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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), 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

APPELLEE SPECIAL LITIGATION COMMITTEE'S CORRECTED ANSWERING BRIEF

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NATURE OF PROCEEDINGS

A special litigation committee ("SLC") comprised of an indisputably independent director concluded that pursuing this stockholder derivative action against officers and directors of AmerisourceBergen Corporation ("ABC") would not serve the best interests of the company. After an exhaustive investigation covering every allegation in the complaint—along with issues not raised by plaintiffs, but which the SLC encountered and proactively addressed—the SLC concluded that the claims for breach of fiduciary duty "lack merit" and would divert company resources while presenting "little likelihood of recovery." A1388-93. The SLC memorialized these findings in a 365-page report supported by 420 exhibits and 1,504 footnotes, concluding that the evidence failed to show that the officer defendants knowingly operated an illegal business model or that the director defendants consciously disregarded "red flags" of potential regulatory violations.

Plaintiffs now invite this Court to second-guess both the sufficiency of the SLC's investigation and the accuracy of its conclusions. But review under *Zapata Corp. v. Maldonado*, 430 A.2d 779 (Del. 1981), does not afford plaintiffs an opportunity to litigate the merits of their claims. *Zapata* instead limits this Court to evaluating the SLC's "independence and good faith" and "the bases supporting its conclusions." *Id.* at 788. After a careful review of the evidence collected by the SLC and the relevant legal standards, the Court of Chancery correctly held that the

SLC had carried its burden of showing both the scope of its investigation and the bases for its conclusions were reasonable. Its judgment dismissing the action should be affirmed.

SUMMARY OF ARGUMENT

1. Denied. The scope of the SLC's investigation was not just reasonable, but exhaustive. The investigation spanned seven months and comprised 77 interviews and a review of 220,000 documents, including material plaintiffs wrongly claim the SLC ignored.

a. Denied. The SLC did not unreasonably confine its investigation to alleged Federal Food, Drug & Cosmetic Act violations. The SLC focused the bulk of its investigation on these allegations because they were the focus of plaintiffs' breach of fiduciary duty claims. Although plaintiffs argue the investigation should have included alleged False Claims Act violations as well, plaintiffs never suggested that the SLC should broaden the scope of its investigation when the SLC solicited their input, and they should be prohibited from doing so belatedly on appeal. In any event, as the Court of Chancery held, the SLC in fact investigated the alleged FCA issues plaintiffs erroneously claim it ignored.

b. Denied. The SLC considered all relevant sources of information, including evidence bearing on the U.S. Department of Justice's investigation.

2. Denied. The SLC also had reasonable bases for concluding that pursuing the breach of fiduciary duty claims is not in the best interest of ABC. The SLC found "no evidence" that the officer defendants "knew MII was operating an illegal business model" or that they "withheld" relevant information from ABC's

board. A1378-82. Similarly, the SLC reasonably concluded that the director defendants did not ignore alleged red flags regarding safety or sterility in the prefilled syringe program. A1357-78. The SLC grounded its conclusions in the evidentiary record and supported them with careful analysis of the applicable law. Plaintiffs' attempt to relitigate the merits of those conclusions is barred by *Zapata*, which requires only that those conclusions have reasonable bases. 430 A.2d at 788. Plaintiffs fail to undermine the bases for the SLC's well-supported conclusions through their blatant distortions of the record.

COUNTERSTATEMENT OF FACTS

I. This Action

This action arises out of a program operated by an ABC subsidiary, Medical Initiatives, Inc. ("MII"), that transferred oncology medication from FDA-approved vials into prefilled syringes. A1189-97. These vials typically contained excess medication beyond the labeled amount, called "overfill," which MII would use to fill extra syringes. A1197-99. In 2017, the U.S. Department of Justice ("DOJ") filed a criminal information alleging that MII's prefilled syringe program unlawfully packaged medication in violation of the Federal Food, Drug & Cosmetic Act ("FDCA"). A1317. AmerisourceBergen Specialty Group ("ABSG"), MII's corporate parent, pleaded guilty to a misdemeanor without admitting the allegations in the information. A1317-21. ABSG also secured the government's agreement that it "may challenge, contest and refute the factual allegations in the Information in any subsequent proceeding." A1319. A year later, ABC entered into a civil settlement to resolve DOJ's allegations that the prefilled syringe program violated the False Claims Act ("FCA"). A1321-24. The company made a business decision to enter both settlements to mitigate legal risk, while maintaining that it had strong defenses to the government's novel and untested legal theories. *Id.*

Following ABC's settlements with the United States, plaintiffs filed this stockholder derivative action asserting claims against certain ABC directors and officers. A0837. The first claim, under *In re Caremark*, 698 A.2d 959 (Del. Ch.

1996), alleges that the director defendants breached their fiduciary duties by failing to respond to "red flags" indicating that the prefilled syringe program might not comply with the FDCA or may have safety or sterility problems. A0929-31. The second asserts that the officer defendants breached their fiduciary duties by knowingly operating a business model that violated federal drug-safety regulations and by failing to inform the board about the same. A0931-32.[1]

II. The Special Litigation Committee

After the Court of Chancery denied defendants' motion to dismiss, *see Teamsters Local 443 Health Servs. & Ins. Plan v. Chou*, 2020 WL 5028065 (Del. Ch. Aug. 24, 2020), the ABC board approved the formation of an SLC and granted it exclusive authority to investigate plaintiffs' claims and determine whether litigating that action was in the best interests of the company. A1064-65. After one of the two independent directors on the SLC identified a potential conflict, the board concluded that Dennis Nally should serve as the sole member. A1067-68. Plaintiffs have not challenged Nally's independence on appeal.

III. The SLC's Investigation

With assistance from outside counsel at Gibson, Dunn & Crutcher LLP and Morris, Nichols, Arsht & Tunnell LLP, the SLC conducted a seven-month investigation into the allegations in the stockholder complaint.

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[1] Plaintiffs also asserted an unjust enrichment claim against ABC's CEO that they have abandoned on appeal.

The SLC collected more than 12 million documents from 30 current and former ABC employees and reviewed 220,000 culled through search parameters. A1076-78. The documents examined by the SLC included proffer memoranda, search warrants and subpoenas, DOJ presentations, and other material relating to DOJ's investigation that plaintiffs erroneously claim was "disregarded," OB 28; the company's resolution of DOJ's civil and criminal claims; oversight of MII and ABC's compliance program; reviews and assessments of the prefilled syringe program conducted by outside counsel; reviews by ABC's compliance department, known as Corporate Security and Regulatory Affairs ("CSRA"); and the original and amended *qui tam* complaints lodged by Michael Mullen, along with documents reflecting concerns he brought to ABC's legal department beforehand. A1078-79.

The SLC also conducted 77 interviews of 67 witnesses, including each of the defendants; other current and former ABC directors and officers; ABC personnel in audit, compliance, finance, and legal roles; and attorneys who conducted compliance reviews or represented ABC in connection with the DOJ investigations. A1081-82.

Along the way, the SLC solicited feedback from plaintiffs' counsel. From developing search terms to identifying documents to be searched, the SLC was transparent as to both its "process and progress." A1074-75. But when the SLC shared proposed custodians and search terms, plaintiffs "asked for some additional information but otherwise did not provide any response or feedback." A1077-78.

