UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

CITY OF BIRMINGHAM RELIEF AND RETIREMENT SYSTEM; and OHIO CARPENTERS' PENSION FUND, Individually and On Behalf of All Others Similarly Situated,

Plaintiffs,

v.

ACADIA PHARMACEUTICALS, INC.; STEPHEN R. DAVIS; and SRDJAN (SERGE) R. STANKOVIC,

Defendants.

Case No. 3:21-cv-00762-WQH-NLS

ORDER

HAYES, Judge:

The matter before the Court is the Motion to Dismiss the FAC filed by Defendants Acadia Pharmaceuticals, Inc., Stephen R. Davis, and Srdjan (Serge) R. Stankovic. (ECF No. 53.)

I. PROCEDURAL BACKGROUND

On April 19, 2021, Denise Marechal initiated this action by filing a Class Action Complaint. (ECF No. 1.) On September 29, 2021, the Court issued an Order appointing City of Birmingham Relief and Retirement System ("Birmingham") as Lead Plaintiff. (ECF No. 38.)

On December 10, 2021, Birmingham and additional Plaintiff Ohio Carpenters' Pension Fund (collectively "Plaintiffs") filed an Amended Class Action Complaint (the "FAC"). (ECF No. 45.) The FAC alleges that Defendants violated federal securities laws by deceiving investors regarding the likelihood of Food and Drug Administration ("FDA") approval of a drug, which Defendant Acadia Pharmaceuticals, Inc. ("Acadia") developed, to artificially inflate the market price of Acadia securities.

On February 15, 2022, Defendants filed the Motion to Dismiss the FAC. (ECF No. 53.) On April 18, 2022, Plaintiffs filed a Response in opposition to the motion. (ECF No. 56.) On June 2, 2022, Defendants filed a Reply. (ECF No. 58.)

II. JUDICIAL NOTICE AND INCORPORATION-BY-REFERENCE

Defendants request that the Court take judicial notice and/or incorporate-by-reference 36 documents attached as exhibits to Defendants' Motion to Dismiss the FAC.[1] (ECF No. 53-5.) The exhibits include Acadia press releases and presentation transcripts, Defendants' SEC filings, and articles and reports.

Plaintiffs "do not contest that … documents which were extensively quoted in the [FAC] are judicially noticeable and/or incorporated by reference into the [FAC]." (ECF No. 57 at 2 n.1.) However, Plaintiffs contend that the following exhibits cannot be considered by the Court at this stage in the proceedings: Exhibits A, B, C, F, K, L, N, O, S, U, V, Y, AA, and DD (the "disputed exhibits").

"Generally, district courts may not consider material outside the pleadings when assessing the sufficiency of a complaint under Rule 12(b)(6) of the Federal Rules of Civil Procedure." *Khoja v. Orexigen Therapeutics, Inc.*, 899 F.3d 988, 998 (9th Cir. 2018). However, "[t]here are two exceptions to this rule: the incorporation-by-reference doctrine, and judicial notice under Federal Rule of Evidence 201." *Id.*

[1] Defendants further request that the Court take judicial notice and/or incorporate-by-reference three additional exhibits—two analyst reports and a record of Acadia's daily stock price. *See* ECF No. 58-2. This request is denied because it was raised for the first time in Defendants' Reply and Plaintiffs have not had an opportunity to respond to the request.

"[I]ncorporation-by-reference is a judicially created doctrine that treats certain documents as though they are part of the complaint itself." *Id.* at 1002. "The doctrine prevents plaintiffs from selecting only portions of documents that support their claims, while omitting portions of those very documents that weaken—or doom—their claims." *Id.*

None of the disputed exhibits are extensively referenced or quoted in the FAC. *See id.* (stating that incorporation-by-reference is proper if the plaintiff refers "extensively to the document"). The documents do not form the basis of Plaintiffs' claims. *See id.* (stating that incorporation-by-reference is proper if the document "forms the basis of the plaintiff's claim"). The overlap between the FAC's allegations and the content of these documents is not sufficient to support incorporation-by-reference. *See id.* at 1007 (denying a request for incorporation-by-reference because "[t]he Complaint only alleges facts that the press release happens to report"). Defendants' request for incorporation-by-reference of the disputed exhibits is denied.[2]

Judicial notice permits a court to notice an adjudicative fact if it is "not subject to reasonable dispute"—i.e. if it is "generally known," or "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b). A district court must clearly specify what fact or facts it judicially notices. *See Khoja*, 899 F.3d at 999. "Just because the document itself is susceptible to judicial notice does not mean that every assertion of fact within that document is judicially noticeable for its truth." *Id.*

Exhibit L is an article on breakthrough therapy designation published by the FDA. The Court takes judicial notice of this article and the factual assertions contained within it regarding when breakthrough therapy designation is granted by

[2] The Court grants Defendants' unopposed request for incorporation-by-reference of Exhibits D, E, G, H, I, J, K, P, Q, R, T, W, X, Z, BB, CC, GG, HH, II, and JJ because these exhibits were extensively referenced in the FAC.

the FDA. *See id.* at 1001 (stating that courts may take judicial notice of agency reports).

The other disputed exhibits are Acadia press releases, an Acadia presentation, SEC filings, and news articles and reports. The fact that Acadia issued these press releases, presentations, and filings, and that the information contained in the documents was available to the market is not subject to reasonable dispute. However, Defendants also cite several of these documents to demonstrate the truth of assertions of fact contained within the documents. *See, e.g.,* ECF No. 53-1 at 11 (citing Exhibit A, a press release, for the proposition that "Acadia developed pimavanserin, the first and still-only FDA-approved therapy for Parkinson's disease psychoses"); *id.* (citing Exhibit C, a news article, for the proposition that "[d]rug testing is inherently uncertain and only a small percentage of drugs ultimately gain FDA approval"). Judicial notice of the fact that Acadia issued these press releases, presentations, and filings, and that the information contained in the documents was available to the market is granted. *See Heliotrope Gen., Inc. v. Ford Motor Co.*, 189 F.3d 971, 981 (9th Cir. 1999) (taking judicial notice of the fact "that the market was aware of the information contained in news articles submitted by the defendants"). Judicial notice of these documents is otherwise denied.

