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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 March 6, 2024

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NATURE OF PROCEEDINGS

This appeal concerns a "criminal enterprise"[1] operated by a subsidiary of AmerisourceBergen Corporation ("ABC" or the "Company")[2] that, according to the Department of Justice, "was known to and approved at the highest levels of the Company."[3] The sole function of ABC's pre-filled syringe program (the "PFS Program") was to illegally extract and monetize extra doses of oncology medication from sterile glass vials, which endangered the safety of the drugs and facilitated the overbilling of government healthcare programs. Following government investigations of the PFS Program, ABC entered a criminal guilty plea and agreed to pay $885 million for violations of the federal Food, Drug, and Cosmetic Act ("FDCA") and the False Claims Act ("FCA").

Derivative *Caremark*[4] claims to recover for this financial and reputational harm overcame a motion to dismiss. A single-member special litigation committee (the "SLC"), comprised of director Dennis M. Nally ("Nally"), seized control of the

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[1] *Teamsters Local 443 Health Servs. & Ins. Plan v. Chou*, 2020 WL 5028065, at *2, *25-26 (Del. Ch. Aug. 24, 2020).

[2] On August 30, 2023, ABC changed its name to Cencora, Inc.

[3] A0690 ¶25.

[4] *In re Caremark Int'l Inc. Deriv. Litig.*, 698 A.2d 959 (Del. Ch. 1996).

claims and was tasked with investigating them. After its investigation, the SLC moved to terminate, and the trial court granted the motion.

Recognizing that the special litigation committee process creates "potentials for abuse," this Court in *Zapata* sought to strike "a balancing point where bona fide stockholder power to bring corporate causes of action cannot be unfairly trampled on by the board[], but the corporation can rid itself of detrimental litigation" and "strike suits."[5] *Zapata* thus created a framework under which an SLC bears the burden "akin to proceedings on summary judgment" to demonstrate adherence to a high standard of independence, open-mindedness, and diligence.[6]

To terminate derivative litigation, the SLC bears the burden to establish "that no disputed issues of material fact exist about the independence, good faith, and reasonableness of the SLC's investigation and whether the SLC had reasonable bases for its conclusions."[7] A single-member SLC, like here, bears an even higher burden, and must demonstrate "unyielding standards of diligence and independence,"[8] so as to be "above reproach."[9]

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[5] *Zapata Corp. v. Maldonado*, 430 A.2d 779, 785-87 (Del. 1981).

[6] *Id.* at 788-89; *London v. Tyrrell*, 2010 WL 877528, at *12 (Del. Ch. Mar. 11, 2010).

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

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

[9] *Lewis v. Fuqua*, 502 A.2d 962, 967 (Del. Ch. 1985).

The SLC did not meet its burden, and the trial court erred by granting the SLC's motion. Multiple material questions of fact concerning the scope, diligence, and reasonableness of the SLC's investigation and conclusions precluded dismissal under the applicable Rule 56 summary judgment standard. The SLC did not faithfully investigate Plaintiffs' claims as *Zapata* and its progeny require, but instead unduly narrowed its investigation, excluded highly relevant evidence from the Department of Justice's ("DOJ") investigation, failed to press or otherwise contend with evidence of officer misconduct, and credited self-serving excuses and explanations that were both unreasonable and refuted by documentary evidence.

First, the SLC inexplicably determined that the Company's FCA violations were "not at issue in this Action"[10] and treated them as outside the scope of its investigation. The SLC thus failed to investigate Defendants' potential liability for the Company's FCA violations, which account for more than 70% of the liability incurred by the Company as a result of the PFS Program.

Second, the SLC blinded itself to evidence from the DOJ's investigation. Unlike a typical SLC investigation which starts anew from allegations in a derivative complaint, this SLC had access to a wealth of evidence from the DOJ's years'-long investigation of the PFS Program, including detailed memoranda of witness proffers

[10] A1581-82.

to the DOJ. The investigation could have (and likely should have) started there, but the SLC took a different—and unreasonable—approach. Instead of building off of the DOJ's evidence, the SLC chose to exclude it, created its own record, and refused to produce the witness proffers in discovery. The SLC thus avoided scrutiny of this underlying evidence, but also scrutiny of its own investigation.

Third, the SLC reached unreasonable conclusions regarding the knowledge and culpability ABC's officers and directors. The SLC ignored or unreasonably discounted documentary evidence that Defendants-Below Steven Collis and John Chou knew or should have known that the PFS Program was operating illegally, yet did nothing to report or correct the illegality. As to the directors, the SLC's investigation confirmed they took no action in response to at least two bright red flags, but credited their unreasonable excuses for why they believed no action was necessary. In light of the available documentary evidence, the SLC did not have reasonable bases to conclude that the officer and director defendants held an honest belief that the PFS Program was operating legally.

This Court reviews the trial court's decision *de novo*. In so doing, the Court should take note that its assessment of opioids-related red flags in *Lebanon County Employees' Retirement Fund v. Collis* concerns substantially the *same* fiduciaries over the *same* time period:

> To say that the red flags that portended a looming corporate trauma were limited to unproven allegations in a few lawsuits strains credulity. In reality…the warning signs identified in the complaint were legion: [] "The directors did not just see red flags; they were wrapped in them."[11]

This SLC, however, commended "management's 'tone at the top,'" and observed that "[s]enior leadership took compliance seriously," and "understood the ramifications of a compliance failure in the highly regulated pharmaceutical industry."[12]

In all events, there are too many material questions about the scope, diligence, and reasonableness of the SLC's investigation to let it stand. The existence of these issues does not "instill confidence" that the SLC "act[ed] with integrity and objectivity."[13] Under the Rule 56 standard—particularly the heightened standard applicable to single-member SLCs—the trial court erred and must be reversed.

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[11] 2023 WL 8710107, at *22 (Del. Dec. 18, 2023) (quoting decision below, 2022 WL 17841215, at *16 (Del. Ch. Dec. 22, 2022)).

[12] A1103. The Court should also note that ABC's board has formed *another* special litigation committee to investigate the allegations in the *Lebanon County* action. Trans. ID 71983275.

[13] *In re Oracle Corp. Deriv. Litig.*, 824 A.2d 917, 940 (Del. Ch. 2003).

SUMMARY OF ARGUMENT

1. The trial court erred in finding that the single-member SLC met its burden of proving the absence of material factual disputes concerning the scope and reasonableness of the SLC's investigation as related to:

   a. *The Company's FCA violations*. The SLC determined that the Company's FCA-related violations were not at issue in the litigation, treated them as outside the scope of its investigation, and failed to demonstrate that it investigated those issues with unyielding diligence.

   b. *The SLC's exclusion of evidence from the DOJ's investigation*. The SLC intentionally chose not to rely on DOJ evidence, including proffer memoranda that summarized witness interviews with the DOJ that the SLC withheld from discovery.

2. The trial court erred in finding that the single-member SLC met its burden of proving that its conclusions had reasonable bases. The record contradicts the SLC's conclusions that ABC's officers and directors reasonably and honestly believed that the PFS Program was operating in compliance with the law. The record also contradicts the SLC's conclusions that ABC's officers and directors adequately responded to red flags of illegality concerning the PFS Program.

