IN THE COURT OF CHANCERY 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 and SAN ANTONIO FIRE & POLICE PENSION FUND,	)	
Plaintiffs,	)	
v.	)	C.A. No. 2019-0816-SG
JOHN G. CHOU, STEVEN H. COLLIS, RICHARD W. GOCHNAUER, LON R. GREENBERG, TIM G. GUTTMAN, JANE E. HENNEY, M.D., KATHLEEN W. YLE, MICHAEL J. LONG, and HENRY W. MCGEE,	)	
Defendants,	)	
–and–	)	
AMERISOURCEBERGEN CORPORATION,	)	
Nominal Defendant.	)	

MEMORANDUM OPINION

Date Submitted: July 12, 2023
Date Decided: November 17, 2023

Gregory V. Varallo and Glenn R. McGillivray, BERNSTEIN LITOWITZ BERGER & GROSSMANN LLP, Wilmington, Delaware; Ned Weinberger and Mark D. Richardson, LABATON SUCHAROW LLP, Wilmington, Delaware; Christine M. Mackintosh and Rebecca A. Musarra, GRANT & EISENHOFER P.A., Wilmington, Delaware; OF COUNSEL: Christopher J. Orrico, BERNSTEIN LITOWITZ BERGER & GROSSMANN LLP, New York, New York; Frank Schirripa, HACH ROSE SCHIRRIPA & CHEVERIE LLP, New York, New York; Nathaniel L. Orenstein and Steven L. Groopman, BERMAN TABACCO, Boston, Massachusetts, *Attorneys for Plaintiffs*.

William M. Lafferty, D. McKinley Measley, and Thomas P. Will, MORRIS, NICHOLS, ARSHT & TUNNELL LLP, Wilmington, Delaware; OF COUNSEL: F. Joseph Warin, Jonathan M. Phillips, and Courtney M. Brown, GIBSON, DUNN & CRUTCHER LLP, Washington, D.C., *Attorneys for the Special Litigation Committee of the Board of Directors for AmerisourceBergen Corporation*.

GLASSCOCK, Vice Chancellor

This is a derivative action, in which the Plaintiff stockholders allege that the board of AmerisourceBergen Corporation ("ABC", "AmerisourceBergen", or the "Company") allowed a division of the Company to act as, in effect, a criminal enterprise. That subsidiary, Medical Initiatives, Inc. d/b/a Oncology Supply Pharmacy Service ("MII" or the "Pharmacy"), repackaged cancer drugs from single-dose vials into syringes, for distribution to physicians. The complaint alleged that the Pharmacy was operated in an illegal manner, including by pooling the small amounts left in vials after charging a syringe, and using the resulting product to fill, and sell, extra syringes, in a manner that was illegal and unsanitary. The Defendant Directors' and Officers' failures to oversee operations were actionable breaches of fiduciary duties, per the complaint, and led to fines and penalties in settlement of DOJ investigations amounting to hundreds of millions of dollars. On a motion to dismiss by the Defendant Directors, I found the allegations of the complaint, taken as true and with the plaintiff-friendly inferences therefrom, sufficient to state a claim for breach of fiduciary duty; and that the majority of ABC's board of directors (the "Board") faced a substantial risk of liability for failure to properly oversee the Pharmacy operations, justifying derivative litigation on the part of the Plaintiff stockholders.

Such a situation, of course, is a departure from the paradigm that the assets of a corporation, including litigation assets, are under the control of the directors.

Operation of a conflicted board may be restored by empowering a special committee of independent directors. Here, the Board appointed such a committee (the "SLC"), ultimately composed of a single independent fiduciary, to review whether the litigation was in the best interest of ABC. I permitted a stay of litigation to facilitate that review. The resulting report of the SLC paints a different picture from that contained in the complaint. After a thorough review, the SLC concluded that there had been no breach of duty on the part of the majority of the Board, that the litigation was inimical to the corporate weal, and recommended that the matter be dismissed.

That does not end my review. Of course, this Court usually defers to the business judgment of directors. Several scenarios exist, however, where pressures on directors, even though technically unconflicted, have the potential to skew their judgment, and in those situations the Court must determine that the directors' review and resulting exercise of judgment are reasonable.[1] One such case is a special committee's review of derivative litigation, where the directors on the committee are asked to evaluate the potential culpability of fellow board members. The resulting examination by the court of a special committee's report

[1] Vice Chancellor Laster has created a scholarly review of various scenarios invoking intermediate scrutiny of fiduciaries. *See In re Columbia Pipeline Grp., Merger Litig.*, 299 A.3d 393 (Del. Ch. 2023).

recommending dismissal is known colloquially as a *Zapata* review.[2] Such a review follows.

Plaintiffs argue that the SLC's work cannot withstand such review, in part, because the report of a single-member committee is inherently suspect. They point out that the independence of such a committee, and the conduct of its investigation, must be "above reproach." Here, because Plaintiffs purport to find ground to reproach the SLC's sole member, they contend the motion to dismiss must be denied.

The Plaintiffs' standard is essentially correct, but I reject Plaintiffs' conclusion. I have considered the facts with which Plaintiffs reproach the SLC member, and find them unpersuasive. I have also considered the scope of the SLC's examination of the allegations in the complaint, and find it adequate; and the bases for the SLC's conclusions, which I find reasonable, even under the "gimlet eye"[3] with which a single-member committee's conclusions should be viewed. Accordingly, the motion to dismiss is granted. The facts developed by the SLC, and my reasoning, follow.

A word about the factual background is in order. An interested reader will find a walk through the Background section below less of a stroll and more like, say,

[2] *Zapata Corp. v. Maldonado*, 430 A.2d 779 (Del. 1981).
[3] *See Chesapeake Corp. v. Shore*, 771 A.2d 293, 323 (Del. Ch. 2000).

the pilgrimage Way of St. James.[4] This detailed statement is justified here, because it informs my review of the reasonableness of the SLC's recommendation. The reader is forewarned.[5]

I. FACTUAL BACKGROUND

The facts that follow are drawn from the record submitted by the special litigation committee (the "SLC") and the Plaintiffs, including the special litigation committee's report ("SLC Report"), the 420 exhibits attached thereto, and the transcript of the deposition taken of the sole SLC member, Dennis M. Nally.[6]

A. AmerisourceBergen Corporation

AmerisourceBergen is a Delaware corporation headquartered in Conshohocken, Pennsylvania.[7] The Company was formed on August 29, 2001, after Bergen Brunswig Corporation merged with AmeriSource Health Corporation and subsequently changed its name to AmerisourceBergen Corporation.[8] Following the merger and the subsequent yearslong integration process, ABC became the largest

[4] I refer to an "interested" reader, because a casual reader, I suspect, will find her faith insufficient to sustain the effort.
[5] Readers will quickly discover that the factual treatment below contains a misery of acronyms. I have attempted to define the acronyms repeatedly in text to reduce the mental effort of comprehending the facts here; in a further attempt to reduce the acro-batics required of the reader, I have appended a list of acronyms and their meaning at the end of this Memorandum Opinion, as Exhibit A.
[6] *See* Letter from D. McKinley Measley to Vice Chancellor Glasscock, Ex. A, Dkt. No. 73 ("SLC Report"). Citations in the form of "SLC Report Ex. __" refer to exhibits to the SLC Report.
[7] ABC Annual Report on Form 10-K (Nov. 19, 2020), at 1.
[8] SLC Report 56–57.

pharmaceutical distribution or services company in the U.S. dedicated only to the pharmaceutical supply channel.[9]

As of 2001, AmerisourceBergen operated its pharmaceutical distribution business through wholesale and specialty drug distribution subsidiaries.[10] Two subsidiaries, AmerisourceBergen Drug Corporation ("ABDC") and AmerisourceBergen Specialty Group ("ABSG" or "Specialty Group"), primarily drove ABC's pharmaceutical distribution and services business.[11] ABSG and its subsidiaries served the specialty drug distribution market, including oncology supply.[12]

1. AmerisourceBergen Specialty Group

Prior to the merger, ABSG was relatively decentralized, holding various portfolio companies that primarily operated independently.[13] One of ABSG's portfolio companies was ASD Specialty Healthcare, LLC d/b/a Oncology Supply ("OS"), which was—and still is—an oncology distribution company based in Dothan, Alabama.[14] OS distributes chemotherapy and other cancer drugs throughout the United States.[15] Another portfolio company owned by ABSG was Medical

[9] ABC Annual Report on Form 10-K (Dec. 19, 2003), at 42.
[10] SLC Report 57.
[11] *Id.* at 4–5, 57.
[12] *Id.* at 57.
[13] ABC Annual Report on Form 10-K (Dec. 28, 2001), at 13.
[14] SLC Report 7, 58. Bergen Brunswig acquired OS in 1996. Bergen Brunswig Annual Report on Form 10-K (Dec. 30, 1996), at II-19.
[15] SLC Report 58.

Initiatives, Inc. d/b/a Oncology Supply Pharmacy Service ("MII" or the "Pharmacy").[16] MII was an Alabama-licensed pharmacy that exclusively provided services to OS and OS customers that purchased certain medications, via MII preparing pre-filled syringes of oncology drugs.[17]

The Specialty Group's portfolio also included subsidiary group purchasing organizations ("GPOs"), such as International Oncology Network ("ION"), that served a variety of medical specialty practices, including oncology practices.[18] ION would negotiate with pharmaceutical manufacturers and vendors, such as OS, on behalf of ION's paying member practices.[19] Vendors would pay ION a fee, typically a percentage of each sale.[20]

Since the merger, the Company has grown the Specialty Group and revised its organizational structure.[21] As ABSG grew by expanding its services and gaining new subsidiaries, it created the ABSG Oncology Group consisting of OS, ION, and MII.[22]

[16] *Id.* at 7, 58. Bergen Brunswig acquired MII in 1998. Bergen Brunswig Form 10-Q (Feb. 16, 1999), at 9.
[17] SLC Report 58–59.
[18] *Id.* at 22–23, 59.
[19] SLC Report Ex. 20, at 3.
[20] *Id.*
[21] SLC Report 60.
[22] SLC Report Ex. 21, at 11.

2. AmerisourceBergen Drug Corporation

ABDC operates twenty-seven distribution facilities throughout the United States.[23] After acquiring ABDC in the merger, ABC grew ABDC through a series of acquisitions, including PharMEDium through which ABDC operated five Food and Drug Administration ("FDA") registered sterile compounding outsourcing facilities to provide sterile compounded preparations to acute hospitals within the United States.[24]

B. AmerisourceBergen's Corporate Governance Structure

1. The Board of Directors' Functions

AmerisourceBergen's board of directors (the "Board") has consisted of ten members since the Company's formation in 2001.[25] From 2001 to 2006, eight of the directors were independent and not employed by the Company; from 2007 to 2015, all but one director were independent.[26] When the Chairman of the Board is not independent, a majority of the independent directors elect a Lead Independent Director annually.[27] In 2016, when Defendant Steven Collis, ABC's CEO, became

[23] SLC Report Ex. 22, at 6.
[24] *Id.*; AmerisourceBergen Annual Report on Form 10-K (Dec. 10, 2004), at 50.
[25] *See, e.g.*, Schedule 14A Proxy Statement (Jan. 22, 2002), at 2.
[26] Schedule 14A Proxy Statement (Jan. 18, 2008), at 1; Schedule 14A Proxy Statement (Jan. 23, 2015), at 15.
[27] Schedule 14A Proxy Statement (Jan. 22, 2016), at 20.

the Chairman, Defendant Dr. Jane Henney was elected Lead Independent Director, a position she holds to this day.[28]

The Board met formally and informally throughout each year.[29] Between 2001 and 2014, the Board conducted five to seven formal meetings each year.[30] The Board also held monthly telephone calls, called "First Monday."[31] At many of the Board meetings, each Board committee's Chair would report to the full Board on topics discussed at the most recent meeting of their committee.[32] The Board received regular reports on legal and compliance-related matters and, on occasion, outside counsel would present to the Board on such matters.[33]

2. The Board of Directors' Standing Committees

From 2001 to 2011, the Board maintained four standing committees: the Audit Committee, Compensation Committee, Executive and Finance Committee, and Governance Committee.[34] In 2011, the Company split the Executive Finance Committee into separate committees to form a Finance Committee consisting of only non-employee directors.[35]

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[28] *Id.* at 18.
[29] SLC Report 71.
[30] *See, e.g.*, Schedule 14A Proxy Statement (Jan. 28, 2004), at 9; Schedule 14A Proxy Statement (Jan. 18, 2008), at 11.
[31] SLC Report 71.
[32] *See, e.g.*, Schedule 14A Proxy Statement (Jan. 23, 2015), at 18.
[33] SLC Report 72.
[34] *See, e.g.*, Schedule 14A Proxy Statement (Jan. 23, 2002), at 4; Schedule 14A Proxy Statement (Jan. 20, 2012), at 10.
[35] SLC Report 62.

Most relevant to this discussion is the Board's Audit Committee, which was charged with overseeing the Company's financial statements and financial reporting practices; reviewing the adequacy of the Company's accounting practices and financial controls; and reviewing financial disclosures in the Company's Annual Report on Form 10-K and quarterly Form 10-Q filed with the Securities and Exchange Commission.[36] The Audit Committee also oversees the Company's internal audit function, reviewing findings from completed internal audits, managements' response to internal audit reports, and the senior internal auditor's performance.[37] Internal audit reports were typically discussed quarterly when ABC's Internal Audit Department ("Internal Audit") leaders met.[38]

The Audit Committee's responsibilities were expanded in 2004 to expressly include oversight of the Company's legal and regulatory compliance function.[39] In 2011, the Audit Committee also assumed responsibility for overseeing and developing an enterprise risk management program "designed to assist the Company with monitoring and mitigating business, operational and technological risks."[40] The Audit Committee retained oversight responsibilities for regulatory compliance,

[36] *See, e.g.*, Schedule 14A Proxy Statement (Jan. 28, 2021), at 23–24; SLC Report Ex. 25, at Ex. A, 1–2; SLC Report Ex. 26, at Ex. A, 1–2; Schedule 14A Proxy Statement (Jan. 9, 2006), at 9–10.
[37] *See, e.g.*, Schedule 14A Proxy Statement (Jan. 28, 2021), at 23–24; SLC Report Ex. 25, at Ex. A, 2–4.
[38] SLC Report 64.
[39] SLC Report Ex. 29, at A-8.
[40] SLC Report Ex. 32, at 6; *see also* Schedule 14A Proxy Statement (Jan. 20, 2012), at 15.

compliance with the Code of Ethics and Business Conduct (the "Code of Conduct"), and the enterprise risk management program through December 2019, at which time the newly-formed Compliance and Risk Committee assumed those responsibilities.[41]

Between 2002 and 2014, the Audit Committee held approximately ten meetings per year.[42] ABC's compliance and legal teams made presentations to the Audit Committee at its meetings that occurred shortly before formal Board meetings.[43] At about half of the Audit Committee meetings each year, the Chief Compliance Officer ("CCO"), the Company's General Counsel, the Corporate Security and Regulatory Affairs ("CSRA") Director, the head of Internal Audit, or the Director of Internal Controls reported to the Committee on compliance matters, including any allegations or incidents, management's mitigating or corrective actions, and Compliance Hotline Reports.[44]

Beyond presenting to the Audit Committee at committee meetings, the CCO and the Vice President of Internal Audit had direct lines of communication to the Audit Committee, including routine meetings prior to Audit Committee meetings to discuss ongoing issues.[45] The Chair of the Audit Committee would review the

[41] Schedule 14A Proxy Statement (Jan. 24, 2020), at 27–28.
[42] SLC Report 65.
[43] *Id.* at 72.
[44] *Id.*
[45] *Id.* at 73.

Compliance Network Hotline and Internal Audit reports before each meeting, and either the Chair or the Head of CSRA or the Head of Internal Audit reviewed them in depth with the rest of the Audit Committee.[46] A member of the Audit Committee would present to the Board about the topics of discussion at the Committee Meeting and CSRA would provide its own overview of key issues with the full Board.[47] Defendant John Chou, as Chief Legal Officer, also presented relevant legal issues first to the Audit Committee before apprising the full Board of the Company's top priority issues.[48]

C. The History of AmerisourceBergen's Compliance Program

1. The Board Adopts a Formal Compliance Program

Following the 2001 merger, the Board created two management-level committees and one Board-level committee to address corporate governance and compliance.[49] The pre-existing management-level Compliance Committee was tasked with overseeing legal and regulatory compliance at the Company.[50] The Board also created the position of Chief Compliance Officer to manage the Company's Compliance Program and ensure compliance with applicable laws and internal policies.[51] The second management-level committee created was the Ethics

[46] *Id.*
[47] *Id.*
[48] *Id.* at 73–74.
[49] *Id.* at 78.
[50] SLC Report Ex. 45, at 11.
[51] *Id.* at 8.