Nor did plaintiffs "express concerns" about the SLC's "planned interviewees." A1074. When the SLC presented its preliminary findings to plaintiffs in April 2021, plaintiffs' counsel "engaged in discussion" at the meeting "but thereafter declined to engage in further discussions about the merits of their claims." A1075.

IV. The SLC Report

At the conclusion of its investigation, the SLC set forth detailed findings and conclusions in a 365-page report supported by 420 exhibits, 1,504 footnotes, and two appendices. A1026-399. After analyzing the factual and legal bases for the claims, the SLC concluded that (1) the director defendants did not fail to respond to any "red flags" of illegality and (2) the officer defendants did not knowingly operate an illegal business model or fail to apprise the board of possible regulatory compliance issues with the prefilled syringe program. A1347-88.

A. Relevant Findings of Fact

1. Prefilled Syringe Program

MII operated the prefilled syringe program in its Dothan, Alabama facility from 2001 to 2014. A1168-69, A1239. When customers ordered oncology medication, MII personnel would draw the product from the manufacturer's vials into syringes and retain excess product, called "overfill," which it used to fill new prescriptions. A1189-98.

2. Legal and Regulatory Reviews

ABC leadership reasonably believed that MII operated as a state-regulated pharmacy not subject to FDA regulation. A1170-80. Accordingly, ABC registered MII with the Alabama Board of Pharmacy rather than the FDA. A1188.

The SLC concluded that "MII was operating during a period of regulatory flux." A1169. The FDA had "increasingly" begun exercising "enforcement authority as to pharmacies that it had historically delegated to the states." *Id.* The SLC's survey of relevant federal and state law demonstrated that the obligations of entities like MII were open to multiple reasonable interpretations. A1170-85. Thus, the SLC found that ABC officers and directors could reasonably believe that MII was operating lawfully even if it was not adhering to federal rules for compounding pharmacies or manufacturers. A1168-70. Indeed, Jane Henney, a board member and former FDA commissioner, "believed that MII was not a manufacturer or a compounding pharmacy and conveyed this view" to the board. A1377.

MII underwent several legal reviews, none of which concluded that the prefilled syringe program was unlawful. During and after the merger of Bergen Brunswig and AmeriSource, which formed ABC, Bergen Brunswig evaluated MII's operations both internally and through outside counsel. A1186-87. These reviews identified potential issues related to MII's billing practices but did not identify FDA regulatory risks or sterility concerns. A1187. For example, in a 2001 memorandum

addressing MII's legal risks, the law firm Reed Smith warned of potential risks of double-billing for "salvage," which is distinct from "overfill." A0064. The memorandum cautioned that the government could possibly allege FCA violations based on this practice, but concluded that the risk was "moderate or less" and did not extend to "MII's use of 'overfill.'" A0065, A1187 n.656. Another review by Reed Smith in 2003 concluded that the prefilled syringe program did not raise significant regulatory, anti-kickback, or double-billing concerns, which led ABSG to conclude that Reed Smith "approved of MII's business model." A1201-04.

The Alabama Board of Pharmacy also conducted inspections of MII in 2007, 2009, 2010, 2011, and 2013, which MII passed "without receiving an adverse observation about the safety or sterility of products dispensed by the pharmacy." A1209-13.

3. Mullen Internal Reporting

In 2010, ABC fired Michael Mullen, ABSG's chief operating officer. A1254. After his termination, Mullen contacted ABC's legal department to report potential Anti-Kickback Statute ("AKS") and price-reporting compliance issues in the prefilled syringe program. A1254-61. Citing *United States ex rel. Westmoreland v. Amgen, Inc.*, a lawsuit in which ABC had received a third-party subpoena, A1242-45, Mullen argued that MII's average sales price "was not reported correctly in connection with how MII handled overfill" and there was "insufficient separation"

between Oncology Supply ("OS") and International Oncology Network ("ION"), other ABC subsidiaries involved in the prefilled syringe program, A1256-57. Mullen did not report concerns about safety or sterility or question whether the program complied with the FDCA. A1255-61.

4. Ober Kaler Review

In light of the concerns raised by Mullen and the *Westmoreland* complaint, ABC retained the law firm Ober Kaler in 2010 to review whether entities in ABC's oncology group, including OS and ION, were complying with the FCA and federal anti-kickback laws. A1261-63. Near the end of its review, Ober Kaler showed a draft presentation to John Chou, ABC's chief legal officer, which included a slide with the heading "Potential Risks/Areas for Improvement" and noted the potential for "Government suspicion" regarding the prefilled syringe program. A1264. Ober Kaler predicted "the government is going to be totally confused by this program" and asked for more information so it would be prepared if "the government comes and asks about it." A1264-65. Chou referred Ober Kaler to ABSG's in-house counsel, who explained that the prefilled syringe program had previously been reviewed by outside counsel and deemed lawful. A1265-66. As a result, Ober Kaler did not conduct any further review of the program. A1266-67.

5. Mullen *Qui Tam* Complaints

After reporting concerns to ABC, Mullen filed a *qui tam* complaint against the company in October 2010, which he then amended in January 2011. A1271-75.

Mullen's initial complaint alleged claims against ABC and certain subsidiaries relating to the FCA, AKS, and price-reporting issues that he raised after his termination. A1271-72. The original complaint did not allege any violations of the FDCA or related regulations. A1272. After the sealed *qui tam* complaint was inadvertently filed on the public docket, ABC management informed the board about the claims and described them in the company's 10-K disclosure. A1273-75.

When Mullen amended his complaint in January 2011, he alleged for the first time that MII violated FDA regulations by operating as an unlicensed drug manufacturer and repackager. A1275-76. Because Mullen's amended complaint remained sealed for five years, ABC's leadership was unaware of its contents until 2016, when prosecutors shared it to facilitate settlement. A1277, A1312-13.

6. DOJ Search Warrant and Subpoena

In July 2012, ABC learned that it was the subject of parallel criminal and civil DOJ investigations when federal agents executed a search warrant at MII's facility in Dothan and served a subpoena for ABSG documents related to prefilled syringes and myriad other topics. A1277-80 & n.1063.

Chou informed the board about the search one day later. A1285. The board evaluated whether the search suggested possible safety or sterility problems at MII's facility, considering such factors as the absence of any history of such issues, the understanding that MII's practices were lawful based on earlier legal reviews, and

the fact that ABC's internal tests of MII's syringes showed no material failures with respect to safety, quality, or sterility. A1287-89. The government's decision to allow MII to reopen after a brief shutdown further contributed to the board's understanding that MII was operating safely and legally. A1287. The board also learned that ABC had engaged Morgan, Lewis & Bockius LLP to represent the company in the DOJ investigation and continued receiving updates from counsel at every meeting until MII permanently shuttered in 2014. A1289, A1372.

7. DOJ Resolutions

After a year of negotiating with prosecutors, ABSG pleaded guilty in September 2017 to a strict-liability misdemeanor violation of the FDCA stemming from its failure to register MII with the FDA. A1317. ABSG admitted to a limited statement of facts, but not to the allegations in DOJ's information. A1317-18. The government also agreed that ABSG "may challenge, contest and refute the factual allegations in the Information in any subsequent proceeding." A1319. ABSG agreed to pay a $260 million penalty. A1317.

