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ERIKA LIETZAN

PROFESSIONAL EXPERIENCE

University of Missouri School of Law, Columbia, MO — 2014 – present

- Associate Professor of Law (food and drug law, administrative law, and intellectual property)

Covington & Burling, LLP, Washington, DC — 2005 – 2014

- Partner (2006–2014), Special Counsel (2005–2006), and Associate (1996–2002) — 1996 – 2002

Pharmaceutical Research and Manufacturers of America, Washington, DC — 2002 – 2005

- Assistant General Counsel

United States Court of Appeals, 11th Circuit — 1995 – 1996

- Law Clerk for the Honorable Gerald B. Tjoflat

EDUCATION

Duke Law School (JD with High Honors) — 1995

- Order of the Coif
- Senior Editor, LAW & CONTEMPORARY PROBLEMS

University of California – Los Angeles (MA, History) — 1992

- Area of Focus: Intellectual History

University of North Carolina – Chapel Hill (BA, History with Honors) — 1990

- Phi Beta Kappa

PUBLICATIONS

Academic Law Reviews and Peer-Reviewed Journals

- The Political Economy of the Hatch-Waxman Amendments, 49 SETON HALL L. REV. __ (2018)
- Paper Promises for Drug Innovation, 25 GEO. MASON. L. REV. __ (2018)
- The Drug Innovation Paradox, 83 MO. L. REV. ___ (2018)
- A Solution in Search of a Problem at the Biologics Frontier, 2018 U. ILL. L. REV. ONLINE 19

- The Uncharted Waters of Competition and Innovation in Biological Medicines, 44 FLA. ST. L. REV. 1 (2017)
- The Law of 180–Day Exclusivity, 71 FOOD & DRUG L. J. 327 (2016) (with Julia Post)
- The Myths of Data Exclusivity, 20 LEWIS & CLARK L. R. 91 (2016)
- Biosimilar Monoclonal Antibodies: The Scientific Basis for Extrapolation, 15 EXPERT OPIN. BIOL. THER. 1633 (2015) (with Huub Schellekens, Jaap Venema, and Freddy Faccin)
- A New Framework for Assessing Clinical Data Transparency Initiatives, 18 MARQUETTE INTELL. PROP. L. REV. 33 (2014)
- Thoughts on Preemption in the Wake of the Levine Decision, 13 J. HEALTH CARE L. & POL'Y 226 (2010) (with Sarah Pitlyk)
- An Unofficial Legislative History of the Biologics Price Competition and Innovation Act of 2009, 65 FOOD & DRUG L. J. 671 (2010) (with Krista Carver and Jeff Elikan)
- A New History and Discussion of 180–Day Exclusivity, 64 FOOD & DRUG L. J. 335 (2009) (with David Korn and Shaw Scott)
- Current Regulatory and Legal Considerations for Follow–On Biologics, 84 CLIN. PHARM. & THER. 633 (2008) (with Richard Kingham)
- Issues in the Interpretation of 180–Day Exclusivity, 62 FOOD & DRUG L. J. 49 (2007) (with David Korn)
- Advisory Committees at FDA: The Hinchey Amendment and "Conflict of Interest" Waivers, 39 J. OF HEALTH LAW 415 (Fall 2006)
- 2004 Update: 180–Day Exclusivity Under the Hatch–Waxman Amendments to the Federal Food, Drug, and Cosmetic Act, 59 FOOD & DRUG L. J. 459 (2004)
- A Brief History of 180–Day Exclusivity under the Hatch–Waxman Amendments, 59 FOOD & DRUG L. J. 287 (2004)
- Disgorgement for Violation of the Good Manufacturing Practice Requirement of the Federal Food, Drug, and Cosmetic Act, 58 FOOD & DRUG L. J. 149 (2003) (with Elizabeth Walsh)
- An Overview of Canada's Personal Information Protection and Documentation Act for Pharmaceutical and Device Manufacturers, 57 FOOD & DRUG L. J. 205 (2002) (with John Fuson)
- Tax Exemptions and the Establishment Clause, 49 SYRACUSE L. REV. 971 (1999)
- Law and the Wisconsin Idea, 47 J. LEGAL EDUC. 297 (Sept. 1997) (with Paul Carrington)
- Anonymous Campaign Literature and the First Amendment, 21 N.C. CENTRAL UNIV. LAW J. 144 (1995)
- Outpatient Civil Commitment in North Carolina: Constitutional and Policy Concerns, 58 LAW & CONTEMP. PROBS. 251 (Spring 1995)

