IN THE COURT OF CHANCERY OF THE STATE OF DELAWARE

ALFRED T. GIULIANO, as Plan Administrator for VJGJ, Inc. (f/k/a Teligent, Inc.),	)	
Plaintiff,	)	
v.	)	C.A. No. 2021-0452-KSJM
JASON GRENFELL-GARDNER, STEVEN KOEHLER, BHASKAR CHAUDHURI, JAMES C. GALE, STEPHEN RICHARDSON, and DAMIAN FINIO,	)	
Defendants.	)	

MEMORANDUM OPINION

Date Submitted: February 11, 2025
Date Decided: September 2, 2025

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McCORMICK, C.

This is a *Caremark*[1] case. The plaintiff alleges that former directors and officers of a pharmaceutical company failed to oversee regulatory risks in a manner that ultimately bankrupted the company. Although the alleged oversight failures are not uncommon, this *Caremark* case is unusual because it is not asserted derivatively. Rather, the plan administrator appointed by the bankruptcy court caused the company's successor in interest to bring this action directly. That is, the company allegedly harmed by the defendants' conduct is the plaintiff. This means that the complaint is not subject to the demand requirement. This also means that the plaintiff had complete access to the company's books and records—including emails between members of management—when crafting its claims. The defendants have moved to dismiss the complaint for failure to state a claim. Given the plaintiff's relative procedural and informational advantage compared to other *Caremark* plaintiffs, it should be no surprise that the complaint states a claim, at least as to most of the defendants. The motion is denied as to the defendant directors and two officers but granted as to the CFO.

I. FACTUAL BACKGROUND

The facts are drawn from the Amended Complaint and the documents it incorporates by reference (the "Amended Complaint").[2]

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

[2] C.A. No. 2021-0452-KSJM, Docket ("Dkt.") 31 ("Mowery Aff."), Ex. 1 ("Am. Compl.").

A. Teligent Lacks Any Reporting Structure Regarding FDA Compliance.

Teligent (or the "Company") was a New Jersey-based generic pharmaceutical company that manufactured and sold topical creams and injectable drugs in the United States. As a pharmaceutical company, Teligent was required to comply with federal Food and Drug Administration ("FDA") regulations. Those regulations included good manufacturing practices and laboratory controls and testing.

Also, Teligent required FDA approval of its Abbreviated New Drug Applications ("ANDAs") to manufacture its products. The FDA refuses to approve applications if a company is not complying with FDA regulations. If a company is noncompliant, it cannot manufacture its products. If no products, then no revenue.

Despite the mission-critical nature of FDA compliance to Teligent's business, Teligent's Board of Directors (the "Board") had no committee charged with overseeing it. The Board had an Audit Committee, but it focused exclusively on SEC compliance and not FDA compliance. This is inferred from the fact that the minutes of the 30 committee meetings held between 2017 and 2021 contain no mention of FDA regulations or compliance.[3]

The Board never instituted a reporting system regarding FDA compliance, not even after it became aware of potential FDA violations during a November 2017 Board meeting. Indeed, the Board renewed its committee charters on April 3, 2018, and made no changes. Teligent's then-former CFO Jenniffer Collins raised concerns

[3] *See id.* ¶¶ 253–256.

about the scope of the Audit Committee's charter a few weeks later, on April 18, 2018. She had received a draft audit committee charter from an outside law firm that was more comprehensive than Teligent's charter. She emailed then-CFO Damian Finio suggesting that Teligent consider adopting the draft. Finio did not act on this advice.

B. FDA Concerns Escalate Beginning In 2016 Through 2021.

The FDA visited Teligent's main lab, the Buena Facility, unannounced on September 12, 2016. It is generally FDA protocol for the FDA inspector to discuss her observations with the company's senior management at the end of an inspection. This is so that "there is a full understanding of what the observations are and what they mean."[4] The FDA also issues a Form 483, or "483 Letter," to "management at the conclusion of an inspection when an investigator has observed any conditions that in their judgment may constitute violations."[5] The FDA will sometimes issue warning letters for "violations of regulatory significance," which are "violations that may lead to enforcement action if not promptly and adequately corrected."[6]

After the September 2016 inspection, continuing through 2021, the FDA issued four 483 Letters, four follow-up letters to the 483 Letters, and one warning letter to Teligent (together, the "FDA Letters"). The FDA Letters came in as follows:

- On September 16, 2016, Teligent received a 483 Letter citing five "clear, specific and significant" observations about Teligent's manufacturing

[4] *Id.* ¶ 85.

[5] *Id.* ¶ 83.

[6] FDA, FDA Regulatory Procedures Manual ch. 4 at 3 (July 2024), *available at* https://www.fda.gov/media/71878/download.

practices.[7] The potential regulatory violations related to the Company's bioequivalence testing for one of its topical ointments.

- On March 3, 2017, Teligent CEO Jason Grenfell-Gardner received a letter from the FDA following up on the September 2016 inspection, which concluded that "you did not adhere to the applicable statutory requirements and FDA regulations governing the conduct of [bioequivalence] studies."[8] The letter "wish[ed] to emphasize" that Teligent had violated two FDA regulations by failing "to meet the regulatory requirements for retention of reserve samples for bioavailability or bioequivalence studies."[9]

- On October 19, 2017, after a second annual inspection, Teligent received a 483 Letter regarding six potential regulatory violations related to the Company's manufacturing and laboratory practices. They included failing to investigate product batches and control tests, and failing to handle materials in a manner to prevent contamination, among other things.

