MICHAEL A. SWIT, ESQ.

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PROFILE

Accomplished FDA attorney who has successfully guided pharmaceutical and medical device clients through the legal and regulatory challenges of getting to the market and ensuring compliance once approved. Expertise reflects a unique blend of private practice FDA legal and consulting experience, plus cutting-edge in-house service both in the drug and medical device industries. Corporate legal tenure included spearheading resolution – as general counsel of major generic drug firm -- of multiple Justice Department, FDA, and Congressional investigations due to actions of prior management. Deep knowledge of FDA policy on drugs, medical devices and diagnostic also gained from service as CEO of top publisher of specialty information products for FDA-regulated firms and on board of national federation devoted to treatments for rare disorders. Adept at transactional work and due diligence relating to FDA-regulated products and companies, as well as advertising and promotion, and clinical study issues.

PROFESSIONAL EXPERIENCE

Law Offices of Michael A. Swit *(11/2017 to present; 1/2012 to 3/2012),* San Diego

Counsel highly-regulated life sciences firms on an array of legal challenges arising due to the demands of complying with FDA's legal requirements to develop and market safe and effective drugs, biologics, medical devices, IVDs and other products. Representative engagements have included providing guidance on the 510(k) process, combination products, human & animal drugs, and the FDA's regulation of clinical research.

Illumina, Inc., Senior Director, Legal, Regulatory (*12/2014 to 11/2017)*, San Diego

Reporting to General Counsel, handled all legal issues impacting the regulatory, quality, and clinical challenges of the world's leading developer of gene sequencing technologies, including overseeing the firm's promotional review process, coordinating recalls, and clearing responses to governmental and customer audits. Focus also included developing new quality agreement templates, working closely with both quality assurance and the company's supply chain function. Implemented new clinical trial agreement templates, helping to launch clinical studies in the U.S., China, and other countries. Also worked closely with legal department colleagues to review regulatory, quality, and clinical terms in transactional documents.

Duane Morris LLP, Special Counsel (*3/2012 to 12/2014),* San Diego

Advised life sciences firms on FDA development strategies, compliance and enforcement initiatives, recalls and crisis management, submissions and related traditional FDA regulatory activities, labeling and advertising, and clinical research efforts for drug, biologic, device, IVD, and other life sciences companies, as well as those in the food and dietary supplement industries. Significant engagements included counseling on FDA emerging policy on mobile medical applications, coordinating recalls, Sunshine Act compliance, advising on regulatory aspects of diagnostics licensing agreements, and review of compliance status of U.S. subsidiary of overseas medical device maker, including assessment of 510(k) deviations and QSR requirement applicable to facility's operations.

The Weinberg Group Inc., Vice President *(11/2004 to 12/2011)*, San Diego

As a senior executive in Global Regulatory & Compliance practice, developed and ensured execution of a broad array of regulatory and other services to pharmaceutical, biologics and therapeutic biotech clients, both directly and through counsel. Practice focuses on drugs, biologics, and therapeutic biotech products, as well as device, IVD, and other life sciences companies, plus those in the food and dietary supplement industries. Key recent accomplishments included:

- Developing overall strategy leading to filing of New Drug Application (NDA) for innovative drug/device combination narcotic product for breakthrough cancer pain.
- Coordinating major remediation effort for device maker facing systemic QSR deficiencies; effort led to FDA follow-up inspection with just a single observation.

The Law Offices of Michael A. Swit, Partner *(6/2003 to 10/2004),* San Diego

Served as outside counsel to drug, device, biologics, biotech and dietary supplement firms, including serving as primary outside counsel on both FDA and general legal issues for a major specialty pharmaceutical client. Advised regulatory clients on a wide range of FDA matters including drug approvals, dietary supplement health claims, and regulatory issues in corporate acquisitions.

Heller, Ehrman, White & McAuliffe, LLP, Special Counsel, West Coast Member of FDA Regulatory Law Group within firm's Life Sciences National Practice Group *(5/2001 to 5/2003),* San Diego

- Served on detail for over six months as in-house regulatory vice president for biotech client involved with combination biologic/device product.
- Served as principal FDA counsel to major compounding pharmacy and led strategy to set up separate subsidiary to seek FDA approval of specialty compounding formulations.
- Worked with several IVD firms active in developing analyte-specific reagents and related analytical device equipment to allow shift from research to FDA commercial operations.
- Counseled extensively on clinical research issues, including drafting and negotiation of clinical research agreements, coordinating with transactional attorneys on FDA due diligence aspects of financings and commercial transactions; reviewing marketing and advertising materials; and advising on the Orphan Drug Act and related procedures.

McKenna & Cuneo, LLP (now: McKenna, Long & Aldridge), **Of Counsel**, *(3/1999 to 5/2001),* Washington, D.C. and San Diego

- Represented manufacturers, developers, and distributors of drugs, medical devices, food, cosmetics and dietary supplements, with a particular emphasis on the generic and brand name drug industries.
- Counseled on issues ranging from drug development and the clinical research process through formal product approval to post-marketing compliance issues.
- Spearheaded efforts to better serve firm's west coast FDA clients, as well as to expand the firm's services to the biomedical and life sciences communities.

Washington Business Information, Inc. (now t/a FDAnews.com)**, President & CEO** *(4/1994 to 9/1998),* Falls Church, Virginia

Led this medium-sized publisher of 10 business-to-business newsletters primarily focusing on federal regulation of pharmaceuticals, medical devices, and consumer products.

- Shared top executive responsibility with founder/owner.

- Managed editorial department and led all acquisition efforts of company.
- Heavily involved in all other aspects of firm's operations, including marketing, fulfillment, administration, and new product development.
- Introduced several new products to company's book line.
- Initiated development of company's first software products.

Par Pharmaceutical Inc., Corporate Vice President, General Counsel & Secretary *(1/1990 to 9/1993),* Chestnut Ridge, New York

Handled all legal matters for publicly-traded generic drug maker with annual legal budget exceeding $1 million. Brought in, as part of new management, to spearhead firm's defense of multiple and complex criminal investigations and civil litigations arising out of illegal actions by former company officers in securing FDA approval of company's products. Successes included:

- Coordinating company's cooperation with federal criminal and congressional investigations leading to a plea bargain agreement that allowed company to stay in business;
- Developing and oversight of first corporate ethics program.
- Negotiating deal ending company's three-year suspension from federal government contracting.
- Working closely with outside counsel on SEC and corporate governance matters;
- Handling all transactional activity from negotiating joint ventures to supplier agreements.
- Counseling regulatory affairs, quality assurance and operations departments on compliance with FDA, DEA, EPA and OSHA regulatory requirements.
- Handling sale of subsidiary's Indiana facility and favorably renegotiating leases on New York corporate offices.