III. ALLEGATIONS IN THE FAC

Acadia is a Delaware biopharmaceutical company with common stock that trades on the Nasdaq Global Selection Market under the ticker symbol "ACAD." (ECF No. 45 ¶ 22.) Defendant Davis "has served as Acadia's Chief Executive Officer and a member of [Acadia's] Board of Directors since September 2015." *Id.* ¶ 23. Defendant Stankovic served as "Acadia's Executive Vice President, Head of Research and Development, from November 2015 through November 2018" and "has served as Acadia's President and Head of Research and Development since November 2018." *Id.* ¶ 24. Davis and Stankovic "possessed the power and authority to control the contents of Acadia's SEC filings, press releases, and other market

communications" and had "access to material information available to them but not to the public." *Id.* ¶ 26.

In July 2011, Acadia initiated a Phase III medical study (the "-020 Study") to "evaluate[] the efficacy, tolerability and safety" of a drug called pimavanserin in patients with Parkinson's disease psychosis ("PDP"), a condition "associated with Parkinson's disease dementia." *Id.* ¶¶ 2, 45. "In November 2012, [Acadia] announced positive top-line results for the -020 Study." *Id.* ¶ 46. In April 2016, the FDA "approved pimavanserin for the treatment of hallucinations and delusions associated with [PDP]." *Id.* ¶ 31. The -020 Study was "the primary basis for the FDA's 2016 approval." *Id.* ¶ 47. Pimavanserin is Acadia's "most valuable drug" and "only commercial product to date." *Id.* ¶¶ 2, 32.

In November 2013, Acadia initiated a Phase II medical study (the "-019 Study") to "evaluate the efficacy and safety of pimavanserin as a treatment for patients with Alzheimer's disease psychosis ('ADP')." *Id.* ¶ 48. "In December 2016, [Acadia] announced positive top-line results from the -019 [S]tudy." *Id.* ¶ 49.

"Following the -019 Study on ADP, in mid-2017, Acadia had an [e]nd-of-Phase II meeting with the FDA," at which Acadia purportedly "proposed a plan for a single Phase III study that would support approval not for an indication of pimavanserin for ADP, but for a broader indication of pimavanserin for [dementia-related psychosis ('DRP')]." *Id.* ¶ 50. DRP "occurs in patients with a *variety* of different types of dementia" including "Alzheimer's disease, dementia with Lewy bodies, Parkinson's disease dementia, vascular dementia, and frontotemporal dementia spectrum disorders." *Id.* ¶¶ 2, 70. Expanding pimavanserin's label to encompass treatment of DRP "would be of significant commercial value" to Acadia because DRP is "about tenfold the size of PDP in terms of addressable population." *Id.* ¶¶ 36-37.

"In October 2017, [Acadia] initiated the Harmony Study, a pivotal Phase III study, to assess pimavanserin as a treatment for DRP." *Id.* ¶ 52. The Harmony Study

"enrolled 392 patients" divided into "subgroups" for each of "the five most common forms of [DRP]." *Id.* ¶¶ 74-75. The same month, Acadia "announced that the FDA had granted Breakthrough Therapy Designation to pimavanserin for the treatment of DRP." *Id.* ¶ 35. "The primary completion date of the Harmony Study … was July 31, 2019," and Defendants "possessed data from the Harmony Study starting in at least early September 2019." *Id.* ¶ 56.

On September 9, 2019, Acadia issued a press release in which Defendants "announced positive results for the Harmony Study." *Id.* ¶ 4. The press release stated:

> Acadia … today announced that its Phase 3 [Harmony Study] … met its primary endpoint, demonstrating a highly statistically significant longer time to relapse of psychosis with pimavanserin compared to placebo in a planned interim efficacy analysis.
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> ….
>
> [Acadia] is planning to meet with the FDA regarding a supplemental [New Drug Application ("sNDA")] submission in 2020….
>
> ….
>
> "We are very excited that today's results bring us one step closer to the potential of offering patients with [DRP] a critically needed treatment option," said Serge Stankovic …. "We look forward to speaking with the FDA about a [sNDA] to support pimavanserin for the treatment of [DRP]."

Id. ¶ 107. During a conference call held on the same day, Defendant Stankovic stated:

> I would also like to remind you that at the end of Phase II meeting with [the] FDA, we confirmed that for our [sNDA] submission in DRP, we could rely on a single, well-controlled study whose results were both statistically and clinically very persuasive.

Id. ¶ 109 (emphasis omitted).

"In response to these positive reports, the price of Acadia's common stock shot up more than 63%, closing at $38.85 on September 9, 2019." *Id.* ¶ 6. "Eight days later, on September 17, 2019, [Acadia] announced a proposed follow-on offering of approximately $250 million of common stock." *Id.* ¶ 59. "On September 20, 2019, the follow-on offering closed and Acadia sold 7,187,500 shares at a price of $40 per

share, for gross proceeds totaling $287.5 million." *Id.* ¶ 60.

"On December 4, 2019, Acadia presented the Harmony Study's top-line results" to medical professionals and "released the full data set of the Harmony Study" in connection with the presentation. *Id.* ¶ 62.

On February 26, 2020, Defendant Stankovic stated: "The pivotal [Harmony Study] results will be the basis of the sNDA submission, which was previously agreed upon at the end of Phase II meeting." *Id.* ¶ 113. On May 7, 2020, Stankovich stated:

> [W]e successfully completed a pre-sNDA meeting with the FDA and confirm that the pivotal data from our [Harmony Study], together with the confirmatory and supportive results from [the -020 Study and -019 Study] will all support the submission of an sNDA for pimavanserin in [DRP] …. Our sNDA preparation remains firmly on track. As previously announced, we plan to submit the sNDA this summer. We expect a priority review with a potential approval for DRP around year-end.

Id. ¶ 115. On May 12, 2020, Defendant Davis stated: "[W]e had our pre-sNDA meeting [with the FDA] in the first quarter. The feedback there was very consistent with what we heard with our end-of-Phase II meeting. The FDA confirmed that the studies conducted can support an sNDA submission." *Id.* ¶ 117.

