PEPICELLI v. INNOCOLL HOLDINGS PUBLIC LIMITED COMPANY et al

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IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA : : IN RE INNOCOLL HOLDINGS PUBLIC : LTD. CO. SEC. LITIG. : CIVIL ACTION : : No. 17-341 :

MEMORANDUM PRATTER, J. SEPTEMBER 5, 2018

The plaintiffs in this securities class action allege that Innocoll Holdings Public Ltd. Co., Chief Executive Officer Anthony Zook, and Chief Medical Officer Dr. Lesley Russell made misleading statements or omissions about XaraColl, a collagen product the pharmaceutical company was developing during the class period. The defendants allegedly made positive statements about the New Drug Application for XaraColl even though they knew, or recklessly failed to know, that XaraColl contained device components that had not yet been tested. The plaintiffs contend that, by making such statements, the defendants misled investors who relied on the positive statements.

The plaintiffs present securities fraud claims against all defendants under Section 10(b) of the Securities Exchange Act of 1934 and Rule 10b-5. They also make individual control liability claims against Mr. Zook and Dr. Russell under Section 20(a).

The defendants filed a motion to dismiss all the claims under Fed. R. Civ. P. 12(b)(6). In doing so, they attached to their motion a declaration from the plaintiffs' confidential witness, which then prompted the plaintiffs to file a motion to convert the motion to dismiss into one for summary judgment.

For the reasons outlined in this Memorandum, the Court: (1) denies the motion to convert and, instead, disregards the declaration; and (2) grants the motion to dismiss with leave to amend because the plaintiffs failed to meet the Private Securities Litigation Reform Act' s heightened pleading standard relating to the element of scienter.

BACKGROUND This is a securities class action on behalf of all persons who purchased or otherwise acquired publicly traded shares of Innocoll between July 25, 2014 and December 29, 2016. The defendant, Innocoll, 1

is a pharmaceutical company based in Ireland with its U.S. headquarters in Newtown Square, Pennsylvania. Innocoll's common shares are traded on the NASDAQ. Innocoll develops and sells medical products based on its patented collagen technologies used in medical sponges, films, powders, and other structures. The plaintiffs allege that Innocoll has consistently operated at a loss

in manufacturing and selling its products. By March 2014, Innocoll had two major products in the pipeline: XaraColl (discussed in detail below) and Cogenzia, which is used for treating diabetic foot infections.

The individual defendants, Anthony Zook and Dr. Lesley Russell, were, respectively, Innocoll' s Chief Executive Officer and Chief Medical Officer during the class period. Mr. Zook has over 30 years of experience in the pharmaceutical industry, including as President and CEO of AstraZeneca's North American division. Dr. Russell also has extensive experience developing pharmaceuticals. The plaintiffs allege that the individual defendants had a hand in making misleading statements to investors.

1 At the start of the class period, Innocoll was Innocoll AG, a German company, but merged into Innocoll Holdings plc on March 16, 2016 and changed its domicile to Ireland. This merger apparently did not have a substantial effect on operations or ownership, and Innocoll Holdings plc is a successor in interest to Innocoll AG.

I. The FDA Approval Process

The U.S. Food and Drug Administration must approve drugs and devices before they can be sold in the United States. A sponsor is the person or company submitting an application for approval to the FDA. The FDA categorizes products as (i) drugs, (ii) devices, and (iii) combination products, and it is ultimately the sponsor' s responsibility to determine which category is the best fit for its product.

Drug Approval: Drugs are typically approved following three phases of clinical trials. Phase I establishes proper dosage and confirms that the drug is safe to be studied. Phase II establishes clinical efficacy. During Phase III, the sponsor must submit a New Drug Application (NDA), which requires the sponsor to test the drug and submit evidence of safety and effectiveness. The FDA' s Center for Drug Evaluation and Research then reviews the NDA.

Device Approval: Devices can follow a variety of paths to approval but a sponsor must generally demonstrate reasonable assurances of the device' s safety and effectiveness. The Center for Devices and Radiological Health reviews device applications.

