

UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

Huey v. Anavex Life Sciences Corporation

Huey · No. 25-1752 · Decided June 26, 2026

OPINION

Huey v. Anavex Life Sciences Corporation

PER CURIAM.

25-1752 Huey v. Anavex Life Sciences Corporation In the United States Court of Appeals For the Second Circuit August Term, 2025 No. 25-1752

QUINTESSA HUEY,

Plaintiff-Appellant,

JONATHAN BLUM,

individually and on behalf of all others similarly situated, Plaintiff, v.

ANAVEX LIFE SCIENCES CORPORATION, CHRISTOPHER U. MISSLING,

Defendants-Appellees. On Appeal from a Judgment of the United States District Court for the Southern District of New York.

ARGUED: FEBRUARY 12, 2026

DECIDED: JUNE 26, 2026

Before: JACOBS, CALABRESI, and NATHAN, Circuit Judges. Plaintiff-Appellant Quintessa Huey appeals from a judgment of the United States District Court for the Southern District of New York (McMahon, J.) dismissing her complaint and denying her request to replead. Huey held shares in Anavex Life Sciences Corporation (“Anavex”), a publicly traded biopharmaceutical company. Huey filed a putative class action against Anavex and its then-CEO, Christopher U. Missling, alleging securities fraud on the basis of an alleged misrepresentation. On the day that Defendants made a disclosure correcting the alleged misrepresentation, Anavex’s share price increased. The share price did not decline until the next two days, when it moved in tandem with the entire market. The district court held that Huey failed sufficiently to plead loss causation given the initial increase and delayed decline in Anavex’s share price. Because we agree that in light of these circumstances Huey failed plausibly to allege loss causation, we AFFIRM the judgment of the district court. ADAM M. APTON, Levi & Korsinsky, LLP, New York, NY, for Plaintiff-Appellant. STEPHEN G. TOPETZES (Theodore L. Kornobis, on the brief), K&L Gates LLP, Washington, DC, for Defendants-Appellees. CALABRESI, Circuit Judge: This case concerns what pleadings are necessary for a plaintiff sufficiently to allege loss causation in a securities-fraud action under Section 10(b) of the Securities Exchange Act. 2 Plaintiff-Appellant Quintessa Huey held shares in Anavex Life Sciences Corporation (“Anavex”), a publicly traded biopharmaceutical company. Huey filed a putative class action against Anavex and its then-CEO,

Christopher U. Missling, alleging that they misled investors by, among other things, implying in various disclosures that the FDA had approved their methodology for measuring a drug candidate's efficacy in clinical trials. On the day Missling announced that the company would abandon the purportedly FDA-approved methodology, Anavex's share price increased. The share price did not decline until the following two days; at that time, it moved in tandem with the entire market. The United States District Court for the Southern District of New York (McMahon, J.) dismissed Huey's complaint for failure to state a claim and denied her request to replead. The district court held that Huey failed sufficiently to plead loss causation given the initial increase then delayed decline in Anavex's share price, and the surrounding market context. Because we agree that Huey failed plausibly to allege loss causation, we AFFIRM the judgment of the district court.

3 I. Background A. Anavex Tests Proposed Treatment for Rett Syndrome Anavex is a public biopharmaceutical company that specializes in early-stage therapies for central nervous system diseases. In 2016, Anavex announced that one of its drug candidates, ANAVEX 2-73, displayed "positive preclinical data" for the treatment of Rett syndrome, a rare genetic neurological disease. P.A. App'x at 16. To obtain FDA approval to sell and market ANAVEX 2-73 for Rett syndrome, Anavex conducted several clinical trials, including: a Phase 2 trial beginning in June 2019 (the AVATAR trial) and a Phase 2/3 trial beginning in September 2019 (the EXCELLENCE trial). As with all clinical trials, these studies used standardized metrics known as "endpoints" to measure the efficacy of the tested drug. One such endpoint is a patient's improvement on the Rett Syndrome Behavioral Questionnaire ("RSBQ"): a survey administered to a Rett syndrome patient by her caregiver that assesses symptoms the patient is experiencing. Another endpoint is a patient's improvement on the Clinical Global Impression-Improvement (CGI-I) scale: an assessment similar to RSBQ that is completed by a patient's clinician, rather than the patient herself. To improve accuracy, these two metrics can be "anchored" to one another to ensure that a patient's self-reported improvements are tied to improvements also observed by a clinical professional. Anavex was not the only company working on a Rett syndrome treatment. A competitor pharmaceutical company, Neuren, developed a Rett syndrome drug candidate called DAYBUE that had reached the end of its Phase 2 trials by 2017. For DAYBUE's final Phase 3 clinical trial, the FDA approved Neuren's use of an anchored RSBQ/CGI-I endpoint to measure the drug's efficacy. Neuren used the typical approach for measuring efficacy in clinical trials. This approach compared the final, end-of-treatment RSBQ/CGI-I score with the baseline, pre-treatment score to determine the patient's net improvement ("RSBQ/CGI-I endpoint"). The trial concluded in 2021 with positive results, and DAYBUE received marketing approval from the FDA in March 2023. Anavex took a different approach in its clinical trials of ANAVEX 2-73. Rather than compare the baseline and end-of-treatment RSBQ/CGI-I scores for each patient, Anavex decided to account also for scores reported during the trial (i.e., mid-treatment RSBQ/CGI-I scores). Anavex called this approach RSBQ-AUC (Area Under the Curve). By including mid-treatment scores in the measurement, the RSBQ-AUC metric might reflect positive results although the end-

of-treatment 5 score showed no improvement from the baseline. Indeed, the RSBQ-AUC result could show a positive result even if the end-of-treatment score was lower than the baseline (i.e., where a patient's Rett syndrome symptoms were worse at the conclusion of the study compared to when it began). Anavex thus could report positive treatment effects for ANAVEX 2-73 using RSBQ-AUC although the RSBQ/CGI-I endpoint used in the DAYBUE trial and approved by the FDA would yield a neutral, or even a negative, effect. B. Anavex's Class Period Disclosures During the Rett syndrome trials for ANAVEX 2-73, Defendants made several public statements about the endpoints used and results obtained.

