United States Court of Appeals
For the First Circuit

No. 10-1048

GORDON L. HILL; NECA-IBEW PENSION FUND;
SOUTHWEST CARPENTERS PENSION TRUST,

Plaintiffs,

ANIMA S.G.R.P.A.,

Plaintiff, Appellant,

v.

SHAI N. GOZANI; W. BRADFORD SMITH;
GARY GREGORY; NEUROMETRIX, INC.,

Defendants, Appellees.

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS
[Hon. Rya W. Zobel, U.S. District Judge]

Before
Boudin, Ripple,[*] and Selya,
Circuit Judges.

Benjamin J. Sweet, with whom Michael Yarnoff, Lauren Wagner Pederson, Richard A. Russo, Jr., Barroway Topaz Kessler Meltzer & Check LLP, David Pastor, and Gilman & Pastor LLP were on brief, for appellant.

Deborah S. Birnbach, with whom Kevin P. Martin, Lauren Stock Craven, and Goodwin Procter LLP were on brief, for appellees.

March 18, 2011

[*] Of the Seventh Circuit, sitting by designation.

RIPPLE, Circuit Judge. The NECA-IBEW Pension Fund, a shareholder in NeuroMetrix, Inc., instituted this action against NeuroMetrix and three of its officers, alleging securities fraud in violation of sections 10(b)(5) and 20(a) of the Securities Exchange Act, 15 U.S.C. §§ 78j(b) and 78t(a). On the plaintiff's motion, the case was consolidated with several other pending shareholder suits against NeuroMetrix. The district court designated Anima S.G.R.P.A. as lead plaintiff for the class of shareholders during the period of October 27, 2005, through March 6, 2007.

In the consolidated action, the defendants moved to dismiss the complaint for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6), as well as under the additional pleading requirements of Rule 9(b), applicable to fraud claims. The district court granted the motion, concluding that the plaintiffs had failed to identify actionable misstatements under the securities laws. The plaintiffs now appeal.

Because the district court correctly analyzed the allegations of the complaint and correctly concluded that, in light of the applicable legal standards, it contained no actionable misstatements, we affirm the judgment of the district court.

I

BACKGROUND

A. Facts

The complaint alleges a scheme in which NeuroMetrix manufactured a medical device that vastly simplified an existing medical procedure. In marketing the device to physicians for use in their offices, NeuroMetrix represented that procedures performed could be billed using existing standardized codes when seeking reimbursement from insurers, including Medicare. These codes had been created to reimburse for the older, specialist-driven, invasive procedure. Use of the "neurology codes" thus resulted in reimbursement at artificially high rates for a procedure performed with NeuroMetrix's device. According to the shareholders, NeuroMetrix knew that its scheme would be discovered shortly and that, as profit margins to physicians' offices fell dramatically, the market value of the device also would plummet. A decrease in revenue and a collapse of stock value would follow. The complaint alleges that NeuroMetrix misled investors into underestimating the risk of this fall in value, while individual officers, with knowledge of the real risk, divested themselves of significant amounts of stock at great personal profit. Federal civil and criminal investigations followed, and the shareholders thereafter brought this action.

Because this case was dismissed for failure to state a

claim upon which relief could be granted, we recount the facts as set forth in the complaint in significant detail.

1. The NC-Stat

NeuroMetrix manufactured and marketed a signature product during the class period, a machine called the NC-Stat. The NC-Stat is a device that permits non-invasive nerve conduction studies to "detect[], diagnos[e], and monitor[] neurological conditions affecting the peripheral nerves." R.32 at 2. The NC-Stat "is comprised of a battery-operated hand-held device and disposable single-use biosensors that are placed on the patient's body . . . to detect neuropathies." Id. at 11. The device was marketed "to provide primary care and specialist physicians with the ability to rapidly diagnose neuropathies in the physician's office at the time the patient is examined." Id. at 12. Prior to the introduction of the NC-Stat, the prevailing standard technology for neurological studies for these conditions was electromyography ("EMG"), an invasive, needle-based test performed by neurologists.

The NC-Stat sold for about $5,000 and the disposable biosensors for roughly $35 a piece. The bulk of the profit to NeuroMetrix came through the sale of the biosensors. The device was marketed as providing non-specializing physicians, who traditionally could not perform diagnostic tests in this field, with a sustainable source of revenue.

2. Billing Codes and Insurance Reimbursement

The ability of physicians to profit from the use of any medical equipment device--a significant factor in the device's market value--depends largely upon reimbursement rates from insurers. Medical reimbursement across insurers begins with a physician's bill to an insurer under a standardized system, which uses five-digit, procedure-specific identifiers, called Current Procedural Terminology ("CPT") codes. CPT codes are assigned by the American Medical Association ("AMA"). A number of "relative value units" ("RVUs") is then recommended for each coded procedure. RVUs attempt to account for the work performed by a physician, the physician's training and expertise, the type of equipment used and the professional liability insurance required to perform a particular coded service. Insurers, including Medicare, assign a physician fee schedule based on a dollar-amount multiplier per approved RVU.[1] In short, in selecting a CPT code to bill for a particular procedure, a physician effectively knows of a determinative reimbursement rate for that procedure from each insurer during a given fiscal year. As part of fraud detection efforts, when use of a particular code increases by 10% or more during a given year, Medicare "is alerted and usually commences an

[1] To arrive at an individual insurer's actual reimbursement amount, an RVU is multiplied by a fixed conversion factor, specific to each insurer, and then generally is adjusted further by geographic region.

investigation." Id. at 17.

When the NC-Stat was introduced to the market, it did not have a specific CPT code assigned to it. Instead, according to the allegations of the complaint, NeuroMetrix instructed its sales personnel to "actively promote" the use of existing, neurology-based CPT codes to seek reimbursement for the NC-Stat procedure. Id. at 14; see also id. at 15-16. According to a confidential NeuroMetrix employee witness, the recommended codes

> were originally value weighted for ***neurologists*** to detect and diagnose neuropathies through combined use of invasive EMG needle tests and conventional nerve conduction studies involving highly calibrated multi-million dollar equipment . . . . Thus, under the RVUs assigned to the nerve conduction CPT billing codes, a neurologist could make between $700 and $900 per exam, . . . because an expensive calibrated machine is utilized. In short, according to [the confidential witness], the expensive equipment used by a neurologist is one of the key factors in determining that the neurology-based CPT codes (95903 and 95904) reimburse at significantly higher dollar amounts than simple, automated procedures such as the NC-Stat System.

Id. at 15 (emphasis in original).

3. Internal Billing Discussions and Recommendations

The complaint further alleges that NeuroMetrix, through its officers, knew that the billing practices it advised physicians to adopt were unsustainable.[2] It employed two separate directors of reimbursement with more than fifty years of collective CPT coding experience. Both of these experts advised Shai Gozani, President and Chief Executive Officer, and Gary Gregory, Chief Operating Officer, that they could not promote the use of the neurology-based codes in marketing the NC-Stat. The first such director advised the executives that NeuroMetrix should instruct physicians to use miscellaneous codes in the short term, which would, "at best, pay one-third or one-fourth of what the existing neurology-based CPT codes paid to physicians." Id. at 16. The director advised that, in the longer term, the company needed to apply to the AMA for a new code for the NC-Stat procedure and, in advance of such application, that NeuroMetrix should obtain certain peer-reviewed articles about the efficacy of the device. Mr. Gregory asked the director what amount physicians would be reimbursed in the interim, and was told "'close to nothing' until the AMA 'validated'" the device. Id. According to the director,

[2] NeuroMetrix sold its products in the healthcare industry to service providers; it merely provided a product to physicians for a price. As such, NeuroMetrix did not bill insurers and was not involved in the actual use of billing codes. Physicians used the CPT codes to seek reimbursement from third-party insurers for individual tests performed on patients with the NC-Stat.

Mr. Gozani and Mr. Gregory hoped instead to "'fly under the radar,'" and Mr. Gregory specifically stated that the company "'could not afford to tell physicians,'" who were "'making $250 a test'" that "'they would possibly get nothing.'" Id. The director informed the executives that such course of proceeding was impossible due to the 10% rule, under which the increased use of the neurology codes was likely to spark a Medicare investigation. The director informed them that Medicare knows which physicians--primary care or neurologists--are seeking reimbursement, because physicians also have a specific identification number included in reimbursement requests. The director advised that recommending the use of improper codes would be Medicare fraud. This first director resigned after the company refused to change its policy. The company's second director of reimbursement, Jan Foote, also advised the company to apply for a new, device-specific code for the NC-Stat. She told an employee that Mr. Gregory and Mr. Gozani "wanted to wait until problems with the AMA actually materialized before making any changes." Id. at 18. She also resigned "out of frustration." Id.

