

# ANNUAL MEETING 2018

## 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, 2<sup>nd</sup> 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

**Speaker:** Manya Deehr, Esq., Cooley LLP, Princeton, NJ

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**

**Register Online** [www.nysba.org/AM2018](http://www.nysba.org/AM2018) | **Get Social: #NYSBA18**



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**IMPORTANT INFORMATION**

**Under New York’s MCLE rule**, his program has been approved for a total of 7.0 credit hours (6.0 Areas of Professional Practice and 1.0 credit hours in Ethics). This program will NOT qualify for credit for newly-admitted attorneys because it is not a basic practical skills program.

**Discounts and Scholarships:** New York State Bar Association members and non-members may apply for a discount or scholarship to attend this program, based on financial hardship. This discount applies to the educational portion of the program only. Under this policy, any member of our Association or non-member who has a genuine basis for their hardship, if approved, can receive a discount or scholarship, depending on the circumstances. Request for discounts or scholarships must be received prior to January 13, 2017. For more details, please contact Lisa Bataille in writing at New York State Bar Association, One Elk Street, Albany, New York 12207 or [lbataille@nysba.org](mailto:lbataille@nysba.org).



**Accommodations for Persons with Disabilities:** NYSBA welcomes participation by individuals with disabilities. NYSBA is committed to complying with all applicable laws that prohibit discrimination against individuals on the basis of disability in the full and equal enjoyment of its goods, services, programs, activities, facilities, privileges, advantages, or accommodations. To request auxiliary aids or services or if you have any questions regarding accessibility, please contact Lisa Bataille at 518-487-5680.



For overnight room accommodations, please call the New York Hilton Midtown at 1-800-445-8667 and identify yourself as a member of the New York State Bar Association or on the web at [www.nysba.org/am18accomm](http://www.nysba.org/am18accomm). The rate will be based on room selection (single/double occupancy) and arrival/departure dates with additional taxes and hotel fees. The discounted rate for January 21st and January 22nd is \$179 per night. The discounted rate for January 23rd through January 28th is \$229 per night. A rate of \$209 will be offered to those with overlapping dates. Rates and availability are not guaranteed after January 11th.



For questions about this specific program, please contact Lisa Bataille at 518-487-5680. **For registration questions only, please call the Member Resource Center at 800-582-2452. Fax registration form to 518-463-5993.**