

# CONFERENCE AGENDA

ACCESS SPEAKER PRESENTATIONS AT [fdli.org/annualmaterials19](https://fdli.org/annualmaterials19)

## THURSDAY, MAY 2

**8:00–9:00 AM**

**Registration and Continental Breakfast** *Atrium*

**9:00–9:15 AM**

**Welcome** *Atrium Hall*

**Amy Comstock Rick**, President & CEO, FDLI

**Amy Norris**, Chief Counsel, Clif Bar & Company and  
Co-Chair, FDLI Annual Conference Planning Committee

**9:15–9:45 AM**

**FDA Keynote Address** *Atrium Hall*

**Norman E. Sharpless**, Acting Commissioner of Food  
and Drugs, FDA

*Introduced by* **Jennifer L. Bragg**, Partner, Skadden,  
Arps, Slate, Meagher & Flom LLP, and Chair, FDLI Board  
of Directors

**9:45–10:45 AM**

**The Industry Perspective: Opportunities and  
Challenges Facing the FDA** *Atrium Hall*

This panel features an interactive, forward-looking  
discussion on the bigger picture direction and  
anticipated short- and long-term issues facing FDA and  
the food and drug communities.

**Jeffrey B. Chasnow**, Senior Vice President and Associate  
General Counsel, Pfizer, Inc.

**Monaya M. Krause**, Senior Legal Director, Medtronic

**Joe Murillo**, Senior Vice President, Regulatory Affairs,  
Altria Client Services LLC

**Amy Norris**, Chief Counsel, Clif Bar & Company

**Paul J. Savidge**, US General Counsel, Spark Therapeutics

**Jesse J. Sevcik**, Sr. Director, Global Government Affairs,  
Elanco Animal Health

*Moderated by* **Rebecca K. Wood**, Partner, Sidley Austin LLP

**10:45–11:15 AM**

**Coffee and Networking Break** *Atrium*

*Sponsored by* **FAEGRE BAKER  
DANIELS**

**11:15–12:15 PM**

**Breakout Sessions**

**Incentivizing Generic Drug Competition** *Polaris*

Recently, FDA has taken policy steps toward  
facilitating more efficient generic drug  
development by reducing barriers with the  
intent to incentivize competition and affect drug  
pricing. Actions include: application of FDARA's  
Competitive Generic Therapy designation;  
GDUFA II pathways for priority and expedited  
reviews; revised FDA guidance documents  
related to ANDAs; and revised thinking regarding  
180-day exclusivity. This panel will address how  
these actions practically impact generic drug  
development and work to meet FDA goals with  
regard to drug price competition and drug  
accessibility, as well as discuss potential new and  
innovative ways FDA might spur competition.

**Jeffrey K. Francer**, Senior Vice President & General  
Counsel, Association for Accessible Medicines  
(AAM) and Member, FDLI Board of Directors

**Chad A. Landmon**, Partner, Axinn, Veltrop &  
Harkrider LLP

**Brian McCormick**, Vice President & Chief  
Regulatory Counsel, Teva Pharmaceuticals USA, Inc.

**Martha C. Nguyen**, Director, Division of Policy  
Development, Office of Generic Drugs, CDER, FDA

**Maryll Toufanian**, Director, Office of Generic  
Drug Policy, CDER, FDA

*Moderated by* **Markham Luke**, Director, Division  
of Therapeutic Performance, Office of Generic  
Drugs, CDER

## Evolving 510(k) Program and De Novo Process

### *Hemisphere B*

CDRH has exponentially increased the number of de novo classification orders in the past 18 months. Should this be a pathway used for a truly novel product? This influx of new regulatory classifications creates a “blank” page for 510(k) submissions claiming substantial equivalence. FDA inherently must take a modified approach to reviewing those early submissions in new regulatory categories, and companies must understand the review risks when using either approval pathway. As FDA continues to deregulate or exempt more device categories from the requirement for a premarket notification, or 510(k), and to down-classify high-risk devices into moderate risk classes, how might this affect other aspects of medical device manufacturers’ legal and regulatory risks?

**Michele L. Buenafe**, Partner, Morgan, Lewis & Bockius LLP

**Bethany Hills**, Member, Mintz, Levin, Cohen, Ferris, Glovsky and Popeo, PC

**Marjorie Shulman**, Director, Premarket Notification (510(k)) Program, Office of Device Evaluation, CDRH, FDA

**Nicole Taylor Smith**, Vice President, Global Regulatory Policy, Medtronic

**Peter Yang**, De Novo Policy Analyst, CDRH, FDA

## Innovative Medical Product Technologies, Novel Products, and FDA Regulation *Horizon*

Medical technology innovation is exploding and disrupting longstanding patterns of innovation, research, development, regulation, and marketing in the life sciences industry. Big data, the Internet of Things, neurotechnology, AI, and cloud computing are just a few recent innovative tools. The pace of change is unrelenting, but is FDA able to regulate these emerging technologies without compromising innovation or delaying the next generation of technology to patients in need? What programs and policies have FDA considered, and must Congress provide new authorities to FDA to address the challenges in line with FDA’s core public health mission?