McKenna, Conner & Cuneo (now: Dentons), **Associate Attorney** *(11/1988 to 1/1990),* Washington, D.C.

- Represented drug, medical device, food and cosmetic companies before FDA, DEA and in courts, with strong emphasis on new and generic drug approval processes and regulatory issues impacting regulated companies.
- Helped expand firm's food, drug and medical device practice by bringing existing clients and developing new ones, many still represented by the firm when he rejoined it in 1999.

Burditt, Bowles & Radzius (now defunct), **Associate Attorney** *(1/1984 to 11/1988)*
Food and drug lawyer for D.C. office of Chicago-based firm. Key activities included:

- Counseling on FDA's implementation of Waxman-Hatch Act, the 1984 generic drug law.
- Advising on regulatory and compliance issues, including FDA criminal investigations,
- Leading consortium of clients fighting FDA's withdrawal of new drug applications for generic versions of Persantine® (dipyridamole).

Walstad, Kasimer, Tansey & Ittig (now: Kasimer & Annino), **Associate Attorney** *(8/1982 to 1/1984),* Vienna, Virginia

- Litigated complex construction and government contract matters from initial investigation through trial.
- Counseled general contractors, subcontractors and architects/engineers at all levels of industry.

EDUCATION

Emory University School of Law **Atlanta, GA**
Doctor of Law **1982**
Best Brief, 1981; Jessup Moot Court Competition
American Jurisprudence Award, Contracts, 1980

Bowdoin College **Brunswick, ME**
A.B., History, *magna cum laude,* with High Honors in History **1979**
Honors Thesis – "Chinese Political Vacillations and the Sino-Soviet Dispute, 1956-1962: A Model for Conceptualizing the Dynamics of Contention"

BAR ADMISSIONS

- State Bar of California (2001; #217806)
- District of Columbia Bar (1984; #383469; inactive[1])
- Virginia State Bar (1982; #22406; inactive)
- Federal courts: Eastern District, VA; D.C. District Court; Fourth Circuit Court of Appeals

PROFESSIONAL AFFILIATIONS & AWARDS

Food & Drug Law Institute (FDLI**)**
Drug Information Association (DIA)
Regulatory Affairs Professionals Society (RAPS)
- Program Committee Member, RAPS Horizons Conference, 2007

BIOCOM (San Diego Regional Biotech Trade Association)
- Co-chair, FDA Committee (2002-2003)
- Planning Leader, Ethics Session and Clinical/Regulatory Workshops, CalBioSummit, 2003
- Member, CalBIO Program Committee, 2005

Orange County Regulatory Affairs (OCRA) Discussion Group
- Program Committee Member (2000 to present)
- Co-Chair, Drug Track, OCRA Annual Conference (2001, 2002, 2003)
- Co-Chair, Warning Letter Session (2005)
- Co-Chair, Generic Drug Session (2013)

San Diego Regulatory Affairs Network (SDRAN)
- Vice President, Programs, 2001 and 2002
- Planning Committee, 2003 IND Conference

[1] As his prior employer, The Weinberg Group, was not a law firm, Mr. Swit currently only maintains his bar membership in California. He is inactive in D.C. and Virginia.

EDITORIAL BOARDS

Food & Drug Law Journal, FDLI, Member, Editorial Advisory Board, 1991-1995.

Newsletter Industry Monitor, Board of Contributors. November 2000 to May 2001 (*publication closed*).

Good Clinical Practice: A Question & Answer Reference Guide, Expert Advisory Panel Member, Barnett International, 2011 to 2013.

PROFESSIONAL TEACHING

In addition to my past presentations detailed below, I co-designed and directed the first intensive course on the FDA *generic drug approval* process. Sponsored by the Center for Professional Advancement (CfPA), this 3-day course was held annually from 1989 to 2009, and in 2013 in the United States and on two occasions in Europe. Ceased association when I joined Illumina.

Since January 2013, I have taught, usually twice annually, a 2-day course on *Ensuring Compliance with FDA Requirements for Advertising of Drugs and Medical Devices*, sponsored by ComplianceOnline.

PUBLICATIONS

Co-author, "FDA Proposed Rule Would Require Generics to Update Label Warnings Even Before Branded Pharmaceuticals Do," Duane Morris Alert, November 12, 2013.

Co-author, "Mobile Medical Apps Guidance" and "Summary of FDA Mobile Medical Apps Guidance. Duane Morris Alert, October 4, 2013.

Co-author, "FDA Enforcement Action Against uChek: Does It Signal an Agency Wake-up Call for Non-compliant Mobile Medical Apps?" Duane Morris Alert, June 3, 2013.

Co-author, "Research-Related Payments and the Physician Payment Sunshine Act: How Reporting Works and What Applicable Manufacturers Should Consider," Duane Morris Alert, March 6, 2013; republished in Healthcare Law360, March 19, 2013.

Good Clinical Practices: A Review of FDA's Enforcement Activity. A Detailed Management Report. FDANews.Com. January 2013.

Co-author, "FDA Suspends Sunland, Inc.; Major Peanut Butter Producer Hit with First Food Facility Suspension Under the Food Safety Modernization Act of 2011," Duane Morris Alert, November 30, 2012; republished by *Life Sciences Law360*, December 12, 2012.

How the Park Doctrine Can Trigger Criminal and Civil Liability for Generic Drug Executives for Unknowing or Unintended FDA Violations. INNSight by GenericsWeb. November 2012.

AliveCor Veterinary ECG Model Paves FDA-Friendly Path to the Market. mHealth Newsletter. Duane Morris LLP. November 14, 2012.

D.C. Circuit Affirms HHS Power to Disqualify Corporate Officials Convicted of Misdemeanors Under the Responsible Corporate Official (RCO) Doctrine. Client Alert. Duane Morris LLP. August 8, 2012.

FDAAA – An Abbreviation in Search of Understanding: A Review of Selected Drugs and Biologics Provisions of the Food and Drug Administration Amendments Act of 2007. RAPS *Focus* 13(2), 27-33, 2007.

Collateral Consequences of a Criminal Crisis. Chapter in Communicating in a Healthcare Crisis, pages 207-214. Edited by Wayne L. Pines. Published by FDAnews, 2007.

Update on Generic Biologics. RAPS *Focus* 12(2), 30-35, 2007.

It's The Law -- The "de Novo" 510(k) Process and the Reclassification of Class III Devices. RAPS *Focus* 11(3), 32-34, 2006.

Hurdles on the Scientific Path to a Biogeneric Approval. RAPS *Focus* 10(3):43-46, 2005.

Western States Medical Center – Supreme Court Reins FDA in on Regulating Commercial Speech, Drug Delivery Technology, July 2002.