STATEMENT OF FACTS

I. THE PFS PROGRAM VIOLATES MULTIPLE FEDERAL STATUTES AND LEADS TO NEARLY $1 BILLION IN LIABILITY

From 2001 to 2014, an ABC subsidiary named Medical Initiatives, Inc. ("MII") operated the PFS Program from its plant in Dothan, Alabama.[14] The PFS Program's sole purpose was to repackage oncology drugs from vials approved by the Food and Drug Administration ("FDA") into single-use syringes.[15] MII was able to produce more doses than it had purchased from the original drug manufacturers—and thus extract additional profit—by harvesting and pooling "overfill" from the FDA-approved vials before placing the drug into syringes.[16]

The PFS Program violated multiple federal statutes. By harvesting overfill from FDA-approved vials, MII created and sold more syringes than the total number of vials ABC had paid for.[17] Because MII did not disclose its extraction and monetization of overfill to customers, or that discounts it provided arose from this practice, the PFS Program caused customers to unwittingly submit false claims to the government,[18] in violation of the False Claims Act ("FCA") and Anti-Kickback

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[14] A0849-50 ¶¶21-22.

[15] A1029-30.

[16] A1198.

[17] A0566, A0587-89; A0596-99.

[18] A0587-89; A0593, A0601, A0615-16, A0659-68.

Statute ("AKS").[19]

MII's practices also compromised patient safety and violated FDA regulations.[20] To validly repackage FDA-approved injectable drugs, MII needed—but failed to seek or obtain—FDA approval, in violation of the FDCA.[21] MII also violated the FDCA by failing to register with the FDA, enabling MII to avoid regulatory scrutiny and inspections.[22] Left unchecked, MII's clean rooms routinely tested positive for bacteria, but MII did not issue recalls or alert cancer practices that injected the drugs into immuno-compromised patients.[23] MII's process also generated thousands of syringes (approximately 100 per week) contaminated with foreign particulate matter, which employees referred to as "floaters."[24] Instead of destroying those syringes, MII used a non-FDA-compliant process to "filter out" the foreign substances, then sold the syringes to cancer practices without advising of the risk of contamination.[25]

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[19] 42 U.S.C. § 1320a-7b; 31 U.S.C. §§ 3729-3733.

[20] A1198; A0691-94, A0696-700, A0701-02, A0704-07.

[21] 21 U.S.C. § 331(d); 21 U.S.C. § 355.

[22] A0704-05 ¶66; 21 U.S.C. § 360; A1308-10.

[23] A0696-98 ¶¶42-44.

[24] A0698-700 ¶¶47-51.

[25] *Id*.; A0638-39 ¶¶242-44; A0569-70.

MII held itself out as a state-regulated pharmacy, but it was nothing of the sort.[26] Per the DOJ, "to qualify as a pharmacy under Alabama law, MII was required to maintain the medication history, diagnosis, laboratory data and other pertinent information for the patients to whom PFS were administered."[27] MII kept no such records, and "did not even know the patients to whom PFS were ultimately dispersed."[28] The DOJ also determined that MII "misrepresented its lack of patient specific prescriptions to the State of Alabama inspectors."[29]

The named officer defendants-below had direct responsibility for the PFS Program. Steven Collis oversaw MII as its President for the entire period of the PFS Program's operations, John Chou was MII's General Counsel from 2007 to 2014, and Tim Guttman served as MII's Vice President from 2012 to 2014.[30]

From the very beginning, at least Collis—who was instrumental in approving and expanding the PFS Program—knew the PFS Program was operating illegally.[31] In 2001, he received an internal memo warning that MII's practice of harvesting

[26] A0704-05 ¶66.

[27] A0705 ¶68.

[28] *Id*.

[29] A0617-22.

[30] A0854 ¶33; A0036-55.

[31] A0565-66; A0599 ¶19, A0614-17.

overfill "creates significant problems" because "salvage amounts are being billed or used to reduce inventory twice (at least)."[32] The memo further warned that MII "misrepresented what it does with … salvage/overfill" to its clients and that the FCA requires that "overfill amounts are documented and properly reported by MII."[33]

In 2002 and 2003, an oncologist informed Collis that the PFS Program was "violating state pharmacy laws" because pre-filled syringes were not ordered for specific patients and were being shipped without patient names.[34]

A. Mullen Reports That the PFS Program Violates the False Claims Act

In September 2009, Michael Mullen assumed Collis's responsibilities as Chief Operating Officer of ABC's specialty drugs operating subsidiary ("ABSG") that housed MII. Mullen undertook a comprehensive review of the unit's businesses—including MII and the PFS Program.[35] The results alarmed him. In March 2010, Mullen raised concerns that the PFS Program violated the FCA and

[32] A0064.

[33] A0065.

[34] A0979-81.

[35] Memorandum Opinion, dated November 17, 2023 at 50 (hereinafter cited as "Op.") (attached hereto as Exhibit A).

AKS with Collis[36] and David Yost, who was then CEO and a member of the board.[37] On April 8, 2010, Mullen was fired.[38]

Even after his termination, Mullen continued to raise his concerns about the PFS Program's violations of the FCA and AKS with the Company.[39] On May 5, 2010, Mullen provided Chou and another member of ABC's legal team a document explaining how MII's business practices gave "an inducement or kickback to physicians to purchase … the overfilled vials," which "results in Medicare, Medicaid, and others, reimbursing well in excess of the statutory mandate ([average sale price ("ASP")] ASP+6) and/or the true cost of the product."[40]

B. Mullen Files a *Qui Tam* Complaint

On October 21, 2010, Mullen filed a *qui tam* complaint (the "Mullen Complaint"). The Mullen Complaint detailed how OSC and MII "engaged in an illegal 'overfill' laundering scheme designed to pass illegal kickbacks to medical providers and… allow[ed] drug manufacturers to overreport the [ASPs] of the

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[36] A1415.

[37] A1250-51; A1416.

[38] A1254.

[39] A0228-339.

[40] A0170-76; A1257-59.

drugs."[41]

Though the Mullen Complaint was filed under seal, it inadvertently appeared on the public docket and was forwarded to Company executives, including Collis and Chou.[42] Collis wrote Chou that "the MII angle [in the Mullen Complaint] is concerning because of the overfill," and postulated that the case "may be focused on the pre filled syringe program."[43]

On November 1, 2010, Chou informed the Board of Mullen's suit.[44] The Board learned that the Company retained Morgan Lewis & Bockius LLP ("Morgan Lewis") to respond to any government investigation and discussed how to describe the existence of the suit in its public disclosures. Other than in connection with these disclosures, there is no evidence that the Board took any action in response to his suit.

C. Collis and Chou Learn That 92% of the PFS Program's Prescriptions Contain Fraudulent Patient Information

In early 2012, MII customers complained about MII's use of fake patient names on prescription labels. One said it "could be interpreted as fraud" and another

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[41] A0234-35 ¶8.

[42] A1273; A0340-41.

[43] A1273.

[44] *Id*.

expressed it would not "fraudulently put patient names on drugs that they are not getting."[45] This prompted a review, which uncovered "a significant number of instances" (92%) where syringes had been labeled with random names from "patient lists" or "fabricated abbreviated names (initials) for patients,"[46] and went directly to Collis and Chou. Collis and Chou determined not to report this to the Board, based on Chou's purported assessment that the practice of fraudulently labeling medication with fake names was technically not a violation of Alabama law.[47]

D. Federal Agents Execute a Search Warrant At MII's Plant and The DOJ Issues A Subpoena

On July 11, 2012, twenty federal agents executed a search warrant (the "DOJ Search Warrant") at MII's Dothan, Alabama facility.[48] The warrant entitled the agents to seize, among other things, "[a]ll pre-filled syringes" of certain cancer drugs, "including any packaging and labeling," as well as such drugs that were "in the process of being extracted from vials and placed into syringes."[49] The warrant provided that such items "are evidence or instrumentalities of violations of" the

[45] A0486-87; A0496.
[46] A0499.
[47] A1232-38.
[48] A0504-07.
[49] A1279.

