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Case Number 5,2024

IN THE SUPREME COURT OF THE STATE OF DELAWARE

TEAMSTERS LOCAL 443 HEALTH SERVICES & INSURANCE PLAN, ST. PAUL ELECTRICAL CONSTRUCTION PENSION PLAN, ST. PAUL ELECTRICAL CONSTRUCTION WORKERS SUPPLEMENTAL PENSION PLAN (2014 RESTATEMENT), and RETIREMENT MEDICAL FUNDING PLAN FOR THE ST. PAUL ELECTRICAL WORKERS,

Plaintiffs below, Appellants,

v.

CENCORA, INC.
(f/k/a AmerisourceBergen Corporation),

Nominal Defendant below, Appellee,

-and-

DENNIS M. NALLY, as the Special Litigation Committee of the Board of Directors of Cencora, Inc. (f/k/a AmerisourceBergen Corporation),

Interested Party below, Appellee.

No. 5, 2024

Court Below:
Court of Chancery of the State of Delaware,
C.A. No. 2019-0816-SG

Public Version filed on April 23, 2024

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PRELIMINARY STATEMENT

The SLC[1] moved to dismiss derivative claims arising from a years-long DOJ investigation culminating in a guilty plea, civil settlement, and $885 million in liability, and which overcame a Rule 23.1 motion to dismiss. Under longstanding precedent, the SLC must demonstrate that "no disputed issues of material fact exist"[2] with respect to whether the SLC conducted a reasonable investigation and had reasonable bases for its conclusions, and that it met "unyielding standards of diligence"[3] required of single-member SLCs.

The SLC did not meet its burden. Rather than confronting the claims fairly and directly, the SLC improperly narrowed the claims, avoided uncomfortable facts and evidence, and even misapprehended the law. The trial court erred by repeatedly excusing the SLC's shortcomings, even going so far as to reverse its prior findings about the scope of the Complaint. In so doing, the trial court failed to properly apply Rule 56 standards to the SLC's motion and ran afoul of the balance articulated in *Zapata*, to ensure that "bona fide derivative actions" cannot be wrested away "from

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[1] Capitalized terms not defined herein have the same definitions ascribed to them in Plaintiffs' Corrected Opening Brief (the "OB").

[2] *Diep v. Trimaran Pollo P'rs, L.L.C.*, 280 A.3d 133, 151 (Del. 2022).

[3] *Sutherland v. Sutherland*, 2007 WL 1954444, at *3 n.10 (Del. Ch. July 2, 2007).

well-meaning derivative plaintiffs through the use of the committee mechanism."[4]

This is an important appeal for the future of both derivative oversight cases and the trial court's application of *Zapata*. If SLCs, like this one, are permitted to dictate the results of investigations by narrowly defining their scope, ignoring or mischaracterizing inconvenient evidence, and crediting self-serving statements made in informal interviews over DOJ-developed evidence, "the derivative suit will lose much, if not all, of its generally-recognized effectiveness as an intra-corporate means of policing boards of directors."[5]

[4] *Zapata v. Maldonado*, 430 A.2d 779, 786 (Del. 1981).

[5] *Id.*

ARGUMENT

I. MATERIAL FACTUAL DISPUTES EXIST REGARDING THE SCOPE AND DILIGENCE OF THE SLC'S INVESTIGATION

A. The SLC Avoided Investigating FCA-Related Misconduct

The SLC concedes that it decided to "focus" on FDCA compliance issues and, correspondingly, took the position that "AKS and price reporting compliance issues… are not at issue in this action."[6] The SLC claims it investigated areas it deemed "not at issue" by pointing to long passages in its report suggesting that SLC Counsel reviewed large volumes of materials, interviewed relevant witnesses, and prepared a timeline of events.[7]

The issue is not the length of the SLC Report, the volume of documents reviewed, or the number of witnesses interviewed, but rather the lens through which the SLC examined the facts and evidence. The SLC's decision not to focus on the Company's FCA-related liability necessarily impacted its determinations on materiality and relevance, what issues merited follow-up, and how to use the available evidence and for what purposes. The record confirms it. The SLC cannot demonstrate that it treated FCA and AKS violations as part of its mandate, or that it

[6] A1581-82.