Supreme Court to Hear Tasini Case on Publishers' "Free" Right to Republish Print Articles Electronically. Newsletter Industry Monitor, March 2001.

Swit, M and Edson, J. *Electronic Signatures Act – Feast or Famine for FDA-Regulated Industries?* FDLI *Update*, January 2001.

Before Merging, Check for FDA Problems. National Law Journal, 4 September, 2000.

Getting Your Generic Drug Approved. Washington Business Information, Inc., Editor, 1995.

Profitability, Patient Populations and the Orphan Drug Act – or – "Should an Orphan Have the Right to More Than One Parent?" Food, Drug, Cosmetic and Medical Device Law Digest, New York State Bar Association, Food, Drug and Cosmetic Law Section, January 2002.

Swit, M. and Yingling, G. *Cosmetics Regulation*. Chapter in Treatise on Food & Drug Law, FDLI, 1991.

SPEAKING ENGAGEMENTS

Upcoming Presentations and Panel Discussions

Understanding the EU IVD Regulation. Moderator. Medical Devices West. February 4, 2017. Anaheim, California.

Delivered Presentations and Panel Discussions

FDA Regulation of Drug and Device Advertising & Promotion. Two-Day Course. ComplianceOnline. November 2017. Boston.

Combination Products, Orphan Drugs and OTC Drugs. SDRAN RAC Review Course. July 2016. San Diego.

Generic Drugs and Biosimilars. SDRAN RAC Review Course. June 2016. San Diego.

FDA Regulation of Drug and Device Advertising & Promotion. Two-Day Course. ComplianceOnline. March 2017. San Francisco.

FDA Regulation of Drug and Device Advertising & Promotion. Two-Day Course. ComplianceOnline. November 2016. Boston.

A Practical Look at Legal & Regulatory Issues in Promoting Diagnostics and Related Products. Food & Drug Law Institute (FDLI) Advertising & Promotion Conference. September 27, 2016. Washington, D.C.

Combination Products, Orphan Drugs and OTC Drugs. SDRAN RAC Review Course. July 20, 2016. San Diego.

The Sunshine Act: Understanding the Essentials of Compliance. DIA Annual Meeting. A Tutorial. June 26, 2016. Philadelphia, Pennsylvania.

Generic Drugs and Biosimilars. SDRAN RAC Review Course. June 16, 2016. San Diego.

Alternative Approaches to FDA Approval for Drug and Device Firms. OCRA/FDA Annual Educational Conference. May 5, 2016. Irvine, California.

FDA Regulation of Drug and Device Advertising & Promotion. Two-Day Course. ComplianceOnline. March 2016. San Francisco.

Biosimilars: Beginning a Conversation. Panel Discussion at JADPRO LIVE Conference. November 7, 2015. Phoenix, Arizona.

Dietary Supplements, Combination Products, and Veterinary Medicine. SDRAN RAC Review Course. July 22, 2015. San Diego.

GCP Enforcement Trends Lessons Learned from FDA Inspections of Sponsors, Sites and IRBs. An FDANews Webinar. July 21, 2015.

ANDAs, OTCs, and Orphan Drugs. SDRAN RAC Review Course. June 24, 2015. San Diego.

FDA Regulation of Mobile Medical Applications. OCRA/FDA Annual Educational Conference. June 3, 2015. Irvine, California.

FDA Regulation of Biosimilars. San Diego Intellectual Property Law Association. February 26, 2015.

Alternative Approaches to FDA Approval for Drug and Device Companies. San Diego Regulatory Affairs Network. February 12, 2015.

Key FDA Challenges in Bringing Orphan Drugs to the Market in the U.S. SABPA 4th Annual Medical Devices & Diagnostics Summit. February 7, 2015. San Diego.

Alternative Approaches to FDA Approval for Drug and Device Companies. A Compliance2go Seminar. January 29, 2015.

FDA Regulation of Drug and Device Advertising & Promotion. Two-Day Course. ComplianceOnline. November 6-7, 2014. Boston.

Clinical Trial Liability Concerns for Small Companies. Arena International's 2nd Annual Outsourcing in Clinical Trials Southern California, September 23-24, 2014. La Jolla, CA

FDA Regulation of Drug and Device Advertising & Promotion. Two-Day Course. ComplianceOnline. September 11-12. 2014. Chicago.

U.S. -- History of Regulation. OCRA RAC Study Group (U.S.). August 2, 2014. Irvine, CA.

Labeling/Advertising and Promotion, Import/Export, & Enforcement Actions. OCRA RAC Study Group (U.S.). August 2, 2014. Irvine, CA.

Overview of FDA Regulation (with a Medical Device Emphasis). DreamIt Health Philadelphia 2014. August 11, 2014. Virtual presentation.

FDA Enforcement of GCP Requirements: A Review of Key Warning Letters (2010-2012). DIA GCP QA Community. Webinar. July 24, 2014.

Leaping the Valley of Death: Keys to Going from the Lab to the Clinic. DIA Annual Conference, June 17, 2014. San Diego.

Understanding the Sunshine Act. DIA Annual Conference. Tutorial. June 15, 2014. San Diego.

Executing a Recall – Legal Implications and Risks Associated with Product Corrections and Removal. CBI Product Recalls Summit. June 11, 2014. San Diego.

Under the Watchful Eye of FDA: Legal and Regulatory Aspects of FDA Warning Letters. Duane Morris Webinar. April 30, 2014.

Global Regulatory Considerations in Clinical Trials. National Institutes of Health In-House Seminar. March 26, 2014. Bethesda, MD.

FDA Regulation of Drug and Device Advertising & Promotion. Two-Day Course. ComplianceOnline. March 6-7. 2014. San Diego.

Orphan Drug Regulation. 2nd Annual Orphan Drugs Research & Commercialization Conference. GTCBio. Feb. 20-21, 2014. San Diego, CA

U.S. Regulation of BioSimilars. BioSimilars And Follow-On Biologics 2014 Americas Conference. February 10-12, 2014. Philadelphia.

Understanding the 510(k) Process. Compliance2Go Webinar. January 29, 2014.

Moderator, Entrepreneur Panel. 11th BVS La Jolla Biotech Day. Biotech Vendor Services. December 11, 2013. San Diego.

FDA Regulation of Drug and Device Advertising & Promotion. Two-Day Course. ComplianceOnline. November 18-19, 2013. Boston.

Digital Health and FDA. Commercializing Software IP: High Tech, Digital Health & Education Conference. Jointly Sponsored by UCSF, UC Berkeley, and the LES Silicon Valley Chapter. November 13, 2013. Berkeley, CA.

FDA Regulation of Social Media. MetricStream Webinar. November 6, 2013.

