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DELAWARE CHANCERY COURT RAISES REQUIREMENTS FOR BOARDS OF EARLY-STAGE PHARMACEUTICAL COMPANIES TO COMPLY WITH THEIR DUTY OF CARE

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Boards of pharmaceutical companies should take notice of the recent opinion coming out of the Delaware Court of Chancery and Vice Chancellor Joseph Slights in *In re Clovis Oncology, Inc. Derivative Litigation*, which breathes new life into certain *Caremark* claims against boards of directors.[1]

It has been clear since the *Caremark* decision in 1996[2] that Boards of Directors owe to shareholders a two-pronged "duty to monitor": *i*) the duty to set up regulatory oversight programs that keep the board informed of a company's state of compliance; and *ii*) the duty to oversee those programs. But the Delaware Chancery Courts have repeatedly stressed that *Caremark* claims are difficult to plead and prove because they require a showing that the directors completely failed to implement a regulatory reporting system *or* consciously failed to monitor regulatory operations.

In October, the court in *Clovis Oncology* declined to dismiss the plaintiffs' allegations that the Clovis Board breached its duty to monitor regulatory operations based on allegedly ignoring "red flags" in management presentations. The complaint in *Clovis Oncology* is likely to provide a roadmap for plaintiffs in future shareholder litigation where shareholders seek to recover damages resulting from a U.S. Food & Drug Administration ("FDA") decision not to approve an investigational drug or other adverse regulatory decisions.

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To guard against *Caremark* claims, pharmaceutical companies must design and implement robust monitoring programs over clinical studies.

Summary of the *Clovis* Case

Clovis Oncology is a small biopharmaceutical company that developed an investigational drug, Rociletinib ("Roci"), to treat lung cancer.[3] The clinical trial protocol for Roci incorporated a protocol known as RECIST, a well-accepted protocol for assessing responses in clinical trials for cancer therapies.[4] RECIST assesses the success of a clinical trial based on the investigational drug's objective response rate ("ORR")—a metric that measures meaningful tumor shrinkage in reaction to the drug.[5] Meaningful tumor shrinkage in RECIST protocols is evaluated based on initial observations of tumor shrinkage that has been "confirmed" in a subsequent scan, and only "confirmed" responses can be included in the ORR calculation.[6]

Clovis Oncology allegedly made public statements referencing an ORR rate for Roci that included both "confirmed" and "unconfirmed" tumor shrinkage, in violation of the RECIST protocol.[7] Plaintiffs filed their complaint after a 70% stock drop associated with a company press release that provided the ORR based only on "confirmed" tumor shrinkage (which at that point was 28% to 34%), and after another 17% drop in stock price when the FDA voted to delay action on Roci's new drug application until the company provided additional data.[8]

According to the plaintiffs, Clovis Oncology's Board knew that management had misrepresented Roci's ORR to investors but did not correct the misrepresentation because Roci was the most promising of Clovis' three developmental drugs and was key to Clovis' prospects. Roci was also in a "race for FDA approval" with a similar drug developed by AstraZeneca.[9]

In its decision, the Delaware Chancery Court found that the Clovis Board had sufficient "reporting or information system or controls" to avoid liability under the first prong of *Caremark*.[10] But the Court found that the plaintiffs had sufficiently pleaded a claim under the second prong of *Caremark*—alleging that the Board failed to use the information provided by Clovis management to monitor the Roci clinical trial adequately and that the Board ignored red flags.

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Notably, the so-called "red flags" that allegedly alerted the Board about these issues were not particularly glaring. For example, the Court expected the Board to understand that management's statement to the Board—that the ORR "would improve 'as patients get to their second and third scans' "—somehow conveyed that the ORR metric presented to them included "confirmed" and "unconfirmed" tumor shrinkage, an expectation that assumes the Board was intimately familiar with both the clinical trial protocol and the industry convention.[11]

Taken to the logical extreme, these types of expectations could effectively require Boards to: *i*) anticipate the types of scientific statements that a company may make to shareholders; *ii*) possess the requisite scientific and medical expertise to ensure that statements made to the public do not omit information that could be perceived as material; and *iii*) actively participate in the review and clearance process for company statements. If a Board fails to take any of these steps, a plaintiff could allege that a Board ignored "red flags" similar to those in the *Clovis Oncology* case anytime a plaintiff also alleges that pharmaceutical company made a scientific statement that omits material information.

Implications of *Clovis Oncology*

Significantly, the defendant's arguments in *Clovis Oncology* were complicated by bad optics—including ongoing investigations by the FDA and the Securities and Exchange Commission ("SEC")—and these bad facts may have led to bad law. In any event, the Court's reasoning arguably imposes new requirements on board members of early-stage pharmaceutical companies to ensure that they are complying with their duty of care.