According to the complaint, sales and customer service staff confirm that they were instructed to recommend the neurology billing codes to customers. NeuroMetrix

> used actual reimbursement payment receipts from other offices as verification of reimbursement under the recommended codes. Specifically, if a physician was skeptical

> about the precise amount of expected insurance reimbursement it would receive after using the NC-Stat System, sales representatives would provide purported actual payment slips from Aetna, Blue Cross, or Medicare to prove that payment had been received in other offices . . . .

Id. at 20. The complaint further details the manner in which the individual defendants were involved in the billing issues. Notably, after physicians started to complain that a particular insurer had a coverage ban on NC-Stat procedures, Mr. Gozani allegedly told physicians not to worry; he noted that, if billed using the general neurology codes, the insurer could not discern whether the NC-Stat or traditional neurologic tests were performed. As a consequence, according to Mr. Gozani, it could not enforce its ban.

4. Kickbacks

The complaint alleges that the company employed several unlawful practices to mask the billing problems with the NC-Stat. At the time of the complaint, investigations by the Office of the Inspector General in the Department of Health and Human Services as well as by the United States Attorney's Office in Massachusetts were focused on the company's sales practices. A former employee claimed that one dubious practice was to offer a free box of biosensors for every box purchased. Biosensors were also given away for referrals and as inducements to purchase the NC-Stat. The

employee claims to have told Mr. Gregory that the company could not give away a product that would be billed out by physicians to insurers, but was ignored. After the investigation was announced, the practice abruptly stopped. Id. at 26.

Another former employee described problems that occurred when the NC-Stat revealed a need for follow-up testing. Primary care physicians had difficulty making referrals for the testing because prior use of the neurology billing code meant that the expensive, invasive tests, for which the code was intended, would not be reimbursed because insurers would see them as second and duplicative tests.

After the company became aware of reimbursement problems, a customer service representative created a spreadsheet of carriers and states in which reimbursement was problematic. The head of the reimbursement department told the employee to "'stop immediately,'" because "'if we don't know, we don't have to tell anyone.'" Id. at 31. Although the company pulled back from some of these sales strategies, "attempted to deliberately avoid answering questions about reimbursement" and employed no reimbursement consultants after late 2007, id. at 32, it continued to inform physicians, through its sales staff, of "'historically how other physicians billed for the NC system,'" including use of the neurology codes. Id. at 33.

5. Stock Prices

The plaintiffs describe the trajectory of stock prices at some length. The essential point, according to the plaintiffs, is that the stock price rose with profits through early 2006 to a high of just over $40, but by the end of the same year, after insurers began denying coverage, the price had dropped to below $15. A July 2006 article in Neurology Today noted a 17% spike in use of the neurology codes at issue, which the article attributed to use of automated devices, such as the NC-Stat. The 17% spike in usage was sufficient to trigger a Medicare investigation. The article also stated the position of an association of neurologists that the NC-Stat did not provide essential information that traditional nerve conduction studies would provide.

On March 6, 2007, The Boston Globe reported that a federal grand jury was convened to investigate health care fraud issues with NeuroMetrix and the NC-Stat. The article described the company's billing recommendations and noted the failure to seek a unique CPT code. Following this article, shares fell to less than $10. At the end of the month, the company's Annual Report for 2006 noted the reimbursement problems, but, according to the complaint, "further falsely reported that the nerve conduction tests performed by the NC-Stat System met the requirements stipulated in the AMA billing code and that these codes were currently being used by physicians to obtain reimbursement . . ., except in the limited

instances in which the local Medicare insurance carrier had denied or limited coverage." Id. at 37. In fall 2007, NeuroMetrix announced that it had made a presentation to an AMA working group on coding and expected recommendations shortly about coding for the procedure. At this point, the share price was $8.61.

On February 11, 2008, TheStreet.com reported that the AMA had met and that the soon-to-be-rendered decision would "result in minimal reimbursement to healthcare providers who used" the NC-Stat "and that the system would not be eligible for reimbursement under Medicare or Medicaid." Id. at 38. The next day, NeuroMetrix disclosed that it anticipated "'significant challenges'" with billing, which "would continue to adversely impact their financial results." Id. at 39.

6. Stock Sales

The plaintiffs allege that the defendants "were motivated to commit fraud by their desire to profit from sales of NeuroMetrix stock at artificially-inflated prices." Id. The plaintiffs claim that the individual defendants sold more than $12 million in stock in 2005 and 2006, before the decline in value caused by the reimbursement issues. The plaintiffs claim that the only sales of company stock by the individual defendants since the company's initial public offering in 2004 were these sales at the height of the market.

B. District Court Proceedings

1. Initial Proceedings

After several shareholders brought related actions in the District of Massachusetts, the cases were consolidated and Anima was appointed lead plaintiff for the putative class. Following its selection, Anima filed an amended complaint.

After setting forth the facts we already have recounted, the complaint reprints more than thirty pages of statements by the defendants alleged to have been misleading to investors, which we shall address individually below. The claimed misstatements include SEC filings as well as conference calls with investors and analysts. In many of the statements, NeuroMetrix and the individual defendants mentioned "risks" to the business relating to potential issues with insurance reimbursement throughout the class period, and they did so with increasing specificity as time went on. They also set forth their "belief" that the studies were reimbursable under the existing neurology codes, that the majority of insurers were reimbursing and that the general outlook was positive. In 2006, they began to report that there were reimbursement issues "from time to time," also noting that several regional carriers had either decided not to reimburse or were evaluating the issue carefully. Id. at 48. Toward the end of 2006, they began stating that the outlook was satisfactory, but that, at any point in time, several insurers might not reimburse

for the procedure and that the AMA had convened a committee to look at the issue. By 2007, they noted that a majority of Blue Cross carriers had indicated they would not reimburse and that the work of the AMA cast a veil of uncertainty on future profitability. Throughout the period, the company reiterated its position that the neurology codes were applicable.

After extensive quotation from company documents and transcripts of conference calls with investors and reporters, the complaint references back in almost every instance to a single paragraph that explains why, in the plaintiffs' view, the statements were misleading. That paragraph, ¶ 135, provides that (1) the defendants refused to apply for a new CPT code for the NC-Stat, despite being informed it was necessary; (2) sales staff promoted the use of the neurology codes by physicians billing for NC-Stat procedures; (3) internal, company-employed experts informed senior executives that use of the neurology codes was fraudulent; and (4) the Company understated the "serious risk that insurers" would not reimburse for the procedure. Id. at 44.

The plaintiffs further alleged that, because of the above-listed misstatements, class members "purchased or otherwise acquired NeuroMetrix common stock at artificially-inflated prices. When the partial corrections and materialization of the risks associated with Defendants' fraud came to light, the artificial inflation in the prices . . . was removed," causing unspecified

losses. Id. at 67.

The defendants moved to dismiss under Rule 12(b)(6), contending that Anima had failed to state a claim upon which relief could be granted. The defendants argued that Anima had failed to allege adequately any actionable misstatements, scienter, loss causation or individual defendant liability.

2. Decision of the District Court

The district court granted the defendants' motion to dismiss. The court began by noting the special pleading rules applicable to securities fraud claims under Rule 9(b) of the Federal Rules of Civil Procedure and the Private Securities Litigation Reform Act ("PSLRA"), which we shall review in detail. Applying these standards, the court found the complaint difficult to parse, given the large block-quotes of text claimed to be misleading. As a consequence, it treated the alleged misstatements together rather than examining each in detail. In its view,

> [a]s best can be discerned, based on the factual allegations in the complaint, the substance of the plaintiffs' argument is that defendants' warnings regarding the risk of non-reimbursement were misleading or false because defendants knew the level of risk, or even a certainty, of non-reimbursement under existing CPT codes was more serious than was disclosed in the warnings.

R.52 at 5. The remaining allegations, the court noted, "could be

understood as support for the central allegation."[3] Id. The court found this central claim "more than the factual allegations in the complaint will bear." Id. at 7. Specifically,

> [t]he complaint establishes, at most, that at certain points in time there was internal disagreement as to the applicability of existing CPT codes, but that a large, albeit declining, percentage of physicians were reimbursed for their use of the NC-Stat. Put simply, the reimbursement environment was uncertain; there was risk.