"On June 3, 2020, Acadia submitted its sNDA for pimavanserin [to the FDA] for the treatment of hallucinations and delusions associated with DRP." *Id.* ¶ 43. The sNDA was "principally" based on the Harmony Study, "with further support from the Phase III '-020 Study,' and the Phase II '-019 Study.'" *Id.* ¶ 44.

From June 15, 2020, to February 25, 2021, Defendants made a series of public statements characterizing the results of the three studies supporting the sNDA as "positive" and "strong," expressing "confiden[ce]" in the studies' data and in the potential for FDA approval, asserting that FDA review was progressing, and describing an agreement between Acadia and the FDA. *Id.* ¶¶ 119, 121, 123, 125, 127, 130, 132, 134-35, 137, 140-41.

Acadia "issued a press release … that provided an update on its pimavanserin

sNDA" on March 8, 2021. *Id.* ¶ 9. The press release stated that Acadia was notified by the FDA that "as part of its ongoing review of the [sNDA], the FDA has identified deficiencies that preclude discussion of labelling and postmarketing requirements/commitments at this time." *Id.* On April 5, 2021, Acadia "issued a press release announcing that [Acadia] had received a Complete Response Letter ('CRL') from the FDA which indicated that the sNDA could ***not*** be approved." *Id.* ¶ 10. The press release stated:

> Despite prior agreements with the [FDA] Division of Psychiatry regarding the pivotal [Harmony Study] design targeting a broad DRP patient population analyzed as a single group, the Division, in the CRL, cited a lack of statistical significance in some of the subgroups of dementia, and insufficient numbers of patients with certain less common dementia subtypes as lack of substantial evidence of effectiveness to support approval.
>
> The DRP pivotal [Harmony Study] met its prespecified primary and secondary endpoints with robust and persuasive clinical and statistical superiority of pimavanserin over placebo, which was a prospectively agreed prerequisite for the DRP indication. Statistical separation by dementia subgroups and certain minimum numbers of patients with specific subtypes were not among the prespecified requirements. 'Acadia stands behind the robustly positive results from the pivotal [Harmony Study] and the prospectively agreed trial design and criteria for establishing efficacy in DRP. Over the entire course of the review, the Division did not raise any concerns regarding the agreed upon study design, including the issues raised in the CRL,' said Steve Davis, Chief Executive Officer of Acadia….
>
> The Division also stated in the CRL that it considers the Phase 2 [-019 Study], a supportive study in the sNDA filing, to not be adequate and well controlled….

Id. ¶ 145. In response to the two announcements, Acadia's common stock price fell $20.76 per share (45.35%) on March 9, 2021, and an additional $4.41 (17.23%) on April 5, 2021.

In their public statements between September 9, 2019 (the day Acadia

announced positive results from the Harmony Study) and April 4, 2021 (the day before FDA approval was denied), "Defendants represented that the FDA had already blessed the adequacy of the study's design for purposes of obtaining … approval" of pimavanserin for the treatment of DRP. *Id.* ¶ 5. These representations were "materially false and misleading" because "[c]ontrary to Defendants' claim that the FDA and Acadia agreed to the pivotal Harmony Study's design …, no such agreement actually existed." *Id.* ¶¶ 7, 92. Acadia has not published "an agreement between the FDA and Acadia that provides for approval based on results for the overall DRP population enrolled in the Harmony Study" and "the FDA's history of issuing [Special Protocol Assessments ('SPAs')] … supports a finding that it is highly unlikely that the FDA *sua sponte* rescinded or changed its course." *Id.* ¶¶ 100, 102. "[E]ven if there was a general agreement that [Acadia] could do a single adequate and well-controlled study, that agreement was obviously contingent on the data being supportive of the subgroups that Acadia sought to treat with pimavanserin …." *Id.* ¶ 103.

Defendants' public statements were further "false and misleading" because Defendants "failed to disclose that in fact the Harmony Study's design was so flawed that … [it] could not support FDA approval of pimavanserin for additional types of DRP beyond [PDP]." *Id.* ¶ 7. "As Defendants knew or recklessly disregarded even before launching the Harmony Study, [the] Harmony [S]tudy … was not reasonably designed to contain a sufficient number of patients … to conclude … that pimavanserin was an effective treatment for patients in [DRP] subgroups." *Id.* ¶ 8. "Instead, the Harmony Study was largely populated by patients suffering from dementia associated with Parkinson's disease – the condition for which pimavanserin was *already* FDA-approved." *Id.* When the results of the Harmony Study became available, "the limited data [Acadia] possessed on each [DRP] subgroup was poor and demonstrated a lack of efficacy, dooming [Acadia's] sNDA from the outset …." *Id.* ¶ 79. "[T]he Harmony Study's data showed that, despite the small sample size,

the drug was actually ineffective or in some cases less effective [than the placebo] in the subgroups Acadia was seeking new approval for." *Id.* ¶ 83. The "-019 Study's poorly analyzed data and poor design … rendered [that] dataset far from 'supportive.'" *Id.* ¶ 90.

Prior to the announcement of the Harmony Study's results on September 9, 2019, neither Defendant Davis nor Defendant Stankovic had sold any Acadia stock. Between September 9, 2019, and April 4, 2021, Davis sold 541,205 shares of Acadia common stock for $24,771,568 and Stankovic sold 368,993 shares for $18,932,729. Much of these sales were made pursuant to Rule 10b5-1 trading plans adopted by Davis on August 22, 2019, and December 19, 2019, and by Stankovic on November 8, 2019, and December 3, 2020. Since April 4, 2021, Davis has sold an additional 10,813 shares of common stock and Stankovic has sold an additional 8,371 shares.

