



2018 FDLI Annual Conference

Exploring Advanced Topics in Food and Drug Law

May 3-4 | Washington, DC

CONFERENCE SCHEDULE

(subject to change)

Wednesday, May 2

5:30–7:00 PM **Out-of-Towners Reception**
JW Marriott Hotel-Penn Avenue Terrace

Thursday, May 3

8:00–9:15 AM **Registration and Continental Breakfast**

9:15–9:30 AM **Welcome**
Amy Comstock Rick, President & CEO, FDLI
Carla Cartwright, Director, Federal Affairs, Johnson & Johnson and Co-Chair,
FDLI Annual Conference Planning Committee

9:30–10:00 AM **FDA Keynote Address**
Scott Gottlieb, Commissioner of Food and Drugs, FDA
Introduced by **Jeffrey N. Gibbs**, Director, Hyman, Phelps & McNamara, PC and
Chair, FDLI Board of Directors

10:00–11:00 AM **Policies and Politics – Opportunities and Challenges Facing the FDA**
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.

Daniel R. Dwyer, Partner, Kleinfeld, Kaplan & Becker, LLP
Lewis Grossman, Professor of Law, American University
Kathleen Hoke, Professor and Director, Network for Public Health Policy and
Center for Tobacco Regulation, University of Maryland Carey School of Law
Sandra Kalter, Vice President and Chief Regulatory Counsel, Medtronic, and
Member, FDLI Board of Directors
Howard R. Sklamberg, Partner, Akin Gump Strauss Hauer & Feld LLP
Moderated by **Amy Comstock Rick**, President & CEO, FDLI

11:00–11:30 AM

Coffee and Networking Break

11:30–12:20 PM

Breakout Sessions

- **Regulatory Implications and Practical Challenges of Real World Evidence and Real World Data**

This session will bring together leading government regulators, legal advisors, and industry professionals to discuss and identify key issues emerging from the current data revolution. Speakers will explore potential use cases, potential pitfalls and regulatory challenges, and real-world implications of real world evidence, as well as the use of "real world evidence" to support regulatory decision making by both CDER and CDRH.

Owen Faris, Clinical Trial Director, Office of Device Evaluation, CDRH, FDA

John Manthei, Partner, Latham & Watkins LLP

Lisa Rachlin, Associate Director & Corporate Counsel, Vertex Pharmaceuticals, Inc.

Moderated by **Meaghan Bailey**, Executive Director, NSF Medical Devices, NSF International

- **Regenerative Medicine and the Changing Regulatory Landscape**

With the creation of the regenerative medicine advanced therapy (RMAT) designation in the 21st Century Cures Act and the announcement of substantive regulatory changes, FDA has taken unprecedented steps in the past year to advance the regulatory framework for human cells, tissues, and cellular- and tissue-based products (HCT/Ps). The panel will explore the legal and regulatory issues related to gene therapy, highlighting the agency's latest actions, and discuss the impact of these changes on all affected stakeholders.

Anne Marie Polak, Senior Director, Leavitt Partners, LLC

Julie Tierney, Senior Policy Advisor for Strategic Planning and Legislation, CBER, FDA

Michael Werner, Partner, Holland & Knight LLP

Moderated by **Barbara Binzak Blumenfeld**, Partner, Buchanan Ingersoll & Rooney PC

- **Medical Device Innovations: Welcome to the Future**

Machine learning and 3D printed technologies for surgical planning and diagnosis; virtual reality in patient care; Artificial Intelligence in medical software: The future is here. Medical devices are at the cutting edge of today's tech innovation trends. Experts in the field will share the regulatory challenges and benefits experienced with these transformative technologies.