An Overview of Issued FDA Warning Letters in the Clinical Research Realm. Compliance2Go Webinar. October 26, 2013.

Review of FDA's Final Guidance on Mobile Medical Applications. DIA Annual Conference Program Committee Audio Conference. October 17, 2013.

FDA Enforcement in the Clinical Research Arena. ACRP San Diego Chapter. September 19, 2013. San Diego.

Regulation of Combination Products, Dietary Supplements, and Veterinary Products. Lecture at SDRAN RAC Review Course. September 4, 2013. San Diego.

FDA Regulation of Social Media. Compliance2Go Webinar. August 21, 2013.

Generic Drug Approvals. Center for Professional Advancement 3-Day Course. August 13-15, 2013. New Brunswick, New Jersey.

Regulation of Generic, OTC and Orphan Drugs, and Cosmetics. Lecture at SDRAN RAC Review Course. August 7, 2013. San Diego.

The Gamechanger: The Impact of the Generic Drug User Fee Act. ACI Generic Drugs Legal & Regulatory Summit. July 17 & 18, 2013. New York City.

Creative Strategies in Dealing With FDA. PSC Creative Learning Webinar. July 10, 2013.

Informed Consent: Promise, Pledge, Contract or Platitude? DIA Annual Conference. June 27, 2013.

The De Novo 510(k) Process. DIA Annual Conference. June 26, 2013.

Regulatory, Clinical and Quality Challenges in Contracting and Due Diligence: The Forgotten Keys to Biopharma Transactions. DIA Annual Conference. June 2013.

FDA Enforcement. DIA Annual Conference. Tutorial. June 23, 2013.

FDA Regulation of Social Media. OCRA Annual Conference. June 12, 2013. Irvine, Ca.

Dietary Supplements -- Overview of Key FDA Issues. Compliance2Go. Webinar. May 30, 2013.

Regulatory Convergence: Impact of FCC, HIPAA/Privacy and FDA on Mobile Health and Medical Devices. Fx Conferences Audio Conference. May 21, 2013.

Combination Products -- Regulatory & Quality Challenges. Joint ASQ/RAPS SF Area Chapter Annual Conference. May 17, 2013. Santa Clara, California.

Clinical Trials: Regulatory and Privacy Issues. THE BLUEPRINT™ Webinar Series, jointly sponsored by the California Healthcare Institute and Duane Morris LLP. May 14, 2013.

FDASIA -- Challenges & Opportunities for Drug and Medical Device Companies. Compliance2Go. Webinar. April 16, 2013.

Regulatory Pitfalls in Product Development. THE BLUEPRINT™ Webinar Series, jointly sponsored by the California Healthcare Institute and Duane Morris LLP. April 16, 2013.

Regulatory & Quality Challenges of Virtual Drug Development; Or How to Avoid Getting in Bed with the Devil. Strategies for Success in Virtual Drug Development. A BDC/BVS/PGC 2000 Conference. April 15, 2013. San Diego.

FDASIA -- Update on FDA Implementation. American Society for Quality, San Diego Chapter. March 12, 2013.

Creative Strategies in Dealing with FDA. Compliance2Go. Webinar. February 21, 2013.

Responding to FDA Inspections & Warning Letters. Compliance2Go. Webinar. February 7, 2013.

FDA Regulation of Drug and Device Advertising & Promotion. Course Instructor, Two-Day Course. ComplianceOnline. January 24-25, 2013. San Francisco.

FDASIA -- Challenges and Opportunities for FDA-Regulated Industries. OCRA. December 4, 2012, Irvine, CA.

FDA and Social Media. Compliance2Go. Webinar. November 27, 2012.

FDA Update: Impact of FDASIA and the Federal Elections. SDRAN. November 15, 2012, San Diego.

Legal and Regulatory Update – Health Care Reform and FDA Developments. BIOCOM. November 13, 2012. San Diego.

Regulation of Dietary Supplements, Combination Products, and Veterinary Products. SDRAN RAC Review Course. August 29, 2012. San Diego.

Regulation of ANDAs, Orphan Drugs, OTC Drugs and Cosmetics. SDRAN RAC Review Course. August 1, 2012. San Diego.

Responding to FDA Inspections and Warning Letters. FxConferences Audio Conference. July 10, 2012.

FDA Enforcement. Pre-conference Tutorial at DIA Annual Conference. June 24, 2012. Philadelphia.

Biosimilar Regulation and CMOs. FierceBiotech Webinar. June 26, 2012.

Leaping the Valley of Death: Keys to Successfully Going From the Lab to the Clinic for Pharmaceutical Products: Drug Information Association (DIA) Annual Conference, Session Chair. June 26, 2012. Philadelphia.

How Do You Look in Stripes? FDA Enforcement Today. Joint FDA/Orange County Regulatory Affairs (OCRA) Annual Conference. June 7, 2012. Irvine, CA.

The 510(k) Premarket Notification Process. FDLI Introduction to Medical Devices Conference. June 5, 2012, Palo Alto, CA.

Crisis Management for Life Sciences Executives. FxConferences Audio Conference. May 22, 2012.

Internet Issues for Regulatory Professionals -- FDA Regulation of Social Media. Orange County Regulatory Affairs Discussion Group. April 17, 2012, Irvine, CA.

FDA – Creative Strategies in Dealing with The Agency. Panel Discussion. March 26, 2012. San Diego.

Biosimilars -- Wave of the Future or Child of The Privileged Few? Licensing Executives Society San Diego Chapter. February 21, 2012.

The de novo 510(k) Process -- The Impact of the New 2011 FDA Guidance. FxTranslations Audio Conference. February 15, 2012.

Crisis Management for Regulatory Professionals. Regulatory Affairs Professionals Society, Rising Leaders Program. Audio Conference. December 15, 2011.

FDA Enforcement Activities in Clinical Trials Arena. FxConferences Audio Conference. November 3, 2011.

Get to the Clinic on Time. LARTA NIH-CAP Commercialization Workshop, November 1, 2011. Los Angeles

An Overview of Issued FDA Warning Letters: What Happened and What Can be Learned. ExL Pharma's 2nd Quality Oversight of Clinical Vendors Conference. October 18, 2011. Washington, D.C.

Regulatory Challenges in Executing Global Clinical Studies. The Conference Forum's 2nd Annual Executing Global Clinical Trials Conference. September 15, 2011, Philadelphia.

Regulation of Dietary Supplements. Lecture at SDRAN RAC Review Course. August 25, 2011. San Diego.

Regulation of Generic, OTC and Orphan Drugs, and Cosmetics. Lecture at SDRAN RAC Review Course. July 27, San Diego.

