883 F.3d 425
United States Court of Appeals, Fourth Circuit.

Phillip J. SINGER, Individually and on behalf of all other persons similarly situated, Plaintiff–Appellant,
and
Joel Caplin, Individually and on behalf of all others similarly situated, Plaintiff,
v.
Kenneth REALI; Joseph P. Slattery; Richard Randall; Michael Luetkemeyer; TranS1, Inc., Defendants–Appellees.
Phillip J. Singer, Individually and on behalf of all other persons similarly situated, Plaintiff–Appellee,
and
Joel Caplin, Individually and on behalf of all others similarly situated, Plaintiff,
v.
Kenneth Reali; Joseph P. Slattery; Richard Randall; Michael Luetkemeyer; TranS1, Inc., Defendants – Appellants.

No. 15-2579, No. 16-1019
|
Argued: January 25, 2017
|
Decided: February 22, 2018

Synopsis

Background: Medical device corporation shareholders brought putative class action against the corporation and corporate officers for allegedly violating section 10(b) of the Securities Exchange Act. The United States District Court for the Eastern District of North Carolina, James C. Fox, Senior District Judge, first dismissed action, 973 F.Supp.2d 596, then vacated that dismissal, 2014 WL 12748534, but ultimately granted officers', 2015 WL 2341907, and corporation's, 2015 WL 13631184, motions to dismiss. Lead plaintiff appealed, and defendants cross-appealed.

Holdings: The Court of Appeals, King, Circuit Judge, held that:

[1] shareholders adequately alleged material misrepresentation by defendants as required to state section 10(b) claim;

[2] shareholders adequately alleged scienter; and

[3] shareholders adequately alleged loss causation.

Ordered accordingly.

Agee, Circuit Judge, filed dissenting opinion.

***428** Appeals from the United States District Court for the Eastern District of North Carolina, at Wilmington. James C. Fox, Senior District Judge. (7:12-cv-00023-F)

Attorneys and Law Firms

ARGUED: Jeremy Alan Lieberman, POMERANTZ LLP, New York, New York, for Appellant/Cross-Appellee. Stephen L. Ram, Aaron C. Humes, STRADLING YOCCA CARLSON & RAUTH, P.C., Newport Beach, California, for Appellees/Cross-Appellants. ON BRIEF: Michele S. Carino, POMERANTZ LLP, New York, New York, for Appellant/Cross-Appellee. John F. Cannon, STRADLING YOCCA CARLSON & RAUTH, P.C., Newport Beach, California; Jonathan D. Sasser, Thomas H. Segars, Kelly Margolis Dagger, ELLIS & WINTERS LLP, Raleigh, North Carolina, for Appellees/Cross-Appellants.

Before KING, AGEE, and FLOYD, Circuit Judges.

Opinion

No. 15-2579 vacated and remanded, and No. 16-1019 affirmed, by published opinion. Judge King wrote the majority opinion, in which Judge Floyd joined. Judge Agee wrote a dissenting opinion.

KING, Circuit Judge:

These appeals arise from the dismissal of a securities fraud class action complaint in the Eastern District of North Carolina. The action relates to the healthcare provider reimbursement practices of defendant TranS1, Inc., and four officers thereof—defendants Kenneth Reali, Joseph P. Slattery, Richard Randall, and Michael

Luetkemeyer (collectively, the "Officers")—in connection with TranS1's AxiaLIF system (the "System"). According to the operative second amended complaint of lead plaintiff Phillip J. Singer (the "Complaint"), TranS1 and the Officers (together, the "Company") conjured up and carried out a scheme that enabled surgeons to utilize the System and secure fraudulent reimbursements from various health insurers and government-funded healthcare programs. The scheme resulted in federal False Claims Act proceedings against TranS1 in the District of Maryland and a fraud investigation conducted by the Department of Health and Human Services (the "DHHS"). On the theory that the Company had concealed the fraudulent reimbursement scheme from the market by way of false and misleading statements and omissions—and that TranS1's stock price dropped precipitously when the scheme was finally revealed—this class action was initiated pursuant to, inter alia, ***429** section 10(b) of the Securities Exchange Act.

In dismissing the Complaint with prejudice, the district court concluded that, although the Complaint alleges the loss causation element of the section 10(b) claim, it does not sufficiently plead the material misrepresentation element or the scienter element of that claim. By his appeal (No. 15-2579), Singer seeks reinstatement of the Complaint, contesting the court's rulings on the misrepresentation and scienter elements. TranS1 and the Officers have cross-appealed (No. 16-1019), asserting that the court erred in rejecting their challenge to the loss causation element. As explained herein, we vacate in No. 15-2579 the court's rulings that the Complaint fails to satisfy the misrepresentation and scienter elements, and we affirm in No. 16-1019 the court's ruling that the Complaint sufficiently alleges the loss causation element. Consequently, we remand for further proceedings.

I.

A.

According to the Complaint, TranS1 is a medical device company that first received approval in 2004 to sell the System, which was designed for minimally invasive surgery on the lower lumbar spine to treat degenerative disc disease. *See* Compl. ¶¶ 2, 25, 27.[1] A System surgery utilizes a "pre-sacral approach"—i.e., the surgery is performed straight up the tailbone, with the patient remaining on her stomach—differentiating it from more common surgeries performed through the anterior portion of the spine. *Id.* ¶¶ 2, 26. TranS1 derives its revenues almost entirely from sales of the System and related surgical instruments, as well as from a share of the reimbursements made by health insurers and government-funded healthcare programs to surgeons for spinal surgeries using the System. *Id.* ¶¶ 3, 25. The financial success of the Company largely hinges on surgeons' reimbursement claims being paid, not only because TranS1 receives a share of those reimbursements, but also because, if the reimbursement claims were denied, surgeons "would simply stop utilizing the [System]." *Id.* ¶ 4.

1 Because we are assessing the dismissal of the Complaint, we accept as true all well-pleaded facts in the Complaint and construe them in the light most favorable to lead plaintiff Singer. *See SD3, LLC v. Black & Decker (U.S.) Inc.*, 801 F.3d 412, 422 (4th Cir. 2015). In so doing, we draw all reasonable inferences in favor of Singer. *See Nemet Chevrolet, Ltd. v. Consumeraffairs.com, Inc.*, 591 F.3d 250, 253 (4th Cir. 2009). We are also entitled to consider matters of which the district court took judicial notice. *See Katyle v. Penn Nat'l Gaming, Inc.*, 637 F.3d 462, 466 (4th Cir. 2011). Facts drawn from the Complaint and from judicially noticed documents are thus recited in the light most favorable to Singer.

In this securities fraud class action, the putative class includes those investors in TranS1 who purchased common stock between February 23, 2009, and October 17, 2011—the period in which the Complaint alleges that the Company's fraudulent reimbursement scheme was concealed from the market. *See* Compl. ¶ 1. Each of the Officers was, in one capacity or another, involved in the management of TranS1 during the relevant time frame.[2]

2 As described in the Complaint, Reali was TranS1's CEO (since January 2011), president (since January 2010), and COO (January 2010 to January 2011), and also on its board of directors (since January 2011); Slattery was TranS1's CFO (since April 2010) and on its board of directors (November 2007 to April 2010); Randall was TranS1's CEO (June 2002 to January 2011), its president (June 2002 to January 2010), and on its board of directors (since June 2002), and also was the executive chairman since leaving his post as

CEO; and Luetkemeyer was TranS1's CFO (April 2007 to March 2010). *See* Compl. ¶¶ 20-23.

***430** The Complaint explains that a healthcare provider submitting a reimbursement claim for a surgery is obliged to use Current Procedural Terminology codes ("CPT codes") promulgated by the American Medical Association (the "AMA"). *See* Compl. ¶ 4. For spinal surgeries, the AMA generally adheres to the coding recommendations provided by the National Association of Spine Surgeons (the "NASS"). *Id.* The various CPT codes fall into three categories, which are designated as Categories I, II, and III. Only the Category I and Category III codes are relevant here. A Category I code indicates that a surgical procedure is "traditional" and widely accepted in the medical community, assuring a full or substantial reimbursement. *Id.* ¶ 6. On the other hand, the use of a Category III code reflects that the procedure is "experimental" and not widely accepted. *Id.* ¶ 5. A Category III code often results in no reimbursement at all, dissuading healthcare providers from performing Category III procedures. *Id.* ¶ 6.

Relevant here, the System was initially coded as a Category I anterior fusion procedure and thus garnered a full or substantial reimbursement. *See* Compl. ¶¶ 5, 29. In February 2008, however, the NASS recommended that the coding for the System be changed to Category III, because the System is unlike traditional anterior fusion procedures and "suffered from a dearth of safety and efficacy data." *Id.* ¶¶ 5, 30. [3] The AMA adopted the NASS recommendation and, effective January 1, 2009, required the System to be coded under Category III. *Id.*

[3] According to the Complaint, the System does not constitute a Category I anterior fusion procedure because, inter alia, System surgeries are "performed straight up the tailbone and never approach[ ] the anterior portion of the spine." *See* Compl. ¶ 33.

B.

The Category III coding requirement threatened TranS1's revenue stream and financial viability, in that surgeons could no longer count on reimbursements from health insurers and government-funded healthcare programs for using the System. *See* Compl. ¶¶ 6, 30. The Complaint alleges that, as a result of the new Category III code, the Company concocted and carried out its multifaceted and sophisticated fraudulent reimbursement scheme. *Id.* ¶ 7. The crux of that scheme was "to convince surgeons to engage in improper reimbursement practices in direct violation of" various statutes, including the federal False Claims Act. *Id.* ¶ 31. That is, the Company "encouraged and coached surgeons to utilize alternate codes, instead of the mandated experimental Category III designation assigned to [the System], in order to allow for reimbursement for the procedure." *Id.*

The Complaint describes the fraudulent reimbursement scheme as it was perpetrated and carried out by the Company. Pursuant to that scheme, the Company on occasion acknowledged the System's new Category III code and some of the difficulty in securing reimbursement for it, but at other times encouraged and instructed surgeons to nevertheless use a Category I code for the System. The fraudulent reimbursement scheme was executed by way of, inter alia, the following:

- The Company formed a reimbursement committee to train surgeons on how to avoid the mandatory Category III code for the System. The head of the committee, a TranS1 employee, gave presentations detailing exactly which non-Category III codes to use and in what manner, and she established a "hotline" for surgeons to call to get coding advice. Pursuant to her instructions, when surgeons did use ***431** the Category III code, they were to "bury" it in the reimbursement claim so that the insurer might overlook it. *See* Compl. ¶¶ 32, 51.

- During conference calls with its third-party product distributors, the Company instructed the distributors to advise surgeons that the System should be coded as a Category I anterior fusion procedure, as it had been prior to the AMA's adoption of the Category III code. In an effort to quell the concerns of surgeons who were aware of the new Category III designation, the Company further advised the distributors to tell such surgeons that "all surgeons" were using a Category I code for the System. *Id.* ¶¶ 33, 56.

- The Company conducted on-site training sessions designed to encourage surgeons to exchange tips on how to "manipulate" coding to get reimbursed. The most popular site was Cincinnati, Ohio, where TranS1's top consultant gave numerous presentations wherein he coded the System under Category I. *Id.* ¶¶ 34, 62.

- The Company drafted and distributed a reimbursement guide, dated January 1 through June 30, 2009, for surgeons to use in making successful claims for reimbursement of System surgeries. It was only on the guide's last page that the Company acknowledged the required Category III code for the System and the unlikelihood of reimbursement for Category III procedures. *Id.* ¶ 35.

- At the behest of the Company, TranS1's top consultant created a template demonstrating how to improperly code the System as a Category I anterior fusion procedure. The template contained suggested post-operation notes meant to disguise the fact that a surgery involved the non-reimbursable System. *Id.* ¶¶ 36, 63.

- At TranS1's annual national meeting in 2009—attended by many of its employees and executives—the Company promoted the continued use of a Category I code for the System, despite the AMA's mandatory Category III code. The "official company line" to surgeons was, " 'We have a [Category III] code, but here's how other [surgeons] are coding it.' " *Id.* ¶¶ 37, 64.

The Complaint describes the Company's fraudulent reimbursement scheme—and especially its efforts to have surgeons code the System under Category I, rather than Category III—as "blatant gamesmanship [that] created an acute risk that [TranS1] would be subject to legal action as well as scrutiny by the DHHS and other regulatory bodies." *Id.* ¶ 38.

