IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

DR. WILLIAM TOMASZEWSKI, Individually and on Behalf of All Others Similarly Situated, *Plaintiffs,* **v. TREVENA, INC., MAXINE GOWEN, and DAVID SOERGEL,** *Defendants.*	**CIVIL ACTION NO. 18-4378**

MEMORANDUM OPINION

Rufe, J. **August 28, 2020**

Plaintiffs brought a federal securities class action on behalf of investors against Trevena, Inc., and its former executives Maxine Gowen and David Soergel, for violations of §§ 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended by the Private Securities Litigation Reform Act of 1995 ("PSLRA"), and Rule 10b-5 promulgated thereunder.[1] This litigation stems from Plaintiffs' allegations that between May 2, 2016 and October 9, 2018 (the "class period"), Defendants materially misrepresented and omitted to disclose material facts about Trevena's interactions with the Food and Drug Administration ("FDA") concerning its drug candidate oliceridine. Defendants have moved to dismiss the Complaint. Plaintiffs oppose Defendants' Motions to Dismiss, and have moved to strike certain exhibits that Defendants' motions rely on. For the reasons that follow, Plaintiffs' Motion to Strike will be granted, Soergel's Motion to Dismiss will be granted in part and denied in part, and Trevena and Gowen's Motion to Dismiss will be denied.

[1] First Consolidated and Amended Class Action Complaint for Violations of the Federal Securities Laws [Doc. No. 52] at 1, 6 ("Complaint").

I. BACKGROUND[2]

Defendant Trevena is a biopharmaceutical company. From the start of the class period, Defendant Maxine Gowen was the Chief Executive Officer of Trevena until she announced her resignation on April 4, 2018, effective October 1, 2018, and Defendant David Soergel was the Chief Medical Officer until he announced his resignation in July 2017. During the class period, Trevena's leading drug candidate was oliceridine, which Trevena promoted as a potential alternative to morphine.

In an August 31, 2015 press release, Gowen touted the positive data from the Phase 2 studies of oliceridine and expressed that Phase 3 studies would begin in early 2016.[3] On January 19, 2016, Trevena issued a press release noting that its "End-of-Phase 2 meeting with the FDA" was "scheduled for later this quarter" and Gowen stated that "we also look forward to discussing the oliceridine Phase 3 program with the FDA later this quarter and remain on track to file a [New Drug Application] for oliceridine in the second half of 2017."[4] Believing that the FDA would agree with their proposals for the Phase 3 studies, and needing to raise significant funds to keep Trevena afloat, Defendants decided to "initiate much of the preparatory work for [the] pivotal efficacy studies ahead of the meeting," even though they recognized that proceeding pre-

[2] The Background is taken from the Complaint and, at this stage of the proceedings, is presumed true.

[3] Phase 2 studies are "controlled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks associated with the drug. Phase 2 studies are typically well controlled, closely monitored, and conducted in a relatively small number of patients, usually involving no more than several hundred subjects." 21 C.F.R. § 312.21. "Phase 3 studies are expanded controlled and uncontrolled trials. They are performed after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling. Phase 3 studies usually include from several hundred to several thousand subjects." *Id.*

[4] Complaint at 8. "The purpose of an end-of-phase 2 meeting is to determine the safety of proceeding to Phase 3, to evaluate the Phase 3 plan and protocols and the adequacy of current studies and plans to assess pediatric safety and effectiveness, and to identify any additional information necessary to support a marketing application for the uses under investigation." 21 C.F.R. § 312.47.

FDA approval was a "risk" because changing course in response to FDA feedback would waste the time and money that went into the preparatory work.[5]

Defendants' gamble did not pay off. On March 3, 2016, the FDA issued private written advice to Trevena asking it to "submit amendments to modify all protocols for ongoing clinical trials" to include certain safety assessments.[6] On March 29, 2016, Trevena attended the End-of-Phase 2 meeting with the FDA, and Plaintiffs allege that the FDA expressed serious disagreement with Trevena's proposed Phase 3 plan:

> FDA did not agree with the proposed dosing in the Phase 3 studies. The Sponsor proposed dosing up to 100 mg daily (including a 0.75 mg every 1 hour as needed clinician administered dose), but had only studied maximum daily doses of 36.8 mg. Further, the Sponsor did not have adequate non- clinical support for the proposed doses.
>
> FDA did not agree with the proposed primary endpoint, as it was unclear how a 30% improvement from baseline based on SPID correlates to an improvement in pain intensity scores on the NRS in the proposed setting of acute postoperative pain and if that change is clinically relevant.
>
> FDA did not agree with the proposed non-inferiority (NI) margin for comparing morphine to oliceridine.
>
> FDA noted that the safety database must include at least 350 patients exposed to the highest intended dose for the longest expected duration of use. It was noted that the safety database requirements might change if safety signals arise during development that require further evaluation.[7]
>
> Nevertheless, Defendants decided to proceed as planned with the Phase 3 studies.

Defendants also decided to publicly express to investors that the End-of-Phase 2 meeting with the FDA was a success without disclosing the FDA's substantial disagreements with its Phase 3 plan. For example, on May 2, 2016, Trevena issued a press release titled "Trevena Announces

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[5] Complaint at 23.

[6] *Id.* at 8–9.

[7] *Id.* at 12.

Successful End-of-Phase 2 Meeting with FDA and Outlines Phase 3 Program for Oliceridine," which stated that the "company has reached general agreement with the FDA on key elements of the Phase 3 program to support a New Drug Application (NDA) for oliceridine."[8] Most of the lengthy Complaint is based on various public statements by Defendants that touted a successful End-of-Phase 2 meeting with the FDA but failed to disclose the FDA's criticism of the proposed studies and trials.

The Complaint is also based on alleged misrepresentations by Defendants following a November 8, 2016 confidential meeting held between Trevena and the FDA. According to Plaintiffs, the "FDA did not agree with Trevena's proposal to evaluate the respiratory safety of oliceridine as compared to morphine . . ."[9] Once again, Plaintiffs allege that Defendants represented to investors that the meeting was successful and failed to disclose the FDA's criticism. On May 5, 2017, Trevena had another private meeting with the FDA, at which the FDA reiterated many of its earlier concerns. Nevertheless, Plaintiffs allege that Defendants continued to make misleading statements about oliceridine, the Phase 3 trials, and the prospects for approval.

