

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA**

IN RE MYLAN N.V. SECURITIES
LITIGATION

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OPINION

Lead Plaintiff Public Employees' Retirement System of Mississippi brings this class action against Defendants Mylan N.V., CEO Heather Bresch, President Rajiv Malik, and CFO Kenneth Parks under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, and Rule 10b-5 promulgated thereunder.

In a May 18, 2023, opinion, the Court granted in part and denied in part Defendants' motion to dismiss (ECF 45) Plaintiff's amended complaint (ECF 39). *See In re Mylan N.V. Sec. Litig.*, No. 20-955, 2023 WL 3539371 (W.D. Pa. May 18, 2023). Before the Court now are two additional pending motions: (1) Defendants' motion for judgment on the pleadings (ECF 105); and (2) Plaintiff's motion for clarification of the Court's May 18, 2023, motion-to-dismiss opinion (ECF 95).

Briefing is completed for both motions, the Court held oral argument on the motions on May 21, 2025, (ECF 120; ECF 121), and so the motions are ready for disposition.

For the reasons below, the Court will **DENY** both motions.

BACKGROUND

The Court writes mainly for the parties, who are familiar with the procedural history and factual background of this case. The Court thus discusses only what is necessary to resolve the two motions, and otherwise adopts its more detailed discussion of the background in its motion-to-dismiss opinion. *See In re Mylan*, 2023 WL 3539371, at *1-4.

I. The Court’s motion-to-dismiss opinion.

Given its importance to the motions, the Court begins with a brief overview of the relevant portions of its motion-to-dismiss opinion.

Defendants argued that Plaintiff failed to allege material misrepresentations or omissions sufficient to sustain its Rule 10b-5(b) misrepresentation/omission claim. The Court held that the claim survived, based on one material misrepresentation: a statement by a Mylan spokesperson in a January 31, 2019, *Bloomberg Law* article, which “responded to allegations of [FDA Current Good Manufacturing Practices (CGMP)] and data integrity failure at Mylan’s plants by stating that ‘any explicit or implicit suggestion that Mylan employees circumvented data and quality systems that jeopardized the quality of the medications we manufacture—for time pressures or any other reason—is simply false.’” *Id.* at *3 (quoting ECF 39, ¶ 299 (cleaned up)).

Much of the opinion was devoted to Plaintiff’s misrepresentation claim under Rule 10b-5(b). But Plaintiff had also pled a “scheme liability” claim under Rule 10b-5(a),(c). With respect to the scheme claim, the Court held that since Defendants had argued only that the scheme claim was derivative of the misrepresentation claim, and the misrepresentation claim was adequately pled, the scheme claim survived, as well. *Id.* at *20.

II. Defendants' motion for judgment on the pleadings (ECF 105).

Defendants raise two primary arguments in their motion for judgment on the pleadings. First, they assert that, with respect to the misrepresentation claim, Plaintiff fails to plead loss causation. ECF 106, pp. 12-20. Second, they argue that the scheme claim is necessarily limited to the *Bloomberg Law* misstatement, and that the scheme claim fails on the merits because (1) there is no loss causation; (2) there was no reliance by investors to trigger scheme liability; and (3) the scheme was not in connection with the purchase or sale of securities. *Id.* pp. 20-26.

III. Plaintiff's motion for clarification (ECF 95).

Plaintiff seeks clarification of the Court's motion-to-dismiss opinion, specifically, whether the scheme claim consists only of the *Bloomberg Law* misstatement, as Defendants contend, or whether the scheme claim consists of deceptive or manipulative conduct, committed in furtherance of a scheme to defraud, independent from any actionable statements. ECF 95, pp. 11-14. Plaintiff argues that the Court's motion-to-dismiss opinion already concluded as much, and that the Court's conclusion there is consistent with longstanding precedent that a scheme claim doesn't require any specific oral or written statement. *Id.*

DISCUSSION AND ANALYSIS¹

I. The Court will deny the motion for judgment on the pleadings as to the misrepresentation claim.

Defendants argue that the Rule 10b-5(b) misrepresentation claim fails because Plaintiff fails to plead loss causation. ECF 106, p. 12. The Court disagrees.²