C.

1.

After implementing the fraudulent reimbursement scheme, the Company concealed the scheme from the market by numerous false and misleading statements and omissions. *See* Compl. ¶ 12. The Company specifically failed to disclose, inter alia, that it "engaged in a scheme to encourage surgeons to continue using the [Category I] code for anterior procedures in direct disregard of the AMA's Category III code assignment for [the System]," and that TranS1's "revenues, derived primarily from sales of [the System] as well as a portion of the insurance reimbursement each performing provider received as a result of using improper billing codes for [the System], were generated as a direct result of [the Company's] improper coding scheme." *Id.*

The Complaint describes various false and misleading statements and omissions ***432** of the Company. For example, on February 23, 2009, Officers Randall and Luetkemeyer participated in a conference call with analysts for TranS1's fourth quarter of 2008. *See* Compl. ¶ 69. During that conference call, without acknowledging the fraudulent reimbursement scheme, Randall stated that the Company was assisting surgeons in obtaining so-called " 'appropriate reimbursement for our procedure.' " *Id.* Both Randall and Luetkemeyer opined that there would not be " 'any significant additional headwind' " with respect to the new Category III coding requirement for the System. *Id.* They did not explain that the reason they expected continuing reimbursements was that the Company was coaching surgeons to improperly avoid the mandatory Category III code. *Id.* ¶ 72.

In the 2008 Form 10-K[4] filed by TranS1 with the Securities and Exchange Commission (the "SEC") on March 13, 2009, TranS1 reported a single source of revenue, i.e., " 'sales of [the System] and related surgical instruments.' " *See* Compl. ¶¶ 70-71. By that Form 10-K, the Company acknowledged the new Category III code for the System and related that merely " 'some' " health insurers and government-funded healthcare programs " 'may not reimburse' " Category III procedures. *Id.* ¶ 71. The Company further downplayed the significance of the Category III code by suggesting that the System was gaining in popularity and thus unlikely to carry the Category III code for long. *Id.* The Company also represented that the Category III code for the System " 'is only one of up to 10 different CPT codes physicians may submit to capture the entirety of a spinal fusion [surgery,] lessening the impact should payment for [the System] be initially denied.' " *Id.* Meanwhile, the Company omitted the fraudulent coding practices that it advised be utilized and that were then being employed by surgeons to secure reimbursements for the System itself. *Id.* ¶ 72.

4 Pursuant to federal securities statutes and regulations, publicly traded companies are required to annually file a Form 10-K with the SEC. *See* 15 U.S.C. §§ 78m, 78*o*(d); 17 C.F.R. § 249.310.

In the subsequent 2009 and 2010 Form 10-Ks and in the various quarterly filings of Form 10-Qs[5] submitted by TranS1 to the SEC, the Company substantially repeated the false and misleading statements and omissions of the 2008 Form 10-K. *See* Compl. ¶¶ 75-76, 78-79, 81-82, 84-86, 89-90, 92-93, 95-96, 98-100, 102-103, 105-106. Those filings variously touted a growing acceptance of the System among health insurers and providers, *see, e.g.*, *id.* ¶¶ 81, 85, 99, and attributed revenue losses to " 'concerns and uncertainty in the marketplace surrounding physician reimbursement for our ... procedure,' " *id.* ¶¶ 89, 92, 95. Like the 2008 Form 10-K, the subsequent filings with the SEC omitted mention of the Company's reliance on the fraudulent reimbursement scheme to generate the revenues that TranS1 did have. Nevertheless, two or more of the Officers signed each of the Form 10-Ks and Form 10-Qs filed by TranS1 during the relevant timeframe, and two Officers certified " 'that the financial information contained in [each filing] was accurate and that they disclosed any material changes to [TranS1's] internal control over financial reporting.' " *Id.* ¶¶ 70, 75, 78, 81, 84, 89, 92, 95, 98, 102, 105.

5 Like a Form 10-K, a Form 10-Q is filed with the SEC under the federal securities statutes and regulations. *See*15 U.S.C. §§ 78m, 78*o*(d); 17 C.F.R. § 249.308a.

2.

As TranS1 suffered losses from 2009 to 2011, the Company communicated the losses ***433** to the market through press releases. *See* Compl. ¶¶ 73, 77, 80, 83, 87, 91, 94, 97, 101, 104. On April 27, 2009, for example, the Company reported a net loss of $5,000,000 for the first quarter of 2009. *Id.* ¶ 73. That very day, Officer Randall participated in a conference call where he assured investors that " 'we remain diligent about helping our surgeons obtain appropriate reimbursement for our procedure.' " *Id.* ¶ 74. Randall cited, for example, the reimbursement committee's "hotline" and the Company's reimbursement guide—without revealing that the Company was instructing surgeons to improperly code the System. *Id.*

Similarly, on May 4, 2010—after reporting a net loss of $6,000,000 in the first quarter of 2010—Officers Slattery and Reali participated in a conference call with financial analysts. *See* Compl. ¶¶ 87-88. During that call, Slattery and Reali described a strategy to earn a Category I code for the System by " 'working with the payers to remove our experimental designation over time,' " " 'working with the spine societies to gain endorsement and acceptance of our procedure in a broad manner,' " and " 'working with our physician customers getting further clinical data published and presented at key meetings.' " *Id.* ¶ 88. Additionally, Slattery falsely asserted that the System's Category III code was " 'not an experimental code,' " but was in fact " 'a tracking code.' " *Id.* Once again, the Company did not disclose the fraudulent reimbursement scheme it had devised to ensure reimbursements despite the Category III code. *Id.* ¶ 90.

3.

In sum, none of the Form 10-Ks or Form 10-Qs filed with the SEC, or the various press releases or conference calls, revealed that the Company was "engaged in a scheme to encourage surgeons to employ CPT codes meant for anterior and other non-Category III procedures in direct disregard of the AMA mandated Category III code for [the System]." *See* Compl. ¶ 72. Nor did any of those SEC submissions or other statements explain that "a substantial portion of [TranS1's] earnings and revenues" were generated by the Company's ongoing fraudulent reimbursement scheme, and that the scheme put TranS1 at "substantial risk" of regulatory scrutiny. *Id.*

D.

According to the Complaint, the truth about the Company's fraudulent reimbursement scheme finally began to emerge in October 2011. *See* Compl. ¶¶ 9-10, 108-11. Specifically, after the market closed on October 17, 2011, TranS1 filed a Form 8-K[6] with the SEC, reporting that it had received a subpoena on or about October 6, 2011, issued by the DHHS " 'under the authority of the federal healthcare fraud and false claims statutes.' " *Id.* ¶ 108. TranS1's Form 8-K explained that the DHHS sought " 'documents for the period January 1, 2008 through October 6, 2011.' " *Id.* The Complaint alleges that, based on the Form 8-K, the market fully apprehended "that the focus of the subpoena related to [TranS1's] reimbursement practices, given that insurance company reimbursement for [the System], [TranS1's]

flagship product, accounted for a majority of its revenue." *Id.* ¶ 9; *see also id.* ¶¶ 109-110.

6 A Form 8-K—like a Form 10-K or a Form 10-Q—is a report filed under law with the SEC, which announces major events of concern to shareholders. *See*15 U.S.C. §§ 78m, 78*o*(d); 17 C.F.R. § 249.308.

As evidence of the market's realization of the Company's fraudulent reimburseme ***434** nt scheme, the Complaint points to an analyst report issued on October 18, 2011, the day after the revelatory Form 8-K was filed. *See* Compl. ¶¶ 9, 109. That analyst report revealed factual information about TranS1 and its subpoena from the DHHS, including that the subpoena " 'included 19 items ranging from patient names to serial lot traceability to reimbursement communications with physicians.' " *Id.* ¶ 109. Additionally, the analyst report revealed the fact that " 'half of TranS1's revenues come from physicians still using [a Category I] code (which provides reimbursement), rather than the designated [Category III] code (which does not provide reimbursement).' " *Id.*

The analyst report also expressed opinions and beliefs, including that " 'we think that [TranS1] has been making strong efforts to educate physicians about correct coding.' " *See* Compl. ¶ 109 (noting that "ultimately the decision regarding which code to use lies in the hands of the physician"). Nevertheless, premised on the known facts, the analyst report concluded that TranS1's subpoena from the DHHS " 'could be due to reimbursement communications.' " *Id.* The analyst report also deduced that, in light of recent downsizing by TranS1, " 'the subpoena could perhaps stem from allegations by a disgruntled former employee.' " *Id.*

The very day of the analyst report—October 18, 2011—the stock price of TranS1 collapsed, as its "securities plummeted $1.27 or 40.7%, to close at $1.85." *See* Compl. ¶ 111. The Complaint describes "a massive selloff of [TranS1] shares" and an "unusually heavy trading volume of 2.1 million shares." *Id.* ¶ 10.

E.

In July 2013, it was publicly confirmed that federal False Claims Act qui tam proceedings relating to the fraudulent reimbursement scheme had been commenced against TranS1 by a former employee in April 2011—six months before TranS1's stock price collapse. *See* Compl. ¶ 8.[7] In other words, the October 18, 2011 analyst report had "surmised with radar precision that the subpoena [issued to TranS1 in early October 2011 by the DHHS] was triggered by 'allegations by a disgruntled former employee' relating to [TranS1's] illicit 'reimbursement communications.' " *Id.* ¶ 9. The qui tam action against TranS1 had been initiated by relator Kevin Ryan, a former sales manager for TranS1, in the District of Maryland on April 21, 2011. *Id.* ¶¶ 8, 39-44. The action was commenced under seal and remained sealed until July 1, 2013. *Id.* ¶ 8.

7 The False Claims Act is codified at 31 U.S.C. §§ 3729-3733. It imposes liability on individuals and entities that have defrauded federal government programs. An individual (i.e., a relator) can initiate a claim under the Act by way of a qui tam action. *See*31 U.S.C. § 3730(b). The United States is entitled to intervene and control any such qui tam action. If the action is successful, by settlement or otherwise, the relator or relators may share in the award. *Id.* § 3730(d).

The qui tam complaint of April 2011 alleged in detail the fraud scheme being carried out by TranS1 in contravention of the federal False Claims Act, as well as the Medicare Act and the North Carolina False Claims Act. *See* J.A. 929-64.[8] Similar to the Complaint in these proceedings, the qui tam complaint specified that TranS1 had "knowingly caused to be submitted and facilitated the submission of false and fraudulent claims, statements and/or documents to federal agencies by causing physicians and hospitals to submit improper ***435** claims for payment to Medicare and state health insurance programs and insurers." *Id.* at 930. The qui tam complaint also alleged that, "[t]hrough the use of incorrect and misleading billing and description codes to represent the [System], [TranS1] fraudulently caused hospitals and physicians to obtain and continue to obtain reimbursement from Medicare and the State of North Carolina Health Plan." *Id.* at 931. The qui tam complaint explained, inter alia, that once the Category III code for the System took effect at the beginning of 2009, the System could "*only*" be billed as a Category III procedure. *Id.* at 941. Nevertheless, TranS1 instructed its sales staff and surgeons "to disregard the [Category III code]," as part of "an intentional and systematic effort to bypass the [Category III code] designation and to obtain reimbursement from Medicare and other insurance

programs despite the non-reimbursable status of [the System]." *Id.* at 951.

[8] Citations herein to "J.A. ___" refer to the contents of the Joint Appendix filed by the parties in these appeals.

On June 6, 2013, the United States intervened in the qui tam action for purposes of settlement. By a settlement agreement consummated on June 28, 2013, TranS1 agreed to pay the United States the sum of $6,000,000 to resolve the fraud allegations of the qui tam action with respect to federal government programs. *See* J.A. 905-28; *see also* Compl. ¶¶ 11, 46. The settlement agreement included various recitals of the contentions of the United States against TranS1. For example, the United States contended that TranS1 had "knowingly caused providers to submit claims [to publicly funded healthcare programs] for [System] procedures using incorrect diagnosis or procedure codes, ... which in some cases resulted in providers receiving greater reimbursement than that to which they were entitled." *See* J.A. 906. In entering the settlement agreement, however, TranS1 denied liability and the various contentions of the relator and the United States. *Id.* at 907. [9]

[9] In addition to being the subject of substantial discussion in the Complaint, the qui tam complaint and the qui tam settlement were judicially noticed by the district court in September 2013. *See* Order, *Caplin v. TranS1, Inc.*, No. 7:12-cv-00023 (E.D.N.C. Sept. 19, 2013), ECF No. 48.