Quality Aspects of Due Diligence for Biopharmaceutical Transactions. DIA Annual Conference. June 21, 2011, Chicago.

FDA Enforcement. Tutorial at DIA Annual Conference. June 19, 2011, Chicago.

Biosimilars. Orange County Regulatory Affairs Discussion Group/FDA Annual Educational Conference. June 9, 2011, Irvine, CA.

Regulatory, Clinical and Quality Challenges in the Regulation of Combination Products. The Weinberg Group Inc. Webinar, May 18, 2011.

Clinical Trial Registries. Association of Clinical Research Professionals Annual Conference. May 3, 2011, Seattle.

IRB Liability. Association of Clinical Research Professionals Annual Conference. April 30, 2011, Seattle.

Overview of FDA Issues for In-Vitro Diagnostics. Southern California Biotech Assn. April 13, 2011, Costa Mesa, CA.

Challenges of Orphan Drug Regulation. The Weinberg Group Inc. Webinar, February 23, 2011.

FDA Enforcement. The Weinberg Group Inc. Webinar, December 15, 2010.

FDA Enforcement and Compliance. Introduction to Medical Device Law. FDLI. November 16, 2010. Costa Mesa, CA.

BioSimilars. RAPS Annual Conference. October 25, 2010, San Jose, CA.

FDA Enforcement. RAPS Annual Conference. October 25, 2010, San Jose, CA.

FDA Regulation of Combination Products. IIR Combination Products Conference, September 23, 2010, Baltimore, MD.

Regulation of Generic, OTC and Orphan Drugs, and Cosmetics. Lecture at SDRAN RAC Review Course. August 11, 2010, San Diego.

Regulatory, Quality & Clinical Due Diligence: The Oft-Overlooked Keys to Successful Transactions. The Weinberg Group Inc. Webinar, June 23, 2010.

Informed Consent – Pledge, Platitude or Contract? DIA Annual Conference, June 16, 2010, Washington, D.C.

FDA Enforcement. Tutorial at DIA Annual Conference. June 13, 2010, Washington, D.C.

FDA Enforcement. ACI FDA Enforcement Conference. May 25, 2010, Philadelphia.

510(k) Process. BayBio Breakfast Meeting. May 11, 2010, Palo Alto, CA.

Review of Key 2009 Cases. FDLI Annual Conference. April 22, 2010, Washington, D.C.

CAPA Program. OCRA, March 10, 2010, Irvine, CA.

Drug Development in Today's Regulatory Environment. NanoTecNexus Webinar. March 4, 2010.

Ethical Issues for Clinical Trials. ACI International Clinical Trials Conference. February 24, 2010, New York.

FDA Enforcement. FXTranslations Webinar. December 9, 2009.

How to Respond to a 483. SoCalBio FDA Audit Preparedness Workshop. SoCalBio. December 3, 2009, Irvine, CA.

FDA Enforcement. Amylin Pharmaceuticals In-House Lecture. December 1, 2009, San Diego.

Regulatory Pitfalls in Drug Development. American Chemical Society, San Diego Chapter. November 18, 2009, San Diego.

Drug Safety. SDRAN/OCRA Drug Development Conference. November 4, 2009, Carlsbad, CA.

Webinar on Biosimilars. RAPS. October 21, 2009.

FDA Law. Keck Graduate Institute. October 7, 2009, Pomona, CA.

FDA Enforcement. MAGI West Coast Clinical Trials Conference. October 6, 2009, San Diego.

Biosimilars. Foley Life Sciences Day. September 30, 2009, San Diego, CA.

ANDA vs. 505(b)(2): When and Why. The Weinberg Group Inc. Webinar, September 30, 2009.

Regulatory Update. Ophthalmic Drug and Delivery Summit. Pharmaceutical Education Associates. September 22, 2009, San Diego.

FDA Enforcement. The Weinberg Group Inc. Webinar. September 9, 2009.

Course on Generic Drug Approvals. In-House at Teva Parenterals. September 1 and 2, 2009, Irvine, CA.

Regulation of Generic, OTC and Orphan Drugs, and Cosmetics. Lecture at SDRAN RAC Review Course. August 12, 2009, San Diego.

Drug Development. Biotech Vendors Services. July 22, 2009, San Diego.

Informed Consent. DIA Annual Meeting. June 25, 2009, San Diego.

Clinical Trial Registries. DIA Annual Meeting. June 24, 2009, San Diego

How to Respond to a 483. SoCalBio FDA Enforcement Workshop. June 12, 2009, Los Angeles.

Biosimilars. Orange County Regulatory Affairs (OCRA)/FDA Annual Educational Conference. June 10, 2009, Irvine, CA.

Drug Safety. Orange County Regulatory Affairs (OCRA)/FDA Annual Educational Conference. June 10, 2009, Irvine, CA.

Corporate Health Panel. Orange County Regulatory Affairs (OCRA)/FDA Annual Educational Conference. June 9, 2009, Irvine, CA.

Regulatory Developments for Drug Delivery. Third Annual Drug Delivery Summit. Arrowhead Conferences. May 14, 2009, San Francisco.

Drug Safety: Perspectives on Industry's Duties in the Post-Vioxx Age. FDLI Annual Conference. April 22, 2009, Washington, D.C.

The Future of Biosimilars, BioGenerics, Follow-on Biologics – A Rose by any Other Name? New York Biotechnology Association Annual Meeting. April 21, 2009, New York.

Crisis Management for Senior Regulatory Professionals. RAPS Horizons Conference. April 2, 2009, San Francisco.

FDA Enforcement Issues for Clinical Trials. ACI International Clinical Trials Conference. February 26, 2009, New York.

Roadmap to Emerging Regions -- Clinical Trials in Developing Countries. ACI International Clinical Trials Conference. February 26, 2009, New York.

Overview of FDA Issues for In-Vitro Diagnostics. Southern California Biotech Assn. February 13, 2009, Pomona, CA.

Overview of FDA Issues for Cardiovascular Devices. Southern California Biotech Assn. January 28, 2009, Laguna Hills, CA.

The Forgotten Keys to Bio-Pharma Transactions -- Regulatory, Clinical & Quality Challenges in Contracting and Due Diligence. Cambridge Healthcare Institute Second Annual Bridging the Business Development /Alliance Management Interface Conference. November 6, 2008, Boston.

Regulatory Aspects of Ophthalmic Drug Development. Pharmaceutical Education Associates Ophthalmic Drug Delivery Conference. September 22-24, 2008, San Diego

Regulation of Generic, OTC and Orphan Drug and Cosmetics. Lecture at SDRAN RAC Review Course. July 3, 2008, San Diego.

FDA Enforcement. Tutorial at Drug Information Association (DIA) Annual Meeting. June 21, 2008, Boston.

