IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

SEB INVESTMENT MANAGEMENT AB, Individually and On Behalf of All Others Similarly Situated	:	**CIVIL ACTION**
v.	:	
ENDO INTERNATIONAL, PLC, SUSAN HALL, ENDO HEALTH SOLUTIONS INC., PAUL V. CAMPANELLI, BLAINE T. DAVIS, MATTHEW W. DAVIS, RAJIV KANISHKA LIYANAARCHCHIE DE SILVA, IVAN GERGEL, DAVID P. HOLVECK, ALAN G. LEVIN, JULIE H. MCHUGH, SUKETU P. UPADHYAY, DANIEL A. RUDIO, ROGER H. KIMMEL, SHANE M. COOKE, JOHN J. DELUCCA, NANCY J. HUTSON, MICHAEL HYATT, WILLIAM P. MONTAGUE, JILL D. SMITH and WILLIAM F. SPENGLER	:	**NO. 17-3711**

MEMORANDUM OPINION

Savage, J. **December 10, 2018**

In this putative class action for violations of the Securities Exchange Act of 1934 (Exchange Act), 15 U.S.C. § 78a *et seq.*, and the Securities Act of 1933 (Securities Act), 15 U.S.C. § 77a *et seq.*, SEB Investment Management AB (SEB) claims that the defendants publicly downplayed the risks of Endo's reformulated opioid pain medication, Opana ER. In essence, SEB alleges that the defendants misrepresented and omitted facts regarding the safety of the reformulated drug and the results of surveillance data that significantly impacted the chances of obtaining FDA approval for abuse-deterrent labeling, which would make the drug more marketable. It contends the defendants,

knowing the adverse consequences of the increase in intravenous abuse the data showed, consciously or recklessly, failed to disclose it. As the true facts were revealed and after the FDA requested that Endo withdraw the drug from the market or face FDA action forcing withdrawal, the market value of Endo stock plummeted.

In moving to dismiss, Endo International plc and Endo Health Solutions Inc. (collectively, Endo) and the individual defendants[1] argue SEB engages in "hindsight pleading" and alleges no facts suggesting any statements were false when made, the challenged statements were merely opinions and optimistic or forward-looking statements protected by the safe harbor provision of the Exchange Act, and the alleged facts do not establish that the defendants knew their statements were untrue. Invoking *Colorado River* abstention, they also maintain that the Securities Act claims should be dismissed because they are being litigated in state court.

We conclude that SEB has stated causes of action for violations of the Exchange and Securities Acts. SEB has alleged that Endo and certain of its officers consciously or recklessly made material representations and omissions regarding the safety and efficacy of reformulated Opana ER, resulting in a significant drop in Endo's share price. Therefore, we shall deny the motion to dismiss, except as to certain individuals who made no misrepresentations.

SEB's Allegations in the Amended Complaint

Endo is a global pharmaceutical company that markets and sells branded opioids.[2] In July 2006, Endo introduced Opana ER, its extended-release pain relief pill designed to work over a twelve-hour period.[3] At the time, it was the only extended release version of oxymorphone hydrochloride on the market.[4] Its formulation made it highly susceptible to

abuse.[5] When the drug is crushed and taken intranasally, the extended-release mechanisms no longer remain intact and 43% of its active ingredient is released immediately.[6]

In July 2010, Endo submitted a New Drug Application (NDA) for a reformulated version of Opana ER.[7] The new drug was designed to make it more difficult to crush the tablets, reducing its propensity for abuse.[8] To support its NDA, Endo provided studies assessing the abuse-deterrent properties of the new formulation.[9] Though the data indicated some resistance to crushing by a pill crusher, it showed that tampering with the drug by other means could compromise the extended release feature, immediately releasing a full dosage of the drug.[10] Based on this information, FDA reviewers recommended excluding language claiming it was crush resistant from the drug's label.[11]

That same year, Endo settled its patent infringement suit against Impax Laboratories, Inc. (Impax), which had submitted the first Abbreviated New Drug Application (ANDA) to introduce a generic version of original Opana ER in 2007.[12] Impax agreed to delay launching its generic version of original Opana ER until January 1, 2013.[13] Because Impax enjoyed first-filer status, other generic manufacturers were precluded from entering the market until 180 days after Impax's generic launch.[14]

On December 9, 2011, the FDA approved reformulated Opana ER, but denied Endo's request to label the drug as abuse-deterrent because the data did not support such a finding.[15] Endo began selling reformulated Opana ER in February 2012.[16]

Three months later, Endo notified the FDA that it planned to discontinue original Opana ER for safety reasons.[17] It anticipated the FDA would act quickly to withdraw all generic versions of the drug, effectively blocking competition.[18] On August 10, 2012,

because the FDA had not acted, Endo filed a Citizen Petition asking the FDA to determine that original Opana ER was discontinued for safety reasons, to reject pending ANDAs for generic versions of original Opana ER, and to withdraw approval of any ANDA for original Opana ER.[19]

On October 26, 2012, the Centers for Disease Control and Prevention (CDC) issued a public health alert for reformulated Opana ER after a dozen illnesses resembling thrombotic thrombocytopenic purpura (TTP), a potentially fatal blood clotting disorder, were observed among intravenous abusers in Tennessee starting in February 2012 after the drug had been placed on the market.[20]

Nonetheless, two weeks later on November 13, 2012, Endo supplemented its Citizen Petition with post-marketing surveillance data from the National Addictions Vigilance Intervention and Prevention Program (NAVIPPRO) and the Researched Abuse Diversion and Addiction-Related Surveillance System (RADARS),[21] which it claimed "indicate[d] that the reformulated Opana ER [was] having the desired effect on the rates and routes of abuse[.]"[22] The reports were not public, allowing Endo's summary of the data to go unchallenged.[23] Endo also compared the new Opana ER to reformulated OxyContin to support its contention that reformulated Opana ER provided superior safety benefits over the original formulation.[24] It did so because reformulated OxyContin was less likely to be abused because it was more difficult to inject.[25] At the same time, it claimed the introduction of reformulated crush-resistant Opana ER caused a dramatic decrease in abuse rates.[26]

On November 30, 2012,[27] Endo filed a lawsuit against the FDA seeking a mandatory injunction requiring the FDA to rule on its Citizen Petition by December 31,

2012.[28] On the same day, it issued a press release claiming that surveillance data submitted in support of the Citizen Petition showed a substantial decrease in abuse rates of reformulated Opana ER.[29] In the press release, Endo's then-President and chief executive officer (CEO), David Holveck, represented there was enough evidence to conclude that original Opana ER had been discontinued for safety reasons.[30]

The district court dismissed the lawsuit three weeks later as groundless.[31] As a result, Impax's generic version of Opana ER went on the market on January 1, 2013.[32]

On February 15, 2013, despite the unfavorable court decision, Endo submitted a Supplemental New Drug Application (sNDA) seeking FDA approval for placing abuse-deterrent language on reformulated Opana ER's label.[33] The application relied upon the post-marketing studies in Endo's Citizen Petition and the same studies that had been submitted with the original application, which the FDA had concluded were inadequate to support abuse-deterrent labeling.[34] The application did not disclose that Endo's own consultant had found that data from substance abuse treatment facilities across the nation did "not necessarily establish that the reformulated Opana ER is tamper resistant" and also "that there were reports of higher levels of abuse of reformulated Opana ER via injection."[35]

Endo's Chief Operating Officer Julie McHugh, Chief Scientific Officer (CSO) Ivan Gergel, and Chief Financial Officer (CFO) Alan Levin, claimed that additional data indicated reformulated Opana ER was misused at lower rates than the original formula and its generic versions.[36] Senior Vice President of Corporate Affairs, Blaine Davis, also commented on the drug's success in reducing intranasal abuse.[37] Citing this data, Endo represented that it had introduced a safer version of Opana ER in the market.[38]

On March 21, 2013, in a second supplement to its Citizen Petition, Endo provided preliminary studies demonstrating lower abuse rates of reformulated Opana ER.[39] It continued to claim that the NAVAPPRO and RADARS data, which was not public, showed a reduction in abuse of intended and unintended routes of administration.[40]

Meanwhile, the FDA approved abuse-deterrent labeling for reformulated OxyContin and granted OxyContin manufacturer Purdue's Citizen Petition seeking a determination that original OxyContin had been withdrawn for safety reasons.[41] Seeking a similar determination, Endo submitted a third supplement to its Citizen Petition on April 23, 2013, which analogized reformulated Opana ER to reformulated OxyContin.[42] Indeed, Endo's President and CEO at the time, Rajiv Kanishka Liyanaarchchie De Silva, explained the purpose of the supplement was to emphasize the similarities between Opana ER and OxyContin.[43]

The two drugs were not the same. They each had different abuse-deterrent properties.[44] Reformulated OxyContin was difficult to inject.[45] On the other hand, the FDA had determined that reformulated Opana ER could be "readily prepared for injection."[46] Nevertheless, Endo and its officers publicly claimed in a supplement to its Citizen Petition that similarities between original Opana ER and original OxyContin required the FDA to make the same determination that it had for OxyContin's Citizen Petition.[47]

On May 10, 2013, the FDA denied Endo's Citizen Petition and its sNDA requesting abuse-deterrent labeling.[48] It determined there was insufficient data to conclude that reformulated Opana ER reduced the potential for abuse or that the benefits of original Opana ER no longer outweighed its risks.[49] Rather, the FDA found that reformulated

Opana ER's extended-release qualities could be compromised when the pill was cut, ground or chewed, and that it could more easily be prepared for snorting and injection.[50] It also found the post-marketing data to be "preliminary," "inconclusive," and replete with deficiencies.[51] In response to the FDA's decision, the price of Endo's common stock declined 5.28% on May 10, 2013. By May 13, 2013, Endo's common stock declined another 3.60%.[52]

In a press release issued on May 10, De Silva, while expressing disappointment with the FDA's decision, reiterated that the company presented data indicating that for every 100,000 prescriptions issued, the rate of abuse of reformulated Opana ER in the past 30 days was 79% lower than for generic non-reformulated versions.[53] De Silva did not distinguish between intranasal and intravenous abuse.[54] At a healthcare conference later that year, he also announced that Endo was conducting an "active clinical program" that would hopefully allow it to reapply for abuse-deterrent labeling by 2015.[55]

By September 2014, Endo completed an insufflation study designed to assess intranasal abuse of the reformulated drug.[56] The results suggested a deterrent effect for intranasal abuse.[57] However, when compared with results from earlier studies, they revealed an increase in intravenous abuse.[58] Based on the data, the FDA concluded that after Opana ER's reformulation there was a shift from inhalation abuse to injection abuse, a significant increase in injection abuse call rates, and a higher abuse call rate than for other opioids.[59]