Id. (emphasis in original). Furthermore, the disclosures themselves contained express warnings, "in more severe terms as reimbursement problems developed." Id. Investors were "fully informed as to both defendants' reimbursement strategy and the substance of the dispute with insurance companies, and they could make their own judgment as to whether that strategy was wise or ill-considered." Id. The defendants' repeated statement about reimbursing under the existing codes, the court noted, "was not only characterized as their 'belief,' but it was immediately followed by cautionary language that any changes in CPT codes may

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[3] The remaining allegations were quickly dismissed by the court. With respect to the plaintiffs' allegation that the reimbursement experts had informed the company that it was engaging in fraud and that it should apply for a new CPT code, the court noted that none of the alleged misstatements misrepresented the experts' opinions. Turning to whether sales staff "'improperly promoted'" an unsupportable reimbursement strategy, the court found the allegation itself "incomprehensible." See R.52 at 7. Concerning the allegation that the defendants had disregarded recklessly the advice of the reimbursement experts, the district court noted that the basis of the experts' opinion was not contained in the factual allegations.

adversely affect reimbursement for NC-Stat." Id. at 8.

The plaintiffs also had alleged that the disclosures by NeuroMetrix were lacking in certain details, the omission of which rendered them materially misleading. The district court disagreed, finding that the undisclosed facts the plaintiffs identified were beyond the scope of the disclosures, and, thus, were not actionable.[4]

Finally, the court addressed the plaintiffs' claims that specific statements were false or misleading for reasons other than the general allegations. The plaintiffs had alleged that the statement that NeuroMetrix was "not involved . . . in billing by our customers" was false or misleading, but the court found that the other allegations of the complaint did not support this accusation. Id. at 9 (omission in original). The plaintiffs had alleged that there were "pervasive" billing problems, while the defendants publicly noted only isolated problems with billing. Id. at 9. The court found that the complaint did not support the claim that the problems were indeed pervasive. The last statements alleged to be false were Mr. Gregory's statements that the device was approved by the federal Food and Drug Administration ("FDA"),

[4] These undisclosed facts included: (1) that the device was being marketed for use by non-medical staff; (2) that reimbursement for NC-Stat could preclude reimbursement for other procedures; and (3) that the Food and Drug Administration ("FDA") had approved the NC-Stat as a supplement, rather than as a replacement, to existing nerve conduction studies.

that the standard codes describe the service it performs and that the Medicare Physician Fee Schedule details reimbursement for these codes. The court found that these allegations did not state that Mr. Gregory claimed that these codes were weighted for the NC-Stat. Further, the court noted that Mr. Gregory expressly characterized his comments as "belief" and that the comments were not inconsistent with the fact that reimbursement experts and two insurance companies "did not share Gregory's reasoning." Id. at 10.

Having determined that Anima did not identify any actionable misstatements, the district court did not reach the defendants' further contentions that the elements of scienter and loss causation were not pleaded sufficiently.

II

DISCUSSION

Anima now appeals the district court's decision dismissing the action for failure to state a claim. Before examining the parties' specific contentions, we begin with an examination of the two statutes that govern securities fraud actions and that provide both the substantive and procedural standards for our evaluation of this complaint.

A. Statutory Background

1. Securities Exchange Act

The substantive standards applicable to the present action by a putative class of NeuroMetrix shareholders are found in the Securities Exchange Act of 1934, 15 U.S.C. §§ 78a-78pp. The protections against securities fraud are located in sections 10(b) and 20(a) of the Act, 15 U.S.C. §§ 78j(b) and 78t(a), and in Rule 10b-5, 17 C.F.R. § 240.10b-5.

Section 10 of the Act provides, in relevant 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 or any security not so registered, or any securities-based swap agreement (as defined in section 206B of the Gramm-Leach-Bliley Act), 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.

15 U.S.C. § 78j(b).

The implementing regulation for this section, Securities and Exchange Commission ("SEC") Rule 10b-5, declares it unlawful:

> (a) To employ any device, scheme, or artifice to defraud,

> (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, or
>
> (c) To engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person,
>
> in connection with the purchase or sale of any security.

17 C.F.R. § 240.10b-5.

Although the statute does not provide for a private right of action, the Supreme Court has implied such a right, "which resembles, but is not identical to, common-law tort actions for deceit and misrepresentation." Dura Pharm., Inc. v. Broudo, 544 U.S. 336, 341 (2005). The elements of a 10b-5 claim, in the context of publicly traded securities, are:

> (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, often referred to in cases involving public securities markets (fraud-on-the-market cases) as "transaction causation";
>
> (5) economic loss; and
>
> (6) "loss causation," i. e., a causal connection between the material misrepresentation and the loss.

Id. at 341-42 (citations omitted) (emphasis in original).

Claims brought under section 20(a) of the Act, 15 U.S.C.

§ 78t(a), are derivative of 10b-5 claims. Specifically, once any "person" is found liable for violating the Act's substantive provisions,

> [e]very 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.

Id.

Importantly, "the statutes make the[] . . . actions available, not to provide investors with broad insurance against market losses, but to protect them against those economic losses that misrepresentations actually cause." Dura Pharm., 544 U.S. at 345.

The courts have long acknowledged that "litigation under Rule 10b-5 presents a danger of vexatiousness different in degree and in kind from that which accompanies litigation in general." Blue Chip Stamps v. Manor Drug Stores, 421 U.S. 723, 739 (1975). "Even weak cases brought under the Rule may have substantial settlement value, . . . because [t]he very pendency of the lawsuit may frustrate or delay normal business activity." Merrill Lynch, Pierce, Fenner & Smith Inc. v. Dabit, 547 U.S. 71, 80 (2006) (final modification in original) (internal quotation marks omitted). As

a result, the Supreme Court cabined the private right of action consonant with the policies of preserving the private enforcement function, but minimizing potential "ill effects," in part by limiting the universe of potential plaintiffs to buyers and sellers of the securities. Id. at 80-81.

2. Private Securities Litigation Reform Act

In the mid-nineties, Congress took up the issue of reforming securities litigation, with "twin goals: to curb frivolous, lawyer-driven litigation, while preserving investors' ability to recover on meritorious claims." Tellabs, Inc. v. Makor Issues & Rights, Ltd., __ U.S. __, 127 S. Ct. 2499, 2509 (2007). As the Court recently recounted:

> Policy considerations similar to those that supported the Court's decision in Blue Chip Stamps [v. Manor Drug Stores, 421 U.S. 723 (1975),] prompted Congress, in 1995, to adopt legislation targeted at perceived abuses of the class-action vehicle in litigation involving nationally traded securities. While acknowledging that private securities litigation was "an indispensable tool with which defrauded investors can recover their losses," the House Conference Report accompanying what would later be enacted as the Private Securities Litigation Reform Act . . . identified ways in which the class-action device was being used to injure "the entire U.S. economy." H.R. Conf. Rep. No. 104-369, p. 31 (1995). According to the Report, nuisance filings, targeting of deep-pocket defendants, vexatious discovery requests, and "manipulation by class action lawyers of the clients whom they purportedly represent" had become rampant in recent years.

> Ibid. Proponents of the Reform Act argued that these abuses resulted in extortionate settlements, chilled any discussion of issuers' future prospects, and deterred qualified individuals from serving on boards of directors.

Dabit, 547 U.S. at 81 (citation omitted). The Private Securities Litigation Reform Act of 1995, Pub. L. No. 104-67, 109 Stat. 737 (codified as amended in scattered sections of 15 and 18 U.S.C.), created a host of substantive reforms addressing issues from class certification and lead plaintiff selection, to limitations on recoverable damages and mandatory sanctions for frivolous litigation. In addition, it created a safe-harbor provision for forward-looking statements when not made with knowledge of falsity or when the statement itself is identified as forward-looking and is accompanied by "meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement." 15 U.S.C. § 78u-5(c)(1)(A)(i).

Finally, and particularly relevant to our analysis in the present case, the PSLRA made a number of procedural changes applicable in securities actions, including the creation of specific pleading requirements for 10b-5 actions. Prior to the PSLRA, such actions were governed by the heightened pleading requirements of Rule 9(b) of the Federal Rules of Civil Procedure. Rule 9(b) provides that, in the context of fraud claims, the usual requirement of "a short and plain statement of the claim," Fed. R.