- On April 11, 2018, Grenfell-Gardner received a letter from the FDA following up on the October inspection. The letter classified Teligent's facility as being in a "minimally acceptable state of compliance with regards to current good manufacturing practice," but stated that the letter was "not intended as an endorsement or certification of the facility" and recommended that Teligent correct the identified regulatory issues to avoid official action.[10]

- On May 20, 2019, after a third annual review that lasted an entire month beginning April 2019, Teligent received a third 483 Letter. This one cited ten potential regulatory violations, many of which were identified in prior years.

- On September 5, 2019, Grenfell-Gardner received a letter from the FDA following up on the 2019 inspection. The letter changed the status of the Buena Facility to "official action indicated," as the FDA warned would happen in the April 11, 2018 letter. The classification meant that the Buena Facility was "considered to be in an unacceptable state of compliance with regards to current good manufacturing practice," and

[7] Am. Compl. ¶ 88.

[8] *Id.* ¶ 112.

[9] *Id.* ¶ 113 (alteration in original).

[10] *Id.* ¶¶ 138–39.

as a result, "the FDA may withhold approval of any pending applications or supplements in which this facility is listed."[11]

- On November 26, 2019, Teligent received a warning letter regarding "significant violations of current good manufacturing practice . . . regulations."[12] The letter concluded that because Teligent's operations did not conform to current good manufacturing processes, Teligent's products were "adulterated."[13] The letter focused on four violations: Teligent's "failure to investigate product batches that failed tests," "Teligent's failure to follow an adequate written testing program to assess the stability of its drug products[,]" "Teligent's failure to follow adequate written procedures regarding complaints about its drug products," and "Teligent's failure to establish written procedures for production . . . designed to assure the drug products Teligent was making had the identity, strength, quality, and purity they purport . . . to possess."[14]

- On August 13, 2020, after Teligent responded to the warning letter, the FDA responded via a letter stating that it had "reviewed [Teligent's] responses to the Warning Letter and deem them to be inadequate as [Teligent has] failed to address and/or provide supporting documentation to several of the concerns raised in the letter."[15] The FDA letter rejected "Teligent's request for a records-only inspection in lieu of an in-person inspection" and informed the Company that the "effectiveness of [its] corrective actions [would] be evaluated during a subsequent, future inspection."[16]

- On August 31, 2021, following an inspection that took over a month and half to complete, Teligent received a 483 Letter regarding 15 potential regulatory violations related to the Company's manufacturing and laboratory practices.

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[11] *Id.* ¶ 164.

[12] *Id.* ¶ 167 (quoting Warning Letter).

[13] *Id.*

[14] *Id.* ¶ 168.

[15] *Id.* ¶ 191.

[16] *Id.* ¶ 193 (second alteration in original).

Teligent's Board held a meeting less than a week after the September 2016 inspection and 483 Letter issuance, but CEO Grenfell-Gardner and Chief Scientific Officer Stephen Richardson did not inform the Board about the inspection or 483 Letter.

Before the September 2016 meeting, Grenfell-Gardner and Richardson discussed over email whether to add a slide to the Board presentation about the inspection. Grenfell-Gardner wrote, "there is nothing in the slides about the FDA inspection. I think we should probably have something in there, no?"[17] Richardson rejected the idea, responding, "my view is no. We need to advise, but formal slides tend to indicate we know exactly where we are going. But we need to be aligned on what we say."[18] Neither the Board minutes from the September 2016 Board meeting nor the slide deck presented at the meeting contain any reference to the 2016 483 Letter or inspection.

The first indication of Board discussion concerning the FDA issues occurred over a year later. Minutes of a November 3, 2017 Board meeting reflect that Grenfell-Gardner provided the Board with an overview of the October 2017 inspection, noting the October 19, 2017 483 Letter. He stated that he "believed there would not be an adverse impact on future approvals out of the facility."[19] Directors Chaudhuri, Gale, and Koehler attended the meeting. The report does not appear to have been made

[17] *Id.* ¶ 102 (cleaned up).

[18] *Id.* ¶ 103 (cleaned up).

[19] *Id.* ¶ 271.

due to any reporting system, but rather, at management's election. According to the Amended Complaint, the Board was also informed of the 2019 483 Letter and the 2019 Warning Letter.

The Company acted in response to the FDA Letters, but the Amended Complaint does not attribute that action to the Board. Following receipt of the 2016 483 Letter, Teligent engaged The Weinberg Group to help revise its standard operating procedures and conduct a mock FDA audit. The Amended Complaint alleges that the Board never asked The Weinberg Group to attend a meeting and did not supervise its work. In 2017, the Company hired Validant to help set up a microbiology lab and aseptic program. In 2018, Teligent expanded Validant's role to include "remediation services such as conducting laboratory investigations into out of specification test results and writing manufacturing process SOPs."[20] The Amended Complaint is silent as to whether the Board authorized this conduct or engaged with Validant.

Although the Company took measures in response to the FDA Letters, none of them worked. And the violations worsened each year.