In November 2017, Trevena submitted its NDA for oliceridine to the FDA. On May 3, 2018, Trevena issued a press release announcing that "[w]e continue to have an ongoing productive dialogue with the FDA as they review our oliceridine NDA, and look forward to an advisory committee meeting later this year and potential approval in November."[10]

On October 9, 2018, the FDA's previously-private disagreements with Trevena finally came to light. The FDA's Anesthetic and Analgesic Drug Products Advisory Committee publicly

[8] *Id.* at 12–13.

[9] *Id.* at 32.

[10] *Id.* at 50.

issued a Briefing Book in advance of its scheduled October 11, 2018 meeting, at which the Committee would vote on its non-binding recommendation concerning the FDA's consideration of oliceridine. In addition to summarizing the meeting minutes from the FDA's prior meetings with Trevena, Plaintiffs allege that the Briefing Book demonstrated that Trevena failed to address the issues raised by the FDA throughout the review process. For example, the Briefing Book explained that while the "FDA sent an advice letter/information request to the Applicant on 3/3/16, indicating that the Applicant should incorporate safety ECG monitoring at baseline . . . [i]n the Applicant's Phase 3 studies, only limited ECG monitoring was obtained . . . and the limited ECG monitoring data obtained in Phase 3 do not appear to be adequate to evaluate the QT effects of oliceridine."[11] Similarly, the Briefing Book noted that "the Applicant was told at the End-of-Phase 2 meeting and the pre-NDA meeting that they would need at least 350 patients exposed to the highest intended doses for the longest expected duration of use" but that "[t]he data are skewed, with most patients receiving doses less than 75 mg."[12] The Briefing Book also reiterated the FDA's prior disagreement with Trevena's proposed primary endpoint and proposed non-inferiority margin for comparing morphine to oliceridine, and explained that the FDA therefore could not determine that oliceridine was safer than morphine.

Upon publication of the Briefing Book, Trevena's stock plummeted 64% in one day. Two days later, on the day of the scheduled Committee meeting, Trevena filed with the SEC a Form 8-K to "clarify and further expand upon the interactions between Trevena and the [FDA] with respect to the primary endpoint for the two pivotal Phase 3 studies, APOLLO-1 and APOLLO-2, conducted by the Company with respect to oliceridine."[13] In that filing, Trevena stated that prior

[11] *Id.* at 55.

[12] *Id.* at 56.

[13] *Id.* at 60.

to the End-of-Phase 2 meeting, the FDA had indicated that "it did not agree with the proposed primary efficacy endpoint for the APOLLO-1 and APOLLO-2 studies."[14] Later that day, Trevena announced that the Committee vote was "8 against, and 7 in favor of, the approval of oliceridine."[15] The trading of Trevena stock was halted, but when trading resumed the next day, the stock dropped another 7%. On November 2, 2018, Trevena disclosed that the FDA had formally rejected its NDA for oliceridine. Although the FDA's letter remains confidential, Trevena stated that two of the reasons for rejection were that Trevena's safety database was not adequate for the proposed dosing and that additional clinical data was required—both issues raised by the FDA prior to the Phase 3 trials.

Several proposed class action lawsuits were filed in this Court against Trevena asserting violations of Sections 10(b) and 20(a) of the Exchange Act, and Rule 10b-5. The Court consolidated the various actions,[16] and appointed the Trevena Group, consisting of Albert Koch, Whittier Pierce, Christopher Beyers, Kevin Walsh, and Peter Palmer, as lead plaintiff for the proposed class.[17] Plaintiffs filed a First Consolidated and Amended Class Action Complaint. Trevena and Gowen together moved to dismiss the Complaint, and included as exhibits the confidential minutes from the meetings between Trevena and the FDA, which the Court allowed to be filed under seal. Soergel filed a separate motion to dismiss, joining Trevena and Gowen's motion and also asserting grounds to dismiss particular to him. Plaintiffs oppose Defendants' motions on the merits, and have also moved to strike the confidential communications between the FDA and Trevena.

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[14] *Id.*

[15] *Id.* at 61.

[16] Doc. No. 18.

[17] Doc. No. 47.

II. STANDARD OF REVIEW

"[F]aced with a Rule 12(b)(6) motion to dismiss a § 10(b) action, courts must, as with any motion to dismiss for failure to plead a claim on which relief can be granted, accept all factual allegations in the complaint as true."[18] Similarly, "courts must consider the complaint in its entirety, as well as other sources courts ordinarily examine when ruling on Rule 12(b)(6) motions to dismiss, in particular, documents incorporated into the complaint by reference, and matters of which a court may take judicial notice."[19] However, "[b]ecause this is a securities fraud case, it is not enough that, 'under any reasonable reading of the complaint, plaintiff[s] may be entitled to relief.'"[20] "Instead, [plaintiffs] must satisfy the heightened pleading rules codified in the [Private Securities Litigation Reform Act of 1995]" ("PLSRA").[21]

"As a check against abusive litigation by private parties" in securities fraud actions,[22] Congress included "two distinct pleading requirements [in the PLSRA], both of which must be met in order for a complaint to survive a motion to dismiss."[23] The complaint must "specify each allegedly misleading statement, why the statement was misleading, and, if an allegation is made on information and belief, all facts supporting that belief with particularity."[24] Essentially, this standard "requires plaintiffs to plead the who, what, when, where and how: the first paragraph of

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[18] *Institutional Inv'rs Grp. v. Avaya, Inc.*, 564 F.3d 242, 252 (3d Cir. 2009) (quoting *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007)).

[19] *Tellabs*, 551 U.S. at 322 (citation omitted).

[20] *Frater v. Hemispherx Biopharma, Inc.*, 996 F. Supp. 2d 335, 345 (E.D. Pa. 2014) (citing *Phillips v. County of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008)).

[21] *Avaya*, 564 F.3d at 252.

[22] *Tellabs*, 551 U.S. at 313.

[23] *Avaya*, 564 F.3d at 252.

