**New York State Bar Association**

**2021 Annual Meeting**

Food, Drug & Cosmetic Law Section

**Hot Topics In FDA Law During The COVID Pandemic**

Monday, January 25, 20218:00 a.m. – 1:00 p.m.

5.0 MCLE Credits
0.5 Credits in Ethics, 4.5 Credits in Areas of Professional Practice

[www.nysba.org/am2021](http://www.nysba.org/am2021)

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

Agenda

8:00 a.m. – 8:10 a.m. Welcome and Introduction

Speaker:

Larissa C. Bergin, Esq.
Jones Day, Washington, D.C.

8:10 a.m. – 9:00 a.m. **Vaccines: Legal Mandates and Challenges**

This panel will discuss the state and federal, considerations raised when considering the distribution of vaccines from legal and ethical perspectives.

**Speakers:**

Mary Beth Morrissey, Esq., Ph.D., MPH
Fordham University, Global Health Care Innovation Management Center
White Plains, NY

Christopher C. Palermo, Esq.
Harris Beach PLLC
White Plains, NY

Jennifer Piatt, J.D.
Network for Public Health Law
Edina, MN

*0.5 Credits in Ethics 0.5 Credit in Areas of Professional Practice*

9:00 a.m. – 9:05 a.m. Break

9:05 a.m. – 9:55 a.m. **Keynote Address**

We are delighted to have the leadership from FDA’s Center for Biologic Evaluation and Research (CBER) to discuss the recent COVID Vaccine authorizations and the difference between an EUA v. BLA and the regulatory implications.

**Speaker:**

Julia Tierney, JD
Chief of Staff, FDA Center for Biologic Evaluation and Research
Silver Spring, Maryland

**Moderator:**

Larissa C. Bergin, Esq.
Jones Day
Washington, D.C.

*1.0 Credits in Areas of Professional Practice*

9:55 a.m. – 10:00 a.m. Break

10:00 a.m. – 10:50 a.m. **IP in a COVID World**

The topic includes COVID-related patents and trademarks, patent licensing, and enforcement (or waiver) of COVID-related intellectual property.

**Speakers:**

Jorge L. Contreras, J.D.
University of Utah, College of Law
Salt Lake City, UT

Laura R. Hammargren, Esq.
3M Company
St. Paul, MN

Bruce S. Weintraub, Esq.
Pfizer Inc., Intellectual Property Department, Legal Division
New York, NY

**Moderator:**

Janet B. Linn, Esq.
Tarter Krinsky & Drogin LLP
New York, NY

*1.0 Credit in Areas of Professional Practice*

10:50 a.m. – 10:55 a.m. Break

10:55 a.m. – 11:45 a.m. **Advertising During a Pandemic.  How Are Regulators Handling the Marketing of Products with Immune Claims In Light Of COVID?**

This panel will discuss how marketers are using unsubstantiated claims to push products promising benefits against COVID and how the regulators are responding.

                                                            This panel includes the FTC Assistant Director of the Division of Advertising Practices and the Vice President of Scientific & Regulatory Affairs for the Natural Products Association (formerly the Associate Director for Research and Strategy at the FDA’s Office of Dietary Supplement Programs)

**Speakers:**

Richard L. Cleland, Esq.
FTC Assistant Director of the Division of Advertising Practices, Bureau of Consumer Protection
Washington, D.C.

Daniel Fabricant, Ph.D.
CEO & President
Natural Products Association

Marc S. Ullman, Esq.

Of Counsel
Rivkin Radler LLP
New York, NY

**Moderator:**

Steven Shapiro, Esq.

Of Counsel
Rivkin Radler LLP
New York, NY

*1.0 Credit in Areas of Professional Practice*

11:45 a.m. – 11:50 a.m. Break

11:50 a.m. – 12:40 p.m. **Precision Medicine & Post-COVID Preparedness**

This panel will discuss next steps for the Precision Medicine Initiative, the benefits of precision medicine, and how to approach privacy and other challenges in precision medicine.

**Speakers:**

Kristie Kuhl, J.D.
Managing Partner, Finn Partners
USA

Ronald W. Lanton, III, Esq.
Lanton Law
Washington, D.C.

Robert B. McCray, Esq.
HIMSS Enterprise
Chicago, IL

Prasun J. Mishra, Ph.D.
President, American Association for Precision Medicine
Belmont, CA

*1.0 Credit in Areas of Professional Practice*

12:40 p.m. – 1:00 p.m. Closing Remarks

**Food, Drug, & Cosmetic Law Section Chair**Larissa C. Bergin, Esq., Jones Day, Washington, D.C.

**Program Chairs:**
Ronald W. Lanton, III, Esq., Lanton Law, Washington, D.C.

Janet B. Linn, Esq., Tarter Krinsky & Drogin LLP, New York, NY

Brian J. Malkin, Esq., McDermott Will & Emery LLP, Washington, D.C.

Christopher C. Palermo, Esq., Harris Beach PLLC, White Plains, NY

I. Steven Shapiro, Esq., Rivkin Radler LLP, New York, NY