[7] Appellee Special Litigation Committee's Answering Brief ("AB" or "Answering Brief"), at 27-29.

actually investigated officer and director culpability flowing from successive FCA-related warnings from counsel, a high-level whistleblower, and a DOJ investigation. The SLC's "selective investigation" treated conduct contributing 70% of the Company's liability for the PFS Program as outside the scope and therefore did not "adequately address all of [Plaintiffs'] claims."[8]

Early due diligence memoranda warning of FCA and AKS compliance risks associated with the PFS Program exemplify the SLC's "selective investigation." The Report acknowledges that the Company, and Collis specifically, received a series of due diligence memoranda that the SLC vaguely describes as identifying "potential issues associated with MII's customer billing practices" and "inventory practices."[9] But the SLC did not (i) connect the dots that the warnings in those memoranda[10] mirrored the DOJ's theories of FCA and AKS liability resulting in $625 million in liability,[11] or (ii) investigate whether the Company implemented the

[8] *Sutherland v. Sutherland*, 958 A.2d 235, 244 (Del. Ch. 2008) (*Sutherland II*) (citing *Electra Inv. Tr., PLC v. Crews,* 1999 WL 135239, at *6 (Del. Ch. Feb. 24, 1999)).

[9] A1186-87.

[10] The memoranda warned that the PFS Program "creates significant problems," including that it runs afoul of the FCA prohibition on "false claims (here double billings) to government programs,'" involves fraudulent practices, and that "[a]rguably, MII has encouraged physicians to file false claims." A0064; A0064; A0061.

[11] *See* A0589-91; A0593-601; A0818-20.

memoranda's recommended remedial measures.[12] Rather, the SLC remarked that the memoranda "did not identify FDA regulatory risks or concerns regarding product quality or sterility,"[13] and falsely painted the memoranda as exculpatory, cherry-picking language that the PFS Program was "standard practice at hospitals," "an acceptable practice," "permissible," and "does not of itself raise concerns."[14] Omitting "problematic information while 'includ[ing] exculpatory information of a similar character'" will "cast doubt on whether the single-member committee had conducted a good faith investigation."[15]

The SLC's treatment of Ober Kaler's investigation illustrates how redefining the scope of an investigation can dictate its results. Chou first defined Ober Kaler's mandate broadly: "to review the business practices of the Company's Oncology Group *as a whole*," and to assess "*overall compliance with federal antikickback/ fraud and abuse laws and the federal false claims act.*"[16] But after Ober Kaler

[12] A0067. The SLC Report did not examine whether the Company implemented the recommended remedial measures. *Cf.* A1269-71.

[13] A1187.

[14] A1197-98.

[15] *In re Baker Hughes Deriv. Litig.*, 2023 WL 2967780, at *22 (Del. Ch. Apr. 17, 2023) (citing *Sutherland v. Sutherland*, 968 A.2d 1027, 1030 (Del. Ch. 2008) (*"Sutherland III"*) and *Sutherland II*, 958 A.2d at 243).

[16] A1261 (emphasis added).

identified serious concerns about the PFS Program, including "Discounting," "ASP Manipulation" and potential "anti-kickback statute violation[s],"[17] Chou narrowed Ober Kaler's investigation, to "not include a review of the legality of the pre-filled syringe program."[18]

The SLC stopped short of investigating this thread because it accepted—without testing—Chou's claim that he believed that the PFS Program had already been reviewed, "was pretty clean," and "was previously blessed."[19] Yet the SLC does not point to any legal opinion or compliance review that "blessed" the PFS Program or indicated it was "clean."[20] "An SLC fails to conduct a reasonable investigation if it simply accepts defendants' version of disputed facts without

[17] A0191-96; A0202; *see also* OB41-42.

[18] A1262, A1269.

[19] A1265-66. ABC internal counsel Rob Stone—the original source of the contention that the PFS Program was "previously blessed"—even told the SLC that "maybe 'blessed' was not the right word," and that all he meant was "that the program had been in place for a long time before [he] got there." A1661-62. The SLC omitted this from its report.

[20] The SLC repeatedly cites Chou's belief as a rationale for why red flags should not be investigated. *See, e.g.*, A1256; A1262; A1381-82. Moreover, Reed Smith clearly disclaimed that it "conduct[ed] a detailed, 'due diligence'-type of review that would enable us to offer a definitive legal opinion with regard to all business practices," and, in all events, Reed Smith expressly raised FCA and AKS concerns about the PFS Program. A0123-27.

consulting independent sources to verify defendants' assertions."[21]

Even the SLC's discussion of Mullen's reporting and complaint alleging FCA and AKS violations avoids any substantive analysis of Mullen's claims.[22] Mullen raised concerns that the PFS Program violated the FCA and AKS as early as March 2010,[23] continued to assert that MII gave "an inducement or kickback to physicians to purchase … overfilled vials" and billed "Medicare and Medicaid for 'free' product—the overfill" even after his termination,[24] and, in October 2010, filed a *qui tam* complaint expanding on his allegations.[25] The Report nonetheless concludes that Mullen's allegations were not red flags, because they were "limited to AKS and price reporting compliance issues *similar* to those at issue in … *Westmoreland*," and "did not contain any allegations relating to sanitation, repackaging, or FDCA violations."[26] By couching Mullen's concerns as limited to FCA and AKS issues

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[21] *See London v. Tyrrell*, 2010 WL 877528, at *17 (Del. Ch. Mar. 11, 2010).