F.

1.

On January 24, 2012, plaintiff Joel Caplin filed this securities fraud class action against TranS1 and the Officers in the Eastern District of North Carolina. Shortly thereafter, Singer moved for appointment as lead plaintiff. The district court appointed Singer as the lead plaintiff on May 8, 2012, and he filed an amended complaint on July 9, 2012. [10]

[10] Caplin is yet a named plaintiff in the class action, but he is not a party to these appeals.

In sum, the amended complaint alleged that TranS1 and the Officers violated section 10(b) of the Securities Exchange Act—as well as § 240.10b-5 of Article 17 of the Code of Federal Regulations ("SEC Rule 10b-5")—by concealing the fraudulent reimbursement scheme from the market through false and misleading statements and omissions. According to the amended complaint, the Company thereby artificially inflated TranS1's stock price during the course of the fraudulent reimbursement scheme and injured investors when the scheme was finally revealed to the public and the stock price plummeted. The amended complaint also spelled out a claim against the Officers, under section 20(a) of the Securities Exchange Act, alleging that they were control persons subject to individual liability for TranS1's violation of section 10(b).

***436** On September 7, 2012, the Company moved to dismiss the amended complaint pursuant to Rules 9(b) and 12(b)(6) of the Federal Rules of Civil Procedure and the Private Securities Litigation Reform Act of 1995. On September 19, 2013, the district court granted the dismissal motion, focusing on the loss causation element of the section 10(b) claim. *See* Order, *Caplin v. TranS1, Inc.*, No. 7:12-cv-00023 (E.D.N.C. Sept. 19, 2013), ECF No. 48. In so ruling, the court recognized that "federal courts have developed two somewhat distinct theories of loss causation: (1) corrective disclosure theory and (2) materialization of a concealed risk." *Id.* at 13. The court analyzed both theories of loss causation and concluded that the amended complaint had not sufficiently pleaded the loss causation element of the section 10(b) claim under either theory. The court dismissed the amended complaint with prejudice, on the belief that "allowing further amendment would be futile." *Id.* at 28.

2.

Singer promptly requested the district court to alter or amend its judgment and submitted his second amended complaint, which is now the operative Complaint. Upon reconsideration of its dismissal ruling eight months later, on May 5, 2014, the court changed its earlier ruling and agreed that the Complaint sufficiently pleads the loss causation element of the section 10(b) claim under the materialization of a concealed risk theory. *See* Order, *Singer v. TranS1, Inc.*, No. 7:12-cv-00023 (E.D.N.C. May 5, 2014), ECF No. 54 (the "Reconsideration Order"). That Order relied on the Complaint's allegations that

the October 18, 2011 decline in TranS1's stock price resulted from the revelation—by way of TranS1's October 17, 2011 Form 8-K, coupled with the October 18, 2011 analyst report—of the Company's long-concealed fraudulent reimbursement scheme. *Id.* at 12 (explaining that the analyst report, "when considered in conjunction with [TranS1's] disclosure of the subpoena, ... calls into question [TranS1's] prior representations that it was educating physicians about proper coding and reveals to the public, at least in some sense, that [TranS1] was potentially improperly manipulating the insurance reimbursement system").

3.

On July 3, 2014, the Company moved to dismiss the Complaint, contending that it fails to allege the material misrepresentation and scienter elements of the section 10(b) claim. TranS1 then filed a bankruptcy petition in Delaware, which resulted in an automatic stay of the class action proceedings with respect to TranS1.

During the bankruptcy stay, this litigation could only proceed in the district court with respect to the Officers. On May 14, 2015, the court dismissed the Complaint as to the Officers. *See* Order, *Singer v. TranS1, Inc.*, No. 7:12-cv-00023 (E.D.N.C. May 14, 2015), ECF No. 72 (the "Officers Order"). With respect to the material misrepresentation element, that Order explained that the Complaint is inadequate to show that any of the Officers "knew TranS1's reimbursement practices were illegal" or "failed to sufficiently disclose TranS1's reimbursement practices." *Id.* at 13-14. On the scienter element, the Officers Order specified that the Complaint "does not allege when and how the [Officers] knew or recklessly failed to know that their disclosures and statements were false or misleading, much less make a powerful or cogent inference of [the Officers'] scienter." *Id.* at 20 (internal quotation marks omitted). The Officers Order further observed that, despite being given "three opportunities to submit a complaint ***437** that meets the requirements set forth herein," Singer had "failed to do so." *Id.* at 23. The Officers Order thus dismissed the Complaint as to the Officers with prejudice.

4.

After lifting the bankruptcy stay on May 14, 2015, the district court requested supplemental briefing on whether the dismissal motion should also be granted as to TranS1. On December 18, 2015—after receiving further briefing—the court granted TranS1's motion to dismiss. *See* Order, *Singer v. TranS1, Inc.*, No. 7:12-cv-00023 (E.D.N.C. Dec. 8, 2015), ECF No. 92 (the "Final Order").

The Final Order first explained that, because the Complaint had been dismissed as to the Officers, "the only way ... to establish liability as to [TranS1], the corporate defendant, is (1) to identify some other corporate agent who made a material misrepresentation or omission, and (2) to make allegations manifesting a strong inference of scienter as to at least one authorized agent." *See* Final Order 5. The court then concluded, on the material misrepresentation element of the section 10(b) claim, that the Complaint "does not sufficiently allege that any authorized corporate agent made a material misrepresentation or omission." *Id.* at 6. With respect to the scienter element, the Final Order reiterated that, as with the Officers, the Complaint fails to allege that TranS1 "knew that its public disclosures and statements were misleading." *Id.* The Final Order thus dismissed the Complaint as to TranS1 with prejudice.

With the Complaint fully dismissed, Singer noted his appeal in No. 15-2579, challenging the district court's rulings that the Complaint does not allege the material misrepresentation and scienter elements of the section 10(b) claim. The Company thereafter cross-appealed in No. 16-1019, taking issue with the Reconsideration Order's earlier ruling that the loss causation element is sufficiently pleaded. We possess jurisdiction over these appeals pursuant to 28 U.S.C. § 1291.

II.

These appeals relate solely to the sufficiency of the Complaint, which we review de novo. *See Teachers' Ret. Sys. of La. v. Hunter*, 477 F.3d 162, 170 (4th Cir. 2007). In reviewing the district court's dismissal, we accept all factual allegations in the Complaint as true, and we consider the Complaint in its entirety. *See Matrix Capital Mgmt. Fund, LP v. BearingPoint, Inc.*, 576 F.3d 172, 176 (4th Cir. 2009). We also draw all reasonable inferences in favor of Singer. *See Nemet Chevrolet, Ltd. v. Consumeraffairs.com, Inc.*, 591 F.3d 250, 253 (4th Cir.

2009). In addition to the Complaint, we are entitled to consider matters of which the district court took judicial notice, including the qui tam complaint and the qui tam settlement. *See Katyle v. Penn Nat'l Gaming, Inc.*, 637 F.3d 462, 466 (4th Cir. 2011); *see also supra* note 9.

III.

We first consider Singer's appeal (No. 15-2579), which implicates the Officers Order and the Final Order. If we were to affirm the district court's rulings in those Orders, the Company's cross-appeal would be moot, as it merely provides an alternative reason for dismissal of the Complaint.

The Complaint advances two separate claims. First, it alleges that TranS1 and the Officers violated section 10(b) of the Securities Exchange Act, as well as its companion regulatory provision in SEC Rule 10b-5. *See*15 U.S.C. § 78j(b); ***438** 17 C.F.R. § 240.10b-5.[11] Second, the Complaint alleges separate violations of section 20(a) against the Officers. *See*15 U.S.C. § 78t(a).[12] Section 10(b) and SEC Rule 10b-5, along with section 20(a), "act to protect the integrity of the market in securities and prohibit fraud in connection with the purchase or sale of a security." *See Cozzarelli v. Inspire Pharm. Inc.*, 549 F.3d 618, 623 (4th Cir. 2008).

11 Section 10(b) of the Securities Exchange Act, which is codified at § 78j(b) of Title 15 of the United States Code, provides in pertinent part:

> It shall be unlawful for any person, directly or indirectly, by the use of any means or instrumentality of interstate commerce or of the mails, or of any facility of any national securities exchange—
>
> * * *
>
> (b) To use or employ, in connection with the purchase or sale of any security registered on a national securities exchange[,] ... any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the Commission may prescribe as necessary or appropriate in the public interest or for the protection of investors.

*See*15 U.S.C. § 78j. SEC Rule 10b-5 is found in section 240.10b-5 of Title 17 of the Code of Federal Regulations, and provides in pertinent part:

> It shall be unlawful for any person, directly or indirectly, by the use of any means or instrumentality of interstate commerce, or of the mails or of any facility of any national securities exchange,
>
> * * *
>
> (b) To make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading ...
>
> * * *
>
> in connection with the purchase or sale of any security.

*See*17 C.F.R. § 240.10b-5.

12 Section 20(a) of the Securities Exchange Act, which is codified at § 78t(a) of Title 15 of the United States Code, provides in pertinent part:

> Every person who, directly or indirectly, controls any person liable under any provision of this chapter or of any rule or regulation thereunder shall also be liable jointly and severally with and to the same extent as such controlled person to any person to whom such controlled person is liable ..., unless the controlling person acted in good faith and did not directly or indirectly induce the act or acts constituting the violation or cause of action.

*See*15 U.S.C. § 78t(a).

[1] The Supreme Court has recognized that a typical claim under section 10(b) and SEC Rule 10b-5 has six elements. *See Stoneridge Inv. Partners, LLC v. Sci.-Atlanta, Inc.*, 552 U.S. 148, 157, 128 S.Ct. 761, 169 L.Ed.2d 627 (2008). Those elements are the following: "(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." *Id.* (citing *Dura Pharm., Inc. v. Broudo*, 544 U.S. 336, 341-42, 125 S.Ct. 1627, 161 L.Ed.2d 577 (2005)). Relatedly, section 20(a) is the vehicle for imposing liability on control persons. The liability of a control person under section 20(a) is derivative of—and dependent upon—liability of a controlled person under section 10(b). *See Yates v. Mun. Mortg. & Equity, LLC*, 744 F.3d 874, 894 n.8 (4th Cir. 2014). Thus, if the complaint "is legally insufficient with respect to the [section] 10(b) claim, the [derivative section] 20(a) claim must also fail." *Id.*[13]

13 The district court dismissed the section 20(a) claim against the Officers solely because the Complaint does not sufficiently plead the section 10(b) claim. Nevertheless, as an alternative ground for affirmance of the court's dismissal of the section 20(a) claim, the Company maintains that the Complaint merely and inadequately "alleges that by virtue of the [Officers'] corporate positions they had control." *See* Br. of Appellees 66. Because the court did not address that contention, we do not address it, though it may be considered on remand. *See United States ex rel. Carson v. Manor Care, Inc.*, 851 F.3d 293, 307 n.7 (4th Cir. 2017).

***439** **[2]** Importantly, the allegations of securities fraud claims in the federal courts are subject to strict pleading standards. As a general proposition, "[i]n alleging fraud ..., a party must state with particularity the circumstances constituting fraud." *See*Fed. R. Civ. P. 9(b). Moreover, the Private Securities Litigation Reform Act of 1995 imposes additional pleading requirements to prevent Securities Exchange Act claims from being "employed abusively to impose substantial costs on companies and individuals whose conduct conforms to the law." *See Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 313, 127 S.Ct. 2499, 168 L.Ed.2d 179 (2007). Pursuant thereto, a securities fraud complaint must "specify each statement alleged to have been misleading, [and] the reason or reasons why the statement is misleading." *See*15 U.S.C. § 78u-4(b)(1). Further, "the complaint shall ... state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." *Id.* § 78u-4(b)(2)(A). If those exacting pleading requirements are not satisfied, the complaint must be dismissed. *See Cozzarelli*, 549 F.3d at 623.

In his appeal, Singer challenges the district court's rulings —in the Officers Order and the Final Order—that the Complaint fails to allege the material misrepresentation and scienter elements of the section 10(b) claim. As explained below, the Complaint sufficiently pleads those elements. Accordingly, we vacate the court's rulings with respect to the misrepresentation and scienter elements.

A.

