UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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HOU LIU, et al.,

Plaintiffs,

-against- 17-cv-7371 (LAK)

INTERCEPT PHARMACEUTICALS, INC., et al.,

Defendants.

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MEMORANDUM OPINION

Appearances:

Richard W. Gonnello
Megan M. Sullivan
Sherief Morsy
FARUQI & FARUQI, LLP
Attorneys for Lead Plaintiffs Hou Liu and Amy Fu and Lead Counsel for the Class

Scott D. Musoff
James R. Carroll
Alisha Q. Nanda
Rene H. DuBois
SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP
Attorneys for Defendants Intercept Pharmaceuticals, Inc., Mark Pruzanski, Sandip S. Kapadia, Richard Kim and Rachel McMinn

LEWIS A. KAPLAN, *District Judge.*

This putative securities class action is born out of thirty reports of death or serious injury (the Serious Adverse Events, or "SAEs") that occurred over a one year period in twenty-seven – out of approximately 3,000 – users of Ocaliva, defendant Intercept Pharmaceuticals's drug to treat patients with the rare liver disease primary biliary cholangitis ("PBC"). The reports indicated that physicians had prescribed incorrect doses of Ocaliva for twelve patients, correct doses in five cases, and unknown doses for the remaining patients. All twelve of the patients administered a dose higher than recommended by the FDA had advanced stages of PBC.

Plaintiffs' claims for violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 ("the Exchange Act") are premised entirely on this small fraction of Ocaliva users. Specifically, plaintiffs accuse defendants of making false or misleading statements in light of the thirty SAEs and twelve instances in which patients were directed to take the wrong dose. Plaintiffs bring their claims against Intercept and four current and former company executives.

Defendants move to dismiss the Amended Complaint ("Complaint") pursuant to Federal Rules of Civil Procedure 9(b) and 12(b)(6) and the Private Securities Litigation Reform Act ("PSLRA").

Background

I. The Parties

The putative class members purchased publicly traded Intercept securities between June 9, 2016 and September 20, 2017.[1] The lead plaintiffs, Hou Liu and Amy Fu, purchased Intercept common stock during that period.[2]

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[1] *Liu et al. v. Intercept Pharmaceuticals et al.*, 17-cv-7371, AC [DI 52] ¶ 1.

Intercept is a public company headquartered in New York that manufactures and markets biopharmaceutical products.[3] Its stock is traded on the NASDAQ Global Select Market.[4]

II. Facts

At issue are allegedly material misrepresentations and omissions concerning Ocaliva, Intercept's drug approved to treat patients with primary biliary cholangitis ("PBC"), a rare liver disease.[5] If untreated, PBC can cause cirrhosis, liver failure, or death.[6] The disease is classified as either early-stage PBC, in which patients have mild hepatic impairment (liver failure), or late-stage PBC, in which patients have moderate or severe hepatic impairment.[7] Approximately 2-3 percent of those afflicted have late-stage PBC.[8]

Prior to Ocaliva, Ursodiol ("URSO" or "UDCA") was the only drug approved to treat PBC.[9] Ocaliva was developed as an alternative treatment, specifically for PBC patients who could

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2 *Id.* ¶ 23.

3 *Id.* ¶ 2.

4 *Id.*

5 *Id.* ¶¶ 31-32.

6 *Id.* ¶¶ 32-33.

7 *Id.* ¶¶ 4, 34.

8 *Id.* ¶ 144.

9 *Id.* ¶ 39.

not tolerate or who did not respond adequately to UDCA.[10] Prior to FDA approval, Intercept conducted clinical trials of Ocaliva. Intercept's Phase 3 clinical trial consisted of 1,325 participants, most of whom had early-stage PBC.[11] Two study participants died during the trial.[12]

On May 27, 2016, the FDA approved Ocaliva under its Accelerated Approval Program (the "AAP").[13] This approval pathway is used for drugs that treat serious conditions and that will provide a "meaningful benefit" over other available treatments.[14] Recognizing that the livers of patients with late-stage PBC are more compromised, and therefore more vulnerable to the drug's toxicity, the FDA recommended that late-stage patients take lower doses of Ocaliva than patients with early stages of the disease.[15] Accordingly, the starting dose for early-stage PBC patients was 5 milligrams of Ocaliva *per day*, and 5 milligrams *per week* for late-stage PBC patients.[16] These recommendations were included on the FDA-approved Ocaliva label.[17]

Given the patient profile in the Phase 3 clinical trial, the FDA was "unable to assess"

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[10] *Id*.

[11] *Id.* ¶¶ 40, 43.

[12] *Id.* ¶ 40.

[13] *Id.* ¶ 44.

[14] *Id.* ¶ 45.

[15] *Id.* ¶¶ 42, 48.

[16] *Id.* ¶ 46.

[17] *Id.* ¶¶ 46, 48.

the safety and tolerance of Ocaliva in late-stage patients.[18] The FDA instructed Intercept to monitor patients with late-stage PBC and conduct a Phase 4 clinical trial, a study required for all drugs approved under the AAP.[19]

Ocaliva became available publicly shortly after its approval. Intercept created Interconnect, an online patient services hub, to communicate directly with Ocaliva users and physicians.[20] Through Interconnect, patients could learn about treatment options and ask questions, and physicians could access Intercept's enrollment form to prescribe Ocaliva.[21]

During the class period, the enrollment form allegedly provided only two dosage options: "5 mg. 30-day supply, qty: 30" and "10 mg, 30-day supply, qty: 30."[22] There was no option on the form by which to select a weekly supply of 5 milligrams, the suggested dose for late-stage PBC patients. An open comment field, which provided space for "additional directions (allergies,

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18 *Id.* ¶ 43.

19 *Id.* ¶¶ 43, 45, 79.

20 *Id*. ¶ 51.

21 *Id.* ¶¶ 52-53, 100. Intercept's founder and chief executive officer Mark Pruzanski stated that the "majority" of Ocaliva prescriptions came through Interconnect. *Id*. ¶ 100.

22 *Id*. ¶ 54; *see also* Enrollment Form, AC Ex. B [DI 52-2] at 2. Defendants improperly seek to attach an "enhanced" enrollment form allegedly implemented in September 2016. In its brief, defendants ask the Court to use the enhanced form's effective date as proof that Intercept added additional dosage options shortly after Ocaliva's launch. Defendants' Memorandum in Support of its Motion to Dismiss [hereinafter "Defs.' Mem."] [DI 62] at 9. This date stamp cannot properly be considered for the truth of the matter asserted, and the Court declines to take notice of it. *See In re Lehman Bros. Sec. & Erisa Litig*., 799 F. Supp. 2d 258, 273 (S.D.N.Y. 2011). Accepting the Complaint's factual allegations as true, for purposes of the motion to dismiss the Court will assume that the enrollment form contained only two dose options during the class period.

concurrent medications, etc.)," was provided below the dose selection.[23] Along with other information, healthcare providers were required to include patients' bilirubin levels when completing the form.[24] A bilirubin level above 3 milligrams indicated that a patient had late-stage PBC.[25]

Once completed, the enrollment form was submitted directly to Intercept, either online through Interconnect or by mail, email, or fax.[26] During the class period – according to plaintiffs' confidential witness ("CW1")[27] – the patient information from the form, including drug dose and bilirubin levels, was entered into the Interconnect database and the prescription then was sent to one of Intercept's three speciality pharmacies.[28] CW1 explained that Intercept did not check whether a correct dose had been prescribed.[29]

Pursuant to the Federal Food, Drug, and Cosmetic Act ("FDCA"), Intercept must

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23 *See* Enrollment Form at 2.

24 *Id.*; AC ¶ 55.

25 AC ¶ 55.

26 *Id*. ¶ 57.

27 A plaintiff may rely on confidential sources in its complaint so long as the source is "described with sufficient particularity to support the probability that a person in the position occupied by the source would possess the information alleged." *Novak v. Kasaks*, 216 F. 3d 300, 314 (2d Cir. 2000). Here, CW1 is identified as a medical director at Intercept who reported directly to the vice president of medical affairs. AC ¶ 58. Defendants challenge the content of CW1's allegations, but do not dispute that the witness was in a position to know of Intercept's enrollment policies.

28 *Id.* ¶¶ 58, 60.

29 *Id*. ¶ 58.

submit reports of any adverse events to the FDA.[30] An adverse event is "any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related."[31] An adverse event is deemed "serious" if it results in death or a life-threatening adverse event.[32] Intercept complied with this regulation and its pharmacovigilance department submitted the reports to the FDA.[33]

Between June 24, 2016 and June 30, 2017, Intercept received reports of thirty Serious Adverse Events ("SAEs") occurring in twenty-seven patients.[34] These thirty SAEs comprised of nineteen deaths and eleven cases of serious liver injury.[35] Some reports included the patient's stage of PBC and/or whether the patient received the correct dose of Ocaliva.[36] Of the twenty-seven patients, twelve of the thirteen known late-stage PBC patients received an incorrect dose.[37] By June

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30 *Id.* ¶¶ 69, 72-75; 21 C.F.R. § 314.80(b), (c).

31 21 C.F.R. § 312.32(a).

32 *See id.*

33 AC ¶¶ 76-77.

34 *Id.* ¶ 86. Plaintiffs obtained this information through a FOIA request. *See id*. ¶ 85.