Plaintiffs are entities that purchased Acadia common stock "at artificially inflated prices." *Id.* ¶¶ 20-21. Plaintiffs seek to bring this action on behalf of a putative class of all those who acquired Acadia stock between September 9, 2019 (the day Acadia announced positive results from the Harmony Study) and April 4, 2021 (the day before FDA approval was denied). "As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of [Acadia's] securities, Plaintiff and other [putative class] members have suffered significant losses and damages." *Id.* ¶ 147. Plaintiffs bring two claims: (1) violation of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder against all Defendants; and (2) violation of Section 20(a) of the Exchange Act against Defendants Davis and Stankovic. Plaintiffs request damages, interest, fees, and costs.

IV. CONTENTIONS

Defendants contend that "Plaintiffs have not met their burden to plead three essential elements of their Section 10(b) claims: falsity, scienter, and loss causation." (ECF No. 53-1 at 10.) Defendants contend that "every statement that Plaintiffs allege to be false or misleading was either demonstrably true or not actionable as a matter

of law" and "[e]very fact that Defendants allegedly concealed was fully disclosed to investors." *Id.* at 8. Defendants contend that "there is no allegation in the [FAC] that even suggests any Defendant intended to deceive investors or acted with reckless disregard of the truth." *Id.* Defendants contend that the FAC's allegations "do not establish that a misstatement (as opposed to some other factor) caused Plaintiffs' losses." *Id.* at 32. Defendants contend that "[b]ecause Plaintiffs fail to plead a primary violation of Section 10(b), their Section 20(a) claim also fails." *Id.*

Plaintiffs contend that at the pleading stage, "the falsity of Acadia's claims to having an 'agreement' with the FDA can be readily inferred from the FDA's rejection of the sNDA on grounds inconsistent with the terms of the purported 'agreement.'" (ECF No. 56 at 16-17.) Plaintiffs contend that the FAC "plausibly alleges that Defendants materially misled investors … by emphasizing cherry-picked positive results while omitting known shortcomings in the studies submitted with the sNDA, including disappointing data, which posed major obstacles to FDA approval." *Id.* at 18 (quotation and alteration omitted). Plaintiffs contend that scienter can be inferred from the same set of facts alleged to demonstrate falsity as well as Defendants' alleged stock sales. Plaintiffs contend that causation is demonstrated by the decline in Acadia's share price following Acadia's disclosures that the FDA identified deficiencies in the sNDA and denied approval of the sNDA. Plaintiffs contend that "[b]ecause the §10(b) claims are well-pled, the §20(a) claims also stand." *Id.* at 30.

V. LEGAL STANDARD

Rule 12(b)(6) of the Federal Rules of Civil Procedure permits dismissal for "failure to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). In order to state a claim for relief, a pleading "must contain . . . a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). Dismissal under Rule 12(b)(6) "is proper only where there is no cognizable legal theory or an absence of sufficient facts alleged to support a cognizable legal theory." *Shroyer v. New Cingular Wireless Servs., Inc.*, 622 F.3d 1035, 1041 (9th

Cir. 2010).

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* However, "a plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555 (alteration in original) (quoting Fed. R. Civ. P. 8(a)). A court is not "required to accept as true allegations that are merely conclusory, unwarranted deductions of fact, or unreasonable inferences." *Sprewell v. Golden State Warriors*, 266 F.3d 979, 988 (9th Cir. 2001). "In sum, for a complaint to survive a motion to dismiss, the non-conclusory factual content, and reasonable inferences from that content, must be plausibly suggestive of a claim entitling the plaintiff to relief." *Moss v. U.S. Secret Serv.*, 572 F.3d 962, 969 (9th Cir. 2009).

"A securities fraud complaint under § 10(b) and Rule 10b–5 must [also] satisfy the dual pleading requisites of Federal Rule of Civil Procedure 9(b) and the [Private Securities Litigation Reform Act ("PSLRA")]." *In re VeriFone Holdings, Inc. Sec. Litig.*, 704 F.3d 694, 701 (9th Cir. 2012). Under Rule 9(b), a complaint "must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). The pleader must "identify the who, what, when, where, and how of the misconduct charged, as well as what is false misleading about the purportedly fraudulent statement, and why it is false." *Davidson v. Kimberly-Clark Corp.*, 873 F.3d 1103, 1110 (9th Cir. 2017), *as corrected* (Mar. 12, 2018) (quoting *Cafasso, U.S. ex rel. v. Gen. Dynamics C4 Sys., Inc.*, 637 F.3d 1047, 1055 (9th Cir. 2011)). "To comply with Rule 9(b), allegations of fraud must be specific enough to give defendants notice of the particular misconduct which is alleged to constitute the fraud

charged so that they can defend against the charge and not just deny that they have done anything wrong." *Bly-Magee v. California*, 236 F.3d 1014, 1019 (9th Cir. 2001) (citation omitted).

Under the PSLRA, a plaintiff must "state with particularity both the facts constituting the alleged violation, and the facts evidencing scienter, *i.e.*, the defendant's intention to deceive, manipulate, or defraud." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 313 (2007). To adequately allege scienter, a complaint's allegations must give "rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u–4(b)(2)(A).

VI. SECTION 10(b) CLAIM

"To state a federal securities fraud claim, in violation of § 10(b), a plaintiff must show: '(1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation.'" *ESG Cap. Partners, LP v. Stratos*, 828 F.3d 1023, 1032 (9th Cir. 2016) (quoting *Thompson v. Paul*, 547 F.3d 1055, 1061 (9th Cir. 2008)).

A. Material Misrepresentation or Omission

"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.'" *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 38 (2011) (quoting *Basic Inc. v. Levinson*, 485 U.S. 224, 238 (1988)) (emphasis in original). "Falsity is alleged when a plaintiff points to defendant's statements that directly contradict what the defendant knew at that time." *Khoja*, 899 F.3d at 1008. "Even if a statement is not false, it may be misleading if it omits material information." *Id.* at 1008-09. "[A] misrepresentation or omission is material if there is a substantial likelihood that a reasonable investor would have acted differently if the misrepresentation had not been made or the truth had been disclosed." *Livid Holdings Ltd. v. Salomon Smith Barney, Inc.*, 416 F.3d 940, 946

(9th Cir. 2005).