FDCA, among other federal statutes.[50]

That same day, the DOJ issued a subpoena (the "DOJ Subpoena") for documents relating to pre-filled syringes, including "relating to pre-filled syringes," and "the process for creating prefilled syringes; equipment used to 'harvest' overfill; quality control and assurance protocols for the syringes; certain communications with federal health care or state agencies;" and other things.[51]

On July 12, 2012, Chou informed the Board of the DOJ Search Warrant and DOJ Subpoena.[52] Morgan Lewis spoke to MII employees who interacted with federal agents during the raid, but no investigation or review of the PFS Program's legality was conducted or requested.

Approximately eighteen months later, MII closed its operations on January 31, 2014.[53] There is no evidence that the Board was involved in this decision,[54] which was purportedly driven by "declining profitability in the face of increasing potential reputational harm caused by continuing the [PFS] Program during the

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[50] *Id*.

[51] A1280.

[52] A1285.

[53] A1239.

[54] A0846-47 ¶11.

government investigation."[55]

E. The Company Enters Into a Guilty Plea and Civil Settlement With the DOJ

On October 28, 2015, the DOJ delivered a 280-slide presentation to ABC's counsel outlining its theories of liability and detailing evidence of the PFS Program's illegality ("DOJ Presentation").[56] In December 2016, the DOJ informed ABC that it might name Collis and other executives as defendants in a civil suit.[57] In July 2017, the DOJ shared a draft civil complaint (the "DOJ Complaint"), leaving the parties blank, but alleging that Collis, Chou, and Guttman all "understood and sanctioned the PFS Overfill and Unopened Vial Scheme."[58]

Both the DOJ Presentation and DOJ Complaint drew heavily from the DOJ's proffer sessions with Company witnesses, including Collis.[59] Company counsel memorialized the proffer sessions in forty-five detailed memoranda ("Proffer Memoranda").[60] Yet the SLC did not rely upon or consider the Proffer Memoranda, except for one (regarding Bill Stickler). Mr. Stickler provided information about

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[55] A1239.

[56] A1308-10; Op. at 66; A0564-91.

[57] A1321-22.

[58] A1322; A0593-670; A0599 ¶19.

[59] A0593-670.

[60] A1902-06.

Collis's personal involvement in the PFS Program, including that Collis: (i) knew MII failed to inform manufacturers that their products were being used for PFS; (ii) personally negotiated with manufacturers structuring rebates and resolving issues with ABC double-billing on chargebacks; and (iii) was intimately aware of how ABC sold PFS to its customers at a discount—a form of illegal kickback.[61]

In September 2017, ABSG entered a guilty plea for FDCA violations and agreed to pay $260 million in monetary penalties.[62] Two months later, in November 2017, the Company agreed to settle FCA liability for $625 million.[63]

II. APPELLANTS BRING THIS ACTION AND OVERCOME A MOTION TO DISMISS

On October 11, 2019, after obtaining book and records following two trials pursuant to 8 *Del. C.* § 220 ("Section 220"), Plaintiffs filed their derivative complaint (the "Complaint"), asserting derivative *Caremark* claims against certain of ABC's directors and officers.[64]

Defendants-Below, represented by Morgan Lewis, moved to dismiss for

[61] A0514, A0545, A0562; A0511-20, A0515-19; A0153-54; A0161-66; A0155-60; A0150-52.

[62] A0710-41.

[63] A0746-817.

[64] A0929-33; A1039-40. The "Director Defendants" are Collis, Richard W. Gochnauer, Lon R. Greenberg, Jane E. Henney, Kathleen W. Hyle, Michael J. Long, and Henry W. McGee. The "Officer Defendants" are Collis, Chou, and Guttman.

failure to plead demand futility. On August 24, 2020, the trial court denied the motion, finding that the Complaint sufficiently pleaded that "a majority of the Demand Board consciously ignored red flags rising to the level of bad faith."[65] The court also sustained Plaintiffs' allegations that "the Officer Defendants consciously breached their fiduciary duties and violated corporate responsibilities by *knowingly operating and maintaining an illegal business model*, and failed to inform the Board about the [PFS] Program's regulatory compliance."[66]

III. THE SLC IS FORMED AND MOVES TO TERMINATE

On September 24, 2020, the Board formed the SLC, which initially was comprised of two members, but ultimately appointed Mr. Nally as its sole member.[67] Mr. Nally interviewed one law firm to serve as counsel for the SLC, Gibson Dunn & Crutcher LLP ("Gibson Dunn").[68] The SLC Report did not disclose that PwC had been sanctioned for discovery misconduct by Nally and Gibson Dunn in a prior representation.[69] Nally even denied having previously worked with the same Gibson

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[65] *Chou*, 2020 WL 5028065, at *17.

[66] *Id.* at *14 (emphasis added).

[67] A1067-68.

[68] A1468 (47:25-48:9).

[69] A0069-74.

Dunn attorney at his deposition.[70]

On September 22, 2021, the SLC issued its report (the "SLC Report") and moved to terminate. During discovery into the SLC, the SLC withheld all but one of the Proffer Memoranda, on the basis that the SLC did not rely upon any of the other Proffer Memoranda.[71]

On November 17, 2023, the Court of Chancery granted the motion to terminate.

[70] A1468 (48:13-21).

[71] A1907.

ARGUMENT

I. THE COURT ERRED IN FINDING NO MATERIAL ISSUES OF FACT REGARDING THE SCOPE OF THE SLC'S INVESTIGATION

A. Question Presented

Whether the trial court erred in finding no material issue of fact concerning the scope of the SLC's investigation despite the SLC's (1) treatment of the Company's FCA violations (and associated $625 million in liability) as "not at issue" and therefore outside the scope of the SLC's investigation, and (2) decision not to rely upon evidence presented in connection with the DOJ's investigation of the Company, including contemporaneously drafted memoranda of witness proffer interviews with the DOJ.

This issue was preserved.[72]

B. Scope of Review

This Court reviews rulings under *Zapata*'s first prong *de novo*.[73]

[72] *See* Op. at 80-84; A1630-31, A1654-66.

[73] *Diep*, 280 A.3d at 149.

C. Merits of Argument

1. Legal Standards

"*Zapata*'s first prong is subject to a summary judgment standard."[74] "To terminate derivative litigation, the SLC must show, and the court must be satisfied, that no disputed issues of material fact exist about the independence, good faith, and reasonableness of the SLC's investigation…."[75] A single-member SLC will be "closely scrutinized" and must meet "unyielding standards of diligence and independence,"[76] so as to be "above reproach."[77]

An SLC "must investigate all theories of recovery" and "should explore all relevant facts and sources of information that bear on the central allegations the complaint."[78] "If the SLC fails to investigate factors or sources of information that cut at the heart of plaintiffs' complaint this will usually give rise to a material

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[74] *Id*.

[75] *Id.* at 151.

[76] *Sutherland v. Sutherland*, 968 A.2d 235, 239-40 (Del. Ch. 2008).

[77] *Gesoff v. IIC Indus., Inc.*, 902 A.2d 1130, 1146 (Del. Ch. 2006). "Above/beyond reproach," in the single-member SLC context, means avoiding even "the appearance of a lack of objectivity" or that the SLC "behave[ed] in a manner inconsistent with the duty to open-mindedly investigate the claims." *Diep*, 280 A.3d at 158, n.3 (Valihura, J., dissenting).

