THE HONORABLE RICARDO S. MARTINEZ

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

SAMIT PATEL, Individually and on Behalf of All Other Persons Similarly Situated,

Plaintiff,

v.

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

Defendants.

CASE NO.: 2:17-cv-00041-RSM

DEFENDANTS' MOTION TO DISMISS CONSOLIDATED AMENDED COMPLAINT

NOTE ON MOTION CALENDAR: Sept. 27, 2017

ORAL ARGUMENT REQUESTED

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Pursuant to FRCP Rule 12(b)(6), Seattle Genetics, Inc. (the "Company"), Clay B. Siegall, Todd E. Simpson and Jonathan Drachman ("Individual Defendants," collectively with the Company "Defendants") move to dismiss the Consolidated Amended Complaint, ECF No. 18 ("Complaint" or "AC") for failure to state a claim.

INTRODUCTION

Seattle Genetics is a company dedicated to fighting cancer with innovative antibody-drug conjugates ("ADCs") that, unlike chemotherapy, are designed to target and destroy cancer cells while sparing healthy, non-cancerous cells. Since receiving FDA approval in 2011, the Company's lead drug ADCETRIS has helped thousands of people suffering from relapsed Hodgkin lymphoma and relapsed systemic anaplastic large cell lymphoma around the world. As it continues its mission, Seattle Genetics is developing many other ADCs for the treatment of other types of cancer, including vadastuximab talirine ("SGN-CD33A" or "33A") for the treatment of Acute Myeloid Leukemia ("AML"), a deadly cancer of the blood and bone marrow.

Plaintiff alleges that Defendants violated federal securities laws for two months from October 27, 2016 through December 27, 2016 by intentionally or recklessly failing to tell investors that 33A "had high, known risks of liver toxicity" (hepatotoxicity) and that patients treated with 33A in clinical trials were "experiencing serious adverse hepatotoxic events." AC ¶¶ 47, 49, 51, 53, 55, 57. Plaintiff bases this claim on allegations attributed to a former low-level employee in the Company's facilities group with no medical or clinical qualifications who purports to have had concerns about potential workplace and environmental safety issues in the manufacture and handling of 33A and its components. But even if true, concerns about daily exposure to a drug by pharmaceutical company employees do not justify an assumption that there was a known risk that the drug causes even generalized toxicity, let alone liver toxicity, in cancer patients receiving the drug as part of a strict clinical trial regimen. Plaintiff also bases this claim on the mere fact that the FDA placed a clinical hold on three of five 33A clinical trials at the end of the purported class period to review certain adverse events. But Plaintiff's efforts to suggest that this shows an undisclosed high risk of hepatotoxicity is undermined by the admitted

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fact that the FDA hold only lasted a couple of months until it was lifted by the FDA after a comprehensive analysis of the safety data.

Formed from these two ill-conceived assumptions, this is precisely the type of lawsuit the Private Securities Litigation Reform Act of 1995 ("Reform Act") was designed to prevent or quickly terminate. The Reform Act imposes pleading standards that far exceed those typically employed by courts in other civil actions, mandating a critical review of the complaint to determine if it alleges with particularity that false statements were actually made and, if so, whether there are factually sufficient allegations that show a "strong inference" that such challenged statements were made with the intent to defraud or with deliberate recklessness, *i.e.*, scienter. A careful review of the Complaint reveals that it fails to satisfy the Reform Act's requirements for pleading falsity or a strong inference of scienter. In essence, Plaintiff asks the Court to accept as "cogent and compelling" a pointless alleged fraud perpetrated by motiveless Defendants who allegedly should have said more when they made accurate statements about particular 33A clinical trials and common adverse events. Plaintiff also asks the Court to accept the theory that the Individual Defendants engaged in securities fraud despite never profiting personally and while observing the Company's lead board director's funds purchasing over 1.5 million shares of the Company's stock at a cost of over $75 million during the two-month class period. The Complaint should be dismissed.

PROCEDURAL BACKGROUND

On January 10, 2017, the initial complaint was filed. On April 7, 2017, the Court entered an order appointing a lead plaintiff and approving the lead plaintiff's selection of counsel. On June 6, 2017, the lead plaintiff filed the Consolidated Amended Complaint. The Complaint alleges claims under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 on behalf of a purported class of purchasers of Seattle Genetics stock from October 27, 2016 through December 27, 2016. The Complaint names as defendants Seattle Genetics, Dr. Clay B. Siegall (the Company's President and CEO), Todd E. Simpson (the Company's Chief Financial Officer), and Dr. Jonathan Drachman (the Company's Chief Medical Officer).

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FACTUAL BACKGROUND

Seattle Genetics is a Bothell, Washington biotechnology company that develops and commercializes a new generation of cancer treatments based on innovative antibody-drug conjugate technology that delivers toxic payloads to cancer cells while sparing healthy cells. AC ¶¶ 16, 28. This approach uses a chemical linker to attach a toxic payload to an antibody. The three components of an ADC are the toxin, the linker, and the antibody. AC ¶¶ 28-31. Unlike chemotherapy which damages all quickly-dividing cells, both cancerous and healthy, ADCs are designed to flow through the bloodstream, and only bind with cells bearing a particular, targeted protein present in cancer cells that is recognized by the antibody. After an ADC binds with a cancer cell, it enters the cancer cell like a Trojan horse, the toxin is released and the cancer cell is destroyed from within. *Id*. Since the ADC's toxic payload is not released and activated until the ADC binds with a cancer cell, payloads can be more potent, and thus more cancer-killing, than untargeted treatments like radiation or chemotherapy. *Id*. ADCETRIS—the Company's lead product that treats Hodgkin lymphoma and related conditions—is one of only two ADCs currently approved by the FDA. AC at 3, n.1.

SGN-CD33A. In addition to ADCETRIS, Seattle Genetics is developing numerous other ADCs to treat cancers, including SGN-CD33A ("33A"). 33A is undergoing clinical trials for the treatment of Acute Myeloid Leukemia ("AML"), an aggressive cancer of the bone marrow and blood that progresses rapidly without treatment. AC ¶ 2. For people with AML, cancerous cells "multiply and crowd out normal cells in the bone marrow and interfere with normal blood cell production, leading to anemia, infection and bleeding." Ex. 1.[1] In the U.S. alone, over 10,000 deaths occur annually from AML. *Id*. With current treatment options, older AML patients have a particularly poor prognosis with an average survival of ten months or less. Currently, the most common treatment for newly diagnosed AML is chemotherapy. *Id*. If chemotherapy brings about remission, many AML patients are also treated with bone marrow transplants to prevent

[1] Citations to "Ex." are to the exhibits attached to the concurrently filed Declaration of Christopher M. Petroni dated July 28, 2017.