Drug/Device Combination Approval: Products with both drug and device components are called drug/device combinations. These products require approval of both the drug and the device elements. The FDA created the Office of Combination Products (OCP) to develop guidance and regulations governing combination products, to assign an FDA center to have primary jurisdiction over combination products, and to ensure timely and effective premarket review of combination products.
II. XaraColl

One of Innocoll' s products is XaraColl, which provides sustained postsurgical pain relief. " XaraColl

is a proprietary collagen matrix" that treats postoperative pain with bupivacaine. Am.

Compl. ¶ 33. In layman' s terms, XaraColl is a collagen matrix that is implanted at, and gradually releases pain medicine directly to, the surgical site. In doing so, it reduces the need for post-surgery opioids and the risks associated with them. XaraColl is absorbed by the patient' s body and does not need to be removed later. XaraColl' s patent, filed in 2008, refers to it as a " drug delivery device" and a " device comprising a fibrillary collagen matrix." Am. Compl. ¶ 50.

Innocoll met with representatives of the FDA twice about XaraColl. The first meeting occurred at the end of Phase II to discuss XaraColl' s Phase III trials. The second meeting was a formal meeting about Phase III trials. At these meetings, Innocoll only discussed filing XaraColl as a drug and never asked the FDA whether XaraColl should be filed as a drug/device combination.

A Medical Affairs Consultant (MAC) employed at Innocoll from July 2015 until November 2015 has claimed that XaraColl had device components. The MAC ensured that the promotional materials were medically and technically accurate and reported directly to then- CMO, Dr. James Tursi. He also worked closely with David Prior, who has been in senior positions at Innocoll since 2004. The MAC, apparently acting as a confidential witness for the plaintiffs in this case, says that Mr. Prior and Dr. Tursi both told him that XaraColl " would be considered a device in the U.S." Am. Compl. ¶ 62.

On May 25, 2016, Innocoll announced that XaraColl was all but ready for NDA filing and the stock prices rose from $7.11/share to $10.51/share. And, on November 3, 2016, Innocoll announced that it was submitting XaraColl' s NDA. That same day, the company announced it was abandoning its other major drug, Cogenzia, because the drug failed Phase III trials.

Innocoll submitted the NDA for XaraColl as a drug and not a drug/device combination.

III. FDA' s "Refusal to File" Letter

On December 29, 2016, Innocoll released a statement that the FDA issued a " Refusal to File" letter for XaraColl. A " refusal to file" letter means the FDA will not conduct a substantive review of the application because it is incomplete. The FDA determined that XaraColl should be characterized as a drug/device combination, which required Innocoll to submit additional information about the device components. Innocoll planned to work with the FDA to " define a path forward for a successful re-filing of [the] application at the earliest point in time." Am. Compl. ¶ 116.

On December 30, 2016, the Company' s shares fell $1.08 per share and closed at $0.69 per share. 2 IV. Allegedly Misleading Statements

The complaint outlines a number of the defendants' statements that the plaintiffs allege are

actionable misrepresentations or omissions, particularly about the two formal meetings Innocoll had had with the FDA. The allegedly misleading statements issued during the class period are recounted in 17 pages of the amended complaint and fall within five categories: (A) statements about the end-of-phase-II meeting with the FDA, (B) statements about the July 2015 meeting with the FDA and phase III study, (C) statements on earnings calls about goals and expectations, (D) answers to questions about non-clinical progress, and (E) statements about expectations and approval of XaraColl' s NDA application.

Shareholders allege that Innocoll, through Mr. Zook and Dr. Russell, made positive public statements about the likelihood that the FDA would approve XaraColl' s NDA. These

2 On June 4, 2016, Innocoll stock fell from the May 2016 $10.51 per share price to $8.85 per share. On June 17, it fell again to $7 per share. Am. Compl. ¶¶ 102–03. T he Innocoll stock apparently had fallen even further since then but the pleadings do not address this.

statements allegedly led investors to believe that Innocoll had raised all potential red flags with the FDA, no non-clinical obstacles remained, the NDA was on schedule, and the FDA was likely to approve XaraColl.

However, the plaintiffs allege that Innocoll and its senior people were always aware that the collagen matrix component of XaraColl was a device and would need to be tested separately to secure approval. Innocoll never asked the FDA if it should test XaraColl as a drug/device product, so, according to plaintiffs, the statements misled investors into believing that the FDA was progressing toward a fully informed opinion when the agency was actually missing key information about XaraColl. Essentially, the plaintiffs contend that the defendants made all of these statements to entice investors, knowing full well that the FDA would not approve XaraColl because the company had not tested the product' s device components. Ultimately, the FDA refused to consider the XaraColl application for exactly that reason.

The defendants claim that all of the statements were factually true and the company was not aware that XaraColl needed to be filed as a drug/device combination. Instead, the defendants argue that they simply made a mistake in believing that XaraColl' s NDA should be tested and filed solely as a drug.

A. Statements about the End-of-Phase-II Meeting with the FDA

Innocoll released three statements that referenced the end-of-Phase-II meeting: the IPO registration statement, the 2014 20-F report, and the F-1 registration statement. Am. Compl. ¶¶ 66, 73, 77. In these statements, Innocoll stated that the FDA agreed to the company' s approach for XaraColl' s Phase III trials. For example, the IPO registration statement stated in part: " Following our end-of-Phase II meeting, the FDA agreed to permit us to pursue such integrated end point in our

Phase III trial." Id. ¶ 66 (emphasis added). And the F-1 registration statement

said: " The primary endpoint in our two planned Phase III trials will use this integrated Silverman method assessment of pain and opioid consumption, as agreed to with the FDA in our end-of-Phase-II meeting." Id. ¶ 77 (emphasis added).

B. Statements about the July 2015 Meeting with the FDA and Phase III Study

Innocoll made a number of statements about the company' s July 2015 Meeting with the FDA, in which the FDA allegedly approved XaraColl' s proposed Phase III study. Those statements were made in the 2015 20-F, amendment to the registration statement, prospectus supplement, and final prospectus supplement. Am. Compl. ¶¶ 83–85, 91, 97, 99, 103. The 2015 20-F stated that the company received guidance from the FDA, the FDA reviewed data from XaraColl' s Phase II study, and the FDA " agreed" with and " approved" the Phase III study protocol. Id. ¶¶ 83–85.

C. Statements on Earnings Calls about Goals and Expectations

Plaintiffs next point to statements Innocoll made on the earnings calls in 2015 about goals and expectations for the company. During those calls Mr. Zook stated that Innocoll " had to complete [its] clinical programs for XaraColl and Cogenzia on time and on budget" and that this was the company' s " highest priority." Am. Compl. ¶¶ 70–72.

D. Answers to Questions about Non-Clinical Progress

During two conference calls, Mr. Zook and Dr. Russell answered questions about whether there were any nonclinincal issues that needed to be solved before Innocoll could file the XaraColl NDA and safety database. Am. Compl. ¶¶ 87, 94. On both calls, the defendants answered in the negative. Id.

E. Statements about Expectations and Approval of XaraColl' s NDA Application

The last group of statements the plaintiffs highlight are about the expectations and likelihood of approval of XaraColl' s NDA. Am. Compl. ¶¶ 89–91, 93, 100, 107, 109, 111–12. In an amendment to the registration statement, Innocoll stated: " The FDA deemed our single- dose approach acceptable in our recent Type C meeting. . . . We expect to submit an NDA for XaraColl at the beginning of the fourth quarter of 2016." Id. ¶ 91. A press release from May 25, 2016 repeated that " Data supports on-schedule NDA filing this year." Id. ¶ 93. And a June 13, 2016 preliminary prospectus supplement " anticipated approval of [XaraColl' s] NDA." Id. ¶ 100. On a November 2016 conference call, Dr. Russell reiterated that she did not think approval was in question. Id. ¶ 107.

PROCEDURAL HISTORY There are two pending motions in this case. The defendants first filed a motion to dismiss under Fed. R. Civ. P. 12(b)(6), arguing that the plaintiffs failed to state a Section

10(b) and Rule 10b-5 claim. The defendants further argue that the plaintiffs have not pled control person liability under Section 20(a). Because the defendants' motion to dismiss included a declaration from the confidential witness quoted in the plaintiffs' complaint, t he plaintiffs filed a motion under Rule 12(d) to convert the motion to dismiss into one for summary judgment. The Court heard oral argument on both motions on March 2, 2018.

LEGAL STANDARD A Rule 12(b)(6) motion to dismiss tests the sufficiency of a complaint. To survive a motion to dismiss, the plaintiff must plead " factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009).