[78] *London*, 2010 WL 877258, at *17 (emphases added).

question about the reasonableness and good faith of the SLC's investigation."[79] Likewise, "[a]n SLC fails to conduct a reasonable investigation if it simply accepts defendants' version of disputed facts without consulting independent sources to verify defendants' assertions."[80]

Under a summary judgment standard, "the Court must view the evidence, and all reasonable inferences taken therefrom, in the light most favorable to the non-moving party" (here, Plaintiffs-Appellants).[81] Further, this Court on appeal is "free to draw [its] own inferences in making factual determinations and in evaluating the legal significance of the evidence because this Court 'is as institutionally competent to discern the existence of factual disputes as is the trial court.'"[82]

2. The Trial Court Erred By Endorsing the SLC's Conclusion That FCA Violations Were Outside the Scope of the Complaint

ABC's FCA-related violations have always been a part of this case. Before the SLC was even appointed, the trial court rejected Defendants' efforts to sever Plaintiffs' FCA-related allegations on two occasions. First, in the Section 220

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[79] *Id*.

[80] *Id.*

[81] *Acro Extrusion Corp. v. Cunningham*, 810 A.2d 345, 347 (Del. 2002).

[82] *Williams v. Geier*, 671 A.2d 1368, 1375 (Del. 1996) (quoting *Hoechst Celanese Corp. v. Certain Underwriters at Lloyd's, London*, 656 A.2d 1094, 1099 (Del. 1995)).

action, the trial court ordered the Company to produce documents referenced in the Mullen Complaint, which asserted FCA-related violations.[83] Second, the trial court expressly rejected Defendants' pleading stage arguments that the Complaint did not plead *Caremark* claims related to ABC's FCA violations.[84] Citing to the Complaint, the trial court held that:

> The allegations specific to the False Claims Act were that by harvesting overfill, ABC was able to bill multiple healthcare providers for the same vial of drug, causing excess billing of federal health care programs, and that the Pre-Filled Syringe Program made it possible for ABC to provide drugs at a discount, enabling ABC to increase its market share. The discounts were in the form of general pharmacy credits provided to customers, constituting "illegal kickbacks"—customers would be billed for the full price of a drug and then a "general credit" would be issued to customers' accounts, resulting in the submission of false claims to federal programs.[85]

The court also discussed the Complaint's allegations that the improper use of overfill led to FCA violations,[86] and that "the Pre-Filled Syringe Program was an 'overfill laundering scheme' involving 'illegal kickbacks and price concessions' to

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[83] Final Order and Judgment, *In Re AmerisourceBergen Corp. Section 220 Litig.*, Consol. C.A. No. 2018-0209-SG, Feb. 13, 2019 at 5 (Trans. ID 62967864).

[84] *Chou*, 2020 WL 5028065, at *8 (citing Compl. ¶¶80-82 (A0873-75)).

[85] *Id.* (citing Compl. ¶82 (A0874-75)).

[86] *Id.* at *12 (citing Compl. ¶¶122-25, 128-29 (A0893-95, A0896-98)).

physician customers and undermined accurate pricing by government healthcare programs."[87] As pled in the Complaint, "ABC's illegal business practices led to nearly a billion dollars in criminal plea agreements and civil settlements,"[88] with "civil claims under the False Claims Act [settling] for $625 million"—the vast majority of damages at issue in this Action.[89] The Court directly rebuked Defendants' arguments that Plaintiffs' *Caremark* claims were limited to safety and sterility issues under the FDCA:

> **[T]he separation of allegations at [MII] into baskets of illegality strikes me as artificial** . . . [because] the factual predicate underlying **Mullen's *qui tam* complaint** was that [MII] was harvesting and selling overfill. While it is illegal to bill for overfill (because it [is] not intended for patient use), it is also illegal to sell overfill for patient use because the harvesting process imperils the safety and purity of the medicine.[90]

The SLC disregarded this ruling and took the position that "AKS and price reporting compliance issues [*i.e.*, FCA issues] . . . are not at issue in this action."[91] The trial court also overlooked its earlier ruling and deferred to the SLC's view,

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[87] *Id.* at *13 (citing Compl. ¶¶137-142 (A0901-04)).

[88] A0869 (capitalization omitted).

[89] *Chou*, 2020 WL 5028065, at *8 (citing Compl. ¶80 (A0873)).

[90] *Id.* at *21 n.288.

[91] A1581-82.

holding that the Complaint was "focused on the alleged breaches of fiduciary duty with respect to drug safety and sterility in the [PFS Program] and FDCA compliance" and "lacks any claims asserting illegal kickbacks or double-billing."[92]

In so doing, both the SLC and the trial court violated the "law of the case" doctrine. "The law of the case is established when a specific legal principle is applied to an issue presented by facts which remain constant throughout the subsequent course of the same litigation."[93] The doctrine "applies to decisions rendered by a court that arise again later in the same court, in the same proceedings" and "operates as a form of intra-litigation *stare decisis*."[94]

This includes pleading stage determinations regarding the scope of a complaint's allegations. *Odyssey Partners v. Fleming Co*. is instructive.[95] There, the court denied defendants' motion to dismiss and the defendants then moved for summary judgment, arguing that the motion to dismiss ruling limited the issues remaining to be decided in the case.[96] Vice Chancellor Lamb noted that "a court's

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[92] Op. at 82.

[93] *Frederick-Conaway v. Baird*, 159 A.3d 285, 296 (Del. 2017).

[94] *Id.* (citing *Carlyle Inv. Mgmt. L.L.C. v. Moonmouth Co. S.A.*, 2015 WL 5278913, at *7 (Del. Ch. Sept. 10, 2015)).

[95] 1998 WL 155543 (Del. Ch. Mar. 27, 1998).

[96] *Id.* at *1.

ruling with regard to certain theories of the complaint will constitute law of the case even though [a] motion to dismiss is denied."[97] The court went on to explain that while the court's earlier decision "could have dismissed one or more of the theories relied on, I find no affirmative statement in the Opinion evidencing an intent to do so."[98] As such, the court did not "accept defendants' argument that the Opinion dismissed all claims or theories of recovery" that were not specifically discussed.[99]

Here, the court's MTD Opinion denied Defendants' motion in its entirety, and specifically criticized Defendants' attempts to exclude FCA issues from the Complaint's *Caremark* claims as "artificial."[100] As such, all of the Complaint's legal theories remain(ed) in play, and it was improper for the trial court to defer to the SLC's view that FCA issues were outside of the scope of the Complaint.

3. The SLC Did Not Adequately Investigate FCA-Related Misconduct

Given that an SLC "must investigate all theories of recovery" and "explore all relevant facts and sources of information that bear on the central allegations in the

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[97] *Id.* at *2 (citing *Porter v. Texas Com. Bancshares, Inc.*, 1989 WL 120308, at *7 (Del. Ch. Oct. 12, 1989) (noting that "rulings with respect to some aspects (theories) of the complaint … will constitute the law of this case")).

[98] *Id.* at *2.

[99] *Id.*

[100] *Chou*, 2020 WL 5028065, at *21 n.288.

complaint,"[101] the trial court's previous finding regarding the scope of the Complaint was particularly important. The SLC's position (in its opening brief below seeking dismissal) that "AKS and price reporting compliance issues . . . are not at issue in this action"[102] all but admits—or at least attempts to excuse—the SLC's failure to investigate "all theories of recovery," which necessarily raises material questions regarding the scope and diligence of the SLC's investigation.[103]

Indeed, each time the SLC's investigation identified a red flag relating to FCA-related misconduct, the SLC would observe that it did not concern safety or sterility issues and end its inquiry. Thus, while the trial court determined that the SLC adequately investigated FCA-related misconduct, it failed to assess *what the SLC did,* merely citing lengthy narratives in the SLC Report that unequivocally stated that FCA-related illegality was outside the scope of its investigation.[104] Had the court done so, it would have had to grapple with the many times that the SLC stopped investigating a promising thread after determining that the thread did not concern issues of safety or sterility, but instead concerned FCA issues. For example:

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[101] *London*, 2010 WL 877258, at *17.