Loss causation is the “causal connection between the material misrepresentation and the loss[.]” *Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 342 (2005). “[T]he loss causation inquiry typically examines how directly the subject of the fraudulent statement caused the loss, and whether the resulting loss was a foreseeable outcome of the fraudulent statement.” *Berkeley Inv. Grp., Ltd. v.*

¹ “A motion for judgment on the pleadings based on the defense that the plaintiff has failed to state a claim is analyzed under the same standards that apply to a Rule 12(b)(6) motion. A motion for judgment on the pleadings should be granted if the movant establishes that there are no material issues of fact, and he is entitled to judgment as a matter of law. In considering a motion for judgment on the pleadings, a court must accept all of the allegations in the pleadings of the party against whom the motion is addressed as true and draw all reasonable inferences in favor of the non-moving party.” *Zimmerman v. Corbett*, 873 F.3d 414, 417-18 (3d Cir. 2017) (cleaned up). “A court presented with a motion for judgment on the pleadings must consider the plaintiff’s complaint, the defendant’s answer, and any written instruments or exhibits attached to the pleadings.” *Brown v. Equifax Info. Servs., LLC*, No. 23-1922, 2025 WL 964873, at *2 (W.D. Pa. Mar. 31, 2025) (Colville, J.) (cleaned up). The Court may also consider documents “integral to or explicitly relied upon in the complaint[.]” such as the Form 8-Ks and earnings calls. *Mele v. Fed. Rsrv. Bank of N.Y.*, 359 F.3d 251, 256 n.5 (3d Cir. 2004), *as amended* (Mar. 8, 2004) (cleaned up).

² Defendants raise a threshold argument that loss causation must be analyzed under the Rule 9(b) specificity standard. ECF 106, p. 13 n.5. Defendants assert that Rule 9’s heightened pleading standard is the “majority” position, and that applying Rule 9(b) to loss causation is consistent with the fact that securities fraud “is itself a species of fraud, and Rule 9(b) clearly applies to fraud.” *Id.* The Third Circuit has not answered this question. But courts in this Circuit that have recently decided the issue have rejected the stricter standard. *See, e.g., Baer v. Shift4 Payments, Inc.*, No. 23-3206, 2024 WL 3836676, at *6 (E.D. Pa. Aug. 14, 2024) (“Importantly, as to loss causation there is not a heightened standard of pleading.” (cleaned up)). The Court agrees with this approach.

Colkitt, 455 F.3d 195, 222 (3d Cir. 2006) (cleaned up). To satisfy this element, “the misstated or omitted facts [must be] a substantial factor in causing an economic loss actually incurred by the plaintiffs.” *McCabe v. Ernst & Young, LLP.*, 494 F.3d 418, 436 (3d Cir. 2007).

In this Circuit, loss causation is generally proven by: (1) corrective disclosures, where the misrepresentation or omission is revealed and a decline in the price of a security follows; or (2) “materialization of the risk,” where the occurrence of an event—the risk of which was hidden by misrepresentations or omissions—reveals the falsity of those misrepresentations or omissions. *See Howard v. Arconic Inc.*, No. 17-1057, 2021 WL 2561895, at *17 (W.D. Pa. June 23, 2021) (Hornak, C.J.) (describing approaches); *see also In re Aurora Cannabis, Inc. Sec. Litig.*, No. 19-20588, 2021 WL 2821167, at *15 (D.N.J. July 6, 2021) (same). Defendants assert that Plaintiff is attempting to prove loss causation through corrective disclosures, and not a materialization-of-the-risk theory, and Plaintiff doesn’t appear to contest that assertion. So the Court turns to the corrective disclosures.