1. February 1, 2022, Statement

On February 1, 2022, Anavex hosted a special conference call to discuss the AVATAR trial results. During the call, a research analyst asked Missling whether the upcoming EXCELLENCE trial would use the same RSBQ-AUC endpoint as the AVATAR trial. Missling replied, "So that's right, the EXCELLENCE study will use the same endpoint . . . because it's just described, it is just the preference of the FDA." P.A. App'x at 37 (¶ 75) (emphasis added). He also said that the trial results 6 could potentially be used "to seek approval for Rett syndrome for adult patients." Id. at 40 (¶ 78).

2. February 2022 through January 2023 Statements

Over the course of the next year, Anavex and Missling made several statements reiterating the company's intention to use the same RSBQ-AUC endpoint in its clinical trials and how the trials could provide a viable path to FDA approval. For example, on February 9, 2022, an equity analyst asked Missling what the FDA would think about Anavex submitting results under the RSBQ-AUC endpoint even though a different company had recently submitted results using a different endpoint. Id. at 43 (¶ 83). Referencing "really specific" "FDA guidance," Missling explained that the RSBQ and CGI-I scores must be anchored to one another, but he did not address whether the RSBQ-AUC endpoint would be acceptable to the FDA. Id. at 35-36 (¶ 83). In subsequent investor calls, Missling similarly responded to questions about the RSBQ-AUC endpoint by discussing the anchoring of RSBQ to CGI-I while avoiding the issue of the mid-treatment AUC methodology. He also repeatedly reaffirmed, or at least implied, that the EXCELLENCE study would use 7 the same RSBQ-AUC endpoint. See, e.g., id. at 45-46 (¶ 86) ("So the RSBQ-AUC includes the CGI-I . . . linked respond analysis, that is the endpoint which we will also propose for the EXCELLENCE study. That is correct. It's consistent with the AVATAR study.").

3. February 2, 2023, Statement

On February 2, 2023, Anavex issued a press release on the EXCELLENCE trial. In addition to announcing that the company exceeded its enrollment target for the study, Anavex also stated: "In communication with the FDA, we received their input on the endpoints, which were utilized in this study." Id. at 49 (¶ 94). Anavex did not say whether the FDA's input on the RSBQ-AUC endpoint was approving or disapproving.

4. February 7, 2023, Statement

Five days later, in a conference call discussing quarterly earnings, an analyst questioned Missling about the FDA's feedback on endpoints in the EXCELLENCE trial: Analyst: So I wanted to confirm that the primary end point is RSBQ AUC similar to – or the same to the one used in the AVATAR study? And – so has the FDA agreed that AUC, the modified RSBQ scale, can be an appropriate end point for Rett syndrome study? 8 Missling: Yes It is the RSBQ as primary end point, and the CGI-I is key secondary end point over the course of the trial. Analyst: Is that the same end point that was used in the AVATAR study? Missling: Slightly different. So it's actually the measurement over time from beginning to end of trial. Analyst: Not AUC? Missling: Not AUC. Analyst: Not AUC? Missling: Exactly, yes. Analyst: Okay. Missling: Because the study is large enough that it can carry the signal by itself without AUC. Id. at 50-51 (¶ 97) (emphasis added). This exchange was the first time that Anavex stated explicitly that it would not be using the RSBQ-AUC endpoint. By market close on the day of this conference call, Anavex's stock price had increased from \$11.11 to \$11.75 per share. The next day, the share price fell to \$10.93 per share, and on the following day it fell again to \$10.41 per share. C. Failure of Key Clinical Trial On January 2, 2024, the last day of the proposed Class Period, Anavex issued a press release announcing the highly anticipated results of the EXCELLENCE study: patients who took ANAVEX 2-73 did not experience statistically significant improvements in their symptoms, as measured by the FDA-approved pre-to-post- 9 treatment RSBQ/CGI-I endpoint. Put simply, the trial failed. After the announcement, Anavex's share price tumbled from \$9.31 to \$6.05 per share at that day's market close. D. Plaintiff's Allegations Huey seeks to represent a class of all persons who purchased Anavex stock on the Nasdaq between February 1, 2022, and January 1, 2024, inclusive (the "Class Period"), against Anavex and Missling for violations of the Securities Exchange Act of 1934. 1 Huey alleges that Anavex and Missling fraudulently used the RSBQ-AUC endpoint to conceal weak clinical data even though they knew that the endpoint would not be acceptable to the FDA. She claims that "the FDA instructed Anavex to use [RSBQ/CGI-I] when discussing and/or approving" Anavex's clinical trials. P.A. App'x at 31 (¶ 58). As evidence of this supposed knowledge, Huey cites to FDA regulations requiring the agency to meet with Anavex and discuss, among other topics, endpoints. She also alleges that Anavex must have 1 The claim brought against Missling is under Section 20(a) of the Securities Exchange Act, which imposes joint and several liability on persons who, directly or indirectly, control any person liable for a primary violation under the respective acts, such as Section 10(b). 15 U.S.C. §§ 77o(a), 78t(a). Where a plaintiff fails to allege a primary violation under Section 10(b), the related Section 20(a) claim must also fail. See *ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 108 (2d Cir. 2007). 10 known the RSBQ-AUC endpoint would be unacceptable because, in 2017, the FDA approved the RSBQ/CGI-I endpoint for Neuren's Rett syndrome treatment. Huey does not, however, make specific allegations about meetings during which the FDA had told Anavex that its endpoint was unacceptable. E. Procedural History Defendants moved to dismiss the putative class action for failure to state a claim. The district court granted Defendants' motion and dismissed