Portions of the facilities were dramatically non-compliant with FDA regulations. In April 2019, Grenfell-Gardner emailed the General Manager of one of Teligent's facilities asking when the facility would be out of its then-active drug compounding area because he wanted the "space to be condemned before [an

[20] *Id.* ¶ 382.

upcoming FDA] inspection."[21] The manager responded that the area would be "decommissioned before the FDA arrives" and noted that he did not want "anyone from the FDA walking in that area again."[22] Grenfell-Gardner responded, "Yeah, I would prefer almost *to drywall it off* . . . until we are ready to move."[23] The manager replied, "[t]hat was the plan. *We don't have enough lipstick for that pig*."[24]

Teligent employees were not informed of FDA manufacturing regulations. In May 2019, the Company's Vice President of Quality sent an email to Grenfell-Gardner and Richardson requesting that the Company buy and distribute pocket guides on the FDA's Current Good Manufacturing Practice regulations to employees. Per the FDA's website, the "CGMP" regulations were established to ensure "proper design, monitoring, and control of manufacturing processes and facilities."[25] In requesting the pocket guides, the VP of Quality noted that some employees said that they "had never seen [the CGMP regulation] book" before.[26] Later in the email exchange, one of Teligent's training managers noted that she had "been rebuffed

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[21] Screenshot of April 2019 Email Chain, *in* Am. Compl. at 53.

[22] *Id*.

[23] *Id*. (emphasis added).

[24] *Id*. (emphasis added).

[25] *Facts About the Current Good Manufacturing Practice (CGMP)*, FDA (Jan. 21, 2025), https://www.fda.gov/drugs/pharmaceutical-quality-resources/facts-about-current-good-manufacturing-practice-cgmp?_hsenc=p2ANqtz-_wTgMtFtJF4kYYDOPhT8Ax38FIGfL0LlnLicV-4mAemmVQLk0imQORObBLPVuopltev0My.

[26] Am. Compl. ¶ 322 (cleaned up).

about the need for thorough training," and further noted: "[i]t is a battle that I have fought and lost."[27]

Teligent's remediation consultant, Validant, underperformed, went unpaid, and ultimately bailed. In late 2019, Validant threatened to sue the Company over more than $500,000 in unpaid invoices. The Amended Complaint alleges that Teligent had withheld payment because it believed that Validant had substantially underperformed. CFO Finio expressed concern to Teligent's General Counsel about the estimated $3.3 million the Company had already spent on Validant, noting "we told the [B]oard we'd spend around $1m in round 1 and potentially another $1m depending on their observations . . . . so . . . Validant made way more off of us than they were expecting."[28] Teligent and Validant settled their dispute over the outstanding invoices for $445,000 in early November 2019.

Two weeks after settling Validant's unpaid invoices, Teligent received its harshest FDA review yet, the 2019 Warning Letter. Following receipt of the Warning Letter, Teligent engaged Jeff Yuen and Associates to be "an unbiased, independent third-party assessor of Teligent's remediation efforts."[29] Despite these efforts, Teligent still continued to struggle with FDA compliance.

Teligent's public disclosures do not reflect its deteriorating FDA compliance. Teligent's 2016 10-K did not mention the 2016 483 Letter. Teligent's 2017 10-K

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[27] Screenshot of May 2019 Email Chain, *in* Am. Compl. at 56.

[28] Am. Compl. ¶ 392.

[29] *Id.* ¶ 405.

inaccurately stated that the Company had an "FDA-registered, [Current Good Manufacturing Processes]-compliant facility."[30] Teligent's 2018 10-K repeated this representation.

C. Teligent Files For Bankruptcy In Late 2021.

On October 14, 2021, six weeks after receiving the last 483 Letter, Teligent filed for Chapter 11 bankruptcy in Delaware bankruptcy court. The bankruptcy court appointed a plan administrator to oversee Teligent's bankruptcy process. The plan administrator was appointed the sole director of Teligent's successor company, VJGJ, Inc.

D. This Litigation

In May 2021, before Teligent received its fifth FDA Letter, Gary Buchanan filed this action asserting derivative claims on behalf of Teligent against Grenfell-Gardner and former Teligent directors Carole Ben-Maimon, John Celentano, Bhaskar Chaudhuri, James C. Gale, Steven Koehler, and Thomas J. Sabatino Jr. Buchanan's complaint alleged that Teligent's directors breached their fiduciary duties by making materially misleading public statements and failing to disclose key information relating to the FDA Letters.[31]

The plan administrator decided to pursue the derivative claims filed by Buchanan. On May 23, 2023, this court entered an order realigning Teligent as the

[30] *Id.* ¶ 444.

[31] *See generally* Dkt. 1.

plaintiff in this action and substituting the plan administrator in place of Teligent as the real party in interest ("Plaintiff").[32]

On June 27, 2023, Plaintiff filed a Notice of Removal pursuant to 28 U.S.C. § 1452, removing this action to bankruptcy court.[33] On July 14, Plaintiff filed a consent motion to change venue in a related ongoing federal derivative action (the "Federal Action") to bankruptcy court. On July 27, the defendants in the derivative actions filed a motion to consolidate and remand the cases to this court, arguing that both mandatory and permissive abstention applied.

On August 10, 2023, Plaintiff filed identical amended complaints for the derivative actions with the bankruptcy court. The amended complaints asserted three causes of action under the federal bankruptcy laws and four causes of action under Delaware law against a subset of the original defendants as well as three Teligent officers. The defendants are Chaudhuri, Finio, Gale, Grenfell-Gardner, Koehler, and Richardson (collectively, "Defendants").

