal of a securities fraud class action alleging that a pharmaceutical company and certain of its executives misled investors in violation of Section 10(b) and Rule 10b-5 by marketing a drug with the slogan “Tongue and Done” because administering it was more complex than just placing it under the “Tongue and Done” and therefore its potential market would be more limited. [*Sneed v. Talphera, Inc.*](#), 2025 U.S. App. LEXIS 21294 (9th Cir. 2025) (Lee, J.). The Ninth Circuit affirmed the district court’s dismissal because plaintiffs failed to adequately plead falsity. The Ninth Circuit held that the slogan was not deceptive because the company provided additional disclosures alongside the slogan in materials intended for investors. The Ninth Circuit explained that a reasonable investor would “not blindly” accept a slogan without considering other information that clarified the slogan’s context.

Background and Procedural History

The company developed a new opioid tablet that could be administered by placing it under the patient’s tongue rather than intravenously, which was a major selling point. To reduce the risk of misuse, the FDA conditioned the drug’s approval on compliance with an agency safety plan called a Risk Evaluation and Mitigation Strategy (REMS), which required the drug to only be administered in medically-supervised settings and also forbid home use and sales to retail pharmacies. The company adopted the slogan “Tongue and Done” for its various investor marketing materials. However, the company ceased using the slogan after receiving an FDA warning letter concluding that for purposes of the Food, Drug and Cosmetic Act (FDCA) the company had made “false or misleading claims” by not providing a balanced description of the drug’s “risks and benefits.” Subsequently, shareholders sued alleging violations of Sections 10(b) and Rule 10b-5, and claiming that the following statements at an investor conference were false or misleading: (i) a tabletop display with the slogan; (ii) a banner advertisement with the slogan; and (iii) the CEO’s statement that you “lift up their tongue, you inject it under and you’re done.” The district court dismissed for a failure to adequately plead facts leading to strong inference of scienter but did not rule on falsity, deeming it a “close call.” On appeal, plaintiffs argued that the statements misled investors because they omitted material information, including about dosing, administration, limitations of use, REMS restrictions and the limited size of the drug’s potential market due to the prohibition on home use.

A Reasonable Investor Would Not View the Slogan in Isolation

Affirming the district court, the Ninth Circuit found the pleadings deficient as to falsity. The Ninth Circuit explained that an omission can mislead by affirmatively giving a reasonable investor “an impression of a state of affairs that differs in a material way from the one that actually exists” and that under *Weston Family Partnership LLP v. Twitter, Inc.*, 29 F.4th 611 (9th Cir. 2022), a court should look at the context surrounding the statement to decide whether a misstatement or omission is misleading. The Ninth Circuit explained that context matters because “we presume that a reasonable investor—who has money on the line—acts with care and seeks out relevant information” and noted that a reasonable investor cares about a statement’s “surrounding text, including hedges, disclaimers, and apparently conflicting information.”

The Ninth Circuit concluded that, in context, the “Tongue and Done” slogan would not mislead a reasonable investor about the need to administer the drug under a REMS plan or about the scale of its potential market. The Ninth Circuit stated that a reasonable investor would read the slogan in the context of a marketing campaign designed to highlight that patients can receive it orally, but that made no representation about REMS restrictions. The Ninth Circuit stated that the company provided “copious clarifying information” next to the slogan, including, among other things, that the tabletop and banner ads included text that disclosed the REMS plan; the tabletop ad directed investors to the company’s booth for more information; and the banner ad expressly noted that the drug has a REMS and must be “administered sublingually by a healthcare professional.” The Ninth Circuit further pointed out that investors who still wanted more information could turn to the company’s SEC disclosures or its dedicated REMS website. As to the CEO’s speech, the Ninth Circuit concluded that it apprised investors of the limitations imposed by the REMS and limited market because the statements warned that the drug has a limited market because only healthcare professionals can administer it under a restrictive REMS.

The Ninth Circuit also rejected plaintiffs’ argument that the FDA warning letter showed that the statements were false because the FDCA imposes “different legal requirements and targets a different audience” (*i.e.*, targeting patients and drug prescribers versus investors). The Ninth Circuit stated that “FDA warning letters are thus not dispositive or even necessarily probative of falsity claims under the Exchange Act.”

For further information regarding this Securities Law Alert, please contact one of the following:

CONTACTS

Martin S. Bell
+1-212-455-2542
martin.bell@stblaw.com

Nicholas S. Goldin
+1-212-455-3685
ngoldin@stblaw.com

Peter E. Kazanoff
+1-212-455-3525
pkazanoff@stblaw.com

Chet A. Kronenberg
+1-310-407-7557
ckronenberg@stblaw.com

Linton Mann III
+1-212-455-2654
lmann@stblaw.com

Joshua Polster
+1-212-455-2266
joshua.polster@stblaw.com

Alan C. Turner
+1-212-455-2472
aturner@stblaw.com

Jonathan K. Youngwood
+1-212-455-3539
jyoungwood@stblaw.com

Simona G. Strauss
+1-650-251-5203
sstrauss@stblaw.com

Stephen P. Blake
+1-650-251-5153
sblake@stblaw.com

Bo Bryan Jin
+1-650-251-5068
bryan.jin@stblaw.com

Meaghan A. Kelly
+1-202-636-5542
mkelly@stblaw.com

Joshua A. Levine
+1-212-455-7694
jlevine@stblaw.com

Lynn K. Neuner
+1-212-455-2696
lneuner@stblaw.com

Karen Porter
+1-202-636-5539
karen.porter@stblaw.com

Craig S. Waldman
+1-212-455-2881
cwaldman@stblaw.com

David Elbaum
+1-212-455-2861
david.elbaum@stblaw.com

Michael J. Garvey
+1-212-455-7358
mgarvey@stblaw.com

Meredith Karp
+1-212-455-3074
meredith.karp@stblaw.com

Jeffrey H. Knox
+1-202-636-5532
jeffrey.knox@stblaw.com

Laura Lin
+1-650-251-5160
laura.lin@stblaw.com

Michael J. Osnato, Jr.
+1-212-455-3252
michael.osnato@stblaw.com

Rachel S. Sparks Bradley
+1-212-455-2421
rachel.sparksbradley@stblaw.com

George S. Wang
+1-212-455-2228
gwang@stblaw.com

Janet A. Gochman
+1-212-455-2815
jgochman@stblaw.com

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