Plaintiff's case with prejudice. Huey v. Anavex Life Scis. Corp., No. 24-CV-1910, 2025 WL 1707581 (S.D.N.Y. June 18, 2025). The court found that, of all the statements alleged to be false or misleading, Huey plausibly alleged the requisite elements of falsity and scienter for only one of them: the February 2, 2023, press release that said, "[i]n communication with the FDA, we received their input on the endpoints, which were utilized in this study." 2 P.A. App'x at 49 (¶ 94); see id. at *6. According to the court, Huey plausibly alleged that the statement was materially false or misleading because, although it disclosed that the FDA said something to Anavex 2 All the remaining statements were either: "(1) literally true at the time they were made; (2) entirely conclusory; (3) forward-looking with appropriate qualification . . . ; (4) puffery; or (5) fraud by hindsight pleading." Huey, 2025 WL 1707581, at *5. 11 about its choice of endpoints, it failed to disclose that the FDA told Anavex the RSBQ-AUC endpoint was unacceptable. Huey, 2025 WL 1707581, at *4-5. The court also held that Huey sufficiently alleged scienter because Anavex admitted just a few days later, on February 7, that it would not be using the RSBQ-AUC endpoint, which gave rise to the plausible inference that the change was due to the recent FDA meeting. Id. at *6. The district court found, however, that Huey did not make it "across the finish line" with respect to loss causation, a requisite element of a 10(b) claim. Id. According to the court, Huey's allegations failed because, on February 7, the day of Anavex's corrective disclosure that it would not be using the RSBQ-AUC endpoint, "the stock price went up, not down." Id. at *8. To the court, that initial increase was fatal because, even though the share price went down during the following two days, it had moved in the same direction as the market. See id. at *7.

The district court denied Huey's motion for leave to amend her complaint, reasoning that amendment would be futile because Huey cannot establish falsity for any other statements and she cannot establish loss causation for the February 2 statement. Id. at *8. Huey timely appealed. 12

II. Standard of Review We review de novo the district court's dismissal under Rule 12(b)(6), accepting all factual allegations in the complaint as true and drawing all reasonable inferences in Plaintiff's favor. *Adelson v. Harris*, 774 F.3d 803, 807 (2d Cir. 2014). "We review a district court's denial of leave to amend the complaint for abuse of discretion, unless the denial was based on an interpretation of law, such as futility, in which case we review the legal conclusion de novo." *Panther Partners Inc. v. Ikanos Commc'ns, Inc.*, 681 F.3d 114, 119 (2d Cir. 2012).

III. Discussion On appeal, Huey challenges the district court's holding that she inadequately pleaded loss causation as to Defendants' February 2, 2023, statement. 3 Defendants argue that the district court's loss-causation determination was correct and also that Huey failed plausibly to allege falsity and scienter. 3 Huey did not challenge the district court's holding that she failed plausibly to allege falsity as to all the other statements, so we consider only the February 2, 2023, statement. 13 Section 10(b) of the Securities Exchange Act of 1934 makes it unlawful to "use or employ, in connection with the purchase or sale of any security . . . any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the Commission may prescribe." 15

U.S.C. § 78j(b). Commission Rule 10b-5 forbids the making of “any untrue statement of a material fact,” and the omission of any material fact “necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading.” 17 C.F.R. § 240.10b-5. “To state a claim under Section 10(b) and Rule 10b-5, a plaintiff must plead: (1) a misstatement or omission of material fact [i.e., falsity]; (2) scienter; (3) a connection with the purchase or sale of securities;

(4) reliance [i.e., transaction causation]; (5) economic loss; and (6) loss

causation.” *Ark. Pub. Emps. Ret. Sys. v. Bristol-Myers Squibb Co.*, 28 F.4th 343, 351- 52 (2d Cir. 2022). Only three of the necessary elements of a Section 10(b) claim are before us on appeal: falsity, scienter, and loss causation. Because we find that Huey failed plausibly to allege loss causation, we need not, and do not, consider whether the remaining elements of falsity and scienter are satisfied. Accordingly, we proceed directly to discuss loss causation. 14 A. The Nature of Loss Causation Before we turn to the specifics of this case, it is worth writing at some length about loss causation.

1. Loss Causation’s Relation to Other Causal Requirements

Loss causation has been the source of some confusion because of its relation to the causation requirements in common-law cases. At common law, there are three general requirements of causation: (1) but-for causation; (2) causal link; and

(3) if each of these is met, that the cause be proximate. See *United States v. Nelson*,

277 F.3d 164, 186 (2d Cir. 2002); see also Guido Calabresi, *Concerning Cause and the Law of Torts: An Essay for Harry Kalven, Jr.*, 43 U. Chi. L. Rev. 69, 71-72 (1975) (identifying and differentiating the three causal concepts). 4 But-for causation asks: would plaintiff have been harmed but for defendant’s conduct? Causal link considers whether defendant’s conduct increased the likelihood that plaintiff’s harm would occur—i.e., is there a relationship between the nature of defendant’s conduct and the harm plaintiff 4 An additional and separate usual requirement at common law is that the plaintiff suffered some ascertainable harm (i.e., damages). 15 suffered. And both but-for cause and causal link are generally necessary to establish tort liability at common law. 5 That is also so in common-law fraud cases. 6 Distinct from but-for cause and causal link is a third requirement that they both be proximate. Courts and scholars alike frequently conflate causal link with proximate cause—seemingly due to the relation of each to foreseeability—but they are separate liability-limiting concepts. A causal link can exist, but it may be so weak that we may choose not to impose liability. 7 Such a decision not to impose 5 The classic common-law torts case where but-for causation existed but causal link did not is *Berry v. Sugar Notch Borough*, 43 A. 240 (Pa. 1899). There, a violent windstorm toppled a tree onto a moving trolley car. At the time of the accident, the trolley car was negligently speeding. In literal terms, the wrongful conduct—the speeding—was a but-for cause of the accident: had the trolley car not been speeding, it would not have reached the spot where the tree fell at that exact moment. What was lacking, however, was a causal link. Speeding does not make it more likely that trees would

