2018

FDLI
Food and Drug Law Institute

FDLI Annual Conference

Exploring Advanced Topics in Food and Drug Law

May 3-4 | Washington, DC

PROGRAM GUIDE

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FDA U.S. FOOD & DRUG ADMINISTRATION

Institute for Food Laws and Regulations
MICHIGAN STATE UNIVERSITY

CONFERENCE AGENDA

THURSDAY, MAY 3

8:00–9:15 AM

Registration and Continental Breakfast *Atrium*

Sponsored by: OXFORD

9:15–9:30 AM

Welcome *Atrium Hall*

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 *Atrium Hall*

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 *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.

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 Cohen 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 *Atrium*

Sponsored by: FAEGRE BAKER DANIELS

11:30–12:20 PM

Breakout Sessions

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

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 Trials 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 *Oceanic*

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 *Horizon*

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 *Hemisphere B*

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, Practice Chair, Polsinelli PC

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

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 *Hemisphere A*

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 *Atrium Ballroom*

- **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
Atrium Hall

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)

Atrium Hall
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)

Oceanic
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)

Horizon
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)

Polaris
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)

Hemisphere A
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)

Meridian
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 *Atrium*

3:50–4:50 PM
Breakout Sessions

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

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 *Polaris*

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 *Hemisphere B*

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 *Meridian*

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 *Hemisphere A*

Panelists will discuss the three recently issued Advanced 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 Center on Drugs and Public Policy, and Member, FDLI Board of Directors
Atrium Hall

5:30–7:00 PM

Networking Reception *Atrium*

FRIDAY, MAY 4

8:00–8:30 AM

Breakfast *Atrium*

8:30–8:40 AM

FDLI Welcome *Atrium Hall*

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

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 *Atrium Hall*

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 Disease, National Institutes of Health
Presented by **Allen R. Sayler**, Senior Director of Food Consulting Services, EAS Consulting Group, LLC

9:00–10:00 AM

International Harmonization Efforts *Atrium Hall*

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 and 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 *Atrium*

10:30–11:20 AM

Breakout Sessions

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

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 *Horizon*

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 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 *Oceanic*

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 the 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 *Hemisphere B*

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 *Hemisphere A*

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
David Levy, Professor, Lombardi Comprehensive Cancer Center, Georgetown University
Matthew Myers, President, Campaign for Tobacco-Free Kids
Moderated by **Scott Ballin**, Tobacco and Health Policy Consultant

Advertising and Marketing in a Mobile World *Meridian*

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 *Hemisphere B*

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 *Polaris*

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 *Oceanic*

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 *Meridian*

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? *Hemisphere A*

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 *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.

1:30–1:35 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 *Polaris*

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.

Kelly Goldberg, Vice President, Law/Senior Counsel for Biopharmaceutical Regulation, PhRMA
Maia Kats, Director of Litigation, Center for Science in the Public Interest
Lynn C. Tyler, Partner, Barnes & Thornburg LLP
Moderated by **James N. Czaban**, Partner, DLA Piper LLP

EU Medical Device Regulation: Implementation and Compliance *Horizon*

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 **Bob Iser**, Vice President, Parexel Consulting

Emerging Issues for Drug Compounders *Oceanic*

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 and Popeo PC

Reading the Tea Leaves for Dietary Supplements *Hemisphere B*

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 *Hemisphere A*

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
FDLI Distinguished Service and Leadership Award *Atrium Hall*

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

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

2018 FDLI AWARDS

DISTINGUISHED SERVICE AND LEADERSHIP AWARDS

These awards recognize individuals from the food and drug law community for their contributions to the field. We are pleased to present this year's awards to;

DAVID V. CERYAK
Senior Director – Assistant General Counsel, Regulatory Legal Team at Eli Lilly and Company.

ELLEN J. FLANNERY
Deputy Center Director for Policy in the Center for Devices and Radiological Health at the Food and Drug Administration.

ARTHUR LEONARD CAPLAN
Drs. William F and Virginia Connolly Mitty Professor and founding head of the Division of Medical Ethics at NYU School of Medicine in New York City.

SERVICE TO FDLI AWARD

The award, established in 2017, honors members who have provided exceptional volunteer services to FDLI. The award criteria centers on a long-standing history of quality contributions to FDLI, both in a visible leadership capacity and less visible roles.

STEVE ARMSTRONG
Independent Advisor at EAS Consulting Group.

DIAGNOSE. TREAT. CURE. MITIGATE. PREVENT.

DLA Piper takes a clinical approach to solving your FDA legal and regulatory challenges, across a broad spectrum of industries, products and proceedings and throughout the entire life cycle of pharmaceutical, medical device, biologic and food products. With more than a dozen attorneys specifically focused on FDA regulatory strategies, compliance and enforcement matters, and a Global Life Sciences Sector team covering more than 30 jurisdictions worldwide, DLA Piper offers the breadth and depth of experience regulated companies look for to address their most challenging FDA issues.

PHARMACEUTICALS AND BIOLOGICS

Clinical Trial Strategies and Compliance

NDAs, 505(b)(2), Biosimilars, Vaccines

Fast-Track, Expanded Access, Priority Reviews

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Orphan Drug and QIDP Designations

Hatch-Waxman Exclusivities and Patent Listing

Global Safety Monitoring

MEDICAL DEVICES AND DIAGNOSTICS

Product Classifications and Exemptions

510(k)s, PMAs, CLIA Waivers

Precision Medicine: Companion and Complementary Diagnostics

Digital Health

Combination Products

Quality System Regulation

FOOD AND DIETARY SUPPLEMENTS

Product and Menu Labeling

Claims Compliance and Substantiation

Preventative Controls

Foreign Supplier Verification

Dietary Supplement Classification

GMP and HACCP

COMPLIANCE, ENFORCEMENT AND ADVOCACY

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OIG and Fraud and Abuse Prevention
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ALSTON & BIRD FDA regulatory, compliance, and litigation matters require experienced counsel who successfully interact with the agency regularly. We analyze risks, help maintain compliance, handle crisis management, and litigate, where required, throughout the product lifecycle of drugs and devices, biologics, food, cosmetics, and other FDA-regulated products and services. With nearly 100 professionals focused on health care products and services, including lawyers and policy advisers who have worked inside government; our group is one of the largest of its kind nationwide. We understand your business, allowing us to spot issues and opportunities, help develop favorable policy, and advance new technologies. Our many Chambers USA-recognized colleagues can help you lower legal and regulatory hurdles so you can focus on your business.

ARENT FOX LLP has one of the premier Food, Drug, Medical Device & Agriculture regulatory teams in the US. The team includes former ranking and senior professionals from FDA, EPA, and USDA to name a few. The group offers a full range of regulatory, transaction, and litigation services for manufacturers, distributors, and retailers of food, dietary supplements, pharmaceuticals, biologics, medical devices, cosmetics, personal care products, and chemical products. We counsel clients at every stage of a product's life cycle, ranging from product development and approval to global marketing and product recalls. Our experience dealing with the sweeping spectrum of US compliance and enforcement matters allows our team to identify and evaluate regulatory issues that can impact a company's bottom line, and devise solutions to help them achieve innovative growth.

ARNOLD & PORTER is a global leader in representing life sciences clients, with a unique depth and breadth of experience. For nearly seven decades, our attorneys have successfully represented a broad spectrum of life sciences clients. In fact, we actively represent approximately 80% of the world's top 50 pharmaceutical companies listed in Pharmaceutical Executive's "2017 Pharma 50," handling the most complex and high-stakes matters for these clients. We have nearly 200 attorneys providing the full range of litigation, regulatory, intellectual property, and transactional services to pharmaceutical, biotechnology, medical device and diagnostic companies, individual scientist entrepreneurs, emerging growth companies, universities, nonprofit institutions, and investors. Our life sciences offerings cover regulatory matters, internal investigations, civil and criminal government investigations, domestic and global compliance programs, patent procurement, structuring and fund raising, corporate transactions, mergers and acquisitions, tax and securities offerings, licensing and other partnering transactions, patent and commercial litigation, antitrust, product liability, and government contracting.

AXINN is a different kind of law firm. It combines the skills, experience and dedication of the world's largest firms with the focus, responsiveness, efficiency and attention to client needs of the best boutiques. Established in the late 1990s by lawyers from premier Wall Street firms with a common vision, Axinn has been joined by lawyers from the best firms and law schools who share that vision. Axinn is devoted to providing the highest conceivable quality of service in three practice areas: antitrust, intellectual property and high-stakes litigation. Axinn achieves that goal with world-class skills and deep trial experience. Time and again, major companies have turned to Axinn for their biggest deals and cases, often on the eve of trial.

BAKER HOSTETLER's Life Sciences Industry Team practices at the intersection of science and the law. We serve pharmaceutical, medical device, pharmacy, and distribution companies seeking to compete and thrive in one of the industry's most complex regulatory and economic marketplaces. Our ideal clients are entrepreneurial, growing, looking to expand their geographic reach, leading innovation in product development and marketing, lifecycle management (efficacy expansion, safety assessment), distribution and dispensing, and active in IP monetization and portfolio management. We are uniquely positioned to serve mid-market and larger pharmaceutical, medical device and research entities. Our clients choose us over the competition because of our depth of specialty in law AND scientific knowledge applied to medical devices, pharmaceuticals and pharmacy operations. Our highly accomplished FDA group is complemented by powerful healthcare, tax, international trade, corporate and intellectual property teams.

BALLARD SPAHR LLP, an Am Law 100 law firm with more than 650 lawyers in 15 offices across the country, provides a range of services in business and finance, intellectual property, litigation, real estate, and public finance. Our clients include Fortune 500 companies, life sciences and technology companies, health systems, financial institutions, investors and developers, government agencies, media companies, educational institutions, and nonprofit organizations. The firm combines a national scope of practice with strong regional market knowledge. Our Life Sciences and Technology Group counsels frontline businesses engaged in innovation, development, and commercialization activities, and the institutions that support them, through contract research, data mining, analytical and product development, formulation, production, and distribution. Our attorneys have vast experience working with the FDA, including negotiating for product approvals, marketing violations, cGMP resolutions, Consent Decrees, and the legal and regulatory issues that follow products throughout their life cycle.

CLIF BAR & COMPANY

Family- and employee-owned, Clif Bar & Company crafts energy food with organic and sustainable ingredients to feed and inspire adventure.

COMPLIANCE ARCHITECTS®

is an innovative, expert provider of compliance and quality consulting, outsourcing, staff augmentation, and technology-related services to companies directly regulated by the United States Food and Drug Administration (FDA). With service capabilities ranging from quality systems implementations to audits, outsourced compliance services, inspection readiness and complex enforcement remediation, Compliance Architects® has the experience, expertise and delivery capability that will result in significantly improved FDA compliance outcomes for any size organization. Compliance Architects® serves the pharmaceutical, medical device, dietary supplement, biologics, cosmetic, and food industries. Our clients range from small, family-owned companies to the world's largest and most diversified healthcare-manufacturers. No matter where you are located, if your organization and/or products are regulated by the US FDA, we can help you manage and reduce your risk from adverse compliance enforcement outcomes, which in turn helps your business and your bottom line.

DELOITTE

's Federal Government Services practice—our people, ideas, technology, and outcomes—are all designed for impact. We bring fresh perspective—from inside and outside government—to help solve our nation's biggest challenges. From cyber and IT modernization to big data and analytics, cloud, anti-fraud, and leadership services, we bring insights from our client experience and research to our consulting and advisory services—to drive bold and lasting results.

DLA PIPER

's FDA Practice Group serves a critical strategic role for the firm's global Life Sciences client base, operating at the intersections of law, science, business, governmental regulation, international trade, and public health policy. Recognizing and embracing the FDA Group's multi-faceted role allows DLA Piper to provide Life Sciences clients with a 360-degree legal perspective in pursuit of their most important business goals. Our FDA practice covers the entire lifecycle of drugs, devices, biologics, and foods including: product development; marketing authorization; advertising, promotion and market access issues; regulatory aspects of intellectual property protection; and regulatory compliance at every stage. Our integration with the firm's Litigation and Investigations Practice Groups adds client value in response to internal and governmental investigations, civil and criminal judicial actions arising under the FDCA and the myriad fraud and abuse related laws being aggressively enforced against Life Sciences companies. DLA Piper is a global law firm with lawyers in more than 40 countries throughout the Americas, Europe, the Middle East, Africa and Asia Pacific.

EAS CONSULTING GROUP, LLC (EAS)

is a leading provider of regulatory services to the pharmaceutical, medical device, food, dietary supplement, tobacco and cosmetic industries. With over 50 years' experience and over 150 independent consultants around the globe, EAS assists clients in developing regulatory strategies, implementing quality assurance programs, filing regulatory submissions and ensuring compliance with FDA and other federal/state regulations. Having a unique team of former Food and Drug Administration (FDA) and US Department of Agriculture (USDA) officials as well as industry experts, EAS offers unparalleled expertise with many consultants having more than 30 years of regulatory experience. From expert witness, GRAS, NDI and pharmaceutical submissions, due diligence assessments for insurance and venture capitalists, mock-FDA audits and compliance assistance with GMPs, structure function claims, product development and more, EAS provides expert guidance in all matters of regulatory compliance.

E.M.M.A. INTERNATIONAL CONSULTING GROUP, INC.

is a global leader in management consulting services, with headquarters in Farmington Hills, MI, as well as offices in FL & PA. We focus on quality, regulatory, and compliance services for the Biotechnology, Pharmaceuticals, and Medical Device industries. E.M.M.A. International Consulting Group has services available to satisfy all your quality and compliance needs. We provide specialized services, backed by extensive knowledge and industry experience. We do not "leave you hanging" with a process or system that is foreign to your organization and ultimately becomes unworkable. Our mission is to provide significant value to your operations and leave you completely satisfied that your expectations were fulfilled. We work within your corporate culture and alongside your employees to do the "heavy lifting" required to make improvements meaningful and permanent. We exclusively offer QualiPro, an Enterprise Quality Management Software (EQMS), through our partnership with Saphir Consult.

EXPONENT, INC.

is a science and engineering consulting firm dedicated to providing solutions to complex problems. Our engineers, health scientists, physicians, and regulatory specialists provide unparalleled, interdisciplinary expertise to address the full range of medical product development, public health, and environmental issues that face our clients and the world. These issues include R&D challenges associated with pharmaceutical products and medical devices (health economics, outcomes research, regulatory science, toxicology, product design and engineering etc.), as well as potential health effects associated with environmental agents, chemicals, consumer products, food, and nutrition. We excel in developing innovative R&D and regulatory strategies that may decrease development time and costs and increase market potential and valuation.

FAEGRE BAKER DANIELS

delivers innovative legal and consulting solutions for the global health and life sciences sector. Since 1863, our professionals have focused on meeting the needs of a constantly evolving marketplace. "Clients first" is our commitment to service.

FOLEY HOAG LLP

is a 260-attorney firm founded in 1943 with offices in Boston, New York, Paris and Washington DC. Foley Hoag provides innovative, strategic legal services to public, private and government clients across the globe. We have premier capabilities in the life sciences, healthcare, technology, energy, professional services and private funds fields, and in cross-border disputes. The diverse backgrounds, perspectives and experiences of our lawyers and staff contribute to the exceptional senior level service we deliver to clients ranging from startups to multinational companies to sovereign states.

FOOD AND DRUG ADMINISTRATION

The Food and Drug Administration (FDA) is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation. FDA also has responsibility for regulating the manufacturing, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors. FDA is responsible for advancing the public health by helping to speed innovations that make medical products more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medical products and foods to maintain and improve their health. FDA also plays a significant role in the Nation's counterterrorism capability. FDA fulfills this responsibility by ensuring the security of the food supply and by fostering development of medical products to respond to deliberate and naturally emerging public health threats.

HOGAN LOVELLS

Navigating complexities in the life sciences and health care industries is no easy task. Successfully competing in the space requires increasingly creative strategies and integrated solutions that protect and support your business day in and day out. Regardless of the sector of the industry in which you operate or the maturity of your products, we understand how to bridge the gap between the challenges you face and the outcome you want. From budding startups to multinational enterprises, we've been there before and know how to position you for success. With more than 500 life sciences and health care lawyers across the globe, we work closely with you and each other to tackle tough issues and difficult-to-enter markets – no matter where you are today or want to be tomorrow. And because we know what makes your industry tick, we have a deep understanding of the issues you face – helping you stay ahead of the curve and on top of your opportunities.

HOLLAND & KNIGHT's Healthcare & Life Sciences Team represents a full range of healthcare-related organizations in every facet of their regulatory issues and business operations. As one of the largest healthcare and life sciences practices in the United States, our dedicated attorneys and professionals are on the leading edge of industry developments. Our regulatory and transactional attorneys work closely with our government and public policy experts to help clients navigate the healthcare industry's legal complexities while effectively seizing opportunities and avoiding risks. Many of our team members have served as in-house counsel to a wide range of healthcare businesses and associations, which provides us with an in-depth understanding of the challenges faced by our clients. Our team combines this extensive, hands-on, experience with a sincere commitment to deliver exceptional service. For timely updates on recent industry developments, visit the Holland & Knight Healthcare Blog at https://www.hklaw.com/news/uniGC.aspx?xpST=BlogList&type=2590.

HYMAN, PHELPS & MCNAMARA has its finger on the pulse of the FDA and extensive experience with the universe of issues faced by companies regulated by FDA. As the largest dedicated FDA law firm in the United States, our technical expertise and industry knowledge are exceptionally wide and deep. From legal challenges based on science to marketing to controlled substances regulation, our legal team stays with your product through every challenge. Indeed, no legal team handles a broader range of food, drug, and medical device issues. We counsel businesses throughout the supply chain and their management, scientists, marketers, and compliance officers on issues involving FDA, DEA, CMS, FTC, CPSC, USDA, and more.

IQVIA (NYSE:IQV) is a leading global provider of information, innovative technology solutions and contract research services dedicated to using analytics and science to help healthcare stakeholders find better solutions for their patients. Solutions are powered by the IQVIA CORE™, which combines big data, advanced technology, analytics and extensive industry knowledge. Formed through the merger of IMS Health and Quintiles, IQVIA has approximately 55,000 employees worldwide.

JOHNSON & JOHNSON The Johnson & Johnson Law Department spans 80 sites across 36 countries reflecting legal support of our business segments and enabling functions. At Johnson & Johnson, we believe good health is the foundation of vibrant lives, thriving communities and forward progress. That's why for more than 130 years, we have aimed to keep people well at every age and every stage of life. Today, as the world's largest and most broadly-based health care company, we are committed to using our reach and size for good. We strive to improve access and affordability, create healthier communities, and put a healthy mind, body and environment within reach of everyone, everywhere. We are blending our heart, science and ingenuity to profoundly change the trajectory of health for humanity.

KELLEY DRYE's Food and Drug Law practice is singled out by the long history and depth of experience its lawyers have in counselling and defending companies that manufacture, supply, and market food and beverage products in the United States, including human and animal food and beverage products, dietary supplements, specialty foods, and ingredients, as well as product packaging materials and containers. Our lawyers counsel and defend U.S. and international companies in legal and regulatory science matters that relate to the safety, labelling, and advertising of consumer health products – before they enter the U.S. market and after. We are experts in the federal and state food, drug, and consumer protection laws that are administered and enforced by FDA, USDA, FTC, and other federal and state agencies.

KELLER & HECKMAN counsels clients—from multinational corporations to start-up companies—on compliance with food and drug laws and regulations throughout the world. The products we help get to market include foods, pharmaceuticals, medical devices, dietary supplements, tobacco products, and cosmetics. Our attorneys advise clients on labeling and advertising issues, crisis management, compliance with U.S. bioterrorism laws and other laws and regulations affecting the global marketing of food and drug products, and product development and approval strategies. Keller and Heckman clients benefit from the in-depth expertise and extensive experience of our attorneys, many of whom have scientific and technical backgrounds. Our attorneys have worked for private industry; state, federal and international agencies; and consulting firms. And, with a staff of over twenty scientists, we are a leader in the use of interdisciplinary approaches to problem-solving.

LACHMAN CONSULTANTS Founded in 1978, Lachman Consultants provides expert compliance, regulatory affairs, and technical services to clients around the world. Lachman helps organizations to prevent and resolve compliance problems and to develop efficient and effective strategies for the submission and approval of drugs and devices. The company deploys highly experienced consultants who consistently deliver top quality results for a diverse base of global clients—including pharmaceutical, biotechnology, medical device, and dietary supplement companies and the law firms that serve them.

LATHAM & WATKINS LLP is an international law firm with a global footprint of more than 2,600 lawyers across more than 30 offices. Our award-winning practices guide clients through their most significant and cutting-edge legal challenges through a combination of in-depth industry knowledge, legal acumen and strategic business advice. Latham's dedicated Healthcare and Life Sciences Practice provides a deep understanding of the industry and comprehensive advice across complex regulatory, transactional, investigatory and litigation challenges. We serve as a one-stop-shop for clients' legal needs — from day-to-day operations to finance, mergers and acquisitions, complex litigation, intellectual property protection, contract negotiations, and governmental enforcement and regulatory compliance.

THE INSTITUTE FOR FOOD LAWS AND REGULATIONS (IFLR)

at Michigan State University offers online food law courses taught by an international network of food science, academic, and legal professionals. Topics include international and region-specific food laws; Codex Alimentarius; regulatory leadership in food law; wine, beer, and spirits laws and regulations; and FSMA rules. Legal and food industry professionals take our graduate-level courses online, on their own schedule. Enrollment is as easy as registering for a conference, no transcripts required. Students can take a single course, or work toward a certificate in international or United States food law. Many students continue on to earn an online LL.M. or M.J. in global food law from MSU College of Law. IFLR is celebrating its 20th anniversary of teaching food law online. We are also introducing FSMA-related online short courses this spring. Learn more about all our programs at www.iflr.msu.edu or email iflr@msu.edu.

MCDERMOTT WILL & EMERY

For life sciences leaders seeking to clear their path to success, McDermott Will & Emery is an industry-leading law firm offering mission-first business solutions that are equally informed by market intelligence and proven experience. We harness the power of collaboration to bring the right combination of people, skills and knowledge to bear at the right time. Composed of top lawyers with demonstrated strength across FDA regulatory, intellectual property, transactional and litigation law, we're a purpose-built team of thought leaders united by a passion for our work. For decades, we have embraced the value of focused knowledge, harnessing both the particular skills of individuals and the collective experience of our team. This makes us uniquely qualified to help you move business initiatives across the finish line when it matters and anticipate what's next. McDermott Will & Emery is a leading international firm with a diversified business practice. Currently numbering more than 1,100 lawyers, we have 19 offices worldwide and a strategic alliance with MWE China Law Offices in Shanghai.

NAVIGANT

is a specialized, global professional services firm. Our teams apply experience, foresight, and industry expertise to pinpoint emerging opportunities to help build, manage, and protect the business value of the clients we serve. Navigant has built an international reputation as a preferred expert and trusted partner for Life Sciences companies seeking to mitigate their risks

NAVIGANT

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Navigant's life sciences consulting team collaborates with and provides services to pharmaceuticals, specialty, and medical technology organizations facing operational, dispute, compliance, and investigative issues.

Stephanie Lewko

Director,
Data Analytics and
Compliance

Colleen Hittle

Managing Director,
Regulatory and
Compliance for
Device, IVD and
Pharma

M. Jason Brooke

Director,
Regulatory and
Compliance for
Device, Connected
Health, and CDS

while achieving exceptional growth. Clients turn to our experts to address an ever changing and increasingly complex and heavily regulated global healthcare market, while striving to deliver innovation to the market in the pursuit of enhanced patient care.

