SpencerFane

Brian Malkin
Presentations and Publications: 1999-2019

- *Initial Report of the New York State Bar Association Committee on Cannabis Law: Regarding Legalized Cannabis Legislation in New York State*, NYSBA, December 2019
- "What is FDA's Role in the Regulation of Cannabis?" FDLI Legal and Practical Issues in the Evolving World of Cannabis Regulation, November 2019
- "An Introduction to FDA and FTC: Insider and Outside Counsel Highlights," NYSBA CLE, Food, Drug and Cosmetic Law Section, November 2019
- "New Challenges of In Vitro Diagnostics," Michigan Institute for Clinical & Health Research Medical Devices in Academic Research Symposium, October 2019
- "Regulatory Compliance During Study Conduct," AdvaMed (Medtech Association) Investigational Device Exemption Submissions Workshop, October 2019
- "Drug Pharmacovigilance Under CDER," FDAnews Post-Market Surveillance Conference, June 2019
- "FDA and DEA Regulation of Opioid Drugs and the Opioid Drug Crisis," CLE Course, DC Bar CLE, June 2019
- "Hot Topics in Cannabis Law: CBD Rulemaking," NYSBA CLE, May 2019
- "Top Ten Intellectual Property and Regulatory Issues for Biotechnology Startups," Webinar, Yeshiva University's Katz School of Science and Health, May 2019
- "Orphan Drug and Rare Disease Developments," FDLI, Annual Conference, May 2019
- "Regulatory developments in Orphan Drugs," Venture Café Cambridge BIO Connect, April 2019
- "Violations, Enforcement and International Issues," FDLI Introduction to Biologics and Biosimilars Law and Regulation, April 2019
- "Concerns Establishing Single Shared ETASU REMS, Waivers and Generic Blocking," ExlEvents 11th Risk Evaluation and Mitigation Strategies Summit, January 2019
- "The Biosimilar Action Plan – Clarify FDA's Guidance," CBI's 14th Annual Biosimilars Summit, January 2019
- "Hot Topics in FDA Law," NYSBA, Annual Meeting, Food, Drug and Cosmetic Law Section, January 2019
- "Hot Topics in Cannabis Law 2019: What Lawyers Need to Know," NYSBA, Annual Meeting, Cannabis Law Committee, January 2019

- "Practical Implications of Decriminalized Marijuana for the Legal Practitioner," NYSBA CLE, October 2018
- "Cannabis Law Update," 2018 Bridging the Gap NYC, NYSBA CLE, August 2018
- "Balancing Unity and Individuality: Leadership Skills for Managing Culturally Divergent Clinical Teams," Drug Information Association (DIA) 2018 Global Annual Meeting, June 2018
- "Launch an Expanded Access Program That Effectively Supports Patient Needs and Compliantly Enhances Drug Development," World Congress Life Sciences Market Access & Oncology Summit, February 2018
- "Embracing the Continuum of Risk: CTP Builds Policy on Product Standards and Tobacco Flavoring, and Reassesses Regulatory Priorities in Aftermath of the Deeming Rule," NYSBA, Annual Meeting, Food, Drug & Cosmetic Law Section, January 2018
- "Beware Marketing Cannabidiol Products: FDA Is Watching," *Law360*, December 2017
- "Violations, Enforcement, and International Issues," FDLI Introduction to U.S. Biologics and Biosimilars Law and Regulation, October 2017
- "Explore How the New Trump Administration Affects the Future of Pre-Approval", IQPC Pre-Approval Access Programs, September 2017
- "Quality Systems Regulation," ACI Fifth Annual FDA Boot Camp: Devices Edition, July 2017
- "The Animal Drug Compounding Debate," FDLI, Annual Conference, May 2017
- "Wearable Health Trackers, FDA's 'General Wellness' Classification, and Patent Protection, Oh My!" ACI Advanced Summit on Medical Device Patents, March 2017
- "Reciprocity Issues for New York-Admitted Lawyers," NYSBA Holiday Networking Event, December 2016
- "Executive Roundtable – Life Sciences Industry Update" and "Business and Legal Issues for Early-Stage Companies," 8th Annual Pharmaceutical and Medical Device Conference, November 2016
- "Deconstructing the New Guidance on Expanded Access and Update on Legal Developments," Expanded Access: FDA's New Regulatory Process How Compassionate Use Fits into Proposed Reforms, October 2016
- "Animal Biologic Development: The Continuing Debate Between Cure and Cost" and "Revisiting the Animal Drug Compounding Debate," ACI's 2nd Annual Legal, Regulatory, and Compliance Forum on Animal Health: Veterinary Drugs, Therapeutics, and Animal Food, September 2016
- "Develop Strategies to Successfully Implement the New Guidance Determine Potential Compliance Obstacles and Financial Penalties to Avoid Unanticipated Delays," The Pharmacovigilance Final Rule Summit on IND Safety Reporting, August 2016