[24] *Id.* at 252–53 (quoting *Winer Family Tr. v. Queen*, 503 F.3d 319, 326 (3d Cir. 2007)).

any newspaper story."[25] The complaint must also, "with respect to each act or omission alleged . . . state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind."[26] Significantly, under the PSLRA's "exacting" standard for pleading scienter, "a complaint will survive . . . only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged."[27] Therefore, the inquiry is "whether *all* of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard."[28]

III. DISCUSSION

Section 10(b) of the Exchange Act makes it unlawful to "use or employ, in connection with the purchase or sale of any security registered on a national securities exchange . . . any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the Commission may prescribe . . ."[29] "Rule 10b-5, which was created under Section 10(b), makes it unlawful '[t]o make any untrue statement of 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.'"[30] To state a claim that Defendants made material misrepresentations or omissions in violation of § 10(b) and Rule 10b–5, Plaintiffs must establish:

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[25] *Id.* at 253 (quoting *In re Advanta Corp. Sec. Litig.*, 180 F.3d 525, 534 (3d Cir. 1999)). When allegations are made on information and belief, the complaint must also "describe the sources of information with particularity, providing the who, what, when, where and how of the sources, as well as the who, what, when, where and how of the information those sources convey." *Id.*

[26] *Id.* (citation omitted).

[27] *Tellabs*, 551 U.S. at 324.

[28] *Id.* at 323 (citations omitted).

[29] 15 U.S.C. § 78j(b).

[30] *Pelletier v. Endo Int'l PLC*, No. 17-5114, 2020 WL 759410, at *8 (E.D. Pa. Feb. 14, 2020) (quoting 17 C.F.R. § 240.10b-5(b)).

"(1) a material misrepresentation or omission by the defendant[s]; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation."[31]

Section 20(a) of the Exchange Act provides that "[e]very person who, directly or indirectly, controls any person liable [for a Section 10(b) violation] 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."[32]

Because Trevena and Gowen's Motion to Dismiss relies extensively on documents that Plaintiffs argue cannot be considered at this stage (some of Soergel's motion also relies on these documents), the Court will begin by analyzing Plaintiffs' Motion to Strike.

A. Plaintiffs' Motion to Strike

"To decide a motion to dismiss, courts generally consider only the allegations contained in the complaint, exhibits attached to the complaint and matters of public record."[33] "However, an exception to the general rule is that a 'document *integral to or explicitly relied* upon in the complaint' may be considered 'without converting the motion [to dismiss] into one for summary judgment.'"[34] "[W]hat is critical is whether the claims in the complaint are 'based' on an extrinsic document and not merely whether the extrinsic document was explicitly cited."[35]

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[31] *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 37–38 (2011) (quoting *Stoneridge Investment Partners, LLC v. Scientific–Atlanta, Inc.*, 552 U.S. 148, 157 (2008)).

[32] 15 U.S.C. § 78t(b).

[33] *Pension Ben. Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1196 (3d Cir. 1993) (citations omitted).

[34] *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997) (quoting *Shaw v. Digital Equip. Corp.*, 82 F.3d 1194, 1220 (1st Cir. 1996)). Moreover, the document must be "undisputedly authentic." *Pension*, 998 F.2d at 1196 (citations omitted).

[35] *In re Burlington*, 114 F.3d at 1426 (citations omitted).

"[T]he justification for the integral documents exception is that it is not unfair to hold a plaintiff accountable for the contents of documents it must have used in framing its complaint, nor should a plaintiff be able to evade accountability for such documents simply by not attaching them to his complaint."[36] In other words, "[w]hat the rule seeks to prevent is the situation in which a plaintiff is able to maintain a claim of fraud by extracting an isolated statement from a document and placing it in the complaint, even though if the statement were examined in the full context of the document, it would be clear that the statement was not fraudulent."[37]

Trevena and Gowen's Motion to Dismiss relies heavily on FDA meeting minutes prepared in April and December 2016 that summarized the March and November meetings between the FDA and Trevena (Exhibits A and B) and, to a lesser degree, on a May 5, 2017 FDA Advice/Information Request (Exhibit C). Defendants argue that these exhibits are properly before the Court because they were incorporated by reference into Plaintiffs' Complaint.[38] According to Defendants, "it is beyond dispute that Plaintiffs made scores of references to the April 28, 2016 minutes or to the meeting memorialized in the minutes" and "[i]t is similarly beyond dispute that Plaintiffs' claims depend on the content of the minutes and the FDA's statements at the meeting."[39] Likewise, Defendants argue that "Plaintiffs refer to the November 8, 2016 meeting or the December 19, 2016 minutes at least 15 times in the Complaint[,] . . . Plaintiffs set out long paragraphs of block text in which they purport to quote or paraphrase the December 2016 minutes[, and] . . . Plaintiffs rely on the purported contents of the minutes or underlying meeting to allege fraud, claiming that comments the FDA made at the meeting or

[36] *Schmidt v. Skolas*, 770 F.3d 241, 250 (3d Cir. 2014) (citing *In re Burlington*, 114 F.3d at 1426).

[37] *In re Burlington*, 114 F.3d at 1426 (citing *Shaw*, 82 F.3d at 1220).

[38] Defendants Trevena, Inc. and Maxine Gowen's Motion to Dismiss and Mem. In Supp. [Doc. No. 59] at 2; Defendant David Soergel's Motion to Dismiss [Doc. No. 79] at 9.

[39] Defendants Trevena, Inc. and Maxine Gowen's Opp. to Pl. Motion to Strike [Doc. No. 71] at 7.

reiterated in the minutes show the falsity of Trevena's challenged statements."[40] Finally, Defendants assert that Plaintiffs "cite" the FDA Advice/Information Request and "rely on its purported contents in claiming that Trevena's challenged statements were false or misleading."[41]

However, Defendants have misidentified the FDA documents that the Complaint relies on. Although the Complaint repeatedly refers to the meeting minutes and the request, Plaintiffs did not, and in fact could not, rely on those documents, because they were never disclosed to the public.[42] Defendants acknowledged that "Exhibits A through C are confidential communications between the FDA and Trevena" when requesting that the exhibits be filed under seal.[43] Because Plaintiffs did not have access to the disputed documents until Defendants attached them to the motion to dismiss, the documents could not have been integral to or explicitly relied upon in the Complaint.[44]

Instead, a careful review of the Complaint demonstrates that Plaintiffs' references to the FDA communications are derived from the publicly available Briefing Book issued by the FDA in 2018.[45] Defendants make much ado about paragraphs of block text in the Complaint which, Defendants argue, are based on the purported contents of the disputed documents.[46] However,

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[40] *Id.* at 8.