fall on trolley cars. For that reason, the plaintiff failed to satisfy the causation requirements for tort liability. If, however, one could have shown that the increased vibrations from speeding indeed caused trees to fall with greater frequency (e.g., vibrations from speeding caused trees to uproot), then a causal link could be said to have existed. 6 In *Loreley*, we offered the example of where a fraudulent misrepresentation caused a buyer to purchase a home (but-for cause), but the nature of the misrepresentation was unrelated to the likelihood that the home would be subsequently destroyed in a storm (causal link). See *Loreley Fin. (Jersey) No. 3 Ltd. v. Wells Fargo Sec., LLC*, 797 F.3d 160, 183-86 (2d Cir. 2015). 7 In the *Berry* case, for example, if the increased vibrations from the speeding trolley cars can be shown to increase the likelihood of trees falling, then a causal link is present. Nevertheless, the vibrations may not be deemed “proximate” enough to the falling trees to warrant the allocation of liability costs to the negligent trolley operator rather than, say, the town that negligently planted the trees close to the road. This determination can be made on foreseeability grounds or any number of other reasons encompassed under the umbrella of proximate cause. 16 liability due to lack of proximity is separate from and does not negate the presence of a causal link. 8 These three causation elements need not be required under every given statute, or, for that matter, even at common law. That is, a society may wish in some statutes or areas of common law to place burdens on (i.e., punish) people who do certain things, regardless of causal relationships. A statute could require Conversely, there are cases where the causal link is so strong that it is sufficient to establish not only proximate but even but-for cause. Someone is punched and their nose becomes broken. Even without direct evidence that the person’s nose was broken due to the impact with the punching hand, the causal link is so strong that but-for causation is readily assumed. On these facts it is up to the tortfeasor to bring in evidence denying but-for cause. Judge Cardozo applied this principle in *Martin v. Herzog*, 126 N.E. 814, 816 (N.Y. 1920), as did we in *Zuchowicz v. United States*, 140 F.3d 381, 391 (2d Cir. 1998), where we held that “when a negative side effect is demonstrated to be the result of a drug, and the drug was wrongly prescribed in an unapproved and excessive dosage (i.e. a strong causal link has been shown), the plaintiff who is injured has generally shown enough to permit the finder of fact to conclude that the excessive dosage was” a but-for cause, even without additional proof of causation. In other words, the causal link between an excessive dose of prescription medication and negative side effects was strong enough to permit the inference of but-for cause. 8The Restatement (Third) of Torts does not speak of “proximity” in the language of causation. See Restatement (Third) of Torts: Liability for Physical and Emotional Harm, ch. 6, Special Note on Proximate Cause (A.L.I. 2010) (characterizing proximate cause as “an especially poor [term] to describe the idea to which it is connected”); see also Restatement (Third) of Torts: Liability for Economic Harm § 12 (A.L.I. 2020) (similarly departing from the term “proximate cause” in the fraud context). Rather, the Restatement categorizes questions of proximity—such as foreseeability—as one aspect of “Scope of Liability,” a term that encompasses rules for when tort law does not impose liability on an actor although the causal requirements of but-for cause and causal link have been met. See Restatement

(Third) of Torts: Liability for Physical and Emotional Harm, ch. 6, Special Note on Proximate Cause (A.L.I. 2010). Nevertheless, because the term proximate cause “has been in widespread use in judicial opinions, treatises, casebooks, and scholarship,” we use that term here. *Id.* 17 one who commits securities fraud to pay damages even though, in an economic sense, the particular harm at issue was purely coincidental. 9 In other words, a defendant could be held liable even if a causal link is not present based on a societal policy position that fraud is bad and deserves punishment, regardless of whether it is linked to a particular harm. And just as liability can exist for but-for cause without causal link, so too can it exist where causal link is present and but-for cause is not. 10 The myriad permutations of causation rules at common law and in various statutes have been noted in our cases. See, e.g., *Loreley Fin. (Jersey) No. 3 Ltd. v. Wells Fargo Sec., LLC*, 797 F.3d 160, 183-86 (2d Cir. 2015) (providing examples of differing causation requirements); *Transatlantic Schifffahrtsgesellschaft mbH & Co. v. Shanghai Foreign* 9 Indeed, in England, that is how statutes analogous to our federal securities laws have been read. See Jane Stapleton, *Benefits of Comparative Tort Reasoning: Lost in Translation*, 1 *J. Tort L.*, no. 3, 2007, at 2 (“[I]n the U.S. it seems to be a principle that a defendant in the tort of deceit cannot be liable for coincidental consequences; but that principle is rejected in England.”). 10 This can be seen in maritime law where the right to “cure” imposes on shipowners the obligation to provide medical care to seamen who become ill or are injured while in service to a vessel, regardless not only of any fault but also of but-for causation. See *Calo v. Ocean Ships, Inc.*, 57 F.3d 159, 162 (2d Cir. 1995); see generally Thomas J. Schoenbaum, *Admiralty and Maritime Law* § 6:28 (7th ed. 2026). The desire to ensure the victim is cared for—and the capacity of the defendant to do that caring—has evidently mattered more than the incentive structures that follow from requiring but-for cause. 18 *Trade Corp.*, 204 F.3d 384, 390-91 (2d Cir. 2000) (comparing the FSIA’s causation requirements with those at common law); Matteo Godi, *Section 1983: A Strict Liability Statutory Tort*, 113 *Calif. L. Rev.* 1933, 1985-86 (2025) (framing Section 1983 as a statutory tort that requires all three causation elements). 11 Because statutory causation rules frequently differ from those at common law, clarity is of utmost importance when addressing the issue in statutory cases. Our first task, then, is to determine the causation requirements for the statute at hand.

