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Gilead Drug Ruling Creates Corporate Governance Dilemma

By Shireen Barday (August 9, 2024)

This article was first published in Law360.

A January decision from the Court of Appeal of the State of California, First Appellate District, in Gilead Sciences Inc. v. Superior Court of the City and County of San Francisco, involving Gilead's alleged delay-for-pay business practices, has drawn significant outcry from all sides.[1]

On one hand, the public is outraged that Gilead may have delayed the commercialization of a safer drug (tenofovir alafenamide, or TAF) for treating HIV/AIDS in order to maximize profits from the drug it already had on the market (tenofovir disoproxil fumarate, or TDF) — allegations Gilead has denied.

On the other hand, businesses in the life science space are outraged that a court in California has upended the well-settled common law rule that a manufacturer can only be held liable for customer injuries if its product was defective in the first place.

That decision, affirmed once on appeal — and now in front of the California Supreme Court — seems to hold that, where a pharmaceutical company has a drug in its pipeline that is safer than another drug it presently has on the market, the company has a duty to commercialize the competing drug with all deliberate speed if there is any indication that the competing drug might be safer or better.

Put otherwise, the California court is saying that companies have a duty to refrain from any commercialization delay for pay today.

While the Gilead court made its pronouncement in the context of interpreting a California tort liability statute, the delay-for-pay holding nevertheless creates an interesting dilemma of corporate governance.

The proposition that corporate officers and directors owe fiduciary duties to shareholders is uncontroversial. Those duties do not require them to maximize short-term profits to the exclusion of other indications of value. As the U.S. Supreme Court pronounced in Burwell v. Hobby Lobby Stores Inc. in 2014, "[m]odern corporate law does not require for-profit corporation to pursue profit at the expense of everything else, and many do not."[2]

But sometimes, maximizing short-term profits is maximizing value more generally and can be consistent with an officer's or a director's fiduciary duties. So, following the money doesn't really tell us whether there is a problem or not.

The case law first recognized such oversight obligations in the landmark case In re: Caremark International Inc. Derivative Litigation, decided by the Delaware Court of Chancery in 1996.

In that case, the board of Caremark International, a Baxter International spinoff, was alleged to have failed to implement sufficient oversight controls and therefore failed to detect significant criminal offenses being committed by Caremark employees.

Recognizing the inherent judgment involved in the many decisions directors are asked to make, the Delaware Court of Chancery articulated a high pleading standard for Caremark claims. In fact, the court held that an oversight claim could be pleaded only in the face of a "systematic failure of the board to exercise oversight — such as an utter failure to attempt to assure a reasonable information and reporting system exists."

These same oversight duties were extended by the court to officers in 2023, in In re: McDonald's Corporation Stockholder Derivative Litigation.[4]

California courts have applied the Delaware standard to oversight liability in the context of fiduciary duties.

Last year, in Kanter v. Reed,[5] the Court of Appeal of the State of California, Second Appellate District, dismissed a complaint against the directors of Southern California Gas Co., who were alleged to have breached their duty to oversee natural gas storage safety at the Aliso Canyon storage facility in the years leading up to the discovery of a leak at that facility.

On appeal, the Court of Appeal made clear that the acceptance of the Caremark standard brought California into compliance with the great majority of jurisdictions in the country, all of which would have applied the Caremark standard under similar circumstances and therefore would likely reach the same conclusion that the directors of Southern California Gas exercised appropriate oversight when they established a committee responsible for natural gas safety and received reports about safety issues from that committee and management.

The policy reasons underlying the body of law governing oversight claims is the same: Absent loyalty issues like bad faith or self-dealing, decisions in the boardroom are left to the sound business judgment of a company's directors.

Indeed, Delaware is so business-focused that it has enacted a new law to ensure corporate boards are able to use their business judgment to sign agreements transferring governance rights to shareholders.