- “High-Risk Devices-Parsing the Premarket Approval Process (PMA)” and “Quality System Regulation,” ACI's 4th Annual FDA Boot Camp, July 2016
- “Biosimilars Patent Litigation in Canada and Japan: A Comparative Strategic Overview and EU and US Update,” *Generics and Biosimilars Initiative (GaBI) Journal*, June 2016
- “Amarin,” 2016 FDLI Annual Conference, May 2016
- 2016 Danish Biotech Conference, McGuireWoods, April 2016
- “New FDA Rules Put Onus On Doctors to Curb Opioid Abuse,” *Law360*, March 2016
- “The Impact of the Evolving US Biosimilar Regulatory Policies on Bringing Biosimilars to Market," CBI 11th Summit on Biosimilars, January 2016
- “Food, Drug, Cosmetic Section Profile: Section Helps Food and Drug Law Attorneys Explore FDA Guidance, Legislation with New York,” *State Bar News*, NYSBA, December 2015
- “FDA Update – Recent Developments and New Initiatives Including a MDUFA Update" and "Off-Label Promotion in the Wake of the Amarin Decision," ACI 7th Annual Medical Device and Life Sciences Conference, November 2015
- “Amarin and the Future of Off-Label Promotion," FDLI, November 2015
- “Biosimilars Patent Litigation in the EU and the US: A Comparative Strategic Overview,” *Generics and Biologics Initiative (GaBI) Journal*, August 2015
- “Foreign Corrupt Practices Act and Corporate Accountability," Pennsylvania Bar Institute 21st Annual Meeting, November 2015
- “Developments in Global Intellectual Property," International Generic Pharmaceutical Alliance (IGPA) 18th Annual Conference, September 2015
- “Drug Compounding in the Animal Drug Industry: Assessing Fair and Foul Practices," ACI Legal, Regulatory, and Compliance Forum on Animal Health, Veterinary Medicines and Therapeutics, September 2015
- “Biosimilars Patent Litigation in the EU and the US: A Comparative Strategic Overview”, *GaBI Journal*, August 2015
- “Develop Strategies to Continue Building Successful Benefit-Risk Assessments," CBI Benefit-Risk Assessment & Decision-Making Summit, August 2015
- “Protecting Both Innovation and Competition: Finding Compromise Within Federal and State Biosimilars Substitution Laws," ACI's 6th Annual Summit on Biosimilars, June 2015
- “Breakout Session: Center for Drug Evaluation and Research (CDER)," FDLI Annual Conference, April 2015
- “Biosimilars Patent Litigation," European Generic Medicines Association (EGMA) 11th Legal Affairs Forum, March 2015

- “FDA, LDT and IVD: The ABC's of Clinical Lab Test Development," NYSBA, Annual Meeting, Food, Drug and Cosmetic Law Section, January 2015
- “Analyze the FDA's Newly Released REMS Standardization Report" and "Highlight Key Consideration to Collaborate Successfully in a Single Shared REMS," ExL Pharma 7th Risk Evaluation and Mitigation Strategies Summit, January 2015
- “The FDA's Ever-Broadening Regulatory Oversight Creates Need for Increased (and More) User Fees: How Will This Affect Enforcement, the Increasing Need for Sponsor Self-Regulation, and the FDA's Regulatory Priorities?” *Recent Developments in Food and Drug Law* (2015 Edition), Aspatore/Thompson Reuters, December 2014
- “Insights into Developing the Best Regulatory Pathway for Your Venture and Methods of Designing an Efficient and Productive Clinical Trial," Climbing the Regulatory Summit, December 2014
- “FDA Update: Recent Developments and New Initiatives," ACI 6th Annual Medical Device and Life Sciences Conference, November 2014
- “Regulations - The Good, the Bad, and the Ugly," Food Safety Challenges in an Era of Change: How to Better Protect Your Food and Beverage Company, Your Customers, and Yourself, October 2014
- “Issues Concerning Development of Rare Disease and Special Population Medical Devices," AdvaMed 2014 The MedTech Conference, October 2014
- “The Case for Small Markets with Large Returns: Orphans/Rare Disease Panel," Life Science Nation: Redefining Early-Stage Investments, September 2014
- “Pre-Conference Primer: Biosimilars 101: Comprehensive Deep Dive into the Relevant Legal, Regulatory, and Scientific Factors Companies Must Know," ACI 5th Annual Conference on Biosimilars, June 2014
- “Breakfast Breakout: Career Opportunities in Food & Drug Law," 2014 FDLI Annual Conference, April 2014
- “Safety v. Competition (Federal Trade Commission Follow-On Biologics Workshop: Impact of Recent Legislative and Regulatory Naming Proposals on Competition February 4, 2014 Overview)," BioCentury This Week, February 2014
- “Biotechnology Roundtable: Innovative Strategies for New Product Development," Montgomery County Department of Economic Development, February 2014
- “FDA Regulation: The Intersection of Policy and Politics, The Opportunities and Challenges for Innovation – Perspectives from Two Former FDA Officials," NYSBA, Annual Meeting, Food, Drug and Cosmetic Law Section Annual Meeting, January 2014
- “Understand the FDA Report [Risk Evaluation and Mitigation Strategies (REMS) Standardization] and the Impact on the Industry," ExL Pharma 6th Risk Evaluation and Mitigation Strategies Summit, January 2014

- "Will the FDA Provide More Guidance or Manage the Process to Share Risk Evaluation and Mitigation Strategies (REMS)?" *Financier Worldwide*, October 2013

- "Free Speech and Off-Label Drug Promotion: Should Recent Cases Change Your Business Practices? Navigating Recent Off-Label Promotion Developments, Understanding Government Relations and the Potential Impact of Noteworthy Cases," *Aspatore Special Report*, *Aspatore / Thompson Reuters*, September 2013

- "The Drugs/Biologics Approval Process: An FDLI Primer," FDLI, January 2013

- "Challenges to the Development of a Biosimilars Industry in the United States," *Aspatore / Thompson Reuters*, December 2012

- "Should FDA Undertake More Than a 'Ministerial' Role with Respect to Patent Information?" *FDLI Policy Forum*, February 2011

- "Disentangling Biobetters Under the Biologics Price Competition and Innovation Act of 2009," *FDLI Update Magazine*, February 2011

- "Biosimilars Are a Reality: Key Features of the Biologics Price Competition and Innovation Act," *FDLI Update Magazine*, June 2010

- "The Letter of the Law: How FDA Regulation Will Impact Your Business," *Tobacco Reporter*, August 2009

- "FDA's Role in Administering the Hatch-Waxman Act," *Food and Drug Law Journal*, January 1999