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relapse. In connection with bone marrow transplants, a patient's own blood-making bone marrow cells are eliminated through intense pre-conditioning chemotherapy and radiation treatment, after which the patient receives a transplant of healthy bone marrow. ***Liver-related complications, including veno-occlusive disease ("VOD"),[2] are common in bone marrow transplant patients because the chemotherapy drugs (not 33A) administered as part of the pre-transplant treatment concentrate in the liver.*** *See* J.P. Norvell, *Liver Disease After Hematopoietic Cell Transplantation in Adults*, 29 Transplantation Revs. at 8 (2015) (Ex. 2). Nearly 80% of bone marrow transplant recipients experience a liver-related complication, and these complications account for 15% of transplantation-related fatalities. *Id*.

Like other ADCs, 33A is composed of a toxin, a linker and an antibody. AC ¶ 30. 33A targets CD33, a protein expressed on AML cancer cells. *Id*. 33A flows through a patient's bloodstream until it finds a CD33-expressing AML cell, and is taken into the AML cell where it releases its toxic payload and destroys it. AC ¶¶ 30-31. During the class period (October 27, 2016 through December 27, 2016), Seattle Genetics had five active clinical trials for 33A:

- **Study 1 (Phase 1)**[3]: Administered 33A to AML patients, including a subset of older AML patients in combination with hypomethylating agents ("HMAs"). Seattle Genetics presented interim results of this study at the American Society of Hematology meeting in December 2016.
- **Study 2** (**Phase 1**): Administered 33A to younger AML patients in combination with an aggressive chemotherapy called "7+3." Seattle Genetics presented interim results of this study at the American Society of Hematology meeting in December 2016.
- **Study 3 (Phase 1/2)**: Administered 33A to AML patients along with chemotherapy as a part of a pre-conditioning regimen before bone marrow transplants and as a maintenance therapy after the transplant.
- **Study 4 (Phase 1/2)**: Administered 33A to patients with myelodysplastic syndromes ("MDS"), a collection of stem cell disorders often characterized by rapid transformation into AML.
- **Study 5 (Phase 3)**: Known as CASCADE, a double-blind study (patients randomly assigned 33A or placebo) administered to newly-diagnosed older AML patients in combination with HMAs.

AC ¶¶ 34-36, 58. Many patients in these clinical studies achieved remission of their AML, making it possible for them to go on to receive bone marrow transplants while in remission to

[2] Veno-occlusive disease or "VOD" is a condition in which some of the small veins in the liver are obstructed, making it difficult for the liver to remove toxins, drugs and waste from the blood.

[3] *See* AC ¶¶ 22-25 describing Phase I, Phase II, Phase I/II and Phase III trials; 21 C.F.R. § 312.21.

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reduce the risk of relapse. *See, e.g.*, Ex. 1 (detailing 73% remission rate for a category of patients in Study 1); Ex. 3 (detailing 76% remission rate for a category of patients in Study 2).

FDA Hold and Release. The FDA issues clinical holds on studies if concerns develop about the safety of a drug being tested in order to give the FDA a chance to gather and review additional information. 21 C.F.R. § 312.42(b). A study may not resume unless the FDA is "satisfie[d]" that the study "can proceed." 21 C.F.R. § 312.42(e).

On December 27, 2016, the end of Plaintiff's purported class period, Seattle Genetics issued a press release announcing that the FDA had placed three of its 33A clinical trials (Studies 1-3) on full or partial clinical hold "to evaluate the potential risk of hepatotoxicity [liver toxicity] in patients who were treated with SGN-CD33A…." AC ¶ 58. The press release noted that of the over 300 patients treated with 33A across multiple treatment settings, only "[s]ix patients have been identified with hepatotoxicity, including several cases of [VOD], with four fatal events." *Id*. ***In other words, only 2 percent of patients treated with 33A experienced liver toxicity during treatment***. *Id*. (6 / 300 = 0.02). The FDA issued a full clinical hold on Study 3, the clinical trial in which all patients received bone marrow transplants (and thus the pre-conditioning regimen that included chemotherapy). The FDA put Studies 1 and 2 on partial clinical holds, meaning the patients already enrolled in those studies could continue to receive treatment, but no new patients could be enrolled. AC ¶¶ 6, 7, 58. ***The FDA did not place Studies 4 or 5 on hold.*** *Id*.

On March 6, 2017, Seattle Genetics announced that ***the FDA had released the clinical holds*** after a "comprehensive analysis of the clinical data from over 300 patients treated to date, evaluation by an independent committee of clinical experts, collaborative interactions with the FDA, and protocol amendments designed to further enhance patient safety." AC ¶ 62; Ex. 4. The Company also announced that it had decided not to resume Study 3—the trial involving pre-conditioning for bone marrow transplant patients—due to the "challenges of developing therapies in this specific setting." *Id*. Studies 4 and 5 were never subject to an FDA hold during the purported class period. *Id*.

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ARGUMENT

I. THE COMPLAINT IS SUBJECT TO RIGOROUS PLEADING REQUIREMENTS

The Complaint alleges violations of Section 10(b) of the Securities Exchange Act and Rule 10b-5 promulgated thereunder. AC at 25-28. The elements of a claim under Section 10(b) and Rule 10b-5 are (1) a material misrepresentation or omission, (2) made with scienter, (3) in connection with the purchase or sale of a security, (4) on which plaintiff relied, (5) economic loss, and (6) "loss causation," *i.e.*, a causal connection between the material misrepresentation and loss. *Stoneridge Inv. Partners, LLC v. Sci.-Atlanta*, 552 U.S. 148, 157 (2008).

Securities fraud plaintiffs must "meet the higher, exacting pleading standards of Federal Rules of Civil Procedure 9(b)." *Or. Pub. Emps. Ret. Fund v. Apollo Grp. Inc.*, 774 F.3d 598, 604 (9th Cir. 2014). Rule 9(b) requires plaintiffs to "state with particularity the circumstances constituting fraud"—the "who, what, when, where, and how" of plaintiff's fraud allegations. *Kearns v. Ford Motor Co.*, 567 F.3d 1120, 1124 (9th Cir. 2009). They must also state a claim that is not just conceivable, but "'plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)).[4]

Securities fraud plaintiffs must also satisfy the "formidable" pleading requirements of the Reform Act. *Metzler Inv. GMBH v. Corinthian Colls., Inc.*, 540 F.3d 1049, 1054-55, 1070 (9th Cir. 2008).[5] To adequately plead falsity under the Reform Act, a complaint must "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 omissions is made on information and belief, . . . state with particularity all facts on which the belief is formed." 15 U.S.C. § 78u-4(b)(1); *In re Silicon Graphics, Inc. Sec. Litig.*, 183 F.3d 970, 985 (9th Cir. 1999) (plaintiffs must

[4] Conclusory allegations and unwarranted inferences are insufficient to defeat a motion to dismiss. *See In re VeriFone Sec. Litig.*, 11 F.3d 865, 868 (9th Cir. 1993). Courts should reject conclusory allegations that are contradicted by documents referenced in the complaint or other information subject to judicial notice. *See Steckman v. Hart Brewing, Inc.*, 143 F.3d 1293, 1295-96 (9th Cir. 1998); *In re Stac Elecs. Sec. Litig.*, 89 F.3d 1399, 1403-05 (9th Cir. 1996).

