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4th Annual Forum on Advanced Therapeutics

March 25 – 26, 2026
Metcalf Trustee Center, Boston University – Boston, MA

Regulatory, IP and Commercialization Strategies for Cell and Gene Therapies, RNA Therapeutics, and Regenerative Medicines

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AMY COMSTOCK RICK
Associate Director for Rare Disease Strategy
U.S. Food and Drug Administration

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Uniting Innovation, Law, and Strategy in RNA, Cell and Gene Therapy, and Regenerative Medicines

ACI's Forum on Advanced Therapeutics returns with a renewed focus on the dynamic forces shaping the future of RNA, cell and gene therapies, and regenerative medicine. Designed for professionals across legal, regulatory, scientific, and business functions, the event **dives into the evolving landscape of policy, IP, funding, innovation, and commercialization**.

Join us in Boston on March 25–26 to learn how your companies and clients can drive forward the most groundbreaking developments in advanced therapeutics, marrying scientific discovery with strategic business and legal acumen for global impact.

From AI in drug discovery to navigating market access and IP challenges, this forum offers practical insights and connections that help bring next-generation treatments to life.

Attend to engage with leading industry thought leaders and legal pioneers who will illuminate the path from groundbreaking research to global market success. Join the community driving meaningful advancement in advanced therapeutics.

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Director, Rare Disease Innovation Hub
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DAY 1 – Wednesday, March 25, 2026

8:00 Registration and Continental Breakfast

9:00 Co-Chairs' Opening Remarks



Rupa Cornell
VP, Legal Commercialization and Head of Compliance
Astria Therapeutics



Tamara Joseph
Chief Legal Officer
AIRNA Corporation



Julie Tierney
Director
Leavitt Partners
Former Deputy Director, U.S. FDA, Center for Biologics Evaluation & Research (CBER)



Jackie Wright Bonilla
Director
Sterne Kessler Goldstein & Fox
Former Deputy Chief Patent Judge, U.S. Patent and Trademark Office

9:15 Navigating Federal Policy Shifts Reshaping Advanced Therapeutics Under Trump 2.0

With the second Trump administration initiating changes across healthcare policy, regulatory priorities, and federal funding programs, the advanced therapeutics sector faces both uncertainty and potential opportunity. This session will examine how shifting priorities under the current administration — including the influence of RFK Jr.'s leadership at HHS — is shaping the regulatory, IP, and commercialization landscape for cell and gene therapies, RNA-based treatments, and regenerative medicines.

Discussion points include:

- Examining the latest federal policy shifts impacting FDA approval pathways, clinical trial requirements, and enforcement approaches for advanced therapeutics
- Exploring how a reconfigured HHS under RFK Jr. is reshaping NIH and FDA funding priorities, scientific independence, and public trust in therapeutic innovation
- A look at the future of pricing, reimbursement, and market access under changing CMS policies and budgetary constraints
- Updates on new and pending IP reforms impacting advanced therapeutics, including the REMEDY Act, PREVAIL Act, and RESTORE Patent Rights Act
- Assessing the current and future landscape of government march-in rights and the latest moves by the current administration to invoke Bayh-Dol



Michael Labson
Partner
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Julie Tierney
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Leavitt Partners
Former Deputy Director, U.S. FDA, Center for Biologics Evaluation & Research (CBER)



Rebecca Wood
Partner
Sidley Austin LLP
Former Chief Counsel, FDA

10:15 **Fireside Chat with the FDA:** Examining The Latest Trends in Advanced Therapeutics Reviews, Safety Standards, and Accelerated Pathways



Amy Comstock Rick
Director, Rare Disease Innovation Hub
U.S. Food and Drug Administration



11:30 Leveraging Global Markets: Securing Multi-Jurisdictional Approvals and R&D Resilience Amid U.S. Policy Uncertainty

As U.S. policy uncertainty continues to raise questions around approval timelines, pricing, and market access, global markets are becoming increasingly critical for the advancement of cell and gene therapies, RNA therapeutics, and other advanced therapies. This session will explore how companies can rebalance their regulatory and commercialization strategies to secure approvals across the EU and UKwhile also addressing the challenges of R&D offshoring and multi-jurisdictional compliance.