**Karen Corallo**, Of Counsel, Skadden, Arps, Slate, Meagher & Flom LLP

**Ellen Flannery**, Deputy Director for Policy, CDRH, FDA

**Grair Sipes**, Deputy Center Director, Regulatory Policy, CDER, FDA

**Andrew Wasson**, Partner, Haug Partners LLP  
*Moderated by* **Elizabeth R. Jungman**, Director, Public Health Programs, The Pew Charitable Trusts and Member, FDLI Board of Directors

## Animal Drugs and Antimicrobial Resistance

### *Meridian DE*

Late last year, FDA released a five-year plan to further address the use of medically important microbials and antimicrobial stewardship in veterinary settings. The detailed strategy includes 32 points of action toward the goals of appropriate antimicrobial use, fostering appropriate use in veterinary settings, and enhanced monitoring of resistance and antimicrobial drug use in animals. What are the potential impacts and implications of this strategy? Is progress being made toward public health goals? Are we having fewer resistant outbreaks in humans? Panelists will discuss these issues and where roadblocks and legal actions are most likely to occur throughout implementation of this voluntary strategy.

**William Flynn**, Deputy Director for Science Policy, CVM, FDA

**John Hallberg**, Director of Regulatory Affairs, Zoetis

**Karin Hoelzer**, Senior Officer, Health Programs, The Pew Charitable Trusts

*Moderated by* **Ron Phillips**, Vice President, Legislative and Public Affairs, Animal Health Institute

## Federal Oversight of Food Biotechnology

### *Oceanic AB*

Recently, there has been an escalation in federal activity regarding the regulation of biotechnology as it relates to food. USDA recently released its final rule for the disclosure and labeling of bioengineered foods. FDA and USDA also announced they will jointly regulate cell-based meat products. USDA is also in the process of finalizing a proposed rule on gene-edited plants. This panel will

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discuss actions in these areas, including how the agencies may move forward in developing a regulatory pathway for novel products and priorities outlined in FDA's Plant and Animal Biotechnology Innovation Action Plan.

**Trevor Findley**, Deputy Director, Food Disclosure and Labeling, Agriculture Marketing Service, USDA

**Gregory Jaffe**, Biotechnology Project Director, Center for Science in the Public Interest (CSPI)

**Matthew Michael**, Director, Issuances Staff, Office of Policy and Program Development, Food Safety and Inspection Service, USDA

**Nicole Negowetti**, Lecturer on Law & Clinical Instructor, Harvard Law School

*Moderated by* **Smitha G. Stansbury**, Partner, King & Spalding LLP

## **Modified Risk Tobacco Product Applications: Status Update** *Hemisphere A*

The Tobacco Control Act requires manufacturers of modified risk tobacco products (MRTP) to submit a premarket application and obtain market authorization before marketing the product. The application must provide information on the product sufficient to allow the agency to determine that the product will or is expected to reduce harm and the risk of tobacco-related disease as compared to commercially marketed tobacco products. In this panel, speakers will delve into the latest developments on the status of MRTP applications, including a discussion of the most recent Tobacco Products Scientific Advisory Committee (TPSAC) hearings and FDA decisions on pending MRTP applications.

**Michael Fisher**, Senior Research Scientist, Altria Client Services LLC

**Dennis Henigan**, Vice President, Legal and Regulatory Affairs, Campaign for Tobacco-Free Kids

**Matthew R. Holman**, Director, Office of Science, CTP, FDA

**James M. Solyst**, Vice President, Federal Regulatory Affairs, Swedish Match North America  
*Moderated by* **J. Benneville (Ben) Haas**, Partner, Latham & Watkins LLP

## **12:15–1:25 PM**

### **Luncheon: FDLI Annual Remarks and FDLI Awards Presentation** *Atrium Ballroom*

#### **FDLI Annual Remarks**

**Amy Comstock Rick**, President & CEO

#### **FDLI Distinguished Service and Leadership Awards**

*Presented by* **Amy Comstock Rick**, President & CEO, FDLI, and **Laura Brown**, Director, Educational Programs, FDLI  
**Award Recipients:**

**Leslie Krasny**, Senior Counsel, Keller and Heckman LLP

**Jeremiah J. Kelly**, Chief of FDA Regulatory Law, Office of the Staff Judge Advocate (JAG), US Army Medical Research and Materiel Command (USAMRMC)

**Captain Martin Shimer**, Deputy Director, Division of Legal and Regulatory Support, CDER, FDA

## **1:25–1:30 PM**

### **Transition**

## **1:30–2:00 PM**

### **Keynote Speaker** *Atrium Hall*

**Stacy Cline Amin**, Chief Counsel, FDA

*Introduced by:* **Jeffrey N. Gibbs**, Director, Hyman, Phelps & McNamara, PC and Immediate Past Chair, FDLI Board of Directors