On April 24, 2015, the CDC issued a public health alert warning of another cluster of HIV-infections among persons who abused Opana ER intravenously.[60] Less than a month later, in a quarterly earnings call on May 11, 2015, De Silva announced an

upcoming meeting with the FDA in June.[61] Though De Silva expressed hope the meeting would advance Endo's labeling efforts, he cautioned that the FDA could deem the insufflation study data inadequate.[62]

On June 2, 2015, Endo filed a Registration Statement and prospectus announcing a $1.75 billion public offering of common stock (June 2015 Offering).[63] The Registration Statement was signed by the Individual Securities Act Defendants, including CFO and Executive Vice President Suketu Upadhyay, Chief Accounting Officer and Vice President Daniel Rudio, and members of the Board of Directors.[64] Two days later, Endo offered an additional 24 million shares of common stock at a price of $83.25 per share.[65] By the June 10 market close, Endo had issued over 27 million shares of common stock at $83.25 per share, yielding $2.3 billion.[66]

On August 10, 2015, in its second quarter earnings call to investors and analysts, Endo announced plans to submit a supplemental request for abuse-deterrent labeling by the end of 2015 or early 2016.[67] In its November 9, 2015 report, Endo stressed the crush resistance of reformulated Opana ER while withholding what it knew about the increase in intravenous abuse the post-marketing data had shown.[68] Endo did not reveal that the data demonstrated a rise in serious adverse events associated with intravenous abuse, particularly TTP and thrombotic microangiopathy (TMA).[69]

During the Stifel Nicolaus Healthcare Conference on November 17, 2015, De Silva reported to the attendees that Endo's submission for re-labeling would include the results of its insufflation study and two years of epidemiological data.[70] At the same time he expressed confidence in the sufficiency of the data, he cautioned that the FDA may have a different view.[71]

On January 29, 2016, relying on the insufflation study and ongoing epidemiological studies based on NAVIPPRO and RADARS data, Endo re-submitted its sNDA requesting a label change.[72] In his February 29, 2016 quarterly earnings call, De Silva opined that Endo's data package "could support an abuse deterrent formulation label expansion."[73]

On June 16, 2016, the FDA announced that it would convene an advisory committee to review Endo's data and to gather input on abuse patterns associated with reformulated Opana ER.[74] Two months later, citing an August 11, 2016 discussion with the FDA, Endo unexpectedly withdrew the sNDA.[75] In its press release, Endo's Executive Vice President and CSO, Susan Hall, announced that, despite the withdrawal, Endo planned to generate additional data to "appropriately advance" Opana ER.[76]

On January 10, 2017, the FDA announced a joint meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee[77] (collectively, Advisory Committee) to discuss the marketing data regarding abuse of reformulated Opana ER, the risk-benefit of the product, and abuse of generic oxymorphone ER and oxymorphone immediate-release products.[78] In response to the announcement, the price of Endo common stock declined 6.70% and 8.49% on January 10 and 11, 2017, respectively.[79]

Endo dismissed the importance of the Advisory Committee meeting.[80] When asked about his level of concern, Endo's new President and CEO, Paul Campanelli, indicated that Endo's studies supported the safety of the drug when used as intended.[81] He also suggested the meeting's purpose was to discuss all oxymorphone products, not just Opana ER.[82]

On March 9, 2017, in advance of the Advisory Committee meeting, the FDA published its briefing documents, which included its preliminary views on the safety and abuse-deterrent properties of reformulated Opana ER.[83] The documents reflected that Endo's post-marketing abuse data presented a "compelling case" that there was an overall increase in abuse and a shift from intranasal to intravenous abuse following reformulation.[84] In response to this news, the price of Endo common stock fell by 2.5% to $10.53 per share.[85]

At its meeting on March 14, 2017, the Advisory Committee concluded that the benefits of reformulated Opana ER did not outweigh its risks.[86] The price of Endo common stock declined 4.22% to $10.22 per share.[87] Analysts immediately issued reports commenting on the uncertainty of reformulated Opana ER's future and the possibility of the drug's withdrawal from the market.[88]

Addressing the Advisory Committee's action in a March 14, 2017 press release, Matthew Davis, a Senior Vice President, reiterated the company's confidence in its clinical research which he claimed demonstrated that Opana ER had "a favorable risk-benefit profile" when used as intended.[89] Campanelli indicated that, pending any follow up conversations with the FDA, it was still "business as usual" with Opana.[90]

On June 8, 2017, the FDA announced it had asked Endo to withdraw reformulated Opana ER from the market voluntarily.[91] Based on its review of all available post-marketing data, the FDA concluded that Opana ER's reformulation caused a significant increase in intravenous abuse and serious outbreaks of HIV and hepatitis C.[92] The FDA sought removal of the drug because the benefits no longer outweighed the risks.[93] It was

the first time the agency had taken such action.[94] In response, the price of Endo common stock dropped 16.62% to close at $11.49 per share the next day.[95]

Endo announced on July 6, 2017 that it had decided to remove reformulated Opana ER from the market.[96]

Standard of Review

A securities fraud complaint must allege much more than a typical complaint to overcome a motion to dismiss. It must do more than satisfy the Rule 12(b)(6) test. Because it alleges fraud, it must also meet the particularity requirement of Rule 9(b). *Williams v. Globus Med., Inc.*, 869 F.3d 235, 240 (3d Cir. 2017). In addition, it must set forth the details necessary to satisfy the Private Securities Litigation Reform Act (PSLRA), 15 U.S.C. § 78u–4(b)(1), (2)(A). *OFI Asset Mgmt. v. Cooper Tire & Rubber*, 834 F.3d 481, 490 (3d Cir. 2016); *Cal. Pub. Emps.' Ret. Sys. v. Chubb Corp.*, 394 F.3d 126, 144 (3d Cir. 2004).

Rule 12(b)(6) Standard

A 12(b)(6) motion may be "granted only if, accepting all well pleaded allegations in the complaint as true, and drawing all reasonable factual inferences in favor of the plaintiff, it appears beyond doubt that the plaintiff can prove no set of facts in support of the claim that would warrant relief." *Cal. Pub. Emps.' Ret. Sys.*, 394 F.3d at 143 (citing *Oran v. Stafford*, 226 F.3d 275, 279 (3d Cir. 2000)); *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210–11 (3d Cir. 2009). But, the court need not accept "unsupported conclusions" and "unwarranted inferences," or legal conclusions couched as factual allegations. *Trzaska v. L'Oreal USA, Inc.*, 865 F.3d 155, 159 (3d Cir. 2017) (quoting *Morrow v. Balaski*, 719 F.3d 160, 165 (3d Cir. 2013)).

When faced with a Rule 12(b)(6) motion to dismiss a § 10(b) action, a court must, as with any motion to dismiss for failure to state a claim, accept all factual allegations in the complaint as true. *Tellabs, Inc. v. Makor Issues & Rights, Ltd.,* 551 U.S. 308, 322 (2007). In addition, a court must consider the complaint in its entirety, as well as documents incorporated into the complaint by reference, and matters of which a court may take judicial notice. *OFI Asset Mgmt.*, 834 F.3d at 490 (citing *Tellabs*, 551 U.S. at 322). Hence, a court may consider and "probe" documents attached to a defendant's motion to dismiss if they are integral to or explicitly relied upon in the complaint. *Winer Family Tr. v. Queen*, 503 F.3d 319, 328 (3d Cir. 2007) (citing *Tellabs*, 551 U.S. at 322); *see also Hartig Drug Co., Inc. v. Senju Pharm. Co., Ltd.*, 836 F.3d 261, 273 (3d Cir. 2016); *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997) (permitting district courts, ruling on a motion to dismiss, to consider matters extraneous to the complaint without converting it to a summary judgment motion if the plaintiff's claims are based on a document and the document is "undisputedly authentic").

Rule 9(b) Requirements

Rule 9(b) requires all averments of fraud or mistake to be stated with particularity. Fed. R. Civ. P. 9(b); *In re Suprema Specialties, Inc. Sec. Litig.*, 438 F.3d 256, 276 (3d Cir. 2006). The particularity requirement is rigorously applied in securities fraud cases. *Cal. Pub. Emps.' Ret. Sys.*, 394 F.3d at 144; *see also Tellabs,* 551 U.S. at 319. The plaintiff must plead the "who, what, when, where, and how" of the fraud. *In re Suprema*, 438 F.3d at 276.

Heightened Pleading Requirements of the PSLRA

The PSLRA imposes two requirements for § 10(b) actions that go beyond Rule 9(b). *See Tellabs*, 551 U.S. at 321. First, the complaint must "specify each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading." *Id.* (quoting 15 U.S.C. § 78u–4(b)(1)). If the plaintiff bases an allegation upon information and belief, the complaint must also set forth all facts supporting that belief with particularity. *Institutional Inv'rs Grp. v. Avaya, Inc.*, 564 F.3d 242, 252 (3d Cir. 2009) (internal quotations omitted) (citing 15 U.S.C. § 78u-4(b)(1)).

Second, for each act or omission alleged, the complaint must state the particular facts substantiating "a strong inference" that the defendant acted with an intent to deceive, manipulate, or defraud. *Tellabs*, 551 U.S. at 321 (quoting 15 U.S.C. § 78u–4(b)(2)); *OFI Asset Mgmt.*, 834 F.3d at 490; *Institutional Inv'rs Grp.*, 564 F.3d at 252 (quoting 15 U.S.C. § 78u–4(b)(2)). An inference is strong if it is "cogent and at least as compelling as any opposing inference of nonfraudulent intent." *Tellabs,* 551 U.S. at 314. A merely plausible or reasonable inference is insufficient. *Id.*

In summary, "unless plaintiffs in securities fraud actions allege facts supporting their contentions of fraud with the requisite particularity mandated by Rule 9(b) and the Reform Act [PSLRA], they may not benefit from inferences flowing from vague or unspecific allegations—inferences that may arguably have been justified under a traditional Rule 12(b)(6) analysis." *Cal. Pub. Emps.' Ret. Sys.*, 394 F.3d at 145 (citation omitted) (alteration in original). Dismissal is the appropriate remedy for a complaint which fails to meet these stringent requirements. *Globus Med.*, 869 F.3d at 241 (citing *Cal. Pub. Emps.' Ret. Sys.*, 394 F.3d at 145).