Discussion points include:

- Strategic approvals outside the U.S.: Evaluating pathways in the EU and UK to ensure early market entry and risk diversification
- Balancing R&D footprints: Managing the shift toward global R&D hubs, clinical trial sites, and manufacturing networks amid rising U.S. policy and cost pressures
- Navigating the complexities of differing regulatory frameworks and post-market obligations across jurisdictions
- Building resilience through global planning: Integrating regulatory, IP, and commercialization strategies to sustain innovation and protect long-term ROI



Jacqueline Berman
Partner
Morgan, Lewis & Bockius LLP



Xisca Borras
Partner
Bristows



Marco de Morpurgo
Partner, Global Co-Chair, Life Sciences
DLA Piper

12:15 Operationalizing Policy Risk: Future-Proofing Corporate Strategies to Protect Pipelines, Timelines, and Value

In today's rapidly evolving policy environment, companies developing advanced therapeutics must be prepared to adapt to shifting regulatory priorities, funding structures, and geopolitical dynamics. From FDA oversight to global market pressures, the ability to anticipate and proactively manage policy swings is becoming a core competency for biotech and pharma leaders. This session will unpack:

- Strategies for embedding policy risk management into corporate planning to safeguard R&D pipelines, commercialization timelines, and investor confidence
- Scenario planning and agility: Building flexible business models and development strategies that can withstand sudden shifts in oversight or funding
- Aligning internal teams and stakeholders: Integrating compliance, legal, R&D, and investor relations into a unified risk management approach
- Protecting long-term value: Using IP strategy, funding diversification, and regulatory engagement to reduce exposure to policy volatility



Tamara Joseph
Chief Legal Officer
AIRNA Corporation



Jenny Robertson
Former Chief Business and Legal Officer
Lexeo Therapeutics

1:00 Networking Luncheon

2:00 Balancing Affordability and Innovation: Tackling Pricing and Reimbursement Challenges for Advanced Therapeutics Under IRA and MFN

The IRA and recently proposed Most Favored Nation (MFN) pricing model, are reshaping the reimbursement and commercialization landscape for advanced therapeutics. For companies in the rare disease space—where development costs are high and patient populations are small—these policies carry significant implications for market access, deal-making, and innovation pipelines. This session will examine the legal, regulatory, and strategic dimensions of evolving federal drug pricing initiatives and provide practical guidance for managing their impact.

Discussion points will include:

- Breaking down the IRA's impact on rare disease therapies: Pricing negotiations, coverage challenges, and long-term reimbursement risks
- Decoding the MFN Executive Order: What it means in practice, whether it is legally binding, and potential enforcement or implementation pathways
- Addressing the tension between cost-containment measures and sustaining R&D for rare and ultra-rare conditions
- Preparing your company and pipelines for shifting federal drug pricing landscapes and cross-border ripple effects
- Exploring how the IRA and proposed MFN are influencing patent litigation strategies for advanced therapies



John Feore
Director, Health Policy & Advocacy
Institute for Gene Therapies



Sharon Small
Director, Counsel Market Access, Government Pricing and Policy
Novartis

2:45 **Preparing for Bayh-Doyle March-In Enforcement:** Protecting Pipelines and Mitigating Risk

As the current administration signals a stronger intent to invoke march-in rights under the Bayh-Dole Act, companies in advanced therapeutics must reassess their exposure and obligations tied to federally funded research. For organizations ranging from early-stage start-ups to established biopharma players, understanding how government rights may apply—and how to safeguard product pipelines—is now a critical strategic priority. This panel will tackle topics including:



Jennifer J. Chheda
Partner
Jones Day



Kelly Morgan
Senior Vice President, Head of Legal and Corporate Secretary
Ring Therapeutics

- Clarifying the scope of government march-in rights under Bayh-Dole and how they may affect cell, gene, and RNA therapy developers
- Assessing the level of risk for companies with past or ongoing federally funded research, including start-ups with early-stage support
- Strategies to mitigate exposure and protect product lines while balancing commercialization goals with compliance
- Preparing for potential government action: proactive steps legal, regulatory, and business teams should be taking now

