

2018 FDLI Annual Conference

Facilitated Table Topic Discussions

Friday, May 4 | Washington, DC

TABLE #	TOPIC	DISCUSSION LEADER
Drugs and Biologics		
1	Scientific Exchange vs. Off-Label Promotion	Kellie Combs, Partner, Ropes and Gray LLP
2	Opioids	Katlin McKelvie Backfield, Principal, Backfield PLLC
3	Naming Biologics	Laura Sim, Senior Counsel, Amgen Inc
4	DSCSA Drug Distribution	Kevin Madagan, Partner, Reed Smith LLP
5	505(b)(2) Applications: Legal and Regulatory Issues	Scott Lassman, Partner, Goodwin Procter LLP
6	FDA's Role in Regulating Cannabis	Emily M. Leongini, Associate, Arent Fox LLP
7	Precision Medicine and Biomarkers	Catherine Clements, Counsel, Regulatory Legal Team, Eli Lilly and Company
8	How to Be in Front on Data Integrity, Not in a Warning Letter	John McShane, VP Quality Compliance, Validant
9	Pre-Approval Communications	Robert Giddings, Attorney, Hutchinson PLLC
10	REMS Restrictions and Generic Entry	Andrew Wasson, Partner, Haug Partners LLP
Medical Devices		
11	Diagnostic Test Regulation – A Critical Juncture	Ralph Hall, Principal, Leavitt Partners, LLP
12	FDA and US Customs Import Issues	Robert Guzman, Regulatory Counsel, Thompson Hine LLP
13	Digital Health	Jeffrey Shapiro, Director, Hyman, Phelps & McNamara, P.C.
14	Next Generation Sequencing	Gail Javitt, Member of the Firm, Epstein Becker Green, PC
15	513 (g) Requests	Mark Levy, Member, Eckert Seamans Cherin & Mellott, LLC
Food, Dietary Supplements, and Cosmetics		
16	Gene Editing in FDA Food Products	Sandra Eskin, Director, Food Safety Campaign, The Pew Charitable Trusts
17	Marketing Claims: Cosmetics and Other Personal Care Products	Laura Venker, Associate, McGuireWoods LLP
18	Food and Beverage Outlooks Under A New NAFTA	Juan Serrano Leets, Partner & José Alberto Campos, Partner, Sanchez Devanny
19	Dietary Supplement Issues	Jason Sapsin, Counsel, Faegre Baker Daniels LLP
Tobacco		
20	MRTP Authorization: Balancing of Probabilities	Ondrej Koumal, Director Reduced Risk Products, Corporate Affairs, Philip Morris International
21	Tobacco Control Act to Today: Is FDA Protecting the Public Health?	Mark Vaders, Counsel, Womble Bond Dickinson (US) LLP
22	The youth appeal issue: causes and solutions	Brittani Cushman, External Affairs, Turning Point, Inc.
Additional Hot Topics		
23	Responding to Public Health Crises, Often Ignored Provisions and Creative Uses of the Law for FDA to Use	John Johnson III, Attorney, FDAImports.com, LLC/ Benjamin L. England & Associates LLC
24	Navigating the FDA Advisory Panel Process	Kristin Zielinski Duggan, Counsel, Hogan Lovells US LLP
25	Emergency Use of Military Medical Products & Enhanced DoD-FDA Collaboration	Jeremiah J. Kelly, Chief, FDA Regulatory Law Division
26	Veterinary Drug Compounding	Ted Sullivan, Partner, Quarles & Brady LLP
27	FDA Archives	Suzanne Junod, Historian, FDA
28	Conducting Your Life Science Career Audit	Stuart TenHoor, President, Stuart TenHoor Legal Search
29	Engage with FDLI	Judy Rein, Director of Publications and Wendy Finn, Director of Membership & Marketing, FDLI