Sonali Gunawardhana, Of Counsel, Shook, Hardy & Bacon LLP

Bakul Patel, Associate Director for Digital Health, CDRH, FDA
Zachary Rothstein, Associate Vice President, Technology & Regulatory Affairs, AdvaMed
Suzanne B. Schwartz, Associate Director for Science and Strategic Partnerships, CDRH, FDA
Moderated by Vernessa Pollard, Partner, McDermott Will & Emery LLP

- **Regulation of Cell-Based Meat and Other Modified Foods**

Numerous companies are developing agricultural products such as "meat" and "poultry" from cell cultures instead of raising and slaughtering animals. At the same time, new traits are being introduced into crops and animals using gene editing techniques that are more precise than genetic engineering. These new products offer the promise of improved food safety and reduced environmental impact. Who will regulate these products? Through what regulatory pathway? What are the relevant issues to consider? How will they be labeled?

Robert G. Hibbert, Partner, Morgan, Lewis & Bockius LLP
Gregory Jaffe, Biotechnology Project Director, Center for Science in the Public Interest
Nicole Negowetti, Clinical Instructor, Harvard Food Law and Policy Clinic
Moderated by Stuart M. Pape, Shareholder, Polsinelli PC

- **Key Trends and Questions in FSMA Inspections and Compliance of Animal Food**

Under the new FSMA requirements, the manufacturers of animal food are now responsible for complying with requirements for Current Good Manufacturing Practices (CGMPs) as well as preventive controls. How is the new regulatory scheme impacting companies' operations and regulatory compliance mechanisms? What are the most pressing issues facing companies thus far with regards to compliance? What are FDA's areas of focus?

Sonya Lambkin, Supervisor, Post-Market Compliance Animal Food Team, CVM, FDA
Anthony T. Pavel, Senior Food Lawyer, Cargill, Inc.
Richard Sellers, Senior Vice President of Public Policy and Education, American Feed Industry Association
Moderated by Riëtte van Laack, Director, Hyman, Phelps & McNamara, PC

- **FDA Implementation of Tobacco Product Pathways**

Panelists will discuss FDA's implementation of the PMTA and MRTPA pathways, as well as impacts on consumers, manufacturers, tobacco harm reduction efforts, and the public health. Opportunities to clarify how the pathways will be implemented to foster innovation and

advance tobacco harm reduction will also be addressed, including the current status of SE applications and the need, recognized by both industry and FDA, for a clear set of achievable requirements for SE applications.

Matthew Holman, Director, Office of Science, CTP, FDA
Joe Murillo, Vice President, Regulatory Affairs, Altria Client Services LLC

Daniel Schultz, Principal, Medical Devices & Combination Products, Greenleaf Health, Inc.

Moderated by Bryan M. Haynes, Partner, Troutman Sanders LLP

12:20–1:30 PM

Networking Luncheon, Awards Presentation, and FDCA Anniversary Presentation

- **FDLI Distinguished Service and Leadership Awards**

Presented by Jeffrey N. Gibbs, Director, Hyman, Phelps & McNamara, PC and Chair, FDLI Board of Directors *and Amy Comstock Rick*, President & CEO, FDLI

Award Recipients:

David V. Ceryak, Senior Director – Assistant General Counsel, Regulatory Legal Team, Eli Lilly and Company

Ellen J. Flannery, Deputy Center Director for Policy, Office of the Center Director, CDRH, FDA

- **FDCA Anniversary Presentation**

Presented by Suzanne Junod, Historian, Office of Communications, FDA History Office, FDA

1:30–2:00 PM

Speaker: Anna Abram, Deputy Commissioner for Policy, Planning, Legislation and Analysis, FDA

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

2:00–2:10 PM

Transition

2:10–3:25 PM

Breakout Sessions: FDA Center Directors

Hear directly from each of FDA's Center Directors and learn about the latest policy developments, enforcement actions, and priority initiatives for 2018. A panel including multi-stakeholder perspectives will follow, along with time for questions from the audience.