3:30 Afternoon Break

3:45 **Securing Capital in a Cautious Market:** Building Financial Resilience for Advanced Therapeutics Through Creative Funding Solutions

In today's cautious capital environment, advanced therapeutics companies face unprecedented challenges in securing sustainable funding. With investors scrutinizing risk profiles, reimbursement uncertainty, and lengthy development timelines, it is more critical than ever to implement resilient financing strategies that balance near-term survival with long-term innovation. This session will explore creative approaches to capital planning, investor engagement, and deal-making that can help companies withstand financial headwinds while keeping pipelines on track. Join our panelists as they provide insights on:



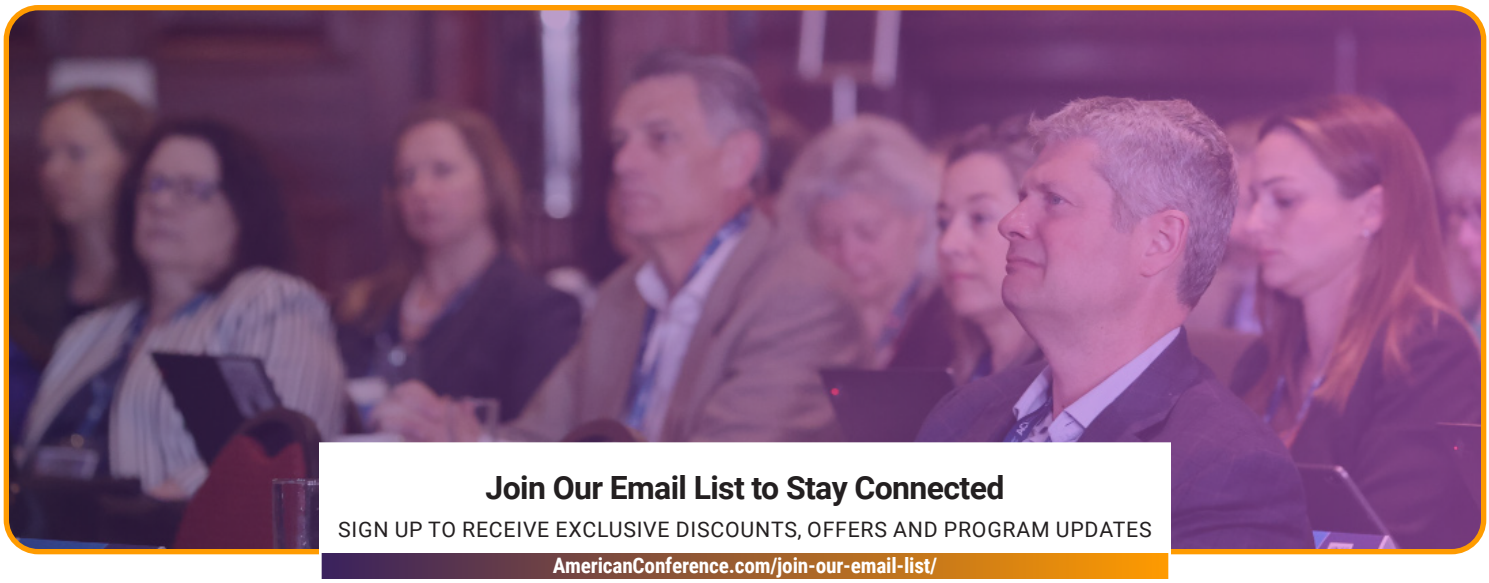
Jennifer Fang
Partner
Wilson Sonsini Goodrich Rosati



Stephanie Nowack
Director, Corporate Counsel
Astria Therapeutics

- What current trends signal for early- and late-stage financing rounds
- Leveraging alternative funding models to sustain operations
- Insights into venture philanthropy, milestone-based financing, and royalty-based investments as alternatives to traditional venture capital
- Balancing short-term liquidity with long-term growth: Building financial resilience without stalling innovation pipelines
- Case studies and lessons learned: How advanced therapeutics companies are navigating capital scarcity in real-world scenarios