Analysis

Exchange Act Claims

Section 10(b) of the Exchange Act and Rule 10b–5

To state a claim under § 10(b) of the Exchange Act and Rule 10b–5 (codified at 17 C.F.R. § 240.10b-5), a plaintiff must allege: (1) a material misrepresentation or omission; (2) made with scienter; (3) in connection with the purchase or sale of a security; (4) reliance by the plaintiff upon the misrepresentation or omission; (4) economic loss; and (5) a causal connection between the material misrepresentation and the loss. *Dura Pharm., Inc. v. Broudo*, 544 U.S. 336, 341-42 (2005); *OFI Asset Mgmt.*, 834 F.3d at 493-94.

Misrepresentations and Omissions

SEB alleges that the Exchange Act Defendants made materially false statements and omitted material facts. It avers that they misrepresented reformulated Opana ER's abuse deterrent properties and its similarity to reformulated OxyContin. It alleges they failed to disclose that reformulated Opana ER could still be manipulated for easy injection and was being abused intravenously at a greater rate than the original drug.

SEB also alleges that the Exchange Act Defendants made material misrepresentations regarding the viability of its Citizen Petition and abuse-deterrent labeling efforts.[97] It asserts that because the Exchange Act Defendants knew reformulated Opana ER was associated with increased intravenous abuse and could be manipulated for such abuse, they had no basis to represent that Endo had "sufficient and robust enough data" to support its Citizen Petition or an abuse-deterrent label.[98]

The amended complaint sets forth the specific statements and omissions SEB alleges were misleading. SEB cites to language in press releases, SEC filings and public

statements in which Endo and its corporate officers referred to reformulated Opana ER's "crush-resistant" design, and claimed that the original formulation was discontinued for safety reasons, that reformulated Opana ER and Oxycontin were "virtually identical" and that the data showed lower abuse rates.[99] It also provides the studies and the data which it claims showed the adverse abuse trends it contends rendered these statements misleading.[100]

The Exchange Act Defendants contend that SEB has not alleged any material omissions or misrepresentations. Endo argues that statements regarding the surveillance data, the Citizen Petition, the similarities to OxyContin, and abuse-deterrent labeling were nothing more than optimistic opinions that later proved to be wrong. The statements, according to the defendants, are inactionable personal opinions, "puffery," or forward-looking statements.

A statement or omission must have been misleading when it was made. *Globus Med.*, 869 F.3d at 244 (citing *In re NAHC, Inc. Sec. Litig.*, 306 F.3d 1314, 1330 (3d Cir. 2002)). If it later turns out a representation was wrong or an omission was material, it is not actionable. In other words, allegations of misrepresentations or omissions cannot be based on hindsight or subsequent events. *Id*.

The Exchange Act Defendants argue that because the NAVIPPRO, RADARS and FAERS[101] charts showing abuse trends for reformulated Opana ER were created in 2016 and 2017, they could not have known that their statements about the abuse rates were false when they made them.[102] In other words, they contend SEB improperly relied on recent studies to show the representations predating those studies were false.

Though the amended complaint cites NAVIPPRO and RADARS results published in 2016 and 2017, SEB alleges that Endo had information it knew contradicted its public statements when the purported statements were made. SEB claims that the Exchange Act Defendants knew as early as 2010 that reformulated Opana ER could be compromised. To support its New Drug Application filed in July 2010, Endo relied upon studies that, according to SEB, showed that reformulated Opana ER could still be ground, cut, or chewed to release a full dosage at once, and be more easily injected than the original formula.[103] Indeed, the FDA denied Endo's request for abuse-deterrent labeling in December 2011 because the drug provided limited resistance to abuse.[104]

In supplements to its Citizen Petition, Endo repeatedly claimed that NAVIPPRO and RADARS post-marketing reports from 2012 and 2013 showed significantly lower abuse rates for reformulated Opana ER.[105] The FDA denied Endo's Citizen Petition in May 2013 because it found that the same data suggested that reformulated Opana ER's extended release features could still be compromised when cut, ground, or chewed, and that it was more readily prepared for injection.[106] It concluded that the data was preliminary, inconclusive and suffered from "significant additional deficiencies," including the small sample size and the likely misclassification of drug exposure.[107] The FDA found that even if the data had been reliable, it still suggested the "troubling possibility" that reformulated Opana ER was being abused intravenously at greater rates than the original drug.[108]

SEB's allegations, if proven, will establish that when they made the statements, the defendants were aware of the negative information. Despite knowing that the data revealed a shift from intranasal to intravenous abuse and a resulting increase in

intravenous abuse, they did not publicly disclose those facts when they touted the decrease in intranasal abuse. According to the amended complaint, the defendants possessed the adverse intravenous abuse data regarding reformulated Opana ER when it relied on the NAVIPPRO and RADARS post-marketing surveillance data in its Citizen Petition supplement filed in November 2012. They had received NAVIPPRO data on February 22, May 18, August 31, and November 2, 2012; and RADARS data on October 12, 2012.[109] In its second supplement to the Citizen Petition filed on March 21, 2013, Endo relied on NAVIPPRO and RADARS data it had received six weeks earlier.[110] Thus, we conclude that SEB has sufficiently alleged that the Exchange Act Defendants' statements regarding abuse deterrent features of reformulated Opana ER were false when made in the November 2012 Citizen Petition and March 2013 supplement.

SEB also alleges that Endo falsely claimed that reformulated Opana ER was "virtually identical" to reformulated Oxycontin.[111] In a third supplement to its Citizen Petition, Endo argued that the FDA should grant the Petition because of the two drugs' shared abuse-deterrent and physiochemical properties. *Id.* In fact, according to SEB, the drugs were "markedly different."[112] The post-marketing data for reformulated Opana ER was only preliminary and limited, unlike that for reformulated Oxycontin.[113] Reformulated Opana ER was also easily prepared for injection. Reformulated Oxycontin was not.[114] When it was placed in a syringe, it became "a viscous hydrogel" that made injection difficult.[115] SEB's allegations, if proven, will show that the Exchange Act Defendants knowingly misstated the similarities between reformulated Oxycontin and Opana ER.

Opinions and Forward-Looking Statements

The Exchange Act Defendants argue the statements were "forward-looking" statements protected by the PSLRA safe harbor provision, 15 U.S.C. § 78u–5(c)(1), and reasonably held expressions of personal belief. Some are protected and some are not. Some were misleading because they failed to disclose countervailing facts.

The PSLRA insulates defendants from liability for "forward-looking" statements such as projections, plans, objectives or assumptions about future performance. 15 U.S.C. §§ 78u–5(c), (i)(1). The PSLRA's safe harbor provision provides that:

> [A] person . . . shall not be liable with respect to any forward-looking statement, whether written or oral, if and to the extent that—
>
> ((A) the forward-looking statement is—
>
> (i) 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; or
>
> (ii) immaterial; or
>
> (B) the plaintiff fails to prove that the forward-looking statement—
>
> (i) if made by a natural person, was made with actual knowledge by that person that the statement was false or misleading; or
>
> (ii) if made by a business entity; was—
>
> (I) made by or with the approval of an executive officer of that entity; and
>
> (II) made or approved by such officer with actual knowledge by that officer that the statement was false or misleading.

Id. § 78u–5(c)(1); *see Avaya*, 564 F.3d at 267.

A forward-looking statement is defined as:

> (A) a statement containing a projection of revenues, income (including income loss), earnings (including earnings loss) per share, capital expenditures, dividends, capital structure, or other financial items;
>
> (B) a statement of the plans and objectives of management for future operations, including plans or objectives relating to the products or services of the issuer;
>
> (C) a statement of future economic performance, including any such statement contained in a discussion and analysis of financial condition by the management or in the results of operations included pursuant to the rules and regulations of the Commission;
>
> (D) any statement of the assumptions underlying or relating to any statement described in subparagraph (A), (B), or (C);
>
> (E) any report issued by an outside reviewer retained by an issuer, to the extent that the report assesses a forward-looking statement made by the issuer; or
>
> (F) a statement containing a projection or estimate of such other items as may be specified by rule or regulation of the Commission.

15 U.S.C. § 78u–5(i)(1).

A person is not liable for a forward-looking statement unless he or she actually knew that the statement was false or misleading. § 78u-5(c)(1)(B)(i). To hold a corporation liable, the plaintiff must prove that the statement was made by and with the approval of an executive officer who knew the statement was false or misleading. § 78u-5(c)(1)(B)(ii).

Statements that are forward-looking, standing alone, do not automatically invoke the safe harbor provision. To qualify for protection, the statements must be identified as forward-looking and include "meaningful cautionary statements." 15 U.S.C. § 78u–

5(c)(1)(A)(i); *OFI Asset Mgmt.*, 834 F.3d at 491. Significantly, they also must be accompanied by disclosure of "important factors that could cause actual results to differ materially" from the forward-looking statements. *OFI Asset Mgmt.*, 834 F.3d at 490 (citing 15 U.S.C. § 78u–5(c)(1)).

Cautionary language must be substantive and specific. *OFI Asset Mgmt.*, 834 F.3d at 491. Merely including language at the beginning or end of a statement that it is a subjective expression of belief is not enough, especially where there are embedded facts in the statement. The statements must include facts that the issuer knows contradict the forward-looking statement.

In addition, subjective statements of motive, intention, optimism or opinion are mere "puffery" that reasonable investors recognize to be nothing more. *In re Aetna, Inc. Sec. Litig.*, 617 F.3d 272, 283 (3d Cir. 2010). "Opinions are only actionable if they are not honestly believed and lack a reasonable basis." *City of Edinburgh Council v. Pfizer, Inc.*, 754 F.3d 159, 170 (3d Cir. 2014).

An opinion about data cannot be considered reasonably held if it is not supported by the evidence or ignores contradictory results in the same data. Affirmative statements about a drug's efficacy and safety may be actionable if the underlying clinical data contradicts or does not support them. *See, e.g.*, *In re PTC Therapeutics, Inc. Sec. Litig*., Civ. A. No. CV161124KMMAH, 2017 WL 3705801, at *11–14 (D.N.J. Aug. 28, 2017); *In re Viropharma, Inc. Sec. Litig.*, No. Civ. A. No. 02-1627, 2003 WL 1824914, at *6 (E.D. Pa. Apr. 7, 2003); *see also Pfizer*, 754 F.3d at 170 (suggesting that a company's failure to accurately disclose clinical data may be actionable where it made affirmative false statements about a drug's safety). A failure to disclose clinical data that is inconsistent

with the defendant's expressed interpretation may also be actionable. *See Pfizer*, 754 F.3d at 170. This is what SEB claims here.