[5] *See Merrill Lynch, Pierce, Fenner & Smith Inc. v. Dabit*, 547 U.S. 71, 82 (2006) (The Reform Act places "special burdens" on securities class action plaintiffs in an "effort to deter or at least quickly dispose of those suits whose nuisance value outweighs their merits.").

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"provide, in great detail, all the relevant facts forming the basis" of their claim), *abrogated on other grounds by S. Ferry L.P., No. 2 v. Killinger*, 542 F.3d 776 (9th Cir. 2008). To prevent the pleading of "fraud by hindsight," facts must show a challenged statement was false *at the time it was made*. *Ronconi v. Larkin*, 253 F.3d 423, 430 (9th Cir. 2001). If alleging fraud by omission, a plaintiff must show the omission allowed a statement to create "an impression of a state of affairs that differs in a material way from the one that actually exists." *Brody v. Trans. Hosps. Corp.*, 280 F.3d 997, 1006 (9th Cir. 2002). To assert a false opinion, a plaintiff must plead specific facts showing the opinion is both objectively *and* subjectively false. *See City of Dearborn Heights Act 345 Police & Fire Ret. Sys. v. Align Tech., Inc.*, 856 F.3d 605, 615 (9th Cir. 2017).

To adequately plead scienter, a plaintiff must "state with particularity facts giving rise to a strong inference that the defendants acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2). Scienter requires a "'strong inference of, at a minimum, 'deliberate recklessness'" or "'conscious misconduct.'" *In re NVIDIA Corp. Sec. Litig.*, 768 F.3d 1046, 1053 (9th Cir. 2014). A court is required to "consider plausible, nonculpable explanations for the defendant's conduct, as well as inferences favoring the plaintiff." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 323-24 (2007). "A complaint will survive . . . only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Id.* at 324. The Reform Act mandates that if a complaint fails to meet these requirements, a court "shall . . . dismiss the complaint." 15 U.S.C. § 78u-4(b)(3)(A).

II. THE COMPLAINT'S TWO FUNDAMENTAL ASSUMPTIONS ARE DEEPLY FLAWED AND DO NOT SUPPORT ALLEGATIONS OF FALSE STATEMENTS OR OMISSIONS

Plaintiff alleges that each of Defendants' challenged statements was misleading for the same reasons: "SGN-CD33A had high known risks of liver toxicity and . . . as a result, patients exposed to SGN-CD33A in clinical trials were experiencing serious adverse hepatotoxic events" that ultimately resulted in the FDA placing a hold on the Company's 33A clinical trials. AC ¶¶ 49, 51, 53, 55, 57. Plaintiff's two basic assumptions are that a) CW1's concerns over the safety of 33A in a laboratory or manufacturing setting somehow show that 33A was hepatotoxic

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when administered to patients in a clinical setting, and b) the FDA's clinical hold of some 33A trials shows that 33A is hepatotoxic, even though the FDA subsequently released those holds. These assumptions are deeply flawed and fail to satisfy the Reform Act's heightened requirements for pleading falsity or scienter.

A. Confidential Witness 1's Allegations Are Wholly Unreliable, Conflating Workplace Safety with Clinical Patient Safety

The Complaint is heavily dependent on allegations made by a single confidential witness ("CW1"), a former Senior Environmental Health and Safety Engineer, who was responsible for providing information to employees about workplace environmental safety.[6] AC ¶¶ 5, 38-46. In order to assess whether CW1's allegations satisfy the Reform Act's pleading requirements, the Court must look at "the 'level of detail provided by [CW1], the corroborative nature of the other facts alleged (including from other sources), the coherence and plausibility of the allegations, the number of sources, the reliability of the sources, and similar indicia.'" *Zucco Partners, LLC v. Digimarc Corp*., 552 F.3d 981, 995 (9th Cir. 2009). A careful examination of the allegations attributed to CW1 reveals that they are unreliable, uncorroborated, incoherent, and implausible. In short, although they are alleged to sound dramatic and telling, they completely miss the mark.

As a former workplace environmental safety engineer, 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, particularly with respect to patient safety in investigational cancer drug studies authorized by the FDA of an innovative ADC like 33A. ***The Complaint does not allege that CW1 is a medical doctor, a medical researcher or a clinician of any kind. Instead, it alleges that CW1 was a low-level employee who reported to a Senior Manager of Facilities, who reported to the Associate Director of Facilities, who reported to the Director of Facilities, who reported to the Chief Financial Officer.*** AC ¶ 39. CW1 did not

[6] Courts have noted that confidential witness allegations should be discounted because "it is hard to see how information from anonymous sources could be deemed 'compelling' or how we could take account of plausible opposing inferences." *Higginbotham v. Baxter Int'l, Inc*. 495 F.3d 753, 756–57 (7th Cir. 2007). Companies should not be subjected to onerous litigation based on the uncorroborated say-so of a single potentially disgruntled former employee. *See id.* ("Perhaps these confidential sources have axes to grind. Perhaps they are lying.")

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have a reporting relationship with anyone involved with or responsible for the Company's clinical trials. ***There is no allegation indicating that CW1 even worked with anyone involved in clinical trials, generally, or the clinical trials of 33A, specifically.*** Instead, the Complaint alleges that CW1 "primarily dealt with the division at Seattle Genetics that was responsible for synthesizing drugs," a division unrelated to conducting clinical trials. AC ¶ 39. In that role, CW1 provided information to employees "about the risks of the environment in which they worked, including the risks of exposure to toxic drug compounds in Seattle Genetics labs, and the stringent handling requirements for those drugs." *Id*.

Since CW1 is not "personally knowledgeable" about the safety of 33A when administered to AML patients in clinical trials, any attempt by CW1 or the Complaint to allege that workplace, *e.g.*, laboratory or manufacturing, toxicity risk somehow translates into known patient risk should be disregarded. *Zucco*, 552 F.3d at 996-98 ("human-resources employee . . . had no firsthand knowledge of the workings of the finance or corporate departments").[7] Indeed, common sense dictates that one risk does not follow the other. Employees in laboratories and manufacturing facilities come in contact with large quantities of the drug, or one or more of the drug's components, on a daily basis over many years while patients receive the finished drug by injection in micro-doses specifically tailored for therapeutic effect. In a laboratory or manufacturing setting, an accident could result in an unsafe exposure to the drug, *e.g.*, an employee spills a beaker of 33A's toxic payload on himself or inhales it when a fire breaks out in the lab. These risks are not present to patients in the clinical setting.

The Complaint and CW1 allege that Safety Data Sheets used for drugs and drug components in the Company's labs indicated "a risk of hepatotoxicity" in 33A. AC ¶¶ 5(b), 41. Like all cancer-killing drugs, 33A's payload (one of its three components) is by definition a toxic

[7] *See also City of Royal Oak Ret. Sys. v. Juniper Networks, Inc*., 2013 WL 2156358, at *5 (N.D. Cal. May 17, 2013) (that CW managed operating expenses does not show he/she had a role in revenue forecasting); *In re NVIDIA Corp. Sec. Litig*., 2010 WL 4117561, at *7 (N.D. Cal. Oct. 19, 2010) (CW who "had no involvement in . . . accounting practices [does] not support a finding that [company] knew of a 'probable loss' for purposes of FAS 5"); *In re Hypercom Corp. Sec. Litig*., 2006 WL 1836181, at *5 (D. Ariz. July 5, 2006) (requiring accounting knowledge or experience for CW to attest to a technical accounting violation).