2. Loss Causation in a Federal Securities Action

Courts have long held that a private damages action under the Securities Exchange Act of 1934 and Rule 10b-5 “resembles, but is not identical to, common-law tort actions for deceit and misrepresentation.” *Dura Pharmaceuticals, Inc. v. Broudo*, 544 U.S. 336, 341 (2005); see also *Bastian v. Petren Res. Corp.*, 892 F.2d 680, 11 In some statutes, such as RICO, the causation requirements are stricter than at common law. Compare, e.g., *Palsgraf v. Long Island R.R.*, 162 N.E. 99, 101 (1928) (finding at common law the element of foreseeability satisfied where the plaintiff was in a foreseeable category of persons who might be harmed), with *Hecht v. Com. Clearing House, Inc.*, 897 F.2d 21, 23-24 (2d Cir. 1990) (requiring additionally under RICO that the kind of harm the victim suffered also be foreseeable). In others, such as the Federal

Employers' Liability Act, they are more relaxed. See *CSX Transp., Inc. v. McBride*, 564 U.S. 685, 688 (2011) (holding that FELA "does not incorporate 'proximate cause' standards developed in nonstatutory common-law tort actions" and construing the statute's causation requirement as, essentially, but-for causation). 19 683 (7th Cir. 1990) (Posner, J.) (describing the federal securities fraud statute as "borrow[ing]" "the standard common law fraud rule"). And in the Private Securities Litigation Reform Act, Congress added an explicit causation requirement: "[T]he plaintiff shall have the burden of proving that the act or omission of the defendant alleged to violate this chapter caused the loss for which the plaintiff seeks to recover damages." 15 U.S.C. § 78u-4(b)(4) (emphasis added). The statutory text and the long history of private actions brought under the Securities Exchange Act make clear that all three common-law causation elements must be met. The Supreme Court confirmed these requirements in *Dura* when it stated that a plaintiff must sufficiently plead "reliance"—which is essentially but- for causation in a fraud-on-the-market context 12—and "loss causation" as elements of a private action. 544 U.S. at 341-42. Loss causation, however, has been defined differently depending on the statutory context in which it arises. While in one 12 That is, "but for the claimed misrepresentations or omissions, the plaintiff would not have entered into the detrimental securities transaction"—i.e., transaction causation. *Emergent Capital Inv. Mgmt., LLC v. Stonepath Group, Inc.*, 343 F.3d 189, 197 (2d Cir. 2003). Based on the hypothesis of efficient capital markets, it is presumed that a company's material misrepresentation distorted the security's price, so but-for causation of any subsequent loss also is presumed. See generally *Basic Inc. v. Levinson*, 485 U.S. 224 (1988) (adopting a presumption of reliance in the fraud-on-the-market context). 20 statute it may contain all three requirements of common-law causation, in another statute it may comprise only causal link. Compare *Moore v. PaineWebber, Inc.*, 189 F.3d 165, 175 (2d Cir. 1999) (Calabresi, J., concurring) (describing loss causation in the RICO context as containing all three common-law requirements), with *Loreley*, 797 F.3d at 184-85 (describing loss causation as only causal link in a common-law case). In the statute before us, the loss-causation element does not contain all the common-law elements because but-for causation is required separately under the rubric of "reliance." See *Dura*, 544 U.S. at 341-42 (listing elements). It does, however, contain the requirements of causal link and proximity. That is clear from the Supreme Court's statement in *Dura* that the plaintiff must prove that the defendant's misrepresentation "proximately caused" her harm. 544 U.S. at 346. That is, there must be a causal link, and it must also be proximate. Because causal link and proximity are both encompassed within the "loss causation" element in this statute, courts must determine which, if either, of the two concepts underlies a finding that the element is unsatisfied. 21

3. Pleading Standards for Loss Causation

An additional, and particularly challenging, question is what causation allegations suffice at the pleading stage. As a general matter, the pleading rules "are not meant to impose a great burden upon a plaintiff." *Dura*, 544 U.S. at 347. But given the "fact-based" nature of the loss-causation inquiry, "the degree of difficulty in pleading will be affected by circumstances." *Lentell v. Merrill*