In September 2018, ABC executed a civil settlement with the DOJ for alleged FCA violations. A1323. Although outside counsel viewed the government's theories as "novel" and ABC's defenses as "strong," the company concluded the settlement was in the best interest of shareholders to avoid the threat of treble damages. A1321-23. ABC agreed to pay $625 million. A1323. Neither ABC nor

any individuals admitted to liability in connection with DOJ's FCA claims. A1323-24.

B. Conclusions of Law

After completing its independent investigation, the SLC concluded that the shareholder claims "lack merit and are unlikely to result in any recovery." A1393. As relevant here, the SLC concluded that plaintiffs had not identified a viable *Caremark* claim against the director defendants because five of the six alleged "red flags" cited by plaintiffs did not amount to red flags at all, and even if they did, the evidence did not show that the directors "did nothing" in response. A1357-58 (quoting *Richardson v. Clark*, 2020 WL 7861335, at *11 (Del. Ch. Dec. 31, 2020)), A1358-78.

More specifically, the SLC concluded that Mullen's report and initial *qui tam* complaint—the only one known to the board until 2016—did not "raise red flags" that MII was "violating FDA regulations." A1363-66. Even if Mullen's complaint could be construed as a red flag, the directors did not "consciously disregard" his concerns, but forwarded them to Ober Kaler for investigation and oversaw implementation of the resulting recommendations. A1365-66. The SLC concluded, in contrast, that DOJ's search warrant and subpoena constituted potential red flags that MII had potential FDCA regulatory issues. A1368-70. But the evidence did not support a *Caremark* claim because it did not show the director defendants

"consciously disregarded the red flags" or engaged in "an intentional dereliction of duty." A1371 (quoting *In re Qualcomm Inc. FCPA S'holder Deriv. Litig.*, 2017 WL 2608723, at *4 (Del. Ch. June 16, 2017)). Instead, the board "actively engaged" with counsel regarding the DOJ investigation and were provided information contradicting FDCA liability. A1371.

For the sake of thoroughness, the SLC also took the initiative to explore whether "concerns about patient-specific labeling at MII" also constituted red flags, even though this allegation was not in plaintiffs' complaint. A1376. Ultimately, the SLC concluded that these issues did not amount to red flags because the board was not aware of them and the company's Compliance Committee found them "not to be an actual legal violation" in any event. A1376 & n.1465.

The SLC also concluded that the breach of fiduciary duty claim against the three officer defendants lacked merit because it found "no evidence" they knew "MII was operating an illegal business model." A1378-86. Instead, the record reflected that these officers "believed in good faith that MII was appropriately operating as a state-regulated pharmacy and was not subject to FDA regulation." A1380-81. The SLC also found no evidence that the officers withheld information the board "needed to perform their statutory and fiduciary roles." A1379-80 (quoting *Amalgamated Bank v. Yahoo! Inc.*, 132 A.3d 752, 780 (Del. Ch. 2016), *abrogated on other grounds*

by Tiger v. Boast Apparel, Inc., 214 A.3d 933 (Del. 2019)). To the contrary, the officers "reported to and discussed" every alleged red flag with the board. A1379.[2]

Balancing the "little likelihood of recovery" against the costs and disruptions of litigation, the SLC concluded that "pursuing this matter further would be detrimental to the Company and its stockholders." A1388-93. The SLC therefore moved for dismissal.

V. Court of Chancery Opinion

The Court of Chancery granted the SLC's motion to dismiss in full using the two-step *Zapata* framework. Op. 78-97. The court recognized that *Zapata* review "is not meant to allow plaintiff to litigate the facts and merits of the derivative cause of action," but instead examines "the conduct and activity" of the SLC. Op. 79. "The first prong of the *Zapata* standard analyzes the independence and good faith of the committee members, the quality of its investigation and the reasonableness of its conclusions." Op. 78.

Applying that prong, the court held that the SLC had conducted an investigation of "reasonable scope" that examined "all theories of recovery" asserted in the complaint. Op. 80-85. The court concluded that the three causes of action all

[2] Plaintiffs erroneously state that Collis and Chou "did not report" an issue concerning MII's alleged "failure to use patient-specific labeling" to the board's Audit Committee. OB 42-44. In fact, the Compliance Committee discussed the labeling issue and declined to escalate it to the Audit Committee because the practice "may be in compliance" with state regulations. A1234.

"focused on the alleged breaches of fiduciary duties with respect to drug safety and sterility in the Pre-Filled Syringe Program and FDCA compliance." Op. 82. Although the complaint "lacks any claims asserting illegal kickbacks or double-billing," the court found that the SLC "nevertheless investigated Defendants' knowledge of those issues." *Id.* "Given the scope of the complaint and the actual scope of the investigation," the court found that "the SLC has met its burden." *Id.*

The court also concluded that the SLC had reasonable bases for its conclusion that the director defendants satisfied their *Caremark* duties. Op. 85-89. With respect to the Mullen complaint, the SLC found that the board "responded by providing Mullen's concerns to outside counsel at Ober Kaler," which then investigated and developed "recommendations to reduce regulatory risks." Op. 86-87. The board also discussed the *qui tam* with Chou and were informed that Morgan Lewis had been retained to defend the company. Op. 87. In a *Caremark* action, the court observed, the directors' actions are evaluated "not for compliance with best practices or in light of what greater rigor the Board could have brought," but only for "failures of oversight so grossly apparent that they amount to bad faith," which were absent here. *Id.*

Finally, the court held that the SLC had reasonable bases for its conclusion that none of the officer defendants "*knowingly* operated and maintained an illegal business model" in the prefilled syringe program. Op. 88. The court rejected

plaintiffs' argument that this conclusion contradicted ABSG's guilty plea, which "involved a strict liability offense and therefore did not implicate the Officer Defendants' knowledge of the violations admitted to." *Id.*

The court then evaluated the SLC's conclusions under *Zapata*'s discretionary second prong, which is designed "to thwart instances where corporate actions meet the criteria of step one, but the result does not appear to satisfy its spirit." Op. 94-95 (quoting *Zapata*, 430 A.2d at 789). Without "formally" addressing prong two, the court expressed the view that the claims are "unlikely to benefit ABC" because the company would prevail only if the directors' "oversight was so inexplicably lax that it amounted to bad faith." Op. 96-97. Because the evidence "does not support such a conclusion," the court held the SLC's recommendation to dismiss the action was "reasonable." *Id.*

ARGUMENT

I. The Court of Chancery Correctly Held that the SLC Undertook a Reasonable, Good-Faith Investigation.

A. Question Presented

Whether the Court of Chancery correctly held that the SLC conducted a good-faith investigation of reasonable scope. A1600-02, A1704-18.

B. Scope of Review

The Court of Chancery's ruling is reviewed *de novo*. *Kahn v. Kolberg Kravis Roberts & Co.*, 23 A.3d 831, 840-41 (Del. 2011).

