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Before the Court is a Motion to Dismiss filed by defendants Insys Therapeutics Incorporated ("Insys"), Michael L. Babich, Darryl S. Baker, John N. Kapoor, and Alec Burlakoff (collectively "Defendants"). (Doc. 85.) Clark Miller ("Plaintiff") is the lead plaintiff for the proposed plaintiff class in this action. He filed a response (Doc. 87), and Defendants filed a reply (Doc. 95). The Court now considers these and all accompanying briefing.

### I. FACTUAL ALLEGATIONS

For this motion to dismiss, the following facts from Plaintiff's second amended complaint are assumed to be true.

### A. Insys and Subsys

Defendant Insys is a publicly traded pharmaceutical company headquartered in Arizona that makes and sells pain management drugs. (Doc. 77, ¶ 1.) Defendants Babich, Baker, Kapoor, and Burlakoff all served as high level executives at Insys during the relevant class period, between 2014 and 2016. (Doc. 77, ¶¶ 30-33.)

Since 2013, roughly 98% of Insys's net revenue has come from a product called Subsys, an under-the-tongue fentanyl spray designed to treat cancer pain in adult patients already taking opioid pain medication (known as "opioid-tolerant adults"). (Doc. 77, ¶ 2.) The power of fentanyl cannot be overstated. The highly addictive drug is 80-100 times stronger than morphine and 40-50 times more potent than heroin. The Drug Enforcement Agency has classified fentanyl as a "Schedule II" substance under the Controlled Substances Act. (Doc. 77, ¶ 73.)

The Food and Drug Administration approved Subsys in 2012 only for opioid-tolerant adults and only for what is known as "breakthrough" cancer pain, intense episodes amid otherwise-steady levels of pain. (Doc. 77, ¶ 6; Doc. 85 at 5.) The FDA also required that any healthcare professionals prescribing, dispensing, or distributing Subsys must first enroll in a program called the Transmucosal Immediate-Release Fentanyl Risk Evaluation and Mitigation Strategy Access Program (the "Access

Program"). (*Id.*) Among other things, the Access Program enabled Insys to monitor all sales of Subsys. (*Id.*) Additional FDA regulations prohibit marketing approved drugs for "off-label" uses, i.e., any uses other than the ones for which the drug was actually approved. Subsys therefore could not be lawfully marketed for anything other than breakthrough cancer pain treatment in opioid-tolerant adults. (Doc. 77,  $\P$  10.)

In addition, a federal anti-kickback law prohibits anyone from paying a doctor to order a good or service reimbursed by a federal healthcare program. (*Id.*) *See* 42 U.S.C. § 1320a-7(b)(2). According to Insys's own SEC filings, sales of Subsys at all relevant times "depend[ed] in significant part on the coverage and reimbursement policies of third-party payers, including government payers such as Medicare and Medicaid, and private health insurers." (Doc. 77, ¶ 9.) Coverage decisions would depend in large part on "pharmacy benefit managers," entities within insurance companies that maintain lists of covered drugs, contract with pharmacies, negotiate prices with drug manufacturers, and process prescription drug claims. (Doc. 77, ¶ 93.)

Because of these tight regulations, only specialty pharmacies can distribute the drug. The resulting scarcity has fueled skyrocketing prices. Even a small quantity (30 doses at 100 micrograms per dose) will run a patient about \$1,000 per month. (Doc. 77, ¶ 77.) A larger, more potent quantity (240 doses at 1,200 micrograms per dose) can exceed \$21,000 per month. (*Id.*)

### **B.** The Underlying Fraud

The class period in this action spans from August 12, 2014, through December 8, 2016. During that time, Insys reported increasing revenues each quarter and attributed most of its upward trajectory to the sale of Subsys. (Doc. 77, ¶ 11.) Company executives publicly attributed the drug's success to vigorous marketing efforts and the company's diligent negotiations with pharmacy benefit managers, third-party payers, and insurers. (Doc. 77, ¶ 12.) The company made no mention of unlawful practices actually taking place. Defendants at different times said (or were reported to have said) that Insys was "only selling a breakthrough cancer pain drug," that "no one at Insys wants to see anyone

taking [Subsys] for anything other than cancer pain," and that Insys was "committed to complying with the laws governing [Subsys's] sales, marketing and promotional practices." (Doc. 77,  $\P$  99.) The defendants told investors that they "properly communicate with all major [insurance] plans and the [pharmacy benefit managers] to ensure proper access for Subsys." (Doc. 77,  $\P$  211.)

According to the complaint, however, Insys was actually raking in large profits because of extensive criminal fraud: the company had made a practice of paying doctors bribes and kickbacks in exchange for prescribing Subsys off-label, which boosted the company's sales and, consequently, its stock price. (Doc. 77, ¶¶ 14, 201-08.) Many of these doctors have been federally indicted beginning as early as 2012, and several have pled guilty to violations of federal anti-kickback statutes. (Doc. 77, ¶¶ 15, 158.)

Central to the fraud was Insys's "Insurance Reimbursement Center," a unit the company created ostensibly "to interact with third-party payers to obtain prior authorization and insurance coverage for invariably expensive Subsys prescriptions." (Doc. 77, ¶ 16.) To ensure coverage for Subsys, employees of the Insurance Reimbursement Center would falsify patient diagnoses, lie to insurance companies using canned scripts written by Insys executives, and even pose as employees of the prescribing doctors. (*Id.*) Insys paid employees bonuses for doing these things, and for securing more Subsys prescriptions. (Doc. 77, ¶ 20.) During the class period, Insys informed investors that the Insurance Reimbursement Center existed but disclosed nothing else beyond its advertised purpose of working with insurers to cover Subsys. The company did not disclose any of the fraudulent conduct in which the Insurance Reimbursement Center was actually engaging. (Doc. 77, ¶ 212.)

The fraud also extended to what Insys called its "speaker series," which it passed off as a series of educational talks by doctors invited (and compensated) to speak about the benefits of Subsys. (Doc. 77, ¶¶ 14, 101.) In reality, however, these events were

<sup>&</sup>lt;sup>1</sup> At oral argument, Plaintiff clarified that the unit went by other names at different points in time, among them the "Prior Authorization Unit."

usually nothing more than social gatherings devoid of any substantive content used as vehicles to funnel cash payments to prescribing physicians. (Doc. 77, ¶ 149.) Insys sales representatives sometimes even forged attendance sheet signatures to make it appear as though the speakers had given presentations before an audience. (Doc. 77, ¶ 164.) Defendant Burlakoff said of the speakers hired by Insys, "[T]hey do not need to be good speakers, they need to write a lot of [Subsys prescriptions]." (Doc. 77, ¶ 14.) Insys's stock continued to climb as all this was going on.

Despite these actions, Insys maintained that it was "taking market share from other competing . . . products and expanding the usage of Subsys for [breakthrough cancer pain] by building awareness among oncologists." (Doc. 77, ¶ 111.) The company touted its "very unique programs within the oncology setting" for increasing sales, all while executives were specifically steering sales representatives away from doctors who prescribed the drug for breakthrough cancer pain. (Doc. 77, ¶¶ 111-12.) Less than 1% of Subsys prescriptions were actually written by oncologists. (Doc. 77, ¶ 112.) Instead Insys pushed its own sales force to cajole doctors into prescribing Subsys for off-label uses, pressuring salespeople to use aggressive tactics and paying them meager base salaries with commissions tethered to their success generating prescriptions. (Doc. 77, ¶¶ 132-33, 139.)

### C. Public Statements

From the beginning of the class period, Insys made a number of public statements regarding its revenue figures and stock price. Plaintiff points to the following statements in the second amended complaint:

- 1) On August 12, 2014, the first day of the class period, Babich stated in a press release that a 200% sales growth compared to the same time the previous year was "largely driven by the successful execution of our Subsys strategy." (Doc. 77, ¶ 251.)
- 2) On a conference call with investors the same day, Babich stated, among other things, "We believe the success to date of Subsys is the result of a clinically

superior product, coupled with the focused market penetration strategy," and "[t]he majority of patients have access to Subsys through their insurance plans." (Doc. 77,  $\P$  252.) The company later made materially similar statements regarding their earnings the next two quarters. (Doc. 77,  $\P$  261, 267.) Babich also told investors, "[W]e continue to properly communicate with all the major plans and the [pharmacy benefit managers] to ensure proper access for Subsys." (Doc. 77,  $\P$  253.)