Panel Discussion on Generic Biologics. Licensing Executives Society, San Diego Chapter. May 20, 2008, San Diego.

IRB Liability. Association of Clinical Research Professionals (ACRP) Annual Meeting. April 28, 2008, Boston

Clinical Trial Registries – Panacea or Pablum? Association of Clinical Research Professionals (ACRP) Annual Meeting. April 27, 2008, Boston

Clearing the US and EU Regulatory Path to Product Approval. Swedish American Chamber of Commerce. Swedish-American Entrepreneurial Days. April 9, 2008, San Diego.

Crisis Management for Regulatory Professionals. Regulatory Affairs Professionals Society (RAPS) Horizons Conference. March 28, 2008, San Francisco.

FDA Regulatory Considerations for the Biomedical Start-Up. Israeli Life Sciences Fellows Program**,** Merage Foundation**.** February 27, 2008, Irvine, CA.

The Food & Drug Administration Amendments Act of 2007 – Understanding the Drug Provisions. San Diego Regulatory Affairs Network. February 26, 2008, San Diego.

Keynote Presentation on FDA Regulatory Developments. Pharmaceutical Education Associates' 2nd Annual Skin Summit Conference, February 20, 2008, Philadelphia.

Regulatory Considerations for Medical Device Firms. NIH-CAP Program. LARTA, February 12 and 13, 2008, via webinar.

Panel Discussion on Biosimilars. BIOCOM Life Sciences Venture Network, February 6, 2008, San Diego.

International Drug Development. Pharmaceutical Education Associates Pipeline to Product Conference, November 30, 2007, Alexandria, VA.

Regulatory Pitfalls in Drug Development. Pharmaceutical Education Associates Pipeline to Product Conference, November 30, 2007, Alexandria, VA.

Compliance in Clinical Research. Eighth Annual Pharmaceutical Regulatory Compliance Congress and Best Practices Forum, November 8, 2007, Washington, D.C.

FDA Regulatory Strategies for Fast Growing Companies. LARTA NIH-CAP Commercialization Training Workshop, October 17, 2007, Marina Del Rey, CA.

Keynote Presentation on FDA Regulatory Developments. Pharmaceutical Education Associates Annual Nasal Drug Delivery Conference, October 4, 2007, Philadelphia.
Legislative Initiatives. RAPS Annual Conference, September 24, 2007, Boston.

Combination Products – Perspectives on FDA Regulation. BVS Orange County Biomedical Day, September 19, 2007, Costa Mesa, CA.

FDA Regulatory Developments. Keynote Presentation at Pharmaceutical Education Associates Annual Ophthalmic Drug Delivery Conference, September 10, 2007, San Diego.

Regulation of ANDAs, OTC Drugs, Orphan Drug, and Cosmetics. Lecture at SDRAN RAC Review Course., August 14, 2007, San Diego.

Clinical Trial Registries. Presented at the University of Southern California Regulatory Science Masters Program, July 27, 2007, Los Angeles.

Clinical Trial Registries. Presented at the American Conference Institute Managing Legal Risks in Clinical Trials Conference, July 16, 2007, San Francisco.

FDA Enforcement. Tutorial at the DIA Annual Meeting, June 17, 2007, Atlanta.

Keynote Presentation on FDA Regulatory Developments. Presented at the Pharmaceutical Education Associates Annual Drug Delivery Conference, June 6, 2007, San Diego.

The Impact of the Democratic Congress on the Biotech Industry. Moderated Panel at the BayBio Annual Meeting, April 26, 2007, San Francisco.

Guilty Until Proven Innocent: A Look at IRB Liability. ACRP Annual Conference, April 23, 2007, Seattle.

Panel Discussion on Generic Biologics. FDLI Annual Conference, April 12, 2007, Bethesda, MD.

Lifecycle Management for Pharmaceutical Companies: A Generic Perspective. Presented at the RAPS Horizons Conference, March 29, 2007, San Francisco.

Non-Patent Market Exclusivity for Pharmaceuticals Under the Drug Price Competition and Patent Term Restoration Act of 1984 ("Waxman-Hatch"). San Diego County Bar Association, IP Section, March 19, 2007, San Diego.

FDA Regulatory Considerations for the Biomedical Start-Up. Israeli Life Sciences Fellows Program**,** Merage Foundation**,** February 21, 2007, Irvine, CA.

Alternative Approaches to Drug/Biologics Approvals. SDRAN, November 28, 2007, San Diego.

Informed Consent: Promise, Pledge, Platitude or Contract? RAPS Annual Conference, October 18, 2006, Baltimore.

State Regulation of Clinical Trials. 5th National Conference on Managing Legal Risks in Structuring & Conducting Clinical Trials, American Conference Institute., September 27-29, 2006, Boston.

Regulation of ANDAs, Orphan Drugs, OTCs & Cosmetics. Lecture at SDRAN RAC Review Course, August 23, 2006, San Diego.

Key Considerations in Developing Clinical Protocols for U.S. and EU Approval. IVT Medical Device Conference, August 15-17, 2006, San Francisco.

Medical Device Advertising. IVT Medical Device Conference, August 15-17, 2006, San Francisco.

Strategies in Designing Clinicals for Fixed-Combination Drugs. DIA Annual Meeting, June 19, 2006, Philadelphia.

FDA Enforcement. Tutorial at DIA Annual Meeting, June 18, 2006, Philadelphia.

Problems Faced by Device Companies in Navigating FDA Promotional Issues. Panel Discussion at the Wilson Sonsini Goodrich & Rosati Medical Device Conference, June 15, 2006, San Jose, CA.

Clinical Trial Registries: Balm or Bane? OCRA/FDA Annual Educational Conference., May 23, 2006, Irvine, CA.

Product Recalls: A Panel Discussion. 3rd Annual Medical Device Quality Congress. Management Roundtable and FDANews, May 3, 2006, San Diego.

Using Clinical Studies to Support Claims for 510(k) Devices. RAPS Advertising, Promotion and Labeling Conference, May 2, 2006, Denver.

The Future of Compliance Governance. FDLI Annual Conference, April 7, 2006, Washington, D.C.

Crisis Management for the Senior RA Professional. RAPS Horizons Conference, March 30, 2006, San Diego.

FDA Regulatory Considerations in Launching Products. Women In Technology International (WITI) San Diego Conference, February 14, 2006, San Diego.

FDA Regulatory Considerations for the Biomedical Start-Up. NIH-CAP Workshop, LARTA, October 7, 2005, Newport Beach, CA.

The "De Novo" 510(k) Process and the Reclassification of Class III Devices. 510(k) Workshop, Medical Device Manufacturers Association, October 1, 2005, Boston.

