RAISING THE BAR: EVOLVING EXPECTATIONS ON BOARDS OF DIRECTORS AND MANAGEMENT TEAMS IN ASSURING CORPORATE COMPLIANCE

In a variety of contexts worldwide, regulators are making clear to boards of directors and senior management that they have personal accountability for failure to exercise effective oversight over company conduct. It is increasingly apparent that governments expect companies to comply with all applicable laws and to have compliance programs that prevent, detect, and respond to wrongdoing. Regulators may view individual incidents of misconduct by company employees or agents as corporate encouraged or sanctioned behavior, resulting in corporate liability that may include criminal charges if a compliance program is not viewed as effective. Stakeholders and the third-party financial community expect that financial, legal, and reputational risks will be managed effectively. These evolving governance expectations on boards and senior management teams have heightened awareness of governance responsibility and provided strong impetus for enhancing corporate compliance programs.

Several recent developments have raised the bar for board and management responsibility for compliance, including the recent settlements entered into by Eli Lilly Company, Bayer Healthcare, and Quest Diagnostics with the Office of Inspector General of the US Department of Health and Human Services; the settlement entered into by Siemens with the Munich, Germany prosecutors office, the US Department of Justice (DOJ), and the US Securities and Exchange Commission (SEC); senior management individual liability imposed under the US "Park Doctrine"; recent proposed anti-bribery legislation in the United Kingdom focusing on corporate compliance responsibilities; and multiple pieces of global legislation requiring effective compliance as part of a corporate control framework. All of these developments point to the need for boards and management teams to make effective compliance programs a high priority in the ongoing agenda for managing the risk of business activities.

The Eli Lilly,[1] Bayer Healthcare,[2] and Quest Diagnostics[3] settlements entered into recently imposed the now familiar obligations of compliance and third party oversight for a period of five years after the settlement. With increasing government concern that companies were not fully prioritizing compliance as an effective response to prevent, detect, and respond to misconduct, the settlements imposed new governance obligations on these companies in the life sciences sector.

1 http://www.oig.hhs.gov/fraud/cia/agreements/eli_lilly_and_company_01142009.pdf

2 http://www.oig.hhs.gov/fraud/cia/agreements/fully_executed_bayer_cia_112508.pdf

3 http://www.oig.hhs.gov/fraud/cia/agreements/quest_diagnostics_incorporated_04142009.pdf

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Under the settlement agreements, the Boards of Directors of Eli Lilly, Bayer Healthcare, and Quest Diagnostics (Board) retain ultimate responsibility for the review and oversight of matters related to compliance obligations of the company. In particular the Board is responsible for:

(i) Meeting at least quarterly to review and oversee the company's compliance program, including an evaluation of the performance of the compliance officer and the compliance department.

(ii) Adopting a resolution, signed by each individual member of the Board, stating it has made a reasonable and due inquiry into the operations of the company's compliance program and that the Board has concluded that, to the best of its knowledge, the company has implemented an effective compliance program to meet the applicable Federal healthcare program requirements, US Food and Drug Administration (FDA) requirements, and settlement agreement obligations.

(iii) Having completed an assessment of the effectiveness of the company's compliance program to assist the Board in its own evaluation process. (The Bayer Healthcare and Quest Diagnostics settlement requires that this review be completed by independent experts that would assess effectiveness and provide the Board with recommendations with respect to the compliance program.)

DOJ has recently added important guidance to Boards, Audit Committees, and senior management on governance responsibilities[4]. In its guidance to federal prosecutors considering prosecuting corporations, DOJ advises consideration of whether the corporation has established corporate governance mechanisms that can effectively prevent, detect, and respond to misconduct. Questions to be considered include:

- Do the corporation's directors exercise independent review over proposed corporate actions rather than unquestioningly ratifying officers' recommendations?
- Are internal audit functions conducted at a level sufficient to ensure their independence and accuracy?
- Have the directors established an information and reporting system in the organization reasonably designed to provide management and directors with timely and accurate information sufficient to allow them to reach an informed decision regarding the organization's compliance with the law?
- Has the corporation provided for a staff sufficient to audit, document, analyze, and utilize the results of the corporation's compliance efforts?