Books and Book Chapters

- FDA Regulation of Biosimilars, chapter 22 in FDA in THE 21ST CENTURY: THE CHALLENGES OF REGULATING DRUGS AND NEW TECHNOLOGIES (Lynch & Cohen, eds.) (Columbia University Press: 2015) (with Henry Grabowski)

- Federal Regulation of Clinical Research, chapter 2 in MEDICAL BIOTECHNOLOGY: PREMARKET AND POSTMARKET REGULATION (ABA, 2015) (with Afia Asamoah)
- Medical Biotechnology: Premarket and Postmarket Regulation (editor) (ABA, 2015)
- Biosimilars, chapter 15 in FOOD AND DRUG LAW AND REGULATION, 3d Ed. (FDLI, 2015) (with Emily Alexander and Laura Sim)
- Biosimilar Law and Regulation: An Essential Guide, FDLI MONOGRAPH SERIES (Vol. 2, Number 5) (2011)
- Biotechnology and the Law (editor) (ABA, 2007)
- The Importance of the Court Decision in Pearson v. Shalala to the Marketing of Food and Dietary Supplements in the United States, in REGULATION OF FUNCTIONAL FOODS AND NUTRACEUTICALS: A GLOBAL PERSPECTIVE (Blackwell Press & Institute of Food Technologists Press, 2004) (with Peter Hutt and Elizabeth Walsh)

Other Publications

- How Colombia's Biosimilar Regulation Departs from International Norms, 41 PAN AMERICAN J PUB HEALTH 1 (2017) (letter to editor)
- The innovation paradox: why complex drug research is not being rewarded, LIFE SCIENCES INTELLECTUAL PROPERTY REVIEW (July 12, 2017)
- A Second Look at the CREATES Act: What's Not Being Said, 17 Fed. Soc. Rev. 38 (2016)
- Bill favoring generic drugs will handicap medical innovation, THE HILL (Nov. 15, 2016) (op ed)
- Pharmacy Compounding after the DQSA, 26:4 HEALTH LAWYER (2014) (with Mingham Ji)
- The Evolving Regulation of Medical Device Clinical Trials in the USA, JOURNAL OF MEDICAL DEVICE REGULATION (May 2013) (with Emily Alexander)
- Biosimilar Naming: How Do Adverse Event Reporting Data Support the Need for Distinct Nonproprietary Names for Biosimilars?, FDLI FOOD & DRUG POLICY FORUM, Vol. 3, Issue 6 (Mar. 2013) (with Laura Sim and Emily Alexander)
- The U.S. Biosimilar Pathway Nearly Three Years Later, GXP LIFELINE (Dec. 2012) (with Laura Sim)
- How Should FDA Use Naming and Labeling to Communicate Information about Biosimilars?, FDLI FOOD & DRUG POLICY FORUM, Vol. 1, Issue 21 (Nov. 2011) (with Michael Labson and Emily Alexander)
- Biosimilar regulation: important considerations and global developments, PLC LIFE SCIENCES HANDBOOK 2011 (Thomson Reuters) (with Peter Bogaert and Laura Sim)
- Paving the biosimilars pathway: the US and beyond, SCRIP PHARMA LAW (Dec. 13, 2010) (with Emily Alexander)
- FDA in Federal Court: The Agency's Ten–Year Record, FDLI Update (Feb. 2008) (with Megan Quinlan)
- The Food and Drug Administration Amendments Act of 2007, 9 BIO–SCIENCE L REV 39 (2008) (with Michael Labson and Shaw Scott)

- Learned Intermediary Doctrine: Required by Law?, LAW360 (July 17, 2007) (with Michael Imbroscio, Paul Schmidt, Michael Labson, and Miriam Guggenheim)
- Clinical Trial Registries & Clinical Trial Results Databases, FDLI UPDATE (Sept. 2005)
- FDA in Federal Court: Statistics on the Agency's Record in Recent Years, FDLI UPDATE (July/August 2002) (with Elizabeth Walsh)
- The Medicine Equity and Drug Safety Act of 2000, FDLI Update (March/April 2001)