35 *Id* ¶ 86. Three patients suffered liver injuries prior to death, but death and serious liver injury are considered discrete SAEs.

36 *Id.* The disease stage is known for eighteen patients: thirteen with late-stage PBC, and five with early-stage. The prescribed dose for seventeen of the patients is known. The dose and disease stage is unknown (or in one instance, an "unapproved indication") for the remaining patients.

37 *Id*.

2017, there were approximately 3,000 Ocaliva users.[38]

On July 31, 2017, Intercept announced that one patient from its earlier Phase 2 clinical trial had died due to acute renal and liver failure.[39] According to Intercept's chief executive Mark Pruzanski, "this [was] a really unfortunate case of an individual who is quite sick and had a lot of clinical complications in the course of his disease. And exercising an abundance of caution given the death, we decided that we couldn't rule out that it was possibly related."[40] According to CW1, the FDA began reviewing Ocaliva safety data as result of this death.[41]

On September 12, 2017, Intercept issued a "Dear Healthcare Provider Letter" (the "HCP Letter") warning providers against prescribing late-stage PBC patients with a dose higher than recommended.[42] The letter explained that Intercept had received reports of "[l]iver injury, liver decompensation, liver failure, and death" after patients had taken incorrect doses.[43] It stated also that some early-stage PBC patients reported serious liver adverse events. Intercept urged healthcare providers to ensure that patients with late-stage PBC received the correct drug dose and to monitor all Ocaliva patients for liver-related adverse reactions.[44]

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38 *Id*.

39 *Id*. ¶ 138.

40 *Id*.

41 *Id*. ¶ 140.

42 *See* Healthcare Provider Letter AC Ex. D [DI 52-4] at 1 [hereinafter the" HCP Letter"].

43 *Id.*

44 *Id*. at 2.

Following publication, Intercept's common stock fell from a close of $113.48 on September 11, 2017 to a close of $90.75 on September 13, 2017.[45]

On September 21, 2017, the FDA issued a drug safety communication (the "Communication") and a corresponding safety alert summarizing the Communication, on the SAEs reported by Ocaliva users.[46] The data included in the Communication came directly from the adverse events reported to the FDA by Intercept.[47] The FDA warned that Ocaliva was "being incorrectly dosed in some patients with moderate to severe decreases in liver function, resulting in an increased risk of serious liver injury and death."[48] It cautioned providers against prescribing higher than the suggested dose and recommended frequent monitoring of Ocaliva patients.[49]

Intercept's common stock price fell from $98.12 per share on September 20, 2017 to close at $61.59 per share on September 22.[50] Plaintiffs filed this class action on September 27, 2017.

Ocaliva remains on the market.[51]

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45 AC ¶ 142.

46 *Id*. ¶ 150.

47 *Id*. The FDA explained further that its letter "includes only reports submitted to FDA, so there may be additional cases about which we are unaware." FDA Drug Safety Communication, AC Ex. F [DI 52-6] at 2.

48 *Id.* at 1.

49 *Id*.

50 AC ¶ 153.

51 Plaintiffs do not allege that the drug has been limited or otherwise modified since the FDA's letter. The FDA did, however, add a "black box warning" to the Ocaliva label on February

II. Plaintiffs' Claims

Plaintiffs assert claims under the Exchange Act against Intercept and four current and former Intercept executives: Mark Pruzanski (founder and chief executive officer), Sandip Kapadia (chief financial officer), Richard Kim (former senior vice president of commercial U.S. and current president of U.S. commercial & strategic marketing), and Rachel McMinn (former chief business and strategy officer) (collectively, the "Individual Defendants"). Plaintiffs allege that twenty-one of defendants' prior statements were materially false or misleading in violation of Sections 10(b) and 20(a) of the Exchange Act.[52] The statements can be categorized broadly as ones (1) concerning Ocaliva's safety and tolerance, (2) related to patients' compliance with the FDA-recommended dosing regimen, and (3) made following the HCP Letter related to the severity and scope of the SAEs. These statements allegedly were made at conferences, on earning calls, or included in public company presentations, analyst reports, and SEC filings.

Defendants move to dismiss for failure to allege a material misstatement or omission. They contend in any case that the Complaint should be dismissed for failure to plead adequately *scienter* as required by Rule 9(b) and the PSLRA. Defendants argue also that plaintiffs' Section 20(a) claim alleging control person liability should be dismissed for failure to plead a primary violation of Section 10(b).

1, 2018 instructing physicians to adhere to the recommended doses and to monitor patients closely. The label required also that Ocaliva patients receive a medication guide informing them about the risk of potential serious liver injury. *Id*. ¶ 156. "A black box warning is the FDA's most prominent label warning and is designed to call attention to serious or life-threatening risks." *Id*. (citing *A Guide to Drug Safety Terms at FDA*, 2 (Nov. 2012)).

52 *Id*. ¶¶ 93, 96, 98, 100, 102, 104, 106, 108, 116, 118, 120, 122, 124, 126, 128, 132, 134, 136, 144, 146, 148. The statements made in ¶ 93 and ¶ 108 were repeated on other occasions (*see id.* ¶¶ 95, 109-13).

Discussion

I. Legal Standards

A. Motion to Dismiss Standard

To survive a motion to dismiss, a plaintiff must allege facts sufficient to "state a claim to relief that is plausible on its face."[53] The Court accepts as true all well-pleaded factual allegations and "draw[s] all reasonable inferences in the plaintiffs' favor."[54] In resolving a motion to dismiss, the Court may consider "any written instrument attached to the complaint, statements or documents incorporated into the complaint by reference, legally required public disclosure documents filed with the SEC, and documents possessed by or known to the plaintiff and upon which it relied in bringing the suit."[55]

A complaint alleging fraud under the securities laws must satisfy the heightened pleading requirements of Rule 9(b) and the PSLRA.[56] Rule 9(b) requires a plaintiff to plead "with

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53 *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citations and internal quotation marks omitted).

54 *Rombach v. Chang*, 355 F.3d 164, 169 (2d Cir. 2004).

55 *ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 98 (2d Cir. 2007).

Defendants submitted twenty-one exhibits with their motion to dismiss. Plaintiffs moved to strike twenty of these documents as well as certain statements and citations to public webpages. DI 70. The Court denied plaintiffs' motion without prejudice. DI 89. In considering defendants' motion to dismiss, the Court concludes that the following publicly available documents, the authenticity of which is not disputed, were incorporated by reference in, or are integral to, the complaint and therefore are properly considered here: DI 63-5 ("Excerpts from FDA Briefing Package"), DI 63-8 ("Interconnect Enrollment Form"), and DI 63-12 ("FDA Office Deputy Director Decisional Memo").

The Court does not convert this motion into one for summary judgment. *See* FED. R. CIV. P. 12(d). It has considered the documents referred to above only for the facts of their contents and not for the truth of any matters asserted.

56 *ATSI,* 493 F.3d at 99.

particularity the circumstances constituting fraud."[57] To meet this standard, the complaint must: "(1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent."[58] The PSLRA requires additionally that the complaint "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed."[59]

B. Section 10(b) of the Exchange Act

Section 10(b) of the Exchange Act makes it unlawful to "use or employ, in connection with the purchase or sale of any security . . . any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the [SEC] may proscribe."[60] Rule 10b-5 implements that statute and prohibits "mak[ing] any untrue statement of a material fact or [omitting] to state a material fact necessary in order to make the statements made . . . not misleading."[61] To state a claim under Section 10(b) and Rule 10b-5, a plaintiff must allege: "(1) a material misrepresentation or omission by the defendant; (2) *scienter*; (3) a connection between the

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57 FED. R. CIV. P. 9(b).

58 *ATSI,* 493 F.3d 87 at 99 (citing *Novak*, 216 F.3d at 306).

59 15 U.S.C. § 78u–4(b)(1)(B).

60 *Id.* § 78j(b).

61 *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 318 (2007) (quoting 17 C.F.R. § 240.10b-5).

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."[62]

II. Material Misrepresentations and Omissions

A statement violates the securities laws if it is a material misrepresentation or omission. Rule 10b-5 distinguishes between untrue statements of fact (misrepresentations) and omissions of fact.[63] As this Court has explained, the requisite showing turns on the nature of the allegation. A complaint alleging that a defendant made an untrue statement of a material fact must plead facts that, if true, are sufficient to show that the statement alleged was "false *at the time it was made*" and must do so with sufficient particularity to satisfy Rule 9(b) and the PSLRA.[64] When alleging omission of a material fact, a plaintiff must plead that the defendant had, and neglected, a duty to disclose the information.[65] "Such a duty may arise expressly, pursuant to a statute or regulation, or implicitly 'as a result of the ongoing duty to avoid rendering existing statements misleading by failing to disclose material facts.'"[66]

The Supreme Court has held that statements of opinion or belief may be false or misleading in certain circumstances. To succeed on such a claim, a plaintiff must show that the

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62 *Halliburton Co. v. Erica P. John Fund, Inc.*, 573 U.S. 258, 267 (2014) (citations and internal quotation marks omitted).

63 17 C.F.R. § 240.10b-5(b).

64 *See City of Westland Police & Fire Ret. Sys. v. MetLife, Inc.*, 129 F.Supp.3d 48, 67 (S.D.N.Y. 2015) (emphasis in original) (citation and internal quotation marks omitted).