Civ. P. 8(a)(2), must be exceeded. Specifically, a party alleging fraud "must state with particularity the circumstances constituting fraud" in the pleading, but "[m]alice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b). The PSLRA went further, requiring that a pleading (1) "specify each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading" and (2) "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." 15 U.S.C. § 78u-4(b)(1). With regard to the element of scienter, the PSLRA requires that the pleading "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). The Supreme Court has held that, in order for the facts to give rise to the requisite "strong inference," the allegations "must be more than merely plausible or reasonable--[they] must be cogent and at least as compelling as any opposing inference of nonfraudulent intent." Tellabs, 127 S. Ct. at 2504-05.

B. Standard of Review

In reviewing the district court's order dismissing the action for failure to state a claim under Rule 12(b)(6), we must determine whether allegations of securities fraud under sections

10(b)(5) and 20(a) of the Securities Exchange Act have been pleaded sufficiently, using the standards set forth in the PSLRA and the Federal Rules. We recently have outlined a roadmap for this task. See ACA Fin. Guar. Corp. v. Advest, Inc., 512 F.3d 46, 58-59 (1st Cir. 2008).

First, as with any 12(b)(6) inquiry, "we accept well-pleaded factual allegations in the complaint as true and view all reasonable inferences in the plaintiffs' favor." Id. at 58; see also Tellabs, 127 S. Ct. at 2509. To survive a motion to dismiss, a complaint must allege facts sufficient to demonstrate "a plausible entitlement to relief." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 559 (2007); see also ACA Fin. Guar., 512 F.3d at 58. In the present case, the plaintiffs must allege six elements to state a 10b-5 claim: "(1) a material misrepresentation or omission; (2) scienter, or 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." ACA Fin. Guar., 512 F.3d at 58; see also Dura Pharm., 544 U.S. at 341-42.

As with all allegations of fraud, a plaintiff must plead the circumstances of the fraud with particularity, pursuant to Rule 9(b). ACA Fin. Guar., 512 F.3d at 58. Under the further requirements of the PSLRA, in order to survive a motion to dismiss, the plaintiff must "'specify each statement alleged to have been misleading [and] the reason or reasons why the statement is

misleading.'" Id. (modification in original) (quoting 15 U.S.C. § 78u-4(b)(1)). Furthermore, the complaint "'shall, with respect to each [alleged] act or omission . . . state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." Id. at 58-59 (omission in original) (first emphasis added) (quoting 15 U.S.C. § 78u-4(b)(2)). As we noted in ACA Financial Guaranty Corp. v. Advest, Inc., 512 F.3d 46, 63 (1st Cir. 2008), "the PSLRA does not require plaintiffs to plead evidence." Nevertheless, a significant amount of "meat" is needed on the "bones" of the complaint. Id.

C. Analysis of the Alleged Misstatements

With these standards providing our decisional matrix, we turn to the parties' contentions and the specific allegations of the complaint. Anima contends that the district court erred in failing to view the facts in their totality, with inferences drawn in its favor. With respect to the alleged misrepresentations, Anima contends that the district court erred in determining that they were not misleading or were within the statutory safe harbor. The defendants counter that the district court was correct to find no actionable material misstatements. We examine each alleged misstatement in turn.

1. 2005 NeuroMetrix Press Release

According to ¶ 134 of the complaint, on October 27, 2005, NeuroMetrix issued a press release concerning its third quarter results. The release reported significant revenue increases. It also contained an express disclosure

> that the statements contained in the release "involve a number of risks, uncertainties (some of which are beyond the Company's control) or other assumptions that ***may cause*** actual results or performance to be materially different from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to, risks associated with . . . **reimbursement by third party payors to the Company's customers for procedures performed using the NC-Stat System**."

R.32 at 43 (quoting Oct. 27, 2005 press release) (emphasis and omission in original). The plaintiffs have not alleged any affirmative misstatement in this release, nor do we perceive one when the statement is read alongside the factual allegations. The claim, therefore, must rest on the omission of some fact, which, by its absence, rendered the release misleading. See 17 C.F.R. § 240.10b-5(b). The omitted material identified by the plaintiffs, as noted above, was: (1) that the company declined to apply for a new code, even though the reimbursement specialists had informed it that it was necessary; (2) sales personnel were advising physicians on use of the neurology codes; (3) reimbursement specialists had advised that use of the neurology codes was fraud; and (4) "[t]here was a serious risk that insurers would not allow NC-Stat tests

. . . to be reimbursed under neurology-based CPT codes." R.32 at 44.

There are sufficient factual allegations in the complaint to permit the conclusion that the principals of NeuroMetrix knew of the four alleged situations as early as 2005. According to the complaint, by mid-2005, the reimbursement expert had resigned because of a conflict with the principals over the coding recommendations, id. at 18; sales representatives were advising physicians to seek reimbursement under the neurology codes, id. at 19. By late 2005, regional insurance carriers had begun denying coverage, id. at 32. Reading the factual allegations of the complaint in whole, they support the assertion that the company was aware of at least some level of risk of non-reimbursement and had been apprised by experts that continuing in its then-current course of billing recommendations could have significant repercussions.

We also agree with the plaintiffs that the omitted facts were material. As we have stated, "information is material only if its disclosure would alter the total mix of facts available to the investor and if there is a substantial likelihood that a reasonable shareholder would consider it important to the investment decision." Cooperman v. Individual, Inc., 171 F.3d 43, 49 (1st Cir. 1999) (quotation marks omitted); see also TSC Indus., Inc. v. Northway, Inc., 426 U.S. 438, 449 (1976) (defining, in another type of securities action, information as material where it "would have

assumed actual significance in the deliberations of the reasonable shareholder"). "The omission of a known risk, its probability of materialization, and its anticipated magnitude, are usually material to any disclosure discussing the prospective result from a future course of action." Lormand v. US Unwired, Inc., 565 F.3d 228, 248 (5th Cir. 2009). As this press release acknowledges on its face, the ability of physicians to receive third-party reimbursement for procedures performed with the NC-Stat is of critical importance to the profitability of the device and of NeuroMetrix itself. That experts flatly had informed the principals that the company's suggested method of billing was unsustainable certainly would have been relevant to a reasonable shareholder's investment decisions. We further have stated that "[i]f an alleged omission involves speculative judgments about future events, . . . materiality will depend at any given time upon a balancing of both the indicated probability that the event will occur and the anticipated magnitude of the event in light of the totality of the company activity." Milton v. Van Dorn Co., 961 F.2d 965, 969-70 (1st Cir. 1992) (emphasis in original) (internal quotation marks omitted). The complaint's allegations regarding the Medicare 10% rule and the company's sales growth are sufficient to demonstrate a significant probability that the noted risks would materialize and that the effect of those risks on the company's future would be significant.

Nevertheless, "the mere possession of material[,] nonpublic information does not create a duty to disclose it." Cooperman, 171 F.3d at 49 (internal quotation marks omitted); see also Chiarella v. United States, 445 U.S. 222, 235 (1980). Instead, the "issue . . . is whether the securities law imposes on defendants a 'specific obligation' to disclose information of the type that plaintiffs claim was omitted." Cooperman, 171 F.3d at 49-50. Rule 10b-5 requires that, when a company speaks, it cannot omit any facts "necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading." 17 C.F.R. § 240.10b-5; see also SEC v. Texas Gulf Sulphur Co., 401 F.2d 833, 862 (2d Cir. 1968) (en banc). "[E]ven a voluntary disclosure of information that a reasonable investor would consider material must be complete and accurate." Backman v. Polaroid Corp., 910 F.2d 10, 16 (1st Cir. 1990) (en banc) (internal quotation marks omitted). Nevertheless, this obligation has its limits: It "does not mean that by revealing one fact about a product, one must reveal all others that, too, would be interesting, market-wise"; a company must reveal only those facts "that are needed so that what was revealed would not be so incomplete as to mislead." Id. (internal quotation marks omitted) (emphasis added).