[3] **[4]** To begin, the Company argues that the Complaint fails to allege the material misrepresentation element. That element of a section 10(b) claim requires an allegation that the defendant acted deceptively, i.e., that the defendant engaged in deceptive acts such as "misstatements" and "omissions by those with a duty to disclose." *See U.S. S.E.C. v. Pirate Inv'r LLC*, 580 F.3d 233, 239-40 (4th Cir. 2009). Furthermore, the deceptive act "must concern a material fact." *Id.* at 240.

1.

As set forth above, the Complaint specifies a series of statements alleged to have been misleading, because of both what was falsely said and what was deceptively omitted. By those statements—made by the Officers in SEC filings, press releases, and conference calls—the Company acknowledged the new Category III code for the System and efforts to eventually return to a Category I code. At the same time, however, the Company misrepresented the assistance and training it was providing to surgeons as being wholly for the attainment of " 'appropriate' "—i.e., legal—reimbursements for the System. *See, e.g.*, Compl. ¶¶ 69, 74. The Company also misrepresented that the Category III code was " 'not an experimental code.' " *Id.* ¶ 88. Meanwhile, the Company downplayed the immediate financial consequences of the Category III code, and suggested that losses would be insignificant and temporary. Throughout the Officers' statements, they omitted key facts: that the Company was coaching surgeons to improperly use a Category I code for the System, rather than the mandatory Category III code, and was relying on that fraudulent reimbursement scheme to generate a substantial portion of TranS1's continuing revenues.

***440** In light of those allegations, the Complaint sufficiently pleads the material misrepresentation element of the section 10(b) claim. That is, the Complaint's allegations of false and misleading statements and omissions easily survive a materiality analysis at the dismissal stage of the proceedings. *See Pirate Inv'r*, 580 F.3d at 240 (explaining that a "fact stated or omitted is material if there is a substantial likelihood that a reasonable purchaser or seller of a security (1) would consider the fact important in deciding whether to buy or sell the security or (2) would have viewed the total mix of information made available to be significantly altered by disclosure of the fact" (internal quotation marks omitted)); *see also Ganino v. Citizens Utils. Co.*, 228 F.3d 154, 162 (2d Cir. 2000) (recognizing that "a complaint may

not properly be dismissed on the ground that the alleged misstatements or omissions are not material unless they are so obviously unimportant to a reasonable investor that reasonable minds could not differ on the question of their importance" (alteration and internal quotation marks omitted)).

[5] Furthermore, the Complaint adequately alleges that the Company acted deceptively by way of misstatements and omissions by those with a duty to disclose. The Complaint's focus is on the Company's repeated failure to divulge its fraudulent reimbursement scheme. Of course, as the Supreme Court has observed, section 10(b) and SEC Rule 10b-5 "do not create an affirmative duty to disclose any and all material information." *See Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 44, 131 S.Ct. 1309, 179 L.Ed.2d 398 (2011); *see also Basic, Inc. v. Levinson*, 485 U.S. 224, 239 n.17, 108 S.Ct. 978, 99 L.Ed.2d 194 (1988) ("Silence, absent a duty to disclose, is not misleading under [SEC] Rule 10b-5."). Nevertheless, disclosure of material information is required "when necessary to make statements made, in the light of the circumstances under which they were made, not misleading." *See Matrixx Initiatives*, 563 U.S. at 44, 131 S.Ct. 1309 (alteration and internal quotation marks omitted). In other words, "companies can control what they have to disclose under [section 10(b) and SEC Rule 10b-5] by controlling what they say to the market." *Id.*

Under the Complaint, by choosing to inform the market that it was training surgeons on how to obtain reimbursements for the System in the wake of the AMA's Category III coding requirement, the Company was obliged to further disclose its fraudulent reimbursement scheme, i.e., its instructions to surgeons to unlawfully code the System under Category I. Otherwise, the Officers' statements about the Company's training efforts were utterly misleading. The same is true of the Officers' statements that the Category III code was causing only limited losses; by not disclosing the Company's fraudulent reimbursement scheme and improper use of Category I codes, the Officers misled the market about the actual source of TranS1's continuing revenues. As such, the Complaint alleges that the Company possessed —and breached—a duty to disclose the fraudulent reimbursement scheme. *See, e.g.*, *Meyer v. Jinkosolar Holdings Co.*, 761 F.3d 245, 250 (2d Cir. 2014) ("Even when there is no existing independent duty to disclose information, once a company speaks on an issue or topic, there is a duty to tell the whole truth."); *seealso* Br. of Appellant 37 ("Having put coding and reimbursement front and center [on every analyst conference call and in every public filing during the class period], [the Company was] compelled to disclose the full extent of [its] reimbursement strategy....").

***441** 2.

The Company nevertheless contends that the Complaint is fatally insufficient on the material misrepresentation element for several reasons. First, the Company argues that the Complaint reflects that the Company fully disclosed its reimbursement practices, rendering the Officers' statements not misleading. We reject that contention. To be sure, the Officers informed the market that the Company was assisting surgeons in obtaining reimbursements for the System by way of, e.g., its "hotline" and reimbursement guide. The Officers also acknowledged the AMA's designation of the System as a Category III procedure and provided some truthful information relevant thereto. Such information included that the Company was making efforts to reobtain a Category I code for the System. It also included that, in the meantime, surgeons using the Category III code might be denied payment for the System itself, but could at least be reimbursed for other aspects of a spinal surgery. Critically, however, the Officers did not disclose that the Company was coaching surgeons to improperly use a Category I code for the System, rather than the mandatory Category III code.

[6] Next, the Company maintains that the Complaint does not properly allege violations of the federal False Claims Act or any other law, in that no court or other adjudicative body has found the Company's reimbursement practices to be illegal, and that the Complaint explains no theory of illegality. Unfortunately for the Company, the duty to disclose may extend to uncharged and unadjudicated illegal conduct. *See, e.g.*, *Menaldi v. Och-Ziff Capital Mgmt. Grp. LLC*, 164 F.Supp.3d 568, 581 (S.D.N.Y. 2016) (observing that "a corporation may be compelled to disclose uncharged wrongdoing if its statements are or become materially misleading in the absence of disclosure"). Moreover, even if the Complaint insufficiently describes how the scheme contravenes the False Claims Act and other statutes, the judicially noticed qui tam complaint fully explains the

scheme's alleged illegality. *See* J.A. 929-64 (enumerating, inter alia, provisions of False Claims Act and compliance rules governing Medicare payments, as well as Company's conduct violative thereof).

Relying on the Sixth Circuit's 2009 decision in *Indiana State District Council of Laborers & Hod Carriers Pension & Welfare Fund v. Omnicare, Inc.*, 583 F.3d 935 (6th Cir. 2009), the Company also contends that it had no duty to disclose its reimbursement practices because the Complaint does not allege that the Company specifically asserted it was complying with a particular law. In *Omnicare*, the plaintiffs were pursuing a section 10(b) claim on the theory that the defendant corporation "had a duty to disclose its involvement in 'illegal' activities," in that it had "made several general statements that it complied with state law and regulations and had a policy of complying with the law." *See*583 F.3d at 945. The court of appeals rejected the plaintiffs' theory, because the complaint did "not sufficiently establish that [the corporation and its officers] actually knew that the 'legal compliance' statements were false when made," and because "the generic claim of lawfulness, in the absence of any specifics, [did not] require the disclosure of the allegedly 'illegal' activities." *Id.* at 947. Contrary to the Company's contention herein, the *Omnicare* decision did not hold that there is never a duty to disclose an illegal activity absent a specific assertion of compliance with the relevant law. Rather, the *Omnicare* court simply concluded that the generic assertions of legal compliance made in that case—without more—did not engender a duty to disclose the illegal activities alleged ***442** by the plaintiffs. Here, the Complaint does not depend on mere generic assertions of legal compliance to establish the Company's duty to disclose its fraudulent reimbursement scheme. The Complaint relies instead on the Company's choice to speak about its reimbursement practices—including, but not limited to, its efforts to train surgeons to attain " 'appropriate' " reimbursements—without telling the whole, material truth. Accordingly, the *Omnicare* decision is inapposite to the material misrepresentation analysis in these proceedings. [14]

14 Notably, the district court incorrectly deemed this case to be "analogous" to *Omnicare* and thus ruled the Complaint to be insufficient on the material misrepresentation element for failing to allege that the Company "knew TranS1's reimbursement practices were illegal" and "made express representations to the contrary." *See* Officers Order 15-16 (citing *Omnicare*, 583 F.3d at 945-47). Because the 2009 *Omnicare* decision is inapposite here, we need not decide whether we agree with it. Were we to do so, however, we would also consider decisions in subsequent *Omnicare* proceedings that were not discussed by the district court or the Company. *See Ind. State Dist. Council of Laborers & Hod Carriers Pension & Welfare Fund v. Omnicare, Inc.*, 719 F.3d 498 (6th Cir. 2013), *vacated and remanded*, *Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, —— U.S. ——, 135 S.Ct. 1318, 191 L.Ed.2d 253 (2015).

Finally, the Company argues that its failure to divulge the alleged fraudulent reimbursement scheme cannot have rendered any of the Officers' statements materially misleading, because the Form 10-Ks filed by TranS1 with the SEC included general warnings about the risks of regulatory scrutiny and litigation. For example, the 2008 Form 10-K cautioned the market that TranS1 "may be subject to or otherwise affected by federal and state healthcare laws, including fraud and abuse and health information privacy and security laws, and could face substantial penalties if we are unable to fully comply with such laws." *See* J.A. 128 (emphasis omitted). The Company's argument that such general warnings effectively satisfy the duty to disclose specific illegal activities was rejected by the Second Circuit in its 2014 *Meyer* decision. There, the defendant had warned the market that it "generates, uses, and stores dangerous chemicals and wastes and is subject to Chinese regulations regarding such chemicals and wastes," plus "that compliance with such regulations is costly and that non-compliance may lead to bad publicity, fines, and even a suspension of the business." *See Meyer*, 761 F.3d at 251 (internal quotation marks omitted). In concluding that those warnings failed to cure the corporation's non-disclosure of ongoing and serious pollution violations, the *Meyer* court explained:

> A generic warning of a risk will not suffice when undisclosed facts on the ground would substantially affect a reasonable investor's calculations of probability. One cannot, for example, disclose in a securities offering a business's peculiar risk of fire, the installation of a comprehensive sprinkler system to reduce fire danger, and omit the fact

> that the system has been found to be inoperable, without misleading investors.

Id. (citation omitted). We agree with the Second Circuit's cogent analysis. Despite the general warnings in TranS1's Form 10-Ks, the Officers' statements about the Company's reimbursement practices may be deemed materially misleading premised on the omission of the fraudulent reimbursement scheme.

At bottom, the Complaint is sufficient to establish that, by choosing to speak about its reimbursement practices, the Company possessed a duty to disclose its alleged illegal conduct. The Company violated that ***443** duty and acted deceptively by way of false statements and statements that were misleading because they omitted the fraudulent reimbursement scheme. Furthermore, the facts of that scheme were material, in that a reasonable investor would have considered the scheme important in deciding whether to buy or sell TranS1 stock, and would have viewed the total mix of information made available to be significantly altered by the scheme's disclosure. We are therefore satisfied that the Complaint adequately alleges the material misrepresentation element of the section 10(b) claim.

B.

[7] [8] [9] Turning to the issue of scienter, the Company argues that the Complaint also insufficiently pleads that element of the section 10(b) claim. In order to allege the scienter element, a plaintiff must demonstrate "that the defendant acted with 'a mental state embracing intent to deceive, manipulate, or defraud.' " *See Zak v. Chelsea Therapeutics Int'l, Ltd.*, 780 F.3d 597, 606 (4th Cir. 2015) (quoting *Tellabs*, 551 U.S. at 319, 127 S.Ct. 2499). A complaint's "[a]llegations of reckless conduct can satisfy the level of scienter necessary to survive a motion to dismiss." *Id.* (citing *Matrix Capital Mgmt. Fund, LP v. BearingPoint, Inc.*, 576 F.3d 172, 181 (4th Cir. 2009)). The reckless conduct sufficient to engender the mandatory strong inference of scienter may be conduct that, inter alia, "is 'so highly unreasonable and such an extreme departure from the standard of ordinary care as to present a danger of misleading the plaintiff to the extent that the danger was either known to the defendant or so obvious that the defendant must have been aware of it.' " *Id.* (quoting *Matrix Capital*, 576 F.3d at 181).