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chemical and is properly treated as such in a laboratory setting. *See Work Precautions for Handling Hazardous Drugs Highlighted by NIOSH, OSHA, Joint Commission*, OSHA Trade Release (Dep't of Labor, April 7, 2011) (Ex. 5) ("Potent therapy drugs can have great benefit for patients when used in proper regimens, where doses are controlled and risks are minimized. But they can also have serious consequences to the workers who handle, dispense, mix, apply, and dispose of them without proper controls and training.…"). It is not surprising (and certainly not a fact supporting falsity or scienter) that laboratory Safety Data Sheets warned of its toxicity. But that is different from whether 33A was toxic/hepatotoxic to patients in a clinical trial.

The Complaint and CW1 also allege that the Company "procured a third party risk assessment of the toxicity associated with SGN-CD33A, and that assessment concluded that the risks were high." AC ¶¶ 5(c), 42. The Complaint does not allege that this assessment concluded that 33A was hepatotoxic, only alleging generally that it concluded that 33A was toxic. Regardless, based upon CW1's role within the Company, it is reasonable to assume that the assessment was about occupational safety risks, not clinical risks. Again, such risks do not translate into risks for patients being administered controlled doses under a specific treatment regimen. In fact, any number of substances that are safe and non-toxic when administered as a medication are nonetheless laboratory hazards. For example, the National Institute for Occupational Safety and Health Pocket Guide to Chemical Hazards describes ethyl alcohol as "targeting" the eyes, skin, respiratory system, central nervous system, liver, blood, and reproductive system and indicates that if swallowed, medical attention should be sought immediately. Barsan, ME, ed., DHHS (NIOSH) Pub. No. 2005-149, at 132 (Sept. 2007) (Ex. 6). It also indicates that exposure to aspirin can lead to irritation of the eyes, skin, and upper respiratory system; increased blood clotting time; nausea and vomiting; and liver and kidney injury. *Id.* at 6. ***Thus, at the most, the third party risk assessment shows that like alcohol or aspirin, 33A can be hazardous to workers handling it in large quantities and/or a laboratory setting on a daily basis over a long period of time***.

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The Complaint and CW1 allege that the third-party assessment was provided to one of the Company's contract manufacturers, leading to it suspending production of some components of 33A. AC ¶¶ 5(d), 42-43. According to the Complaint, the contract manufacturer did not even supply the completed ADC—only the toxic payload and the linker. AC ¶ 42. A manufacturer's decision to (temporarily) suspend production of some of 33A's components out of a concern for the safety of its workers has nothing to do with the alleged hepatotoxicity of the finished 33A in clinical trials. Regardless, the Complaint's allegations about the contract manufacturer should be disregarded because they lack required details, such as when it stopped production, for how long, or even the name of the manufacturer. *Id*.; *see Kearns*, 567 F.3d at 1120.

The Complaint and CW1 also allege that an unidentified in-house toxicologist "expressed concerns" about 33A's toxicity, but apparently not hepatotoxicity in particular, and was "coerced to moderate his views" by the Company's Associate Director of Facilities and Senior Manager of Facilities (neither a defendant in this lawsuit). AC ¶¶ 5(f), 41, 43-45. This allegation fails to satisfy Rule 9(b) or the Reform Act's pleading requirements. It does not identify the toxicologist by title, tenure, department, division or responsibilities. It does not identify how or when such alleged coercion took place. It does not even allege if or how CW1 learned of this alleged coercion. *See Lloyd v. CVB Fin. Corp*., 811 F.3d 1200, 1208 (9th Cir. 2016) (CW hearsay report unreliable if it is not "specific in time, context, and details"); *Kearns*, 567 F.3d at 1120.

Finally, the Complaint and CW1 allege 33A was "known" to be hepatotoxic due to "[e]arly data" from a clinical trial conducted in 2011 and 2012 on a different drug that had "similar components." AC ¶¶ 5(a), 38, 40. ***But CW1 did not join Seattle Genetics until March 2015, three years after these clinical trials of another company's drug were conducted.*** AC ¶ 39. Moreover, nothing in CW1's job description suggests that CW1 would have firsthand knowledge of clinical data, knew whether the 2011/2012 trial was of the payload itself or of an ADC containing the payload (thus designed to not release it until it attached to a cancer cell), or was qualified to interpret it or analyze how relevant "similar components" might be. Such

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allegations are simply too vague to be reliable. *Metzler*, 540 F.3d at 1069-70 (courts should disregard CW allegations if they are opinions, conclusions, or vague assertions).

B. The FDA's Clinical Hold Does Not Show that 33A Is Hepatotoxic

Plaintiff's primary claim that 33A was known to cause hepatotoxicity in clinical trial patients is based on the Company's December 27, 2016 press release announcing the FDA's clinical hold on three of five 33A trials. AC ¶¶ 58-62. Other than a conclusory allegation that "the truth emerge[d]" in that press release, Plaintiff does not explain how 33A's alleged hepatotoxicity was revealed by the hold. AC ¶ 58. The Complaint's allegations, documents incorporated by reference into the Complaint, and judicially noticeable facts show that the FDA hold does not support an allegation that 33A is hepatotoxic or that Defendants knew or know that it is. *See Fort Worth Emp'rs Ret. Fund v. Biovail Corp*., 615 F. Supp. 2d 218, 221 (S.D.N.Y. 2009) ("Complaint's own allegations fatally undermine the premise on which plaintiff's theory of securities fraud rests."). In fact, they show just the opposite.

First, the FDA placed holds on three of the then-ongoing clinical trials of 33A, but allowed enrolled patients in two of those trials to continue to receive 33A after signing a new consent form. The FDA also allowed two other 33A trials to continue without a hold. AC ¶ 58; Ex. 7. ***If the FDA was convinced that 33A was causing hepatotoxicity, it would have placed holds on all five of the Company's 33A trials and refused to allow patients to continue receiving 33A during those holds***.

Second, the FDA holds "were initiated to evaluate the ***potential risk*** of hepatotoxicity in patients who were treated with SGN-CD33A and received" bone marrow transplants "either before or after treatment." AC ¶ 58; Ex. 7 (emphasis added). The fact that the FDA hold primarily concerned potential risks of hepatotoxicity in patients who received both 33A and bone marrow transplants is fundamentally at odds with Plaintiff's claim. As discussed above, hepatotoxicity is a common side effect of the intense chemotherapy (not 33A) patients receive before bone marrow transplants. In fact, nearly 80% of patients undergoing bone marrow transplants will suffer from hepatotoxicity, including VOD. *See* Norvell, Liver Disease, Ex. 2 at

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8. Thus, instances of hepatotoxicity and VOD in the population of patients in the 33A clinical trials would be expected as a byproduct of the chemotherapy associated with their bone marrow transplants even if none of those patients had received 33A at all.