We begin with the issue central to two of the four claimed omissions in the 2005 press release: the opinion of the

experienced reimbursement experts that the billing practices were incorrect and possibly fraudulent. We previously have held that the existence of internal disagreement about strategy is not the kind of fact that must be disclosed to investors. In Cooperman v. Individual, Inc., 171 F.3d 43 (1st Cir. 1999), we evaluated claims that a company had failed to disclose that its CEO had significant strategic disagreements with the board about the future direction of the company. After noting that the existence of a board-level conflict was material, we concluded that disclosure was not required. "Disclosure of the business strategy supported by a majority of the directors did not obligate defendants also to disclose information about the extent to which each individual Board member supported that model." Id. at 51. Indeed, we held, "[m]ore specifically," that "disclosure of the business strategy supported by the majority of the Board did not obligate defendants also to disclose the fact that [the CEO]--a distinct minority of a multi-member Board--opposed that strategy." Id.

By contrast, in Lormand v. US Unwired, Inc., 565 F.3d 228 (5th Cir. 2009), our colleagues in the Fifth Circuit did find the statements misleading, and therefore actionable. In Lormand, the plaintiffs alleged that US Unwired had been pressured by Sprint, with whom it had an affiliate relationship, to extend services to customers with sub-prime credit without requiring the usual safeguards. Through a series of negotiations, it became clear that

the management of US Unwired knew the business strategy would prove "disastrous," saw some of the risks actually materialize, and fought hard--if unsuccessfully--to prevent the policy's full implementation. Id. at 237; see also id. at 247. At the same time, US Unwired's public statements touted the benefits of the program and "omitted [the] serious risks inherent" in the initiatives. Id. at 249. When risks were referenced, it was by way of generalized risk factors, and the real potential problems were "glossed over as a future risk of limited magnitude." Id. at 247 (emphasis in original). The Fifth Circuit found our decision in Cooperman distinguishable because, in Lormand, "the entire management team of the company knew that disastrous effects would result" from the strategy Sprint had forced upon US Unwired, but continued to present to the public a contrary, or incomplete, view. Id. at 250.

Finally, in In re Cabletron Systems, Inc., 311 F.3d 11 (1st Cir. 2002), we evaluated a complaint in which the allegations were that company officials, like the principals in Lormand, saw disaster looming on the horizon. According to the complaint, a number of "adverse factors" converged on the company nearly simultaneously, making clear that the company's immediate future was less than rosy. Id. at 23 (internal quotation marks omitted). In response, the leadership of the company engaged in a host of fraudulent practices designed to give the false impression that the

company's prospects for success were much higher than they actually were: (1) They falsified sales records; (2) they timed shipments of goods to create the false impression of high sales for a quarter while knowing that massive returns would occur in the next quarter, sometimes with the cooperation of customers interested in the company's success; (3) they delayed reporting liabilities, including parking raw materials with suppliers to avoid entering them on balance sheets; and (4) they concealed negative facts about the products from sales staff to avoid disclosure to potential customers, although the facts were widely known internally. See id. at 24. We characterized the pleading as portraying a "frenzied effort by a troubled company to conceal its difficulties for as long as possible," and concluded that the allegations were sufficient to survive dismissal. Id.

In our view, the situation we confront in this case is closer to that of Cooperman than to that of Lormand or Cabletron. The kind of information the plaintiffs wanted the company to disclose--that the reimbursement experts informed the principals that they needed to apply for a new code and that the persistence in recommending the neurology codes was fraudulent--is not on the order of the information withheld from investors in Lormand. There, the principals unquestionably were forced into a losing strategy and fully understood the near-certainty of financial disaster to come. Here, although knowledgeable employees of

NeuroMetrix believed the strategy was both losing and potentially dangerous, there is simply nothing in the complaint to suggest that the expert opinions demonstrated that the danger posed by the reimbursement strategy was, at the time the statement was made, a near certainty of ruin. The principals of NeuroMetrix had this information to factor into their decision-making about coding recommendations to buyers of their device. They, however, had no obligation to make it public simply because they mentioned the risk associated with non-reimbursement by third-party payers in a profit statement. Moreover, although there are allegations of other questionable business practices, such as the use of potentially illegal incentive programs, there is no allegation, as there was in Cabletron, that the principals were engaged in a comprehensive scheme to disguise negative information "to keep the house of cards standing." Cabletron, 311 F.3d at 24. The "total mix of information" available to investors in the short press statement at issue was not "highly skewed," Lormand, 565 F.3d at 249, by the failure to disclose the opinions of the reimbursement experts.

The plaintiffs submit, however, that Cooperman is inapposite because there is no evidence of "disagreement." In their view, the facts of the complaint show that the only informed opinion was that of the experts; the principals did not disagree with that opinion, but disregarded it to maximize profits and shed their own stock at an artificially inflated market price. We

cannot accept this argument. At bottom, Cooperman discusses when factors that predate a company's chosen course of action must be disclosed to investors, and that question encompasses more than the issue of board-level strategic disagreements. In neither Cooperman nor the present case was the undisclosed information insignificant; both involved something material to the investment decision and both predicted that significant risks would materialize from the course the company ultimately chose. But in neither case did the undisclosed opinion even approach the widely-accepted certainty of failure or the comprehensive cover-up in Lormand or Cabletron.

At the time the statement was made, the final resolution of the third-party reimbursement issue was indeed unknown. As our colleague in the district court noted, the RVUs for a CPT code "reflect[] the estimated physician, practice, and malpractice costs for the service represented by that code." R.52 at 2. Although the company took an aggressive, and in the view of some, an unrealistically aggressive view of the appropriate resolution in the promotion of its product, its press release does state explicitly that the ultimate resolution of the issue is unknown and, by reasonable implication, out of its hands.

Turning to the other alleged omissions, we conclude that they too were not sufficient to demonstrate that the statement itself was misleading. First, that the company's sales team provided advice on appropriate billing practices is plainly beyond

the scope of the disclosure. The statement as quoted by the plaintiffs was not incomplete for failure to state specifically that the company had a reimbursement-advice strategy, or for failure to state what that strategy specifically was. Finally, the plaintiffs maintain that the statement was misleading for failing to disclose a "serious risk" of non-reimbursement. Nevertheless, a risk of non-reimbursement specifically was disclosed. To the extent that the plaintiff's complaint is that the precise degree of risk was not stated, that failure is not sufficient to have rendered the statements misleading. Cf. In re Cabletron Sys., Inc., 311 F.3d at 23-24 (noting that allegations of a company's "unremittingly optimistic" statements in the face of numerous adverse factors, coupled with company efforts to "hide th[e] downward spiral," were sufficient to state a claim).

A statement that discloses a level of risk may be so understated as to be misleading. In Backman v. Polaroid Co., 910 F.2d 10, 16 (1st Cir. 1990) (en banc), we considered claims regarding misleading statements made in reference to the Polavision camera. We concluded that the company's disclosure "that Polavision was being sold below cost was not misleading by reason of not saying how much below. Nor was it misleading not to report the number of sales, or that they were below expectations." Id. We contrasted those statements with another allegation, namely, that the principals knew that the Polavision camera was "a

commercial failure," but stated only that earnings were negative; we noted that the negative-earnings statement "might well be found to be a material misrepresentation by half-truth and incompleteness." Id. Although we ultimately dismissed the "commercial failure" claim as not supported by the allegations of the complaint, the distinction between our treatment of these two allegations is instructive, and it is mirrored again in the Fifth Circuit's decision in Lormand. A statement of risk does not insulate the speaker from liability, particularly where it is "generic and formulaic." See Lormand, 565 F.3d at 245. At the same time, neither does it create liability simply because it does not disclose, at the level of detail the plaintiffs request in retrospect, all of the factors that contribute to the risk assessment. In cases where the risk approaches a certainty, courts have no difficulty in finding a duty of disclosure. But where the level of risk is unknown and the existence of a risk is disclosed, we shall hesitate to conclude that disclosure is misleading merely because it did not state that the risk was "serious." R.32 at 44.[5]

[5] Read in the plaintiffs' favor, the factual allegations of the complaint would support the view that the company actually had experienced some reimbursement problems, potentially as early as this October 2005 statement. See R.32 at 32 (noting some regional denials of coverage in "late 2005"). That said, even if the plaintiffs had alleged that the statement was misleading for failing to include this specific information, we would be unpersuaded. In circumstances where some level of risk materializes, we have not required complete disclosure of all of the details when the overall risk is disclosed and the nature of the future risk remains uncertain. See Backman v. Polaroid Corp.,

In sum, we agree with the district court that the November 2005 NeuroMetrix press release is not misleading because it failed to include the four facts alleged by the plaintiffs.

