The Hon. Chief Judge Ricardo S. Martinez

UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

SAMIT PATEL, individually and on behalf of all others similarly situated,

Plaintiff,

v.

SEATTLE GENETICS, INC., CLAY B. SIEGALL, TODD E. SIMPSON, and JONATHAN DRACHMAN,

Defendants.

No. C17-00041 RSM

LEAD PLAINTIFF'S OPPOSITION TO DEFENDANTS' MOTION TO DISMISS CONSOLIDATED AMENDED COMPLAINT

NOTE ON MOTION CALENDAR:
Wednesday, September 27, 2017

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INTRODUCTION

Seattle Genetics Inc. is a development stage biopharmaceutical company that develops antibody drug conjugates ("ADC") to treat cancer. This case arises out of material misrepresentations and omissions that Defendants made between October 27, 2016 and December 27, 2016 (the "Class Period") related to known liver toxicity ("hepatotoxicity") in one of the Company's most important ADCs, SGN-CD33A ("33A") and resulting deaths.

Specifically, the Consolidated Amended Complaint ("CAC") sufficiently alleges that Defendants touted positive results observed in 33A's preliminary clinical trials and expressed optimism about 33A's long-term prospects, but simultaneously withheld material information concerning high, known risks of hepatotoxicity, including six serious adverse hepatotoxic events and four patient deaths.

Defendants' motion to dismiss is largely based on flawed assumptions about the reliability of Lead Plaintiff's confidential witness ("CW1") and the implications of the FDA's decision to place the 33A trials on a clinical hold.

Defendants primarily contend that CW1 is not qualified to evaluate patient safety in clinical trials, but the law in this Circuit does not require CW1 to have that kind of expertise. Defendants also rely on cherry-picked, self-serving statements from their own press releases to minimize the impact of the clinical holds imposed on multiple trials for 33A. In other words, Defendants attempt to "conduct a trial by paper," *see In re Juno Therapeutics*, No. 16-1069 RSM, 2017 U.S. Dist. LEXIS 91608, at *18 (W.D. Wash. Jun. 14, 2017), in an attempt to discredit CW1's account by mischaracterizing his allegations, ignoring the well-pleaded facts alleged in the CAC, and repeatedly referring to facts outside the four corners of the CAC to support their defenses.

Defendants' attempt to argue around the strong inference of scienter alleged in the CAC elevates the scienter standard far higher than required. *See, e.g.*, Defs.' Mot. at 2 (incorrectly stating that lack of personal financial windfall negates scienter). Motive is not required to plead scienter, and the CAC sufficiently alleges that Defendants acted with deliberate recklessness, concealing from investors known material adverse information relating to the Company's core

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operations, resulting in a clinical hold and remedial actions impacting a broad array of clinical trials.

At the core, Defendants' arguments impermissibly contradict the well-pleaded facts alleged in the CAC. Lead Plaintiff is not required to prove his case at the pleading stage. *See Juno Therapeutics*, 2017 U.S. Dist. LEXIS 91608, at *17 (ruling that plaintiffs "need not prove their case" to survive a motion to dismiss). Factual disputes, such as those raised by the Defendants, are trial issues, not appropriately resolved on a motion to dismiss. *See In re UTStarcom, Inc. Sec. Litig.*, 617 F. Supp. 2d 964, 972 n.12 (N.D. Cal. 2009). Because Defendants' motion shows no defects in the *pleading* of Lead Plaintiff's claims, their motion to dismiss should be denied.

FACTUAL BACKGROUND

Seattle Genetics is a clinical-stage biotechnology company focusing on the use of ADCs to treat a type of blood cancer called Acute Myeloid Leukemia ("AML"). CAC ¶¶ 2, 28.[1] ADCs are combination anti-cancer drugs that aim to harness antibodies to target the delivery of toxic "payloads" to cancerous cells without damaging healthy cells that are otherwise susceptible to destruction in non-targeted treatments such as chemotherapy and radiation. ¶ 28. 33A, also known as Vadastuximab Talirine, was one of Seattle Genetics' most important ADCs that aspired to successfully treat AML patients. ¶ 2. The elements of 33A consist of an antibody, a toxic payload known as a pyrrolobenzodiazepine ("PBD") dimer, and a linker that attaches the antibody to the PBD dimer, and releases the PBD dimer inside the targeted cancerous cell to purportedly maximize therapeutic effects. ¶¶ 29-30.

33A is a successor to an earlier ADC, Mylotarg, that Pfizer developed which had deadly side effects. ¶ 3. Pfizer manufactured and developed Mylotarg until June 2010 when it was forced to withdraw the ADC from the market because an advanced stage clinical trial showed a fatal rate of hepatotoxicity that was significantly higher than standard chemotherapy, with no corresponding benefit to cancer patients. ¶¶ 3, 33. Defendants repeatedly told investors that 33A's superior linker

[1] All "¶" references are to the CAC, Dkt. 18 (Jun. 6, 2017).

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and PBD dimer differentiated 33A from Mylotarg and its known deficiencies. *See, e.g.*, ¶ 37 (Defendant Siegall stating that, with 33A, "you just don't see the same toxicity" as Mylotarg).

Between July 2013 and November 2015, Seattle Genetics initiated several clinical trials of 33A. ¶¶ 34-36. In July 2013, the Company initiated a Phase I open-label study of 33A in combination with hypomethylating agents ("HMA Phase I"). ¶ 34. The HMA Phase I trial sought to evaluate anti-leukemic activity, pharmacokinetics and overall survival in older patients with AML. *Id.*

In December 2014, Seattle Genetics initiated a Phase I study to evaluate the effects of 33A in combination with a chemotherapy regimen known as 7+3 in younger patients diagnosed with AML ("7+3 Phase I"). ¶ 35. In November 2015, Seattle Genetics initiated the Stem Cell Phase I/II trial in patients with relapsed or refractory AML to evaluate 33A as a pre-conditioning regimen before the administration of stem cell transplants and as a maintenance therapy after stem cell transplant. ¶ 36.

Even before the Class Period, Seattle Genetics and the Individual Defendants were well aware that 33A posed a high risk of hepatotoxicity. The Company's former Senior Environmental Health and Safety Engineer from March 2015 to February 2017, referenced in the Complaint as CW1, explained that Seattle Genetics experienced hepatotoxicity problems on another drug that it had collaborated on with Spirogen Ltd. that was a molecule similar to 33A. ¶ 40. According to CW1, "almost all of the safety correlations [with 33A] were based off that Spirogen compound." *Id.*

However, the Company terminated development of the Spirogen compound because early data from animal studies indicated a high risk of hepatotoxicity. *Id.* Even though these events took place before CW1 began working at Seattle Genetics, CW1 has personal knowledge of these facts because the data from the predecessor drug was used to develop the safety protocols that CW1 was assigned to communicate to Seattle Genetics' various divisions. *Id.*

CW1 also coordinated with the Company's in-house toxicologist to prepare Safety Data Sheets that listed specific levels of toxicity associated with each organ in the human body. ¶ 41.