## **2:00–2:10 PM**

### **Transition**

**2:10–3:25 PM**

## Breakout Sessions: FDA Center Directors

### Center for Drug Evaluation and Research (CDER)

#### *Horizon*

**Janet Woodcock**, Director, Center for Drug Evaluation and Research, FDA

**Jeff Allen**, President & CEO, Friends of Cancer Research

**Dave Ceryak**, Senior Director, Assistant General Counsel, Regulatory Legal Team, Eli Lilly and Company

**Philip Katz**, Partner, Hogan Lovells US LLP

**Christine Simmon**, Senior Vice President, Policy & Strategic Alliances, Association for Accessible Medicines

*Moderated by* **Deborah M. Shelton**, Partner, McCarter & English LLP

### Center for Biologics Evaluation and Research (CBER)

#### *Oceanic AB*

**Peter W. Marks**, Director, Center for Biologics Evaluation and Research, FDA

**Barbara A. Binzak Blumenfeld**, Shareholder, Buchanan Ingersoll & Rooney PC

**Richard A. Moscicki**, Chief Medical Officer and Executive Vice President, Science and Regulatory Advocacy, PhRMA

**Rachel Sher**, Vice President, Policy and Regulatory Affairs, National Organization for Rare Disorders

*Moderated by* **Neil Di Spirito**, Member of the Firm, Epstein Becker & Green, PC

### Center for Devices and Radiological Health (CDRH)

#### *Polaris*

**Jeffrey E. Shuren**, Director, Center for Devices and Radiological Health, FDA

**Mahnu Davar**, Partner, Arnold & Porter LLP

**Heather S. Rosecrans**, Executive Vice President, Medical Devices & Combination Products, Greenleaf Health, Inc.

**Kristi Schrode Travers**, Assistant General Counsel and Group Leader, Medical Device Regulatory Law, Johnson & Johnson

*Moderated by* **Vernessa Pollard**, Partner, McDermott Will & Emery LLP

### Center for Food Safety and Applied Nutrition (CFSAN)

#### *Hemisphere B*

**Susan T. Mayne**, Director, Center for Food Safety and Applied Nutrition, FDA

**Jessica Almy**, Director of Policy, The Good Food Institute

**Amy E. Hancock**, Executive Vice President | General Counsel, American Beverage Association

**Meredith Quinn Olearchik**, Vice President and Associate General Counsel – Intellectual Property, Marketing and Food Law, Campbell Soup Company

**Megan Olsen**, Assistant General Counsel, Council for Responsible Nutrition

*Moderated by* **Stuart M. Pape**, Shareholder, Polsinelli PC

### Center for Tobacco Products (CTP)

#### *Hemisphere A*

**Mitchell R. Zeller**, Director, Center for Tobacco Products, FDA

**Tony Abboud**, Executive Director, Vapor Technology Association

**Moira Gilchrist**, Vice President, Scientific and Public Communications, Philip Morris International

**Seth A. Mailhot**, Partner, Husch Blackwell LLP

*Moderated by* **Kathleen Hoke**, Professor & Director, Network for Public Health Policy and Center for Tobacco Regulation, University of Maryland Carey School of Law

### Center for Veterinary Medicine (CVM)

#### *Meridian DE*

**Steven M. Solomon**, Director, Center for Veterinary Medicine, FDA

**Rachel Cumberbatch**, Director, International and Regulatory Affairs, Animal Health Institute

**Brian D. Eyink**, Counsel, Hogan Lovells US LLP

**Kristin Landis**, Deputy General Counsel, Biotechnology Innovation Organization

*Moderated by* **Sean Lee**, Of Counsel, Shook, Hardy & Bacon LLP

**3:25–3:50 PM**

## Coffee and Networking Break *Atrium*

**3:50–4:50 PM**

## Breakout Sessions

### Clinical Trials and the Use of Real-World Data in Medical Product Development *Horizon*

FDA, companies, and clinical researchers are increasingly making use of real-world data. Expanded use of real-world evidence (RWE) and data registries could reduce the time and cost of new product approvals, while providing greater

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understanding of how products perform under “real life” conditions. Given this increased focus on real-world data in clinical research, FDA has recently published multiple guidance and draft guidance documents aimed at encouraging greater use of RWE and product and patient registries in new product approvals. This panel will explore the circumstances under which FDA will accept real-world evidence, different possible uses of RWE and Data Registries for regulatory purposes, potential challenges associated with their use, and how to work collaboratively with the agency to take advantage of these new approaches.

**Kara Kilpatrick**, Senior Manager, Center for Observational Research, Amgen Inc.

**David B. Martin**, Associate Director for Real World Evidence Analytics, CDER, FDA

**Eric Solowey**, Vice President and Assistant General Counsel, Parexel International

*Moderated by* **John R. Manthei**, Partner, Latham & Watkins LLP

## **FDA's Software Precertification Program** *Hemisphere B*

FDA has recently unveiled its Software Precertification Pilot Program version 1.0. This new regulatory paradigm will fundamentally shift FDA's oversight of software, with the goal of speeding up premarket access for new software-based technologies, and at the same time giving FDA greater control over the total product lifecycle of the software. Panelists will discuss the strengths and weaknesses of the program and how it might be adopted for technologies beyond standalone software in the future.

