# FDLI Annual Conference

**May 6–7, 2026**
Ronald Reagan Building and International Trade Center
1300 Pennsylvania Avenue NW, Washington, DC 20004

## Agenda

*Subject to Change*
*All Times Are Eastern Standard Time*

## Day 1 | Wednesday, May 6, 2026

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| ***8:15–9:15 AM*** | ***Registration and Breakfast*** |
| **9:15–9:30 AM** | **FDLI Welcome and Introductory Remarks**<br>**Christine M. Simmon**, President & CEO, FDLI<br>**Kalah Auchincloss**, President & Principal, Canal Row Advisors and Co-Chair, 2026 FDLI Annual Conference Planning Committee<br>**Sharon Mayl**, Partner, DLA Piper LLP (US) and Co-Chair, 2026 FDLI Annual Conference Planning Committee |
| **9:30–10:00 AM** | **Fireside Chat: FDA Commissioner**<br>\| Drugs \| Devices \| Biologics \| Food \| Cannabis \| Cosmetics \| Veterinary \| Tobacco \|<br>**Marty Makary,** Commissioner of Food and Drugs, U.S. Food and Drug Administration<br>*Moderated by* **Vernessa T. Pollard**, Partner, DLA Piper LLP (US) and Chair, FDLI Board of Directors |
| ***10:00–10:10 AM*** | ***Networking Break*** |
| **10:10–10:40 AM** | **Keynote Address: FDA Chief Counsel**<br>\| Drugs \| Devices \| Biologics \| Food \| Cannabis \| Cosmetics \| Veterinary \| Tobacco \|<br>**Sean R. Keveney**, Chief Counsel, FDA<br>*Moderated by* **Raymond A. Bonner**, Partner, Sidley Austin LLP |
| ***10:40–10:50 AM*** | ***Networking Break*** |
| **10:50–11:50 AM** | **FDA Today: Milestones, Modernization, and MAHA**<br>\| Drugs \| Devices \| Biologics \| Food \| Cannabis \| Cosmetics \| Veterinary \| Tobacco \|<br>In 2026, FDA modernization is in full swing. From innovative review pathways and MAHA-related priorities to updated manufacturing and quality expectations, FDA's evolving policies are affecting approval timelines, compliance risk, and enforcement across all FDA-regulated products. This session examines the most significant developments, offering insights into the agency's actions and strategies for navigating the shifting regulatory landscape.<br>**Sara Brenner**, Principal Deputy Commissioner, Office of the Commissioner, FDA<br>**Grace Graham**, Deputy Commissioner for Policy, Legislation, and International Affairs, FDA<br>**Lowell M. Zeta**, Deputy Commissioner for Strategic Initiatives and Special Counsel, Office of the Chief Counsel, FDA |

*Moderated by* **Kalah Auchincloss**, President & Principal, Canal Row Advisors and Co-Chair, 2026 FDLI Annual Conference Planning Committee

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***11:50 AM–12:00 PM*** ***Networking Break***

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**12:00–12:45 PM**

## Funding, Regulation, and Science: The Future of the U.S. Innovation Model

| Drugs | Devices | Biologics | Food | Cannabis | Cosmetics | Veterinary | Tobacco |

The U.S. has long led global product innovation, even as rising international competition reshapes the landscape. This panel examines how FDA's review speed, evidence standards, single-trial approvals, advisory committee use, and NIH's funding priorities highlight fundamental questions of scientific judgement, regulatory certainty, responsive regulatory systems, and institutional credibility. Panelists will discuss the future of U.S. innovation, including how PDUFA can be leveraged to support stakeholder engagement in this space.