2. Quarterly Report, Third Quarter 2005

The complaint next alleges that, on November 10, 2005, NeuroMetrix filed its Quarterly Report with the SEC on form 10-Q and included various statements regarding reimbursement, including the following:

> Reimbursement from third-party payers is an important element of success for medical products companies. Generally, we believe that the nerve conduction studies performed by our customers with the NC-Stat System have been satisfactorily covered by third-party payers. As our presence in the market expands and the use of the NC-Stat System increases, we have experienced and are likely to continue to experience an increased focus from third-party payers regarding the reimbursement of nerve conduction studies performed using the NC-Stat System and an increased focus from third-party payers regarding the professional requirements for performing nerve conduction studies in general. Widespread adoption of the NC-Stat System by the medical community is unlikely to occur if physicians do not receive satisfactory reimbursement . . . .

R.32 at 44-45. Further, the report stated explicitly that reimbursement problems could lead to "future product sales [being] severely harmed." Id. at 45 (emphasis omitted). Finally, the

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910 F.2d 10, 16 (1st Cir. 1990) (en banc) (not requiring the company's disclosure to include how far below expectations sales were occurring and related details).

report stated that "[f]uture regulatory action" relating to Medicare/Medicaid reimbursement could change the reimbursement landscape, but closed, "We are unable to predict what changes will be made in the reimbursement methods used by private or governmental third-party payers. Additionally, we may be required to expend substantial resources to address potential reimbursement issues with third party payers." Id. at 46. The plaintiffs claimed these statements to be misleading for the identical four reasons set forth above, relating to the internal expert opinions, company advice to physicians regarding billing and the "serious risk" of non-reimbursement. Id. at 44.

The same reasons that led to our conclusion that the first alleged misstatement was not misleading require that we also conclude that this disclosure cannot give rise to liability. Indeed, this disclosure is more explicit about the nature of the risks the company faced regarding third-party reimbursement and specifically references the possibility of future government action. Although the alleged omissions are material, the "total mix" of statements in the November 2005 disclosures was not skewed to present a rosy picture. Although cautious in tone and substance, it acknowledged some attention from third-party payers and the significant impact that either that attention or attention from federal regulators could have on the profitability of the business.

3. 2005 Annual Report to the SEC

The plaintiffs next alleged that NeuroMetrix misled investors in its 2005 Annual Report filed with the SEC. In that report, the company explained briefly the mechanics and the significance of CPT coding:

> According to present Medicare guidelines, nerve conduction studies may be performed by medical doctors, or M.D.s, and doctors of osteopathic medicine, or D.O.s, and are reimbursable under the three CPT codes: 95900, 95903, and 95904. We believe that the nerve conduction measurements performed by the NC-Stat System meet the requirements stipulated in the code descriptions published by the AMA and that these [neurology] codes are currently used by physicians performing nerve conduction studies with the NC-Stat System. If the CPT codes that apply to the procedures performed using our products are changed, reimbursement for performances of these procedures may be adversely affected.

Id. at 46.

This statement is not misleading because it failed to include the opinions of the reimbursement experts or the reimbursement advice strategy or because it failed to characterize explicitly the risk of non-reimbursement as serious.

In addition to repeating the same four omissions urged with respect to the documents discussed earlier, the plaintiffs further claim that this statement is misleading for its omission of several additional facts: (1) that the sales staff for NeuroMetrix marketed the device for use by non-medical office staff; (2) that the device was marketed for primary care physicians to determine

whether referral to neurology was appropriate, but after the codes were used for a NC-Stat procedure, claims for follow-up neurology diagnostics under the same code were denied; and (3) that the FDA had approved the NC-Stat as a supplement rather than as a replacement for traditional nerve conduction studies. See id. at 46-47.

The district court stated succinctly that these facts were "beyond the scope of the reimbursement disclosures." R.52 at 8 (emphasis added). We agree. In making this determination, we recall the perspective from which we must make this evaluation. We must determine whether the omission of any of these facts from the statement that appeared in the 2005 Annual Report rendered that statement misleading. We can assume, for the sake of this analysis, that these statements are material in the sense that a reasonable shareholder would consider these matters important in making an investment decision. See Cooperman, 171 F.3d at 49. Nevertheless, we agree with the district court that the absence of this material did not render the statements that actually were made about the application of CPT codes to the NC-Stat System misleading. We are not persuaded that the allegations concerning limitations on FDA approval of the device or secondary billing problems occurring for patients requiring follow-up traditional nerve testing are sufficiently related to the quoted statement that failure to disclose those facts rendered that statement misleading.

The allegation that the device was marketed for use by non-medical office staff poses the closest case for a material misrepresentation. The Annual Report does state explicitly that the Medicare guidelines call for procedures billed under the neurology codes to be "performed by medical doctors, or M.D.s, and doctors of osteopathic medicine, or D.O.s" and that NeuroMetrix's belief is that "the nerve conduction measurements performed by the NC-Stat System meet the requirements stipulated in the code descriptions." R.32 at 46. That sales personnel of NeuroMetrix attempted to induce members of the medical profession to circumvent these billing requirements and delegate the performance of this test to employees without their training is a serious accusation and, if true, could no doubt make an investor think twice about the desirability of investment in such a company. Nevertheless, the more narrow inquiry before us is simply whether non-disclosure of such a practice makes the statement in the report misleading. We do not believe that it does. Whether the product conforms to the current or future CPT codes is not dependent on the company's alleged attempt to sell the machine to unscrupulous members of the medical profession.

4. Quarterly Report, First Quarter 2006

The plaintiffs' next allegations concern the third quarter report for 2006. In that report, NeuroMetrix maintained its position on reimbursement:

> ***Generally, we believe that the nerve conduction studies performed by our customers with the NC-Stat System have been satisfactorily covered by third-party payers.*** As our presence in the market expands and the use of the NC-Stat System increases, we have experienced and are likely to continue to experience an increased focus from third-party payers and governmental agencies regarding . . . reimbursement . . . [and] the professional requirements for performing nerve conduction studies in general. ***Widespread adoption of the NC-Stat System is unlikely to occur if physicians do not receive satisfactory reimbursement from third-party payers for procedures performed with the NC-Stat System*** . . . . A successful market expansion will depend upon, in part, our targeting of primary care and specialty physicians who traditionally have not been targeted by companies selling equipment used to perform nerve conduction studies and our ability to alter physicians' practices relating to the diagnosis of neuropathies.

Id. at 47 (emphasis in original).

The complaint first alleges that the statements were false and misleading because they failed to make the same disclosures discussed above, relating to the advice of the reimbursement experts, the advice by sales personnel to bill under neurology codes and the "serious risk" of non-reimbursement. We again conclude that the statements are not misleading because of

the failure to include any of those alleged facts. The statement is clear that "generally," reimbursement is satisfactory, but that the company "ha[s] experienced and [is] likely to continue to experience" scrutiny from third-party payers, which could have a significant effect on future profitability. Id. (emphasis omitted). Nothing about this statement changes our view that, under Cooperman, 171 F.3d at 50-51, disclosure of the internal opinions of two qualified employees was not required to prevent skewing of the total mix of information available to shareholders. Although by mid-2006, when this statement was made, NeuroMetrix certainly was aware that its customers were experiencing reimbursement issues, the complaint alleges only that the complaints were sporadic and regional; that is consistent with the qualified statement about reimbursements actually made in this disclosure.[6]

5. Quarterly Report and Conference Call, Second Quarter 2006

The plaintiffs next challenge the sufficiency of the disclosures contained in a July 2006 conference call with analysts and investors and the second quarter report issued in August 2006.

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[6] Furthermore, the complaint does not allege that the statements were misleading for failing to include the fact of non-reimbursement by particular insurers. In this regard, the complaint alleges only that the statements failed to disclose the more generic "serious risk" of non-reimbursement. See R.32 at 44.

In the conference call, Mr. Gozani stated:

> **Basically, the reimbursement situation for NC-Stat is very positive.** We believe that over 600 payors have reimbursed our customers and on a routine basis, our customers are clearly being reimbursed. Obviously as for any medical device company in today's reimbursement environment, there are from time to time reimbursement issues that come up that have to be addressed, many of them often are just the way customers code, the way they code their insurance claims or other very straightforward administrative issues. Sometimes they pertain to the misunderstandings of the technology and so forth. That is just par for the course in this type of business. . . . We continue to work with payors to explain our technology who continue to do studies demonstrating the viability and strength of our technology and are very positive about the situation.