Because the Court found only the January 31, 2019, *Bloomberg Law* misstatement actionable for the misrepresentation claim, Defendants and Plaintiff agree that there are only two putative corrective disclosures at play: (1) the February 26, 2019, Form 8-K and Q4 2018 and FY 2018 earnings call, where Mylan disclosed a 5% and 4% decline in total quarterly and yearly revenues, and a 16% decrease in North American net sales for the quarter and 18% for the year, which it attributed, in part, to the Morgantown restructuring and remediation, ECF 39, ¶¶ 18, 207-214; and (2) the May 7, 2019, Form 8-K and Q1 2019 earnings call, where Mylan disclosed a 7% decline in revenues, a 15% decline in earnings-per-share, and a decline in quarterly adjusted free cash flow to 2015 levels, which it attributed, in part, to the Morgantown remediation, along with an additional \$70 million in expenses for the Morgantown restructuring, ECF 39, ¶¶ 19, 217-218. ECF 106, pp. 14-15; ECF 110,

pp. 20-21.

Defendants argue that these corrective disclosures are insufficient for three reasons: (1) they don't reveal anything about the misrepresentation in the *Bloomberg Law* article; (2) the misrepresentation in the *Bloomberg Law* article referred to the factory in Nashik, India, and not the factory in Morgantown, West Virginia, and the corrective disclosures pertain only to the latter; and (3) the disclosures don't reveal any new information.

The Court concludes that Plaintiff has met its burden to plead loss causation.

A. Plaintiff plausibly alleges that the corrective disclosures reveal some falsity of the *Bloomberg Law* misrepresentation.

Defendants argue that the corrective disclosures do not reveal the fraudulent activities—the “circumvention of quality and data systems[,]”—but just Mylan's financials, and that a decline in financial metrics can't establish loss causation without any suggestion that the fraud was revealed to the market. ECF 106, pp. 16-17; ECF 111, p. 10. Defendants contend that since there aren't any such allegations “that the market interpreted these disclosures regarding Mylan's ongoing remediation efforts as revealing purported circumvention[,]” loss causation is therefore absent. ECF 106, pp. 15-16.

“Disclosure of disappointing earnings or other indications of the true financial condition of the company, without any evidence of a link between the disclosure and the fraud, is not a corrective disclosure.” *Martin v. GNC Holdings, Inc.*, No. 15-1522, 2017 WL 3974002, at *19 (W.D. Pa. Sept. 8, 2017) (Hornak, J.), *aff'd*, 757 F. App'x 151 (3d Cir. 2018) (cleaned up). The purported corrective disclosures here, however, aren't limited to the recitation of financial metrics; they also link the decrease in Mylan's financials to the restructuring and remediation at the Morgantown facility. ECF 107-12, p. 6; ECF 107-13, p. 7; ECF 107-14, p. 7; ECF 107-15, p. 7. The question, then, is whether tying the financials to the Morgantown restructuring and

remediation suffices.

The Third Circuit has directed that “to satisfy the loss causation requirement” in a “typical ‘fraud-on-the-market’ § 10(b) action, [in which] the plaintiff shareholder alleges that a fraudulent misrepresentation or omission has artificially inflated the price of a publicly-traded security, . . . the plaintiff must show that the **revelation** of that misrepresentation or omission was a substantial factor in causing a decline in the security’s price[.]” *McCabe*, 494 F.3d at 425-26 (emphasis added); *see also Pure Earth, Inc. v. Call*, 531 F. App’x 256, 260 (3d Cir. 2013) (“[T]o prove loss causation in a *typical* § 10(b) case, the plaintiff must show that his losses are related specifically to the **market’s discovery of the misrepresentation** and the corresponding decrease in price due to that misrepresentation.” (emphasis added)). Thus, while “there is no requirement that the disclosure mirror the earlier misrepresentation[.] . . . the disclosure must still reveal at least part of the falsity of the alleged misrepresentation.” *Howard*, 2021 WL 2561895, at *17 (cleaned up).

Plaintiff brings a fraud-on-the-market case,³ and so must plausibly allege this revelation. How, then, does the effect of the restructuring and remediation at Morgantown “reveal at least part of the falsity” of the January 31, 2019, *Bloomberg Law* misrepresentation?