4 http://www.usdoj.gov/usao/eousa/foia_reading_room/usam/title9/28mcrm.htm#9-28.710

These guidelines make clear that Boards must maintain responsibility for effective compliance and for providing sufficient funding to enable programs to achieve their purposes. Even during the economic time of diminished corporate resources, effective compliance programs must remain a priority.

Misdemeanor liability of individual executives for failure to prevent violations of the Federal Food Drug and Cosmetic Act (FFDCA) has been long established under *United States v. Park* (1975) where the Supreme Court of the United States held that individuals who have authority to prevent violations can be held vicariously liable for the illegal acts of subordinates or agents. Under the *Park Doctrine*, responsible corporate officers have an affirmative duty to seek out and remedy violations and implement measures to prevent violations. Failure to exercise proper care in carrying out duties creates liability, and delegation to subordinates does not negate liability. Individual executives also risk felony liability for compliance failures of the company if the government can show that the individual acted with intent to defraud or mislead or had committed a prior violation of the statute.

FDA and DOJ have indicated a willingness to bringing charges against individual executives in these circumstances. The FDA Regulatory Procedures Manual (RPM) states that it is FDA policy to cite officers of corporations and members of partnerships and associations in administrative actions, when evidence establishes that the individual stood in a "responsible relationship" to the violation. The RPM also indicates that individuals who have the authority and responsibility to correct or prevent violations should be named as defendants in complaints for injunctions. Likewise, the DOJ Office of Consumer Litigation Monograph states that individuals who are responsible for criminal violations of the FFDCA are normally named as defendants along with the corporate entity.

Recent cases have highlighted the risk of liability for individual executives:

(i) In *AbTox* (2006),[5] two executives received 10-year and six-year prison sentences, respectively, for felony FFDCA violations relating to the introduction of adulterated and misbranded sterilizers into interstate commerce;

(ii) In *Purdue Pharma* (2007),[6] the company and three executives pleaded guilty to misdemeanor FFDCA violations relating to the promotion and marketing of the painkiller OxyContin;

(iii) In *Advanced Bionics* (2008),[7] the company and an executive agreed to pay civil money penalties of US$1.1 million and US$75,000, respectively, for alleged FFDCA violations relating to failure to file supplemental information regarding a change to the company's Cochlear Implants;

(iv) In *InterMune* (2008),[8] a former executive was indicted for wire fraud and felony FFDCA violations relating to the promotion and marketing of Actimmune; and

(v) In Pharmco (2009),[9] a former Regional Manager pled guilty to a misdemeanor FFDCA violation relating to the promotion and marketing of Bextra. The company has also agreed to pay US$2.3 billion as part of a yet to be approved settlement of the federal investigation regarding the marketing and promotion of Bextra.

The focus on Board responsibility for effective governance of compliance risks is not limited to the United States. Several recent developments highlight this evolving global governance standard. Several recent developments highlight this evolving global governance standard. After a raid by Munich, Germany authorities, Siemens launched an internal investigation of an unprecedented scale into allegations of bribery that occurred worldwide. As part of a recent comprehensive settlement, Siemens accepted responsibility for misconduct and agreed to pay a total €596 million fine in Germany, and pled guilty to criminal violations of the US Foreign Corrupt Practices Act (FCPA), paying a US$450 million fine and disgorgement of profits of US$350 million. Led by the Siemens Board, the company initiated a robust internal compliance program and cooperated fully with the various investigations, likely preventing even greater penalties. The Board required all divisions and groups, no matter in what part of the world, to be subject to effective compliance controls. Another strong compliance response was noted in the recent US FCPA settlement with Novo Nordisk, where the government noted the "enhanced compliance policies" as key to the resolution of the investigation. Boards everywhere are now on notice regarding the tremendous risk and cost of not having effective controls in place, and should recognize the role that an effective compliance remediation response had in the ultimate resolution of the Siemens and Novo Nordisk investigations.