4:30 Conference Adjourns



DAY 2 – Thursday, March 26, 2026

8:00 Registration and Continental Breakfast

8:45 Co-Chairs Welcome Back

9:00 **From Algorithms to Approvals:**
Harnessing AI to Accelerate Advanced Therapeutics While Managing Regulatory and IP Risks

Artificial intelligence and data science are reshaping the trajectory of advanced therapeutics, yet the integration of AI also raises novel challenges around regulatory acceptance, data integrity, and intellectual property protections. This session will explore how AI can be leveraged to enhance speed, precision, and scalability in advanced therapeutic development while navigating the emerging legal and policy questions tied to its use. Our panelists will tackle topics including:



Michael Harlin
Partner
Neal, Gerber & Eisenberg



Janet Xiao
Partner
Morrison & Foerster LLP

- How companies can effectively harness AI and machine learning for target selection, biomarker discovery, and trial optimization in advanced therapies
- Manufacturing innovation: Using AI to predict variability, optimize supply chains, and scale production for cell, gene, and RNA-based treatments
- Regulatory considerations: How FDA and global authorities are approaching AI-enabled therapeutic development and data validation
- IP and ownership questions: Who owns AI-generated insights, and how do they fit into patentability and freedom-to-operate frameworks? What are companies including in their patent filings when AI was used in the drug-discovery process?
- Strategic integration: Best practices for aligning AI-driven insights with existing R&D and commercialization strategies in advanced therapeutics

10:00 **Exclusivity Under Pressure:**
Reinforcing IP Protections to Maintain Market Position in Advanced Therapeutics

With more players entering the cell and gene therapy, RNA, and regenerative medicine arenas, exclusivity protections are facing unprecedented scrutiny. Companies must not only build robust IP portfolios but also defend them against challenges from competitors, regulators, and shifting policy frameworks. This session will provide practical strategies for safeguarding innovation and maximizing the value of IP assets in an increasingly competitive advanced therapeutics landscape.



Briana Erickson
VP, Head of Intellectual Property
Intellia Therapeutics



Adam Gregory
Partner, Patent Attorney (Life Sciences)
Mewburn Ellis



Mary Till
Of Counsel
Finnegan, Henderson, Farabow, Garrett & Dunner LLP
Former Policy Advisor, USPTO

Discussion points include:

- Building durable exclusivity: Best practices for layering IP protections across composition, methods, platforms, and manufacturing processes
- Navigating challenges: Addressing freedom-to-operate risks, competitor overlap, and evolving patentability standards in advanced modalities
- Litigation insights: Key takeaways from recent disputes involving cell, gene, and RNA therapies and their implications for future cases
- Global alignment: How to strengthen and harmonize IP protections across multiple jurisdictions with varying regulatory and legal frameworks
- Strategic alliances: Leveraging licensing, partnerships, and cross-licensing to expand portfolio strength and reduce litigation exposure

11:00 Morning Coffee Break

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11:30 Navigating IPR Strategy Amid Shifting USPTO Policy and Discretionary Denials

Recent changes in USPTO policy have made discretionary denials of inter partes reviews (IPRs) more common, altering the risk-benefit calculus for both challengers and patent holders. This session will provide both offensive and defensive perspectives to help stakeholders make more informed IP and business decisions in a rapidly changing landscape.

- Offensive considerations: Key factors in deciding whether and when to initiate an IPR petition against a competitor in light of higher discretionary denial rates
- Defensive posture: Strategies for preparing strong portfolios that can withstand IPR attacks under the USPTO's updated framework
- Timing and coordination: How litigation, settlement discussions, and parallel district court actions impact IPR viability and outcomes
- Risk management: Assessing costs, reputational implications, and competitive dynamics when using (or defending against) IPRs in advanced therapeutics



Jackie Wright Bonilla
Director
Sterne Kessler Goldstein & Fox
Former Deputy Chief Patent Judge, U.S. Patent and Trademark Office