As Defendants note, it doesn’t directly; the Form 8-Ks and earnings calls don’t mention data and quality control systems. So Plaintiff instead advances an indirect theory: that, by way of the Morgantown restructuring and remediation, the financial disclosures pertain to the “scope and impact” of Mylan’s circumvention of data and quality control systems. ECF 110, pp. 14-15. Plaintiff’s allegations are, essentially, that while the February and May 2019, reports and earnings calls didn’t mention

³ ECF 39, ¶ 328 (“As a result of Defendants’ materially false or misleading statements, omissions of material facts, and fraudulent course of conduct, Mylan’s common stock traded at artificially inflated prices during the Class Period.”).

circumvention, they contextualized the earlier revelations—for example, those made in the Form 483 and Warning Letter—that Mylan had data and quality system issues. ECF 39, ¶¶ 195-204, 329-31. In other words, Plaintiff contends that they revealed some partial truth about the falsity of Mylan’s *Bloomberg Law* representations; that Mylan was, in fact, circumventing the data and quality systems.

This is enough. Corrective disclosures “need not . . . explicitly or exhaustively reveal[] the fraud, so long as fair inferences of fraud that would affect investors can be drawn from the disclosures.” *Allegheny Cnty. Emps.’ Ret. Sys. v. Energy Transfer LP*, 744 F. Supp. 3d 350, 358 (E.D. Pa. 2024); *see also Hull v. Glob. Digit. Sols., Inc.*, No. 16-5153, 2017 WL 6493148, at *14 (D.N.J. Dec. 19, 2017) (“[A] corrective disclosure need not take a particular form; it is the exposure of the falsity of the fraudulent representation that is the critical component.”). Nor must corrective disclosures “occur all at once; instead, the truth may be revealed through a series of partial disclosures through which the truth gradually ‘leaks out.’” *De Vito v. Liquid Holdings Grp., Inc.*, No. 15-6969, 2018 WL 6891832, at *39 (D.N.J. Dec. 31, 2018) (cleaned up); *see also In re Bradley Pharms., Inc. Secs. Litig.*, 421 F. Supp. 2d 822, 828-29 (D.N.J. 2006) (disclosure of SEC investigation that didn’t identify defendant’s “sham” sale of cold medication to inflate financials was partial corrective disclosure when viewed in connection with post-class disclosure explicitly identifying the scheme).

Important too is the posture of the present challenge. The only thing required of Plaintiff right now is “a short and plain statement of the claim” providing Defendants with “some indication of the loss and the causal connection that the plaintiff has in mind.” *Dura Pharms., Inc.*, 544 U.S. at 346-47 (cleaned up). This is not a “heavy” burden, “and when it is unclear whether the plaintiff’s losses were caused by the fraud or some other intervening event, the chain of causation is not to be decided [at the pleadings stage].” *In re Coinbase Glob., Inc. Sec. Litig.*, No. 22-

04915, 2024 WL 4053009, at *17 (D.N.J. Sept. 5, 2024) (cleaned up) (quoting in parenthetical *Gross v. GFI Grp., Inc.*, 162 F. Supp. 3d 263, 269 (S.D.N.Y. 2016)). So, while Defendants suggest that “remediation can occur whenever there is something to address for any reason,” ECF 111, p. 13, how the market interpreted the disclosures is “a factual dispute [that] cannot be adjudicated at this early, [judgment-on-the-pleadings] stage of the litigation.” *Hall v. Johnson & Johnson*, No. 18-1833, 2019 WL 7207491, at *28 (D.N.J. Dec. 27, 2019).

Plaintiff’s allegations thus satisfy its pleading burden.

B. The *Bloomberg Law* misrepresentation could be fairly read to encompass Morgantown.

Defendants next argue that the *Bloomberg Law* misrepresentation concerned the Nashik facility, not Morgantown, and Morgantown was the facility referenced in the corrective disclosures. ECF 106, p. 17. In support, they explain that the *Bloomberg Law* article’s title referenced issues with Indian manufacturers, that the article discussed the Nashik plant, and that the misrepresentation directly followed from and responded to statements by Nashik employees. *Id.* pp. 17-18.

The Court disagrees. The Mylan spokesperson’s statement in the *Bloomberg Law* article is broad and nonspecific enough that it could plausibly be understood to be referring to all of Mylan’s facilities, including Morgantown. It would be premature, at this stage in the proceedings, for the Court to decide how the market interpreted the alleged misrepresentation. *Cf. McDermid v. Inovio Pharms., Inc.*, 520 F. Supp. 3d 652, 662 (E.D. Pa. 2021) (noting, with respect to falsity of alleged misrepresentations, “how investors and analysts interpreted [the] statements are questions of fact inappropriate for resolution at the motion to dismiss stage of the litigation”).