Plaintiffs' allegations regarding falsity fall into two general categories. First, Plaintiffs allege that Defendants' assurances "that the FDA had already blessed the adequacy of the [Harmony Study's] design for purposes of obtaining … approval" of pimavanserin for the treatment of DRP were "materially false and misleading" because "no such agreement actually existed." (ECF No. 45 ¶¶ 5, 7, 92.) Second, Plaintiffs allege that Defendants' statements concerning the results of the Harmony Study and approval process were "false and misleading" because Defendants "failed to disclose that in fact the Harmony Study's design was so flawed that … [it] could not support FDA approval of pimavanserin for additional types of DRP beyond [PDP]," and that "the limited data [Acadia] possessed on each [DRP] subgroup was poor and demonstrated a lack of efficacy, dooming [Acadia's] sNDA from the outset." *Id.* ¶¶ 7, 79.

1. Statements Concerning an Agreement with the FDA

Defendants contend that the allegation in the FAC "that Defendants fabricated the existence of an agreement with the FDA is entirely conclusory and unsupported by any well-plead[ed] facts." (ECF No. 53-1 at 25-26 (quotations, citation, and alteration omitted).) Defendants contend that "Plaintiffs mischaracterize Acadia's agreement with the FDA" by conflating an agreement regarding submission of the sNDA with an agreement regarding approval. (ECF No. 58 at 7.) Defendants contend that the absence of a public, written copy of an agreement does not support Plaintiffs' allegations because "[i]t is Plaintiffs' burden to adequately plead falsity." (ECF No. 53-1 at 26.) Defendants contend that the allegation regarding the FDA's history of issuing SPAs is inapposite because "Defendants never claimed that their agreement with the FDA was a formal SPA." *Id.* at 27.

Plaintiffs contend that at the pleading stage, "the falsity of Acadia's claims to having an 'agreement' with the FDA can be readily inferred from the FDA's rejection of the sNDA on grounds inconsistent with the terms of the purported 'agreement.'"

(ECF No. 56 at 16-17.) Plaintiffs contend that "additional factual averments, such as confidential witness statements," are not necessary at the pleading stage. *Id.* at 18.

According to Acadia's April 5, 2021, press release, the FDA denied approval of Acadia's sNDA based on concerns with the design and results of the Harmony and -019 Studies. *See* ECF No. 45 ¶ 145 (stating that the FDA cited the Harmony Study's "lack of statistical significance in some of the subgroups of dementia, and insufficient numbers of patients with certain less common dementia subtypes" as well as issues with the -019 Study, as grounds for denying approval of the sNDA). The FAC alleges that prior to the FDA's denial of approval of the sNDA, Defendants repeatedly stated that Acadia had an agreement with the FDA. To the extent that Defendants represented that the agreement contained terms that are inconsistent with the FDA's basis for ultimately denying approval—namely, that the FDA had approved the design of the Harmony and -019 Studies or would base its decision on the overall results of the Harmony Study rather than on the data for individual subgroups—a plausible inference may be drawn at the pleading stage that Defendants misrepresented the existence or terms of the agreement.

On August 19, 2020, Defendant Davis stated:

> [O]ne of the things we hear very consistently among … physicians generally is … [that] the "subtypes" of dementia are very difficult to diagnose. They overlap many times. And so it's a little bit of an artificial distinction to say someone has Alzheimers, dementia with Lewy bodies or vascular dementia, et cetera.
>
> …. [A]s a reminder, we got a clear agreement from … the FDA at our end of Phase II meeting [to "pursue DRP broadly"], and we executed the plan that we agreed to with them.
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> ….
>
> [T]he sNDA that we've submitted includes the [relapse prevention Harmony Study] … but also includes … acute data [from the -020 and -019 Studies] …. So we have both in the submission ….
>
> …. [W]e agreed with the FDA on that approach at the [end-of-Phase II]

> meeting and agreed on the plan for Phase III, and then we've executed that plan.

Id. ¶ 125. On November 17, 2020, Davis stated:

> [O]ur sNDA submission included an efficacy package, which was agreed upon with the FDA at the [end-of-Phase II meeting] ….
>
> …. [A]t our [end-of-Phase II] meeting, we went to the FDA. We said … [w]e'd like you to agree to 3 things: one, that we studied DRP generally …. Two, that we run a relapse-prevention study now to demonstrate … a durable effect over time. And then three, that … a single relapse prevention study serve as the basis of approval, together with the other supporting acute studies we've done. And they've agreed to all 3 of those …. So fast forward to today, we then executed the exact plan that we laid out for them.
>
> ….
>
> …. One thing that I didn't mention in that in the [end-of-Phase II] meeting] we had setting up our Phase III program that we then executed … we also just asked FDA[:] … we just want to make certain that you are on board with approving a drug to treat [DRP] …. We want to make certain that you are on board with the concept of doing this if we followed the plan that we've agreed to.
>
> And they say, absolutely, we wouldn't agree to your Phase III plan if we weren't … of that mind.

Id. ¶ 132. On January 12, 2021, Davis further stated: "[W]e're seeking the treatment of [DRP]. So we're not looking at individual subtypes .... So we're seeking that broad indication. That's supported by a[n] … alignment we established with the FDA." *Id.* ¶ 135.

The assertions that the FDA prospectively agreed on the "plan" for Phase III (i.e. the Harmony Study), that Acadia subsequently "executed that plan," and that the FDA was "on board" with the concept of "approving a drug to treat [DRP]" if Acadia "followed the plan" plausibly connote to a reasonable investor that the Harmony Study's design had been prospectively approved by the FDA and would not represent a further barrier to approval. Likewise, considered in context, the assertions that the

FDA agreed that Acadia "studied DRP generally" and that "a single relapse prevention study serve as the basis of approval," and that the FDA supported Acadia's decision to not "look[] at individual subtypes" suggest that the FDA would base its decision on the overall results of the Harmony Study rather than on the data for individual subgroups.

Defendant Davis' statements asserting an agreement with the FDA plausibly contradicted what he is alleged to have known at the time the statements were made and were material because they concerned the likelihood of approval of Acadia's "only commercial product to date." (ECF No. 45 ¶ 32.) The Court concludes that the FAC alleges sufficient facts to support a plausible inference that Defendant Davis' statements concerning an agreement with the FDA were materially false or misleading.

