2025 WL 2406424
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United States Court of Appeals, Ninth Circuit.

Aaron SNEED, Jr.; Yaacov Musry; David O'Grady, Plaintiffs - Appellants,

v.

TALPHERA, INC., formerly known as: AcelRx Pharmaceuticals, Inc.; Vincent J. Angotti; Pamela P. Palmer, Defendants - Appellees.

No. 24-3560
|
Argued and Submitted June 12, 2025 San Francisco, California
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Filed August 20, 2025

Appeal from the United States District Court for the Northern District of California Beth Labson Freeman, District Judge, Presiding, D.C. No. 5:21-cv-04353-BLF

Attorneys and Law Firms

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Patrick J. Hayden (argued), Cooley LLP, New York, New York; Tijana Brien, Patrick E. Gibbs, Janelle M. Fernandes, and Shannon M. Eagan, Cooley LLP, Palo Alto, California; Allison O'Neill, Cooley LLP, San Diego, California; for Defendants-Appellees.

Before: Sidney R. Thomas and Kenneth K. Lee, Circuit Judges, and Roslyn O. Silver, District Judge. *

* The Honorable Roslyn O. Silver, United States District Judge for the District of Arizona, sitting by designation.

OPINION

LEE, Circuit Judge:

Can a snappy slogan for a potent pharmaceutical be deceptive and lead to liability under our securities laws? Not in this case where the company provided additional disclosures alongside the slogan in materials intended for investors.

Talphera, a pharmaceutical company, marketed its under-the-tongue opioid with the slogan "Tongue and Done" in advertisement displays and a speech at an investor conference. Several Talphera shareholders sued alleging that the slogan misled investors because administering the opioid drug is more complex than just "Tongue and Done" and thus its potential market would be more limited.

We affirm the dismissal of this securities fraud lawsuit because the plaintiffs failed to adequately plead falsity under Section 10(b) of the Securities Exchange Act of 1934 and Rule 10b-5. 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." The plaintiffs point to the FDA's warning letter objecting to the slogan, but that does not mean the slogan is necessarily deceptive, given that we apply a different standard for a reasonable investor than for a medical professional. We also hold that the plaintiffs have not shown a strong inference of scienter: The flimsy evidence of falsity necessarily undermines the ability to show scienter.

I. Background

A. Talphera develops an under-the-tongue opioid painkiller.

***2** Talphera specializes in developing drugs for acute pain management. Previously known as AcelRx, Talphera developed a sublingually-administered—*i.e.*, below the tongue—opioid tablet called DSUVIA. The new drug contains 30 micrograms of sufentanil, a powerful opioid. To reduce the risks of misusing such a potent painkiller, the FDA conditioned the drug's approval on compliance with an agency safety plan called a Risk Evaluation and Mitigation Strategy (REMS). REMS are generally designed to help ensure safe use of medications with serious safety concerns. The REMS plan for DSUVIA aimed to prevent the unauthorized distribution of the drug outside of healthcare settings. It thus required that patients receive this painkiller

only in medically-supervised settings such as hospitals, surgical centers, and emergency departments.

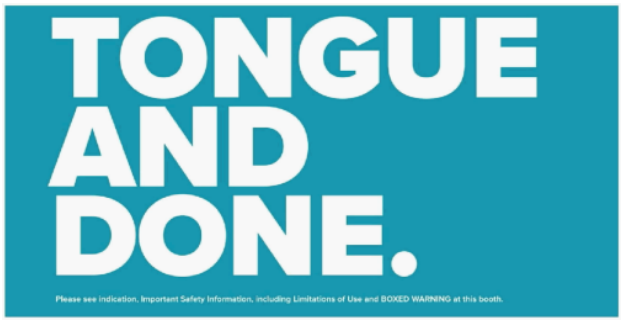
The REMS plan contained specific rules underscoring that retail pharmacies cannot carry DSUVIA and that patients cannot use it at home. For example, the REMS required hospitals to "[d]esignate an authorized representative to carry out [a] certification process" to verify the healthcare providers' compliance with the REMS. The REMS also required healthcare providers to train staff in how to administer the drug and to avoid distribution outside the hospital. And to obtain certification to administer DSUVIA, the healthcare provider needed a license "to carry Schedule 2 opioids[, and to] attest to the fact that they can manage acute opioid overdoses, [by having] either [ ] Narcan, opioid reversal agents, or other ways to manage the airways."