In evaluating the sufficiency of a complaint, the Court adheres to certain well-recognized parameters. For one, the Court " must consider only those facts alleged in the complaint and accept all of the allegations as true." ALA, Inc. v. CCAIR, Inc., 29 F.3d 855, 859 (3d Cir. 1994). Also, the Court must accept as true all reasonable inferences emanating from the allegations, and view those facts and inferences in the light most favorable to the nonmoving party. See Revell v. Port Auth., 598 F.3d 128, 134 (3d Cir. 2010). If a claim " is vulnerable to 12(b)(6) dismissal, a district court must permit a curative amendment, unless an amendment would be inequitable or futile." Phillips v. Cty. of Allegheny, 515 F.3d 224, 236 (3d Cir. 2008).

" In analyzing a motion to dismiss under the [Private Securities Litigation Reform Act (PSLRA)], this Court must examine the complaint in its entirety, as well as documents incorporated into the complaint by reference or matters of which a court may take judicial notice." In re NutriSystem, Inc. Sec. Litig., 653 F. Supp. 2d. 563, 566 n.2 (E.D. Pa. 2009) (citing Tellabs v. Makor Issues & Rights, Ltd., 551 U.S. 308 (2007); Winer Family Trust v. Queen, 503 F.3d 319, 327 (3d Cir. 2007)).

Congress enacted the PSLRA as a " check against abusive litigation by private parties" levied at " companies and individuals whose conduct conforms to the law." Tellabs, 551 U.S. at 313. The PSLRA imposes " exacting pleading requirements" that oblige " plaintiffs to state with particularity both the facts constituting the alleged violation, and the facts evidencing scienter, i.e., the defendant' s intention ' to deceive, manipulate, or defraud.'" Id.; see also OFI Asset Mgmt. v. Cooper Tire & Rubber, 834 F.3d 481, 490 (3d Cir. 2016) (quoting Institutional Inv' rs Grp. v. Avaya, Inc., 564 F.3d 242, 252 (3d Cir. 2009)) (" [I]n cases alleging securities fraud, plaintiffs must ' satisfy the heightened pleading rules codified in' the PSLRA."). The

PSLRA' s provision governing scienter pleading, discussed in detail below, is particularly stringent and "exacting".

DISCUSSION There are two, arguably competing, motions pending. The Court will first address the motion that came second in time: the plaintiffs' motion, under Fed. R. Civ. P. 12(d), to convert the defendants' motion to dismiss into one for summary judgment. " If, on a motion under Rule 12(b)(6)

or 12(c), matters outside the pleadings are presented to and not excluded by the court, the motion must be treated as one for summary judgment under Rule 56." Fed. R. Civ. P. 12(d). When a party attaches exhibits outside the pleadings, the decision to convert the motion to dismiss into a motion for summary judgment is within the discretion of the district court. As discussed and for the reasons then explained during oral argument, the Court declines to convert the pending motion to dismiss into a motion for summary judgment. Quite simply, a summary judgment motion deserves a thoughtful and deliberate record for the benefit of the litigants, the Court, and the litigating public. No such record is extant here. Instead, the Court will simply disregard the outside-the-pleading declaration and rule on the defendants' motion as intended, a motion to dismiss.

Under Section 10(b) of the Securities Exchange Act, it is unlawful for a person to " use or employ, in connection with the purchase or sale of any security . . . any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the Commission may prescribe as necessary or appropriate in the public interest or for the protection of investors." 15 U.S.C. § 78j(b). SEC Rule 10b-5 makes " it unlawful to, among other things, ' 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 the light of the circumstances under which they were made, not

misleading.'" Matrixx Initiatives, Inc. v. Siracusano, 563 U.S. 27, 37 (2011) (quoting 17 CFR § 240.10b-5(b)). In order to make a claim under Rule 10b-5, a plaintiff must plead that the defendants acted with scienter. Williams v. Globus Medical, Inc., 869 F.3d 235, 240 (3d Cir. 2017) (citing Cal. Pub. Employees' Ret. Sys. v. Chubb Corp., 394 F.3d 126, 143 (3d Cir. 2004)).