**Mary Denigan-Macauley**, Director, Health Care, U.S. Government Accountability Office
**Jeremiah J. Kelly**, Partner, Faegre Drinker Biddle & Reath LLP
**Lance L. Shea**, Partner, Foley Hoag LLP
*Moderated by* **John W.M. Claud**, Partner, Nelson Mullins Riley & Scarborough LLP

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**12:45–2:00 PM**

## Luncheon: FDLI Distinguished Service and Leadership & Rising Star Awards Presentations

*In-person only*

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**2:00–3:00 PM**

## Concurrent Breakout Sessions 1

- ### FDA Update: Center for Drug Evaluation and Research (CDER)

  | Drugs |

  **Winston S. Kirton**, Partner, BakerHostetler and Member, FDLI Board of Directors
  **Katlin McKelvie**, Partner, Gibson Dunn & Crutcher LLP
  **Lynn Mehler**, Partner, Paul Hastings LLP
  **James R. Ravitz**, Partner, McDermott Will & Schulte LLP
  *Moderated by* **Jennifer L. Bragg**, Partner, Latham & Watkins LLP

- ### Wristbands, Walled Gardens…Warning Letters? FDA, Wearables, and Wellness Tech

  | Devices |

  Learn the latest wearable device trends, from recent high-profile warning letters to CMS/FDA collaboration on the TEMPO pilot. The panel will also cover recent FDA guidances, including the agency's general wellness policy for low-risk devices and the latest CDS software guidance. Finally, panelists will discuss data privacy, patient protection, and broader compliance challenges in today's connected health landscape.

**Rick Abramson**, Director, Digital Health Center of Excellence (DHCoE), CDRH, FDA
**Jared Seehafer**, Senior Advisor, Office of Policy, Legislation, and International Affairs, Office of the Commissioner, FDA
**Ariel Z. Seeley**, Of Counsel, Morgan, Lewis & Bockius LLP
**Kyle Thomson**, Associate General Counsel, Senior Director of Privacy and Regulatory Compliance, Oura Ring
*Moderated by* **Rick Ball**, Partner, Duane Morris LLP

- **From States to Plates: Coordinating Food Inspections, Recalls, and Outbreak Response**
  | Food |
  Hear HFP's inspection, recall, and outbreak response updates, including the BRIDGE program's inspection shifts to states and recall modernization efforts. Panelists will also examine state testing initiatives, congressional information-sharing proposals, retailer recall execution, and related issues.
  **Kelly Higgins**, Managing Scientist-Chemical Regulation and Food Safety, Exponent
  **Steven Mandernach**, Executive Director, Association of Food and Drug Officials (AFDO)
  **Erik Mettler**, Associate Commissioner for Integrated Food Safety Systems, HPF, FDA
  **Ann M. Oxenham**, Director, Office of Compliance and Enforcement, HFP, FDA
  *Moderated by* **Douglas Stearn**, Principal, Canal Row Advisors

- **From Patchwork to Preemption—State Laws, Litigation, and AG Action**
  | Drugs | Devices | Biologics | Food | Cannabis | Cosmetics | Veterinary |Tobacco |
  This session explores the growing impact of consumer challenges to and state regulation of FDA-regulated products. Panelists will examine risks of regulatory disuniformity, federal preemption limits, class action litigation trends, and how states are responding to shifts in federal enforcement through indirect enforcement and empowering private litigation.
  **Michael Hering**, Director and Chief Counsel, Center for Tobacco and Public Health, National Association of Attorneys General (NAAG)
  **Abby Meyer**, Partner, Sheppard Mullin Richter & Hampton LLP
  **Patti J. Zettler**, John W. Bricker Professor of Law, The Ohio State University
  *Moderated by* **Samantha N. Hong**, Partner, Kleinfeld, Kaplan & Becker, LLP

- **FDA Update: Center for Tobacco Products (CTP)**
  | Tobacco |
  **Bret Koplow**, Acting Director, CTP, FDA
  *Moderated by* **Beth G. Oliva**, Partner, Fox Rothschild LLP and Member, FDLI Board of Directors