[41] *Id.*

[42] *See Schmidt*, 770 F.3d at 250 (reversing a district court that considered publicly available evidence attached to a motion to dismiss which the plaintiff claimed he did not see when he drafted his complaint).

[43] Defendants Trevena, Inc. and Maxine Gowen's Motion to Seal [Doc. No. 58] at 2, 6; *see also* Plaintiffs' Mem. In Supp. of Motion to Strike [Doc. No. 66-1] at 5.

[44] Plaintiffs also argue that the exhibits are not properly authenticated. *See* Plaintiffs' Mem. In Supp. of Motion to Strike [Doc. No. 66-1] at 9. However, at this stage of the proceedings, the Court will accept Defendants' counsel's sworn declaration regarding the authenticity of the exhibits. *See* Decl. of Charlotte K. Newell in Supp. of Mot. to Dismiss and Mem. in Supp. [Doc. No. 59-16] at 1–2.

[45] Ex. D, Defendants Trevena, Inc. and Maxine Gowen's Motion to Dismiss and Mem. In Supp. [Doc. No. 59] ("Briefing Book").

[46] Defendants Trevena, Inc. and Maxine Gowen's Opp. to Pl. Motion to Strike [Doc. No. 71] at 8; Defendants Trevena, Inc. and Maxine Gowen's Sur-Reply in Further Opp. to Pl.'s Motion to Strike [Doc. No. 78] at 5.

each quotation in the Complaint that references the disputed documents is a verbatim quotation[47] from the "Points of discussion or Agency recommendations" provided in the Briefing Book's section on "Key Regulatory Interactions."[48] Similarly, a careful review of the Complaint demonstrates that every reference to confidential FDA communications with Trevena comes from the Briefing Book, not the disputed documents.[49] Because "[t]he mere fact that the documents are referenced or quoted in . . . the [] Complaint does not render the exhibits themselves appropriate for consideration on a motion to dismiss,"[50] it is the Briefing Book that is incorporated by reference in the Complaint, not the underlying documents.[51]

The purpose of the integral documents exception is to avoid the situation where a plaintiff "selected only portions of documents that support their claims, while omitting portions of those very documents that weaken—or doom—their claims."[52] That is not what Plaintiffs did here; they did not have access to the confidential FDA communications, and instead their Complaint relies on the Briefing Book for support. It is Defendants who seek to submit "document[s that]

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[47] *Compare* Complaint at 9, *with* Briefing Book at 12; *Compare* Complaint at 9–10, 12, *with* Briefing Book at 12; *Compare* Complaint at 32–33, *with* Briefing Book at 13; *Compare* Complaint at 43–44, *with* Briefing Book at 13; *see also* Defendants Trevena, Inc. and Maxine Gowen's Motion to Dismiss and Mem. In Supp. [Doc. No. 59] at 10 ("Plaintiffs' claims in this case are based almost entirely on the three points of disagreement registered in the Preliminary Comments section of the April 28, 2016 minutes and repeated in the Briefing Book.").

[48] Briefing Book at 11–14.

[49] For example, Defendants cite to ¶ 60 of the Complaint which states that a statement by Gowen "is directly contradicted by the FDA's minutes from that Phase 2 meeting, as described in ¶¶ 41, 47" for the proposition that the Complaint is based on the disputed documents. Defendants Trevena, Inc. and Maxine Gowen's Sur-Reply in Further Opp. to Pl.'s Motion to Strike [Doc. No. 78] at 5. However, ¶ 41 is a quotation taken from the Briefing Book's description of the minutes, and ¶ 47 relates back ¶ 41 and other paragraphs that reference the Briefing Book.

[50] *Hall v. Johnson & Johnson*, No. 18-1833, 2019 WL 7207491, at *11 (D.N.J. Dec. 27, 2019) (citing *In re Burlington*, 114 F.3d at 1426).

[51] *See Global Network Commc'ns, Inc. v. City of New York*, 458 F.3d 150, 156–57 (2d Cir. 2006) (holding that a complaint's reference to guilty pleas did not incorporate the testimony proffered in exchange for the pleas).

[52] *Khoja v. Orexigen Therapeutics, Inc.*, 899 F.3d 988, 1002 (9th Cir. 2018), *cert. denied sub nom. Hagan v. Khoja*, 139 S. Ct. 2615 (2019) (citations omitted).

merely create[] a defense to the well-pled allegations in the complaint."[53] "Although the incorporation-by-reference doctrine is designed to prevent artful pleading by plaintiffs, the doctrine is not a tool for defendants to short-circuit the resolution of a well-pleaded claim."[54]

The Ninth Circuit recently explained that there is "a concerning pattern in securities cases" where defendants "exploit[]" the incorporation by reference doctrine to "improperly . . . defeat what would otherwise constitute adequately stated claims at the pleading stage."[55] Because there is "a heightened pleading standard, and the defendants possess materials to which the plaintiffs do not yet have access . . . the unscrupulous use of extrinsic documents to resolve competing theories against the complaint risks premature dismissals of plausible claims that may turn out to be valid after discovery."[56] Because "[o]nly in the clearest of cases should a district court reach outside the pleadings for facts necessary to resolve a case at that point,"[57] the Court will not deny Plaintiffs the opportunity for discovery to respond to Defendants' "new version of the facts" based on these documents.[58] The motion to strike will be granted.

Without these documents, Trevena and Gowen's Motion to Dismiss must be denied in its entirety because, after careful consideration, the Court has determined that the stricken documents are so intertwined with and integral to the arguments raised in the motion that it is not

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[53] *Id.*

[54] *Id.* at 1003.

[55] *Id.* at 998.

[56] *Id.* (citations omitted).

[57] *Victaulic Co. v. Tieman*, 499 F.3d 227, 236 (3d Cir. 2007), *as amended* (Nov. 20, 2007).