65 *Id.* (citation omitted).

66 *Id*. (quoting *In re Lululemon Sec. Litig.*, 14 F.Supp.3d. 553, 572 (S.D.N.Y. 2014)).

opinion or belief (1) "constitutes a factual misstatement" by alleging that the speaker "did not hold" the stated belief, or (2) is "rendered misleading by the omission of discrete factual representations" in that the speaker omitted material facts "going to the basis for the [speaker's] opinion . . . whose omission makes the opinion statement at issue misleading to a reasonable person reading the statement fairly and in context."[67]

A plaintiff must allege also that the statement or omission in question is material. "At the pleading stage, a plaintiff satisfies the materiality requirement of Rule 10b–5 by alleging a statement or omission that a reasonable investor would have considered significant in making investment decisions."[68]

A. Statements Concerning Ocaliva's Safety and Tolerability

1. The Statements

Plaintiffs challenge ten statements concerning the drug's safety and patients' tolerance of Ocaliva.[69] They contend that those statements were misleading because, at the time they were made, defendants did not disclose that SAEs had been reported.[70] Some of these

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67 *Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension Fund*, 135 S. Ct. 1318,1325-29, 1332 (2015).

68 *Ganino v. Citizens Utilities Co.*, 228 F.3d 154, 161 (2d Cir. 2000) (citing *Basic Inc. v. Levinson*, 162 485 U.S. 224, 231) (1998)).

69 AC ¶¶ 116, 118, 120, 122, 124, 126, 128, 132,134, 136.

70 Defendants argue also that, because the FDA published the SAE reports in a public online database, statements related to safety and tolerability cannot be material. Despite defendants' attempt to avoid labeling it as such, this "truth on the market" defense is "rarely an appropriate basis for dismissing a [Section] 10(b) complaint." *Gannino*, 228 F.3d at 167. This is because the defense is "intensely fact-specific" and requires that the Court consider whether the information was "reasonably available"(or whether, as plaintiffs here claim, the

statements were made by Pruzanski, Kim, McMinn at conferences and on earnings calls. One was included in an Intercept presentation. Three were included in analyst reports.

A bit more must be said about statements in the latter category. "Plaintiffs may state a claim against corporate officials for false and misleading information disseminated through analysts' reports by alleging that the officials either: (1) 'intentionally foster[ed] a mistaken belief concerning a material fact' that was incorporated into reports; or (2) adopted or placed their 'imprimatur' on the reports."[71] A plaintiff cannot plead fraud "through completely unattributed statements,"[72] and must instead "identify the circumstances of the statements—including dates and participants."[73]

Plaintiffs have met this burden with respect to the February 23, 2017 RBC report. The Complaint alleges the date, the circumstances (a conference), and the speakers (Pruzanski and McMinn).[74] While it identifies the date and circumstances of the statements contained in the other reports, it does not identify the speakers and attributes the comments only to "management."[75] Nor

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information is not located or processed easily) and if it was "conveyed to the public with a degree of intensity and credibility sufficient to counter-balance effectively any misleading information." *Id*. (citations omitted). These inquiries cannot be resolved at this stage.

71 *Novak*, 216 F.3d at 314 (quoting *Elkind v. Liggett & Mters, Inc.*, 635 F.2d 156, 163-64 (2d Cir. 1090)).

72 *In re Time Warner Inc. Sec. Litig*., 9 F.3d 259, 265 (2d Cir. 1993).

73 *Novak*, 216 F.3d at 315.

74 AC ¶ 134.

75 *Id*. ¶¶ 132, 136. Plaintiffs' reliance on *In re Abercrombie & Fitch Co. Sec. Leg*., 2003 WL 22705131 (S.D.N.Y. Nov. 17, 2003) is misplaced. There, the Court found that references only to "management" in an analyst report sufficed. However, the complaint alleged that the management team was "small and tightly knit" and that there were only three officers who

does it allege which members of Intercept's management were present at the time the statements were made. The statements from the December 5, 2016 Leerink report and the June 12, 2017 Cowen report therefore cannot be attributed to Intercept and form the basis of plaintiffs' claim.

The following are representative examples of the eight remaining statements and plaintiffs' arguments as to why the statements were misleading:

- McMinn's September 13, 2016 statement that "overall I think the headlines that we're trying to mention now is, no big surprises" and Pruzanski's follow up comment that "I think with respect to persistency . . . it's too early days, but the one issue of course that might be of concern is the one notable side effect that we see with the drug, which is dose-dependent pruritus." This allegedly implied that Ocaliva's only side effect was pruritus, an itching of the skin, though there had been two reports of serious liver injury.[76]
- Pruzanski's January 11, 2017 comment that "while it's still early days, we have come to understand that in the real world, the real world experience of patients has been largely very positive." This allegedly was misleading because five deaths and four cases of serious liver injury had been reported.[77]
- A presentation slide used during Intercept's Second Quarter 2017 Earnings Conference Call, and published on Ocaliva's website during the class period, containing survey results that "149 doctors were motivated to prescribe

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"spoke frequently with security analysts." There are no such allegations in plaintiffs' Complaint.

[76] *Id.* ¶¶ 118-19. The two SAEs were reported in early-stage PBC patients. *Id.* ¶ 86.

[77] *Id.* ¶¶ 120-21.

> Ocaliva because it had 'no serious side effects' and 93 were motivated to prescribe it because it was 'easily tolerated.'" This allegedly was misleading because Intercept had received reports of nineteen deaths and eleven cases of serious liver injuries when the presentation was made.[78]

2. Whether the Safety and Tolerability Statements were Material Misstatements or Omissions

Plaintiffs' argument that the safety and tolerability statements were materially false or misleading is premised on defendants' failure to disclose the reported SAEs at the time the statements were made. The Second Circuit has recognized that though there is a "distinction between concepts of a duty to disclose [an omitted fact] and materiality," when, as here, the duty to disclose arises from the need to prevent a statement from being misleading, "the inquiries as to [the disclosure] duty and materiality coalesce."[79] These challenged statements were misleading under the securities laws only if the SAEs were material.

Even still, "[section] 10(b) and Rule 10b–5(b) do not create an affirmative duty to disclose any and all material information."[80] Disclosure is required when there is "a substantial likelihood that the disclosure of the omitted fact would have been viewed by a reasonable investor as having significantly altered the 'total mix' of information made available."[81] In the context of

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78 *Id*. ¶¶ 126-27.

79 *In re Time Warner Inc. Sec. Litig*., 9 F.3d, at 267.

80 *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 44 (2011) (quoting 17 CFR § 240.10b–5(b)).

81 *Basic Inc. v. Levinson*, 485 U.S. 224, 232 (1987).

adverse events, the Supreme Court in *Matrixx* held that the "total mix" standard "does not mean that pharmaceutical manufacturers must disclose all reports of adverse events."[82] "The mere existence of reports of adverse events" is not material.[83] "[S]omething more is needed[.]"[84] Adverse events are material when there is a "scientifically reliable basis for inferring a potential causal link" between the drug and the adverse event.[85] This link may be demonstrated through statistically significant evidence of causation or "can come from the source, content, and context of the reports."[86]

In this case, materially thus cannot be established solely because twenty-seven out of 3,000 Ocaliva patients – or approximately 0.9 percent of Ocaliva users – experienced an SAE during the one year class period. Plaintiffs contend that they sufficiently have pled "something

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82 *Matrixx*, 563 U.S. at 43.

83 *Id*. at 44.

84 *Id*.

85 *Id*. at 40.

The parties dispute whether the Complaint must plead facts alleging that Ocaliva *caused* the adverse events, as defendants contend, or that Ocaliva was *associated* with adverse events. Though causation and association are distinct concepts, the latter informing the former, *see Id.* at 41, the sufficiency of plaintiffs' allegations will be held to the same standard: Is there "a substantial likelihood that the disclosure of the omitted fact would have been viewed by a reasonable investor as having significantly altered the 'total mix' of information made available"? *Id*. at 38 (quoting *Basic*, 485 U.S. at 232). Indeed, as plaintiffs do here, the Supreme Court in *Matrixx* framed the plaintiff's grievance as one of association. *Id*. at 30 ("This case presents the question whether a plaintiff can state a claim for securities fraud under [Section 10(b)] . . . based on a pharmaceutical company's failure to disclose reports of adverse events *associated* with a product if the reports do not disclose a statistically significant number of adverse events.") (emphasis added). *Matrixx* simply reaffirmed *Basic*'s "total mix" standard and that materiality is a fact-specific inquiry.

86 *Id*. at 44.

more" through their allegations about Ocaliva's history and prior FDA action. They point to the increase in number of patient deaths from the Phase 3 trial (two out of 1,325 patients) to the post-trial period (nineteen out of approximately 3,000 Ocaliva patients) as one such example. Other examples of "something more" include: the FDA's historic concern with liver injuries and related agency actions; the agency's "repeated[]" concern about the liver-related adverse events in Ocaliva's clinical trial and requirement that Intercept conduct a Phase 4 clinical trial "to provide more data" on Ocaliva's safety and efficacy; Intercept's knowledge that, as a recipient of accelerated approval, the FDA would continue to scrutinize the safety and efficacy data and could withdraw Ocaliva if the product proved to be unsafe; the FDA's concerns about the "vulnerabilities" of patients with late-stage PBC and the known need for these patients to receive a lower dose of Ocaliva; and the FDA's investigation into the SAEs following Intercept's July 31, 2017 announcement that a patient in the Phase 2 trial had died. Taken together, plaintiffs argue that the Complaint pleads that the thirty SAEs were material.