C. Merits of Argument

"An important aspect of a board's managerial decisions is whether to initiate, or refrain from initiating, litigation on the corporation's behalf." *Diep ex rel. El Pollo Loco Holdings, Inc. v. Trimaran Pollo Partners, LLC*, 280 A.3d 133, 149 (Del. 2022). When a board's judgment about whether to pursue a derivative suit is potentially "tainted by the self-interest of a majority of its members," the board can "delegate its authority" to a committee of "disinterested directors." *Zapata*, 430 A.2d at 786. The committee can then "move to dismiss derivative litigation that is believed to be detrimental to the corporation's best interest." *Id.*

Where, as here, an SLC determines that a derivative action should be dismissed, the Court accords deference to that judgment, if not "the full deference of the application of the business judgment rule." Op. 77. "In reviewing the Special Committee's conclusions, the Court does not take an independent look at the merits

of [the] lawsuit." *Katell v. Morgan Stanley Grp.*, 1995 WL 376952, at *12 (Del. Ch. June 15, 1995). Instead, the Court's role is limited to evaluating the SLC's (1) "independence and good faith" and (2) "the bases supporting its conclusions." *Zapata*, 430 A.2d at 788.

As to those "limited issues," the SLC has the burden of "demonstrating that there is no genuine issue as to any material fact and that the corporation is entitled to dismiss the complaint as a matter of law." *Kaplan v. Wyatt*, 484 A.2d 501, 507 (Del. Ch. 1984). Although framed in the language of Rule 56, the Court's review of an SLC's motion to dismiss does not "correspond directly" with the summary judgment standard, *Zapata*, 430 A.2d at 787, because the Court is not charged with evaluating whether plaintiffs' claims "would be subject to termination on a summary judgment motion," *In re Oracle Corp. Deriv. Litig.*, 824 A.2d 917, 929 n.20 (Del. Ch. 2003). The question is whether any "genuine dispute of material fact" exists "as to what the Special Litigation Committee did" or "as to the information actually utilized by it in reaching its conclusions." *Kaplan*, 484 A.2d at 519. The Court's inquiry thus focuses on "the scope of the investigation and the reasonableness of the SLC's conclusions" and does not invite the plaintiffs to litigate "merits-based issues." *Diep*, 280 A.3d at 155.

The Court of Chancery correctly held that the SLC conducted "a good faith investigation of reasonable scope." Op. 80-85. The scope of the SLC's investigation

was not just reasonable, but exhaustive—extending not just to the alleged FDCA violations that were the focus of the complaint, but also to the alleged FCA violations that plaintiffs claim the SLC ignored. *See* pp. 27-29, *infra*. With the assistance of counsel, the SLC conducted 77 interviews of 67 witnesses; collected more than 12 million documents covering a 21-year period; and ultimately reviewed 220,000 documents culled with search parameters. A1076-78, A1081. In scope and depth, this investigation meets or exceeds other SLC inquiries that have withstood scrutiny under *Zapata*. *See In re Baker Hughes*, 2023 WL 2967780, at *17 (Del. Ch. Apr. 17, 2023) (110,000 documents and 22 interviews); *Diep ex rel. El Pollo Loco Holdings, Inc. v. Sather*, 2021 WL 3236322, at *12, *19 (Del. Ch. July 30, 2021) (249,000 documents and 12 interviews).

As outlined above (at 7-8), the SLC disclosed its investigative steps to plaintiffs' counsel and sought their feedback. Plaintiffs, however, only "asked for some additional information but otherwise did not provide any response or feedback." A1077-78. When the SLC presented its preliminary findings to plaintiffs' counsel, they at no point raised the alleged "FCA violations" they incorrectly claim the SLC ignored. OB 3. This Court should not permit plaintiffs to lie in wait when they had the opportunity to influence the investigation and then attack its sufficiency on appeal.

1. The SLC Reasonably Focused on Compliance with the FDCA Because that Was the Target of the Complaint.

Plaintiffs first fault the SLC for supposedly excluding their FCA allegations from the scope of its inquiry. OB 19. But even if this were correct—and it is not, *see* pp. 27-29, *infra*—the SLC need only "explore all relevant facts and sources of information that bear on the central allegations *in the complaint*." *Diep*, 2021 WL 3236322, at *19 (emphasis added). Here, as the Court of Chancery recognized, the complaint attacks "alleged breaches of fiduciary duties with respect to drug safety and sterility in the Pre-Filled Syringe Program and FDCA compliance" and is "largely silent" on alleged FCA violations involving "kickbacks or double-billing." Op. 82. Because the alleged FCA violations did not figure in the complaint, the SLC reasonably focused its investigation on alleged safety and sterility issues in the prefilled syringe program—while still investigating the alleged "FCA-related misconduct" plaintiffs erroneously claim the SLC ignored. OB 26.

A review of the complaint confirms the Court of Chancery correctly apprehended the nature of the allegations. First consider the "Nature of the Case," the section of the complaint that summarizes plaintiffs' allegations. If plaintiffs had intended to bring claims premised on alleged FCA violations, then surely this theory would have surfaced in the overview. Instead, the allegations here focus on supposed inadequacies in the board's compliance and reporting systems that failed to detect violations of "the FDCA or FDA rules or regulations." A0842, A0846.

According to plaintiffs, ABC allegedly "created and packaged" prefilled syringes in an "unsterile" facility and then "exacerbated these dangers" through its "failure to comply" with "FDA label requirements," A0841-42—ultimately leading to ABSG's guilty plea "to a criminal violation of the Food, Drug, and Cosmetic Act," A0842-44. By contrast, the Nature of the Case contains *no* reference to alleged FCA violations involving kickbacks or double-billing—the theory that plaintiffs claim the SLC unreasonably ignored.

The remainder of the complaint likewise describes alleged FDCA violations that allegedly went unnoticed by the board. The complaint asserts that the prefilled syringe program "depended on . . . skirting oversight by the FDA." A0858. And it alleges that ABC's officers and directors breached their "obligation to implement adequate reporting systems to ensure that the Company and its subsidiaries were complying with FDA regulations." A0876-77. These themes then repeat in the counts alleging breach of fiduciary duty, where plaintiffs claim the board failed "to implement and monitor policies and systems to ensure drug safety and the Company's compliance with laws and regulations governing the creation, packaging, and distribution of its drug products." A0929-30.

Not only does the complaint fail to allege a breach of fiduciary duty premised on alleged "FCA-related misconduct," OB 26, but plaintiffs at no point suggested during the SLC's investigation that this should be a focus of the inquiry. When the

SLC presented its preliminary findings to plaintiffs in April 2021 and invited feedback before issuing its final report, plaintiffs never suggested that the SLC should have more expansively investigated what they now call "FCA issues." OB 23; A1075. Their position on appeal that the SLC unreasonably disregarded a theory they never raised attempts to rewrite history.

2. Plaintiffs' "Law of the Case" Argument Is Meritless and Unpreserved.

Equally meritless is plaintiffs' argument that the lower court violated the law-of-the-case doctrine by overlooking its alleged ruling at the motion-to-dismiss stage that the breach of fiduciary duty claims do not relate solely to alleged FDCA violations. OB 23-25. This argument fails both procedurally and substantively.

At the outset, plaintiffs waived this argument by failing to "fairly present[]" it to the Court of Chancery, as required to preserve it for appeal. Sup. Ct. R. 8; *Holifield v. XRI Inv. Holdings LLC*, 304 A.3d 896, 933 (Del. 2023) (applying rule); A0929-33. This Court should thus "adhere to the well settled rule which precludes a party from attacking a judgment on a theory which was not advanced in the court below." *Danby v. Osteopathic Hosp. Ass'n of Del.*, 104 A.2d 903, 908 (Del. 1954).