- 3) In its Form 10-Q for the second quarter of 2014, Insys stated, "The increase in Subsys revenue is primarily as a result of increased prescriptions and change in mix of prescribed dosages as Subsys was a relatively new product during the three months [and six months] ended June 30, 2012 and also price increases in January 2014 and April 2014. ..." (Doc. 77, ¶ 254.)
- 4) On November 11, 2014, Insys issued a third quarter press release reporting "another strong quarter, in which our revenue and gross profit doubled largely driven by the continued, successful execution of our Subsys strategy." (Doc. 77, ¶ 260.)
- 5) In a conference call on the same day, Babich stated, "We continue to proactively work with managed care providers to ensure coverage for our patient population. We maintain Tier 3 coverage under nearly all major commercial plans, and the majority of patients have access to Subsys through their insurance plans." (Doc. 77, ¶ 261.)
- 6) The next day, in its Form 10-Q for the third quarter of 2014, the company reported, "[T]he increase in Subsys revenue is primarily as a result of increased prescriptions and change in mix of prescribed dosages as Subsys was a relatively new product during the three months ended September 30, 2013 and also price increases in January 2014 and April 2014." (Doc. 77, ¶ 262.)
- 7) On a March 3, 2015 conference call with analysis, Babich said of the company's high fourth quarter earnings,

We keep hitting new highs in the number of new doctors that we activate on a weekly basis. We have some very unique programs within the oncology setting that we continue to execute on and any growth that we see in this overall [drug] class is specifically coming from Subsys.

(Doc. 77, ¶ 268.)

8) Also on March 3, 2015, Insys filed a Form 10-K for the fiscal year 2014. Among other things, the company asserted,

Subsys has been, and will likely continue to be, subject to these restrictions and impediments from third-party payers, administrative patient support assistance, in large part through our patient services hub, which provides administrative support assistance to help patients work with their insurance companies.

(Doc. 77,  $\P$  269.) The company made similar statements amid a similar growth in revenue throughout the class period. (Doc. 77,  $\P$  284, 293, 302.)

- 9) The Form 10-K also stated, "[W]e commercialize Subsys through a cost-efficient commercial organization utilizing an incentive-based sales model similar to that employed by" some of its competitors. (Doc. 77, ¶ 271.)
- 10) Among "key factors" in its growth, Insys identified the following:

taking market share from other competing . . . products and expanding the usage of Subsys for [breakthrough cancer pain] by building awareness among oncologists of its rapid onset of action, improved bioavailability, most complete range of dosage strengths and ease of administration relative to other [fentanyl] products.

(Doc. 77,  $\P$  272.)

11) On April 24, 2015, the Southern Investigative Reporting Foundation published an article quoting Burlakoff as saying,

[T]here is a very, very easy way to get fired on your first day at this company,...and that is to mention selling off-label. We are only selling a breakthrough cancer pain drug. That's all we want to address with a doctor. You don't run a unit at a company like this by cutting corners. . . . I can say that no one at Insys wants to see anyone taking [Subsys] for anything other than cancer pain.

 $(Doc. 77, \P\P 278-79.)^2$ 

- 12) On May 7, 2015, Insys issued a press release regarding its earnings in the first quarter of 2015, which stated, "Insys had another strong quarter driven by our twelfth consecutive quarter of Subsys sales growth." (Doc. 77, ¶ 281.)
- 13) Babich conducted a conference call with analysts and investors the same day in which he stated, "[T]hree years post-launch our Subsys business remains healthy and continues to grow. This clearly demonstrates that a better product can succeed in a crowded playing field, and we believe there is even more opportunity for Subsys on the horizon." (Doc. 77, ¶ 282.)
- 14) In its Form 10-Q for the first quarter of 2015, Insys stated, "The increase in Subsys revenue is primarily as a result of increased prescriptions and change in mix of prescribed dosages and also price increases in January 2014, April 2014, July 2014, and January 2015." (Doc. 77, ¶ 283.) The company made similar statements regarding revenue increases during the second quarter of that year several months later. (Doc. 77, ¶ 292.)
- 15) On August 6, 2015, Insys issued a press release addressing, among other things, a then-recent settlement with the Oregon Department of Justice regarding allegations that it promoted Subsys illegally. (Doc. 77, ¶¶ 289, 322.) In the press release, Insys wrote that it was "committed to complying with laws governing its sales, marketing and promotional practices and has implemented a comprehensive

<sup>&</sup>lt;sup>2</sup> Plaintiff's complaint is replete with added emphasis in the form of italics, underlining, and bold text—and sometimes all three at once. The Court here, as elsewhere, silently omits that emphasis, as it is immaterial to deciding this motion.

compliance program based on the elements of an effective compliance program and industry practices." (Doc. 77, ¶ 289.)

- 16) That same day, in a conference call with investors and analysts, Babich stated, "[T]he Company continues to be committed to complying with laws governing in sales, marketing, and promotional practices. And then we've implemented a comprehensive compliance program based on the elements of an effective compliance program and industry practices." (Doc. 77, ¶ 291.)
- 17) On November 5, 2015, in a conference call with investors and analysts pertaining to Insys's high quarterly earnings, Kapoor stated that patients "like [Subsys] because it helps them, it helps their lives. It's not that they get addicted to it, as some people imply. It's a product that they it helps their lives and that's why the product gained the market share and will continue to gain market share." (Doc. 77, ¶ 297.)
- 18) In the same call, Kapoor said, "[W]e only call on [risk evaluation and mitigation strategy] . . . doctors, and so once we get to 50% [of the market share], further growth is going to be slower than it has been in the past and that why we have accelerated the development of Subsys in other indications." (Doc. 77, ¶ 298.) Kapoor also stated that Babich's sudden resignation as CEO was not related to investigations of Insys, attributing it instead to Babich's desire to spend time with his family "and pursue other interests." (Doc. 77, ¶ 299.)
- 19) In its Form 10-Q pertaining to the third quarter of 2015, the company characterized an increase in Subsys revenue as "primarily as a result of a 31% increase in shipments to pharmaceutical wholesalers for the three months ended September 30, 2015 as compared to the three months ended September 30, 2014," and "a 26% increase in net sales price, which was impacted by price increases in

<sup>&</sup>lt;sup>3</sup> "Risk Evaluation and Mitigation Strategy" doctors are "doctors who have already qualified to prescribe Subsys and other [transmucosal immediate-release fentanyl drugs] under the FDA's [Risk Evaluation and Mitigation Strategy] program." (Doc. 85 at 30.) *See* § I(A) above.

July 2014, January 2015 and July 2015, combined with changes in mix of prescribed dosages and changes in provisions for wholesaler discounts, patient discounts, rebates and returns." (Doc. 77,  $\P$  300.) The company made a similar statement about Subsys's increased revenue over the nine month period ending September 30, 2015. (Doc. 77,  $\P$  301.)

- 20) Regarding criminal allegations made against one specific doctor, the Form 10-Q stated that "we have taken a number of remedial actions and implemented enhancements to the Company's compliance controls regarding relationships with health care providers. We will continue to assess these matters to ensure we have an effective compliance program." (Doc. 77, ¶ 303.)
- 21) In a publicly released statement on November 23, 2015, Insys stated:

Insys has a compliance program in place with protocols that are designed to ensure its sales and marketing practices comply with applicable laws. . . . Insys believes that existing data strongly support that prescribing decisions have been driven primarily by the clinical attributes of Subsys and its market share gains have come from patients and [healthcare providers] switching to Subsys from other [fentanyl] products.

(Doc. 77,  $\P$  309.)

22) On January 25, 2016, in response to a Southern Investigative Reporting Foundation article detailing fraud allegations against Insys, Insys issued a statement saying, "Insys rejects the recent media reports' account of the Company's practices as misleading and unreliable, especially in light of the biased agenda held by the individuals who made these misrepresentations." (Doc. 77, ¶ 313.) The statement additionally said, "Insys requires its Patient Services Center personnel undergo specific training on applicable laws and regulations and continues to strive to comply with applicable laws and regulations through its compliance policies and procedures." (*Id.*)

### **D.** News of Criminal Fraud Allegations

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Revelations of Insys's alleged fraud soon began trickling into the public sphere. Insys itself disclosed in a September 12, 2014 SEC filing that it had received a subpoena from the United States Attorney's Office for the District of Massachusetts, seeking documents related to the company's sales and marketing of Subsys. (Doc. 77, ¶ 315.) Two months later, on November 27, the New York Times published an article detailing allegations of the company's kickback scheme. (Doc. 77, ¶ 316.) Insys's stock fell 8.58% over the next several days. (*Id.*) Similarly, an April 24, 2015 article published by the Southern Investigative Reporting Foundation provided further details of the company's alleged criminal fraud. (Doc. 77, ¶¶ 317-18.) Over the next three days the company's stock fell 9.61%. (Id.) Other news items preceded similar drops: a May 20, 2015 federal indictment of two doctors accused of conspiring to unlawfully prescribe Subsys (triggering a 4.43% drop), a June 23, 2015 New York Times article disclosing the guilty plea of a Connecticut nurse charged with accepting kickbacks (triggering a 12.64% drop), a November 4, 2015 CNBC article detailing the Oregon Department of Justice's investigation into Insys (triggering an 8.50% drop), a December 3, 2015 article by the Southern Investigative Reporting Foundation detailing the alleged Insurance Reimbursement Center fraud (triggering an 18.54% drop), and a January 25, 2016 article by the Southern Investigative Reporting Foundation expanding on the Insurance Reimbursement Center's practices (triggering a 4.72% drop). (Doc. 77, ¶¶ 19-20, 319-20, 323-24, 326-27, 330).