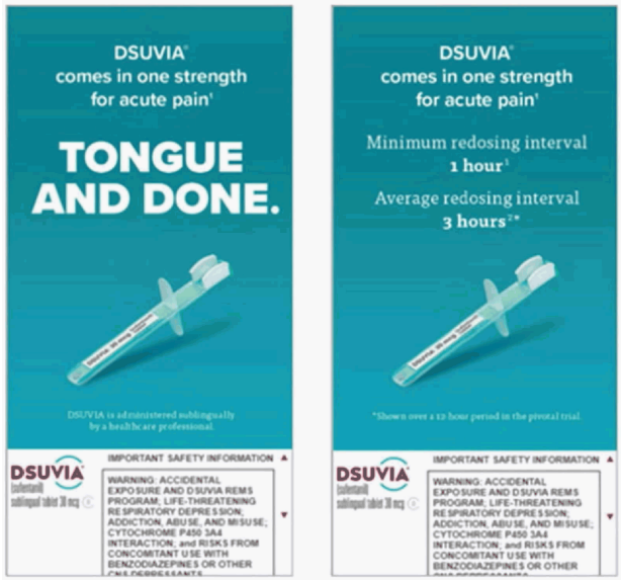
Despite these risks, DSUVIA still had a major selling point that distinguished it from many other powerful opioids: Patients could receive the drug orally instead of through an IV. This eliminated the need for (and the risks of) frequent redosing. It also allowed the drug to satisfy unmet demand, given the national shortage of IV-administered opioids.

B. Talphera uses the slogan "Tongue and Done" at investor conferences.

Talphera adopted the slogan "Tongue and Done" to advertise DSUVIA's desirable sublingual mode of delivery. The company ran all its marketing campaign material through an internal Promotional Review Committee (PRC) to help ensure marketing complied with FDA regulations. That body —which included the company's scientists, lawyers, and executives—approved the slogan. PRC members and co-defendants Chief Executive Officer Vincent Angotti and Chief Medical Officer Pamala Palmer also favored the slogan.

The "Tongue and Done" slogan soon appeared on marketing materials used at investor conferences. The tabletop display and banner (shown below) appeared at the DSUVIA booth during the Oppenheimer Health Care investors conference in March 2019. The "Tongue and Done" tabletop ad incorporated cautionary language that warned "[p]lease see indication, Important Safety Information, including Limitations of Use and BOXED WARNING *at this booth.*" The banner ad expressly noted that DSUVIA has a REMS plan and that only a healthcare professional may administer the drug. The banner ad also announced, "WARNING: ACCIDENTAL EXPOSURE AND *DSUVIA REMS PROGRAM* ..."





At the Oppenheimer Healthcare Conference, Angotti, the company's CEO, gave an address promoting DSUVIA. He began the speech by "level set[ting]" when he cautioned "[i]t's important if you take anything away [ ] that, you take this away. Our interests and investments lie in acute pain, always in a medically supervised setting.... You will never find our products in a CVS, a Rite-Aid, a Walmart, or a Walgreens." He also disclosed that DSUVIA "has a REMS to accompany it as well." Later in the speech, Angotti again cautioned "the product does have a REMS, a risk and evaluation mitigation strategy, with the whole goal to mitigate the risk of respiratory depression resulting from accidental exposure; accidental exposure meaning they don't want this outside of the hospital and neither do we as AcelRx."

***3** Angotti sandwiched his discussion of how healthcare providers administer DSUVIA between these two disclaimers. He started that discussion by describing the single dose applicator (SDP), a syringe-like device used to insert the DSUVIA tablet under the patient's tongue. Then he explained "[y]ou would simply remove the lock[,] ... tilt [the patient's] head back, lift [up] their tongue, inject it under, and you're done. It's basically as simple as that."