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According to CW1, these reports were widely available to the Company's employees, including the Individual Defendants, and these reports indicated a risk of hepatotoxicity associated with 33A. *Id.*

CW1 stated that, in the middle of 2016, a third party provided an assessment concluding that the risk of toxicity associated with 33A was high. ¶ 42. Seattle Genetics then contracted with a different third party to manufacture the PBD dimer and linker components of 33A. *Id.*

CW1 explained that the third-party manufacturer suspended manufacturing these components because it was concerned about the third party risk assessment of 33A's toxicity. *Id.* Seattle Genetics instructed CW1 to collaborate with its in-house toxicologist to respond to the third-party risk assessment in order to convince the contract manufacturer to continue production of 33A's components. ¶ 43.

Both CW1 and the in-house toxicologist expressed concerns about 33A's level of toxicity consistent with the findings of the third-party risk assessment. ¶ 44. Seattle Genetics' Director of Facilities, who directly reported to Defendant Simpson, instructed CW1 not to discuss the issue with the in-house toxicologist, and the Company threatened to fire CW1 if he violated this directive. *Id.* The Director of Facilities and the Associate Director of Facilities, CW1's immediate supervisor, coerced the in-house toxicologist to moderate his views regarding 33A's level of toxicity, and CW1 understood that this coercion ultimately originated from Defendant Simpson. ¶ 45.

Before the end of his employment at Seattle Genetics, CW1 sought to address these concerns directly with the Individual Defendants and other senior-level executives within the Company. ¶ 46. In particular, CW1 asked for an audience with Defendant Simpson, but Defendant Simpson rebuffed CW1. *Id.* CW1 also emailed Defendant Siegall's executive assistant seeking a meeting to address these concerns, and copied Defendant Siegall's executive assistant on several emails that he sent to the Human Resources department regarding his safety concerns. *Id.* Defendant Siegall did not agree to meet with CW1. *Id.*

Despite knowing these undisclosed risks of hepatotoxicity associated with 33A,

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Defendants omitted from their positive statements to investors regarding the Phase I trials material information regarding 33A's high, known risks of liver toxicity.

For example, on October 27, 2016, Defendant Drachman attended an earnings conference call in which he bragged about the "pretty high" complete remission rates observed in the 7+3 Phase I trial, and affirmatively represented that a "substantial number of patients" treated with 7+3 chemotherapy – with or without stem cell transplants – are in remission. ¶ 48.

On the same conference call, Defendant Siegall represented that 33A was well positioned compared to the drug candidates of the Company's competitors; that 33A "could make a difference for patients"; and that the 33A therapies "could be very user friendly from a combination standpoint . . ." ¶ 50. These statements not only failed to acknowledge the risks of hepatotoxicity but suggested that those risks did not exist.

On November 8, 2016, Defendant Siegall attended the Credit Suisse Healthcare Conference. ¶ 52. At this healthcare conference, Defendant Siegall gloated about the "good safety profile" deduced from the preliminary data observed in the HMA Phase I trial, touted that the complete remission rate in the HMA Phase I trial exceeded 70%, and expressed confidence that the low 30- and 60-day mortality rate seen in the HMA Phase I trial supported the Company's vision to press forward with a Phase III trial. *Id.*

Most egregiously, Seattle Genetics and the Individual Defendants released two glowing press releases on December 3, 2016 and December 5, 2016 after hepatotoxic events had already occurred in the trials those press releases discussed. The December 3, 2016 press release announced that the 7+3 Phase I trial showed high rates of remission in excess of 70% "without significantly adding to the toxicity of the treatment." ¶ 54. The December 3, 2016 press release also listed several adverse events observed in the 7+3 Phase I trial, and affirmatively represented that no veno-occlusive disease or hepatotoxicity was observed in treatment. *Id.*

Similarly, the December 5, 2016 press release touted "high remission rates" for AML patients, and omitted the risk of veno-occlusive disease or hepatotoxicity from the list of treatment related adverse events. ¶ 56. In the December 5, 2016 press release, Defendant Drachman

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expressed satisfaction with the "growing body of data demonstrating that [33A] has a promising overall tolerability and activity profile for patients with AML." *Id.*

On December 27, 2016, three weeks after the highly misleading December press releases, the Company was forced to disclose that ***six patients*** in the 33A trials experienced hepatotoxic events, including "several cases of veno-occlusive disease" and ***four deaths***. ¶ 58. As a result, the Company conceded that the three aforementioned Phase I trials were placed on a clinical hold by the FDA. ¶ 58.

Defendants have not revealed precisely when during the course of multi-year clinical trials the four deaths and two other serious hepatotoxic events occurred, but circumstantial details render it highly implausible, if not impossible, for all six events to have occurred after the December 2016 press releases. ¶¶ 5, 47. As an initial matter, at the time the clinical hold was announced, the three Phase I trials had been proceeding for 13 months (Stem Cell Phase I/II, *see* ¶ 36), for 24 months (7+3 Phase I, *see* ¶ 35), and for 40 months (HMA Phase I, *see* ¶ 34), respectively. Given the long period in which patients were exposed to 33A, it would be highly improbable for all six events to have occurred exclusively within the last few weeks of December 2016.

Additionally, FDA regulations described in the CAC require a course of events that take several days to weeks before a clinical hold is initiated, meaning that the events triggering the hold must have occurred before that time. ¶¶ 26-27.

First, sponsors conducting clinical trials have seven calendar days to notify the agency "of any unexpected fatal or life-threatening suspected adverse reaction[s]." 21 U.S.C. § 312.32. Then, the FDA must process and review the adverse events reports, consult with the sponsor, and determine whether an adverse event-related issue can be resolved before initiating a clinical hold. ¶¶ 5, 47.

Consequently, the factual assumption underpinning Defendants' motion—that all four deaths and the two other serious hepatotoxic events might have suddenly occurred ***after*** the December 3, 2016 and December 5, 2016 press releases—is not only improbable, but inconceivable.