On April 11, 2016, Insys issued a press release disclosing quarterly revenues of between \$61 million and \$62 million, about \$25 million below previous projections, triggering a 19.37% drop in the company's stock price. (Doc. 77,  $\P$ ¶ 21, 332.) Analysts attributed the fall to the company's lower-than-expected sales and revenues for the first quarter of 2016. (Doc. 77,  $\P$  333.)

On December 8, 2016, the last day of the class period, the federal government announced the arrest and criminal indictment of defendants Babich, Burlakoff, and other

former Insys executives. (Doc. 77,  $\P$  23.) The indictment, unsealed and made available to the public on December 8, accused Babich and Burlakoff of leading "a nationwide conspiracy to bribe medical practitioners to unnecessarily prescribe a fentanyl-based pain medication and defraud healthcare insurers." (Doc. 77,  $\P$  343.) By the end of December 8, Insys's stock had fallen 11.87% compared to its closing price the previous day. (Doc. 77,  $\P$  344.) Since the start of the class period, Insys's stock dropped from \$44.92 per share to \$9.43. (Doc. 77,  $\P$  24.)

### E. Plaintiffs

The proposed class of plaintiffs in this case purchased Insys stock during the class period. (Doc. 77,  $\P$  28.) Lead plaintiff Clark Miller made his first purchase of Insys stock, 250 shares for \$59.64 each, on May 19, 2015. (Doc. 34-1 at 3.) Less than a month later, on June 8, 2015, Miller's nominal stockholdings doubled to 500 shares after a stock split with no additional stock purchase. (*Id.*) On July 8, 2015, Miller sold all 500 shares for \$35.38 per share. (*Id.*) The next day, on July 9, 2015, Miller purchased 4,000 shares of Insys stock throughout the day at various prices ranging from \$36.29 to \$36.71 per share. (*Id.*)

### II. LEGAL STANDARDS

### A. Motion to Dismiss: Securities Fraud Pleading Standards

A complaint alleging securities fraud is subject to the requirements of both Federal Rule of Civil Procedure 9(b) and the Private Securities Litigation Reform Act (PSLRA). Under Rule 9(b), a plaintiff alleging fraud "must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). Each and every element of securities fraud must meet this pleading standard. *Or. Pub. Emps. Ret. Fund v. Apollo Gp. Inc.*, 774 F.3d 598, 605 (9th Cir. 2014). In addition, under PSLRA, the 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 omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u-4(b)(1)(B).

### B. Section 10(b) and Rule 10b-5

Under section 10(b) of the Exchange Act of 1934, it is unlawful "for any person... [t]o use or employ, in connection with the purchase or sale of any security... any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the [Securities and Exchange] Commission may prescribe[.]" 15 U.S.C. § 78j(b). *In re Daou Systems, Inc.*, 411 F.3d 1006, 1014 (9th Cir. 2005). SEC Rule 10b-5 accordingly provides:

It shall be unlawful for any person . . .

(a) To employ any device, scheme, or artifice to defraud,

(b) To make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading, or

(c) To engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person,

in connection with the purchase or sale of any security.

17 C.F.R. § 240.10b-5. The basic elements of securities fraud are thus sixfold:

(1) a material misrepresentation or omission; (2) scienter (*i.e.*, a wrongful state of mind); (3) a connection between the misrepresentation and the purchase or sale of a security; (4) reliance upon the misrepresentation (often established in "fraud-on-the-market" cases via a presumption that the price of publicly-traded securities reflects all information in the public domain); (5) economic loss; and (6) loss causation

23 (5) economic loss; and (6) loss causation.

Loos v. Immersion Corp., 762 F.3d 880, 886-87 (9th Cir. 2014) (citing Dura Pharmaceuticals, Inc. v. Broudo, 544 U.S. 336, 341-42 (2005)).

### C. Section 20(a) of the 1934 Exchange Act

Section 20(a) of the 1934 Exchange Act states that:

Every person who, directly or indirectly, controls any person liable under any provision of this chapter or of any rule or regulation thereunder shall also be liable jointly and severally with and to the same extent as such controlled person . . . is liable . . . unless the controlling person acted in good faith and did not directly or indirectly induce the act or acts constituting the violation or cause of action.

15 U.S.C. § 78t(a). Under this "control-person" theory of liability, a defendant employee can be held liable for a company's securities fraud where the plaintiff demonstrates "a primary violation of federal securities law' and that 'the defendant exercised actual power or control over the primary violator." *In re VeriFone Holdings, Inc. Sec. Litig.*, 704 F.3d 694, 711 (9th Cir. 2012) (quoting *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 990 (9th Cir. 2009)).

### III. ANALYSIS

Plaintiff's second amended complaint alleges securities fraud by all Defendants under section 10(b) and control-person liability for all defendant individuals (the executives only, not Insys itself) under section 20(a). Defendants move to dismiss the securities fraud count on grounds that it fails to plead two of the six required elements: material misrepresentations or omissions and loss causation. Defendants also seek dismissal as to Kapoor and Baker for failing to plead scienter, as well as to Burlakoff for failing to establish his statements were made "in connection with" the purchase or sale of securities. Finally, Defendants move to dismiss the control-person liability count in its entirety.

### A. Judicial Notice

Defendants have asked the Court to take judicial notice of fifty-two documents that are items referenced in the complaint, public filings, news articles, or undisputedly authentic documents made publicly available by the government. (Doc. 81.) Plaintiff opposes judicial notice of only one of the documents. The Court will thus take judicial notice of the unopposed fifty-one documents, but notes that judicial notice as to court

filings made outside of this case is limited to the fact that the filings were made. The Court does not (and cannot) take judicial notice of their substantive content as true.

Plaintiff's only opposition is to a September 29, 2008 Corporate Integrity Agreement between pharmaceutical company Cephalon, Inc. ("Cephalon") and the Office of the Inspector General of the United States Department of Health and Human Services. (Doc. 88 at 2.) As discussed at oral argument, the Court will take judicial notice only of the fact that the agreement exists. The truth or falsity of any of its contents cannot be discerned at this stage in the litigation.

Plaintiff separately sought judicial notice of three documents filed in other courts. Those documents all relate to the indictments and subsequent guilty pleas of healthcare providers charged in connection with Insys's alleged fraud. (Doc. 99.) As explained in the Court's previous order (Doc. 104), judicial notice has been granted only to the extent that such documents were filed in those courts. The Court will not consider their contents for this motion.

### B. Section 10(b) and Rule 10b-5

### 1. Material Misrepresentation or Omission

To make out a claim for securities fraud, a plaintiff "must allege a misrepresentation or a misleading omission with particularity and explain why it is misleading." *Retail Wholesale & Dep't Store Union Local 338 Retirement Fund v. Hewlett-Packard Co.*, 845 F.3d 1268, 1274 (9th Cir. 2017). Additionally, "applying an objective standard, that misrepresentation or omission must have been material to investors." *Id.* Defendants here do not argue that the statements identified in the second amended complaint were immaterial. Rather, Defendants move to dismiss on grounds that the second amended complaint fails to identify any false or misleading statements with sufficient particularity and fails to explain why those statements are false or misleading.

Rule 10b-5 prohibits only "misleading and untrue statements." *Brody v. Transitional Hosps. Corp.*, 280 F.3d 997, 1006 (9th Cir. 2002). "[A] statement is

misleading if it would give a reasonable investor the impression of a state of affairs that differs in a material way from the one that actually exists." *In re Cutera Sec. Litig.*, 610 F.3d 1103, 1109 (9th Cir. 2010). A statement must be "capable of objective verification" in order to be false or misleading. *Retail Wholesale*, 845 F.3d at 1275. This stands in contrast to "puffing," which "concerns expressions of opinion." *Or. Pub. Emps.*, 774 F.3d at 606. Qualitative buzzwords such as "good," "well-regarded," or other "vague statements of optimism" cannot form the basis of a false or misleading statement. *Id.* (citing *Cutera*, 610 F.3d at 1111). *See, e.g., Or. Pub. Emps.*, 774 F.3d at 606 (statements were neither false nor misleading where defendant company hedged statements about revenue growth with "we believe" and cited only "general terms" such as "educational content" and "teaching resources"); *Retail Wholesale*, 845 F.3d at 1276 (finding no objectively verifiable statements where plaintiff only pointed to defendant company's code of conduct filled with "aspirational" statements not capable of objective verification).

Beyond merely pleading that the defendant made false or misleading statements, for each statement a plaintiff must also "explain why it is misleading." *Id.* at 1274. PSLRA's pleading requirements cannot be met "by conclusory allegations that a company's class period statements regarding its financial well-being are *per se* false based on the plaintiff's allegations of fraud generally." *Metzler Inv. GMBH v. Corinthian Colleges, Inc.*, 540 F.3d 1049, 1070 (9th Cir. 2008).