R.32 at 48-49 (emphasis in original). Defendant Gregory added that the company would not "comment specifically on what our overall reimbursement mix is," but that it was "very pleased with the reimbursement landscape[] [a]nd that it allows physicians to appropriately perform these tests and be reimbursed appropriately for doing them." Id. at 48. Mr. Gozani then clarified that the company was "not involved obviously . . . in billing by our customers . . . other than providing them with basic published information on expected coding practices." Id. at 49.

One month later, NeuroMetrix filed its quarterly report for the second quarter of 2006, which was not materially different from those of prior quarters. Indeed, it repeated that it believed the procedure was reimbursed "satisfactorily," even though it was

the subject of "increased focus" from payers. Id.

Anima claims that these statements are false and misleading for the same reasons it has cited repeatedly in the complaint. We again conclude that these statements are not rendered misleading by the omission of any of the information Anima claims it should have included. The statements continue to acknowledge some difficulties, and although they are certainly optimistic about the future, they are not misleading because they fail to identify a "serious risk" of non-reimbursement. See Backman, 910 F.2d at 16 (distinguishing between the "commercial failure" allegations and the allegations of undisclosed details relating to risks).

With respect to this disclosure, the plaintiffs also claim that the statement was misleading for what the plaintiffs term a "reckless[]" failure to disclose that NeuroMetrix was "aware of pervasive problems with insurer reimbursement for NC-Stat tests." R.32 at 49-50. Although this alleged misstatement might give us pause if the allegations of the complaint were sufficient to support it, they are not. The complaint is more than seventy pages in length, but it is relatively thin on specific claims regarding reimbursement denials.[7] Moreover, because of its

[7] The complaint includes very few specific facts about reimbursement denials: (1) In late 2005, regional Blue Cross providers began denying coverage; (2) "some insurers discovered in 2006" that physicians were billing under the neurology codes and began denying coverage, id. at 34; (3) a single clinic in Florida

structure, it is difficult to place any of the information regarding the reimbursement along the timeline of the disclosures. The failure of the complaint to detail with some greater degree of specificity what these "pervasive" problems were is fatal to this allegation. See ACA Fin. Guar., 512 F.3d at 63 ("It is true, as the plaintiffs argue, that the PSLRA does not require plaintiffs to plead evidence. But more meat was needed on these bones." (internal citations omitted)).

6. Conference Call, Third Quarter 2006

On October 26, 2006, NeuroMetrix held a conference call for analysts and investors. In it, the defendants spoke at some length about reimbursements:

> We wanted to cover some basic information which may offer some insights towards the reimbursement landscape. First and foremost, the NC-Stat System is a FDA-cleared technology that is supported by strong language held

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was denied reimbursement sometime in 2006; (4) one insurer, Cigna, proposed a local coverage ban before September 2006; (5) sometime after the middle of 2006, a confidential witness put together a spreadsheet of "insurance carriers in specific states where reimbursement had become a problem," id. at 31; (6) sometime between November 2006 and May 2007, Defendant Gregory was aware of a "growing number of complaints from physicians about reimbursement," id. at 23; and (7) in March 2007, a sales manager leaving NeuroMetrix sent a letter to clients warning of "reimbursement problems," id. at 32. Even if these facts were sufficiently specific to satisfy the particularity requirements, a question we do not address, they do not amount to "pervasive" problems. Although the complaint does include other information about denials, that information comes from quoted language in the disclosures themselves. See, e.g., R.32 at 50.

> within our FDA clearance. And I quote, "Clinical data submitted in the 510(k) demonstrates the nerve conduction measurements obtained using the NC-Stat System are comparable to those obtained using conventional nerve conduction measurement equipment." As detailed here, the NC-Stat System performs standard nerve conduction measurements.
>
> * * *
>
> Furthermore, as reported by our customers, we believe the technology has been routinely reimbursed by over 600 payors, including all Medicare carriers and nearly all commercial and worker's compensation payors throughout the nation. Several Medicare carriers have draft LCDs or local coverage determinations, which includes select potential concerns for NeuroMetrix, which if implemented as a final policy could adversely impact the reimbursement for the NC-Stat. . . .
>
> Another Medicare carrier, Cigna, has issued a draft LCD for NCS test[s] recently. And in our review with Cigna, we noted that this does not include any reference to the NC-Stat System. Of course, this does not surprise us, as the NC-Stat System performs standard nerve conduction measurements. Our concern with the draft is that if it implies that needle EMG should be performed with the majority of nerve conduction studies, we believe that the decision to perform NCS and/or needle EMG should be left up to the physician's clinical judgment and also supported by the evidence-based medical guidelines.

R.32 at 50 (omissions in original). The principals then took questions from the analysts. Specifically, an analyst noted:

> Obviously, there are a couple of policies out there, a couple of others in draft. Just wanted to see what type of feedback you are getting from your client base. . . . Are we continuing to see good reimbursement etcetera?

Id. at 50-51. In response, Mr. Gregory replied:

> The reimbursement landscape today remains straightforward for the vast majority of our customers.
>
> And if you look at the areas where we have some draft LCDs in question, when you really distill it, it's a relatively small portion of the country. As importantly, it's only for Medicare, which we estimate to be less than 30% of the total testing that is done with the NC-Stat System. So, as a broad sweeping statement, the landscape on reimbursement for our customers is straightforward and it remains so for nearly all of them.
>
> As importantly and as you all know, many of these areas of question are just that--still in question. And the LCDs are just that draft and not implemented. So, that gives you a little bit of a flavor but I think that the landscape has certainly got some elements in front [of] it before us but nothing has been implemented and we have already given you some good flavor I believe on our view on this and how we are approaching it.

Id. at 51. Thereafter, another analyst asked how the "reimbursement team" had responded to the draft coverage determinations. Id. Mr. Gozani stated that the position of NeuroMetrix "is always to deliver the facts to our customer base . . . and allow[] the customer to be equipped with the information to be able to perform their own activities and billing practices." Id.

Anima claims that all of these statements on the call were misleading for failing to state the serious risk of non-reimbursement, the opinions of the reimbursement experts, and the facts concerning use by non-medical office staff. We find no merit

to these objections, for reasons set forth above. Anima also submits that in these statements, the "Defendants failed to disclose that the Company was by this time receiving widespread and pervasive complaints from sales representatives, physicians and other customers regarding reimbursement and billing problems." Id. at 51-52. As noted above, the factual allegations are simply insufficient to support the charge that the company was aware of "widespread and pervasive complaints" at this time or any other. See supra note 7.

7. Quarterly Report, Third Quarter 2006

On November 9, 2006, the company filed its report for the third quarter. In it, in addition to the same statements made in the previous quarters that "[g]enerally, . . . the nerve conduction studies performed by our customers with the NC-Stat System have been satisfactorily covered by third-party payers," id. at 52 (emphasis omitted), the company made additional statements regarding the reimbursement landscape:

> ***At any point in time, a number of third-party payers may take the position of not reimbursing our customers for their use of the NC-Stat System. Recently, two local Medicare carriers covering Florida, Texas and several additional states issued policies indicating that physicians using the NC-Stat System will not be reimbursed under the existing Current Procedural Terminology ("CPT") codes for nerve conduction testing (95900, 95903 and 95904) but rather should submit for reimbursement***

> ***under a separate miscellaneous neurological procedure code (95999).*** We do not know what success our customers will have in obtaining reimbursement under this code and what level of reimbursement they may receive. This decision could potentially adversely impact our future revenues. In addition, several additional local Medicare carriers have issued draft local coverage determinations, which if implemented as final policies, could adversely impact the reimbursement received by our customers and therefore potentially adversely impact our future revenues.

Id. at 52 (emphasis in original). The risk factors also were updated to include a reference to the possibility that providers would be unable to receive sufficient reimbursement and that, as a result, "our future product sales will be severely harmed." Id. at 53 (emphasis omitted).

The quarterly report is alleged to be misleading for failure to include the factual allegations made by the plaintiffs regarding the serious risk of non-reimbursement and the marketing techniques employed by the company, as well as that the company was receiving "widespread and pervasive complaints." Again, we find no support in the factual allegations of the complaint for allegations of widespread reimbursement problems. Further, none of the other omitted facts alleged in the complaint rendered this statement so incomplete as to mislead. Indeed, this statement specifically disclosed more about the problems with reimbursement (including the references to regional Medicare carriers) than we are able to discern elsewhere in the factual allegations of the complaint.

