Attorney Review

Articles: **Overstating FDA Regulatory Prospects Puts Stock at Risk**

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Drug Delivery Technology Company is First Target of FDA-SEC Cooperative Enforcement Initiative

On April 1, 2004, the Securities and Exchange Commission (SEC) suspended trading in the stock of a drug delivery company whose focus is transdermal drug delivery products, pending an investigation of alleged false and misleading statements in the company's press releases, annual report, SEC registration statements, and other public statements to investors. The allegedly false statements related to FDA approval of key company products and the regulatory consequences of the future application of the company's primary product. Significantly, this SEC action is likely just the first example of heightened enforcement scrutiny of medical product companies by SEC under a recently announced cooperative enforcement initiative with the FDA. In this new era of corporate accountability and heightened FDA/SEC scrutiny, medical product companies should exercise extra caution to assure that public statements about FDA regulatory matters affecting the company or its products are truthful and not misleading. In addition, publicly traded medical product companies must commit to correcting the record if subsequent events reveal that the company has made an announcement in error.

BACKGROUND

The ImClone Systems insider trading scandal highlighted what any life science company that has been through the FDA approval process knows: no matter how promising a drug, device, or biologic product appears to be based upon early clinical trials, FDA approval requires a very

high level of scientific support for a product's safety and efficacy, and approval is never certain until it happens. ImClone also highlighted another fact of life for such companies – both public and private investors are strongly influenced by the perceived regulatory status and prospects of a company's products. These facts create a strong temptation, especially for struggling early stage companies, to aggressively tout the results of promising, but preliminary, clinical studies and even preclinical studies, and to overstate the chances of eventual FDA marketing approval of their products. Giving into such temptations has always been short-sighted and risky, but as the aforementioned trading suspension illustrates, those risks have now been raised significantly.

THE SEC/FDA ENFORCEMENT INITIATIVE

The ImClone scandal also exposed a practical loophole in government oversight of company statements regarding FDA regulatory issues. Specifically, the SEC lacks the technical and regulatory expertise in FDA matters to adequately judge the accuracy of nuanced scientific and regulatory disclosures, and the FDA generally has not closely scrutinized investor-directed communications about regulated medical products. Although the FDA and SEC have historically cooperated on an ad-hoc basis to evaluate the accuracy of FDA-related statements in SEC filings, there has not been an efficient systematic process for conducting integrated reviews.

In an effort to remedy this enforcement gap, on February 5, 2004, the FDA and SEC announced a new cooperative initiative "designed to improve the manner by which FDA assists the SEC whose primary mission is to protect the investing public and maintain the integrity of the securities market." As then-FDA Commissioner McClellan stated in announcing the initiative:

- *"Unfortunately, companies sometimes violate the public trust by issuing false or misleading statements about FDA-related issues, such as the progress of FDA's premarket review. When we identify suspected misstatements, we have a new process to bring them to the attention of the SEC staff as quickly and efficiently as possible."*

The key element of the initiative is a direct referral procedure for FDA employees to report false or misleading statements by FDA-regulated companies for investigation by the SEC Division of Enforcement. To facilitate use of the referral system, the FDA is implementing several administrative measures, including cooperative training programs, designation of an FDA liaison officer and specific SEC contact persons within each FDA division, and enhanced inter-agency electronic communications procedures to facilitate responses to SEC requests for confidential information from the FDA. In addition, the FDA will designate specific employees as having "blanket authorization" to share non-public information about pending product applications with the SEC. This will streamline and speed up investigative cooperation by eliminating the need for individual ad-hoc grants of authorization in response to SEC information requests.

The FDA's announcement attempts to assure regulated companies that FDA employees are not expected to become special enforcement agents for the SEC, but rather will merely be given a centralized procedure to report false or misleading statements that they become aware of "in the normal course of their activities." Nevertheless, with heightened FDA employee training and awareness of SEC issues, and a system designed for bottom-up reporting of potential SEC violations, FDA-regulated companies should make every effort to maintain good relationships with FDA project managers and other FDA employees assigned to review company applications. Moreover, companies should aggressively pre-review all public statements about both marketed and investigational products to assure that they are truthful, not misleading, and not inconsistent with positions taken in interactions with the FDA itself. The drug company noted in the beginning of this column is learning the hard way that the consequences of even the perception of a false or misleading statement can be severe.

THE ALLEGATIONS

The company, whose stock was suspended by the SEC, focuses on commercializing products that utilize its proprietary drug delivery technology. The company went public in 2003 and has marketed products for treatment of topical fungal infections (athlete's foot) and osteoarthritis. As of the writing of this column the trading suspension is just a few days old and the facts surrounding the alleged SEC violations have not been fully reported. The SEC's press release states simply that the trading suspension related to statements concerning "among other things: (1) FDA approval of certain key products, and (2) the regulatory consequences of the future application of their primary product."

Based on publicly available information, the allegedly objectionable statements may include an interview by the company's CEO with an investment publication suggesting that the company's product pipeline would be subject to an expedited FDA review and approval process that would not require consideration of any safety or efficacy issues. Moreover, a shareholder class action lawsuit filed in the wake of the SEC's suspension order alleges that the company made false and misleading statements regarding a 5-year old pilot study of approximately 20 subjects. The company allegedly described this study as having been "supervised by independent physicians" and that the results, which purported to show dramatic superiority over a competing product, were analyzed by the Tufts New England Medical Center. However, it is alleged, the only supervising physician was a paid consultant, and the New England Medical Center did not actually conduct the trial and was unable to draw any clinical conclusions from the study data.

SUMMARY

Without passing judgment on the legitimacy of the company's challenged statements, it has been our experience in advising companies on drafting FDA-related statements for press release and SEC filing purposes, that a long-term market view is most conducive to achieving compliance with the FDA and SEC reporting requirements and restrictions. In other words, targeting a short-term stock effect by making overly optimistic regulatory assertions is now, more than ever, a risky strategy. It is also our experience that, given the nuances of the FDA regulatory scheme, even public statements drafted with the best intentions of compliance can easily run afoul of the complex and often unwritten expectations of the FDA as to how companies should characterize clinical trial results and future regulatory prospects. In the era of the new FDA-SEC enforcement initiative, regulated companies need to realize that it is more cost-effective than ever to engage FDA regulatory counsel before issuing statements concerning FDA matters, than it is to engage civil or criminal defense counsel after the SEC and FDA have objected to allegedly false or misleading statements.

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