Lynch & Co. Inc., 396 F.3d 161, 174 (2d Cir. 2005). In some contexts, even though a defendant's wrongful act was clearly the but-for cause of plaintiff's harm, our common knowledge is such that we readily say that the loss was entirely coincidental. 13 To plead causation sufficiently in such circumstances, the plaintiff must say something additional that leads us plausibly to believe that our common-sense understanding of the situation being coincidental does not apply. 14 That is so in the case of the tree falling on the trolley, or the case of the destruction of a 13 home by a flood. See *supra* footnotes 5-6. 14 That is, he must plausibly plead that vibrations from speeding trolleys cause trees to fall more often, or that the house bought was in an area particularly prone to floods. 22 In other circumstances, the causal link between the misrepresentation and the harm is plausible at first glance. For example, someone buys a house because the real-estate company falsely said it was hurricane-proof, but a hurricane still destroys it. In those cases, the burden shifts to the defendant to render implausible the causal link. The real-estate company must show, for example, that the hurricane was so devastating that it destroyed everything, including all of the homes that were properly marketed as hurricane-proof. The analogous question in the securities context is whether a plaintiff can disaggregate changes in a company's share price from general market trends. Was a company's misrepresentation and its correction the cause of the decline in its share price, or did the market decline universally, taking the company's share price with it? What we have tended to say in the fraud-on-the-market context is that if the share price did not go down when the misrepresentation was corrected, then the misrepresentation was coincidental. And where instead the share price went down once the misrepresentation was revealed, we have tended to find that to be enough plausibly to show causality rather than coincidence. But these general statements are not completely accurate. One can conceive of situations—fairly common ones—where they are too crude. Say the price does 23 not go down on the day of the corrective disclosure, but on that day the rest of the market goes up by a huge amount. Had the company not misrepresented, the shareholder would have bought a different security that would have soared. The shareholder lost money, and that loss was causally linked. Or, say the share price goes down, but on that day the entire market dropped significantly. The question then becomes, what additional pleadings are necessary in such circumstances to survive a 12(b)(6) motion? Under the *Iqbal* pleading standard, we ask not whether it is possible that the misrepresentation caused the share price decline independent of market movements, but whether that causal explanation is plausible. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). A plausible causal link is easy to establish where the share price declines while the market does not. But more must be pleaded when that is not so. “[W]hen the plaintiff's loss coincides with a marketwide phenomenon causing comparable losses to other investors, the prospect that the plaintiff's loss was caused by the fraud decreases.” *Lentell*, 396 F.3d at 174. A plaintiff's claim thus fails when “it has not adequately plead[ed] facts which, if proven, would show that its loss was caused by the alleged misstatements as opposed to 24 intervening events.” *First Nationwide Bank v. Gelt Funding Corp.*, 27 F.3d 763, 772 (2d Cir. 1994). 15 In fraud-on-the-market cases, a key determinant of what showing is necessary to

establish plausible loss causation is the timing of the alleged loss in relation to the corrective disclosure. Once the misrepresentation is revealed to the public, how soon thereafter does the share price adjust? In an efficient market, “courts will assume that the stock price reacts immediately” “once a misstatement or corrective disclosure is publicly known.” *Bricklayers & Trowel Trades Int’l Pension Fund v. Credit Suisse Sec. (USA) LLC*, 752 F.3d 82, 89 (1st Cir. 2014). Indeed, we witness the market’s haste every trading day when share prices respond promptly to a company’s quarterly earnings results or the release of any other material information. 15 Our circuit has confronted any number of cases where plaintiffs had to allege loss causation in the midst of systemwide market declines. Cf. *Fed. Hous. Fin. Agency for Fed. Nat’l Mortg. Ass’n v. Nomura Holding Am., Inc.*, 873 F.3d 85, 158 (2d Cir. 2017) (“[I]n the wake of the Great Recession, the mandate of Congress [in its securities laws] weighs heavy on the docket of the Southern District of New York.”). Some claims succeeded, some did not. Compare *Loreley*, 797 F.3d 163 (adequately pleading loss causation amidst the Great Recession), with *Cent. States, Se. & Sw. Areas Pension Fund v. Fed. Home Loan Mortg. Corp.*, 543 F. App’x 72 (2d Cir. 2013) (summary order) (inadequate pleading). 25 But that is not to say we should have a per se rule rendering implausible any claim where the share price did not immediately adjust. To the contrary, we expressly reject a per se rule that a plaintiff can only establish loss causation by showing a loss on the exact day of the corrective disclosure. Several of our sister circuits have rejected similar categorical arguments. See, e.g., *Shash v. Biogen, Inc.*, 84 F.4th 1, 21 (1st Cir. 2023) (“[N]othing requir[es] that a stock’s price must drop immediately following a corrective disclosure for loss causation to be sufficiently pled.”); *Lormand v. US Unwired, Inc.*, 565 F.3d 228, 266 n.33 (5th Cir. 2009) (“The market could plausibly have had a delayed reaction,” so an increase in share price before an eventual decrease is “not enough to dismiss a complaint that alleges a specific causal link.” (emphasis omitted)); *In re Gilead Scis. Sec. Litig.*, 536 F.3d 1049, 1058 (9th Cir. 2008) (“A limited temporal gap between the time a misrepresentation is publicly revealed and the subsequent decline in stock value does not render a plaintiff’s theory of loss causation per se implausible.”). The fact-intensive nature of the loss-causation inquiry is not conducive to such absolutism. Rather, where a plaintiff alleges a loss that occurs some time after the corrective disclosure is made, it becomes that plaintiff’s burden to allege 26 plausibly why the loss was not immediate. 16 In some situations, the reason might be self-evident. Say, for example, a corrective disclosure is made at 3:59 PM Eastern Time on a Friday. A minute later, at 4:00 PM, the New York Stock Exchange closes for the weekend. It is more than plausible that the share price would not reflect the corrective disclosure until three days later, when the market opens on Monday. In other situations, the necessary showing may be difficult to make. A corrective disclosure is made on a Tuesday morning during a widely covered quarterly earnings call. On that day, the share price increases and plaintiff does not allege a loss until a week later. Notwithstanding the influence of broader market movements, it is difficult to conceive of why the loss would be so delayed. The task of courts in evaluating loss causation, then, is to conduct a precise inquiry to ascertain the