Third, as the Complaint admits, ***the FDA hold was lifted in March 2017*** after a "comprehensive analysis of the clinical data from over 300 patients treated to date, evaluation by an independent committee of clinical experts, collaborative interactions with the FDA, and protocol amendments designed to further enhance patient safety." AC ¶ 62; Ex. 4. The FDA would not have lifted the hold unless it was "satisfie[d]" that the studies could safely "proceed." 21 C.F.R. § 312.42(e).

Finally, Plaintiff may contend that the December 27, 2016 press release announcing the FDA hold is significant because it disclosed that "[s]ix patients have been identified with hepatotoxicity, including several cases of [VOD], with four fatal events," and that 33A somehow caused those adverse events. AC ¶ 58. However, neither the FDA hold nor the Company's announcement of the hold suggests that 33A was responsible for any of the six cases of hepatotoxicity suffered among the more than 300 patients who had received 33A in clinical trials at that time. *Id*. In fact, the press release merely states that the Company was "working diligently with the FDA to determine whether there is any association between hepatotoxicity and treatment with SGN-CD33A." *Id*. Regardless, ***a 2 percent occurrence of hepatotoxicity in patients treated with 33A across multiple studies does not identify it as the cause or, as the Complaint asserts, "high known risks of hepatotoxicity."***

Thus, Plaintiff's allegation that the FDA hold revealed that 33A was associated with "high known risks of hepatotoxicity" which should have been disclosed is not "plausible" on its face. *Iqbal*, 556 U.S. at 678-79. Nor does it rise "above the speculative level." *Bell Atl.*, 550 U.S. at 555. Rather, it is contradicted by the Complaint, the documents referenced in the Complaint and facts subject to judicial notice. *See Steckman*, 143 F.3d at 1295-96 (courts "are not required to accept as true conclusory allegations which are contradicted by documents referred to in the complaint.").

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III. PLAINTIFF FAILS TO PLEAD A FALSE STATEMENT OR ACTIONABLE OMISSION

A. Defendants' October 27, 2016 Statements Were Not False, Had Nothing to Do with Safety, and Therefore Were Not Misleading Due to Any Omission

Plaintiff alleges that statements made during an October 27, 2016 conference call were false or misleading. AC ¶¶ 48, 50; Ex. 8. These statements were about cancer remission rates for patients enrolled in Study 2, that "we're excited about our interim data" regarding the Study 2 remission rates, and are "happy with our positioning in this field" of AML treatment. *Id*. at 16, 20. Plaintiff does not even attempt to articulate how these statements were false. There is no allegation that Study 2 patients were not experiencing the stated remission rates,[8] that Dr. Drachman and others were not "excited" about this interim remission rate data, or that Dr. Siegall was not "happy" with 33A's position in the AML treatment field. Even if facts were adequately alleged that Defendants were not "excited" or "happy," the Ninth Circuit has noted that "vague statements of optimism like 'good,' 'well-regarded,' or other feel good monikers" are not actionable under the federal securities laws. *Apollo Grp.*, 774 F.3d at 606; *In re Cutera Sec. Litig.*, 610 F.3d 1103, 1111 (9th Cir. 2010) (same); *see also DeMarco v. DepoTech Corp.*, 149 F. Supp. 2d 1212, 1231 (S.D. Cal. 2001) (statement that drug had "extremely promising" prospects for FDA approval was nonactionable). Moreover, these statements have nothing to do with 33A's safety, generally, or hepatotoxicity, specifically. *See Norfolk Cty. Ret. Sys. v. Tempur-Pedic Int'l, Inc.*, 22 F. Supp. 3d 669, 679 (E.D. Ky. 2014) ("there must be a relationship between the omission and the [mis]statement itself."), *aff'd*, 614 F. App'x 237 (6th Cir. 2015).

B. Defendants' Statements Concerning 33A's Safety Profile, Tolerability and Most Common Adverse Events Were Not False or Misleading by Omission

Plaintiff alleges that due to the omission of 33A's alleged hepatotoxicity and related adverse events like VOD in clinical trial patients, the statements about 33A's safety profile, tolerability and most common adverse events were misleadingly incomplete despite being

[8] This is equally true of Defendants' statement of a "high rate of remissions" in Study 2 patients made in the Company's December 3, 2016 press release. AC ¶ 54. Indeed, 76% of Study 2 patients achieving complete remission of their AML is certainly a high remission rate. *Id*.; Ex. 3. Plaintiff does not allege that these disclosed remission rates were false.

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technically accurate. AC ¶¶ 49, 51, 53, 55, 57. As explained above, Plaintiff has not sufficiently alleged these factual predicates—workplace safety issues do not translate into clinical patient safety issues, and an FDA hold that was quickly lifted to allow the studies to continue following extensive review of the available safety data does not mean the studied drug is toxic.

Plaintiff incorrectly claims that when Defendants made statements concerning the safety or tolerability of 33A in patients enrolled in a particular study, they committed fraud by not also disclosing safety information for patients enrolled in other 33A studies. AC ¶¶ 52-57. However, the Ninth Circuit's binding decision in *In re Rigel Pharmaceuticals, Inc. Securities Litigation* rejected the notion that "once a company chooses to disclose any safety information, it must disclose all material information regarding safety," 697 F.3d 869, 880 n.8 (9th Cir. 2012). "[A]s long as the omissions do not make the actual statements misleading, a company is not required to disclose every safety-related result from a clinical trial, even if the company discloses some safety-related results and even if investors would consider the omitted information significant." *Id.*; *see also Brody*, 280 F.3d at 1006 (Section 10(b) "prohibit[s] only misleading and untrue statements, not statements that are incomplete"; "[n]o matter how detailed and accurate disclosure statement are, there are likely to be additional details that could have been disclosed but were not.").

On ***November 8, 2016***, Dr. Siegall stated orally that "7+3" chemotherapy was such a "tough regimen" that AML patients had to remain hospitalized for 30 days during treatment, and that adding 33A "on top of 7+3" in Study 2 patients created a comparatively "good safety profile." AC ¶ 52; Ex. 9 at 6. (In late December, the FDA partially held Study 2, allowing enrolled patients to continue to receive treatment, and later released the hold in early March.) This statement, therefore, was only about Study 2 and said nothing about other 33A studies or patients. The absence of this other information is not a material omission. *See Rigel*, 697 F.3d at 880-81. Besides, Plaintiff has not alleged any facts indicating that the safety profile of Study 2 patients was not relatively "good," that any Study 2 patients were identified with hepatotoxicity or VOD, or that any Study 2 patients died from hepatotoxicity or VOD.

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On ***December 3, 2016***, the Company issued a press release discussing interim results for Study 2 that stated "[i]n this trial, 33A in combination with 7+3 was well-tolerated, with a low early mortality rate," that 33A did not "significantly add[] to the toxicity of the treatment" for Study 2 patients, and that "no veno-occlusive disease/sinusoidal obstruction syndrome or significant hepatotoxicity was observed on treatment" in Study 2 patients. AC ¶ 54. As with the November 8 statements, all of these statements were specifically about Study 2 and said nothing about other 33A studies or patients. *See Rigel*, 697 F.3d at 880-81.