According to the Complaint, TranS1 and its Officers responded to the new, financially threatening Category III code for the System with a mix of legal and illegal strategies. Their legal strategies included advising surgeons to "bury" the Category III code for the System among the CPT codes for other parts of a spinal surgery so that the Category III code might be overlooked; touting efforts to move the System from the Category III code back to a lucrative Category I code in the near future; and emphasizing that, even though the System itself might be presently non-reimbursable, surgeons could yet be compensated for a surgery's other aspects.

Meanwhile, as for the illegal strategies, the Company engaged in its fraudulent reimbursement scheme to encourage and coach surgeons to continue coding the System under Category I despite the mandatory Category III code. Significantly, the Complaint reflects that the illegality of the fraudulent reimbursement scheme was obvious and known to TranS1 and the Officers. That is, the law was clear that, once the System was assigned the Category III code, only the Category III code could be used for the System. *See, e.g.*, Complaint ¶ 29 (alleging that "[f]ederal law, including the False Claims Act, requires surgeons to label services rendered with an appropriate CPT code, to insure that reimbursement[s] from [health insurers and government-funded healthcare programs] are legitimately procured"); J.A. 941 (qui tam complaint) (explaining that, once the Category III code for the System took effect, the System could "*only*" be billed as a Category III procedure). That the Company knew the law is further evidenced by its public acknowledgment of the System's Category III code and related reimbursement issues. Indeed, if the Company believed that the System could still lawfully be coded under Category I, it certainly would have said so. It is striking that—throughout the Officers' statements in the relevant SEC ***444** filings, press releases, and conference calls—they spoke in detail about the Company's legal strategies to deal with the new Category III coding requirement, without ever mentioning the Company's illegal efforts to persuade surgeons to use a Category I code instead. Those recurring omissions are particularly remarkable because the undisclosed scheme was the primary source of TranS1's continuing revenues, while the strategies discussed in the Officers' various statements

generated far less significant returns. *See Zak*, 780 F.3d at 611 (explaining that "the scienter inquiry necessarily involves consideration of the facts and of the nature of the alleged omissions or misleading statements within the context of the statements that a defendant affirmatively made").

The Company contends, however, that the Complaint is insufficient on the scienter element because it fails to allege facts demonstrating that the Officers knew of the fraudulent reimbursement scheme's existence, much less the scheme's illegality. Of course, the Complaint is premised on the proposition that the Officers directed the fraudulent reimbursement scheme, not that lower-level agents or employees independently conjured up and carried out the scheme without the Officers' knowledge. And, in any event, the fact that the System's new Category III code did not result in substantially greater losses to TranS1 would have put any otherwise-innocent Officer on notice that the fraudulent reimbursement scheme was afoot.

By alleging that the fraudulent reimbursement scheme was known to the Officers, clearly illegal, and fundamental to TranS1's financial success, the Complaint establishes that the Officers' failure to disclose the scheme presented a danger of misleading Singer and other investors—a danger that was also known to the Officers, or so obvious that the Officers must have been aware of it. That is, the Complaint gives rise to a strong inference that TranS1 and the Officers intended to deceive the market, or at the very least acted recklessly, when they made false and misleading statements about the Company's reimbursement practices that omitted the fraudulent reimbursement scheme. *See Zak*, 780 F.3d at 610 (concluding that there was a strong inference of scienter where "the plaintiffs' allegations, when considered in the context of the entire complaint, [demonstrated] that the defendants either knowingly or recklessly misled investors by failing to disclose critical information ..., while releasing less damaging information that they knew was incomplete"); *cf. Pirate Inv'r*, 580 F.3d at 243 (affirming scienter finding where defendant, acting on financial motive, made statement knowing it was false).

In these circumstances, we are satisfied that the Complaint adequately pleads the scienter element of the section 10(b) claim against both TranS1 and the Officers. Consequently, in Singer's appeal, we vacate the district court's rulings in the Officers Order and the Final Order that the Complaint fails to allege the scienter element, along with the court's rulings in those same Orders that the Complaint is insufficient as to the material misrepresentation element of the section 10(b) claim.

IV.

[10] Because we rule in favor of Singer in his appeal, the Company's cross-appeal (No. 16-1019) must now be addressed. In that regard, we assess whether the Complaint sufficiently pleads the loss causation element of the section 10(b) claim, as the district court concluded in its Reconsideration Order.

[11] [12] [13] We are obliged to review a complaint's "allegations of loss causation for sufficient specificity, a standard largely ***445** consonant with Fed. R. Civ. P. 9(b)'s requirement that averments of fraud be pled with particularity." *See Katyle v. Penn Nat'l Gaming, Inc.*, 637 F.3d 462, 471 (4th Cir. 2011) (internal quotation marks omitted). The loss causation element requires the pleading of "a sufficiently direct relationship between the plaintiff's economic loss and the defendant's fraudulent conduct," which may be accomplished by alleging facts establishing that the defendant's "misrepresentation or omission was one substantial cause of the investment's decline in value." *Id.* at 472 (internal quotation marks omitted). In such circumstances, the plaintiff must plead (1) the "exposure" of the defendant's misrepresentation or omission, i.e., the revelation of "new facts suggesting [the defendant] perpetrated a fraud on the market," and (2) that such exposure "resulted in the decline of [the defendant's] share price." *Id.* at 473 (emphasis and internal quotation marks omitted).

On appeal, the Company challenges the district court's ruling that the Complaint alleges exposure of the Company's false and misleading statements and omissions under the materialization of a concealed risk theory. The Company maintains that the Complaint fails under that theory, as well as the related, but somewhat distinct, corrective disclosure theory. For his part, Singer contends that the Complaint sufficiently pleads exposure under each theory. We conclude that the Complaint demonstrates exposure by way of an amalgam of the two theories and, thus, affirm.

A.

[14] **[15]** As we have recognized, exposure for purposes of the loss causation element can be alleged pursuant to the corrective disclosure theory and the materialization of a concealed risk theory. On the one hand, under the corrective disclosure theory, a complaint may allege that the defendant company itself made a disclosure that "publicly revealed for the first time" that the company perpetrated a fraud on the market by way of a material misrepresentation or omission. *See Katyle*, 637 F.3d at 473. On the other hand, utilizing the materialization of a concealed risk theory, a complaint may allege that news from another source revealed the company's fraud. *Id.* at 477 n.10 (explaining that, "[i]n such a case, the plaintiffs would not need to identify a public disclosure that corrected the previous, misleading disclosure because the news of the materialized risk would itself be the revelation of ... fraud that caused plaintiffs' loss" (quoting *Teachers' Ret. Sys. of La. v. Hunter*, 477 F.3d 162, 187 n.3 (4th Cir. 2007))). The materialization of a concealed risk theory has been generally accepted as a means of proving loss causation because, inter alia, a company "accused of securities fraud should not escape liability by simply avoiding a corrective disclosure." *See Ohio Pub. Emps. Ret. Sys. v. Fed. Home Loan Mortg. Corp.*, 830 F.3d 376, 384-85 (6th Cir. 2016). [15]

15 Although we recognized in our *Katyle* and *Teachers' Retirement System* decisions that exposure for purposes of the loss causation element can be proved by way of the materialization of a concealed risk theory, we have not heretofore had occasion to apply that theory. Meanwhile, a decisive majority of our fellow courts of appeals have applied the materialization of a concealed risk theory or, like we have, recognized it as a viable means for a securities fraud plaintiff to prove exposure. *See In re Omnicom Grp., Inc. Sec. Litig.*, 597 F.3d 501, 513 (2d Cir. 2010) (applying materialization of concealed risk theory); *Ohio Pub. Emps. Ret. Sys. v. Fed. Home Loan Mortg. Corp.*, 830 F.3d 376, 384-85 (6th Cir. 2016) (same); *Schaaf v. Residential Funding Corp.*, 517 F.3d 544, 550-553 (8th Cir. 2008) (same); *Nakkhumpun v. Taylor*, 782 F.3d 1142, 1156 (10th Cir. 2015) (same); *see also McCabe v. Ernst & Young, LLP*, 494 F.3d 418, 428-29 (3d Cir. 2007) (recognizing materialization of concealed risk theory); *Ray v. Citigroup Glob. Mkts., Inc.*, 482 F.3d 991, 995 (7th Cir. 2007) (same); *Nuveen Mun. High Income Opportunity Fund v. City of Alameda*, 730 F.3d 1111, 1120 (9th Cir. 2013) (same); *In re Harman Int'l Indus., Inc. Sec. Litig.*, 791 F.3d 90, 110 (D.C. Cir. 2015) (same). Two courts of appeals have ruled that there should be an alternative to the corrective disclosure theory, albeit without adopting the "materialization of a concealed risk theory" by name, and another has simply refrained from unnecessarily deciding the validity of the materialization of a concealed risk theory. *See Mass. Ret. Sys. v. CVS Caremark Corp.*, 716 F.3d 229, 240 (1st Cir. 2013) (recognizing importance of alternative theory to prove loss causation absent company's corrective disclosure); *Lormand v. US Unwired, Inc.*, 565 F.3d 228, 264 & n.32 (5th Cir. 2009) (same); *Hubbard v. BankAtlantic Bancorp, Inc.*, 688 F.3d 713, 726 n.25 (11th Cir. 2012) (deeming it unnecessary to decide whether material of concealed risk theory may be used to prove loss causation).

***446** **[16]** Importantly, the ultimate loss causation inquiry under either the corrective disclosure theory or the materialization of a concealed risk theory is the same: whether a "misstatement or omission concealed something from the market that, when disclosed, negatively affected the value of the security." *See In re Vivendi, S.A. Sec. Litig.*, 838 F.3d 223, 261-62 (2d Cir. 2016) (emphasis omitted). That is, pursuant to each theory, the plaintiff must show "that the loss caused by the alleged fraud results from the 'relevant truth ... leak[ing] out.' " *Id.* at 261 (quoting *Dura Pharm., Inc. v. Broudo*, 544 U.S. 336, 342, 125 S.Ct. 1627, 161 L.Ed.2d 577 (2005)).

[17] **[18]** As we have recognized in the context of corrective disclosures, "neither a single complete disclosure nor a fact-for-fact disclosure of the relevant truth to the market is a necessary prerequisite to establishing loss causation (although either may be sufficient)." *See Katyle*, 637 F.3d at 472. Rather, the truth may have "gradually emerged through a series of partial disclosures," with the "entire series of partial disclosures [prompting] the stock price deflation." *Id.* Moreover, the disclosure or series of partial disclosures "need not precisely identify the misrepresentation or omission" about which the plaintiff complains, but "must reveal to the market in some sense the fraudulent nature of" such misrepresentation or omission, and "must at least relate back to the misrepresentation [or omission] and not to some other negative information about the company." *Id.* at 473 (emphasis and internal quotation marks omitted).

B.

Here, to establish exposure for purposes of the loss causation element, the Complaint relies on a partial corrective disclosure by the Company (TranS1's Form 8-K of October 17, 2011, reporting that it had received a subpoena from the DHHS), coupled with news from another source (the October 18, 2011 analyst report addressing the subpoena). At the time, the market already knew from the Officers' public statements that, as of January 1, 2009, the System was required to be coded under Category III and thus was largely non-reimbursable. The market also knew of TranS1's lawful efforts to return the System to a lucrative Category I code and to deal with the Category III code in the meantime. Together, the Form 8-K and analyst report revealed to the market the following additional facts: that TranS1 had received a subpoena on or about October 6, 2011, issued by the DHHS " 'under the authority of the federal healthcare fraud and false claims statutes' "; that the items sought by the subpoena included " 'reimbursement communications with physicians' "; and that, despite the System's nearly three-year-old Category III coding requirement and the Company's purported ***447** " 'strong efforts to educate physicians about correct coding,' " approximately " 'half of TranS1's revenues [were coming] from physicians still using [a Category I] code.' " *See* Compl. ¶¶ 108-109.