C. Plaintiff plausibly alleges that the disclosures revealed new information.

Defendants' last argument is that the disclosures didn't reveal any new information about the Morgantown restructuring and remediation. ECF 106, pp. 18-19.

"In general, a 'corrective disclosure' must reveal . . . new information to the market." *In re DVI, Inc. Sec. Litig.*, No. 03-05336, 2010 WL 3522090, at *6 (E.D. Pa. Sept. 3, 2010) (collecting cases); *see also SLF Holdings, LLC v. Uniti Fiber Holdings, Inc.*, 499 F. Supp. 3d 49, 70 (D. Del. 2020), *aff'd on other grounds*, No. 20-3427, 2022 WL 3442353 (3d Cir. Aug. 17, 2022) ("Defendants' disclosures did not reveal any new facts regarding the alleged omissions, and so could not have caused Plaintiff's losses associated with the decline in stock price." (collecting cases)).

As the Court explained previously, "Mylan was being forthright about the challenges facing the Morgantown facility" before the corrective disclosures, *In re Mylan*, 2023 WL 3539371, at *15 (discussing 2018 earnings calls), including: the receipt of a Form 483; issues with product supply and operations; the receipt of a Warning Letter; and the resultant restructuring and remediation of the Morgantown facility. *Id.* at *14-15; ECF 111, pp. 15-16. Defendants assert that the only new information presented was thus "the continued impact of remediation and restructuring at Morgantown, *i.e.*, additional product discontinuations, expenses, and financial impacts in the form of revenue and net sales declines[.]" and continued impacts aren't new news. ECF 106, p. 19 (cleaned up); ECF 111, p. 16. The Court disagrees, for at least two reasons.

First, as Plaintiff persuasively contends, the corrective "disclosures revealed for the first time that the reduction in volume and products at Morgantown was permanent and had resulted in previously undisclosed negative financial results." ECF 110, pp. 22-23. It notes that the stock price declined following the disclosures,

and analysts commented on the disclosures, which are both indicators of novelty. *Id.* p. 22. Further, Plaintiff alleges that in August 2018, Defendants downplayed the effects of the restructuring and remediation, and many analysts “rel[ied] on Defendants’ reassuring statements and remain[ed] encouraged about the Company’s outlook.” ECF 39, ¶¶ 186-190. So the disclosure of impacts exceeding those that Defendants had forecast would be new news. *Compare with Lopes v. Fitbit, Inc.*, No. 18-6665, 2020 WL 1465932, at *12 (N.D. Cal. Mar. 23, 2020), *aff’d*, 848 F. App’x 278 (9th Cir. 2021) (company disclosed it made significant shipments of product, demand was flattening, and it was unsure whether demand would recover, so subdued retail sales and heightened inventory—consistent with these announcements—wasn’t new news).

Second, the disclosures were new news in the sense that the January 31, 2019, *Bloomberg Law* statement wiped the slate clean. Any inference that the market may have drawn about Mylan’s circumvention of data and quality control systems based on the previous revelations, such as the Form 483, would clash with Mylan’s express disavowal of that circumvention. So the February and May 2019, disclosures belied Mylan’s *Bloomberg Law* statement, plausibly resetting the market’s understanding about the data and quality control issues at the Morgantown facility.⁴

The Court thus denies Defendants’ motion for judgment on the pleadings as to the Rule 10b-5(b) misrepresentation claim based on loss causation.

⁴ Defendants respond that the *Bloomberg Law* statement couldn’t have walked back the previous disclosures because it didn’t say anything about restructuring and remediation. ECF 121, pp. 34:20-35:21. But the point is that the previous disclosures revealed not the restructuring and remediation but widespread data and quality system issues at the Morgantown facility. So saying that Mylan wasn’t circumventing those systems nips in the bud any suggestion that the data and quality system issues were circumvented “to cut corners for time pressure and in a way that jeopardized the quality of the medications.” *In re Mylan*, 2023 WL 3539371, at *16.