[22] AB27-29.

[23] A1250-51; A1415.

[24] A0175.

[25] A0228-339; A0234-35 ¶8.

[26] A1242, A1272; *see also* A1364. The allegations in *Westmoreland* are far narrower than those in the Mullen Complaint and do not concern the PFS Program or the double-billing scheme alleged by Mullen. The evidence the SLC cites for the similarities between the Mullen and *Westmoreland qui tam* actions is inapposite. *Compare* A1260 with AR0006-8.

similar to *Westmoreland*, and taking the position that those issues were "not at issue" in this action,[27] the SLC avoided investigating the issues that Mullen raised.

The SLC took the same approach to the DOJ's raid of MII.[28] Even though *the search warrant itself referenced potential FDCA violations*,[29] the SLC excused the Board's lack of action on the basis that the directors reported believing the DOJ's investigation related only to Mullen's *qui tam* action (and thus concerned FCA and AKS issues that the SLC determined was outside the scope).[30]

B. The SLC and the Trial Court Violated the "Law of the Case" Doctrine

The SLC's Answering Brief offers no persuasive response to Plaintiffs' argument that the SLC violated the "law-of-the-case" doctrine by treating FCA issues as outside the scope of the litigation.[31] The SLC instead attempts to blame *Plaintiffs* for its investigatory failures.

The SLC first suggests that the law-of-the-case argument was not preserved.[32]

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[27] A1581-82.

[28] AB28-29.

[29] A1279 (referencing potential "violations of U.S.C. § 331(a), (d), (k), and (p), which prohibit adulteration, misbranding, and failing to register with the FDCA").

[30] A1284; A1287; A1299; A1302.

[31] OB21-25.

[32] AB24.

Plaintiffs argued below on multiple occasions that the SLC's treatment of FCA matters as outside the scope was inconsistent with both the record and prior rulings of the trial court. In their answering brief below, Plaintiffs argued that the SLC's exclusion of FCA-related claims conflicted with the court's decisions on Defendants' motions to dismiss and in the Section 220 litigation.[33] Plaintiffs made this point again during oral argument.[34]

The SLC next contends that the law-of-the-case doctrine does not apply because the trial court never upheld *Caremark* claims based on FCA violations.[35] This contention cannot be squared with the trial court's opinion sustaining Plaintiffs' *Caremark* claims and rejecting Defendants' efforts to "separat[e] allegations at [MII] into baskets of illegality."[36] This issue was litigated and decided below.

The weakness of the SLC's response is evident from its heavy reliance on a single paragraph of the Complaint.[37] Even that paragraph demonstrates Plaintiffs were asserting claims for a failure of "Board oversight" as a result of "illegal

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[33] A1654-56; OB21-22.

[34] A1839-42; A1899-1900.

[35] AB24.

[36] *Teamsters Local 443 Health Servs. & Ins. Plan v. Chou*, 2020 WL 5028065, at *21 n.288 (Del. Ch. Aug. 24, 2020).

[37] AB22-23.

conduct."[38] Of course, complaints must be read as a whole, not piecemeal.[39] The rest of the Complaint explains the various forms illegal conduct took, including the submission of false claims, leading to a *qui tam* action and civil settlement for $625 million.[40] Defendants recognized this and attacked the FCA-related allegations in their motion to dismiss.[41] The SLC has no basis to argue it was not on notice that FCA-related misconduct and liability were part of the case, particularly after the trial court rejected Defendants' arguments to exclude them from the case.[42]

The SLC also oddly suggests *Odyssey Partners* is inapplicable.[43] *Odyssey Partners* explains that a prior ruling regarding the scope of theories in a complaint is law of the case and that where, as here, the issue has been decided, that resolution

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[38] A0841 ¶1.

[39] *See KnighTek, LLC v. Jive Commc'ns, Inc.*, 225 A.3d 343, 351 (Del. 2020).

[40] *See, e.g.*, A0844-46 ¶¶5-6, 8, A0859 ¶45, A0873-76 ¶¶80-83 & A0821-27, A0891-92 ¶117 & A0343-483, A0896-97 ¶128, A0901-04 ¶¶137-42.

[41] Notably, the very first sentence and most of the first paragraph of Defendants' motion to dismiss brief focused on FCA issues (AR0024); applying the SLC's own logic, this demonstrates that Defendants knew that Plaintiffs' oversight claims were based on both overbilling issues as well as safety/sterility issues.