NSF INTERNATIONAL's medical device and pharma biotech experts partner with life science companies to provide customized end-to-end services throughout the product lifecycle - from development to manufacturing and distribution. Our services help ensure regulatory compliance, implement effective quality management systems, maximize the contribution of your people and assure the highest levels of product quality and safety.

OXFORD With constant regulatory changes, technology advancements, and the need to drive innovative products to market, having the right partner for your staffing and consulting needs is essential. Oxford provides quality industry expertise to more than 165 Life Sciences organizations across the US and Europe, successfully completing more than 6,500 Life Sciences engagements. Drawing on our extensive talent network, we provide immediate access to professionals who have the skills, industry background, and project experience required to support your initiative. For projects that require an additional level of support and control, Oxford offers a full suite of customized consulting services for project delivery, engagement management, and risk & quality management. Let us deliver *The Right Talent*. Right Now.® for your staffing and consulting needs.

PAREXEL is the world's leading innovator of biopharmaceutical services. We simplify our clients' journey of transforming scientific discoveries into new medical treatments for patients with high-quality Phase I-IV clinical research, regulatory, consulting, and market access services. PAREXEL develops breakthrough innovations and solutions by leveraging its comprehensive therapeutic, technical, and functional expertise, in more than 100 countries. For more information visit www.PAREXEL.com.

ROPES & GRAY regularly represents medical device, pharmaceutical and biotechnology companies and investors in cutting-edge, high-stakes matters. We offer a multidisciplinary team with the experience, insight and strategic perspective to help clients achieve their financial and commercial goals and successfully navigate the complex regulatory and enforcement landscape in which today's life sciences industry operates.

SHOOK, HARDY & BACON

With a well-earned reputation as a litigation powerhouse, Shook, Hardy & Bacon is the go-to firm for the world's leading health, science and technology companies. In addition to fielding the largest product liability practice in the world, Shook handles commercial litigation, environmental and toxic tort, and intellectual property disputes for the pharmaceutical and medical device, food and beverage, and consumer goods industries. While its high-stakes, complex litigation expertise is second to none, the firm also has the regulatory compliance and risk management experience upon which companies have come to rely. Established in Kansas City in 1889, Shook has grown to approximately 500 attorneys and 200 research analysts and paraprofessionals, many of whom have advanced scientific and technical degrees. Shook's offices are strategically located in Chicago, Denver, Houston, Kansas City, London, Miami, Orange County, Philadelphia, San Francisco, Seattle, Tampa and Washington, DC.

SIDLEY AUSTIN LLP

is a premier international law firm. Our Food, Drug and Medical Device Regulatory, Compliance and Enforcement practice is a recognized world-class practice representing major pharmaceutical, biotechnology, medical device, food, dietary supplement, tobacco product and cosmetic companies in the U.S., the European Union and Asia. Sidley has the only life sciences practice with a top-tier ranking across these three geographic areas. Sidley has won LMG Life Sciences' "Regulatory Firm of the Year", for the fifth year in a row. Most recently, we received first-tier national rankings in Biotechnology Law, FDA Law and Healthcare Law in the U.S. News – Best Lawyers "Best Law Firms" rankings for 2018.

SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP

With 22 offices, approximately 1,700 attorneys and more than 50 distinct areas of practice, Skadden, Arps, Slate, Meagher & Flom LLP and affiliates serves clients in every major international financial center, providing the specific legal advice companies across a spectrum of industries need to compete most effectively in a global business environment. Our clients include approximately 50 percent of the Fortune 250 industrial and service corporations, as well as financial and governmental entities, small, entrepreneurial companies and nonprofits. Skadden's attorneys and staff share a commitment to providing our clients with the highest-quality and most cost-effective legal services in an atmosphere emphasizing teamwork, creativity, responsiveness and diversity.

STUART TENHOOR LEGAL SEARCH works with attorneys, law firms, corporations and trade associations to seek the best career match for all parties. Stuart has been a member of FDLI for almost 10 years, is a member of the Finance Committee and has even referred attorneys to the FDA itself as the Agency lawyer talent pool continues to broaden and deepen. Simply put, our professional purpose is to help every attorney we interact with better achieve his or her professional goals.

VALIDANT At Validant, we deliver an end-to-end Quality, Compliance, and Regulatory consulting service that is simply best in class. We partner with healthcare companies around the world to ensure safe and reliable access to life-saving healthcare products. We do so by blending industry expertise with innovation to create custom solutions for companies on the frontier of health. The Validant network represents the most qualified consultant base of strategists, operators, and regulators. Our track record of success has earned us the trust of 20 of the top 30 Global Pharmaceutical firms, 25 of the top 30 Medical Device firms, and 7 of the top 10 Biotechnology firms in the world.

ZUCKERMAN SPAEDER combines a reputation as one of the nation's premier litigation firms with in-depth expertise in food and drug law, leading to our ranking as among the best FDA law firms in the country by U.S. News Best Law Firms. We successfully manage high stakes litigation disputes, handle complex regulatory matters, and counsel our clients on a wide range of FDA-related issues. Our clients include generic pharmaceutical, medical device, biologics, and food companies, as well as anti-smoking groups, other non-profit entities, and many other stakeholders on FDA-related issues. We pursue cutting edge legal theories and find creative solutions to complex legal problems on behalf of all these clients. When the stakes are highest, clients count on Zuckerman Spaeder.

UPCOMING PROGRAMS

fdli.org/programs

Webinar: DEA Law for the Food and Drug Community
May 30 | 2–3:30 PM

Webinar: Organic Chemistry for the Food and Drug Community
June 21 | 2–3:30 PM

Webinar: Drug Pricing for the Food and Drug Community
July 17 | 2–3:30 PM

Introduction to US Drug Law and Regulation
July 24–25 | South San Francisco, CA

Introduction to US Medical Device Law and Regulation
July 26–27 | South San Francisco, CA

Introduction to US Food Law and Regulation
September 24–25 | Washington, DC

Food Advertising, Labeling, and Litigation Conference: *For the Food and Dietary Supplements Industries*
September 26–27 | Washington, DC

Introduction to US Biologics and Biosimilars Law and Regulation
October 3–4 | Washington, DC

Introduction to Advertising and Promotion: *For the Drug, Medical Device, and Veterinary Industries*
October 15 | Washington, DC

Advertising & Promotion Conference: *For the Drug, Medical Device, and Veterinary Industries*
October 16–17 | Washington, DC

Introduction to US Tobacco Law and Regulation
October 24 | Washington, DC

Tobacco Products Regulation and Policy Conference
October 25–26 | Washington, DC

Food and Drug Law Journal Symposium: *What is the Path Forward for Federal Regulation of Cannabis?*
November 2 | Washington, DC

Introduction to US Medical Device Law and Regulation
November 7–8 | Washington, DC

Introduction to US Drug Law and Regulation
November 7–8 | Washington, DC

Enforcement, Litigation, and Compliance Conference: *For the Drug, Medical Device, Food, and Tobacco Industries*
Two Days in December | Washington, DC

2019 FDLI Annual Conference: *Exploring Advanced Topics in Food and Drug Law*
May 2–3 | Washington, DC

FDLI
Food and Drug Law Institute

SPEAKER BIOGRAPHIES

ANNA ABRAM is FDA Deputy Commissioner for Policy, Planning, Legislation and Analysis. Ms. Abram plays a critical role in overseeing the development and implementation of key policy initiatives and provides strategic policy direction to advance FDA's mission and vision of protecting and promoting public health. Ms. Abram is a respected FDA policy thought leader with more than 14 years of health care policy experience, including serving in the Office of the Secretary at the Department of Health and Human Services and, working on health care policy in the United States Senate as the long-time Health Policy Director and Senior Advisor to Senator Richard Burr at the Senate Health, Education, Labor and Pensions (HELP) Committee. Ms. Abram also has served as an Associate Director for the Domestic Policy Council at The White House during President George W. Bush's administration. Ms. Abram graduated magna cum laude from the University of Pennsylvania.

MARGARET ANDERSON is Managing Director with Monitor Deloitte based in Arlington. She brings a variety of health and translational medicine experience and perspectives to the work at Deloitte. At Deloitte, she is focused on bringing forward her patient engagement experience and biomedical research ecosystem perspectives to federal, nonprofit, and commercial life sciences engagements. She is also focused on strengthening nonprofit organizations to achieve impact for patients through strategic planning and organizational assessments. She joined Deloitte from FasterCures, a Washington DC-based center of the Milken Institute, where she served as Executive Director. While at FasterCures, she oversaw programs advancing the science of patient input, examining the metrics for collaborative research models, and policy related to federal research and regulatory and pioneered the Partnering for Cures conference. She has also worked on public health issues at the American Public Health Association, women's health issues at the Society for Women's Health Research, and in a consulting capacity for HIV/AIDS programs. She was a founding board member and past-president of the Alliance for a Stronger FDA and she served as a founding member of the NIH National Center for Advancing Translational Sciences Advisory Council and the Cures Acceleration Network Review Board. She served on the National Health Council board, United for Medical Research board, the Food and Drug Administration's Science Board, Science Looking Forward Committee, and the National Academy of Medicine's Forum on Drug Discovery, Development and Translation. She currently serves on the Board of Act for NIH, the Asthma and Allergy Foundation of America, and the Melanoma Research Alliance. She has her BA from University of Maryland in government and politics and her MA from George Washington University in science, technology, and public policy.

STEVE ARMSTRONG is an independent advisor at EAS Consulting Group who has over 20 years of experience advising leading consumer products companies on marketing and regulatory matters. Prior to EAS, Mr. Armstrong served as Chief Food Law Counsel at Campbell Soup Company, where he counseled Campbell businesses on food safety, food policy, labeling and regulatory compliance, including matters involving FDA, USDA, and food agencies around the world. Mr. Armstrong also served as a marketing and regulatory counsel for Unilever and Colgate-Palmolive before coming to Campbell, and he enjoyed a brief career as a newspaper reporter and editor before going to law school. Mr. Armstrong served on

FDLI's Board of Directors from 2014 to 2017 and currently teaches food law at Georgetown University. He frequently speaks on food law and policy issues and especially enjoys participating in FDLI events and writing for FDLI's *Update* magazine. Steve earned his bachelor's degree from Harvard College and his law degree from Columbia University.

DONALD ASHLEY is Director of CDER's Office of Compliance, where he leads efforts to protect the American public from unsafe, ineffective and low-quality drug products through measures designed to assist industry-wide compliance with federal standards for quality and safety, as well as regulatory and enforcement measures to address violations of those same standards. Mr. Ashley joined FDA after more than 18 years of criminal enforcement and investigation experience with the Department of Justice (DOJ). His many positions with DOJ included serving as a Trial Attorney in the Office of Consumer Litigation (now the Consumer Protection Branch), where he prosecuted consumer fraud offenses and violations of the Food Drug and Cosmetic Act (FD&C Act), and as Associate Director of the Office of International Affairs, where he managed international criminal law enforcement cooperation with countries throughout the world, represented DOJ's interests within the United Nations, and negotiated law enforcement cooperation treaties. In addition, Mr. Ashley served as the DOJ Attaché stationed at the US Embassy in Rome, Italy, where he was responsible for facilitating closer cooperation between Italy and United States in organized crime and terrorism investigations. Mr. Ashley also served as the DOJ Attaché at the U.S. Embassy in Manila, Philippines, where he managed international law enforcement collaboration on behalf of the United States with the Philippines, Singapore, Malaysia, and Indonesia. His work focused on money laundering, public corruption, bribery, and fraud investigations. Before joining DOJ, Mr. Ashley served as senior litigation associate with the King & Spalding law firm, specializing in white-collar criminal defense work, often involving clients under investigation for FD&C Act violations. He also served on active duty as an Army captain assigned to the Office of General Counsel, Department of the Army. Mr. Ashley was an adjunct professor of law at Georgetown, George Washington, American, and Catholic Universities teaching a course on the role of federal prosecutors. He also served as Vice President of the Board of Trustees at the International School Manila while in the Philippines. Mr. Ashley received a bachelor's degree in political science from John Carroll University in Ohio and earned a law degree from Harvard Law School.

MEAGHAN BAILEY is Executive Director for NSF International's Medical Device Consulting. Her expertise is in the analysis of complex regulatory challenges, and she supports the development and compliant marketing of innovative medical devices. Specifically, she creates regulatory strategies, writes regulatory submissions, and provides

regulatory guidance throughout the design controls process. Ms. Bailey has expertise in managing Medical Devices Advisory Committee panel meetings and supporting other premarket FDA interactions on behalf of a sponsor. Ms. Bailey has experience in a range of therapeutic areas and advising both established international companies as well as start-ups. Prior to NSF Health Sciences, Ms. Bailey was a managing director for Innovative Healthcare Products at Becker & Associates Consulting.

FREDERICK R. BALL is a partner at the law firm of Duane Morris LLP in Chicago, IL. He is vice-chair of Duane Morris's White-Collar Government Regulatory Division of the Trial Practice Group and heads its Pharmaceutical, Pharmacy and Food Group. He focuses his practice on assisting companies or individuals when they are adverse to state or federal governments, including administrative, civil and criminal matters with the FDA, DEA, CMS and other federal and state regulatory agencies. Mr. Ball helps generic pharmaceutical companies, biologics manufacturers, food companies (including supplement manufacturers), pharmacies, long-term care providers and other health care providers navigate the complex challenges faced by state and federal regulation of their industries, including complying with current Good Manufacturing Practices, price reporting (AMP, AWP, ASP, etc.), the Foreign Corrupt Practices Act, fraud and abuse laws including and labeling and advertising requirements. Mr. Ball also assists generic manufacturers bring products to market through patent analysis and Hatch-Waxman litigation. He is experienced in conducting internal investigations and advising companies on actions following the investigation. Finally, he helps companies maintain their trade secrets and competitive advantage through trade secrets litigation and enforcement of restrictive covenants. Mr. Ball emphasizes a team approach to client problem solving and manages matters to achieve client goals both financially and legally. In his spare time, he is an adjunct professor of law at DePaul University School of Law and serves on the FDLI Board. He is admitted to the Illinois State Bar, the Trial Bar of the US District Court for the Northern District of Illinois, the Seventh Circuit and the US Supreme Court. A member of the American and Illinois State bar associations, Mr. Ball is a 1996 cum laude graduate of Cornell Law School and a graduate of the University of Colorado at Boulder.

SCOTT BALLIN is a tobacco and health policy consultant in Washington, DC, and has spent more than 30 years involved in issues related to tobacco and health. He was Vice President for Public Policy and Legislative Counsel at the American Heart Association and Chairman of the Coalition on Smoking OR Health (ASC, ALA, AHA). More recently, he served on the Steering Committee of the Alliance for Health Economic and Agriculture Development (AHEAD), an informal organization committed to bringing parties together to discuss controversial issues, remove barriers, foster constructive dialogue, and look for new opportunities to find common ground. He continues to advocate for dialogue and is currently serving as an advisor to the Institute for Environmental Negotiation at the University of Virginia in putting together a series of dialogues on harm reduction.

CLIVE BATES is the Director of Counterfactual Consulting Limited. Mr. Bates has had a diverse career in the public, private, and not-for-profit sectors. He started out in IT marketing for IBM then switched careers to work in the environment movement, including for Greenpeace. From 1997-2003 he was Director of Action on Smoking and Health (UK), campaigning to reduce the harms caused by tobacco. In 2003, he joined Prime Minister Blair's Strategy Unit as a civil servant and worked in senior roles in the public sector in the UK and for the United Nations in Sudan. At the start of 2013, he opened a new venture, Counterfactual, a consulting and advocacy practice focused on a pragmatic approach to sustainable development, energy policy, and public health.

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DON BECKER is Assistant General Counsel for Turning Point Brands, Inc. (TPB) in Louisville, Kentucky, where he has primary responsibility for FDA compliance for TPB's affiliates including National Tobacco Company, Vapor Beast and Vapor Shark. Don also serves as a generalist for contracts, antitrust issues, M&A, marketing, sales, quality assurance and franchising. Don has been with TPB for over two years. Prior to that, Don worked for a major restaurant company for 18 years where he had legal department responsibilities including tort litigation, insurance, contracts, FCPA, general compliance, risk management, food safety and crisis management. Don was also general counsel for two franchised restaurant chains during his tenure. Don has participated in multiple panels in each of these areas. He is a graduate from the University of Louisville (MBA and JD).

ARUNI BHATNAGAR is widely regarded for spearheading the new field of Environmental Cardiology, Dr. Aruni Bhatnagar, a Smith and Lucille Gibson Professor of Medicine at the University of Louisville, has spent more than 25 years studying the impact of toxic substances, tobacco smoke constituents and environmental pollutants on heart disease. He is a graduate of Kanpur University, India and received his post-doctoral training at the University of Texas Medical Branch at Galveston. Dr. Bhatnagar is known for his pioneering work on the metabolism of toxic substances in ambient air and tobacco smoke, and how they affect the development of cardiovascular disease and diabetes. He has published over 225 research papers, commentaries and review articles, and 20 book chapters. A leader in cardiovascular health, he has participated in more than 50 peer-review panels of the National Institutes of Health, and has served as a member of the Institute of Medicine's Committee on Secondhand Smoke Exposure and Acute Coronary Events, as well as the Committee on Long-Term Health Consequences of Exposure to Burn Pits in Iraq and Afghanistan. For the last 7 years, Dr. Bhatnagar has served as Deputy Editor of the American Heart Association journal - Circulation Research. His research has been supported by the National Institutes of Health, the Environmental Protection Agency, the Department of Defense, and the American Heart Association. He currently serves as Director of the Diabetes and Obesity Center at the University of Louisville and Director of the American Heart Association Tobacco Regulation and Addiction Center.

BARBARA BINZAK BLUMENFELD is a shareholder in the FDA & Biotechnology practice group at Buchanan Ingersoll & Rooney PC. Since joining Buchanan in March 2003, Barbara has capitalized on her unique background, integrating her training in molecular biology (Ph.D.) and biomedical ethics (M.A.) into her legal practice. She advises clients in all areas of food and drug law, including drugs, biologics, medical devices, medical foods, and dietary supplements. Barbara also counsels companies on regenerative medicine products, including small start-ups, established companies, and investors. She is currently Vice Chair of the Editorial Advisory Board for FDLI's *Food and Drug Law Journal*, is a member of the Board of Directors and the Ethics and Standards Committee of the American Academy of Regenerative Medicine, and serves on the College of Arts and Sciences Advisory Committee of her alma mater, Cardinal Stritch University.

MICHAEL BLUME is a partner at Venable LLP, where he focuses on issues related to compliance and corporate liability for clients in the pharmaceutical, food, dietary supplements, and consumer products industries. Prior to joining Venable, Mr. Blume served as Director of the Consumer Protection Branch at the US Department of Justice. There, he oversaw record-setting prosecutions in food, drug, and consumer product safety. Mr. Blume has also worked with leaders across multiple components of the DOJ and at numerous government agencies, including US Attorney's Offices nationwide, FDA, FTC, and state

attorneys general. Mr. Blume clerked for a judge on the U.S. Court of Appeals for the Third Circuit, and served as an Assistant United States Attorney. He is a 1996 graduate of Harvard Law School, where he was an Editor of the *Harvard Law Review*.

JENNIFER BRAGG is a partner with Skadden, Arps, Slate, Meagher & Flom LLP where she advises FDA-regulated companies, as well as hospitals and health care systems, facing government investigations and US FDA enforcement challenges. Ms. Bragg frequently represents pharmaceutical, medical device, and food companies in crisis management situations related to products that have manufacturing or quality issues, helping them navigate the myriad matters that arise in the context of product recalls, and counsels on compliance, advertising, and promotion issues. Her work involves developing strategies to help companies resolve regulatory issues to minimize litigation and enforcement risks, as well as overcome transactional hurdles. Ms. Bragg served in FDA's Office of Chief Counsel as associate chief counsel for enforcement, where she provided advice to FDA's Office of Criminal Investigations. During that time, she tried to verdict four criminal jury trials involving violations of the Federal Food, Drug and Cosmetic Act and other federal statutes. Ms. Bragg is Vice Chair of the FDLI Board of Directors.

CATHY BURGESS is a partner in the Healthcare Group of Alston & Bird LLP in Washington, DC. Her practice focuses on regulatory compliance, product risk management, enforcement, and policy matters affecting industries regulated by FDA. Prior to joining the firm, Ms. Burgess served as associate general counsel for the American Red Cross. In this role she provided legal assistance and strategic advice to Red Cross senior management and the Board of Governors on matters related to the Red Cross Amended Consent Decree. Ms. Burgess served as the defense team's first chair for expert testimony on cGMPs and analytical method validation in *United States v. Barr Laboratories*, widely recognized as the leading case on cGMPS.

CYNTHIA CABRERA is President of the Cating Group and has been an integral part of the vapor space: beginning in 2011 as VP of Compliance & Logistics for VMR Products, then Executive Director of the Smoke-Free Alternatives Trade Association, and now as founder and president of the Cating Group. She is a frequent speaker on business trends, regulatory and legislative issues, and the future of the vapor industry. An avid supporter of harm-reducing technologies like alternative nicotine products, Cynthia has presented for the Tobacco Merchants Association (TMA), the Global Tobacco Nicotine Forum (GTNF), the Global Forum on Nicotine (GFN), the Food & Drug Law Institute (FDLI), the Responsible Retailers Forum (RRF), ECIG USA, the Morven Dialogues, and at a wide variety of vapor shows and exhibits. Cynthia has appeared on Fox Business, CNN Español, NBC, CBS, AP News, and has been quoted in The Washington Post, The New York Times, The Wall Street Journal, and various industry publications.

KHATEREH CALLEJA is Senior Vice President of Technology and Regulatory Affairs for AdvaMed, the Advanced Medical Technology Association (AdvaMed). AdvaMed is the world's largest association representing manufacturers of medical devices, diagnostic products, and medical information systems. In that role, she works on a variety of device regulatory issues and also leads the Association's policy efforts of various working groups, including the AdvaMed Advertising and Promotion Working Group. Calleja joined AdvaMed's Technology and Regulatory Affairs Department in December 2007, as FDA was embarked on implementing the provisions of the Medical Device User Fee Act II (MDUFMA II) legislation to support innovation and improve the device regulatory review process. Since that time, she has also played an instrumental role in assuring appropriate

implementation of key device provisions in the Food and Drug Administration Safety and Innovation Act (MDUFA III). Ms. Calleja has extensive policy, regulatory, legal, and government affairs background in health, device, and diagnostic issues. Calleja previously served as federal affairs manager and established a Washington office for the American Society of Plastic Surgeons. Prior to that, she directed legislative and regulatory affairs outreach activities at the American Academy of Otolaryngology—Head and Neck Surgery, in Alexandria, VA. She has also provided strategic consulting for the pharmaceutical industry, health care professional groups, and Fortune 500 companies. Calleja is a graduate of Emory University and Villanova University School of Law.

