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Emerging Life Sciences Companies  
second edition

Chapter 3

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Corporate Governance Issues

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### CORPORATE GOVERNANCE ISSUES

Corporate governance is a combination of (i) principles, (ii) policies, and (iii) procedures designed to enable the board of directors to manage the Company in accordance with duties owed to stockholders and other Company stakeholders. The board of directors of the Company should understand the issues and challenges presented when governing the Company. The following outline addresses a board of directors' general fiduciary duties and its duties in connection with specific transactions. The outline also addresses certain SEC disclosure challenges faced by public life sciences companies.

#### General Fiduciary Duties

- A. Each director is obligated to act in the best interests of the Company and all of its stockholders
- B. Directors may face personal liability if they breach their fiduciary duties
- C. Duty of care
  - 1. Each director must act on an informed basis, in good faith, and in a manner he or she reasonably believes to be in the best interests of the Company
  - 2. Each director must act with such care as a reasonable person would use under similar circumstances
- D. Duty of loyalty
  - 1. Each director must put the Company's interests ahead of his or her personal interests
  - 2. Each director must refrain from conduct that would injure the Company and its stockholders or deprive them of profit or advantage
- E. Duty of good faith
  - 1. Broader concept (expands duty of care)
  - 2. Requires more active role of oversight by board members
- F. Duty of disclosure or candor
  - 1. Directors have a duty to be truthful when disseminating information to the Company's stockholders

2. Limited disclosure duty to private company stockholders in the absence of contractual information rights
- G. Duty of oversight
1. Directors have a duty to ensure that the Company management adopts an effective program to detect and prevent violations of law—particularly in regulated industries
  2. The board may appoint oversight committees (e.g., audit committee, compensation committee, merger committee)
- H. The Business Judgment Rule—case law created
1. A presumption that directors acted on an informed basis, in good faith, and believing that their action was in the Company’s best interests
  2. Serves as safe harbor from “bad decisions” reviewed in retrospect provided that directors fulfill their duties
  3. Courts generally will not substitute their own notions of what is or is not sound business judgment
- I. Exculpation
1. For example, Section 102(b)(7) of the Delaware General Corporation Law (DGCL) permits a charter provision eliminating the personal liability of a director for breach of fiduciary duty as a director
  2. Section 102(b)(7) does not apply to:
    - a. Any breach of the director’s duty of loyalty
    - b. Acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of the law
    - c. Unlawful payments of dividends or stock redemptions
    - d. Any transaction from which the director derived an improper personal benefit
- J. Indemnification
1. Section 145 of the DGCL permits indemnification of directors for expenses and other losses incurred in connection with litigation and other proceedings relating to their services as directors
  2. Only allowed where the director acted in good faith and in a manner the director reasonably believed to be in or not opposed to the best interests of the Company

### **Merger and Acquisition Transactions: Additional Duty-of-Care Issues**

- A. Heightened duty to inform oneself and be active in sale process

- B. May use outside experts (e.g., investment bankers, valuation consultants, and counsel); however, the involvement of experts does not excuse the directors from actively informing themselves and exercising their own judgment in making the ultimate decision
- C. Consideration of defensive measures

### **Corporate Opportunity Doctrine**

- A. If a director, in his or her role as a director of the Company, is presented with a business opportunity that (i) the Company is financially able to undertake, (ii) falls into the line of the Company's business, and (iii) is of practical advantage to it, the director is prohibited from taking the opportunity for himself or herself
- B. Section 122(17) of the DGCL permits a Company to renounce, in its charter or by action of its board of directors, any interest or expectancy of the corporation in, or in being offered an opportunity to participate in, specified business opportunities that are presented to the corporation or one or more of its officers, directors, or stockholders

### **Interested-Party Transactions**

- A. Who is an interested director?
  - 1. A director is "interested" when he or she, directly or indirectly, has a financial or personal interest in a transaction in which the Company is a party
  - 2. Thus, the duty of loyalty is implicated
- B. When does the Business Judgment Rule apply?
  - 1. The Business Judgment Rule applies if a disinterested majority of the board makes a decision
  - 2. Beware of a "dominated" or "controlled" disinterested majority
- C. Demonstrate the independence of the disinterested majority
  - 1. Form an independent board committee
  - 2. Retain separate advisors, including financial advisors and counsel
  - 3. Exclude the interested directors from the discussions of the independent committee, as well as the vote itself
- D. If the Business Judgment Rule does not apply, then the "entire fairness" standard will apply
  - 1. The "entire fairness" test is met where (i) the procedures followed by the directors in approving the transaction or making the decision were fair to the corporation and all stockholders, and (ii) the substantive terms of the transaction were fair to the corporation and all stockholders