Committee, which was comprised of senior ABC managers, to receive regular reports from the Compliance Committee.[52] The Compliance Committee reported quarterly to the Ethics Committee, which in turn reported directly to the Board's Audit Committee.[53]

On February 27, 2003, the Board was informed by the Vice President of CSRA that the Drug Enforcement Administration (the "DEA") was the Company's primary federal regulator.[54] The Vice President further identified the FDA, Environmental Protection Agency ("EPA"), Occupational Safety & Health Administration ("OSHA"), and the Department of Transportation ("DOT" and "FAA") as other federal agencies that regulate the Company.[55]

In 2004, the Board built on ABC's existing compliance framework to further formalize its compliance program.[56] The corporate compliance program included a Code of Conduct, a Network Hotline for anonymous reporting, and compliance training.[57] The Code of Conduct, in relevant part, encompassed the Company's policy on the handling of ABC work product.[58] Calls made to the Network Hotline were by compiled by the Compliance Committee alongside non-network compliance

[52] *Id.* at 11.
[53] SLC Report Ex. 47, at 2–3.
[54] *See* SLC Report Ex. 48.
[55] *Id.* at 19–20.
[56] SLC Report 76.
[57] *Id.* at 76–77.
[58] SLC Report Ex. 52, at 2–4.

complaints in a "Compliance Incident Report" ("CIR") that tracked things such as the number of calls, the number of call-related inquiries that remained open, and the details of each complaint.[59] Under this formalized compliance program, local compliance officers at each business unit reported to the CCO, who was a member of the Compliance Committee.[60] The CCO then reported directly to the Company's General Counsel, who was a member and Chair of the Ethics Committee.[61]

a. Corporate Security and Regulatory Affairs

From 2001 until 2012, CSRA was solely responsible for all aspects of regulatory compliance oversight and physical security at the Company.[62] CSRA focused on compliance with federal and state regulations, in addition to processing all of the Company's DEA registration renewals, while each respective Distribution Center processed its own state and local licensing.[63] Though CSRA assisted, the Company's pharmacies were primarily responsible for their own DEA and state board of pharmacy licensing.[64] After hiring a CSRA Senior Director to handle specialty group- and pharmacy-related assessments, reviews, investigations, and periodic compliance counseling for the ABSG and ABC pharmacies in 2007, CSRA

[59] *See, e.g.*, SLC Report Ex. 56.
[60] SLC Report Ex. 50, at 9.
[61] SLC Report 82. According to a 2007 David Polk report, this relationship was common at the time. SLC Report Ex. 57, at 18.
[62] SLC Report 85.
[63] SLC Report Ex. 60, at 1.
[64] *Id.*

had four leaders who all reported to CSRA's Vice President, who in turn reported to the Company's General Counsel.[65]

The senior directors of CSRA reviewed and audited the Distribution Centers' licensing and regulatory processes, providing a bi-weekly update to the Company's General Counsel.[66] The audits conducted by CSRA included "Health & Safety Program Compliance Audits" and "Security and Regulatory Compliance Audits" at Distribution Centers.[67] CSRA performed these audits without notice to the chosen Distribution Centers and conducted a review of the Distribution Centers' compliance with federal, state, and local law.[68] If a Distribution Center received a high risk score, CSRA would perform a follow-up audit to ensure that the Distribution Center implemented a corrective action plan.[69] The results of CSRA's audits were shared with the Company's legal department to review for legal risk.[70]

CSRA was also tasked with managing the Network Hotline until the establishment of the Company's Office of Compliance in 2012.[71] While the Company contracted with an independent company to operate the Network Hotline, CSRA reviewed the resulting reports and triaged them as appropriate within the

[65] SLC Report 86; *see also* SLC Report Ex. 61.
[66] SLC Report 90; *see also* SLC Report Ex. 64, at 1.
[67] *See, e.g.*, SLC Report Exs. 66–67.
[68] SLC Report Ex. 68, at 2.
[69] SLC Report Ex. 69, at 1.
[70] SLC Report 91.
[71] *Id.*

Company.[72] Network calls were logged in the Company's tracking system, LawTrac, and a copy of the report was sent to Employment Counsel and the Vice President of CSRA.[73] The nature of the call was then evaluated by these individuals and assigned appropriate personnel for follow-up investigation, which was updated in LawTrac to ensure a response.[74] The final disposition of the investigations were forwarded to the Manager of Corporate Security who distributed monthly reports and quarterly summary reports to the Vice President of CSRA and the Director of Corporate Security and Investigations.[75] Not only did the Audit Committee Chair receive all Network Hotline reports, but as of 2012, the Audit Committee was also provided quarterly updates from the CSRA Director.[76]

b. Internal Audit Department

The Company's Internal Audit manages reviews of financial controls, financial audits, and distribution audits.[77] Internal Audit was required to keep the Audit Committee "informed of emerging trends. . . in internal auditing," develop and submit an annual audit plan to the Audit Committee, "[i]ssue periodic reports to the [A]udit [C]ommittee and management summarizing result[s] of audit activities," and provide the Audit Committee with a "list of significant measurement goals and

[72] SLC Report Ex. 70, at 1.
[73] *Id.* at 2.
[74] *Id.*
[75] *Id.*
[76] SLC Report Ex. 53, at 24; *see, e.g.*, SLC Report Ex. 71, at 4.
[77] SLC Report 92.

results."[78] The Audit Committee received updates from Internal Audit at least quarterly, including executive sessions that excluded management, to provide a review of the Company's financials and internal controls.[79] Internal Audit also executed an annual risk assessment survey, which asked each Distribution Center's management to rank their perceived top risks to the Company.[80]

2. Reporting to the Ethics and Audit Committees Under ABC's Corporate Compliance Program

Under the Company's 2004 compliance program, the Ethics Committee consisted of senior leadership at the Company, including the General Counsel, Head of Human Resources, and Vice President of Internal Controls.[81] At the Ethics Committee meetings, the General Counsel presented legal updates and discussed the Network Hotline Reports; the Vice President of CSRA and the CCO updated the Committee on compliance policies and investigations; and Internal Audit summarized its quarterly audit reports.[82]

Between 2001 and 2008, the Audit Committee held at least seventy-three meetings.[83] The CFO often addressed the impact of compliance concerns on ABC's

[78] SLC Report Ex. 72, at 2.
[79] *See, e.g.*, SLC Report Exs. 73–76.
[80] *See, e.g.*, SLC Report Ex. 35, at 2; SLC Report Ex. 77, at 9; SLC Report Ex. 78, at 6; SLC Report Ex. 79; SLC Report Ex. 80, at 8; SLC Report Ex. 81, at 4.
[81] SLC Report Ex. 47, at 9. Defendant Chou became the Ethics Committee Chair on February 7, 2007. SLC Report Ex. 107, at 2.
[82] *See, e.g.*, SLC Report Ex. 106.
[83] SLC Report 103–04.

business.[84] In 2007, the CFO kept the Audit Committee updated on the FDA's issuance of a "black box" warning "on Aranesp & Procrit[,]"[85] two drugs that ABSG distributed.[86] Defendant Tim Guttman, ABC's former CFO, would address risk factors pertaining to the Company's compliance with federal law during the Audit Committee's discussions of risk factors to be listed in the Company's Annual Report.[87]

The General Counsel reviewed matters related to the Company's Code of Ethics and provided updates on ongoing legal matters, investigations, and the compliance policies.[88] The CCO reported on the Company's Corporate Compliance program, key policies and procedures, ongoing investigations at ABC subsidiaries, and implementation of new compliance measures.[89] The CSRA Director began providing quarterly updates to the Audit Committee in 2012.[90] Between the Compliance, Ethics, and Audit Committees, representatives from all major compliance departments presented regularly to both management and Board-level committees.[91]

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[84] *See, e.g.*, SLC Report Ex. 113, at 3.
[85] *See* SLC Report Ex. 114, at 16; *see also* SLC Report Ex. 115, at 5.
[86] *See* SLC Report Ex. 16; SLC Report Ex. 304, at 5–7.
[87] *See, e.g.*, SLC Report Ex. 116, at 1–3; SLC Report Ex. 117, at 1–3; SLC Report Ex. 28, at 1–4.
[88] *See, e.g.*, SLC Report Ex. 36, at 4–5.
[89] SLC Report 106.
[90] *See, e.g.*, SLC Report Ex. 119.
[91] SLC Report 106.

3. The 2007 Davis Polk Report

In March 2007, while auditing the billing practices of a delivery and courier service used by the Company's Sacramento Distribution Center, the Company "identified substantial questionable billing practices and irregularities [] and [a] consequential lack of detection controls by ABDC to prevent erroneous billing errors."[92] A month later, the DEA suspended the license of a Distribution Center located in Orlando, Florida, which distributed DEA-controlled substances, for allegedly "not maintain[ing] effective controls against diversion of controlled substances" in 2006.[93] In response, Defendant Chou engaged David Polk in June 2007 to conduct a "high-level review. . . of certain aspects of the compliance, legal and regulatory functions at [ABC]."[94] Davis Polk was specifically hired to (1) "[e]valuate the adequacy of the [compliance] program," (2) "[r]ecommend improvements, if any," and (3) "[r]eport to the Board on findings, conclusions and recommendations."[95]

After conducting its review, Davis Polk presented its findings in a report (the "Davis Polk Report") to the Audit Committee, concluding that, in light of the Board's *Caremark* duties, the Company: met the "[b]asic legal requirements" for

[92] SLC Report Ex. 120, at 2.
[93] SLC Report Ex. 121, at 1.
[94] SLC Report Ex. 122, at 1.
[95] SLC Report Ex. 57, at 2.

compliance; had "[c]omprehensive and high-quality written materials;" had a "[h]igh level of professionalism and dedication" by its compliance staff; and had a "[g]ood overall compliance track record."[96] Davis Polk also presented five "areas of improvement" for the Company's compliance program.[97] Following Davis Polk's presentation, the CCO presented the Audit Committee with the Company's "Preliminary Action Plan in Response to Davis Polk Assessment," which addressed all areas of improvement.[98] The Audit Committee met at least twice more to receive updates on the Company's response to the Davis Polk Report.[99]

The Company's response included developing a penalty matrix to standardize penalties for violations of the Company's Code of Conduct;[100] integrating ABSG into the corporate compliance program by adding a senior level CSRA employee to oversee ABSG compliance, tasking other corporate departments with oversight of ABSG, and creating a more "streamlined organizational structure[;]"[101] and began expanding its use of its internal electronic matter management system to track hotline calls, compliance complaints, and all issues arising from the Ethics and/or Compliance Committees in one, centralized location.[102]

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[96] *Id.* at 34.
[97] SLC Report 109.
[98] *Id.*
[99] SLC Report Ex. 91, at 1–2; SLC Report Ex. 134, at 6.
[100] SLC Report Ex. 129, at 1.
[101] SLC Report Ex. 130, at 5.
[102] SLC Report Ex. 91, at 1–2.

The CCO also engaged an outside ethics compliance organization through the Compliance and Ethics Leadership Council of the Corporate Executive Board ("CEB") to conduct a "cultural diagnostic survey."[103] Of the nine categories surveyed and analyzed, ABC scored above benchmark in all but one.[104] The CCO continued to engage with CEB to understand and implement industry best practices for compliance risk.[105] The Board was kept apprised of the updates on ABC's compliance program including the integration of ABSG.[106] From August 2009 through May 2012, the Board received no less than eight such updates specifically concerning the Company's response to the Davis Polk Report.[107]

4. AmerisourceBergen Reorganizes its Compliance Program

When the then-CCO left ABC in January 2012, the Company conducted a review of its compliance program.[108] The Head of CSRA, who had been at the Company since 1990 and in the health care industry since 1984, was appointed as the new CCO.[109] Defendant Chou led the Company to establish a second senior compliance position, Chief Compliance Counsel ("CCC"), which was filled by the

[103] SLC Report Ex. 134, at 6; *see also* SLC Report Ex. 144, at 1.
[104] SLC Report Ex. 144, at 16–17; *see also* SLC Report Ex. 134, at 6.
[105] SLC Report Ex. 145.
[106] SLC Report 123.
[107] *See* SLC Report 123–27.
[108] *Id.* at 127.
[109] *Id.* at 127–28.

Group General Counsel who had worked in the health care industry since 1985.[110] Both the CCO and CCC reported to the Audit Committee.[111]

Prior to 2012, the CCO's methods of communicating with the Board were limited to either directly reporting to the General Counsel who reported to the Audit Committee or reporting to the Compliance Committee, of which the CCO was a member, that reported directly to the Ethics Committee, which then in turn reported to the Audit Committee.[112] Starting in 2012, the CCO participated directly in the executive sessions of the Audit Committee after each regularly scheduled meeting.[113] The CCO and CCC were instructed by the Audit Committee to "review ABC's Compliance Program annually with the [Audit] Committee."[114] At that time, the CCO and CCC also began working under a newly created "Office of Compliance" that was charged with, among other things, notifying, investigating, and tracking all compliance-related investigations and incidents; providing quarterly reports to the Audit Committee; and continuously monitoring the changing compliance environment through various outside organizations to ensure that ABC's compliance program was up to date and comprised of industry best practices.[115]

[110] *Id.* at 128.
[111] *Id.* at 129.
[112] *Id.*
[113] SLC Report Ex. 160.
[114] SLC Report Ex. 159.
[115] SLC Report Exs. 163–64.

The Compliance Committee began implementing internal reforms in 2012.[116] One such reform was to double the frequency of its meetings to twice per month.[117] The agenda for these meetings was standardized to include a review of all new CIRs and all pending investigations into incident reports, in addition to approving the closures of completed incident investigations when appropriate.[118] All actions taken by the Compliance Committee were required to "be documented in either a [CIR] or an assigned Compliance project, and [to] be maintained in the ABC Corporate Risk Management System."[119] The CIRs were provided to the Audit Committee at least once a quarter, prior to each Committee meeting.[120] The CCC provided the Audit Committee updates on the Company's progress updating compliance initiatives on at least four occasions between May 2012 and February 2013.[121]

The Audit Committee continued to meet more frequently than was required, with at least half of these meetings focusing on financial reviews and performance, meeting seventy-four times from 2012 to 2018.[122] Twenty-six of the Committee's seventy-four meetings included an update specifically about the Company's

[116] SLC Report 133.
[117] SLC Report Ex. 157, at 1.
[118] *Id.*
[119] *Id.* at 1–2.
[120] SLC Report 133.
[121] SLC Report Ex. 151, at 4; SLC Report Ex. 158, at 4–5; SLC Report Ex. 159, at 6; SLC Report Ex. 168, at 4.
[122] SLC Report 134.

compliance program.[123] At all meetings, the Committee reviewed the Network Hotline and incident reports in addition to receiving updates on any corrective actions taken by management.[124] Once a year, the Committee received an update on the enterprise risk management system and risk assessment results and discussed any ongoing investigations and any significant legal matters.[125] The Audit Committee continued to also be notified by senior management of ongoing updates to the Company's compliance response as new regulations and compliance concerns emerged.[126]

D. The Legal and Regulatory Landscape Relating to Pharmacies

From 2001 to 2014 (the "Relevant Period"), the regulatory landscape shifted significantly as federal regulators increased scrutiny of state-regulated pharmacies.[127] This shift was of particular relevance to pharmacies like MII that pooled or compounded pharmaceuticals to dispense to health care providers for treatment of patients.[128] Between 2002 and 2012, "there [was] a lack of consensus regarding whether states should have primary responsibility for regulating

[123] *See, e.g.*, SLC Report Ex. 71; SLC Report Ex. 151; SLC Report Ex. 158; SLC Report Ex. 159.
[124] *See, e.g.*, SLC Report Ex. 71.
[125] *See, e.g.*, SLC Report Ex. 171, at 5; SLC Report Ex. 172, at 3.
[126] SLC Report 136.
[127] *Id.* at 143.
[128] *Id.*

[compounding pharmacies] as pharmacies, or [whether the] FDA should have primary responsibility to regulate them as manufacturers."[129]

The U.S. Supreme Court recognized the tradition that the regulation of the practice of pharmacy was left to the states.[130] Pharmacies are not required under federal law to register with the FDA if they "maintain establishments in conformance with any applicable laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs or devices."[131]

1. Alabama Law

MII was located in Dothan, Alabama, and subject to Alabama's State Board of Pharmacy, which promulgates regulations, issues licenses, and inspects pharmacies to evaluate their compliance with state pharmacy law.[132] Alabama law defines a pharmacy as a "place licensed by the [Alabama State Board of Pharmacy] in which prescriptions, drugs, medicines, medical devices, chemicals, and poisons are sold, offered for sale, compounded, or dispensed."[133] Prescription[134] labels are required under Alabama law to include the "name and address of the pharmacy from

[129] U.S. GOV'T ACCOUNTABILITY OFF., GAO-13-702, DRUG COMPOUNDING: CLEAR AUTHORITY AND MORE RELIABLE DATA NEEDED TO STRENGTHEN FDA OVERSIGHT 9–12 (2013).
[130] *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 361 (2002).
[131] 21 U.S.C. § 360(g)(1).
[132] SLC Report 144.
[133] Ala. Code § 34-23-1(21) (2019).
[134] Prescription is statutorily defined as "[a]ny order for drug or medical supplies, written or signed or transmitted by word of mouth, telephone, telegraph, closed circuit television, or other means of communication by a legally competent practitioner." Ala. Code § 34-23-1(25).

which the prescriptions are dispensed, the prescriber's directions for use, the name of the drug as it is dispensed, and the strength per dosage unit."[135]

A "traditional component" of pharmaceutical practice is "compounding," the "process by which a pharmacist or doctor combines, mixes, or alters ingredients to create a medication tailored to the needs of an individual patient."[136] Compounding is statutorily defined as "[t]he preparation, mixing, assembling, packaging, and labeling of a drug or device as the result of a licensed practitioner's prescription drug order or initiative based on the practitioner/patient/pharmacist relationship in the course of professional practice."[137] Also included in compounding is "the preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns."[138]

The regulation of compounding pharmacies in Alabama consists primarily of requirements relating to drug purity, storage conditions, qualifications and training of pharmacists and technicians, facilities, security, and record retention.[139] The chief pharmacist is responsible for the pharmacy's operations, as well as for supervision of pharmacy technicians.[140] Pertinent to MII's operations, Alabama law allows

[135] Ala. Admin. Code r. 680-X-2-.13 (1982).
[136] Ala. Code § 34-23-1(5) (2019).
[137] *Id.* § 34-23-150 (1975).
[138] *Id.*
[139] SLC Report 146.
[140] Ala. Code § 34-23-70(a) (2018).

