The FDA's Resumption of Public Release of Complete Response Letters: **What It Means for Life Sciences Companies and D&O Liability**

The U.S. Food and Drug Administration's recent decision to resume its controversial policy of publicly releasing Complete Response Letters (CRLs) has reignited debate around regulatory transparency, investor protection, and corporate disclosure obligations.[1] While the immediate focus has been on whether the FDA can legally disclose CRLs associated with unapproved products, the broader implications extend well beyond regulatory policy. For pharmaceutical and biotechnology companies, the controversy highlights a growing convergence between FDA regulation, securities disclosure requirements, and Directors & Officers (D&O) liability risk.[2]

A Transparency Initiative Meets Industry Resistance

In July 2025, the FDA launched what Commissioner Marty Makary described as a "radical transparency" initiative, publishing more than 200 historical CRLs issued between 2020 and 2024. The agency argued that public access to these letters would provide greater insight into its regulatory decision-making and help sponsors avoid common mistakes in future submissions. The FDA also signaled its intention to begin releasing CRLs in near real time, including letters associated with products that had not yet received approval.[3]

However, the initiative was met with significant pushback from industry stakeholders and legal experts. Critics argued that public disclosure of CRLs could expose confidential commercial information, reveal proprietary development strategies, and conflict with longstanding FDA practices that treat the existence of unapproved applications as confidential.[4] In April 2026, a pharmaceutical company filed a citizen petition challenging the policy, leading the FDA to temporarily pause publication while evaluating its legal and procedural framework.[5]

The pause, however, was short lived, as the FDA released fourteen new drug rejection letters after the three month pause on transparency. FDA leadership has continued to pursue regulatory and legislative pathways that would expand the agency's authority to proactively disclose CRLs in the future. The agency has even proposed rulemaking designed to eliminate the long-standing presumption that the existence of a marketing application constitutes confidential commercial information.[6]

Why CRLs Matter to Investors

A Complete Response Letter is issued when the FDA determines it cannot approve a New Drug Application (NDA) or Biologics License Application (BLA) in its current form.[7] These letters often identify deficiencies involving clinical efficacy, safety concerns, manufacturing controls, chemistry and manufacturing processes, or the need for additional studies. Because CRLs can materially affect a company's valuation and a product's commercial prospects, they represent some of the most consequential regulatory communications received by life sciences organizations.

Historically, investors have relied largely on company-issued press releases to understand the significance of a CRL. Yet the FDA has repeatedly expressed concern that sponsors do not always fully disclose the agency's rationale when communicating adverse regulatory decisions. The agency cited research showing that companies often omitted significant FDA concerns regarding safety and efficacy when announcing non-approvals, and that requests for additional clinical studies were frequently underreported.[8]

This perceived disclosure gap was among the primary motivations behind the transparency initiative. By making CRLs publicly available, the FDA sought to provide investors and stakeholders with direct access to the agency's actual findings rather than relying solely on sponsor summaries.[9]

The Emerging D&O Liability Challenge

For public pharmaceutical and biotechnology companies, the most important implication may not be the regulatory debate itself, but rather the heightened exposure to securities litigation and D&O claims.

Historically, plaintiffs in securities litigation often faced information asymmetry when attempting to challenge company statements about FDA interactions. Public disclosures were frequently the only available source of information regarding the substance of regulatory discussions. **Real-time publication of CRLs would fundamentally alter that dynamic by giving investors direct access to the FDA's assessment of a product application.**[10]

As a result, any divergence between company disclosure and FDA conclusions could become immediately apparent. Statements characterizing a CRL as relating to "minor manufacturing issues," for example, could face enhanced scrutiny if the publicly released FDA letter highlighted broader efficacy, safety, or clinical concerns. Plaintiffs' attorneys would no longer need to rely exclusively on inferences; they would possess a contemporaneous regulatory document against which management's public statements could be compared.[11]

This reality has profound implications for D&O insurers and corporate boards. The increased availability of regulatory information could create additional grounds for allegations involving:

+ Material misstatements or omissions;
+ Inadequate risk factor disclosures;
+ Failure of oversight by directors;
+ Misleading statements regarding approval timelines; and
+ Overly optimistic assessments of regulatory outcomes.

Governance Implications for Boards

Boards of directors should view the controversy as a governance issue rather than simply a regulatory matter.

The expectation of transparency is unlikely to diminish. **Investors, analysts, and regulators increasingly demand more detailed disclosure around regulatory setbacks and approval risks.** While this controversial practice is still being debated, future FDA rulemaking or congressional action could eventually establish a framework for public disclosure.[12]

As a result, boards should be asking several critical questions:

1. Are public disclosures fully aligned with information received from regulators?
2. Do risk factors adequately describe known regulatory uncertainties?
3. Are disclosure controls and procedures sufficiently robust to withstand external scrutiny?
4. Does management have a contemporaneous process for escalating significant FDA communications to the board?
5. Would current disclosures remain defensible if the underlying CRL became public tomorrow?