ARTHUR LEONARD CAPLAN is currently the Drs. William F and Virginia Connolly Mitty Professor and founding head of the Division of Medical Ethics at NYU School of Medicine in New York City. Prior to NYU School of Medicine, Dr. Caplan was the Sidney D. Caplan Professor of Bioethics at the University of Pennsylvania Perelman School of Medicine in Philadelphia, where he created the Center for Bioethics and the Department of Medical Ethics. Caplan has also taught at the University of Minnesota, where he founded the Center for Biomedical Ethics, the University of Pittsburgh, and Columbia University. He received his PhD from Columbia University. Dr. Caplan is the author or editor of 35 books and over 725 papers in peer reviewed journals. His most recent books are The Ethics of Sport, (Oxford University Press, 2016 with Brendan Parent) and Vaccination Ethics and Policy, (MIT Press, 2017 with Jason Schwartz). He has served on several national and international committees including as the chair of the National Cancer Institute Biobanking Ethics Working Group, chair of the Advisory Committee to the United Nations on Human Cloning; chair of the Advisory Committee to the Department of Health and Human Services on Blood Safety and Availability. He has also served on the Presidential Advisory Committee on Gulf War Illnesses, the special advisory committee to the International Olympic Committee on genetics and gene therapy, the Special Advisory Panel to the National Institutes of Mental Health on Human Experimentation on Vulnerable Subjects, the Wellcome Trust Advisory Panel on Research in Humanitarian Crises, and the co-director of the Joint Council of Europe/United Nations Study on Trafficking in Organs and Body Parts. He is currently the ethics advisor to the US Department of Defenses's Defense Advanced Research Projects Agency on synthetic biology, a member of the University of Pennsylvania's External Advisory Committee for its Orphan Disease Center, a member of the Ethics and Ebola Working Group of the World Health Organization and an advisor to the National Institutes of Health on organ transplantation. Dr. Caplan also serves as the chairperson of the Compassionate Use Advisory Committee (CompAC), an independent group of internationally recognized medical experts, bioethicists and patient representatives which advises Johnson & Johnson's Janssen Pharmaceuticals about requests for compassionate use of some of its investigational medicines. Dr. Caplan is a regular commentator on bioethics and health care issues for WebMD/Medscape, for WGBH radio in Boston and WMNF public radio in Tampa. He appears frequently as a guest and commentator on various other national and international media outlets. Dr. Caplan is the recipient of many awards and honors including the McGovern Medal of the American Medical Writers Association and the Franklin Award from the City of Philadelphia. He was a USA Today 2001 "Person of the Year and was described as one of the 10 most influential people in science by Discover magazine in 2008. He has also been honored as one of the 50 most influential people in American health care by Modern Health Care magazine, one of the 10 most influential people in America in biotechnology by the *National Journal*, one of the ten most influential people in the ethics of biotechnology by the editors of *Nature Biotechnology*, and one of the 100 most influential people in biotechnology by Scientific American magazine. He received the Patricia Price Browne Prize in Biomedical Ethics for 2011. In 2014 he was selected to receive the Public Service Award from the National Science Foundation/National Science Board, which honors individuals and groups that have made substantial contributions to increasing public understanding of science and engineering in the United States. In 2016 the National Organization for Rare Disorders (NORD) honored

him with their Rare Impact Award. He holds seven honorary degrees from colleges and medical schools and is a fellow of the Hastings Center, the New York Academy of Medicine, the College of Physicians of Philadelphia, the American College of Legal Medicine, and the American Association for the Advancement of Science.

CARLA CARTWRIGHT is the Director of Federal Affairs at Johnson & Johnson where she focuses on FDA matters and supports the oncology and immunology portfolios. Prior to joining Federal Affairs, Ms. Cartwright was a part of the Global Regulatory Policy and Intelligence team where she was the US policy lead on topics including clinical trial innovation, patient engagement, expedited approval pathways, disease interception, and combination products. Prior to joining Johnson & Johnson, Ms. Cartwright was an attorney and team leader in FDA's Office of the Chief Counsel where she advised the Center for Drug Evaluation and Research on legal and policy issues, working closely with the Offices of Policy and Legislation. Ms. Cartwright is a graduate of Washington University in St. Louis and has a JD from Yale Law School and an LLM from Georgetown University Law Center. Ms. Cartwright is co-chair of the 2018 FDLI Annual Conference.

KRISTA HESSLER CARVER is a partner at Covington & Burling LLP in Washington, DC. Ms. Carver's practice focuses on FDA regulatory and legislative matters for clients in the pharmaceutical and biotechnology industries. Ms. Carver counsels clients on an array of FDA regulatory issues, including orphan-drug designation and exclusivity, priority review vouchers, FDA's expedited programs, pediatric testing, risk evaluation and mitigation strategies (REMS), and Hatch-Waxman and biosimilars issues. Ms. Carver also assists clients with advocacy before FDA, including formal dispute resolution requests and citizen petitions, and with legislative issues concerning amendments to the Federal Food, Drug, and Cosmetic Act. Ms. Carver received her JD, magna cum laude, from Harvard Law School and her BS in Chemistry, summa cum laude, from William & Mary.

DAVID V. CERYAK is Senior Director – Assistant General Counsel, Regulatory Legal Team at Eli Lilly and Company. In this role, he leads the team that provides counsel on drug and device legal matters, including issues related to clinical development, registration, labeling, Hatch-Waxman, biosimilars, GMPs/manufacturing, diagnostics, and drug safety, as well as legal counsel on health, safety, and environmental matters. Mr. Ceryak has also worked for three years in Lilly's Medical division as the head of Global Clinical Quality and, prior to joining Lilly, practiced law with the Indianapolis firm Baker & Daniels. He has served as a subcommittee member on the HHS Secretary's Advisory Commission on Human Research Protections (SACHRP) and as Chair of the FDA Focus Group of the Pharmaceutical Research and Manufacturers of America (PhRMA). Mr. Ceryak graduated *magna cum laude* from Miami University and received his JD, *magna cum laude*, from the Indiana University School of Law.

AZIM CHOWDHURY is a partner at the law firm of Keller and Heckman LLP in Washington, DC. In this role, he advises domestic and foreign corporations in matters of FDA and international regulatory compliance. In particular, he assists corporations in establishing clearances for food and drug additives in the US, Canada, and European Union, with an emphasis on indirect additives used in food-contact materials. Chowdhury has also developed expertise in tobacco product regulation and has experience representing drug, dietary supplement, medical device, and tobacco companies in FDA regulatory matters. He is also a frequent contributor to the Food and Drug Law Institute's (FDLI) *Update Magazine*, and is Editor of FDLI's publication, *Tobacco Regulation and Compliance: An Essential Resource*. Chowdhury received a BA and BS from Johns Hopkins

University; an MBA from the University of Maryland Robert H. Smith School of Business; and a JD, cum laude, from the University of Maryland School of Law.

KATHERINE CIAMBRONE is Senior Vice President of Product Integrity and Compliance and Chief Compliance Officer with ITG Brands in Greensboro, NC. Katherine worked for 23 years in the pharmaceutical industry in various clinical and preclinical risk management, quality and operations roles. She holds a Master's degree in quality assurance and regulatory affairs from Temple University in Philadelphia, PA, as well as a Master's degree in organizational development from the University of Pennsylvania in Philadelphia, PA. She was previously employed as Vice President, Global Ethics and Compliance and Chief of Staff with GlaxoSmithKline in London and Philadelphia where she led their global ethics and compliance strategy.

DEAN CIROTTA is President and Chief Operating Officer for EAS Consulting Group where he is responsible for the day to day management of the technical aspects of the company with responsibility for client relations and personnel management. Mr. Cirotta has 30 years of experience in the pharmaceutical and dietary supplement industries, including executive management roles with responsibility for regulatory affairs, compliance, quality assurance, laboratory operations, and overall corporate management. In addition, Mr. Cirotta regularly speaks on GMP compliance and initiatives and is a lead trainer for EAS. He often performs audits of manufacturers and works with clients in responding to FDA 483 observations and warning letters. He also assists the Tobacco Industry in complying with the Deeming Rule requirements and ensuring compliance with the Family Smoking Prevention and Tobacco Control Act. Mr. Cirotta has a Bachelor of Science degree in chemistry from the University of North Carolina at Greensboro and a Master's degree in business administration from the University of North Carolina at Chapel Hill.

RICHARD CLELAND is an assistant director at the Bureau of Consumer Protection's Division of Advertising Practices. Mr. Cleland joined the Federal Trade Commission's Division of Advertising Practices in 1991. In 1996, Mr. Cleland was appointed Assistant to the Director of the Bureau of Consumer Protection and, in 1998, he was appointed Assistant Director of the Division of Service Industry Practices. He currently serves as Assistant Director of the Division of Advertising Practices. His primary area of expertise is the advertising and marketing of health-related products and services. He also supervises many of the Commission's health fraud and weight-loss product and service law enforcement initiatives. Mr. Cleland supervised the FTC's review of the Endorsement and Testimonial Guides and the revision of the FTC's guidance on making effective disclosures on the Internet and other digital platforms (.com Disclosures). Recent projects have included social media marketing and native advertising.

DALE COOKE is President of PhillyCooke Consulting, which helps companies communicate about FDA-regulated products using 21st century tools, while remaining compliant with regulations written in the 1960s. Mr. Cooke has worked with more than 50 pharmaceutical and medical device clients and more than 20 advertising agencies around the world. His insights have been featured in the *Wall Street Journal*'s Health blog, *The Pink Sheet*, *MedAdNews*, *PharmExec*, and others. Mr. Cooke is an active member of the Regulatory Affairs Professionals Society (RAPS), Drug Information Association (DIA), Food and Drug Law Institute (FDLI), the Alliance for a Stronger FDA, and the Google Health Advisory Board. Mr. Cooke is the author of Effective Review and Approval of Digital Promotional Tactics, which is now in its second edition in FDLI's Topics in Food and Drug Law series. Mr. Cooke earned his BA in Philosophy from Southern Methodist University, an MA in Philosophy from the University of Arizona, and studied Epidemiology and Biostatistics at Drexel University's School of Public Health and Healthcare Compliance at

Seton Hall University's School of Law. Mr. Cooke is currently enrolled at Drexel University's Kline School of Law with anticipated JD completion in 2019.

JAMES CZABAN is a Partner and the Chair of the FDA and Medical Products Practice Group at DLA Piper LLP in Washington, D.C. In more than 25 years of practice he has represented pharmaceutical, biotechnology, medical device, food, and life sciences clients in all aspects of FDA regulation, including product approvals, lifecycle management strategies, FDA compliance, and myriad enforcement matters. His practice also covers advertising and promotional matters before the FDA and the FTC, legislative strategies and advocacy, Administrative Procedure Act litigation, and regulatory aspects of corporate transactions. He has twice received the Burton Award for Distinguished Legal Writing for his scholarship on FDA regulation of biosimilars (2010) and precision medicine (2018). Mr. Czaban serves on the Editorial Boards of Bloomberg-BNA's Pharmaceutical Law and Industry Report, and the Journal of Precision Medicine. He is a graduate of the University of Virginia School of Law and the University of California, Berkeley.

BRIAN DAHL is the Compliance Practice Lead at EMMA International. He spearheads EMMA International's Compliance service offerings by providing practical corporate compliance solutions to the pharmaceutical, biotech, and medical device industries. Brian is focused on supporting our clients with: building and implementing Corporate Compliance Programs, and evaluating the effectiveness of Corporate Compliance Programs. Mr. Dahl's career in compliance began in 2001. He is credited with creating the compliance programs at TEVA Pharmaceuticals and Takeda Pharmaceuticals. In 2015, Mr. Dahl published two chapters in the Food and Drug Law Institute's (FDLI) book, Bringing Your Pharmaceutical Drug to Market. He is a frequent participant in panel discussions at various Enforcement, Litigation, or Compliance related events and conferences. He currently serves on the editorial advisory board of FDLI's *Food and Drug Law Journal*. Mr. Dahl earned his Juris Doctor from the University of Iowa College of Law and his Master of Health Administration degree from University of Iowa College of Public Health.

MARK R. DAHLBY is FDA Regulatory and Healthcare Compliance Counsel at IBM. In this role, he supports all business units globally, such as IBM Research, Watson Health and Merge Healthcare. Mr. Dahlby advises executive, offering management, sales and partnerships, product development, researchers, clinical and medical affairs, legal, government programs and quality/regulatory teams on the full range

of regulatory legal and compliance issues involving FDA and related regulatory agencies worldwide. He also lead the establishment and operation of IBM Watson Health's healthcare compliance program relative to fraud and abuse and transparency requirements, including the US Anti-Kickback Statute and False Claims Act. Prior to his work at IBM, Mr. Dahlby was an attorney at Hall Render Killian Heath & Lyman, and Lead – Regulatory Compliance Initiatives, Intelligence & Strategy at GE Healthcare, both in the Milwaukee area. He received his JD from the University of Wisconsin-Madison.

NEIL Di SPIRITO is of counsel at Ballard Spahr LLP, and a member of the firm's Business and Finance Department and its Life Sciences and Technology and Health Care Groups. He has more than two decades' experience helping pharmaceutical, medical device, and life sciences clients comply with US and international drug, biologic, and medical product regulation. His practice focuses on providing regulatory and enforcement counsel to companies of all sizes on products regulated by FDA. He has litigated against FDA and negotiated with its Office of General Counsel. He also handles licensing, patent and labeling issues, managed care issues, FDA enforcement defense and state enforcement matters, civil seizure claims, consent decrees, Medicare and Medicaid issues, and federal supply issues. Before becoming an attorney, Mr. DiSpirito worked as an executive for major pharmaceutical manufacturers in marketing, manufacturing, advertising, FDA regulatory and compliance, new drug approval, and worldwide business development. He also negotiated with regulatory authorities to launch products and manage them through the product life cycle. He also teaches pharmaceutical law at the Food and Drug Law Institute and to FDA's newly hired attorneys and reviewers. Mr. DiSpirito is co-chair of the 2018 FDLI Annual Conference.

SCOTT DRENKARD is an economist and the Director of State Projects for the Tax Foundation. He is co-author of the annual *State Business Tax Climate Index* and editor of the 2012 and 2013 editions of the popular handbook, *Facts & Figures: How Does Your State Compare?* He has co-authored books on North Carolina, Nebraska, and Louisiana tax policy which laid the groundwork for fundamental tax reforms in each state. Scott and the Center for State Tax Policy were highlighted in *State Tax Notes*' "most influential in state tax policy" feature in 2011, 2012, and 2013. His analysis of tax and spending policy has been featured hundreds of times in media outlets across the country, including the *Economist*, the *Wall Street Journal*, *USA Today*, the *Daily News*, the *Washington Post*, the *New York Post*, CNN.com, Yahoo News, the *Huffington Post*, *Kiplinger*, Reuters, the Associated Press, CNN, ABC, CBS, Fox News, NPR, the trade publication *State Tax Notes*, and the peer-reviewed *Journal of State Taxation*. Scott has given legislative testimony or presented to officials in 26 states and before the U.S. Senate Finance Committee. He has also served as an expert witness in court on tax issues. In 2015, he was appointed by the Louisiana legislature to serve on the state's Sales Tax Streamlining & Modernization Commission. Prior to joining the Tax Foundation, Scott held research positions at the Institute for Humane Studies and the Goldwater Institute. He holds a B.S. in Economics from the University of Mary Washington and an M.A. in Economics from George Mason University. In 2014, he was briefly featured as a staffer to the First Lady in the second season of *House of Cards*. Scott lives in Southeast Washington, D.C. with his wife, Molly.

DANIEL R. DWYER is a partner with Kleinfeld, Kaplan and Becker, LLP. His practice focuses primarily on representing food, dietary supplement, pharmaceutical, cosmetic, medical device, and consumer products companies on a variety of matters involving FDA law and advertising law. Mr. Dwyer has substantial expertise in food and drug safety issues, clinical trials, labeling and advertising claim

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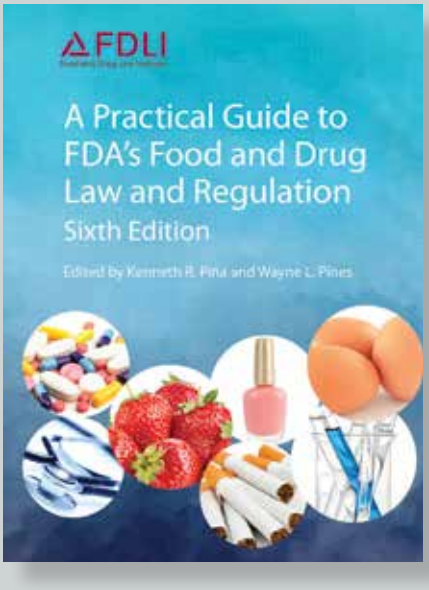

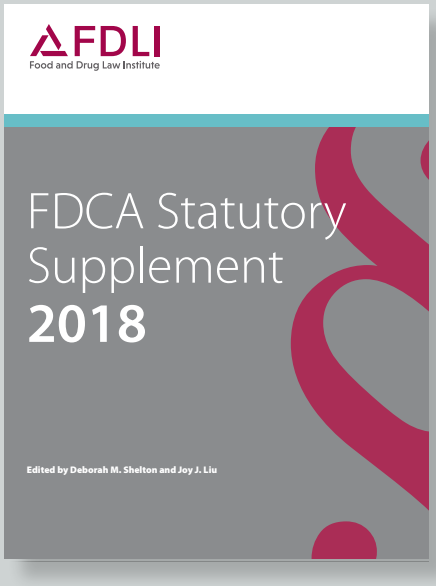

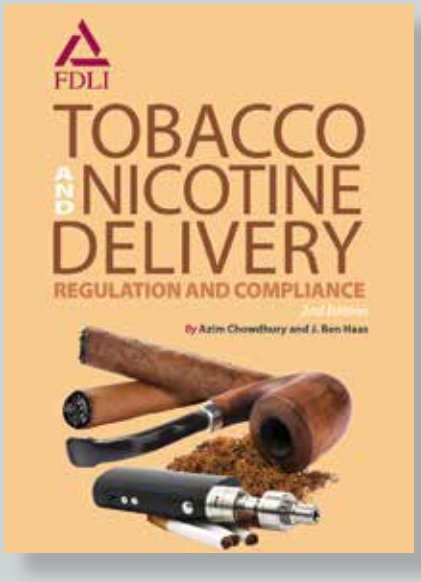

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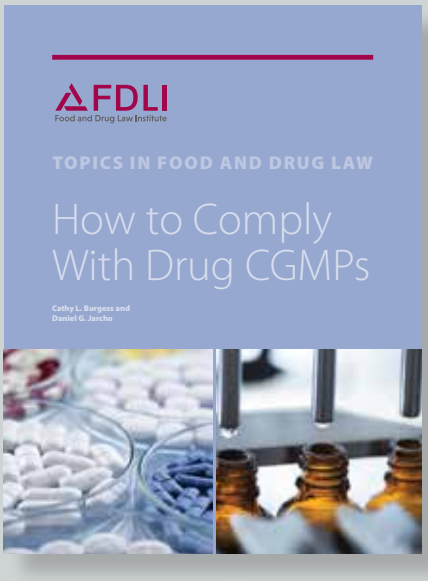

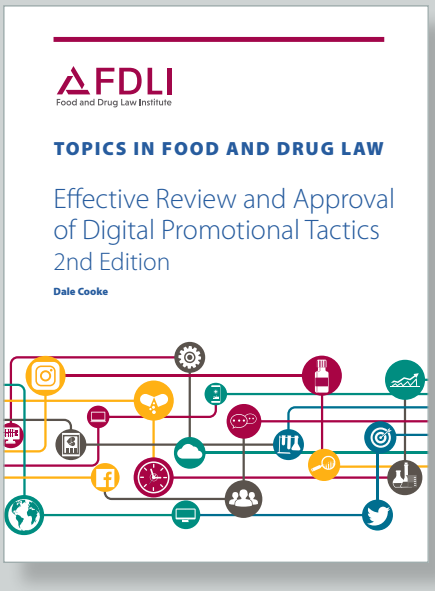

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substantiation, sales and marketing practices, good manufacturing practices, FDA inspections, recalls, corporate compliance programs, and related matters. He regularly advises clients on developing strategies for FDA compliance and compliance with federal and state advertising law.

STACY EHRLICH is a partner at the law firm of Kleinfeld, Kaplan & Becker, LLP in Washington, DC. In her 20th year with the firm, Ms. Ehrlich's practice focuses on counseling and advocating on behalf of pharmaceutical, food, dietary supplement, tobacco, cosmetic, and medical device companies on a variety of matters involving FDA, USDA, and FTC, as well as state agencies. Ms. Ehrlich also serves as outside counsel for the Coalition of Independent Tobacco Manufacturers of America and has been involved in FDA's regulation of tobacco products since early in the legislative process of the Family Smoking Prevention and Tobacco Control Act. Ms. Ehrlich is a member of the FDLI Board of Directors.

ADAM EKONOMON is Vice President and Deputy General Counsel at The J.M. Smucker Company where he is primarily responsible for legal compliance of all Marketing and Regulatory matters. Mr. Ekonomon's practice focuses on advertising, marketing and promotion law, including advertising compliance, product claims and substantiation, agency, license and talent agreements, and promotion structure and compliance. Mr. Ekonomon also advises in the areas of food labeling, food safety, and food regulatory compliance. Mr. Ekonomon earned his BS in Finance at Youngstown State University, his JD from the University of Akron School of Law, and his Masters from the University of Akron Graduate School of Business. In 2015, he received his LLM in Global Food Law from Michigan State University College of Law, and is currently an Adjunct Professor teaching Advertising Law – Food Focus in MSU COL's Global Food Law program.

BENJAMIN ENGLAND is the CEO and Founder of Benjamin L. England & Associates, LLC. He routinely represents domestic and foreign companies of all sizes, assisting them in identifying FDA, USDA, FTC, EPA, and state requirements. His representation enables his clients to better understand and fully comply with federal and state requirements, and thereby reduce the risk of regulatory interference with products being imported, exported, or distributed in interstate commerce. A 17-year veteran of FDA, Mr. England served as the Regulatory Counsel to the Associate Commissioner for Regulatory Affairs. Before this, he served in scientific, inspectional, compliance and criminal and civil enforcement capacities as an FDA Consumer Safety Officer, Compliance Officer, a Senior Special Agent with FDA's Office of Criminal Investigations (OCI) and an analytical regulatory microbiologist.

SANDRA ESKIN is the Director of the Safe Food Project, at The Pew Charitable Trusts in Washington DC, which seeks to reduce health risks from foodborne pathogens by working collaboratively with federal and state government, industry, and other stakeholders. Before joining Pew, Sandra spent nearly 20 years as a public-policy consultant to numerous consumer and public-interest organizations, during which time she provided strategic and policy advice on a broad range of consumer protection issues, in particular, food safety, and food and drug labeling and advertising. A lawyer, Eskin previously worked as a staff attorney at a federal agency and as a legislative representative for the Consumer Federation of America. She has served on a number of federal advisory committees and has authored numerous reports and articles on food safety topics. Eskin received her bachelor's degree from Brown University and her JD from UC-Hastings College of the Law.

OWEN FARIS is the Director of the Clinical Trials Program in the Center for Devices and Radiological Health at the FDA and has been in that position since its creation in 2014. Dr. Faris received his BS in Mechanical Engineering from Rice University in 1997, and his PhD in Biomedical Engineering from Johns Hopkins University in 2003. Dr. Faris joined the FDA in 2003. Prior to directing the Clinical Trials Program, he was the Deputy Director for the Division of Cardiovascular Devices. Dr. Faris has been very involved in the development of clinical trial policy for several years including developing policy regarding FDA's decisions and communications for device clinical trials. In his current role, he oversees FDA's decisions and policies for medical device clinical trials including Early Feasibility studies and oversees CDRH's Breakthrough Devices Program. Dr. Faris is also the co-chair of CDRH's strategic priority effort focused on the access and use of real-world evidence for regulatory decision making.