[58] *Khoja*, 899 F.3d at 1002–03. The Court also notes that Exhibit A only includes selected portions of the meeting minutes. Pages 13-17, 19-30, and all pages after 31 are excluded from the exhibit. This selective submission bolsters the inference that Defendants are seeking to use the incorporation by reference doctrine to create a defense to Plaintiffs' claims without allowing Plaintiffs to obtain discovery. *See Bank of New York Mellon Tr. Co. v. Morgan Stanley Mortg. Capital, Inc.*, No. 11-505, 2011 WL 2610661, at *3 (S.D.N.Y. June 27, 2011) (quoting *Rothman v. Gregor*, 220 F.3d 81, 88–89 (2d Cir. 2000) ("In deciding a motion to dismiss, this Court may consider the full text of documents that are quoted in or attached to the complaint, or documents that the plaintiff either possessed or knew about and relied upon in bringing the suit.")).

possible to excise the documents or parse the proper arguments from the improper.[59] In contrast, although some of Soergel's motion relies on the stricken exhibits, the Court is able to consider his arguments that are independent of the documents: 1) that Plaintiffs' § 10(b) claim should be dismissed on the grounds that Plaintiffs have not adequately alleged that he misrepresented the FDA's communications regarding the Phase 3 plan or that he acted with scienter; 2) that under § 10(b), he cannot be held liable for Gowen and Trevena's statements; and 3) that Plaintiffs have not established that he is a controlling person under § 20(a).

B. Plaintiffs' § 10(b) Claim Against Soergel

1. Soergel's alleged material misrepresentations

"[Section] 10(b) and Rule 10b-5(b) do not create an affirmative duty to disclose any and all material information."[60] The duty to disclose arises "when there is insider trading, a statute requiring disclosure, or an inaccurate, incomplete or misleading prior disclosure."[61] "Once a company has chosen to speak on an issue—even an issue it had no independent obligation to address—it cannot omit material facts related to that issue so as to make its disclosure misleading."[62] "To prevail on a § 10(b) claim, a plaintiff must show that the defendant made a statement that was '*misleading* as to a *material* fact.'"[63] "[T]his materiality requirement is satisfied when there is 'a substantial likelihood that the disclosure of the omitted fact would have

[59] Trevena and Gowen's 35-page Motion to Dismiss references the documents that the Court is unable to consider at this stage on pages 2-7, 10-11, 14-28, and 32-35.

[60] *Williams v. Globus Med., Inc.*, 869 F.3d 235, 241 (3d Cir. 2017) (quoting *Matrixx*, 563 U.S. at 44).

[61] *Id.* (quoting *Oran v. Stafford*, 226 F.3d 275, 285–86 (3d Cir. 2000)).

[62] *Id.* (citing *Kline v. First W. Gov't Sec., Inc.*, 24 F.3d 480, 490–91 (3d Cir. 1994)).

[63] *Matrixx*, 563 U.S. at 38 (quoting *Basic Inc. v. Levinson*, 485 U.S. 224, 238 (1988)).

been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available.'"[64]

i. Soergel's June 2016 and February 2017 Statements

In June 2016, after Soergel met with the FDA on March 29, 2016 and received a copy of the meeting minutes, he told investors that: "We expect the data from our Phase III pivotal efficacy studies in the first quarter of 2017 with an NDA submission in the second half of 2017. And hopefully, we can get this important new drug to patients quickly."[65] In February 2017, Soergel and Gowen held a conference call with investors during which Soergel explained that Trevena used a responder analysis to measure the primary endpoint because "it reflects the efficacy in the cleanest way."[66] Soergel also discussed the secondary endpoints "including respiratory safety compared to morphine and non-inferiority on efficacy compared to morphine."[67] Plaintiffs assert that these statements were materially misleading by omission because Soergel failed to disclose that the FDA disagreed both with the primary endpoint used in Trevena's Phase 3 studies and with the proposed non-inferiority margin for comparing morphine to oliceridine, and that, as a result, the NDA submission was going to be deficient.

Soergel argues that his omission of the FDA's disagreements is not actionable for three reasons: 1) the June 2016 statement was only about timing, which is a distinct subject from the FDA communications; 2) the NDA was submitted months after the challenged statements so Soergel could not have misled investors about the contents of the NDA; and 3) the Briefing Book

[64] *Id.* (quoting *Basic*, 485 U.S. at 231–32).

[65] Complaint at 28–29.

[66] *Id.* at 38.

[67] *Id.* at 39.

demonstrates that Defendants did, in fact, comply with the FDA's primary endpoint requirements.

Plaintiffs have adequately alleged a material misrepresentation by omission. First, Soergel's June 2016 statement implied that he expected the NDA to be submitted in 2017 and—by stating that he hoped "to get this important new drug to patients quickly"—that the NDA would be approved.[68] However, Soergel failed to disclose that the NDA would be deficient because, Plaintiffs allege, Trevena's studies were using endpoints already rejected by the FDA.[69] Second, at the time he made the statements, Soergel knew that the NDA would be deficient because he knew that Trevena's studies did not conform the primary or secondary endpoints to the FDA's requirements. Third, Trevena's NDA did not include the analysis of the primary endpoint required by the FDA; the FDA explained in the Briefing Book that the only primary efficacy analysis submitted by Trevena was the "primary efficacy analyses . . . based on a novel responder definition" that it disagreed with.[70] In response, the FDA—not Trevena—"conducted an analysis using SPIDs rather than the proposed responder definition."[71]

Soergel's decision to discuss the NDA and tout Trevena's choice of endpoints required him "to speak truthfully and completely on the subject to not mislead investors."[72] Taking Plaintiffs' allegations as true, however, Soergel made "affirmative statement[s] that painted a favorable picture without including the details that would have presented a complete and less

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[68] Complaint at 28–29.

[69] Soergel also asserts that his statement about the secondary endpoints was a distinct subject from the FDA communications and, therefore, he did not have a duty to disclose the FDA's disagreements. However, Soergel's decision to discuss the trial design without informing investors about the FDA's disagreements with the design made the disclosure misleading. *See Williams*, 869 F.3d at 241.

[70] Briefing Book at 37.