Nonetheless, there is no duty to disclose all material information. *Globus Med.*, 869 F.3d at 241. Non-disclosure of material information is actionable only if there is an affirmative duty to disclose. *Globus Med.*, 869 F.3d at 241. A duty arises when disclosure is necessary to make statements not misleading. *In re Aetna*, 617 F.3d at 283.

A corporation is not required to disclose a fact simply because a reasonable investor would like to know it. *In re Burlington*, 114 F.3d at 1432 (quoting *In re Time Warner Inc. Sec. Litig.*, 9 F.3d 259, 267 (2d Cir. 1993)). However, once a company has chosen to speak on an issue, even one it had no independent obligation to discuss, it cannot omit material facts related to that issue. *In re Aetna*, 617 F.3d at 283.

With these standards in mind, we consider whether SEB has sufficiently alleged facts which, if proven, would establish that the Exchange Act Defendants' statements and omissions regarding anticipated FDA approval of the Citizen Petition and abuse-deterrent labeling, and their characterization of the surveillance data were false or misleading. We must determine whether the statements are protected by the safe harbor provision.

SEB alleges that the Exchange Act Defendants made material misrepresentations regarding the sufficiency of the surveillance data.[116] It argues the defendants' statements heralding favorable abuse trends and the crush-resistant formulation were false and misleading because they were only half-truths. SEB claims the defendants did not disclose the adverse data that was known to them. In other words, SEB accuses the Exchange Act Defendants of failing to identify the increased injection abuse rates that

they knew would likely result in the disapproval of abuse-deterrent labeling and withdrawal of reformulated Opana ER from the market.

The Exchange Act Defendants contend most of the challenged statements are subjective interpretations of data. Some are. Some are not.

Some of the Individual Exchange Act Defendants' statements appear to be expressions of personal belief. But, the allegations that they knew of the countervailing information show that the beliefs were not reasonably held. Given the FDA's attitude towards opioid drug abuse, the Individual Exchange Act Defendants had to know that the actual surveillance data would jeopardize FDA approval of abuse-deterrent labeling.

Certain Exchange Act Defendants represented there was sufficient clinical data to support a determination that reformulated Opana ER was safer and less prone to abuse.[117] At the time they made those statements, they knew the data actually indicated intravenous abuse had increased significantly. In claiming there was enough evidence to support the drug's abuse-deterrent effect, these defendants did not express opinions but made affirmative false statements about reformulated Opana ER's efficacy and safety. *See In re PTC Therapeutics*, 2017 WL 3705801, at *14 (finding the defendants made actionable misrepresentations where they stated or implied that clinical data showed the effectiveness of the drug, but trial results actually failed to meet statistical endpoints); *Local 731 I.B. of T. Excavators & Pavers Pension Tr. Fund v. Swanson*, Civ. A. No. 09-799, 2011 WL 2444675, at *10–11 (D. Del. June 14, 2011) (finding the defendant made material misrepresentations by publicly confirming the strength of the print yellow pages market when it knew that print sales were declining). These statements reporting a reduction of abuse were misrepresentations.

Endo submitted its Citizen Petition in August 2012 requesting the FDA to declare that original Opana ER was discontinued for safety reasons.[118] While the petition was pending, Endo insisted there was sufficient data to support its request.[119] In a supplement to the Citizen Petition, Endo likened reformulated Opana ER to reformulated OxyContin, which the FDA had recently approved for abuse-deterrent labeling.[120] Nevertheless, in its Form 10-Q, Endo cautioned that "uncertainty remain[ed] with respect to how the FDA [would] respond" to its Citizen Petition.[121] Despite "believ[ing] [Endo's] situation share[d] many similarities to the original OxyContin," Endo warned there was "no assurance that a similar determination [would] be made" for reformulated Opana ER.[122] In other words, even though they were instilling hope in their investors, the Exchange Act Defendants made no promises regarding the ultimate outcome of Endo's request. However, at the same time, they failed to disclose the unfavorable data that would inform the FDA's decision.

In a November 30, 2012 press release, David Holveck, then Endo's President and Chief Executive Officer, is quoted as claiming, "[s]ufficient evidence exists to support the determination that the old formulation of OPANA ER was discontinued for reasons of safety."[123] He retired two weeks later.[124] He argues that his statement was a subjective interpretation of data and a general expression of his belief. This statement was not false. Without more, these allegations are insufficient to show that Holveck made any material misrepresentations or omissions.

Blaine Davis, Ivan Gergel and Julie McHugh participated in a quarterly earnings conference call on February 28, 2013 during which they made statements regarding

surveillance data results. They characterized the results as encouraging, robust and compelling evidence of a reduction in abuse rates.[125]

Characterizations of clinical data as "robust" and "compelling" may be subjective interpretations recognized as immaterial opinions. *Pfizer*, 754 F.3d at 170. As subjective interpretations of clinical data, they are mere opinions and statements of optimism. *Id.* However, statements that the data showed a significant reduction in abuse between the original and new formulation were not completely accurate.

Davis represented that the data "clearly show a significant reduction in abuse by those methods [those related to the original formulation, such as intranasal] which I think is some of the most important characteristic [*sic*] of the data we've generated so far."[126] McHugh added, "[W]e have an additional quarter of surveillance data that indicates our abuse deterrent formulation of Opana ER is abused or misused at a rate that is 80% lower than the generic versions of extended release oxymorphone that were on the market in 2012."[127]

Gergel elaborated, "We think the epidemiological surveillance that we're getting in is very supportive of what we expect these abuse deterrent formulations should do i[n] supporting our original contention in this regard."[128] He emphasized that "[i]t's all going in the right direction."[129] He added, "[I]ntuitively one would expect these abuse deterrent formulations to lower rates of abuse and that's what we're seeing. From our perspective, as I said, the data is very encouraging and it's reasonably robust."[130]

Referencing NAVIPPRO and RADARS, Gergel reported that "when we look at comparisons between our current formulation and generic [original] formulations on the market, we see a difference in abuse rates. We saw differences in abuse rates when we

first brought our product to market so I think we very much stand by our data. It's robust and compelling."[131]

The truth, as alleged by SEB, was that the data was not going in the right direction. On the contrary, it was demonstrating an increased rate of abuse by injection. The statements were tantamount to a claim that abuse rates were reduced when in fact the intravenous abuse rate had increased. The Exchange Act Defendants argue that these statements reflected subjective interpretation of the data and were not affirmative statements. Blaine Davis also claims that he was merely expressing his belief. At most, according to these defendants, their statements were puffery and forward-looking.

Of course, characterizing the data as "robust," "reasonably robust," and "very encouraging" was both puffery and a statement of belief. But, the statements were much more. They claimed that the abuse rates decreased when in fact the intravenous abuse rate increased. The defendants omitted this fact. Without that information, the statements were clearly misleading.

On March 6, 2013, responding to a question about post-marketing safety data at the Cowen Health Care Conference, Alan Levin, Endo's CFO, reported that "[w]e also saw a 59% reduction in abuse from the new formulation of Opana tamper-resistant versus the classic formulation . . . [a]nd we've now gotten data for the fourth quarter that would indicate that, that percentage is close to 80% . . . ."[132] He was speaking with authority and portraying himself as knowledgeable about the data.

Levin's statement is not a subjective interpretation or expression of belief. It is an affirmative statement that painted a favorable picture without including the details that would have presented a complete and less favorable one. In short, the statement was

misleading because it failed to disclose the countervailing evidence of the increase in intravenous abuse rates.

In May 2013, the FDA denied Endo's Citizen Petition.[133] It also denied Endo's sNDA request for abuse-deterrent labeling, which had been submitted in February of that year.[134] Several months later, De Silva stated at a healthcare conference that Endo was conducting a clinical program which would "hopefully" allow it to resubmit data to the FDA in support of potential relabeling.[135] In Endo's quarterly earnings call on February 28, 2014, he reiterated Endo's "hope[ ] . . . to apply for a label change sometime in the recent future[.]"[136] In a May 1, 2014 quarterly earnings call, he predicted that, if "all [went] well[,]" Endo would apply for a stronger label by early 2015.[137]

De Silva was "cautiously optimistic" about the amount of supporting data required by the FDA, which he understood might exceed that which Endo could produce.[138] During the May 11, 2015 quarterly earnings call, he stated, "[a] lot is going to depend on [the FDA's] view on how much epi data is required to make the case [for re-labeling]. So in our view, we have sufficient and robust enough data for their decision, but they may take a different view[.]"[139] Later that year, he also cautioned, replying to questions from analysts and conference attendees, "I would not say that we have a very clear view to how the FDA will look at this[,]" and "[t]here's always the debate with the FDA as to what [epidemiological data] is sufficient [for re-labeling]. But our beliefs [*sic*] is based on our discussion with the FDA[.]"[140]

In January 2016, Endo re-submitted its sNDA seeking abuse-deterrent labeling.[141] During Endo's second quarter 2016 earnings call on August 8, 2016, De Silva noted there was "a lot of debate" regarding the "FDA's own determination of what constitutes [abuse

deterrent]."[142] He indicated Endo would be speculating as to the future of abuse deterrent drugs in the market.[143]

De Silva's statements appear to be forward-looking and to contain cautionary language. They express optimism and, at the same time, warn that the FDA may have a different review of the data. But, the statements are incomplete. They were not accompanied by disclosure of the actual increase in intravenous abuse. That increase in abuse was certain to negatively impact the FDA's decision. Thus, because they did not disclose facts that contradicted them, the statements do not qualify for protection under the safe harbor provision.

In an August 12, 2016 press release, Susan Hall, who was Executive Vice President and CSO at the time, was quoted, "We anticipate the generation of additional data and we will seek collaboration with FDA to appropriately advance OPANA® ER."[144] This statement was not "false or misleading." Hall stated only that she believed that Endo would produce additional data and attempt to collaborate with the FDA to "appropriately advance" the drug. She did not comment on what that data might show, whether the FDA would agree to collaborate with Endo, and, even if it did, what might be the result of any "appropriate advancement" of Opana ER. Her statement was an accurate description of Endo's plan.

A March 2017 press release quotes Matthew Davis, then Senior Vice President, Research & Development Branded Pharmaceuticals, as saying, "Endo remains confident that the body of evidence established through clinical research demonstrates that OPANA® ER has a favorable risk-benefit profile when used as intended in appropriate patients[.]"[145] The statement was true. It was also qualified because it used the words

"when used as intended in appropriate patients." Indeed, the press release, commenting on the Advisory Committee's vote, announced that it would "evaluate the range of available options for maintaining access for legitimate use."[146] The press release promised nothing more. Therefore, the statement was not a misrepresentation.

