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Watch Out: SEC Is Watching Your Dealings With Regulators

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There has been an emerging enforcement trend by the U.S. Securities and Exchange Commission focusing on public companies' omissions of key feedback received from regulatory agencies and statements inconsistent with that feedback in the companies' public filings and corporate communications. This has resulted in corporate defendants being required to disgorge illegal gains plus interest and pay millions of dollars of civil penalties, and in some cases, top executives being permanently barred from senior positions at public companies. In light of these recent SEC enforcement actions, it would be prudent for public companies operating in regulated industries, such as life sciences, medical device and cleantech, to take special care in assessing how to share a regulatory update with investors and avoid making misleading public statements concerning their dealings with regulators.


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Understand Where the Liabilities Come From

A recurring theme in these types of cases is that the public companies in question, according to the SEC, were not entirely forthcoming with investors about important communications with regulatory agencies that might cast serious doubt on whether the companies' products could meet required regulatory approvals or standards. Under SEC rules and regulations, public companies not only shall refrain from making any untrue statement of a material fact but also may not omit a material fact necessary to render the statements made, in light of the circumstances under which they are made, not misleading. Below, we provide a brief overview of situations that have given rise to SEC enforcement actions.

In Connection with Raising Capital

Securities law prohibits fraud and misrepresentations in a company's offer or sale of securities. In its action against Aveo Pharmaceuticals Inc.,[1] the SEC alleged that when Aveo raised $53 million in a public offering, the company concealed the U.S. Food and Drug Administration's level of concern about the company's flagship drug, tivozanib, in public statements to investors by omitting the critical fact that the FDA staff had explicitly recommended a second clinical trial for tivozanib to address their concerns before they could approve the drug.[2]

In Connection with SEC Filings

SEC filings have to be factually accurate and nonmisleading. In addition, a public company's CEO and chief financial officer are required to certify in the company's annual and quarterly reports that such reports are in compliance with SEC rules and regulations. In its action against Navistar International Corp.[3] regarding Navistar's efforts in obtaining a certificate of conformity from the U.S. Environmental Protection Agency for Navistar's next-generation diesel engine, the SEC alleged that four days after a meeting in which the EPA staff told Navistar that the proposed engine did not appear to meet the certification requirements, Navistar filed its 2011 annual report on Form 10-K, which stated that it believed the engine met EPA's certification requirements.[4]

In Connection with Press Releases and Analyst Conferences

Investors commonly make investment decisions in response to companies' corporate communications, and public companies should be careful to avoid the appearance of deception and manipulation in connection with investors' purchase or sale of securities. In its action against Imaging3 Inc.[5], the SEC alleged that during a conference call with investors after the FDA had three times denied clearance for the company's proprietary medical imaging device, Imaging3's former CEO told investors that the FDA's issues were "not substantive" and largely "administrative," even though the FDA denial letter cited concerns about the device safety and the image quality.[6]

Dealings with Foreign Regulators

The SEC also closely examines public companies' disclosures about their dealings with foreign regulators. For example, in its action against Immunosyn Corp. and Argyll Biotechnologies LLC,[7] the SEC alleged that Immunosyn misleadingly stated that the regulatory approval process in Europe for human clinical trials for Immunosyn's sole product, SF-1019, was imminent or underway, when in fact an application in Europe to conduct such human clinical trials was never submitted to the European regulators.[8]

SEC's Access to Nonpublic Submissions and Information

Interagency Cooperation

The SEC and other federal agencies have been enhancing their cooperative efforts in support of the SEC's enforcement actions, including the continued sharing of nonpublic information with the SEC. For example, in 2004, the SEC and FDA announced measures designed to improve the manner by which the FDA assists the SEC in protecting the public from false and misleading statements by public biopharmaceutical companies. In its action against Immunosyn, the SEC explicitly acknowledged the assistance of the FDA. According to the FDA,[9] it gives specified FDA employees a "blanket" authorization to enable them to share nonpublic information with the SEC or its staff.