[71] *Id.*

[72] *In re Celgene Corp. Sec. Litig.*, No. 18-4772, 2019 WL 6909463, at *16 (D.N.J. Dec. 19, 2019).

favorable one."[73] Notwithstanding the FDA's serious disagreements with the Phase 3 studies, Soergel's statements would have caused a reasonable investor to believe that Soergel had no reason to expect that the NDA would not be approved. Therefore, the Complaint has alleged a claim that Soergel's failures to disclose the FDA's disagreements were material misrepresentations.

ii. Soergel's July 20, 2017 Statement

On July 20, 2017, Soergel attended an Analyst Day conference. During the Q&A portion of his presentation, an analyst asked: "just 1 final question related to commercial. It's a bit early yet – you haven't even submitted – but wondering your thoughts on how you see ultimately the labeled indication coming out? Do you see any kinds of particular restrictions?"[74] Soergel responded "our goal has been to have a label that looks like other opioids from the perspective of lack of a maximum dose, huge flexibility of administration and then language around titration. So take care of the patient's pain with as much drug as you need to and balance their side effects, in summary as a (inaudible). So that's been our goal and that's been what we've guided the development plan towards."[75]

At the End-of-Phase 2 meeting, the FDA informed Trevena that its safety database must include "at least 350 patients exposed to the highest intended dose for the longest expected duration of use."[76] Plaintiffs allege that although Trevena had proposed 100 mg of daily dosing at the End-of Phase 2 meeting, "during the review cycle," Trevena reduced the proposed maximum daily dose "to 40 mg daily to try to address the adequacy of the safety database and

[73] *SEB Inv. Mgmt. AB v. Endo Int'l, PLC*, 351 F. Supp. 3d 874, 900 (E.D. Pa. 2018).

[74] Complaint at 44.

[75] *Id.* at 44–45.

[76] *Id.* at 10.

nonclinical concerns regarding the adequacy to qualify the major metabolites."[77] According to Plaintiffs, Soergel's July 2017 statement was misleading because "despite Soergel suggesting there would be no labeling restrictions, oliceridine was not being measured at a maximum daily dose of 100 mg, only 40 mg" and therefore, "if approved, oliceridine would require a labeling restriction, and a patient would be unable to take 'as much drug' as they 'need[ed].'"'[78]

That review cycle, however, did not begin until Trevena submitted its NDA for oliceridine in November 2017—four months *after* Soergel's statement suggesting there would be no dosing limitation on the label.[79] Therefore, Trevena's amendments to the NDA during the review cycle do not demonstrate that Soergel knew, in July 2017, that the data would not support a label without any restrictions. In fact, as of July 2017, the safety database was substantially incomplete: Of the 768 patients in the trial, only 418 patients' data had been analyzed.[80] Thus, the only support for Plaintiffs' allegation that "[b]y the time of the July 20, 2017 statements, . . . Soergel knew, or recklessly disregarded, that the safety database did not meet the FDA's minimum requirements" is Plaintiffs' bare assertion.[81] Because conclusory allegations do not satisfy the PSLRA's heightened standards, Plaintiffs' cannot maintain a claim based on Soergel's July 20, 2017 statement.[82]

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[77] Briefing Book at 66; Complaint at 56.

[78] Plaintiffs' Opposition to Soergel's Motion to Dismiss [Doc. No. 80] at 6.

[79] *See* 21 C.F.R. § 314.100.

[80] Complaint at 48. The Court also notes that, as many of the patients in the trial received doses of over 100mg, there is no reason to believe that data available in July 2017 showed that, by the end of the trial, there would not be 350 patients who received a daily dose of 100 mg. *See* Briefing Book at 66.

[81] Complaint at 45.

[82] *See In re Burlington*, 114 F.3d at 1418); *Endo*, 2020 WL 759410, at *8; *City of Edinburgh Council v. Pfizer, Inc.*, 754 F.3d 159, 163 n.3 (3d Cir. 2014).

2. Scienter

To adequately plead a claim under § 10(b), a plaintiff must plead "the facts evidencing scienter, i.e., the defendant's intention 'to deceive, manipulate, or defraud.'"[83] "A complaint adequately pleads a strong inference of scienter 'only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged.'"[84] Importantly, "[t]he inference that the defendant acted with scienter need not be irrefutable, *i.e.*, of the 'smoking-gun' genre, or even the 'most plausible of competing inferences."[85] "Indeed, scienter may also be established if a Plaintiff sets forth facts that constitute circumstantial evidence of either reckless or conscious behavior."[86] "[I]n conducting the scienter analysis, courts must analyze the complaint holistically to determine whether its allegations, 'taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard.'"[87]

Accepting Plaintiffs' allegations as true,[88] the evidence supporting an inference that Soergel intended to deceive investors by failing to disclose the FDA's disagreements with its Phase 3 program is that: 1) Trevena was struggling to survive;[89] 2) oliceridine was Trevena's only viable drug candidate;[90] 3) before the End-of-Phase 2 meeting with the FDA, Defendants

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[83] *Rahman v. Kid Brands, Inc.*, 736 F.3d 237, 241–42 (3d Cir. 2013) (quoting *Tellabs*, 551 U.S. at 313).

[84] *In re Hertz Glob. Holdings Inc*, 905 F.3d 106, 114 (3d Cir. 2018) (quoting *Tellabs*, 551 U.S. at 324).

[85] *Tellabs*, 551 U.S. at 324 (citations omitted).

[86] *Teamsters Local 456 Pension Fund v. Universal Health Servs.*, No. 17-2817, 2020 WL 2063474, at *13 (E.D. Pa. Apr. 29, 2020)). However, allegations limited to defendants' knowledge of the misleading nature are not enough to establish scienter. *See GSC Partners CDO Fund v. Washington*, 368 F.3d 228, 239 (3d Cir. 2004). Rather, plaintiffs must also establish the "who, what, when, where and how" of the events at issue. *Id.* (citation omitted).

[87] *In re Hertz*, 905 F.3d at 114 (quoting *Tellabs*, 551 U.S. at 323).

[88] *Martin v. GNC Holdings, Inc.*, 757 F. App'x 151, 154 (3d Cir. 2018) (citing *Tellabs*, 551 U.S. at 322).

[89] Complaint at 51–52.

[90] *See id.* at 25.

took the risk of initiating the preparatory work for the Phase 3 studies which meant that changing course in reaction to the FDA's feedback would have cost time and money;[91] 4) Soergel attended the relevant FDA interactions, received the FDA minutes, and knew about the FDA's concerns;[92] and 5) Soergel made statements expressing that the FDA approved of the Phase 3 program without disclosing the FDA's serious disagreements.[93] Taken collectively, the facts alleged give rise to a cogent and compelling inference that, in response to a time and money crunch, Soergel (with the other defendants) took—and lost—a calculated gamble to initiate the preparatory work for the Phase 3 studies without FDA approval, and that when the FDA expressed disagreement, Soergel deceived investors in the hope that the FDA would end up agreeing with the data from the Phase 3 studies and approve oliceridine.[94]

Nonetheless, the Court must still "take into account plausible opposing inferences."[95] Soergel argues that a number of factors "undermine Plaintiffs' scienter allegations" including: 1) that Plaintiffs failed to identify any stock sales or financial motivation for him to deceive investors; 2) that there are no confidential witness allegations; 3) that Soergel lacked a motive to "perpetrate[] a fraud on the investors of a company he was leaving"; 4) that Trevena's continued investment in oliceridine demonstrates a belief that oliceridine would succeed; and 5) that the

[91] *See id.* at 23–24.

