FDA Transparency Plans Raise Investor Disclosure Red Flags

By **Eva Temkin, Jane Norberg and Mahnu Davar** (September 11, 2025)

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On July 10, the U.S. Food and Drug Administration, as part of what it's calling a push toward "radical transparency" led by U.S. Department of Health and Human Services Secretary Robert F. Kennedy Jr., released 200 complete response letters, or CRLs, for now-approved drugs and devices.[1]

The FDA also announced on July 17 that the agency intends to start publishing CRLs in real time for unapproved drugs and devices.[2]

The FDA's push toward radical transparency — particularly the intent to publish CRLs in real time — would be subject to considerable judicial scrutiny, as it runs contrary to the agency's long-standing practice and its regulations governing disclosure prior to approval.[3]

This is the case even if the CRLs are properly redacted for trade secret and commercially confidential information; the FDA has always maintained that it is precluded from disclosing the existence of an investigational new drug or device with only very narrow exceptions.

As such, should the FDA begin disclosing CRLs regarding unapproved products, there will be a robust argument that such an action would violate the Administrative Procedure Act because, among other things, the policy was promulgated without notice and comment, because it violates existing FDA regulations, and because the agency's about-face may constitute an unreasoned change in position.

There may also be constitutional arguments raised if the FDA in fact makes good on this announcement.

Commissioner Martin Makary appears to have contemplated at least some of these potential challenges, as he has framed the information contained in CRLs as only reflecting the agency's thinking, which, he has asserted, is owned by the public. This argument does not address the idea, which is fundamental to the FDA's disclosure regulations, that a CRL reflects the existence of an application, which itself is the sponsor's confidential, proprietary information, as well as the proprietary, strategic aspects of information that may not be captured in the FDA's typical approach to redaction.[4]

The potential release of CRLs also implicates the critical intersection of FDA regulation and investor disclosures under securities laws. Publicly traded life sciences and biotech companies must constantly assess whether, and how, to disclose developments in clinical trials or provide updates regarding the FDA's regulatory review process. Further, federal and state securities laws may require disclosures, even when a company has incomplete information, forcing companies to make difficult decisions while balancing investor perceptions against fully complying with applicable securities laws.

Parallel enforcement by the FDA and the U.S. Securities and Exchange Commission is not new, and it appears to be gaining favor among regulators. The SEC regularly scrutinizes

statements and disclosures about the status of FDA review and recommendations. The SEC may open investigations into life sciences companies that it believes made an untrue statement of material fact or that omitted a material fact that makes other disclosures or statements misleading.

Historically, the SEC has been aided with nonpublic information provided by the FDA under agreements between the two agencies.[5] Since 2004, in fact, the FDA and SEC have had a coordination mechanism that enables the FDA to refer "possible instances of securities laws violations by public companies regulated by the FDA" to the SEC.[6] And the SEC enforcement manual similarly provides guidance and authority for SEC staff to request nonpublic information from the FDA.[7]

Not only may the SEC be interested in CRLs, but the U.S. Department of Justice may be as well. The DOJ has prosecuted and convicted biotech CEOs for securities fraud and insider trading surrounding false and misleading statements about the timeline and status of regulatory submissions to the FDA.

Prospectively, it's conceivable the DOJ could review CRLs for potential marketing-based cases. For example, if a company with an approved product but modified or rejected indication is now on the market making money off that indication, is it potential fraud on the FDA?

There also is the threat of shareholder lawsuits. Typically, shareholder lawsuits follow stock declines and regulatory action. For example, when there are setbacks in obtaining FDA approval of a drug or device, securities class action plaintiffs scrutinize companies' past statements regarding product developments.

With the real-time release of CRLs for unapproved drugs or devices, information that historically remained confidential until after approval now will be publicly available for potential plaintiffs to review against a company's statements. The market also will naturally react to CRLs, which will affect stock prices and provide additional threats of shareholder litigation.

Life sciences and biotech companies should prepare now for the FDA to begin releasing CRLs for unapproved drugs and devices. Key considerations in reviewing past disclosures related to drugs or devices under review by the FDA and for adapting disclosure controls moving forward are discussed below.

Revisit strategic engagement with the FDA and how issues are framed.

If the FDA does indeed begin disclosing CRLs prior to approval, it will be critical to build appropriate records requesting confidential treatment and to tee up issues before the agency, remaining mindful that the discussion may be released as part of a CRL.

Ensuring that meeting minutes are accurate and reflect company positions, for instance, will gain even more importance. Companies should also be mindful that these discussions will form the basis of the administrative record in litigation raising the issues discussed above.

Review past disclosures related to FDA review of drugs and products.

Ensure that past disclosures will not contradict FDA interpretations in CRLs. The FDA has already released 200 CRLs for now-approved products and indicated that it intends to begin releasing CRLs for unapproved products.

Regulators and the investing public can perform detailed reviews of what companies were told by the FDA against information disclosed to investors. If the FDA has a different interpretation of the data, careful consideration should be given to whether and when to disclose the FDA's differing interpretation.

Analyze past public statements that rely on assumptions about the FDA's regulatory review process.

A company should carefully analyze statements about the company's business initiatives that are based, whether implicitly or explicitly, on the company's expectations with respect to regulatory review. The underlying assumptions can now be assessed against FDA communications released in CRLs.

Carefully consider statements related to FDA correspondence, actions and review timelines.

Life sciences companies frequently need to make decisions regarding what, whether and when to communicate to investors regarding the FDA review process. Life sciences companies dealing with FDA review should constantly evaluate the need to make or update disclosures.

Any statements about the FDA review process likely will receive close attention. This is especially true now that the FDA plans to release information that previously remained confidential. Regulators and shareholders may view statements that downplay bad news as materially misleading or omissions of material information.

Ensure proper disclosure controls and training.

Proper training of management and directors, as well as effective disclosure controls, can prevent disclosure problems before they happen. Consider whether a dedicated disclosure committee is appropriate.

Ensure management, directors and any disclosure committee members are aware of the FDA's intent to release CRLs of unapproved products in real time and the implications that publicly releasing this information will have on a company's disclosure regime. It is critical that management and directors understand what new information will be made public that previously would have remained confidential.

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[1] https://www.fda.gov/news-events/press-announcements/fda-embraces-radical-transparency-publishing-complete-response-letters.

[2] https://www.fda.gov/news-events/fda-direct-podcast/fda-direct-ep-12-menopause-food-safety-fdas-latest-regulatory-priorities.

[3] 21 C.F.R. §§ 314.430, 601.50, 812.38.

[4] In addition, CRLs contain significant information reflecting not only the agency's thinking but also the sponsor's application and the sponsor's development and marketing strategy.

[5] 21 C.F.R. § 20.85 (providing for FDA release of nonpublic information pursuant to agreements with other agencies).

[6] Press Release, U.S. Sec. & Exchange Comm'n, SEC and FDA Take Steps to Enhance Inter-Agency Cooperation (Feb. 5, 2004).

[7] SEC Enforcement Manual § 5.3 ("Cooperation with the Food and Drug Administration Authority").