[102] A1581-82.

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

[104] Op. at 82-83.

- Between 2001 and 2003, the company (including Collis personally) received memoranda detailing FCA-related risks stemming from the PFS Program.[105] The SLC deemed these concerns as irrelevant because the issues "did not identify FDA regulatory risks or concerns regarding . . . sterility."[106]

- When evaluating the concerns Mullen raised to Chou and other executives, the SLC discounted Mullen's concerns as "limited to AKS and price reporting compliance issues . . . ."[107] The SLC came to the same conclusion regarding the Mullen Complaint, finding the allegations "did not contain any allegations relating to sanitation, repackaging, or FDCA violations," and ended its analysis there.[108]

- The SLC deemed a 2010 internal investigation by Ober Kaler to be inconsequential because it "focus[ed] on AKS and FCA compliance."[109]

- Finally, the SLC excused the lack of any remedial action in response to the DOJ's FCA investigation into the PFS Program due to the Company's initial view that the investigation related to "Mullen's original *qui tam* complaint (which did not include any FDCA-related assertions)."[110]

That the SLC used FCA-related issues as an excuse to *stop* investigating shows it failed to "investigate all theories of recovery,"[111] and, accordingly, material

[105] A0056-62; A0063-66; A0075-84; A0085-149.

[106] A1187.

[107] A1242.

[108] A1272, A1364-65.

[109] A1263-64.

[110] A1299.

[111] *London*, 2010 WL 877258, at *17.

questions abound about the reasonableness and good faith of the SLC's investigation.[112] Under the applicable summary judgment standard, the trial court had to weigh the evidence in the light most favorable to the non-moving party.[113] Here, the court did the opposite, awarding improper inferences to the SLC, constituting reversible error.[114]

4. The SLC Excluded DOJ Evidence From Its Investigation

Despite having "full and exclusive power and authority of the Board" to evaluate Plaintiffs' claims and allegations and unfettered access to "any and all documents and/or any other information that the SLC deem[ed] necessary to carry out [its] duties,"[115] the SLC disregarded the evidence amassed by the DOJ in its years' long investigations into the Company. This includes the Proffer Memoranda, the DOJ Presentation, the DOJ Complaint, and the materials underlying each of them (collectively, "DOJ Evidence").[116]

The Company considered the DOJ Evidence before pleading guilty to

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[112] *See Id*.

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

[114] *See Diep*, 280 A.3d at 149, 151; *Acro Extrusion Corp.*, 810 A.2d at 347.

[115] A0940-41.

[116] A1079-80; A1308-12, A1317-19, A1321-24; A0564-91; A0593-670.

criminal misconduct and paying $885 million in fines and settlements.[117] Instead of starting there, and supplementing the DOJ Evidence with its own interviews and documentary investigation as necessary, the SLC curated its own record and chose concealment over transparency.[118] The court erred by finding that these decisions did not raise any material issues concerning the diligence and reasonableness of the SLC's investigation.

The court concluded that it was reasonable for the SLC to "decline to rely on [the Proffer Memoranda] after concluding that the information contained [in them] was duplicative of information the SLC had already obtained from its witness interviews."[119] This was reversible error. The Proffer Memoranda summarize DOJ proffer sessions with forty-five ABC employee witnesses, including Collis, and individuals the SLC determined were responsible for compliance at MII.[120] They were drafted contemporaneously with the interviews, *years* closer to the events at issue, and are thus more reliable. Yet the SLC cited *only one* of them (for an immaterial point).[121] The SLC determined not to rely on or cite the rest, and refused

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[117] A1037-38; A1308-12.

[118] A1029-30, A1308-10, A1322; A1717-18.

[119] Op. at 84.

[120] A1307; A1665-66; A0593-670.

[121] *See* A1188, A0508-63.

to produce them in discovery.[122]

The single memo that was produced (Bill Stickler) shows the Proffer Memoranda were comprehensive and high-value—they reflected responses to DOJ questions targeting alleged misconduct and the Company's knowledge thereof.[123] In fact, Stickler's memo reveals Collis's direct role in addressing ABC's suppliers' concerns about double-billing while leaving in place the practices that illegally double-billed the government.[124] Nevertheless, the SLC *did not interview* Stickler or even acknowledge that Stickler's proffer inculpated Collis.[125]

Nor did the SLC assess the memo summarizing Collis's own proffer session. Indeed, the SLC Report strongly suggests that the SLC or its counsel *did not even read* Collis's DOJ proffer memo:

> The SLC *understands* that DOJ asked Mr. Collis about

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[122] The SLC asserted that the Company claimed privilege over the Proffer Memoranda. A1907. But the SLC produced other materials subject to the Company's privilege, such as Morgan Lewis's memo summarizing the DOJ Presentation (A0564-91) and Stickler's proffer memo (A0508-63), indicating "cherry-picking." The SLC also had full authority to access "any and all documents and/or any other information" and undoubtedly could have compelled production of the Proffer Memoranda. A0940-41. The SLC ultimately took the position that by not relying on the Proffer Memoranda, they fell "outside the scope of discovery in this matter." A1907.

[123] *See* A0508-63.

[124] A0517 (recounting how that the "the government pressed this issue").

[125] A1082 ft 182, A1188.

> topics such as overfill, MII's licensing, sterility testing performed at MII, audits of MII, the capital expansion request, ION, administrative fees, and rebates, and Mr. Collis discussed how he learned that MII had issues with obtaining patient-specific information at a previous point.[126]

This failure is particularly glaring, given the DOJ's allegation that Collis demonstrated "intimate knowledge" of the how the PFS Program functioned and was personally involved in aspects of the PFS Program that he either knew, or should have known, were illegal.[127] The SLC chose to willfully blind itself to this evidence, and deferred to the recollection of ABC's in-house counsel (who report to Collis) and attorneys from Morgan Lewis (Collis's former counsel in this case and where Chou was a former partner) that "they viewed DOJ's interest in Mr. Collis (and Mr. Chou) as a reflection of their positions rather than evidence of wrongdoing."[128]

The Proffer Memoranda also contradict the SLC's conclusion that MII was integrated into ABC's compliance systems and had "clear reporting lines to the Board's Audit Committee."[129] Per the DOJ, "MII had no chain of responsibility for compliance reviews" and that in their respective proffer sessions "[e]ach compliance

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[126] A1307 (emphasis added).

[127] A0565; A0153-54; A0161-66; A0155-60; A0150-52.

[128] A1307-08.

[129] A1348-49.

authority pointed to someone else as having responsibility for the compliance review."[130] According to the DOJ:

- "Brad King was MII's designated compliance officer, but he stated that he was unfamiliar with MII's operations."[131]
- "Dave Leverette, President of OSC, did not know what King's responsibilities were other than business licensing. He went to Paul Ross with compliance issues from 2008 forward."[132]
- "[Paul] Ross claimed that Dan Newton was responsible for compliance."[133]
- "Dan Newton said he went to Paul Ross with compliance questions."[134]
- "The top ABC compliance officer, Chris Zimmerman … said ABC's legal department was responsible for compliance oversight."[135]

The SLC did not address these allegations in its report.

The SLC's decision not to consider or produce the proffer memo for Dan

[130] A0613 ¶95.

[131] *Id*. ¶96.

[132] A0614 ¶97.

[133] *Id*. ¶98.

[134] *Id*. ¶99.

[135] *Id*. ¶100.