Other high-profile investigations outside of the US have also demonstrated the importance of a robust compliance response. In early 2008, a trader for Societe Generale was indicted for engaging in unauthorized trades that resulted in losses of over €4.9 billion for the company. Audit reports revealed widespread internal control failures, after compliance officers failed to respond to 75 alerts triggered by the unauthorized trading. In response to these reports, the French Banking Commission fined the company US$6.36 million for "serious failings" in its internal control procedures. Societe Generale has pledged to invest as much as €100 million to improve its risk-management systems. Satyam, India's fourth largest software and computer services provider, collapsed in January 2009 when CEO and Chairman Ramalinga Raju confessed to overstating revenue and bank balances by over 90% (nearly US$1 billion) for more than two years. During that time, the company had been heralded for having a world-class Board and compliance structure, including Board compliance committees and an independent auditor who reviewed and certified financial statements. Satyam won the prestigious UK-Based World Council for Corporate Governance Golden Peacock Global Award for excellence in corporate governance in 2008 (the Council withdrew the award earlier this year). Satyam was seized and sold to Mahindra in an auction last month. Indian Government investigations into Satyam, Satyam officers, and the independent auditor are

5 http://www.va.gov/oig/publications/press-release.asp?id=51

6 http://www.usdoj.gov/usao/vaw/press_releases/purdue_frederick_10may2007.html

7 http://origin.www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2008/ucm116922.htm

8 http://www.usdoj.gov/opa/pr/2008/March/08_civ_217.html

9 http://www.usdoj.gov/usao/ma/Press%20Office%20-%20Press%20Release%20Files/Mar2009/HollowayMaryPleaPR.html

ongoing. Last month 13 class action lawsuits seeking over US$500 million were filed in the US by American Depositary Receipts (ADR) holders against Satyam, the independent auditor, and individual directors.

The global governance response is not limited to this increased enforcement emphasis. In the United Kingdom legislation has been proposed that seeks to bring English bribery law into compliance with international standards for preventing public corruption (the "Bribery Bill").[10] The Bribery Bill (if enacted in its current draft form) would consolidate the current multitude of laws into one statute broadly prohibiting public and private corruption for anyone "closely connected" to the UK including all British citizens and companies incorporated in the UK. For corporations, the Bribery Bill bars negligently failing to prevent someone working on behalf of a corporation from paying a bribe in connection with the corporation.[11] If the person paying the bribe is an employee of the corporation, the Bribery Bill presumes that the person was working on behalf of the corporation when the bribe was paid. Corporations can defend themselves by showing that they have adequate procedures in place to prevent these types of violation, and companies operating in the UK will need to implement such procedures if the Bribery Bill becomes law. While the proposed legislation, if enacted, will have many ramifications for companies based in the United Kingdom, the most immediate impact is likely to be that companies will need to enhance their compliance programs. Governing Boards will need to make those enhancement efforts a corporate priority well in advance of the effective date of the Bribery Bill.

The Siemens and Novo Nordisk settlements, the Societe Generale and Satyam investigations, and the UK Bribery Bill are only several of many examples of an emerging standard of global requirements that effective Board governance requires detecting and responding to potential misconduct through operation of a robust compliance program. Other examples include legislation in Australia, Canada, Italy, Japan, and South Africa. All of these efforts recognize in some fashion or another that governing Boards have overall responsibility for ensuring company employees and those acting on a company's behalf act appropriately and that good governance now demands effective compliance.

Boards of directors and senior management are, as part of their responsibilities to serve their companies, charged with managing risk and creating an environment and framework for employees and third parties acting on a company's behalf to comply with applicable legal obligations. Whether a company operates principally within the United States or on a global basis, this responsibility increasingly means being active in providing oversight of a company's compliance response, recognizing that such oversight means demonstrating leadership in the commitment to conducting business ethically and legally, independently assessing compliance efforts, providing sufficient funding to ensure effective program operation, and enabling program modification to meet evolving risks and changing business environments. Boards and senior management should fully expect that these emerging global expectations will soon achieve global governance consensus and they should be prepared to meet these increasing standards of conduct.

10 Ministry of Justice, Bribery Bill of 2009, Cm. 7570.

11 Bribery Bill, Section 5.

We hope that you have found this advisory useful. If you have additional questions, please contact your Arnold & Porter attorney or:

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