On September 12, Defendants renewed their motion to remand the Delaware law claims to this court. On March 24, 2024, the bankruptcy court issued an order granting Defendants' motion and staying the bankruptcy law claims. On April 8, the plan administrator filed a motion for reconsideration and clarification, seeking to stay the Federal Action while the identical derivative claims from the Buchanan action were remanded to this court. On May 23, 2024, the bankruptcy court granted the

[32] Dkt. 13.

[33] Dkt. 14.

plan administrator's motion. The operative complaint in this action is the amended complaint Plaintiff filed in bankruptcy court.[34]

The Amended Complaint asserts four causes of action. In Counts I and II, Plaintiff asserts *Caremark* claims against Grenfell-Gardner, Koehler, Chaudhuri, and Gale in their capacity as directors (collectively, the "Director Defendants"), as well as Richardson. In Count III, Plaintiff asserts a claim for breach of the duty of loyalty against the Director Defendants and against Grenfell-Gardner, Richardson, and Finio in their capacities as officers (collectively, the "Officer Defendants").[35] In Count IV, Plaintiff asserts a claim for breach of the duty of care against the Officer Defendants.

On July 12, 2024, Defendants moved to dismiss the Amended Complaint.[36] The parties completed briefing the motion on September 16, 2024.[37] The court heard argument on February 11, 2025.[38]

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[34] *See* Mowery Aff., Ex. 1. The Plan Administrator is instructed to file the Amended Complaint on the docket in this action as a separate pleading.

[35] Plaintiff includes Richardson in Counts I and II and the Director Defendants in Count III, but it is unclear why. *See* Am. Compl. ¶¶ 508, 517, 533–535. The wrongful conduct underlying each count appears the same. And *Caremark* claims are loyalty claims.

[36] Dkt. 28.

[37] *See* Dkts. 29 ("Defs.' Opening Br."), 33 ("Pl.'s Answering Br."), 37 ("Defs.' Reply Br.").

[38] *See* Dkt. 44 (Judicial Action Form).

II. LEGAL ANALYSIS

After Teligent was substituted as Plaintiff for Buchanan to pursue this action directly, this suit ceased being derivative. Court of Chancery Rule 23.1 thus does not apply. Defendants move to dismiss the Amended Complaint under Rule 12(b)(6) for failure to state a claim.

"[T]he governing pleading standard in Delaware to survive a motion to dismiss is reasonable 'conceivability.'"[39] When considering such a motion, the court must "accept all well-pleaded factual allegations in the [c]omplaint as true, . . . draw all reasonable inferences in favor of the plaintiff, and deny the motion unless the plaintiff could not recover under any reasonably conceivable set of circumstances susceptible of proof."[40] The court, however, need not "accept conclusory allegations unsupported by specific facts or . . . draw unreasonable inferences in favor of the non-moving party."[41]

A. The Director Defendants

"A breach of fiduciary duty claim that seeks to hold directors accountable for the consequences of a corporate trauma is known colloquially as a *Caremark* claim[.]"[42] "[A] *Caremark* claim contends that the directors set in motion or 'allowed

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[39] *Cent. Mortg. Co. v. Morgan Stanley Mortg. Cap. Hldgs. LLC*, 27 A.3d 531, 537 (Del. 2011).

[40] *Id.* at 536 (citing *Savor, Inc. v. FMR Corp.*, 812 A.2d 894, 896–97 (Del. 2002)).

[41] *Price v. E.I. DuPont de Nemours & Co.*, 26 A.3d 162, 166 (Del. 2011) (citing *Clinton v. Enter. Rent-A-Car Co.*, 977 A.2d 892, 895 (Del. 2009)), *overruled on other grounds by*, *Ramsey v. Ga. S. Univ. Advanced Dev. Ctr.*, 189 A.3d 1255 (Del. 2018).

[42] *La. Mun. Police Empls.' Ret. Sys. v. Pyott*, 46 A.3d 313, 340 (Del. Ch. 2012), *rev'd on other grounds*, 74 A.3d 612 (Del. 2013).

a situation to develop and continue which exposed the corporation to enormous legal liability and that in doing so they violated a duty to be active monitors of corporate performance.'"[43]

A well-pled *Caremark* claim must allege that "(a) [a company's] directors utterly failed to implement any reporting or information system or controls; *or* (b) having implemented such a system or controls, consciously failed to monitor or oversee its operations thus disabling themselves from being informed of risks or problems requiring their attention."[44] Such claims are referred to as "prong-one" and "prong-two" claims, or "information-systems" and "red-flags" claims, respectively.[45] "In either case, imposition of liability requires a showing that the directors knew that they were not discharging their fiduciary obligations."[46]

Plaintiff asserts both types of *Caremark* claims against the Director Defendants. In Count I, Plaintiff claims that the Director Defendants failed to implement a reporting system that would keep the Board informed of Teligent's regulatory compliance issues. In Count II, Plaintiff claims that although Teligent lacked a reporting system, the Director Defendants became aware of the FDA Letters and consciously ignored them, prompting the Company's bankruptcy.

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[43] *Id*. (quoting *Caremark*, 698 A.2d at 967).

[44] *Stone ex rel. AmSouth Bancorporation v. Ritter*, 911 A.2d 362, 370 (Del. 2006) (emphasis in original).

[45] *See In re McDonald's Corp. S'holder Deriv. Litig.*, 289 A.3d 343, 359–60 (Del. Ch. 2023).

[46] *Stone*, 911 A.2d at 370.