Center for Drug Evaluation and Research (CDER)

Janet Woodcock, Director, Center for Drug Evaluation and Research, Office of Medical Products and Tobacco, FDA

Margaret Anderson, Managing Director, Deloitte Consulting LLP

Daniel A. Kracov, Partner, Arnold & Porter LLP and Member, FDLI Board of Directors

Peter Pitts, President, Center for Medicine in the Public Interest
Frances Zipp, President, Lachman Consultants
Moderated by Carla Cartwright, Director, Federal Affairs, Johnson & Johnson and Co-Chair, FDLI Annual Conference Planning Committee

Center for Biologics Evaluation and Research (CBER)

Peter W. Marks, Director, Center for Biologics Evaluation and Research, Office of Medical Products and Tobacco, FDA

Margo Heath-Chiozzi, Senior Vice President, Regulatory Affairs, Celldex Therapeutics, Inc.

Christopher Mikson, Partner, Mayer Brown LLP

John Murphy, Deputy General Counsel for Healthcare, Biotechnology Innovation Organization

Moderated by Neil DiSpirito, Of Counsel, Ballard Spahr LLP and Co-Chair, FDLI Annual Conference Planning Committee

Center for Devices and Radiological Health (CDRH)

Jeffrey E. Shuren, Director, Center for Devices and Radiological Health, Office of Medical Products and Tobacco, FDA

Khatereh Calleja, Senior Vice President, Technology and Regulatory Affairs, AdvaMed

Brian A. Dahl, Compliance Practice Lead, E.M.M.A. International Consulting Group, Inc.

Eric Rogers, Global Head, Regulatory and Development Law, Alcon Laboratories, Inc.

Moderated by Paul Gadiock, Senior Attorney, Arent Fox LLP

Center for Food Safety and Applied Nutrition (CFSAN)

Susan T. Mayne, Director, Center for Food Safety and Applied Nutrition, Office of Foods and Veterinary Medicine, FDA

Sandra B. Eskin, Director, Safe Food Project, The Pew Charitable Trusts

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

Moderated by Martin Hahn, Partner, Hogan Lovells LLP

Center for Tobacco Products (CTP)

Mitchell R. Zeller, Director, Center for Tobacco Products, Office of Medical Products and Tobacco, FDA

Katherine Ciambrone, Chief Compliance Officer and Senior Vice President, ITG Brands

Stacey Gagosian, Managing Director of Public Policy, Truth Initiative

J. Benneville (Ben) Haas, Partner, Latham & Watkins LLP

Moderated by Dean R. Cirotta, President & COO, EAS Consulting Group, LLC

Center for Veterinary Medicine (CVM)

Steven M. Solomon, Director, Center for Veterinary Medicine, Office of Foods and Veterinary Medicine, FDA

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

Peter Tabor, Vice President, Regulatory and International Affairs, Pet Food Institute

Moderated by **Madeleine McDonough**, Chair, Shook, Hardy & Bacon LLP

3:25–3:50 PM

Coffee and Networking Break

3:50–4:50 PM

Breakout Sessions

- **Generic Drug Initiatives: FDARA, GDUFA II, and Administrative Proposals**

Congress and FDA have both advanced efforts to enhance generic drug availability. Some efforts include changes to the generic drug user fee agreement (GDUFA), provisions in FDARA aimed at increasing transparency and providing assistance to certain generic drug sponsors, and new administrative proposals from FDA to accelerate the review of certain drugs. Panelists will assess these initiatives and discuss FDA's current plan for implementation.

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

Elizabeth Jex, Attorney Advisor, Office of Policy Planning, Federal Trade Commission

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

Moderated by **William B. Schultz**, Partner, Zuckerman Spaeder LLP

- **Biosimilars: New Developments and Updates**

This session will examine developments concerning biosimilars in the past year with particular attention to analytical similarity, reference product exclusivity, and an update on the "patent dance" and the resolution of patent disputes since the Supreme Court's decision in *Sandoz, Inc. v. Amgen, Inc.*

Joseph Franklin, Associate Director for Policy, Therapeutic Biologics and Biosimilars Staff, CDER, FDA

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

Bruce A. Leicher, Senior Vice President and General Counsel, Momenta Pharmaceuticals, Inc.