Defendants point to thirty different statements from the second amended complaint concerning Insys's revenue and profits, or its strategies for marketing Subsys, that they contend are insufficiently pled as false or misleading. (Doc. 85 at 14 n.6, 15 n.8, 16-17, 18 n.11.) For most of them, Plaintiff contends they are false or misleading because they were spoken against the backdrop of Insys's ongoing criminal fraud. But *Metzler* precludes that line of argument. *See Metzler*, 540 F.3d at 1070 (holding complaint did not sufficiently plead securities fraud where plaintiff alleged public statements were false or misleading solely by virtue of defendants' "fraudulent practices

generally along with its failure to make earlier disclosures of regulatory investigations"). In light of that broadly applicable principle, most of the statements Plaintiff points to do not qualify as false or misleading under Rule 10b-5:

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- 1) Paragraphs 251 and 262 point to statements asserting that Subsys's recent sales growth was "largely driven by the successful execution of [Insys's] Subsys strategy." That statement is essentially true, even if the "strategy" referred to involved breaking the law. In any event the term "Subsys strategy" is general enough to put the statement outside the scope of what can be misleading or untrue. See Or. Pub. Emps., 774 F.3d at 606.
- 2) Paragraphs 252 and 261 cite statements by Babich attributing Insys's success to "a clinically superior product, coupled with a focused market penetration strategy." However, the statements begin with "We believe" and are thus sufficiently hedged. The second part of each statement goes on to say, "We continue to proactively work with managed care providers to ensure coverage for our patient population. We maintain Tier 3 coverage under nearly all major insurance plans. The majority of patients have access to Subsys through their insurance plans." Plaintiff has not explained how this was false or misleading beyond merely being said against the backdrop of ongoing fraud.
- 3) Paragraph 253 alleges that Babich said during a conference call that "[w]e continue to properly communicate with all the major plans and the [pharmacy benefit managers] to ensure proper access for Subsys." That they were continuing "to properly communicate" is neither false nor misleading based on what Plaintiff has alleged. That they were doing so "to ensure proper access for Subsys" is too vague to be actionable, since it is unclear what "proper access" means.
- 4) Paragraphs 254, 283 and 292 assert that "[t]he increase in Subsys revenue is primarily as a result of increased prescriptions and change in mix of prescribed dosages and also price increases" throughout the year. Paragraphs 300 and 301

allege substantively similar statements. Plaintiffs have failed to allege that these statements are untrue. The only basis on which they could be deemed misleading is precluded by *Metzler*. *See Metzler*, 540 F.3d at 1070.

- 5) Paragraph 260 points to a press release noting a "strong quarter, in which our revenue and gross profit doubled largely driven by the continued, successful execution of our Subsys strategy." Again, there is no indication the financial growth figures are untrue. "Successful execution" is a qualitative assessment, and "Subsys strategy" leaves it too vague as to what the company was asserting.
- 6) Paragraph 261 points to three statements, the first of which begins with "We believe." That statement was sufficiently hedged not to qualify as false or misleading. *See Or. Pub. Emps.*, 774 F.3d at 606. The second statement, that Insys "continues to proactively work with managed care providers to ensure coverage" for patients is highly general and neither false nor misleading. Plaintiff has not challenged as false the third part, that Insys "maintain[s] Tier 3 coverage under nearly all major commercial plans, and the majority of patients have access to Subsys through their insurance plans," beyond being spoken against the backdrop of the company's ongoing fraud.
- 7) The statement cited in Paragraph 267 again begins with "We believe." It is neither false nor misleading.
- 8) The only questionable part of the statement in paragraphs 269, 284, 293, and 302 is the assertion that Insys "provide[s] administrative reimbursement support assistance, in large part through our insurance reimbursement support hub, which provides administrative support assistance to help patients coordinate with their insurance companies." While this might be misleading on some level, it is also highly general and vague. As such it is not actionable.
- 9) Paragraph 270 includes the statement "We believe that physicians and payers will develop greater familiarity with both the differentiated features of Subsys and the process to achieve patient access to the product from continued and broader usage

- of Subsys by their patients. We offer patients a free trial of Subsys to allow for titration to their effective dose and bridge the prior authorization process." None of this is false or misleading based on Plaintiff's allegations.
- 10) Paragraph 271 states that the company "commercialize[s] Subsys through a cost-efficient commercial organization utilizing an incentive-based sales model similar to that employed by" some competitors. "Cost-efficient commercial organization" is too vague to be false or misleading, and the rest of the statement appears to be true.
- 11) Paragraph 282 is a prime example of mere "puffing." The assertion that Subsys's business "remains healthy" is simply qualitative, and that it "continues to grow" was true. Babich's assertion that "[t]his clearly demonstrates that a better product can succeed in a crowded playing field" is qualitative, general, and a mere expression of general feeling rather than fact. The statement "we believe there is even more opportunity for Subsys on the horizon" is both hedged and nothing more than qualitative puffing.
- 12) Paragraphs 289 and 291 point to nearly identical statements by Insys and Babich following the settlement with the Oregon Department of Justice that the company is "committed to complying with laws governing its sales, marketing and promotional practices" and has "implemented a comprehensive compliance program based on the elements of an effective compliance program and industry practices." Plaintiff nowhere asserts that Insys had not in fact implemented a compliance program, however ineffective it might have been. And stating that the company was "committed" to legal compliance immediately after reaching a settlement with state regulators is, in that context, too vague to be actionable.
- 13) Paragraph 297 points to a conference call in which Kapoor said of Subsys patients: "They like [Subsys] because it helps them, it helps their lives. It's not that they get addicted to it, as some people imply. It's a product that they it helps their lives and that's why the product gained the market share and will

continue to gain market share." Whether or not these assertions are objectively true, nothing alleged in the complaint contradicts them.

- 14) Paragraph 298 quotes Kapoor as saying during a conference call, "[W]e only call on [Risk Evaluation and Mitigation Strategy] . . . doctors, and so once we get to 50%, further growth is going to be slower than it has been in the past and that's why we have accelerated the development of Subsys in other indications." This simply addresses projections about Subsys's market share. There is nothing false or misleading about this statement.
- 15) Paragraph 303 points to a statement from the company's 2015 SEC filings that says, "[W]e have taken a number of remedial actions and implemented enhancements to the Company's compliance controls regarding relationships with health care providers. We will continue to assess these matters to ensure we have an effective compliance program." Plaintiff nowhere asserts that Insys did not in fact take remedial actions or enhance compliance controls when this statement was made. In any event the statement is vague and general enough not to qualify as false or misleading.
- 16) Paragraph 309 points to a statement that says, among other things:

Insys has a compliance program in place with protocols that are designed to ensure its sales and marketing practices comply with applicable laws.... Insys believes that existing data strongly support that prescribing decisions have been driven primarily by the clinical attributes of Subsys and its market share gains have come from patients and [healthcare providers] switching to Subsys from other [fentanyl] products.

Though both are convoluted, neither of these statements is false or misleading. Plaintiff has not alleged that Insys's compliance protocols, however weak and ineffective, were not designed to ensure legal compliance. As for the second statement, it is hedged as the company's belief and is not actionable.

17) Paragraph 313 of the second amended complaint cites an Insys press release issued after a January 25, 2016 news article shed light on the company's alleged off-label marketing and kickback scheme. The press release stated:

Insys rejects the recent media reports' [sic] account of the Company's practices as misleading and unreliable, especially in light of the biased agenda held by the individuals who made these misrepresentations. . . . Insys requires its Patient Services Center personnel undergo specific training on applicable laws and regulations and continues to strive to comply with applicable laws and regulations through its compliance policies and procedures.

This statement specifically asserts that Insys was making efforts to ensure the Patient Services Center's practices were lawful. (It is unclear what the "Patient Services Center" is, though it might be another name for the Insurance Reimbursement Center.) There is reason to think it is therefore false. However, in the second amended complaint, Plaintiff only contends it is false because of the alleged criminal fraud occurring behind the scenes. (Doc. 77, ¶ 314.) As already discussed, that alone cannot ballast a securities fraud pleading. *See Metzler*, 540 F.3d at 1070.

