**New York State Bar Association**

**2020 Annual Meeting**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Food, Drug & Cosmetic Law Section

**Food and Drug Hot Topics with a Look at Corporate Responsibility**

# \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Thursday, January 30, 2020** New York Hilton Midtown | NYC **CLE Program**

# 12:00 p.m. – 5:25 p.m. | Gibson Room, Second Floor

# **6.0 Credits** 6.0 Areas of Professional Practice *This program is transitional and is suitable for all attorneys including those newly admitted.*

# <https://www.nysba.org/AM2020FDC>

**Agenda**

11:50 a.m.- 12:00 p.m. **Welcome and Introduction**

Chair: Brian J. Malkin, Esq.

Arent Fox LLP

Washington, D.C.

12:00 p.m. – 1:40 p.m. **Drug and Biologics Update**

Speakers: Larissa Bergin

Jones Day

Washington, DC

Janet Linn

Tarter Krinsky & Drogin

New York, NY

Ronald W. Lanton, Esq.   
Lanton Strategies & Lanton Law  
Boston, MA

* + - * + Patent invalidating agreements and overboard claims (*Helsinn v. Teva; Idenix v. Gilead*)
        + Avoiding invalidity under Section 101, will the Supreme Court weigh in? Claiming natural ingredients (National Alternatives v. Creative Compounds) and method of treatment/dose adjustment (*Hikma v. Vanda and Endod v. Teva*)
        + Recent case precedent impacting the FTC’s ability to obtain monetary remedies (*FTC v. Shire ViroPharma, Inc.*)
        + State and federal policy trends with biologics/biosimilars as well as pertinent litigation

*(2.0 Credits in Areas of Professional Practice)*

1:40 p.m. – 1:50 p.m. Break

1:50 p.m. – 2:40 p.m. **Corporate Responsibility in Cosmetics and Other Regulated Products**

Speakers:Jamie Lee Mattison  
Senior Manager  
Climate Change and Sustainability Services  
Ernst & Young LLP  
New York, NY

Alphonse Iannuzzi, Jr., Ph.D.   
Vice President, Sustainability  
Global Corporate Citizenship & Sustainability   
The Estée Lauder Companies  
New York, NY

Moderators: Thomas Cohn, Esq.

New Avon Company

New York, NY

Jennifer Orendi, Esq.

Dalimonte Rueb Stoller

Washington, DC

* + Animal testing/ Cruelty-free/ Vegan
  + Packaging / Environmental
  + Use of sustainable ingredients
  + Truth in advertising / Transparency
  + Free-from claims / Revealing potential toxicities
  + Certifications / Seals

*(1.0 Credit in Professional Practice)*

2:40 p.m.– 3:55 p.m. **Tobacco/Deeming Rule Update**

Moderator: Anne Pierson Allen, Esq.

New York, NY

Speakers: David Dobbins, JD, MPH  
Chief Operating Officer  
Truth Initiative  
Washington, D.C.

Morenike Fajana, Esq.   
Special Counsel, Executive Division  
NYS Office of the Attorney General  
New York, NY

Kim Kessler, JD  
Assistant Health Commissioner  
Bureau of Chronic Disease Prevention & Tobacco Control  
NYS Department of Mental Health & Hygiene  
New York, NY

* + ENDS products
  + Federal v. State Laws
  + Vaping, Lawsuits, and Regulations

*(1.5 Credits in Areas of Professional Practice)*

3:55 p.m. - 4:10 p.m. Break

4:10 p.m. – 5:00 p.m. **Keynote**

Speaker: Douglas Stearn  
Deputy Director for Regulatory Affairs  
Center for Food Safety and Applied Nutrition  
U.S. Food and Drug Administration  
Washington D.C.

*(1.0 Credit in Areas of Professional Practice)*

5:00 p.m. – 5:25 p.m. **Off label Promotion Update**

Moderator: Brian Malkin, Esq.

Arent Fox LLP

Washington, D.C.

Speakers: Jeffrey B. Chasnow, Esq.   
Senior Vice President & Associate General Counsel  
Pfizer  
New York, NY

: Steve Shapiro, Esq.

Of Counsel, Rivkin Radler  
New York, NY

o   Update on FDA and Off-label Promotion

o   Promotion of CBD following Epidiolex for Rx, OTC drugs and other products

*(0.5 Credit in Areas of Professional Practice)*

5:25 p.m. - 5:35 p.m. Business Meeting (Elections)

5:40 p.m. – 7:00 p.m. **Reception**Arent Fox LLP  
1301 Avenue of the Americas, NYC

# **Section Chair:** Brian J. Malkin, Esq. | Arent Fox LLP | Washington D.C.

**IMPORTANT INFORMATION**

Under New York’s MCLE rule, this program has been approved for a total of 5.0 credits (4.0 areas of professional practice, 1.0 ethics,). This program is transitional and is suitable for NY MCLE credit for both newly-admitted attorneys and experienced attorneys. Further information about the NY CLE Rules is available at [www.nycourts.gov/Attorneys/CLE](http://www.nycourts.gov/Attorneys/CLE). To receive credit in other jurisdictions, a uniform MCLE certificate can be issued.

**Tuition Assistance | Discounts and Scholarships:** Any attorney experiencing financial hardship, may apply for tuition assistance to attend this program. Tuition assistance applies to the educational portion of the program only. Requests for financial assistance must be received via email by Monday, January 6, 2020. For further information, please visit [www.nysba.org/AnnualMeetingTuitionAssistance](http://www.nysba.org/AnnualMeetingTuitionAssistance).

**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 Cindy O’Brien at cobrien@nysba.org.

For overnight room accommodations, please contact the New York Hilton Midtown at 1-800-445-8667 and identify yourself as a member of the New York State Bar Association. You can book your room online at [www.nysba.org/am2020hotel](http://www.nysba.org/am2020hotel). 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 26th and January 27th is $179 per night. The discounted rate for January 28th through February 1st is $229 per night. Reservations must be made by December 22, 2019.

For questions about this program, please contact Lisa Bataille, Section Liaison at 518-487-5680 or lbataille@nysba.org. To register by phone, please call the Member Resource Center at1-800-582-2452.

**Register Online | www.nysba.org/AM2020**