**Lesley Maloney**, Head, US Regulatory Policy, Roche Diagnostics

**Bakul Patel**, Associate Director of Digital Health, CDRH, FDA

**Ian Pearson**, Senior Associate, Jones Day

*Moderated by* **Frederick R. Ball**, Partner, Duane Morris LLP and Treasurer, FDLI Board of Directors

## **New Advances and Updates in the Biologics and Biosimilars Landscape** *Polaris*

This panel will address new developments and updates in the biosimilar landscape, including regulatory, legal, and state updates. Speakers will address: takeaways from FDA's September 2018 hearing on enhancing competition and innovation in the marketplace by facilitating availability of biosimilar and interchangeable products and current barriers; insight from both innovator and biosimilar perspectives on how FDA's final naming guidance has impacted their own business and practices; an update on patent dance cases and interpretations of BPCIA provisions by patent courts; biosimilar reimbursement; and how international agencies, including FDA, approach biosimilar extrapolation of indications and how outcomes can vary across agencies.

**Daniel A. Kracov**, Partner, Arnold & Porter LLP and Secretary and General Counsel, FDLI Board of Directors

**Teresa Stanek Rea**, Partner, Crowell & Moring LLP

**Sarah Yim**, Acting Director, Therapeutic Biologics and Biosimilars Staff, CDER, FDA

*Moderated by* **Freddy A. Jimenez**, Vice-President, Law and Compliance, Celldex Therapeutics, Inc. and Member, FDLI Board of Directors

## **Updates in Animal Food and Feed: State Changes, GRAS, and FSMA** *Meridian DE*

There is quite a lot happening in the animal food and feed space from both manufacturer and consumer perspectives, particularly surrounding concerns about what is in the food being consumed by pets, as well as livestock that will become food production animals. Speakers will delve into the issues surrounding pet food and heart disease, how pet food regulation differs in the US and EU, updates on state actions, and how the treatment of food and feed additives is evolving for both pets and to improve livestock



health and performance. The implementation of the FSMA rule on Preventive Controls for Animal Food, updates on third-party certification bodies for animal food safety audits, and current enforcement actions and policy initiatives with respect to animal food and feed will also be discussed.

**John Dillard**, Principal Attorney, Olsson Frank Weeda Terman Matz PC

**Jeanette Murphy**, Consumer Safety Officer, Office of Surveillance and Compliance, CVM, FDA

**Peter Tabor**, Vice President, Regulatory & International Affairs, Pet Food Institute

*Moderated by* **Jason W. Sapsin**, Counsel, Faegre Baker Daniels LLP

### Food and Dietary Supplement Class Action

#### Litigation: Developments and Strategies *Oceanic AB*

Recently, more courts are holding that class action plaintiffs lack standing to seek injunctive relief where they now understand that the food labels or advertisements over which they are suing are deceptive, and thus are in no danger of being misled in the future. There are also advancements in personal jurisdiction, failure to state a claim under the “reasonable consumer” standard, and settlements. This panel will consider litigation developments and procedural strategies to protect your client in class action suits.

**Marisol C. Mork**, Partner, Squire Patton Boggs (US) LLP

**Ronald Y. Rothstein**, Partner, Winston & Strawn LLP

**Nury H. Yoo**, Counsel, Keller and Heckman LLP

### What’s New in the World of Combustible

#### Tobacco Products *Hemisphere A*

Since the announcement of the Comprehensive Plan for Tobacco and Nicotine Regulation in 2017, FDA has recently issued policy statements and taken actions regarding combustible tobacco products. FDA seeks to regulate nicotine levels in combustible products so that they are minimally or non-addictive by promulgating a nicotine product standard. In addition, it is moving forward with a proposed rule to ban flavored cigars, as well as considering proposals to prohibit menthol in cigarettes. This panel will contemplate the legal considerations of these

actions, public health implications, and potential impacts on the marketplace and illicit trade.

**Carole Folmar**, Director, Regulatory and Scientific Affairs and Associate General Counsel, ITG Brands, LLC

**Stacey Younger Gagosian**, Managing Director, Public Policy, Truth Initiative

**Eric N. Lindblom**, Director, Tobacco Control and Food & Drug Law, O’Neill Institute for National and Global Health Law, Georgetown University Law Center