The Court disagrees. First, it is well known that "[h]epatotoxicity is a known complication of most prescribed drugs."[87] In any case, even if "liver injury has been the most frequent single cause of safety-related drug marketing withdrawal over the past 50 years," that is because the FDA took action against drugs *other* than Ocaliva manufactured by companies *other* than Intercept.[88] This does not provide the requisite link between Ocaliva and the reported adverse events or otherwise make the thirty SAEs material. Nor does the FDA's instruction to conduct a Phase 4 trial. The need for this trial was not, as plaintiffs suggest, born of a heightened concern

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87 *In re Rezulin Prods. Liab. Litig.,* 210 F.R.D. 61, 64 (S.D.N.Y. 2002).

88 AC ¶¶ 36-37.

about liver-related adverse events in Ocaliva users. As the Complaint makes clear, Phase 4 clinical trials are required for any drug approved under the AAP.[89] Plaintiffs' argument that Intercept's *general* awareness of the FDA's drug safety monitoring – and the agency's power, *generally*, to withdraw drugs from the market if the safety data is concerning – evidences the SAE's materiality is also unavailing. Finally, allegations about the FDA's actions after July 31, 2017 do not supply the requisite "something more." Plaintiffs' argument here falsely equates FDA action taken *after* the statements at issue were made with whether adverse events were material under the securities laws *at the time* the statements were made.

Plaintiffs' arguments about the late-stage PBC patients also do not advance their claim that the SAEs were material. The prognosis of this patient population undermines plaintiffs' argument. To the extent that there were concerns about the vulnerabilities of late-stage patients, it bears repeating that these patients has compromised livers and already were quite sick. As the Second Circuit has recognized, "[s]ome adverse events may be expected to occur randomly, especially with a drug designed to treat people that are already ill."[90] Plaintiffs' related argument about the once weekly dosing requirement is only moderately helpful to their position. In substance, plaintiffs contend that the materiality of SAEs in all twenty-seven Ocaliva users – which include both late-stage and early-stage PBC patients – is sufficiently pled, in part, based on Intercept's knowledge that increased exposure to drug toxicity could be dangerous in late-stage PBC patients. While this does allege a known link between the drug and potential adverse events, the link is

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89 *Id.* ¶ 45 ("Because pharmaceutical companies do not need to provide as much confirmatory safety data, as a condition of Accelerated Approval, the FDA continues to scrutinize the safety and efficacy of the drug and requires phase 4 post-marketing confirmatory trials.").

90 *In re Carter-Wallace, Inc., Sec. Litig.*, 220 F.3d 36, 41 (2d Cir. 2000).

cabined to a tiny subset – 2-3 percent – of patients. Its value is therefore limited.

What remains is plaintiffs' claim that it has pled "something more" than the existence of adverse events by comparing the smaller number of deaths in the Phase 3 clinical trial to the slightly larger number deaths in the post-trial period. This is no different than an allegation that the "mere existence" of adverse events in one group of Ocaliva users is smaller than the "mere existence" of adverse events in a larger sample size.[91] As explained previously, "the mere existence of reports of adverse events—which says nothing in and of itself about whether the drug is causing the adverse events—will not satisfy [the total mix materiality] standard."[92]

When plaintiffs' argument is stripped of its allegations of "something more," they are left only with the occurrence of serious liver injury or death in fewer than 1 percent of Ocaliva. Particularly when compared to the overwhelming number of allegations made by the *Matrixx* plaintiffs, plaintiffs' allegations here fall short.[93] Without more, plaintiffs have not alleged

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91 Even if a sufficient allegation, this argument would have limited relevance. Plaintiffs allege that two out of 1,325 patients died during the clinical trial, or .15 percent of patients. Therefore, at any point that .15 percent of Ocaliva users died during the class period – roughly five patients, assuming for purposes of this example that there were approximately 3,000 users throughout the period – plaintiffs' argument that a death toll comparison is indicative of a link between Ocaliva and adverse events is moot. At the time defendants made three of the allegedly misleading statements, *see* AC ¶¶ 116, 118, 120, there were zero to five reported deaths. *Id*. ¶ 86.

92 *Matrixx*, 563 U.S. at 44.

93 There, plaintiffs sufficiently alleged evidence of a reliable causal link between the drug and adverse events because: "Critically," the drug manufacturer was aware of previous studies showing a casual biological link between one of the drug's ingredients and the type of adverse event reported; received "reports from three medical professionals and researchers about more than 10 patients" who suffered an adverse event; was the subject of four product liability lawsuits alleging a causal link between the drug an adverse event; knew of a medical conference presentation during which physicians presented findings about the causal link; and was "sufficiently concerned" that it hired a consultant to review the relevant information. *Id*. at 45-6, 49.

adequately that a reasonable investor would have viewed the thirty reported SAEs as "significantly alter[ing] the 'total mix' of information available."[94]

B. Statements Related to Dosage Compliance

1. The Statements

Defendants made eight allegedly false or misleading statements related to patient dosing and compliance when discussing Interconnect's capabilities, patients' dosing regimens, and factors potentially impacting Intercept's commercial prospects.[95] For example:

- Intercept's June 9, 2016 public presentation described Interconnect Support Services as facilitating "[c]ompliance and persistency."[96] This was allegedly misleading because it did not disclose that the company-created enrollment form "caused" patients to receive an incorrect dose of Ocaliva, nor disclosed that patients had been misdosed when the presentation slide was later repeated.[97]
- Pruzanski's May 17, 2017 comment that "compliance [and] persistency are key here . . . As we've said, this early in the launch, it's too early to make definitive comments about persistency and compliance other than,

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94 *Basic*, 485 U.S. at 231-32.

95 AC ¶¶ 93, 96, 98, 100, 102, 104, 106, 108. The statements made in ¶ 93 and ¶ 108 were repeated (*see id.* ¶¶ 95, 109-13).

96 *Id.* ¶ 93.

97 *Id.* ¶¶ 94-95.

anecdotally, we're happy with where we are. There've been no surprises." This allegedly was misleading because Intercept had received SAE reports showing that eight late-stage patients had been prescribed an incorrect dose.[98]

- Kim's July 31, 2017 statement that "[w]e are encouraged by the persistency and compliance with Ocaliva thus far . . . our compliance and persistency initiatives have been enhanced [through patient outreach via Interconnect]." This allegedly was misleading because he did not mention that twelve late-stage PBC patients were known to have been mid-dosed.[99]
- Pruzanski's August 16, 2017 remark that "we now have some visibility on compliance and persistency. And I'm very pleased to say that in the real world, our drug is performing at least as well if not better than the standard-of-care generic product URSO." This was allegedly misleading because he did not disclose that the enrollment form "caused" late-stage PBC patients to receive the incorrect dose and that twelve late-stage PBC patients were misdosed. [100]

2. Whether the Statements Were Misleading in Light of the Enrollment Form

The Complaint alleges that statements about dosing compliance and Interconnect's ability to facilitate the drug enrollment process were misleading because the speaker did not disclose

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98 *Id* ¶¶ 100-01.

99 *Id.* ¶¶ 102-03.

100 *Id*. ¶¶ 104-05.

that some patients were prescribed an incorrect dose. This argument is premised, in part, on plaintiffs' unsupported assertion that because enrollment form did not contain a weekly dosing option, the form "forced" providers to prescribe late-stage patients a higher than recommended drug dose.[101]

This argument ignores the fact that physicians – not pharmaceutical companies – prescribe prescription drugs. These prescribing decisions are based on a variety of factors, including "an individual patient's diagnosis, past and current medications being taken by the patient, the physician's own experience with prescribing [the drug], and the physician's knowledge regarding [its] side effects," in addition to the information provided by the drug company.[102] And there are no allegations that Intercept disseminated incorrect dosing instructions or that Ocaliva's label was unclear as to the recommended dose for late-stage patients. Plaintiffs' claim therefore depends on the theory that Intercept, through the enrollment form – which included a space for physicians to list "additional directions" – compelled physicians to ignore considerations typically made when prescribing drugs and Ocaliva's prescribing directive, simply because the form did not contain an option to select a weekly supply.

Even accepting plaintiffs' flawed premise, the Complaint does not allege plausibly that the dosing statements were misleading in light of the enrollment form's design. Critically, plaintiffs do not allege any facts that plausibly demonstrate a link between the twelve known instances of misdosing and the enrollment form. For example, plaintiffs do not allege whether – or how many – of these patients were prescribed Ocaliva through the form or any facts sufficient to

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101 *Id.* ¶¶ 56, 93-107.