Plaintiff has not alleged any facts indicating that these December 3 Study 2-specific statements were false. Plaintiff apparently proceeds on the theory that Study 2 treatment was not "well-tolerated" due to the occurrence of adverse events.[9] But Plaintiff does not allege any facts indicating that a single Study 2 patient experienced significant hepatotoxic events or died from such events. Plaintiff has not alleged any facts showing that Study 2 patients did not have a "low early mortality rate." AC ¶ 54. In fact, a 30-day mortality rate of 2%, as the press release disclosed, certainly qualifies as "low." Ex. 3. Moreover, the press release clearly stated that longer term mortality rates were unavailable since "[o]verall survival" statistics were "still evolving and median OS [overall survival] has not yet been reached." *Id.* Plaintiff has not alleged facts indicating that, contrary to Defendants' statement, 33A significantly added to the toxicity of Study 2 patients' 7+3 chemotherapy treatment or that significant hepatotoxicity or VOD was observed in treatment. In short, Plaintiff does not explain how any of these Study 2-specific statements were false or misleading. *See Kovtun v. VIVUS, Inc.*, 2012 WL 4477647, at *7 (N.D. Cal. Sept. 27, 2012) (dismissing because "nowhere does plaintiff point to a statement made by defendants regarding a specific Phase III trial result and explain exactly what in the trial

[9] The statement that 33A was "well-tolerated" was made in the context of announcing that more than 20% of the patients in Study 2 suffered from Grade 3 or Grade 4 (*i.e.* severe, medically significant, or life threatening) febrile neutropenia (fever and low white blood cell count), thrombocytopenia (low platelet count), anemia (low red blood cell count), and neutropenia (low white blood cell count). AC ¶ 54. The statement therefore cannot be understood to imply an absence of adverse events. Rather, it must be understood in the context of a group of AML patients who were already very sick and receiving high dose chemotherapy, and its associated side effects, in an attempt to save their lives.

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data (or elsewhere) shows that the statement about the trial results was false at the time it was made."), *aff'd*, 591 F. App'x 592 (9th Cir. 2015).

On ***December 5, 2016***, Dr. Drachman stated in a press release primarily devoted to interim results for Study 1 that "[w]e are pleased with the growing body of data demonstrating that [33A] has a promising overall tolerability and activity profile in clinical trials for patients with AML." AC ¶ 56. This is the only statement alleged in the Complaint that is not specific to a particular clinical trial but instead about 33A studies generally. Nonetheless, as discussed above in Section II, there is no alleged fact showing that 33A was known to or in fact causes hepatotoxicity. "Tolerability" is defined as "the degree to which overt adverse effects can be tolerated by the subject/patient."[10] Tolerability, therefore, is relative to the severity of the medical condition a drug is designed to treat. Cancer patients will tolerate much more pain, discomfort or risk of a serious adverse event from a treatment like chemotherapy with the hope of prolonging survival or finding a cure than patients suffering from a less severe illness. As to the 33A clinical trial patient population generally, assuming for the sake of argument that all of the events disclosed on December 27 were known on December 5, Plaintiff does not show that the presence of severe hepatotoxicity in six (and four fatal events) out of more than 300 patients treated with 33A would render a statement about "promising overall tolerability" false or misleading. This is particularly true when the traditional forms of AML treatments of chemotherapy, radiation, and bone marrow transplants present their own set of adverse event risks, including the risk of hepatotoxicity. *See In re EDAP TMS S.A. Sec. Litig.*, 2015 WL 5326166, at *11 (S.D.N.Y. Sept. 14, 2015**)** ("Defendants were not obliged to reproduce a comprehensive enumeration of adverse events every time they mentioned [the drug]'s safety profile.")

On ***December 3 and 5, 2016***, Defendants made statements concerning the ***"most common"*** adverse events experienced during treatment by patients enrolled in Studies 2 and 1,

[10] *Segen's Medical Dictionary*. S.v. "safety and tolerability." Retrieved July 19 2017 from http://medical-dictionary.thefreedictionary.com/safety+and+tolerability.

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respectively. AC ¶¶ 54, 56. As disclosed by Defendants, these most common Grade 3 or 4 adverse events occurring in 20% or more of the patients in each of these studies were febrile neutropenia, thrombocytopenia, anemia and neutropenia. *Id*. Plaintiff alleges that Defendants committed securities fraud by not also disclosing any ***uncommon*** but serious adverse events experienced by patients in those two studies or in other 33A studies. AC ¶¶ 54-57. However, the Ninth Circuit's decision in *Rigel* makes clear that a pharmaceutical company's ***accurate report of "key safety results" from a clinical trial were not false or misleading just because the company did not report all safety results***. 697 F.3d at 880-81 (emphasis added). Here, just as in *Rigel*, "for each category of side effect the press release did address, the press release made clear what the criteria were for including patients in the category." *Id*. Here, just as in *Rigel*, Defendants "never claimed that these [common adverse events, those occurring in 20% or more of the study's patients] were all of the safety results or that the results included every occurrence of every possible side effect." *Id*. These statements were not false or misleading by omission. *Id*. at 880 n.8; *Police Ret. Sys. v. Intuitive Surgical, Inc*., 759 F.3d 1051, 1061 (9th Cir. 2014) (rejecting contention that accurate statement was required to provide additional details).

IV. PLAINTIFF DOES NOT ADEQUATELY PLEAD SCIENTER

To adequately plead scienter, Plaintiff must show that Defendants made "false or misleading statements either intentionally or with deliberate recklessness." *Zucco*, 552 F.3d at 991; 15 U.S.C. § 78u-4(b)(2). To do so, Plaintiff must allege particularized facts demonstrating that each Defendant who allegedly made a misleading statement possessed contemporaneous contrary information that rendered his statement false when made. *See Lipton v. Pathogenesis Corp.*, 284 F.3d 1027, 1036 (9th Cir. 2002). In other words, Plaintiff cannot merely allege the existence of information contrary to Defendants' statements; Plaintiff must allege with specificity how Defendants were aware of that contrary information. *Cf. Berson v. Applied Signal Tech. Inc.*, 527 F.3d 982, 987 (9th Cir. 2008) (absent specific circumstances creating an inference of knowledge, plaintiffs must allege that defendants "actually knew" about contrary information). This is the essence of scienter, and the Complaint falls far short of this standard.

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A. Plaintiff's Allegations Are Not Particularized to Each Defendant's Scienter

The Complaint lumps Dr. Drachman, Dr. Siegall, and Mr. Simpson together, referring to them collectively, along with the Company, as "defendants." AC ¶¶ 2, 4, 5, 9 14, 15, 37, 38, 41, 47, 63, 65, 67, 69, 71-86. This is insufficient because scienter must be alleged with particularity as to each defendant separately. *See* 15 U.S.C. § 78u-4(b)(2)(A); *e.g. In re Silicon Graphics, Inc. Sec. Litig.*, 970 F. Supp. 746, 752 (N.D. Cal. 1997) (plaintiffs "obligated to 'distinguish among those they sue and enlighten each defendant as to his or her part in the alleged fraud.'")