**Barry Schaevitz**, Partner, Fox Rothschild LLP

**4:50–5:00 PM**

**Transition**

**5:00–5:30 PM**

**Prescription for Change: Disruption in the Health Care Industry** *Atrium Hall*

*Speaker:* **Randall J. Ortman**, Product Counsel, Verily Life Sciences LLC

*Interviewed by* **Margaret (Peggy) Dotzel**, Partner, Zuckerman Spaeder LLP

**5:30–7:00 PM**

**Networking Reception** *Atrium*

## FRIDAY, MAY 3

**8:00–8:40 AM**

**Continental Breakfast** *Atrium*

**8:40–8:45 AM**

**FDLI Welcome** *Atrium Hall*

**Amy Comstock Rick**, President & CEO, FDLI

**William B. Schultz**, Partner, Zuckerman Spaeder LLP and Co-Chair, FDLI Annual Conference Planning Committee

**8:45–8:55 AM**

**Service to FDLI Award** *Atrium Hall*

*Presented by* **Amy Comstock Rick**, President & CEO, FDLI and **Laura Brown**, Director, Educational Programs, FDLI

**Award Recipient:** **Sarah Roller**, Partner, Kelley Drye & Warren LLP

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**8:55–9:20 AM**

## **Dr. Harvey Wiley Lecture and FDAAA Award** *Atrium Hall*

A lectureship named in honor of Dr. Harvey W. Wiley, the renowned physician-chemist who, at the turn of the 20<sup>th</sup> century, championed a legislative crusade against food adulteration, earning him the title of “Father of the Pure Food and Drugs Act” when it was enacted into law in 1906.

**Richard Pazdur**, Director, Oncology Center of Excellence, FDA

*Presented by* **Nancy Myers**, President, Catalyst Healthcare Consulting

**9:20–10:20 AM**

## **Challenges and Approaches for FDA-Regulated Companies Operating Globally** *Atrium Hall*

How is FDA interacting with regulatory bodies in countries outside of the US? What are key priorities for both the US FDA and related agencies in other jurisdictions? In what collaborative programs is FDA engaged with other countries? During this panel, speakers will discuss some of the current legal and regulatory actions and trends in globalization and harmonization, including FDA's involvement with the International Council for Harmonization, global issues in emerging technologies, and foreign inspections. Speakers will also address how to approach regulatory issues in a global business setting, how different regulatory schemes impact mergers & acquisitions, and the culture of compliance across foreign business units.

**Anna Abram**, Deputy Commissioner for Policy, Legislation and International Affairs, Office of the Commissioner, FDA

**Deborah M. Autor**, Senior Vice President, Head of Strategic Global Quality and Regulatory Policy, Mylan Pharmaceuticals, Inc.

**Howard R. Sklamberg**, Partner, Akin Gump Strauss Hauer & Feld LLP

*Moderated by* **James N. Czaban**, Partner, DLA Piper LLP

**10:20–10:40 AM**

## **Coffee and Networking Break**

*Sponsored by* **sánchez devanny**

**10:40–11:30 AM**

## **Breakout Sessions**

### **Understanding DEA Regulations and FDA Interactions: A Case Study on Opioids** *Polaris*

Controlled substances are subject to both the Drug Enforcement Administration (DEA) and FDA regulation and requires coordination between the agencies to ensure compliance. The DEA is taking more aggressive enforcement actions against drug manufacturers, distributors, importers, exporters, pharmacies, and practitioners in response to the current opioid abuse crisis. This panel will explain what every controlled substance manufacturer, distributor, pharmacy, and practitioner must do to comply with federal controlled substance requirements and how FDA is involved in these processes and inspections, with a specific eye to recent actions by both agencies on opioids.

**Larry K. Houck**, Director, Hyman, Phelps & McNamara, PC

**Lynn Mehler**, Partner, Hogan Lovells US LLP

**Loren Miller**, Policy Section Chief, Diversion Control Division, DEA

### **Machine Learning, AI, and Digital Health** *Horizon*

Digital health technologies are rapidly integrating into healthcare and life sciences – from wearables in clinical trials to digital tools for disease management and clinical decision support. Many of these technologies are and will deploy machine learning and artificial intelligence. This panel will discuss how these new technologies are being integrated and how FDA's role in regulation will continue to evolve. FDA's recent discussion paper on AI devices, as well as the challenges of AI regulation, generally, such as liability, quality assurance, and approval pathways for a product that continually evolves will also be discussed.

**Wade Ackerman**, Partner, Covington & Burling LLP

**Carla Cartwright**, Director, Global Regulatory Policy, Johnson & Johnson and Member, FDLI Board of Directors

**Mark C. Levy**, Partner, Eckert Seamans Cherin & Mellott, LLC

**Bakul Patel**, Associate Director of Digital Health, CDRH, FDA

### Current Proposals for Diagnostics Reform

#### *Meridian DE*

These fields have evolved drastically in recent years, leading FDA and others to call for regulatory clarification and reform. How should these advancements be regulated? What are the key considerations that should guide diagnostics regulatory reform moving forward? What has been the impact of recent guidance on the precision medicine industry? How might regulatory reform impact product development, manufacturing, and the use of diagnostics in clinical trials and treatment? How might the recent legislative and regulatory proposals ensure accuracy and reliability without stifling innovative technologies?