Angotti omitted some rather obvious additional steps in the FDA "administration instructions," like "[1] TEAR OPEN the notched pouch," "7. VISUALLY CONFIRM tablet placement in the sublingual space," and, lastly, "8. DISCARD the used SDA [single dose applicator] in biohazard waste after administration."

C. The FDA issues a warning letter about the slogan.

Talphera ceased using the "Tongue and Done" slogan after receiving a warning letter from the FDA dated February 11, 2021. The warning letter alleged that Talphera "misbrand[ed] Dsuvia within the meaning of the Federal Food, Drug and Cosmetic Act [FDCA]." The FDA concluded that Talphera made "false or misleading claims" for purposes of the FDCA by not providing a balanced description of the "risks and benefits" of the drug. 21 C.F.R. § 202.1(e)(5)(ii). Talphera had repeatedly warned investors about the risk of such a letter, even though the PRC had worked with the FDA in trying to ensure its marketing complied with FDA regulations.

D. Plaintiffs sue Talphera for securities fraud.

Several shareholders sued Talphera, Angotti, and Palmer, seeking damages for alleged violations of "Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b–5." They claimed that the following statements are false or misleading: (1) "Tongue and Done" tabletop display, (2) "Tongue and Done" banner advertisement, and (3) "Angotti's statement ... at the March 20, 2019 Oppenheimer Health Care Conference that you 'lift up their tongue, you inject it under and you're done.' "

The district court dismissed the shareholders' complaint for a failure to adequately plead facts leading to strong inference of scienter. It, however, did not rule on the falsity issue, deeming it a "close call."

On appeal, the plaintiffs repeat their argument that the challenged statements misled investors "because they omitted material information, including information about dosing, administration, and limitations of use." They also contend that these statements omitted material information about REMS restrictions and the size of DSUVIA's potential market. In other words, because DSUVIA is not a product that can be used at home by a patient, its market potential was much more limited. After twice granting Plaintiffs leave to amend, the district court dismissed the complaint with prejudice.

II. Standard of Review

Our jurisdiction arises under 28 U.S.C. § 1291 and we review de novo the dismissal of a complaint under Rule 12(b)(6). *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 989 (9th Cir. 2009). We accept the complaint's allegations as true and construe them in the light most favorable to the plaintiffs. *Id.* The Private Securities Litigation Reform Act of 1995 (PSLRA) also requires the complaint to (1) "specify each statement alleged to have been misleading [and the] reasons why the statement is misleading," and (2) "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 319, 321, 127 S.Ct. 2499, 168 L.Ed.2d 179 (2007) (quoting 15 U.S.C. § 78u–(4)(b)).

III. Discussion

Section 10(b) of the Securities Exchange Act of 1934 bars the use of "manipulative or deceptive device[s]" in "connection with the purchase or sale" of registered securities. 15 U.S.C. § 78j(b). Rule 10b-5 clarifies and builds upon this statutory anti-fraud provision. 17 C.F.R. § 240.10b-5. Based on this statute and regulation, we have held that a securities fraud plaintiff must allege: "(1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation." *Police Ret. Sys. of St. Louis v. Intuitive Surgical, Inc.*, 759 F.3d 1051, 1057 (9th Cir. 2014) (quoting *Halliburton Co. v. Erica P. John Fund, Inc.*, 573 U.S. 258, 267, 134 S.Ct. 2398, 189 L.Ed.2d 339 (2014)). Claims under § 20(a) of the Exchange Act—which establishes controlling-person liability—require pleading the same elements. *Zucco*, 552 F.3d at 990; 15 U.S.C. § 78t.

***4** Here, the parties only dispute whether the plaintiffs adequately pleaded falsity and scienter. We find the pleadings deficient on both fronts and affirm the district court.

A. Plaintiffs failed to adequately allege that the "Tongue and Done" slogan would mislead a reasonable investor.

Section 10(b) and Rule 10b–5 bar false or misleading statements and omissions. *In re Alphabet, Inc. Sec. Litig.*, 1

F.4th 687, 699 (9th Cir. 2021). But these anti-fraud provisions do not impose a duty to disclose all material information. Rather, they require disclosure only when necessary "to make ... statements made, in light of the circumstances under which they were made, not misleading." *See Khoja v. Orexigen Therapeutics, Inc.*, 899 F.3d 988, 1009 (9th Cir. 2018) (quoting *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 44, 131 S.Ct. 1309, 179 L.Ed.2d 398 (2011)). An omission of information 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." *Intuitive Surgical*, 759 F.3d at 1061 (quoting *Brody v. Transitional Hosps. Corp.*, 280 F.3d 997, 1006 (9th Cir. 2002)).