The organizations best positioned to navigate this evolving environment will be those that integrate regulatory affairs, legal, investor relations, and board oversight functions rather than treating them as separate disciplines.

Why Insurers Are Paying Attention

IMPACTS TO THE D&O INSURANCE MARKET

Although it is not likely the FDA's transparency initiative alone would immediately create a broad hard market for Life Sciences D&O, it could absolutely become a contributing factor to harder underwriting conditions, particularly for development-stage biotechnology and specialty pharmaceutical companies.

From an insurance perspective, the issue is not the publication of CRLs itself. **The issue is what greater transparency does to claim frequency, claim severity, and underwriting uncertainty.**

Increases in event-driven securities suits following CRLs and increased derivative litigation against boards, means increased defense costs and larger settlements due to stronger documented evidence.

Likely underwriting responses may include:

+ Increased retention
+ Tightening Side-C capacity
+ Higher premium
+ Increase scrutiny of disclosure controls
+ Requesting more information about regulatory governance

Underwriter may also begin asking more detailed questions regarding:

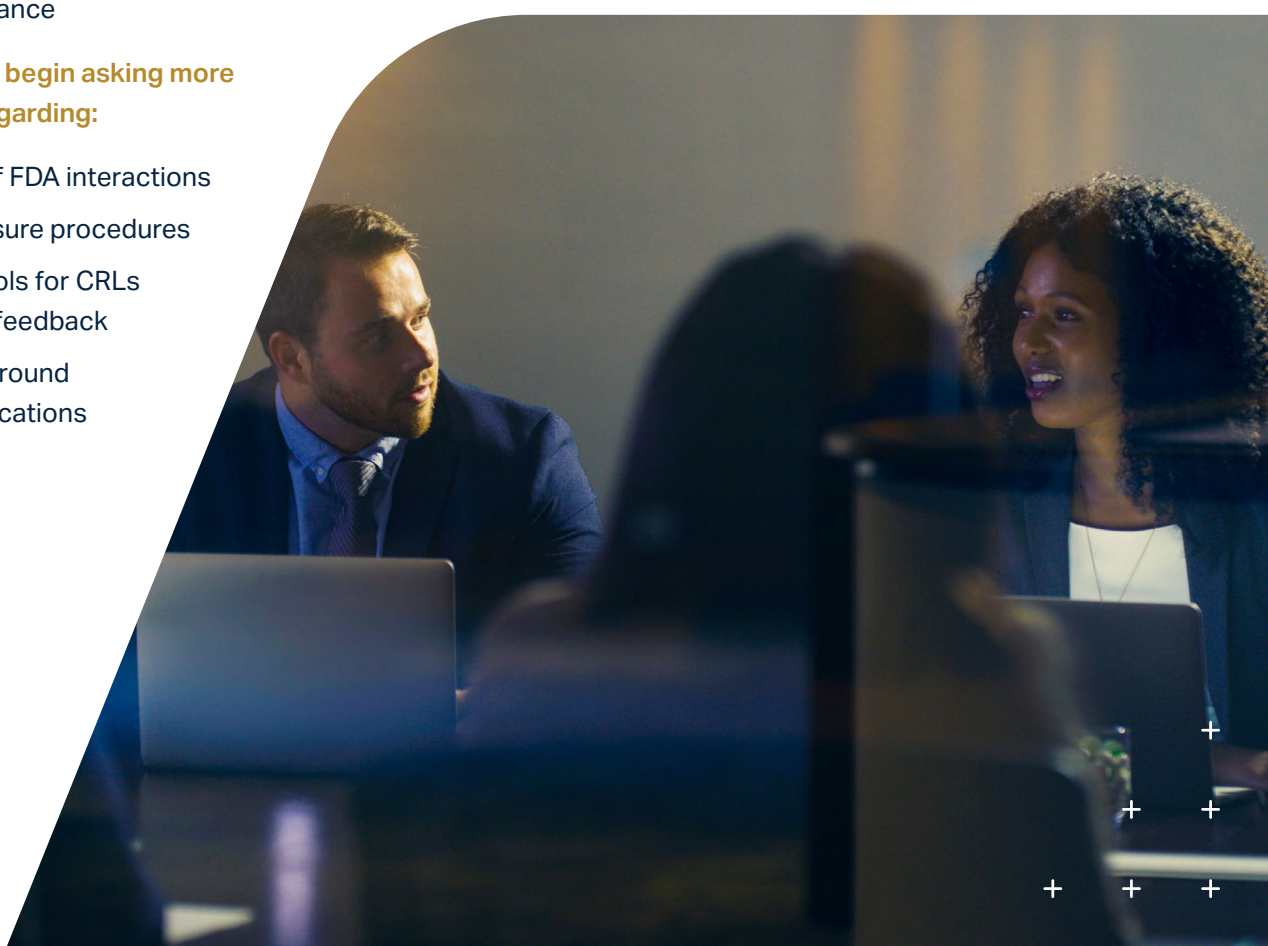
+ Board oversight of FDA interactions
+ Regulatory disclosure procedures
+ Escalation protocols for CRLs and FDA meeting feedback
+ Internal controls around investor communications