**Elizabeth Hillebrenner**, Associate Director for Scientific and Regulatory Programs, CDRH, FDA

**Aaron L. Josephson**, Senior Director, ML Strategies LLC

**Eric M. Marshall**, Senior Director, Leavitt Partners LLC

*Moderated by* **Elizabeth Richardson**, Director, Health Care Products Project, The Pew Charitable Trusts

### Updates in International Food Regulation and Trade: Foreign Supplier Verification Program, Efforts in Harmonization, and the United States-Mexico-Canada Agreement *Oceanic AB*

Canada, the US, and Mexico have recently achieved a new free trade agreement (USMCA). What are the new provisions under the USMCA that may affect trade of food and beverage products vis a vis NAFTA? This session will focus on international requirements, practical issues, and legal differences between Canada, the US, and Mexico regarding the importation and exportation of food and beverage products under the new trade agreement.

**Jose Alberto Campos-Vargas**, Partner, Sanchez Devanny

**Teresa A. Reguly**, Partner, Torys LLP

**Sarah Roller**, Partner, Kelley Drye & Warren LLP

### Electronic Nicotine Delivery Systems Part I: Regulation to Prevent Youth Initiation and Use

#### *Hemisphere A*

FDA and CTP have focused recent efforts on limiting youth access to and appeal of electronic nicotine delivery systems (ENDS). Recent actions include targeted education on the dangers of e-cigarettes in the Real Cost Campaign and regulatory actions to ensure that flavored ENDS products are sold in ways that make them less accessible and appealing to minors. What are the results of these efforts? What are cutting-edge, evidence-based ways to prevent youth from initiating use of ENDS? What are the public health implications and concerns of these actions?

**Clive Bates**, Director, Counterfactual Consulting Limited

**Aruni Bhatnagar**, Professor of Medicine and Distinguished University Scholar, University of Louisville and Fellow, American Heart Association

**Tevi D. Troy**, Vice President of Public Policy, JUUL Labs

*Moderated by* **Stacy L. Ehrlich**, Partner, Kleinfeld, Kaplan & Becker, LLP and Member, FDLI Board of Directors

### Focus on Investigations: Government Trends and Best Practices for Internal Investigations

#### *Hemisphere B*

What are the latest trends in federal investigations in the drug, device, and food space? How does a company know if a parallel investigation is underway, and how does that affect the course of an investigation? In this panel, speakers will discuss FDA and DOJ enforcement priorities and provide best practices for conducting an internal investigation. Learn when you need to do an Upjohn warning and how to do one well to avoid consequences. Speakers will also provide guidance on specific types of investigations, such as cGMP or data integrity, marketing practices, and safety reporting.

**John Bentivoglio**, Partner, Skadden, Arps, Slate, Meagher & Flom LLP



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**John Claud**, Assistant Director, Consumer Protection Branch, US Department of Justice  
**William F. Gould**, Partner, Holland & Knight LLP  
*Moderated by* **Beth P. Weinman**, Counsel, Ropes & Gray LLP

**11:30–11:40 AM**

**Transition**

**11:40 AM–12:30 PM**

**Breakout Sessions**

## **Orphan Drug and Rare Disease Developments** *Polaris*

How far can orphan drug exclusivity extend and can FDA require clinical superiority for the same drug? What are the implications of sub-classifications of rare diseases for clinical trials, drug developers, regulators, industry, and payers? This panel will explore the history of the Orphan Drug Act, the concept of clinical superiority for drugs with the same active moiety, and the principles of drug development in the rare disease setting.

**Kendra Martello**, Executive Director, Public Policy and Corporate Social Responsibility, Mallinckrodt Pharmaceuticals

**Adora Ndu**, Executive Director, Global Regulatory Policy, Research & Engagement, BioMarin Pharmaceutical Inc.

**Julia (Julie) Tierney**, Senior Policy Advisor for Strategic Planning and Legislation, CBER, FDA  
*Moderated by* **Brian J. Malkin**, Counsel, Arent Fox LLP

## **Issues in Drug Quality and Manufacturing: ConOps, Quality Metrics, and Outsourcing** *Meridian DE*

Drug manufacturing is often global in nature, with multiple parties involved throughout the

supply chain process, creating potential risks in ensuring product safety and efficacy. Panelists will delve into some of the important considerations manufacturers may encounter along the way, including regulatory requirements for servicing vs. remanufacturing, how to assign vulnerability and risk in virtual manufacturing networks, and how to establish appropriate metrics that are in line with the latest FDA guidance and at the same time drive the desired business results. Also, panelists will discuss inspectional issues including ConOps, OAI classification letters, and risk mitigation opportunities.

**Cathy L. Burgess**, Partner, Alston & Bird LLP and Member, FDLI Board of Directors

**Lori F. Hirsch**, VP of Regulatory Compliance and External Engagement, Bristol-Myers Squibb Company

**John McShane**, Managing Partner, Validant

## **Drug and Device Privacy and Cybersecurity Considerations** *Hemisphere B*

Today, national health authorities are requiring cybersecurity and privacy considerations and supporting programs to be part of medical product design, development, and maintenance. This is especially true for conducting clinical trials, marketing activities overseas, and interoperability of medical devices and machine learning in clinical care. This session will address current privacy, cybersecurity, and data protection requirements such as the EU GDPR and the forthcoming California Consumer Privacy Act (CCPA), where a duty to protect personal data applies; and how to ensure there is full informed consent – issues that need to be top of mind for drug and device companies.