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Indeed, Defendants' hypothetical appears to have been manufactured solely for purposes of this litigation. Nothing in Defendants' press releases or the public record even remotely supports this proposition. *Compare* ¶ 58 (quoting Seattle Genetics press release regarding clinical hold, which was silent regarding the timing of the deaths) with press releases announcing clinical holds in *In re Juno Therapeutics, Inc.*, 2:16-cv-1069-RSM, Dkt. No. 47 at ¶¶ 64-65, 82 (specifically identifying that a death occurred in May 2016, two additional deaths occurred in late June 2016 that caused the FDA to initiate a clinical hold, and two more deaths occurred in the third week of November 2016 that caused the company to abandon the clinical trial).

Following the December 27, 2016 disclosure, Seattle Genetics' stock price declined by $9.50 per share, or by over 15% to close at $52.36 on December 27, 2016. ¶ 59. Analysts expressed surprise because Seattle Genetics had repeatedly insisted that 33A's components were designed to avoid the pitfalls of Mylotarg, and the Company did not previously report hepatotoxicity related serious adverse events. ¶ 60. Moreover, a Credit Suisse analyst expressed concern "surrounding [the] potential CD33 target-mediated hepatoxicity," and reduced the probability of success for the HMA Phase I trial to 30% (from 70%) and the probability of success for the 7+3 Phase I trial to 15% (from 30%), which resulted in a $10 reduction in the targeted price of the Company's shares. *Id.*

On March 7, 2017, Seattle Genetics issued a press release and announced that the Company had abandoned the Stem Cell Phase I/II trial. ¶ 61. In this press release, the Company also announced that it had implemented a series of risk mitigation measures with respect to hepatotoxicity for all other 33A trials. The announcement identified modifying eligibility standards to exclude patients with liver cirrhosis, and establishing an adjudication committee to verify incidences of hepatotoxicity, and potentially terminating treatment if additional hepatotoxic events were observed. With these measures, the Company indicated that the FDA had agreed to

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allow it to resume enrollment in the HMA Phase I and 7+3 Phase I trials. ¶ 62.[2]

ARGUMENT

I. Legal Standard

On a 12(b)(6) motion, the court must "accept the Plaintiffs' allegations as true and construe them in the light most favorable to Plaintiffs." *In re Atossa Genetics Inc. Sec. Litig.*, No. 14-35933, 2017 U.S. App. Lexis 15658, at *13 (9th Cir. Aug. 18, 2017) (internal quotation marks and brackets omitted).

"[T]he purpose of a 12(b)(6) motion to dismiss is to test the sufficiency of the complaint, not to decide its merits." *Craig Frazier Design, Inc. v. Zimmerman Agency*, No. 10-1094, 2010 U.S. Dist. LEXIS 107170, at *18 (N.D. Cal. Sep. 24, 2010) (citing *Navarro v. Block*, 250 F.3d 729, 732 (9th Cir. 2001)). The Supreme Court has cautioned, "when a complaint adequately states a claim, it may not be dismissed based on a district court's assessment that the plaintiff will fail to find evidentiary support for his allegations or prove his claim to the satisfaction of the fact finder." *Bell At. Corp. v. Twombly*, 550 U.S. 544, 563 n.8 (2007).

SEC Rule 10b-5 implements Section 10(b) of the Exchange Act by making it unlawful to, among other things, "make any untrue statement of a material fact or to omit to state a material

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[2] Defendants ask this Court to draw inappropriate factual inferences from facts outside the four corners of the CAC involving other clinical trials and the eventual release of the clinical hold on the 7+3 Phase I trial and the HMA Phase I trial on March 7, 2017. *See* Defs.' Mot. at 12-13. Defendants' assertions impermissibly contradict the well-pleaded facts alleged in the CAC, which demonstrate that trials were only permitted to proceed after the Company adopted risk-mitigation measures to address the hepatotoxic risks concealed from investors during the Class Period. ¶ 62; *see also Juno Therapeutics*, 2017 U.S. Dist. LEXIS 91608, at *17 (ruling that plaintiffs "need not prove their case" to survive a motion to dismiss); *In re UTStarcom, Inc. Sec. Litig.*, 617 F. Supp. 2d at 972 n.12 (declining to entertain argument because factual disputes are not appropriately resolved at the pleading stage).

At any rate, if Defendants reiterate these assertions at trial, they soundly will be refuted. Evidence already in the public record indicates that the Company discontinued the Phase III 33A trial due to a higher rate of death in the 33A arm versus the control arm. *See* http://investor.seattlegenetics.com/phoenix.zhtml?c=124860&p=irolnewsArticle&ID=2281531. As a result of this failure, the Company has suspended enrollment and treatment in *all* 33A trials, including the HMA Phase I trial and the 7+3 Phase I trial. *Id.*

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fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading." *Matrixx Initiatives, Inc. v. Siracusano,* 563 U.S. 27, 37 (2011) (quoting 17 C.F.R. § 240.10b–5(b)).

To establish a violation of § 10(b) and Rule 10b-5, plaintiffs must prove "(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." *Stoneridge Investment Partners, LLC v. Scientific-Atlanta, Inc.*, 552 U.S. 148, 157 (2008). Defendants here only challenge the first two requirements: (1) material misstatements/omissions and (2) scienter.

"[W]hether a statement is misleading and whether adverse facts are adequately disclosed are generally questions that should be left to the trier of fact." *In re Immune Response Sec. Litig.*, 375 F. Supp. 2d 983, 1017 (S.D. Cal. 2005) (citing *Fecht v. Price Co.*, 70 F.3d 1078, 1081 (9th Cir. 1995)). The issue should be resolved as a matter of law "only if the adequacy of the disclosure . . . is 'so obvious that reasonable minds [could] not differ.'" *Fecht*, 70 F.3d. at 1081 (quoting *Durning v. First Boston Corp.*, 815 F.2d 1265, 1268 (9th Cir. 1987)).

A statement is misleading if it gives a reasonable investor the "'impression of a state of affairs that differs in a material way from the one that actually exists.'" *Berson v. Applied Signal Tech., Inc.*, 527 F.3d 982, 985 (9th Cir. 2007) (quoting *Brody v. Transitional Hospitals Corp.*, 280 F.3d 997, 1006 (9th Cir. 2002)).

"Once 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." *Schueneman v. Arena Pharms., Inc.*, 840 F.3d 698, 705-06 (9th Cir. 2016) (internal quotation marks and citations omitted); *Juno Therapeutics*, 2017 U.S. Dist. LEXIS 91608, at *10, *17-18. Even statements that are literally true may nonetheless be misleading, due to their context and manner of presentation. *Miller v. Thane, Int'l Inc.*, 519 F.3d 879, 886 (9th Cir. 2008).