Even if plaintiffs had not waived the argument, the law-of-the-case doctrine does not apply because the Court of Chancery never held that plaintiffs pleaded *Caremark* claims premised on alleged FCA violations. Plaintiffs contend that the court "expressly rejected" ABC's argument that these alleged "FCA violations" did

not give rise to the breach of fiduciary duty claims. OB 22 (citing *Chou*, 2020 WL 5028065, at *8). But they cite only to the factual background of the court's opinion, which observed that ABC entered a settlement with DOJ "to resolve civil claims under the False Claims Act." *Chou*, 2020 WL 5028065, at *8. That recitation of facts does not amount to a holding concerning the scope of the claims that would bind the court at the motion-to-terminate stage. *Washington v. Del. Transit Corp.*, 226 A.3d 202, 212 (Del. 2020) (doctrine "only applies to issues the court actually decided").

Plaintiffs next point to a footnote in the motion to dismiss opinion where the Court of Chancery supposedly "rebuked" the argument that their "*Caremark* claims were limited to safety and sterility issues under the FDCA," OB 23, but they once again misrepresent the opinion. At the motion-to-dismiss stage, the individual defendants argued that the Mullen *qui tam* did not operate as a "red flag" that the prefilled syringe program "operated illegally" because that complaint asserted claims under only the FCA and AKS, not the FDCA. *Chou*, 2020 WL 5028065, at *21 n.288. The court rejected that argument, observing that the Mullen complaint was based on the same "*factual* predicate" as plaintiffs' claims—if not the same legal theory—and thus should have alerted the board to "mission critical compliance failures." *Id.* (emphasis added). Far from holding that FCA violations are at issue

here, the court emphasized that this case concerns "the drug health and safety regulations implicated by overfill harvesting." *Id.*

Plaintiffs also suggest that "FCA-related violations have always been a part of this case" because the Court of Chancery ordered production of documents relating to the Mullen *qui tam* in the Section 220 books-and-records litigation. OB 21-22. But the Section 220 litigation does not help plaintiffs because the law-of-the-case doctrine does not apply across "two different civil actions." *Frederick-Conaway v. Baird*, 159 A.3d 285, 297 (Del. 2017). Nor could the Court of Chancery's books-and-records opinion have somehow construed the scope of the allegations in the instant complaint, which followed later in time.

Finally, *Odyssey Partners v. Fleming Co.*, 1998 WL 155543 (Del. Ch. Mar. 27, 1998), on which plaintiffs rely, is not "instructive" here. OB 24. *Odyssey* recognized the unremarkable proposition that a dismissal of certain claims at the motion-to-dismiss stage will limit the issues to be decided on summary judgment. 1998 WL 155543, at *1-2. That decision—which *rejected* the defendant's law-of-the-case arguments—has no application here, where no party is arguing that the motion to dismiss opinion narrowed the live issues in the case.

In short, plaintiffs lack any support for their unpreserved argument that the Court of Chancery's ruling violates the law-of-the-case doctrine.

3. The SLC Thoroughly Investigated Allegations of FCA Violations.

Even if the complaint pleaded *Caremark* claims premised on FCA violations, which it did not, the SLC did not unreasonably exclude those allegations from its investigation. As the Court of Chancery recognized, the SLC "investigated" all facts and sources of information relating to potential FCA violations even though "the complaint lacks any claims asserting illegal kickbacks or double-billing." Op. 82. Indeed, the SLC's report "is replete with discussion and analysis of the kickback and double-billing allegations underlying Mullen's *qui tam* complaint, the Ober Kaler Report, and the DOJ's investigation." *Id.*

Plaintiffs' assertion that the SLC would "end its inquiry" each time it "identified a red flag relating to FCA-related misconduct" is thoroughly belied by the record. OB 26. The SLC did not, for example, refuse to investigate Mullen's reporting or *qui tam* complaint because it "discounted Mullen's concerns as limited to AKS and price reporting compliance issues." OB 27 (quotations omitted). In reality, the SLC thoroughly examined the complaint's allegations concerning Mullen and devoted 30 pages of its report to explaining its investigative steps, factual findings, and analysis of those findings under applicable law. A1079-82, A1241-61, A1271-77.

Nor did the SLC decline to consider Ober Kaler's 2010 internal investigation and report because it "focused on AKS and FCA compliance." OB 27 (brackets

omitted). To the contrary, the SLC collected and reviewed documents from Ober Kaler, interviewed two former Ober Kaler attorneys who authored the report, and spoke with the ABC in-house attorneys and executives who engaged the firm and reviewed its findings. A1076, A1079, A1397-80. The SLC detailed this process in a 10-page section of its report, where it described the scope of Ober Kaler's mandate and ABC's implementation of Ober Kaler's recommendations. A1261-71.

The SLC also fully considered the DOJ investigation into the prefilled syringe program. A1034-39. Far from dismissing this investigation, OB 27, the SLC explored all relevant facts and sources of information, including DOJ subpoenas and other government records, internal ABC documents and emails, proffer memoranda, and presentations to DOJ, A1079. The SLC also reviewed a report by the law firm Fried Frank that was commissioned in response to a shareholder demand and that covered the same "subject matter of DOJ's investigation"—and ultimately found "no evidence" that the directors named in the demand "failed in their oversight responsibilities." A1082-84. Above and beyond those efforts, the SLC interviewed each defendant and other relevant witnesses, including five Morgan Lewis attorneys who served as outside counsel for ABC in connection with the DOJ investigation. A1050, A1281, A1397-98. The SLC then dedicated more than 50 pages of its report to describing the federal search of the Dothan facility and related subpoena; the changing focus of DOJ's investigation over five years; and the response of ABC's

officers and directors throughout this period. A1277-90, A1297-328. The SLC then detailed the DOJ's presentation of its legal theories to ABC, along with ABC's decision to resolve the criminal and civil cases to mitigate legal risk, notwithstanding its belief that it had strong defenses. A1308-24.

Finally, the SLC did not ignore memoranda received by ABC between 2001 and 2003 because they "did not identify FDA regulatory risks," as plaintiffs contend. OB 27. The SLC not only carefully read these decades-old memoranda, but also interviewed the authors of those documents, including a former Reed Smith attorney who wrote a 2001 memo concerning the "invoicing and billing" of oncology drugs dispensed by MII. *See* A0056-62, A1397.

Ultimately, plaintiffs' real quarrel is with the SLC's conclusions, which they (incorrectly) complain "discounted Mullen's concerns," deemed the Ober Kaler report "inconsequential," and "excused the lack of remedial action" related to DOJ's investigation. OB 27. But *Zapata* limits the Court to reviewing only the scope and adequacy of the SLC's investigation. Tellingly, plaintiffs do not identify a single investigative step the SLC should have taken or source of information it unreasonably ignored. As the Court of Chancery held, the SLC conducted "a good faith investigation of reasonable scope." Op. 80-82.