However, a hardening of the D&O market for life sciences companies is more likely to be done in a targeted manner rather than across the entire marketplace.

The companies most likely to be affected are:

+ Pre-commercial biotech companies
+ Single-asset companies
+ Companies awaiting FDA approval decisions
+ Rare disease companies with binary regulatory outcomes
+ Gene therapy developers
+ Cell therapy companies

These organizations already represent some of the highest-severity D&O risks because valuation is often tied to a single regulatory catalyst. **A CRL can erase a significant majority of market capitalization overnight, immediately creating shareholder litigation exposure.** The prospect of publicly available CRLs increases transparency around what management knew and when they knew it.



D&O Policy Coverage Considerations

CRL transparency has been anything but stable. The initiative was launched in July 2025, then paused in April 2026 after an industry legal challenge, and **has since partially resumed even though the underlying legal question remains unresolved**. For pharma/biotech D&O programs, that back-and-forth is itself a risk factor, not just a regulatory footnote, and it means companies can't fully predict which past or future FDA communications may eventually become public, complicating disclosure planning today.

The following are specific D&O coverage considerations to review:

SECURITIES CLASS ACTION AND DERIVATIVE LITIGATION EXPOSURE

If and when investors gain reliable access to the FDA's actual findings, there's a lot less room between what a company said and what the FDA concluded. That points to the potential for more event-driven securities suits tied to CRL publication (or to a company's later disclosure once a paused letter surfaces), plus the potential for derivative suits alleging board level failures to ensure accurate disclosures.

REGULATORY AND ENTITY INVESTIGATION COVERAGE

Confirm that the company has investigation coverage, along with the breadth of the coverage, and confirm whether it includes formal SEC orders, informal inquiries, subpoenas, and other regulatory investigations that could stem from a CRL-related disclosure gap. Entity coverage needs to be broad enough to respond to this trigger regardless of whether the publication policy is currently paused, resumed, or reformulated.

CONDUCT EXCLUSIONS

As more of these claims turn on whether management's characterization of FDA feedback held up, life sciences companies should confirm that conduct and fraud exclusions require a final, non-appealable adjudication before they apply (not just a trial court finding), that they include adequate carve-backs for defense costs, and that severability protects directors/officers who weren't involved.

REPRESENTATIONS, WARRANTIES, AND KNOWLEDGE EXCLUSIONS

As a go-forward best practice, boards should assume any given CRL could eventually become public. That raises the stakes on what a company knew and when, and whether it was disclosed at D&O policy renewal. Companies should be proactive about notifying their insurance carrier of material adverse FDA feedback to avoid rescission fights or knowledge-exclusion disputes later. These are items that should be proactively addressed in the D&O policy.

SIDE A DIC CONSIDERATIONS

For development stage and single-asset biotechnology companies, a CRL can wipe out most of their market cap overnight, and the odds of a securities or derivative suit following close behind it increase significantly, regardless of where the FDA's publication policy currently stands. If the balance sheet is thin or insolvency risk is present, Side A DIC is what protects individual directors and officers when the company can't indemnify them. Companies should ensure that they are buying dedicated Side A DIC coverage and that they are partnering with financially strong insurance markets.

Looking Ahead

The FDA's pause on CRL disclosure reflects unresolved legal and policy questions, but it does not change the broader trajectory toward greater transparency in healthcare regulation. Investor demand for access to regulatory information remains strong, and the FDA continues to pursue mechanisms that would formalize disclosure authority. Meanwhile, legal commentators increasingly recognize that FDA transparency initiatives have meaningful implications for securities regulation and corporate governance.[13]

For pharmaceutical and biotechnology companies, the lesson is clear: transparency risk is becoming disclosure risk, and disclosure risk is becoming D&O risk.

Boards and management teams that proactively strengthen governance, disclosure controls, and communication practices today will be better positioned to withstand the heightened scrutiny that tomorrow's regulatory environment may bring.

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