Daniel Orr, Partner, Womble Bond Dickinson (US) LLP

Christine M. Simmon, Executive Director, Biosimilars Council and Senior Vice President, Policy & Strategic Alliances, Association for Accessible Medicines

- Digital Health Developments and Changing Regulatory Approaches**
 Over the past several years, there have been a number of regulatory developments related to digital health, including the 21st Century Cures Act, FDARA, and an ever-increasing amount of FDA guidance documents. This panel will discuss FDA's proposed changes to how it regulates digital health products, the status of the precertification pilot, whether and how FDA can implement these significant changes without additional legislative changes, and what the new programs mean for digital health developers, consumers, and the healthcare system.

Mark R. Dahlby, FDA Regulatory and Healthcare Compliance Counsel, IBM

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

Bakul Patel, Associate Director for Digital Health, CDRH, FDA
Moderated by Nancy Stade, Partner, Sidley Austin LLP

- FSMA Inspections and Compliance for Human Food: Key Trends and Questions**
 FSMA is the first substantive change in over 70 years to the food safety system, and implementation has begun for all seven foundational rules. What has been industry's experience with inspections and enforcement? What are the key concerns of industry going forward? Does the focus on prevention by industry seem to be effective? This session will look at early trends and discuss some of the key questions impacting implementation.

Steven H. Armstrong, Independent Advisor, EAS Consulting Group, LLC

Marc C. Sanchez, Regulatory Attorney, CIHCC, LLC

Jennifer Thomas, Interim Director for FSMA Operations, CFSAN, FDA

- Trends in Animal Food Litigation**
 Claims that had been seen exclusively in human food lawsuits are now starting to show up in pet food litigation. This panel will examine the recent case law, NAD challenges, and FTC enforcement in the pet food arena, and consider the types of challenges the pet food industry may face in the future.

Adam Ekonomon, Vice President and Deputy General Counsel, J.M. Smucker Company

Emily M. Leongini, Associate, Arent Fox LLP

Moderated by Jeannie Perron, Partner, Covington & Burling LLP

- A Survey of FDA's Advance Notices of Proposed Rulemaking for Tobacco Products**

Panelists will discuss the three recently issued Advance Notices of Proposed Rulemaking on nicotine, flavors, and premium cigars. Discussion will focus on implications for tobacco harm reduction, product innovation and public health, and possible next steps as FDA implements its Comprehensive Plan for Tobacco and Nicotine.

Clive Bates, Director, Counterfactual Consulting Limited
Dennis Henigan, Vice President, Legal and Regulatory Affairs, Campaign for Tobacco-Free Kids
Raymond Niaura, Professor, Department of Social and Behavioral Sciences, New York University
Moderated by Robyn Gougelet, Senior Associate, Pinney Associates, Inc.

4:50–5:00 PM

Transition

5:00–5:30 PM

Speaker: **Rebecca K. Wood**, Chief Counsel, FDA
Introduced by **Francis B. Palumbo**, Professor and Executive Director, University of Maryland School of Pharmacy and Member, FDLI Board of Directors

5:30–7:00 PM

Networking Reception

Friday, May 4

8:00–8:30 AM

Breakfast

8:30–8:40 AM

FDLI Welcome

Neil DiSpirito, Of Counsel, Ballard Spahr LLP and FDLI Annual Conference Planning Committee Co-Chair

Service to FDLI Award

Presented by **Miriam Guggenheim**, Partner, Covington & Burling LLP and Member, FDLI Board of Directors and **Amy Comstock Rick**, President & CEO, FDLI

Award Recipient: Steven H. Armstrong, Independent Advisor, EAS Consulting Group, LLC

8:40–9:00 AM

Dr. Harvey W. Wiley Lecture and FDA Alumni Association Award Presentation

A lectureship named in honor of Dr. Harvey W. Wiley, the renowned physician-chemist who, at the turn of the 20th 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.

