

Food, Drug and Cosmetic Law Section

2019 NYSBA Annual Meeting CLE Program

Hot Topics in FDA Law

Thursday, January 17, 2019 | 1:00 p.m. - 6:00 p.m.

New York Hilton Midtown | Gibson Room, Second Floor

1:00 p.m. – 1:10 p.m.

Welcoming Remarks

Brian J. Malkin, Esq., Section Chair
Arent Fox LLP
Washington, DC

1:10 p.m. – 2:25 p.m.

Overview of Biologic Policy Initiatives

- What's new with specialty medications? (an examination of the biologics/biosimilars industry)
- Update on gene therapy
- Approvals in Europe/UK
- Payment models in the US and access to therapy
- Obstacles for future development of novel gene therapy products, including scientific, regulatory, and financial
- Wholesaler's perspective on their role with the supply chain including the payer community, as well as biological product supply chain evolution

Panelists: Ronald W. Lanton, III, Esq. (Panel Chair)
Frier Levitt Government Affairs, LLC
Pine Brook, NJ

Sheila M. Arquette, R.PH.
Executive Director
National Association of Specialty Pharmacy
Washington, D.C.

Kelly A. Ryan
Senior Director
State Advocacy PhRMA
Albany, NY

Timothy Ward
President
Hercules Pharmaceuticals, Inc.
Port Washington, NY

(1.5 Credits in Areas of Professional Practice)

2:25 p.m. – 2:30 p.m.

Refreshment Break

2:30 p.m. – 3:45 p.m.

Hot Topics in Devised: LDT and Digital Health

- Insights on FDA's 2018 "technical assistance" to Congress
- How New York State leads in test oversight
- FDA's evolving approach to digital health technologies
- Risks and opportunities of the FDA's proposed regulatory model.

Panelists: Bethany Hills, Esq. (Panel Chair)
Mintz, Levin, Cohn, Ferris, Glovsky and Popeo,
P.C.
New York, NY

Aaron Josephson, M.S.
ML Strategies, LLC
Washington, DC

Lesley Maloney
PharmD.Roche
Washington, DC

Howard Zucker, M.D., JD
Commissioner
New York State Department of Health
Albany, NY

(1.5 Credits in Areas of Professional Practice)

3:45 p.m. – 3:50 p.m.

Refreshment Break

3:50 p.m. – 4:15 p.m.

Blockchain in Healthcare

How blockchain can be used to comply with the Drug Supply Chain Security Act

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

Panelists: Combiz Richard Abdolrahimi, Esq.
Deloitte & Touche LLP
New York, NY

Colleen M. Heisey, Esq.
Jones Day
Washington, DC

(0.5 Credits in Areas of Professional Practice)

4:15 p.m. – 4:40 p.m.

GDPR Compliance: What You Need to Know

Speaker: Amy B. Goldsmith, Esq. (invited)
Tarter Krinsky & Drogin
New York, NY

(0.5 Credits in Areas of Professional Practice)

4:40 p.m. – 5:05 p.m.

***Helsinn v. Teva* and Secret Prior Art**

When are secret sales and offers for sale prior art? How confidential agreements with third parties may invalidate your patents

Speaker: Janet B. Linn, Esq.
(Section Vice Chair)
Tarter Krinsky & Drogin LLP
New York, NY

Bruce S. Weintraub, Esq.
Senior Corporate Counsel
Pfizer Inc.
New York, NY

(0.5 Credits in Areas of Professional Practice)

5:05 p.m. – 5:10 p.m.

Refreshment Break

5:10 p.m. – 5:35 p.m.

Animal Testing Legislation

Moderator: Thomas A. Cohn, Esq.
Director and Senior Counsel
Avon USA
New York, NY

Speaker: Sharon A. Blinkoff, Esq.
Lock Lorde LLP
New York, NY

(0.5 Credits in Areas of Professional Practice)

5:35 p.m. – 6:00 p.m.

Talcum Powder Products Litigation

Moderator: Jennifer Orendi, Esq.
Managing Attorney
Dalimonte Rueb Litigation Group LLP
Washington, DC

Speaker: Victoria J. Maniatis, Esq.
Sanders Phillips Grossman, LLC
Garden City, NY

(0.5 Credits in Areas of Professional Practice)

6:00 p.m. – 6:15 p.m.

Food Drug & Cosmetic Law Section Annual Meeting,
Business Meeting and Strategic Planning

6:30 p.m. – 7:30 p.m.

Off-Site Reception
Arent Fox LLP (next door to the Hilton)
1301 Avenue of the Americas, 42nd Floor
New York, NY 10019

Total Credits: 5.5 Credits in Areas of Professional Practice.

This program is co-sponsored by the New York Bar Foundation.

BEO # 152

Powerpoint/AV needs: