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Parallel SEC, FDA Regulatory Enforcement: What Life Sciences Companies Should Know

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Life sciences companies, take note: While parallel enforcement by the Securities and Exchange Commission (SEC) and the Food and Drug Administration (FDA) is not new, it appears to be gaining favor among regulators. Cooley partners Luke Cadigan and Sonia Nath recently co-authored **an article in the Food and Drug Law Journal** discussing this phenomenon and the interplay between SEC and FDA regulatory regimes. Below, we've included some highlights from the article.

Parallel enforcement: considerations and dynamics

Life sciences companies frequently must determine what information to communicate to investors about key developments in clinical trials or the FDA's regulatory review process. Although the details of a company's interactions with the FDA during its approval process are not public, the valuation of a life sciences company often depends on its ability to bring a drug or device to market – making information about the likelihood of FDA approval critical to investors.

Deciding what to disclose is further complicated when a company has incomplete information. For example, a publicly traded pharmaceutical company may have only partial results from a pivotal clinical trial. When deciding what to say in such circumstances, the company must be mindful that its disclosures will be scrutinized by a separate regulatory agency – the SEC. Should the SEC conclude that the company's disclosures were inaccurate or misleading, the consequences of enforcement may be severe, including prohibiting individuals from serving as directors or officers of publicly traded companies, substantial financial sanctions and, in extreme cases, referral to the Department of Justice (DOJ) for criminal prosecution.

The article provides an in-depth analysis on the interplay between the SEC and the FDA regulatory regimes concerning life sciences companies, including:

- The FDA's enforcement powers.
- The SEC's regulatory framework and enforcement actions that may specifically target FDA-regulated companies.
- The circumstances in which the SEC and the FDA act in conjunction to enforce their various statutes and regulations.
- Examples of companies that have experienced parallel enforcement.

Key takeaways for life sciences companies

Stay vigilant about compliance

Life sciences companies must remain vigilant to ensure compliance with the laws and regulations of other agencies, specifically the SEC. The FDA and the SEC have a formal policy concerning interagency cooperation, under which the FDA may inform the SEC of potential securities violations by FDA-regulated companies and share nonpublic information with the SEC.

Understand what's important to regulators

Companies that are facing parallel enforcement should take care to understand the statutory mandates and key issues that will be important to each set of regulators, as well as the potential exposure presented by the allegations under the various statutes.

- For example, both the SEC and the DOJ are likely to be interested in evidence showing the necessary intent for various potential charges.
- However, the FDA, including its Office of Criminal Investigations, is likely to also be focused on public health risks and the elements required to prove violations (both civil and criminal) of the Federal Food, Drug, and Cosmetic Act (FDCA), such as the number of shipments that crossed state lines to support the interstate commerce

elements required for most charges.
- Additionally, criminal investigations involving FDA-regulated products are likely to include other federal crimes, such as healthcare fraud, smuggling, and mail and/or wire fraud.

Anticipate enforcement strategies and timing

Being able to anticipate the government's enforcement strategies and the timing of parallel investigations is crucial for companies and their C-suites as they navigate responses to government enforcement actions.

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