

Managing FDA Uncertainty as Enterprise Risk:

Governance, Disclosure & Insurance
Strategies for Life Sciences Legal Leaders

March 11, 2026

Educational presentation for CLE purposes — not legal advice



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ACC
Association of
Corporate Counsel
— SAN FRANCISCO BAY AREA —

Session Overview & Agenda

01

Executive Perspective

Real-world impact of
FDA unpredictability

02

Regulatory & Legal Analysis

Approval dynamics,
disclosure implications,
evolving agency posture

03

Enterprise Risk & D&O Framing

How regulatory volatility
translates into liability
exposure

04

Q&A

Speakers



Stephen Brady
Chairman of the
Board
*Tempest
Therapeutics*



Sonia Nath
Partner and Chair,
Global Life Sciences
and Healthcare
Regulatory Practice
Cooley



Eric Tausend
SVP, Senior Director
& West Regional
ERS Leader
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EVP, Life Science
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Today's Discussion Themes

- What's happening with the FDA approval process?
- Turnover, bandwidth & increase in CRLs
- Podium policy & regulator speech
- Transparency vs. consistency
- Science, policy & geopolitical influence
- When to push back
- Managing complexity of risk & disclosures

Enterprise Risk & D&O Considerations

Enterprise Risk

- FDA dynamics as enterprise exposure
- Board oversight expectations
- Disclosures

D&O Insurance

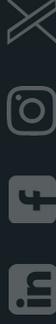
- Limits Adequacy
- Program Structure
- Terms & Conditions
- Insurance Partners

Thank You

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Connect with our expert team to
continue exploring insurance solutions
for the life science industry



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