That law, Delaware General Corporation Law Section 122, which went into effect on Aug. 1, was a direct response to a holding from the Delaware Court of Chancery in West Palm Beach Firefighters' Pension Fund v. Moelis & Co.

That holding invalidated a corporate governance agreement between Moelis & Co. and its founder, CEO and chairman, Ken Moelis, on grounds that it impermissibly restricted the ability of the directors to manage the business and affairs of the corporation.[6]

The Legislature swiftly and definitely responded to make clear that even the delegation of control over governance is entrusted to the sound business judgment of directors.

Let's be clear about what that really means: Consistent with Delaware corporate law, governance rights can be bartered and sold and, while we might disagree on the right price, the law now holds expressly that directors may, consistent with their fiduciary duties, sell their decision-making power if the deal makes business sense.

The Gilead decision, by contrast, would impose liability for a decision driven by profit.

As the Court of Appeal wrote: "the critical question ... is simply whether Gilead's years-long delay in bringing TAF to market, despite knowing its equivalent efficacy and superior safety to TDF, breached a duty of reasonable care to users of TDF if the reason was solely to maximize Gilead's profits."[7]

In the context of evaluating fiduciary duties, even if the business decision to delay for pay were protected as a valid exercise of fiduciary duties, will the resulting damages exposure from the scientific negligence in prioritizing profits over product safety be given the same deference?

More complicated still, the Gilead decision leaves open the possibility that mere constructive knowledge of the comparative safety of TAF is enough to expose Gilead to liability for the business decision about when and if to commercialize TAF.[8]

Therefore, it appears that there is also an avenue for hindsight bias as a result of the Gilead decision in that there is a risk of liability to directors or officers from not having been adequately informed about the fact that the scientists should have known better in the first place, something that will only be knowable after the fact: when the competitor drug comes to market.

The issues are particularly remarkable, given the context in which Gilead was operating: The drug on the market, TDF, was approved by the U.S. Food and Drug Administration, adequately disclosed known risks, involved no manufacturing or design defects and, while the competitor product may have looked promising, 25%-30% of drugs fail to receive approval after Phase III, which TAF had not yet reached.

Framed with this context, the decision not to commercialize TAF seems to fit squarely into the sound business judgment with which we vest officers and directors, yet the Gilead decision would nevertheless hold the company liable for this decision.

In this way, the holding in Gilead threatens to undermine long-standing rules of corporate law by exposing life science companies to liability, not for problems associated with existing pharmaceutical products, but for the failure to act on the possibility that the company could make a better or safer product.

This holding, if it stands, seems calculated to hinder future innovation because the message it sends is that there is always risk with hitting pause once on a path to commercialization, and crucially, the associated corporate governance exercise will be one of liability management rather than reasoned business judgment.

Correction: An earlier version of this article included an incorrect title for the author. The error has been corrected.

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[1] Gilead Tenofovir Cases, A165558 (Cal. Court of App. First App. Dist. Div. Four) (Jan. 9, 2024) (appeal from San Francisco City & County Super. Ct. No. CJC-19-005043, JCCP No. 5043).

[2] Burwell v. Hobby Lobby Stores, Inc., No. 13-354 (S. Ct.) (June 30, 2014).

[3] In re Boeing Co. Derivative Litig., 2019-0907 (Del. Ch.) (Sept. 7, 2021).

[4] C.A. No. 2021-0324-JTL (Del. Ch.) (Jan. 25, 2023).

[5] 92 Cal. App. 5th 206.

[6] West Palm Beach Firefighters' Pension Fund v. Moelis & Company, C.A. No. 2023-0309-JTL, at *4 (Del. Ch.) (Feb. 23, 2024).

[7] Gilead Tenofovir Cases, A165558 (Jan. 9, 2024), at *32.

[8] Id. at *12 n.5 ("We therefore analyze plaintiffs' claim as premised on actual knowledge, although we take no position on whether plaintiffs should be permitted to include a constructive knowledge theory on remand, should they seek to do so.")