

Annual Meeting of the Food, Drug and Cosmetic Law Section

Thursday, January 30, 2014
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 credit hours in areas of professional practice and 1.5 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 15, 2014**. 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.

Bethany J. Hills, Esq.
Section Chair and Program Chair
Epstein Becker & Green, P.C., New York City

8:30 - 8:35 a.m.

Welcome
Bethany J. Hills, Esq.
Section Chair and Program Chair

8:35 - 9:25 a.m.

FDA Regulation: The Intersection of Policy and Politics, The Opportunities and Challenges for Innovation — Perspectives from Two Former FDA Officials

Muldoon was formerly an FDA Chief of Staff, overseeing operations and liaising with Senior leadership on key issues including the Affordable Care Act, Deepwater Horizon, food safety regulations and food borne outbreaks. Malkin is a former regulatory counsel at the FDA who specializes in the strategic analysis of how policy affects FDA and IP innovation.

Panelists:

Molly Muldoon
GMM Health Strategies
Washington, DC

Brian J. Malkin, Esq.
Frommer Lawrence & Haug LLP
Washington, DC

9:30 - 10:20 a.m.

The Role of the FDA Ombudsmen — Who They Are, What They Do and How They May Assist You

A former ombudsman shares his views on interacting with the FDA, lessons learned, pitfalls, complaints, dispute resolution and appeals. The new regulatory scheme for tobacco products will also be discussed.

Speaker:

Les Weinstein, Esq.
Former Ombudsman for The Center for Devices and Radiological Health (CDRH) and The Center for Tobacco Products (CTP)
Washington, DC

10:25 - 11:15 a.m.

Compounding Pharmacies: Regulatory Solutions to a National Health Crisis

Panelists:

Frederick H. Fern, Esq.
Harris Beach PLLC
New York City

John A. Murphy III, Esq.
Assistant Counsel
PhRMA
Washington, DC

Irving L. Wiesen, Esq.
Law Offices of Irving L. Wiesen, P.C.
New York City



11:15 - 11:30 a.m.	Coffee Break
11:35 - 12:50 a.m.	<i>Ethical Conflicts in Clinical Medicine and Research: Consent to DNA Screening, Research on Extremely Premature Infants and International Drug Trials</i> Noted bioethicist George J. Annas will discuss: • Guidelines on Genomic Screening of the American College on Human Genetics & Genomics • FDA Action regarding: 23 and Me Advertising • FDA and Personalized Medicine • FDA and the SUPPORT Study (consent and study design) • Revisions of the WMA's Declaration of Helsinki Speaker: George J. Annas, JD, MPH William Fairfield Warren Distinguished Professor and Chair Department of Health Law, Bioethics & Human Rights Boston University School of Public Health, School of Medicine and School of Law Boston, MA Moderator: David S. Weinstock, Esq. LifeCell Corporation Branchburg, NJ
12:50 - 1:00 p.m.	Annual Business Meeting Bethany J. Hills, 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 \$249.00 for single/double occupancy. Reservations must be made by Monday, December 23, 2013. You also can reserve your overnight room on the web at www.nysba.org/14accomm.



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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