In evaluating scienter, "the court reviews all allegations holistically, rather than in isolation,

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to determine if a complaint is well-pleaded." *Petrie v. Elec. Game Card, Inc.*, 761 F.3d 959, 970 (9th Cir. 2014). A complaint adequately pleads scienter if the specific facts allege reckless conduct that involves "an extreme departure from the standards of ordinary care . . . that is either known to the defendant or is so obvious that the actor must have been aware of it." *In re Verifone Holdings Inc. Sec. Litig.*, 704 F.3d 694, 702 (9th Cir. 2012) (internal quotation marks and citations omitted). "The inference that the defendant acted with *scienter* need not be irrefutable, i.e., of the 'smoking-gun genre,' or even the 'most plausible of competing inferences.'" *Tellabs Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 324 (2007) (internal citations omitted).

To evaluate whether a complaint adequately pleads a strong inference of *scienter*, courts must consider "*all* of the facts alleged, taken collectively, and refrain from "scrutiniz[ing] [them] in isolation." *In re Verifone Holdings*, 704 F.3d at 701 (internal quotation marks and citations omitted) (emphasis in original). A complaint should survive a motion to dismiss 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. Plaintiffs are only required to "provide a narrative of the fraud—facts which, if true, substantiate an explanation at least as plausible as a nonfraudulent alternative." *ESG Capital Partners v. Stratos*, 828 F.3d 1023, 1035 (9th Cir. 2016).

II. The CAC Sufficiently Pleads Materially Misleading Misrepresentations and Omissions

A. Defendants Omitted Risks of Hepatotoxicity from Their Oct. 2016 and Nov. 2016 Positive Statements To Investors regarding Phase I Trials Of 33A

Defendants principally argue that the statements made by Drachman and Siegall on October 27, 2016 and November 8, 2016 cannot be false or misleading because they are literally true. This is not the standard.

Under the PSLRA, even literally true statements can be misleading where, as here, they omit material information. *Miller*, 519 F.3d at 886. In addition, once defendants choose to tout positive information to investors, "they [are] bound to do so in a manner that wouldn't mislead

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investors." *Berson*, 527 F.3d at 987.

On October 27, 2016, Defendant Drachman attended an earnings conference call, in which he bragged about the "pretty high" complete remission rates observed in the 7+3 Phase I trial, and affirmatively represented that a "substantial number of patients" treated with 7+3 chemotherapy, with or without, stem cell transplants, are in remission. ¶ 48. On the same conference call, Defendant Siegall represented that 33A was well positioned compared to the drug candidates of the Company's competitors; that 33A "could make a difference for patients;" and that the 33A therapies "could be very user friendly from a combination standpoint . . . " ¶ 50.

On November 8, 2016, Defendant Siegall attended the Credit Suisse Healthcare Conference. ¶ 52. At this event, Defendant Siegall touted the "good safety" profile observed in the HMA Phase I trial, promoted a complete remission rate of over 70% observed in the HMA Phase I trial, and expressed confidence that the low 30- and 60-day mortality rate seen in the HMA Phase I trial supported the Company's vision to press forward with the Phase III trial for 33A. *Id.* Given that Defendants Drachman and Siegall chose to discuss then existing positive information about the 7+3 Phase I trial and the HMA Phase I trial, "they were bound to do so in a manner that wouldn't mislead investors." *Berson*, 527 F.3d at 987.

While Defendants Drachman and Siegall touted the high rates of remission and low rates of mortality observed in the 7+3 Phase I trial and the HMA Phase I trial, and expressed confidence in 33A's prospects based on these observed results, they failed to disclose "adverse information that cuts against [this] positive information." *See Schueneman*, 840 F.3d at 705-06; *Juno Therapeutics*, 2017 U.S. Dist. LEXIS 91608, at *10, *17-18. Specifically, they failed to disclose known, high risks of hepatotoxicity with 33A. ¶¶ 49, 51. Because Defendants Drachman and Siegall touted the results of the 7+3 Phase I and HMA Phase I trials and simultaneously withheld negative, material information regarding high, known risks of hepatotoxicity associated with 33A, they "affirmatively created an impression of a state of affairs that differs in a material way from the one that actually exists." *Brody*, 280 F.3d at 1006; *Juno Therapeutics*, 2017 U.S. Dist. LEXIS

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91608, at *10, *17-18.[3]

Defendants' reliance on *In re Rigel Pharm., Inc. Sec. Litig.*, 697 F.3d 869, 880 n.8 (9th Cir. 2012) is misplaced. In *Rigel*, the plaintiffs alleged that once a company chooses to disclose any safety information, the Company must disclose all information regarding safety. *Id.* Plaintiffs here make no such assertion. Instead, they contend that Defendants were obligated if discussing safety and efficacy to disclose known liver toxicity risks so severe that they undermined two prior drugs and threatened the lives of workers and patients exposed to 33A, thereby providing a misleading overall perception of the drug's safety and efficacy. ¶¶ 38-47; *see also Cunha v. Hansen Natural Corp.*, No. 08-1249, 2012 U.S. Dist. LEXIS 191744, *10-11 (C.D. Cal. Oct. 22, 2012) (distinguishing and declining to apply *Rigel* because defendant's literally true statement omitted material facts that, in context, rendered the statement misleading).

B. Defendants Omitted Multiple Deaths and Other Hepatotoxic Events from Their December 2016 Statements To Investors Regarding 33A

Seattle Genetics and the Individual Defendants released two glowing press releases regarding the 7+3 Phase I trial and the HMA Phase I trial on December 3, 2016 and December 5, 2016 respectively. The December 3, 2016 press release announced that the 7+3 Phase I trial showed high rates of remission "without significantly adding to the toxicity of the treatment." ¶ 56. It also listed several adverse events observed in the 7+3 Phase I trial, and affirmatively represented that veno-occlusive disease or hepatotoxicity was not observed in treatment. *Id.*

Similarly, the December 5, 2016 press release touted "high remission rates" for AML patients, and omitted the risk of veno-occlusive disease or hepatotoxicity from the list of treatment

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[3] *See also Rhin v. Acadia Pharms., Inc.*, No. 15-575, 2016 U.S. Dist. LEXIS 128291 at *16-18 (S.D. Cal. Sep. 19, 2016) (defendants misled investors by omitting from claim that New Drug Application was "on track" fact that a proper assessment of the company's quality controls had not been undertaken); *In re Iso Ray Sec. Litig.*, 189 F. Supp. 3d 1057, 1072 (E.D. Wash. 2016) (defendants misled investors omitting from statements touting a study on survival rates as "peer-reviewed" fact that defendants sponsored the study); *In re Questcor Sec. Litig.*, No. 12-1623, 2013 U.S. Dist. LEXIS 142865, at *33 (C.D. Cal. Oct. 1, 2013) (defendants created a false impression of the scientific basis of their drug by failing to disclose that they had cancelled studies that would not yield favorable results).