2. Omissions of the Negative Harmony Study Results

Defendants contend that Defendants' other allegedly misleading statements "are inactionable as a matter of law because they are: (a) demonstrably true, (b) corporate optimism (or puffery), (c) opinions, or (d) forward-looking statements accompanied by meaningful cautionary language." (ECF No. 53-1 at 19.) Defendants contend that Defendants "fully disclosed the trial designs and results of every study … cited in support of [the] sNDA." *Id.* at 22. Defendants contend that Defendants "made no misrepresentations regarding clinical study design or data" and that the FAC "presents a quintessential example of pleading 'fraud by hindsight.'" *Id.* at 24-25.

Plaintiffs contend that the FAC "plausibly alleges that Defendants materially misled investors … by emphasizing cherry-picked positive results while omitting known shortcomings in the studies submitted with the sNDA, including disappointing data, which posed major obstacles to FDA approval." (ECF No. 56 at 18 (quotation and alteration omitted).) Plaintiffs contend that "when a pharmaceutical company touts purportedly positive results from a drug study, it must *also* disclose

known material facts that undercut the company's boosterism to avoid misleading investors." *Id.* Plaintiffs contend that the disclosure of the Harmony Study's dataset was not sufficient to counterbalance the misleading impression created by Defendants' statements.

The FAC alleges that Defendants made a series of at least fifteen statements during the class period that were misleading because they failed to disclose that the Harmony Study was not properly designed and had disappointing data, and that these known shortcomings posed major obstacles to FDA approval. These statements included objective descriptions of the results of the Acadia studies, *see, e.g.,* ECF No. 45 ¶¶ 107, 119 (the Harmony Study "met its primary endpoint," "demonstrate[ed] a highly statistically significant longer time to relapse of psychosis," and showed a "nearly three-fold reduction in the risk of relapse"), as well as Defendants' interpretations of the data and results of the studies, *see, e.g., id.* ¶¶ 119, 127, 132, 135 (the data and results of the studies were "meaningful," "positive," "pivotal," "robust," and "strong").

The FAC alleges that in fact, "[the] Harmony [S]tudy … was not reasonably designed to contain a sufficient number of patients … to conclude … that pimavanserin was an effective treatment for patients in [DRP] subgroups." *Id.* ¶ 8. "Instead, the Harmony Study was largely populated by patients suffering from dementia associated with Parkinsons' disease – the condition for which pimavanserin was *already* FDA-approved." *Id.* The FAC alleges that "the Harmony Study's data showed that, despite the small sample size, the drug was actually ineffective or in some cases less effective [than the placebo] in the subgroups Acadia was seeking new approval for." *Id.* ¶ 83. The FAC alleges that "-019 Study's poorly analyzed data and poor design … rendered [that] dataset far from 'supportive.'" *Id.* ¶ 90. The FAC alleges that "[t]herefore, undisclosed by Defendants, FDA approval was extremely unlikely." *Id.* ¶ 108.

There are no adequately alleged facts from which the Court can infer that

Defendants' objective descriptions of the Acadia studies were false. Further, Defendant's interpretation of the data and results of the studies were plainly expressions of opinion. However, statements that are demonstrably true or expressions of opinion are nevertheless actionable if the statements omit additional material information whose absence makes the fact or opinion misleading to a reasonable person reading the statement fairly and in context. *See Khoja*, 899 F.3d at 1008-09 ("Even if a statement is not false, it may be misleading if it omits material information."); *City of Dearborn Heights Act 345 Police & Fire Ret. Sys. v. Align Tech., Inc.*, 856 F.3d 605, 616 (9th Cir. 2017) (stating that a plaintiff can plead that an opinion statement is misleading based "on a theory of omission" by "alleg[ing] 'facts going to the basis for the issuers opinion … whose omission makes the opinion statement at issue misleading to a reasonable person reading the statement fairly and in context.'" (quoting *Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension Fund*, 575 U.S. 175, 194 (2015))).

The allegation that Defendants Davis and Stankovic were high-level corporate officers with "access to material information available to them but not to the public," (ECF No. 45 ¶ 26), supports an inference at the pleading stage that Defendants were aware of the shortcomings of the Harmony and -019 Studies. Despite allegedly possessing information that the studies were not properly designed and that the Harmony Study had disappointing subgroup data, Defendants touted the studies' results. Defendants' alleged misrepresentations concerning the agreement with the FDA support an inference that Defendants knew that the studies' shortcomings would materially increase the risk that the sNDA would not be approved. At the pleading stage, the allegations in the FAC are sufficient to show that a failure to disclose that the studies were not properly designed and that the Harmony Study had disappointing subgroup data rendered Defendants' positive statements regarding the results of the studies materially misleading. *See Schueneman v. Arena Pharms., Inc.*, 840 F.3d 698, 705-06 (9th Cir. 2016) ("'[O]nce defendants cho[o]se to tout' positive information to

the market, 'they [are] bound to do so in a manner that wouldn't mislead investors,' including disclosing adverse information that cuts against the positive information." (quoting *Berson v. Applied Signal Tech., Inc.*, 527 F.3d 982, 987 (9th Cir. 2008)) (alteration in original)).

The FDA's subsequent citation of the shortcomings of the Harmony and -019 Studies in denying approval of the sNDA supports a plausible inference that this same information would have been material to a reasonable investor at the time the statements were made. *Cf. Matrixx Initiatives*, 563 U.S. at 43 ("Given that medical professionals and regulators act on the basis of [certain evidence], it stands to reason that in certain cases reasonable investors would as well.").