8. Quarterly Report, Fourth Quarter 2006

On February 1, 2007, NeuroMetrix hosted another conference call with investors. In the discussion of reimbursement, Mr. Gregory stated:

> Through the course of 2006, several Medicare carriers issued draft LCDs, or local coverage determinations, which included select potential concerns for NeuroMetrix. . . . We're pleased that the majority of these draft LCDs across Palmetto, Cigna, and NIHC were modified and/or not implemented.
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> * * *
>
> In response, we have retained a team of reimbursement experts to assist us in assessing and challenging these coding articles. Based upon their review, . . . ***we believe our customers should be able to perform medically appropriate NCS tests and appropriately bill them under standard NCS codes***. . . .

Id. at 54-55 (certain omissions in original). This statement was not misleading for failing to include the same facts regarding reimbursement repeated throughout the complaint. Further, the complaint does not allege specifically that the information regarding the positive developments for reimbursement are incorrect or overstated, nor are any contrary facts specifically alleged that would alter the total mix of facts.

9. Annual Report, 2006

In the 2006 Annual Report, issued March 29, 2007, the Company issued "more extensive risk disclosures." Id. at 55. Those disclosures included that (1) five regional Medicare carriers

covering a total of twenty states issued draft local coverage determinations that could adversely affect reimbursement, including several that would not reimburse for NC-Stat procedures under the neurology codes; (2) the AMA Editorial Panel formed a committee to examine coding practices for similar devices; and (3) local coverage determinations and "coding articles" addressed other issues, including the background and training of physicians performing the tests. Id. The report stated that the company did not believe that the local coverage determinations prohibited physicians from receiving reimbursement for the NC-Stat, but acknowledged that "they do appear targeted at limiting access to perform and/or reimbursement for nerve conduction studies." Id. at 56.

As with its fourth quarter 2006 statement, this disclosure provides more information about the reimbursement landscape than do the company's earlier statements and reports. We cannot find it to be materially misleading under these circumstances.

10. Quarterly Report & Earnings Call, First Quarter 2007

On a conference call detailing first quarter 2007 results, held May 1, 2007, Mr. Gregory reiterated his usual statements about generally satisfactory reimbursement. He again noted that the AMA Editorial Panel had the coding of the procedure

under review and that the timing of its decision was uncertain. Finally, he reiterated the company's belief that the existing neurology codes were appropriate, listing a number of factors, including "that the Medicare Physician Fee Schedule details the codes and corresponding RVUs for [the] procedure." Id. at 56.

Anima claims that the statement is misleading for all of the same reasons cited with respect to the other statements. In addition, Anima contends that the statement regarding the Medicare Physician Fee Schedule "was blatantly false," because "[t]he Director of Reimbursement had expressly told [the defendants] that the fee schedule and RVUs assigned to [the neurology codes] were not weighted or valued for the NC-Stat and could not be used for automated nerve conduction studies performed with the NC-Stat test." Id. at 57. The difficulty for Anima remains that, like the other allegations concerning the experts' opinions, we have not required dissenting internal opinions to be disclosed. See Cooperman, 171 F.3d at 49; see also discussion supra at II.C.1.[8]

On May 9, 2007, NeuroMetrix filed its quarterly report for the first quarter of 2007, a full two pages of which are excerpted into the complaint. In the excerpt, the company modified its language in earlier statements about satisfactory reimbursement to reflect several then-emerging problems and stated that "[a]

[8] The plaintiffs make an identical argument with respect to the near-identical disclosure in the July 2007 earnings call. We do not address it separately.

number of third-party payers, including commercial payers, have taken and may continue to take the position of not reimbursing our customers for their use of the NC-Stat System." R.32 at 57. The disclosure then notes that Medicare providers covering twenty states had indicated at various times that they would not reimburse under the existing codes, but that one of those decisions subsequently had been reversed; further, regional Blue Cross Blue Shield carriers had adopted policies of not reimbursing the procedure, calling it "experimental and investigational." Id. at 58. The statement noted that, in certain regions, lower reimbursement and higher claim denials had been reported and that the future outcome of the reimbursement picture "could materially and adversely impact our revenues and profitability." Id. at 58. It included information about the AMA Editorial Panel's examination of the appropriate codes, noting that the AMA "could potentially take a position that could reduce or eliminate the reimbursement for the NC-Stat System and could have the impact of deterring usage by our customers." Id. Further, it noted that new paperwork requirements to document the medical necessity of the procedure were "negatively impacting" the use of the system and were "having an adverse impact on our revenues." Id. Finally, it repeated the statements in a prior disclosure that various reimbursement policies from insurance carriers concerning related topics--such as training requirements for physicians performing nerve conduction

studies--seemed targeted at limiting reimbursement for the NC-Stat and similar procedures; these policies were already affecting NeuroMetrix revenues.

Again, we conclude that these statements are not misleading for failure to include the facts advanced by the plaintiffs. Indeed, the company's statements are specific about the reimbursement problems and their probable impact on the company's earnings.

11. Quarterly Report, Second Quarter 2007

On August 9, 2007, NeuroMetrix issued its second quarter report. After restating much of what appeared in the prior quarter's report, it noted that "a growing number of commercial payers, including a significant number of regional Blue Cross Blue Shield carriers have adopted policies indicating that they will not provide reimbursement for the use of the NC-Stat System" for various reasons. R.32 at 61. On the issue of future profits, the statement noted:

> We anticipate that revenues in the remainder of 2007 may continue to decline. In the second quarter of 2007, we experienced a decline in revenues of 17.9% from the second quarter of 2006, which we believe primarily resulted from the uncertainty created by the issuance of draft LCDs, final LCDs and coding articles addressing reimbursement for nerve conduction studies and policies issued by commercial payers intended to deter usage or limit the reimbursement for the NC-Stat System. These developments and other future

> reimbursement decisions could continue to adversely impact reimbursement for procedures performed using the NC-Stat System. Our revenues in the remainder of 2007 are likely to be impacted by (a) the level of reimbursement, if any, established for procedures performed using the NC-Stat System by these carriers and other third-party payers; (b) whether final LCDs are applied in a manner that places additional restrictions or qualifications on the performance of these procedures; (c) any other reimbursement determinations relating to nerve conduction studies that may be issued by third party payers; (d) any other events causing uncertainty as to the existence or amount of reimbursement physicians are likely to receive for performing procedures using the NC-Stat System or (e) decisions potentially forthcoming from the AMA CPT Editorial Panel regarding reimbursement codes for nerve conduction studies.

Id. at 61-62. Anima claims that the disclosure was misleading for failing to include all of the same information we already have set forth. Again, this statement is far more detailed and includes actual negative results, a consideration far more relevant to an investor than prior predictions of these results.

12. Quarterly Report & Earnings Call, Third Quarter 2007

Finally, Anima challenges the third quarter 2007 disclosures. In the earnings call, the defendants noted that the AMA Panel's work was underway, and they anticipated that any of a number of recommendations could result, including continued reimbursement under the existing codes or new codes that could

reimburse at various levels. They reiterated their belief that the current codes were sufficient and appropriate and their reasoning.

On November 8, 2007, the company filed its third quarter report. In the three pages of excerpts included in the complaint, the defendants noted declining revenues, which they attributed to "adverse developments over the last several quarters relating to . . . reimbursement." Id. at 63. They further noted that they expected recommendations from the AMA Editorial Panel, "which may or may not be beneficial," in early 2008. Id. They noted the ongoing difficulties with reimbursement and added that "[a]dditional third-party payers, including local Medicare carriers and commercial payers, could potentially take a position that could reduce or eliminate the reimbursement for the NC-Stat System and could have the impact of deterring usage by our customers." Id. at 66.

As with the other statements from late in the class period, this disclosure is more comprehensive on the problems being faced by NeuroMetrix than are the factual allegations in the complaint. The district court was correct to dismiss the claim based on this statement.

Conclusion

In summary, because the allegations of the complaint do not identify any actionable misstatements under the securities

laws, we affirm the judgment of the district court dismissing the 10b-5 claims.[9] Further, because the 20(a) claims are derivative of the 10b-5 claims, ACA Fin. Guar., 512 F.3d at 67-68, we affirm the district court's judgment that those claims must fail as well. The judgment of the district court is affirmed.

AFFIRMED.

[9] Accordingly, we do not address the defendants' alternate theories, that the complaint fails to allege adequately scienter and loss causation.