Jonathan Caplan
Partner, Head of Intellectual Property, US
Herbert Smith Freehills Kramer LLP

12:15 Networking Luncheon

1:15 **Partnering for Progress:** Strategic Considerations for Deal-Making Across Early Research, Clinical Development & Commercialization

As advanced therapeutics evolve from discovery through clinical development and toward commercialization, strategic partnerships are increasingly essential at every stage of the lifecycle. From early-stage academic and biotech collaborations to global licensing and co-development deals, partnering can unlock critical expertise, capital, and infrastructure—while introducing new regulatory, IP/ownership and operational complexities. This session will examine how companies and their partners are structuring collaborations to advance innovation, manage risk, and preserve long-term value in a highly competitive and regulated environment.

Discussion topics include:

- Key considerations in academic–pharma and biotech–pharma collaborations, including IP ownership, data rights, publication controls, and translational risk
- Structuring IP rights across different types of deal lifecycles, from joint ventures, to partnerships, to licensing deals
  - » Allocation of patent ownership, exclusivity and sublicensing rights from discovery through commercialization
- Aligning incentives and milestones across discovery, clinical development, and commercialization
- Risk allocation and governance: Managing regulatory responsibility, development costs, compliance obligations, and exit scenarios as programs advance
- Lessons learned from recent collaborations: insights from advanced therapeutics collaborations that navigated the path from lab to clinic



Seema Basu
Head of Strategic Partnerships
Mass General Brigham



Marcus Colucci
Special Counsel
Herbert Smith Freehills Kramer (US) LLP



Chia-Feng Lu
Partner
Greenberg Traurig LLP

2:15 **Litigation Watchlist:** Breaking Down the Latest Disputes in mRNA, LNP, and ADC Patents

Patent litigation remains one of the most closely watched dynamics in advanced therapeutics, with high-stakes disputes shaping the future of innovation, exclusivity, and commercialization. From ongoing battles over mRNA and lipid nanoparticle (LNP) technologies to the rising wave of litigation surrounding antibody-drug conjugates (ADCs), these cases reveal not only the value of platform technologies but also the pressure points where innovators are most vulnerable. This session will unpack the litigation landscape to clarify what's really at stake—and what it means for the next wave of advanced medicines.

Discussion points include:

- mRNA and LNP litigation trends: Breaking down the core claims, defenses, and outcomes shaping platform IP battles
- ADCs in the spotlight: Why antibody-drug conjugates are becoming a new IP flashpoint and what disputes signal for innovators
- Freedom-to-operate risks: Practical considerations for companies navigating crowded patent spaces and overlapping claims
- Strategic implications: What ongoing disputes mean for licensing, collaborations, and portfolio-building in advanced therapeutics



Barbara Fiacco
Partner, Co-Chair Patent Litigation Practice
Foley Hoag LLP



Ryan Hagglund
Partner
Loeb & Loeb LLP



Daniel Shores
Member
Rothwell Figg

3:00 Closing Roundtable: Preparing for the 2027 Advanced Therapeutics Landscape: Science, Law, and Strategy

During our closing roundtable, our co-chairs will share perspectives on what lies ahead and how to strategically prepare for 2027. Our panelists will share forward-looking insights on:

- The most transformative innovations expected to define the next phase of cell, gene, RNA and immunotherapies
- The regulatory horizon for advanced therapies
- IP and litigation outlook for this space
- Commercialization considerations for the year ahead and strategies for strategic positioning



Rupa Cornell
VP, Legal Commercialization and Head of Compliance
Astria Therapeutics



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Julie Tierney
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Former Deputy Director, U.S. FDA, Center for Biologics Evaluation & Research (CBER)



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3:30 Conference Ends

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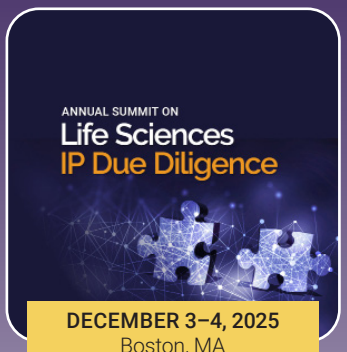

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