**3:10–4:10 PM** **Concurrent Breakout Sessions 2**

- **FDA Update: Center for Biologics Evaluation and Research (CBER)**
  | Biologics |
  **Katherine B. Szarama**, Acting Director, CBER, FDA
  *Moderated by* **Elizabeth Jungman**, Partner, Global Regulatory, Hogan Lovells US LLP

- **Do You Copy? Biosimilars, Generics, Fast Tracks and Fine Prints**
  | Drugs | Biologics |
  Panelists will discuss how FDA is advancing generics and biosimilars by streamlining evidence requirements—including using PK/PD and immunogenicity data—easing interchangeability, speeding approvals, promoting formulation transparency, and addressing skinny labeling and induced infringement. For biosimilars, speakers will cover biosimilar evidentiary standards; for generics, ANDA evidentiary standards and legislative developments, including GDUFA reauthorization.
  **Aziz Burgy**, Partner, Axinn, Veltrop & Harkrider LLP
  **Marshall Florence**, Vice President, Labeling and Strategy, ProPharma Group
  **Martha Nguyen**, Director, Division of Policy Development, Office of Generic Drugs, CDER, FDA
  **Mustafa Ünlü**, Policy Staff Director, Office of Therapeutic Biologics and Biosimilars, CDER, FDA
  *Moderated by* **Rachel Turow**, Of Counsel, Skadden, Arps, Slate, Meagher & Flom LLP

- **FDA Update: Human Foods Program (HFP)**
  | Food |
  **Kyle Diamantas**, Deputy Commissioner for Human Foods, HFP, FDA
  *Moderated by* **Sharon Mayl**, Partner, DLA Piper LLP (US) and Co-Chair, 2026 FDLI Annual Conference Planning Committee

- **Hack to the Future: Cybersecurity in FDA-Regulated Technologies**
  | Devices |
  Delve into cybersecurity in FDA-regulated technologies, including pre- and post-market expectations such as QMS integration and ongoing monitoring requirements. This panel explores unique risks for AI-enabled and networked medical devices, particularly in hospital settings, and reviews enforcement trends, including False Claims Act implications highlighted by recent high-profile DOJ settlements.
  **William F. Gould**, Partner, Holland & Knight LLP
  **Nastassia Tamari**, Division Director, Division of Medical Device Cybersecurity, CDRH, FDA
  **Christopher Terranova**, Assistant Director, Civil Division, Fraud Section, U.S. Department of Justice (DOJ)

**Jessica Wilkerson**, Technical Lead, Cybersecurity, Roche
*Moderated by* **Alex Smith**, Director of Regulatory Sciences, Hogan Lovells US LLP

- **ENDS and Outcomes: FDA CTP's Public Health Strategy**
  | Tobacco |
  Panelists will evaluate FDA CTP's approach to tobacco and nicotine products, examining competing end states and their trade-offs, the agency's goals, and the boundaries of its statutory authority. Discussion will focus on how public health progress is measured over time, FDA's current strategy, and what success would look like for reducing tobacco-related harm.
  **Donald Kenkel**, Andrew Dickson White Professor, Cornell University
  **Vaughan Rees**, Senior Lecturer on Social and Behavioral Sciences, Harvard T.H. Chan School of Public Health
  **Sally Satel**, Senior Fellow, American Enterprise Institute
  *Moderated by* **Joe G. Gitchell**, CEO, Pinney Associates, Inc.

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**4:20–5:20 PM** **Concurrent Breakout Sessions 3**

- **FDA Update: Center for Devices and Radiological Health (CDRH)**
  | Devices |
  **Michelle E. Tarver**, Director, CDRH, FDA
  *Moderated by* **Mike Ryan**, Executive Vice President, Regulatory Affairs Practice – U.S., ELIQUENT Life Sciences