Specific Payments of Other Sorts -- Understanding SPOOS. Clinical Trials – Controlling Costs Conference, Institute for International Research (IIR), September 28, 2005, Philadelphia.

Regulatory Considerations in Combination Product Development. Panel Discussion at the Drug Delivery & Technology Conference, Strategic Research Institute, September 27, 2005, New Brunswick, NJ.

Specific Payments of Other Sorts – Understanding SPOOS and Clinical Research. DIA Annual Meeting, June 29, 2005, Washington, DC.

FDA Enforcement – What You Need To Know To Avoid – Or Respond. Tutorial at DIA Annual Meeting, June 26, 2005, Washington, DC.

Warning Letters. Session Moderator at OCRA/FDA Joint Educational Conference, June 15-16, 2005, Irvine, CA.

Abbreviated New Drug Applications. FDLI Introduction to Biotechnology Conference, June 14-15, 2005, San Francisco, CA.

California Stem Cell Research and Cures Act. RAPS West Coast Conference & Exhibition, March 22-24, 2005, San Francisco, CA.

Challenges for FDA-Regulated Companies in Addressing Current Corporate Responsibility Trends. Workshop on Corporate Responsibility Issues for Regulatory Affairs Professionals. RAPS West Coast Conference & Exhibition, March 22-24, 2005, San Francisco, CA.

The "De Novo" 510(k) Process and the Reclassification of Class III Devices. 510(k) Workshop. sponsored by the Medical Device Manufacturers Association, March 8, 2005, Costa Mesa, CA.

Strategies in Designing Clinicals for Fixed-Combination Drugs. Combination Drug Development Conference sponsored by Barnett International Conferences, March 7-8, 2005, San Diego, CA.

Recalls by FDA-Regulated Companies. Products Liability for FDA-Regulated Firms sponsored by FDLI, January 26-27, 2005, Washington, DC.

Sarbanes-Oxley – Implications for Life Sciences Companies. SDRAN, January, San Diego, CA.

Financial and Legal Implications of Risk Management: The Broader Picture. Developing a Risk Management Strategy: A Hands-On Workshop sponsored by the Pharmaceutical Education & Research Institute (PERI), November 10-11, 2004, Washington, DC.

Managing Financial Disclosure in Clinical Trials. West Coast Drug Development Forum: Challenges in the Development of Therapeutic Products, DIA, October 25-27, 2004, San Francisco, CA.

FDA Enforcement and Clinical Research. Annual Education Symposium, North Texas Chapter, ACRP, October 16, 2004, Dallas, TX.

Specific Payments of Other Sorts -- Understanding SPOOS and Clinical Research. RAPS Annual Meeting, October 12, 2004, Washington, DC.

Can We Do Better? Innovation in Clinical Trial Agreements. 14th International Contracting & Negotiating Clinical Trials, Strategic Research Institute, September 27-28, 2004, La Jolla, CA.

Case Study: The Generic Drug Scandal. Ethics in Regulatory Affairs Seminar, OCRA, August 30, Irvine, CA.

Regulation of Generic Drugs, OTCs, Orphan Products and Cosmetics, Lecture at SDRAN RAC Review Course, August 18, 2004, San Diego, CA.

FDA Enforcement – What You Need To Know To Avoid – Or Respond. Tutorial at DIA Annual Meeting, June 2004, Washington, DC.

Legal and Regulatory Concerns in the Sourcing of FDA-Regulated Products, Components & Services. Center for Professional Advancement In-House Seminar on Vendor & Supplier Qualification, Siemens, January 2004, Concord, CA.

FDA Enforcement and Compliance. SDRAN, October 2003, San Diego, CA.

State Regulation of Clinical Research. Clinical Track of Annual Meeting of the Society of Quality Assurance, October 2003, Washington, DC.

FDA Regulation of Advertising and Promotion. OCRA, September 2003, Irvine, CA.

Regulation of Generic Drugs, OTCs, and Orphan Products. Lecture at SDRAN RAC Review Course, September 10, 2003, San Diego, CA.

What Every Clinical Director Must Know About FDA Regulatory Compliance. Tutorial at DIA Annual Meeting, June 2003, San Antonio, TX.

Recent Developments in Generic and OTC Drug Regulation. Annual Joint Educational Conference , OCRA/FDA, June 2003, Irvine, CA.

FDA Legal and Regulatory Strategies for Start-up Companies. BioMedTrak Program, Tech Coast Angels, March 2003, La Jolla, CA.

To CRO or Not to CRO. Moderator and organizer of the Workshop on Use of Contract Research Organizations in Biomedical Research at the SDRAN IND Conference, February 2003.

FDA's "Combination" Product Policy. Scripps-BIO 5th Annual Drug Development Conference, February 2003, La Jolla, CA.

Financial Disclosure in Clinical Research. San Diego Chapter, ACRP, January 2003, San Diego, CA.

MDUFMA – A Review of Key Provisions. Program on MDUFMA, OCRA, December 2002, Irvine, CA.

"Specific Payments of Other Sorts:" Sifting Through the SPOOS. Barnett-Parexel Conference on Financial Disclosure, November 2002, Philadelphia, PA.

Legal Issues in Drug Sampling. Audioconference sponsored by FDAnews.com, November 2002.

Financial Disclosure Issues in Clinical Research. FDA Regulatory Law Group Breakfast Briefing, entitled "What You Need to Know Before Beginning Your Clinical Trial," sponsored by Heller, Ehrman, White & McAuliffe, October 2002, San Diego, CA.

FDA Regulation of Dietary Supplements, University of Southern California Masters Program on Regulatory Affairs, September 2002, Los Angeles. CA.

Current Legal Issues Impacting the Generic Drug Industry. Course on Biotechnology Law, Practicing Law Institute, September 2002, San Francisco, CA.

The Collateral Legal Consequences of Violating the Food, Drug, and Cosmetic Act – or Why Crime Doesn't Pay. Association of Medical Diagnostic Manufacturers (AMDM) IVD Conference, September 2002, Del Mar, CA.

Legal Strategies in Sourcing of FDA-Regulated Goods and Services – Seeking a Win-Win Relationship with Your Contract Manufacturing Organization. IBC Conference on "Scale-Up: From Bench to Clinic", August 2002, San Diego, CA.

Where FDA Leaves Off, Another Agency Picks Up. Joint FDA Regulatory Law Group/Environmental Law Group Breakfast Briefing, entitled "Beyond FDA – What Every Biomedical Company Must Know About Regulation by Other Federal and State Agencies," sponsored by Heller, Ehrman, White & McAuliffe. June 2002, Menlo Park, CA.

What Every Clinical Director Must Know About FDA Regulatory Compliance. Tutorial at DIA Annual Meeting, June 2002, Chicago, IL.