[42] *See In re Match Grp., Inc. Deriv. Litig.*, 2024 WL 1449815, at *6 (Del. Apr. 4, 2024) (even vague allegations "will be considered 'well pleaded' if they provide the opposing party with notice of the claim") (internal citation omitted).

[43] AB26; *Odyssey P'rs v. Fleming Co.*, 1998 WL 155543 (Del. Ch. Mar. 27, 1998).

will not be disturbed absent a "'compelling reason.'"[44] The only legal authority the SLC cites in response is *Frederick-Conaway v. Baird*,[45] arguing that the trial court's rulings in the Section 220 proceeding are irrelevant.[46] Even if that were the case—and it is not[47]—the court's ruling on the motion to dismiss in the plenary action forecloses the SLC from contesting the issue now. The SLC does not cite or rely upon any other law-of-the-case authority.

Finally, the SLC seeks to blame Plaintiffs for the SLC's own investigatory shortcomings by arguing that Plaintiffs "had the opportunity to" but "at no point suggested during the SLC's investigation that [FCA-related misconduct] should be a focus of the inquiry."[48] This is wrong. As the SLC notes, "on December 9, 2020, Plaintiffs' counsel gave a presentation to the SLC and SLC Counsel."[49] That presentation—which was transmitted to SLC Counsel—urged the SLC to investigate FCA-related misconduct and even pointed out (on the first substantive slide) that

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[44] *Odyssey P'rs*, 1998 WL 155543, at *1 (quoting *Zirn v. VLI Corp.*, 1994 WL 548938, at *2 (Del. Ch. Sept. 23, 1994)).

[45] *Frederick-Conaway v. Baird*, 159 A.3d 285 (Del. 2017).

[46] AB26.

[47] *Frederick-Conaway* does not say that issues determined in a books-and-records proceeding are not "law of the case" for the plenary proceeding. Indeed, it does not address that question at all.

[48] AB21, AB23.

[49] A1074.

Defendants previously "tried to improperly limit the scope of this action" by excising FCA-related issues from the case.[50] The slides repeatedly discuss FCA and AKS-related matters, including Mullen's *qui tam*, kickbacks, illegal discounts, and the Company's agreement to pay $625 million.[51]

Each of the SLC's arguments attempts to deflect from the fact that the *SLC* has the burden to conduct a reasonable investigation of sufficient scope. Because the FCA violations served as a basis for Plaintiffs' *Caremark* claims and were thus part of the case, the SLC's failure to investigate them is a material shortcoming that prevents the SLC from meeting that burden.

C. Material Questions Exist Regarding the SLC's Treatment of DOJ Evidence

Genuine questions abound regarding the reasonableness and credibility of an SLC investigation that fails to "explore all relevant facts and sources of information"[52] or fails "to deal openly and honestly with all relevant and material information."[53] Such is the case here, where the SLC's strategic decision not to rely on or produce the DOJ Proffer Memoranda raises serious concerns: "*Avert not thine*

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[50] AR0086, AR0101.

[51] *See* AR0101-02, AR0106, AR0112, AR0117, AR0119, AR0123.

[52] *London*, 2010 WL 877528, at *17.

[53] *Sutherland III*, 968 A.2d at 1030.

eyes....[I]gnoring difficult issues or embarrassing facts that bear centrally upon what the committee is supposed to be doing is likely to lead a reviewing court to conclude that the committee was more interested in avoiding unpleasantness than doing its duty."[54]

It is beyond debate that the forty-five DOJ Proffer Memoranda were thorough, informative, and highly relevant to the SLC's investigation.[55] They also summarized interviews that occurred closer to the events at issue and, thus, were more reliable than the SLC's own interviews years later.[56] But the SLC concedes it "did not rely" on them and withheld them in discovery on that basis.[57] This alone raises a material issue: "'It is a well established principle that the production of weak evidence when strong is, or should have been, available can lead only to the conclusion that the strong would have been adverse.'"[58]

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[54] Gregory V. Varallo, Srinivas M. Raju & Michael D. Allen, *Special Committees: Law and Practice* 171 (2d ed. 2011) (emphasis in original).

[55] *See* OB15-16, 28-35; A0508-91, A0593-670, A0681-741, A1902-906.

[56] *See* A1475 at 77:1-23.

[57] AB30 ("The SLC withheld these documents in discovery and did not attach them to the report because it did not rely on them.").

[58] *Smith v. Van Gorkom*, 488 A.2d 858, 878–79 (Del. 1985).