4. The SLC Considered All Relevant Sources of Information Bearing on the DOJ's Allegations.

Just as the SLC did not "stop investigating" any allegation of FCA violations, it did not "disregard[] the evidence amassed by the DOJ," including proffer memoranda, DOJ's presentation to ABC on October 25, 2015, DOJ's draft civil complaint, and related documents. OB 27-28. The SLC not only collected and reviewed these materials, but also conducted an independent assessment of both the DOJ's legal theories and the underlying facts. A1079, A1082-84, A1308-15, A1322 nn.1259-61, A1397-98. The Court of Chancery made no error, much less "reversible error," in concluding that the SLC's investigation into the DOJ's allegations was reasonable. OB 29.

Plaintiffs argue that the Court of Chancery erroneously endorsed the SLC's decision not to "rely on" proffer memoranda summarizing DOJ's interviews of ABC witnesses or produce these documents in discovery. OB 29-30. But this argument rests on a false premise. Far from ignoring the proffer memoranda, the SLC collected and reviewed each of these documents, A1079, A1717-18—and did not, as plaintiffs claim, either "willfully blind itself" to their contents or "defer[] to the recollection" of ABC's in-house lawyers, OB 31. The SLC withheld these documents in discovery and did not attach them to the report because it did not rely on them. A1717-18. In any event, if plaintiffs believed the documents were within the limited scope of *Zapata* discovery, they could have—but failed to—move to

compel. Their late-breaking plea that the SLC should have "cite[d]" these documents or "produce[d] them in discovery," OB 29-30, does not excuse their failure to pursue these documents below.

The SLC, in any event, indisputably considered the *information* available in the proffer memoranda but reasonably determined those memoranda need not be relied upon because they were "duplicative of information the SLC had already obtained from its witness interviews." Op. 84 (citing A1277-90, A1297-1324). The SLC's decision not to include other redundant proffer memoranda on top of the 420 exhibits attached to its report does not render its investigation unreasonable.[3]

Plaintiffs claim, without evidence, that the SLC "did not even read" the proffer memorandum for Steven Collis, ABC's chairman and chief executive. OB 30. Plaintiffs draw this unsupported inference from a sentence in the SLC report stating that "the SLC *understands* that DOJ asked Mr. Collis about topics such as overfill." OB 30-31 (quoting A1307). This misleading argument ignores that the SLC's outside counsel reviewed each memorandum in its entirety. A1079. Such "good faith reliance by an SLC on independent, competent counsel to assist the SLC in

[3] Plaintiffs argue that the proffer memoranda "contradict the SLC's conclusion that MII was integrated into ABC's compliance systems." OB 31-32. But plaintiffs misrepresent the SLC's conclusions, which were that the board's Ethics and Compliance Committees "exercised clear reporting lines" to the Audit Committee and that ABC's compliance department "reported at least annually to the Audit Committee." A1348-49.

investigating claims is legally acceptable, practical, and often necessary." *Carlton Invs. v. TLC Beatrice Int'l Holdings, Inc.*, 1997 WL 305829, at *12 (Del. Ch. May 30, 1997).

Plaintiffs next argue that the SLC unreasonably failed to credit "the DOJ Evidence" and instead "curated its own record." OB 29, 33-34. Putting aside that this argument improperly attacks the SLC's conclusions, rather than its process, plaintiffs' position rests on the flawed premise that the "DOJ Evidence" constitutes unimpeachable fact and that DOJ investigated the same thing the SLC did—alleged breaches of fiduciary duty. While the SLC carefully considered both the DOJ presentation and draft civil complaint, the SLC was not required to accept "DOJ's allegations" at face value, as plaintiffs suggest. OB 33. As the SLC learned, ABC's outside counsel unmasked significant weaknesses in the DOJ's allegations and legal theories. For example, Morgan Lewis extracted concessions from DOJ that its testing of seized syringes did not reveal any contamination and that DOJ had no evidence of patient harm caused by MII's products. A1310-11.

That ABSG pleaded guilty to the misdemeanor offense and ABC settled the threatened civil case does not suggest that the SLC should have accepted the DOJ's unproven allegations as "credible." OB 33-34. To the contrary, ABSG admitted only "a limited statement of facts" when it entered its guilty plea, A1317, and reserved its right to "challenge, contest and refute the factual allegations in the

Information in any subsequent proceeding," A1319. Similarly, as to the civil complaint, ABC believed the company had "good legal defenses" to the government's "novel theories" but ultimately settled to avoid even the "theoretical exposure" to treble damages. A1321-23.

Plaintiffs contend that the SLC unreasonably credited Morgan Lewis's "conflicted views" that DOJ lacked evidence of misconduct by "high-level personnel at ABSG" and that this Court should "second guess" the SLC's reliance on Morgan Lewis witnesses. OB 34-35. But *Carlton*, on which plaintiffs rely, addressed when Delaware courts should examine an SLC's reliance on *its own counsel* to perform "legal and factual research"—and held that such scrutiny is warranted only where there is "evidence of overreaching by counsel or neglect by the SLC." 1997 WL 305829, at *12. Even assuming *Carlton* in any way restricts an SLC's authority to rely on attorney *witnesses*—a doubtful proposition—plaintiffs present no evidence of "overreaching" by Morgan Lewis or "neglect by the SLC." *Id.*

This case bears little resemblance to those cited by plaintiffs where courts found that material issues of fact remained as to the good faith or reasonableness of an SLC's investigation. In *London v. Tyrrell*, 2010 WL 877528 (Del. Ch. Mar. 11, 2010), the court denied an SLC's motion to dismiss because the SLC accepted a defendant's testimony "without adequately exploring contrary evidence," including the defendant's own contradictory emails; failed to "explore why management

pervasively used forecasts it did not believe were realistic"; "declined altogether" to investigate a transaction that "likely would have shed light" on the allegations in the complaint; and contained numerous other shortcomings. *Id.* at *20-24. And in *Sutherland v. Sutherland*, 968 A.2d 1027 (Del. Ch. 2008), the court denied re-argument of a motion to dismiss where the SLC "consciously omitted" material information from its report, "destroyed its original interview notes," and failed "to deal openly and honestly with all relevant and material information." *Id.* at 1030. No remotely similar facts exist here.

On this record, as the Court of Chancery correctly held, "there is no genuine question as to whether the SLC investigation was reasonable in scope and conducted in good faith." Op. 85.

II. The Court of Chancery Correctly Ruled that the SLC Had Reasonable Bases for Its Conclusions.

A. Question Presented

Whether the SLC had reasonable bases for its conclusion that the breach of fiduciary duty claims should be dismissed because they were not in the best interest of ABC. A1600-14, A1722-28.

B. Scope of Review

The Court of Chancery's ruling is reviewed *de novo*. *Kahn*, 23 A.3d at 840-41.

C. Merits of Argument

The SLC reasonably concluded that pursuing the breach of fiduciary duty claims "would not be in the best interests of ABC." A1389. Plaintiffs now invite the Court to substitute its judgment for that of the SLC, arguing that the SLC's conclusions are "factually wrong" or at least "disputed." OB 39. But review of the SLC's motion to dismiss a derivative claim is "not" an invitation to "take an independent look at the merits of [the] lawsuit." *Katell*, 1995 WL 376952, at *12; pp. 19-20, *supra*. The SLC must simply satisfy the Court that "there is no material factual dispute that [it] had a reasonable basis for its decision to seek termination." *Oracle*, 824 A.2d at 929 n.20. The SLC has readily carried that burden on the force of its voluminous investigation and 365-page report explaining its conclusions.