During the May 9, 2017 quarterly earnings call, Paul Campanelli, the President and Chief Executive Officer, answered questions regarding Opana ER.[147] He claimed it was "business as usual" with the drug.[148] He stated that Endo was "being a little proactive" about the "things that we had pitched at the Ad Com" and that Endo wanted to "follow up" with the FDA regarding reformulated Opana ER.[149] He stated that Endo was "in preparation on concepts and ideas" that it wanted to communicate to the FDA, but acknowledged that at that time any such communications or follow up would be "premature" and that no formal discussions had taken place.[150] SEB characterizes these comments as "downplaying" the import of the Advisory Committee's vote and "touting" the possibility that reformulated Opana ER would remain on the market.

Campanelli's optimism appears to be unwarranted in light of the Committee's vote that the drug's benefits did not outweigh its risks. However, he was not hiding anything. A few days prior to the vote, the FDA published briefing documents showing that Endo's own post-marketing surveillance data and the insufflation and epidemiological studies had demonstrated a shift to intravenous abuse. At that point, the truth was out. Campanelli's optimistic statements regarding future discussions with the FDA were mere puffery that did not alter the mix of substantive information available to investors. They also contained cautionary language regarding the "premature" timing of any discussions with the FDA

and an acknowledgement that no formal discussions had occurred. His statements are not actionable.

In summary, the Exchange Act Defendants did not guarantee favorable outcomes. Nor did they represent the data was absolutely sufficient for FDA approval. They warned that the FDA may have a different view of the sufficiency of the data. They conveyed their personal assessments of the information. Representations related to the Citizen Petition and sNDA determinations were not, by themselves, materially false or misleading. *See In re Amarin Corp. PLC Sec. Litig.*, 689 F. App'x 124, 131 & n.10 (3d Cir. 2017) (finding no false or misleading statement in part because the defendants never stated that its special protocol assessment would be accepted by the FDA and warned approval was not guaranteed); *Bauer v. Eagle Pharm., Inc.*, Civ. A. No. 16-3091(JLL), 2017 WL 2213147, at *9 (D.N.J. May 19, 2017) (finding statements relating to anticipated FDA approval to be forward-looking).

Standing alone, the qualified cautionary statements about the prospect of FDA approval facially appear to be forward-looking statements protected by the safe harbor provision. But, when considered in context with the actual known data showing an increase in intravenous abuse, the statements of Blaine Davis, Gergel, McHugh, Levin and De Silva are not protected because they did not identify the data that contradicted those statements. These defendants expressed optimism that approval of abuse-deterrent labeling would come. When they did so, they emphasized the favorable abuse data in support of their FDA submissions without disclosing the unfavorable data. Withholding the evidence of increased intravenous abuse, undoubtedly would, as indeed it did, influence the FDA's decision. Thus, it was a material omission. *See Schueneman*

v. Arena Pharm., Inc., 840 F.3d 698, 707–08 (9th Cir. 2016) (finding that once the defendants affirmatively represented that all of its animal studies supported its case for FDA approval, they had a duty to disclose the adverse study showing tumor growth related to their drug); *In re Viropharma Inc. Sec. Litig.*, 21 F. Supp. 3d 458, 471 (E.D. Pa. 2014) (determining defendants made material omissions by failing to reveal the FDA's conclusion that its Genzyme Study was deficient because it bore directly on its discussions regarding market exclusivity); *cf. Pfizer*, 754 F.3d at 170 (indicating that a company's failure to accurately disclose clinical trial data may be actionable, but suggesting no duty to disclose where there were no affirmative statements about its Phase 2 study results).

The statements made by Holveck, Matthew Davis, Hall and Campanelli were not misleading. Unlike Blaine Davis, Gergel, McHugh, Levin and De Silva, these individuals did not tout the data supporting reformulated Opana ER's safety while ignoring contrary data. Their statements were not false, and the Section 10(b) and Rule 10b-5 claims against them must be dismissed.

Materiality

Only material omissions and misrepresentations are actionable. *Dura Pharm.*, 544 U.S. at 341. A statement or omission is material if there is a substantial likelihood a reasonable shareholder would consider it in making an investment decision. *In re Aetna*, 617 F.3d at 283. It must significantly alter the "total mix" of available information, rendering it false or incomplete. *Id*.

The materiality of a misrepresentation or omission is measured by the effect of the disclosure of the facts on the stock's price. *In re Constar Int'l Inc. Sec. Litig.*, 585 F.3d

774, 783 (3d Cir. 2009) (citing *Oran*, 226 F.3d at 282); *In re Merck Derivative & "ERISA" Litig.*, 543 F.3d 150, 168 (3d Cir. 2008).[151] Thus, for stock traded in an efficient market, "the materiality of disclosed information may be measured post-hoc by looking to the movement, in the period immediately following disclosure, of the price of the firm's stock." *In re Constar Int'l*, 585 F.3d at 783 (quoting *Oran*, 226 F.3d at 282).

Where the price of the stock falls immediately after the disclosure of the real or the omitted facts, the prior nondisclosure is presumed to have caused the downward adjustment of the price because it was one of those components that the investor had factored into his decision to buy the stock. In that case, the information is material. *See In re Merck*, 432 F.3d at 269. Conversely, if the price does not fall or falls only negligibly, the information is deemed immaterial. *See In re Merck Derivative & "ERISA" Litig.*, 543 F.3d at 168; *Oran*, 226 F.3d at 282; *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d at 1425.

Endo's stock price dropped significantly after each revelation of actual facts about the drug's safety and its lack of abuse-deterrent properties were revealed. When the market learned that FDA approval of abuse-deterrent labeling was jeopardized because there was increased evidence of abuse through injection and that the drug was not similar to reformulated OxyContin, the price plummeted. When the FDA denied Endo's Citizen Petition on May 10, 2013 because Endo's data was "preliminary," "inconclusive," and deficient, the stock price fell 8.88% over the next three days.[152] Later, in response to the FDA's announcement on January 10, 2017 that it was commencing an Advisory Committee to address concerns with the risk-benefit of the drug, the stock price dramatically dropped that day and the next.[153] Two months later, on March 9, 2017, in

the wake of the FDA's release of its preliminary views of the safety and abuse-deterrent properties of the drug, the price fell again.[154] Five days later, the FDA Advisory Committee concluded that the benefits of reformulated Opana ER did not outweigh its risks to the public. In response, stock prices tumbled from its March 13, 2017 closing price.[155]

The substantial fall in Endo's stock price upon each revelation about Opana ER's lack of safety and abuse-deterrent properties demonstrate that the representations and the omissions were material. The market's reaction shows than an investor would want to know that surveillance data was revealing an increase in the injection abuse rate.

Scienter

"To establish liability under § 10(b) and Rule 10b–5, a private plaintiff must prove that the defendant acted with scienter, 'a mental state embracing intent to deceive, manipulate, or defraud.'" *Tellabs*, 551 U.S. at 319 (quoting *Ernst & Ernst*, 425 U.S. at 193-94 & n.12 (1976)). The plaintiff must show that the defendant intended to mislead investors or acted recklessly in the face of a danger of misleading investors. *Belmont v. MB Inv. Partners, Inc.*, 708 F.3d 470, 493 (3d Cir. 2013). In other words, to satisfy the scienter element, the plaintiffs must establish that the defendants acted consciously or recklessly. *Avaya,* 564 F.3d at 267.

As noted earlier, the PSLRA's scienter requirement imposes a greater burden than Rule 9(b), which permits state of mind to be averred generally. For each act or omission, the plaintiffs must allege the specific facts creating a strong, not just a reasonable, inference that the defendant acted with the required state of mind. 15 U.S.C. § 78u–4(b)(2); *Globus Med.*, 869 F.3d at 245.

A "strong inference" means "more than merely plausible or reasonable—it must be cogent and at least as compelling as any opposing inference of nonfraudulent intent." *Tellabs,* 551 U.S. at 314. A court must consider "plausible nonculpable explanations for the defendant's conduct" against the "inferences favoring the plaintiff." *Avaya*, 564 F.3d at 267 (quoting *Tellabs*, 551 U.S. at 324). 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." *Rahman v. Kid Brands, Inc.*, 736 F.3d 237, 247 (3d Cir. 2013) (quoting *Tellabs*, 551 U.S. at 323) (emphasis in *Tellabs*). Vague and ambiguous allegations militate against inferring scienter. *Tellabs*, 551 U.S. at 325–26.

Proof of motive and opportunity may not, on its own, establish scienter, but its presence "can be persuasive when conducting a holistic review of the evidence." *Rahman*, 736 F.3d at 245. It may be considered along with the other allegations in the complaint. *Avaya*, 564 F.3d at 277.

To show actual knowledge, SEB alleges the defendants used NAVIPPRO and RADARS data in 2012 and 2013 to support its Citizen Petition and sNDA for abuse-deterrent labeling.[156] SEB also alleges that once the FDA approved reformulated Opana ER, Endo held mandatory Risk Evaluation and Mitigation Strategy (REMS) meetings to discuss the drug's post-marketing safety data and prepare annual REMS assessments for submission to the FDA.[157] The REMS assessments addressed the status of any post-approval trials or clinical studies conducted to investigate the drug's safety.[158] Beginning in July 2014, the assessments included observed drug utilization patterns and surveillance data for misuse, abuse, overdose, and addiction of the drug.[159] Clearly, Endo

was regularly reviewing the post-marketing safety data which contradicted their public statements.

To plead recklessness, the plaintiff must allege that the reckless statement or omission "involved not merely simple, or even excusable negligence, but 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." *Belmont,* 708 F.3d at 493 (citations omitted). Although the Supreme Court in *Tellabs* did not consider whether and when recklessness satisfies the scienter requirement, the Third Circuit has held that a plaintiff may meet the scienter requirement by showing the defendant acted in reckless disregard of the truth. *Tellabs*, 551 U.S. at 319 n.3; *In re Hertz Global Holdings Inc.*, 905 F.3d 106, 114 (3d Cir. 2018); Avaya, Inc., 564 F.3d at 252.

If a plaintiff alleges conscious misbehavior or recklessness, "it is not enough for plaintiffs to merely allege that defendants 'knew' their statements were fraudulent or that defendants 'must have known' their statements were false." *GSC Partners CDO Fund v. Washington*, 368 F.3d 228, 239 (3d Cir. 2004). Nor can a plaintiff rely solely on an allegation that imputes knowledge to a defendant because of his or her position within the company. *Oran*, 226 F.3d at 290. A plaintiff must specifically allege facts constituting strong circumstantial evidence that a defendant actually knew or recklessly disregarded the false nature of the statement. *In re Urban Outfitters, Inc. Sec. Litig*., 103 F. Supp. 3d 635, 653 (E.D. Pa. 2015).