To decide whether a misstatement or omission can mislead, we need to look at "the context surrounding the statement[ ]." *See Weston Fam. P'ship. LLLP v. Twitter, Inc.*, 29 F.4th 611, 622 (9th Cir. 2022). Context matters because we presume that a reasonable investor—who has money on the line—acts with care and seeks out relevant information. *See Sec. Exch. Comm'n v. Monarch Fund*, 608 F.2d 938, 942 (2d Cir. 1979) ("All reasonable investors seek to obtain as much information as they can before purchasing or selling a security."). A reasonable investor cares about a statement's "surrounding text, including hedges, disclaimers, and apparently conflicting information." *Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension Fund*, 575 U.S. 175, 190, 135 S.Ct. 1318, 191 L.Ed.2d 253 (2015). For example, to determine whether a sentence in a company blog post could mislead investors, we looked at the entire blog post in *Weston Family.* 29 F.4th at 622.

Sometimes other information outside the immediate document can form the context in which a reasonable investor would view a particular statement. In other words, courts sometimes look at falsity through the lens of a "total mix" of information that forms part of the materiality analysis. *See In re Oracle Corp. Sec. Litig.*, 627 F.3d 376, 390 (9th Cir. 2010) ("Plaintiffs must 'demonstrate that a particular statement, when read in light of all the information then available to the market, or a failure to disclose particular information, conveyed a false or misleading impression.' " (quoting *In re Convergent Techs. Sec. Litig.*, 948 F.2d 507, 512 (9th Cir. 1991))). We, for example, have explained that a reasonable investor would interpret vague and optimistic statements by considering other information "the market already knew" about the "difficulties facing" a company. *Intuitive Surgical*, 759 F.3d at 1060.

1. A reasonable investor would not view "Tongue and Done" in isolation.

Considered in context, the "Tongue and Done" slogan would not mislead a reasonable investor, as plaintiffs claim, about the need to administer DSUVIA under a REMS or about the scale of the drug's potential market.

***5** To start, a reasonable investor would not blindly accept a marketing slogan by itself when she has access to other contextual information. Rather, a reasonable investor takes slogans for what they are—catchy phrases designed to highlight a desirable or unique product feature.[1] Talphera used "Tongue and Done" merely as a pithy marketing slogan and then accompanied it with ample disclosures and caveats. A reasonable investor would read "Tongue and Done" in the context of a marketing campaign designed to highlight its key selling point—that patients can receive the drug orally without the frequent redosing required with IV-administered painkillers. The slogan itself makes no representation about REMS-related restrictions on who may administer the drug or in what settings.

1 *See, e.g.*, Mayukh Dass et al., *A Study of the Antecedents of Slogan Liking*, 67 J. Bus. Rsch. 2504, 2505 (2014) ("The purpose of a slogan is to deliver a clear and focused message to consumers to help articulate the benefits provided by the brand ....").

Indeed, even a reasonable consumer—who, unlike a reasonable investor, is not presumed to carefully scour all the fine print—understands that a slogan is just that. *Cf. Moore v. Trader Joe's Co.*, 4 F.4th 874, 883–84 (9th Cir. 2021) (discussing reasonable consumer standard under California law). To use an analogy, a reasonable consumer understands that the slogan for Lay's chips—"Betcha can't eat just one"—just highlights the addictive taste of its potato chips. That slogan will not convey the number of grams of sodium, cholesterol, or saturated fat (which is far from "just one")—such information is provided elsewhere in the Nutrition Facts box. If a reasonable consumer understands the limits of a slogan, a reasonable investor certainly knows not to trust a slogan without investigating further.