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related adverse events. ¶ 56. In it, Defendant Drachman also touted the "growing body of data demonstrating that [33A] has a promising overall tolerability and activity profile for patients with AML." *Id.*

Neither press release disclosed the most important information regarding 33A: that multiple patients in the 33A trials had already experienced hepatotoxic events, including "several cases of veno-occlusive disease" and four fatalities. ¶¶ 47, 58. *See also* pp. 6-7 above (establishing that at least some and likely most of these events most likely occurred prior to the December 2016 press releases, even though Defendants refused to reveal the timing of the events).

Defendants again principally argue that their misleading statements were literally true. However, the failure to disclose the six hepatotoxic events, including four fatalities, rendered misleading the rosy picture portrayed in the December 2016 press releases. *See Schueneman,* 840 F.3d at 705-06; *Juno Therapeutics*, 2017 U.S. Dist. LEXIS 91608, at *17-18. Remarkably, Defendants also argue (without citation to any relevant authority) that their failure to disclose the six hepatotoxic events, including four patient deaths, does not render Drachman's statements about 33A's "promising overall tolerability and activity profile for patients with AML" false or misleading. ¶ 56.

This is both illogical and inconsistent with prior rulings of this Court. *See Juno Therapeutics*, 2017 U.S. Dist. LEXIS 91608, at *17-18 (agreeing with plaintiffs that defendants may have had a duty to disclose that a single patient died in a clinical trial given that defendants touted partial, incomplete results from a Phase I trial throughout the Class Period).

Nor does *Rigel*, cited by Defendants, justify their non-disclosure. *Rigel* only holds that not every detail need be provided. 697 F.3d at 880 n.8. *Rigel* neither states nor suggests that pharmaceutical companies developing drugs with a known risk of hepatotoxicity are not required to disclose the occurrence of hepatotoxicity as a treatment related side-effect. *Id.* Defendants' failure to disclose known hepatotoxicity, including four patient deaths, withheld material information from investors that "altered the 'total mix' of information . . . and investors reacted negatively to the subsequent disclosure [of hepatotoxic events, including four fatalities] with a

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drop in [Seattle Genetics'] stock price." *Juno Therapeutics*, 2017 U.S. Dist. LEXIS 91608, at *18.

Defendants' reliance on *Police Ret. Sys. v. Intuitive Surgical, Inc.*, 759 F.3d 1051, 1061 (9th Cir. 2014) is also inappropriate. In *Intuitive*, the defendants' annual report accurately reflected the company's yearly growth rate, and "did not speak to any trends in Intuitive's growth or revenues and [did] not alter the total mix of information available to investors." *Id.* Here, Defendants spoke to the safety and tolerance of 33A, but chose to withhold material information about hepatotoxic events, including four patient deaths, altering the total mix of information available to investors. *See Juno Therapeutics*, 2017 U.S. Dist. LEXIS 91608, at *17-18.[4]

The misleading statements alleged in the CAC are capable of objective verification and address information material to investors. Thus, contrary to Defendants' assertion, the statements cannot fairly be characterized as "puffery." *See Todd v. STAAR Surgical Co.*, No. 14-5263, 2016 U.S. Dist. LEXIS 186511, at *24-26 (C.D. Cal. Apr. 12, 2016) (ruling that even optimistic statements "can be capable of objective verification and do not constitute 'puffery.'").

III. The CAC Pleads a Strong Inference of Scienter

A. Lead Plaintiff Alleges That Each Defendant Knew Or Deliberately Ignored Information Undermining Their Public Statements

The CAC sufficiently identifies the statements and the facts concerning scienter for each Individual Defendant. The CAC identifies each specific false statement made by Defendants Drachman and Siegall, and every Individual Defendant is responsible for the misleading press

[4] Nor do *Kovtun v. Vivus, Inc.*, No. 10-4957, 2012 U.S. Dist. LEXIS 139548, at *24-25 (N.D. Cal. Sep. 27, 2012) or *In re EDAP TMS S.A. Sec. Litig.*, No. 14-6069, 2015 U.S. Dist. LEXIS 121960, at *27-28 (S.D.N.Y. Sep. 14, 2015) provide Defendants with any support. In *Kovtun*, the court found that the defendants' statements were not misleading because the omitted information was actually disclosed in their SEC filings, and the omitted information was not the reason cited by the FDA as a reason for non-approval. 2012 U.S. Dist. LEXIS 139548, at *24-25. Similarly, in *EDAP*, the district court found that the allegedly omitted information was publicly disclosed in published studies, and that the "total mix" of information available to investors included the publicly published studies. 2015 U.S. Dist. LEXIS 121960, at *27-28. Here, there is no dispute that investors did not know about the hepatotoxic events, including four patient deaths, prior to the December 27, 2016 corrective disclosure or that analysts expressed surprise upon being apprised of this material, previously withheld, information. ¶¶ 58-60.

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releases issued in December 2016. *See* Section IV. The information provided by CW1 also shows each Individual Defendant's direct knowledge of 33A's high, known risks of hepatotoxicity. That is all the law requires. *See Mauss v. NuVasive, Inc.*, No. 13-2005, 2015 U.S. Dist. LEXIS 178117, at *33-34 (S.D. Cal. Aug. 28, 2015).

The Safety Data Sheets were widely available to the Company's employees, including Individual Defendants, and these reports indicated a risk of hepatotoxicity associated with 33A. ¶ 41. CW1 sought to resolve these toxicity risks with both Defendants Simpson and Siegall, who declined to meet with him. ¶ 46.

In particular, CW1 attempted to directly reach Defendant Simpson, but Simpson rebuffed CW1. *Id.* That CW1 was instructed to deflect the contract manufacturer's concerns regarding toxicity, ¶ 43, and the Company's in-house toxicologist was coerced to minimize his concerns about 33A's toxicity at the direction of Defendant Simpson provide further circumstantial evidence of scienter, ¶¶ 44-45. *See In re Levi Strauss & Co. Sec. Litig.*, 527 F. Supp. 2d 965, 988-89 (N.D. Cal. 2007) (considering statement that CW was asked not to analyze accounts in the financial statements as evidence of scienter); *In re Petco Animal Supplies Inc. Sec. Litig.*, No. 05-cv-823, 2006 U.S. Dist. LEXIS 97927, at *34-35 (S.D. Cal. Jul. 31, 2006) (allegation that employees felt coerced by their supervisors to violate ethical rules provided circumstantial evidence of scienter).