The SLC even admits it did not use the DOJ Proffer Memoranda as impeachment evidence or to refresh witness recollections,[59] and nothing in record suggests it used them to investigate or clarify DOJ allegations, formulate investigatory leads, or for any other purpose.[60] In fact, the SLC's explanations actually suggest that SLC counsel only considered the Proffer Memoranda *after* the SLC completed witness interviews.[61] While the SLC seeks credit for "collect[ing] and review[ing]" the Proffer Memoranda,[62] the SLC's failure to actually use this valuable evidence as a tool *during* its investigation, as impeachment evidence or otherwise, was not reasonable.[63]

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[59] *See* AR0146-48 (confirming SLC's production of all documents shown to witnesses during SLC interviews and that such documents did not include the Proffer Memoranda).

[60] *See*, *e.g.*, AR0125-45. The SLC's interview memo for Collis contains no references to Collis's DOJ proffer memo, anything he told the DOJ, or anything the DOJ presented to him, despite the DOJ's allegations that Collis demonstrated "intimate knowledge" of the PFS Program at his proffer. *See* A0565; A0150-54; A0155-66.

[61] *See* AB31 (the SLC "reasonably determined [the DOJ Proffer Memoranda] need not be relied upon because they were 'duplicative of information the SLC had *already obtained* from its witness interviews'") (quoting Op. 84) (emphasis added); *see also* A1717-18 ("SLC Counsel collected and reviewed the proffer memoranda[,] which the SLC found (in relevant part) [were] duplicative of information provided by the same witnesses in the SLC's own interviews.").

[62] A1717.

[63] It also raises a sword and shield issue. *See Air Prods. & Chems., Inc. v. Airgas,*

The SLC's other arguments regarding the Proffer Memoranda only confirm the existence of material questions. The SLC argues it was "misleading" for Plaintiffs to claim that the SLC did not read the memorandum summarizing Collis's proffer because counsel reviewed it.[64] But it is undisputed that the SLC member, Mr. Nally, did not even know that the Proffer Memoranda *existed*, let alone read Collis's proffer memo (or any others).[65] The SLC similarly accuses Plaintiffs of "misrepresent[ing] the SLC's conclusions" regarding MII's compliance reporting lines,[66] but fails to address the actual issue (also ignored in its report): the DOJ concluded, based on what multiple witnesses said during proffer interviews, that MII was excluded from ABC's compliance systems and "had no chain of responsibility for compliance reviews."[67] And the SLC has nothing to say about why it did not produce Dan Newton's proffer memo, even though (i) the SLC did not interview Mr. Newton, (ii) the SLC determined Mr. Newton was the person primarily responsible

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Inc., 2011 WL 284989, at *3 (Del. Ch. Jan. 20, 2011) (parties are precluded "from shielding evidence from an opposing party and then relying on the evidence at trial to meet its burden of proof").

[64] AB31.

[65] A1475 at 77:1-23.

[66] AB31 n.3.

[67] OB31-32.

for compliance at MII, and (iii) other witnesses told the SLC that Mr. Newton's DOJ proffer session led to ABC's settlement with the government.[68]

The SLC also attempts to shift blame onto Plaintiffs for not moving to compel the Proffer Memoranda, despite conceding it did not rely upon them, use them, cite or attach them to its Report, or even share them with Mr. Nally,[69] and despite the SLC's position that the memos were not "within the limited scope of *Zapata* discovery."[70] The SLC stood behind the numerous Court of Chancery rulings holding that *Zapata* discovery is narrowly tailored and that only materials the SLC relied upon for its conclusions must be produced.[71] Further, it is the SLC's burden to demonstrate that it conducted a diligent and reasonable investigation.[72] The SLC

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[68] OB32-33.

[69] *See* A1717-18; A1902-07; A1475 at 77:1-23; AR0146; AB30.

[70] AB30.

[71] *See, e.g.*, *In re Oracle Corp. Deriv. Litig.*, 2019 WL 6522297, at *18 (Del. Ch. Dec. 4, 2019) (limiting discovery to documents "actually reviewed and relied upon by the SLC or its counsel in forming its conclusions"); *Kikis v. McRoberts*, No. 9654-CB, Tr. at 22-23 (Del. Ch. Feb. 4, 2016) (TRANSCRIPT) (holding plaintiffs "don't get everything [the SLC] reviewed" and limiting discovery to the SLC's report and exhibits, interview memos, and minutes); *Grimes v. DSC Commc'ns Corp.*, 724 A.2d 561 (Del. Ch. 1998) (declining to compel production of documents reviewed by SLC); *Carlton Invs. V. TLC Beatrice Int'l Hldgs., Inc.*, 1997 WL 38130, at *1, *5-6 (Del. Ch. Jan. 29, 1997) (same); *Kaplan v. Wyatt*, 1984 WL 8274, at *3 (Del. Ch. Jan. 18, 1984) (same).