When *Caremark* Claims May Be More Easily Proved

Under *Caremark* and its progeny, a shareholder in a Delaware corporation can bring a derivative claim against the company's Board for failing to monitor operations. Of course, Delaware courts recognize the distribution of duties between the Board and management. Consequently, Delaware courts have bluntly stated that *Caremark* claims are "possibly the most difficult theory in corporation law upon which a plaintiff might hope to win a judgment."[12]

However, the *Clovis Oncology* Court distinguished "the board's oversight of a company's *management of business risk* that is inherent in its business plan from the board's oversight of the company's *compliance with positive law*—including regulatory mandates."[13]

Relying on recent decisions in *Marchand v. Barnhill*[14] and *In re Facebook, Inc. Section 220 Litigation*,[15] the Court indicated that *Caremark* claims premised on the Board's failure to oversee regulatory compliance are easier to plead and prove: "[W]hen 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."[16] Indeed, *Clovis Oncology* emphatically rejected the view that clinical protocols are operational details that can be left to management, finding that reliance on management to ensure compliance with the clinical protocol would be "unreasonable in light of the Board presentations and the competitive pressures Roci faced."[17]

Clovis Oncology therefore upsets the general distribution of duties between management and the Board, requiring a deeper level of Board involvement in clinical studies for investigational drugs that are key to the company's success.[18]

Lessons for Boards

In light of *Clovis Oncology*, boards of pharmaceutical companies should rethink their oversight of clinical trials. Under certain circumstances, the board should take a more active role in overseeing clinical trials than they may have historically:

- ***Boards of smaller companies should pay particularly close attention to clinical protocols***—It is unlikely that a court would require the same level of oversight from the board of a large, established pharmaceutical company with numerous drugs in the market and many ongoing trials. Therefore, board oversight will be particularly important for companies with few or no approved drugs on the market and a small number of investigational drugs in development.

- ***Boards should pay increasing attention to later-stage investigational drugs***—Board oversight should increase as a drug becomes more material to the company's financial outlook. Generally, as a drug moves through FDA's approval process, management will increasingly tout its potential, investors will more closely follow developments, and analysts will incorporate the drug into their projections. Therefore, the Board may be able to rely on management to comply with clinical protocols for Stage 1 and 2 trials, but nonetheless need to understand more fully the clinical protocol for a Stage 3 trial.

- ***Relevant specialized experience on the board may make it harder to defeat an ineffective oversight claim***—The *Clovis Oncology* Court determined that the Board was aware of the clinical protocol allegedly violated in part because "[t]he Board was comprised of experts and the RECIST criteria are well-known in the pharmaceutical industry."[19] Although pharmaceutical companies are generally well served by board members with scientific and medical training, such specialized experience may make it harder to defeat ineffective oversight claims when the "red flags" pertain to scientific and medical issues.

- ***Board members should compare management's board presentations with public disclosures of clinical results***—Board members may be subject to liability under securities laws for management's allegedly false or misleading statements.[20] In addition to understanding the clinical protocols, the Board should assure itself that the internally reported results match any externally reported data. Boards should exercise caution about the release of preliminary clinical data; and when data is preliminary or subject to additional rounds of testing, boards must ensure that appropriate cautionary language is provided to ensure that investors understand that final or confirmed results may differ materially from the preliminary results.

Conclusion

The opinion in *Clovis Oncology* focused on the second *Caremark* duty, and found that the plaintiffs had adequately pled that Clovis' board had failed to monitor the oversight program that was in place and had, in fact, ignored red flags. Given that failure-to-monitor claims were previously perceived as hard to prove, the complaint in *Clovis Oncology* is likely to provide a roadmap for plaintiffs in shareholder litigation to come. Specifically, similar allegations are likely to emerge when shareholders seek to recover losses from stock drops due to FDA decisions not to approve an investigational drug.

ENDNOTES:

[1]*In re Clovis Oncology, Inc. Derivative Litigation*, 2019 WL 4850188 (Del. Ch. 2019).

[2]*In re Caremark Intern. Inc. Derivative Litigation*, 698 A.2d 959 (Del. Ch. 1996).

[3]*Caremark* at *10.

[4]*Caremark* at *11-12.

[5]*Caremark* at *12.

[6]*Caremark* at *14.

[7]*Caremark* at *14-17.

[8]*Caremark* at *21-22.

[9]*Caremark* at *38-42.

[10]*Caremark* at *36-37.

[11]*Caremark* at 15 (internal record citation omitted). According to the Court, "[b]y definition, then, [this] ORR was partially based on unconfirmed results" and "not RECIST compliant."

[12]*Caremark* at 967; *see also Stone ex rel. AmSouth Bancorporation v. Ritter*, 911 A.2d 362 (Del. 2006) ("[A] claim that directors are subject to personal liability for employee failures is possibly the most difficult theory in corporation law upon which a plaintiff might hope to win a judgment." (internal quotation marks omitted)).