ANTHONY FAUCI has worked at National Institute of Allergy and Infectious Disease, NIH since 1968 and was named Director in 1984. As an immunologist and researcher, he conducted research on infectious and immune -mediated diseases. Dr. Fauci developed therapies for diseases that were once fatal, such as granulomatosis. He is a prominent figure in public health through his research. In 2017, analysis of Google Scholar citations, Dr. Fauci ranked as the 24th most highly cited researcher of all time. He frequently is featured in the press as an expert in HIV/AIDS, Zica, influenza and other diseases. Dr. Fauci has played an

important role in vaccine development and is a prominent figure in public health through his research and communications on public health matters. He promotes support for FDA and FDA's mission. His efforts have touched the roles of CBER, CDER, CVM and CFSAN and he encourages communications with FDA in support of promoting public health.

ROCHELLE CHODOCK FINK, MD, JD is a Senior Health Science Specialist at FDA. In that capacity, she works on joint CMS-FDA efforts to accelerate the regulatory and coverage decision making process. This responsibility includes spending a portion of each week working in CMS's Coverage and Analysis Group (CAG) and the remainder of the week working at FDA's Center for Devices and Radiological Health (CDRH). Dr. Fink is involved in the FDA-CMS Parallel Review Program and CDRH's Pre-Submission Program. As a registered patent attorney, Dr. Fink works on CDRH's technology transfer and patent matters. Additionally, she establishes collaborations with CDRH and has been involved in the FDA-Medical Device Innovation Consortium (MDIC) effort. Prior to joining CDRH, Dr. Fink worked in CDER's Office of Regulatory Policy where her primary responsibilities included responding to citizen petitions. Dr. Fink received her undergraduate and medical degrees from Brown University and her law degree from the University of Pennsylvania Law School. She has worked as an associate at Paul, Weiss, Rifkind, Wharton & Garrison, LLP and Sidley Austin, LLP.

ELLEN J. FLANNERY serves as Deputy Center Director for Policy in the Center for Devices and Radiological Health at the Food and Drug Administration. Prior to joining FDA in March 2018, she was an attorney for 38 years with the law firm of Covington & Burling LLP, advising and representing pharmaceutical and medical device companies and trade associations in matters arising under the Federal Food, Drug, and Cosmetic Act. Ms. Flannery regularly participated in the FDLI/CDRH medical device law training program, made presentations on drug and device law to delegations of the China FDA in programs organized by the Yale University School of Public Health, was a member of three device-related committees of the Institute of Medicine (National Academies of Science, Engineering and Medicine), and taught food and drug law seminars at three law schools. She is a Fellow of the American Bar Foundation and chair of the ABF Board of Directors, has served for many years in the American Bar Association House of Delegates, and is a member of the Mount Holyoke College Board of Trustees. Ms. Flannery received a JD degree from Boston University School of Law and AB degree from Mount Holyoke College.

JONETTE (JONI) FOY currently serves as the Associate Director for Policy in the Office of the Center Director in the Center for Devices and Radiological Health (CDRH) at the FDA. Dr. Foy received her PhD in Bioengineering from Clemson University and served as a faculty member at Virginia Tech prior to joining CDRH in 2000. Dr. Foy has been involved in many matters which directly impact medical device oversight, including the implementation of Cures and FDARA, development of regulations, cross-cutting and device-specific guidance, user fee negotiations, legislative directives, strategic priorities, policy initiatives, addressing/resolving engineering and scientific issues, among other duties. During her tenure at FDA, Joni has served as a scientific reviewer of cardiovascular devices, Chief of the Orthopaedic Joint Devices and most recently as the Deputy Director for Engineering and Science Review in the Office of Device Evaluation.

JEFF FRANCER is Senior Vice President and General Counsel of the Association for Accessible Medicines, where he leads legal and international trade advocacy. Mr. Francer served as Associate Chief Counsel of the Food and Drug Administration from 2003 to 2005, where he advised agency leaders on issues involving the regulation of

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AT KELLEY DRYE & WARREN LLP, we counsel and defend companies on legal matters that relate to the safety, labeling and advertising of food and consumer health products – before these products enter the U.S. market and afterward. From pre-market clearance requirements through manufacturing and marketing, we provide clients with legal strategies that mitigate risk throughout the product's life cycle, and in every country the product's supply chain touches.

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drugs and biologics including clinical investigation, manufacturing, promotion, enforcement and legislative matters. After leaving the FDA, Mr. Francer served as Associate General Counsel, US Compliance Officer, and Chief Privacy Officer of Biogen Idec, Inc. At Biogen Idec, he was the primary in-house counsel on FDA issues, fraud and abuse prevention and patient privacy. Mr. Francer was also responsible for overseeing the US corporate compliance program. Immediately prior to joining AAM, Mr. Francer served as Vice President and Senior Counsel of the Pharmaceutical Research and Manufacturers of America (PhRMA) where he was the principal counsel to the association on issues relating to the research, development and regulation of medicines in the US and globally. Mr. Francer received his AB in Public Policy and Economics from Brown University, his MPP from Harvard University, and his JD from the University of Virginia.

JOSEPH FRANKLIN is the Director of the Policy Staff within the Therapeutic Biologics and Biosimilars Staff, CDER, FDA. The Policy Staff is responsible for developing and implementing regulatory policy related to biosimilars and therapeutic biologics. Previously, Dr. Franklin was an Associate Chief Counsel in FDA's Office of the Chief Counsel and has also served as Deputy Chief of Staff at FDA.

JEAN FRYDMAN is a partner with Fox Rothschild LLP. A former general counsel for multinational pharmaceutical companies and a multinational retail dietary supplement company, Ms. Frydman has significant experience handling regulatory compliance matters for both private and publicly held pharmaceutical, medical device and dietary supplement companies. She regularly provides strategic legal and compliance reports to boards of directors and serves as a trusted legal adviser to executive management and business leaders. Ms. Frydman's practice has a particular focus on operations and compliance systems, including Foreign Corrupt Practices Act, anti-bribery, consent decrees and off-label promotion. Having spent more than 30 years in-house at major multinational pharmaceutical companies and a major dietary supplement company, Ms. Frydman possesses an in-depth knowledge of the regulatory and compliance issues facing clients in the pharmaceutical, medical device and dietary supplement industries. She has extensive experience in drug, medical device and dietary supplement promotional review and advises senior management on FDA rules, proactive submissions to FDA, cGMP compliance and other significant enforcement issues. She regularly counsels clients on commercial and regulatory/compliance efforts, helping to establish and execute comprehensive compliance programs as well as implement strategies to manage and reduce legal expenses.

CHRISTIAN FULDA is a partner at the Munich location of Jones Day. Mr. Fulda focuses his practice on the pharmaceutical, biotechnology, and medical device industries and acts for major European, American, and Japanese multinationals. He has broad experience covering the legal issues that these heavily regulated industries face, including product development and issues related to securing IP rights; entering into development agreements and setting up clinical trials; advising on regulatory questions regarding marketing authorizations and reimbursement; negotiating manufacturing and distribution and related agreements; accompanying the development and implementation of digital health and telehealth applications, including related data privacy issues; and advising on day-to-day operations, including advertising regulation, health care compliance, and product liability issues. Mr. Fulda routinely carries out multijurisdictional projects for life sciences clients. He also assists clients in M&A transactions in these industries. In addition, Mr. Fulda has an extensive track record in global dispute matters, covering injunction and main proceedings before state courts in cross-jurisdictional litigations and in international arbitrations. Mr. Fulda is a Fellow of the International Institute for Law and Medicine and a member of BIO Germany (Regulatory Affairs Committee

and Healthcare Policy Committee), Licensing Executives Society Germany (Life Sciences Working Group), the Federal Association of Pharmaceutical Manufacturers (BAH), Forum MedTech Pharma, the Middle-European Society for Regulatory Affairs (MEGRA), and the German Institution of Arbitration (DIS).

JOHN H. FUSON is a partner at Crowell & Moring's Washington, DC office. Also, a member of Crowell & Moring's Advertising & Product Risk Management, Health Care, and White Collar and Regulatory Enforcement groups, specializing in U.S. Food and Drug Administration (FDA) enforcement and counseling matters. Before joining Crowell & Moring, John served as associate chief counsel at FDA, with broad law enforcement responsibilities, from 2007-2012. At FDA, John handled all types of major enforcement actions brought by the agency, including seizure actions, injunction actions, actions for civil money penalties, and contempt actions. His cases have involved drugs, devices, food, and veterinary drugs. John is a frequent speaker on FDA enforcement practices and has written extensively on food policy. He received his undergraduate degree from Grinnell College, and his law degree from the University of Pennsylvania.

PAUL GADIOCK is a senior attorney in the Food, Drug, Medical Device & Agriculture group at Arent Fox LLP where he provides premarket and postmarket regulatory solutions on a variety of subject matters for medical device clients. As a former policy director at FDA and business development leader at a national biotechnology company, Paul brings unique first-hand experience with the development and application of regulatory programs to counsel clients at all stages of the medical product life cycle. Paul's practice primarily focuses on representing medical device companies, small and large alike, in efficiently navigating local and national regulatory requirements.

STACEY YOUNGER GAGOSIAN has worked in politics and policy for more than 20 years. Currently, she is Managing Director of Public Policy at Truth Initiative, which focuses on making tobacco a thing of the past. In that position she develops and promotes policies to prevent youth from using tobacco and to help tobacco users quit. She has held progressively responsible roles at Truth Initiative since 2008. From 2003 until 2008, she was Legislative Associate at the National Breast Cancer Coalition, successfully working to secure research funding and passing legislation requiring more research into the environmental causes of breast cancer. Previously, Ms. Gagosian worked on Capitol Hill in the US House of

Representatives and the U.S. Senate. Other positions include a Fundraising Manager for a Senate campaign, and Outreach Coordinator at the Close Up Foundation. Ms. Gagosian has a Bachelor of Arts degree from Kalamazoo College.

JEFFREY N. GIBBS is a director in the Washington, DC law firm of Hyman, Phelps & McNamara, PC. Before entering private practice, he was an Associate Chief Counsel for Enforcement at the Food and Drug Administration. Mr. Gibbs also served as a Special Assistant United States Attorney in the District of Columbia in the Civil Division. He is currently Chairman of FDLI's Board of Directors and was previously FDLI's General Counsel. Mr. Gibbs has assisted in vitro diagnostic and medical device companies with a variety of regulatory issues, including FDA product approval, product labeling, clinical studies, promotional and marketing programs, product appeals and enforcement actions. He received FDLI's Distinguished Service and Leadership Award in 2013, and LMG Life Science's Star Award in 2016. Mr. Gibbs previously served on the Human Subjects Review Board of George Mason University, and has written and spoken extensively on a wide variety of FDA regulatory topics. Mr. Gibbs graduated from Princeton University and New York University School of Law.

MOIRA GILCHRIST is Vice President Scientific & Public Communications at Phillip Morris International. Dr. Gilchrist was appointed to this position in January 2018 after spending one year leading PMI's Reduced Risk Products Corporate Affairs. Prior to this she was based in our R&D function where she was Director of Scientific Engagement from 2014 to 2016. Dr. Gilchrist joined PMI in 2006, to work on our Reduced-Risk Product program and held roles in Research and Development as well as Commercialization. Prior to joining PMI, Dr. Gilchrist worked in the pharmaceutical sector for more than 10 years. She was a Principal Consultant in PwC and IBM's pharmaceutical industry consulting groups and prior to that held positions in both industry and charity sectors developing new drug formulations. Dr. Gilchrist holds a degree in Pharmacy and a PhD. in Pharmaceutical Sciences, both from the University of Strathclyde in Glasgow, Scotland.

KELLY GOLDBERG is a vice president, law/senior counsel for biopharmaceutical regulation at PhRMA. Kelly joined PhRMA in April 2017. In her role, Kelly has responsibility for FDA and related regulatory law issues. Prior to joining PhRMA, Kelly spent over a decade at Pfizer. At Pfizer, Kelly was responsible for counseling internal clients on a wide-range of regulatory law issues, including data exclusivity, biosimilars, orphan drug provisions, drug safety and risk evaluation and mitigation strategies, drug labeling, drug approval standards and pathways, and advertising and promotion. Kelly was an associate in the Food and Drug practice group at Covington & Burling LLP before joining Pfizer. She earned her JD, cum laude, from the University of Pennsylvania Law School and clerked for the Honorable Joseph E. Irenas on the United States District Court for the District of New Jersey.

JASON GORDON is of counsel at Reed Smith LLP in Chicago, and a member of the firm's Entertainment & Media Group. He represents Fortune 100 brands, media companies, consumer packaged goods companies, and other advertisers in all aspects of advertising, marketing, new media, branding, privacy, mobile marketing, behavioral advertising, right of publicity, and traditional trademark and copyright prosecution and counselling.

SCOTT GOTTLIEB was sworn in as the 23rd Commissioner of Food and Drugs on May 10, 2017. Dr. Gottlieb is a physician, medical policy expert, and public health advocate who previously served as the FDA's Deputy Commissioner for Medical and Scientific Affairs and before that, as a senior advisor to the FDA Commissioner. He also worked on implementation of the Medicare drug benefit as a Senior Adviser to the Administrator of the Centers for Medicare and Medicaid Services, where he supported policy work on quality improvement and the agency's coverage process, particularly as it related to new medical technologies. In 2013 Dr. Gottlieb was appointed by the Senate to serve on the Federal Health Information Technology Policy Committee, which advises the Department of Health and Human Services on healthcare information technology. Dr. Gottlieb was a Resident Fellow at the American Enterprise Institute, and a Clinical Assistant Professor at the New York University School of Medicine in Manhattan, where he also practiced medicine as a hospitalist physician. He completed a residency in internal medicine at the Mount Sinai Medical Center in New York, New York and is a graduate of the Mount Sinai School of Medicine and of Wesleyan University, in Middletown, Connecticut, where he studied Economics.

ROBYN GOUGELET is a senior associate at PinneyAssociates, and advises on public health legislative and regulatory policy strategy for tobacco harm reduction efforts. PinneyAssociates provides consulting services on smoking cessation and tobacco harm minimization (including nicotine replacement therapy and electronic vapor products) to Niconovum USA, Inc., R.J. Reynolds Vapor Company, and RAI Services Company, all subsidiaries of Reynolds American Inc. RAI was acquired by British American Tobacco (BAT) in July 2017. Before joining PinneyAssociates in 2015, Robyn worked at Trust for America's Health (TFAH), a non-profit, non-partisan organization in Washington, DC dedicated to saving lives by protecting the health of every community and working to make disease prevention a national priority.

LINDA GOUSIS, JD is a technical advisor at the Centers for Medicare & Medicaid Services in the Coverage and Analysis Group (CAG), Division of Policy Coordination and Implementation. CAG develops, interprets, communicates, and updates evidence based national coverage policies. These policies help provide timely access to services and technologies that improve health outcomes for Medicare beneficiaries. Linda plays an integral role in the coordination and development of Medicare national coverage policies on a wide range of topics. Linda has also worked in the Part C and Part D programs at CMS since joining the agency in 2005. She earned her JD from the University of Maryland School of Law and BS in Biology & Society from Arizona State University.

JANA GRIEB is Council at McDermott Will & Emery where she focuses on the health care and life sciences sector. In her over 15 years of practice, Jana has advised German and international pharmaceutical and medical devices companies in a variety of transactions and contractual matters across the European Union, and has represented them in litigation with regard to public procurement law, unfair competition and Anti-kickback regulation. Ms. Grieb has long standing experience in the regulatory issues that are of importance to pharmaceutical, med tech, food and cosmetics companies entering the market in the European Union. She has accompanied med tech companies in entering the medical devices market and obtaining registration and CE-certification as well as pharmaceutical companies regarding market access in Germany and the EU.

LEWIS GROSSMAN, a former member of the FDLI Board of Directors, is Professor of Law at American University's Washington College of Law, where he has taught since 1997. During academic year 2017-18, he is a Law and Public Affairs (LAPA) Fellow at Princeton University. He was a Visiting Professor at Cornell Law School in 2015. He is also Of Counsel with the Food and Drug Practice Group at Covington & Burling LLP in Washington, DC Professor Grossman teaches and writes in the areas of food and drug law, health law, civil procedure, and American legal history. Prior to joining the American University faculty, he was an associate at Covington & Burling, and before that he clerked for Chief Judge Abner Mikva of the US Court of Appeals for the DC Circuit. Professor Grossman's scholarship has appeared in the *Cornell Law Review*, *Law and History Review*, *Yale Journal of Health Policy, Law & Ethics*, and *Administrative Law Review*, among others. He has made recent contributions to volumes published by Oxford University Press and Columbia University Press. He is the co-author of *Food and Drug Law: Cases and Materials* (with Peter Barton Hutt and Richard A. Merrill) and of a widely used supplement to the first-year civil procedure course titled *A Documentary Companion to A Civil Action* (with Robert G. Vaughn). Professor Grossman is currently at work on a book titled *You Can Choose Your Medicine: Freedom of Therapeutic Choice in American Law and History*, which is under contract with Oxford University Press. He has been a legal advisor or member of three committees of the Health and Medicine Division (formerly the Institute of Medicine) of the National Academies of Sciences, Engineering, and Medicine. He earned his PhD in History from Yale University, where he was awarded the George Washington Egleston Prize for Best Dissertation in the Field of American History. He received a JD magna cum laude from Harvard Law School and a BA summa cum laude from Yale University.

MIRIAM GUGGENHEIM is a partner at Covington & Burling LLP and co-chair of the Food, Drug and Device practice. Her practice focuses primarily on the food and dietary supplement industries. Ms. Guggenheim counsels clients in all aspects of food and dietary supplement development and marketing, from product formulation, manufacturing, and safety considerations to labeling and advertising. Her work for a broad range of leading global food and dietary supplement companies and major trade associations includes regulatory advice, advocacy before regulators, courts and legislative bodies, and strategic counseling in light of overarching public health and nutrition policy considerations. Ms. Guggenheim is ranked as one of America's Leading Business Lawyers, Food & Beverages: Regulatory & Litigation by Chambers USA. Ms. Guggenheim received her BA, magna cum laude, from the University of Pennsylvania and her JD, with honors, from Columbia University School of Law.

SONALI P. GUNAWARDHANA is of counsel at the law firm of Shook, Hardy & Bacon L.L.P. in Washington, DC. She draws on her nearly 10 years' experience as an attorney at FDA to offer clients detailed and practical guidance on how to avoid and resolve FDA regulatory challenges. Ms. Gunawardhana's

practice focuses on the rapidly changing FDA regulatory requirements for bringing pharmaceuticals and medical devices to market; the complex emerging rules applicable to domestic and foreign food manufacturers, suppliers, and importers; clinical trial compliance requirements for drug and medical device studies; and the defense of FDA enforcement actions against drug, device, food and dietary supplement companies, Clinical Research Organizations (CROs), academic medical research institutions and individual researchers. Ms. Gunawardhana received a BA from Syracuse University, a MA from Webster University, a MPH from Boston University, a JD from the University of New Hampshire School of Law and a LLM from Washington College of Law, American University.

J. BENNEVILLE (BEN) HAAS is a partner at the law firm of Latham & Watkins LLP in Washington, DC, and a corporate partner in the firm's Health Care and Life Sciences Practice Group. Mr. Haas focuses his practice on regulatory, transactional, and legislative matters involving the medical device, pharmaceutical, biotechnology, tobacco, food, cosmetic, and dietary supplement industries. He has counseled clients on a wide variety of regulatory matters involving FDA, including, among others, premarket product development and clinical and pre-clinical testing; FDA submissions; product promotion and labeling; compliance with good manufacturing practice requirements; agency inspections, and recalls. Mr. Haas has authored and co-authored articles on FDA regulatory matters, including articles in the Food and Drug Law Institute's *Update* Magazine and the *Pharmaceutical Law & Industry Report*, and has been a featured speaker and lecturer on FDA regulatory and policy matters at industry-sponsored events. He also served as a member of the firm's Global Training and Career Enhancement Committee. Mr. Haas received a BS from Georgetown University and a JD from the University of Virginia School of Law.

MARTIN J. HAHN is a partner in the Washington, DC office of Hogan Lovells US LLP and is a member of the firm's Food and Agriculture Practice Group. His practice focuses on a wide variety of regulatory issues affecting the food, dietary supplement, and functional food industries. He assists numerous companies and trade associations in complying with the requirements fo the U.S. Food and Drug Administration (FDA), the Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA), and the advertising requirements of the Federal Trade Commission (FTC). Mr. Hahn received a BS in Food Technology from the Ohio State University (1986), where he graduated *cum laude* with Honors, and a JD from Northwestern University (1989). Mr. Hahn is an associate member of the Association of Food and Drug Officials and a member of the District of Columbia Bar.

RALPH HALL is a principal and works in association with the Washington, DC, office. In this role, Ralph provides consulting services to clients in the areas of FDA statutes and regulations, regulatory compliance, as well as health care policy and legislation, and particularly the application of those regulatory systems to the medical device industry. Ralph's rich background with drug and medical device regulation and corporate compliance matters makes him one of the nation's foremost experts. Ralph previously served as counsel at Faegre Baker Daniels where he provided legal services, including FDA-related matters, corporate compliance, the design and implementation of multiple cross-disciplinary, corporate legal strategies, corporate law department organization and management, and general corporate counseling. Ralph has also served as General Counsel for Guidant CRM and Chief Compliance Officer for Guidant. Ralph furthermore serves as a Professor of Practice at the University of Minnesota Law School. He received his BA from Indiana University and his juris doctorate from the University of Michigan where he was a Weymouth Kirkland Scholar.

MARTINE HARTOGENSIS is the Deputy Director of FDA's Office of Surveillance and Compliance in the Center for Veterinary Medicine. Martine also leads the Science Policy Team for the office which functions to coordinate scientific and communications efforts throughout the office. Martine previously served as CVM's Promotion and Advertising Liaison from 2002 to 2007 and was a reviewer in the Division of Surveillance. Dr. Hartogensis received her D.V.M. from the Virginia-Maryland Regional College of Veterinary Medicine in 1999 and spent several years in private clinical practice prior to beginning employment at the FDA in 2001.

JONATHAN HAVENS is Co-Chair of Saul Ewing Arnstein & Lehr's Cannabis Law Practice and Vice Chair of the Firm's Food and Beverage Practice. Mr. Haven's unique perspective on cannabis regulation is informed by his congressional, federal agency, and national and international law firm experience. He advises prospective growers, processors, and dispensaries on how to obtain state agency licensure, including regarding applicable requirements, application content and strategies, post-licensing compliance considerations, and relevant federal law. In addition to having represented entities that applied for state medical cannabis licensure and advised ancillary service and product providers, Mr. Havens follows existing and prospective cannabis regulations throughout the country, as well as federal policy developments affecting the cannabis industry. Before entering private practice, Mr. Havens served as a regulatory counsel with the US Food and Drug Administration (FDA), where he focused on compliance and enforcement related to promotion, advertising, and labeling. Prior to law school, Mr. Havens held legislative and government affairs positions in which he facilitated the development and execution of strategic communications to members of Congress and their staff aides, and managed several areas of policy and drafted legislative proposals.

JOANNE HAWANA is Of Counsel with Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, based in the firm's Washington DC office. She counsels global clients on the business impact of new US federal and state actions related to foods, drugs, biologics, and medical devices. Her counseling and compliance support work reaches into all aspects of FDA-regulated companies' operations, including determining regulatory status of novel products like mobile health systems and genetic tests; pre-market and post-market compliance requirements; and enforcement-related matters. She also provides regulatory expertise to her colleagues in class action and other types of litigation that involve FDA-regulated products, and she works with the Mintz Levin Corporate & Securities Practice on transactions and offerings for companies regulated by the FDA. Ms. Hawana has a master's degree in molecular genetics from UMDNJ and a bachelor's degree in biology from the College of William & Mary. She received her JD from the University of Maryland Francis King Cary School of Law in 2007.

