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Prepping For SEC's Changing Life Sciences Enforcement

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The life sciences sector remains a critical area of focus for the U.S. Securities and Exchange Commission under the current administration.

Companies operating in the healthcare, pharmaceutical, biotechnology and medical device industries can expect heightened regulatory scrutiny, particularly concerning financial disclosures, insider trading, cybersecurity and selective disclosures. These companies should be proactive in managing risks and preparing for potential investigations.

The SEC Under the Current Administration

Under the second Trump administration, the SEC is expected to shift its enforcement approach. Certain areas, such as crypto cases, stand-alone off-channel communications violations and internal controls-only charges, are no longer a focus.

Instead, we expect the SEC to return to back-to-basics enforcement focused on insider trading, fraud and fraudlike conduct, misleading claims regarding artificial intelligence, and cybersecurity-related misconduct.

In terms of remedies, we expect the SEC to emphasize disgorgement, i.e., returning money to harmed investors, over the imposition of hefty penalties. The penalties themselves are expected to align more closely with established precedent rather than escalating from prior cases. We also expect the SEC to take a less aggressive stance on officer and director bars, unless an individual held a senior leadership role at the time of the misconduct.

What This Means for Life Sciences, Healthcare and Biotech

Disclosures and Financial Fraud

Life sciences companies face substantial pressure to accurately disclose information related to U.S. Food and Drug Administration interactions, clinical trials, product approvals and marketing uses. Misrepresentations, whether intentional or inadvertent, can trigger SEC investigations, especially when stock price movements, large trading volumes, whistleblower tips, or referrals from other agencies, such as the FDA or the U.S. Department of Justice, raise red flags.

The SEC typically views drug and other product developments as material to investors. Companies that misstate clinical trial outcomes, the approval status of products, or permissible uses of drugs could face charges involving penalties and disgorgement, and individuals could face these remedies along with officer and director bars.

Financial reporting also remains a key focus. Historically, SEC scrutiny has included allegations such as inflating sales figures, prematurely recognizing revenue, channel stuffing or misclassifying financial data. Even metrics outside standard generally accepted accounting principles, such as sales trends or disclosures regarding the mix of customers, can become problematic if presented in a materially misleading manner.

Investigations into financial disclosures often involve forensic reviews of internal accounting records and can result in serious consequences, such as large monetary penalties; clawbacks of incentive compensation; and professional practice bans for directors, officers and accountants.

Insider Trading

Life sciences companies tend to possess an abundance of material, nonpublic information, making them prime targets for insider trading investigations. SEC and Financial Industry Regulatory Authority surveillance tools are highly sophisticated and monitor trading activity around key events such as mergers, licensing agreements, earnings announcements, clinical trial results and FDA decisions.

Even seemingly minor profits — or avoided losses — based on material, nonpublic information can prompt investigations depending on timing. Importantly, SEC investigators consider not only executives but also all potential sources of leaks, including information technology staff, consultants and contractors — and even family members and friends.

Regulation Fair Disclosure

Reg FD prohibits public companies from selectively disclosing material, nonpublic information to favored analysts or investors without broadly disseminating the information to the public. Due to the complexity and materiality of FDA-related developments, life sciences companies face particular risks in this area.

The SEC has charged companies where executives provided additional details to sell-side analysts about regulatory events, even when public filings used cautious, neutral language. Companies can face penalties even in the absence of insider trading allegations.

To mitigate Reg FD risk, companies should ensure that any material updates shared with select audiences are made public immediately, and that investor communications are properly coordinated and documented.

Cybersecurity

Cybersecurity continues to be a growing focus of SEC scrutiny, especially in the life sciences industry, where companies often store sensitive customer, patient and proprietary information.

Following a cybersecurity incident, the SEC is likely to investigate the following:

- How the breach occurred, and whether the company adequately identified and addressed it;

- Whether internal communications matched public disclosures; and
- Whether insiders or attackers traded on information about the breach before public disclosure.

The February announcement establishing the SEC's Cyber and Emerging Technologies Unit underscores the agency's commitment to investigating cyber-related misconduct. Even if a company is a victim of a hack, failures in disclosure or insider trading safeguards can lead to enforcement investigations and may ultimately result in enforcement actions.

Key Takeaways for Life Sciences Companies

To mitigate enforcement risks and prepare for potential regulatory scrutiny, life sciences companies should consider taking the following steps.

Review and update disclosures regularly.

Public companies should periodically revisit SEC filings, websites, and investor communications to ensure accuracy and materiality, particularly concerning FDA interactions, clinical trial updates and financial performance.

Enhance insider trading controls.

Robust policies and blackout procedures should be in place to guard against insider trading by employees, contractors and associated persons. Companies should also anticipate insider trading risks following cybersecurity incidents and work protections into their policies and procedures.

Strengthen cybersecurity incident response.

Ensure that cybersecurity protocols are well documented and emphasize early involvement of legal and disclosure teams after an incident.

Focus on employee training.

Tailored training on information handling, Reg FD compliance, insider trading and cybersecurity should be conducted regularly across all levels of the organization.

Maintain accurate public statements.

Even privately held life sciences companies should ensure that their public-facing statements are accurate and current, as the SEC can pursue enforcement actions based on material misstatements to investors, including those posted on websites or other public forums.

Conclusion

By proactively addressing these risk areas, companies in the life sciences sector can position themselves to better withstand SEC scrutiny and minimize potential exposure under the current regulatory environment.

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