II. The Court will deny the motion for clarification and the motion for judgment on the pleadings as to the scheme claim.

The Court now turns to the so-called “scheme claim.” “To state a claim based on conduct violating Rule 10b-5(a) and (c), a private plaintiff must allege (1) that the defendant committed a deceptive or manipulative act, (2) in furtherance of the alleged scheme to defraud, (3) with scienter, and (4) reliance.” *Takata v. Riot Blockchain, Inc.*, No. 18-2293, 2023 WL 7133219, at *10 (D.N.J. Aug. 25, 2023) (citation omitted). Further, the “deceptive or manipulative act” must have occurred “in connection with the purchase or sale of any security.” 15 U.S.C. § 78j(b); 17 C.F.R. § 240.10b-5.

Plaintiff argues that the scheme claim isn’t limited to the *Bloomberg Law* misrepresentation. Defendants argue that: (1) the Court already limited the claim to the *Bloomberg Law* misrepresentation; (2) Plaintiff has failed to plead a scheme claim; and (3) Plaintiff is impermissibly invoking scheme liability to bypass Rule 10b-5(b).

The Court addresses each argument below, starting with the merits-related arguments.

A. Plaintiff has adequately alleged the scheme claim.

Defendants contend that Plaintiff has failed to allege a scheme claim because: (1) there is no loss causation; (2) there is no reliance;⁵ and (3) the alleged conduct was directed to the FDA, not to investors. ECF 106, pp. 20-24. The Court disagrees.

Loss causation. Defendants’ loss-causation challenge is resolved easily enough. As explained above, the Court holds that Plaintiff has alleged loss causation with respect to the *Bloomberg Law* misrepresentation. So even if the scheme claim

⁵ Plaintiff asserts that Defendants have not moved for judgment on the pleadings on the reliance issue. ECF 110, p. 26 n.11. While Defendants raise reliance chiefly to bind the scheme claim to the *Bloomberg Law* misstatement, the Court understands Defendants to also bring a merits challenge on reliance. ECF 106, p. 24; ECF 111, p. 20.

were limited to that statement alone, loss causation doesn't sink it.

Reliance. “Reliance, also known as transaction causation, establishes that but for the fraudulent misrepresentation, the investor would not have purchased or sold the security. Reliance may be proven directly, but requiring proof of individualized reliance from each member of a proposed plaintiff class effectively would prevent plaintiffs from proceeding with a class action, since individual issues then would overwhelm the common ones.” *In re DVI, Inc. Sec. Litig.*, 639 F.3d 623, 631 (3d Cir. 2011) (cleaned up), *abrogated on other grounds by Amgen Inc. v. Conn. Ret. Plans & Tr. Funds*, 568 U.S. 455 (2013). So Plaintiff, like other securities-class-action plaintiffs, turns to presumptions of reliance. The Third Circuit recognizes two.

First is the “*Affiliated Ute*”⁶ presumption, applying “in cases ‘involving primarily a failure to disclose’ material facts by defendants obligated to disclose such facts.” *Malack v. BDO Seidman, LLP*, 617 F.3d 743, 747 (3d Cir. 2010) (quoting *Affiliated Ute*, 406 U.S. at 153). And second is the “fraud-on-the-market” or “*Basic*”⁷ presumption, which requires plaintiffs to “show they traded shares in an efficient market, and the misrepresentation at issue became public.” *In re DVI*, 639 F.3d at 631-32 (cleaned up).

While the parties extensively briefed these two presumptions, the Court’s analysis is, for now, straightforward. Defendants concede that the *Bloomberg Law* misrepresentation “provides a basis for Plaintiff to invoke *Basic*[.]” meaning “Plaintiff’s scheme claim rises and falls on that statement.” ECF 111, p. 24. Since the Court holds that Plaintiff has alleged loss causation for that misrepresentation, then, Plaintiff has alleged reliance, as well.

Conduct directed to the FDA. Defendants argue that Plaintiff alleges

⁶ *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972).