- **DTC Enforcement—From Ad-equate to Audited**
  | Drugs | Biologics |
  This panel dives into FDA's enforcement against misleading DTC ads, including recent Warning and Untitled Letters and the rollback of the 1997 "adequate provision" loophole and return to full risk disclosure. It also examines social media ad campaigns and expectations for influencer marketing, including sponsorship disclosure and balancing product risks and benefits.
  **Dominic Cirincione**, Associate Director, US Advertising and Promotion Regulatory, Takeda
  **Michael Ostheimer**, Attorney, National Advertising Division, BBB National Programs
  **Joshua Oyster**, Partner, Ropes & Gray LLP
  **Lauren Roth**, Partner, King & Spalding LLP
  *Moderated by* **Melissa K. Mannion**, Of Counsel, Jones Day

- **What's on HFP's Table? MAHA, UPFs, Additives, Supplements, and Nutrition Policy Trends**
  | Food |
  This panel highlights FDA's nutrition policy priorities, including increased focus on food dyes and additives, scrutiny of ultra-processed foods tied to the new Dietary

Guidelines, dietary supplement innovation, labeling developments, infant formula transparency enhancements, and sodium and added sugar reduction initiatives.

**Kathryn Deschenes**, Director of Regulatory Affairs, Danone US
**Maia C. Kats**, Managing Member, Just Food Law
**Sarah Sorscher**, Director of Regulatory Affairs, Center for Science in the Public Interest
**Cara Welch**, Director, Office of Dietary Supplement Programs, HFP, FDA
*Moderated by* **Evangelia C. Pelonis**, Partner, Keller & Heckman LLP

- **FDA Update: Center for Veterinary Medicine (CVM)**
  | Veterinary |

  **Timothy C. Schell**, Director, CVM, FDA
  *Moderated by* **Daniel A. Kracov**, Partner, Arnold & Porter LLP

- **Risk, Reward, and Responsibility—From Data to Dialogue on Nicotine Communication**
  |Tobacco |

  This panel explores how scientific evidence informs the assessment and communication of nicotine product risk. It reviews what FDA has communicated to date, explores how messaging could evolve, and considers strategies for educating adults who smoke without appealing to youth. The discussion will also cover the role of non-FDA stakeholders in supporting clear and responsible nicotine communication.

  **Kathy Crosby**, CEO and President, Truth Initiative
  **Robyn Gougelet**, Vice President, US Regulatory Affairs, Juul Labs
  **Dorothy K. Hatsukami**, Professor, University of Minnesota
  **Mohamadi Sarkar**, Director of Regulatory Sciences, Altria Client Services
  *Moderated by* **Barry S. Schaevitz**, Partner, Fox Rothschild LLP

- **Building Your Brand in the Food and Drug Law Space**
  | Drugs | Devices | Biologics | Food | Cannabis | Cosmetics | Veterinary | Tobacco |

  Join a candid, practical discussion with seasoned legal and regulatory professionals with experience spanning the government, industry, private practice, and beyond. This panel will explore how professionals can expand their career potential by understanding what organizations really value. You will learn how to "build a brand" that matters and moves you ahead in the food and drug law space.
  ***Please note:*** *This session is in-person only and will not be livestreamed or recorded.*

  **Anna K. Abram**, Senior Advisor, Akin
  **Jeff Senger**, Lecturer, Columbia Law School and Mediator/Arbitrator, JAMS
  **Tony Subketkaew**, Assistant General Counsel, General Mills, Inc.
  *Moderated by* **Stuart TenHoor**, President, Stuart TenHoor Legal Search