Blogging

- OBJECTIVE INTENT, objectiveintent.wordpress.com
- NOTICE & COMMENT, a blog from the Yale Journal on Regulation and the ABA Section of Administrative Law & Regulatory Practice

PROFESSIONAL AFFILIATIONS

American Law Institute (since 2006)

Food & Drug Law Institute

American Society of Law, Medicine, and Ethics

American Association for the History of Medicine

American Health Lawyers Association

FDA Alumni Association (honorary member)

American Intellectual Property Lawyers Association

Center for the Protection of Intellectual Property (CPIP), Scalia Law School, George Mason University

PROFESSIONAL SERVICE AND AWARDS

Husch Blackwell Distinguished Faculty Award 2018

Best Lawyers in America

- FDA Law Since 2013
- Biotechnology Law Since 2007
- Washington Biotechnology Lawyer of the Year 2013

Food and Drug Law Institute

- Academic Programs Committee 2018
- Drug and Biologics Committee 2014 – 2017
- Austern Writing Awards Committee, Long Papers 2013 – 2014
- Board of Directors 2008 – 2012
- Food & Drug Law Journal, Editorial Advisory Board 2004 – 2008

Microbiota Transplantation: Recommendations for a Regulatory Framework — Working Group: NIH/NIAID Grant: R21 AI119633–01 (PI: Diane Hoffmann) 2015 – 2018

Thomas Edison Innovation Fellowships 2016 – 2018

American Bar Association: Various positions including, within the Section of Science and Technology, Chair of the Biotechnology Committee (five years), Chair of the Life Sciences Division (five years), and Section Council (four years) 2001 – 2017

Leonardo Da Vinci Fellowship Research Grant 2016

Institute of Medicine: Consultant to Committee on Strategies for Responsible Sharing of Clinical Trial Data 2014

American Health Lawyers Association: Life Science Practice Group, Regulatory Group Co–Chair 2007 – 2012

UNIVERSITY SERVICE

University of Missouri

- Committee on Residency for Tuition Purposes 2016 – present

University of Missouri School of Law

- Diversity Committee 2017 – present
- Clerkship Committee 2014 – present
- Career Services Committee 2016 – present
- Dean Search Committee 2016 – 2017

PEER REVIEW

Yale Journal of Health law, Policy, and Ethics; Generics and Biosimilars Initiative Journal; Mercatus Center

PRESENTATIONS

Congressional Testimony

- "Antitrust Abuses and the FDA Approval Process," Statement before the Committee on the Judiciary's Subcommittee on Regulatory Reform, Commercial, and Antitrust Law, U.S. House of Representatives (July 27, 2017)

Academic Workshops, Conference, and Lectures

- "Effective Incentives to Develop New Uses of Established Drugs," Webcast for the NYS Science & Technology Law Center at Syracuse University College of Law (March 29, 2018)
- "The Political Economy of the Hatch-Waxman Amendments," Scalia Law School, George Mason University (March 28, 2018)