None of the above statements meets the pleading requirements of the PSLRA. However, three others do:

1) In the statement cited in paragraph 272, the company's Form 10-K from fiscal year 2014, filed on March 3, 2015, points to "taking market share from" competitors as key to Subsys's growth. That is neither false nor misleading. But the statement goes on to assert that Insys is "expanding the usage of Subsys for [breakthrough cancer pain] by building awareness among oncologists of" several of the drug's features. However, according to Plaintiff's other allegations,

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Subsys's growth had little—if anything—to do with breakthrough cancer pain and instead depended chiefly on doctors prescribing it off-label to treat conditions such as migraines or back pain. Moreover, the company's sales force was deliberately avoiding oncologists. The complaint alleges that "Insys sales representatives were instructed not only to avoid meeting with oncology doctors and pain specialists . . . but to aggressively court healthcare professionals who did not have any patients with cancer, much less [breakthrough cancer pain], or who did not have any experience in prescribing Schedule II narcotics such as Subsys." (Doc. 77, ¶ 275.) The complaint also cites multiple alleged statements that further support this picture of Insys's actual practices. See, e.g., Doc. 77, ¶ 112 (quoting a former sales representative who said that "when she approached her managers about reaching out to palliative care facilities to tell them about Subsys, she was told not to approach them because 'those patients would die soon anyway and couldn't titrate (increase the dosage)"); ¶ 113 (quoting Burlakoff as instructing his sales force, "If I can successfully sell you the [unintelligible] for the breakthrough pain, do you have a thousand people in your practice, a thousand patients, twelve of them are currently on a rapid-onset opioids [sic]. That leaves me with at least five hundred patents [sic] that can go on this drug."). The practices alleged in the complaint amount to the complete opposite of "building awareness among oncologists." The statement alleged in paragraph 272 therefore qualifies as false or misleading.

2) Most of Babich's March 3, 2015 statement alleged in paragraph 268 is neither false nor misleading. Many of the sentences are hedged with "I think." The statement "We keep hitting new highs in the number of new doctors that we activate on a weekly basis" is again true and not misleading aside from the underlying bribe and kickback schemes. But Babich goes on to say, "We have some very unique programs within the oncology setting that we continue to execute on and any growth that we see in this overall [fentanyl] class is

specifically coming from Subsys." The second part of that is true. The first part, however, is again misleading and arguably false in light of the company's practice of steering its sales force away from oncologists altogether. *See* Doc. 77, ¶ 275. The specific mention of a physician class they were making a point to avoid renders this statement misleading at best and outright false at worst.

3) Paragraphs 278 and 279 point to statements by Burlakoff saying of the company's speaker program, "[T]here is a very, very easy way to get fired on your first day at this company,...and that is to mention selling off-label. We are only selling a breakthrough cancer pain drug. That's all we want to address with a doctor. . . . I can say that no one at Insys wants to see anyone taking [Subsys] for anything other than cancer pain." There is no question this is false or misleading. However, as discussed below, this statement is quoted in a news article published by the Southern Investigative Reporting Foundation, which is not something investors would presumptively rely on. So while it meets the PSLRA's "falsity" requirement, it fails under the "in connection with" requirement. See § III(B)(3) below.

Defendants alternatively offer three blanket contentions as to why none of these statements meets the pleading requirements of Rule 9(b) and PSLRA. They are not persuasive. First, Defendants contend that none of the statements alleged in the complaint could have been misleading because Insys "informed investors of specific law enforcement investigations into" the alleged criminal fraud. (Doc. 85 at 15-16.) But disclosing an investigation is not the same thing as disclosing specific fraudulent practices the company was actually carrying out. Unless Insys disclosed the specific practice of discouraging its sales force from pursuing oncologists, the statements identified above as false or misleading remain false or misleading.

Second, Defendants argue that "in each SEC filing since Insys went public, the Company informed investors of the significant risks associated with employee

misconduct in marketing and sales practices and other activity." (Doc. 85 at 16.) In particular, Defendants point to specific statements in the company's SEC filings that warn "employees may engage in misconduct or other improper activities' including 'intentional failures to comply with FDA regulations" as well as "with federal and state healthcare fraud and abuse laws and regulations' and that '[e]mployee misconduct could also involve...illegal promotion of a drug product for off-label use." (*Id.* (quoting Doc. 81-2 at 44-49).) But hypothetical disclaimers such as these do not insulate companies from all fraud liability. The Ninth Circuit has rejected the mollifying power of abstract risk warnings that fail to "alert[] the reader that some of these risks may already have come to fruition." *Berson v. Applied Signal Tech., Inc.*, 527 F.3d 982, 986 (9th Cir. 2008). *See also Siracusano v. Matrixx Initiatives, Inc.*, 585 F.3d 1167, 1181 (9th Cir. 2009) (rejecting warning issued in company's Form 10-Q of risk that products may be subject to product liability claims only "in the abstract, with no indication that the risk 'may already have come to fruition'"). Here as well, Insys's repeated disclosures offered no indication that its employees were currently breaking the law.

Third, Defendants argue that some of their statements are covered by PSLRA's "safe harbor" provision. (Doc. 85 at 19-20.) PSLRA protects from securities fraud liability any "forward-looking statement" made under several different circumstances, two of which are relevant here. First, a forward-looking statement is protected if it is "identified as a forward-looking statement, and is accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement." 15 U.S.C. § 78u-5(c)(1)(A)(i). Second, a forward-looking statement is protected if "the plaintiff fails to prove" that, if made by a "natural person," the statement "was made with actual knowledge by that person that the statement was false or misleading." 15 U.S.C. § 78u-5(c)(1)(B)(i). Defendants point to part of the statement cited in paragraph 268 of the second amended complaint, in which Babich discusses the company's market share of Subsys's class of drugs. (Doc. 85 at 20.) As discussed, this part of Babich's statement is neither false nor misleading, so the Court

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need not decide whether it is forward-looking. (The part of the cited statement asserting that Insys has programs in which they work with oncologists is misleading, as discussed above.) That is the only specific statement from the second amended complaint to which Defendants point. Defendants broadly contend that "[t]his and other forward-looking statements are in the 'safe harbor'" (Doc. 85 at 20), yet they cite no other specific statements for which they believe dismissal is warranted. The Court is not at liberty to guess which other statements they had in mind. Defendants have not established that PSLRA's safe harbor provision warrants dismissal of the complaint or any part of it.

#### 2. Scienter

Under PSLRA, a securities fraud complaint must "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2)(A). The plaintiff must show "scienter," i.e., that any false or misleading statements were made "either intentionally or with deliberate recklessness." Zucco Partners, LLC v. Digimarc Corp., 552 F.3d 981, 991 (9th Cir. 2009). "Deliberate recklessness" is "an extreme departure from the standards of ordinary care...which presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious that the actor must have been aware of it." Schueneman v. Arena Pharm., Inc., 840 F.3d 698, 705 (9th Cir. 2016) (emphasis in original). "The inquiry . . . is whether all of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard." Tellabs Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 322-23 (2007) (emphasis in original). But see VeriFone Holdings, 704 F.3d at 703 (permitting courts to examine specific allegations of scienter before looking at all allegations taken together "so long as [the analysis] does not unduly focus on the weakness of individual allegations to the exclusion of the whole picture"). "The inference that the defendant acted with scienter need not be irrefutable . . . or even the most plausible of competing inferences" but must merely be "cogent and at least as compelling as any opposing inference one

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could draw from the facts alleged." *Tellabs Inc.*, 551 U.S at 324 (internal quotation marks omitted).

Under certain circumstances, one may infer that corporate officers had scienter by virtue of their "knowledge of the critical core operation of their companies." Police Retirement System, 759 F.3d at 1062. Even without particularized allegations, this "core operations" theory of scienter may apply "in rare circumstances where the nature of the relevant fact is of such prominence that it would be absurd to suggest that management was without knowledge of the matter." Id. A plaintiff can produce either "specific admissions by one or more corporate executives of detailed involvement in the minutia of a company's operations, such as data monitoring," or "witness accounts demonstrating that executives had actual involvement in creating false reports." Id. Compare Daou, 411 F.3d at 1022-23 (finding inference of scienter where complaint alleged specific executives "personally directed [the company's] recognition of revenue, financial reporting and public statements" and directed practices of fraudulently reporting revenue figures), and Nursing Home Pension Fund, Local 144 v. Oracle Corp., 380 F.3d 1226, 1231 (9th Cir. 2004) (finding strong inference of scienter where executives had consolidated database with real time sales information and admitted to knowing "exactly how much we have sold in the last hour around the world"), with Lipton v. Pathogenesis Corp., 284 F.3d 1027, 1036 (9th Cir. 2002) (finding no inference of scienter where complaint alleged "merely in conclusory terms that defendants had access to internal data demonstrating a decline in sales" of a prescription drug and did not "allege with particularity any specific information showing that prescription data informed defendants that patient demand for [the drug] was flat").

Defendants contend the second amended complaint does not adequately plead scienter as to Kapoor and Baker. The Court considers their arguments as to each one in turn.

### a. Kapoor

The statements identified in paragraph 272 of the second amended complaint come from Insys's Form 10-K from the fiscal year 2014, which was signed by Babich, Baker, and Kapoor. (Doc. 77, ¶¶ 269, 272.) Because Kapoor signed the filing, the contents constitute his statements, and the complaint alleges sufficient facts giving rise to a strong inference of scienter, i.e., that he either knew they were false or misleading or exhibited deliberate recklessness in making them. Kapoor had direct contact with some of the doctors who were targets of the company's bribes and kickbacks. The complaint alleges that a member of the Insys sales force, also the son of a physician sought after by Insys to write off-label Subsys prescriptions, made reference on multiple occasions to positive meetings between his father and Kapoor. (Doc. 77, ¶¶ 123-24.) In addition, Kapoor attended a dinner at Ruth's Chris Steak House in Mobile, Alabama, where he and other Insys executives sealed an agreement to sell Subsys directly to a pharmacy owned by those doctors for a cut rate. (Doc. 77, ¶¶ 194.) Finally, many of the company's allegedly fraudulent "speaker series" events took place at locations of a restaurant owned by Kapoor. (Doc. 77, ¶¶ 148.)