1. The Information-Systems Claim

In the words of *Caremark*, "only a sustained or systematic failure of the board to exercise oversight—such as an utter failure to attempt to assure a reasonable information and reporting system exists—will establish the lack of good faith that is a necessary condition to liability."[47] When adopting a version of this quote as the prong-one standard, the *Stone* court was "quite deliberate" in endorsing the adverb "utterly"—a "linguistically extreme formulation" intended "to set a high bar when articulating the standard to hold directors personally liable for a failure of oversight under the first *Caremark* prong."[48] This high bar gives boards a wide berth to exercise discretion with respect to business risk. As the Delaware Supreme Court later emphasized, "directors have great discretion to design context- and industry-specific approaches tailored to their companies' businesses and resources."[49]

Although a board has great latitude in crafting and implementing its risk-monitoring and reporting system, "*Caremark* does have a bottom-line requirement that is important: the board must make a good faith effort—*i.e.*, try—to put in place a reasonable board-level system of monitoring and reporting."[50] To avoid rendering this bottom-line requirement "a chimera,"[51] this court must look beyond the mere

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[47] *Caremark*, 698 A.2d at 971.

[48] *Fisher on Behalf of LendingClub Corp. v. Sanborn*, 2021 WL 1197577, at *11 (Del. Ch. Mar. 30, 2021) (quoting *Horman v. Abney*, 2017 WL 242571, at *8 n.46 (Del. Ch. Jan. 19, 2017)).

[49] *Marchand v. Barnhill*, 212 A.3d 805, 821 (Del. 2019).

[50] *Id.*

[51] *Id.* at 824.

existence of a system to some indicia of effectiveness when determining whether a board made the required good faith effort.[52]

This bottom-line requirement calls for a substantive analysis at the pleading stage. The court must evaluate whether the system was "reasonably designed to provide to senior management and to the board itself timely, accurate information sufficient to allow management and the board . . . to reach informed judgments concerning both the corporation's compliance with law and its business performance."[53]

The Delaware Supreme Court clarified that a reasonably designed monitoring and reporting system, at a minimum, addresses "mission critical" risks.[54] In *Marchand*, the ice cream manufacturer Blue Bell Creameries USA, Inc. caused a listeria outbreak that required a massive product recall, shut down production, and killed three people. The plaintiff filed claims to hold the Blue Bell board accountable for the corporate trauma resulting from the listeria outbreak, advancing as its

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[52] *See, e.g.*, *Hughes v. Hu*, 2020 WL 1987029, at *14 (Del. Ch. Apr. 27, 2020) ("The mere existence of an audit committee and the hiring of an auditor does not provide universal protection against a *Caremark* claim."); *Rich ex rel. Fuqi Int'l, Inc. v. Yu Kwai Chong*, 66 A.3d 963, 983 (Del. Ch. 2013) (holding that the plaintiff adequately alleged a *Caremark* claim, despite the existence of an audit committee and independent auditor, where the company had no "meaningful controls in place").

[53] *Caremark*, 698 A.2d at 970.

[54] *Marchand*, 212 A.3d at 824.

principal argument a prong-one theory that the company lacked board-level reporting systems sufficient to satisfy *Caremark*'s baseline requirements.[55]

The trial court granted the defendant's Rule 23.1 motion, observing that the complaint described "at length the intense regulatory scrutiny" under which the company operated, and affirmatively alleged that the company distributed a "sanitation manual with standard operating and reporting procedures, and promulgated written procedures for processing and reporting consumer complaints."[56] The court further observed that the company's Vice President of Plant Operations was responsible for operations, reported directly to the CEO, and with the CEO provided regular reports to the board and the company's independent safety auditor.[57] These allegations led the court to conclude that the plaintiff "really attempts to challenge . . . not the *existence* of monitoring and reporting controls, but the *effectiveness* of monitoring and reporting controls in particular instances."[58] Citing the linguistically extreme formulation of *Caremark*'s first prong, the trial court concluded that "[t]his is not a valid theory."[59]

The Delaware Supreme Court reversed on appeal, rejecting the finding that the affirmative allegations of the complaint evidenced a monitoring and reporting

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[55] *Marchand v. Barnhill*, 2018 WL 4657159, at *17 (Del. Ch. Sept. 27, 2018), *rev'd*, 212 A.3d 805 (2019).

[56] *Id.*

[57] *Id.*

[58] *Id.* at *18 (emphasis in original).

[59] *Id.*; *see also Sanborn*, 2021 WL 1197577, at *11.

system at Blue Bell sufficient to satisfy *Caremark*. Despite the essential aspect of food safety to Blue Bell's business, its board left compliance with food safety issues to management and received reports on food safety only at management's discretion.

The board's failure gave rise to *Caremark* claims. As the high court explained, "*Caremark* does have a bottom-line requirement that is important: the board must make a good faith effort—*i.e.*, try—to put in place a reasonable board-level system of monitoring and reporting."[60] Restating the rule of *Caremark*, the court concluded that "[a]lthough *Caremark* may not require as much as some commentators wish, it does require that a board make a good faith effort to put in place a reasonable system of monitoring and reporting about the corporation's central compliance risks."[61]

Teligent pleads many of the same circumstances and information-systems deficiencies that were alleged in *Marchand*: It operated in a heavily regulated

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[60] *Marchand*, 212 A.3d at 821.