Talphera provided copious clarifying information next to the "Tongue and Done" slogan. For example, the tabletop and

banner ads displayed at the investor conferences included text that disclosed the REMS plan for DSUVIA. The tabletop ad cautioned, "Please see indication, Important Safety Information, including Limitations of Use and BOXED WARNING *at this booth.*" Upon approaching the booth, a reasonable investor would have quickly learned of the REMS because the banner ad expressly noted DSUVIA has a REMS. It says, "WARNING: ACCIDENTAL EXPOSURE AND *DSUVIA REMS PROGRAM* ..." Staff at the booth could have presumably answered questions about the REMS. The banner ad also revealed that DSUVIA could not be used by a patient at home, noting that it is "administered sublingually by a healthcare professional." That statement informs a reasonable investor that DSUVIA's market may be limited because of the requirement of a supervised medical setting.

And investors who still wanted more information could turn to Talphera's SEC disclosures or its dedicated REMS website to learn how the REMS may affect DSUVIA's potential market. In short, the "Tongue and Done" slogan used at the investor conferences would not mislead a reasonable investor about DSUVIA's REMS program, given these disclosures.

Similarly, Angotti's statement at the Oppenheimer Health Conference touting DSUVIA's sublingual mode of delivery was not misleading. He stated that a doctor could "tilt [the ER or post-op patient's] head back, lift up their tongue, inject it under, and you're done." The plaintiffs contend that this was misleading. Not so.

A reasonable investor would consider Angotti's description of how medical staff administer DSUVIA in the context of his entire talk. *See Weston Fam.*, 29 F.4th at 622. That talk apprised investors of the limitations imposed by the REMS and of DSUVIA's limited market. For instance, Angotti began by cautioning "[o]ur interests and investments lie in acute pain, always in a medically supervised setting." Angotti also disclosed that DSUVIA "does have a REMS" and "[t]he whole goal here is controlled distribution that only goes to hospitals that are certified to carry Schedule 2 opioids that have and can attest to the fact that they can manage acute opioid overdoses ... and that they will not allow this for distribution outside the hospital." These statements warn reasonable investors that DSUVIA has a limited market because only healthcare professionals can administer the drug under a restrictive REMS. Further, a reasonable investor would not expect minute details of the REMS plan in Angotti's TED-like talk and would know that she could find such information elsewhere.

2. An FDA warning letter is not dispositive of a falsity claim under the Securities Act.

***6** The plaintiffs largely hitch their claim of falsity on the FDA's warning letter to Talphera about the "Tongue and Done" slogan. But the FDCA is not the same legal vehicle as the Exchange Act. The FDCA imposes different legal requirements and targets a different audience. FDA warning letters are thus not dispositive or even necessarily probative of falsity claims under the Exchange Act.

For falsity claims under our securities law, we look to the perspective of the reasonable investor. *Intuitive Surgical*, 759 F.3d at 1058-61. In contrast, FDA regulations focus on the perspective of patients and "prescribers of drugs." 21 C.F.R. § 202.1(e)(5)(ii). The disparate audiences require different sets of information and in different formats.

This case provides an example of how FDA regulations may require the disclosure of information to medical personnel that a reasonable investor would not need. *See Intuitive Surgical*, 759 F.3d at 1061. Angotti provided investors with a materially accurate—and thus not misleading—picture of how a healthcare professional would administer the 30-gram DSUVIA tablets under a patient's tongue using a single dose applicator. The only steps from the "administration instructions" Angotti omitted are obvious steps like "[1] TEAR OPEN the notched pouch," "7. VISUALLY CONFIRM tablet placement in the sublingual space," and, lastly, "8. DISCARD the used SDA [single dose applicator] in biohazard waste after administration." Contrary to the plaintiffs' argument, omitting such obvious steps would not mislead a reasonable investor because, for investment purposes, the steps do not materially change the overall picture. *See Intuitive Surgical*, 759 F.3d at 1061. By comparison, the FDA might find such specific information to be relevant because it mitigates risks to patients. Just because the FDA requires disclosure of specific instructions to healthcare providers does not make the omission of that information relevant for investors.