[72] *Diep*, 280 A.3d at 151.

could have produced the Proffer Memoranda in furtherance of meeting its burden, but chose not to do so. Nor is the Company's assertion of privilege a valid excuse—there was a Rule 510(f) non-waiver stipulation in place,[73] and the SLC attached to its report other documents subject to the Company's attorney-client privilege.[74]

The SLC next mischaracterizes Plaintiffs as asserting that the DOJ Evidence "constitutes unimpeachable fact" that the SLC was "required to accept."[75] This is a strawman. Plaintiffs' argument is not that DOJ's allegations should have been taken as gospel, but that that the SLC unreasonably favored the views of conflicted counsel at Morgan Lewis and self-serving witness statements that lacked documentary support, without meaningfully investigating the DOJ's conclusions and the evidence supporting them. While the SLC argues that it "conducted an independent assessment of both the DOJ's legal theories and the underlying facts,"[76] the SLC almost exclusively cites Morgan Lewis interviews and work product to discount the DOJ's evidence and conclusions.[77] The passages of the SLC Report cited in the

[73] Trans. ID 66942395.

[74] *See*, *e.g.*, AR0011-13 (reflecting Morgan Lewis's perceptions of the "Strengths and Weaknesses" of the DOJ's case against ABC).

[75] AB32.

[76] AB30.

[77] AB30 (citing A1308-15, A1322 nn.1259-61).

Answering Brief contain *fifteen* consecutive cites to Morgan Lewis without referencing the specific evidence the DOJ presented to corroborate its allegations.[78]

The SLC's reliance on Morgan Lewis's claim that it "extracted concessions from DOJ that its testing of seized syringes did not reveal any contamination" illustrates the SLC's selective emphasis.[79] The Report says that "Morgan Lewis informed the Board that the Company had good legal defenses" but warned of potential treble damages.[80] But in the cited exhibit, Morgan Lewis explained there are "a number of bad facts" including that "[o]ut of the 5 million syringes dispensed, less than 100 were tested, and several of those 100 were found to be contaminated by bacteria" and the "[p]resence of 'floaters' in syringes, which pharmacy filtered out but never tested."[81] The SLC then claims Morgan Lewis "unmasked significant weaknesses in the DOJ's allegations" without citing anything,[82] and despite the Company's agreement to plead guilty and pay $885 million.

Finally, confronted with its failure to consider evidence the DOJ developed in a years-long investigation, the SLC attempts to minimize the significance of the

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[78] *See* A1308-15, A1322 nn.1259-61 (cited at AB30).

[79] AB32.

[80] A1322-23.

[81] AR0011.

[82] AB32.

Company's criminal guilty plea and suggests that the allegations leading to the plea may never have been credible.[83] The SLC relies on the contention that the Company only admitted a "limited set of facts";[84] but the SLC does not explain why it failed to treat as "credible" even those "limited" facts.[85] Similarly, the Company "admit[ed], acknowledge[d] and accept[ed] responsibility for" the conduct alleged in the settlement agreement,[86] which formed the basis for its $625 million civil settlement concerning FCA violations.[87] The SLC's dismissal of these weighty concessions by the Company as mere "unproven allegations"[88] was unreasonable and illustrates a results-oriented process, rather than a good faith investigation.

[83] AB32-33.

[84] AB32.

[85] A0712-14 ¶2; A0729-32; A0753-66 ¶K; A0812-17.

[86] A0749.

[87] A0813-17.

[88] A1720.

II. MATERIAL ISSUES EXIST REGARDING THE REASONABLENESS OF THE SLC'S CONCLUSIONS

A. The SLC Did Not Have Reasonable Bases to Conclude That the Officer Defendants Adequately Responded to Red Flags

In its Answering Brief, the SLC continues to misstate the standard for *Caremark* liability and falsely accuses Plaintiffs of "blatant misrepresentations of the record."[89]

As this Court recently reaffirmed, *Caremark* liability attaches when fiduciaries "fail to act in the face of a known duty to act, thereby demonstrating a conscious disregard for their responsibilities."[90] Where fiduciaries "knew that they were not discharging their fiduciary obligations," they have "breach[ed] their duty of loyalty."[91] The same standard applies to both officers and directors—neither can "consciously ignore red flags,"[92] and the SLC acknowledges that, where officers "knew of evidence of corporate misconduct," they cannot "consciously fail[] to take action in response," *and* that "gross negligence" is sufficient to establish liability.[93]

Nevertheless, the SLC continues to insist upon an improperly narrow view of

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[89] AB36-37.