Where fraud is based on non-disclosure, scienter may be shown through evidence that defendants had actual knowledge of the information. *GSC Partners*, 368 F.3d at 239.

Knowledge under a recklessness theory can be established by demonstrating that the fact "'was so obviously material that the defendant must have been aware both of its materiality and that its non-disclosure would likely mislead investors.'" *Anderson v. Stonemor Partners, L.P.*, 296 F. Supp. 3d 693, 704 (E.D. Pa. 2017) (citing *City of Phila. v. Fleming Co.*, 264 F.3d 1245, 1261 (10th Cir. 2001)) (additional citation omitted).

Viewing the allegations proffered to satisfy the scienter requirement as a whole and considering all plausible opposing inferences of scienter, we conclude that SEB has sufficiently pled facts raising a strong inference of scienter. SEB alleges that the Individual Exchange Act Defendants had access to information and surveillance data showing that reformulated Opana ER was unsafe, associated with increased intravenous abuse, and not the same as the new OxyContin.[160]

Scienter cannot be imputed to the Individual Exchange Act Defendants by virtue of their positions alone. However, when the misrepresentations and omissions involve "core matters of central importance" to a company and its executives, an inference of scienter may arise. *In re Urban Outfitters*, 103 F. Supp. 3d at 653–54; *see also Rahman*, 736 F.3d at 246 (citing *Avaya*, 564 F.3d at 268); *In re Stonepath Grp., Inc. Sec. Litig.*, 397 F. Supp. 2d 575, 589 (E.D. Pa. 2005) (collecting cases).

SEB alleges the individual defendants, as executives, had access to detailed information regarding the company's business operations and financial condition, including information regarding the efficacy of reformulated Opana ER.[161] Their public comments regarding the clinical data in press releases and earnings calls confirm they had intimate knowledge of the data. Indeed, that is what they wanted the public, particularly investors, to think. These officers were speaking as authoritative sources who

possessed the information to support their statements. When they did so, they knew that withholding the negative data that contradicted their public statements was misleading to investors.

Opana ER was a significant profit generating product which was of great interest to Endo's executives.[162] It was Endo's second largest revenue source.[163] In 2010, original Opana ER earned roughly $240 million in sales.[164] The following two years, revenue from the drug totaled $384 and $300 million, respectively.[165]

After reformulated Opana ER was introduced, De Silva described it as Endo's "primary product."[166] From 2013 to 2016, Endo generated between $159 million and $227 million in annual revenue from the drug.[167] From 2010 to 2016, Endo earned over one billion dollars from Opana ER alone. It was a critical part of Endo's business.[168] *Cf. In re Viropharma*, 21 F. Supp. 3d at 473 (finding an inference of scienter where sales of Vancocin accounted for more than half of company revenue); *W. Palm Beach Police Pension Fund v. DFC Glob. Corp.*, Civ. A. No. 13-6731, 2015 WL 3755218, at *16 (E.D. Pa. June 16, 2015) (finding a strong inference of scienter where payday loans accounted for a majority of defendant's revenues). The executive officers undoubtedly would have been involved in or were familiar with the drug's development, approval process and marketing.

Considering the Individual Exchange Act Defendants' positions within the company, the information available to them, and their public statements, there is a strong and compelling inference they were aware of the adverse surveillance data. *See In re Urban Outfitters*, 103 F. Supp. 3d at 654. At least, the plaintiff's allegations raise a cogent inference that the defendants recklessly disregarded the facts they knew contradicted

their public statements. Given the importance of Opana ER to the company, the defendants' representations regarding the sufficiency and the results of the data created a serious risk of misleading investors. *See id.* at 653. Thus, when viewed collectively, the alleged facts give rise to a strong inference that Blaine Davis, Gergel, McHugh, Levin and De Silva acted with scienter when they failed to disclose the material evidence of increased intravenous abuse while touting reformulated Opana ER's safety.

Section 20(a) of the Exchange Act

Section 20(a) imposes liability on "controlling persons" for Exchange Act violations. *Belmont*, 708 F.3d at 484. It states:

> 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 to any person to whom 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).

For § 20(a) secondary liability to attach to any Exchange Act Defendants, SEB must allege facts showing they were "controlling persons" and had actual or constructive knowledge of the acts giving rise to primary liability, in which case the controlling persons are liable "to the same extent as" the controlled person. *See id.*

Showing that a controlled person is liable for an Exchange Act violation is insufficient to impose secondary liability upon a controlling person. *Belmont*, 708 F.3d at 484 (citing *In re Alpharma Inc. Sec. Litig.*, 372 F.3d 137, 153 (3d Cir. 2004), *abrogated on other grounds by Tellabs*, 551 U.S. 308). In addition to showing that the controlling person had power and influence over the controlled person, the plaintiff must show the

controlling person's culpable participation in the fraud. *Rochez Bros. v. Rhoades*, 527 F.2d 880, 890 (3d Cir. 1975). Culpable participation necessarily requires actual or imputed knowledge of the fraud. *Belmont*, 708 F.3d at 485 (citation omitted). It may be premised on the controlling person's failure to take action to correct the fraud, but the inaction must intentionally advance the fraud and prevent its discovery. *Id.* In other words, the inaction must be "consciously intended to aid the securities law violation." *Rochez Bros.*, 527 F.2d at 890 (citing *SEC v. Coffey*, 493 F.2d 1304, 1317 (6th Cir. 1974); *Hochfelder v. Midwest Stock Exch.*, 503 F.2d 364, 374 (7th Cir. 1974)) (additional citations omitted).

Corporate executives may be liable under § 20(a) where they participated in the daily management of the company, had intimate knowledge of the business, or otherwise had decision-making power. *See Rochez*, 527 F.2d at 891 (finding company's CEO and president was a controlling person where he ran the day-to-day business activities, owned a significant amount of stock, and had the power to influence company policies); *In re NUI Sec. Litig.*, 314 F. Supp. 2d 388, 417 (D.N.J. 2004) (denying motion to dismiss § 20(a) claim where executives had "direct and supervisory involvement in the day-to-day operations" of the company, intimate knowledge of its finances, and decision-making authority); *In re Rent-Way Sec. Litig.*, 209 F. Supp. 2d 493, 524 (W.D. Pa. 2002) (finding plaintiffs sufficiently alleged control person liability where individual defendants had direct and supervisory involvement in daily operations of the company, had ownership rights, and signed SEC filings).

SEB argues that all of the Individual Exchange Act Defendants were controlling persons because they were high-level executives or officers who directly participated in

the management of the company and had regular access to confidential information.[169] According to SEB, by virtue of their positions, the Individual Exchange Act Defendants "directly participated in the management" of Endo, were involved in Endo's day-to-day operations, and had direct and supervisory involvement in the company.[170] Further, SEB alleges they had access to confidential information concerning reformulated Opana ER and had the power to influence and control public statements during the Class Period.[171]

A controlling person is only liable "to the same extent" as the person he or she controls is liable. 15 U.S.C. § 78t(a). Controlling person liability cannot exist unless the controlled person is liable. *Chubb Corp.*, 394 F.3d at 159 n.21. Here, misleading statements were made by De Silva, Levin, Gergel, McHugh and Blaine Davis. The question is who, if any, of the Individual Exchange Act Defendants controlled these defendants at the time of each one's misleading statement.

De Silva, as president and CEO, was at the top of the Endo corporate hierarchy and was not controlled by any other Individual Exchange Act Defendant. He faces liability not only for his own misleading statements, but also for the misleading statements of the other defendants. SEB's allegations that he exercised supervisory control, had access to the studies and the data showing a shift to intravenous abuse, and had the power to influence and control others' statements are plausible in light of his position.

De Silva was CEO when CFO Levin made his misleading statement at a March 6, 2013 conference, and when Gergel, McHugh and Blaine Davis made their misleading statements on a quarterly earnings conference call on February 28, 2013.[172]

SEB has adequately alleged that De Silva controlled Levin, Gergel, McHugh and Blaine Davis at the time of their misleading statements. Although De Silva had access to

the studies and the data that contradicted these statements, he did nothing to correct them. This inaction was motivated by the desire to keep investors hopeful and stock prices elevated.

Endo's reformulated Opana ER was intended to stave off generic competition. The plan was two-pronged: create a reformulated drug that was abuse-deterrent in place of the original drug and then have the FDA declare the original drug withdrawn for safety reasons. If Endo was successful in having the original drug declared unsafe, all generics based upon the original formula would also have to be withdrawn. If the new drug was not abuse deterrent, there was no chance of obtaining FDA approval of abuse-deterrent labeling. Thus, if the data showing an increase in intravenous abuse were known, investors would think that FDA approval would be jeopardized, in which case the new drug, without abuse-deterrent labeling, would be a less desirable product and less likely to be prescribed.

De Silva's inaction advanced the fraud and makes him a culpable participant in the fraud. He had access to and knowledge of detailed information regarding the data for reformulated Opana ER. This data contradicted the statements made by those subordinate to him, but he failed to disclose it. Thus, SEB has stated a § 20(a) claim against De Silva.

No other Individual Exchange Act Defendant controlled Levin, Gergel, McHugh or Blaine Davis at the time of their misleading statements in February and March 2013. Matthew Davis, Campanelli, Hall and Holveck were not employed by Endo at that time.[173] Nor did Levin, Gergel, McHugh or Blaine Davis control each other. Levin, Gergel and McHugh were chief financial, scientific and operating officer, respectively.[174] There is no

basis to infer that any of these chief officers controlled any other chief officer, especially one in another department. Blaine Davis was Senior Vice President of Corporate Affairs, apparently also a different department from Levin, Gergel and McHugh.[175] He would not have controlled or been controlled by any of them. Thus, SEB has not stated a § 20(a) claim against any of the other Individual Exchange Act Defendants.

Securities Act Claims

Section 11 of the Securities Act

The Individual Securities Act Defendants argue that the claims for violations of § 11 of the Securities Act, 15 U.S.C. § 77k, should be dismissed under the *Colorado River* doctrine because SEB has made nearly identical allegations in a parallel state court complaint.[176] In addition, they maintain the Securities Act claims fail because SEB has not alleged any false or misleading statements or omissions in its offering materials.[177]

The *Colorado River* doctrine permits district courts to abstain from exercising jurisdiction where there is an ongoing parallel state court action. *Colorado River Water Conservation Dist. v. United States*, 424 U.S. 800 (1976); *Nat'l City Mortg. Co. v. Stephen*, 647 F.3d 78, 83 (3d Cir. 2011). It is narrowly applied and invoked only in exceptional circumstances. *Colorado River*, 424 U.S. at 813.