## **Distressed Company Issues**

- A. Expansion of fiduciary duties to creditors as well as stockholders
- B. Does the Business Judgment Rule continue to apply?
  - 1. Unclear
  - 2. Because this issue has not been definitively settled, directors should not assume that they will automatically receive the benefit of the Business Judgment Rule
- C. Increased risks of personal liability
  - 1. For breach of fiduciary duties
  - 2. For nonpayment of wages and trust fund taxes
  - 3. Misrepresentation of the Company's financial condition to creditors
  - 4. D&O insurance may not protect directors

## **SEC Disclosure Challenges for Directors**

- A. Need accurate and timely disclosures
  - 1. Disclosure of the status of FDA proceedings for drugs and other products in the development pipeline is an especially sensitive area for biotechnology companies
  - 2. FDA approval proceedings are lengthy and complicated
  - 3. Extreme care is required for biotech companies to accurately and timely describe the status of the FDA approval process for material drug discoveries and product development
  - 4. Failure to take due care can result in
    - a. Liability for the company and others under securities antifraud rules
    - b. Exposure to charges of insider trading by individuals
    - c. Violations of Regulation FD for impermissible selective disclosure
- B. Complying with Regulation FD
  - 1. Regulation FD prohibits a public company from disclosing material nonpublic information about the company to market professionals and holders of the company's securities who could be expected to trade on that information, without disclosing that information to the public generally
- C. Response to investor demands
  - 1. Companies feel pressure to have proactive disclosure about early-stage drug development and preliminary clinical trial results

- D. Disclosure pressure points for issuers
  - 1. Achievement and failures in clinical trials
  - 2. Risks associated with clinical trial design
  - 3. Prospects for FDA/European regulatory approval
  - 4. Scientific literature from third parties
  - 5. Differing expert opinions
  - 6. Serious adverse effects
  - 7. Warning of regulatory action by FDA (warning letters)
  - 8. Freedom to operate issues
  - 9. Comparisons to competitors' products
- E. Disclosure tips
  - 1. Avoid disclosing positive partial or preliminary results from clinical trials without disclosing how those trials related to the Company's overall development program
    - a. What was the trial designed to show?
    - b. Was statistical analysis of data conducted?
    - c. What was the role of the Company and collaborators in the trial?
    - d. Prevent potential erroneous conclusions by third parties
  - 2. Avoid selective disclosure information on FDA process without considering:
    - a. If selective disclosure is intentional, then the Company must make the public disclosure simultaneously
    - b. If the selective disclosure is unintentional, then the Company must make the public disclosure promptly
    - c. The method selected for public disclosure must be reasonably designed to effect broad dissemination
    - d. SEC uses a "materiality by hindsight" analysis to determine violations of Regulation FD often based on price and volume movements of the Company's stock
    - e. Be careful of indirect disclosures by researchers and experts working on the Company's behalf

3. Conform statements made to FDA and statements made in press releases and SEC filings
    - a. FDA and SEC will review for accuracy and whether statements mislead public
    - b. Reduce the “spin” placed on results of trials or discussions with FDA
  4. Minimize risks from disclosure obligations
    - a. Create internal procedures and processes to detect and report disclosure problems
      - (i) Establish standard practices and procedures for public disclosure of material developments that warrant prompt public notice
      - (ii) Form a disclosure committee that meets regularly, and document meetings
  5. Devote sufficient preparation and review time to public statements; create proper “tone at the top”
    - a. Internal team, senior management, and counsel should have sufficient time to prepare and review a public statement prior to its release
    - b. Do not allow public communication to be released before all relevant parties have completed review and are comfortable with the disclosure
  6. Frequent consultation with internal and external experts and counsel
    - a. FDA, IP, and SEC experts
    - b. Securities and regulatory counsel
    - c. Senior managers overseeing development programs and regulatory affairs
  7. CEOs and CFOs should not certify the adequacy of internal controls in SEC filings without the implementation of disclosure and insider trading programs
- F. Alternative entity structures
1. Managers of a limited liability company have similar fiduciary duties to members as directors have to corporate stockholders
  2. A general partner of a limited partnership has similar fiduciary duties to limited partners as directors have to corporate stockholders