- "Direct-to-Consumer (DTC) Genetic Testing and Population Health," Frontiers in Precision Medicine III, University of Utah (March 16, 2018)
- "New Indications for Approved Drugs: Changing the U.S. System," Clinical Innovation: Fair and Effective Incentives for New Uses of Established Drugs, University College London & Georgetown Law (Feb. 9, 2018)
- "Regulation of Pharmaceuticals in the United States," UFR Droit et Sciences Économique et Politique, l'Université de Bourgogne (Dec. 10, 2017)
- "Vers une adaptation de la propriété intellectual à des stratégies de recherche et developpement – Perspective americaine," Conference on "Le droit des affaires pharmaceutiques" hosted Maison des Sciences de l'Homme, Universite de Bourgogne, Dijon, France (Dec. 8, 2017)
- "Paper Promises for Drug Innovation," Fifth Annual Fall Conference, Center for Protection of Intellectual Property, Antonin Scalia Law School, George Mason University (Oct. 13, 2017)
- "Sandoz v. Amgen," 8th Annual Supreme Court IP Review, Chicago–Kent College of Law (Sept. 28, 2017)
- "The Challenges of Encouraging Long Term Innovation," Fourth Annual CPIP Summer Institute (July 12, 2017)
- "The Drug Innovation Paradox," Fourth Annual CPIP Summer Institute (July 11, 2017)
- "The New Role of the Administrative State in the Innovation Economy," Roundtable co–sponsored by the Center for the Study of the Administrative State (CSAS) and the Center for the Protection of Intellectual Property (CPIP), Antonin Scalia Law School, George Mason University (May 22, 2017) (discussant)
- Economics Institute for Law Professors, The Henry G. Manne Program on the Law and Economics, Antonin Scalia Law School, George Mason University (May 13 – 21, 2017) (participant)
- "The Drug Innovation Paradox," St. Louis University School of Law Faculty Workshop (Nov. 16, 2016)
- "A Framework for Thinking about Biologics Innovation and Competition," 39th Annual Health Law Professors Conference (June 6, 2016)
- "Set Shifting to the New Biologics System," Law and Biomedicine Colloquium, S.J. Quinney College of Law at the University of Utah (Feb. 8, 2016)
- "The Myths of Data Exclusivity," BioIP New Scholars Workshop, Boston University School of Law (May 7, 2015)
- "The Myths of Data Exclusivity," Washington University School of Law (Mar. 4, 2015)
- "A New Framework for Assessing Clinical Data Transparency Initiatives," Marquette Law School (Apr. 4, 2014)
- "Reverse–Payment Settlements: Thoughts on the Regulatory Context and the Scope of the Patent," 36th Annual Health Law Professors Conference, Seton Hall University School of Law (Jun. 7, 2013)
- "Trade Secrets and the BPCIA," The Georgetown University Law Center Conference: The Changing Patent Landscape (Mar. 11, 2013)

- "Biosimilars: Recent Developments and Hot Issues," Indiana University Robert H. McKinney School of Law Annual CLE Program: Health Care and Market Forces: Current Issues (Oct. 9, 2012)
- "Thoughts on the Impact of Wyeth v. Levine on the Preemptive Effect of FDA–Approved Labeling," Emerging Issues in Food & Drug Law, University of Maryland School of Law (Nov. 16, 2009)
- "Scientific and Educational Activities" and "Introduction to FDA & Overview of New Drug Approval Process," Seton Hall University Law School, Health Care Compliance Certification Program (June 20, 2006)
- "Bioethics Panel," Third Annual Conference on Public Service and the Law, University of Virginia School of Law (Feb. 16, 2002)

Testimony Before Agencies and Education/Training of Regulators

- "A Global Perspective on Regulatory Standards and Expectations for Biosimilar Biological Medicines," Presentation to CFDA, Beijing, China (Jun. 18, 2013)
- "Approval Pathways and Exclusivity Consequences for Protein Products and Other Biologics," FDA–CDER In–House Training (Dec. 11, 2012)
- "Biosimilar Substitution in the EU," Presentation to SFDA, Beijing, China (Nov. 5, 2009)
- "Exclusivity Issues Surrounding Therapeutic Biotech–Derived Proteins," FDA–CDER In–House Training (Nov. 29, 2007)
- "Exclusivity Issues Surrounding TBPs and Drugs, and, Follow–On Protein Products," FDA–CDER In–House Training (June 14, 2007)
- "Post–Approval and Post–Licensure Issues – Biologics vs. Drugs," FDA–CDER In–House Training (Sept. 28, 2006)
- "DTC Advertising, the First Amendment & Learned Intermediary Doctrine: A General Introduction to the Legal Framework," West Virginia Cost Containment Council (Oct. 20, 2005)

Expert Witness Testimony

- Fera Pharmaceuticals, LLC v. Akorn, Inc., Case No. 12-cv-07694-LLS (S.D.N.Y.)
- In re Androgel Antitrust Litigation (No. II), Case No. 1:P09–MD–2084 (TWT) (N.D. Ga.) (all cases) & Federal Trade Commission v. Actavis (Case No. 1:09–CV–955–TWT) (N.D. Ga.)
- GlaxoSmithKline LLC & Smithkline Beecham (Cork) Ltd. v. Teva Pharmaceuticals, 1:14–cv–00878 (D.Del.) and GlaxoSmithKline LLC & Smithkline Beecham (Cork) Ltd. v. Glenmark Pharmaceuticals, 1:14–cv–00877 (D. Del.)
- In Re Gabapentin Litigation, Master Docket No. 00–CV–2931 (D.N.J.)
- Eli Lilly & Co. et al. v. 8 PM Chemist Limited et al., HC07C No. 02877 (UK High Court of Justice, Chancery Division, Intellectual Property)