Further, the FDA regulations on misleading marketing conflict with our expectation of how reasonable investors behave. We expect reasonable investors to read an entire document, including the fine print and caveats, while FDA regulations dictate that "a brief statement[ ]" "in another distinct part of an advertisement" does not correct misleading

statements made elsewhere in an ad. 21 C.F.R. § 202.1(e)(3)(i). FDA regulations also explain that an "advertisement does not satisfy the requirement that it present a 'true statement' of information ... [if it] fails to present a fair balance between ... side effects and contraindications and ... benefits." 21 C.F.R. § 202.1(e)(5)(ii). But we expect reasonable investors to pay attention to caveats and disclaimers even if less prominently displayed. *See Omnicare*, 575 U.S. at 190, 135 S.Ct. 1318.

B. Plaintiffs have not pleaded a strong inference of scienter.

As the district court found, the plaintiffs also failed to plead facts giving rise to a strong inference that the defendants acted with scienter. *See Tellabs*, 551 U.S. at 326, 127 S.Ct. 2499. A strong inference arises "only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Id.* at 324, 127 S.Ct. 2499. Showing scienter necessarily becomes harder when the allegedly misleading statements are not flagrantly false because in those cases an innocent alternative explanation becomes more likely. *Cf. Merck & Co v. Reynolds*, 559 U.S. 633, 649–50, 130 S.Ct. 1784, 176 L.Ed.2d 582 (2010) (holding certain blatantly false statements lend support for a finding of scienter). Here, we find no strong inference of scienter because, viewed holistically, the facts suggest that Angotti and Palmer most likely made a good-faith determination that the "Tongue and Done" slogan would truthfully highlight DSUVIA's major selling point.

***7** Plaintiffs depend heavily on statements from confidential witnesses, a permissible and common practice in securities lawsuits. *Zucco*, 552 F.3d at 995; *see also Nguyen v. Endologix, Inc.*, 962 F.3d 405, 416 (9th Cir. 2020). But the confidential witness statements here do not show scienter for two reasons. *Zucco*, 552 F.3d at 995. First, few witnesses had the required personal knowledge of Angotti's or Palmer's decision-making to show scienter, as most witnesses never interacted with either executive. *Id.* Second, that one employee told Angotti and Palmer that the "Tongue and Done" slogan "oversimplified the use of a powerful opioid" speaks more to a good-faith difference of opinion. That difference of opinion may have arisen from Angotti and Palmer's own knowledge of the product.

The plaintiffs also try to show scienter through a core operations theory. The core operations doctrine allows courts to infer "that facts critical to a business's 'core operations' or an important transaction are known to the company's key officers." *Webb v. Solarcity Corp.*, 884 F.3d 844, 854 (9th Cir. 2018) (quoting *S. Ferry LP, No. 2 v. Killinger*, 542 F.3d 776, 783 (9th Cir. 2008)). Under this theory, "reporting false information will only be indicative of scienter where the falsity is patently obvious." *Zucco*, 552 F.3d at 1001. But any knowledge imputed to Angotti and Palmer does not yield a strong inference of scienter because, at the time, it was a matter of speculation whether the "Tongue and Done" slogan could mislead investors. The plaintiffs simply fail to plausibly show the core operations doctrine applies here because no "fact" existed that would have led Angotti and Palmer to "know" the "Tongue and Done" slogan conveyed "patently false" information. *See Zucco*, 552 F.3d at 1001.

The facts in the pleadings do not establish a strong inference of scienter because it is more probable that Angotti and Palmer wanted to use the "Tongue and Done" slogan to help market DSUVIA's biggest selling point. This alternative explanation is more probable because Angotti and Palmer likely did not intend to defraud investors by concealing the REMS and its restrictions on DSUVIA's use while simultaneously disclosing that information in myriad contexts. *See Webb*, 884 F.3d at 856–58 ("honest mistake" a more probable explanation for an accounting error because defendants publicly revealed the company had no profits, the very information any accounting fraud would seek to conceal).

Conclusion

We affirm the district court. The plaintiffs failed to plead facts sufficient to establish either falsity or scienter. Further, the inability to plead a § 10(b) or Rule 10b–5 claim precludes them from pleading a § 20(a) claim.

All Citations

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