As such, TranS1's own Form 8-K and the analyst report revealed enough facts for the market to finally recognize what the Officers' previous statements had materially omitted: the existence of the Company's fraudulent reimbursement scheme to encourage surgeons' continued use of a Category I code for the System, rather than the mandatory Category III code, and to thereby bolster TranS1's System-dependent revenues. Indeed, the plausibility of that interpretation of the facts revealed in the Form 8-K and the analyst report is evidenced by the analyst report's opinion that the subpoena " 'could be due to reimbursement communications.' " *See* Compl. ¶ 109. As the Complaint understandably emphasizes, based on the new facts, the analyst report "surmised with radar precision that the subpoena ... relat[ed] to [TranS1's] illicit 'reimbursement communications.' " *Id.* ¶ 9. In these circumstances, pursuant to an amalgam of the corrective disclosure and materialization of the concealed risk theories, the facts revealed in the Form 8-K and the analyst report were sufficient to establish exposure for purposes of the loss causation element, because those facts collectively "suggest[ ] [the Company] perpetrated a fraud on the market." *See Katyle*, 637 F.3d at 473.

Finally, to the extent the Company argues that the Complaint fails to allege that the exposure of the Company's concealment of its fraudulent reimbursement scheme resulted in the decline of TranS1's stock price, we disagree. According to the Complaint, the revelations in the October 17, 2011 Form 8-K and the October 18, 2011 analyst report caused the value of TranS1's stock to plummet more than 40% on October 18, 2011, alone. Such an allegation is wholly adequate to demonstrate that the exposure of the Company's fraud was at least "one substantial cause of the investment's decline in value." *See Katyle*, 637 F.3d at 472 (internal quotation marks omitted).

Having conducted a thorough and holistic assessment of the Complaint, we conclude that its allegations are sufficient to plead the loss causation element of the section 10(b) claim, as the district court properly determined. That is, the Complaint satisfies the ultimate loss causation inquiry by alleging losses resulting from "the relevant truth ... leak[ing] out" about the Company's previously concealed fraudulent reimbursement scheme. *See Dura Pharm.*, 544 U.S. at 342, 125 S.Ct. 1627. We therefore affirm the court's loss causation ruling in its Reconsideration Order and reject the Company's cross-appeal. [16]

16 Because we conclude that the Complaint sufficiently pleads the material misrepresentation, scienter, and loss causation elements of the section 10(b) claim, we need not address the contention made in Singer's appeal that the district court erred in denying leave to amend when it dismissed the Complaint.

V.

Pursuant to the foregoing, we vacate the judgment of the district court and remand in No. 15-2579 for such other and further proceedings as may be appropriate. We affirm the ruling being challenged in the cross-appeal, that is, No. 16-1019.

No. 15-2579 *VACATED AND REMANDED, and* No. 16-1019 *AFFIRMED*

AGEE, Circuit Judge, dissenting:

According to plaintiff Phillip Singer, defendant TranS1, Inc. (the "Company") and ***448** its officers engaged in a years-long pattern of behavior that violated federal securities law. That behavior is alleged to have deceived healthcare providers, the Medicare and Medicaid administrative agencies and violated the False Claims Act, 31 U.S.C. §§ 3729–33. Singer now asserts that the Company's alleged actions establish liability to investors under sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Act"), 15 U.S.C. §§ 78a–78qq. Although the district court convincingly found the complaint deficient as a matter of law, the majority agrees with Singer, vacates the judgment of the district court and reinstates Singer's complaint.

I disagree and respectfully dissent. Singer has not pled the necessary elements of either a section 10(b) claim or a section 20(a) claim. I would affirm the district court's judgment dismissing the complaint. [1]

[1] Singer's section 20(a) claim against the Company's officers fails because liability under section 20(a) is derivative of liability under section 10(b). *Yates v. Mun. Mortg. & Equity, LLC*, 744 F.3d 874, 894 n.8 (4th Cir. 2014). I therefore discuss only Singer's section 10(b) claim.

I.

Section 10(b) of the Act prohibits the use of "any manipulative or deceptive device or contrivance" with regard to securities. 15 U.S.C. § 78j(b). The associated regulation provides that section 10(b) prohibits "mak[ing] any untrue statement of a material fact or ... omit[ting] to state a material fact necessary in order to make the statements made [in connection with the sale of a security] not misleading." 17 C.F.R. § 240.10b-5(b).

Expounding on that definition, the Supreme Court has stated that a section 10(b) claim has six elements. A securities fraud plaintiff must plead "(1) a material misrepresentation (or omission); (2) scienter, *i.e.*, a wrongful state of mind; (3) a connection with the purchase or sale of a security; (4) reliance ...; (5) economic loss; and (6) loss causation, *i.e.*, a causal connection between the material misrepresentation and the loss." *Dura Pharm., Inc. v. Broudo*, 544 U.S. 336, 341–42, 125 S.Ct. 1627, 161 L.Ed.2d 577 (2005). [2] Primarily at issue in the district court were the first, second, and sixth of these elements. That is: did Singer sufficiently plead that the Company made a material misrepresentation with scienter that also established loss causation? The district court held that Singer had failed to do so with respect to the first and second elements, but had made the requisite showing for loss causation. In my view, Singer fails on all three elements.

[2] I have omitted internal quotation marks, alterations, and citations here and throughout this dissent, unless otherwise noted.

II.

We review the grant of a motion to dismiss de novo, applying the traditional Federal Rule of Civil Procedure 12(b)(6) standards. *Teachers' Ret. Sys. of La. v. Hunter*, 477 F.3d 162, 170 (4th Cir. 2007). The Private Securities Litigation Reform Act of 1995, Pub. L. No. 104-67, 109 Stat. 737 (codified as amended in scattered sections of 15 U.S.C.) (the "PSLRA"), also governs our review.

Under Rule 12(b)(6), we determine "whether the complaint states a claim upon which relief can be granted in light of the pleading requirements of Rules 8 and 9, as well as the larger design of the Federal Rules [of Civil Procedure]." *Hunter*, 477 F.3d at 170. Rule 9, and in particular ***449** Rule 9(b), requires that fraud be pled "with particularity." We "accept as true [the complaint's] well-pleaded factual allegations, but owe no allegiance to unwarranted inferences, unreasonable conclusions, or arguments drawn from those facts." *Katyle v. Penn Nat'l Gaming, Inc.*, 637 F.3d 462, 466 (4th Cir. 2011).

We also apply the PSLRA, which "provides that in pleading a material misrepresentation or omission, ... and the scienter necessary to such a misrepresentation or omission, the plaintiff must plead *facts*," *Hunter*, 477 F.3d at 172, and cannot rely on mere speculation. The "complaint must include *each statement* alleged to have been misleading, *the reason* ... why the statement is misleading, and if an allegation regarding the statement or

omission is made on information and belief, the complaint shall state *with particularity all facts* on which that belief is formed." *Id.*; *see also*15 U.S.C. § 78u-4(b)(1). Similarly, "in alleging scienter, the plaintiff must, with respect to each act or omission alleged to violate [section 10(b)], state with particularity *facts giving rise to a strong inference* that the defendant acted with the required state of mind." *Hunter*, 477 F.3d at 172; 15 U.S.C. § 78u-4(b)(2).

With this background in mind, I turn to the merits of Singer's appeal.

III.

On appeal, the parties again dispute the elements of omission, scienter, and loss causation. A failure to plead any one of those elements in accord with the PSLRA or Rules 8 and 9(b) would doom Singer's case. But Singer's complaint fails under each of the three disputed elements.

A.

First, Singer has failed to plead any actionable misrepresentation or omission. A misrepresentation or omission is actionable if it is factual, false or misleading, and material. *See Longman v. Food Lion, Inc.*, 197 F.3d 675, 682–83 (4th Cir. 1999). In the abstract an issuer generally has no duty to disclose damaging information. *See Basic Inc. v. Levinson*, 485 U.S. 224, 239 n.17, 108 S.Ct. 978, 99 L.Ed.2d 194 (1988) ("Silence, absent a duty to disclose, is not misleading under Rule 10b-5."). Thus, the omission of damaging information often is not actionable, even if the corporation fails to divulge illegal conduct. *See City of Pontiac Policemen's & Firemen's Ret. Sys. v. UBS AG*, 752 F.3d 173, 184 (2d Cir. 2014) ("[D]isclosure is not a rite of confession, and companies do not have a duty to disclose uncharged, unadjudicated wrongdoing." (footnote omitted)).

That is not an absolute rule, however. For example, if the corporation's silence on a subject "would make other [of its] statements misleading or false," then it must speak. *Taylor v. First Union Corp. of S.C.*, 857 F.2d 240, 243–44 (4th Cir. 1988); *accord City of Monroe Emps. Ret. Sys. v. Bridgestone Corp.*, 399 F.3d 651, 669 (6th Cir. 2005) ("In order to be actionable, a misrepresentation or omission must pertain to material information that the defendant had a duty to disclose.... A duty to affirmatively disclose may arise when there is insider trading, a statute requiring disclosure, or ... an inaccurate, incomplete or misleading prior disclosure.").

Any misrepresentation or omission also must be material. That is to say, it must be one that a reasonable investor "would consider ... important in deciding whether to buy or sell the security" or a fact that would have "significantly altered" the "total mix of information made available" to the investor. *See Longman*, 197 F.3d at 683.

***450** 1.

The Company made no material misstatement or omission in its various descriptions of its reimbursement practices. To the contrary, the Company was forthcoming about the fact that the American Medical Association ("AMA") had given a "Category III CPT" classification to the AxiaLIF System (the "System") for billing purposes, told investors that Category III CPT codes were unlikely to be reimbursed, and described in detail the steps it was taking to preserve its revenues—including by encouraging the use of a multiple-step coding sequence.

To begin, the Company repeatedly disclosed to investors that the AMA gave the System a Category III CPT code for reimbursement purposes. In a February 2009 conference call with investors, the Company indicated that "a portion of [its] surgeon fee migrated from an unlisted code to a category three CPT ... code[.]" J.A. 1196 ¶ 69. The Company further stated that the Category III code may create some difficulty in obtaining reimbursements, but that any difficulty would be no more than that experienced before the System received any tracking code. *See* J.A. 1196 ¶ 69 ("[W]e do not anticipate that [the Category III CPT reimbursement code] will create any significant *additional* headwind with regards to adoption.... [W]e feel that [the] unlisted code gave us about a 5% kind of a headwind and it's probably consistent again this year."). Finally, the Company revealed in a Form 10-K filed with the Securities and Exchange Commission ("SEC") in March 2009 that "some payors ... may not reimburse" Category III CPT codes. J.A. 1197 ¶ 71.

The Company also disclosed that it was encouraging surgeons to use a multiple-step coding sequence to obtain reimbursement. In the March 2009 Form 10-K, the

Company stated "[the Category III CPT code] is *only one of up to ten different CPT codes physicians may submit to capture the entirety of a spinal fusion procedure* lessening the impact should payment for our code be initially denied." J.A. 1197 ¶ 71 (emphasis added). And on an investor conference call in April 2009, the Company described in detail how it was teaching surgeons to use its multiple-step coding procedure:

> We have an 800 number and call-in resource center, up and running to assist surgeons with reimbursement issues that may arise.
>
> We have also added two additional reimbursement specialists in the field to work with our surgeon customers and their billing specialists, to help them determine the appropriate coding for the fusion procedures they are performing.
>
> As a strong case volume this quarter would suggest, we have not seen a drop off in procedure volumes as a result of the current weak economic conditions. Having said that, we have begun to see some insurance companies raising the bar on whether to pay for fusion surgery in general or asking more patients to get a second opinion, before agreeing to cover the procedure.
>
> [W]e had the category-three code put in place in January and that was a change in coding. We have actually put out a coding guide now, which has been blessed by everyone. And coding fusions is fairly complex and *what we saw initially with the category-three code was right away a lot of coders in the practice went to the concern that like the Charité disc they are just not going to get paid.*
>
> The reality is, as we've discussed in the past, this access code is one of several codes that they employ during a typical fusion. So I would say our coding issues have been grassfires, not forest fires, and so, this flare is up. A coder ***451** becomes concerned, because they see a category-three code. And we either work through the rep, or we work through the hotline, or now we've actually, as I have mentioned, brought on a couple of field related personnel, who had worked by the way at Saint Francis Medical, where they knew category-three code inside and out. Those people are then, if needed, deployed and we put these fires out.
>
> I don't think we've had many instances, if any, where we just have surgeons stop doing this, but often times *there is a concern when they see the category-three code*. We need to work with them and once they understand the coding sequence, based on the particular operation that the surgeon does, we move through the process. So, that's why we proactively hired these folks.

J.A. 1198–99 ¶ 74 (emphases added).