[61] *Marchand*, 212 A.3d at 824. *Marchand* has been interpreted by this court as standing for the proposition that "when a company operates in an environment where externally imposed regulations govern its 'mission critical' operations, the board's oversight function must be more rigorously exercised." *In re Clovis Oncology, Inc. Deriv. Litig.*, 2019 WL 4850188, at *13 (Del. Ch. Oct. 1, 2019); *see also In re Boeing Co. Deriv. Litig.*, 2021 WL 4059934, at *26 & n.244 (Del. Ch. Sept. 7, 2021) (same, quoting *Clovis*). And that is fair. But this summary of *Marchand* risks supplanting the thematically dominant "mission critical" rhetoric with the "central compliance risks" rule statement, as Vice Chancellor Laster observed in *In re McDonald's Corporation Shareholder Derivative Litigation*. 291 A.3d at 678. The language is important. As the Vice Chancellor also observed, although it is fair to infer that all "essential and mission critical risks" qualify as "central compliance risks," it is also possible that some "central compliance risks" may not reach the level of "essential and mission critical." *Id.*

industry.[62] It lacked a board committee responsible for overseeing any central compliance risk, or aspect of regulatory compliance.[63] It lacked processes and protocols requiring management to keep the board apprised of central compliance risks, or any regulatory compliance risks.[64] Plus it lacked training protocols designed to inform employees of central compliance risks.[65] This is about as close to an utter failure as it gets.

In response, the Director Defendants point to email correspondence between members of management as evidence that they did in fact relay news of the 2016 FDA Letter to the Board, even though the Board minutes do not reflect any report.[66] They argue that the employees' concern about a lack of training "suggests Teligent could have improved training, not that it was not training employees at all or that the

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[62] *Compare* Am. Compl. ¶ 355 ("Teligent was subject to . . . FDA regulations designed to protect human health."), *with Marchand*, 212 A.3d at 810 ("As a U.S. food manufacturer, Blue Bell operates in a heavily regulated industry.").

[63] *Compare* Am. Compl. ¶¶ 236–237 ("[N]o Board committee had the responsibility to oversee and ensure Teligent's compliance with FDA regulations."), *with Marchand*, 212 A.3d at 813 ("Blue Bell had no board committee charged with monitoring food safety.").

[64] *Compare* Am. Compl. ¶¶ 98–111 ("If the [Director] Defendants had a reporting system in place . . . they would have learned about the [2016] FDA inspection" and the 2016 483 Letter.), *with Marchand*, 212 A.3d at 822 (Blue Bell had "no regular process or protocols that required management to keep the board apprised of food safety compliance practices, risks, or reports existed.").

[65] *See* Am. Comp. ¶¶ 223 ("[Good Manufacturing Practices] training is not conducted on a continuing basis and with sufficient frequency . . . ." (quoting 2019 483 Letter)), 226 ("[E]mployees engaged in the manufacture, processing, packing and holding of a drug product lack[ed] the education, training and experience required to perform their assigned functions." (quoting 2019 483 Letter)).

[66] Defs.' Opening Br. at 8–9.

Board was unaware that training was an issue at the Company."[67] They say that Teligent's Board must have properly exercised its oversight function because it knew of the FDA Letters and inspections.[68] During oral argument, counsel similarly argued that FDA compliance was "too important for the [C]ompany not to be discussed."[69] But these arguments ignore the well-pled allegations and call for defense-friendly inferences the court cannot make at this procedural stage.[70]

Even if the court accepts the Director Defendants' factual arguments, they support an inference that management could have made the Board aware of specific issues at specific times. They do not reflect that the Board adopted an information system for overseeing central compliance risks. *Marchand* explains that a board's reporting practice that allows management to elect to report (or not) on central compliance risks fails *Caremark*'s baseline requirement. It is reasonably conceivable that the Board failed to do so here.

Plaintiff has adequately alleged an information-systems claim. Defendants' motion to dismiss Count I is denied.

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[67] *Id*. at 43.

[68] *Id*. at 26 ("The Amended Complaint's allegations belie any finding that the Board Defendants 'utterly failed' to exercise oversight because the Board knew of the various inspections conducted by the FDA, as well as the subsequent letters detailing the FDA's observations.").

[69] Dkt. 45 at 18:18–22.

[70] *See Gantler v. Stephens*, 965 A.2d 695, 709 (Del. 2009) ("On a motion to dismiss, the Court of Chancery [is] not free to disregard [a] reasonable inference, or to discount it by weighing it against other, perhaps contrary, inferences that might also be drawn.").

2. The Red-Flags Claim

To adequately allege a red-flags claim, "a *Caremark* plaintiff can plead that 'the directors were conscious of the fact that they were not doing their jobs,' and that they ignored 'red flags' indicating misconduct in defiance of their duties."[71] "Red flags 'are only useful when they are either waved in one's face or displayed so that they are visible to the careful observer.'"[72] In other words, a plaintiff must plead the existence of red flags that "should have put the director defendants on notice of the offensive conduct or the weakness of the corporation's internal controls."[73]

Plaintiff alleges that FDA Letters were red flags, the Director Defendants were made aware of these letters beginning in February 2017, and they consciously disregarded them.[74] But these allegations are unreasonable to infer. Where management has wide latitude to fashion what it reports to the Board, and the alleged red flag is delivered and framed by management, it can be hard to understand what the Board was told. In these circumstances, it is more challenging to answer basic questions posed by the red-flag analysis: Did the flag look red? Was it waved in front of the Board?