Before we reach the issue whether there are extraordinary circumstances warranting abstention, we must determine whether the state court proceeding is a parallel one. *Nationwide Mut. Fire Ins. Co. v. George V. Hamilton, Inc.*, 571 F.3d 299, 307–08 (3d Cir. 2009) (citing *Yang v. Tsui*, 416 F.3d 199, 204 n.5 (3d Cir. 2005)). Proceedings are parallel if they involve identical or effectively similar parties and claims. *Kelly v. Maxum Specialty Ins. Grp.*, 868 F.3d 274, 285 (3d Cir. 2017). If the claims in federal court

are distinct from those in state court, "like where parties in 'the two cases employ [ ] substantially different 'approaches' [which] might 'achieve potentially different results,'" they are not parallel. *Id.* (citation omitted).

The Securities Act Defendants argue the Securities Act claims have already been asserted by the same plaintiff class in a state court action.[178] We disagree.

Though both actions involve the June 2015 Offering, the alleged misrepresentations are different. Here, SEB alleges misrepresentations regarding abuse of reformulated Opana ER. It claims that the offering materials failed to disclose information demonstrating a rise in intravenous abuse, focusing only on the crush-resistant formulation.[179] The state court action, *Public Employees' Retirement System of Mississippi v. Endo International PLC*,[180] focuses exclusively on Endo's generic division, its unsustainable trade practices, and declining sales of hydrocodone and generic pain medications.[181] In short, the two suits concern different products and different conduct. Therefore, because the two actions are not parallel, we decline to abstain.

We turn to the substance of SEB's claims regarding the registration statements. Purchasers of securities may sue for material misstatements or omissions in registration statements. 15 U.S.C. § 77k(a); *Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund,* -- U.S. --, 135 S. Ct. 1318, 1323 (2015). To establish a *prima facie* § 11 cause of action, plaintiffs must establish that the registration statement, as of its effective date, contained an untrue statement of material fact, omitted a material fact that was required to be stated, or omitted a material fact necessary to make the statement not misleading. *In re Constar Int'l*, 585 F.3d at 782–83 (citing *In re Suprema,* 438 F.3d at 269).

An issuer of a registration statement is liable not only for a misrepresentation of a material fact, but also for an omission of a material fact necessary to make statements not misleading. In other words, liability arises out of not only "what the statement says," but also "what it leaves out." *Omnicare*, 135 S. Ct. at 1323.

Fraud is not a necessary element to establish a *prima facie* case under § 11. *In re Suprema*, 438 F.3d at 270. Only if the claims are grounded in fraud are they subject to heightened pleading standards under Fed. R. Civ. P. 9(b). *Id*. Thus, Rule 9(b) does not apply to Securities Act claims based on negligence. *Id.* at 274; *see also Se. Pa. Transp. Auth. v. Orrstown Fin. Servs., Inc.*, Civ. A. No. 12-CV-00993, 2016 WL 7117455, at *9 (M.D. Pa. Dec. 7, 2016) (finding no heightened pleading requirement under Rule 9(b) where the plaintiff prefaced its Securities Act allegations by excluding any allegations that could be construed as alleging fraud and rooting its claims exclusively in the theories of negligence and strict liability).

SEB affirmatively pleads negligence, not fraud. In the preface to the Securities Act claims, SEB states that it "expressly excludes and disclaims any allegation that could be construed as alleging or sounding in fraud or intentional or reckless misconduct. *This claim is based solely on negligence and/or strict liability*."[182] Accordingly, heightened Rule 9(b) pleading is not required. *See In re Suprema*, 438 F.3d at 272.

Section 11 is virtually an absolute liability statute that does not require allegations of scienter. *Id.* at 269 (citation omitted); *Omnicare*, 135 S. Ct. at 1323. A plaintiff who purchased a security issued pursuant to a registration statement must only show a material misstatement or omission to establish a *prima facie* case. *In re Constar Int'l*, 585

F.3d at 782; *In re Suprema*, 438 F.3d at 270. The test for materiality under § 11 and § 10(b) are the same. *In re Constar Int'l*, 585 F.3d at 783.

Statements of opinion are material misrepresentations under § 11 if the opinion is not subjectively believed or the facts embedded within the opinion are untrue. *Omnicare*, 135 S. Ct. at 1327. Opinions are actionable if the registration statement omits material facts about "the issuer's inquiry into or knowledge concerning" the opinion and the facts "conflict with what a reasonable investor would take from the statement itself." *Id.* at 1329.

SEB alleges the June 2015 Offering Materials[183] contained material misstatements by extolling the crush-resistant formulation of reformulated Opana ER without presenting the data demonstrating the drug could be manipulated.[184] Contrary to Endo's repeated assurances that the studies demonstrated a decrease in abuse rates, the truth was that there was an increase in intravenous abuse.[185] This shift to the more dangerous intravenous abuse was documented in reports from NAVIPPRO and RADARS no later than the third quarter of 2013.[186] By this time, Endo's own post-marketing surveillance data also showed an increasing number of serious adverse events linked to injection, such as TTP.[187] SEB maintains that despite knowing the increased rate in injection use, Endo failed to disclose to investors that it faced a serious risk of regulatory action, including removal of the drug from the market.[188]

In other words, SEB alleges the June 2015 Offering Materials contained the same misrepresentations and omissions that we have already determined were material under § 10(b). Because SEB has alleged material misrepresentations and omissions regarding the safety and the abuse of reformulated Opana ER, it has stated a § 11 claim.

Section 15 of the Securities Act

Section 15 of the Securities Act imposes joint and several liability on any person who controls anyone liable under § 11 of the Securities Act. 15 U.S.C. § 77o(a); *In re Suprema*, 438 F.3d at 285. A plaintiff must show that one person controlled another and the controlled person violated securities laws. *In re Suprema*, 438 F.3d at 284. Establishing liability of the controlled person is required for relief under § 15. *Id.* at 285.[189]

SEB has alleged that the Individual Securities Act Defendants controlled Endo. It claims that each was a director or officer of Endo, participated in the day-to-day operation and management of the company, signed the offering materials, and controlled the material contents.[190] *See Peltz v. Polyphase Corp.*, 36 F. App'x 316, 321 (9th Cir. 2002) (directors' awareness and participation in filing of allegedly misleading SEC filing exposed them to control person liability notwithstanding lack of participation in company's daily operations); *In re Wilmington Tr. Sec. Litig.*, 29 F. Supp. 3d 432, 454 (D. Del. 2014) (finding that plaintiffs adequately pled control under §§ 15 and 20 where defendants sent emails, controlled the content of public statements, and signed 10-K forms, offering documents and the registration statement); *In re Am. Bus. Fin. Servs., Inc. Sec. Litig.*, Civ. A. No. 05-232, 2007 WL 81937, at *12 (E.D. Pa. Jan. 9, 2007) ("Allegations that a director signed a fraudulent SEC filing and was in a position to exercise control over the primary violator are sufficient to withstand a motion to dismiss" for control person liability) (citation omitted). Therefore, SEB has stated a claim for control person liability under § 15 against the Individual Securities Act Defendants.

Conclusion

SEB has sufficiently alleged that De Silva, Levin, Gergel, McHugh and Blaine Davis, consciously or recklessly made material misrepresentations and omissions regarding the safety of Opana ER, including its susceptibility to manipulation for intravenous abuse and the results of surveillance data. These misrepresentations and omissions expose Endo and these defendants to liability under § 10(b) of the Exchange Act and Rule 10b-5 and De Silva to control person liability under § 20(a) of the Exchange Act. SEB also alleges that in the June 2015 offering materials the Securities Act Defendants similarly overstated Opana ER's safety while failing to disclose the shift toward intravenous abuse of the drug. These misrepresentations and omissions expose them to liability under § 11 of the Exchange Act and to control person liability under § 15 of the Exchange Act.

SEB has not alleged facts stating claims against Holveck, Matthew Davis, Hall and Campanelli. SEB has stated a claim under § 20 of the Exchange Act against De Silva only. Thus, we shall grant the motion as to Holveck, Matthew Davis, Hall and Campanelli and deny it as to the other defendants.

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[1] The Individual Exchange Act Defendants are Paul Campanelli, Blaine Davis, Matthew Davis, Rajiv Kanishka Liyanaarchchie De Silva, Ivan Gergel, Susan Hall, David Holveck, Alan Levin, and Julie McHugh. With Endo, they are the Exchange Act Defendants. Am. Compl. (Doc. No. 36) ¶¶ 27–36.

The Individual Securities Act Defendants are De Silva, Suketu Upadhyay, Daniel Rudio, Roger Kimmel, Shane Cooke, John Delucca, Arthur Higgins, Nancy Hutson, Michael Hyatt, William Montague, Jill Smith, and William Spengler. With Endo, they are the Securities Act Defendants. *Id.* ¶¶ 354–65.

[2] *Id.* ¶ 38.

[3] *Id.* ¶¶ 50–51, 55.

[4] *Id.* ¶ 55.

[5] *Id.* ¶¶ 54–55.

[6] *Id.* ¶ 54.

[7] *Id.* ¶ 66.

[8] *Id.*

[9] *Id.* ¶ 67.

[10] *Id.* ¶¶ 68–69, 72–74.

[11] *Id.* ¶ 76.

[12] *Id.* ¶¶ 60–61, 64–65.

[13] *Id.* ¶ 65.

[14] *Id.* ¶ 61.

[15] *Id.* ¶ 78.

[16] *Id.* ¶ 80.

[17] *Id.* ¶ 83.

[18] *Id.* ¶ 84.

[19] *Id.* ¶¶ 84–85.

[20] *Id.* ¶ 86.

[21] NAVIPPRO is a national program that performs surveillance of substance abuse. *Id.* ¶ 88. RADARS provides surveillance data to meet the needs of pharmaceutical companies, policy makers, regulatory agencies, medical and public health officials, and the public in addressing concerns of prescription drug abuse. *Id.*

[22] *Id.* ¶¶ 87–88.

[23] *Id.* ¶ 91.

[24] *Id.* ¶ 89.

[25] *Id.*

[26] *Id.*

[27] The proposed class period is from November 30, 2012 June 8, 2017. *Id.* ¶ 322.