**5:30–7:00 PM** **Networking Reception**

## Day 2 | Thursday, May 7, 2026

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| ***8:30–9:30 AM*** | ***Manufacturers Circle Breakfast****—Invitation Only* |
| ***9:00–9:30 AM*** | ***Registration and Breakfast*** |
| **9:30–9:45 AM** | **FDLI Welcome & FDLI Distinguished Service and Leadership Award Presentation**<br>**Paige Samson**, Director, Education, FDLI<br>*Honoree:* **Scott Ballin**, Tobacco and Health Policy Consultant *(posthumously)* |
| ***9:45–10:00 AM*** | ***Networking Break*** |
| **10:00–11:00 AM** | **Top Cases in Food and Drug Law**<br>**\| Drugs \| Devices \| Biologics \| Food \| Cannabis \| Cosmetics \| Veterinary \| Tobacco \|**<br>Learn about the most significant legal cases shaping food and drug regulation of the past year, covering both government enforcement actions and impactful private litigation.<br>**Gustav W. Eyler**, Partner, Gibson, Dunn & Crutcher LLP<br>**Neal D. Fortin**, Professor and Director, Institute for Food Laws & Regulations, Michigan State University and Member, FDLI Board of Directors<br>**Perham Gorji**, Partner, Alston & Bird LLP<br>**Lewis A. Grossman**, Ann Loeb Bronfman Professor of Law, Washington College of Law, American University<br>*Moderated by* **Stacy Amin**, Vice President & Chief Counsel, Global Health Regulatory & Policy, Oracle Health and Member, FDLI Board of Directors |
| ***11:00–11:15 AM*** | ***Networking Break*** |
| **11:15 AM–12:15 PM** | **Concurrent Breakout Sessions 4** |

- **How is FDA Using AI? Algorithms and Action Across the Centers**
  **\| Drugs \| Devices \| Biologics \| Food \| Cannabis \| Cosmetics \| Veterinary \|Tobacco \|**
  This panel explores how FDA uses AI to enhance oversight, regulatory review, and decision-making across its centers. Experts will discuss AI validation, transparency, data privacy, IP concerns, and how FDA evaluates and inspects manufacturers' AI systems, highlighting practical approaches to model governance, compliance, and ethical implementation.
  **Tiffany Branch**, Director, Office of Management and Enterprise Services, Office of the Commissioner, FDA
  **Sridhar Mantha**, Acting Chief Information Officer, Office of Digital Transformation, FDA

**Steven Musser**, Associate Commissioner for Human Foods Research, Human Foods Program, FDA
*Moderated by* **Tala H. Fakhouri**, Vice President Consulting: AI & Digital Policy, Real-World Research, Parexel

- **Personalized Medicine and Plausible Mechanisms: CGT and Rare Disease Innovation**
  | Drugs | Biologics |
  Hear from FDA leaders on emerging evidentiary standards, the new plausible mechanism pathway, and ongoing developments shaping personalized medicine and rare disease innovation. For cell and gene therapies (CGTs), speakers will highlight key points from FDA's recent guidances, the newly flexible approach to CMC, and FDA's broader stance on cGMPs. For rare disease therapies, discussions will cover alternatives to standard trials, reimbursement, safety, regulatory categorization, and the Rare Disease Innovation Hub's strategic agenda for 2026.
  **Phillip Kurs**, Associate Director for Policy, CBER, FDA
  **Amy Comstock Rick**, Director, Rare Disease Innovation Hub, FDA
  **Cara Tenenbaum**, Director of Regulatory Affairs, National Organization for Rare Disorders (NORD)
  **Julie Tierney**, Principal, Leavitt Partners, LLC
  *Moderated by* **Matthew Hegreness**, Partner, Covington & Burling LLP

- **Through the GRAS Grapevine—Loophole, Legislation, and Local Laws**
  | Food |
  This panel examines FDA's proposed rule to require mandatory GRAS notices and limit self-affirmed GRAS exemptions, recent congressional GRAS legislation, state initiatives on ingredient transparency, and the impact of the GRAS landscape on the food and dietary supplement industries.
  **Claire Chisolm**, Senior Manager, U.S. Pharmacopeia
  **Scott Faber**, Senior Vice President, Government Affairs, Environmental Working Group
  **Carly Pavia**, Managing Consultant, Ramboll US
  **Brian P. Sylvester**, Partner, Morrison Foerster
  *Moderated by* **Andrea Ferrenz**, Senior Food Law Counsel, The Campbell's Company

- **QMSR Goes Live! Inspection Insights, Audit Approaches, and QMS Queries**
  | Devices |
  This panel explores QMSR implementation insights, including what FDA's transition away from QSIT-based inspections means for management reviews, internal audits, and supplier audits. It examines early inspection trends from the first months of QMSR, strategies for maintaining transparency without increasing risk, and how expanded access to QMS documentation affects enforcement and product liability.