Defendants assert that the allegedly negative information about the studies was fully disclosed to investors because the FAC alleges that "[o]n December 4, 2019, Acadia presented the Harmony Study's top-line results" to medical professionals and "released the full data set of the Harmony Study" in connection with the presentation. (ECF No. 45 ¶ 62; *see also* ¶ 87 (stating that the -019 Study's dataset was presented in full in August 2018)). Under the "truth-on-the-market" doctrine, "[i]n a 'fraud on the market' case 'an omission is materially misleading only if the information has not already entered the market.'" *Provenz v. Miller*, 102 F.3d 1478, 1492 (9th Cir. 1996) (quoting *In re Convergent Tech. Sec. Litig.*, 948 F.2d 507, 513 (9th Cir. 1991)). "However, before the 'truth-on-the-market' doctrine can be applied, the defendants must prove that the information that was withheld or misrepresented was 'transmitted to the public with a degree of intensity and credibility sufficient to effectively counterbalance any misleading impression created by insider's one-sided representations.'" *Id.* at 1492-93 (quoting *Kaplan v. Rose*, 49 F.3d 1363, 1376 (9th Cir. 1994)). The allegation that the data set of the Harmony Study was released in connection with a presentation to medical professionals is not sufficient at the pleading stage to establish that this disclosure was sufficient to counterbalance any misleading impression generated by Defendants' omissions. Further, the release of

the data set did not occur until December 4, 2019, almost three months after the first allegedly misleading statement.

The Court concludes that the allegations contained in the FAC support a plausible inference that Defendants' statements touting the results of the Harmony Study and -019 Study, (ECF No. 45 ¶¶ 107, 109, 113, 115, 119, 127, 128, 132, 134, 135), misled investors by omitting the adverse information the FDA later cited in denying approval of the sNDA.

B. Scienter

In a § 10(b) action, scienter refers to "a mental state that not only covers intent to deceive, manipulate, or defraud, but also deliberate recklessness." *Schueneman*, 840 F.3d at 705. "[D]eliberate recklessness is 'an extreme departure from the standards of ordinary care ... which presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious that the actor must have been aware of it.'" *Id.* (quoting *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 991 (9th Cir. 2009)).

Under the PSLRA, the allegations of a complaint must give "rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u–4(b)(2)(A). This requires a weighing of competing inferences from the underlying allegations—"[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." *Tellabs*, 551 U.S. at 324. With respect to omissions, "the plaintiff must plead 'a highly unreasonable omission, involving not merely simple, or even inexcusable negligence, but an extreme departure from the standards of ordinary care, and which presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious that the actor must have been aware of it.'" *Zucco Partners*, 552 F.3d at 991. To determine if the scienter requirement is satisfied, a "court's job is not to scrutinize each allegation in isolation but to assess all the allegations holistically." *Id.* at 326.

Defendants contend that the FAC does not contain a single allegation "suggesting that any Defendant intended to deceive investors" or "believed any fact that contradicted any statement they made" during the class period. (ECF No. 53-1 at 28.) Defendants contend that Defendants' alleged omissions do not create a strong inference of scienter. Defendants contend that allegations concerning Defendants' sales of stock are conclusory and do not support an inference of scienter because "many of the sales … were made pursuant to Rule 10b5-1 plans" or "to cover taxes." *Id.* at 29-30.

Plaintiffs contend that the same allegations supporting the element of falsity also demonstrate scienter. Plaintiffs contend that Defendants' sales of stock establish a motive that "weigh[s] heavily" in favor of a scienter inference. (ECF No. 56 at 27 (quotation omitted).) Plaintiffs contend that the Rule 10b5-1 plans do not shield Defendants from an inference of scienter because the plans were adopted during or shortly before the class period.

Defendants Davis and Stankovic "possessed the power and authority to control the contents of Acadia's SEC filings, press releases, and other market communications" and had "access to material information available to them but not to the public." *Id.* ¶ 26. Accordingly, Defendants plausibly would have been aware of the terms of any agreement with the FDA and the alleged shortcomings with the design and results of the Harmony and -019 Studies. The FAC's allegations that Defendants affirmatively misrepresented the terms of the purported agreement with the FDA support an inference that Defendants acted with intent or deliberate recklessness. Further, Acadia's press release announcing that the FDA had denied approval stated:

> Despite prior agreements with the [FDA] Division of Psychiatry regarding the pivotal [Harmony Study] design targeting a broad DRP patient population analyzed as a single group, the Division, in the CRL, cited a lack of statistical significance in some of the subgroups of dementia, and insufficient numbers of patients with certain less common

> dementia subtypes as lack of substantial evidence of effectiveness to support approval.
>
> The DRP pivotal [Harmony Study] met its prespecified primary and secondary endpoints with robust and persuasive clinical and statistical superiority of pimavanserin over placebo, which was a prospectively agreed prerequisite for the DRP indication. Statistical separation by dementia subgroups and certain minimum numbers of patients with specific subtypes were not among the prespecified requirements. 'Acadia stands behind the robustly positive results from the pivotal [Harmony Study] and the prospectively agreed trial design and criteria for establishing efficacy in DRP. Over the entire course of the review, the Division did not raise any concerns regarding the agreed upon study design, including the issues raised in the CRL,' said Steve Davis, Chief Executive Officer of Acadia….
>
> The Division also stated in the CRL that it considers the Phase 2 [-019 Study], a supportive study in the sNDA filing, to not be adequate and well controlled….

Id. ¶ 145. This press release asserts that the FDA agreed to the Harmony Study's design, agreed to analyze DRP as a single group, and did not require statistical separation by subgroup, but that the FDA denied approval "despite" these prior agreements. These assertions support an inference that Defendants intended that their earlier statements be understood by investors as suggesting that Acadia and the FDA had reached agreements concerning test design and analysis that were ultimately not consistent with the FDA's rationale for denying approval.

Unusual or suspicious stock sales by corporate insiders may also constitute circumstantial evidence of scienter. *See Zucco*, 552 F.3d at 1005. "Among [the] factors that must be considered to determine whether stock sales raise a strong inference of deliberate recklessness are: '(1) the amount and percentage of shares sold by insiders; (2) the timing of the sales; and (3) whether the sales were consistent with the insider's prior trading history.'" *Id.* (quoting *In re Silicon Graphics Inc. Sec. Litig.*, 183 F.3d 970, 986 (9th Cir. 1990)).

