



Observations on *Clovis Oncology, Inc.* Derivative Litigation

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Editor's note: Peter J. Walsh, Jr. is a partner, and Nicholas D. Mozal is counsel, at Potter Anderson & Corroon LLP. This post is based on their Potter Anderson memorandum and is part of the [Delaware law series](#); links to other posts in the series are available [here](#).

On October 1, the Delaware Court of Chancery denied a motion to dismiss a Caremark claim in *In re Clovis Oncology, Inc. Derivative Litigation*. Under *In re Caremark Int'l Inc. Deriv. Litig.*, 698 A.2d 959 (Del. Ch. 1996), directors have a duty to exercise oversight and monitor a corporation's operational viability, legal compliance, and financial performance. *Clovis* is the first decision to allow a *Caremark* claim to proceed beyond the pleadings since the Delaware Supreme Court's June 2019 decision in *Marchand v. Barnhill*, which reversed a Court of Chancery decision dismissing a *Caremark* claim. The *Clovis* decision highlights (i) the importance of board level efforts to oversee compliance with governing law and regulatory mandates, particularly in situations where compliance issues are critical to a "monoline" company, and (ii) how stockholders are using books and records demands under 8 *Del. C.* § 220 to pursue fiduciary claims focused on those same compliance issues.

The complaint's allegations focused on Clovis Oncology, a "monoline" biopharmaceutical company with no products, no sales revenue, and only a single promising drug in its pipeline. Clovis started clinical trials for its lung cancer drug, committing to a well-known clinical trial protocol and FDA regulations. The Court described the Company's "serial non-compliance" with the protocol and regulations, with the most crucial being its reporting of the drug's objective response rate ("ORR"). The ORR measured the percentage of patients experiencing meaningful tumor shrinkage verified by confirmation scans. The Company consistently stated to the public and regulators that the drug achieved certain ORR rates. The board, however, received reports that the ORR was inflated because it included responses not verified by confirmation scans. The opinion details at length the discrepancies between the information the board received, and the Company's public statements, describing the board as approving an annual report "[w]ith hands on their ears to muffle the alarms." Once the FDA identified the same discrepancies, the Company announced the actual clinical results. The fallout included a large drop in the Company's stock price, and significant securities fraud and regulatory settlements and penalties.

The Court of Chancery reviewed these allegations and concluded the board faced a substantial likelihood of liability under *Caremark* such that it could not impartially consider a stockholder demand. Focusing on the board's alleged failure to monitor established systems in the face of "red flags," the Court described *Marchand* as requiring 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." Because "protocols and related FDA regulations" governing the company's clinical trial were "mission critical regulatory issues" for the Company's "mission critical product," the Court was satisfied that, at the pleadings stage, the plaintiffs had pled the board consciously ignored red flags by failing to correct the Company's reporting.

In reaching that conclusion, the Court noted that it was not considering some of the Company's books and records provided to the plaintiffs that the defendants believed undercut the complaint's allegations. Although the parties had agreed that any books and records provided to the plaintiffs would be incorporated by reference into the complaint, documents "hand selected by the company, cannot be offered to rewrite an otherwise well-pled complaint." The Court thus limited its analysis to the allegations of the complaint, and did not rely upon documents identified by defendants that "might suggest the facts are otherwise." The *Clovis* decision thus not only illustrates the type of "red flags" sufficient to overcome the high bar to stating a Caremark claim, but also counsels caution in the handling of books and records demands preceding such claims.