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[71] *David B. Shaev Profit Sharing Account v. Armstrong*, 2006 WL 391931, at *5 (Del. Ch. Feb. 13, 2006), *aff'd*, 911 A.2d 802 (Del. 2006) (footnote omitted).

[72] *Wood v. Baum*, 953 A.2d 136, 143 (Del. 2008) (quoting *In re Citigroup Inc. S'holders Litig.*, 2003 WL 21384599, at *2 (Del. Ch. June 5, 2003) *aff'd sub nom. Rabinovitz v. Shapiro*, 839 A.2d 666 (Del. 2003)).

[73] *Citigroup*, 2003 WL 21384599, at *2.

[74] Pl's. Answering Br. at 38–39.

These problems are front and center here. Plaintiff's allegations suggest that the allegedly red flags were communicated to the Board at the election of management, who framed the information presented. For example, before the September 2016 Board meeting, Richardson told Grenfell-Gardner that "we need to be aligned on what we say" on the topic of FDA compliance.[75] And during the November 2017 meeting, Grenfell-Gardner stated that he "believed there would not be an adverse impact on future approvals out of the facility" due to the FDA compliance issues.[76] The Amended Complaint creates the impression that the Board was uninformed of the significance of the FDA compliance issues, not that they consciously disregarded red flags waved in their face. Teligent's Board-authorized public disclosures, which lack any indication of the Company's deteriorating FDA compliance, reinforce this impression.

The requirement that Plaintiff plead facts sufficient to support that a director consciously disregarded a red flag also underscores the limited utility of Plaintiff's informational advantage relative to stockholder plaintiffs. Plaintiff is the Company, not the former Board. Plaintiff has access to management's emails, not the Director Defendants' communications. When pleading its red-flag theory, therefore, Plaintiff is informationally situated similar to a stockholder plaintiff in derivative actions.

[75] Am. Compl. ¶ 103.

[76] *Id.* ¶ 271.

Plaintiff analogizes its claims to three cases where the plaintiff adequately alleged a red-flag theory: *In re Clovis Oncology, Inc.*,[77] *Teamsters Loc. 443 Health Services & Insurance Plan v. Chou*,[78] and *In re Boeing*.[79] But each is distinguishable.

In *Clovis*, the plaintiffs adequately alleged a red-flag claim but not an information-systems claim. The board established a committee "'specifically charged' with 'providing general compliance oversight with respect to Federal health care program requirements and FDA requirements.'"[80] The reports arising from that committee were sufficiently detailed to constitute red flags. As the plaintiffs acknowledged: "the Board reviewed detailed information regarding [the drug trial] at each Board meeting."[81] Here, Plaintiff alleges that there was no committee established to monitor FDA compliance, and Plaintiff identifies no Board reports containing detailed information on the Company's FDA compliance issues.

In *Chou*, the court denied the defendants' motion to dismiss the plaintiffs' red-flags claim. The court held that the plaintiffs had adequately pled the existence of two red flags: a lawsuit initiated by a former employee, which contained allegations regarding the company's illicit use of overfill medication, and a subpoena the DOJ issued to the company based on those allegations.[82] Those red flags came from

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[77] 2019 WL 4850188 (Del. Ch. Oct. 1, 2019).

[78] 2020 WL 5028065 (Del. Ch. Aug. 24, 2020).

[79] 2021 WL 4059934 (Del. Ch. Sept. 7, 2021).

[80] *Clovis*, 2019 WL 4850188, at *13. (cleaned up).

[81] *Id*. (cleaned up).

[82] *Chou*, 2020 WL 5028065, at *21–24.

external sources. And it was reasonable to infer that the board knew of each red flag because the board had disclosed them in different SEC filings it had submitted and signed.[83] Here, the red flags were elevated to the Board from management, and Plaintiff can point to no SEC disclosures revealing the Board's knowledge of the red flags. To the contrary, Plaintiff alleges that the Company's SEC filings fail to disclose the FDA compliance issues.

In *Boeing*, the court denied a motion to dismiss a claim that the company's board "turn[ed] a blind eye to a red flag representing airplane safety problems."[84] One of the red flags at issue was a highly publicized plane crash involving a Boeing 737 MAX in 2018. The court noted that the crash "and its causes were widely reported in the media; those reports reached the Board; and the Board ignored them."[85] The company's board minutes reflected that the board discussed the 2018 crash but decided to forgo an internal investigation.[86] Here, the alleged red flags were the FDA Letters, not sensational and tragic news events. And the Company's Board minutes do not support the inference that Plaintiff seeks.

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[83] *See id*. at *21 ("[T]he Board *did* sign [the company's] 2010 and 2011 Form 10-Ks that disclosed [the former employee's] suit. I may consequently draw the inference that the Defendant Directors then serving on the Board were aware of [the former employee's] allegations." (emphasis in original)); *id.* at *24 ("As to the [DOJ] subpoena, I can draw a reasonable inference of the Board's knowledge because the Board disclosed the subpoena in [the company's] 10-K.").

[84] *Boeing*, 2021 WL 4059934, at *1.

[85] *Id*. at *34.

[86] *Id*. at *15.

This is a classic instance when an information-system theory and red-flag theory covering the same events stand in tension. The strength of one undermines the other. Often, the red-flag theory undermines an inference that the board failed to implement a reporting system; where it is reasonably conceivable that the board received and ignored red flags, it is hard to infer that the board failed to create a system for reporting them.[87] Here, the opposite is true—well-pled allegations concerning the lack of a reporting system makes it hard to infer that the Board received red flags of non-compliance. For that reason, Plaintiff has failed to adequately allege a red-flags theory. Count II is dismissed.

