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Compliance Today - October 2020
Tips for optimizing life sciences board oversight over clinical trials

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Life sciences companies wanting to market new drugs, biological products, and medical devices across state lines must conduct clinical trials to obtain approval from the U.S. Food and Drug Administration (FDA) to do so.[1] These companies' compliance professionals and board members face unique and evolving compliance challenges. This article provides practical tips for board members and compliance professionals for optimizing clinical trial oversight. It first reviews the fundamental duty established in the Delaware case of *In re Caremark* to monitor a corporation's legal and regulatory compliance and business performance.[2] Second, it discusses the lack of guidance for life science companies in *Caremark*. Third, it provides practical suggestions for life sciences companies' boards and compliance professionals for fulfilling *Caremark* oversight duties based on analysis of two cases, *Marchand v. Barnhill*[3] and *In re Clovis Oncology*,[4] as well as a review of advice from legal scholars and compliance professionals. It offers suggestions for identifying compliance risks associated with clinical trials. Finally, the article notes challenges that arise from the differing perceptions of *Caremark* duties between compliance professionals and board members, as well as the effect of other incentives to fulfill monitoring duties.

The article does not provide tax, accounting, or legal advice but instead aspires to contribute to fulfilling the compliance profession's duties "to the general public, to employers and clients, and to the legacy of the profession," as noted in the preamble to the Code of Ethics for Health Care Compliance Professionals.[5]

The fundamental *Caremark* duty to monitor

Compliance professionals who are Certified in Healthcare Research Compliance (CHRC)[6] are familiar with board members' duty to monitor, which the Delaware Court of Chancery established in dicta in the *In re Caremark* case.[7] This oversight duty requires directors to "attempt in good faith" to be "reasonably informed" about the corporation to "reach informed judgments concerning both the corporation's compliance with law and its business performance." Directors should assure themselves that "reasonably designed" systems exist that provide timely and accurate information and reports to enable senior management and the board to make "informed judgments" about the corporation's business performance and legal compliance. The *Caremark* court noted the incentives under the Federal Sentencing Guidelines for corporations to establish compliance programs to obtain reduced penalties for compliance failures.[8] In the case of Stone v. Ritter, the Delaware Supreme Court noted that *Caremark* liability for failure to monitor occurs only if shareholder-plaintiffs prove that directors acted in bad faith.[9] Directors' personal liability for failure to monitor under *Caremark* occurs in either of two circumstances: (1) "utter failure" to implement an information and reporting system (Type 1 *Caremark* Claim) or (2) conscious failure to monitor despite having implemented a monitoring system (Type 2 *Caremark* Claim).[10]

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Compliance professionals can enhance their engagement with boards by understanding how boards typically experience Type 1 or Type 2 *Caremark* claims. Disputes usually arise in the context of shareholder derivative litigation. In derivative litigation, shareholder-owners bring an action on behalf of the corporation against present and former directors, officers, or controlling shareholders.[11] In the *Caremark* context, these lawsuits allege that harm resulted to the corporation as a result of directors not fulfilling their duty to monitor under the duty of loyalty. The burden of proof is high because *Caremark* claims can result in directors being personally liable for their breach of the duty of loyalty. Delaware fiduciary law prohibits companies from eliminating a director's personal liability for a breach of the duty of loyalty.[12] The typical *Caremark* claim cases proceed as follows: (1) shareholder plaintiffs present facts to the court that purport to show a board's bad-faith breach of the duty of loyalty, (2) the court reviews the facts under the *Caremark* standards to determine the probability of a successful *Caremark* claim, and (3) the court dismisses the shareholder's case for failure to state a claim because the alleged misconduct does not rise to the level of bad faith.[13] Most *Caremark* claim cases are dismissed.

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