Although the defendants attacked the sufficiency of the complaint on numerous grounds, the Court will focus on the question of whether the plaintiffs sufficiently pled scienter. Because the Court concludes that the plaintiffs did not quite meet the PSLRA' s heightened, "exacting" pleading standard for scienter, the Court grants the motion to dismiss, but with leave to plaintiffs to amend.

I. Scienter Pleading Requirements under the PSLRA

" Under the PSLRA' s heightened pleading instructions, any private securities complaint alleging that the defendant made a false or misleading statement must . . . ' state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind'" . Tellabs, 551 U.S. at 321. Furthermore, under section " 78u–4(b)(2), ' a plaintiff can no longer plead the requisite scienter element generally, as he previously could under [Fed. R. Civ. P.] 9(b).'" Avaya, 564 F.3d at 253 (quoting Mizzaro v. Home Depot, Inc., 544 F.3d 1230, 1238 (11th Cir. 2008)); see also id. (" The PSLRA' s requirement for pleading scienter . . . marks a sharp break with Rule 9(b).").

" This scienter standard requires plaintiffs to allege facts giving rise to a ' strong inference' of ' either reckless

or conscious behavior.'" Id. at 267 (quoting In re Advanta Corp. Sec. Litig., 180 F.3d 525, 534–35 (3d Cir. 1999)) (internal footnote omitted). " Reckless statements are ' not merely simple, or even inexcusable 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.'" In re Urban Outfitters, Inc. Sec. Litig., 103 F. Supp. 3d 635, 652 (E.D. Pa. 2015) (alteration in original) (quoting Advanta, 180 F.3d at 535). A complaint may survive a motion to dismiss if it offers a collection of circumstantial evidence that leads to a strong inference that the defendants' statements were at least reckless. See Avaya, 564 F.3d at 269; see also Urban Outfitters, 103 F. Supp. 3d at 653.

A strong inference of scienter " must be 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. Thus, under the PSLRA, courts must " weigh the ' 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 inference that the defendant acted with scienter need not be irrefutable, i.e., of the smoking-gun genre, or even the most plausible of competing inferences." Tellabs, 551 U.S. at 324 (internal quotation marks omitted). " The pertinent question 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.'" Avaya, 564 F.3d at 267 (quoting Tellabs, 551 U.S. at 323): see also Tellabs, 551 U.S. at 326 (" We reiterate, however, that the court' s job is not to scrutinize each allegation in isolation but to assess all the allegations holistically."). " Omissions and ambiguities ' count against inferring scienter.'" Avaya, 564 F.3d at 267 (quoting Tellabs, 551 U.S. at 326).

A. Evidence of Scienter

Ultimately, this case presents the core question: when the defendants told investors that the FDA would approve XaraColl, did the defendants know, or so very recklessly not know, that XaraColl had device components that would need to be tested separately? The plaintiffs lack

direct evidence that the defendants were aware of XaraColl' s device components. Instead, the plaintiffs rely on circumstantial evidence they believe leads to the conclusion that the defendants knew, or should have known, that XaraColl' s collagen matrix was a device.

The plaintiffs point to several pieces of evidence articulated within the complaint to support their scienter allegations. Those pieces of evidence include: (1) a statement from a confidential "in the know" witnes s, (2) allegations that collagen is regularly regulated as a device, (3) Innocoll' s experience with collagen products, (4) XaraColl' s patent, and (5) allegations that Innocoll was underfunded. In retort, the defendants attack the plaintiffs' complaint on the grounds that, even so, it does not meet the heightened pleading standard of the PSLRA. The defendants further contend that

the plaintiffs' theory that executives at Innocoll knew XaraColl should be filed as a drug/device combination and filed it as a drug anyway is not the most cogent or compelling narrative because it assumes that Innocoll's executives intentionally botched the company's last hope for profitability .

Because the plaintiffs failed to sufficiently plead scienter specifically as to Mr. Zook and Dr. Russell (the human actors on behalf of Innocoll), they have failed to plead scienter for Innocoll as well. 3

3 The plaintiffs, alternatively, ask the Court to impute to Innocoll the alleged scienter of former CEO Mr. Myers, Dr. Tursi, and/or Mr. Prior. Pls.' Opp. to Mot. to Dismiss at 30 (Doc. No. 29). The plaintiffs contend that, as people in management positions, these individuals must have been consulted in making public statements about XaraColl and their scienter, even though they are not defendants, can substitute for that of the company. The Third Circuit Court of Appeals has yet to accept or reject " the doctrine of corporate scienter in securities fraud actions." Rahman v. Kid Brands, Inc., 736 F.3d 237, 246 (3d Cir. 2013). This is not a compelling case to accept the doctrine outright.