"compounded product" to be "prepared in advance in reasonable amounts in anticipation of estimated needs."[141]

2. Federal Regulation of Pharmacies

The Federal Food, Drug, and Cosmetic Act ("FDCA") regulates the manufacturing, marketing, and distribution of drugs,[142] including all "new drugs," i.e., "any drug. . . the composition of which is such that such drug is not generally recognized [among experts] as safe and effective for use under the conditions prescribed."[143] Manufacturers of new drugs must register with the FDA, comply with various pre- and post-market requirements, and comply with current Good Manufacturing Practices ("cGMPs").[144] The FDCA defines the term "manufacturer" to include entities engaged in "preparation, propagation, compounding, or processing" of drugs, such as drug repackaging and relabeling.[145] A "repackager" is defined as an entity that "repackag[es] or otherwise chang[es] the container, wrapper, or labeling of any drug package or device package in furtherance of the distribution of the drug or device from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user."[146]

[141] Ala. Code § 34-23-159 (1975).
[142] *See, e.g.*, 21 U.S.C. §§ 355h, 356a, 356i.
[143] 21 U.S.C. § 321(p).
[144] *See, e.g.*, 21 C.F.R. §§ 210, 211 (2011).
[145] 21 U.S.C. § 360(a)(1).
[146] *Id.*

The FDA has concluded that "[c]ompounded drugs" are encompassed by the FDCA's definition of "new drugs" and, therefore, all federal regulations applicable to "new drugs" apply to "compounded drugs."[147] However, the FDA has not historically required pharmacies to apply for FDA approval of "compounded drugs;" rather, the FDA has left the regulation of compounded drugs to the states.[148]

a. FDA Regulation of Compounded Drugs

In response to concerns that some pharmacies were "engag[ing] in manufacturing, distributing, and promoting unapproved new drugs for human use in a manner that [wa]s clearly outside the bounds of traditional pharmacy practice[,]" the FDA issued Compliance Policy Guide 7132.16 in 1992 (the "1992 CPG").[149] In the 1992 CPG, the FDA warned that it would consider "initat[ing] enforcement action when pharmacy practice extends beyond the reasonable and traditional practice of retail" after considering several factors, such as whether a pharmacy solicited business, compounded "inordinate amounts" of drugs, and used commercial scale equipment.[150]

Portions of the 1992 CPG were adopted into Section 503A of the Food and Drug Administration Modernization Act ("FDMA") by Congress in 1997.[151] These

[147] SLC Report 148.
[148] *Id.*
[149] Compliance Policy Guide ("CPG") 7132.16 ("1992 CPG")
[150] *Id.*
[151] *See* Food and Drug Administration Act of 1997, Pub. L. No. 105-115, § 503A, 111 Stat. 2296 (codified at 21 U.S.C. § 353a).

provisions were challenged in court and, in April 2002, the Supreme Court determined that some of these provisions were unconstitutional but did not rule on the severability of the unconstitutional provisions from others adopted in 1997.[152] In response to this ruling, the FDA issued a revised CPG (the "2002 CPG") that removed the unconstitutional provisions of the 1992 CPG.[153] The 2002 CPG reaffirmed the FDA's intent to "seriously consider enforcement action" when "the scope and nature of a pharmacy's activities raise the kinds of concerns normally associated with a drug manufacturer[,]" and included a non-exhaustive list of factors relevant to its determination of whether "compounding pharmacies" were actually "manufacturers" of new drugs.[154]

b. FDA Enforcement Activity Related to Pharmacies

From February 2002 to May 2012, the FDA conducted 194 "for cause" inspections of compounding pharmacies and issued thirty-one Warning Letters.[155] The FDA frequently cited entities for issues such as dispensing an unreasonably large volume of drugs and/or drugs that were copies of FDA-approved, commercially available products, and compounding drugs without a patient-specific medical need.[156] For example, in 2010, the FDA issued a Warning Letter to MII's

[152] *Thompson*, 535 U.S. at 366, 377.
[153] Compliance Policy Guide 460.200 ("2002 CPG").
[154] *Id.*
[155] SLC Report 153.
[156] *Id.*

competitor, Med Prep Consulting, Inc. ("Med Prep"), for shipping pre-filled syringes to health care providers without receiving prescriptions for individual patients.[157] Med Prep's Warning Letter specifically stated that Med Prep's "practice of repackaging and distributing drugs without patient-specific prescriptions" exceeded "the regular course of a pharmacy's business," therefore subjecting Med Prep to cGMP regulations as a "repackager."[158]

3. United States Pharmacopeia <797>

In 2004, Congress moved guidelines title "Sterile Compounding" to chapter <797> of the U.S. Pharmacopeia ("USP") standards, thereby making those guidelines enforceable by the FDA.[159] Among the issues covered by USP <797> was sterility and purity of dispensed compounded sterile preparations ("CSPs").[160] Despite Congress authorizing the FDA to enforce USP <797>, individual states remained the principal regulators of pharmacy compounding activity and sterility.[161] Alabama did not adopt USP <797>, but in 2009, the Alabama Board of Pharmacy

[157] Warning Letter from Diana Amador Toro, Director, New Jersey District, U.S. Food & Drug Admin., to Gerald R. Tighe, Pres., Med Prep Consulting (July 9, 2010), https://web.archive.org/web/20130324195733/http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2010/ucm222283.htm ("Med Prep Warning Letter").
[158] *Id.* at 1.
[159] SLC Report 156.
[160] Pharmaceutical Compounding—Sterile Preparation (USP <797>), United States Pharmacopeial Convention, 2008.
[161] Pew Charitable Trs., *National Assessment of State Oversight of Sterile Drug Compounding* 1 (Feb. 2016), https://www.pewtrusts.org/~/media/assets/2016/02/national_assessment_of_state_oversight_of_sterile_drug_compounding.pdf.

interpreted its comparable provision on the "strength, quality, or purity" of compounded drugs as "requir[ing] sterile products to be compliant with USP <797> standards."[162] On December 31, 2010, the Alabama State Board of Pharmacy began enforcing compliance with USP <797>.[163]

E. MII and its Pre-Filled Syringe Program

At the time it was acquired by Bergen Brunswig in 1998, MII was a Florida corporation that operated a Tampa, Florida, pharmacy providing compounding services and pre-filled syringes for physicians.[164] As part of the acquisition, Bergen Brunswig engaged outside counsel to review MII's operations.[165] Potential issues associated with MII's customer billing practices were identified by the review, but the review did not focus on nor identify FDA regulatory issues concerning MII's pharmacy operations.[166] MII's operations were reviewed again during the 2001 merger process between Bergen Brunswig and AmeriSource,[167] again raising questions related to MII's customer billing and inventory practices while not identifying FDA regulatory risks or concerns regarding product quality or sterility.[168]

[162] SLC Report Ex. 184.
[163] *Id.*
[164] SLC Report 158.
[165] SLC Report Ex. 186, at 3.
[166] SLC Report 158–59.
[167] SLC Report Ex. 189, at 1; SLC Report Ex. 187, at 1.
[168] SLC Report 159.

Bergen Brunswig moved MII to a pharmacy in the OS warehouse in Dothan, Alabama, where MII focused solely on the pre-filled syringe program ("PFS Program").[169] During the Relevant Period, MII was an ABSG subsidiary and incorporated in Florida.[170] After its move to Alabama, the Company registered MII with the Alabama Board of Pharmacy, but not the FDA.[171]

When MII's pharmacist-in-charge, who was tasked with overseeing MII's operations, stepped down in 2005, the Chief Pharmacist was promoted to the role.[172] The Chief Pharmacist had more than twenty-five years of experience as a pharmacist.[173] Generally, the Chief Pharmacist reported to OS's Head of Operations but also reported to OS's President for a time during the Relevant Period.[174] The Chief Pharmacist was responsible for MII's pharmacy license in Alabama and he worked closely with OS's Compliance Manager on licensing issues.[175] The Chief Pharmacist was responsible for with overseeing a technician supervisor, who managed the Pharmacy technicians, and the Pharmacy's policies and procedures, including those intended to ensure that MII prepared sanitary and sterile pre-filled syringes.[176]

[169] SLC Report Ex. 190, at 3.
[170] SLC Report 160.
[171] SLC Report Ex. 14; SLC Report Ex. 15, at 1.
[172] SLC Report 160.
[173] *Id.*
[174] *Id.* at 160–61.
[175] *Id.* at 161.
[176] SLC Report Ex. 15, at 1.

1. The Pre-Filled Syringe Program

MII pre-filled syringes with oncology products for OS's customers upon request.[177] Under the terms of the PFS Program agreement between OS and its customer oncology practices, the practices were required to provide a patient-specific physician's order to MII.[178] If a customer ordered products in pre-filled syringes rather than vials, OS would transfer product vials to MII to pre-fill syringes with the drug contained in the vials.[179]

Over time, MII developed extensive policies and procedures requiring strict adherence to aseptic techniques and sterilization protocols.[180] As of April 1, 2005, MII required all "personnel working in the sterile environment" to be tested for compliance with these policies and procedures "at least once a year."[181] When pre-filling syringes, technicians were required to follow a six-step procedure to ensure the product's integrity.[182] Once the syringes were filled, MII technicians transferred the labeled syringes to a separate room of the Pharmacy where MII pharmacists performed a quality check by using a magnifying glass to check that the syringes included the appropriate product volume and did not include particulates.[183] Next,

[177] SLC Report 161.
[178] SLC Report Ex. 193, at 1; SLC Report Ex. 194, at 1.
[179] SLC Report Ex. 15, at 2.
[180] SLC Report 163–65.
[181] SLC Report Ex. 199.
[182] SLC Report 167.
[183] *Id.* at 167–68.

MII staff matched the syringes with orders and labeled them with the product name, dose, batch number, and expiration date.[184] The syringes were then placed in bags with printed physician order information and another label was affixed to the outside of the bags.[185] MII then transferred the syringes to OS for packaging and delivery.[186]

OS usually delivered the pre-filled syringes to oncology practices overnight for use the next day.[187] This time pressure resulted in a significant rush during the latter half of the working day at MII, as the Pharmacy prepared pre-filled syringes in response to customers' orders.[188] To alleviate this pressure, MII began preparing some pre-filled syringes before receiving particularized orders based on Alabama regulations that permitted advanced preparation "in anticipation of estimated needs."[189]

2. MII's Harvesting of Overfill

MII provided the pre-filled syringe service in exchange for customers agreeing to let MII retain the product overfill remaining in the vials after the pre-filled syringes were drawn.[190] Overfill is the amount of product within a vial that exceeds the amount of product stated on the vial's label; manufacturers generally

[184] SLC Report Ex. 208; SLC Report Ex. 192, at 14; SLC Report Ex. 215, at 1.
[185] SLC Report Ex. 215, at 1.
[186] SLC Report 168.
[187] *Id.*
[188] *Id.* at 168–69.
[189] Ala. Code § 34-23-159 (1975).
[190] SLC Report Ex. 15, at 1.

include slightly more product in each vial than the label indicates to ensure that end users can successfully draw and administer the necessary amount of product.[191] Historically, healthcare practices often salvaged overfill for clinical use.[192] In May 2001, Reed Smith advised Bergen Brunswig that MII's practice of harvesting overfill was considered "standard practice at hospital[s] and other large pharmacies"; that "the dispensing of the prescribed amount from the billing units" purchased from the manufacturer was "an acceptable practice[;]" and the "[s]alvage of drug remaining in [the original] containers [wa]s also permissible."[193] Filling new prescriptions with this harvested overfill also did not "itself raise concerns."[194]

MII harvested overfill to satisfy customer orders while saving numerous unopened vials, which it called "overfill inventory."[195] These unopened, overfill vials were sold monthly by MII back to OS, which then distributed the overfill vials to other affiliates of ABC or directly to customers.[196] MII derived profits from its sale of overfill vials to OS.[197] This incentivized MII's technicians to harvest as much

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[191] *Pharmaceutical Dosage Forms—Injections* (USP <1151>); *see also* SLC Report Ex. 187; SLC Report Ex. 195.
[192] Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011, 75 Fed. Reg. 73467 (Nov. 29, 2010); *cf.* Vanessa Romo, *Some Vials of COVID-19 Vaccine Contain Extra Doses, Expanding Supply, FDA Says*, NPR (Dec. 16, 2020, 9:47 PM), https://www.npr.org/sections/coronoavirus-live-updates/2020/12/16/947386411/some-vials-of-covid-19-vaccine-contain-extra-doses-expanding-supply.
[193] SLC Report Ex. 189, at 2, 5.
[194] *Id.*
[195] SLC Report Ex. 15, at 2.
[196] *Id.* at 3.
[197] *Id.* at 4.

overfill as possible while maintaining quality standards,[198] as laid out in MII's incentive compensation program.[199]

In 2003, ABC's then-General Counsel and his staff conducted a preliminary risk assessment of ABSG companies, including OS and MII.[200] This assessment resulted in a memorandum describing, in relevant part, MII's PFS Program and its use of overfill.[201] While the former Assistant General Counsel noted that some of MII's customer contracts did not explicitly authorize MII to collect and sell overfill, he did not identify concerns related to FDA regulatory issues, quality, or sterility.[202]

ABC's Assistant General Counsel also engaged health care regulatory attorneys at Reed Smith to conduct a compliance review and risk assessment of ABSG companies, including OS and MII.[203] Reed Smith prepared a memorandum in which it stated that the PFS Program did not appear to raise significant regulatory, anti-kickback, or double chargeback concerns.[204] The Reed Smith memorandum recommended that MII disclose to physicians that it collected overfill and that OS convey the need for customers to account for their discounts when reporting to the government, to ensure compliance with safe harbors to the federal Anti-Kickback

[198] SLC Report 170–71.
[199] *See* SLC Report Ex. 216, at 2, 4.
[200] SLC Report 171.
[201] SLC Report Ex. 188, at 5–6.
[202] SLC Report 171–72.
[203] *Id.* at 172.
[204] SLC Report Ex. 195, at 26–27, 37.

