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A Director’s Mission: Understanding, Monitoring and Accurately Reporting Mission Critical Operations

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Insights

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On October 1, 2019, the Court of Chancery rendered an opinion in *In re Clovis Oncology, Inc. Derivative Litigation*,[1] denying a motion to dismiss a *Caremark* claim for breach of fiduciary duty and reinforcing a director’s duty to monitor and oversee corporate operations. While not a decision on the merits, the Clovis decision highlights the board’s important role in understanding, overseeing and accurately reporting “mission critical” operations and is of particular importance to companies operating in highly regulated industries.

Legal Framework

Under *In re Caremark Int’l Derivative Litig.*[2] and *Marchand v. Barnhill*[3], directors have a duty to exercise oversight and to monitor the corporation’s operational viability, legal compliance, and financial performance. If a board utterly fails to implement reasonable reporting systems or to monitor those systems to ensure that they are providing reliable information regarding operating results, legal compliance or financial performance, the board acts in bad faith in breach of its duty of loyalty. A board fails to adequately monitor its reporting systems when a “red flag” of non-compliance is brought to the board’s attention and ignored. When a company’s

"mission critical operations" are governed by externally imposed regulations, the oversight function must be more rigorously exercised; boards must be sensitive to compliance issues intrinsically critical to the companies they govern.

Facts

In *Clovis*, the plaintiffs alleged that the Clovis directors breached their fiduciary duty by failing to adequately monitor and oversee the clinical trial for the company's lead drug candidate. Specifically, the plaintiffs alleged that the directors failed to ensure that the clinical trial was conducted in accordance with trial protocols and FDA regulations. Clovis, a "monoline" biopharmaceutical company, had no approved products or revenues and only one lead drug candidate, which it was developing for the treatment of lung cancer and was progressing in a Phase 2 clinical trial. The trial was examining the drug's objective response rate ("ORR"), a measure of tumor shrinkage that would be reviewed by the FDA in determining whether to approve the drug. The study also required certain reporting and disclosure of side effects experienced by patients known as serious adverse events ("SAEs").

The plaintiffs alleged that the company continuously disclosed an ORR of approximately 60% in press releases and other filings with the SEC and FDA notwithstanding that the board knew that the reported percentage was overstated because it included "unconfirmed" responses (i.e., those that had not been verified with adequate confirmatory scans demonstrating tumor shrinkage). The plaintiffs assert that unconfirmed responses were not permitted under the trial protocol and would not be considered by the FDA. According to the complaint, despite this knowledge, the company continued to publicly disclose ORR higher than would actually be considered in the FDA's review. It was only when the FDA requested additional data and a meeting with Clovis executives that the company publicly disclosed the "confirmed" ORR, which at 28%, was markedly lower than previous disclosures. After that announcement, Clovis' stock price dropped precipitously. In addition to faulty ORR disclosures, the complaint alleged numerous violations of the trial protocol's reporting requirements for SAEs, which went unreported and undisclosed publicly. After Clovis' stock price drop, the company and its CEO and CFO were named as defendants in securities fraud class action suits, which resulted in a $142 million cash and stock settlement, the CFO's disgorgement of unjust profits, and a consent decree and civil penalties against the company and its executives.

Ruling and Takeaways

Defendants moved to dismiss the complaint arguing plaintiffs had not stated a viable failure to monitor claim under *Caremark* and its progeny. While noting that the defendants disputed several factual and regulatory issues alleged in the complaint, the Court denied the motion to dismiss, finding that a plausible claim had been pleaded and permitting the suit to continue. For Clovis, the trial protocol and FDA regulatory framework governing the clinical trial was mission critical to the company. This drug was Clovis' only promising product and the regulatory framework was the most central compliance issue facing the company. The Court was satisfied that the plaintiff pled facts showing the board received several red flags that were consciously ignored in failing to update or correct public disclosures of ORRs or

SAEs. Many of the directors had extensive experience in the pharmaceutical industry; therefore, it could be inferred that they understood the distinction between confirmed and unconfirmed responses and the implications thereof.

The *Clovis* decision did not reach the merits of the claim, but it marks the second time this year that a Delaware court has declined to dismiss a *Caremark* claim at the pleadings stage. It is too soon to tell if this marks a new trend in how *Caremark* claims are viewed by the courts or if they remain, as former Chancellor Allen noted, "possibly the most difficult theory in corporation law upon which a plaintiff might hope to win a judgment." In *Clovis*, the Court distinguished between the board's oversight of the company's management of business risk inherent in a company's business plan from the board's oversight of the company's compliance with positive law, including regulatory mandates, and identified that failure to monitor positive law is more likely to give rise to oversight liability. *Clovis* reinforces that the board's oversight function does not stop in merely establishing compliance controls, but extends to active monitoring and reporting. This is especially true for companies that operate in heavily regulated industries or have one or two key product lines. For directors on these boards, it is important to monitor compliance controls for products or services that are vital to the operation of the business.