**Seth Carmody**, Cybersecurity Program Manager, CDRH, FDA

**Kimberly J. Gold**, Partner, Reed Smith LLP

**Tara Sklar**, Professor of Health Law, University of Arizona

## **“Sugar” and “Natural” Food Label Claims and Litigation – What’s Next?** *Oceanic AB*

“Sugar,” “natural,” and “clean label” – oh my! Food label claims are at the forefront of current consumer focus and litigation trends. This includes the broad-ranging cereal cases, with their alleged health halo marketing; *ABA v. San Francisco*, on the city’s attempt to impose warning notices on advertising; advancement of “natural” and “artificial” cases in light of FDA non-action; and the clean label movement. This panel will discuss the hot areas currently being seen in label claim litigation and challenges companies face when responding to consumers with new and improved products and labels.

**Susan M. Bond**, VP, Regulatory and Scientific Affairs, Kerry, Inc.

**Maia C. Kats**, Of Counsel, Kaplan Fox & Kilsheimer, LLP

**Suzie L. Trigg**, Partner, Haynes and Boone LLP

## **Electronic Nicotine Delivery Systems Part II: Adult Smoker Cessation and Harm Reduction** *Hemisphere A*

ENDS may play an important role in public health by providing an alternative to combustible cigarettes for current adult smokers. At least one recent study has shown that traditional smokers were more likely to quit combustible products by switching to e-cigarettes than people who used other cessation methods, such as nicotine patches or gum. Speakers will discuss how new technologies can encourage adult smokers to switch to a less harmful product while still getting access to nicotine, the public health benefits and concerns of adults switching to non-combustible products, and marketing strategies to target adults.

**Aruni Bhatangar**, Professor of Medicine and Distinguished University Scholar, University of Louisville and Fellow, American Heart Association

**Katherine Ciambrone**, Legal, Regulatory & External Affairs – US, Fontem Ventures

**Gregory Conley**, President, American Vaping Association

*Moderated by* **Robyn Gougelet**, Senior Associate, Pinney Associates, Inc.

## **Marijuana, CBD, and Hemp: Understanding the Current Regulatory Landscape and How it Might Change** *Horizon*

Cannabis-related substances, whether marijuana, cannabidiol (“CBD”), or hemp, appear in the news daily. Much is happening on the federal and state regulatory fronts with respect to those substances. FDA recently approved Epidiolex, a CBD product, DEA rescheduled certain CBD products from schedule I to schedule V, and Congress, with passage of the 2018 Farm Bill, removed hemp from the federal Controlled Substances Act. FDA is also considering its options for potential regulatory pathways for cannabis products. Speakers will address the current state of regulation and where we might be headed in the near future.

**Miriam Guggenheim**, Partner, Covington & Burling LLP and Member, FDLI Board of Directors

**Jonathan A. Havens**, Partner, Saul Ewing Arnstein & Lehr LLP

**Sarah Sorscher**, Deputy Director of Regulatory Affairs, Center for Science in the Public Interest (CSPI)

**12:30–1:40 PM**

**Luncheon** *Atrium Ballroom*

### **Facilitated Table Topic Discussions**

Led by FDLI-member experts, these informal facilitated discussions provide an ideal way to engage with colleagues, gain new information, and share best practices on a hot topic in food and drug law. Attendees have the option to choose from one of the 30+ topics or enjoy open-seating during lunch.

**1:40–1:45 PM**

**Transition**

**1:45–2:30 PM**

**Breakout Sessions**

## **Regenerative Medicine, Gene Therapies, and FDA Regulation** *Horizon*

The tools provided to FDA under the 21<sup>st</sup> Century Cures Act have been used by CBER to promote the development of new gene,

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cell, and tissue therapies. We have seen trends emerging in the regenerative medicine/stem cell fields, including science-based development of cell therapies via the RMAT designation in the Cures Act, and efforts FDA is taking to regulate rogue stem cell clinics.

**Marc J. Scheineson**, Partner, Alston & Bird LLP

**Michael Werner**, Partner, Holland & Knight LLP

**Celia M. Witten**, Deputy Director, CBER, FDA

*Moderated by* **Joanne Hawana**, Of Counsel, Mintz, Levin, Cohen, Ferris, Glovsky and Popeo, PC

## Patient Input in Medical Product Development *Hemisphere B*

It is only since the passage of PDUFA V in 2012 that we have seen a major focus by FDA and companies on Patient-Focused Drug Development (PFDD). This session will take a closer look at how the rapidly developing field of PFDD has introduced specific legal and/or regulatory compliance issues that, in some regard, are different than what sponsors encounter in a “traditional” drug development process (e.g., clinical trials compliance). Speakers will address the discussion documents and early drafts of the yet-to-be-released FDA PFDD-related guidances, which will provide a more specific look at FDA’s thinking, and discuss potential compliance issues related to PFDD.