[28] *Id.* ¶ 93.

[29] *Id.* ¶ 157.

[30] *Id.* ¶ 158.

[31] *Id.* ¶ 94.

[32] *Id.*

[33] *Id.* ¶ 95.

[34] *Id.* ¶ 95.

[35]*Id.* ¶ 98.

[36] *Id.* ¶¶ 97, 170–73.

[37] *Id.* ¶ 174.

[38] *See id.* ¶ 168; *see also, e.g.*, *id.* ¶¶ 97, 179.

[39] *Id.* ¶¶ 99–101.

[40] *Id.* ¶ 100.

[41] *Id.* ¶¶ 103–04.

[42] *Id.* ¶¶ 105–06.

[43] *Id.* ¶ 198.

[44] *Id.* ¶ 107.

[45] *Id.*

[46] *Id.*

[47] *Id.* ¶ 185.

[48] *Id.* ¶ 109.

[49] *Id.*

[50] *Id.* ¶ 110.

[51] *Id.* ¶ 111.

[52] *Id.* ¶ 113.

[53] *Id.* ¶ 200.

[54] *See id.*

[55] *See id.* ¶¶ 115, 204; *see also id.* ¶¶ 116, 206, 210–11.

[56] *Id.* ¶ 119.

[57] *Id.*

[58] *Id.*; *see also id.* ¶¶ 121–25, 130–31.

[59] *Id.* ¶ 127.

[60] *Id.* ¶ 132.

[61] *Id.* ¶ 225.

[62] *Id.* ¶¶ 226–27.

[63] *Id* ¶¶ 352, 366.

[64] *Id.* ¶¶ 354–65.

[65] *Id.* ¶ 368.

[66] *Id.* ¶ 369.

[67] *Id.* ¶¶ 231–32.

[68] *Id.* ¶ 235.

[69] *Id.* ¶ 236; *see also id.* ¶¶ 18, 19, 304.

[70] *Id.* ¶ 237.

[71] *Id.*

[72] *Id.* ¶ 133.

[73] *Id.* ¶ 241.

[74] *Id.* ¶ 134.

[75] *Id.* ¶ 135.

[76] *Id.* ¶ 250.

[77] The Drug Safety and Risk Management Advisory Committee is an FDA advisory committee that advises the Commissioner of Food and Drugs on risk management and evaluation of drugs for which the FDA has regulatory responsibility. It also advises the Commissioner on the scientific and medical evaluation of information regarding the safety, efficacy, and potential abuse of drugs. *Drug Safety and Risk Management Advisory Committee*, U.S. FOOD AND DRUG ADMINISTRATION (FDA), https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/DrugSafetyandRiskManagementAdvisoryCommittee/default.htm (last visited December 10, 2018). The Anesthetic and Analgesic Drug Products Advisory Committee is an FDA advisory committee that reviews and evaluates data on the safety and effectiveness of drugs used in anesthesiology and surgery. *Anesthetic and Analgesic Drug Products Advisory Committee*, U.S. FOOD AND DRUG ADMINISTRATION (FDA), https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndAnalgesicDrugProductsAdvisoryCommittee/default.htm (last visited December 10, 2018).

[78] Am. Compl. ¶¶ 137–38.

[79] *Id.* ¶ 139.

[80] *Id.* ¶ 140.

[81] *Id.*

[82] *Id.*

[83] *Id.* ¶ 141.

[84] *Id.* ¶ 141–44 (quotation omitted).

[85] *Id.* ¶ 145.

[86] *Id.* ¶ 146.

[87] *Id.* ¶ 148.

[88] *Id.* ¶ 147.

[89] *Id.* ¶ 255.

[90] *Id.* ¶¶ 261–62.

[91] *Id.* ¶ 149.

[92] *Id.*

[93] *Id.*

[94] *Id.*

[95] *Id.* ¶ 150.

[96] *Id.* ¶ 151.

[97] Resp. to Mot. to Dismiss (Doc. No. 38) at 12, 15; *see also, e.g.*, Am. Compl. ¶¶ 96, 206–07.

[98] Resp. to Mot. to Dismiss at 15.

[99] *See* Am. Compl. § VI; *see also, e.g.*, *id.* ¶¶ 105-06, 163, 177, 185-86, 198; Resp. to Mot. to Dismiss Ex. A (Doc. No. 38-1) § 1, at 1–17.

[100] *See, e.g.*, Am. Compl. ¶¶ 71–73, 87–88, 123–31.

[101] FAERS is the FDA's Adverse Event Report System, which SEB alleges demonstrated a significant rise in rates of abuse after reformulated Opana ER came to market. Am. Compl. ¶ 130.

[102] Mot. to Dismiss (Doc. No. 37-1) at 19.

[103] *Id.* ¶¶ 66–69, 73.

[104] *Id.* ¶ 78.

[105] *Id.* ¶¶ 87–88, 99, 101.

[106] *Id.* ¶¶ 109–10.

[107] *Id.* ¶ 111.

[108] *Id.*

[109] *Id.* ¶ 88.

[110] *Id.* ¶ 99.

[111] *Id.* ¶ 106.

[112] *Id.* ¶ 107.

[113] *Id.*

[114] *Id.*

[115] *Id.*

[116] Resp. to Mot. to Dismiss at 11-13.

[117] *See, e.g.*, Am. Compl. ¶¶ 158, 163, 171, 173, 179, 182–83.

[118] *Id.* ¶¶ 84–85.

[119] *Id.* ¶¶ 158, 163, 166, 168, 177, 191.

[120] *Id.* ¶¶ 105, 185–87.

[121] *Id.* ¶ 195.

[122] *Id.*

[123] *Id.* ¶ 158.

[124] *Id.* ¶ 33.

[125] *Id.* ¶¶ 170–74.

[126] *Id.* ¶ 174.

[127] *Id.* ¶ 170.

[128] *Id.* ¶ 171.

[129] *Id.* ¶ 172.

[130] *Id.*

[131] *Id.* ¶ 173.

[132] *Id.* ¶ 179.

[133] *Id.* ¶ 200.

[134] *Id.* ¶¶ 95, 109.

[135] *Id.* ¶ 204.

[136] *Id.* ¶ 206.

[137] *Id.*; *see also id.* ¶ 211.

[138] *Id.* ¶ 211.

[139] *Id.* ¶ 226.

[140] *Id.* ¶¶ 232, 237.

[141] *Id.* ¶ 133.

[142] *Id.* ¶ 246.

[143] *Id.*

[144] *Id.* ¶ 250.

[145] *Id.* ¶ 255.

[146] *Id.*

[147] *Id.* ¶¶ 261–62.

[148] *Id.*

[149] *Id.* ¶ 262.

[150] *Id.* ¶ 261.

[151] *See In re Merck*, 432 F.3d at 269 (stating that the Third Circuit, "as compared to the other courts of appeals, has one of the 'clearest commitments' to the efficient market hypothesis") (citing Nathaniel Carden, Comment, *Implications of the Private Securities Litigation Reform Act of 1995 for Judicial Presumptions of Market Efficiency*, 65 U. Chi. L. Rev. 879, 886 (1998)). *See also id.* at 264 n.3 (a court may take judicial notice of stock prices at any stage of the proceeding because they are "not subject to reasonable dispute and are capable of accurate and ready determination by resort to a source whose accuracy cannot be reasonably questioned") (citing *Ieradi v. Mylan Labs., Inc.*, 230 F.3d 594, 600 n.3 (3d Cir. 2000)).

[152] Am. Compl. ¶¶ 109–13.

[153] *Id.* ¶¶ 137–39.

[154] *Id.* ¶¶ 141–45.

[155] *Id.* ¶¶ 146–48.

[156] *Id.* ¶¶ 87–88, 95, 99.

[157] *Id.* ¶ 297.

[158] *Id.*

[159] *Id*.

[160] *Id.* ¶ 296.

[161] *Id.* ¶ 296. SEB also argues that defendants De Silva, Holveck, Campanelli, and Levin, as CEOs and CFO of Endo, had access to copies of SEC filings containing the misleading statements. *Id.* ¶ 300.

[162] *Id.* ¶ 306.

[163] *Id.* ¶ 307.

[164] *Id.*

[165] *Id*.

[166] *Id.* ¶¶ 197, 308.

[167] *Id.* ¶ 307–08.

[168] Endo also relied on the revenue for Opana ER to fund new research and development. *Id.* ¶ 309.

[169] *Id.* ¶¶ 344–45.

[170] *Id.* ¶ 344.

[171] *Id.* ¶¶ 345–47, 349–50.

[172] *Id.* ¶¶ 170–74.

[173] *Id.* ¶¶ 29, 32-34.

[174] *Id.* ¶¶ 31, 34-35.

[175] *Id.* ¶ 35.

[176] Mot. to Dismiss at 10.

[177] *Id.* at 14–21.

[178] *Id.* at 10.

[179] Am. Compl. ¶ 371.

[180] No. 17-02081-MJ (Ct. Comm. Pl. Oct. 16, 2017).

[181] Mot. to Dismiss Ex. 2 (Doc. No. 37-3).

[182] Am. Compl. ¶¶ 353, 376 (emphasis added); *see also id.* ¶¶ 352, 388.

[183] The Offering Materials are the Registration Statement, the preliminary prospectus supplement, and the final prospectus supplement, which incorporate by reference the 2014 Form 10-K and 1Q15 Form 10-Q. *Id.* ¶¶ 352, 370.

[184] *Id.* ¶¶ 371, 378.

[185] *Id.*

[186] *Id.* at ¶ 371.

[187] *Id.*

[188] *Id.* ¶¶ 373, 378.

[189] It is not clear whether culpable participation is also required for a § 15 violation. The Third Circuit in *In re Suprema* only indicated that culpable participation is required under § 20. 438 F.3d at 284 n.16. It did not discuss whether culpable participation was required to state a claim under § 15. Some district courts have included culpable participation as an element of a § 15 claim. *See, e.g.*, *Carmack*, 258 F. Supp. 3d at 466; *Dutton v. Harris Stratex Networks, Inc.*, 270 F.R.D. 171, 178 (D. Del. 2010); *In re Ravisent Techs., Inc.*, Civ. A. No. 00-1014, 2004 WL 1563024, at *15 (E.D. Pa. July 13, 2004). Others have not. *See, e.g.*, *In re Washington Mut., Inc.*, 462 B.R. 137, 142–43 (Bankr. D. Del. 2011) (comparing conflicting case law and determining culpable participation need not be pled for § 15 claim).

[190] Am. Compl. ¶¶ 390–93.