Newton, MII's Chief Pharmacist who the SLC found *primarily responsible* for MII's legal compliance,[136] is particularly concerning. The SLC did not interview Newton, claiming he was unavailable.[137] Despite this gap in the SLC's investigation, the SLC did not consider or produce Newton's DOJ proffer memo. This is despite other witnesses telling the SLC that Newton's proffer session with the DOJ was an abject disaster and "led to the ultimate settlement between the Company and the Government."[138] Indeed, Newton was a "horrible witness" who if asked "if he broke the law every day, [Newton] would have said yes."[139]

The SLC's treatment of the DOJ's allegations that senior ABC officers were culpable for the PFS Program also gives rise to material questions. The DOJ alleged Collis "demonstrated intimate knowledge"[140] of the illegal scheme, and that Collis, Chou, and Guttman all "understood and sanctioned the PFS Overfill and Unopened Vial Scheme."[141] The DOJ Evidence was credible enough to cause the Company to

[136] A1082 n.182; A1188-89.

[137] A1892.

[138] A1892; A1402.

[139] A1892; A0967; *see also* A0948.

[140] A0565.

[141] A1321-22; A0592; A0599 ¶19.

plead guilty and pay hundreds of millions of dollars in penalties.[142] But it was not credible enough for the SLC, which concluded it amounted to "unproven allegations" that the DOJ made "in order to induce a monetary settlement."[143] This conclusion was primarily based, again, on the conflicted views of Morgan Lewis,[144] who told the SLC they "did not recall that DOJ had evidence of high-level personnel at ABSG engaging in misconduct" and that ABC "had strong defenses."[145] The court erred by blessing the SLC's reliance on conflicted counsel.[146]

On these facts, the SLC failed to meet its burden of demonstrating that it "explore[d] all relevant facts and sources of information."[147] The SLC's exclusion and obfuscation of the DOJ Evidence raises genuine questions as to its "willingness to deal openly and honestly with all relevant and material information."[148] Where, like here, "the record shows that material information is consciously omitted from

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[142] A0821-27. It was also credible enough to cause the Company to agree that it could not contest in future litigation the illegal conduct to which it was stipulating. *See* A0712-14 ¶2, A0729-32; A0753-66 ¶K, A0812-17.

[143] A1720; Op. at 85.

[144] A1312-24.

[145] A1320, A1323.

[146] Op. at 29.

[147] *London*, 2010 WL 877258, at *17.

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

[ ] the report …, the court must wonder what other information was omitted or what other information might have been uncovered by a more diligent inquiry."[149] And where, as here, there is "evidence of overreaching by counsel or neglect by the SLC," the court should "second guess the SLC's decision regarding the role in which counsel played in assisting them in their task."[150] The materiality of these open questions should have precluded dismissal on a summary judgment standard, and the lower court erred by disregarding them.

[149] *Id.*

[150] *Carlton Invs. v. TLC Beatrice Int'l Hldgs., Inc.*, 1997 WL 305829, at *12 (Del. Ch. May 30, 1997).

II. THE COURT ERRED IN FINDING NO MATERIAL ISSUES OF FACT REGARDING THE REASONABLENESS OF THE SLC'S CONCLUSIONS

A. Question Presented

Whether the trial court erred in finding no material issues of fact concerning the reasonableness of the SLC's conclusions that: (1) the Officer Defendants did not face *Caremark* liability, despite their failure to address or report red flags, including learning that 92% of the prescriptions prepared for the PFS Program were fraudulent; and (2) the Director Defendants did not face *Caremark* liability, despite failing to take any action in response to the Mullen Complaint or the DOJ's search warrant and subpoena directed at the PFS Program.

This issue was preserved.[151]

B. Scope of Review

Rulings under *Zapata*'s first prong are subject to a summary judgment standard and are reviewed *de novo*.[152]

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[151] A1667-79; Ex. C. at 95-105.

[152] *Diep*, 280 A.3d at 149.

C. Merits of Argument

To dismiss an action under *Zapata*'s first step, a court must determine that the SLC met its burden of demonstrating that there are no genuine issues of material fact regarding whether there are "reasonable bases for [the SLC's] conclusions."[153]

"[I]f the SLC gets the undisputed facts wrong in its report, and then relies on its erroneous recitation of the undisputed facts in making its dismissal recommendation, it also goes without saying that the basis for the recommendation is not reasonable."[154] Likewise, "the SLC must show that it correctly understood the law relevant to the case."[155]

The legal standard for oversight liability under a "red flags" theory is well understood. Directors and officers violate their oversight duties if they "knew of evidence of corporate misconduct—the proverbial 'red flag'—yet acted in bad faith by consciously disregarding [their] duty to address that misconduct."[156] Importantly,

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[153] *Diep*, 280 A.3d at 151; *see also London*, 2010 WL 877528, at *12; *In re WeWork Litig.*, 250 A.3d 976, 997 (Del. Ch. 2020).

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

[155] *Id*.

[156] *Horman v. Abney*, 2017 WL 242571, at *10 (Del. Ch. Jan. 19, 2017) (quoting *Reiter v. Fairbank*, 2016 WL 6081823, at *8 (Del. Ch. Oct. 18, 2016)); *Ontario Provincial Council of Carpenters' Pension Tr. Fund v. Walton*, 2023 WL 3093500, at *32 (Del. Ch. Apr. 26, 2023) (sustaining red flags claim where fiduciaries "were put on notice that the corporation was violating the law or otherwise headed for a

as this Court recently affirmed in relation to *substantially the same* ABC directors' response to opioid-related red flags, the "absence of an admission of liability or warning from a regulator or third-party expert" does not "absolve[] [directors] of liability."[157] Instead, "'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.'"[158] A plaintiff "does not have to point to actual confessions of illegality;"[159] rather, information regarding "investigations, subpoenas, and lawsuits"[160] can constitute red flags.

Further, in response to red flags, directors and officers must show "tangible action taken to remedy the underlying misconduct."[161] "A claim that a fiduciary had

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corporate trauma, but willfully ignored the evidence and consciously decided to do nothing"); *see also In re McDonald's Corp. S'holder Deriv. Litig.*, 289 A.3d 343, 358-64 (Del. Ch. 2023) ("officers owe the same duties as directors," discussing "diverse authorities").

[157] *Lebanon Cnty.*, 2023 WL 8710107, at *20.

[158] *Id.* (quoting *Lebanon Cnty.*, 2022 WL 17841215, at *16).

[159] *La. Mun. Emps.' Ret. Sys. v. Pyott*, 46 A.3d 313, 357 (Del. Ch. 2012).

[160] *Walton*, 2023 WL 3093500, at *44.

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

notice of serious misconduct and simply brushed it off or otherwise failed to investigate states a claim for breach of duty."[162]

1. The SLC Lacked Reasonable Bases for Its Conclusions Regarding the Officer Defendants' Responses to Red Flags

The Complaint names three Officer Defendants: Collis, Chou, and Guttman. Each served as directors and/or officers of MII during the entire period the PFS Program was in operation.[163] The SLC concluded that (i) there was "*no evidence* supporting Plaintiffs' allegations that any of the three Defendant Officers knew that MII was operating an illegal business model" and (ii) there was "*no indication* that the Defendant Officers possessed information regarding the [PFS Program's] regulatory compliance and withheld such information from the Board of Directors."[164] Both of these conclusions are factually wrong, or, at the very least, hotly and credibly disputed. The court ran afoul of the applicable Rule 56 standard by ignoring the disputed issues and deferring to the SLC.

Collis and Chou, in particular, knew or should have known that the PFS Program involved illegal conduct, yet allowed the program to continue operating unchecked. Shortly after ABC acquired MII, in May 2001, Collis received a memo

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[162] *McDonald's*, 289 A.3d at 376-77.

[163] A0036-55.