Anthony S. Fauci, Director, National Institute of Allergy and Infectious Diseases, National Institutes of Health

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

9:00–10:00 AM

International Harmonization Efforts

As manufacturing, sales, and product development become more global in nature, government agency coordination and cooperation are increasingly relevant. This session will focus on international cooperation efforts, including FDA's inspection recognition agreements as well as coordinated actions on imported products.

Benjamin L. England, Founder and CEO, FDAImports.com, LLC |
Benjamin L. England & Associates, LLC

Leigh Verbois, Assistant Commissioner for International Programs
(Acting), Office of the Commissioner, FDA

Domenic Veneziano, Independent Advisor for Import Operations, EAS
Consulting Group, LLC

Moderated by **Robert A. Rhoades**, Managing Partner, Validant and
Member, FDLI Board of Directors

10:00–10:30 AM

Coffee and Networking Break

10:30–11:20 AM

Breakout Sessions

- **Guidance on Guidance: FDA, DOJ, and Enforcement**

In late January, then-Associate Attorney General Brand released a memorandum announcing that DOJ will not use its civil enforcement authority to enforce agency guidance documents. This has the potential to impact FDA-regulated industry, as non-compliance with guidance documents will not be used to establish violations of the law. In this session, panelists will look into the history of DOJ cases to see where this policy may have impacted prior actions and will also consider the potential implications for both industry and FDA moving forward.

Michael S. Blume, Partner, Venable LLP

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

John H. Fuson, Partner, Crowell & Moring LLP

- **FDA's New Approach to Drug and Device Inspections**

This panel will address recently issued policy and procedures impacting FDA drug and device inspections, including the new Concept of Operations, the New Inspection Protocol Project, Quality Metrics, FDARA, program alignment, and other recent changes. It will highlight what these changes are and will give both FDA and industry viewpoints on the what impact these changes will have on inspection processes and on resolution of inspection issues.

Donald Ashley, Director, Office of Compliance, CDER, FDA

Cathy Burgess, Partner, Alston & Bird, LLP

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

*Moderated by Cynthia Schnedar, Executive Vice President,
Regulatory Compliance, Greenleaf Health, Inc.*

- **The Evolving Regulatory Landscape for Orphan Drugs**

This session will address recent regulatory developments and key policy issues affecting orphan drugs. Topics to be addressed include FDA's Orphan Drug Modernization Plan; the recent changes to orphan drug laws as part of the 21st Century Cures Act and FDARA; FDA's implementation of the rare pediatric disease priority review voucher, orphan drug designation, and orphan drug exclusivity laws; and key policy issues regarding orphan drugs.

Debra Lewis, Acting Director, Office of Orphan Products Development, FDA

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

Alexander J. Varond, Associate, Goodwin Procter LLP

Moderated by Krista Carver, Partner, Covington & Burling LLP

- **Challenges and Developments in Nutrition Labeling**

In May 2016, FDA published a final rule to update the Nutrition Facts Label. Changes in the effective date and new guidances covering compliance and declaration of dietary fiber and added sugars will impact implementation. Panelists will provide insight into evolving areas of the rule and challenges currently facing industry.

Leslie Krasny, Partner, Keller and Heckman LLP

Amy Norris, Chief Counsel, Clif Bar & Company

Moderated by Bruce Silverglade, Principal, Olsson Frank Weeda Terman Matz PC

- **A Smoke-Free World: Evolving Technologies and Policies**

Are we moving in the direction of a smoke-free world? What policies and behavior must be altered to reduce the demand for cigarettes? What technologies are available or required to transition to a smoke-free world? What can FDA do to facilitate these changes and technologies?

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

Matthew Myers, President, Campaign for Tobacco-Free Kids

David Levy, Professor, Lombardi Comprehensive Cancer Center, Georgetown University

Moderated by Scott Ballin, Tobacco and Health Policy Consultant

- **Advertising and Marketing in a Mobile World**

The mobile sphere poses diverse advertising and marketing challenges and opportunities across all FDA-regulated industries. Panelists will explore recent FTC and FDA guidance, including how to approach the review and approval of such materials. In addition to providing updates on how to ensure that mobile apps comply with all relevant laws and regulations, advertising within mobile apps and other platforms will be discussed.