Statute ("AKS").[205] With respect to the pre-filled syringes, Reed Smith observed that customers provided MII with lists of patients with the pharmacy staff used to mark syringes with patient-specific labels.[206] When responsibility for the Specialty Group shifted to ABSG's General Counsel, he received the Reed Smith memorandum, which he reviewed, and concluded that Reed Smith approved of MII's business model.[207]

3. MII is Expanded

In March 2006, OS submitted an official Capital Expenditure Request ("CER") to ABSG management[208] seeking approval to purchase vacant land adjacent to OS's facility and to remodel the warehouse.[209] According to the CER, MII was a "significant contributor" to OS's profitability, but MII's pharmacy space where product was drawn into syringes was inadequate to meet ABSG's Fiscal Year 2006 target sales.[210] ABSG's executive team, ABC's executive team, and the ABC Board approved the CER in 2006.[211] In 2007, OS expanded its Dothan Distribution

[205] *Id.* at 40.
[206] *Id.* at 24, 36.
[207] SLC Report 175–76.
[208] SLC Report Ex. 230, at 1.
[209] SLC Report Exs. 224–28.
[210] SLC Report Ex. 222, at 7.
[211] *Id.* at 1; SLC Report Ex. 221, at 8–9.

Center,[212] increasing the size of the Distribution Center by 70,000 square feet and expanding MII's pharmacy from 1,000 square feet to 3,000 square feet.[213]

4. MII's Alabama License and Board of Pharmacy Inspections

Although the CSRA Senior Director was primarily responsible for general pharmacy oversight, an OS Compliance Manager in Dothan handled the particulars of MII's state licenses.[214] The OS Compliance Manager understood MII to be a mail-order pharmacy because it shipped syringes to physicians, who owned and administered the medications.[215] During the Relevant Period, MII had an active license as a parenteral[216] and mail-order pharmacy in Alabama.[217]

The Alabama Board of Pharmacy inspected MII in 2007, 2009, 2010, 2011, and 2013, with MII passing each of these inspections without any adverse observations about the safety or sterility of products dispensed by the Pharmacy.[218] All inspections prior to 2010 were announced, in-person reviews of MII's storage conditions, facilities, security, record-keeping, and written policies and procedures.[219] After Alabama began enforcing USP <797> in 2010, its inspectors

[212] SLC Report 176.
[213] SLC Report Ex. 221, at 8; SLC Report Ex. 222, at 7.
[214] SLC Report 181.
[215] *Id.*
[216] "Parenteral" here is used to mean a pharmacy preparing drugs to be administered by injection.
[217] *See, e.g.*, SLC Report Ex. 233.
[218] SLC Report Exs. 234–38.
[219] SLC Report Ex. 239.

focused on sterility, dose containers, personnel cleansing and garbing, and quality testing and documentation, among other things.[220]

5. Sterility Testing at MII

During the Relevant Period, MII tested its pre-filled syringes, as well as its pharmacists, technicians, and workspaces, for sterility and safety.[221] An external testing service conducted a majority of MII's sterility tests every six to twelve months.[222] MII tested the sterility of its syringes at least once per year from 2009 through 2013.[223] Some years, MII tested its syringes internally while other years MII shipped syringes to an external laboratory for shelf-life testing.[224] For example, in September 2012, MII conducted internal tests of syringes drawn by its technicians.[225] The following month, MII shipped syringes to BioScreen Testing Services for additional testing.[226] The September and October 2012 testing results of these syringes did not find any sterility problems.[227]

While MII passed the vast majority of its sterility tests, it did have occasional failures.[228] These failures were generally addressed internally with MII taking

[220] SLC Report Ex. 240; *see also* SLC Report Ex. 241.
[221] SLC Report 183.
[222] *Id.*
[223] *Id.* at 184.
[224] *E.g.*, SLC Report Ex. 246, at 2; SLC Report Ex. 200, at 8, 11; SLC Report Ex. 247, at 1; SLC Report Ex. 248, at 1.
[225] SLC Report Ex. 200, at 11.
[226] *Id.*; SLC Report Ex. 247, at 1; SLC Report Ex. 250, at 1.
[227] SLC Report Ex. 247, at 1; SLC Report Ex. 248, at 1.
[228] *See, e.g.*, SLC Report Ex. 249, at 5, 23; SLC Report Ex. 245, at 5–6.

corrective measures and retesting when deemed necessary.[229] Through its inspections, the Board of Pharmacy reviewed each of MII's sterility test results, including the occasional failures, to ensure that MII documented its testing and to certify that MII's results comported with International Organization for Standardization standards.[230] Despite the occasional sterility test failures considered by the inspectors, MII passed each Alabama Board of Pharmacy inspection without any issues.[231]

6. CSRA Audits and Reviews of OS and MII

Prior to 2007, the audits of OS by the Company's Corporate Security and Regulatory Affairs group ("CSRA") focused on OS Distribution Center's operations.[232] These audits were conducted by the Compliance Manager at OS in accordance with a 400-page checklist, which, other than licensing, did not focus on the Pharmacy.[233] The Company's audit of MII included evaluating the licensing status of MII under applicable state board of pharmacy requirements.[234]

[229] SLC Report Ex. 250, at 1–2; SLC Report Ex. 251, at 17.
[230] *See* SLC Report Ex. 239, at 1; SLC Report Ex. 241, at 6–7.
[231] SLC Report Exs. 234–38.
[232] SLC Report 188.
[233] *Id.* at 188–89.
[234] *See, e.g.*, SLC Report Ex. 256, at 5–6; SLC Report Ex. 257.

a. CSRA's Pharmacy-Related Experience and Expertise

In July 2007, a new Senior Director joined CSRA and provided additional regulatory oversight of MII.[235] From his experience as a pharmacist and Compliance Officer of another ABC entity,[236] the Senior Director was familiar with pharmacy regulations, including the distinctions between state-regulated pharmacies and FDA-regulated manufacturers or repackagers.[237] The OS Compliance Manager reported to the CSRA Senior Director who then in turn reported to the CSRA Vice President.[238] The Senior Director frequently consulted with the OS Compliance Manager on issues relating to MII and also served as a resource to MII's Chief Pharmacist.[239]

The CSRA Senior Director conducted regular in-person reviews of MII roughly once a quarter, including during the annual CSRA audit of the OS Distribution Center,[240] with his attention on regulatory compliance issues.[241] When all of his visits were considered together, the Senior Director spent approximately one month of every year at the Dothan facility.[242] The Senior Director did not follow

[235] SLC Report 189.
[236] *Id.*
[237] *Id.*
[238] *Id.* at 190.
[239] *Id.*
[240] *Id.* at 191.
[241] *Id.*
[242] *Id.*

a formal checklist nor file a separate formal written report when reviewing MII;[243] instead he would follow a prescription through the Pharmacy's processes by asking the Pharmacy to walk through the process of receiving a prescription or order, entering the associated data into the computer system, generating the label of the pre-filled syringes, filling the prescription, conducting a prescription check, and then packaging the syringes before they were dispensed to customers.[244]

b. CSRA's 2008 Review of MII

In January 2008, the CSRA Senior Director expressed concerns that "some customers request not to have patient names on the syringes which is a concern due to the fact that the FDA could potentially say that the [P]harmacy is wholesaling and not dispensing which would require us to meet extra requirements similar to a manufacturer/repackager."[245] The Senior Director also questioned a pending non-resident sterile compounding license in California and documentation for the Pharmacy's policy on expiration dates.[246]

The Senior Director reiterated his concerns during a formal CSRA audit of the OS Distribution Center in September 2008.[247] He instructed the OS Compliance

[243] *Id.* MII was the only pharmacy under CSRA's purview, so the Company saw no urgent need to develop a formal checklist that could be used at other locations. *Id.*
[244] *Id.* at 192.
[245] SLC Report Ex. 259.
[246] *Id.*
[247] SLC Report Ex. 257.

Manager to ensure that MII's license in California was properly maintained[248] and took steps to gather documentation to justify the Pharmacy's expiration-date practices.[249] The Senior Director further instructed MII personnel to secure patient-specific orders because he was concerned by the lack of patient-specific names on each dispensed order.[250]

In his November 2008 CSRA Compliance Audit Report, the Senior Director only recommended MII's California license as a "Risk Value," but that had been resolved by the time the Report was issued.[251] The Senior Director was not alarmed that MII's practices were non-compliant with FDA regulations because the FDA was permitting the Alabama Board of Pharmacy to enforce the relevant requirements.[252] He further believed that the FDA would, if it had concerns, issue a Warning Letter before taking any additional action, which would allow the Company to address the concerns before the FDA would pursue more severe enforcement activity.[253]

c. Alabama's Implementation of USP <797>

On March 30, 2009, the Alabama Board of Pharmacy sent a letter to all pharmacies "known to prepare sterile compounds" in Alabama, including MII,[254]

[248] SLC Report 193.
[249] SLC Report Ex. 260, at 1–2.
[250] SLC Report 193.
[251] SLC Report Ex. 257, at 4.
[252] SLC Report 195.
[253] *Id.*
[254] SLC Report Ex. 184.

explaining that Board of Pharmacy would begin enforcing USP <797> on December 31, 2010.[255] MII's Chief Pharmacist received another letter from the Alabama Board of Pharmacy in May 2009, announcing that "[t]he first action taken by the [Alabama] Board [of Pharmacy] [would be] to assist pharmacies in evaluating their degree of compliance with USP <797>."[256] The Alabama Board of Pharmacy asked MII to complete a Risk Level Assessment Form to define its compounding category as low-risk, medium-risk, or high-risk.[257] This form contained questions about the sterility of the pharmacy, such as whether the pharmacy practiced routine disinfection and air quality testing.[258] The Alabama Board of Pharmacy also requested that MII to complete a Compliance Self-Assessment and, as necessary, a Compliance Action Plan.[259]

MII reported that it was compliant with a range of USP <797> requirements, including the activities of compounding personnel, personnel training, aseptic technique, personnel cleansing and garbing, quality checks, and maintaining the sterility, purity, and stability of products.[260] On the Risk Level Assessment Form, MII reported that it was a "medium-risk level" pharmacy because it "pool[ed]" products, a process that USP <797> defines as combining "multiple individual or

[255] *Id.*
[256] SLC Report Ex. 262.
[257] *Id.*
[258] SLC Report Ex. 263.
[259] SLC Report Ex. 262.
[260] SLC Report Exs. 263–64.

small doses of sterile products. . . to prepare a [Compounded Sterile Preparation]."[261] MII further noted that it expected to be compliant with USP <797> by October 2009, fifteen months before the USP standard's effective date.[262] After completing its self-assessment, the Compliance Manager worked with operations personnel within OS to execute MII's action plan by, among other things, updating new Standard Operating Procedures and upgrading air pressure and air exchange systems.[263]

d. CSRA's 2009, 2010, 2011, and 2012 Reviews of MII

CSRA's Senior Director conducted further reviews of MII in 2009 and 2011.[264] The Chief Pharmacist periodically informed the Senior Director that MII customers[265] often complained about MII's requirement that they submit patient-specific orders for pre-filled syringes.[266] During these reviews of MII, the Senior Director saw patient names placed on the bags containing the pre-filled syringes.[267]

In January 2012, following a complaint from a customer regarding MII "put[ting] a random name on a medication, call[ing] it a prescription and sell[ing] it to us. . . without the name being on any of the packaging or anywhere else,"[268] the

[261] SLC Report Ex. 263, at 2.
[262] SLC Report Ex. 265, at 9.
[263] SLC Report 198.
[264] SLC Report Exs. 267–68.. The Senior Director did not conduct the 2010 review; rather, other CSRA personnel conducted these reviews and did not identify issues related to patient names. *See* SLC Report Exs. 269–70.
[265] That is, the physician-purchasers of the pre-filled syringes.
[266] SLC Report 199.
[267] *Id.*
[268] *See* SLC Report Ex. 271, at 2; SLC Report Ex. 272, at 1.

Chief Pharmacist and the OS President escalated the complaint to CSRA and ABSG's General Counsel.[269] In February 2012, the Senior Director conducted an in-person review of MII's operations as requested by ABSG's General Counsel.[270] The Senior Director provided an update to ABSG's General Counsel, noting that only fifty-nine of 869 of the prescriptions in his sample had been "completed with a 'proper [patient] name.'"[271]

Due to the significance of the Senior Director's findings, CSRA added this review to the agenda for the upcoming February 23, 2012, Ethics Committee Meeting.[272] At the meeting, CSRA's Vice President "discussed the MII investigation" and stated that "[t]here is a concern that the [P]harmacy is not providing the patient name" because "[i]t appears that 90% of the [P]harmacy records were incomplete."[273] Following this meeting, the Senior Director continued to investigate the MII issues alongside ABSG's Corporate Counsel.[274] Based on their research, ABSG's Corporate Counsel and the Senior Director concluded that the conduct observed at MII did not violate Alabama law, which was relatively lax on patient-specific labeling.[275]

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[269] SLC Report 200.
[270] *Id.*
[271] SLC Report Ex. 273, at 1.
[272] SLC Report Ex. 274.
[273] SLC Report Ex. 276, at 2.
[274] SLC Report 203.
[275] *Id.* at 204.

On March 15, 2012, ABC's Compliance Committee met and discussed what should be included on the list of CIRs to be presented to the Company's Audit Committee.[276] The Compliance Committee decided against adding the MII syringe dispensing procedure review to the CIR because "it appear[ed] that the practice may be in compliance with State regulations. If this should change, the MII matter will be added to the CIR Report."[277]

Two months later, ABSG's Corporate Counsel sent a memorandum to MII's Chief Pharmacist stating that "a recently conducted audit directed by ABC's legal department of randomly inspected orders dispensed by [MII] revealed that prescriptions filled under these orders were indeed consistent" with Alabama law, which did not require a prescription label to contain a patient's name.[278] It continued on to caution that "[r]ecent guidance from the [FDA] suggests additional prescription label requirements may be necessary" because "processing and repacking (including repackaging) of approved drugs may be viewed by the FDA as exceeding the traditional practice of pharmacy and, as such, requiring licensure with the FDA as a repackager."[279] Therefore, the memorandum directed that MII add "[t]he name of the patient" to each "prescription label" at the Pharmacy.[280]

[276] *Id.* at 205.
[277] SLC Report Ex. 282, at 1.
[278] SLC Report Ex. 284, at 1.
[279] *Id.* at 1–2.
[280] *Id.* at 2.

e. ABSG Monitored FDA's Warning Letter to Med Prep

In July 2013, Morgan Lewis notified ABC and ABSG legal counsel of a federal complaint against an ABC competitor, Med Prep, related to sterility issues and its practice of repackaging drugs without a patient-specific prescription described in the Med Prep Warning Letter, as discussed *supra* in Section I.D.2.b.[281] While Morgan Lewis advised ABC personnel that the sterility concerns related to Med Prep's practices were not present at MII, Morgan Lewis suggested that Med Prep's requirement to adhere to cGMP regulations as a repackager was relevant to MII and recommended that ABC and ABSG monitor developments in the Med Prep case.[282]

f. MII's Closure

MII closed its operations on January 31, 2014, primarily because of its declining profitability in the face of increasing potential reputational harm caused by continuing the PFS Program during the federal government's investigation, discussed *infra* at Section I.F.6.[283] The exit of MII's largest customer, Florida Cancer Specialists & Research Institute, from the PFS Program—which significantly reduced MII's profitability and demonstrated the reputational harm

[281] SLC Report Ex. 290, at 1; Med Prep Warning Letter, at 1.
[282] *Id.*
[283] SLC Report 211.

caused by the government's investigation—was the primary trigger for the decision to close MII.[284]

F. Michael Mullen and the DOJ Investigation

Michael Mullen served as CFO of ABSG from May 2003 until September 2008, President of Distribution Services at ABSG from September 2008 until September 2009, and COO of ABSG from September 2009 until April 2010.[285] After his termination in April 2010, he raised concerns about violations of the Anti-Kickback Statute ("AKS") and price reporting compliance issues, similar to those at issue in an earlier *qui tam* complaint brought against the Company and others, described below.[286]

1. *United States ex rel. Westmoreland v. Amgen et al.*

On June 5, 2006, a *qui tam* lawsuit was filed against Amgen, Inc., as well as AmerisourceBergen Corporation, and its subsidiaries, INN, Oncology Supply ("OS"), and AmerisourceBergen Specialty Group.[287] The relator alleged that defendants Amgen, INN, and OS violated the federal AKS by inappropriately encouraging providers to submit claims for payment by Medicare for the value of the excess product, or "overfill," that was contained in the vials of their drug

[284] *Id.* at 212–13.
[285] *Id.* at 213.
[286] *Id.*
[287] *See United States ex rel. Westmoreland v. Amgen et al.*, Compl., No. 06-10972-WGY, ECF No. 1 (D. Mass. 2006).