[90] *Lebanon Cnty. Emps' Ret. Fund v. Collis*, 2023 WL 8710107, at *1-2 (Del. Dec. 18, 2023) (quoting *Stone v. Ritter*, 911 A.2d 362, 370 (Del. 2006)).

[91] *Id.*

[92] *In re McDonald's Corp. S'holder Deriv. Litig.*, 289 A.3d 343, 376 (Del. Ch. 2023).

[93] AB37 & n.4 (quoting *McDonald's*, 289 A.3d at 376).

Caremark liability that only attaches if the fiduciaries "knowingly operate[d] an illegal business model."[94] But that describes just one type of oversight liability, sounding in *Massey*, where "a corporate fiduciary ma[kes] a conscious decision to violate the law."[95] The SLC ignores that, as this Court recently discussed, *Massey* claims and red-flags claims are "two distinct theories" of liability and that, under the latter, fiduciaries who do not have actual knowledge of illegality can still be held liable for failing to respond to red flags.[96]

The SLC even argues that "[P]laintiffs cannot sustain a breach of fiduciary duty claim with evidence that these defendants merely 'should have known' about purported illegality because the claim requires actual knowledge or gross negligence."[97] This is incorrect. "A settlement of litigation or a warning from a regulatory authority—irrespective of any admission or finding of liability—may demonstrate that a corporation's directors *knew or should have known* that the corporation was violating the law."[98] Material issues of fact exist where the SLC

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[94] AB36.

[95] *In re Massey Energy Co.*, 2011 WL 2176479, at *20 (Del. Ch. May 31, 2011).

[96] *Collis*, 2023 WL 8710107, at *2, *20.

[97] AB37.

[98] *Collis*, 2023 WL 8710107, at *20 (emphasis added) (quoting trial court decision, 2022 WL 17841215, at *16 (Del. Ch. Dec. 22, 2022)); *see also* OB37-38.

cannot "show that it correctly understood the law relevant to the case."[99]

The SLC's response to the memorandum sent to Collis is a perfect example of how the SLC both misapplied the law and ignored inculpatory facts.[100] After acknowledging that the memo warned of FCA non-compliance (including "double-bill[ing]," "misrepresent[ations]," and "submission of a false claim"),[101] the SLC accuses Plaintiffs of "omitting" the memo's advice that "the risk of sanctions being imposed is moderate or less."[102] That statement—coupled with a conscious decision to take no action—implicates *Massey*, or at the very least a red-flags theory of *Caremark* liability. Where fiduciaries learn that a company "is not currently in compliance," but "the likelihood of an enforcement action is quite low," the "decision to pursue the project would constitute a conscious decision to violate the law."[103] Moreover, it is the SLC who is omitting facts from the memo, which goes on to say that legal actions by MII's clients "pose a greater risk" of "high to moderate," and could allege "fraud, misrepresentation, and conversion, for which

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[99] *London*, 2010 WL 877528, at *17.

[100] *See* AB37-38; OB39-40; A0064-65.

[101] *See* AB38; OB39-40.

[102] A0065; AB38.

[103] *See*, *e.g.*, *Ontario Provincial Council of Carpenters' Pension Tr. Fund v. Walton,* 2023 WL 3093500, at *34 (Del. Ch. Apr. 26, 2023).

substantial compensatory and punitive damages may be assessed."[104]

Because it must admit that Collis and Chou learned of serious FCA-related compliance issues, the SLC falls back on its improper exclusion of FCA-related misconduct from its investigation. *See supra* Section I.A. The SLC argues that the Reed Smith memo could not have alerted Collis that the PFS Program "possibly violated FDA health and safety regulations," which the SLC wrongfully characterizes as "the only violations at issue in [Plaintiffs'] complaint."[105] The SLC likewise excuses Chou for learning about FCA-related issues from Ober Kaler (*see supra* at 5-6) because the firm's concerns about the PFS Program were about "anti-kickback and billing concerns, not FDCA compliance," and because "Ober Kaler's mandate did not include a review of FDCA compliance, product sterility, or the legality of the pre-filled syringe program."[106] The SLC in effect asks this Court to blind itself to the same evidence the SLC ignored.

The SLC also seeks credit for identifying that Collis and Chou learned that 92% of the PFS Program's prescriptions were fraudulent and failed to report that

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[104] A0065.

[105] AB37; *but see* A0842-44 ¶4, A0858 ¶43, A0859-69 ¶¶46-71, A0870-76 ¶¶75-83.