BRYAN HAYNES is a partner at the law firm Troutman Sanders, where he devotes his practice to representing businesses in disputes and regulatory compliance matters initiated by governmental agencies, including by state Attorneys General, and in other commercial litigation. Mr. Haynes is an accomplished trial lawyer who has served as lead counsel in state and federal courts across the country. Mr. Haynes is a member of the firm's Tobacco Law practice and is focused on representing tobacco manufacturers, distributors, retailers and suppliers in all aspects of their businesses, including regulatory compliance, Food and Drug Administration (FDA) requirements, administrative disputes involving a federal or state governmental entity, commercial agreements and tobacco taxation matters.

MARGO HEATH-CHIOZZI is the Celldex Therapeutics, Senior Vice President of Global Regulatory Affairs. She joined Celldex in October 2017 with over 25 years of experience in senior leadership roles in regulatory sciences, pharmacogenetics and product development within the pharmaceutical industry and as a practicing physician and clinical researcher. Prior to Celldex, she led global regulatory strategy in several business units at Bristol Myers-Squibb including Oncology, Immunology, Virology and Genetically Defined Diseases with successful initial approvals or new indications for nine major products. Prior to BMS she served in roles of increasing responsibility at Abbott Laboratories including Medical Director of Pharmacogenetics and Senior Director of Global Marketed Product Development and Outcomes Research. Before Abbott, she established the HIV Clinical

Research Program for the University of Hawaii. Dr. Heath-Chiozzi received her BS and MD degrees from the University of Hawaii. She completed her internal medicine residency at Duke University and infectious disease fellowship at Harvard University.

DENNIS HENIGAN is Vice President, Legal and Regulatory Affairs at the Campaign for Tobacco-Free Kids. He focuses on issues involving FDA regulation of the tobacco industry and related litigation, as well as providing legal guidance on federal, state and local tobacco control legislation. Prior to joining the Campaign in September, 2012, he worked for over two decades at the Brady Center to Prevent Gun Violence, first as Director of the Center's Legal Action Project, and then as the Center's Vice President. Before his tenure at the Brady Center, Denny was a partner in the law firm Foley & Lardner.

ROBERT G. HIBBERT is a partner at Morgan Lewis & Bockius LLP and advises clients in the food and agricultural industries on federal regulation, particularly relating to the U.S. Department of Agriculture (USDA), as well as the U.S. Food and Drug Administration (FDA). Clients seek his counsel on labeling, advertising, recalls, food safety compliance, animal health, and new product development issues. Bob's experience with civil litigation in federal court includes successful challenges to the scope of USDA jurisdiction and authority over major segments of the food processing industry.

LORI F. HIRSCH is the Vice President, Regulatory Compliance and External Engagement, Quality at Bristol-Myers Squibb Company. In this role, she leads an End to End GxP Quality Assurance group responsible for such areas as regulatory compliance, auditing, ITQA and training. Prior to this, Ms. Hirsch was a Managing Counsel at Merck & Co., Inc. where she represented Merck's global manufacturing division on a variety of matters, including those involving pharmaceuticals, vaccines, biologics, OTC, and animal health products. For the past 25 years, Ms. Hirsch has specialized in compliance matters, with an emphasis on cGMPs. Ms. Hirsch received a BA from Tufts University, magna cum laude, and a JD from The University of Michigan Law School.

KATHLEEN SUSAN HOKE, JD, is a law school professor, Director of the Legal Resource Center for Public Health Policy, and Director of the Network for Public Health Law-Eastern Region, at the University of Maryland Carey School of Law. Through the Center and Network, Kathleen provides technical legal assistance to state and local health officials, legislators, researchers, and organizations working to use law and policy change to improve public health. Hoke graduated as a member of the Order of the Coif from the University of Maryland School of Law in 1992, completed a clerkship with the Honorable Lawrence Rodowsky of the Maryland Court of Appeals and served with distinction as an Assistant Attorney General and Special Assistant to the Attorney General of Maryland prior to joining the School of Law in 2002.

MATT HOLMAN became Director of the Office of Science (OS) at FDA's Center for Tobacco Products in January 2017. OS is responsible for identifying, developing, and enhancing the science related to tobacco products, their use, and the resulting morbidity and mortality. They provide scientific support for regulations and guidance, review tobacco product applications, and carry out research to fill the gaps in scientific knowledge related to tobacco product regulation. Before his current position, Dr. Holman served as Director of the Division of Product Science within OS for six years. In this position, he served as Technical Project Lead (TPL) for over a thousand SE

Reports. Before his tenure at CTP, he served as Deputy Director of the Division of Nonprescription Regulation Development in FDA's Center for Drug Evaluation and Research and earned his PhD in Biochemistry from the University of Maryland at College Park.

AUGUST HORVATH a partner in Foley Hoag's Advertising & Marketing practice, is a noted advertising and antitrust attorney. He counsels clients on how to substantiate and defend marketing claims they wish to make for their products and services, helps them challenge false and disparaging advertising by their competitors, and assists them in managing relationships with competitors, customers and suppliers without running afoul of antitrust laws.

BOB ISER is currently a Vice President with PAREXEL Consulting where he provides technical leadership and expertise including development of global regulatory strategies on behalf of PAREXEL clients interfacing with Regulatory Agencies and through leading a team of global regulatory experts. Prior to joining PAREXEL, Bob spent 14 years with the U.S. FDA (most recently as the Director of the Office of Process and Facilities in CDER) with experience in CMC review, pre-approval inspections, CGMPs, guidance & policy development, and training. Bob has co-authored a number of articles including several CMC common deficiency articles, has served on both ICH and USP expert working groups. Before joining the FDA, he worked for seven years in the biopharmaceutical industry.

GREGORY JAFFE is the Director of the Project on Biotechnology for the Center for Science in the Public Interest ("CSPI"), a non-profit consumer organization located in the United States. Mr. Jaffe came to CSPI in 2001 after a long and distinguished career in government service as a Trial Attorney for the US Department of Justice's Environmental and Natural Resources Division and as Senior Counsel with the US EPA, Air Enforcement Division. He is a recognized international expert on agricultural biotechnology and biosafety and has published numerous articles and reports on those topics. He was worked on biosafety regulatory issues in the United States and throughout the world, including the countries of Kenya, Uganda, Tanzania, Ghana, Malawi, South Africa, Indonesia, Vietnam, and Nigeria. He was a member of the Secretary of Agriculture's Advisory Committee on Agricultural Biotechnology and 21st Century Agriculture from 2003-2008 and was reappointed for another term from 2011-2016. He was a member of FDA's Veterinary Medicine Advisory Committee from 2004-2008. Mr. Jaffe earned his BA with High Honors from Wesleyan University in Biology and Government and then received a law degree from Harvard Law School. He is also currently a Visiting Fellow at Cornell University's College of Agriculture and Life Sciences.

WILLIAM M. JANSSEN is a professor of law at the Charleston School of Law in Charleston, South Carolina, where he teaches products liability, mass torts, civil procedure, and first amendment (church/state) law. He has published and spoken widely on the legal environment impacting the pharmaceutical, medical device, and biologics communities, as well as on federal civil practice and procedure. Before his appointment to the Charleston faculty, Professor Janssen was a litigation partner in a mid-Atlantic AmLaw 200 law firm where he served as Chair of his firm's Life Sciences interdisciplinary practice group and a member of the firm's executive committee. He has been named a "Key Author" by West Publishing Company, is "AV"-rated by Martindale-Hubbell, and has been honored six times by the students of his law school as their "professor-of-the-year".

ELIZABETH JEX is an attorney advisor specializing in biopharmaceutical health policy in the Federal Trade Commission's Office of Policy Planning. She is a career staff attorney with over 28 years of experience in public service. She is a frequent speaker for the FTC on the issues concerning biosimilar competition. Ms. Jex was the chief architect of the FTC's 2014 workshop on biosimilars, and the primary staff author of the Comment of the Staff of the FTC submitted to the FDA on its draft guidance regarding the nonproprietary naming of biological medicines (Oct. 28, 2015) and the FTC's Report "Follow-On Biologic Drug Report Competition" (June 2009). She has co-authored two articles: "The Promise of Follow-on Biologics to Spur Both Biologic Drug Innovation and Competition," Journal of Generic Drugs (Sept. 8, 2009); and "Follow-on Biologic Drug Competition – No Need for New Marketing Exclusivities," Journal of Commerical Biotechnology (Sept. 22, 2009). From 1990 to 2009, Ms. Jex was an attorney in the FTC's Bureau of Competition, Mergers I Division, where she investigated biopharmaceutical mergers, acquisitions, and licensing agreements. Significant among her investigations were Roche/Genentech, Ciba-Geigy/Sandoz, Amgen/Immunex, Cephalon/Cima, and Fresenius/Daiichi, all of which resulted in Consent Orders. In addition to the numerous other health care and intellectual property cases, she was part of the successful trial team that stopped the Olin/Alliant merger in federal district court (1992). Ms. Jex has received several team and individual awards at the FTC, including the prestigious Paul Rand Dixon Award (2009) for her expertise in the pharmaceutical industry and antitrust and the Janet Steiger Award for the Remedies Study Report (2017). She has also served as a Special Assistant United States Attorney for the Eastern District of Virginia. Ms. Jex is a graduate of Williams College (1983) and obtained her Juris Doctor from Georgetown University Law Center (1987).

ELIZABETH JUNGMAN is the Director of public health programs at The Pew Charitable Trusts, overseeing initiatives related to antibiotics, drug safety, and health care products. Before joining Pew, she served as a senior health policy adviser with the Senate Committee on Health, Education, Labor, and Pensions, where she played a key role in drafting and negotiating the Food and Drug Administration (FDA) Safety and Innovation Act of 2012, the FDA provisions in the Pandemic All-Hazards Preparedness Reauthorization Act of 2013, and the Drug Quality and Security Act of 2013. Before moving to the Hill, Ms. Jungman was in private legal practice, where she counseled clients on a broad range of FDA regulatory matters and other health care issues related to the human pharmaceutical industry. She has an undergraduate biology degree from Harvard College, a law degree from Georgetown University, and a master's degree in public health from Johns Hopkins University. Ms. Jungman is a member of the FDLI Board of Directors.

SUZANNE JUNOD is a historian at the US Food and Drug Administration in the Office of External Affairs/Office of Communications in the Office of the Commissioner. She has been with FDA for over 30 years and was its first

professional historian. In 1995-1996, she worked with the President Clinton's Advisory Committee on Human Radiation Experiments, and she has worked with the Food and Drug Law Institute for many years, writing a column for *Update* for over a decade and working on the 2006 FDLI Centennial book, *A Century of Consumer Protection*. In 2006, she received the Food and Drug Law Institute (FDLI) Distinguished Service and Leadership Award. Suzanne has her PhD from Emory University, where she specialized in the history of Medicine and she has a long list of publications on various food and drug related history topics.

SANDRA COHEN KALTER is Vice President and Chief Regulatory Counsel at Medtronic, where she leads a team of legal regulatory experts in various areas of government regulation, including FDA law, import and export trade laws, environmental health and safety, advertising, promotion and social media. Ms. Kalter is on the Board of Directors of the Food and Drug Law Institute in Washington D.C. She also serves as Co-Chair of AdvaMed's Advertising and Promotion Working Group and is a member of AdvaMed's Legal Committee and AdvaMed's Case for Quality Working Group. Prior to joining Medtronic, she practiced FDA law with King & Spalding for 13 years, with an emphasis on medical devices. Before joining King & Spalding, Ms. Kalter practiced law at Weil, Gotshal & Manges in Washington, DC, specializing in food and drug law, advertising and consumer product safety. She received her BS in journalism from Northwestern University's Medill School and her JD from The National Law Center of George Washington University. Ms. Kalter is a member of the District of Columbia Bar and the American Bar Association.

MAIA KATS is the Litigation Director for the Center for Science in the Public Interest (CSPI), the leading non-profit advocacy organization on nutrition and public health. As Litigation Director, she prosecutes

deceptive advertising class actions in the food and supplements context. Recent litigations and settlements involved vitaminwater (Coke), Plum Organics (Campbell's), Naked Juice (PepsiCo), and Cheerios Protein (General Mills). Ms. Kats is also lead counsel in a suit against Coca-Cola and the American Beverage Association over marketing on the link between sugar drinks and health harms. Prior to joining CSPI, she was a partner with the class action firm of Sprenger & Lang, PLLC, and earlier, an associate with Hughes Hubbard & Reed. Ms. Kats earned her JD from the University of Michigan Law School, where she received multiple honors. She is a frequent speaker on food and class action law.

DAN KRACOV is a partner in Arnold & Porter Kaye Scholer's Washington, DC office, where he co-chairs the firm's Life Sciences & Healthcare practice. He helps life sciences manufacturers, trade associations, and early-stage ventures negotiate challenges relating to the development, manufacturing, approval, and promotion of drugs, biologics, medical devices, and diagnostics. In addition to day-to-day regulatory counseling, he regularly handles high stakes investigations and enforcement proceedings, the development of global compliance programs, and due diligence in financings, mergers, and acquisitions. He has a widely recognized expertise in biomedical product-related public policy matters, including congressional investigations and FDA-related legislation. Mr. Kracov is a member of the FDLI Board of Directors.

LESLIE T. KRASNY manages the San Francisco office of Keller and Heckman. Ms. Krasny practices regulatory/administrative law, focusing primarily on food/dietary supplements, including safety (FSMA and other regulatory requirements, ingredient evaluations, GRAS/food additive/color additive submissions, recalls, inspections, defense of government investigations, import issues, agricultural practices), labeling and advertising (ingredient/allergen statements, claim eligibility and substantiation, challenges to food marketing, country of origin, Made in USA statements), organic requirements, "green" packaging claims, and California's Proposition 65. She represents food companies throughout the supply chain: growers/shippers, manufacturers, distributors, retailers, food service, and trade associations, and serves as General Counsel to the Produce Marketing Association. She serves on the Editorial Advisory Board of Food Processing magazine, and is a frequent speaker and writer on food law topics. Ms. Krasny is ranked in Chambers USA, America's Leading Lawyers for Food & Beverages, Regulatory & Litigation, and is listed in Best Lawyers in America – FDA Law.

SONYA LAMBKIN is Supervisory Consumer Safety Officer in the Division of Compliance at the U.S. Food and Drug Administration's Center for Veterinary Medicine. In her current position, she is responsible for managing FDA's animal food compliance programs, animal food regulatory cases, animal food imports, and implementation of several aspects of the Food Safety Modernization Act and associated regulations pertaining to animal food.

CHAD LANDMON is a partner at Axinn, Veltrop & Harkrider LLP, where he chairs the FDA and IP Practice Groups. Mr. Landmon has extensive experience in food and drug law and patent litigation and counseling. FDA matters involve client counseling and petitioning FDA and litigating issues relating to the Biologics Price Competition and Innovation Act (BPCIA), including the requirements for the demonstration of biosimilarity and the patent resolution provisions, and the Hatch-Waxman Act, including marketing exclusivities, patent listing, certification and notification requirements, bioequivalence, labeling, and other issues. His patent litigation practice is national in scope and concentrates on the life sciences industry. He has litigated a wide variety of FDA and Paragraph IV cases in numerous jurisdictions, including cases involving blockbuster

drugs. Mr. Landmon's practice also includes matters involving the intersection of the antitrust and patent laws, such as issues arising from the settlement of patent and Hatch-Waxman exclusivity disputes.

EMILY M. LEONGINI is an associate in Arent Fox's Washington, DC office. As a member of the firm's FDA Practice, Emily focuses her practice on an array of highly regulated products, including laws governing prescription, generic, and over-the-counter drugs; dietary supplements; foods; alcoholic beverages; and cannabis. Before joining Arent Fox, Emily worked at the FDA for nearly six years, first in the Center for Drug Evaluation and Research and most recently in the Office of Regulatory Affairs. Before joining the FDA in 2009, she worked for a boutique administrative litigation firm, focusing on matters of food safety. Emily earned a JD from American University, Washington College of Law; a Master of Public Policy from the University of Southern California; and BA from the University of Texas at Austin.

DAVID LEVY is a professor at Georgetown University. David Levy has a PhD from UCLA in Economics. He is currently Professor of Oncology at Georgetown University. He has published over 250 papers, including articles in the American Economic Review, BMJ, AJPH, *JAMA*, Lancet, Medical Care, AJPM, Tobacco Control, Nicotine and Tobacco Research, PLOS Medicine, and Review of Economics and Statistics. He has been principal investigator of grants from the CDC, WHO, NCI, NIDA, Bloomberg/Gates Foundation, European Union, and the Robert Wood Johnson Foundation. He is currently Principal Investigator of a 5-year grant from NCI's CISNET program, a 4-year grant from NIDA, and a 5-year P-50 with the ITC group. Dr. Levy is currently overseeing the design and development of the *SimSmoke* tobacco policy simulation model, with models for the US and 10 states, and for over 40 countries covering 90% of the world population. He is now developing models of smokeless tobacco and e-cigarette use.

DEBRA LEWIS is the Deputy Director of the Office of Orphan Products Development (OOPD) at the Food and Drug Administration (FDA). She is currently also serving as the OOPD Acting Director overseeing the operation of incentive programs to encourage the development of promising drugs, devices, and medical foods for rare diseases and conditions. Dr. Lewis has served as the OOPD Grants Director and the OOPD Humanitarian Use Device Director. Prior to joining the Office of Orphan Products, she served as Deputy Director for the Office of Health and Industry Programs, in the FDA Center for Devices and Radiological Health (CDRH); Director of the CDRH Staff College; Chief of the Ophthalmic Diagnostic & Surgical Devices Branch and Premarket Approval Application (PMA) Staff; and an FDA

Clinical/Scientific Reviewer. She has previously served as an officer in the US Public Health Service Commissioned Corps and the US Air Force.

ERIKA LIETZAN is an Associate Professor of Law at the University of Missouri School of Law, where she researches, writes, and teaches in the areas of food and drug law, intellectual property, and administrative law. She is also the Director of Life Sciences Research and Policy for the Center for Protection of Intellectual Property (CPIP), part of the Antonin Scalia Law School at George Mason University. Before joining academia, she was a partner in the FDA practice group of Covington & Burling. She practiced at Covington from 1996 to 2014, except for a stint as Assistant General Counsel of PhRMA from 2002 to 2005.

ERIC LINDBLOM is Director for Tobacco Control and Food & Drug Law at Georgetown Law's O'Neill Institute for National and Global Health Law. He works on a range of law and policy projects relating to U.S. and global tobacco control efforts, FDA regulation, the First Amendment, legalized cannabis, and other domestic and international regulatory matters. Before joining the O'Neill Institute, Mr. Lindblom was Director of the Office of Policy at the FDA Center for Tobacco Products. Prior to that, Mr. Lindblom served as General Counsel and Director for Policy Research at the Campaign for Tobacco-Free Kids, and previously held positions with the federal government, a member of Congress, political campaigns, a law firm, and nonprofit advocacy organizations. Mr. Lindblom has a JD from Harvard Law School and a BA in Political Science from Yale University.

DEBORAH LIVORNESE is Of Counsel in the Food and Drug Practice at Arnall Golden Gregory LLP. Ms. Livornese focuses her practice on a broad range of FDA matters concerning prescription and OTC drugs, medical devices, biological products, and cosmetics. She assists pharmaceutical drug and device companies on regulatory requirements and strategies related to obtaining FDA approvals and other paths to market, as well as on post-marketing regulatory requirements. Ms. Livornese spent seven years in the Office of Regulatory Policy in FDA's Center for Drug Evaluation and Research. As a Senior Regulatory Counsel at FDA, she was involved in a wide variety of policy issues affecting drug approvals and routinely met with senior leaders in the agency on controversial issues, in addition to providing guidance to the Office of New Drugs and Office of Generic Drugs on issues related to approvals and withdrawals, the regulation of unapproved drugs, and user fees. She served as one of the key members of FDA negotiating team for the OTC Monograph Reform user fee efforts. Prior to joining FDA, Ms. Livornese was Of Counsel with an FDA boutique law firm in Washington DC where she advised drug companies on promotional activities for compliance with FDA and FTC requirements, assisted clients in responding to investigational findings, warning letters, and inquiries from the agency.

JOHN MANTHEI, Global Co-chair of Latham's Healthcare & Life Sciences Practice, focuses his practice on regulatory matters involving the US Food and Drug Administration (FDA) for the medical device, pharmaceutical, and biotechnology industries. He advises clients on all aspects of the FDA-regulated product life cycle, post market enforcement, and administrative litigation. Mr. Manthei currently serves as outside FDA counsel to the Medical Device Manufacturers Association (MDMA), a member of the Food & Drug Law Institute (FDLI) Advisory Committee for Medical Devices, and a former member of the FDLI Advisory Committee for Drugs and Biologics. He previously served as Majority Counsel for the US House of Representatives' Committee

on Energy and Commerce (1998-2000). Mr. Manthei is recognized as a top FDA attorney in industry publications including *Chambers USA* (2010-2017) and as a Leading Lawyer by *The Legal 500 US* (2012-2017), a distinction shared with only thirteen individuals across all legal practice areas nationwide in his category. He was recently named only one of five Life Sciences MVPs by *Law360* (2016) and has also been featured as a Life Sciences Star by *Euromoney* (2012-2017) and a Top 40 Lawyers Under 40 by *Washingtonian* magazine (2006), and as one of Washington's top lawyers in the *Washingtonian*. In addition, Mr. Manthei has been quoted in *CBS News, Washington Post, CNN, USA Today, CNBC, Boston Globe, San Francisco Chronicle, Forbes, Business Week,* and other leading national and international business journals on FDA regulatory, enforcement, and policy matters.

PETER MARKS is the Director of the Center for Biologics Evaluation and Research (CBER) at FDA. He received his graduate degree in cell and molecular biology and his medical degree at New York University and completed Internal Medicine residency and Hematology/Medical Oncology training at Brigham and Women's Hospital in Boston. He has worked in academic settings teaching and caring for patients and in industry on drug development. He joined the FDA in 2012 as Deputy Center Director for CBER and became Center Director in January 2016.

SUSAN MAYNE is the Director of the Center for Food Safety and Applied Nutrition (CFSAN) at FDA. In this position, Dr. Mayne leads the center's development and implementation of programs and policies related to the composition, quality, safety, and labeling of foods, food and color additives, and cosmetics. An internationally recognized public health leader and scientist, Dr. Mayne received a BA in chemistry from the University of Colorado. She earned a PhD in nutritional sciences, with minors in biochemistry and toxicology, from Cornell University. She comes to the FDA from Yale University, where she was the C-EA Winslow Professor of Epidemiology. Her distinguished career there includes two leadership positions: Chair of the Department of Chronic Disease Epidemiology and Associate Director of the Yale Cancer Center. Dr. Mayne has conducted extensive research into the complex role of food, nutrition, and other health behaviors as determinants of chronic disease risk. She is author or coauthor of more than 200 scientific publications. She recently completed two consecutive terms on the Food and Nutrition Board of the National Academy of Sciences,

and a five-year term on the Board of Scientific Counselors for the US National Cancer Institute. She also served on a nutrition advisory committee for the FDA. She has worked closely with other government agencies, including the US Department of Agriculture, on developing practical applications of research.