[92] *See id.* at 25.

[93] *See Aldridge v. A.T. Cross Corp.*, 284 F.3d 72, 83 (1st Cir. 2002) (citation omitted) ("[T]he fact that the defendants published statements when they knew facts suggesting the statements were inaccurate or misleadingly incomplete is classic evidence of scienter.").

[94] *See Endo*, 351 F. Supp. 3d at 906–07 (holding that a plaintiff sufficiently pled scienter where the plaintiff alleged that defendants recklessly disregarded facts they knew contradicted their public statements about a product that was a critical part of defendants' business).

[95] *Martin*, 757 F. App'x at 154 (quoting *Tellabs*, 551 U.S. at 323)

closely divided Advisory Committee vote shows that the FDA was extremely close to approving oliceridine, so Soergel's confidence was not misplaced.[96]

Taking these factors into account is not enough to refute the strong inference that Soergel had scienter to mislead investors. First, although the Third Circuit has held that "motive allegations" are not necessary to support an inference of scienter, Plaintiffs have alleged that Soergel was motivated by the need to raise funds to keep Trevena afloat.[97] Second, there is no requirement that plaintiffs in a securities fraud action support their allegations with information attributed to confidential witnesses.[98] Third, the allegations in the Complaint only establish that Soergel had plans to leave Trevena before making the final challenged statement (which the Court has determined was not a material misrepresentation). Finally, Plaintiffs do not allege that oliceridine had no path to approval; rather, they allege that Defendants deceived investors about the increased *risk* that it would not be approved.[99] While the Court agrees with Soergel that some of these factors support an inference that he subjectively, though incorrectly, believed oliceridine

[96] Defendant David Soergel's Motion to Dismiss [Doc. No. 79] at 13–14. With regard to the July 20, 2017 Analyst Day presentation, Soergel argues that the challenged statement was a response to the final question which indicates that it was not his intent to deceive investors. *See id.* However, the Court has already determined that this statement was not a material misrepresentation.

[97] *Avaya*, 564 F.3d at 277. The Court also notes that "[t]here is no evidence regarding the alleged lack of stock sales by the insiders before the Court. (Defendants just point out that Plaintiffs did not allege that such sales took place.)" *In re Amylin Pharm., Inc. Sec. Litig.*, No. 01-1455, 2003 WL 21500525, at *5 (S.D. Cal. May 1, 2003).

[98] *See In re Synchronoss Sec. Litig.*, 705 F. Supp. 2d 367, 400 (D.N.J. 2010).

[99] Soergel also argues that "Trevena's repeated warning to investors that approval could not be assured . . . undermines Plaintiff's scienter allegations." Defendant David Soergel's Motion to Dismiss [Doc. No. 79] at 14. No warnings, though, are alleged in the Complaint. Soergel's claim appears to be a reference to a Form 10-K (which Plaintiffs concede is subject to judicial notice), which was attached to Trevena and Gowen's Motion to Dismiss, and included a number of standard risk disclosures about the drug approval process. *See* Ex. L., Defendants Trevena, Inc. and Maxine Gowen's Motion to Dismiss and Mem. In Supp. [Doc. No. 59-12]. However, the boilerplate disclaimers included in the "risk factors" section of the Form 10-K do not evince a lack of scienter when the particularized risk that the FDA disagreed with the design of the Phase 3 studies was not disclosed. *Cf. Avaya*, 564 F.3d at 256 (quoting *GSC Partners CDO Fund v. Washington*, 368 F.3d 228, 243 n.3 (3d Cir. 2004) ("[A] vague or blanket (boilerplate) disclaimer which merely warns the reader that the investment has risks will ordinarily be inadequate to prevent misinformation. To suffice, the cautionary statements must be substantive and tailored to the specific future projections, estimates or opinions in the prospectus which the plaintiffs challenge.").

would eventually be approved despite some bumps in the road, they do not provide a nonculpable explanation for Soergel's incomplete statements omitting the FDA's disagreements with the Phase 3 program and the accompanying increased risk that oliceridine would not be approved.[100] Because "a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged," the Court concludes that Plaintiffs have adequately alleged scienter.[101] Therefore, Soergel's motion will be denied as to the June 2016 and February 2017 statements.

3. Soergel's liability for Gowen and Trevena's statements

Plaintiffs also argue that Soergel can be held primarily liable under Rule 10b-5—which makes it unlawful for "any person, directly or indirectly, . . . [t]o make any untrue statement of a material fact" in connection with the purchase or sale of securities[102]—for Gowen and Trevena's allegedly false and misleading statements.[103] Soergel argues that he cannot be held liable for these statements because the Supreme Court held in *Janus Capital Group Inc. v. First Derivative Traders* that only the maker of a misstatement can be sued in a private action, and that "the

[100] *See Amylin*, 2003 WL 21500525, at *5 ("Based on the facts alleged by Plaintiffs, the most plausible inference to be drawn is that Amylin knew that there may be a problem with the methodology used in conjunction with the Phase III trials but took the calculated risk of continuing the trials and application process as originally planned. There is nothing unlawful about taking a calculated risk. However, if, as Plaintiffs allege, Defendants misled Plaintiffs about such risk by making assurances regarding the completeness of the data and the likelihood of FDA approval, Defendants may be held liable."). For the same reasons, Defendants' recently submitted notice of the FDA's approval of oliceridine on August 7, 2020—based on "receipt of [Trevena's] amendment dated February 7, 2020, which constituted a complete response to [the FDA's] November 2, 2018, action letter"—is irrelevant. Attachment 1, Defendants' Notice of Regulatory Approval [Doc. No. 89-1] at 1. Even assuming that the August 2020 document is admissible on a motion to dismiss, the eventual approval was based on an NDA amended 486 days after the end of the class period; therefore, the approval has no bearing on Plaintiffs' allegation that during the class period Defendants deceived investors. Plaintiffs allege that Defendants made material misrepresentations about the FDA's communications concerning the 2016-17 Phase 3 studies, which caused Plaintiffs economic loss when the FDA rejected the NDA in October 2018. Whether Trevena eventually obtained approval is not relevant at this stage.