Richard Cleland, Assistant Director, Bureau of Consumer Protection, Division of Advertising Practices, FTC

Toam Rubinstein, Associate, Reed Smith LLP

Moderated by Dale A. Cooke, President, PhillyCooke Consulting

11:20–11:30 AM **Transition**

11:30 AM–12:20 PM **Breakout Sessions**

- **OTC Drug Monograph Reform**

New flexibility for OTC monograph products will present opportunities and challenges. Panelists will discuss the prospects for final passage of legislation and implementation plans, including discussion of new processes and transition to the new system. Potential implications of the new rule for manufacturers and patients will also be addressed.

Elizabeth Jungman, Director, Public Health Programs, The Pew Charitable Trusts, and Member, FDLI Board of Directors

David C. Spangler, Senior Vice President, Policy, and General Counsel & Secretary, Consumer Healthcare Products Association (CHPA)

Moderated by Deborah Livornese, Of Counsel, Arnall Golden Gregory LLP

- **Evolving Regulatory Pathways for Medical Devices**

In recent years, FDA has finalized several medical device guidance documents that could dramatically impact the regulatory pathways available to medical device manufacturers. Are manufacturers effectively taking advantage of these new options, for example, by leveraging non-traditional data sources, like real world evidence or patient preference information, for regulatory purposes? Are the new options making the regulatory process more efficient for manufacturers and FDA? Has FDA's decision-making process been impacted by the new options?

Jonette Foy, Associate Director for Policy, CDRH, FDA

Judith O'Grady, Partner, Pepper Hamilton LLP

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

*Moderated by Cassie Scherer, Principal Legal Counsel,
Corporate Legal Regulatory, Medtronic*

- **From Approval to Coverage – FDA and CMS Jurisdictional Lines**
FDA and CMS have been working together on many initiatives. Panelists will provide a background and overview of the tie in between FDA regulatory approval and the Medicare coverage process, and will address the endpoints that both agencies consider in their decision-making process and the ways in which the two agencies coordinate their efforts.

Rochelle Fink, Senior Health Science Project Specialist, CDRH, FDA

Linda Gousis, Senior Advisor, Coverage and Analysis Group, Center for Clinical Standards and Quality, Centers for Medicare and Medicaid Services (CMS)

Moderated by David R. Zook, Partner, Faegre Baker Daniels LLP

- **Cannabis: FDA's Role in Regulation**
Federal agencies like FDA have largely taken a hands-off approach to regulating state-authorized cannabis activities. However, FDA has suggested that the agency would be looking into health claims made about medical cannabis products. This session will both offer a high-level overview of FDA's (and DEA's) authority over cannabis products, as well as discuss what, if any, role FDA will take in regulating cannabis products that may also fall under its purview. The panelists will also address foods and other FDA-regulated products to which cannabinoids are added.

Jonathan Havens, Associate, Saul Ewing Arnstein & Lehr LLP

Rick Scarpello, CEO and Founder, MC Brands LLC

Sara Beth Watson, Of Counsel, Steptoe & Johnson LLP

- **Risk Communication as Part of FDA's Comprehensive Approach to Nicotine: Whose Job is it Anyway?**
In July 2017, FDA announced a comprehensive approach to regulating tobacco and nicotine products that placed nicotine as the keystone of their efforts. A potential barrier to the success of this integrated approach is the widely-held belief that nicotine itself is the cause of smoking-related diseases, while science indicates that it is the byproducts of combustion that are responsible for the preponderance of harm. This panel considers how to overcome this risk communication challenge, as well as the array of opportunities and barriers to success.

Aruni Bhatnagar, Professor of Medicine and Distinguished University Scholar, University of Louisville

Azim Chowdhury, Partner, Keller and Heckman LLP

James Solyst, Vice President, Federal Regulatory Affairs,

Swedish Match North America

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

12:20–1:30 PM

Luncheon

- **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.

