

Annual Meeting of the Food, Drug and Cosmetic Law Section

Thursday, January 29, 2015
New York Hilton Midtown
1335 Avenue of the Americas, New York City

Program
8:30 a.m.
Nassau West, 2nd Floor

IMPORTANT INFORMATION

Under New York's MCLE rule, this program has been approved for a total of up to 4.5 credit hours, consisting of 3.5 credit hours in areas of professional practice and 1.0 in ethics for experienced attorneys only. **This course 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 of hardship, if approved, can receive a discount or scholarship, depending on the circumstances. Request for discounts or scholarships must be received **by January 14, 2015**. For more details, please contact Catheryn Teeter at the New York State Bar Association, One Elk Street, Albany, New York 12207 or cteeter@nysba.org.

Brian J. Malkin, Esq.
Section Chair and Program Chair
McGuireWoods LLP, Washington, DC

8:30 - 8:35 a.m.

Welcome
Brian J. Malkin, Esq.
Section Chair and Program Chair

8:35 - 9:25 a.m.

***Food Labeling, Patent Settlements, Forced Switches, and Gene Patents:
A Review of Recent Legal Developments in Antitrust, Intellectual Property,
and False Advertising Affecting Food and Drugs in 2014***

Cases to be discussed will include:

- *State of New York v. Actavis PLC and Forest Laboratories LLC*
- Hatch-Waxman settlements in light of *FTC v. Actavis*
- *POM Wonderful LLC v. Coca Cola Co.*
- Developments since *Association for Molecular Pathology v. Myriad Genetics*

Moderator:

Janet B. Linn, Esq.
Bleakley Platt & Schmidt, LLP
White Plains

Panelists:

Eric J. Stock, Esq.
Chief of Antitrust Bureau
NYS Office of the Attorney General
New York City

Christopher C. Palermo, Esq.
Bleakley Platt & Schmidt, LLP
White Plains

9:30 - 10:20 a.m.

FDA, LDT and IVD: The ABC's of Clinical Lab Test Development

Panelists will discuss the proposed guidance from the FDA on regulatory oversight of clinical laboratory developed tests, proposed comments from the NYSBA Health Law Committee on Medical Research and Biotechnology, and the current status of New York State oversight of such methods, as well as the impact of these regulatory systems on test manufacturers and laboratories.

Panelists:

Brian J. Malkin, Esq.
Section Chair and Program Chair
McGuireWoods LLP
Washington, DC

Dimitra Georganopoulou, Ph.D.
Vice President of Research & Development
Ohmx Corporation
Evanston, Illinois

Ann M. Willey, Ph. D., J.D.
Former Director, Office of Laboratory
Policy/Planning, NYS Health Dept.
Wadsworth Center;
Professor, Genetics & Public Health Law
Albany Law School
Albany

Harry Ostrer, M.D.
Director of Genetic and Genomic Testing,
Montefiore Medical Center;
Professor, Genetics, Pathology & Pediatrics,
Albert Einstein College of Medicine,
Yeshiva University
Bronx



10:25 - 10:35 a.m.

Coffee Break

10:35 - 11:25 a.m.

Through the Smoke: Attorney Ethics in Representing Clients in the Medical Marijuana Industry

On July 5, 2014, New York became the 23rd state with an effective medical marijuana law when the Compassionate Care Act (CCA) was signed. The CCA allows doctors to prescribe marijuana in a nonsmokable form to patients with serious ailments that are recognized by the state on a predefined but flexible list of conditions. However, when lawyers are asked to work for companies involved in the production or dispensing of medical marijuana, ethical issues often arise because marijuana is a controlled drug substance. This panel will take a look at the ethical issues raised and how firms are able to engage clients and the types of issues encountered by New York's medical marijuana rules.

Panelists:

Lisa Ayn Padilla, J.D., LLM
Estates for Lifemates
New York City

Catherine A. Sheridan, Esq.
Scalise Hamilton & Sheridan LLP
Scarsdale

John F. Dunn, Esq.
McGuireWoods LLP and McGuireWoods Consulting
Chicago, Illinois

11:30 - 12:45 a.m.

FDA and FTC: Complementary Schemes for Regulating Labeling, Advertising and Promotion of Medical Devices

The Federal Food, Drug and Cosmetic Act (FDCA) established FDA jurisdiction over the labeling of all devices and the advertising of restricted Class III devices. Meanwhile, the FTC has jurisdiction over the advertising for all other medical devices. This panel will address: the requirements for "restricted" and "prescription" devices, the differences between the drug and device portions of the FDCA, the requirements for combination products, and the different standards used by the agencies in their review of promotional materials. The speakers will also discuss current and future enforcement priorities and possible policy changes (e.g., due to citizens petitions and First Amendment considerations).

Moderator:

David S. Weinstock, Esq.
Bayer Corporation
Whippany, NJ

Panelists:

Richard L. Cleland, Esq.
Assistant Director
Division of Advertising Practices
Federal Trade Commission
Washington, DC

Deborah Wolf, J.D.
Regulatory Counsel
Center for Devices and Radiological Health
Food and Drug Administration
Washington, DC

12:50 - 1:00 p.m.

Annual Business Meeting

Brian J. Malkin, Esq.
Section Chair



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 Catheryn Teeter at 518-487-5573.



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. Room rates are \$259.00 for single/double occupancy. Reservations must be made by Monday, December 23, 2014. You also can reserve your overnight room on the web at www.nysba.org/15accomm.



For questions about this specific program, please contact Catheryn Teeter at 518-487-5573. **For registration questions only, please call 518-487-5621. Fax registration form to 518-463-5993.**

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