Moreover, Plaintiff fails to allege any specifics about their knowledge or mental state at the time the challenged statements were made. Plaintiff does not allege that CW1 ever communicated with any of the Individual Defendants about CW1's concerns regarding the alleged toxicity of 33A. While Plaintiff alleges that CW1 approached "several senior-level administrative divisions" within the Company, Plaintiff does not allege that these approaches resulted in the communication of any relevant information, and certainly does not allege that CW1 communicated with any of the three Individual Defendants. AC ¶ 46. Similarly, Plaintiff alleges that CW1 "raised concerns" about the 33A toxicity risks to the Director of Facilities, but not any of the Individual Defendants. AC ¶ 39. While Plaintiff alleges that CW1 "attempted" to reach Mr. Simpson to discuss CW1's concerns, the Complaint makes clear that this discussion did not take place. AC ¶ 46. Similarly, while Plaintiff alleges that CW1 emailed Dr. Siegall's executive assistant to schedule a meeting, the Complaint makes clear that he never had a meeting with Dr. Siegall. *Id*. This deficiency alone requires dismissal. *See Zucco*, 552 F.3d at 998 (rejecting witness statement where it failed to establish "reliable personal knowledge of the defendants' mental state"); *In re Conventry Healthcare, Inc. Sec. Litig.*, 2011 WL 1230998, at *6 (D. Md. Mar. 30, 2011) ("defies logic to conclude" that witness with no direct contact with defendants "knew what the[y] knew or recklessly disregarded"); *Alaska Elec. Pension Fund v. Adecco S.A.*, 434 F. Supp. 2d 815, 830 (S.D. Cal. 2006) (no showing how CW "would know what [CFO] was aware of"), *aff'd*, 256 F. App'x 74 (9th Cir. 2007).

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Plaintiff alleges that CW1 somehow "understood" that alleged coercive comments made by the Company's facilities managers "originated from Defendant Simpson" (AC ¶ 45), but this amounts to nothing more than vague third-hand speculation that does not support an inference of scienter. *See City of Roseville Emps.' Ret. Sys. v. Sterling Fin. Corp.*, 963 F. Supp. 2d 1092, 1134 (E.D. Wash. 2013) ("Plaintiff provides only speculation of fraudulent intent."), *aff'd*, 2017 WL 2241820 (9th Cir. May 22, 2017).

B. The Individual Defendants Cannot Be Presumed to Have Known About CW1's Opinions, the Third-Party Assessment, or the Safety Data Sheets

The Complaint's scienter allegations are conclusory, alleging that "[b]y virtue of their positions" as "senior managers of Seattle Genetics," the Individual Defendants "had actual knowledge of the materially false and misleading statements and material omissions," including "SGN-CD33A and its known risk of hepatotoxicity." AC ¶ 76. This type of general scienter pleading is impermissible under the Reform Act. 15 U.S.C. § 78u-4(b)(2)(A). It is illogical to presume that the three most-senior executives at the Company would be aware of the opinions of an employee at least four levels down in the corporate hierarchy and about workplace safety associated with one of the many drugs under development. Similarly, it would be unreasonable to presume that these senior executives would know about an assessment of occupational exposure limits for 33A or drug-specific Safety Data Sheets for 33A in a laboratory or manufacturing setting. AC ¶¶ 39-42.

C. The FDA Hold Does Not Show a Strong Inference of Scienter

Plaintiff speculates that the Company's reports of fatalities or other severe adverse events to the FDA and related communications with the FDA before the clinical hold must have revealed 33A's alleged hepatotoxicity to Defendants. AC ¶ 47.[11] However, as discussed above, the FDA hold did not reveal that 33A caused hepatotoxicity in patients. *See* Section II.A.

[11] Because these allegations are made on information and belief, Plaintiff "must provide, *in great detail*, all the relevant facts forming the basis of [Plaintiff's] belief." *Silicon Graphics*, 183 F.3d at 984 (emphasis added) (rejecting scienter allegations based on existence of internal reports when plaintiff failed to plead "their contents, who prepared them, which officers reviewed them and from whom [plaintiff] obtained the information"). Plaintiff's mere speculation of FDA communications and Defendants' awareness of it falls short of this standard.

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The First Circuit recently rejected analogous claims in *In re ARIAD Pharm. Sec. Litig.*, 842 F.3d 744, 751-52 (1st Cir. 2016). In *ARIAD*, plaintiffs challenged a series of press releases discussing data from clinical trials of a developmental leukemia drug. *Id.* The plaintiffs claimed that the press releases, which discussed adverse effects and contained statements such as "initial safety data show [the drug] to be well tolerated," misled investors because they omitted cardiovascular events suffered by patients in the trials. *Id.* Plaintiffs based their scienter claims on an FDA report issued late in the purported class period which raised concerns regarding the drug's cardiovascular side effects, claiming that because the FDA issued the report Defendants must have been aware of these side effects leading up to the report "based on their continuous monitoring of the . . . trial data." *Id.* The First Circuit held that these allegations failed to allege "any specific facts about when the defendants learned of these adverse events or even when the adverse events occurred" and noted that these allegations "impermissibly seek to establish fraud by hindsight." *Id.* Plaintiff's nearly identical attempt to use the FDA hold to establish scienter leading up to the hold does not support a strong inference of scienter. *Id.*; *Ronconi*, 253 F.3d at 430 (rejecting "fraud-by-hindsight"); *Fialkov v. Microsoft Corp.*, 72 F. Supp. 3d. 1220, 1231 (W.D. Wash. 2014) (rejecting plaintiffs' "attempt to turn Defendants' earlier statements into fraud based on later-in-time information"), *aff'd*, 2017 WL 2629127 (9th Cir. June 19, 2017).

D. The Complaint's Lack of Any Motive Allegations and Insider Purchases of Company Stock During the Purported Class Period Undermines a Strong Inference of Scienter

Conspicuous by its absence is any allegation in the Complaint that any of the Defendants attempted to benefit from the purported "fraud" in any way. If a motive to commit fraud can help support a claim of scienter, it follows that an inability to allege motive can indicate a lack of scienter. *See Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 48 (2011) ("absence of a motive allegation" is "relevant" to scienter analysis); *Beck v. Mfrs. Hanover Tr. Co.*, 820 F.2d 46, 50 (2d Cir. 1987) ("Where motive is not apparent . . . the strength of the circumstantial allegations [of scienter] must be correspondingly greater.") Here, the Complaint's total failure to show *any kind of motive* cuts against a strong inference of scienter.