The Company's statements in 2009 laid out each aspect of the Company's reimbursement practices. As the district court observed, "[u]nless [Singer] is contending that the [Company] needed to disclose each and every aspect of [its] reimbursement practices, down to the most minute detail, [I do] not see how [the Company] failed to sufficiently disclose ... [those] practices." J.A. 1348. In sum, "[n]o further disclosure was required because the [Company's] statements were" truthful and accurate in the main and were "not misleading under the circumstances [in which] they were made." J.A. 1348.

2.

Nevertheless, the majority holds that the Company's failure to disclose its "scheme to encourage surgeons to employ CPT codes meant for anterior and other non-Category III procedures in direct disregard of the AMA's mandated Category III code for the System" is an actionable omission for section 10(b) purposes. Majority Op. 433. They conclude that the Company "cho[se] to speak about its reimbursement practices," and thus "possessed a duty to disclose its alleged illegal conduct." Majority Op. 442–43.

The majority faults the Company for "misrepresent[ing] the assistance and training it was providing to surgeons as being wholly for the attainment of 'appropriate'—i.e., legal—reimbursements for the System." Majority Op. 439. But the majority's narrow focus on "appropriate reimbursement" ignores reality. Statements made on the Company's April 2009 investor conference call, for example, acknowledge that the System's Category III CPT code could result in disallowed coverages and describe the steps taken by the Company to improve prospects for reimbursement, including the use of a hotline and field representatives to walk surgeons through coding the procedure. In addition, the Company told investors it was encouraging surgeons to use multiple CPT codes, saying the Category III CPT code was "*one of up to ten*

different CPT codes" that surgeons could use to obtain reimbursement. J.A. 1197 ¶ 71 (emphasis added).

The majority also faults the Company for suggesting that the System's Category III CPT code was "not an experimental code," but rather was a "tracking code." Majority Op. 433, 439. The majority's focus on the Company's use of the phrase "tracking code" ignores the context in which that word was used. Although the Company called the Category III CPT code a "tracking code," it also was clear that such code was *not* a generally reimbursable Category I CPT code. And the Company's investors knew that the System had been given a Category III code, which is generally not reimbursable, from the Company's multiple disclosures.

***452** More generally, the majority's analysis errs in its central assumption that the Company, if speaking about its reimbursement practices at all, not only had to characterize those practices fairly, but also had to further describe them as fraudulent or illegal. When the Company settled a related False Claims Act lawsuit with the United States, nowhere did the settlement agreement "indicate that using multiple codes, in and of itself, [was] inappropriate." J.A. 1352. Neither Singer nor the majority cites to a statute, regulation, or case that establishes this practice to be either illegal or fraudulent. Nevertheless, the majority's holding creates an inflexible rule that requires a publicly traded corporation engaged in ambiguous activity to represent its behavior as illegal or else risk being the subject of a securities fraud lawsuit. Neither section 10(b) nor the PSLRA requires that result and the majority cites no case for such a rule. *See Taylor*, 857 F.2d at 243–44 ("Rule 10b-5 imposes ... a duty to disclose only when silence would make other statements misleading or false.").

3.

Other aspects of the majority opinion warrant closer scrutiny. For instance, it obliquely concludes that the Company made a material omission, claiming that, if the Company had informed the market that its reimbursement mechanism was illegal, such disclosure would have changed the "total mix of information" available to investors. Majority Op. 443. Yet, the majority is unable to fully describe how an additional disclosure by the Company would have altered that total mix of information. Its inability is unsurprising for two reasons. First, Singer has failed to allege materiality with the required specificity. That is to say, Singer has not demonstrated under Rule 9(b) and the PSLRA that additional information would have changed the total mix of information available to investors.

Second, and more importantly, the majority cannot identify any additional information that the Company could have disclosed. As the district court correctly noted, the Company disclosed "its reimbursement practices to the public in conference calls and public filings," where it acknowledged that the System "had received a Category III CPT code designation," it "had set up an 800 number and call-in resource center to help surgeons with billing," it "had reimbursement specialists in the field to work with its surgeons," and it "had published a coding guide." J.A. 1347. In view of these numerous, accurate disclosures, the majority errs in concluding that the Company omitted any material information from its disclosures.

* * * *

At bottom, as the district court correctly noted, there was no need for the Company "to disclose each and every aspect of [its] reimbursement practices, down to the most minute detail." J.A. 1348. What the Company did disclose was sufficient to avoid section 10(b) liability—a result that is bolstered, in part, by Singer's failure to plead what was missing. I agree with the district court that Singer fails to adequately plead the required element of a material misrepresentation or omission and I would dismiss the complaint for that reason.

B.

Even if Singer adequately pled a material misrepresentation or omission, he has not sufficiently alleged the element of scienter. Certainly, Singer has alleged that the Company's officers knew the mechanics of the Company's reimbursement practices. Yet, he has not provided material factual allegations from which it could be ***453** reasonably inferred that the Company's officers knew those practices violated any fraud statute, whether related to healthcare or otherwise.

Scienter is "a mental state embracing [the] intent to deceive, manipulate, or defraud." *Zak v. Chelsea*

Therapeutics Int'l, Ltd., 780 F.3d 597, 606 (4th Cir. 2015). To survive a motion to dismiss, the complaint must allege sufficient facts that, when "taken collectively, give rise to a strong inference of scienter." *Pub. Emps.' Ret. Ass'n of Colo. v. Deloitte & Touche LLP*, 551 F.3d 305, 312 (4th Cir. 2009). That "strong inference" must be "at least as compelling as" any other reasonable inference. *Id.*

Typically, a plaintiff pleads scienter through allegations of intentional misconduct. But he may also plead scienter through allegations of "severe recklessness"—"a slightly lesser species of intentional misconduct." *Ottmann v. Hanger Orthopedic Grp., Inc.*, 353 F.3d 338, 343–44 (4th Cir. 2003). The severe recklessness standard "comports with the observation of the Supreme Court that the words 'manipulative or deceptive' used in conjunction with 'device or contrivance' strongly suggest that § 10(b) was intended to proscribe knowing or intentional misconduct." *Id.* at 344. *See generally*15 U.S.C. § 78j(b) (prohibiting the "use ... in connection with the purchase or sale of any security registered on a national securities exchange or any security not so registered ... any *manipulative or deceptive device or contrivance* in contravention of [regulations promulgated by the SEC]" (emphasis added)). A "severely reckless" act is one that is "so highly unreasonable and such an extreme departure from the standard of ordinary care as to present a danger of misleading the plaintiff to the extent that the danger was either known to the defendant or so obvious that the defendant must have been aware of it." *Ottmann*, 353 F.3d at 343.

1.

The allegations in the complaint, taken as a whole, do not plausibly suggest—much less strongly so—that the Company or its officers acted with the requisite intent to deceive. To the contrary, the complaint details a series of frequent and accurate disclosures, from which the strong inference can be drawn that the Company endeavored to tell the truth.

Importantly, the complaint "fails to allege that the defendants knew the [Company's reimbursement] practices were illegal." J.A. 1354. Instead, as the district court correctly understood the complaint, Singer alleges only that the Company's officers "knew about or recklessly disregarded[ ] practices to encourage surgeons to illegally dupe insurance companies." J.A. 1349. But Singer's allegations "are merely conclusory and are unsupported by any specific allegations." J.A. 1349. Thus, without supporting factual matter, Singer's complaint is without merit under the strictures of Rule 9(b) and the PSLRA.

Just as damning, the complaint is bereft of evidence that the Company "encourage[d] [the] omission of the Category III CPT Code." J.A. 1355. Singer's best evidence is an allegation that the Company instructed surgeons to "bury the [code] in the bottom part of the reimbursement request so that insurance companies might overlook it," J.A. 1189 ¶ 51, but he fails to allege any act by the Company to encourage those surgeons to delete or falsify a Category III code.

To be sure, the Company offered surgeons use of a coding guide that "direct[ed] [them] to use [multiple] codes to secure reimbursements." J.A. 1185 ¶ 35. However, the coding guide clearly indicated ***454** "that [the System] had received a Category III code." J.A. 1355. Moreover, investors were already aware that the Company was instructing surgeons to use a multiple-step coding sequence to help them secure the maximum potential reimbursement. Nowhere does the complaint "allege that such a practice was improper." J.A. 1352. In addition, the Company was forthright about potential adverse consequences of its reimbursement strategy, as it disclosed to investors "the increased risk of regulatory scrutiny and litigation" in its Form 10-K. J.A. 1348. Such disclosures are inconsistent with any inference that the Company was trying to hide the alleged illegality of its reimbursement practices.

It is unsurprising that the complaint "does not allege that the defendants knew that using multiple codes was inappropriate." J.A. 1352. Not even the Company's settlement agreement with the Government "indicate[s] that using multiple codes, in and of itself," is prohibited. J.A. 1352. And, as already noted, neither Singer nor the majority cites to a statute, regulation, or case that establishes that the multiple-step coding process was illegal or fraudulent. But even if the complaint had made such allegations, the Company fully disclosed the specifics of its reimbursement scheme, as discussed above.

Like the district court, I "do[ ] not see how the defendants failed to sufficiently disclose [the Company's]

reimbursement practices." J.A. 1348. The complaint "shows (1) that the defendants openly admitted that [the System] had received a Category III CPT code, (2) that the [coding] guide noted that [the System] had received the Category III code, and (3) that the defendants did not encourage omission of the Category III CPT code." J.A. 1354–55. Singer cannot show scienter under these circumstances.

2.

Nonetheless, the majority concludes that the Company acted with scienter because it responded to the Category III CPT code assigned to the System "with a mix of legal and illegal strategies." Majority Op. 443. Further, the majority finds that the Company selectively downplayed its illegal strategies in communications with investors. It also holds that the Company and its officers knew the Company's conduct was illegal because "the illegality of the fraudulent reimbursement scheme was obvious." Majority Op. 443. But the majority puts too much stock in the "obvious" illegality of the alleged scheme. Majority Op. 443.

It incorrectly assumes that, because the Company's reimbursement framework was allegedly illegal, the Company axiomatically intended to defraud its investors. That premise is not supported by statute or precedent. Even if it were fair to infer that the Company's officers were aware that the Company's reimbursement scheme was illegal, it is unfair to carry that inference one step further and conclude that *because* the Company acted illegally it therefore *also* intended to deceive its investors. *See Maguire Fin., LP v. PowerSecure Int'l, Inc.*, 876 F.3d 541, 547–48 (4th Cir. 2017) ("First, an inference that Hinton may have known his statement was false does not alone satisfy the scienter requirement."). By concluding otherwise, the majority has effectively "read the scienter element out of the analysis in contravention of the PSLRA's exacting pleading standard." *Id.* at 548. Under the majority's reasoning, an illegal action on the part of a publicly traded company automatically qualifies as fraud on investors for securities law purposes if its conduct was "clearly illegal." Majority Op. 444. That is simply not the law. *See City of Pontiac*, 752 F.3d at 184 ***455** ("[D]isclosure is not a rite of confession, and companies do not have a duty to disclose uncharged, unadjudicated wrongdoing." (footnote omitted)). Just because a plaintiff alleges an illegal act does not mean he has also pled fraud.

Nor is the majority's analysis a correct application of the recklessness standard. Even assuming that the Company may have been reckless about the *legality* of its conduct, it doesn't follow that the Company also acted recklessly with regard to its conduct as to investors. The Company's description of the alleged scheme was in the main forthcoming and accurate, touching on each component of the alleged reimbursement scheme, discussing its reimbursement practices in detail, and explaining why those practices were used. *E.g.*, J.A. 1196 ¶ 69; J.A. 1198 ¶ 74. [3]

3 While Singer may have expected that the Company would rely only on legal reimbursement practices, "an investor's view of a statement is not itself evidence of the speaker's state of mind." *Maguire*, 876 F.3d at 548.

* * * *

I agree with the district court and would dismiss the complaint for failure to adequately plead the required element of scienter. The complaint contains no plausible allegations to support the required "strong inference" that the Company and its officers knew, or even suspected, that their conduct was illegal. It fails to address the individual officers' knowledge of the illegality of the Company's reimbursement practices. At best, Singer alleges only that the Company and its officers knew or recklessly disregarded practices to encourage surgeons to make it harder for insurance companies to process claims. The district court correctly dismissed Singer's complaint regarding the element of scienter.

C.