B. The Officer Defendants

Officers owe the same fiduciary duties as directors, including oversight obligations, although the scope and application of those duties is situationally specific.[88]

In Count III, Plaintiff asserts both types of *Caremark* claims against the Officer Defendants, alleging that they breached their duty of loyalty by failing to "attempt to implement a reporting system and by consciously ignoring red flags regarding Teligent's FDA compliance. . . ."[89]

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[87] *See, e.g.*, *City of Detroit Police & Fire Ret. Sys. v. Hamrock*, 2022 WL 2387653, at *12 (Del. Ch. June 30, 2022) ("[T]he plaintiff must concede the existence of a board-level monitoring system to plead under prong two that the board ignored red flags generated by that system").

[88] *McDonald's*, 289 A.3d at 362–74.

[89] Am. Compl. ¶ 529.

Officers owe oversight obligations. An officer has an obligation to establish a reporting system.[90] To hold an officer liable for information-system violations under *Caremark*, "the alleged oversight violation would need to fall within [the corporate officer's] sphere of corporate responsibility."[91] That means, for example, a "Chief Financial Officer is responsible for financial oversight and for making a good faith effort to establish reasonable information systems to cover that area[,]" but an "executive officer in charge of sales and marketing is not responsible for . . . financial or legal reporting systems."[92] An officer also has a duty, when confronted with red flags, to "either address them or report upward to more senior officers or to the board."[93]

To state a claim for breach of fiduciary duties against an officer who is also a director, the complaint must "highlight . . . specific actions [she] undertook as an officer (as distinct from actions as a director)."[94]

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[90] *McDonald's*, 289 A.3d at 361 ("For relevant and timely information to reach the board, the officers who serve as the day-to-day managers of the entity must make a good faith effort to ensure that information systems are in place so that the officers receive relevant and timely information that they can provide to the directors. . . . It follows that officers must have a duty to make a good faith effort to establish an information system as a predicate to fulfilling their obligation to provide information to the board.").

[91] *Segway Inc. v. Hong Cai*, 2023 WL 8643017, at *4 (Del. Ch. Dec. 14, 2023); *see also McDonald's*, 289 A.3d at 370 ("[O]fficers generally only will be responsible for addressing or reporting red flags within their areas of responsibility[.]").

[92] *McDonald's*, 289 A.3d at 369–70.

[93] *Id.*

[94] *Arnold v. Soc'y for Sav. Bancorp, Inc.*, 650 A.2d 1270, 1288 (Del. 1994).

Plaintiff adequately alleges at least a red-flags claim against Grenfell-Gardner and Richardson. Just as it is reasonably conceivable that the Board failed to receive notice of red flags, it is reasonably conceivable that Grenfell-Gardner and Richardson were aware of the red flags and failed to report them to the Board.

CFO Finio is differently situated. FDA compliance is not typically conceived of as a financial risk, although it has financial implications. Tacitly acknowledging this, Plaintiff does not fault Finio for failing to report the FDA issues. Rather, Plaintiff claims that Finio breached his oversight obligations by failing to inform the Board of "what Teligent paid Validant or the settlement over unpaid invoices – presumably to keep his job after telling the [B]oard Validant would cost millions less."[95] It is not clear, however, what harm Plaintiff contends flowed from Finio's alleged non-disclosure. Plaintiff does not allege that this information was a red flag that could have tipped the Board off to the Company's regulatory compliance issues. Nor does Plaintiff allege that Finio should have but failed to implement a reporting system that would have informed the Board of Validant's costs. Count III does not state a claim against Finio.

Count IV is framed as a claim for breach of the duty of care. A breach of the duty of care exists where the fiduciary acted with gross negligence.[96] "Gross negligence involves more than simple carelessness. To plead gross negligence, a

[95] Pl.'s Answering Br. at 51.

[96] *Morrison v. Berry*, 2019 WL 7369431, at *22 (Del. Ch. Dec. 31, 2019).

plaintiff must allege 'conduct that constitutes reckless indifference or actions that are without the bounds of reason.'"[97]

Although framed as a duty of care claim, Count IV alleges what are in essence oversight violations. *Stone* states that oversight claims require a showing of bad faith.[98] Officers cannot face *Caremark* liability for gross negligence. Count IV is dismissed.[99]

III. CONCLUSION

Counts II and IV are dismissed and Count III is dismissed as to Finio. The motion to dismiss is otherwise denied.

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[97] *Id*. (quoting *Zucker v. Hassell*, 2016 WL 7011351, at *7 (Del. Ch. Nov. 30, 2016)).

[98] *See Stone*, 911 A.2d at 367 ("Critical to this demand excused argument is the fact that the directors' potential personal liability depends upon whether or not their conduct can be exculpated by the section 102(b)(7) provision contained in the [company's] certificate of incorporation.").

[99] If oversight claims against officers *do not* require a showing of bad faith, or if Count IV states something other than an oversight claim, then the outcome is the same. Grenfell-Gardner and Richardson breached their duties of loyalty as officers. It is reasonably conceivable that the failings of Grenfell-Gardner and Richardson, if not caused by bad faith, were the result of reckless indifference. It is not reasonably conceivable that Finio was recklessly indifferent in reporting to the Board.