Defendants' attacks on the detailed information provided by CW1 are misplaced. Complaints in securities fraud actions properly rely on confidential witnesses where, as here, they are "describe[d] with sufficient particularity to establish their reliability and personal knowledge. Second, those statements which are reported by confidential witnesses with sufficient reliability and personal knowledge must themselves be indicative of scienter." *See In re Quality Sys.*, No. 15-55173, 2017 U.S. App. LEXIS 13708, at *30 (9th Cir. Jul. 28, 2017) (citations omitted).[5]

[5] In a footnote, Defendants cite *Higginbotham v. Baxter Int'l. Inc.*, 495 F.3d 753, 756-57 (7th Cir. 2007) to claim that confidential witness allegations should be discounted, but they omit that in *Makor Issues & Rights, Ltd. v. Tellabs Inc.*, 513 F.3d 702, 712 (7th Cir. 2008), the Seventh Circuit tempered the strong language of *Higginbotham* and accepted confidential witness

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Falsity and scienter are a single inquiry in this Circuit because they are both generally inferred from the same facts. *See In re Read-Rite Corp. Sec. Litig.*, 335 F.3d 843, 846 (9th Cir. 2003). Thus, a reliable confidential witness's statements may support both falsity and scienter. *Id.*

The CAC describes CW1 with sufficient particularity to establish his reliability and personal knowledge by identifying his title and job description, and CW1's statements are sufficiently plausible to show that he "would know" or "could reasonably deduce" facts regarding the high, known risks of hepatotoxicity associated with 33A. That is all the law requires. *See Berson*, 527 F.3d at 985; *In re BofI Holding Sec. Litig.*, No. 15-2324, 2016 U.S. Dist. LEXIS 132574, at *28-29 (S.D. Cal. Sep. 27, 2016).

Defendants erroneously urge the Court to disregard CW1's allegations primarily based on the contention that CW1 "may be qualified to opine on workplace safety in handling and working with 33A and its components, but CW1 is wholly unqualified to opine on medical or clinical safety . . . " Defs.' Mot. at 8. This argument misstates CW1's assertions, and ignores the controlling standard. CW1 does not "opine on medical or clinical safety," but rather explains that there were risks involving 33A that were known within Seattle Genetics and that he knew about as a result of his job duties. That he may not have been an expert or personally involved in every aspect of hepatotoxicity is irrelevant. *See, e.g.*, *Berson*, 527 F.3d at 985 (rejecting claim that engineers and technical editors were not qualified to observe stop work orders because any employee could infer that a stop work order would put employees out of work).[6]

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allegations as a basis for finding that a strong inference of scienter was established. To the extent that Defendants rely on *Higginbotham* to support the claim that allegations of a single confidential witness should be disregarded, the weight of authority in this Circuit is overwhelmingly against them. *See In re Intuitive Surgical Sec. Litig.*, 65 F. Supp. 3d 821, 837-38 (N.D. Cal. 2014); *In re Cell Therapeutics, Inc. Class Action Litig.*, No. 10-414, 2011 U.S. Dist. LEXIS 11157, at *10 (W.D. Wash. Feb. 4, 2011); *Backe v. Novatel Wireless, Inc.*, 642 F. Supp. 2d 1169, 1187 (S.D. Cal. 2009).

[6] *See also Mulligan v. Impax Labs., Inc.*, 36 F. Supp. 3d 942, 963 (N.D. Cal. 2014) (noting that defendants "viewed the inquiry too narrowly" and declining to disregard CW accounts because the CWs had no connection to the Company's remediation efforts); *Loritz v. Exide Techs.*, No. 13-2607, 2014 U.S. Dist. LEXIS 111491, at *29-30 (C.D. Cal. Aug. 7, 2014) (rejecting defendants'

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Defendants incorrectly quibble that CW1's account does not provide every little detail, including the name of the third-party manufacturer, the amount of time production of 33A's components was suspended, the title tenure, department, division or responsibilities of the coerced in-house toxicologist, and granular details of how the coercion took place. However, the PSLRA does not require the granular level of detail that Defendants demand.[7]

Finally, Defendants assert that CW1's statements regarding the Company' decision to terminate the clinical trial for a predecessor drug due to a high risk of hepatotoxicity should be ignored because CW1 did not join Seattle Genetics until March 2015, and his job responsibilities do not indicate that he would possess personal knowledge about the failed trial. Defs.' Mot. at 11.

But this assertion overlooks well-pleaded allegations in the CAC. CW1 had personal knowledge of the failed trial for the predecessor drug because the data from the predecessor drug was used to develop the safety protocols that CW1 was assigned to communicate to Seattle Genetics' various divisions. ¶ 40. Moreover, the fact that a clinical trial for a predecessor drug failed due to a high risk of hepatotoxicity is precisely the kind of knowledge any employee would be able to infer. *See Berson*, 527 F.3d at 985.

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attempt to discredit CWs on the ground that they worked in different facilities because the argument was relevant to whether the statements were indicative of scienter, not relevant to reliability, and "once the court determines that the [confidential witnesses] are reliable, it must take the statements as true for purposes of ruling on a motion to dismiss."); *In re CV Therapeutics, Inc. Sec. Litig.*, No. 03-3709, 2004 U.S. Dist. LEXIS 17419, at *31-32 (N.D. Cal. Aug. 5, 2004) (refusing to entertain argument that CWs "lack[ed] the necessary qualifications" because, on a motion to dismiss, courts must consider all the facts alleged holistically).

[7] *See Flynn v. Sientra, Inc*., No. 15-7548, 2016 U.S. Dist. LEXIS 83409, at *43 n.8 (C.D. Cal. June 9, 2016) (ruling that while confidential witnesses did not possess personal knowledge regarding certain details, the complaint contained sufficient details to show why the witness knew that it was important for the defendants to monitor another company's manufacturing process); *In re Intuitive Surgical Sec. Litig.*, No. 13-1920, 2014 U.S. Dist. LEXIS 173088, at *16 (N.D. Cal. Dec. 15, 2014) (ruling that the complaint did not need to allege the contents of adverse event reports because CW provided enough information to plausibly assert that defendants received information about the product's defects); *Loritz*, 2014 U.S. Dist. LEXIS 111491, at *32 (considering CWs' allegations of an information chain even though CWs did not provide information regarding who drafted the reports and which officers received them).