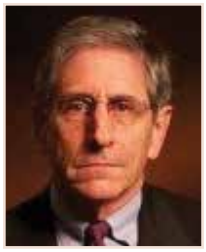
MADELEINE McDONOUGH is Chair of Shook, Hardy & Bacon, a firm recognized for its strength in life sciences, health, and technology litigation. A former clinical pharmacist, she represents multinational companies in a range of industries: pharmaceutical, animal health, medical device, food, cosmetics, and beverage. Madeleine advises organizations on preventive litigation approaches, policy and governance issues, emerging international legal developments, creative resolution strategies, risk management, corporate social responsibility, and crisis management. During her tenure as Chair of Shook's pharmaceutical and medical device practice, the firm represented dozens of major pharmaceutical clients, including each of the top 10 pharmaceutical companies worldwide. Shook's pharmaceutical clients have described Madeleine as "a true visionary and trusted counsel" and "one of the finest lawyers I have ever worked with—brilliant, innovative, with enormous integrity." Most recently, Madeleine was honored as one of the Top Authors for both Food and Beverage and Class Action by JD Supra.

CHRISTOPHER M. MIKSON is a partner and co-leader of the Health Care practice at Mayer Brown in Washington, DC. Chris focuses his practice on regulatory, intellectual property, and other complex litigation and transactional matters involving health care and the life sciences. He has extensive experience in the regulation of drugs, biologics, and medical devices by FDA and other federal and state agencies. Chris has counseled and represented a wide range of clients in matters concerning product development, preclinical and clinical trials, premarket clearance and approval, citizen petitions, inspections, recalls, enforcement actions, and litigation under the Administrative Procedures Act. He has taught patent and FDA law at the University of Pennsylvania and has spoken and written extensively on intellectual property and regulatory issues, including those concerning Hatch-Waxman, biosimilars, and medical devices. Most recently, he served as chair of ACI's FDA Boot Camp Drug and Biologics Edition in Boston.

JOE MURILLO serves as Vice President, Regulatory Affairs, Altria Client Services. Mr. Murillo leads FDA-related regulatory strategy, engagement, communications, and advocacy for Altria's tobacco operating companies. Joe also develops regulatory and research strategies related to Altria's pursuit of tobacco harm reduction and FDA authorization of modified risk tobacco products. Before being appointed to his current position, Mr. Murillo served as President and General Manager of Nu Mark, LLC. In that role, Mr. Murillo led the company's development and marketing of innovative tobacco products for adult tobacco consumers. Previously, Joe was Vice President and Associate General Counsel of Altria Client Services, where he led the company's Brand Integrity efforts and provided legal support to a number of different areas at Altria. During the course of his career, Mr. Murillo has developed extensive knowledge of the marketing, sales, distribution, regulatory, and communications aspects of bringing tobacco products to market. Mr. Murillo is a 1986 graduate of Columbia Law School and a 1983 graduate of the University of Miami, where he was elected to Phi Beta Kappa.

JOHN MURPHY serves as the Deputy General Counsel at the Biotechnology Innovation Organization (BIO). BIO is the largest trade association in the world representing biotechnology companies. BIO members are involved in the research and development of innovative healthcare, agricultural, and environmental

biotechnology products, thereby expanding the boundaries of science to benefit humanity by providing better healthcare, enhanced agriculture, and a cleaner and safer environment. Mr. Murphy's role encompasses all legal issues impacting healthcare biotechnology across the country. His responsibilities include issues in congressional legislation, FDA, CMS and various other federal agency regulatory issues, litigation, and support on state-developed biotechnology laws and regulations. Mr. Murphy is a frequent speaker on issues associated with patient access to prescription medicines, prescription drug abuse, drug pricing, and more general issues impacting medicine approvals and innovation in the United States. Mr. Murphy is a graduate of Villanova University and the Catholic University Columbus School of Law. He worked on healthcare regulatory and enforcement issues at Hogan Lovells, LLP, and served as Assistant General Counsel for the Pharmaceutical Research and Manufacturers of America before joining BIO.



MATTHEW MYERS is President and CEO of the Campaign for Tobacco-Free Kids, a privately funded organization established to reduce tobacco use and its devastating consequences in the United States and around the world. Over the last 25 years, Mr. Myers has participated in virtually every major national tobacco-related legislative effort and has worked with state tobacco prevention advocates and officials around the country. In 1999, Mr. Myers was asked to serve on the first advisory committee established to advise the Director General of the World Health Organization on tobacco issues. The following year, Mr. Myers was named by President Clinton to co-chair a Presidential Commission to examine the economic problems being experienced by tobacco farmers and their communities and recommend possible solutions. In

October 2004, the Harvard School of Public Health bestowed its highest honor, the prestigious Julius B. Richmond award, on Mr. Myers for his work as an advocate in preventing tobacco industry marketing to children.

ADORA NDU is the Head and Executive Director for Global Regulatory Policy, Research and Engagement at BioMarin Pharmaceuticals Inc. In this role she leads and provides strategic oversight to the regulatory policy, regulatory research, outcomes research, patient engagement, and health authority engagement functions across the US, European markets, and other regions globally. Prior to joining BioMarin, she served in multiple roles at the Food and Drug Administration (FDA), most recently as Director for the Division of Medical Policy Development where she led the development of a broad range of FDA guidances and regulations. At FDA, she also held leadership roles in the Office of Prescription Drug Promotion (OPDP) and was involved in FDA's pharmacovigilance program. Adora received her Doctor of Pharmacy degree from Howard University and her JD from the University of Maryland.

NICOLE NEGOWETTI is a Lecturer on Law and Clinical Instructor at the Harvard Law School Food Law and Policy Clinic (FLPC). Prior to joining the FLPC, she was Policy Director of the Good Food Institute, a nonprofit organization focused on creating a sustainable, healthy, and humane food system by supporting plant-based and clean food technology companies. Nicole also served as Associate Professor of Law at the Valparaiso University School of Law from 2011-2016. As a law professor, her teaching and research focused on food law and policy, agricultural law, and sustainability. Nicole serves on the Food & Drug Law Journal Editorial Advisory Board and is a founding member of the Academy of Food Law & Policy. She is also a co-founder of the Northwest Indiana Food Council, whose mission is to build a just, sustainable, and thriving locally-oriented food system.

RAYMOND NIAURA is the Director of Science and Director of Training at the Schroeder Institute for Tobacco Research and Policy Studies at Truth Initiative; Professor (adjunct) in the Department of Health Behavior and Society at the Johns Hopkins Bloomberg School of Public Health; and Professor (adjunct) in the Department of Oncology, Lombardi Comprehensive Cancer Center, at the Georgetown University Medical Center. He has been PI or co-I of over 30 NIH-funded grants and he is the former President of the Society of Nicotine and Tobacco Research. While at Brown University, he was Director of Transdisciplinary Research and Director of Postdoctoral Training in Behavioral Medicine in the Department of Psychiatry and Human Behavior. In his capacity as Director of Science and Training at the Schroeder Institute, he supports grant development and promotes cross-institutional research collaboration and training activities with Georgetown, Johns Hopkins, University of Maryland, and George Washington University faculty. He is a co-Investigator on the Population Assessment of Tobacco and Health (PATH) study sponsored by the National Institute on Drug Abuse and FDA Center for Tobacco Products.

AMY NORRIS is the Chief Legal Counsel for Clif Bar & Company, a leading maker of nutritious and organic foods and drinks. Amy advises the company on a variety of operational and strategic matters, including food safety, food labeling, advertising, litigation, and domestic and international business risk. Ms. Norris also oversees the regulatory compliance group. Amy has been with Clif Bar for more than eight years. Prior to joining Clif Bar, Ms. Norris was in private practice for ten years. Ms. Norris earned her juris doctorate from the University of San Francisco and a Bachelor of Arts from UC San Diego. Ms. Norris has previously spoken on food labeling, food advertising, food law litigation, and Proposition 65. She co-authored an article entitled *When Regulation Can Lead to Litigation: Top Issues in Food & Dietary Supplements* and contributed a chapter of the American Health Lawyers Association's Enterprise Risk Management Handbook for Healthcare Entities.

JUDITH O'GRADY is a partner with Pepper Hamilton LLP, resident in the Washington office. Ms. O'Grady is a member of the firm's Health Sciences Department. Ms. O'Grady regularly counsels medical device and pharmaceutical companies on matters governed by the Food and Drug Administration (FDA). As part of her FDA counseling practice, she has counseled clients regarding INDs, NDAs, 510k applications, facility registration, product listings, product labeling, good manufacturing practices, drug sampling, clinical trials, and adverse event reporting. She advises clients on risk management, marketing, and promotional claims. Ms. O'Grady also counsels clients regarding compliance with the Medicare Secondary Payer Act and Section 111 of the Medicare, Medicaid, and SCHIP Extension Act of 2007. In addition, Ms. O'Grady has extensive experience defending pharmaceutical and medical device manufacturers in products liability actions.

MEREDITH OLEARCHIK is Vice President and Associate General Counsel, Intellectual Property, Marketing and Food Law, at Campbell Soup Company. As the company's food lawyer, she counsels Campbell's domestic and international businesses on food safety, labeling compliance, and food policy and provides advice on compliance and policy matters involving the Food and Drug Administration and the US Department of Agriculture, as well as food agencies around the world. In addition, she manages the intellectual property, marketing, and food law groups within the Campbell legal department. Ms. Olearchik joined Campbell in May 2013 after 8 years with the law firm of Montgomery, McCracken, Walker & Rhoads LLP in Philadelphia, PA, where she defended and advised global pharmaceutical companies subject to government investigations. Prior to law school, she spent four years working at various museums and non-profits, including the Museum of Jewish Heritage: A Living Memorial to the Holocaust in New York. Ms. Olearchik received her JD from Rutgers University School of Law at Camden, a master's degree in history from Northeastern University, and a bachelor's degree in history from The College of New Jersey, from which she also received an Honors Program degree.

MEGAN OLSEN is Assistant General Counsel for the Council for Responsible Nutrition (CRN) in Washington, DC. At CRN, she provides legal counsel and advice to CRN's staff and members in the areas of legislation, regulatory compliance and advocacy, and international policy development with respect to dietary supplements and nutrition issues. Prior to joining CRN, Ms. Olsen was in-house counsel for Walgreen Co., where she provided legal advice about Food and Drug Administration, Federal Trade Commission, and other consumer protection regulatory requirements for a wide variety of consumer products,

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DANIEL ORR is a partner in the Washington, DC office of Womble Bond Dickinson. He advises clients concerning regulatory issues in the pharmaceutical, biotech, and medical device sectors. Before joining Womble in January 2018, Mr. Orr was Regulatory Counsel in FDA's Center for Drug Evaluation & Research (CDER) where he resolved regulatory issues in a portfolio of products with combined annual sales of more than $37 billion. Mr. Orr was the Regulatory Counsel assigned to three of the nine biosimilars that FDA has approved to date, and worked on many of the Agency's guidances and proposed rules related to biosimilars. He also served on the CDER Exclusivity Board and was the subject-matter expert concerning reference product exclusivity for biological products.

FRANCIS B. PALUMBO, PhD, is Professor and Executive Director, University of Maryland School of Pharmacy Center on Drugs and Public Policy in Baltimore, MD. He is a licensed pharmacist and a member of the Maryland Bar. He has practiced both pharmacy and law. Dr. Palumbo and his colleagues at the University of Maryland conducted much of the early work on drug use review, a subject on which they have published widely. He has been the principal investigator on major federal research grants examining the use of drugs in long term care patients. Dr. Palumbo has many journal articles and presentations to his credit and co-authored a book on containing costs in third party drug programs. He maintains an interest in pharmacoeconomics, pharmacoepidemiology and health services research as well as healthcare and food and drug law. He has also been very active in several national professional organizations, including the American Pharmacists Association, where he served as President of the Academy of Pharmaceutical Research and Science, and the American Society for Pharmacy Law, where he is a past president. He received his BS in pharmacy from the Medical University of South Carolina, MS and PhD in health care administration from the University of Mississippi, and JD from the University of Baltimore School of Law. He served in the US Army from 1969-1971.

STUART PAPE helps clients understand and face challenges presented by regulations imposed by the US Food and Drug Administration (FDA), US Department of Agriculture (USDA), and similar health and safety regulatory bodies worldwide. He focuses on assisting clients in obtaining approval of new food ingredients, pharmaceuticals, and medical devices; advising on labeling and advertising of regulated products; assisting in enforcement proceedings initiated by regulatory bodies; helping clients develop sound strategies in the face of challenges from NGOs; and lobbying in connection with legislative consideration of statutory changes to the laws governing FDA-regulated products. Regularly appearing before the FDA, USDA, the Consumer Product Safety Commission, numerous other federal and state regulatory bodies, and the Congress of the United States, Mr. Pape serves clients across the US and around the world in many capacities. Previously, he served in various positions in the Office of the Chief of Counsel at FDA, including as Associate Chief Counsel for food. He also served as Executive Assistant to FDA Commissioner Donald Kennedy. Mr. Pape is a 1970 graduate of the University of Virginia and a 1973 graduate of its School of Law.

BAKUL PATEL is Associate Director for Digital Health at the Center for Devices and Radiological Health (CDRH), at the Food and Drug Administration (FDA). Mr. Patel leads regulatory policy and scientific efforts at the Center in areas related to emerging and converging areas of medical devices, wireless, and information technology. This includes responsibilities for mobile health, health information

technology, cyber security, medical device interoperability, and medical device software. Mr. Patel is the FDA liaison between the Federal Communications Commission (FCC) and the Office of the National Coordinator (ONC). Since its inception in 2013, Bakul chairs the International Medical Device Regulators Forum (IMDRF) "software as a medical device" working group, a global harmonization effort. Before joining FDA, Mr. Patel held key leadership positions working in the telecommunications industry, semiconductor capital equipment industry, wireless industry, and information technology industry. His experience includes Lean Six Sigma, creating long and short-term strategy, influencing organizational change, modernizing government systems, and delivering high technology products and services in fast-paced, technology-intensive organizations. Mr. Patel earned an MS in Electronic Systems Engineering from the University of Regina, Canada, and an MBA in International Business from The Johns Hopkins University.

TONY PAVEL is Cargill Inc.'s Senior Food Lawyer responsible for food and feed law across Cargill's North American businesses. Prior to joining Cargill, Tony was the Deputy Chair of the FDA Practice at Morgan Lewis & Bockius, served as General Counsel and Secretary to the Enzyme Technical Association, and as the past Chair of the Institute of Food Technologist's Food Laws and Regulations Division. During his undergraduate and legal studies, he worked for a food HACCP consulting business. Tony has been named one of the leading food lawyers in the US by Chambers and Partners and Law360.

JEANNIE M. PERRON is a partner in Covington & Burling LLP's Food and Drug Practice Group. In addition to being an attorney, Dr. Perron also holds a degree in veterinary medicine and has practiced as a veterinarian. Dr. Perron specializes in food and drug law and advises clients in the regulation of dietary supplements, over-the-counter drugs, cosmetics for humans, and import and export of products regulated by the U.S. Food and Drug Administration as well as those having animal or microbially-derived ingredients regulated by the U.S. Department of Agriculture. The primary focus of Dr. Perron's practice, however, is all aspects of animal food and drug law, including pioneering animal drug approvals and defense, issues relating to veterinary biologics, approval or other clearance of animal feed and pet food ingredients, regulation of veterinary medical devices, review of claims for animal products, recalls of such products, and associated areas. Her work encompasses advising companies that manufacture feed, feed ingredients, drugs, biologics, and medical devices for animals, as well as clients in related industries.

PETER PITTS is President of the Center for Medicine in the Public Interest. A former member of the United States Senior Executive Service, Mr. Pitts was FDA's Associate Commissioner for External Relations, serving as Senior Communications and Policy Advisor to the Commissioner. He supervised FDA's Office of Public Affairs, Office of the Ombudsman, Office of Special Health Issues, Office of Executive Secretariat, and Advisory Committee Oversight and Management. He served on the agency's obesity working group and counterfeit drug taskforce and as a Special Government Employee (SGE) consultant to the FDA's Risk Communications Advisory Committee. His comments and commentaries on health care policy issues regularly appear in *The New York Times, The Los Angeles Times, The Washington Post, The Wall Street Journal, The Financial Times, Health Affairs, The Boston Globe, The Washington Times, The Chicago Tribune, The Chicago Sun Times, The San Francisco Examiner, Investor's Business Daily, The Baltimore Sun, The Economist, Nature Biotechnology, The Journal of Life Sciences the BBC World Service, Fox News,* and *The NewsHour with Jim Lehrer*, among others. He has given healthcare policy presentations throughout Europe, Canada, and the United States, as well as in Russia, China, the Philippines, Malaysia, Saudi Arabia, Lebanon, Israel, Turkey, The United Arab Emirates, Jordan, Kenya, South Africa, Egypt, Algeria, Ukraine, Taiwan, Thailand, Japan, Brazil, Mexico, Vietnam, Indonesia, and Colombia. His book, *Become Strategic or Die*, is widely recognized as a cutting edge study of how leadership, in order to be successful over the long term, must be combined with strategic vision and ethical practice. He is the editor of *Coincidence or Crisis*, a discussion of global prescription medicine counterfeiting, and *Physician Disempowerment: A Transatlantic Malaise*. He is a Visiting Lecturer at the École Supérieure des Sciences Économiques et Commerciales, and has served as an adjunct professor at Indiana University's School of Public and Environmental Affairs and Butler University.

ANNE MARIE POLAK is a senior director, based in Washington, DC. In her role, Ms. Polak provides policy counsel and analysis to clients with matters involving regulations, legislation, and business implications. Her experience includes developing strategic messages and policy positions for Capitol Hill, administration, trade associations, and corporate audiences. Prior to joining Leavitt Partners, Ms. Polak was a vice president for Faegre BD Consulting in the firm's health and biosciences group. She also spent five years with the Podesta Group in Washington, DC, while completing her law degree in the evenings at the George Mason University School of Law, graduating cum laude in 2010. Ms. Polak also worked in the government and legal affairs office of Novo Nordisk in Washington, DC, and as a congressional aide to Rep. Michael Ferguson of New Jersey. In 2004, Ms. Polak served as a policy research assistant on the Bush-Cheney campaign after graduating, with distinction, from the University of Virginia. Ms. Polak also was an assistant to the chief of staff for House Majority Leader Dick Armey (R-TX-26). Ms. Polak received her law degree from the George Mason University School of Law and a bachelor's degree in government from the University of Virginia.

VERNESSA T. POLLARD is a partner at McDermott Will & Emery where she advises companies on regulatory, compliance, enforcement, and policy matters involving pharmaceuticals, medical devices, health information technology (HIT) and digital health solutions, services, and software. She advises companies and investors on regulatory and compliance issues arising from mergers, acquisitions, and other transactions involving Food and Drug Administration (FDA)-regulated products. She also counsels manufacturers, distributors, and retailers on regulatory and compliance issues related to food and cosmetic marketing and safety. Ms. Pollard regularly counsels companies on product development and premarket strategy, Good Manufacturing Practice (GMP) and Quality System (QS) requirements, advertising and

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RACHAEL PONTIKES is a partner in the Life Sciences Health Industry Group and practices in the Chicago office of Reed Smith. She counsels compounding pharmacies, in both human and animal health, regarding compliance with various applicable state and federal law. She also acts as litigation counsel for compounding pharmacies in disputes with the state boards of pharmacy, the Food and Drug Administration (FDA), and the Drug Enforcement Administration (DEA) in administrative proceedings and federal courts. Rachael is a nationally recognized authority in the FDA's Drug

Quality and Security Act (DQSA) Compounding Quality Act (CQA), and participated in various discussions with the Senate HELP Committee staffers as the law was drafted. She is frequently invited to speak on the DQSA-CQA and its implications for compounding pharmacies, most recently by the Food and Drug Law Institute (FDLI) for their enforcement conference and the American Pharmacist Association (APhA) for their annual conference. Her deep experience with the laws governing compounding pharmacies stems from her role as trial and appellate counsel for two seminal cases that shaped the legal landscape. Rachael served as trial counsel in *Medical Center v. Mukasey* through defeat of the motion to dismiss, and trial and appellate counsel in *Wedgewood Village Pharmacy v. United States*. She also has an active commercial and appellate litigation practice, acting as lead counsel in representing companies in a broad range of business disputes.

LISA RACHLIN is Commercial Counsel at Vertex Pharmaceuticals, where she serves as product attorney for multiple assets and advises the company's product support program. Prior to joining Vertex, Lisa was a senior litigation associate at Ropes & Gray, where she focused on healthcare, data privacy, and securities law. While in private practice, Lisa represented pharmaceutical and biotechnology clients on product liability matters, as well as government investigations involving allegations of off-label promotion and anti-kickback statute violations.

ROBERT A. RHOADES is managing partner at Validant. Throughout his 38-year career, Mr. Rhoades has been a preferred advisor to senior pharmaceutical and medical device executives seeking counsel on compliance and its impact on corporate direction and business strategy. A skilled practitioner of both the Quality System Regulation (QSR) and the pharmaceutical cGMPs, he has designed and implemented compliance improvement initiatives for manufacturers in the US, Europe, India and China. He frequently provides post-Warning-Letter guidance and remediation project management to re-establish client credibility with the FDA. In addition, he assists manufacturers in proactively designing and optimizing quality systems. Mr. Rhoades often works in concert with client counsel on a wide variety of legal cases. He was selected by client counsel to advise in the contaminated heparin crisis that reached global proportions in 2008, and has provided third-party expert services in several Consent Decree cases. Prior to joining Validant, he led the Quality & Compliance Consulting Practice at Quintiles for more than 7 years. Prior to Quintiles, Bob held various Quality leadership roles for Solvay Pharmaceuticals, Bausch & Lomb and Baxter Healthcare. He holds a Masters of Business Administration in Operations Management and Strategic Planning from Lake Forest Graduate School of Management and a Bachelor of Science degree in Microbiology from Purdue University.

AMY COMSTOCK RICK, JD, the President and Chief Executive Officer of the Food and Drug Law Institute, having joined in August 2014. Prior to joining FDLI, Ms. Rick was the Chief Executive Officer of the Parkinson's Action Network (PAN) from 2003-2014. PAN is a Washington, DC-based national nonprofit focused on educating the public and government leaders on better policies for research and therapy development and an improved quality of life for people living with Parkinson's disease. Ms. Rick has also served as the President of the Coalition for the Advancement of Medical Research and on the Boards of Directors of Research!America, the National Health Council, and the American Brain Coalition. Before joining PAN, she was the Senate-confirmed Director of the US Office of Government Ethics from 2000-2003 and the Associate Counsel to the President in the White House Counsel's Office from 1998-2000. Ms. Rick began her federal service as a career attorney at the U.S. Department of Education in 1989 and became the Assistant General Counsel for Ethics in 1993. Prior to her government service, Ms. Rick was an associate attorney at the law firm of Beveridge & Diamond. She received a Bachelor of Arts degree from Bard College and a Juris Doctor degree from the University of Michigan.

ERIC ROGERS is Global Head of Regulatory and Development Law for Alcon, a division of Novartis. Alcon is the global leader in eye care, with a complete line of surgical devices for use in cataract, vitreoretinal, refractive, and glaucoma-related ophthalmic surgeries, as well as a differentiated contact lens and OTC lens care portfolio to help patients see, look and feel their best. At Alcon, Mr. Rogers is responsible for coordinating the team of lawyers that support the US and global promotional material review processes, including managing incoming and outgoing competitive challenges. In addition, his team supports the Regulatory Affairs, Quality Affairs, Safety, Clinical Development, and Medical Affairs functions. Before joining Alcon, Mr. Rogers worked as an in-house attorney at Genentech and Pfizer, and was an associate in the Washington, DC offices of Ropes & Gray and Hyman, Phelps & McNamara. He is a proud graduate of Iowa State University and the Boston University School of Law.