Investigative Subpoenas

With a formal order of investigation, SEC staff may by subpoena compel companies to produce books, records and other relevant documents and witnesses to testify. For example, in Securities and Exchange Commission v. Navistar International Corp., Navistar was obligated to produce all nonattorney documents identified in the SEC's investigative subpoenas to the SEC.

Takeaways

When to Disclose

Under SEC rules and regulations, a public company must provide periodic updates on and timely disclose significant regulatory developments. Even when disclosure is not required, a public company that receives interesting news from regulatory agencies may want to share that information with the public to enhance its visibility. Additionally, after a company discloses information, it can have a duty to update or correct that information if new information becomes available.

What to Disclose (or Not to)

Whether information is disclosed to the public to meet securities law requirements or is disclosed voluntarily, the disclosure must be complete and accurate to avoid misleading the investing public. If a public company has already received critical feedback from regulators that renders the meeting of the required regulatory approvals or standards unlikely based on industry norms, the company should refrain from giving optimistic forecast about meeting the regulatory requirements, and at the same time, withholding such information from investors.

While complying with securities law and preserving the company's credibility may require disclosing negative regulatory feedback that is material for the company as well as its implications, a public company can mitigate that disclosure's suboptimal effect by providing reasonable explanations as to why the regulatory agencies' decisions are not conclusive and describing the company's remedial options and genuine plans together with the associated risks, as appropriate.

Being Vigilant

Because of the importance of getting nonmisleading information to the investing public, the increasing scrutiny from the SEC and the severe consequences of SEC enforcement actions not only for the company but also for the executives responsible, we recommend a public company that develops regulated products to create and maintain standard procedures and policies to ensure timely and accurate flow of information, both internally and externally, regarding its dealings with regulatory bodies.

Seeking Advice

Every situation is unique and no advice can fit all circumstances, therefore, it is important for a public company and its executives in each case to promptly seek experienced counsel's advice with respect to how to best handle unfavorable regulatory developments so that they will not run afoul of securities law and provoke SEC enforcement actions.

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[1] Securities and Exchange Commission v. Aveo Pharmaceuticals Inc. et al., Civil Action No. 1:16-cv-10607-NMG (D. Mass., filed March 29, 2016)

[2] When the FDA made public months later that it had recommended an additional clinical trial, the company's stock price declined more than 30 percent. Aveo never conducted the additional trial, and the FDA later refused to approve tivozanib. Aveo agreed to pay a $4 million penalty to settle the SEC's charges, and the SEC's case continued against the company's former CEO, CFO and chief medical officer.

[3] Securities and Exchange Commission v. Navistar International Corp., Civil Action No. 1:14-cv-10163 (N.D. Ill., filed Dec. 18, 2014).

[4] Navistar reached a settlement with the SEC and agreed to pay a $7.5 million penalty, and the SEC's case continued against the company's former CEO.

[5] Securities and Exchange Commission v. Imaging3 Inc. & Dean Janes, Civil Action No. CV13-04616 GAF (AJWx) (C.D. Cal., filed June 25, 2013).

[6] Even when asked on the call whether any of the FDA's concerns were "safety-related" or involved image quality, the former CEO responded, "Nope," and that there was "really and honestly not one question about the technology or its consistency. It just doesn't make sense to me." Imaging3 did not officially issue the full text of the FDA denial letter until more than two years after the conference call. Imaging3 agreed to continuously undertake certain self-remediation measures, as part of the consent agreement to resolve the SEC enforcement action, and the SEC's case continued against the company's former CEO.

[7] Securities and Exchange Commission v. Stephen D. Ferrone et al., Civil Case No. 1:11-cv-05223(N.D.Ill., filed Aug. 1, 2011).

[8] As a result of the SEC enforcement action, two executives at Immunosyn were permanently banned from being an officer or director at any public drug company.

[9] http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2004/ucm108239.htm