102 *UFCW Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121, 135 (2d Cir. 2010).

allege that the receipt of an incorrect dose ordered via the enrollment form was a systemic problem such that any patient misdosing could be attributed to the form itself, rather than to a particular pharmacy, physician, or other actor. Instead, plaintiffs rely on the statistic that the "majority" of prescriptions were filled using the enrollment form.[103] Plaintiffs proclaim that defendants "do not provide an alternative explanation for how overdosing become so prevalent that Intercept and the FDA had to issue warnings reminding doctors of the proper doses."[104] Yet no such explanation is required. Indeed, it is *plaintiffs*' responsibility to plead facts with sufficient particularity to establish their claims. Plaintiffs have not met this burden. Moreover, plaintiffs cannot bolster their otherwise unsupported allegation that the form "forced" the administration of incorrect doses by pointing to the fact that FDA issued a warning letter and that Intercept issued the HCP Letter when neither mentioned the enrollment form.

Plaintiffs' one specific allegation of form-related misdosing falls short of meeting the heightened pleading standard.[105] According to plaintiffs' confidential witness, a physician prescribed a late-stage PBC patient with what he or she knew to be the wrong dose of Ocaliva, but did so because there was no other option on the form.[106] The physician "incorrectly expected

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103 AC ¶¶ 77, 100.

104 Plaintiffs Memorandum in Opposition to Defendants Motion to Dismiss [hereinafter "Pls.' Op."] [DI 74] at 25.

105 Plaintiffs cite an Ocaliva user's Facebook post stating that she was prescribed an improper dose and later experienced an adverse liver reaction as further support for its claims. AC ¶ 63. Plaintiffs do not plead, however, that the Facebook user's incorrect prescription resulted from the enrollment form. Instead, they summarily allege that"Intercept had recommended" the incorrect dose, without facts regarding how or when such a recommendation was made. *Id.*

106 *Id.* ¶ 62.

Intercept to instead provide the weekly dose when it reviewed the form and saw that the patient had a high bilirubin level."[107] While for purposes of the motion to dismiss the Court must accept these facts as true, plaintiffs have not sufficiently alleged that the enrollment form was the source of any other prescribing errors. They have failed to allege who, if anyone other than CW1, at Intercept was aware of this misunderstanding or instance of improper dosing,[108] whether other physicians shared this confusion and repeated the error, or any other particularized indicia that the form caused other patients to be misdosed. Accordingly, they have not alleged that defendants' statements about dosing compliance were misleading in light of the form's limited prescription options.

3. Whether the Statements were Misleading in Light of Known Instances of Misdosing

Plaintiffs contend that defendants' statements on dosing compliance were false and misleading also in light of known instances of misdosing.

The Court accepts as true that Intercept received at least twelve reports that patients were prescribed an incorrect dose. But this fact does not render the statements false or misleading. Where, as here, "[t]he statements at issue are couched in general terms and make no concrete representations [regarding dosing compliance],"[109] Intercept did not mislead investors by stating that it was "very much focused on [] compliance and persistency,"[110] wanting "patients on the right

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107 *Id.*

108 Plaintiffs concede that the Individual Defendants were unaware of this incident: Plaintiffs specifically note "[t]he AC does not allege that CW1 spoke with the Individual Defendants[.]" Pls.' Op. at 23 n.25.

109 *In re Sanofi Sec. Litig.*, 87 F.Supp.3d 510, 537 (S.D.N.Y. 2015).

110 AC ¶ 106.

starting dose,"[111] and that, "generally, people are becoming better experienced in how to manage these patients [with advance disease and hepatic impairment] in the marketplace,"[112] by omitting that prescriptions for twelve out of 3,000 of patients did not comply with recommended dosing regimen.

Nor have plaintiffs alleged that the statements were false when made. For example, plaintiffs cite the statement "we've got basically everybody starting on the 5 milligram dose" to illustrate that defendants misrepresented that patients received the correct dose of Ocaliva.[113] Yet, when the statement was made on September 13, 2016, Intercept had not received a single report of misdosing.[114] Similarly, plaintiffs have not alleged any facts to suggest that statements such as "we're very careful to make sure people understand how to actually start, initiate, and manage patients with hepatic impairment"[115] or "we now have some visibility on compliance and persistency . . . our drug is performing at least as well if not better than the standard-of-care generic product"[116] were untrue statements of fact.

Plaintiffs have failed also to allege sufficiently that the statements related to misdosing reflecting the speaker's opinion – *e.g.*, "I think its been well communicated on how to

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111 *Id.* ¶ 96.

112 *Id*. ¶ 98.

113 *See* Pls.' Op. at 8 (quoting AC ¶ 96).

114 AC ¶ 86.

115 *Id*. ¶ 98.

116 *Id*. ¶ 104.

properly manage those patients [with late-stage PBC],"[117] "we are encouraged by the persistency and compliance with Ocaliva thus far,"[118] and "we're happy with where we are"[119] – were misleading. The Complaint must, and does not, allege more than that the speaker "kn[e]w[], but fail[ed] to disclose, some fact cutting the other way."[120]

Plaintiffs claim also that Intercept's risk statement in the company's 10-K and 10-Q filings during the class period was misleading. Intercept there stated that "the use of Ocaliva in a non-trial setting may result in the occurrence of unexpected or a greater incidence of side effects, adverse reactions or misuse that may negatively affect the commercial prospects of Ocaliva."[121] Plaintiffs argue that, as evidenced by the misdosed patients, the risk factor for Ocaliva's "misuse" had materialized, but defendants misled investors by using the cautionary language – "may result . . . in misuse"– to describe the risk.[122]

The key question when evaluating cautionary language in securities offerings is whether a "reasonable investor could have been mislead about the nature of the risk when he invested."[123] Relevant to this inquiry is whether the risk is described generally or with specificity.

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117 *Id*. ¶ 100.

118 *Id*. ¶ 102.

119 *Id*. ¶ 100.

120 *Omnicare*, 135 S.Ct. at 1329.

121 AC ¶ 108.

122 *Id*. ¶¶ 109-10.

123 *Halperin v. eBanker USA.com, Inc*, 295 F.3d 352, 359 (2d Cir. 2002).

For example, "a caution that 'input prices may rise next quarter' would not cause a reasonable investor to conclude that the prices of all inputs had remained flat or declined in the previous quarter," whereas a caution that "the price of our primary input may rise above $5 next quarter could certainly cause a reasonable investor to conclude that the price was, at present, $4.99 or less."[124]

Plaintiffs point to *In re Mylan* as support for their position the Intercept's risk statement was misleading. There, the court found defendants' statement misleading because the *specific* event warned against already had occurred.[125] In contrast, the risk identified in Intercept's filings was broader. The company warned investors about a potential for a negative impact on earnings. The statement that the use of Ocaliva "may result in side effects, adverse reactions or misuse" was made in the context that these events were ones that could affect Intercept's income. If, when the statements were made, any misuse or adverse events had affected Intercept's earnings negatively, then the statement would have been misleading. But there are no such allegations.

For the aforementioned reasons, plaintiffs have failed to plead any material misstatements or omissions related to dosing compliance.

C. *Statements Following the HCP Letter*

On September 12, 2017 Intercept issued the HCP Letter with the subject: "Liver injury, liver decompensation, liver failure, and death have been reported in primary biliary

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124 *In re Mylan N.V. Sec. Litig.*, No. 16-cv-7926 (JPO), 2018 WL 1595985, at *9 (S.D.N.Y. Mar. 28, 2018).

125 There, the risk statement included "[s]hould there be ambiguity with regard to how to properly calculate and report payments—and even in the absence of any such ambiguity—a governmental authority may take a position contrary to a position we have taken" and "any failure to comply with [our] obligations could subject us to investigation," though both events had transpired. *Id.* at *9-*10.

cholangitis (PBC) patients *with moderate or severe hepatic impairment* (Child-Pugh B and C) when Ocaliva was dosed more frequently than recommended."[126] It explained that Intercept had received reports of SAEs in late-stage PBC patients who were misdosed and reiterated the dosing recommendations for patients with late-stage PBC.[127] While the letter references early-stage patients once ("serious liver adverse events have been reported in patients initiating therapy without cirrhosis or with mild liver impairment"),[128] it is squarely focused on late-stage patients. It is silent as to whether Intercept believed Ocaliva did or did not cause the adverse events.

On September 12, 2017, Pruzanski and McMinn spoke at a Morgan Stanley Healthcare Conference about the HCP Letter. Plaintiffs allege that defendants' statements that the letter refers to "the 2% to 3%, the tiny proportion of this population who have the most advanced disease" (Pruzanski) and "as you get into these very, very advanced cirrhotics, you're going to have to back off the dose. I think that's really the main takeaway message from [the HCP Letter]" (McMinn) misrepresent the scope and severity of the reported SAEs.[129]

Plaintiffs' claim is premised entirely on the conclusory allegation that the HCP Letter "did not only result from late-stage PBC patients receiving the incorrect daily dose of Ocaliva, because in the adverse events reviewed by the FDA, at least 1 patient died and 4 patients experienced serious liver injury, even when they took the correct dosage of Ocaliva."[130] Missing

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126 HCP Letter at 1 (emphasis added).

127 *Id*.

128 *Id*.

129 AC ¶¶ 144-45.

130 *Id*. ¶ 145.

from the Complaint are allegations to suggest that the HCP Letter resulted from anything other than the SAE reports involving patients who were administered an incorrect dose of Ocaliva.[131] That Intercept received SAE reports indicating that correctly dosed patients suffered adverse events is not enough.