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B. By Concealing Damaging Information from Investors, Defendants Were at Least Deliberately Reckless

The well-pleaded facts alleged in the CAC compel the conclusion that Defendants were aware of the deaths and other hepatotoxic events at the time they made statements to investors omitting this information in their December 2016 press releases, or deliberately disregarded this adverse information. Speaking about drug safety without disclosing the most important life-and-death safety information amounts to deliberate recklessness. *See Schueneman*, 840 F.3d at 709; *Juno Therapeutics*, 2017 U.S. Dist. LEXIS 91608, at *21.

The fact that the FDA placed a full clinical hold on one of 33A's Phase I trials and a partial hold on two other trials within weeks of the misleading press releases also supports a strong inference of scienter. *Twindle v. Threshold Pharms., Inc.*, No. 07-4972, 2009 U.S. Dist. LEXIS 33644, at *32-35 (N.D. Ca. Apr. 3, 2009).[8]

Defendants' omission of known risks of hepatotoxicity from the October 2016 and November 2016 press releases also was at least deliberately reckless. Prior to the Class Period, Defendants knew that 33A had high, known risks of hepatotoxicity because (a) Defendants abandoned a clinical trial for a predecessor drug that was very close to 33A due to hepatotoxicity (b) Defendants had access to Safety Data Sheets that indicated a risk of hepatotoxicity associated with 33A, and (c) Defendants were aware of a third party risk assessment that confirmed toxicity,

[8] *In re ARIAD Pharm. Sec. Litig.*, 842 F.3d 744, 751-53 (1st Cir. 2016) does not help Defendants. In *ARIAD*, the plaintiffs alleged that defendants were aware of serious cardiovascular events because they were in the "process of collecting, QCing, [and] processing" data from a clinical trial. *Id.* The First Circuit held that this allegation was conclusory, and failed to address when the serious adverse events occurred or when the defendants became aware of them. *Id.* The plaintiffs also claimed that defendants were aware of a report that required dose interruption and dose reduction, but the complaint did not contain any facts regarding when the defendants became aware of the dose reductions. *Id.* Unlike the complaint in *ARIAD*, the CAC adequately alleges that Defendants were aware of the hepatotoxic events before they misled the market about 33A's safety and efficacy in December 2016. Based on the FDA regulations that Defendants were required to comply with, the time the FDA needed to review and process the hepatotoxic events, and the temporal proximity between Defendants' reckless misconduct and the clinical holds, it is inconceivable that Defendants were unaware of the hepatotoxic events, including four patient deaths before the December 2016 press releases were issued.

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especially after it caused a contract manufacturer to suspend production of 33A's key components. ¶¶ 38-46.

Omitting such information was "an extreme departure from the standards of ordinary care." *See In re Verifone Holdings*, 704 F.3d at 702.

C. The Core Operations Doctrine Supports a Strong Inference of Scienter

Scienter is also properly inferred because the facts at issue here were critical to Seattle Genetics' "core operations." *See S. Ferry LP No. 2 v. Killinger*, 542 F.3d 776, 783-84 (9th Cir. 2008). Because 33A was one of Seattle Genetics' most important ADCs, it would be absurd to assume that the Individual Defendants did not know that 33A posed a high risk of hepatotoxicity. *See Rihn*, 2016 U.S. Dist. LEXIS 128291, *26 (finding that it would be absurd to suggest that defendants did not act with scienter, in part, because Nuplazid was Acadia's "most advanced product candidate."); *In re Iso Ray Sec. Litig.*, 189 F. Supp. 3d at 1078 (finding that the core operations inference applied because it would be "absurd" to suggest that defendants did not know the import of a clinical study that related to their leading product when the success of that product was critical to the company's success).

D. Absence of Insider Sales Is Irrelevant To Scienter

While personal financial gain "may weigh heavily in favor of a scienter inference," motive is not necessary to plead scienter. *Matrixx*, 563 U.S. at 48-49; *Tellabs*, 551 U.S. at 325; *In re Daou Sys., Inc.*, 411 F.3d 1006, 1022 (9th Cir. 2005). In particular, the absence of stock sales is not a basis for dismissal. *Tellabs*, 551 U.S. at 325 (lack of sales by executive did not establish lack of scienter). Defendants' "suggestion here that the lack of insider sales . . . negates scienter is contrary to controlling case law." *Flynn*, 2016 U.S. Dist. LEXIS 83409 at *46; *see also Thomas v. Magnachip Semiconductor Corp.*, 167 F. Supp. 3d 1029, 1044 (N.D. Cal. 2016); *In re Diamond Foods, Inc.*, No. 11-5386, 2012 U.S. Dist. LEXIS 170704, at *22-23 (N.D. Cal. Nov. 30, 2012).[9]

[9] Defendants mischaracterize the Court's ruling in *Juno* with regard to insider sales. In *Juno*, the Court found *Schueneman* "instructive and on point," and concluded that the complaint alleged

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Nor is the scienter of the named Defendants, who made no Class Period purchases, impacted by the fact that entities unnamed in the CAC decided to purchase stock. *See* Defs.' Mot. at 22 (referencing a purchase by entities related to a director, Felix Baker). These references are highly improper because they go outside the four corners of the CAC, and establish unwarranted inferences that are unrelated to the allegations of the CAC. Baker's knowledge is irrelevant to this Action, and his purchase provides no cover for Defendants' own misconduct.

E. The Competing Inferences Urged by Defendants are neither Plausible nor Compelling

The scienter analysis specified by the Supreme Court in *Tellabs* allows consideration of competing inferences, but only to the extent such inferences are "rationally drawn from the facts alleged." *Tellabs*, 551 U.S. at 314. Defendants here advance competing inferences that are neither rational nor based on the four corners of the CAC. That is not enough to defeat scienter or discredit a confidential witness's allegations at the pleadings stage. *See Lloyd v. CVB Fin. Corp.*, 811 F.3d 1200, 1208-09 (9th Cir. 2016) (reversing the district court's decision to dismiss the complaint, in part, because competing inference raised by defendants did not directly refute the inference raised by CW account alleged in the complaint).

For example, relying on facts outside the four corners of the CAC, Defendants claim that "laboratory Safety Data Sheets" warn of an entirely different kind of toxicity than hepatotoxicity. Defs.' Mot. at 9-10. But, Defendants must accept as true at this pleadings stage CW1's statement that the Safety Data Sheets indicated a risk of *hepatotoxicity* associated with 33A. ¶ 41. *See also Tellabs*, 551 U.S. at 322 (even a competing inference must "accept all factual allegations in the complaint as true"). By definition, hepatotoxicity is drug-induced liver damage that occurs in a clinical trial. Defendants' inability to explain away this fact crumbles their unfounded attack on CW1's reliability.