Each of these individually raises at least a plausible inference of scienter. One could reasonably infer from each one that Kapoor knew Insys was running a fraudulent speaker series and paying doctors bribes and kickbacks to increase prescriptions of Subsys. One could even infer that Kapoor himself was leading the operation. Of course one could also plausibly infer that Kapoor made or facilitated contact with doctors absent any such knowledge. But the test is not whether scienter is the only plausible inference; it must simply be "cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Tellabs Inc.*, 551 U.S. at 324. Especially taken altogether, the inference is strong and compelling: Kapoor interacted (or facilitated interactions) with doctors who do not treat cancer pain and did so in environments reasonably interpreted as designed to sell them on Subsys.

### b. Baker

scienter as to Kapoor.

Baker, too, signed the Form 10-K containing the statements identified in paragraph 272 of the second amended complaint. As a result, the statement is fairly attributed to him as much as it is to Babich and Kapoor.

Scienter is also plausible on the "core operations" theory. Kapoor served in one

high-level leadership role or another throughout the class period: he was Insys's co-

founder, served as Executive Chairman of the Board of Directors throughout much of the

class period, and served as acting president and CEO of Insys from November 5, 2015,

until the end of the class period. (Doc. 77, ¶ 32.) Revenue from Subsys accounted for

roughly 98% of Insys's total revenue since 2014. (Doc. 77, ¶ 363.) At a conference in

December of 2015, Kapoor himself stated that he and other Insys officials "have a

meeting everyday [sic] . . . looking at what happened yesterday. I can tell you how many

[prescriptions] we did yesterday. And we do that every single day, because Subsys is so

important to us." (Doc. 77, ¶ 349.) Even though Kapoor was only acting CEO from

November 2015 on, it is implausible that even as executive chairman of its board of

directors he would not have known 98% of the company's revenue was coming from

Subsys prescriptions. And it is absurd to think he would not have known that Subsys's

revenue, which was glaringly high among comparable fentanyl products, was being

driven by fraud. Even on the core operations theory, Plaintiff has sufficiently pled

The complaint, however, contains less evidence of Baker's state of mind. Plaintiff first points to the fact that Baker was CFO of Insys during the class period and signed not only the Form 10-K but each and every one of the company's SEC filings. (*See, e.g.*, Doc. 77, ¶¶ 254, 262, 269, 283, 292, 300.) In those filings, Plaintiff argues, Baker "made detailed factual statements" about Subsys revenues "while misrepresenting and omitting the sources of those revenues." (Doc. 87 at 22.) Plaintiff also points to Defendants' collective access to information, such as sales figures from the Access Program and Kapoor's general statement that high-level executives closely monitored Subsys

prescriptions, as warranting an inference of scienter as to Baker specifically. (Doc. 87 at 20-21.) Finally, Plaintiff at oral argument pointed out that because Insys paid a glaringly high amount to a small number of Subsys prescribers, those payments—not to mention the high commissions Insys gave to its otherwise-low-paid sales reps—almost certainly required approval by Baker and at the very least were subject to his review on the company's books. *See* Doc. 77, ¶ 374.

All of that suffices to meet the threshold for giving rise to a plausible inference of Baker's scienter. Either way, scienter can be inferred on the core operations theory: as the company's CFO, it is absurd to think Baker knew about Subsys's anomalous market dominance but did not know how the company had pulled off the feat when he signed on to the company's SEC filings. The complaint has adequately alleged that he did.

### 3. Connection with Purchase or Sale of a Security

To make out a claim of securities fraud, a plaintiff must also show the alleged fraud "somehow touches upon or has some nexus with any securities transaction." *S.E.C. v. Rana Research, Inc.*, 8 F.3d 1358, 1361-62 (9th Cir. 1993) (internal quotation marks omitted). "Where the fraud alleged involves public dissemination in a document such as a press release, annual report, investment prospectus or other such document on which an investor would presumably rely, the 'in connection with' requirement is generally met by proof of the means of dissemination and the materiality of the misrepresentation or omission." *Id.* at 1362. The crux of the inquiry is whether "assertions are made . . . in a manner reasonably calculated to influence the investing public." *Id.* 

Defendants only challenge this requirement as to Burlakoff and argue that, among other things, the only statements of his cited in the second amended complaint "are not actionable because Plaintiff does not allege that they were made in a publication 'on which an investor would presumptively rely," such as "an SEC filing, press release, call with analysts or a financial news publication," or were "intended to influence the investing public." (Doc. 85 at 32.) Defendants are correct.

Burlakoff's only allegedly false statements identified in the complaint are quotations from a Southern Investigative Reporting Foundation article from April of 2015, which quoted him as saying, "We are only selling a breakthrough cancer pain drug. That's all we want to address with a doctor. . . . I can say that no one at Insys wants to see anyone taking [Subsys] for anything other than cancer pain." (Doc. 77, ¶¶ 278-79.) The complaint does not say when, where, or to whom Burlakoff made this statement, only that it was published in the article. The kinds of statements courts have found to satisfy the "in connection with" requirement are typically documents directly targeted to investors or the investment community—and at the very least documents produced by the defendants themselves. See, e.g., McGann v. Ernst & Young, 102 F.3d 390, 397 (9th Cir. 1996) (audit report that would be included in SEC filings); S.E.C. v. Retail Pro, Inc., 673 F. Supp. 2d 1108, 1132 (S.D. Cal. 2009) (annual and quarterly reports, press releases, and conference calls); S.E.C. v. Trabulse, 526 F. Supp. 2d 1001, 1006 (N.D. Cal. 2007) (account statements and newsletters sent directly to investors); S.E.C. v. Pirate Investor LLC, 580 F.3d 233, 250-51 (4th Cir. 2009) (collecting cases and concluding email message with fraudulent insider information met "in connection with" requirement where email authors "certainly should not have been shocked to learn that their fraudulent statements induced securities transactions").

The Southern Investigative Reporting Foundation news article at issue here is a far cry from these examples and certainly not the kind of document on which investors would presumably rely. But even if it were, there is no allegation that Burlakoff wrote or published it, only that it contained a quote attributed to him. The published quote might correctly reflect what Burlakoff said, but it might also contain inaccuracies over which he had no control. Since he did not produce the article, and since it is not something upon which investors would presumably rely, the statement from the Southern Investigative Reporting Foundation attributed to Burlakoff fails to meet the "in connection with" requirement. All claims against him under Section 10(b) are dismissed.

### 4. Loss Causation

Loss causation is the requirement that a securities fraud plaintiff "must demonstrate that the defendant's deceptive conduct caused [the plaintiff's] claimed economic loss." *Lloyd v. CVB Fin. Corp.*, 811 F.3d 1200, 1209 (9th Cir. 2016). *See* 15 U.S.C. § 78u-4(b)(4) ("[T]he plaintiff shall have the burden of proving that the act or omission of the defendant alleged to violate this chapter caused the loss for which the plaintiff seeks to recover damages."). Loss causation is established where "the market learns of a defendant's fraudulent act or practice, the market reacts to the fraudulent act or practice, and a plaintiff suffers a loss as a result of the market's reaction." *In re Oracle Corp. Sec. Litig.*, 627 F.3d 376, 392 (9th Cir. 2010).<sup>4</sup>

A plaintiff can establish that a market became aware of fraud by showing "corrective disclosures," news or announcements to investors that revealed the company's prior misstatements to have been false or misleading. *Lloyd*, 811 F.3d at 1209. The revelation may be direct or require steps of inference. *See, e.g., Cement & Concrete Workers Dist. Council Pension Fund v. Hewlett Packard Co.*, 964 F. Supp. 2d 1128, 1146 (N.D. Cal. 2013) (finding loss causation adequately pled where CEO's resignation amid misconduct allegations preceded stock drop, giving rise to plausible inference that market treated resignation as disclosure of fraud); *Daou*, 411 F.3d at 1026 (loss causation adequately pled where defendant company's below-expected revenue figures preceded sharp drops in stock price).