1:30–1:35 PM

Transition

1:35–2:20 PM

Breakout Sessions

- **Pre-Approval Communications, the First Amendment, and Compelled Speech: To Say or Not to Say, That is the Question**

First Amendment issues continue to be prominent in all areas of FDA-regulated industry, including in scientific exchange, product promotion, and as a defense to lawsuits. This panel will discuss FDA and industry perspectives on First Amendment issues and the regulatory landscape in the wake of recent cases and FDA guidance and statements.

Maia Kats, Director of Litigation, Center for Science in the Public Interest

Kelly Goldberg, Vice President, Law/Senior Counsel for Biopharmaceutical Regulation, PhRMA

Lynn C. Tyler, Partner, Barnes & Thornburg LLP

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

- **EU Medical Device Regulation: Implementation and Compliance**

The recent passage of the new Medical Device Rule (MDR) in the EU requires action from manufacturers with regards to regulatory pathways and development timelines. Product updates need to be completed before 2020, and new notified bodies may have to be selected as early as of 2018. The new rules and compliance obligations also impact US companies doing business abroad. This session offers an analysis of requirements and practical advice for companies operating in the US and EU.

Christian Fulda, Partner, Jones Day

Jana Grieb, Counsel, McDermott Will & Emery LLP

Sarah H. Stec, Associate, Squire Patton Boggs LLP

*Moderated by **Robert Iser**, Vice President, Parexel Consulting*

- **Emerging Issues for Drug Compounders**

Compounding remains a priority for FDA, with an announcement earlier this year of its “Compounding Priorities Plan.” The agency expects to produce significant new guidance documents and rules regarding cGMPs, bulk substances, and FDA-State partnerships. This session will explore FDA’s recent actions as well as current issues facing compounding pharmacy and outsourcing facility industries, including emerging legal and logistical issues for compounders.

Martine Hartogensis, Deputy Director, Office of Surveillance and Compliance, CVM, FDA

Rachael G. Pontikes, Partner, Reed Smith LLP

Lee Rosebush, Partner, Baker Hostetler LLP

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

- **Reading the Tea Leaves for Dietary Supplements**

This panel will address the latest in dietary supplement issues, with an emphasis on recent activities and trends in litigation. Speakers will cover FDA’s current enforcement priorities and actions, retailer liability, and the status of the New Dietary Ingredient Guidance. Dietary supplement jurisdictional standards, as outlined in *Amarin v. International Trade Commission* will also be discussed.

Jean Frydman, Partner, Fox Rothschild LLP

Megan Olsen, Assistant General Counsel, Council for Responsible Nutrition

Suzanne Trigg, Partner, Haynes and Boone LLP

- **Risk-Based Regulation of Tobacco Products**

Panelists will discuss the potential opportunities and public health challenges associated with regulating tobacco products based on their relative risks, including differential tax treatment, use restrictions, manufacturing standards and accelerated product authorization pathways for reduced-risk products. Panelists will also compare and contrast tobacco harm reduction philosophies with alternative approaches.

Donald Becker, Assistant General Counsel, Turning Point Brands, Inc.

Scott Drenkard, Director of State Projects, Tax Foundation

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

Moderated by Cynthia Cabrera, President, The Cating Group

2:20–2:30 PM

Transition

2:30–3:00 PM

Award Presentation and Remarks

Arthur L. Caplan, Drs. William F. and Virginia Connolly Mitty Professor of Bioethics and Founding Director, Division of Medical Ethics, New York University School of Medicine

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

3:00–4:15 PM

Top Cases in Food and Drug Law

Always informative and entertaining, this perennially popular session promises insight into the most significant litigation from 2017, and a look at cases to keep an eye on in 2018. Annual Conference attendees receive the companion publication, *Top Food and Drug Law Cases 2017, and Cases to Watch, 2018*.

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

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

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

Moderated by August Horvath, Partner, Foley Hoag LLP

4:15 PM

Conference Adjournment