The discussion will also cover AI applications in the QMS and supply chain management.

**Philip R. Desjardins**, Partner, Arnold & Porter LLP
**Bobbi Druyor-Sanchez**, Expert Consultant, ProPharma Group
**Jaimi Gaffe**, Vice President, Regulatory Law, MedTech, Johnson & Johnson
**Keisha R. Thomas**, Associate Director for Compliance and Quality, Office of Product Evaluation and Quality, CDRH, FDA
*Moderated by* **Jennifer D. Newberger**, Director, Hyman, Phelps & McNamara PC

- **Next Gen Nicotine? Lessons from CTP's Nicotine Pouch Pilot**
  |Tobacco |
  Learn about FDA CTP's nicotine pouch pilot program, including changes introduced and lessons learned from recent authorizations. Panelists will cover implications for APPH, SE exemptions, and supplemental PMTAs, and consider whether features of the pilot could be applied to ENDS or other tobacco and nicotine product categories.
  **Jonathan Foulds**, Professor of Public Health & Psychiatry, Penn State University
  **Paige Magness**, Senior Vice President, Regulatory Affairs, Altria Client Services
  **Sarah Marking**, Chief Strategy Officer, Sanova
  **Cristi Stark**, Associate Director, Office of Science, CTP, FDA
  *Moderated by* **Stacy L. Ehrlich**, Partner, Kleinfeld, Kaplan & Becker, LLP

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**12:15–1:30 PM**

## Luncheon: Service to FDLI Award & Dr. Harvey Wiley Lecture and FDAAA Award

A lectureship in honor of Dr. Harvey W. Wiley, featuring the recipient of the namesake award bestowed by the FDA Alumni Association.
*In-person only*

**Joe Levitt**, Former Senior FDA Executive
*Introduced by* **Deborah M. Autor**, Chief Policy Officer, Hims & Hers, Inc. and Chair, Board of Directors, FDA Alumni Association

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**1:45–2:45 PM**

## Concurrent Breakout Sessions 5

- **AI, Devices, and Drug Development: Model Behavior in Medical Products**
  | Drugs | Devices | Biologics | Veterinary |
  This panel explores AI policy, NAMs, and digital tools across drug development and device regulation. Experts will discuss governance and patient protection in AI-driven research and how FDA assesses model drift and data integrity alongside "sameness" principles under core adulteration standards. For devices, speakers will examine SaMD, evolving CDRH guidance, and design control challenges for adaptive models. For drugs, the panel will discuss AI in preclinical research, clinical trials, and regulatory submissions.
  **Nakissa Sadrieh**, Associate Director for New Alternative Methods (NAM), CDER, FDA

**Anindita (Annie) Saha**, Associate Director for Strategic Initiatives, DHCoE, CDRH, FDA
**Sarah Thompson Schick**, Partner, Reed Smith LLP
**Rumi Young**, Director, Regulatory Policy, Novo Nordisk
*Moderated by* **Eric Henry**, Sr. Advisor, Head of Quality Compliance, Brooke & Associates

- **Compounding Conundrums: SAFE Act, State Bills, and FDA Scrutiny**
  | Drugs |
  Gain insight into recent compounding updates, including federal developments from the SAFE Act to FDA updates on the green list and Category II peptide restrictions; advertising scrutiny and high-profile lawsuits tied to compounded products, including GLP-1s; and state legislative activity affecting API sourcing, substance limits, labeling, and pharmacy operations.
  **Ilisa Bernstein**, Principal & Co-Founder, Compounding Strategy Advisors, LLC
  **Scott Brunner**, CEO, Alliance for Pharmacy Compounding
  **Matthew Lash**, Acting Director, Office of Compounding Quality and Compliance, Office of Compliance, CDER, FDA
  **Rachael G. Pontikes**, Partner, Blank Rome, LLP
  *Moderated by* **Julie A. Dohm**, Partner, Covington & Burling LLP