[164] A1378-79 (emphases added).

stating that "Medicare appears to have been double-billed, just like MII's clients," explaining that MII "appears to have misrepresented what it does with salvage/overfill" and because overfill amounts were not being "documented and properly reported" as the FCA required "MII could be accused of causing the submission of a false claim."[165] The SLC points to no evidence that Collis reported the issue or took any action to investigate or remediate.

In June 2010, Chou engaged Ober Kaler as outside legal counsel to conduct a review.[166] Ober Kaler had serious concerns with the PFS Program and wanted to investigate further, because, in part, the government's "knee jerk reaction for below cost sales is that it is an anti-kickback statute violation."[167] Ober Kaler provided Chou with a draft presentation that included a slide regarding "Potential Risks / Areas for Improvement" for the "Prefill Syringe Program," noting "Government suspicion" and "NEED FURTHER ANALYSIS."[168] Chou, however, instructed Ober Kaler not to review MII or the PFS Program, remove any mention of its concerns from the Board presentation, and avoid alerting the Board to its concerns.[169]

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[165] A0064-65.

[166] A1261.

[167] A0202.

[168] A0196.

[169] A0202.

Ober Kaler complied, removing mention of Ober Kaler's concerns from the final August 11, 2010 Audit Committee Presentation[170] but memorialized Chou's instructions in an internal memo.[171]

Chou proceeded to misrepresent to the Audit Committee that Ober Kaler's investigation was a "periodic[]" review of "business operations from a regulatory compliance standpoint," rather than a targeted review prompted by ABSG's former CCO—without any mention of the PFS Program, Mullen's concerns, or his termination.[172]

In October 2010, Collis and Chou received and reviewed the Mullen Complaint. Collis observed that "[t]he MII angle is concerning because of the overfill," and "[t]his may be focused on the pre filled syringe program."[173] As discussed above, Collis already knew the PFS Program was operating illegally under the FCA and was violating state pharmacy laws[174] and Chou knew from Ober Kaler that the PFS Program implicated "ASP Manipulation," "Anti-Kickback

[170] *Compare* A0203-21, *with* A0177-97.
[171] A0202.
[172] A0222-23.
[173] A0340.
[174] A0064-65; A0979-81; *see also* A0517.

Violation[s]," and "Violation of Manufacturer Contracts."[175] Yet they never shared their concerns with the Board, and the SLC made no effort to investigate why. Collis downplayed the allegations, stating that technically "[o]f course *we* never bill Medicare and Medicaid for drugs distributed to Medical Oncologist[s]" (*i.e.*, MII's customers did).[176] Chou then reminded Collis and others to avoid creating a paper record.[177]

The SLC obtained evidence that internal reporting on MII's failure to use patient-specific labeling met a similar fate. In 2002 and 2003, an ABC oncologist informed Collis that the PFS Program was violating state pharmacy laws because pre-filled syringes were being shipped without patient names.[178] But while Collis was instrumental in *expanding* the PFS Program's facility in 2006, the SLC points to nothing Collis did to report or address the problem.[179]

In early 2012, two years after the FDA issued a public "Warning Letter" that patient-specific labeling was required for state licensed pharmacies,[180] an MII

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[175] A0191.

[176] A0340 (emphasis added).

[177] *Id*.

[178] A0979-81.

[179] A0565; A0664-65.

[180] A1182-83.

customer flagged that MII's failure to use patient-specific labeling "could be interpreted as fraud."[181] Another MII customer reported that it would no longer "fraudulently put patient names on drugs that they are not getting."[182] The customer complaints prompted a review of MII's practices, which went directly to both Collis and Chou.

The review revealed "a significant number of instances"—*92 percent*—where MII "fabricated abbreviated names (initials) for patients" or randomly selected them from "patient lists."[183] Collis and Chou both served on the officer-level Ethics Committee, and they attended the February 23, 2012 meeting where MII's patient labeling issue was discussed.[184] Per the Ethics Committee's procedures, this issue would next be raised to the Audit Committee of the Board of Directors. But Collis and Chou did not report the issue to the Board's Audit Committee.[185]

Instead, Chou and his team removed the issue from the report that would have been presented to the Audit Committee because "it appear[ed] that the practice may

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[181] A0487.

[182] A0496.

[183] A0499.

[184] A0500-01.

[185] A1000.

be in compliance with State regulations."[186] Chou determined that MII's practice of fraudulently labeling pre-filled syringes with fake patient names "did not violate Alabama law" because Alabama pharmacy regulations technically did not require "patient-specific names" to be included on prescription labels.[187] The SLC Report accepted Chou's conclusion and found that he had acted appropriately but Nally later conceded at his deposition that ABC's conduct had been illegal.[188]

The SLC's already-unreasonable acceptance of Chou's dubious explanation is even more unreasonable because it conflicts with the admitted facts accompanying the guilty plea and civil settlement that the Company agreed could not be challenged in any future proceeding.[189] The Company admitted MII's practices violated Alabama law, by failing to maintain accurate patient information.[190] Relatedly, the SLC gave an unreasonable amount of weight to MII's inspections with the Alabama Board of Pharmacy to absolve Collis and Chou.[191] According to the DOJ, MII

[186] A0502; *see also* A1495-96 (155:11-158:20) (fabricating patient names "was not a violation of the law, per se" and "it did not have to go forward to the ethics and, ultimately, the audit committee of the Board").

[187] A1232-33, A1385.

[188] A1381-82; A1495 (157:10-17).

[189] A0712-13 ¶2 & A0731-32; A0753 ¶K & A0814-16.

[190] A0732 ¶10.

[191] *See* A1207-15.

"misrepresented its lack of patient specific prescriptions to the State of Alabama inspectors,"[192] and thus did not qualify for a state pharmacy exemption, which the Company *also* admitted and cannot challenge.[193]

Nor did the SLC press Collis or Chou (or any other witness) regarding why the Company entered into the guilty plea with a sentencing enhancement for "High Level Personnel" that "Participated In, Condoned, or [Were] Willfully Ignorant of the Offense."[194] There is no explanation in the SLC Report for this. When asked why the Company agreed to this enhancement and to identify the "high-level personnel" involved, the SLC conceded that the issue "*wasn't the focus of our investigation*."[195]

A "critical part of an officer's job is to identify red flags, report upward, and address them if they fall within the officer's area of responsibility."[196] Here, Collis and Chou engaged in no effort to "investigate or address" the alleged misconduct, and remained in "business-as-usual mode."[197] The SLC did not press Collis or Chou

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[192] A0617-22.

[193] A0712-13 ¶2 & A0731-32; A0753 ¶K & A0814-16.

[194] A1320 (quoting Plea Agreement, ¶2 (A0712-14)); A0714 ¶2.

[195] A1482 (104:23-105:5) (emphasis added).

[196] *McDonald's*, 289 A.3d at 366.

[197] *McDonald's*, 291 A.3d at 683.

on these events (to the extent it even raised them), but instead gave them a pass by accepting their self-serving and facially unreasonable explanations for their failure to act. On these facts, the SLC failed to establish that its conclusions regarding Collis's and Chou's culpability under *Caremark* were reasonable, and the lower court erred by deferring to the SLC's conclusions.

2. The SLC Lacked Reasonable Bases for Its Conclusions Regarding the Director Defendants' Responses to Red Flags

At the pleading stage, the trial court found that "the directors ignored such red flags as did exist," i.e., they were "aware of the [PFS Program's] contravention of mission critical drug health and safety regulations, and that the Board failed to act in response."[198] Despite a voluminous Section 220 production, Defendants "put forth nothing to show *tangible action* taken to remedy the underlying drug health and safety issues."[199] The court added that "[c]alling attention to the hiring of law firms to review alleged illegality, without more, is insufficient" and that "nothing from the Section 220 production show[s] a *tangible reaction* to—as opposed to a review of—the mission critical compliance failures at [MII]."[200]

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[198] *Chou*, 2020 WL 5028065, at *1, *25.