plausible existence of causal link and proximity. Bearing in mind that “ordinary pleading rules are not meant to impose a great burden upon a plaintiff,” *Dura*, 544 U.S. at 347, courts must view the loss-causation allegations in a fraud-on-the-market case in light of the market’s broader 16 Put differently, the purpose of these additional pleadings is to explain why the market did not operate with 100% efficiency in absorbing the material information. Discounting the efficiency of the market, however, may undermine a plaintiff’s presumption of reliance, which is predicated on the efficient-market hypothesis. See *Basic Inc.*, 485 U.S. at 245-48. 27 movements and the gap in time between the corrective disclosure and the alleged loss. That is the task we must now undertake in the instant case. B. Huey’s Loss Pleadings Generally speaking, a securities-fraud complaint must meet the heightened pleading standards of Rule 9(b) and be stated with particularity. Our Court has held, however, that loss-causation pleadings are not subject to those heightened requirements. *Gimpel v. The Hain Celestial Grp., Inc.*, 156 F.4th 121, 151 (2d Cir. 2025); see also *Lentell*, 396 F.3d at 174 (stating that loss causation is generally a “fact- based inquiry” appropriate for trial). Accordingly, we evaluate Huey’s allegations under the default pleading standard of Rule 8(a)(2), which requires “a short and plain statement of the claim showing that the pleader is entitled to relief.” Fed. R. Civ. Proc. 8(a)(2). Huey alleges, and we assume *arguendo*, that the February 2, 2023, statement was materially misleading because it “created the false impression that the FDA [had] approved” the RSBQ-AUC endpoint. P.A. App’x at 41 (¶ 79). The corrective disclosure to this misrepresentation was made the morning of February 7, 2023, when “Defendants revealed to investors and analysts that they would not be using 28 the RSBQ AUC endpoint in the EXCELLENCE trial pursuant to FDA guidance.” *Id.* at 59 (¶ 115). On that day, Anavex’s share price increased by 5.8% to \$11.75 per share from the previous trading day’s closing price of \$11.11 per share. The following day, the share price fell by 7.0% to \$10.93, and the day after that it fell again by 4.8% to \$10.41. These losses, Huey contends, were caused by Defendants’ February 2, 2023, misrepresentation. We note first that the alleged losses did not occur on the day of the Defendant’s corrective disclosure. Huey alleges that the losses began on the day after the corrective disclosure. More plausibly, however, they did not begin until two days after the disclosure because the sum of the movements on February 7 and 8 essentially balance out and track the market: Anavex’s share price fell only 1.6% from market close on February 6 to market close on February 8. Over that same period, the Nasdaq Composite stayed essentially level (0.2% increase). 17 Not 17 See NASDAQ Composite Historical Data, Yahoo Finance, <https://perma.cc/VB34-ULKN>. Contrary to Huey’s claim, the district court can properly “take judicial notice of well-publicized stock prices,” including composite indices such as the Nasdaq Composite, at the pleading stage. *Ganino v. Citizens Utils. Co.*, 228 F.3d 154, 166 n.8 (2d Cir. 2000). Here, the data was not used to resolve disputes of fact but rather to provide objective market context against which the plaintiff’s allegations could be evaluated. 29 until February 9 did the share price decline notably more than the market (4.8% vs. 1.0%). To the district court, the initial increase and subsequent delay in the loss were dispositive. See *Huey*, 2025 WL 1707581, at

*6, *8. But as previously explained, we have never adopted a per se rule that loss causation cannot be plausibly alleged when a stock price increases on the day of a corrective disclosure. While we have held that “plaintiffs sufficiently plead loss causation when they allege that their share’s ‘price fell significantly after the truth became known,’” *Abramson v. Newlink Genetics Corp.*, 965 F.3d 165, 179 (2d Cir. 2020) (quoting *Dura*, 544 U.S. at 347), the sufficiency of that type of pleading does not render all other circumstances implausible. Such a rule would belie the common-sense reality that a share price may rise yet nevertheless underperform the broader market significantly, thereby leaving a plaintiff with a cognizable loss. The district court also noted a 2010 case that we affirmed, in which the district court explained that it “cannot find . . . a single section 10b-5 case in which the plaintiff prevailed on a motion to dismiss when the stock price increased after an announcement revealing an alleged fraud.” *Waters v. Gen. Elec. Co.*, No. 8-CV- 8484, 2010 WL 3910303, at *8 (S.D.N.Y. Sept. 29, 2010) (emphasis omitted), *aff’d* sub nom. *GE Invs. v. Gen. Elec. Co.*, 447 F. App’x 229 (2d Cir. 2011) (summary order). Besides the fact that the district court immediately thereafter acknowledged the existence of such a case, see *Swanson v. Interface, Inc.*, No. 20-CV-5518, 2022 WL 2003990 (E.D.N.Y. June 6, 2022), the rarity of these cases does not create a per se rule. It goes simply to our point that the necessary showing at the pleading stage increases—sometimes dramatically—where the loss does not immediately follow the corrective disclosure. 18 Here, because Huey’s alleged losses took place only subsequently in the two days following the corrective disclosure, she bears a heightened burden to establish a plausible causal link between the misrepresentation and the delayed drop in Anavex’s share price. Huey’s plausibility burden increases further because, on the days of the alleged losses, the market also declined. On February 8 and 9, when Anavex’s share price declined, the Nasdaq also fell. The district court correctly observed that Anavex’s “stock price movements mirrored the direction of leading market 18 Defendants and the court below also cite a summary order in which we said that a plaintiff failed to “adequately plead [loss causation] in view of the fact that the price of [the security] increased the day after [the corrective] disclosure.” *Ross v. Lloyds Banking Grp.*, 546 F. App’x 5, 12 n.2 (2d Cir. 2013) (summary order). Besides the fact that this summary order has no precedential effect and is premised on distinguishable facts, the quoted language is dicta because we affirmed the lower court’s dismissal for lack of scienter, not loss causation. 31 indices on February 7, 8, and 9.” Huey, 2025 WL 1707581, at *7. And while the court put perhaps too much emphasis on immediate market movements, its conclusion as to loss causation was not wrong. Because Huey’s alleged loss “coincide[d] with a marketwide phenomenon” of loss, she must say more to establish plausibly that her loss was attributable to the misrepresentation and its correction. *Lentell*, 396 F.3d at 174. In such cases where it is difficult to know whether the defendants’ misrepresentation rather than larger market forces influenced a company’s share price, it is not the role of district courts to undertake their own complex causal disaggregation analysis or event study at the pleading stage. See generally *Glickenhau & Co. v. Household Int’l, Inc.*, 787 F.3d 408 (7th Cir. 2015) (describing the complexities of conducting a disaggregation analysis).