⁷ *Basic Inc. v. Levinson*, 485 U.S. 224 (1988).

deceptive conduct directed only to the FDA, not investors, and so it is not conduct “in connection with the purchase or sale of any security.” 15 U.S.C. § 78j(b); 17 C.F.R. § 240.10b-5; ECF 106, pp. 23-24 & 24 n.14.

“[Section] 10(b) does not reach all commercial transactions that are fraudulent and affect the price of a security in some attenuated way.” *Gallup v. Clarion Sintered Metals, Inc.*, 489 F. App’x 553, 557 (3d Cir. 2012) (cleaned up) (quoting *Stoneridge Inv. Partners, LLC v. Sci.-Atlanta*, 552 U.S. 148, 162 (2008)). Indeed, courts have dismissed securities-fraud claims lacking this nexus. *See, e.g., id.* (dismissing for lack of reliance despite “the fact that Plaintiffs allege serious misconduct which, if true, probably diminished the value of their Class A shares”); *Trustcash Holdings, Inc. v. Moss*, 668 F. Supp. 2d 650, 662 (D.N.J. 2009) (“[E]ven if there was impropriety in Defendants’ activities, the impropriety involved evading the registration requirements and reselling limitations of the securities laws, and was not an inherent deception perpetrated on [the company’s] then-existing shareholders.”); *Eden Alpha CI LLP v. Polished.com Inc.*, 763 F. Supp. 3d 270, 318 (E.D.N.Y. 2025) (“But these purported acts of fraud—committed against [the corporation], customers, and credit card companies—do not establish a deceptive scheme to defraud *investors*.”).

Plaintiff’s response is that deceiving the FDA deceives the market, because of the FDA’s role as gatekeeper of drug marketing. ECF 110, pp. 29-30. While this argument is interesting,⁸ the Court need not reach it because, again, Plaintiff’s *Bloomberg Law* misrepresentation survives. With that market hook, Plaintiff has plausibly alleged “conduct and participation in a deceptive scheme that involves

⁸ *See, e.g., Klein v. Altria Grp., Inc.*, 525 F. Supp. 3d 638, 651, 665 (E.D. Va. 2021) (denying motion to dismiss scheme liability claim where plaintiffs alleged “that Defendants acted in concert to deceive the FDA into not regulating mint [JUUL pods] so that they could continue to target youth with the mint product, including submitting falsified data and studies[,]” as part of a “scheme to protect the profits of JUUL’s mint pods, the most popular flavor among youth”).

misrepresentation[.]” even under Defendants’ reading of similar FDA-facing cases as requiring deceptive communications to the market. *In re Able Lab’s Sec. Litig.*, No. 5-2681, 2008 WL 1967509, at *22 (D.N.J. Mar. 24, 2008) (denying motion to dismiss scheme claim involving allegations of deceptive conduct directed to the FDA—such as falsifying and fabricating drug test data—and allegations of misrepresentations in public statements about compliance with CGMP and FDA regulations).

B. Plaintiff’s scheme claim isn’t duplicative of the misrepresentation claim.

Defendants also argue that Plaintiff’s Rule 10b-5(a),(c) scheme claim should be dismissed because it impermissibly “repackag[es] allegations of misstatements and omissions under Rule 10b-5(b) as scheme liability claims under Rules 10b-5(a) and (c). ECF 106, p. 25 (cleaned up).

“[W]here the primary purpose and effect of a purported scheme is to make a public misrepresentation or omission, courts have routinely rejected the plaintiff’s attempt to bypass the elements necessary to impose ‘misstatement’ liability under subsection (b) by labeling the alleged misconduct a ‘scheme’ rather than a ‘misstatement.’” *Takata*, 2023 WL 7133219, at *11 (cleaned up). To that end, “[m]isstatements and omissions can form part of a scheme liability claim, but an actionable scheme liability claim also requires something beyond misstatements and omissions, such as dissemination.” *SEC v. Mintz*, 723 F. Supp. 3d 386, 407 (D.N.J. 2024) (cleaned up).