**Andrea Furia-Helms**, Director of Patient Affairs Staff, FDA

**Annie Kennedy**, Senior Vice President, Legislation & Public Policy, Parent Project Muscular Dystrophy

**David R. Zook**, Partner, Faegre Baker Daniels LLP

*Moderated by* **Eleanor Perfetto**, Executive Vice President, Strategic Initiatives, National Health Council

## Issues and Updates in Combination Products Regulation *Polaris*

With the ongoing implementation of the 21st Century Cures Act, including the recently released guidance for industry, “Principles of Premarket Pathways for Combination Products Guidance for Industry and FDA Staff,” where does the current regulatory landscape stand for combination products? This session will discuss regulatory challenges for products and whether there are alternative pathways to market, including for products that have a digital health element. Panelists will also discuss improvements in human factors review for combination products, impacts of FDA’s digital health programs on combination digital health products, and recent approval of generic combination products.

**Jeffrey N. Gibbs**, Director, Hyman, Phelps & McNamara, PC and Immediate Past Chair, FDLI Board of Directors

**Rachel Turow**, Executive Counsel – Regulatory Law, Teva Pharmaceuticals USA, Inc.

**John (Barr) Weiner**, Associate Director for Policy and Product Classification Officer, Office Combination Products, FDA

*Moderated by* **Nathan A. Brown**, Partner, Akin Gump Strauss Hauer & Feld LLP

## International Medical Device Regulation and Harmonization *Meridian DE*

As the market continues to become more global in all areas of FDA regulated products, it is imperative that both industry and the regulating bodies understand the overlaps of jurisdiction. FDA has been exploring international convergence of some of its policies and processes as it continues to work under the auspices of the International Medical Device Regulators Forum (IMDRF), which aims toward regulatory harmonization. This forum also addresses the Medical Device

Single Audit Program, adoption of ISO 13485, and Unique Device Identifiers (UDI). The impact of these processes on companies, as well as the new EU Medical Device Regulation (EU MDR) requirements on post-market surveillance planning and vigilance reporting, will be discussed.

**Sonali P. Gunawardhana**, Of Counsel, Shook, Hardy & Bacon LLP

**Kimberly Snyder**, Senior Partner, Validant

**Jur Strobos**, Partner, Baker & McKenzie LLP

*Moderated by* **Suzan Onel**, Partner, Kleinfeld, Kaplan & Becker, LLP

### **An In-Depth Look at GRAS and Food Ingredient Regulation** *Oceanic AB*

FDA's authority requires it to maintain a responsive premarket review program for ingredient additives with decisions based on the best-available science. FDA must vouch for the safety of new ingredients, and industry must be able to rely on FDA processes in order to move forward with product innovation. However, consumers are confused about ingredient safety, efficacy, and representation. This panel will consider the current state of food additive approvals, the GRAS process, where the Delaney Clause comes in, and the future of food additive reform.

**Ricardo Carvajal**, Director, Hyman, Phelps & McNamara, PC

**Dennis Keefe**, Director, Office of Food Additive Safety, CFSAN, FDA

**Mark Mansour**, Partner, Locke Lord LLP

### **Tobacco Litigation Update** *Hemisphere A*

What's the latest in tobacco and nicotine litigation? Panelists will provide an update on recent and current cases, including: lawsuits against e-cigarette manufacturers on a variety of claims including product safety; the American Academy of Pediatrics case in Maryland challenging FDA's decision that delays requirements of the Deeming Rule and enables electronic cigarettes and cigars to remain on the market prior to agency review; and the outcome of the recent case compelling FDA to require graphic warning labels on cigarette packages and advertisements.

**Eric Gotting**, Partner, Keller and Heckman, LLP

**Eric Heyer**, Partner, Thompson Hine LLP

*Moderated by* **Tara Lin Couch**, Senior Director of Dietary Supplement and Tobacco Services, EAS Consulting Group, LLC

### **2:30–2:45 PM**

#### **Coffee and Networking Break** *Atrium*

### **2:45–4:00 PM**

#### **Top Cases in Food and Drug Law** *Atrium Hall*

Always informative and entertaining, this perennially popular session promises insight into the most significant litigation from 2018, and a look at cases to keep an eye on in 2019. Annual Conference attendees receive the companion publication, *Top Food and Drug Law Cases 2018, and Cases to Watch, 2019*.

**Ralph F. Hall**, Professor of Practice, University of Minnesota Law School

**William M. Janssen**, Professor of Law, Charleston School of Law

**Erika Lietzan**, Associate Professor, University of Missouri-Columbia School of Law

*Moderated by* **August T. Horvath**, Partner, Foley Hoag LLP

### **4:00 PM**

#### **Conference Adjournment**