Food, Drug and Cosmetic Law Section

Hot Topics in Food, Drug & Cosmetic Law

January 25, 2018 | New York Hilton Midtown | NYC

7.0 Total Credits: 1.0 Ethics | 6.0 Professional Practice (Non-Transitional)

Program:
8:30 a.m. - 5:00 p.m. | Nassau West, 2nd Floor

SECTION & PROGRAM CHAIR
Brian J. Malkin, Esq.
Arent Fox LLP
Washington, DC

8:30 a.m. – 8:35 a.m. Introduction – Brian J. Malkin, Section Chair

8:35 a.m. – 9:00 a.m. Tobacco Law

Embracing the Continuum of Risk: CTP Builds Policy on Product Standards and Tobacco Flavoring, and Reassesses Regulatory Priorities in Aftermath of the Deeming Rule.

- The feasibility and impacts of FDA's decision to delay regulatory deadlines for newly deemed products while undertaking rulemaking and eliminating the sunset provision
- The complications and potential public health benefits and harms related to FDA's proposed product standards for nicotine levels, tobacco flavors, and re-evaluation of premium cigars
- Analysis of FDA's request for input on most efficient use of its resources and review of provisional substantial equivalence reports

Moderator: Brian J. Malkin, Esq., Arent Fox LLP, Washington, DC
Speakers:
Anne Pierson Allen, Esq., King & Spalding (former FDA Office of Chief Counsel (OCC) representative to the Center for Tobacco Products (CTP)), New York, NY

Christina Young, Ph.D., King & Spalding (former Chemist to the FDA's CTP), New York, NY

9:05 a.m. – 9:55 a.m. Animal Health Law

Are All Human Drugs Actually Animal Drugs Waiting to Be Developed? What it Takes to Develop a New Animal Drug and Other Animal Health Product Considerations

Moderator: Janet Linn, Esq., Eaton & Van Winkle, New York, NY

Speakers:
Manya Deehr, Esq., Cooley LLP, Princeton, NJ

Nancy E. Halpern, Esq., Fox Rothschild, LLP, Princeton, N.J.

10:00 a.m. – 10:25 a.m. Food Law

From Farm to Table – The Future of GMO Plants and Animals

- An update on the rulemaking the US Department of Agriculture (USDA) is undertaking to implement the Bioengineered Food Disclosure Law
- The status of regulatory proposals relating to the regulation of plant and animal products of biotechnology proposed by USDA and FDA, respectively
- Other emerging issues related to the regulation of plant and animal products of biotechnology

Moderator: Suchira Ghosh, Esq., Axinn Veltrop Harkrider LLP, New York, NY
Speakers:
Karen Carr, Esq., Arent Fox LLP, Washington, DC

Kristin Landis, Esq., Deputy General Counsel, Agriculture & Environmental, Biotechnology Innovation Organization (BIO), Washington, DC

10:25 a.m. – 10:40 a.m. Coffee Break

10:40 a.m. – 12:00 p.m. Biologics Law

Gene Therapies Now FDA-Approved for Use: What You Need to Know to Address Safety and IP Considerations – Plus an Update on Biosimilars

- FDA Discusses New Gene Therapy Approval and Safety Considerations for REMS for Gene Therapy

- IP Considerations for Patenting Gene Therapies – When and How Do You Do It?
- Update on Biosimilar Approvals: The Legal Pathway After the Supreme Court Ruling in Sandoz v. Amgen and Marketing Challenges

Moderator: April Polikoff, Esq., Akorn Pharmaceuticals, Amityville, NY

Speakers:
JP Ahluwalia, Ph.D., Medical Officer, FDA, Center for Biologics Evaluation and Research, Analytic Epidemiology Branch, Silver Spring, MD

Janet Linn, Esq., Eaton & Van Winkle, New York, NY

Vicki Malia-Piekarz, Esq., General Counsel, New York Genome Center, New York, NY

12:00 p.m. – 1:30 p.m. Lunch on Your Own

1:30 p.m. – 2:20 p.m.
Ethics in Early Clinical Trials – How Does an Attorney Balance the Duty to Represent the Client with the "Greater Good" of Early Access and the "Right to Try" that Benefit Patients?

Moderator: David S. Weinstock, Esq., Weston, CT

Speakers:
Anne Pierson Allen, Esq., King & Spalding, New York, NY

Ilene Wilets, Ph.D., Institutional Review Board Chair, Program for the Protection of Human Subjects – Icahn School of Medicine at Mount Sinai, New York, NY

2:25 p.m. – 3:40 p.m. Drug Law
Opioid Drug Crisis: Measures to Control
- Do Laws Mandate Drug Company Collaboration: A look at recent public meetings, held by FDA and US Federal Trade Commission (FTC), and recent rulemaking efforts to increase competition and reduce Rx prices?
- Using Sovereign Immunity as a Competitive Tool: Allergan's patent assignment to the St. Regis Mohawk Tribe

Moderator: Larissa Bergin, Esq., Jones Day, Washington, DC

Speakers:
Professor Michael Carrier, Distinguished Professor of Law, Rutgers Law School, Camden, NJ

Lisa Landau, Esq., Chief, Health Care Bureau, New York State Office of the Attorney General, Albany, NY

James Klaiber, Esq., Hughes Hubbard & Reed, New York, NY

Michael Knight, Esq., Jones Day (Former Assistant Director, FTC Bureau of Competition), Washington, DC

James Major, Esq., Lucas & Mercanti, LLP, New York, NY

3:40 p.m. – 3:55 p.m. Coffee Break

3:55 p.m. – 4:45 p.m. Medical Devices
Innovation and Regulation of Emerging Technologies: Safety and Data Security
- Updates in FDA device and software regulation following the 21st Century Cures Act
- Practical guidance on when my software is regulated by FDA
- Data transfers as a treatment tool
- Privacy and security risks and regulation

FDA's Evolving Policy on Personalized Medicine Tests
- Direct-to-Consumer genetic health tests
- Update on Laboratory Developed tests
- Developments in pharmacogenomics tests

Moderator: Christopher C. Palermo, Esq., Bleakley Platt & Schmidt, LLP, White Plains, NY
Speakers:
Nancy L. Perkins, Esq., Arnold & Porter Kaye Scholer LLP, Washington, D.C.
Mahnu V. Davar, Esq., Arnold & Porter Kaye Scholer LLP, Washington, D.C.
Nancy K. Stade, Esq., Sidley Austin LLP, Washington, D.C.

4:45 p.m. – 5:00 p.m. Section Business/Elections

5:30 p.m. – 7:00 p.m. Off-Site Reception | Arent Fox LLP, 1675 Broadway, New York, NY 10019

Reception Co-Sponsors: Arent Fox | Axinn, Veltrop & Harkrider | Sanchez Devanny