Plaintiffs erroneously attempt to reframe the question as whether the SLC reasonably concluded that the defendants "did not face *Caremark* liability." OB 36. But the ultimate question the SLC was charged with answering is not simply whether defendants breached their duties, but whether pursuing the claims serves "the best interest of the corporation." *Zapata*, 430 A.2d at 787 (brackets omitted). To be sure, the leading factor in that analysis was whether the claims had a probability of success. A1389. Here, however, the SLC also considered that this litigation would divert resources from ABC's "core business functions," "result in harmful and unjustified public relations consequences," and "erode relations" with employees—considerations plaintiffs do not challenge. A1389-92. The only question before this Court is whether the SLC's decision to seek dismissal had a reasonable basis. *Zapata*, 430 A.2d at 787. For the reasons explained below, the answer is yes.

1. The SLC Reasonably Concluded that the Officer Defendants Did Not Knowingly Operate an Illegal Business Model.

To succeed on a breach of fiduciary duty claim against the officer defendants, plaintiffs would need to prove either that the officers (1) knowingly or with gross negligence managed MII "in an illegal fashion," *Metro Commc'n Corp. BVI v. Advanced Mobilecomm Techs. Inc.*, 854 A.2d 121, 131 (Del. Ch. 2004), or (2) failed to provide board members with information needed "to perform their statutory and

fiduciary roles," *Amalgamated Bank*, 132 A.3d at 781.[4] Plaintiffs challenge the factual basis for the SLC's finding that "no evidence" shows the officer defendants "knew that MII was operating an illegal business model" or that they "withheld" relevant information from the board. A1378. Putting aside that the factual correctness of the SLC's findings is not the relevant issue, *see* pp. 19-20, *supra*, plaintiffs' attacks on those findings rest on blatant misrepresentations of the record.

Plaintiffs contend, first, that defendants Collis and Chou "knew or should have known" that the prefilled syringe program "involved illegal conduct" in light of a memo Collis received in 2001. OB 39. At the outset, plaintiffs 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. *See Morrison v. Berry*, 2019 WL 7369431, at *25 (Del. Ch. Dec. 31, 2019). Plaintiffs are wrong, in any event, that the memorandum would have alerted these defendants that the prefilled syringe program possibly violated FDA health and safety regulations—the only violations at issue in their complaint.

[4] After the SLC completed its investigation, the Court of Chancery resolved the open question of whether *Caremark* claims may be brought against corporate officers. The SLC's report fully disposes of any *Caremark* allegation that the officer defendants "knew of evidence of corporate misconduct" and "consciously failed to take action in response." *In re McDonald's Corp. S'holder Derivative Litig.*, 289 A.3d 343, 376 (Del. Ch. 2023).

That memorandum identified potential FCA issues with MII's billing practices, as the SLC acknowledged. A1187 n.656. But it neither identified FDA regulatory risks or sterility concerns nor suggested that MII had what plaintiffs call an "illegal business model." OB 39. Plaintiffs also omit key findings from the memorandum, including that "the risk of sanctions" for potential FCA violations was "moderate or less" and that the company possessed "[s]ubstantial defenses." A0065. Plaintiffs also elide the SLC's finding that the author's concerns about how MII billed for "salvage" (not overfill) became moot after MII stopped retaining or reusing salvage. A0064, A1187 n.656.

Plaintiffs also ignore that other reviews of MII's prefilled syringe program conducted around the same time identified no safety or sterility issues or questioned the program's compliance with the FDCA. These included a risk assessment by ABC's legal department in 2003 that flagged no FDA regulatory concerns with MII. A1199-200. A compliance review performed shortly thereafter by Reed Smith concluded that the prefilled syringe program did not raise significant regulatory, anti-kickback, or double-billing risks. A1200-01. ABSG's general counsel concluded that this analysis endorsed MII's business model and conveyed to management that the "program was previously 'blessed'" and "everything looks good." A1203-04 (alterations omitted).

Plaintiffs next argue that Chou breached his duties by not "alerting" the board to Ober Kaler's "serious concerns" with the prefilled syringe program, OB 40-41, but they once again mischaracterize the facts. ABC engaged Ober Kaler to review the Oncology Group's "overall compliance with federal anti-kickback/fraud and abuse laws and the federal false claims act." A1263 (alterations omitted). Because Ober Kaler's mandate did not include a review of FDCA compliance, product sterility, or the legality of the prefilled syringe program, the firm neither investigated nor identified FDA regulatory concerns at MII. A1262, A1266-69. As a result, Ober Kaler's investigation could not have alerted the officer defendants to the supposed FDA compliance issues underlying the breach of fiduciary duty claims. A1384.

Plaintiffs argue that, when Ober Kaler provided Chou with a draft slide regarding "Potential Risks" in the prefilled syringe program that might arouse "Government suspicion," Chou directed Ober Kaler to "remove any mention" of these concerns from an upcoming board presentation. OB 40-41 (quoting A0196). Once again, the record reflects that Ober Kaler asked about the prefilled syringe program in the context of anti-kickback and billing concerns, not FDCA compliance. A1264. And Ober Kaler simply relayed its view that "the government is going to be totally confused by this program" and that the firm needed "to understand it" in case "the government comes and asks about it." A1265. Chou then directed Ober Kaler to ABSG's in-house lawyers, who had asked similar questions and "felt better after

examining the facts" and reviewing the recommendations of outside counsel who had "blessed" the program. A1265, A1384-85. Because the program "had already been reviewed" by an outside law firm, Ober Kaler did not engage in "further follow-up." A1265-66. Plaintiffs have provided no basis to undercut the reasonableness of the SLC's conclusion that Chou was "entitled to rely on the efforts of his staff" and the recommendations of outside counsel. A1384 (citing *Cirillo Fam. Tr. v. Moezinia,* 2018 WL 3388398, at *12 (Del. Ch. July 11, 2018)).

Plaintiffs claim, finally, that Chou "misrepresent[ed]" to the Audit Committee that Ober Kaler's investigation was a "periodic" compliance review, rather than a "targeted" review prompted by Mullen's report. OB 41. In fact, Chou had made plans to hire Ober Kaler as early as April 2010, months before Mullen raised his concerns regarding OS's billing practices. A1261. When ABC officially engaged the firm in June 2010, shortly after Mullen made his initial report, Chou instructed Ober Kaler to consider the questions raised by Mullen and the *Westmoreland* case on which he relied. A1261-62. After completing its investigation, Ober Kaler made a presentation to the Audit Committee and, with input from Chou, identified "action items" for improvement—which the company swiftly implemented and reported to the board. A1266-71, A1383-85. Plaintiffs, again, have provided no basis to dispute the reasonableness of the SLC's conclusion that Chou's directive to Ober Kaler did not breach any fiduciary duty. A1383-85.