Plaintiffs take issue with several other statements made after the HCP Letter that appeared in a September 18, 2017 analyst report from BMO Capital Markets. These statements can be attributed to Intercept corporate officials.[132] The report stated that:

> "Management reiterated lack of adherence to the label and known risk in end-stage liver disease [late-stage PBC] as the cause of the observed AEs and deaths in ~10 patients, given Ocaliva exposure is significantly increased in these patients. . . . Management noted that no causality was established with patient deaths and Ocaliva given advanced stage of patients. . . . [T]he population referenced in the Dear HCP Letter represents 2-3% of addressable PBC patients" [133]

Plaintiffs argue that the first and last sentence falsely implied that the HCP Letter was prompted only by SAEs in late-stage patients. They contend also that the report misrepresented the number

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131 To the contrary, the Complaint describes the letter as: "When the market opened on September 12, 2017, the Company posted a 'Dear Healthcare Provider' Letter warning about the danger of *late-stage* PBC patients receiving an excessive dose of Ocaliva." *Id.* ¶ 141 (emphasis added).

The allegation is deficient also because plaintiffs have not alleged adequately that McMinn's statement, which expresses her opinion, is misleading because they have not alleged facts sufficient to show that McMinn "did not hold the stated belief" or that the statement did not "rest on some meaningful . . . inquiry." *Omnicare*, 135 S. Ct. at 1325-28, 1332.

132 *See supra* notes 71-75 and accompanying text. The Complaint alleges the date, the circumstances (a client lunch), and the speakers (Pruzanski and Kapadia). AC ¶ 148.

Plaintiffs take issue with statements about the HCP Letter published in a UBS report. However, in contrast to the BMO report, and as with the Cowen and Leerink reports, the UBS report attributes the comments to "management," and the Complaint does not allege who from Intercept were present when the statement was made. *Id.* ¶ 136.

133 *Id*. ¶ 148.

of patients who suffered SAEs because there had been reports of thirty adverse events rather than "~10." Finally, they argue that the statement that "no causality was established" misrepresented the information available to Intercept because Intercept's comments on the SAE reports revealed that a causation was still an open question.[134]

The Complaint does not allege sufficiently that statements in the BMO report were false or misleading. Plaintiffs' first argument fails because, as explained above, there are no allegations that the HCP Letter resulted from anything other than SAE reports involving late-stage patients who took an incorrect dose. Indeed, aside from a single sentence, the HCP Letter focuses on late-stage PBC patients known to have been misdosed, of which there were twelve. For that reason, plaintiffs' argument that the reference "~10" is false or misleading fails also. To be sure, a difference of two patients does not make the statement materially false or misleading under the securities laws. Finally, plaintiffs have not alleged that as of September 18, 2017, "no causality [had been] established" between Ocaliva and the SAEs in late-stage patients.[135] To the contrary, the HCP Letter, from which the Complaint quotes, specifically states that "[a]lthough a temporal association exists, *it is not sufficient to establish,* or rule out a causal relationship between Ocaliva and the events reported."[136]

For the foregoing reasons, plaintiffs have not alleged adequately that the statements concerning the HCP Letter were false or misleading.

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134 *Id.* ¶ 149. With respect to the causation data, the company comments stated: "Although temporal association exists, it is not sufficient to establish, *or rule out*, a causal relationship between Ocaliva and the events reported in this case." (emphasis in original). *Id.*

135 *Id*. ¶ 148.

136 *Id.* ¶ 149 (emphasis added).

III. Scienter

Scienter is pled by alleging facts demonstrating either (1) "that defendants had both motive and opportunity to commit fraud," or (2) "strong circumstantial evidence of conscious misbehavior or recklessness."[137] Particularized facts supporting an inference of *scienter* must be pled as to each Individual Defendant.[138] "When the defendant is a corporate entity . . . the pleaded facts must create a strong inference that someone whose intent could be imputed to the corporation acted with the requisite *scienter*."[139]

Even if the Complaint sufficiently pled that defendants made false or misleading statements, for the reasons set forth below, the Complaint is dismissed for failure to plead *scienter*.

A. Motive and Opportunity

To allege *scienter* based on motive and opportunity, plaintiffs must demonstrate that defendants "benefitted in some concrete and personal way from the purported fraud."[140] This generally is done by alleging that "corporate insiders [] ma[d]e a misrepresentation in order to sell their own shares at a profit."[141]

Nothing of the sort is alleged here. Instead, the Complaint alleges only that McMinn

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137 *Kalnit v. Eichle*r, 264 F.3d 131, 138 (2d Cir. 2001).

138 *Dobina v. Weatherford Int'l Ltd.*, 909 F.Supp.2d 228, 240 (S.D.N.Y. 2012).

139 *Teamsters Local 445 Freight Div. Pension Fund v. Dynex Capital Inc*., 531 F.3d 190, 195 (2d Cir. 2008).

140 *ECA & Local 134 IBEW Joint Pension Trust of Chicago v. JP Morgan Chase Co.*, 553 F.3d 187, 198 (2d Cir. 2009) (citation and internal quotation marks omitted).

141 *Id*.

and Pruzanski sold 11 and 15 percent of their Intercept common stock, respectively, during the class period.[142] McMinn sold her shares for approximately $223,000 and Pruzanski sold his shares for approximately $12.8 million.[143] The Complaint does not allege any facts showing that these sales were suspicious or indicative of a motive to profit or to otherwise personally benefit from the alleged fraud. Plaintiffs make no similar allegations against the other Individual Defendants, Kapadia and Kim. Because stock sales alone are insufficient to demonstrate *scienter*, plaintiffs have not demonstrated that Pruzanski or McMinn had a motive to commit fraud.[144]

Plaintiffs allege also that defendants had motive to conceal the repeated administration of incorrect doses in order to increase company profits. Plaintiffs estimate that a patient incorrectly prescribed a daily dose of Ocaliva, rather than the correct weekly dose, would spend an additional $60,000 per year on the drug.[145] This type of generalized profit motive fails to meet the heightened pleading standard, and accordingly, this allegation of motive and opportunity fails as well.[146]

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142 AC ¶¶ 26, 29.

143 *Id*.

144 *In re Lululemon Sec. Litig*., 14 F.Supp.3d 553, 584–85 (S.D.N.Y. 2014) (citation and internal quotation marks omitted) ("While unusual executive stock trading under some circumstances may give rise to an inference of fraudulent intent, executive stock sales, standing alone, are insufficient to support a strong inference of fraudulent intent.").

145 AC ¶ 64.

146 *See Kalnit*, 264 F.3d at 140.

B. Recklessness

If a plaintiff cannot plead motive and opportunity, allegations of conscious misbehavior or recklessness "must be correspondingly greater."[147] Here, plaintiffs allege only recklessness, which requires factual allegations that, if true, would permit a finding that defendants' conduct was an "extreme departure from the standards of ordinary care to the extent that the danger was either known to the defendant or so obvious that the defendant must have been aware of it."[148] The non-disclosure of known, relevant information alone does not demonstrate *scienter*; the alleged conduct must be more egregious. Examples include a defendant's "knowledge of facts or access to information contradicting their public statements . . . [when the defendant] knew . . . or should have known that they were misrepresenting material facts" or if a defendant "failed to review or check information that [it] had a duty to monitor, or ignored obvious signs of fraud."[149]

Plaintiffs argue that the Complaint sufficiently pleads that defendants acted with *scienter* because defendants either (1) were aware of or had access to information about the SAEs or dosing compliance that contradicted their public statements or, in the alternative, (2) failed to monitor the dosing data and SAEs in contravention of their duty.[150]

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147 *Id.* at 142.

148 *In re Lululemon Sec. Litig.*, 14 F. Supp. 3d at 573 (citation omitted).

149 *Novak*, 216 F.3d at 308.

150 AC ¶¶ 157-170.

1. Knowledge or Access to Information

a. Individual Defendants

The Complaint alleges that the Individual Defendants were aware of the reported SAEs because the Individual Defendants made statements about Ocaliva's safety and tolerability and therefore "would necessarily have had to review the safety information collected by the Company."[151] Plaintiffs make the same argument with respect to the statements related to dosing compliance, contending that the Individual Defendants' statements "evidenc[e] their familiarity with Interconnect and the Ocaliva dosing data" from which *scienter* can be inferred.[152]

Plaintiffs' arguments fail for several reasons. First, for the statements made prior to the HCP Letter, there are simply no particularized facts as to when or how each Individual Defendant learned about prescription dose errors or the adverse events. There is thus no basis from which the Court could infer that the Individual Defendants knew, *at the time the statements were made*, that patients had been misdosed or of the existence, scope, or severity of the adverse events that had been reported. The Complaint's conclusory allegation that the Individual Defendants "would necessarily" have had to know about the dosing data and reported SAEs[153] is insufficient.[154] Further, plaintiffs must, but do not, "plead circumstances providing a factual basis for s*cienter* for

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151 *Id*. ¶ 166.