[106] AB39.

issue to the Board.[107] The SLC claims that the officers believed the PFS Program complied with Alabama law, but it is simply unreasonable to credit this explanation, given the obviously fraudulent practices, particularly where the Company later admitted it was never in compliance.[108] Nor was it reasonable to credit the officers for a memorandum sent to MII's chief pharmacist, when the SLC concedes that compliance review efforts were "pause[d]" after the DOJ raid of MII,[109] and the fraudulent misconduct continued for approximately eighteen more months.[110]

Finally, the SLC completely ignores that Collis and Chou, upon learning of the Mullen Complaint and the DOJ's raid of MII, failed to take any action or report what they already knew to the Board.

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[107] AB41; OB12.

[108] The practices did not comply with Alabama law because they were *fraudulent*, but also because Alabama law expressly required MII to maintain patient information, which MII was not doing. OB9; A0705, A0617-22.

[109] AB41; A1236.

[110] A0690 at ¶25 ("This business model for the PFS Program remained consistent during the entire time of its operation, between 2001 and January 2014."); *see also* A0750-52, A0814-17; A0824-25.

B. The SLC Did Not Have Reasonable Bases to Conclude That the Director Defendants Adequately Responded to Red Flags

The SLC's Answering Brief still does not identify any tangible reaction from the directors to either Mullen's complaint or the DOJ's raid of MII, raising material questions about the reasonableness of the SLC's conclusions.[111]

As to the Mullen Complaint, the SLC has not shown that the directors took *any* action upon learning of Mullen's allegations or that he was fired after raising his concerns.[112] After quibbling that the Mullen Complaint may not have been a "red flag,"[113] the SLC points to only two events to demonstrate actions the directors purportedly took in response: (i) the Ober Kaler investigation and (ii) the hiring of Morgan Lewis.[114]

But the SLC admits that Ober Kaler was hired *before* the Mullen Complaint was filed.[115] The hiring thus could not possibly have been a "reaction" to a *subsequently* occurring red flag. The SLC's own brief acknowledges that "Chou had made plans to hire Ober Kaler as early as April 2010, months before Mullen raised

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[111] AB43.

[112] AB43-44.

[113] AB43.

[114] AB40.

[115] AB44.

his concerns regarding OS's billing practices."[116] The SLC also concedes that Chou expressly limited Ober Kaler's mandate to exclude the PFS Program,[117] even though Mullen's complaint referred to the PFS Program as an "overfill laundering scheme."[118] Crediting the directors for Ober Kaler's *preexisting* investigation that did *not* include investigating the PFS Program implicated in Mullen's complaint makes no sense and is not reasonable.

The only other director "action" the SLC identifies is learning that management had hired Morgan Lewis to "handle Mullen's claims and any resulting investigative activity."[119] But the trial court had already rejected the mere retention of counsel to provide updates as an "insufficient" reaction,[120] raising a material question about the SLC's conclusion to the contrary.[121]

With regard to the DOJ Search Warrant and Subpoena, the SLC's Answering Brief confirms that the SLC merely engaged counsel, "received updates," and

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[116] AB40.

[117] AB28, 38; A1261-71.

[118] A0286-87.

[119] AB44.

[120] *Chou*, 2020 WL 5028065, at *25.

[121] The SLC insists it did not rely on the statements from directors Hyle and Long that Plaintiffs cited. *See* AB45. The SLC Report states otherwise. *See* A1288 n.1104.

presumed that the DOJ investigations were based on Mullen's complaint, which they assumed lacked merit.[122] As noted, merely hiring counsel, passively receiving updates, and relying on earlier, misguided assessments does not satisfy directors' obligations to take "tangible action . . . to remedy the underlying [misconduct]."[123] Even if directors were aware that, following the search, ABC tested MII's products and detected "no issues,"[124] the SLC made no attempt to square those test results with multiple previous testing incidents in which bacteria were identified in MII's facilities and in the pre-filled syringes themselves,[125] or to investigate what the directors knew about those previous tests. Nor was it reasonable for the SLC to credit the Alabama Board of Pharmacy inspections where (i) the DOJ determined that MII personnel had made fraudulent misrepresentations to the inspectors, and (ii) the SLC made no effort to investigate those allegations.[126]

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[122] AB45.

[123] *Chou*, 2020 WL 5028065, at *25.

[124] AB46.

[125] A0696-700.

[126] *See* AB46; OB9, 44-45; A0614-17. Remarkably, Mr. Nally was under the impression that the PFS Program engaged in no illegal activity whatsoever. A1482 at 102:16-103:5.

CONCLUSION

For the foregoing reasons and the reasons stated in Appellants' Opening Brief, this Court should reverse the trial court's ruling and remand the action for further proceedings.

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