The Third Circuit Court of Appeals considered the doctrine of corporate scienter in City of Roseville Employees' Retirement Sys. v. Horizon Lines. 442 F. App' x 672, 676–77 (3d Cir. 2011). Although the Sixth Circuit and Seventh Circuit Courts of Appeals have adopted corporate scienter in cases of " extraordinary" wrongdoing, the Third Circuit Court of Appeals declined to follow suit because

1. Confidential Witness

The complaint here includes a statement from a confidential witness that two senior executives, who are not defendants in this case, knew that XaraColl needed to be regulated as a device. Plaintiffs making securities litigation claims may certainly use confidential witnesses to support their allegations. Avaya, 564 F.3d at 262. " Where, as here, plaintiffs lack documentary evidence such as internal memoranda, ' reliance on confidential sources to supply the requisite particularity for their fraud claims . . . assumes a heightened importance.' " Id. (quoting Chubb, 394 F.3d at 146).

When plaintiffs use such a confidential witness, however, they must state with particularity facts that support the probability that the witness was in a position to possess the alleged information. See Chubb, 394 F.3d at 146; Avaya, 564 F.3d at 262; Urban Outfitters, 103 F. Supp. 3d at 648. In considering the reliability of a confidential witness' statements, courts should consider " the detail provided by the confidential sources, the sources' basis of knowledge, the reliability of the sources, the corroborative nature of other facts alleged, including from other sources, the coherence and plausibility of the allegations, and similar indicia." Chubb, 394 F.3d at 146; see Urban Outfitters, 103 F. Supp. 3d at 648–49.

the facts in Roseville were a " far cry" from those before other circuits. Id. at 676; see City of Monroe Employees Retirement Sys. v. Bridgestone Corp., 399 F.3d 651, (6th Cir. 2005) (applying corporate

scienter when the company engaged in a large scale cover up to hide tire safety issues from regulators and investors); Makor Issues & Rights, Ltd. v. Tellabs Inc., 513 F.3d 702, 710 (7th Cir. 2008) (providing a hypothetical example of corporate scienter: " Suppose General Motors announced that it had sold one million SUVs in 2006, and the actual number was zero. There would be a strong inference of corporate scienter, since so dramatic an announcement would have been approved by corporate officials sufficiently knowledgeable about the company to know that the announcement was false."). As currently formulated, the complaint here does not present such high level, stark, or rampant wrongdoing that this Court is moved to apply the doctrine of corporate scienter.

In Chubb, the Third Circuit Court of Appeals disregarded statements by confidential witnesses because the plaintiffs failed to allege when the witnesses were employed by the company, the dates they acquired the information alleged, or how they had access to such information. Chubb, 394 F.3d at 148. The confidential witnesses' statements left the court " to speculate whether the anonymous sources obtained the information they purport[ed] to possess by firsthand knowledge or rumor." Id.

The complaint in this case includes five paragraphs about the confidential witness, four of which are background information. This witness worked at Innocoll from July 2015 to November 2015 as a Medical Affairs Consultant and his responsibilities included ensuring that XaraColl' s promotional materials were medically and technically accurate. Am. Compl. ¶ 59. He reported to then-CMO, Dr. James Tursi, and worked closely with another executive, David Prior. Id. The witness " reports that both Prior and Tursi told him during his tenure that XaraColl was a device" and was further told that XaraColl " would be considered as a device" in the U.S. Id. ¶ 62.

The witness, however, apparently is not alleging that the specific defendants in this case made these statements. Instead, the plaintiffs ask the Court to infer that, if Dr. Tursi and Mr. Prior knew of XaraColl' s device components, then Mr. Zook and Dr. Russell must have known this as well.

The complaint has sufficiently " described the duration of [the confidential witness'] employment, the time period during which the [witness] acquired the relevant information, and how [the witness] had access to such information." Avaya, 564 F.3d at 262. And the confidential witness' statement supports the plaintiffs' narrative that some high level executives

knew, at least at some point, that XaraColl needed to be regulated as a device. However, the witness' statement in this case goes no further.