Relying on an issue first identified by the *SLC*, not their complaint, plaintiffs next contend that, in 2012, Collis and Chou learned that MII failed to collect names of patients ordering prefilled syringes but declined to escalate that information to the Audit Committee. OB 42-44; A1230-31. But the SLC concluded Collis and Chou reasonably believed MII was complying with Alabama law and MII merely needed to improve its processes to ensure that it remained a state-regulated pharmacy (rather than an FDA-regulated manufacturer). A1231-38, A1379-86. ABC's Compliance Committee declined to elevate the labeling issue to the Audit Committee because it believed "the practice may be in compliance with State regulations." A1234. At the same time, ABSG's corporate counsel decided "MII needed to change its practices" in light of "recent FDA guidance" and sent a memorandum to MII's chief pharmacist directing that MII add "the name of the patient" to "each prescription label." A1232-36. Plaintiffs' assertion (at 45) that Collis and Chou made "no effort" to address the labeling issue lacks any support.

Plaintiffs argue, finally, that the SLC unreasonably accepted Chou's "dubious explanation" that MII's labeling of prefilled syringes "did not violate Alabama law," which supposedly "conflicts with the admitted facts accompanying the guilty plea and civil settlement." OB 44. But the SLC's conclusion that Collis and Chou did not *knowingly* operate and maintain an illegal business model "does not contradict" ABSG's guilty plea—which involved a strict-liability offense that "did not

implicate" Chou's or Collis's knowledge of the alleged violations. Op. 88 (citing A1317-20). Nor is there any merit to plaintiffs' assertion that the SLC failed to "press" any witness on why ABSG's plea contained a sentencing enhancement that applies when "High Level Personnel" participated in or remained willfully ignorant of the offense.[5] OB 45. In fact, the SLC pressed the witnesses most likely to have information—the attorneys who negotiated the plea—and those attorneys did not recall that DOJ had any evidence that high-level personnel engaged in or condoned illegal behavior. A1320.

In short, plaintiffs have failed to undercut the SLC's showing that it had a reasonable basis to conclude the claims against the officer defendants should be dismissed.

2. The SLC Had Reasonable Bases To Conclude that the Director Defendants Fulfilled Their *Caremark* Duties.

To sustain a *Caremark* claim for breach of fiduciary duty, plaintiffs would need to prove that the director defendants "knew of evidence of corporate misconduct—the proverbial 'red flag'—yet acted in bad faith by consciously disregarding [their] duty to address that misconduct." *Horman v. Abney*, 2017 WL

[5] The SLC did not "concede[]" that this issue "wasn't the focus of our investigation." OB 45 (alterations omitted). During his deposition, Nally testified that the SLC considered, as to the individual defendants, "did they operate an inappropriate business model" and "did they withhold information from the board." A1482.

242571, at *7, *10 (Del. Ch. Jan. 19, 2017).[6] In the Court of Chancery, plaintiffs asserted that the director defendants ignored six alleged red flags. On appeal, they have abandoned all but two of those allegations, arguing only that the board failed to take action in response to (1) Mullen's complaints and (2) the DOJ search warrant and subpoena. OB 47-53. For the reasons explained below, the SLC had reasonable bases to conclude that the Mullen *qui tam* complaints did not raise red flags regarding safety or sterility and that the director defendants responded appropriately to both the *qui tam* and the DOJ search and subpoena.

a) The Board Responded Reasonably to Mullen's Allegations and *Qui Tam* Complaint.

Plaintiffs have offered no basis to gainsay the SLC's conclusion that Mullen's complaints were not a "red flag" that alerted the board that "MII or its prefilled syringe program were violating FDA regulations." A1363. Mullen's internal reporting and initial *qui tam* addressed "potential AKS and price reporting compliance concerns," not potential FDCA violations, and those pricing concerns had already been evaluated by company counsel in the context of the *Westmoreland* case. A1363-64. Although Mullen later amended his complaint to raise "FDCA compliance and sterility concerns," the SLC found that the board "did not become

[6] Plaintiffs have abandoned the theory they pressed below under *Caremark* prong one that the director defendants "utterly failed to implement any reporting or information systems or controls." *Stone ex rel. AmSouth Bancorporation v. Ritter*, 911 A.2d 362, 370 (Del. 2006).

aware of the substance of that complaint" until 2016, two years after MII closed. A1364-65. Plaintiffs' brief nowhere addresses the SLC's conclusion that the Mullen *qui tam* complaints were not "red flags" or attempts to explain why that conclusion lacks a reasonable basis.

Plaintiffs instead attack the SLC's alternative conclusion that, even if the Mullen complaints were a red flag, the director defendants did not "consciously disregard" his allegations. A1365. When Mullen first reported "possible AKS and price reporting compliance concerns," Chou forwarded them to Ober Kaler to investigate and report back to the board, even though Mullen's concerns "mirrored those contained in *Westmoreland*, which ABC already knew well." A1260, A1364-66. The board then "monitored" the company's implementation of Ober Kaler's recommendations. A1366.

Plaintiffs misleadingly state that Ober Kaler's investigation concluded two months *before* Mullen filed his *qui tam* complaint. OB 48. But Ober Kaler addressed Mullen's report to ABC's legal department—which included the same allegations he later raised in the *qui tam*. A1260-63. And after Mullen filed the *qui tam*, the director defendants discussed the action with Chou and learned that Morgan Lewis had been retained to handle Mullen's claims and any resulting investigative activity, A1366—not just "how to handle a public disclosure," as plaintiffs claim,

OB 48. Plaintiffs fail to describe what other "affirmative steps" they believe the director defendants should have taken. OB 47.

Nor does the record support plaintiffs' assertion that the SLC unreasonably relied on "paper-thin, self-serving statements" by directors Kathleen Hyle and Michael Long in concluding that the director defendants fulfilled their *Caremark* duties. OB 49. The language that plaintiffs quote from Hyle's and Long's witness interviews does not even appear in the SLC's report, let alone in its analysis of the directors' potential *Caremark* liability. These statements therefore do nothing to undermine the reasonableness of the SLC's conclusion that the director defendants did not "consciously disregard" Mullen's allegations. A1365.

b) The Board Responded Reasonably to the DOJ Search Warrant and Subpoena.

The SLC also reasonably concluded that the director defendants did not engage in "an intentional dereliction of duty" when they learned about the DOJ search and subpoena. A1369, A1371. As the SLC found, board members knew that the company had engaged Morgan Lewis to handle the DOJ investigation, and they "received updates" from counsel at every meeting. A1372. Board members also "discussed" whether "there were any concerns about MII's operations." A1287. They reasonably surmised that the search likely stemmed from Mullen's *qui tam* complaint, "which they understood had no merit." *Id.* They believed, indeed, that "MII's practices were lawful based on earlier legal reviews." A1288.

Plaintiffs argue that a more "reasonable reaction would have been to inspect the facility or conduct a review" of MII's "business model." OB 52. But, as the board knew, the company in fact performed the type of testing that plaintiffs argue should have been done. A1288. Following the government's search, ABC tested MII's products and found "no issues" with safety or sterility. *Id.* The board also knew that the Alabama Board of Pharmacy regularly inspected MII's facility and had not identified any material safety or sterility failures. A1381.

In any event, as the Court of Chancery correctly held—and plaintiffs do not challenge on appeal—a *Caremark* claim does not evaluate the directors' actions "for compliance with best practices," only for "failures of oversight so grossly apparent that they amount to bad faith." Op. 87. Plaintiffs have not explained why the SLC's conclusion that the directors did not engage in "an intentional dereliction of duty," A1371, lacks a reasonable basis.

CONCLUSION

The Court of Chancery's judgment granting the SLC's motion to dismiss should be affirmed.

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