

Food, Drug and Cosmetic Law Section 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

5.5 Credits

5.5 Areas of Professional Practice

This program is transitional and is suitable for all attorneys including those newly admitted.

Agenda

1:00 p.m. – 1:10 p.m.

Welcoming Remarks

Brian J. Malkin, 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, DC

JP Ahluwalia, M.D., M.PH.

FDA Center for Biologics Evaluation & Research, Silver Spring, MD

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.

Medical Device Hot Topics: New Regulatory Models in Lab Developed Tests and Digital Health

- Insights on FDA's 2018 "technical assistance" to Congress for LDT regulation
- New York State laboratory test oversight and FDA third party review framework
- FDA's evolving regulatory approach to digital health technologies
- Intersecting issues in diagnostics and digital health

Panelists:

Bethany J. Hills, Esq. (Panel Chair)

Mintz Levin, New York, NY

Aaron Josephson, M.S.

ML Strategies, LLC, Washington, DC

Lesley R. Maloney

Head of US Regulatory Policy, Roche Diagnostics, Washington, DC

NYSBA 2019 ANNUAL MEETING

Howard A. 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 C. 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.

Tarter Krinsky & Drogin LLP, 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

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



SECTION CHAIR

Brian J. Malkin, Esq. | Arent Fox LLP | Washington, D.C.