

“Mission-Critical Risks” and the Fiduciary Duties of Directors of Life Sciences Companies

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In early September, the Delaware Chancery Court allowed a derivative action based on the theory that the board had failed properly to oversee safety risks to proceed against directors of Boeing Co.¹ This decision is the latest in a set of similar decisions, a number of which involved companies in the life sciences sector. Though grounded in Delaware law, the message of these cases appears to be universal: Boards have heightened responsibility to oversee “mission critical” regulatory and safety risks.

In *Boeing*, the plaintiffs alleged that the board had failed to establish a reporting system for airplane safety.² None of the company’s board committees was specifically tasked with overseeing airplane safety,³ and airplane safety was not a regular agenda item at board meetings.⁴ Compounding those issues, management allegedly did not report to the board on safety issues, and the board did not have a means of receiving internal complaints about safety.⁵ Based on these allegations, the court concluded that the plaintiffs had satisfactorily pled that the board had failed in its duty of oversight, and it allowed the case to proceed to further discovery and perhaps trial.

The *Boeing* case is grounded in the Delaware Chancery Court’s *Caremark* decision 25 years ago. In *Caremark*, the court said that directors could be held liable for failure to implement or monitor a system for overseeing corporate compliance but set a high bar for “failure of oversight” claims. Because of that high bar, it has been rare for such claims to survive motions to dismiss, but since 2019, the Delaware courts have allowed six such cases to proceed. Three of those cases — like *Caremark* itself — involved companies in the life sciences or food industries where consumer health and safety issues are of paramount importance. One involved a listeria outbreak in ice cream.⁶ Though the company “nominally complied” with certain relevant Food and Drug Administration (FDA) requirements,⁷ the Delaware Supreme Court allowed the case to proceed, citing, among other factors, that the company lacked

- a board committee to oversee food safety
- a full board-level process to address food safety issues
- a protocol for advising the board of food safety reports
- evidence in board minutes of discussion by the board of food safety issues⁸

A second case alleged that a biotechnology company failed to comply with FDA rules for reporting clinical results.⁹ In that case, the Chancery Court emphasizing that “the board’s oversight function must be more rigorously exercised” for “mission critical” risks.¹⁰ And in a third case, the plaintiffs alleged that the directors had failed properly to oversee compliance at

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a subsidiary specialty pharmacy.¹¹ The court concluded that for a manufacturer of drugs, “[l]aws and regulations governing the health and safety of drugs are ... the ‘most central ... safety and legal compliance issue facing the company’ ” and that a company’s board must actively oversee compliance with such laws and regulations.¹² The message from these cases is clear: Under Delaware law, boards have responsibility to ensure that systems are in place to identify and monitor compliance and safety risks, and they must do so “rigorously” with respect to “mission critical” risks. This message is particularly important for the boards of life sciences companies, which are among the most heavily regulated in the world.

Of course, not all life sciences companies are incorporated in Delaware, but the courts in other jurisdictions frequently look to Delaware law on corporate governance, and — more fundamentally — it makes sense that boards should pay particularly close attention to the most critical issues. Based on this, boards in the life sciences sector should consider the following steps:

- Periodically review their business to identify mission-critical risks.
- Ensure that the board has the right structure to engage in oversight in this area.
 - Consider whether the board has clearly and adequately delegated responsibility for oversight of compliance and safety risk.
 - Consider whether the board should establish a specialized committee for this task.
 - Be sure committee charters clearly reflect the delegated responsibilities.
- Ensure that the board has the right processes to ensure appropriate oversight.
 - Review reporting processes.
 - Establish a regular cadence for discussion of compliance and safety at board meetings.
 - Carefully document board efforts in meeting minutes.
- Ensure that the members of any committee responsible for oversight of mission-critical risk have the appropriate background and experience.

¹ *In re Boeing Co. Derivative Litigation*, 2019-0907 (Dec. Ch. Sept. 7, 2021).

² *In re: Boeing*, slip op at 2.

³ *Id.* at 6.

⁴ *Id.*

⁵ *Id.* at 6.

⁶ *Marchand v. Barnhill*, 212 A.3d 805 (Del. 2019).

⁷ *Id.* at 823 (emphasis added).

⁸ *Id.* at 809.

⁹ *Id.* at *7.

¹⁰ *Id.* at *13.

¹¹ *Id.* at 23-35.

¹² *Id.*