Rather, it is the party asserting loss causation that must do more. Accordingly, where, as here, the share price did not substantially decline until two days after the corrective disclosure, and even that decline coincided with broader market losses, we hold that Huey failed plausibly to allege loss causation. Specifically, Huey did not adequately plead a causal link between the disclosure about abandoning the RSBQ-AUC endpoint, and the delayed drop in Anavex's share price. Huey claims that "[t]hese declines are more than sufficient to validate 32 Plaintiff's loss causation theory at the pleading stage." Appellant's Br. at 27. That might be so if the declines had been immediate and had clearly deviated from the market. But that was not the case here. To establish plausibility, Huey must provide "some indication" of why the loss was delayed and why it was caused by the corrective disclosure rather than intervening market forces. *Dura*, 544 U.S. at 347. Her pleadings did not. Nowhere in Huey's complaint does she explain why the loss was delayed or why the increase in Anavex's share price on the day of the corrective disclosure should not undermine the plausibility of her loss-causation allegations. All Huey pleads is the fact of the loss. She conclusorily alleges that "[t]he timing and magnitude of the price declines in Anavex stock negate any inference that the losses suffered . . . were caused by changed market conditions," P.A. App'x at 61 (¶ 118), but just the opposite is the case. As explained, the initial increase in Anavex's share price, the mirroring of the market over the first two days, and the delayed loss subsequently all undermine the plausibility of a causal link. Huey argues on appeal that because the corrective disclosure was "technical in nature" and its ramifications "were not readily apparent to most investors," it was only "once the market had time to understand the significance of Defendants' 33 disclosure" that Anavex's share price declined. Appellant's Reply Br. at 4, 6. That argument on appeal was essentially conclusory and, in any event, cannot save the absence of plausible assertions in the complaint. It is not the district court's role to devise new theories of causation to save a deficient complaint. See *Furlong v. Long Island Coll. Hosp.*, 710 F.2d 922, 927 (2d Cir. 1983); *Teletronics Proprietary, Ltd. v. Medtronic, Inc.*, 687 F. Supp. 832, 836 (S.D.N.Y. 1988). Having provided no indication in her complaint as to why realization of the loss was delayed—or why Anavex's share price initially increased after the corrective disclosure—we hold that Huey failed plausibly to plead loss causation. 19 Huey separately argues that the district court erred in refusing to include the much later January 2, 2024, disclosure of ANAVEX 2-73's failed clinical trial results and the ensuing share-price drop in its loss-causation analysis. But Huey only cited those statements insofar as they "spoke to the strength of ANAVEX 2-73's clinical data." Appellant's Br. at 35. That broader theory of fraud was rejected by the district court on other grounds (lack of falsity), and Huey does not appeal that falsity holding here. See Huey, 2025 WL 1707581, at *6. For that reason, Huey's reliance on *Abramson*, 965 F.3d 165, falls short. There, a company's announcement that its drug trial failed was considered a corrective disclosure for a misrepresentation about defects in the trial's patient enrollment. But here, the misrepresentation was fully corrected by the February 7 statement. Anavex had nothing left to correct with the later statement about the failed trial unless we adopt the broader theory of fraud (i.e., misrepresentation

of the strength of clinical data) that was already rejected and is not before us. As such, we affirm the district court's decision to exclude the January 2 statement and the ensuing decline in share price. 34 C. Denial of Leave to Amend The district court denied Huey's motion for leave to amend her complaint for futility, finding that she "cannot plead falsity with respect to any statement other than the February 2, 2023 press release, and she cannot plead loss causation resulting from that statement because the stock price went up, not down, on the date of the corrective disclosure." Huey, 2025 WL 1707581, at *8. The court also noted that Huey did not offer a proposed second amended complaint. We have frequently upheld such a failure as grounds for denying leave to replead. See, e.g., *Noto v. 22nd Century Grp., Inc.*, 35 F.4th 95, 107-08 (2d Cir. 2022) (affirming denial of leave to replead where the party's request gave no indication about how the plaintiff would cure the pleading defects in its amended complaint); *In re Lehman Bros. Mortg.-Backed Sec. Litig.*, 650 F.3d 167, 188 (2d Cir. 2011) (same). Like the district court, we are not persuaded that Huey could, upon amendment, plausibly plead loss causation as to the February 2, 2023, statement. In her appellate briefing and at oral argument, Huey did not provide any new information that would cure the deficiencies in her complaint; all additions 35 proposed were substantially duplicative of existing allegations. 20 Accordingly, we agree with the district court that Huey's motion to amend should be denied as futile. IV. Conclusion For the foregoing reasons, the district court's judgment is **AFFIRMED**. Our loss-causation holding is based on the absence of a plausible causal link. But even 20 if a causal link were established, Huey would still face the additional burden of establishing proximity. Though we do not address the issue of proximity here, that remaining burden lends further support to our conclusion that amendment would be futile. 36