Aranesp, but not included in calculating Aranesp's average sales price ("ASP").[288] In relevant part, the relator also alleged that the defendants improperly gave special incentives to Aranesp purchasers who contracted with INN and encouraged physicians to prescribe medically unnecessary drugs and bill Medicare for overfill amounts that were not administered.[289]

The *Westmoreland* relator also alleged that Amgen created INN ostensibly to be an independent entity that would focus on nephrology practices and physicians, but that actually acted as a "de facto marketing arm for Amgen" that pushed Amgen products to businesses.[290] Amgen allegedly funneled business to INN and OS, which then targeted customers based on lists provided by Amgen and used an administrative fee as a way to pass through discounts to customers.[291] The *Westmoreland* complaint did not contain allegations of violations of the FDCA or of product quality or safety deficiencies.[292]

By January 2009, the Company became aware of the *Westmoreland* complaint. Defendant Chou informed the Board of its existence at the Board's "Monday call" on February 2, 2009, and to the Audit Committee on February 4, 2009.[293]

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[288] *Id.* ¶¶ 41–48.
[289] *Id.* ¶¶ 55–70.
[290] *Id.*¶¶ 71–72.
[291] *Westmoreland* Fourth Am. Compl. ¶ 303.
[292] SLC Report 216.
[293] *Id.* at 216–17.

2. Mullen Raises Concerns Internally

a. Mullen's Time as COO/President of ABSG

Mullen was named COO/President of ABSG in September 2009 after David Yost, former CEO and Chairman of the Board, announced his plan to retire.[294] By way of a succession plan, the Board decided to move Defendant Collis from his role as President of ABSG to ABDC to give Defendant Collis more experience with other parts of ABC's business so that he could one day take over as ABC's CEO.[295] Mullen was chosen to take over leadership of ABSG as President and COO.[296]

In his position as COO of ABSG, OS came under Mullen's purview,[297] so Mullen undertook an effort to drill down into the OS business and learn how OS went to market.[298] However, Mullen learned about OS's pricing structure, which caused him to have questions because he observed that profitability at OS was highly variable across products and customers.[299] He believed that ION was too close to OS, its distributor, which allowed the entities to coordinate which manufacturers were or were not providing favorable pricing.[300] After attending ION meetings with manufacturers and physicians,[301] Mullen assumed that if these meetings were

[294] *Id.* at 218.
[295] *Id.* at 218–19.
[296] *Id.* at 219.
[297] *Id.*
[298] *Id.*
[299] *Id.*
[300] *Id.* at 220.
[301] *Id.*

occurring openly and as a matter of course, they must be "above board."[302] Similarly, Mullen assumed that the PFS Program was a compliant business practice.[303]

After completing his review of the ABSG business units in January 2010, Mullen delivered a "strategic initiatives" presentation at an ABSG Team Lead Retreat[304] that included the results of a survey of the ABSG business unit general managers, broad strategy discussions, and efforts to optimize services provided by external vendors.[305] However, the presentation did not contain any specific regulatory or compliance-related concerns regarding ABSG's oncology business.[306]

Throughout his time at ABSG, Mullen never raised any of the allegations contained in his *qui tam* action or this action with either ABSG's Corporate Counsel or ABSG's Group General Counsel, whose offices abutted that of Mullen, before his departure from the Company.[307]

b. Mullen Raised Concerns Post-Termination

On April 8, 2010, Mullen was terminated from his role as COO/President of ABSG due to his underperformance in the COO position.[308] As part of his separation

[302] *Id.*
[303] *Id.*
[304] *Id.*
[305] *See* SLC Report Ex. 293.
[306] *Id.* at 4.
[307] SLC Report 223–24.
[308] SLC Report Ex. 297.

package, Mullen was required to inform ABC of any concerns not otherwise known to ABC management.[309] Because Mullen had previously been considered to be the corporate representative in *Westmoreland*, he had reviewed the court records and allegations contained within the complaint in preparation.[310] He came to believe that the *Westmoreland* allegations potentially applied to ION, OS, and the PFS Program.[311] Mullen contacted Defendant Chou stating he had concerns he wished to share with the Company.[312]

In May 2010, ABSG's Group General Counsel met with Mullen,[313] at which point Mullen summarized his two categories of concerns: (1) that average sales price ("ASP") was not reported correctly in connection with how MII handled overfill, and (2) that there was insufficient separation of OS and ION.[314] Mullen did not raise any concerns about FDA regulatory compliance, pharmacy licensing, safety, sterility, or any other matter that ultimately became the basis for the resolutions of the DOJ's criminal and civil investigations that resulted in the corporate trauma at issue here, discussed *infra* at Section I.F.9.[315] After the meeting, Mullen sent the Group General Counsel an email outlining the process through which MII's business

[309] SLC Report Ex. 300.
[310] SLC Report 228.
[311] *Id.*
[312] SLC Report Ex. 302.
[313] SLC Report 229.
[314] *Id.*
[315] *Id.*

model purportedly allowed manufacturers to transfer free product in the form of overfill to wholesalers that then distributed the free product to physicians.[316] The Board was informed by Defendant Chou of Mullen's concerns in the context of explaining the Ober Kaler review and introducing the presentation of Ober Kaler's report (the "Ober Kaler Report").[317]

3. Ober Kaler Report

In June 2010, the Company engaged Ober Kaler to review the business practices of the Company's Oncology Group as a whole[318] and Defendant Chou shared the documents provided by Mullen for Ober Kaler's analysis.[319] Ober Kaler was charged not only with conducting a target review of ION's GPO compliance[320] but also to assess "overall compliance with federal anti-kickback/fraud and abuse laws and the federal false claims act" at both ION *and* OS.[321] As neither the *Westmoreland* complaint nor Mullen raised concerns about FDCA compliance or

[316] SLC Report Ex. 204, at 2–4.
[317] SLC Report 232.
[318] SLC Report Ex. 308.
[319] SLC Report Ex. 306.
[320] Group purchasing organizations ("GPOs") are regulated entities. *See* SLC Report Ex. 390. As a GPO, ION would negotiate with pharmaceutical manufacturers and vendors, such as OS, on behalf of ION's paying member physician practices. *See* Section I.A.1. Similar to the allegation in the *Westmoreland* complaint that INN was a "de facto marketing arm for Amgen" that pushed Amgen products to businesses, Mullen alleged that there was insufficient separation between ION and its vendor, OS, such that it violated regulations pertaining to GPOs. *See* Section I.F.1; Section I.F.2.b. As part of this scheme, the *Westmoreland* relator alleged that Amgen funneled business to INN and INN would use an administrative fee to pass through discounts to customers, thereby violating the Anti-Kickback Statute. *See* Section I.F.1.
[321] SLC Report Ex. 20, at 2.

sterility, Ober Kaler's mandate did not include a review of those concerns.[322] Also excluded from Ober Kaler's mandate was a review of the legality of the PFS Program because it was not at issue in the *Westmoreland* case or with Mullen.[323]

As part of its review, Ober Kaler interviewed the Chief Pharmacist at the Dothan facility regarding his role in the PFS Program.[324] The Chief Pharmacist explained how the syringes were filled, how the Pharmacy made money, and how the service is marketed.[325] However, Ober Kaler did not ask about, and the Chief Pharmacist did not discuss, FDCA regulations or sanitation issues.[326]

Ober Kaler discussed an early version of its draft presentation with Defendant Chou, the ABC CCO, the ABSG General Counsel, the ABSG Corporate Counsel, the ABSG CEO, an attorney at Morgan Lewis, and an attorney at Buchanan Ingersoll.[327] On the call, Ober Kaler asked about the PFS Program in the context of AKS and GPO[328] concerns, specifically asking about a discount under the program and what the physician took possession of after placing an order.[329] After an attorney from Ober Kaler requested to "have an adequate explanation of the program when or if the government comes and asks about it[,]" Defendant Chou suggested that

[322] SLC Report 234.
[323] *Id.*
[324] SLC Report Ex. 313.
[325] *Id.* at 1–2, 4.
[326] *Id.*
[327] SLC Report Ex. 314, at 20.
[328] *See* n.320, *supra.*
[329] SLC Report Ex. 307, at 4–5.

Ober Kaler "talk to [ABSG General Counsel and [ABSG Corporate Counsel] because they had a similar reaction to the program but felt better after examining the facts more clearly."[330] ABSG's General Counsel believed that the PFS Program was "previously blessed" by external counsel before he joined the Company, and ABSG's Corporate Counsel believed that the Pharmacy was not subject to FDA regulations or cGMPs at the time of the meeting.[331] In light of this understanding and the fact that neither the *Westmoreland* case and nor the Mullen allegations raised concerns about the PFS Program's FDA compliance or sterility, Ober Kaler's review did not include follow-up on the PFS Program.[332]

On August 11, 2010, Ober Kaler presented its findings to the Audit Committee.[333] Ober Kaler's presentation specifically referenced the PFS Program in its general description of the "[r]ole of Oncology Supply," but Ober Kaler did not reference sterility or FDCA concerns.[334] Beyond describing three aspects of the PFS Program, the final presentation did not otherwise refer to MII or the PFS Program.[335] At the end of the presentation, the Audit Committee "instructed management to undertake appropriate consideration and follow-up of the recommendations."[336]

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[330] *Id*
[331] SLC Report 237.
[332] *Id.* at 237–38.
[333] SLC Report Ex. 81, at 1–2.
[334] SLC Report Ex. 20, at 4, 9–12.
[335] *Id.* at 4.
[336] SLC Report Ex. 81, at 1–2.

On October 19, 2010, Ober Kaler sent a final memorandum to Defendant Chou containing action items for the Company to consider, including four broad categories: (1) the definition of the roles of ION and OS; (2) discounting practices at OS; (3) ION services to pharmaceutical manufacturers; and (4) GPO safe harbor compliance.[337] The Company began implementing new policies in response to Ober Kaler's report even before the suggested action items were finalized by Ober Kaler.[338] The Audit Committee received at least two updates from Defendant Chou on the Company's progress in addressing Ober Kaler's recommendations.[339] By November 21, 2010, the Company implemented nearly all of Ober Kaler's recommended action items.[340]

4. Mullen's October 2010 *Qui Tam* Complaint

On October 21, 2010, Mullen filed a *qui tam* complaint under the Federal Claims Act (the "FCA") against ABC, ABSG, ION, OS, and MII in the U.S. District for the Eastern District of New York.[341] This complaint largely mirrored the allegations that Mullen raised in his May 2010 meeting with ABSG's General Counsel, including that the free services provided by ION and OS constituted kickbacks in violation of the AKS and FCA.[342] He also alleged that ION, OS, and

[337] SLC Report Ex. 317, at 1–3.
[338] SLC Report 241.
[339] *Id.* at 242.
[340] SLC Report Ex. 323, at 9–13.
[341] SLC Report Ex. 4.
[342] *Id.* ¶ 7.

MII engaged in an illegal overfill laundering scheme designed to pass kickbacks to medical providers and allow drug manufacturers to overreport the drugs' ASPs.[343] The October 2010 *qui tam* complaint did not contain any allegations relating to sanitation, repackaging, or FDCA violations.[344]

While *qui tam* complaints are kept under seal,[345] on October 27, 2010, Mullen's *qui tam* complaint was inadvertently unsealed.[346] An attorney with Buchanan Ingersoll transmitted the unsealed complaint to the ABC's CCO who notified Defendant Chou, attorneys from Morgan Lewis, and the broader ABC executive team and ABSG's President and Group General Counsel.[347] Defendant Chou notified the Board of the suit[348] and the Board discussed "the status of a *qui tam* matter involving Amgen Inc. and two business units of [ABSG], ABSG, and the Company" at its November 12, 2010, meeting.[349]

5. Mullen's January 2011 Amended *Qui Tam* Complaint

In January 2011, Mullen filed a First Amended FCA *Qui Tam* Complaint (the "FAC")[350] that added new allegations related to violations of the FDCA and

[343] *Id.* ¶ 8.
[344] *See generally* SLC Report Ex. 4.
[345] 31 U.S.C. § 3730(b)(2).
[346] *See* SLC Report Ex. 324.
[347] *Id.*
[348] SLC Report Ex. 325, at 4.
[349] SLC Report Ex. 326.
[350] SLC Report Ex. 5.

Alabama state pharmacy regulations.[351] Specifically, the FAC alleged that MII was operating as an unlicensed manufacturer and repackager of drugs and thus was operating without proper FDA oversight.[352] MII allegedly violated "any number" of FDA protocols designed to protect against contamination, product mix-ups, misidentification, mislabeling, deficient inventory control, etc.[353] For the first time, Mullen alleged that MII operated as a drug repackager or manufacturer under the FDCA because it "compounded" pre-filled syringes, used large-scale vacuum and centrifuge equipment to extract drugs from manufacturer's vials in a facility designed solely for that purpose, and sold the pre-filled syringes to other companies as opposed to individual patients.[354]

The FAC was filed under seal and stayed under seal.[355] The Company was not informed of the allegations contained within the FAC until January 29, 2016, when federal prosecutors shared three complaints with the Company as part of efforts to facilitate a settlement.[356]

[351] SLC Report 247.
[352] FAC ¶ 8.
[353] *Id.* ¶ 9.
[354] *Id.* ¶ 201.
[355] SLC Report 249.
[356] SLC Report Ex. 328.

6. The Department of Justice's Investigation

Around the time Mullen filed his *qui tam* lawsuit, the Department of Justice ("DOJ") initiated parallel criminal and civil investigations into ABC.[357]

a. July 2012 Search of MII

On July 11, 2012, an FDA search warrant was executed at OS's Dothan facility with a focus on MII's pharmacy.[358] At the time the search warrant was executed, federal agents also served a subpoena on ABSG as part of an investigation into potential federal fraud, false claims, and other offenses.[359] While executing the search warrant and subpoena, federal agents seized product—pre-filled syringes, partially filled syringes, and empty vials—and interviewed some employees.[360]

b. ABC Officers' Response to the Search

The Company engaged Morgan Lewis on the day of the search to help the Company respond to the search warrant and subpoena.[361] After interviewing the employees who were interviewed by federal agents during the search,[362] Morgan Lewis learned, and shared with Defendant Chou, that the federal agents asked about topics like the employees' job duties; how MII fit into the corporate structure; how

[357] SLC Report 249.
[358] Matt Elofson, *FDA Agents Search Oncology Supply Business*, DOTHAN EAGLE (July 11, 2012), https://dothaneagle.com/news/fda-agents-search-oncology-supply-business/article_a9cb93fc-0e3d-5701-9958-35f8544b1f82.html; SLC Report Ex. 239, at 2.
[359] SLC Report Ex. 331, at 1.
[360] SLC Report Ex. 332.
[361] *See* SLC Report Exs. 334–35.
[362] SLC Report Ex. 340.

overfill was captured, "stored," and "tracked"; whether MII profited off of overfill; the sterility and stability of the pre-filled syringes, including testing performed at MII and employee training; the packaging and labeling of pre-filled syringes with patient and lot information and how patient information was protected; the rebate program for pre-filled syringes; patient records; and whether MII used a "centrifuge" in the pre-filled syringe process.[363]

To better understand what prompted the search, Defendant Chou and Company counsel collected and considered earlier legal reviews and work product related to the Pharmacy, including the 2003 Reed Smith memorandum discussing MII's PFS Program; the May 2012 Pharmacy Directive regarding patient-specific labeling at MII; and the then-current version of the PFS Program agreement.[364] ABC in-house counsel also received Mullen's May 2010 allegations, Ober Kaler's 2010 review of ION and OS, and a summary of ABC's action items in response to Ober Kaler's review.[365]

c. The Board's Response to the Search

The Board was informed of the search of MII and the subpoena on July 12, 2012, a day after the search occurred.[366] At the August 9, 2012, Board meeting,

[363] SLC Report Ex. 341.
[364] SLC Report Ex. 343, at -498130.
[365] SLC Report Exs. 344–47.
[366] SLC Report 257.

Defendant Chou updated the Board on "significant legal matters affecting the company" and on "certain matters that would be disclosed in the Company's. . . Form 10-Q for the quarterly period ended June 30, 2012."[367] The Board members discussed the search, the basis for the government's action, and whether there were any concerns about MII's operations, including any concerns about product adulteration, sterility, or patient safety.[368] At that time, the Company was only aware of Mullen's original October 2012 *qui tam* complaint, which did not contain any FDCA-related allegations.[369] The Board was also unaware of any prior history of patient safety or sterility issues at MII; ABC management confirmed to the Board that such problems had not occurred in the past.[370]

While the Board and management considered closing the Pharmacy after the July 2012 search, MII remained open in light of the lack of clear indicia that it was operating in violation of regulations.[371] In August 2012, the Board, in consultation with Morgan Lewis, decided to disclose the subpoena in the Company's upcoming Form 10-Q[372] and in the Company's Annual form on Form 10-K for the fiscal year ending September 30, 2012.[373]

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[367] SLC Report Ex. 353, at 5.
[368] SLC Report 259.
[369] *Id.*
[370] *Id.* at 260.
[371] *Id.* at 260–61.
[372] *Id.* at 261; *see also* SLC Report Ex. 355.
[373] ABC Annual Report on Form 10-K (2012), at 57.