Strategies for Success in Dealing with FDA Advisory Panels. Joint FDA/OCRA Educational Conference, June 2002, Irvine, CA.

FDA Regulation of Pre-Approval Marketing and Advertising. FDA Regulatory Law Group Breakfast Briefing sponsored by Heller, Ehrman, White & McAuliffe. April 2002, San Diego, CA.

FDA Regulation of the Importing and Exporting of Drugs and Devices. OCRA Conference on Import/Export, March 2002, Irvine, CA.

The De Novo Petition Process for Medical Devices. FDA Regulatory Law Group Breakfast Briefing sponsored Heller, Ehrman, White & McAuliffe, November 2001, San Diego, CA and Seattle, WA.

Ethics in Clinical Research. Panel Member, Scripps Institute/BIO Joint Conference on Clinical Research, October 2001, San Diego, CA.

FDA Legal and Regulatory Aspects of Good Clinical Practice. Society of Quality Assurance (SQA) Annual Meeting, October 2001, San Diego, CA.

Regulation of Generic Drugs. Lecture at SDRAN RAC Review Course, October 2001, San Diego, CA.

FDA Advisory Committees – A Regulatory Overview. Program on FDA Advisory Committees, SDRAN, September 2001, San Diego, CA.

Legal Consequences of Violating the Food, Drug, and Cosmetic Act. Program on Legal Aspects of Recalls, San Diego Regulatory Affairs Network (SDRAN), July 2001, San Diego, CA.

Legal and Regulatory Strategies in Sourcing of Products, Components and Services for FDA-Regulated Companies. Biotechnology Industry Organization (BIO) Annual Conference, June 2001, San Diego, CA.

FDA Regulation of Imports. Food, Drug and Cosmetic Division of the American Society for Quality (ASQ) Conference on "Business Strategies within The Boundaries of the Law," March 2001, Anaheim, CA.

FDA Legal and *Regulatory* Considerations in Drug Development. Institute for International Research (IIR) Conference on Drug Discovery, March 2001, San Diego, CA.

The Collateral Legal Consequences of Violating the Food, Drug, and Cosmetic Act – or Why Crime Doesn't Pay. OCRA Conference on Risk Management, Recalls and Crisis Management, March 2001, Costa Mesa, CA.

Indemnification in Clinical Research. DIA Good Clinical Practice Conference, February 2001, Tucson, AZ.

International Harmonization of Regulatory Requirements for Biotechnology Products. Drug Information Association (DIA) Conference on Biotechnology, February 2001, Dana Point, CA.

Indemnification in Clinical Research. San Diego Chapter of ACRP, November 2000, San Diego, CA.

Functional Foods: Claims & Labeling. Dietary Supplements Conference, RAPS, November 2000, Pasadena, CA.

An Overview of Global Harmonization of the Regulation of Pharmaceuticals and Medical Devices. "Regulatory 101" Seminar, RAPS, November 2000, Pasadena, CA.

Understanding How to Source Information on FDA Regulatory Activities. Panel member, Discussion Presentation at San Diego State University Masters Program on Regulatory Affairs, September 2000. San Diego.

The Institutional Review Board (IRB) and the Clinical Investigator – Legal/Regulatory Requirements and Perspectives. FDA/Orange County Regulatory Affairs (OCRA) Discussion Group Annual Educational Conference, July 2000, Irvine, CA.

Investigational Device Exemptions (IDE)s. Introduction to Device Law Course, FDLI, January 2000, San Diego, CA.

Device Registration and Listing. Introduction to Device Law Course, FDLI, January 2000, San Diego, CA.

Overview of FDA Regulation of Medical Devices. Introduction to Device Law Course, FDLI, January 2000, San Diego, CA.

Federal Civil and Criminal Laws – How They Impact Medical Device and Drug Companies and Their Employees. Compliance with U.S. Regulatory Requirements: FDA Inspections Seminar, RAPS, January 2000, Santa Monica, CA.

Indemnification in the Clinical Research Context. Fall Seminar of the Charlotte Chapter of the Association of Clinical Research Professionals (ACRP), October 1999, Charlotte, NC.

Legal and Regulatory Aspects for Purchasers of Drug Components, Drugs, and Devices. Course on Vendor & Contract Supplier Qualification, CfPA, October 1999, New Brunswick, NJ.

Global Harmonization Issues and the Protection of Intellectual Property. Salud Americas 99 Conference on Latin America's Health Sector Policies, Regulation, and Investment Climate, Institute for the Americas, October 1999, Philadelphia, PA.

Challenges to Generic Drug Approvals. IBC Generic Drug Conference, September 1999, Washington, DC.

Violations and Enforcement. Introduction to Drug Law Course, FDLI, June 1999, Washington, DC.

Drug Imports and Exports. Introduction to Drug Law Course, FDLI, June 1999, Washington, DC.

Potential Legal Consequences of Product Recalls. FDLI Recalls Conference, March 1999, Washington, DC.

Boosting Awareness of Generics Quality Compared to Brand Name Drug. IBC Generic Drug Conference, November 1998, San Diego, CA.

Health Care Reform and the Generic Drug Industry. IBC Generic Drug Conference, January 1994, Orlando, FL.

Health Care Reform and the Generic Drug Industry. IBC Generic Drug Conference, October 1993, Philadelphia, PA.

FDA Enforcement: A Perspective from Industry on How to Prepare for and Respond to FDA's Knock on Your Door. RAPS Annual Conference, October 1993, Washington, D.C..

Impact of FDA's Regulatory Activities on the Generic Drug Industry: Market Share Through Approvals vs. Market Share Through Attrition. International Business

Communications (IBC) Conference on Generic Drugs, Competitive Strategies for Pharmaceutical Companies, October 1992, Philadelphia, PA.

Determining the Regulatory Status of a Drug. Seminar on New Drug Applications, RAPS, January 1990, Washington, DC.

FDA Regulation of Advertising. Center for Professional Advancement Conference. December 1989, Palm Beach, Florida.

Importing Drugs. McKenna & Cuneo in-house seminar for Embassy Officials on Importing-FDA Regulated Products, July 1989, Washington, DC.

Impact of Generic Drug Scandal. Regulatory Affairs Professional Society (RAPS) Seminar, July 1989, Washington, DC.

Exclusivity. Advanced Drug Law Course, FDLI, October 1988 and May 1989, Washington, DC.

Orphan Drug Exclusivity. Understanding the Orphan Drug Act Seminar, FDLI, October 1988, Washington, DC.

The Development of Good Manufacturing Practices Under the Food, Drug, and Cosmetic Act. Good Manufacturing Practices in the Drug and Allied Industries course sponsored by CfPA, June 1987, St. Louis, MO.