LEE ROSEBUSH is a partner at BakerHostetler with a background as a defense, regulatory, and registered patent attorney who has also worked as a registered pharmacist. Mr. Rosebush provides his clients with legal counsel that is grounded in first-hand experience. Whether his clients are confronted with legal issues related to the naming of a drug, clinical trials, marketing, promotions, or advertising, Mr. Rosebush possesses a strong understanding of the pharmaceutical industry which, combined with his attention to detail and experience working with biologics, medical device, and healthcare companies, gives clients a single source for regulatory and litigation counsel. With post-graduate degrees in finance and business, Mr. Rosebush is frequently sought out to help expedite corporate deals involving healthcare entities. He also advises private equity and public and private companies in due diligence matters and buy-sell transactions. Mr. Rosebush's ability to smoothly shift between the legal, governmental, and pharmaceutical environments further helps him to efficiently secure operating licenses or assist drug manufacturers in avoiding compliance actions from governmental agencies. Active with the Drug Quality and Security Act (DQSA), as well as the Federal Food and Drug Administration's (FDA) regulation of pharmacy compounding, Lee speaks and writes on both issues, and is passionate about orchestrating and advocating for pharmacists and pharmacies. Additionally, Mr. Rosebush is Leader of BakerHostetler's Pharmacy and Reimbursement team and Co-Leader of the FDA, Products Promotion, and Defense team.

ZACH ROTHSTEIN is Associate Vice President for Technology & Regulatory Affairs at AdvaMed. In this position, Zach advocates for medical device regulatory policies that are transparent, predictable, consistent, timely, and science-based. Zach's particular areas of focus include digital health, medical device software, cybersecurity, labeling, and postmarket surveillance. Prior to joining AdvaMed, Zach was Deputy Senior Counsel for Public Policy at Samsung Electronics where he was responsible for the company's medical device and healthcare regulatory and policy issues. In this position, Zach counseled Samsung's global business units through all stages of product development on U.S. regulations affecting digital health, Health IT, and medical devices. Zach also planned and executed the company's FDA and healthcare regulatory and legislative policy objectives. Prior to joining Samsung, Zach was an Associate Attorney in the FDA and Healthcare practice at the law firm of Morgan, Lewis & Bockius LLP. Zach is an active member of the Food and Drug Law Institute, teaches an introduction to FDA law class at the Johns Hopkins University, and was recognized by i3 magazine as a digital health and fitness innovator.

TOAM RUBINSTEIN is an associate at Reed Smith, and a member of the firm's Entertainment & Media Group. Toam focuses her practice on advertising and brand development matters for Fortune 100 brands, media companies, consumer packaged goods companies, and other advertisers in all aspects of marketing, new media, and related initiatives, including product innovation, claims substantiation, media distribution, and influencer marketing. Toam advises clients on how to minimize legal risks associated with traditional and emerging platforms. Toam also handles transactional matters relating to the execution of advertising campaigns, including mobile application development agreements, agency-client agreements, sponsorship agreements, talent and music agreements, and production agreements. Prior to joining Reed Smith, Toam worked as Counsel in Restaurant Brands International's Marketing and Intellectual Property Group, supporting the marketing and advertising initiatives of Burger King, Popeyes and Tim Hortons brands in the US and internationally. She previously worked as Associate Counsel for Ultra Music Festival.

MARC SANCHEZ is an FDA & USDA regulatory attorney, adjunct professor, and textbook author. Marc is the founder of Contract In-House Counsel and Consultants, LLC (d/b/a FDA Atty), where he represents FDA-regulated companies in the food, dietary supplement, beverage, cosmetic, medical device and drug industries. He also teaches as a part-time adjunct professor at Northeastern University on regulatory topics including U.S. and international food law and regulation. Marc is also the author of two textbooks, including Springer International's first food law text, which was published in its second edition in 2018.

ALLEN SAYLER is Senior Director of Food and Cosmetic Consulting Services at EAS Consulting Group. Mr. Sayler has 16 years of experience as a state, FDA and USDA dairy and food program manager. He has worked for the last 18 years as a food processing industry consultant, specializing in evaluation, assessments, and trouble-shooting of food plant processing operations and their food safety and quality programs, and carries ISO 22000 and BRC auditor certifications. He is a certified "Lead Instructor" though FDA's Food Safety Preventive Controls Alliance (FSPCA), a frequent contributor to *Dairy Foods* monthly magazine, as well as a frequent speaker at national dairy and food processor meetings. Mr. Sayler is active in the National Conference on Interstate Milk Shipments (NCIMS), the International Association of Food Protection (IAFP), the Institute of Food Technologist (IFT), the International Dairy Federation (IDF), the FDA Alumni Association, Codex Alimentarius, the American Society of Quality (ASQ), and served on the Board of Directors of 3-A Sanitary Standards, Inc. and the Dairy Practices Council (DPC). He received Group Excellence Awards from both FDA and USDA. In 2009, Mr. Sayler received the Harold Barnum Industry Award from IAFP.

RICK SCARPELLO, CEO of MC Management LLC, owner of Medically Correct LLC which owns the brands incredibles Food and incredibleCBD, is a food expert with a focus on operations, compliance, and accounting. Rick's background includes running large scale food operations like Il Fornaio Bakeries, Udi's Bakery Division and Chesapeake Bagel Bakeries. His experience includes building company-wide quality control plans, food safety controls, food defense plans, organic certifications, kosher certifications, food recall systems, and quality assurance plans.

CASSIE SCHERER is Principal Legal Counsel and part of the Corporate Legal Regulatory team at Medtronic where she advises on FDA legal and regulatory matters relating to medical devices. Ms. Scherer joined Medtronic from Covington & Burling, where she was Special Counsel in the Food, Drug, and Device Practice. Prior to that, Cassie served as an Associate Chief Counsel in FDA's Office of Chief Counsel and as Director of Strategy and Regulatory Operations in CDRH's Office of Center Director. While at FDA, Ms. Scherer was involved in policy and regulatory matters related to medical devices. Ms. Scherer worked on implementing provisions of the FDA Safety and Innovation Act of 2012 relating to medical devices, reviewing premarket appeals of regulatory decisions made by CDRH, and developing key guidance documents. Cassie received her BA from University of Pennsylvania summa cum laude and her JD from the University of Virginia School of Law.

CYNTHIA SCHNEDAR is Executive VP of Regulatory compliance at Greenleaf Health where she provides strategic advice to clients in the life sciences industry. She was formerly Director of the Office of Compliance for FDA CDER, where she spearheaded efforts to protect the American public from unsafe and ineffective drug products by ensuring that companies comply with federal standards for quality and safety. Cynthia previously served at the Department of Justice (DOJ) as Acting Inspector General and in other leadership positions focused on compliance and enforcement issues. Cynthia also served as a prosecutor and a civil trial attorney for DOJ. Cynthia clerked for a judge on the US Court of Appeals for the Ninth Circuit and worked as a television reporter for local stations in New Mexico and Texas. Cynthia earned a BA with Distinction from the University of New Mexico and a JD with Honors from the University of Texas School of Law.

DANIEL SCHULTZ joined Greenleaf Health following a 35-year career devoted to advancing Americans' public health as a physician, teacher, FDA official and member of the U.S. Public Health Service. As Director of CDRH, FDA from 2004 to 2009, Dan was responsible for seven FDA offices and more than 1,000 agency employees. He led the development, implementation and evaluation of regulatory policies concerning medical devices and radiation-emitting products. He also established national goals and policies to ensure that FDA and HHS objectives were met. During postings at Indian Health Service hospitals in Arizona and New Mexico, he provided medical care for people living in the Navajo Nation and Indian Pueblos. Dan continues his commitment to public health at Greenleaf, where as Principal for Medical Devices and Combination Products he provides strategic consulting services and works with Greenleaf clients to bring innovative devices to patients.

WILLIAM B. SCHULTZ is a partner at Zuckerman Spaeder, where he provides strategic advice and litigation support to generic drug companies and other clients before the FDA and HHS. Between 2011 and 2016, he was General Counsel of the Department of Health and Human Services. He is a member of the Committee on Science, Law and Technology, National Academy of Sciences, and for 10 years he taught Litigation and Food and Drug Law at Georgetown University Law Center. He was also: Deputy Assistant Attorney General, US Department of Justice in charge of appellate litigation nationwide; Deputy Commissioner for Policy, FDA; and Counsel to the House Subcommittee on Health and the Environment (Rep. Henry A. Waxman, Chairman). He began his legal career clerking for Judge William B. Bryant, US District Court, DC, and litigating at Public Citizen Litigation Group. Mr. Schultz received his undergraduate degree from Yale College and his law degree from the University of Virginia School of Law.

SUZANNE B. SCHWARTZ is the Associate Director for Science and Strategic Partnerships in the Center for Devices and Radiological Health (CDRH) at FDA. Suzanne's programmatic efforts in medical device cybersecurity have since evolved beyond response to include increasing awareness, educating, outreach, partnering and coalition-building within the Healthcare and Public Health Sector (HPH) as well as fostering collaborations across other parts of government and the private sector. Suzanne chairs the CDRH Cybersecurity Working Group which is tasked with formulating policy on medical device cybersecurity on behalf of the Agency. She also serves as co-chair of the Government Coordinating Council (GCC) for the HPH Critical Infrastructure Sector, focusing on the sector's healthcare cybersecurity initiatives. Suzanne earned an MD from Albert Einstein College of Medicine of Yeshiva University in New York in 1988, trained in General Surgery and Burn Trauma at the New York Presbyterian Hospital – Weill Cornell Medical Center; an executive MBA from NYU Stern School of Business in 2012, and completed Cohort X of the National Preparedness Leadership Initiative – Harvard School of Public Health & Harvard Kennedy School of Government executive education in June 2013.

RICHARD SELLERS, is Senior Vice President for Public Policy and Education of the American Feed Industry Association in Arlington, VA. He joined AFIA in 1991 and was promoted to his current position in 2012. He holds a BS from the University of Memphis and MS from the University of Arkansas in animal sciences. He is a board certified professional animal scientist (diplomate) in the American College of Animal Nutrition.

JESSE SEVCIK is Director of Corporate Affairs for Elanco Animal Health, a division of Eli Lilly and Company. Elanco develops, manufactures, and markets animal health and veterinary products in more than 70 countries. Mr. Sevcik joined Elanco in September 2008 and recently completed a multiyear

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JEFFREY SHUREN is the Director of the Center for Devices and Radiological Health (CDRH) at FDA. He previously served as Acting Center Director. Dr. Shuren has held various policy and planning positions within FDA from 1998 to 2009, including Acting Deputy Commissioner for Policy, Planning, and Budget; Associate Commissioner for Policy and Planning; and Special Counsel to the Principal Deputy Commissioner. Dr. Shuren is board-certified in Neurology and served as an Assistant Professor of Neurology at the University of Cincinnati. In 1998, Dr. Shuren joined FDA as a Medical Officer in the Office of Policy. In 2000, he served as a detailee on the Senate HELP Committee. In 2001, he became the Director of the Division of Items and Devices in the Coverage and Analysis Group at the Centers for Medicare and Medicaid Services. From 1998 to 2003, he

served as a Staff Volunteer in the National Institutes of Health's National Institute of Neurological Disorders and Stroke Cognitive Neuroscience Section supervising and designing clinical studies on human reasoning. Dr. Shuren returned to FDA as the Assistant Commissioner for Policy in 2003 and assumed his current position in September 2009.

BRUCE A. SILVERGLADE is a principal at the law firm of Olsson Frank Weeda Terman Matz PC in Washington, DC. His practice includes management and resolution of competitive disputes, regulatory development and implementation, enforcement matters, Congressional oversight, appropriations and legislation. Mr. Silverglade works on devising creative solutions to a wide variety of controversies involving labeling, advertising, safety, economic adulteration and nutrition. He has extensive experience with such matters on both the national and international levels working with top officials at FDA, USDA, FTC, the Canadian government, the European Commission and international health agencies including the Codex Alimentarius Commission and the World Health Organization. Mr. Silverglade received his BA *cum laude* in political science from the University of Illinois, where he was a member of Phi Beta Kappa, and his JD from Boston College Law School.

CHRISTINE SIMMON joined the Association for Accessible Medicines (formerly GPhA) in 2012 as the Senior Vice President of Policy & Strategic Alliances, and most recently was named Executive Director of AAM's Biosimilars Council, founded in 2015. In her current role, Ms. Simmon is responsible for leading policy development and issues management for AAM, directing the Biosimilars Council, and building relationships with strategic partners in the health care sector, including patient advocacy groups. Ms. Simmon had previously served as Vice President of Policy, Public Affairs & Development at AAM from 2002-2006. Before rejoining the association, she was the Senior Director of Public Policy for CVS Caremark, where she was the policy lead for the integrated retail, convenient care clinic and PBM enterprise at both the state and federal levels. Previously, Ms. Simmon was a Senior Policy Analyst at BlueCross BlueShield Association, where she helped position the insurer as a leading voice on pharmaceutical cost and safety issues. Ms. Simmon received her JD from Georgetown University Law Center and her BA in American Studies from Georgetown University.

HOWARD SKLAMBERG is a partner in the health care and life sciences practice at Akin Gump Strauss Hauer & Feld LLP, who focuses on regulatory compliance and strategy involving food and drug law. From January 2014 to April 2017, Mr. Sklamberg was FDA's Deputy Commissioner for Global Regulatory Operations and Policy at the U.S. Food and Drug Administration (FDA), which is the directorate comprising the Office of Regulatory Affairs (ORA) and the Office of International Programs (OIP). Mr. Sklamberg provided executive oversight, strategic leadership, and policy direction to many of FDA's domestic and international product quality and safety efforts, including global data-sharing, development and harmonization of standards, field operations, compliance, and enforcement activities. Prior to being named Deputy Commissioner in January 2014, Mr. Sklamberg served for one year as Director of the Office of Compliance at FDA's Center for Drug Evaluation and Research (CDER). He led the office in its efforts to protect the American public from unsafe and ineffective drug products. Mr. Sklamberg played key leadership roles in global drug supply chain security, pharmacy compounding oversight, pharmaceutical quality, and expanded cooperation with international regulatory partners. Mr. Sklamberg also served as FDA's Deputy Associate Commissioner for Regulatory Affairs in the ORA from July 2011 until he joined CDER in January 2013. Prior to that, he was Director of ORA's Office of Enforcement. Mr. Sklamberg's work at ORA led to the development and use of FSMA's new enforcement tools. Mr. Sklamberg earned a JD from Harvard Law School, a master's degree from the Fletcher School of Law and Diplomacy, and a bachelor's degree in economics and political science from Yale University.

STEVEN M. SOLOMON was appointed Center Director of the Food and Drug Administration's Center for Veterinary Medicine in January 2017. Dr. Solomon previously served as the Deputy Associate Commissioner for Regulatory Affairs within the Food and Drug Administration's Office of Regulatory Affairs since April 2014. He joined FDA in 1990 as a Veterinary Medical Officer in the Center for Veterinary Medicine, and has served in various policy and leadership positions including in the Office of Enforcement, Office of Regional Operations and Office of Global Regulatory Operations and Policy. Dr. Solomon has a Doctor of Veterinary Medicine from Ohio State University and a Master's in Public Health from Johns Hopkins University.

JAMES M. SOLYST is Vice President, Federal Regulatory Affairs with Swedish Match North America, where he coordinates the Company's Modified Risk Tobacco Product (MRTP) process and related regulatory science engagements. He has held senior positions in Washington, DC-based companies and associations, including the National Governors' Association, American Chemistry Council, and the consulting firm Ramboll-Environ. During his over 35 years in Washington, he has worked closely with federal agencies, including the U.S. Environmental Protection Agency (EPA), U.S. Food and Drug Administration (FDA), and the Office of Management and Budget (OMB). He has also worked with international organizations, including the United Nations (UN), World Health Organization (WHO), and Organisation for Economic Co-operation and Development (OECD). Mr. Solyst is a member of the Food and Drug Law Institute (FDLI) Tobacco Committee and has served on the American Chemical Society (ACS) Committee on Environmental Improvement, the National Academy of Sciences (NAS) Chemical Sciences Roundtable, and the NAS Committee on Promoting Safe and Secure Chemical Management in Developing Countries. He also served as an External Affiliate to the Johns Hopkins Risk Sciences and Public Policy Institute. Mr. Solyst has written several articles for FDLI and other journals and has given numerous presentations on a range of regulatory science and public policy issues.

DAVID SPANGLER is Senior Vice President, Policy, and General Counsel & Secretary of Legal Affairs and International Affairs. He oversees association policy initiatives at the Consumer Healthcare Products Association CHPA's. Mr. Spangler joined CHPA in 1984 as a legislative analyst. He subsequently served in a number of roles in the president's office, project management, international affairs, and legal affairs. His responsibilities were expanded to lead the legal function in 2011. Mr. Spangler is a member of the DC Bar and the American Society of Association Executives. He authored a chapter on OTC medicines in *Modern Pharmaceutical Industry: A Primer* (Jacobsen and Wertheimer, eds., 2009) and is on the editorial board of the Food and Drug Law Journal. He served on the board of directors of the World Self-Medication Industry from 2002 to 2015. Spangler earned his Certificate in Organizational Management in 1991 from the US Chamber of Commerce's Institute for Organization Management. Education: AB Miami University (Ohio) JD, George Washington University Law School.

NANCY STADE is a partner in Sidley Austin's Food, Drug, and Medical Device Regulatory practice group, where she specializes in counseling health technology companies on device regulatory law. Ms. Stade joined Sidley Austin after holding a variety of senior positions with the U.S. Food and Drug Administration (FDA), including Counselor in the Office of the Commissioner and Deputy Director for Policy at the Center for Devices and Radiological Health (CDRH), where she led the development and implementation of FDA's device regulatory policy. During her tenure with FDA, Ms. Stade led many high-profile legislative and regulatory initiatives in areas on the leading edge of

health technology, including clinical diagnostic tests, digital health, health IT, and combination products. Key initiatives she led include a pilot program to implement parallel review of innovative technologies. Ms. Stade also oversaw the implementation of all FDASIA device-related provisions, including key provisions related to Unique Device Identification, risk-based classification of devices, and modifications to 510(k) devices. Additionally, she oversaw the Office of the Ombudsman, providing strategic input on Center-level 10.75 appeals related to device jurisdiction, substantial equivalence, and 510(k) and PMA data requirements. She represented CDRH in two proceedings invoking the Dispute Resolution Panel to review PMA denials. Ms. Stade provided strategic direction to several novel initiatives to transform FDA's regulation of device labeling, including a proposed rule to allow symbols in device labeling. She led the CDRH guidance program and oversaw development of all CDRH guidance documents, including recent updates to guidance on appeals and substantial equivalence.

SARAH STEC is an associate in the Healthcare Practice at Squire Patton Boggs (US) LLP in Washington DC. She has experience assisting healthcare and life sciences companies in understanding new and evolving regulatory duties, including how international regulations can work together. She also provides guidance on international corporate accreditation and regulatory issues. Her background in quality systems and experience with international regulators gives her a unique view on the legal and regulatory requirements for medical device, pharmaceutical, and food manufacturers.

PETER TABOR is the vice president, regulatory and international affairs of the Pet Food Institute, whose members account for 98 percent of US dog and cat food production. Peter coordinates PFI's interaction with federal and state regulatory officials and he also engages US and foreign government officials regarding market access for US pet food products. Prior to joining PFI in early 2013, Peter served in variety of capacities in the US Department of Agriculture's Foreign Agricultural Service, most recently as the Director of the Plant Division, charged with addressing export challenges for US plants and plant products. A California native, Peter holds degrees in law and international trade and policy from schools in his home state.

JENNIFER THOMAS works for the US Food and Drug Administration in the Center for Food Safety and Applied Nutrition (CFSAN), Office of Compliance, where she is the Director of the Compliance Policy Staff. She is currently serving as the Interim Associate Director for FSMA Operations for CFSAN. Prior to her current role, Ms. Thomas worked in FDA in different capacities related to compliance and enforcement, including CFSAN's Office of Compliance, Division of Enforcement and the Office of Regulatory Affairs/Baltimore District Office.

JULIA C. TIERNEY is a senior policy advisor for Strategic Planning and Legislation in the Office of the Director in FDA's Center for Biologics Evaluation and Research. In that role, she works on a wide range of issues related to regulatory policy, statutory implementation, and legislative strategy. From 2015 to 2016, Ms. Tierney served as FDA's detailee to the US Senate Health, Education, Labor & Pensions (HELP) Committee as a Senior Health Policy Advisor, where she negotiated many of the FDA-related provisions of the 21st Century Cures Act. She was an Associate Chief Counsel for Drugs in FDA's Office of Chief Counsel from 2008 through 2015. Prior to working at FDA, Ms. Tierney practiced food and drug law at Arent Fox LLP and Buc & Beardsley. She received her JD from Georgetown University Law Center and her undergraduate degree in Biology and History from Johns Hopkins University.

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MARYLL W. TOUFANIAN serves as Acting Director of FDA's Office of Generic Drug Policy (OGDP), which provides oversight and direction in the development of policies concerning all aspects of generic drug regulation and advises the generic drug program on application-specific policy issues. OGDP also publishes the "Orange Book." She earned her JD from New York University School of Law, an MA in English Literature from the University of Texas at Austin, and a BA from the University of Michigan.

SUZIE TRIGG is a partner at Haynes & Boone, LLP where she is a go-to lawyer for companies tackling supply chain changes or strategic growth transactions. She works to integrate FDA regulatory requirements into companies' contracts with manufacturers and other supply chain partners, and advises them on how to comply with FDA regulations in their operations, labeling, or advertising. Ms. Trigg also leads companies through mission critical supply chain crises, such as food safety investigations and high stakes disputes with supply chain partners. Ms. Trigg frequently contributes to publications and conferences on food, cosmetics law and supply chain matters, and serves on the Food and Dietary Supplements Committee of the Food and Drug Law Institute. Accolades Ms. Trigg has received include: Acquisition International's Best in Supply Chain Negotiations and Best in Supply Chain Management Disputes Thomson Reuters' Texas Super Lawyers Rising Star in Food and Drug Law for the past three years, and one of the Best Lawyers in Dallas by D Magazine.

RACHEL TUROW is Executive Counsel – Regulatory Law at Teva Pharmaceuticals Ltd. In this role, Ms. Turow provides regulatory legal support to Teva's specialty and generic pharmaceutical businesses and supports Teva's drug-device combination products and digital health projects. Previously, Ms. Turow was Director, Regulatory Policy, at Novo Nordisk Inc. Prior to joining Novo Nordisk, Rachel spent five years at FDA. She was Regulatory Counsel in CDER's Office of Regulatory Policy and served as Special Assistant to Jeff Shuren, Director of CDRH. Ms. Turow holds a JD and MPH from the University of Michigan and a BA in Biology from Stanford University.

LYNN TYLER is a partner in the Indianapolis office of Barnes & Thornburg LLP and the Chair of its Food, Drug & Device Group. Mr. Tyler helps innovative companies secure and preserve their market position and competitive advantage by navigating their way through the FDA to the marketplace and enforcing their intellectual property rights. He counsels food industry clients on matters such as advertising and promotion, FDA inspections, imports, labeling, registration, reporting and packaging, and medical device companies on matters such as inspections, 510(k)s, and labeling and promotion issues. Mr. Tyler is a member of FDLI's Medical Device Committee and the chair of AIPLA's Food and Drug Law Committee. Mr. Tyler is also a registered patent attorney who litigates intellectual property matters and represents clients at all stages of the process, including pre-litigation counseling, alternative dispute resolution, formal and informal discovery, trial, and appeal.