Disclosures can come in many forms but must occur under the right circumstances to establish loss causation. News of an investigation, for example, only informs the

<sup>&</sup>lt;sup>4</sup> Some courts have noted a potential inconsistency in the Ninth Circuit's loss causation legal standard as it has developed over time. *See Smilovits v. First Solar Inc.*, 119 F. Supp. 3d 978, 986-92 (D. Ariz. 2015) (Campbell, J.) (observing two lines of cases, one finding loss causation only where market learns of underlying fraud, the other where fraud causes plaintiff's loss regardless of market's knowledge). Because the Ninth Circuit has not resolved this question, the Court here applies the standard from the circuit's most recent cases, which require a plaintiff to show the market actually learned of the alleged fraud that caused its securities to decline in value. *See Oracle*, 627 F.3d at 392; *Metzler*, 540 F.3d at 1063. However, it is the Court's judgment that the motion here would come out the same way under either approach.

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market of fraud "if the complaint also alleged a subsequent corrective disclosure by the defendant." Lloyd, 811 F.3d at 1210. Accord Loos, 762 F.3d at 890 (holding that "the announcement of an investigation, without more, is insufficient to establish loss causation"). This would come into play where a security lost value on news of the investigation but then did not respond to a later disclosure by the defendant. In a case like that, one can infer that investors interpreted the investigation as a disclosure of fraud and thus treated the actual disclosure of fraud as something they already knew. See, e.g., Lloyd, 811 F.3d at 1210 (finding loss causation where company's stock dropped 20% on news of an SEC subpoena but reacted "hardly at all" to later news that the company's largest borrower was charging off millions in the company's loans). "[T]he ultimate issue is whether the defendant's misstatement, as opposed to some other fact, foreseeably caused the plaintiff's loss." *Lloyd*, 811 F.3d at 1210.

The complaint alleges that ten different partial corrective disclosures revealing false or misleading statements caused losses to Plaintiff as an investor.<sup>5</sup> As a preliminary matter, Defendants argue generally that none of the relevant risks was ever concealed; risks of government investigations, legal action, negative publicity, and employee misconduct were repeatedly disclosed in Insys's SEC filings. (Doc. 85 at 26.) But none of the disclaimers stated in those filings specifically discloses the risk of company-wide fraud orchestrated by the company's highest level executives. That risk was never disclosed in any document, much less anything public and available to investors. Since that argument is unavailing, the Court must consider one by one whether each alleged disclosure is sufficiently pled.

<sup>&</sup>lt;sup>5</sup> The complaint also raises a second theory known as "materialization of the risk," by which several disclosures reveal fraud to the market gradually over time. *See* Doc. 77, ¶¶ 428-30.) However, at oral argument Plaintiff clarified that he is no longer pursuing that argument. The Court will thus only consider the ten corrective disclosures individually.

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### a. First and Second Disclosures: November 27, 2014 New York Times Article and April 24, 2015 Southern Investigative Reporting Foundation Article

Defendants argue that the articles published on November 27, 2014, by the New York Times and April 24, 2015, by the Southern Investigative Reporting Foundation cannot constitute partial corrective disclosures because they occurred before Plaintiff purchased Insys stock. (Doc. 85 at 22.) Defendants also argue that the Southern Investigative Reporting Foundation article merely identifies a government investigation into Insys that the company had previously disclosed. (Doc. 85 at 22.)

Despite reciting more than 170 pages of allegations against Defendants, the complaint fails to mention exactly when Plaintiff bought and sold his Insys stock. However, the record does contain a certification by Plaintiff that he first purchased Insys stock on May 19, 2015. (Doc. 34-1 at 3.) Indeed, the two articles at issue here were published before he made any Insys stock purchases. Whether or not these were corrective disclosures (the Court does not decide that question), they could not have caused him any loss.

## b. Third and Fourth: May 20, 2015 Indictment of Two Physicians and June 23, 2015 Guilty Plea of Heather Alfonso (and New York Times Article Two Days Later)

Defendants argue that the third partial disclosure, the May 20, 2015 indictment of two doctors for unlawful distribution of controlled substances, "does not mention Insys, Subsys, or any off-label marketing or kickback scheme." (Doc. 85 at 23.) Additionally, Defendants argue that the complaint does not state any new information disclosed by the fourth partial disclosure, the June 23, 2015 guilty plea by Heather Alfonso (and the New York Times article that followed). (Doc. 85 at 23.)

More fundamentally, though, the records of Plaintiff's stock transactions show that after purchasing his first batch of Insys stock on May 19, 2015, he sold his stockholdings on July 8, 2015—for a profit. (Doc. 34-1 at 3.) The next day, he made the purchase of

4,000 shares that he currently holds today.<sup>6</sup> (*Id.*) In other words, no corrective disclosures, however damning, could have caused Plaintiff any loss before July 9, 2015, since he suffered no loss up until that point. These two disclosures are not actionable here.

### c. Fifth: November 4, 2015 CNBC Article

Defendants argue that the fifth alleged partial disclosure, a November 4, 2015 article published on CNBC's website, simply revealed that the Department of Health and Human Services had recently classified Subsys as commonly prescribed for unintended uses but did nothing to reveal securities fraud on the part of Insys. (Doc. 85 at 23-24.) Taken in isolation, this would be correct. But by late 2015, allegations against employees and collaborating healthcare providers sufficiently saturated the public sphere to create a different context for the CNBC article. The public knew Insys faced fraud allegations and knew multiple physicians had been charged with accepting bribes or kickbacks in exchange for prescribing Subsys. One had even pled guilty. (Doc. 81-4 at 26-35.) Against this backdrop, the complaint alleges that the CNBC article lent itself to an obvious inference: doctors were overprescribing Subsys because they were getting bribes and kickbacks from Insys. The CNBC article did not prove this to be conclusively true. But it sufficed to constitute a partial disclosure of the company's underlying fraud.

Over the next day, Insys's stock dropped 8.50%. (Doc. 77,  $\P$  324.) Plaintiff has thus sufficiently pled that the article's new revelations caused a drop in Insys's stock price.

### d. Sixth: November 5, 2015 Resignation of Babich

Defendants contest Plaintiff's sixth alleged partial disclosure, the November 5, 2015 announcement of Babich's resignation as CEO, on two separate grounds. First, they argue Babich's resignation did not reveal anything more than the fact he was resigning. (Doc. 85 at 24.) Second, they argue that either way, announcement of his

<sup>&</sup>lt;sup>6</sup> Though it is not in the record, Plaintiff's counsel clarified at oral argument that Plaintiff still owns the shares he purchased on July 9, 2016.

resignation caused no loss; Insys's stock price dropped from \$26.38 to \$25.43 between November 4 and 5 but then rebounded to \$27.39 by November 6. (*Id.*) For this fact, Defendants point the Court to the official Nasdaq website with publicly available records of Insys's stock price over time. *See* "Insys Therapeutics, Inc. Common Stock Historical Stock Prices," Nasdaq, http://www.nasdaq.com/symbol/insy/historical (last visited August 1, 2017). While Defendants' reference to these records is not a formal request for judicial notice, the Court may take judicial notice of certain facts "on its own." Fed. R. Evid. 201(c)(1). Those facts of which it can take notice include anything "not subject to reasonable dispute because it . . . can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b)(2). Publicly traded companies' historical stock prices stand among them. *ScripsAmerica, Inc. v. Ironridge Global LLC*, 119 F. Supp. 3d 1213, 1232 (C.D. Cal. 2015). Accordingly the Court takes judicial notice of Insys's closing stock prices on November 4, 5, and 6, 2015.

At least one other circuit has concluded that news of an executive's resignation does not by itself amount to a "corrective disclosure," but courts may consider the event as "a portion of the totality" that must be considered. *See Pub. Emps. Ret. Sys. of Miss.*, *P.R. Teachers Ret. Sys. v. Amedisys, Inc.*, 769 F.3d 313, 322-23 (5th Cir. 2014), *cert denied*, 135 S. Ct. 2892 (2015). As the Fifth Circuit pointed out, even a large market decline following a high-level resignation "could have simply been a market reaction to sudden news that two key executives had left the company." *Id.* at 322. The broader context of Babich's announcement makes this a close question because of all the allegations swirling in the background. But the significance of Babich's resignation need not be determined, because Defendants are correct that Insys's stock experienced no actual loss as a result of the announcement. A securities fraud plaintiff must show that he "suffer[ed] a loss as a result of the market's reaction." *Oracle*, 627 F.3d at 392. With no loss, there can be no loss causation.

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### e. Seventh and Eighth: December 3, 2015 and January 25, 2016 Southern Investigative Reporting Foundation Articles

Defendants contend that the seventh and eighth alleged partial disclosures, articles from December 3, 2015, and January 25, 2016, published by the Southern Investigative Reporting Foundation, merely restated allegations from a separate 2014 securities complaint about fraud by the company's "Prior Authorization Unit" and otherwise leaned on unreliable statements by an anonymous source concerning Babich's resignation. (Doc. 85 at 24-25.)

The Court has not taken judicial notice of the 2014 complaint's contents, and thus cannot consider them in deciding this motion. At this stage, Plaintiff's allegations recited in his second amended complaint are assumed to be true unless contradicted by something of which the Court has taken notice. The Court therefore assumes that the revelations detailed in the Southern Investigative Reporting Foundation articles were sufficiently novel to constitute partial disclosures.