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sufficient facts to show deliberate recklessness, even though *Schueneman* had nothing to do with insider sales. 2017 U.S. Dist. LEXIS 91608, at *21. Defendants' insider sales in *Juno* created an additional, compelling inference of scienter, but they were not necessary to plead scienter.

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Defendants again rely on facts outside the four corners of the CAC to argue that CW1's allegations regarding the third party risk assessment of 33A's toxicity should be assumed to relate only to occupational safety risks and not address at all risks to exposure in a clinical context. Defs.' Mot. at 11. This is both implausible and unfounded. It makes no sense that a chemical compound could be fatally toxic in a laboratory environment but safe when ingested within the human body. At any rate, if Defendants have evidence that the third party risk assessment was so limited, they are free to present that evidence at trial. The well-pleaded allegations of the CAC cannot be assumed to be untrue merely because Defendants would prefer not to address them.

Defendants' assumptions about the implications of the FDA's decision to initiate clinical holds on the 33A Phase I trials fare no better. *See* Defs.' Mot. at 12-13. Lead Plaintiff alleges that the hold was caused by hepatotoxic events, including the fact that the hold was revealed in the same press release that revealed, for the first time, six hepatotoxic events including four deaths, the fact that risks of hepatotoxicity were acknowledged internally, and the fact that hepatotoxicity was observed in related chemical compounds. ¶¶ 38-47, 58-62. Defendants ask the Court to assume, contrary to the well-pleaded allegations and without any supporting admissible evidence, that the clinical hold was unrelated to hepatotoxicity. This is a trial issue, to be addressed by testimony of competent experts. It cannot be resolved by assuming the truth of cherry-picked self-serving statements made by Defendants in the December 27, 2016 press release. *See Diversified Capital Invs., Inc. v. Sprint Communs., Inc.*, No. 153796, 2016 U.S. Dist. LEXIS 68757, at *11-14 (N.D. Cal. May 24, 2016) (complaint reference to a press release does not allow the court to assume the truth of facts asserted in the press release, or to take judicial notice of the press release as substantive evidence of a factual issue that is disputed by the parties).[10]

[10] The Court should completely disregard Defendants' attempt to rely on a medical journal for the claim that nearly 80% of patients undergoing bone marrow transplants will suffer from hepatotoxicity, including VOD. This fact is outside the four corners of the CAC and it is not incorporated by reference in the CAC or subject to judicial notice. See *Juno Therapeutics*, 2017 U.S. Dist. LEXIS 91608, at *17 n.2.

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The plain language of the relevant FDA regulation also flatly contradicts Defendants' assumption that the clinical holds were not placed because 33A's protocol itself exposed patients to an unreasonable and significant risk of harm. Defs.' Mot. at 12-13. Pursuant to FDA regulations, a total or partial clinical hold is placed when the trial protocol exposes subjects to unreasonable and significant risk. 21 C.F.R. § 312.42(b); ¶ 27.

Moreover, that the trials in question and other trials were eventually allowed to proceed does not support an inference that no problem existed. As the CAC details, these trials were permitted to proceed only after the Company implemented additional risk mitigation measures with respect to hepatotoxicity for all 33A trials. ¶ 62. This demonstrates, rather than undercuts, the link between the clinical holds and observed hepatotoxicity.

IV. The Complaint Adequately States a Claim against Defendant Simpson

Defendants incorrectly argue that Defendant Simpson is immune from liability because no statement is expressly attributed to him. Defs.' Mot. at 24.

However, as CFO, Defendant Simpson was responsible for the day-to-day management of the Company and thus, under the group published information doctrine, he is responsible for information contained in the December 3, 2016 and December 5, 2016 press releases. *In re BP Prudhoe Bay Royalty Tr. Sec. Litig.*, No. 06-1505, 2007 U.S. Dist. LEXIS 83007, at *21 (W.D. Wash. Oct. 26, 2007).[11] The CAC, therefore, sufficiently alleges that Defendant Simpson made material misrepresentations and omissions. Moreover, the Court cannot dismiss the claims against

[11] Although many district courts in California have rejected the group pleading doctrine as inconsistent with the PSLRA, *see, e.g., Okla. Firefighters Pension & Ret. Sys. v. Ixia*, 50 F. Supp. 3d 1328, 1354-55 (C.D. Cal. 2014), this District has taken the opposite approach. In *BP Prudhoe*, the Court ruled that group pleading survived the PSLRA, and the Court has continued to apply *BP Prudhoe* without dissent. *See In re Wash. Mut., Inc. Sec., Derivative & ERISA Litig.*, No. 08-1919, 2010 U.S. Dist. LEXIS 73628, at *32 (W.D. Wash. Jun. 21, 2010). The Supreme Court's decision in *Janus Capital Group, Inc. v. First Derivative Traders*, 564 U.S. 135 (2011), does not affect the group published information doctrine. *See City of Pontiac Gen. Emples. Ret. Sys. v. Lockheed Martin Corp.*, 875 F. Supp. 2d 359, 374 (S.D.N.Y. 2012) (ruling that *Janus* is not inconsistent with the group published information doctrine).

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Defendant Simpson because he is also liable for the Company's and Defendants' Drachman's and Siegall's misleading statements as a "control person" pursuant to Section 20(a) of the Exchange Act. *See Oaktree Principal Fund V, LP v. Warburg Pincus LLC*, No. 15-8574, 2017 U.S. Dist. LEXIS 122725, at *22-24 (C.D. Cal. Jan. 17, 2017).

V. The CAC Properly Alleges a Section 20(a) Claim

Defendants do not challenge the CAC's Section 20(a) claim except for contesting that an underlying primary violation has been alleged. *See* Defs.' Mot. at 24. Because the CAC sufficiently alleges primary violations as discussed above, Lead Plaintiff's claim for control person liability under Section 20(a) of the Exchange Act should be sustained. *See* 15 U.S.C. § 78t(a).

CONCLUSION

For the above reasons, Defendants' Motion to Dismiss should be denied in its entirety.[12]

Respectfully submitted,

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[12] If, however, the Court reaches a contrary conclusion with respect to any of the claims, leave to amend should be granted, particularly as no prior complaint has been dismissed.

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Plaintiffs' Lead Counsel

Certificate of Service

I certify that, on the date stamped above, I caused this document to be filed with the Clerk of the Court using the CM/ECF system, which will send notification of filing by email to counsel of record for all parties.

s/ *Cliff Cantor*

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