[13]*Clovis Oncology*, slip op. at *34-35.

[14]*Marchand v. Barnhill*, 212 A.3d 805 (Del. 2019). In *Marchand*, the Delaware Supreme Court found to be adequately pleaded a *Caremark* claim alleging that the Blue Bell board "failed to implement any system to monitor Blue Bell's food safety performance or compliance," and thereby allowed Blue Bell to distribute mass quantities of ice cream tainted by listeria. Marchand at 809.

[15]*In re Facebook, Inc. Section 220 Litigation*, 2019 WL 2320842 (Del. Ch. 2019), as revised, (May 31, 2019) and judgment entered, 2019 WL 2616518 (Del. Ch. 2019). In *Facebook*, the Delaware Chancery Court found that plaintiff shareholders had sufficiently pleaded (to justify a books and records request) a *Caremark* claim alleging that the Facebook board failed to monitor Facebook's compliance with a consent decree from the Federal Trade Commission related to data security and privacy. Facebook at *2.

[16]*Clovis*, slip. op. at 36 (citing *Marchand*, 212 A.3d at 824).

[17]*Clovis* at 40 n.210.

[18]The *Clovis Oncology* Court did note that Plaintiffs will have difficulty proving causation but declined to consider causation on a motion to dismiss. *Clovis* at 42 n.217 ("Plaintiffs' causation case will be challenging. It appears that Roci was not what Clovis hoped it would be. If that proves true, the Plaintiffs may have difficulty connecting the oversight failure(s) to the corporate trauma. It might well be that Roci simply did not work and nothing the Board did or did not do would change that."). Of course, this is cold comfort to potential defendants, because surviving a motion to dismiss dramatically increases Plaintiffs' settlement leverage.

[19]*See Clovis* at 39-40 (noting that "[t]he Board was comprised of experts and the RECIST criteria are well-known in the pharmaceutical industry").

[20]Indeed, the Clovis board settled a federal securities class action based on similar allegations for $142 million in cash and Clovis stock. *Clovis* at 26-27.

FROM THE EDITOR

As we approach the end the year, we often spend a moment to reflect back on the biggest stories of the year, as well as looking ahead to what the new year might bring.

And while certainly some major issues came to a head in 2019, the bigger stories may be those that began here and are stretching out into 2020. For example, this issue of how (or whether) the Securities and Exchange Commission will regulate matters pertaining to proxy advisory firms, such as like Glass Lewis and Institutional Shareholder Services ("ISS"). This long-simmering issue came to boil late this year and is likely to play out more fully next year, especially as the corporate annual meeting season gets into full swing. (For more on the SEC's recent moves on this front, check out the SEC/SRO Update in this issue.)

Several members of our Editorial Advisory Board cited this issue as one of the top concerns going into the new year. "Efforts by the SEC to come to grips with the proxy process (perhaps timidly), including the issues surrounding proxy advisory firms and shareholder proposals, is something to stay alert to going forward," advised one member. Indeed, another member said that the recent attack by ISS on the SEC's issuance of guidance on shareholder proposals would likely inflame the issue.

Another topic that is likely to spill over into 2020 is how the SEC and other government regulators will finally deal with cryptocurrency and the robust trading activity that surrounds it. (Again, more on the regulation of cryptocurrency can be found elsewhere in this issue.) "Looking back, the SEC's approach to dealing with crypto-currency offerings, and especially some recent enforcement actions, merits attention," one Board member noted, adding that, looking forward, this situation will likely remain a hot one in the new year.

Certainly, the past year can also be seen as notable for the (continuing) move toward deregulation that has been undertaken by the Trump Administration and has been keenly felt in the securities industry. And as the SEC—now at full strength after several absences over the past couple of years—grapples with how it will oversee such hot-button issues as those described above, other entities will also have their say in the next year. For example, the Supreme Court has already said it would weigh in on several key issues impacting the securities industry, including how the SEC levies and manages financial penalties (the so-called disgorgement issue), which goes to the heart of how the SEC operates.

The old saw about living in interesting times is likely to be replayed in 2020 . . . and we'll be keeping an eager eye on it.

Goodbye & Thank You!

As I wrote this year-end editorial, the exercise was a bit more poignant to me because this issue represents my last at the helm of *Wall Street Lawyer*. My editorial duties will be aptly handled by the publication's new managing editor, Chris O'Leary. I encourage all of you to welcome him heartily.

As I move on, it is with great satisfaction that over the past several years, I was able to continue publishing insightful, cutting-edge analysis of issues of concern to securities industry lawyers, litigators, corporate defense counsel, plaintiffs' counsel, legal scholars, and government regulators. Of course, this task was only made possible by the countless acts of assistance—both in written work and sage advice—from members of our Editorial Advisory Board. This publication seriously wouldn't exist without their contributions, and for that, I am eternally grateful.

—Gregg Wirth, Managing Editor

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