- **Testing Times: Whole Genome Sequencing, Sanitation, and the Future of Food Safety**
  | Food |
  Explore the future of food safety testing—from FDA's draft sanitation guidance for low-moisture ready-to-eat foods to its updated Listeria control guidance for RTE facilities, and the growing role of Whole Genome Sequencing (WGS). Hear legal insights on expert testimony, examine real-world case studies, and unpack how FSMA validation expectations are reshaping modern pathogen testing and compliance strategies.
  **Michael Hansen**, Senior Scientist, Consumer Reports
  **Benjamin Warren**, Senior Science Advisor for Food Safety, HFP, FDA
  **William A. McConagha**, Partner, Latham & Watkins LLP
  **Emily Moyer**, Managing Scientist, Exponent, Inc.
  *Moderated by* **Taryn Horr**, Senior Managing Consultant, Ramboll US

- **Remote, Risk-Based, and 'Round the World: FDA Inspections Reimagined**
  | Drugs | Devices | Biologics | Food | Cannabis | Cosmetics | Veterinary |Tobacco |
  FDA is transforming inspections through risk-based targeting, expanded unannounced foreign inspections, and increased use of remote regulatory assessments. The panel will unpack these developments and what they mean for inspection scope, global oversight, and industry readiness.
  **James R. Johnson**, Partner, Sidley Austin LLP

**Elizabeth Miller**, Associate Commissioner for Inspections and Investigations, Office of Inspections and Investigations, FDA
**Uta O. Rawson**, Senior Regulatory Legal Counsel, Philips
*Moderated by* **Laura Akowuah**, Special Counsel, Cooley LLP

- **Pathway to Progress: Regulatory Process Performance at CTP**
  |Tobacco |
  Gain insight into FDA CTP's PMTA, sPMTA, and EX pathways and efforts to enhance regulatory efficiency and consistency. This panel will highlight recent trends in submissions and reviews, CTP's resource allocation and regulatory process improvements, and best practices for industry to support higher-quality submissions and requests.
  **Shelly Blackwell**, Senior Director for Dietary Supplement and Tobacco Services, EAS Consulting
  **Matthew Farrelly**, Director, Office of Science, CTP, FDA
  **Alayna P. Tackett**, Associate Professor, The Ohio State University
  **Erin Warren**, Head of Regulatory and Public Policy, Philip Morris International
  *Moderated by* **Liz Oestreich**, SVP, Regulatory Compliance, ELIQUENT Life Sciences

**3:00–4:00 PM** **Full Circle: In-House Counsel Roundtable Across FDA-Regulated Products**

| Drugs | Devices | Biologics | Food | Cannabis | Cosmetics | Veterinary | Tobacco |

Join in-house counsel from leading manufacturers across the FDA-regulated landscape for a dynamic roundtable on the challenges shaping today's regulatory environment. Panelists driving legal strategy for companies with expansive portfolios will explore risk management, enforcement trends, and compliance strategies their teams are using to respond to the current regulatory environment. Gain cross-sector insights, practical takeaways, and a rare opportunity to hear from industry counsel.

**Karen Gally**, General Counsel, Otsuka America
**Mark Leonard**, General Counsel, Sunsweet Growers
**Tyler Mace**, Chief Legal Officer, Juul Labs
**Anne K. Miller**, Senior Strategic Legal Counsel, Medtronic and Member, FDLI Board of Directors
*Moderated by* **Alexander Gaffney**, Vice President, Regulatory Policy and Intelligence, Politico's AgencyIQ

***4:00–4:10 PM*** ***Closing Remarks and Adjournment***