By the end of the day on December 3, 2015, Insys's stock had fallen from \$31.99 per share to \$26.06 per share from the day before, a drop of 18.54%. (Doc. 77, ¶ 327.) The drop on January 25, 2016, was somewhat less dramatic: the stock price fell to \$21.58 from a price of \$22.65 the previous trading day, a drop of 4.72%. (Doc. 77, ¶ 330.) Nonetheless the complaint suffices to plead loss causation as to both of these disclosures.

### f. Ninth: April 11, 2016 Press Release

Defendants argue that the ninth alleged partial disclosure, an April 11, 2016 press release announcing Insys's lower-than-expected net revenues, "itself does not reveal anything about an alleged off-label marketing or kickback scheme." (Doc. 85 at 25.)

Two Ninth Circuit cases have addressed whether news of a revenue shortfall can support loss causation. In *In re Gilead Sciences Sec. Litig.*, 536 F.3d 1049, 1057-58 (9th Cir. 2008), the court concluded loss causation was sufficiently pled via allegations that news of the defendant pharmaceutical company's poor quarterly performance caused its stock to drop. The complaint in that case accused the company of marketing and selling

an HIV drug for off-label uses, which generated between 75% and 95% of all its sales. *Id.* at 1051. Several years into these practices, the FDA issued a public Warning Letter chastising one of the company's employees for making "oral statements that minimized the risk information and broadened the indication for" the drug. Id. at 1052-53. After quarter upon quarter of reported revenue growth, the company eventually issued a press release in late 2003 revealing lower-than-expected sales, which triggered a 12% drop in the company's stock. *Id.* at 1054. In concluding the press release sufficed as a public disclosure, the court connected the stock drop to the FDA warning letter:

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Importantly, the drop occurred immediately after Gilead disclosed lessthan-expected revenues resulting from the reduction wholesalers' . . . inventories [of the drug], which analysts ascribed to lower end-user demand. That lower end-user demand, in turn, is expressly alleged to have been caused by the Warning Letter. In this light, the market did react immediately to the corrective disclosure—the October 28 press release. The Warning Letter, which discussed only two instances of offlabel marketing, would not necessarily trigger a market reaction because it did not contain enough information to significantly undermine Gilead's July 2003 pronouncements concerning demand for [the drug].

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*Id.* at 1058.

However, later in the same year, the Ninth Circuit separately held in *Metzler* that a for-profit education company's announcement of lower-than-expected earnings did not suffice to establish loss causation. 540 F.3d at 1064. In that case, the complaint alleged that the company engaged in a variety of fraudulent practices such as falsifying financial aid applications, improperly calculating student enrollment, falsifying student grades, and other similar practices in order to maximize the funding it received from the federal government. Id. at 1055. One of two disclosures the complaint identified as triggering loss to investors was a press release detailing earnings shortfalls that the company attributed to "higher than anticipated attrition" at its schools, which the complaint interpreted as "a euphemism for an admission that they had enrolled students who should

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not have been signed up at all." *Id.* at 1059-60. In rejecting this inference, the court reasoned that

[s]o long as there is a drop in a stock's price, a plaintiff will always be able to contend that the market "understood" a defendant's statement precipitating a loss as a coded message revealing the fraud. Enabling a plaintiff to proceed on such a theory would effectively resurrect what *Dura* discredited—that loss causation is established through an allegation that a stock was purchased at an inflated price. . . . Loss causation requires more.

Id. at 1064 (citation omitted).

The takeaway from *Metzler* is that "loss causation is not adequately pled unless a plaintiff alleges that the market learned of and reacted to the practices the plaintiff contends are fraudulent, as opposed to merely reports of the defendant's poor financial health generally." *Oracle Corp.*, 627 F.3d at 392 (citing *Metzler*, 540 F.3d at 1063). But *Gilead* makes clear that just the right causal chain between fraud and a below-expectations financial report can suffice to show the market reacted to the fraud rather than to the poor results themselves.

The allegations here, however, do not establish an adequate causal link. True, the second amended complaint does contend that analysts attributed the revenue shortfall to a "decline in [prescriptions]," specifically prescriptions "at the lower doses of Subsys," which suggested that "fewer patients were initiating therapy." (Doc. 77, ¶ 336.) But in *Gilead*, the lower end-user demand was "expressly alleged to have been caused by the [FDA] Warning Letter," which stated particular accusations of the company's fraudulent conduct. *Gilead*, 536 F.3d at 1058. By contrast, all the complaint here alleges is that news of Insys's lower revenues "revealed the remaining undisclosed relevant truth concealed and/or obscured by Defendants' prior misstatements and omissions surrounding Subsys, including the negative impact on Company revenues that resulted from the [Insurance Reimbursement Center's] decreased ability to obtain third-party payer approval for Subsys prescriptions." (Doc. 77, ¶ 433.) In other words, Plaintiff here

has failed to explicitly connect the decrease in Subsys prescriptions to accusations of fraud. It would require several steps of inference to get from fewer third-party-payer approvals to the market having learned about Insys's fraudulent practices. Those inferences are not explicitly stated in the complaint. The crux of *Gilead* is that a revenue shortfall establishes loss causation where the complaint "expressly allege[s]" the requisite inferential chain. *Gilead*, 536 F.3d at 1058. That is a perfectly sensible requirement in light of the stringent pleading standards of Rule 9(b) and the PSLRA.

Given *Metzler*'s resistance to giving mere market loss too much meaning, the absence of an expressly alleged connection linking each step of reasoning cannot stand on its own. The April 11, 2016 revenue announcement therefore does not suffice to establish loss causation.

### g. Tenth: December 2016 Indictment

Defendants next contend that the complaint fails to identify how the tenth and final partial disclosure, the December 8, 2016 unsealing of an indictment charging numerous former Insys executives with racketeering, "identif[ies] with the required particularity any alleged misstatement that was rendered untrue by this disclosure." (Doc. 85 at 25.) Plaintiff responds only with the general assertion that the indictment "revealed additional new facts, including internal Insys communications, demonstrating that Defendants deliberately perpetrated the Company-wide and nationwide Off-Label/Kickback Scheme and [Insurance Reimbursement Center] Fraud to increase Insys's sales revenues." (Doc. 87 at 36.)

The question is not whether the indictment "rendered" any statement untrue, but whether it revealed to the market that prior statements by Insys and its executives were in fact false or misleading. Plaintiff has not adequately alleged that it did. It is not enough to say generally that a corrective disclosure "revealed additional new facts" and then describe those facts only as "internal Insys communications." To permit that explanation would be to dispense with the requirement that securities fraud actions be pled with "particularity." Fed. R. Civ. P. 9(b). No defendant could possibly defend themselves

against allegations that are so vague. If the December 2016 indictment did reveal anything new, Plaintiff has not pled it here.

To summarize, only the fifth, seventh, and eighth purported corrective disclosures suffice to allege loss causation. The rest either fall outside of when Plaintiff had suffered losses or are insufficiently pled to meet the PLSRA pleading standards.

### C. 20(a)

Section 20(a) requires both an underlying violation and that the defendant had actual power or control over the primary violator. Defendants here challenge the complaint only on the grounds that there was no underlying violation of Section 10(b). Where a plaintiff fails to plead a violation of 10(b) adequately, a Section 20(a) claim may be dismissed summarily. *Zucco*, 552 F.3d at 990. As to Burlakoff, this is the case. The claim against him under Section 20(a) is dismissed. But the above discussion makes clear that claims under Section 10(b) remain as to all other Defendants. Since Defendants challenged the Section 20(a) claim only on that ground, their challenge fails.

### IV. SUMMARY

In summary, the Court finds as follows:

- Only the statements alleged in paragraphs 268 and 272 of the second amended complaint meet PLSRA's falsity requirement. All others cannot be part of this action.
- Scienter has been adequately pled as to both Kapoor and Baker.
- The allegations against Burlakoff are dismissed for failing to meet the "in connection with" requirement.
- Loss causation has been adequately pled only as to the November 4, 2015 CNBC article, and the December 3, 2015 and January 25, 2016 Southern Investigative Reporting Foundation articles. All other alleged "corrective disclosures" are no longer part of this action.

| 1  | IT IS THEREFORE ORDERED that Plaintiff's Motion to Dismiss (Doc. 85) is                     |
|----|---------------------------------------------------------------------------------------------|
| 2  | granted in part and denied in part as summarized in the preceding paragraph.                |
| 3  | IT IS FURTHER ORDERED that Defendants' Request for Judicial Notice (Doc.                    |
| 4  | 81) is denied to the extent that Defendants ask the Court to take notice of the substantive |
| 5  | content of filings in other judicial proceedings, but granted in all other respects.        |
| 6  | Dated this 1st day of August, 2017.                                                         |
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| 8  | NeilVWalso                                                                                  |
| 9  | Neil V. Wake                                                                                |
| 10 | Senior United States District Judge                                                         |
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