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

[200] *Id*.

The SLC confirmed that the Board became aware of at least two red flags: (1) the Mullen *Qui Tam* Complaint; and (2) the July 2012 DOJ search warrant and subpoena in connection with the raid of MII's facility.[201] The SLC concluded that the directors did not fail to respond to these red flags because they reasonably believed that the PFS Program complied with the law.[202]

The SLC's investigation did not refute, but instead confirmed, the trial court's pleading-stage finding that Defendants failed to take any tangible action in response to these red flags. There is nothing in the SLC's Report demonstrating that the directors took *any* affirmative steps to investigate or remediate the PFS Program's illegality. The SLC instead credited self-serving excuses for why Defendants took no corrective action. Again, the trial court's deference to the SLC ignored material fact issues and constitutes reversible error.

(a) The Board Took No Action In Response to Mullen's *Qui Tam* Complaint

The SLC Report confirms that Chou "notified the Board of the suit" and provided a copy of the Mullen Complaint,[203] but does not mention any action taken to investigate or address the allegations. The Board merely learned that Morgan

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[201] A1273-4, A1285.

[202] A1277-78.

[203] A1273.

Lewis had been retained to respond to any government investigation and discussed how to handle a public disclosure. The SLC Report recounts Morgan Lewis's involvement in the Company's internal and external disclosures[204]—but not any request to or discussion of investigating Mullen's allegations, devising remedial measures, or conducting any review of the PFS Program. The SLC uncovered no evidence that any of the ABC directors even asked a question about Mullen's allegations, or why he was terminated after raising FCA-related issues with management.

The trial court also misconstrued the facts. The court found that the Board responded to the Mullen Complaint "by providing Mullen's concerns to outside counsel at Ober Kaler who then investigated the concerns to develop recommendations to reduce regulatory risks and reported these findings to the Board."[205] That is not what happened.

First, Ober Kaler's investigation and report concluded in August 2010, *preceding* Mullen's *qui tam* by two months.[206] Second, the Board was not involved in Ober Kaler's retention, and when Chou presented its report to the Audit

[204] Op. at 87 n.506 (citing SLC Report at 245-57 (A1273-85), 338 (A1366)).

[205] *Id.* at 86-87.

[206] *Id.* at 87 n.503 (citing A1260-71, A1365-66).

Committee, he failed to mention Mullen and described it as a "periodic[]" review of "its business operations from a regulatory compliance standpoint."[207] Third, the SLC conceded that "Ober Kaler's mandate did not include a review of the legality of the pre-filled syringe program"[208] and that "[t]he concerns [Ober Kaler] investigated and recommendations identified were not related to MII."[209]

The SLC Report merely regurgitates—and accepts—Defendants' excuses for *why* they took no action, including that they believed Mullen's allegations "were limited to the AKS and price reporting compliance theories underlying *Westmoreland*," which was a *qui tam* suit involving another company.[210] The SLC also relies heavily on paper-thin, self-serving statements by two of the investigations' targets. Director Kathleen Hyle told the SLC that Mullen's complaint "was seen as retaliatory," and that "her view was that the Company did not do anything wrong" because it was "the Company's belief that it did nothing wrong."[211] Director Michael Long told the SLC he discounted Mullen's allegations because ABC lacked sufficient motive "to do something wrong at MII because it is

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[207] A0222-23.

[208] A1262.

[209] A1366.

[210] A1364.

[211] A1011.

not a big enough business to make a financial difference for ABC."[212] These explanations hardly excuse a lack of action, but instead show the Board's "declination to test the modicum of information it received and seek the truth."[213]

The SLC's investigation confirmed that the Director Defendants took no tangible action in response to the Mullen Complaint, and their self-serving explanations do not provide a sufficiently reasonable basis to absolve them of *Caremark* liability.

(b) The Board Took No Action in Response to the DOJ Search Warrant and Subpoena

At the pleading stage, the lower court found that the absence of any discussion in Board materials made it reasonable to infer that, "even after receiving the subpoena the Board did nothing to correct the underlying mission critical compliance shortcomings at [MII]."[214] The SLC confirmed that, following federal law enforcement's raid of MII's facility, both the DOJ Search Warrant and the DOJ Subpoena were disclosed to the Board the next day.[215] But, after the Board received the DOJ Search Warrant and DOJ Subpoena, it took no action to investigate why

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[212] A1021.

[213] *In re Boeing Co. Deriv. Litig.*, 2021 WL 4059934, at *34 (Del. Ch. Sept. 7, 2021).

[214] *Chou*, 2020 WL 5028065, at *24.

[215] A1369.

MII was raided. Again, the SLC credited unreasonable excuses for why the directors failed to act.

First, the SLC found that the "[d]irectors reasonably held a commonly shared belief that the search warrant and subpoena stemmed from Mr. Mullen's 2010 *qui tam* complaint, which did not raise FDCA allegations."[216] So what? Even if the directors honestly held that belief, Mullen's *qui tam* action raised serious allegations of illegal behavior under the FCA and AKS that the Board never investigated. The SLC also conceded that the language of the subpoena and search warrant extended to FDCA issues (and clearly placed the PFS Program in the government's crosshairs):

- The DOJ Subpoena sought "documents and information relating to pre-filled syringes, including, the process for creating pre-filled syringes; equipment used to 'harvest' overfill; quality control and assurance protocols for the syringes," among other things.[217]

- The DOJ Search Warrant sought seizure of "[a]ll pre-filled syringes … including any packaging and labeling" and drugs "in the process of being extracted from vials and placed into syringes."[218] The search warrant also contained citations to federal statutes that "prohibit adulteration,

[216] A1370.

[217] A1280.

[218] A1279.

> misbranding, and failing to register with the FDCA."

Second, the SLC concluded that, given that "the breadth and scope of the subpoena and search warrant went far beyond potential FDCA violations," the subpoena and search warrant "limited the Board and management's ability to identify DOJ's ultimate theories about MII and the pre-filled syringe program."[219] This facially absurd explanation seeks to excuse the Board for doing *nothing* because the government potentially raised *too many* issues concerning the PFS Program. A reasonable reaction would have been to inspect the facility and/or to conduct a review of the PFS Program's business model. The Board consciously chose to do nothing instead.

Third, the SLC endorsed the directors' view that the government's willingness to keep MII operational meant that the "FDA did not find quality or sterility issues that warranted follow-up regulatory activity."[220] That too is a stunning and unreasonable conclusion that does not justify the failure to take any investigatory or remedial action. That the initial investigative steps (a *raid* of MII's facility) did not result in an immediate shutdown does not remotely suggest that MII's operations

[219] A1370.

[220] A1287, A1370.

had been blessed as legally compliant. The SLC relatedly assumed the truth of the directors' representations regarding "testing and analysis" that purportedly showed no quality or safety issues.[221] The DOJ recounted substantial evidence that MII's facilities repeatedly tested positive for bacteria,[222] yet the SLC made no effort to investigate this discrepancy in testing results, or what the directors knew about it.

In sum, instead of pointing to any "tangible action taken"[223] in response to indisputable red flags, the SLC again credited self-serving—and unreasonable—excuses for why no action was necessary. The "record does not reveal evidence of any director seeking or receiving additional written information," let alone that they focused on "potential remedial steps, or safety generally."[224] The trial court erred under the applicable Rule 56 standard by reversing course, deferring to the SLC, and crediting the SLC's conclusions as reasonable.

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[221] A1288, A1370.

[222] *See* A0698-700.

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

[224] *Boeing*, 2021 WL 4059934, at *34.

CONCLUSION

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

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