Here, Plaintiff does not merely recast its misrepresentation claim. Rather, Plaintiff alleges that, as part of Defendants’ “scheme to deceive the market[.]” ECF 39, ¶ 328, Defendants’ conduct included: “testing into compliance”; corrupting data files and crashing computers to hide this practice; using “cooked” data “to hasten approval of critical products”; disguising drug impurities; ignoring testing results or invalidating them for pretextual reasons; and creating a “façade of documents” to

fend off FDA inquiry. *Id.* ¶¶ 86-88, 92-93, 96, 98-103, 109-120, 146, 154-55.

These allegations of deceptive conduct—actions “fraudulent in [their] own right”—are *in addition to* the actionable *Bloomberg Law* misrepresentation. *De Vito*, 2018 WL 6891832, at *42. That distinguishes Plaintiff’s scheme claim from those found to be insufficient in other cases cited by Defendants. *See, e.g., In re Ocugen, Inc. Sec. Litig.*, 659 F. Supp. 3d 572, 598 (E.D. Pa. 2023) (“Plaintiff does not allege any deceptive or fraudulent acts, scheme, or practices separate from the fifteen statements alleged.”), *aff’d*, No. 23-1570, 2024 WL 1209513 (3d Cir. Mar. 21, 2024); *Pub. Pension Fund Grp. v. KV Pharm. Co.*, 705 F. Supp. 2d 1088, 1106 (E.D. Mo. 2010) (scheme allegations that defendants “employed devices, schemes and artifices to defraud . . . and engaged in acts, practices, and a course of conduct” were conclusory (cleaned up)), *aff’d in part, rev’d in part and remanded*, 679 F.3d 972 (8th Cir. 2012).

The Court thus declines to dismiss Plaintiff’s scheme claim as duplicative of the misrepresentation claim.

C. The Court need not narrow (or broaden) the scheme claim at this time.

Last are Plaintiff’s motion for clarification and Defendants’ argument related to the scope of the claim. The dispute centers on whether the Court limited the scheme claim solely to the *Bloomberg Law* misrepresentation. Plaintiff argues that the scheme claim isn’t so limited because a scheme claim doesn’t require a misrepresentation or omission. ECF 95, p. 12. Defendants, meanwhile, argue that the scheme claim is limited to the *Bloomberg Law* misrepresentation; by way of example, Defendants note that reliance requires communication of the underlying deceptive acts to the public, and the Court struck all but the *Bloomberg Law* misrepresentation. ECF 106, pp. 22-24.

After careful consideration, the Court holds that there is no need to narrow the scheme claim to the *Bloomberg Law* misrepresentation (or affirmatively broaden it),

for three reasons.

First, to the extent that the dispute is really about the scope of discovery, discovery will be the same either way—the *Bloomberg Law* misrepresentation refers to circumvention of data and quality control systems, which captures (and therefore makes discoverable) the deceptive or fraudulent conduct alleged as part of the scheme claim.

Second, whether the Court limits the scheme claim has no bearing on the success of Defendants’ motion for judgment on the pleadings. The Court is rejecting Defendants’ loss-causation argument related to the misrepresentation claim. Meaning that, even if the scheme claim were limited to the *Bloomberg Law* misrepresentation, Plaintiff has adequately alleged loss causation for at least that statement.

Third, the Court finds that it would benefit from a developed record. Plaintiff is right that a scheme claim is not limited to actionable statements. *Stoneridge Inv. Partners, LLC*, 552 U.S. at 158 (no “specific oral or written statement” required). But Defendants are also right that, at least with respect to the *Basic* presumption of reliance, the scheme must have been communicated in some manner to the market. *In re DVI*, 639 F.3d at 649 (“[A] plaintiff cannot invoke the fraud-on-the-market presumption of reliance in a private action under Rule 10b–5(a) and (c) unless the deceptive conduct has been publicly disclosed and attributed to the actor.”). Discovery is likely to broaden or narrow the scope of communications pertaining to the scheme, and so this issue is better resolved after discovery and potentially at summary judgment.

The Court thus declines, for now, to fix the boundary of the scheme claim.

CONCLUSION

For these reasons, the Court will deny Defendants' motion for judgment on the pleadings (ECF 105) and Plaintiff's motion for clarification (ECF 95). Separate orders follow.

Dated: July 8th, 2025

BY THE COURT:

/s/ J. Nicholas Ranjan

United States District Judge