The entirety of the witness' allegations in the complaint are: " I was told in the U.S. that it would be considered as a device. That' s what I remember being told." Am. Compl. ¶ 62. This account is " little more than generalized allegations with few specifics and even less concrete support." Rahman, 736 F.3d at 244–45. The complaint thus far lacks details about when the statements were made and in what context, making it difficult for the Court to jump to the conclusions the plaintiffs ask of it.

Furthermore, the confidential witness' statement in this case lacks the support found in other cases that used confidential witnesses. In other such cases, complaints often included statements from multiple confidential witnesses that corroborate one another. See Avaya, 564 F.3d at 249–50 (analyzing statements of least five confidential witnesses); Urban Outfitters, 103 F. Supp. 3d at 648 (finding plaintiffs provided adequately particularized allegations of six confidential witnesses). In this case, the plaintiffs presented the Court with only the one confidential witness whose statement only goes so far as to say that the former CMO and another executive apparently believed that XaraColl would be regulated as a device.

Although the Court will consider the statement as part of the pleading, it will deeply discount the statement because it is conclusory in nature, lacks corroboration, and only imputes knowledge of XaraColl' s device components to non-defendants. See Avaya, 564 F.3d at 264 (advising courts to steeply discount confidential witness allegations when they lack detail, a basis for knowledge, reliability, corroborative facts, are incoherent or implausible, and similar indicia); Rahman, 736 F.3d at 244–45 (discounting witness statements that were too general).

2. Collagen Regulation

The plaintiffs allege that, " [s]ince its first use as a medical product, collagen has consistently been regulated as a ' device.'" Am. Compl. ¶ 9. Although the Court is required to accept the allegations in the complaint as true, the plaintiffs offer no further examples or explanation to support this claim.

3. Innocoll' s Experience with Collagen Products

The plaintiffs also ask the Court to consider that Innocoll has a decade' s worth of experience working with collagen and has brought at least eight collagen products to market. Am. Compl. ¶¶ 9, 52– 53 (" Indeed, Innocoll itself, on eight separate occasions, sought and obtained FDA approval for use of its collagen technologies as devices.") (emphasis in original). These products included " CollaGUARD (2006), Collieva (2008), Collagen Sponge (2010), Collexa (2010), Collacare Dental (2011), Collagen Powder (2011), Procoll (2012), and Collacare Dental (2014)." Am. Compl. ¶ 53.

The plaintiffs provided the Court with no information about what each of these other products is or does. The only information included in the complaint on this subject was that Innocoll brought eight collagen products to market, the names of those products, and the years Innocoll brought them to market. Based on those allegations alone, it is impossible for the Court to know whether those products are, in fact, substantially similar to XaraColl such that Innocoll should have known of XaraColl' s device components.

Indeed, the defendants attempt to distinguish those products from XaraColl in their memorandum in support of their motion to dismiss. The defendants argue that those products involve a " collagen matrix that itself performs the function of the product," whereas XaraColl

uses collagen solely as an excipient to deliver another active ingredient. Defs.' Mot. to Dismiss at 16–17 (Doc. No. 21) .

That is not to say that the plaintiffs' reasoning could never be sufficient to satisfy the pleading standard. If those products are substantially similar to XaraColl, that similarity may show that Innocoll was at least reckless in not knowing or reasonably anticipating that XaraColl was a drug/device combination. However, the complaint does not currently provide the Court with enough information under the PSLRA' s heightened "exacting" pleading standard to reach that conclusion.

4. XaraColl' s Patent

XaraColl' s patent may be the plaintiffs' strongest piece of evidence to demonstrate that Innocoll executives were aware of the XaraColl' s device components. Filed on March 8, 2008, the patent is titled " A drug delivery device for providing local analgesia, local anesthesia or nerve blockade." Compl. ¶ 50. The patent further describes XaraColl as a " device comprising a fibrillary collagen matrix, and at least one drug substance . . . being substantially homogeneously dispersed in the collagen matrix." Id. (emphasis added).

During oral argument, counsel for the defendants contended that (1) " device" is a defined term under FDA rules but patent attorneys did not necessarily intend this meaning in drafting XaraColl' s patent and (2) the patent was written six years before any of the named defendants started working at Innocoll. Oral Argument Tr. 8:23–11:2; 37:1–37:24.