152 Pls.' Op. at 25 (referencing AC ¶¶ 80, 81, 96, 98, 100, 102, 104, 118, 120, 162).

153 AC ¶¶ 160 (as to dosing compliance), 166 (as to safety and tolerance).

154 *In re PXRE Grp., Ltd., Sec. Litig.*, 600 F. Supp. 2d 510, 535 (S.D.N.Y. 2009) (citation omitted).

each defendant."[155] It is thus idle speculation that when each statement was made, the Individual Defendants had knowledge of facts that "contradict[ed] their public statements."[156]

Nor do the statements made before the HCP Letter "contradict" the reports of misdosing and adverse events. For example, statements such as "the vast majority of patients are

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155 *In re DDAVP Direct Purchaser Antitrust Litig*., 585 F.3d 677, 695 (2d Cir. 2009) (emphasis added); *see also The Penn. Ave. Funds v. Inyx Inc*., No. 08-cv-6857 (PKC), 2010 WL 743562, at *12 (S.D.N.Y. Mar. 1, 2010) ("'[G]roup pleading' of *scienter* . . . runs afoul of the PSLRA's requirement that a plaintiff 'state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.'") (citation omitted).

The Complaint's two particularized allegations as to an Individual Defendant fail.

According to CW1, Pruzanski "would have been able to access" the data by calling White. AC ¶ 66. This allegation does not plead adequately Pruzanski's awareness or knowledge because the mere possibility for an internal communication to occur does not demonstrate *scienter*. *See, e.g.*, *Fadem v. Ford Motor Co.*, 352 F. Supp. 2d 501, 522-23 (S.D.N.Y. 2005) (finding testimony showing employees "could" speak to one another, without evidence of what information actually was in fact shared and with whom, was insufficient to support a theory of *scienter*).

Pruzanski and Kapadia's signatures on the SEC filings containing the allegedly false or misleading risk statement are also insufficient to allege *scienter*. *See Susie Ong v. Chipotle Mexican Grill, Inc*., No. 16-cv-141 (KPF), 2017 WL 933108, at *15 n.7. (S.D.N.Y. Mar. 8, 2017) (citations and internal quotation marks omitted) ("Individual Defendants' signatures on SEC filings contribute, at most, a weak inference of *scienter*. To hold otherwise would allow plaintiffs to plead the *scienter* of whole classes of defendants solely by alleging a misstatement.").

156 *Novak*, 216 F.3d at 308.

Plaintiffs' comparison to *In re Delcath Sys., Inc. Sec. Litig*., 36 F. Supp. 3d 320, 335 (S.D.N.Y. 2014), is unavailing. There, the court found that the defendant CEO was aware of the adverse events experienced by study participants because his "public statements evinced a familiarity with the data in the [clinical] trials." *Id*. 335. This finding was based on the defendant's specific statements about comparative data between the drug group and control group. *Id*. ("For example, [defendant] . . . stat[ed] that the Drug Group had a more than three-fold increase in hepatic progression-free survival as compared with the Control Group."). Here, as discussed *supra*, plaintiffs made only general comments about the treatment approach, the features of Interconnect, and the average dose prescribed. *See, e.g.,* AC ¶¶ 80, 100.

being started appropriately at the 5 milligram daily doses,"[157] "[we're] encouraged by the persistency and compliance with Ocaliva thus far,"[158] and "we do see patients with complicated cirrhosis that are being treated with Ocaliva, but we're not really seeing major differences as far as the treatment approach"[159] are not contradicted by data showing that a small number of patients received more than the recommended dose. Similarly, statements that "the real world experience of patients has been largely very positive,"[160] "[i]n general, when people have prescribed with Ocaliva, feedback has been quite positive. But there's a lot more physicians we still have to reach"[161] and, when describing a survey of prescribing physicians, "[t]op motivation to prescribe are based on strong beliefs on efficacy and no serious side effects," are not incongruent with the small fraction of Ocaliva users who suffered adverse events.

The Complaint does, however, allege sufficiently that when the Individual Defendants made statements about the HCP Letter, they had knowledge of the adverse event reports. Indeed, the Individual Defendants were speaking directly about those reports. But, as explained above, the HCP Letter focused on the late-stage PBC patients who had experienced adverse events. Hence, the information in the adverse event reports did not "contradict" the statements made by the Individual Defendants.

Plaintiffs argue that, in the alternative, if the Individual Defendants did not review

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157 *Id.* ¶ 118.

158 *Id.* ¶ 128.

159 *Id.* ¶ 98.

160 *Id.* ¶ 120.

161 *Id.* ¶ 124.

the Interconnect data or adverse event reports prior to making statements about dosing compliance and Ocaliva's safety and tolerability, they were recklessness in not doing so. If true, perhaps the Individual Defendants were negligent in failing to review this data. But recklessness requires a "state of mind approximating actual intent, and not merely a heightened form of negligence."[162] Plaintiffs have not alleged facts sufficient to raise such an inference.[163]

Finally, the FDA's actions further undermine plaintiffs' *scienter* claim. *Scienter* can be shown where "management knows that certain facts will necessarily prevent the regulatory approval or the marketing of the drug and conceals these facts from the investing public[.]"[164] Yet here, armed with knowledge that Ocaliva patients were misdosed and experienced SAEs, the FDA did not withdraw the drug from the market or otherwise restrict or modify its availability.[165]

For the foregoing reasons, the Complaint fails to give rise to a strong inference of *scienter* as to the Individual Defendants based on their alleged knowledge or access

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162 *Novak*, 216 F.3d at 312 (citation and internal quotation marks omitted).

163 *Compare Matrixx*, 563 at 49 (plaintiffs' allegations "g[a]ve rise to a 'cogent and compelling' inference that Matrixx elected not to disclose the reports of adverse events not because it believed they were meaningless but because it understood their likely effect on the market," because, among other allegations, defendants hired a consultant to review the product, convened a panel of scientists and physicians to review the reported adverse events, and, "most significantly," released a press release affirmatively denying any link between the drug and adverse event when the evidence was in fact inconclusive) (citing *Tellabs*, 551 U.S. at 323).

164 *In re AstraZeneca Sec. Litig*., 559 F. Supp. 2d 453, 470 (S.D.N.Y. 2008).

165 *See, e.g.*, *In re Sanofi Sec. Litig*., 87 F. Supp. 3d at 533 (finding that "[d]espite the concerns the FDA had expressed about the design of the clinical trials, it allowed those trials to proceed" undermined plaintiffs' *scienter* allegations).

b. Intercept

The "most straightforward way" to raise a strong inference of corporate *scienter* is to plead facts sufficient to show *scienter* for an individual defendant.[166] Having failed to do so, in order to plead *scienter* as to Intercept, plaintiffs must allege adequately that some employee(s) other than the Individual Defendants acted with the requisite intent and that intent could be imputed to the corporation.[167] Plaintiffs attempt to do so by pleading that Intercept employees were aware of or had access to information about misdosing and the safety and tolerance of Ocaliva through the data aggregated in Interconnect and collected by the company's pharmacovigilance department.[168] Plaintiffs allege that Intercept employees were aware of the misdosing also because they knew that the enrollment form allowed only for a daily dose prescription.[169] They argue that this knowledge is imputed to Intercept.

One of the Complaint's fatal flaws with respect to *scienter* is its failure to allege sufficient facts about those with knowledge. While there is no "seniority prerequisite for employee

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166 *Teamsters Local 445*, 531 F.3d at 195.

167 In some instances, it is possible to raise an inference of *scienter* against a corporation without raising such an inference as to any individuals. This is not the case here. *See id.* at 195-96 ("It is possible to draw a strong inference of corporate *scienter* without being able to name the individuals who concocted and disseminated the fraud. Suppose General Motors announced that it had sold one million SUVs in 2006, and the actual number was zero. There would be a strong inference of corporate *scienter*, since so dramatic an announcement would have been approved by corporate officials sufficiently knowledgeable about the company to know that the announcement was false.") (quoting *Makor Issues & Rights, Ltd. v. Tellabs, Inc.*, 513 F.3d 702, 710 (7th Cir. 2008)).

168 AC ¶¶ 66, 69-77, 165-69.

169 *E.g.*, *id.* ¶¶ 53-59, 66, 104, 106.

scienter to be imputed to the corporation,"[170] it is generally sufficient where the employee "enjoy[s] some oversight over the company's public-facing representations."[171] Plaintiffs' brief – but not the Complaint – asserts that "management level employees" in the pharmacovigilance department had access to the adverse event reports, which revealed both that patients received an incorrect dose of Ocaliva and that Ocaliva users suffered adverse events. Given that Complaint is silent as to any particular department positions or hierarchy,[172] the Court need not credit the assertion that management level employees were aware of this information, as "[i]t is well-settled that a claim for relief may not be amended by the briefs in opposition to a motion to dismiss."[173]

Plaintiffs' brief states also that "management level employees" were aware of or had access to the enrollment form, including those in the managed market department. The Complaint, however, refers only to Keith White, the executive director of the managed markets department.[174] Plaintiffs' brief claims that White "would have been the person responsible for compiling the data [in Interconnect.]"[175] However, the Complaint does not make any such allegation. Instead, White

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170 *Patel v. L-3 Commc'ns Holdings,* Nos. 14-cv-6038, 14-cv-6182, 14-cv-6939 (VEC), 2016 WL 1629325, at *12 (S.D.N.Y. Apr. 21, 2016) (citation omitted).

171 *Rex & Roberta Ling Living Tr. u/a Dec. 6, 1990 v. B Commc'ns Ltd.*, 346 F. Supp. 3d 389, 410 (S.D.N.Y. 2018) (citations omitted).

172 *See* AC ¶ 77 (describing the pharmacovigilance department).

