

Speakers' Biographies

Michael McCaughan is a founding member of Prevision Policy LLC and an editor with *The RPM Report*, a leading publication focusing on the intersection between biopharmaceutical regulation, policy and business. Previously, he was Editor-in-Chief of FDC-Windhover's Biopharma Group, the leading publisher of news and information services for the pharmaceutical industry, including *The Pink Sheet*, *IN VIVO*, *The RPM Report*, *PharmAsia News*, and *The IN VIVO Blog*. Mr. McCaughan speaks frequently on regulatory and policy developments affecting the biopharmaceutical industry.

Robert A. Dormer is a founding member of the law firm Hyman, *Phelps & McNamara P.C.*, based in Washington, D.C. Before entering private practice, Mr. Dormer was Associate Chief Counsel for Enforcement and Associate Chief Counsel for Radiological Health at the U.S. Food and Drug Administration. He served at the FDA from 1976 to 1979. Prior to joining FDA, Mr. Dormer served as an attorney for the White House Special Action Office for Drug Abuse Prevention and the National Institute of Drug Abuse.

Kathleen M. Sanzo is a partner in and leader of the firm's FDA & Healthcare Practice, resident in the Washington, D.C. office of the law firm *Morgan, Lewis & Bockius LLP*. Her practice focuses on advising pharma and biotech companies on all regulatory and compliance matters of the FDA relating to drug and biologics manufacture, approval, marketing and distribution; pre-clinical and clinical testing; drug and device promotional and labeling issues; state and federal compliance issues; healthcare regulatory and enforcement matters of the Office of Inspector General of the Department of Health and Human Services. Following graduation from Duke University in 1979, Ms. Sanzo received her J.D. from Emory Law School in 1982, and her LL.M. from The George Washington University National Law Center in 1985, as the Food and Drug Law Institute Fellow.