The FAC alleges that prior to the announcement of results for the Harmony

study on September 9, 2019, neither Defendant Davis nor Defendant Stankovic had sold any Acadia stock. The FAC alleges that during the class period, Davis sold 541,205 shares of Acadia common stock for $24,771,568 and Stankovic sold 368,993 shares for $18,932,729. The FAC alleges that many of these sales were made pursuant to Rule 10b5-1 trading plans adopted by Davis on August 22, 2019, and December 19, 2019, and by Stankovic on November 8, 2019, and December 3, 2020. The FAC alleges that since April 4, 2021, Davis has sold an additional 10,813 shares of common stock and Stankovic has sold an additional 8,371 shares.

The FAC does not allege the percentage of shares sold by the individual Defendants or the timing of the sales within the nineteen-month period relative to any of the allegedly misleading statements or omissions. However, the amount of Acadia stock sold by the individual Defendants during the class period is substantial. Although the FAC alleges that many of these sales were made pursuant to Rule 10b5-1 trading plans, the trading plans in question were not adopted until after the motive and opportunity to mislead investors allegedly arose. Further, the absence of any sales of stock prior to the class period supports an inference that the individual Defendants' sales were unusual or suspicious and weigh in favor of an inference of scienter.

The competing inference—that Defendants did not intentionally or recklessly mislead investors—is supported in part by Defendants' release of the Harmony Study's dataset in connection with a presentation to medical professionals. However, this disclosure occurred almost three months after the initial actionable omission and was followed by Defendants' assurances that Acadia had an agreement with the FDA.

Defendants further assert that it "defies common sense" for them to have misrepresented the terms of an agreement with the FDA and the likelihood of approval, knowing the whole time that approval would not be granted. (ECF No. 53-1 at 27.) However, Defendants' actions plausibly demonstrate that that they misled investors into overestimating the likelihood of approval, not that Defendants knew from the start that the sNDA would not be approved. Further, Defendants' substantial

stock sales provide a motive for Defendants to temporarily prop up Acadia's stock price, despite the risk that the company's stock price would fall when the truth was uncovered. *See Nguyen v. Endologix, Inc.*, 962 F.3d 405 (9th Cir. 2020) (stating that a theory that the defendants promised that a medical device would be approved by the FDA despite knowing approval would not be granted "does not make a whole lot of sense," but acknowledging that "[i]f defendants had sought to profit from this scheme in the interim, such as by selling off their stock or selling the company at a premium, the theory might have more legs"). Weighing all of the allegations holistically, the Court finds that a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw.

C. Loss Causation

Loss causation is a plaintiff's "burden of proving that the act or omission of the defendant alleged to violate this chapter caused the loss for which the plaintiff seeks to recover damages." 15 U.S.C. § 78u-4(b)(4). "To prove loss causation, plaintiffs need only show a 'causal connection' between the fraud and the loss, by tracing the loss back to 'the very facts about which the defendant lied." *Mineworkers' Pension Scheme v. First Solar Inc.*, 881 F.3d 750, 753 (9th Cir. 2018) (quoting *Nuveen Mun. High Income Opportunity Fund v. City of Alameda*, 730 F.3d 1111, 1120 (9th Cir. 2013)). "Disclosure of the fraud is not a sine qua non of loss causation, which may be shown even where the alleged fraud is not necessarily revealed prior to the economic loss." *Nuveen*, 730 F.3d at 1120.

Defendants contend that the FAC alleges a causation theory based on market revelation of the fraud but fails to allege facts relevant to that theory. Defendants contend that "there was no disclosure of fraud or correction of any prior misstatement." (ECF No. 53-1 at 32.)

Plaintiffs contend that Acadia's disclosures in March and April of 2021 "were plainly construed by shocked investors as evidence" that they had been misled as to the purported agreement with the FDA, the strength of the sNDA supporting studies,

and the risk that the sNDA would be rejected. (ECF No. 56 at 30.)

The Court has determined that the FAC alleges sufficient facts to support an inference that Defendants' statements concerning the agreement with the FDA and omissions of adverse information about the Harmony and -019 Studies misled investors into underestimating the risk that the FDA would deny Acadia's sNDA. The FAC alleges that Acadia's April 5, 2021, press release disclosed that the FDA cited issues with the designs of Acadia's studies and DRP subgroup results as the basis for denying approval. The FAC alleges that Acadia's common stock price fell $20.76 per share (45.35%) on March 9, 2021, and an additional $4.41 (17.23%) on April 5, 2021. A reasonable investor could plausibly infer from Acadia's March and April 2021 press releases that they had previously been misled by Defendants' alleged misrepresentations and omissions. Further, the FDA's denial of approval of the sNDA represented the materialization of the risk about which investors had allegedly been misled. *See Nuveen*, 730 F.3d at 1120 ("[M]aterialization of the risk recognizes that 'a misstatement or omission is the "proximate cause" of an investment loss if the risk that caused the loss was within the zone of risk *concealed* by the misrepresentations and omissions alleged by a disappointed investor.'" (quoting *Lentell v. Merrill Lynch & Co., Inc.*, 396 F.3d 161, 173 (2d. Cir. 2005))). The Court concludes that the FAC alleges sufficient facts to support an inference that Plaintiffs' losses were caused by Defendants' alleged misrepresentations.

VII. SECTION 20(a) CLAIM

Defendants request dismissal of the § 20(a) claims on the basis that the Plaintiffs fail to adequately plead an underlying § 10(b) violation. *See Lipton v. Pathogenesis Corp.*, 284 F.3d 1027, 1035 n.15 (9th Cir. 2002) ("[T]o prevail on their claims for violations of § 20(a) and § 20A, plaintiffs must first allege a violation of § 10(b) or Rule 10b5."). The Court has determined that Plaintiffs adequately allege facts in support of their § 10(b) claims against Defendants. Defendants' motion to dismiss Plaintiffs' § 20(a) claims is denied.

VIII. CONCLUSION

IT IS HEREBY ORDERED that the Motion to Dismiss the FAC (ECF No. 53) is denied.

Dated: September 27, 2022

Hon. William Q. Hayes
United States District Court