7. November 2012 Potential Negative News Article

In October 2012, Katherine Eban,[374] a journalist for *Fortune* magazine, contacted a Vice President for Corporate & Investor Relations at ABC about an article she was writing regarding the July 2012 search of OS.[375]

After working with CSRA leadership, in-house counsel, and Defendant Chou, who consulted outside counsel to develop talking points, the Vice President spoke with Ms. Eban by phone on October 22, 2012.[376] During the call, Ms. Eban focused on the government's investigation, the Pharmacy's parenteral license, whether the syringe labels included the lot number, the harvesting of overfill, and whether the Pharmacy was engaged in the manufacturing process.[377] Ms. Eban did not raise any concerns about safety or sterility; however, Ms. Eban did inquire into how MII used overfill to offer pre-filled syringes at a discount.[378] Ultimately, Ms. Eban did not publish the article on October 24, 2012, but she continued to ask the Vice President follow-up questions into early November.[379] The Vice President followed public relations firm Starkman & Associates' recommendation to contact Ms. Eban's editor

[374] Ms. Eban had previously written a book entitled *Dangerous Doses* that criticized ABC and other drug companies for allegedly distributing counterfeit or adulterated drugs, which caused the Company to become apprehensive of how Ms. Eban would portray the Company. SLC Report 263–64.
[375] SLC Report Ex. 356, at 4–5; SLC Report Ex. 357, at 1.
[376] SLC Report Ex. 356, at 2–3.
[377] SLC Report Ex. 357, at 2.
[378] SLC Report Ex. 252, at 2.
[379] SLC Report Ex. 360, at 2.

regarding the falsity of Ms. Eban's allegations that the Pharmacy did not have a parenteral license, explaining to the editor that the Pharmacy had recently passed an inspection by the Alabama Board of Pharmacy.[380]

The Board was apprised of the potential *Fortune* article at its November 15, 2012, meeting.[381] The Board did not express concern that Ms. Eban was exposing wrongdoing at the Company, or that there were compliance issues at MII, because the Board was confident in the legality of MII's business model and its classification as a traditional pharmacy as of November 2012.[382] On November 16, 2012, Ms. Eban's editor at *Fortune* e-mailed the Vice President to inform her that *Fortune* had decided against running the article.[383]

8. Evolution of the DOJ Investigation

a. DOJ Interactions: 2012–2013

Following the July 2012 subpoena, the DOJ issued an additional three subpoenas in 2013 alone, all of which were generally focused on financial issues related to MII, overfill, and the PFS Program, although one requested information regarding sterility testing and communications about the quality of the pre-filled

[380] SLC Report Ex. 363, at 1–2.
[381] SLC Report 267.
[382] *Id.* at 267–68.
[383] SLC Report Ex. 366, at 1–2.

syringes.[384] Both in-house counsel and Morgan Lewis viewed Mullen's *qui tam* complaint as the likely impetus for the requests in these subpoenas.[385]

Throughout 2013, Morgan Lewis reviewed these subpoenas and advised ABC on the subpoenas and the status of the MII investigation.[386] At a May 2013 presentation to ABC's Legal Department, Morgan Lewis described the regulatory landscape for pharmacies, addressed when a pharmacy would be subject to FDA regulation, and explained why MII was exempt from federal regulation as a state-regulated pharmacy.[387] By the end of 2013, the DOJ's subpoenas and interviews did not provide the Company with a clear understanding of DOJ's investigative theories, although they appeared to derive from Mullen's *qui tam* allegations about AKS and pricing issues.[388] Although ABC employees and Morgan Lewis considered potential FDCA theories, they concluded that the Company had a strong defense that MII was not subject to FDA regulation.[389]

b. DOJ Interactions: 2014–2016

While MII closed in January 2014, ABC continued to receive subpoenas related to its operations. From 2014 through March 2016, the DOJ issued twelve more subpoenas seeking documents and information about MII and the PFS

[384] *See* SLC Report Ex. 369; SLC Report Ex. 371.
[385] SLC Report 272–74.
[386] *Id.*
[387] SLC Report Ex. 376, at 6–17, 53–54.
[388] SLC Report 274.
[389] *See, e.g.*, SLC Report Ex. 376.

Program, including MII's closure, "bubbles, floating ('floaters') or other particulate matter" in pre-filled syringes, and the volume of drug product contained in the syringes.[390] These requests also focused on the Company's compliance program and audits of MII.[391] On October 27, 2014, Morgan Lewis presented to the DOJ on behalf of MII and argued that MII did not violate the FDCA, FCA, AKS, or the Prescription Drug Marketing Act.[392] Following this presentation, the DOJ issued a subpoena about "filter syringes" used at MII and appeared to be focusing on MII's practice of removing particulate from syringes of Procrit.[393]

The 2014 DOJ subpoenas suggested a possible interest in senior executives' and the Board's role in MII oversight as evidenced by the DOJ requesting documents and information about how sales of overfill or pre-filled syringes factored into compensation and performance evaluations of Company personnel, including directors and officers;[394] the Board's involvement in the decision to construct the Pharmacy;[395] and presentations to the Board about MII during the process of AmeriSource Health's merger with Bergen Brunswig.[396]

[390] SLC Report Exs. 378–87.
[391] SLC Report 275.
[392] SLC Report Ex. 389.
[393] SLC Report Ex. 392; *see also* SLC Report Ex. 384.
[394] SLC Report Ex. 385.
[395] SLC Report Ex. 386.
[396] SLC Report Ex. 387.

c. The DOJ Presentation

In October 2015, attorneys from ABC, Morgan Lewis, and the DOJ Civil and Criminal Divisions met to discuss DOJ's theories of liability in the MII investigation.[397] During this meeting, federal attorneys, both civil and criminal, presented a 280-slide PowerPoint deck to the attendees over the course of approximately four and half hours.[398] From a liability standpoint, DOJ's presentation focused on alleged FDCA violations, many of which hinged on the argument that MII was a repackager or manufacturer, therefore not falling within FDA's exception for "bona fide pharmacies."[399] The FDCA violations were alleged as misdemeanors.[400] The DOJ also presented two civil FCA theories: (1) MII caused physicians to submit false claims for payment by providing adulterated and unapproved new drugs that were not reasonable or medically necessary, and (2) the use of overfill resulted in double billing and improper reimbursement.[401] The Audit Committee received an update about the DOJ investigation and were informed of this meeting between ABC's counsel and the United States Attorney's Office.[402]

[397] SLC Report Ex. 393, at 2.
[398] *Id.* at 1.
[399] *Id.* at 4, 14.
[400] *See id.* at 27.
[401] *See id.* at 26–27.
[402] SLC Report Ex. 394, at 3.

d. The Company's Response

Following the October 2015 presentation, the Company asked Morgan Lewis to conduct a further investigation into, and to prepare a rebuttal of, the DOJ's theories.[403] On February 29, 2016, Morgan Lewis presented its investigative findings to civil and criminal DOJ attorneys.[404] While Morgan Lewis acknowledged that some of MII's conduct was problematic, Morgan Lewis emphasized that certain aspects of the case presented serious litigation risk for DOJ.[405] Morgan Lewis also contended that the federal regulatory landscape with respect to compounding was ambiguous at the time, and thus it was unclear when a state-regulated pharmacy would be deemed a drug manufacturer subject to FDA's registration and cGMP requirements.[406] The Board was updated again on the MII investigation at its March 3, 2016, meeting.[407]

9. DOJ Resolutions

Following the February 29, 2016, presentation by Morgan Lewis, ABC and the DOJ began negotiating resolutions of both the criminal and civil allegations.[408]

[403] SLC Report 284.
[404] *Id.* at 285.
[405] SLC Report Ex. 400, at 2–3; SLC Report Ex. 401, at 2–3.
[406] SLC Report Ex. 400, at 109; SLC Report Ex. 401, at 125–26.
[407] SLC Report Ex. 402, at 14.
[408] SLC Report 288.

The Board received seven updates on the investigation at Board meetings, including three from Morgan Lewis.[409]

As the investigation progressed and the DOJ's legal theories and financial demands became apparent, ABC's management, in close consultation with the Board, determined that resolving the criminal case based on a single, strict liability misdemeanor count under the FDCA was in the Company's best interests, notwithstanding the Company's legal defenses.[410] In September 2017, ABSG pleaded guilty to a misdemeanor FDCA violation stemming from ABSG's failure to register MII with FDA and agreed to pay a $260 million monetary penalty and to comply with the terms of a Compliance Agreement.[411] The plea agreement was a compromised resolution in which ABSG admitted to a limited statement of facts but not to the factual allegations in DOJ's Information.[412] During the resolution negotiations, the parties "agree[d] that defendant ABSG may challenge, contest and refute the factual allegations in the Information in any subsequent proceeding."[413] No current or former employees were charged as defendants by the DOJ.[414] ABSG

[409] SLC Report Ex. 402, at 5; SLC Report Ex. 403, at 5; SLC Report Ex. 404, at 13–14; SLC Report Ex. 405, at 4; SLC Report Ex. 406, at 15; SLC Report Ex. 407, at 7; SLC Report Ex. 43, at 2–3.
[410] SLC Report 250.
[411] Plea Agreement, *United States v. AmerisourceBergen Specialty Group, LLC*, No. 17-507 (NG) (E.D.N.Y. Sept. 27, 2017).
[412] SLC Report 289.
[413] Plea Agreement, *United States v. AmerisourceBergen Specialty Group, LLC*, No. 17-507 (NG), ¶ 2 (E.D.N.Y. Sept. 27, 2017).
[414] SLC Report 292.

did not take any disciplinary action against individuals involved in the conduct that led to the guilty plea, because MII had already been closed and many of its employees had been let go.[415]

After several additional months of unsuccessful negotiations related to the civil matter, the DOJ showed the Company a draft complaint in July 2017.[416] Due to the gap between the parties' settlement offers, and the Company and outside counsel's views that DOJ's case relied on novel theories to which the Company had strong defenses, ABC prepared to litigate the case.[417] However, after being informed that the potential civil penalties and trebled damages could exceed $6.6 billion, the Board agreed with Morgan Lewis's recommendation to continue resolution negotiations with DOJ.[418] The DOJ eventually accepted the Company's offer to settle the matter for $625 million on November 16, 2017,[419] and the settlement agreement and related CIA were fully executed on September 28, 2018.[420] As part of the resolution, the Company admitted only to facts expressly included in the Statement of Facts contained in the civil settlement agreement.[421]

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[415] SLC Report Ex. 409; Tr. of Plea and Sentencing Hr'g, *United States v. AmerisourceBergen Specialty Group, LLC*, No. 17-507 (NG) (E.D.N.Y. Sept. 27, 2017)).
[416] SLC Report Ex. 43, at 3.
[417] *See id.*; SLC Report Ex. 412.
[418] SLC Report Ex. 43, at 2–3.
[419] SLC Report Ex. 413.
[420] Settlement Agreement (Sept. 28, 2018); SLC Report Ex. 179.
[421] Settlement Agreement (Sept. 28, 2018), at Recitals ¶ K.

10. Compensation Considerations Relating to Defendants Chou and Collis after the MII Resolution

On multiple occasions, the Board considered whether to reduce executive compensation or bonus amounts for Defendants Chou and Collis as a result of the DOJ Resolutions.[422] The Chief HR Officer contacted Pearl Meyer & Partners LLC, an executive compensation consulting firm, to receive advice on how to handle the situation.[423] The firm was unaware of any instances of Compensation Committees reducing compensation or bonus amounts, in situations comparable to ABC's current posture, absent "executive misconduct or gross negligence."[424] They had only seen "voluntary bonus give backs in situations involving poor company performance that was not already reflected in annual bonus payouts."[425] The Compensation Committee met on November 14, 2018, and, following an executive session, decided against reducing Defendants Chou's and Collis's salaries as a result of the DOJ Resolutions after concluding that the conduct of Defendants Collis and Chou did not rise to the standard to find individual culpability for intentional fraud.[426]

[422] SLC Report 296.
[423] SLC Report Ex. 414.
[424] *Id.*
[425] *Id.*
[426] SLC Report 300; SLC Report Exs. 417–18.

G. Litigation Ensues

On October 11, 2019, Plaintiffs filed the complaint pleading two counts of breach of fiduciary duty and one count of unjust enrichment.[427] On August 24, 2020, I denied the Defendants' motions to dismiss under Rule 23.1 for failure to make demand or show that demand would have been futile and, in the alternative, under Rule 12(b)(6) for failure to state a claim.[428] I concluded that Plaintiffs sufficiently pled that "a majority of the Demand Board faces a substantial likelihood of liability for Count I because the Plaintiffs have adequately pleaded that a majority of the Demand Board consciously ignored red flags rising to the level of bad faith."[429]

H. The Company Forms the SLC

On September 24, 2020, the Company authorized a two-person special litigation committee to investigate and evaluate the allegations and issues raised in this action, in addition to determining whether prosecuting this action was in the best interests of the Company or if the action should be dismissed or settled.[430] Initially, the two SLC members were D. Mark Durcan and Dennis M. Nally.[431] Durcan was removed from the SLC on December 11, 2020, because Durcan had previously

[427] Verified S'holder Deriv. Compl. for Breach of Fiduciary Duties, Dkt. 1 ("Verified Compl.").
[428] *See Teamsters Local 443 Health Servs. & Ins. Plan v. Chou*, 2020 WL 5028065 (Del. Ch. Aug. 24, 2020) ("*Teamsters I*").
[429] *Id.* at *17.
[430] SLC Report Ex. 6, at 5.
[431] SLC Report 36.

served on the Company's Audit Committee that had received an earlier stockholder demand referenced in Mullen's *qui tam* complaint.[432]

1. Dennis M. Nally

Nally is the former chairman of PricewaterhouseCoopers ("PwC") International Ltd. and currently serves on the boards of Morgan Stanley, The HOW Institute for Society, and the Royal Poinciana Golf Club.[433] Prior to joining the Company's board, Nally knew only one other director, nonparty Richard Gozon, the former chairman of the Board.[434] Nally's relationship with Gozon was attenuated; limited to being members of the same golf club.[435]

I. The SLC Investigation and its Report

On November 10, 2020, I granted the SLC's motion to stay the proceedings pending its investigation.[436] The SLC moved to extend the stay on May 7, 2021, and I granted the stay from May 10, 2021, to May 28, 2021.[437]

The SLC conducted a seven-month-long investigation. During this time, the SLC collected more than 12 million documents, of which the SLC reviewed

[432] *Id.* at 39–40.
[433] *See id.* at 41–42; *see also* SLC's Opening Br. in Supp. of Its Mot. to Dismiss 6, Dkt. No. 98 ("SLC OB").
[434] SLC OB 7.
[435] Reply Br. in Supp. of Mot. to Dismiss by the SLC of the Board of Directors for Nominal Def. ABC 29–30, Dkt. No. 109 ("SLC RB").
[436] Signed Order Granting Mot. to Stay by the SLC of the Board of Directors of Nominal Def. AmerisourceBergen Corp., Dkt. No. 58.
[437] Order Granting Mot. to Extend Stay by the SLC of the Board of Directors of Nominal Def. AmerisourceBergen Corp., Dkt. No. 62.

approximately 220,0000.[438] The SLC also conducted 77 interviews of 67 witnesses.[439] The Report itself was 365 pages in length, containing over 1500 footnotes, with 420 exhibits attached. Ultimately, the SLC concluded that pursuing this action any further is not in the best interests of the Company in light of "all relevant factors—including the factual findings and applicable legal standards, potential costs to the Company, public relations, and distraction to the Board, management, and other ABC employees[.]"[440]

With respect to Count I of the complaint, the SLC concluded that the Director Defendants did not fail to implement and monitor reporting or information systems, or otherwise exercise their oversight duties, but rather had "implemented a system of reporting that was more than adequate to meet the *Caremark* standards."[441] Specifically, the SLC found that the Company had an Audit Committee with clear reporting lines and the Company repeatedly updated the compliance program as the Company's business grew, providing sufficient evidence that the directors did not "utterly fail[]" to fulfill their duty to implement and monitor a compliance system.[442] The Audit Committee considered and determined which compliance and regulatory matters needed the full Board's attention and the Audit Committee Chairman