RIETTE van LAACK is a director at Hyman, Phelps & McNamara PC. Ms. van Laack provides regulatory counsel on foods, dietary supplements, OTC drugs, cosmetics, and animal feed and drugs on a range of FDA, USDA, FTC, and CPSC issues. With advanced degrees in nutrition and meat science and more than 15 years as a food science and technology researcher, Ms. van Laack possesses specialized knowledge of the scientific aspects of products under review. Ms. van Laack has substantial experience with food and dietary supplement issues, labeling and advertising issues that arise from the use of

health, nutrient content, structure/function, and disease claims. She counsels clients regarding GMP and HACCP compliance issues, Reportable Food Registry issues, and responses to warning letters. Ms. van Laack advises clients on regulatory strategy, including requirements pertaining to self-determinations of GRAS status and determinations of new dietary ingredient status, and provides expert opinions on FDA regulatory matters. Ms. van Laack also has substantial experience with regulation regarding over-the-counter (OTC) drugs and cosmetics. Among other things, she counsels clients regarding labeling and advertising of OTC drug products and cosmetics. Ms. van Laack's practice includes USDA regulatory issues, including requirements for import of animal products, use of ingredients in meat, poultry, and egg products, as well as the methods used for their processing and handling and organic labeling requirements.

ALEXANDER VAROND is a senior FDA associate in Goodwin's Technology & Life Sciences Group. Mr. Varond advises drug, biotech, and device clients on FDA regulatory matters. He has extensive experience in drug and medical device development, Hatch-Waxman patent and exclusivity issues, and regulatory strategy. Mr. Varond also counsels on advertising and promotional issues, defends companies in civil and criminal investigations on a variety of issues, including off-label promotion and GMPs, and regularly advises on corporate transactions. His perspective is reinforced by his in-house counsel experience during a recent six-month secondment to a leading biotech company, where he advised on orphan drug development, compliance, NDA preparation, and exclusivity issues. Mr. Varond's professional experience includes roles as a medical device engineer, operations manager, and deputy management representative to FDA in the medical device industry. Mr. Varond received his JD from The George Washington University Law School and a BS in biomedical engineering and management science from UC San Diego.

DOMENIC J. VENEZIANO is an Independent FDA Regulatory and Strategic Consultant, contracted by EAS Consulting Group. A 24 year veteran of the U.S. Food and Drug Administration (FDA) and U.S. Public Health Service (USPHS), Domenic served as a senior FDA leader with prominent roles in the oversight of FDA's National import operations program, including the development and implementation of FDA's Targeting System PREDICT and the Import trade communication system (ITACS), the integration of Customs and Border Protections Automated Commercial Environment (ACE) with FDA's systems, and the new Food Safety Modernization Act (FSMA) and Food and Drug Safety and Innovations Act. He has testified in federal court and before Congress, initiated and approved enforcement actions, represented the FDA for media inquiries, and represented FDA on the Automated Commercial Environment/International Trade Data System board of directors and the Border Interagency Executive Council. Domenic has been the recipient of numerous awards, including the Department of Human Services Secretary's Award for Distinguished Service. Domenic began his FDA career as a field investigator in the New England District office where he conducted domestic and foreign inspections and investigations. He was selected as a Supervisory Investigator, where he was responsible for assessing investigator's inspectional reports, evaluating their findings, the evidence supporting them, and endorsing the inspection classification. He was also responsible for the New England Districts import program. In 2003, Domenic transferred to FDA Headquarters when he was asked to establish, staff, and Direct FDA's first 24/7/365 operational center in response to the Bioterrorism Act of 2002. Domenic created and operationalized the Prior Notice Center in two short months and served as its Director for 2 years. In 2005, Domenic became the Director of the Division of Import Operations and Policy, where he enforced the import laws, developed and implemented field operational policy and procedures across the country covering over 320 port of entries, and advised FDA senior executives on all issues related to import operations. As an Independent FDA Regulatory and Strategic Consultant, Domenic works

closely with EAS's clients to provide expertise related to the importation and compliance of FDA-regulated commodities. Domenic received his BS in Engineering from the University of Maine.

LEIGH VERBOIS, PhD, is currently Assistant Commissioner/Deputy Director (Acting) with US Food and Drug Administration's (FDA) Office of International Programs (OIP) where she develops coordinated strategies to protect and promote public health through international collaboration. Recently, she has served in numerous roles within the Office of International Programs including Senior Advisor and Acting Director of the Office of Policy Coordination and Communication. Previously, she served in Beijing as FDA Country Director for the People's Republic of China where she served as the overall lead for FDA's efforts in China. Before posting to China she oversaw FDA regulatory engagement with countries in the Asia-Pacific (excepting China and India), Middle East, Africa and Canada as Director of the Office of Regional and Country Affairs within OIP. Dr. Verbois began her FDA career as a reviewer in Center for Drug Evaluation's Office of New Drugs. Subsequently, she developed and directed strategies, activities, and policies to reduce threats to the global drug supply chain through increased transparency and accountability, effective enforcement, and promotion of proactive industry vigilance and voluntary compliance in CDER's Office of Compliance. Dr. Verbois has previously served in the Office of Global Regulatory Operations and Policy as Senior Advisor, Acting Assistant Commissioner for Compliance Policy in the Office of Regulatory Affairs. In these capacities, she guided multidisciplinary teams to facilitate strategic decisions, develop policy that is data driven and risk-based and manage resources. Dr. Verbois received her undergraduate degree from Tulane University, her PhD in Pharmaceutical Sciences from the College of Pharmacy at the University of Kentucky, and completed her postdoctoral training at the National Institutes of Health.

SARA BETH WATSON is Of Counsel in the Washington, DC office of Steptoe & Johnson LLP where she focuses on a wide range of life sciences issues, including compliance with FDA, the US Drug Enforcement Administration, and the U.S. Environmental Protection Agency regulatory schemes as well as state regulatory schemes. The federal regulatory programs and the various state-specific cannabis programs impact a variety of areas including medicinal products, foods, packaging, and pesticide use. Ms. Watson assists companies and trade associations in identifying and navigating the myriad issues in the changing cannabis landscape.

MICHAEL J. WERNER is a partner in Holland & Knight's Washington, DC office and co-chair of the firm's national Healthcare & Life Sciences Industry Team. He has three decades of healthcare law, regulatory, reimbursement, and lobbying experience in Washington. He focuses on issues affecting FDA-regulated entities, primarily biotechnology and pharmaceutical companies, with particular expertise in cell and gene therapy and regenerative medicine products. He also represents medical research and research institutions, physicians, and patients. Mr. Werner's specific areas of knowledge include FDA regulations regarding prescription drug/biological product review, approval, and distribution; FDA review and approval of biosimilars, over-the-counter (OTC) drugs, and supplements; IRB review, informed consent, and other clinical trial issues; Medicare and Medicaid reimbursement; as well as conflicts of interest and other bioethics issues arising from research and uses of new technologies.

REBECCA K. WOOD is Chief Counsel to the US Food and Drug Administration (FDA) and Associate General Counsel in the Office of the General Counsel, US Department of Health and Human Services (DHHS). Ms. Wood is an experienced and

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accomplished litigator who has managed complex litigation and appeals in federal and state courts, including matters arising under the Federal Food, Drug, and Cosmetic Act and US Constitution. Ms. Wood received her BA from Yale University and her JD from New York University School of Law. She previously served as a law clerk to the Honorable Pasco M. Bowman II of the United States Court of Appeals for the Eighth Circuit.

JANET WOODCOCK is Director of the Center for Drug Evaluation and Research (CDER), at the Food and Drug Administration (FDA). In 2015, Dr. Woodcock also assumed the role of Acting Director of CDER's newly formed Office of Pharmaceutical Quality (OPQ). Dr. Woodcock first joined CDER in 1994. For three years, from 2005 until 2008, she served FDA's Commissioner, holding several positions, including Deputy Commissioner and Chief Medical Officer, Deputy Commissioner for Operations, and Chief Operating Officer. Her responsibilities involved oversight of various aspects of scientific and medical regulatory operations. Before joining CDER, Dr. Woodcock served as Director, Office of Therapeutics Research and Review, and Acting Deputy Director in FDA's Center for Biologics Evaluation and Research. Dr. Woodcock received her MD from Northwestern Medical School and completed further training and held teaching appointments at the Pennsylvania State University and the University of California in San Francisco. She joined FDA in 1986.

MITCH ZELLER became director of the US Food and Drug Administration's (FDA) Center for Tobacco Products (CTP) in March 2013. The mission of CTP—established by enactment of the 2009 Family Smoking Prevention and Tobacco Control Act—is "to make tobacco-related death and disease part of America's past, not America's future, and, by doing so, ensure a healthier life for every American family." "Today, FDA has an unprecedented opportunity to use the new tools in the Tobacco Control Act," Zeller said. "Product regulation is a powerful component of a comprehensive strategy to reduce the death and disease from tobacco use. We will marshal the science to support new policies to help combat the leading cause of preventable disease and death in the United States," he added. Mr. Zeller, a graduate of Dartmouth College and the American University Washington College of Law, has been working on FDA issues for more than 30 years. He began his career as a public interest attorney in 1982 at the Center for Science in the Public Interest (CSPI). In 1988, Mr. Zeller left CSPI to become counsel to the Human Resources and Intergovernmental Relations Subcommittee of the House of Representatives Government Operations Committee where he conducted oversight of enforcement of federal health and safety laws. Mr. Zeller joined the staff of then FDA Commissioner David Kessler, MD, in 1993. What began as a two-week assignment by Kessler to examine the practices of the tobacco industry led to his serving as associate commissioner and director of FDA's first Office of Tobacco Programs. Instrumental in crafting the agency's 1996 tobacco regulations, Mr. Zeller also represented FDA before Congress, federal, and state agencies. Mr. Zeller also served as an official U.S. delegate to the World Health Organization (WHO) Working Group for the Framework Convention on Tobacco Control. In 2000, Mr. Zeller left the FDA to continue his work for tobacco control as executive vice president of the American Legacy Foundation. His responsibilities there included marketing, communications, strategic partnerships, and, in 2002, creating the foundation's first Office of Policy and Government Relations. That year, Mr. Zeller joined Pinney Associates where, as senior vice president, he provided strategic planning and communications advice on domestic and global public health policy issues involving the treatment of tobacco dependence and the regulation of tobacco products and pharmaceuticals. Mr. Zeller, who is also a professorial lecturer at American University School of Law, lives with his family in Montgomery County, Maryland.

FRANCES (FRAN) M. ZIPP is President & CEO of Lachman Consultant Services, Inc. Lachman Consultants provides compliance, regulatory and technical consulting services to the global pharmaceutical and related industries and Ms. Zipp delivers the strategic guidance and direction toward implementation of effective solutions to client needs. As an expert in compliance enhancement, she develops program solutions to meet GXP compliance requirements. Ms. Zipp has extensive experience in the pharmaceutical, biologic, and biotechnology industries from R&D through post-market approval. She assists and counsels Senior-level management in areas of Corporate Governance, Corporate Integrity Agreement Compliance, Consent Decree Negotiations and Resolutions, Application Integrity Policy resolution, Due Diligence evaluations (facilities, products, technologies), and more. For nearly four decades, Lachman Consultants has been the leader in providing cost-effective consultation and remediation services to the worldwide pharmaceutical, biotechnology, biologic, medical device, diagnostic, and dietary supplement industries. With its strong and extensive cadre of consultant specialists and an unparalleled management team, its Compliance, Science & Technology, and Regulatory Practices provide the most expert counsel and array of services available. Lachman Consultants is proud of its tradition of supporting industry efforts to develop and ensure safe, effective, and high-quality medical products. It remains committed to helping the industry anticipate and address its challenges through the development and implementation of practical, sustainable, and cost-effective solutions based on the integration of scientific principles, evolving regulatory expectations, and technology.

DAVID R. ZOOK is a partner at Faegre Baker Daniels. He is an advisor to private and public sector clients on federal legislative, regulatory, and program matters. His practice focuses on public policy and regulatory initiatives in the health, higher education, and research arenas. Dave leads the firm's health and FDA group and serves as head of the Washington, DC office. Dave has a nearly three-decade record of achieving results with Congress and the Executive Branch on complex federal issues. Recent accomplishments include health and science policy legislation, patient-focused drug development projects, and an array of competitive funding outcomes. Several projects involved building nationwide coalitions such as the Collaborative for Effective Prescription Opioid Policies. Dave's background includes serving as associate counsel to the U.S. House Appropriations Committee where he focused on energy research and nuclear defense matters across the National Labs. Dave also worked in legislative and communications positions for two members of Congress. Later, he served as a senior executive of a national health organization to establish its policy and medical affairs division.

GENERAL INFORMATION

SPEAKER PRESENTATIONS

The 2018 Annual Conference speaker presentations are available via FDLI's website at ***fdli.org/annual2018***

Please note that while we make every effort to obtain speaker presentations prior to the conference, some may not be received until the day of the meeting. The website is continuously updated as we receive speaker handouts.

EVALUATIONS

Please take a moment to fill out an evaluation for each day of the conference. Your feedback is vital to FDLI's program development and we appreciate your comments. Evaluations will be sent daily by email.

NETWORKING RECEPTION

Network and catch-up with colleagues during Thursday's Opening Night Reception in the Atrium from 5:30–7:00 PM.

CLE

The conference is approved for 10.0 CLE credits in Ohio, Pennsylvania, and Virginia. CLE forms will be available at the registration desk on May 4 at 2:00 PM. You may be able to obtain CLE credit in other states through reciprocity. Please contact your bar association for guidance. Certificates of attendance are available upon request, and will be sent post conference.

WIFI

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- ✓ Expert Witness
- ✓ Remediation, Warning Letters, and 483 Responses
- ✓ Due Diligence
- ✓ Label and Claim Review
- ✓ GRAS and Food Contact Notifications
- ✓ New Dietary Ingredients (NDI)
- ✓ Pre-Market Approvals (PMA), Investigational Device Exemption (IDE), Investigational New Drug (IND), New Drug Application (NDA), Drug Master File (DMF) and more
- ✓ Novel Foods, Novel Food Ingredients, New Food Additives
- ✓ Labeling Advertising Assistance
- ✓ Facility and Product Registration and Listing
- ✓ Consent Decrees Remediation
- ✓ Import and Export Assistance
- ✓ Product Classification
- ✓ Adverse Event Reporting Assistance and Tracking
- ✓ Recall Management Plans and Executions

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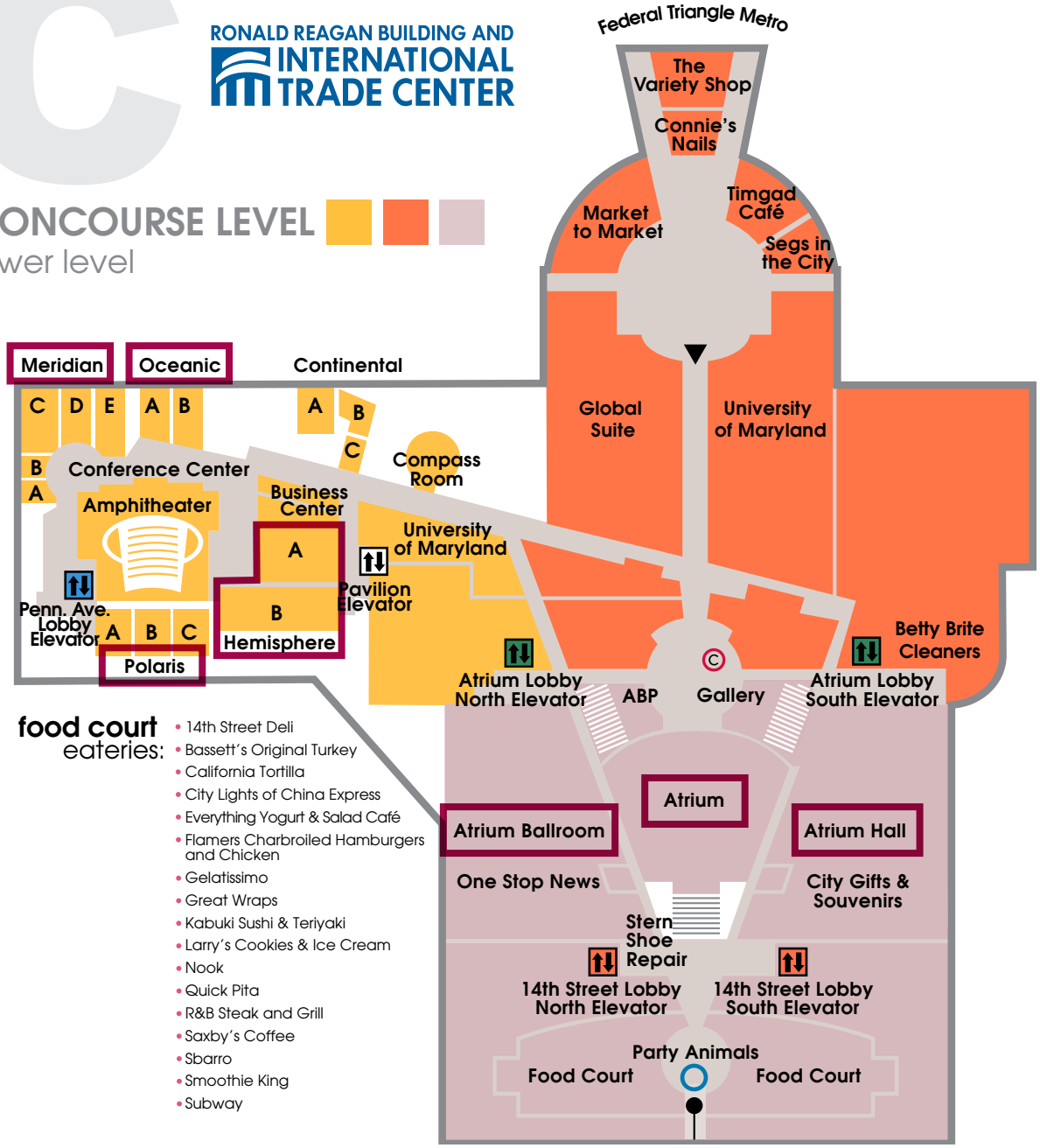
lower level



food court eateries:

- 14th Street Deli
- Bassett's Original Turkey
- California Tortilla
- City Lights of China Express
- Everything Yogurt & Salad Café
- Flamers Charbroiled Hamburgers and Chicken
- Gelatissimo
- Great Wraps
- Kabuki Sushi & Teriyaki
- Larry's Cookies & Ice Cream
- Nook
- Quick Pita
- R&B Steak and Grill
- Saxby's Coffee
- Sbarro
- Smoothie King
- Subway

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- C Amphitheater
- C Atrium, Atrium Ballroom and Atrium Hall
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- C Betty Brite Cleaners
- C Business Center
- C City Gifts & Souvenirs
- C Compass Room
- C Conference Center Suites
  Meridian, Oceanic, Continental, Polaris and Hemisphere
- C Connie's Nails
- C Continental Suite
- C Food Court
- C Gallery
- C Global Suite
- C Hemisphere Suite
- C Market to Market
- C Meridian Suite
- C Oceanic Suite
- C One Stop News
- C Polaris Suite
- C Segs in the City
- C Stern Shoe Repair
- C The Variety Shop
- C Timgad Café
- C C University of Maryland Robert H. Smith School of Business

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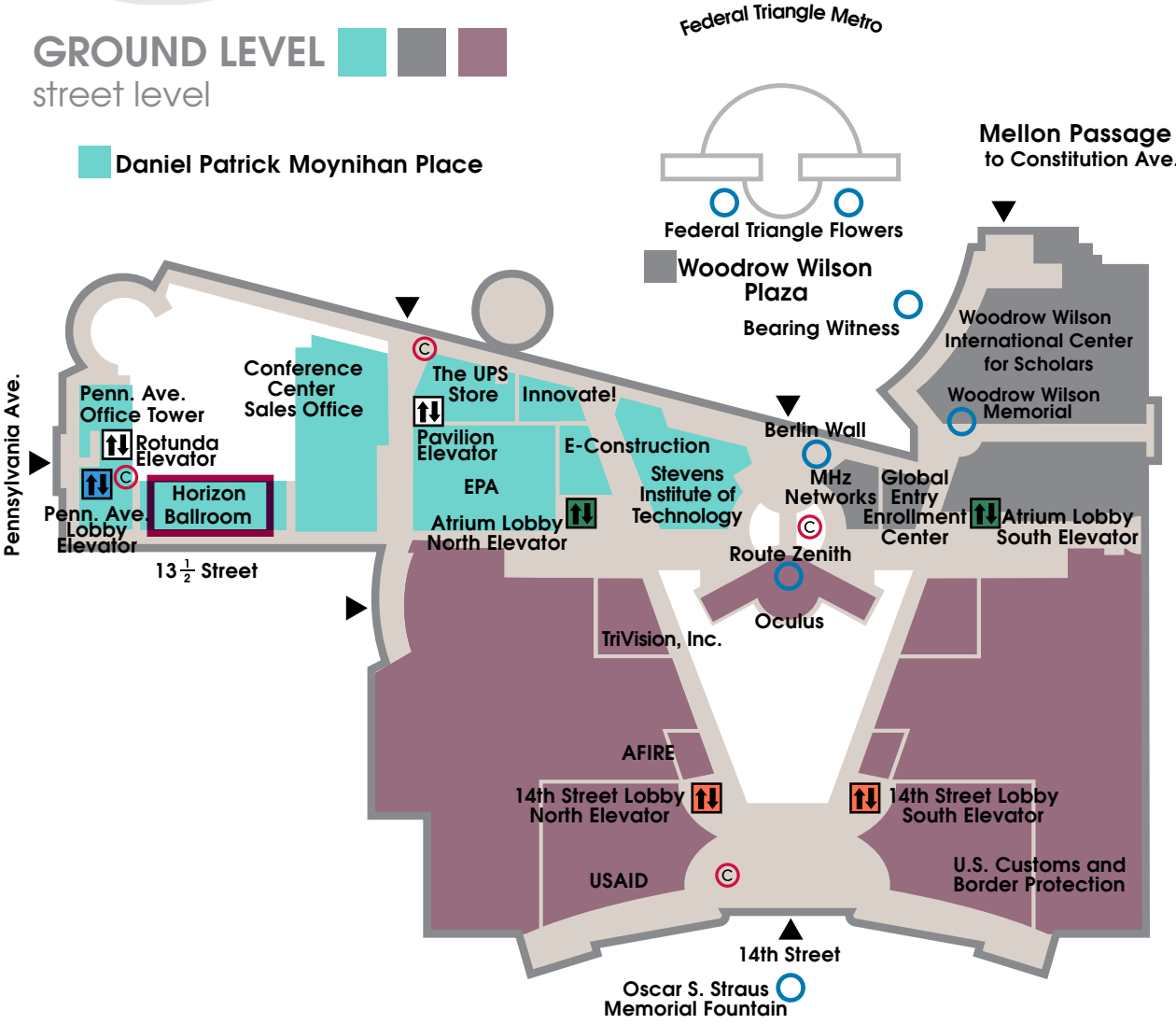
street level



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- G Association of Foreign Investors in Real Estate (AFIRE)
- G Conference Center Sales Office
- G Daniel Patrick Moynihan Place
- G E-Construction Group
- G Global Entry Enrollment Center
- G Horizon Ballroom
- G Innovate!
- G MHz Networks
- G Oculus
- G Pavilion (elevator to 2nd floor)
- G Pennsylvania Avenue Office Tower (Suites 200-880)
- G Rotunda (elevator to 8th floor)
- G Stevens Institute of Technology
- G The UPS Store
- G TriVision, Inc.
- G U.S. Agency for International Development (USAID)
- G U.S. Customs and Border Protection (CBP)
- G U.S. Environmental Protection Agency (EPA)
- G Woodrow Wilson International Center for Scholars
- G Woodrow Wilson Plaza

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