173 *Teamsters Allied Benefit Funds v. McGraw*, No. 09-cv-140 (PGG), 2010 WL 882883, at *8 (S.D.N.Y. Mar. 11, 2010); *see also Wright v. Ernst & Young LLP*, 152 F.3d 169, 178 (2d Cir. 1998).

174 AC ¶ 66.

175 Pls'. Op. at 23.

is mentioned only for the proposition that "CW1 stated that Pruzanski would have been able to access this information simply by calling [White] and requesting a report."[176] This single allegation cannot shoulder the burden of sufficiently pleading that an Intercept employee was aware that (1) the enrollment form allowed only for a daily dose prescription and this resulted in patient misdosing and (2) that data in Interconnect indicated that some late-stage patients improperly were prescribed a daily dose of Ocaliva.

Yet even if the Complaint did so allege, to plead corporate *scienter* based on recklessness, a plaintiff must allege "some connection at the corporation between a misstatement and the requisite quantum of knowledge of its falsity."[177] Plaintiffs do not bridge this gap. There are no allegations that "management level" Intercept employees knew both of the adverse event reports and approved or were aware of the allegedly misleading statements. Plaintiffs' allegations fail.

2. Defendants' Alleged Duty to Monitor

Plaintiffs argue alternatively that if defendants were unaware of the dosage data and SAEs, defendants recklessly disregard their duty to monitor (1) patients' dosing data and (2) patients' tolerance of Ocaliva. They do not make either showing.

Equating Intercept to a pharmacy, plaintiffs argue that defendants had and neglected

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176 AC ¶ 66.

177 *Silvercreek Mgmt., Inc. v. Citigroup, Inc.*, 248 F. Supp. 3d 428, 441 (S.D.N.Y. 2017) (rejecting corporate *scienter* for failure to "sufficiently connect any of [the] individuals [alleged to possess the requisite intent] to both knowledge of [the corporation's] wrongdoing and the dissemination of the misstatements at issue.") (citing *Teamsters Local 445*, 531 F.3d at 195-96).

a duty to ensure that patients received proper doses of Ocaliva, follow up with patients, and monitor dosing compliance. Though Intercept "collect[ed] prescriptions from physicians [and] processs[ed] the prescriptions,"[178] it did not dispense Ocaliva to patients or otherwise assume the role of a pharmacist. A pharmacist's duty, therefore, cannot be imposed on Intercept simply because the company acted as an intermediary between physician and pharmacy.

Plaintiffs' arguments concerning the alleged duty to monitor patients' tolerance of Ocaliva similarly are unavailing. They contend that if defendants did not review the safety data, they recklessly disregarded "a federally-mandated duty to collect accurate information about adverse events and monitor any potential safety signals that may arise" and an FDA-imposed duty "to collect accurate information about adverse events and monitor adverse events and pay special attention to serious liver injury."[179]

Plaintiffs' allegations concerning the federally imposed duty to monitor tolerability, as to Intercept, is belied by the Complaint. Plaintiffs plead that the FDA's September 21, 2017 Safety Announcement was based "on information in the adverse event reports Intercept submitted to the FDA as part of its pharmacovigilance responsibilities"[180] and that "the Company took note of all adverse events, pursuant to a statutory duty of pharmacovigilance and a specific FDA imposed duty as a condition of Ocaliva's approval."[181] The Complaint thus alleges that defendants adhered to, rather than recklessly disregarded, its federally-mandated duty to monitor patients' tolerance of

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178 Pls.' Op. at 28.

179 AC ¶ 170; *see also id.* ¶¶ 78-82.

180 *Id.* ¶ 85.

181 *Id.* ¶ 71.

Ocaliva.

Plaintiffs suggest that this federally-mandated duty to monitor extended to the Individual Defendants because, as "high-level executives within Intercept, [they] had a duty to carry out the Company's legal obligations."[182] The Complaint is devoid of facts sufficient to allege that the Individual Defendants' had or neglected such a duty. It states instead that "*[i]f* Defendants did not access the information concerning patents' tolerance of Ocaliva, they recklessly disregarded FDA and regulatory imposed duties."[183] To create a strong inference of *scienter* as to the Individual Defendants, plaintiffs must do more than plead that defendants, collectively, had a general responsibility to monitor the data.[184] Such conclusory allegations do not satisfy the PSLRA's heightened pleading standard.

The alleged FDA-imposed duty to monitor allegations fall victim to the FDA's own statements. Plaintiffs' securities fraud allegations are tethered to defendants' conduct outside the clinical setting. Yet, the FDA Briefing Package – on which plaintiffs rely, in part for their FDA-imposed duty to monitor claims[185] – makes clear that at least some of the agency's instruction that Intercept monitor late-stage PBC patients was for the "post-marketing trial," rather than in the non-clinical setting suggested by plaintiffs.[186] Further, the FDA Decisional Memo reveals that

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182 Pls.' Op. at 31.

183 AC ¶ 170 (emphasis added).

184 *See In re DDAVP*, 585 F.3d at 695.

185 *See, e.g.*, AC ¶ 43.

186 *See* Excerpts from FDA Briefing Package [DI 63-5] at 132. Plaintiffs concede that this statement was made in the context of the Phase 4 clinical trial surveillance but argue the FDA's directive should be read more broadly. Pls.' Op. at 31.

Intercept's alleged duty to monitor patients for "alterations in liver biochemical tests and development of liver-related adverse reactions"[187] was directed at healthcare providers, not at Intercept.[188] For purposes of the motion to dismiss, the Court assumes that the remaining FDA instructions – "[i]t is important to monitor these patients closely and adjust dose or discontinue treatment for evidence of liver injury" and late-stage patients "should be monitored closely"– are intended for Intercept rather than at healthcare providers.[189] Even still, these directives do not reasonably create a separate duty to monitor patient data beyond what is already required by the FDCA and tracked by Intercept's pharmacovigilance department.[190] Plaintiffs' allegations concerning an FDA-imposed duty, separate from the federally imposed duty, fail.

3. Additional Circumstantial Evidence of Recklessness

Plaintiffs' remaining allegations do not support a strong inference of *scienter*.

Plaintiffs attempt infer *scienter* on the parts of the Individual Defendants by virtue of the "core operations" or "core product" theory. Arguing that because Ocaliva was Intercept's "lead product and only FDA approved product," and thus critical to the company's commercial success, the Individual Defendants knew that some patients were prescribed incorrect dose and suffered SAEs.[191] On this theory, knowledge of alleged problems with a company's core product

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187 *See* AC ¶ 49. Paintiffs omitted this context from the Complaint.

188 *See* FDA Office Deputy Director Decisional Memo [DI 63-12] at 19.

189 AC ¶ 49.

190 *Id.* ¶¶ 72-77.

191 *Id.* ¶ 171.

can be imputed to key officers.[192]

The Second Circuit has not expressly addressed whether the doctrine survived the PLSRA.[193] When courts do consider this theory, it is used "to bolster other substantial grounds for *scienter*" rather than constitute independent means to plead the requisite mental state.[194] Because the Complaint does not sufficiently allege other allegations of *scienter*, plaintiffs' core operations theory fails.

Plaintiffs advance two additional baseless theories of *scienter*. First, they allege that by legally challenging plaintiffs' request for confidential company documents from the European Medicines Agency, Intercept "intentionally obstructed" plaintiffs' access to these documents.[195] The complaint merely details the chronology; it is devoid of any – let alone sufficiently particularized – facts showing how Intercept's lawful action raises an inference of *scienter*. Finally, plaintiffs cite an unrelated 2016 settlement involving allegations that "Intercept withheld significant safety information" about a clinical trial as evidence that "concealing important safety information is Intercept's *modus operandi*."[196] That Intercept was involved in a prior settlement based on allegations of securities fraud does not support an inference that defendants acted recklessly in the

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192 *Shemian v. Research In Motion Ltd.*, No. 11-cv-4068 (RJS), 2013 WL 1285779, at *17 (S.D.N.Y. Mar. 29, 2013), *aff'd*, 570 F. App'x 32 (2d Cir. 2014).

193 *See Frederick v. Mechel OAO*, 475 F. App'x 353, 356 (2d Cir. 2012).

194 *Bd. of Trustees of City of Ft. Lauderdale Gen. Employees' Ret. Sys. v. Mechel OAO,* 811 F. Supp. 2d 853, 872 (S.D.N.Y. 2011) (citations omitted); *see also In re Wachovia Equity Sec. Litig*., 753 F. Supp. 2d 326, 353 (S.D.N.Y. 2011) (considering "'core operations' allegations to constitute supplementary but not independently sufficient means to plead *scienter*.").

195 AC ¶¶ 172-74.

196 *Id.* ¶ 175.

present matter. This is particularly true when, as here, plaintiffs have not adequately pled any other viable allegations of *scienter*.

IV. Section 20(a) Claims

To state a claim under Section 20(a), "a plaintiff must allege both a primary violation of the Exchange Act and the defendant's control over the primary violator."[197] Having failed to allege a primary violation of the Exchange Act, plaintiffs' claims under Section 20(a) are dismissed.

Conclusion

For the foregoing reasons, defendants' motion to dismiss is granted in its entirety.

SO ORDERED.

Dated: March 26, 2020

/s/ Lewis A. Kaplan

Lewis A. Kaplan.
United States District Judge

[197] *See City of Westland.*, 129 F.Supp.3d at 87 (citations omitted).