[438] SLC Report 47–53.
[439] *Id.* at 53–54.
[440] SLC OB 39.
[441] SLC Report 319.
[442] *Id.* at 320.

reported to the Board accordingly.[443] The SLC also found that ABSG was not intentionally nor actually segregated from the rest of ABC's compliance program.[444] Furthermore, the SLC concluded that MII's operations were not "mission critical" for the Company under *Marchand* and therefore did not present a strong basis for pursuing *Caremark* claims against the Defendant Directors.[445] Thus, "the SLC concluded that the Audit Committee and Board's efforts amounted to more than a mere 'attempt' to oversee MII's compliance with applicable laws[.]"[446]

The SLC also determined that five of the six "red flags" alleged in the complaint did not amount to red flags for the purposes of the second prong of *Caremark*.[447] The SLC found that the Board responded to each of the six events, specifically (1) the 2007 Davis Polk Report; (2) Mullen's *qui tam* allegations; (3) the Ober Kaler Report; (4) the 2012 FDA search warrant and subpoena; (5) the 2012 *Fortune* magazine article; and (6) the 2006 Capital Expenditure Report.[448] The SLC also considered whether unpled events might also qualify as red flags, such as patient-specific labeling concerns, and concluded that none did.[449] Even if the Court were to consider the cumulative effects of these multiple events, the SLC concluded

[443] *Id.* at 325–26.
[444] *Id.* at 326.
[445] *Id.* at 327.
[446] *Id.* at 329.
[447] *Id.* at 329–30.
[448] *Id.* at 330–47.
[449] *Id.* at 330, 348–49.

it would not change its conclusion that the Board responded to and actively monitored each issue.[450]

With respect to Count II of the complaint, the SLC concluded that the Officer Defendants did not knowingly operate an illegal business model or fail to inform the Board about problems with the PFS Program's regulatory compliance.[451] Specifically, the SLC concluded that the CSRA Senior Director's review of MII in 2012 did not put the Officer Defendants on notice of "noncompliance because they were informed that state law, rather than the FDCA, applied to the Pharmacy, and because they understood that any issues had been corrected and were not recurring[,]"[452] nor were the Officer Defendants grossly negligent in their management of MII; rather, "the Officers believed in good faith that MII was operating legally as a pharmacy and dispensing safe, sterile products."[453] As to Defendant Chou, the Company's General Counsel, the SLC concluded that he did not breach his fiduciary duties with respect to how he handled the Ober Kaler Report, CSRA's 2012 review of MII, and the Company's handling of the DOJ investigation.[454]

[450] *Id.* at 349–50.
[451] *Id.* at 350–51.
[452] *Id.* at 351.
[453] *Id.* at 352–53.
[454] *Id.* at 355–58.

Finally, with respect to Count III, the SLC concluded that there is no basis for an unjust enrichment claim against Defendant Collis because he did not breach his fiduciary duties as alleged in Counts I and II of this action.[455] Because the breach of fiduciary duty and unjust enrichment counts rely on the same alleged acts or omissions, the SLC's conclusion that there were no breaches of fiduciary duty forecloses the unjust enrichment count.[456]

The SLC filed its Report and moved to dismiss this derivative action on September 22, 2021.[457] The parties finished briefing the SLC's motion to dismiss on March 6, 2023,[458] and I heard oral arguments on July 12, 2023.[459]

II. ANALYSIS

I found in *Teamsters I*, based on the allegations of the complaint and the plaintiff-friendly inferences therefrom appropriate at the motion-to-dismiss analysis, that a majority of the ABC directors could not bring their business judgment to bear because there existed a substantial risk that they may be liable for breaches of fiduciary duty.[460] Thus, the traditional deference to the board's control of corporate litigation assets was unwarranted, and the matter could proceed derivatively. ABC

[455] *Id.* at 359.
[456] *Id.* at 360.
[457] *See* SLC Report.
[458] *See* SLC RB.
[459] *See* Judicial Action Form re Mot. Dismiss before Vice Chancellor Sam Glasscock dated 7.12.23, Dkt. No. 115.
[460] *Teamsters I*, 2020 WL 5028065, at *26.

has attempted to reassert directorial control over the suit by creating a special litigation committee consisting of an unconflicted director. That SLC has investigated the claims in Plaintiffs' complaint and recommended dismissal of the action.

That recommendation is entitled to some credit but not to the full deference of the application of the business judgment rule. There is a tension in review by any special litigation committee, which this Court recognizes is faced with the rather daunting task of evaluating publicly the behavior of fellow board members. That tension is not a conflict sufficient to sterilize the business judgment of the SLC, but it is sufficient to cause the Court, in evaluating a determination that a derivative action should be dismissed, to review the Committee's work and the bases for its conclusion, for reasonableness. The pressure on a sole-member SLC is especially evident, and causes a need for close review by the Court.

When a special litigation committee concludes that it is in the best interest of the corporation to dismiss a derivative action, the Court reviews the motion to dismiss under "a procedural standard akin to a summary judgment inquiry[.]"[461] Under this standard, "the SLC bears the burden of demonstrating that there are no

[461] *In re Oracle Corp. Deriv. Litig.*, 824 A.2d 917, 928 (Del. Ch. 2003).

genuine issues of material fact as to its independence, the reasonableness and good faith of its investigation, and that there are reasonable bases for its conclusions."[462]

A special litigation committee's motion to dismiss a derivative action is reviewed under the two-pronged analysis—the first prong mandatory, the second discretionary—set forth in *Zapata Corporation v. Maldonado*.[463] The first prong of *Zapata* requires that the Court "inquire into the independence and good faith of the committee and the bases supporting its conclusions."[464] Regardless of what the Court finds during its inquiry in the first prong, the Court may, in its discretion, move to the second prong, under which the Court must "determine, applying its own independent business judgment, whether the motion should be granted."[465]

A. Zapata's *First Prong*

"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."[466] The burden lies with the SLC to prove "independence, good faith and a reasonable investigation."[467]

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[462] *London v. Tyrrell*, 2010 WL 877528, at *12 (Del. Ch. Mar. 11, 2010).
[463] 430 A.2d 779 (Del. 1981).
[464] *Id.* at 788.
[465] *Id.* at 789; *accord. Diep ex rel. El Pollo Loco Hldgs., Inc. v. Trimaran Pollo P'rs, L.L.C.*, 280 A.3d 133, 158 (Del. 2022) (reiterating that the Court may apply its own business judgment to determine whether the action should be dismissed).
[466] *Kahn v. Kolberg Kravis Roberts & Co., L.P.*, 23 A.3d 831, 836 (Del. 2011).
[467] *Zapata*, 430 A.2d at 788.

1. Nally Conducted a Good Faith Investigation

In reviewing whether the SLC conducted a reasonable investigation, the Court considers whether there are "material issue[s] of fact" and whether "the SLC acted in good faith and had a reasonable basis for its conclusion."[468] The Court considers the reasonableness of the scope of the investigation to ensure that the SLC thoroughly investigated all causes of action and theories of recovery contain in a plaintiff's complaint, rather than merely "accept[ing] defendants' version of disputed facts without consulting independent sources to verify defendants' assertions."[469] The purpose of the Court's inquiry is narrow at this "prong one" stage of the proceedings. The Court's inquiry is not meant to allow plaintiff to litigate the facts and merits of the derivative cause of action, "[r]ather, it is the conduct and activity of the Special Litigation Committee in making its evaluation of the factual allegations and contentions contained the plaintiff's complaint which provide the measure for the Committee's independence, good faith and investigatory thoroughness."[470] Thus, it is the SLC and its investigation that are examined under the first prong of *Zapata*, and not this Court's independent conclusions about "the merits of the plaintiff's [case]."[471]

[468] *Kahn*, 23 A.3d at 842.
[469] *London*, 2010 WL 877528, at *17.
[470] *Kaplan v. Wyatt*, 484 A.2d 501, 519 (Del. Ch. 1984).
[471] *Id.*

Plaintiffs put forth five ways that they allege the SLC failed to conduct a reasonable investigation. First, Plaintiffs allege that the SLC deemed the Company's FCA-violating "kickback scheme" to be beyond the scope of the SLC's investigation. Second, Plaintiffs claim that the SLC did not consider materials from the DOJ's investigation of the Company. Third, Plaintiffs assert that the SLC's investigation of the Officer Defendants was inadequate. Fourth, Plaintiffs contend that the SLC's conclusion that the Director Defendants satisfied their *Caremark* duties lacks a reasonable basis. Finally, Plaintiffs argue that the SLC's conclusion that the Company did not violate the law lacks a reasonable basis. Plaintiffs' attacks on the SLC's investigation can be grouped into two categories: (a) reasonableness of the scope of the SLC's investigation and (b) reasonableness of the bases for the SLC's conclusions.

a. The Scope of the Investigation was Reasonable

"To conduct a good faith investigation of reasonable scope, the SLC must investigate all theories of recovery asserted in the plaintiffs' complaint."[472] If the SLC totally fails "to explore the less serious allegations in the plaintiffs' complaint[,]" doubt may be cast on the reasonableness of the SLC's investigation if exploring those allegations "would have helped the SLC gain a full understanding

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

of the more serious allegations in plaintiffs' complaint."[473] "The court will not fault the SLC for failing to evaluate claims that were not asserted in the Complaint."[474]

Plaintiffs first contend that the SLC "intentionally chose not to investigate Defendants' potential liability in connection with the Company's FCA [False Claims Act] violations."[475] Specifically, Plaintiffs point to SLC allegedly declaring that the FCA violations, which involved kickbacks and double-billing, were outside the scope of its investigation when it declared that "AKS [Anti-Kickback Statute] and price reporting compliance issues. . . are not at issue in this Action."[476] As evidence of the SLC's failure to investigate the FCA violations, Plaintiffs point to the SLC's (1) dismissal of Mullen's initial *qui tam* complaint as "irrelevant" because "the assertions he raised were limited to AKS and price reporting compliance issues[,]"[477] (2) deeming the Ober Kaler Report "inconsequential" because it "focused on. . . AKS and price-reporting allegations[,]"[478] as well as the SLC's "nonsensical[] dismiss[al]" of consideration of the DOJ's investigation that resulted in the Company admitting to liability for violating the FCA.[479]

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[473] *Id.*
[474] *Diep ex rel. El Pollo Loco Hldgs., Inc. v. Sather*, 2021 WL 3236322, at *20 (Del. Ch. July 30, 2021), *aff'd sub nom. Diep ex rel. El Pollo Loco Hldgs., Inc. v. Trimaran Pollo P'rs, L.L.C.*, 280 A.3d 133 (Del. 2022).
[475] Lead Pls.' Answering Br. Opp'n SLC's Mot. to Dismiss 29, Dkt. No. 104 ("Pls. AB").
[476] SLC OB 27–28.
[477] Pls. AB 31 (quoting SLC OB 27–28).
[478] *Id.* (quoting SLC OB 56).
[479] Pls. AB 33.

The complaint contains three causes of action, all of which are focused on the alleged breaches of fiduciary duties with respect to drug safety and sterility in the Pre-Filled Syringe Program and FDCA compliance.[480] That is, the complaint is largely silent with respect to violations of the AKS, and to the same extent the SLC would have been justified in not addressing such violations.[481] While the complaint lacks any claims asserting illegal kickbacks or double-billing, however, the SLC nevertheless investigated Defendants' knowledge of those issues. The SLC 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.[482] Given the scope of the complaint and the actual scope of the investigation, I find that the SLC has met its burden here.

Regarding Mullen's *qui tam* complaint, the SLC Report lays out Plaintiffs' allegations that Mullen raised the AKS and double-billing issues in his *qui tam* complaint and explains the steps the SLC took to investigate these issues.[483] The SLC Report also details its investigation into the Ober Kaler Report that resulted from Mullen's *qui tam* complaint, including Ober Kaler's mandate that included, in relevant part, assessing the Company's "'overall compliance with federal anti-

[480] *See* Verified Compl. ¶¶ 207–23.
[481] To be clear, a sufficiently glaring omission by the SLC to thoroughly investigate issues as they arise in the ordinary course of the SLC's investigation of the claims contained in a derivative action complaint would cause the Court to invoke *Zapata*'s second prong.
[482] *See* SLC Report 30–32, 48 n.173, 51–52, 53 n.181, 213–33, 243–62, 269–96, 338–40.
[483] *Id.* 30–32, 48 n.173, 51–52, 53 n.181.

kickback/fraud and abuse laws and the federal false claims act[;]'" the process Ober Kaler used to conduct its investigation; the findings contained within the Ober Kaler Report; and the Company's response to the Ober Kaler Report.[484] The SLC was not "dismissive" of the DOJ's FCA Investigation; rather, the SLC dedicated over 40 pages of its report to exploration of the facts and sources relating to the DOJ's five-year investigation.[485]

Next, Plaintiffs contend that the SLC improperly failed to take into consideration the materials underlying the Company's criminal and civil settlements with the DOJ.[486] They point to documents containing allegations relating to Defendant Collis's role in creating the PFS Program and his knowledge that the program caused double-billing in violation of federal law.[487] It is Plaintiffs' position that the SLC further failed to review the DOJ's proffer memoranda and the implications those memoranda have on this action.[488]

However, I find that not only did the SLC consider both the DOJ's draft civil complaint and the presentation the DOJ gave to ABC about its theories of liability,[489] the SLC investigated the allegations underlying it, for example, by interviewing two Morgan Lewis attorneys who attended the presentation and reviewing the

[484] *Id.* at 233–43, 338–40.
[485] *Id.* at 249–62, 269–96.
[486] Pls. AB 37.
[487] *Id.* at 38.
[488] *Id.* 38–39.
[489] SLC Report 249–62, 269–96.

contemporaneous memorandum that documented the meeting.[490] In the SLC Report, the SLC concluded that the DOJ's investigation focused on FDCA violations.[491] The SLC Report stated that the SLC reviewed the proffer memoranda but declined to rely on those documents after concluding that the information contained within the proffer memoranda was duplicative of information the SLC had already obtained from its witness interviews.[492]

Plaintiffs' last contention with respect to the reasonableness of the scope of the SLC's investigation pertains to Plaintiffs' allegation that the SLC failed to adequately investigate the Officer Defendants. In support of this contention, Plaintiffs point out that the SLC's conclusions are contradicted by the DOJ's allegations against the Officer Defendants, including that they "understood and sanctioned" the PFS Program and the kickback scheme; Defendant Collis's "demonstrated intimate knowledge" of how the scheme worked; and Defendant Collis's personal intervention to satisfy manufacturer concerns while keeping illegal double-billing in place.[493]

With respect to the SLC's investigation of the Officer Defendants, Plaintiffs rely on a mistaken assertion that the SLC failed to consider the allegations contained

[490] *Id.* at 280–83 & nn.1197–1206.
[491] *Id.* at 281–82.
[492] SLC RB 16–17; *see* SLC Report 249–62, 269–96. The sole proffer memorandum that the SLC did cite to in its Report was that of a witness the SLC was unable to interview. SLC RB 17; *see also* SLC Report 54 n.182.
[493] Pls. AB 42.

within the DOJ's draft civil complaint. As explained *supra*, the SLC considered the DOJ's allegations but found that these were unproven allegations used by the DOJ to negotiate a settlement with ABC.[494] To investigate these allegations, the SLC Report explains that the SLC reviewed relevant documents and interviewed third-party witnesses about the regulatory landscape during the Relevant Period and about the legal reviews of MII that were conducted, such as those conducted by Reed Smith and Davis Polk.[495] These documents also support the SLC's conclusion that Defendant Collis, at most, had an understanding of MII's business model and that all Officer Defendants believed in good faith that MII was operating as a state-regulated pharmacy, not subject to FDA regulations.[496]

The burden is on the SLC to show that its scope and thoroughness of review were adequate to its task of evaluating the legal action. This, I conclude, it has done. Despite Plaintiffs' best efforts to attack the reasonableness of the scope of the SLC's investigation, I find there is no genuine question as to whether the SLC investigation was reasonable in scope and conducted in good faith.

b. There are Reasonable Bases for the SLC's Conclusions

Plaintiffs first allege that the SLC's conclusion that the Director Defendants satisfied their *Caremark* duties lacks a reasonable basis. To support this argument,

[494] SLC's RB 18–19.
[495] SLC Report 141–80.
[496] *See id.* at 353–54.