Even assuming that Singer adequately pleaded the elements of omission and scienter, his complaint fails to plead loss causation with "sufficient specificity." *Katyle*, 637 F.3d at 471. The district court initially dismissed Singer's complaint because it failed to plead loss causation with the required specificity, but upon reconsideration changed its view. The district court was right the first time.

"Loss causation is the causal link between the alleged misconduct and the economic harm ultimately suffered by

the plaintiff." *Lentell v. Merrill Lynch & Co.*, 396 F.3d 161, 172 (2d Cir. 2005); *accord Gasner v. Bd. of Supervisors*, 103 F.3d 351, 360 (4th Cir. 1996) ("In a suit brought under Rule 10b-5, the plaintiff must show ... loss causation—that the misrepresentations or omissions caused the economic harm...."). In other words, there must be allegations of "facts to show ... that the misrepresentation or omission was one substantial cause of the investment's decline in value." *Katyle*, 637 F.3d at 472.

Loss causation is typically pled in one of two ways. One such form is "corrective disclosure" of the alleged fraud, *see id.* at 472–73, by which a plaintiff establishes loss causation by alleging a "corrective disclosure ... [that] reveal[s] to the market the falsity of the prior" statements, *Lentell*, 396 F.3d at 175 n.4.

The second method of alleging this element is known as "materialization of the concealed risk." *See Katyle*, 637 F.3d at 477 & n.10. Under this theory, a plaintiff pleads loss causation "by showing that the loss was foreseeable and caused by the materialization of the risk concealed by the fraudulent statement." ***456** *New Orleans Emps.' Ret. Sys. v. Omnicom Grp., Inc.* (*In re Omnicom Grp., Inc. Sec. Litig.*), 597 F.3d 501, 513 (2d Cir. 2010). So long as "the risk that caused the loss was within the zone of risk concealed by the misrepresentation[ ]," *id.*, "the plaintiff [does] not need to identify a public disclosure that correct[s a] previous, misleading disclosure," *Hunter*, 477 F.3d at 187 n.3. Once the risk materializes, "the news of the materialized risk would itself be the revelation of fraud that caused [the] plaintiff['s] loss." *Id.* [4]

4 This Court has neither explicitly adopted nor applied the materialization of the concealed risk theory of loss causation. And it does not do so here. Rather, we have "acknowledged the possibility" that the materialization of the concealed risk theory is viable. *See Hunter*, 477 F.3d at 187 n.3. Significantly, the majority neither adopts nor applies the materialization of the concealed risk theory here. They instead focus on an "amalgam" of the two loss causation theories. Majority Op. 445–47.
While the materialization of the concealed risk theory may be deemed at some point too vague to withstand scrutiny, for purposes of this case I assume the majority's amalgam paradigm is feasible and address the end result.

Both theories of loss causation drive at the same point: did "the misstatement or omission conceal[ ] something from the market that, when disclosed, negatively affected the value of the security"? *Lentell*, 396 F.3d at 173; *accord Schleicher v. Wendt*, 618 F.3d 679, 683–84 (7th Cir. 2010). The Seventh Circuit has provided a useful example to illustrate the commonality between the theories:

> If a firm that is losing money says "we expect to lose $100 million next quarter" when the managers actually expect the loss to be $200 million, that statement will keep the price higher than it ought to be, and when the next quarterly results show the real $200 million loss the price will adjust.... The parties are wont to call the bad outcome (the $200 million loss) a "materialization of the risk" that the loss would exceed $100 million. But it should be clear that this is just a mirror image of the situation for the same figures in black ink, rather than red. If the firm projects a $200 million profit, when the managers actually expect $100 million, then the eventual disclosure of the expected result could be called a "materialization of the risk" that the real profit would be less than the managers' optimistic number of $200 million.

Schleicher, 618 F.3d at 683–84. Because of their common end point, it follows that materialization of the concealed risk is simply an alternate way of framing the same causation principle embodied by corrective disclosure. *Id.*; *Norfolk Cty. Ret. Sys. v. Cmty. Health Sys., Inc.*, 877 F.3d 687, 695–96 (6th Cir. 2017) (observing that true corrective disclosures "can be hard to come by, and courts have otherwise held that revelations can come from many sources, including whistleblowers, analysts, and newspaper reports").

1.

In a securities fraud case, "the fraud lies in an intentionally false or misleading statement, and the loss is realized when the truth turns out to be worse than the statement implied." *Schleicher*, 618 F.3d at 684. For example, in *Katyle*—a corrective disclosure case—this Court hypothesized that damaging, fact-based disclosures such as canceled meetings, express investor doubts, and lack of regulatory approval could meet the section 10(b) pleading standard, depending on the context. 637 F.3d at 469. The Court then observed that, in the light most favorable to the plaintiff, such disclosures could have "alerted investors

to the ever-mounting risk that the deal [at the heart of the suit] was unlikely to close." *Id.* at 477.

***457** Here, the critical allegations in the complaint reveal disclosures to the market from two different sources: (1) an October 17, 2011, Form 8-K—which the Company filed with the SEC—that disclosed the existence of a subpoena received from the U.S. Department of Health and Human Services ("DHHS"), and (2) an analyst's report discussing the subpoena, which was published a day later. But neither source meets the requirement of pleading loss causation, which necessitates specific, fact-based allegations. The Company's Form 8-K disclosure and the analyst's report here do not rise to the relevant level as the examples posited in *Katyle* reflect.

a.

The analyst's report does not contain plausible factual allegations sufficient to meet the required pleading standard. *See Nemet Chevrolet, Ltd. v. Consumeraffairs.com, Inc.*, 591 F.3d 250, 255 (4th Cir. 2009) ("Ultimately, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face."). The portion of the analyst's report recited in the complaint provides in full:

> Management mentioned in our conversation that they have "let so many reps go in the last year and a half" (due to downsizing), which makes us think the subpoena could perhaps stem from allegations by a disgruntled former employee. Another speculation would be since about half of [the Company's] revenues come from physicians still using the [Category I CPT] code (which provides reimbursement), rather than the designated [Category III CPT] code (which does not provide reimbursement), the issue could be due to reimbursement communications, although we think that the Company has been making strong efforts to educate physicians about correct coding. Note that ultimately the decision regarding which code to use lies in the hands of the physician.

J.A. 1210 ¶ 109.

The primary revelation—that the Company had received a DHHS subpoena—is not actionable because it discloses only the fact of a DHHS investigation. Typically, the disclosure of an investigation, "without more, is insufficient to constitute a[n] [actionable] disclosure for purposes of § 10(b)." *Meyer v. Greene*, 710 F.3d 1189, 1201 (11th Cir. 2013) (applying this principle to commencement of a government investigation); *accord Loos v. Immersion Corp.*, 762 F.3d 880, 890 (9th Cir. 2014) (holding the same for an internal investigation). The possibility that some unspecified negative information may eventually come to light as a result of the investigation is not the same thing as the possibility that information about fraud will also be reflected. After all, fraud is but one of a panoply of reasons that a given company could be under investigation. Drawing anything more from the report is simply conjecture. For that reason, disclosure of the fact of the DHHS investigation itself is not actionable.

Putting aside the disclosure of the investigation, the analyst's report does not otherwise meet the loss causation element because it does not tie the decline in value of the Company's stock to the alleged fraud. *See Lentell*, 396 F.3d at 173 ("[T]o establish loss causation, a plaintiff must allege that the subject of the fraudulent statement or omission was the cause of the actual loss suffered[.]").

Singer has not alleged facts from which it reasonably could be inferred that the Company's allegedly fraudulent billing practices caused his injury. The analyst's report does not detail, describe, or discuss *how*, or even *if*, the Company violated the "federal healthcare fraud and false claims ***458** statutes." J.A. 1210 ¶ 108. The analyst's report states only that the subpoena *potentially* concerned the Company's billing "communications," but called that hypothesis "speculation." J.A. 1210 ¶ 109. Because the analyst's report itself calls its conclusion speculative, it is remarkable that the majority concludes otherwise.

Indeed, the report offers several facts that just as likely reflect non-fraudulent activity. For example, the report reveals "the Company has been making strong efforts to educate physicians about correct coding." J.A. 1210 ¶ 109. To be sure, the report does suggest that "about half" of the Company's revenues come from surgeons using the Category I code. J.A. 1210 ¶ 109. But when considered alongside the analyst's report's discussion of the Company's "strong efforts" to educate surgeons about "correct coding," the report just as plausibly suggests that the Company directed physicians away from using the Category I CPT code.

b.

The same problems affect the Company's Form 8-K disclosure. There, the Company revealed that it had "received a subpoena" from DHHS, which "s[ought] documents for the period January 1, 2008 through October 6, 2011." J.A. 1210 ¶ 108. This bare-bones revelation may have given the market a reason to speculate, but it does not establish loss causation. It neither corrects a prior statement nor conceals a later-materialized risk. Instead, the Form 8-K discloses only that the Company was under investigation. And "without more, [that fact] is insufficient to constitute a[n] [actionable] disclosure for purposes of § 10(b)." *Meyer*, 710 F.3d at 1201.

2.

The majority examines the same allegations, but reaches a different conclusion. Their error is in relying on the complaint's speculative allegations as opposed to the sort of plausible factual allegations that our sister circuits have required. For example, in *Sparling v. Daou* (*In re Daou Sys., Inc.*), 411 F.3d 1006 (9th Cir. 2005), a case cited by Singer, the Ninth Circuit held that the plaintiff had adequately pled loss causation when the defendants "began to reveal [financial information that showed] the company's true [and lackluster] financial condition." *Id.* at 1026. Likewise, in *Hubbard v. BankAtlantic Bancorp, Inc.*, 688 F.3d 713 (11th Cir. 2012), the Eleventh Circuit concluded the plaintiff had sufficiently pled loss causation when the defendant, an investment company, revealed to the market the weak contents of its commercial real estate portfolio. *Id.* at 727–28. And in *Ohio Public Employees Retirement System v. Federal Home Loan Mortgage Corp.*, 830 F.3d 376 (6th Cir. 2016), the Sixth Circuit concluded that allegations of a financial disclosure that reported a $2 billion loss sufficiently pled loss causation. *Id.* at 381–82, 388. Factual allegations of that quality are simply absent here.

* * * *

In sum, Singer's section 10(b) claim fails because he has pled no "revelation of the truth." *In re Vivendi, S.A. Sec. Litig.*, 838 F.3d 223, 261 (2d Cir. 2016); *see also Dura Pharm., Inc.*, 544 U.S. at 342, 125 S.Ct. 1627 (noting that loss causation requires the "relevant truth ... to leak out"). There is an insufficient nexus to connect any loss in the value of the Company's stock with the discovery that the truth was worse than the Company implied. Neither the Form 8-K disclosure nor the analyst's report, the only evidence proffered, confirm any such "relevant truth." *Dura Pharm., Inc.*, 544 U.S. at 342, 125 S.Ct. 1627. Instead, the Form 8-K suggested, and the ***459** analyst's report speculated, only that the Company was involved in a government investigation. Such speculative allegations as part of a complaint are not enough to survive a motion to dismiss because the loss causation element is not adequately pled. *See Nemet Chevrolet, Ltd.*, 591 F.3d at 259 (observing that speculation is not enough to survive a motion to dismiss); *see also Vitol, S.A. v. Primerose Shipping Co.*, 708 F.3d 527, 543 (4th Cir. 2013) (stating that allegations in the complaint must allege "more than the mere possibility of misconduct"). I therefore conclude the district court erred in finding a sufficient pleading of loss causation, which, in and of itself, requires dismissal of Singer's complaint because he failed to adequately plead a required element of the cause of action.

IV.

The majority's holding impermissibly expands the scope of liability under section 10(b) and elides our Rule 12(b)(6) and PSLRA jurisprudence. Singer will be allowed to go on to discovery—and to tax the district court and defendants' valuable time and resources—despite his failure to show loss causation related to a decline in the Company's stock price that was caused by a false statement or omission made with scienter. That is error.

For the reasons discussed above, I conclude that Singer has failed to properly plead the elements of material misrepresentation or omission, scienter, and loss causation as required by Rule 8 and 9(b), as well as the PSLRA. Any one of those failures undermines his claim, and here Singer flunks all three. I would thus affirm the judgment of the district court dismissing this case on the scienter and misrepresentation or omission arguments, and reverse on its finding that loss causation was adequately pled. Because the majority reaches a different conclusion, I respectfully dissent.

All Citations

883 F.3d 425