Although the defendants may be correct that the word " device" as it is used in the patent is different than how the word is used by the FDA, the patent' s own language is certainly an arrow in the plaintiffs' quiver. However, the fact that the patent calls XaraColl a device is not

enough in and of itself to survive a motion to dismiss under the PSLRA's heightened pleading standard.

5. Motive Allegations of Underfunding

The plaintiffs also urge the Court to consider Innocoll' s financial situation when analyzing the defendants' scienter. Innocoll allegedly sought to secure financing " to assure the company' s continued survival." Pls.' Opp. to Mot. to Dismiss at 27 (Doc. No. 29). The plaintiffs argue that Innocoll' s financial situation was dire and, after Cogenzia failed, XaraColl was the last hope for keeping the company alive.

As set forth in the complaint, Innocoll was only marginally successful in commercializing drugs and devices and regularly incurred operating losses greater than its revenues. Am. Compl. ¶ 48 (" By March 31, 2014, shortly before its IPO, Innocoll had accumulated deficit of €90.8 million, and its

current liabilities exceeded its current assets by €6.9 million.”). The fact that Innocoll was generally underfunded may provide some evidence of a motive for Innocoll executives to hide any flaws in XaraColl’ s NDA; however, general allegations that Innocoll was underfunded do not necessarily mean that the company would cease to exist if XaraColl failed or that the defendants acted with the requisite scienter.

B. Analysis of Scienter

Based on the facts currently in the complaint, the plaintiffs have not adequately pled scienter. Although what the plaintiffs have alleged would surely be enough to survive a motion to dismiss under the normal standard of Fed. R. Civ. P. 12(b)(6), the allegations in the complaint do not reach the exacting standard set forth in the PSLRA. Currently, the complaint fails to allege facts that “ give rise to a ‘ strong inference’ of ‘ either reckless

or conscious behavior.’” Avaya, 564 F.3d at 267. This is especially true when the Court considers that a strong inference

of scienter “ must be 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.

The plaintiffs’ current narrative is that XaraColl’ s patent (written well before Mr. Zook and Dr. Russell joined Innocoll) called it a device, a statement from a confidential witness stating that former executives apparently called XaraColl a device, Innocoll has experience bringing collagen products (that may or may not be similar to XaraColl) to market as devices, and the company was underfunded.

The defendants offer a competing narrative: that Innocoll was mistaken about the need to test XaraColl as a device. If Innocoll really was aware of XaraColl’ s device components, why, they ask, would Innocoll not test those components at the same time as the drug components?

Based on the totality of the circumstances in the complaint, the Court cannot find a more cogent or compelling answer to that question than the defendants simply made a very expensive and unintended mistake. The Court is loath to jump to the conclusions the plaintiffs ask of it at this time because the complaint lacks specificity and particularity in the key areas that would hold their narrative together. In particular, the confidential witness’ statement amounts to generalized allegations that non-defendants knew of XaraColl’s device components. Furthermore, the plaintiffs failed to explain the similarities between XaraColl and Innocoll’ s other collagen technologies. II. Section 20(a) Claims

“ Section 20(a) of the Exchange Act imposes joint and several liability upon one who controls a violator of Section 10(b).” In re Suprema Specialties, Inc. Sec. Litig., 438 F.3d 256, 284 (3d Cir. 2006). “ Accordingly, liability under Section 20(a) is derivative of an underlying violation of Section 10(b) by

the controlled person." Avaya, 564 F. 3d at 252; see also In re

Viropharma, 21 F. Supp. 3d 458, 470 (E.D. Pa. 2014) (" Because this Court finds that Plaintiff indeed does state a claim under Rule 10b-5, Plaintiff' s Section 20(a) claim survives.").

Because the plaintiffs failed to adequately plead scienter, their Section 20(a) claims must also be dismissed, also with leave to amend.

CONCLUSION For the reasons set out in this Memorandum, the Court denies the plaintiffs' motion to convert and grants the defendants' motion to dismiss with leave to amend. An appropriate order follows.

BY THE COURT:

S/Gene E.K. Pratter GENE E.K. PRATTER UNITED STATES DISTRICT JUDGE