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Attorney Article

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"Should I Stay or Should I Go?" The Products Liability Dilemma for Pharmaceutical and Medical Device CEOs

The chief executive officer (CEO) of a large pharmaceutical company receives an internal report that several manufacturing plants do not meet Current Good Manufacturing Practices (CGMP). Another CEO is aware that the sales team may be promoting the company's product for unapproved, "off-label" uses. In these cases, the CEO has to decide, to quote The Clash, "Should I stay or should I go?" *Should I refrain from doing anything, let the company's regulatory affairs or quality assurance personnel handle matters, or should I act to address regulatory issues presented?*

CEOs may have legitimate business reasons to refrain, because regulatory compliance can be costly and time-consuming. Taking corrective action can make the company look like it is admitting guilt on an issue that could blow over without attracting the attention of the Food and Drug Administration (FDA) or another regulatory body. But failure to comply with government regulations and inactivity if a company falls out of compliance can lead to serious product liability issues in the long-term.

Unfortunately, CEOs often do not consider the potential cost of product liability enforcement when they evaluate whether or not to act. As The Clash song explains, "If I go there will be trouble, an' if I stay it will be double." You can pay now or you can pay later. Acting now may be costly in the short-term, but may be a wise long-term decision. Conversely, refraining from action may lead to substantial regulatory, legal and public relations costs down the road if product liability risks materialize. Despite the impact that expenses required to address regulatory deficiencies have on short-term earnings, it is prudent for a company to take necessary corrective action where regulatory issues arise, because it gives the company long-term control over its relationships with the FDA, other regulatory bodies, healthcare professionals and consumers. In the end, these relationships are critical for the future health and productivity of the company.

Recent headlines have demonstrated the risks of refraining from corrective action. In early May, Johnson & Johnson recalled many common over-the-counter children's medications after a routine plant inspection by the FDA revealed problematic manufacturing and quality control practices. (An FDA press release about the recall is available here.[1]) The FDA and the company both issued statements affirming that the recall was a precautionary measure, but the company has not been able to contain the repercussions of the failed

1 http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm210441.htm

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FDA inspection. The House of Representatives Oversight and Government Reform Committee is investigating the manufacturing and quality control flaws that led to the recall and whether the government should pursue criminal charges against the company. (Please click here[2] to see the Committee's web page providing coverage of the investigation and recent hearing.)

Infusion pumps have also attracted recent media attention as the FDA investigates and reviews potential product defects. For Baxter International, manufacturer of the Colleague infusion pump, the FDA crackdown has resulted in a forced recall and consumer refunds that have cost the company up to $600 million in the last quarter.[3] To read an FDA press release about the recall, please click here.[4] Additionally, the company has had to deal with the fallout from the FDA's public statement that the recall "is based on longstanding failure to correct many serious problems with the pumps" (*Id.*).

If a company CEO decides to overlook regulatory violations, the violations can (and often will) attract FDA attention. Once the FDA and other government agencies become involved, the company loses a significant amount of control over the public relations and general management of the situation. (The authors are not commenting on whether Johnson & Johnson and Baxter International made appropriate decisions about how to handle the regulatory issues that led to product recalls. We provide these companies as examples because their cases are current and have attracted industry attention.) In such cases, voluntary corrective action, before the FDA forces the company's hand, can minimize the enforcement cost or even prevent FDA enforcement altogether if appropriate steps are taken to fix regulatory deficiencies. At the very least, proactive enforcement will show the FDA and the public that the company took the issue seriously and immediately addressed any potential safety issues, rather than overlooking or attempting to cover up such issues. As one financial analyst stated about the Johnson & Johnson recall, "when a company looks like it's hiding something or isn't fully disclosing [...] that's where it can get hurt" (Jan Wald, Noble Financial Group, quoted in "FDA Still Probing Friday's J&J Recall," *Reuters*, on May 4, 2010).[5]

In addition to the risk of corporate liability for faulty products or regulatory violations, CEOs and other senior executives face potential individual criminal liability in cases where the government can show that the executives could have reasonably prevented the violations. The United States Supreme Court first validated the "responsible corporate officer doctrine" in *United States v. Dotterweich*, holding that senior executives can be convicted of criminal misdemeanor charges for company violations of the Federal Food, Drug and Cosmetic Act (FFDCA) (320 U.S. 277 (1943)). The Court continues to uphold this doctrine and has affirmed that executives can be held liable under the FFDCA, even where they had no "consciousness of wrongdoing" (See, e.g., *US v. Park*, 421 U.S. 658, 671 (1975) (a case involving contaminated food plants, where the Supreme Court affirmed that the FFDCA imposes a duty upon supervisory executives to seek out and remedy regulatory violations.)). A CEO can be held liable merely because he or she "failed to exercise [...] supervisory responsibility." (Id.).

2 http://oversight.house.gov/index.php?option=com_content&view=article&id=4950:oversight-daily-committee-examines-johnson-a-johnsons-recall-of-popular-pediatric-medicines&catid=88:blog&Itemid=57
3 "FDA Deal Leads to Recall of Infusion Pumps," *New York Times* (May 3, 2010)
4 http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm210664.htm
5 http://uk.reuters.com/article/idUKTRE64255D20100503

These Supreme Court cases are reflected in current FDA enforcement policy. The FDA is currently reviewing its standards for prosecuting corporate officers and has warned officers to take proactive steps to remain in compliance.[6] Indeed, FDA Commissioner Margaret Hamburg told Congress in April that the agency plans to enhance enforcement under the responsible corporate officer doctrine.[7] Analysts have interpreted Commissioner Hamburg's announcement to mean that the FDA will pursue individual criminal liability in more cases, not only in those cases where the violations are flagrant, and that the FDA may begin to treat board members, in addition to senior executives, as responsible individuals (*Id.*). As Eric Blumberg, the FDA's Deputy Chief Counsel, said recently, "very soon [...] some corporate executive is going to be first."[8]

Although future FDA enforcement is hard to predict, the central theme in the "responsible corporate officer doctrine" is clear: failure to monitor and take proactive corrective action against internal regulatory violations can result in individual criminal liability. Drug and device executives have enough on their plate and can hardly afford to tempt fate when double the trouble is at stake. Recent enforcement actions against Johnson & Johnson and Baxter have sent shockwaves through the industry, but companies can learn from these actions and look for opportunities to act before the FDA gets involved. Self-regulation has some short-term costs, but, in the long-term, it is the best way for executives to minimize company product liability and individual criminal liability.

6 *The Pink Sheet*, p. 7 (May 24, 2010)
7 *The Pink Sheet*, p. 9 (May 24, 2010)
8 *The Pink Sheet*, p. 8 (May 24, 2010)

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