Plaintiffs attack the SLC's portrayal of ABC's compliance program as it pertained to MII by asserting that, during his deposition, Nally could not explain the evidence that supported this conclusion.[497] Although Plaintiffs rely on the Davis Polk Report to argue that the Company's compliance system was not uniform throughout the Company,[498] the SLC Report explains that despite Davis Polk recommending areas needing improvement, the Davis Polk Report ultimately concluded that the Company's compliance program met the "[b]asic legal requirements" under *Caremark*.[499] Moreover, the Company *responded* to the Davis Polk Report, by implementing the recommendations contained therein.[500] Plaintiffs' reliance on Nally's lack of recall about specific facts investigated by the SLC is not significant, in light of the fact that SLC's conclusion that MII was included in ABC's compliance program is well-documented and supported by facts.[501]

Plaintiffs also posit that the SLC relied exclusively on self-serving statements in concluding that the Director Defendants did not breach their *Caremark* duties in their response to Mullen's *qui tam* complaint.[502] With respect to Mullen's *qui tam* complaint, the SLC found that the Board responded by providing Mullen's concerns to outside counsel at Ober Kaler who then investigated the concerns to develop

[497] *See* Pls. AB 48–50.
[498] *Id.* at 47.
[499] SLC Report 108–11, 331–32.
[500] *Id.* at 113–22, 333–35.
[501] *Id.* at 86–88, 90, 189–92, 324.
[502] Pls. AB 52–53.

recommendations to reduce regulatory risks and reported these findings to the Board.[503]

Plaintiffs go on to criticize the Company's compliance program as it applied to MII because the reviews CSRA conducted of MII were, according to Plaintiffs, not "formal" enough and failed to raise all issues to the Board level.[504] The SLC Report concludes that while CSRA found MII's failure to use patient-specific labels an issue of concern, CSRA and the Company's in-house counsel determined that this practice was compliant with state law and therefore did not raise the issue to the Board.[505] Once the allegations in Mullen's *qui tam* complaint were made known to the Board, the Board discussed them with Defendant Chou and were informed that Morgan Lewis had been retained to defend the Company against the claims and represent the Company in any investigative action.[506] This is a *Caremark* action; the Defendant Directors' action would be evaluated, if this case were to go forward, not for compliance with best practices or in light of what greater rigor the Board could have brought to the process; the Defendant Directors would instead be liable only for failures of oversight so grossly apparent that they amount to bad faith. I find the SLC's conclusions in this regard have a reasonable basis.

[503] SLC Report 232–43, 337–38.
[504] Pls. AB 50–51.
[505] SLC Report 192–95, 200–10, 348.
[506] *Id.* at 245–47, 338.

Plaintiffs next assert that the SLC's conclusion that the Company did not knowingly violate the law also lacks a reasonable basis.[507] This conclusion allegedly "flies in the face of ABSG's September 27, 2017 federal criminal plea" and "contradicts the admissions in ABC's September 28, 2018 FCA Settlement Agreement with the DOJ[.]"[508] SLC concluded that none of the Officer Directors *knowingly* operated and maintained an illegal business model.[509] This conclusion does not contradict the Company's federal guilty plea: that plea involved a strict liability offense and therefore did not implicate the Officer Defendants' knowledge of the violations admitted to.[510] Additionally, Plaintiffs point again to Nally's deposition during which Nally incorrectly stated that states are responsible for enforcing the FCA with respect to Medicare billing.[511] Plaintiffs' reliance on Nally's limited understanding of Medicare billing and the FCA as indicative of the unreasonableness of the SLC's conclusions is unfounded—Nally is not an attorney, nor has he claimed to be an expert on these specific matters.[512] He is entitled to reasonably rely on the SLC counsel in drawing the conclusions laid out in the SLC Report.

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[507] Pls. AB 53.
[508] *Id.* at 54–55.
[509] SLC Report 350–51.
[510] *Id.* at 289–92.
[511] Pls. AB at 55.
[512] SLC RB at 27.

I find that Plaintiffs have failed to discredit the legal bases for the conclusions reached by the SLC in its report. Again, however, the burden is on the SLC, and I find that the SLC, via its report, has demonstrated that its conclusions have a reasonable basis.

2. Nally is Independent

"To establish independence the court must be persuaded that the SLC can base its decision on the merits of the issue rather than being governed by extraneous consideration or influences."[513] In determining whether extraneous considerations or influences existed, the Court considers "the members' personal interest in the disputed transaction, and scrutinizes the members' relationship with the interested directors."[514] Where, as here, the SLC has a single member, it is more closely scrutinized and the SLC has the burden of proving that its member was able to bring her business judgment to bear without any suspicion of extraneous influence.[515] I find Nally facially independent, and scrutinize him in light of Plaintiffs' allegations of more cryptic extrinsic conflicts.

a. Nally's Relationship with Gozon

Nally did not join the ABC Board until months after I denied the Company's motion to dismiss this action. He is, therefore, free of the suggestions of liability

[513] *Sutherland v. Sutherland*, 958 A.2d 235, 239 (Del. Ch. 2008) (quotations omitted).
[514] *Id.* (quotations omitted).
[515] *Lewis v. Fuqua*, 502 A.2d 962, 967 (Del. Ch. 1985).

that caused me to allow this matter to proceed derivatively.[516] I will focus my analysis of Nally's independence on whether his relationships "with [D]efendants are of such a nature that they might have caused [Nally] to consider factors other than the best interests of the corporation in making [his] decision to move for dismissal."[517] Here, Nally did not have a relationship with any of the named Defendants prior to joining the Board. The only relationship that Plaintiffs point to is between Nally and a *nonparty* Board member, Gozon, who served as ABC's Chairman from 2006 to 2016.[518] Nally asserts that this relationship is limited to seeing Gozon on occasion at a golf club where they are both members and serve on the board.[519] This is not disabling or suspicious.

Plaintiffs, however, contend that this relationship is closer, and is sufficient to undermine Nally's independence. Plaintiffs point to Nally's admission that the golf club is an important outlet for him and his wife, both socially and through his ability to serve in leadership at the golf club.[520] Further, Plaintiffs attack the SLC's alleged failure to disclose that Gozon was on the golf club's nominating committee that is charged with nominating directors to the golf club's board.[521] Plaintiffs speculate

[516] *See Teamsters I*, 2020 WL 5028065, at *3–4, 25.
[517] *London*, 2010 WL 877528, at *13.
[518] Pls. AB 60–61.
[519] SLC OB 44 (citing Tr. of Deposition of Dennis Nally ("Nally Tr.") at 34:22–36:16, Ex. A to Transmittal Aff. of Thomas P. Will, Dkt. No. 99).
[520] Pls. AB 61 (citing Nally Tr. at 35:10–36:16).
[521] *Id.* at 61.

that Gozon nominated Nally for his initial term of the golf club's board (and renominated him during the pendency of this litigation).[522]

Moreover, Plaintiffs allege that dismissing this derivative lawsuit would inherently benefit Gozon, despite his non-Defendant status, because this litigation implicates actions taken during Gozon's tenure as the former chairman of the ABC Board during the Relevant Period and would, therefore, expose Gozon to potential litigation or, at the very least, reputational harm and personal embarrassment.[523] However, Gozon is not a named defendant in the instant action and therefore is not an "interested director[]" for purposes of *Zapata*'s first prong.[524] Even if I were to assume that Gozon's previous role as chairman of the ABC Board during the Relevant Period was sufficient to make Gozon an interested director such that his relationship with Nally needs to be more closely examined, Nally and Gozon's service on the board of the golf club is, in and of itself, insufficient to compromise Nally's independence.[525] While Plaintiffs contend that Gozon was likely instrumental in Nally being nominated for his seat on the golf club's board, the evidence shows that Gozon was not a member of the nominating committee until

[522] *Id.* at 61–62.
[523] *Id.* at 63–64.
[524] *Sutherland*, 958 A.2d at 239.
[525] *See, e.g., In re Walt Disney Co. Deriv. Litig.*, 731 A.2d 342, 357 (Del. Ch. 1998), *rev'd on other grounds sub. nom. Brehm v. Eisner*, 746 A.2d 244 (Del. 2000).

after Nally's appointment in 2018.[526] I find this relationship too attenuated to disable reliance on Nally's exercise of judgment in the best interest of ABC.

b. Nally's Ability to be Impartial in Light of His Historical Involvement with Lawsuits

Next, Plaintiffs argue that Nally is incapable of considering the merits of this action because (1) Nally was involved in (but not a party to) a separate class action lawsuit that alleged that his former employer PwC violated the FCA (the "Arkansas Class Action") and (2) through the course of his employment with PwC, Nally acquired an allegedly "long history of adversarial litigation against (and multi-million settlements secured by) the *law firms* representing Plaintiffs."[527] Plaintiffs do not cite to any case law to support their contentions that either of these allegations would have an impact on Nally's independence.[528] Nor do Plaintiffs allege how Nally's experience with his former employer's entirely separate, now-concluded suit, alleging different facts, makes him personally interested in the instant action. Their theory instead seems to be that Nally should be suspected to have sympathy for the Devil, having been accused of being associated with devils, himself.

First, Plaintiffs allege that Nally's involvement in the Arkansas Class Action gave Nally personal experience with pertinent issues such as allegations of

[526] *See* Aff. of Thomas P. Will Supp. SLC RB, Ex. I, Dkt. No. 109.
[527] Pls. AB 57–60, 64–66 (emphasis in original).
[528] *See id.*

fraudulent overbilling, a whistleblower *qui tam* complaint, and a DOJ investigation and civil action alleging FCA violations.[529] These personal experiences allegedly explain why Nally, in Plaintiffs' opinion, failed to meaningfully investigate similar issues in the instant lawsuit.[530] Contrary to these allegations, Nally's involvement in the Arkansas Class Action was limited to the court determining, over PwC's objection, that Nally had relevant knowledge and should be deposed.[531] Nally was not a named defendant in the Arkansas Class Action, nor was he implicated in the alleged misconduct.[532] Given Nally's limited role and that I have already determined that Nally conducted a thorough and good faith investigation of the issues which Plaintiffs allege are "striking[ly] similar[]",[533] I find that Nally's involvement in the Arkansas Class Action does not raise a genuine issue with respect to Nally's independence.

Next, Plaintiffs assert that Nally's long history of adversarial litigation involving Plaintiffs' counsel's law firms makes it "reasonable to infer that Nally may harbor bias against Plaintiffs' counsel or class actions in general."[534] Specifically, Plaintiffs' law firms brought multiple class action suits against PwC during Nally's tenure as the chairman of PwC's U.S. affiliate and PwC International, resulting in

[529] *Id.* at 57–60.
[530] *Id.*
[531] SLC RB 28.
[532] *Id.*
[533] Pls. AB 58.
[534] *Id.* at 65.

PwC paying out millions to settle those suits.[535] There are no allegations that Nally was personally involved in those suits, nor are there allegations that Nally was even aware of the attorneys or the law firms representing the plaintiffs in those suits.[536] Plaintiffs' argument, as I understand it, is that even if Nally were otherwise able to conduct an independent investigation in the best interests of ABC, once he learned that his nemeses, these class action attorneys, represented Plaintiffs, he was willing to skew the investigation to vindicate some personal animosity. This is, I suppose, a theory, but not one which deserves serious consideration on these facts.

In sum, neither Nally's relationship with Gozon, nor Nally's limited involvement in the Arkansas Class Action, nor Nally's history with Plaintiffs' law firms are enough to establish a genuine dispute of material fact as to Nally's independence. Therefore, I find that the SLC has met its burden in establishing Nally's independence.

B. Zapata*'s Second Prong*

The second prong of *Zapata* can be described as a "fiduciary out" for the Court, giving it a method to review and, if warranted, set aside conclusions not disabled under a prong one analysis, but which nonetheless cause the Court to harbor doubts as to whether dismissal is in the corporate interest. Under this prong, "the

[535] *Id.*
[536] SLC RB 32.

trial court's task. . . is to determine whether the SLC's recommended result falls within a range of reasonableness that a disinterested and independent decision maker for the corporation, not acting under any compulsion and with the benefit of the information then available, could reasonably accept."[537] The purpose of *Zapata* prong two is "to thwart instances where corporate actions meet the criteria of step one, but the result does not appear to satisfy its spirit, or where corporation actions would simply prematurely terminate a stockholder grievance deserving of further consideration in the corporation's interest."[538]

I have already concluded that the SLC conducted an independent, good faith, and reasonable investigation that resulted in conclusions not "'irrational' or 'egregious' or some other extreme[]" invoking *Zapata*'s second prong.[539] Where, as here, however, the stockholder-Plaintiffs have not only pointed to substantial corporate trauma but have withstood the rigors of a motion to dismiss under Rule 23.1, I think it is incumbent upon the Court, in review of a special litigation committee's motion to dismiss, to go beyond a review of independence and reasonableness of the scope of the investigation and the bases for its conclusion. The Court should, implicitly in its prong one analysis or explicitly via prong two, apply its own judgment of the reasonableness of the special litigation committee's

[537] *In re Primedia, Inc. S'holder Litig.*, 67 A.3d 455, 468 (Del. Ch. 2013).
[538] *Zapata*, 430 A.2d at 789.
[539] *Kindt v. Lund*, 2003 WL 21453879, at *3 (Del. Ch. May 30, 2003).

conclusions as well. Because such an analysis is implicit in the review of the SLC and its motion, *supra*, I need not formally address prong two—I do not find that a dismissal here tends to implicate a result problematic to the corporate weal. For the sake of completeness, however, I will briefly address my findings were I to invoke the second prong. I largely limit myself here to the *Caremark* claims against the Director Defendants, since that was the sole ground found in *Teamsters I* to justify the stockholder-Plaintiffs proceeding derivativity.[540]

First, I must address the underlying corporate trauma that the Plaintiffs are trying to vindicate via this action. I acknowledge that the Company has paid hundreds of millions of dollars to settle the DOJ's civil and criminal investigations. Plaintiffs assert as well that this action may be the only opportunity for the Company's stockholders to have a meaningful role in addressing the Company's compliance and oversight deficiencies through governance reforms.[541] Nonetheless, for this litigation to come to a conclusion in favor of ABC, the Court would have to conclude that the Defendant Directors' oversight was so inexplicably lax that it amounted to bad faith, a knowing abdication of duty. The evidence before me, including the facts found by the SLC, does not support such a conclusion, nor does it indicate that material facts in this regard are in dispute. Given the facts of record,

[540] *Teamsters I*, 2020 WL 5028065, at *26.
[541] Pls. AB 68–69.

it is unlikely that Plaintiffs could prove either prong of a *Caremark* claim. Finding such, with the benefit of the information that the SLC acquired through its investigation, I would conclude under *Zapata*'s second prong that the litigation is unlikely to benefit ABC, and that the SLC's recommendation to dismiss this action was reasonable.

III. CONCLUSION

The SLC has met its burden in demonstrating that it conducted an independent, good faith, and reasonable investigation of the allegations contained in Plaintiffs' complaint. Its conclusion to seek dismissal of this action rests on a reasonable basis. The SLC's motion to dismiss is therefore GRANTED. The parties should provide an appropriate form of order.

Exhibit A

Term	Definition
ABC/AmerisourceBergen/the Company	AmerisourceBergen Corp.
ABDC	AmerisourceBergen Drug Corp.
ABSG/Specialty Group	AmerisourceBergen Specialty Group
AKS	Anti-Kickback Statute
ASP	average sales price
Board	AmerisourceBergen's Board of Directors
CCC	Chief Compliance Counsel
CCO	Chief Compliance Officer
CER	Capital Expenditure Report
cGMPs	Current Good Manufacturing Practices
CIA	Corporate Integrity Agreement
CIR	Compliance Incident Report
CSPs	Compounded Sterile Preparations
CSRA	Corporate Security and Regulatory Affairs
DEA	Drug Enforcement Administration
DOJ	Department of Justice
DOT/FAA	Department of Transportation
EPA	Environmental Protection Agency
FAC	Mullen's First Amended *Qui Tam* Complaint
FCA	Federal Claims Act
FDA	Food and Drug Administration
FDCA	Food, Drug, and Cosmetic Act
FDMA	Food and Drug Administration Modernization Act
GPO	Group Purchasing Organization
Internal Audit	ABC's Internal Audit Department
ION	International Oncology Network
MII/the Pharmacy	Medical Initiatives, Inc. d/b/a Oncology Supply Pharmacy Service
OS	ASD Specialty Healthcare, LLC d/b/a Oncology Supply

OSHA	Occupational Safety & Health Administration
PFS Program	Pre-Filled Syringe Program
SLC	Special Litigation Committee
USP	U.S. Pharmacopeia