[101] *Tellabs*, 551 U.S. at 324.

[102] *Janus Capital Grp., Inc. v. First Derivative Traders*, 564 U.S. 135, 141 (2011) (quoting 17 CFR § 240.10b–5(b)).

[103] Plaintiffs' Opposition to Soergel's Motion to Dismiss [Doc. No. 80] at 1 n.6; Plaintiffs' Sur-Reply in Response to Soergel's Reply in Support of Motion to Dismiss [Doc. No. 82] at 3–4.

maker of a statement is the person or entity with ultimate authority over the statement including its content and whether and how to communicate it."[104]

The Court agrees that *Janus* shields Soergel from liability for Gowen's statements; as CEO, there can be no dispute that she had "ultimate authority" over her statements.[105] However, at this stage of the proceedings, *Janus* cannot prevent Soergel from being held liable for Trevena's statements. Because "*Janus* does not alter the well-established rule that 'a corporation can act only through its employees and agents,"' *Janus* does not "restrict liability for Rule 10b-5 claims against corporate officers to instances in which a plaintiff can plead, and ultimately prove, that those officers—as opposed to the corporation itself—had 'ultimate authority' over the statement."[106] At this stage, the Complaint contains sufficient allegations to conclude that, "pursuant to his responsibility and authority to act as an agent" of Trevena, Soergel had "ultimate authority" over Trevena's alleged misrepresentations.[107]

C. Plaintiffs' Section 20(a) Claim Against Soergel

Section 20(a) of the Exchange Act "opens the possibility of making 'controlling persons jointly and severally liable with the controlled person' for violations of the Exchange Act."[108] "The three elements of a § 20(a), or 'control person' claim, are as follows: (1) the defendant

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[104] 564 U.S. at 142; *see also City of Cambridge Ret. Sys. v. Altisource Asset Mgmt. Corp*, 908 F.3d 872, 881 (3d Cir. 2018).

[105] *Id.* at 142; *see also Ho v. Duoyuan Glob. Water, Inc*., 887 F. Supp. 2d 547, 572 n.13 (S.D.N.Y. 2012); *Pomeroy v. GreatBanc Tr. Co.*, No. 14-6162, 2014 WL 7177583, at *3 (N.D. Ill. Dec. 16, 2014).

[106] *In re Merck & Co., Inc. Sec., Derivative, & ERISA Litig.*, No. 05-1151, 2011 WL 3444199, at *25 (D.N.J. Aug. 8, 2011) (quoting *Suez Equity Investors, L.P. v. Toronto–Dominion Bank*, 250 F.3d 87, 101 (2d Cir. 2001)).

[107] *Universal Am. Corp. v. Partners Healthcare Sols. Holdings, L.P.*, 176 F. Supp. 3d 387, 394 (D. Del. 2016) (quoting *In re Merck*, 2011 WL 3444199, at *25); *see also In re Pfizer Inc. Sec. Litig*., No. 04-9866, 2012 WL 983548, at *4 (S.D.N.Y. Mar. 22, 2012) ("While statements in Pfizer's press releases were not explicitly attributed to the Individual Defendants, *Janus* recognized that attribution can be implicit from surrounding circumstances.") (cleaned up).

[108] *Belmont v. MB Inv. Partners, Inc.*, 708 F.3d 470, 484 (3d Cir. 2013) (quoting *In re Merck & Co., Inc. Sec. Litig.*, 432 F.3d 261, 275 (3d Cir. 2005)).

controlled another person or entity; (2) the controlled person or entity committed a primary violation of the securities laws; and (3) the defendant was a culpable participant in the fraud."[109] "[T]he heightened standard of the PSLRA requires that a claim under Section 20(a) state with particularity the circumstances of both the defendants' control of the primary violator, as well as of the defendants' culpability as controlling persons."[110]

Soergel argues that Plaintiffs have not sufficiently alleged that either Trevena or Gowen is primarily liable for securities violations or that "Dr. Soergel (Trevena's Chief Medical Officer) controlled Dr. Gowen (Trevena's CEO), who is the only other individual defendant alleged to have made a false or misleading statement, and who outranked Dr. Soergel."[111]

As previously discussed, the question of Trevena or Gowen's possible liability cannot be assessed because the arguments depend on stricken documents, and although, as Soergel argues, "there is no allegation" in the Complaint and "[i]ndeed it would have been an implausible allegation" that Soergel controlled Gowen,[112] viewing the evidence in the light most favorable to Plaintiffs, Soergel can be held liable as a controlling person of Trevena.[113] Therefore, Plaintiffs can proceed on their § 20(a) claim against Soergel.[114]

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[109] *Howard v. Arconic Inc.*, 395 F. Supp. 3d 516, 575 (W.D. Pa. 2019) (quoting *In re Suprema Specialties, Inc. Sec. Litig.*, 438 F.3d 256, 286 (3d Cir. 2006)).

[110] *Universal Am. Corp. v. Partners Healthcare Sols. Holdings, L.P.*, 176 F. Supp. 3d 387, 397 (D. Del. 2016) (citation omitted).

[111] Defendant David Soergel's Motion to Dismiss [Doc. No. 79] at 15.

[112] *In re SunEdison, Inc. Sec. Litig.*, 300 F. Supp. 3d 444, 497 (S.D.N.Y. 2018).

[113] *See In re Suprema Specialties*, 438 F.3d at 285–86 (quoting *In re Hayes Lemmerz Intern., Inc.,* 271 F. Supp. 2d 1007, 1022 n.11 (E.D. Mich. 2003) ("[I]f the complaint states a primary violation by the Company, even if the Company is not named in the complaint as a defendant, then a § 20 claim can stand if the individuals were controlling persons.")).

[114] Soergel does correctly assert that he cannot be held liable as a controlling person for any statements made after he left Trevena.

IV. CONCLUSION

For the foregoing reasons, Plaintiffs' Motion to Strike will be granted, Trevena and Gowen's Motion to Dismiss will be denied, and Soergel's Motion to Dismiss will be granted in part and denied in part. An order will be entered.