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Managing FDA Uncertainty as Enterprise Risk

Governance, Disclosure & Insurance Strategies for Life Sciences
Legal Leaders

ACC SFBA Life Sciences Conference 2026
March 11, 2026 | 10:45 AM – 11:45 AM PT

Panelists

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Executive Overview

FDA decisions no longer operate in isolation. Approval delays, evolving evidentiary expectations, public regulatory commentary, and policy shifts increasingly trigger downstream disclosure complexity, market volatility, securities litigation exposure, and board-level scrutiny.

For life sciences companies, regulatory unpredictability is not simply a compliance issue, it is a core enterprise risk.

This session examines:

- How evolving FDA posture influences disclosure obligations
- Where litigation exposure emerges when agency tone shifts
- How governance frameworks should respond to regulatory volatility
- How D&O insurance functions within broader enterprise risk architecture

The program integrates executive, regulatory, and enterprise risk perspectives to provide practical guidance for in-house legal leaders navigating uncertainty.

The Evolving FDA Environment

Public Regulatory Commentary (“Podium Policy”)

Senior agency officials increasingly speak publicly about regulatory philosophy and evidentiary standards. Even informal commentary can materially influence market perception.

Key considerations:

- When does regulatory tone become material?
 - How should companies assess market sensitivity?
 - What documentation supports disclosure decisions?
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Approval Variability & Evidentiary Expectations

Companies report increased variability in:

- Acceptance of surrogate endpoints
- Informal feedback versus formal agency action

- Mid-cycle shifts or reversals
- Policy overlays affecting review posture

Regulatory unpredictability increases the risk that internal optimism diverges from final agency outcomes.

Transparency vs. Consistency

Greater public visibility does not necessarily equate to predictability. Informal signals, evolving policy priorities, judicial developments (post-Chevron), and geopolitical considerations may introduce additional complexity into approval dynamics.

Legal teams must assess how increased transparency interacts with disclosure discipline.

When Regulatory Volatility Becomes Legal Exposure

Securities Litigation Risk

Plaintiffs frequently focus on:

- Statements regarding likelihood or timing of approval
- Characterization of FDA feedback
- Revenue projections tied to regulatory milestones

Courts evaluate whether public disclosures align with internal records, meeting notes, and risk assessments.

Derivative & Board-Level Exposure

Board oversight claims may arise when:

- Safety signals escalate
- Confirmatory trials falter
- Regulatory posture shifts unexpectedly
- Escalation pathways lack clarity

Documentation of board engagement and structured oversight becomes critical in defending such claims.

FDA Uncertainty as Enterprise Risk

When regulatory unpredictability escalates, impact extends across:

- Market capitalization volatility
- Securities and derivative litigation
- Executive and fiduciary exposure
- Strategic and operational disruption

Enterprise alignment requires coordination across:

- Executive leadership
- Regulatory affairs
- Legal & compliance
- Investor relations
- Board governance
- Risk transfer strategy

Regulatory uncertainty should be addressed through proactive governance architecture rather than reactive response.

Enterprise Risk & D&O Considerations

When regulatory events translate into litigation or fiduciary exposure, D&O insurance becomes a structural enterprise consideration.

Key focus areas include:

Limits Adequacy

Benchmarking against peer litigation severity and modeling event-driven claim scenarios.

Program Structure

Side A/B/C alignment, Independent Director coverage, lifecycle transitions (IPO, M&A, runoff).

Terms & Conditions

Definition of “Securities Claim,” conduct exclusions (final adjudication standard), regulatory exclusions, and “Related Claims” aggregation language.

Insurance Partners

Carrier stability and claims handling sophistication during volatile periods.

Disclosures & Warranty Considerations

Alignment between regulatory correspondence and insurance applications at renewal.

Insurance functions as part of enterprise risk architecture — not as a standalone solution.

Governance & Disclosure Alignment Checklist

Legal leaders should consider:

Governance

- Clear regulatory escalation pathways
- Board-level visibility into safety and milestone risk
- Documentation reflecting substantive oversight

Disclosure Discipline

- Alignment between internal FDA interactions and external statements
- Calibrated opinion language
- Risk factors that reflect current regulatory posture

Enterprise Preparedness

- Cross-functional “FDA event” protocol
- Litigation-ready documentation practices
- Coordinated crisis response framework

Risk Transfer Strategy

- Annual D&O structural review
 - Limits benchmarking
 - Term negotiation focused on life sciences exposure
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Key Takeaways

1. FDA uncertainty increasingly represents enterprise risk.

2. Disclosure alignment and governance discipline are critical in volatile regulatory environments.
 3. Regulatory unpredictability amplifies securities and derivative exposure.
 4. D&O insurance should be structured proactively within broader enterprise risk planning.
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Continue the Conversation

For further discussion on enterprise risk and insurance considerations in the life sciences sector:

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