SEC and FDA Formalize Information-Sharing Framework: What FDA-Regulated Public Companies Need to Know

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Public companies in the life sciences sector have long faced enforcement risk from the U.S. Securities and Exchange Commission (SEC) and the risk of shareholder litigation stemming from alleged misstatements or failures to disclose material information and other alleged violations of securities laws. Recently, the SEC and the U.S. Food and Drug Administration (FDA) signed a Memorandum of Understanding (MOU) that increases the likelihood of agency enforcement and shareholder litigation if there is a misstep or misstatement. The MOU establishes a formal framework for the two agencies to share nonpublic information relating to companies subject to both FDA and SEC regulation. The MOU confronts the uniquely challenging area of risk that lies at the intersection of product development and securities law disclosure obligations, as well as other similarly overlapping, though not always harmonious, aspects of the FDA's and SEC's respective regulatory schemes. Until now, interagency information-sharing in this space has lacked a formalized, standing framework.

Under the MOU, the SEC may use nonpublic information received from the FDA to inform its reviews of public companies' filings and in connection with enforcement investigations, proceedings and civil actions. The FDA may similarly obtain nonpublic information from the SEC to the extent there is a demonstrated need and is subject to adequate confidentiality assurances.

What Does This Mean for FDA-Regulated Public Companies?

This MOU changes the interagency dynamic in important ways:

- **The SEC now has a direct pipeline to FDA intelligence.** Rather than relying solely on publicly available FDA actions and disclosures, the SEC can proactively request, and the FDA can proactively share, nonpublic information about life sciences companies and their regulated products and product candidates. This could include information about ongoing inspections, pending enforcement actions, manufacturing deficiencies or the true and complete status of a premarket application. If the FDA's information is not consistent with the company's characterization or related disclosures in its public filings, the Agencies may now more easily share that information.
- **The FDA can refer potential securities violations to the SEC.** The MOU specifically designates the FDA Office of the Chief Counsel as the lead for communicating potential securities violations to the SEC, outside the context of an SEC request for information. This clear allocation of responsibility and formal referral mechanism could increase the likelihood that an FDA representative who encounters an apparent misstatement or omission about FDA-related matters will flag them for SEC investigation.
- **Confidentiality protections are robust but not absolute.** The MOU provides certain confidentiality safeguards, including restrictions on further disclosure, Freedom of Information Act (FOIA) protocols, and requirements for the recipient agency to obtain the disclosing Agency's advance written consent before sharing information received under the MOU with

third parties. However, those safeguards do not restrict the SEC's use of FDA-sourced nonpublic information in enforcement investigations and proceedings.

It is also helpful to note areas that are *not* affected by the MOU. The MOU does not create new legal obligations or expand either Agency's existing authority, nor does it affect or supersede existing arrangements between the agencies. What it *does* change is the infrastructure for interagency cooperation, which suggests a commitment to routine information exchange that has not historically been a significant factor for FDA-regulated public companies to consider in managing SEC-related risks.

Key Takeaways and Recommendations

1. **Audit FDA-related disclosures.** Companies should review all public statements, SEC filings and investor communications that touch on FDA-regulated matters, including product pipeline status, clinical trial results, manufacturing compliance and regulatory approval timelines, among others, to identify disclosures that may warrant correction or clarification or information that warrant disclosure in light of what the FDA may now share with the SEC.
2. **Assume the SEC knows what the FDA knows.** The practical effect of this MOU is to close the information gap between the two agencies. Companies should operate on the assumption that any nonpublic information about their products, facilities, compliance history and any other related information known to the FDA could reach the SEC.
3. **Strengthen internal coordination between regulatory affairs and securities counsel.** Regulatory affairs teams and securities counsel should be in close communication. Statements about any FDA-related matters in earnings calls, press releases, investor presentations and SEC filings should be reviewed by personnel with direct knowledge of the company's FDA-regulatory posture.
4. **Reframe compliance policies and practices to account for heightened enforcement risk.** Publicly traded companies operating in FDA-regulated sectors should consider implementing additional measures to ensure consistency between what they tell investors and what their FDA-regulatory record objectively reflects and to prevent disclosures that may be deemed misleading.
5. **Monitor trading activities closely and ensure that all personnel and contractors are mindful of trading restrictions.** Because the MOU effectively treats nonpublic FDA information as accessible to the SEC, companies should remind their employees, officers, directors and contractors with access to material, non-public information about FDA-regulated matters — such as inspection outcomes, premarket application status or manufacturing deficiencies — and reinforce their understanding of applicable trading restrictions under the insider trading policies. Companies should also review their internal policies on insider trading and Section 16 reporting procedures for any possible updates to improve compliance and prevent violations, as the SEC may now be in a position to use an expanded universe of information when scrutinizing trading activity.