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The Complaint does not allege any unusual or suspicious sales of stock by Defendants or other Company insiders during the class period—indeed, it ***does not allege any insider sales at all***. The fact that Defendants held on to their stock and incurred the same losses as Plaintiff belies an inference of scienter. *See Rigel*, 697 F.3d at 884-85 (defendants' failure to sell stock during the class period does not support an inference of scienter; "[i]n fact, it supports the opposite inference"); *Metzler*, 540 F.3d at 1067 (a lack of stock sales by the COO indicated there was "no insider information from which to benefit").[12]

Indeed, SEC filings indicate that ***entities controlled by Felix Baker, the lead director on the Company's Board, purchased over 1.5 million shares of Seattle Genetics stock at a total purchase price of over $75 million during the purported two-month class period when it is alleged that Defendants knew the Company's stock price was fraudulently inflated***. Ex. 10. These massive purchases by a powerful insider are fundamentally inconsistent with an inference of scienter. If, as the Ninth Circuit held in *Metzler*, a lack of stock sales by an insider indicates that "there was no insider information from which to benefit," certainly an insider's purchase of stock during the class period, when the stock price was allegedly inflated, indicates a lack of negative inside information. 540 F.3d at 1067. *See also Ronconi*, 253 F.3d at 436 (one defendant's suspiciously timed stock sales do not support an inference of scienter if other insiders did not act in a way consistent with a view that the stock was fraudulently inflated); *Cho v. UCBH Holdings, Inc.*, 2011 WL 3809903, at *17 (N.D. Cal. May 17, 2011) ("defendant's stock purchases . . . weigh[] against an inference of scienter"); *In re PEC Sols. Sec. Litig.*, 2004 WL 1854202, at *16 (E.D. Va. May 25, 2004) (stock purchase "negates any idea that [defendant] had a motive to commit fraud."), *aff'd*, 418 F.3d 379 (4th Cir. 2005).

[12] Thus, Plaintiff's scienter allegations are significantly weaker than those recently before this Court in *In re Juno Therapeutics, Inc.*, 2017 WL 2574009 (W.D. Wash. June 14, 2017), where plaintiffs alleged suspiciously timed insider sales of company stock, profiting them over $15 million. Here, the Complaint "says nothing about suspicious stock transactions by any of the [defendants], an omission that weighs against inferring scienter." *Mizzaro v. Home Depot, Inc.*, 544 F.3d 1230, 1253 (11th Cir. 2008); *See also, e.g.*, *Pugh v. Tribune Co.*, 521 F.3d 686, 695 (7th Cir. 2008) (same); *In re Cerner Corp. Sec. Litig.*, 425 F.3d 1079, 1085 (8th Cir. 2005) (same); *Ottmann v. Hanger Orthopedic Grp., Inc.*, 353 F.3d 338, 348 (4th Cir. 2003) (weighing the fact that plaintiffs "do not allege [defendants] had any personal motives . . . such as to facilitate personal sales of [company] stock").

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E. A Holistic Analysis of Competing Inferences Shows Plaintiff Fails to Plead a Strong Inference of Scienter

As part of a holistic analysis, the Court must look to competing inferences of scienter, "assess all the allegations" to see if there are "plausible, nonculpable explanations" for Defendants' conduct, and weigh the competing inferences. *Tellabs*, 551 U.S. at 324-26. "A complaint will survive . . . only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Id*. at 324.

Plaintiff's theory is simply not compelling: Defendants engaged in a two-month motiveless, profitless fraud in which they touted the remission rates and safety profiles of patients enrolled in several 33A clinical studies, all while knowing that 33A was hepatotoxic. That Defendants possessed this knowledge from occupational safety documents and a low-level confidential witness (to whom they never spoke) who had no medical training or clinical trial responsibility. And, that Defendants possessed the prophetic foresight that the FDA was going to initiate a hold of those clinical trials to review some hepatotoxic adverse events.

Here, the more cogent and compelling inference is clearly against a finding of scienter. Quite simply, patients in 33A clinical trials were expected to develop hepatotoxicity not because of 33A but because those patients received bone marrow transplants and the associated intense chemotherapy. To the extent Defendants were aware that a few patients in the 33A clinical trials suffered hepatotoxic effects when they made the challenged statements, Defendants had no reason to suspect that 33A was the reason. The FDA hold substantiates this inference because it a) primarily raised concerns in patients who received bone marrow transplants before, during or after 33A treatment; b) only initiated holds on three of five 33A trials; c) two of the three trials were only partially held, allowing patients to continue treatment after signing a revised consent; and d) the FDA released these holds very quickly upon review of additional data. *See supra* at II.B. Defendants voluntarily chose to issue a press release disclosing the existence of the FDA hold, which they were not otherwise obligated to reveal. *See Gillis v. QRX Pharma Ltd.*, 197 F.

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Supp. 3d 557, 584-85 (S.D.N.Y. 2016) ("It is well established that there is no affirmative duty to disclose the substance of interim feedback received from the FDA.").

V. PLAINTIFF FAILS TO STATE A CLAIM AGAINST MR. SIMPSON

While Plaintiff fails to state a claim against any of the Defendants that complies with the Reform Act's pleading requirements (as shown above), Plaintiff's claims against Mr. Simpson are especially tenuous. The Complaint contains no allegation that Mr. Simpson, the Company's Chief Financial Officer, made any of the allegedly false or misleading statements. AC ¶¶ 48-57. He is not alleged to have uttered any of the alleged misstatements on earnings calls or in investor conferences. AC ¶¶ 48-53. He is not alleged to have authored the press releases the Complaint identifies as false or misleading. AC ¶¶ 54-57. Where a "complaint contains no specific factual allegations to link [a particular defendant] to any of the allegedly false statements," the complaint should be dismissed as to that defendant. *In re Impac Mortg. Holdings, Inc. Sec. Litig.*, 554 F. Supp. 2d 1083, 1093 (C.D. Cal. 2008). The Complaint does not allege that Mr. Simpson had "ultimate authority" over statements made by others on earnings calls, in investor conferences, or in clinical trial-related press releases. *See Janus Capital Grp., Inc. v. First Deriv. Traders*, 564 U.S. 135, 142 (2011) ("For purposes of Rule 10b-5, the maker of a statement is the person or entity with ultimate authority over the statement, including its content and whether and how to communicate it."). The Supreme Court has repeatedly "declined to extend Rule 10b-5 liability to entirely new categories of defendants who themselves had not made any material, public misrepresentation." *Halliburton Co. v. Erica P. John Fund, Inc.*, 134 S. Ct. 2398, 2412 (2014). This Court should do likewise and dismiss the claims against Mr. Simpson.

VI. PLAINTIFF'S SECTION 20(A) CLAIM FAILS

Because the Complaint does not plead a predicate Section 10(b) claim, Plaintiff's Section 20(a) claim should also be dismissed. *Lipton*, 284 F.3d at 1035 n.15.

CONCLUSION

For the foregoing reasons, Defendants respectfully request that this Court dismiss the Complaint for failing to satisfy the Reform Act's heightened pleading requirements.

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Dated: July 28, 2017

s/ Barry M. Kaplan

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CERTIFICATE OF SERVICE

I hereby certify that on July 28, 2017, I filed the foregoing with the Clerk of the Court using the CM/ECF system, and served all parties via ECF.

Dated: July 28, 2017

s/ Barry M. Kaplan
Barry M. Kaplan, WSBA #8661

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