Other Speaking Engagements

- Featured on "This Week in Healthlaw" (Podcast hosted by Professors Terry and Pasquale) (Aug. 1, 2017)

- "Law and Labels: A Regulatory View of Biosimilars," Wolters Kluwer Clinical Drug Information Webinar (Oct. 30, 2015)
- "Biosimilar Labeling," DIA Biosimilars 2014 Conference (Sept. 18, 2014)
- "Something to Talk About: Biosimilars Naming, Interchangeability, and Substitution – an FDLI Webinar" (Mar. 10, 2014) (moderator)
- "Naming and Labeling of Biosimilars," DIA Biosimilars 2013 (Nov. 14, 2013)
- "The AbbVie Citizen Petition," 14th Annual Business of Biosimilars, IIR USA (Oct. 16, 2013)
- "Pliva v. Mensing: Consequences for FDA Labeling and Product Liability," Presentation to BIO General Counsels Committee (Oct. 2012)
- "Interchangeability of Biosimilars: the Legal Perspective," DIA/FDA Biosimilars Conference: Guidances, Science, and BsUFA (Sept. 12, 2012)
- "Fourth Annual Pharmaceutical Reimbursement and Market Access Conference: Biosimilars," Q1 Productions (Aug. 27, 2012)
- "Insider Insight on PDUFA V: How Will the Changes Impact You?," FDA News Webinar (Aug. 7, 2012)
- "Understanding the U.S. Biosimilar Pathway in 2012: An In–Depth Look at the Debate and Its Implications," FDA News Webinar (June 28, 2012)
- "FDA's Guidance on Biosimilars: Understanding the Impact on Patent Prosecution and Litigation," webinar for Intellectual Property Owners Association IP Chat Channel (Mar. 22, 2012)
- "Biosimilars Master Class," American Conference Institute, FDA Boot Camp (Mar. 21, 2012) (also conference co–chair)
- "Hatch–Waxman and BPCIA Overview," American Conference Institute, FDA Boot Camp (Mar. 20, 2012) (also conference co–chair)
- "Track & Trace / Pedigree," Presentation to the PhRMA Law Section Executive Committee (Feb. 2012)
- "The Basics: Understanding and Working with FDA," American Conference Institute, FDA Boot Camp (Sept. 22, 2011) (also conference co–chair)
- "A Global Perspective on Regulatory Standards and Expectations for Biosimilar Biological Medicines," FDLI's US–China Food and Drug Law: Ensuring Quality, Improving Safety, Expanding Access (June 14, 2011) (Beijing, China)
- "Generic Drugs and Biosimilars in the United States: An Overview of the Regulatory / Intellectual Property Provisions," PhRMA / SINO–PhIRDA Workshop (June 14, 2011) (Beijing, China)
- "Nomenclature & Naming: Public Health Considerations and Emerging Global Standards," FDLI/DIA's The Future of Biosimilars in the US (May 5, 2011)
- "REMS Compliance Obligations and Enforcement Risks for Sponsors and Third Parties," DIA Annual Meeting (June 14, 2010)
- "Risk Evaluation and Mitigation Strategies (REMS): We've come so far...we have so far to go," 2010 BIO International Convention (May 5, 2010)

- "The Nature of the Approval Process," American Conference Institute, FDA Boot Camp (Sept. 15, 2009)
- "The Basics: Understanding and Working with FDA and the New Administration," American Conference Institute, FDA Boot Camp (July 21, 2009)
- "Preemption of Product Liability Litigation on FDA–Regulated Products," BIO International Convention (May 19, 2009)
- "Follow–on Biologics Update: International Approaches and Developments in the US," Presentation to BIO–NJ (May 7, 2009)
- "The New Drug Approval Process: Basic Concepts and Regulatory Approval Pathways," FDLI's Introduction to Drug Law and Regulation Workshop (Feb. 3, 2009)
- "The FDA Regulatory Process—A Practical Primer," AHLA Fundamentals of Health Law Institute (Nov. 11, 2008)
- "The Nature of the Drug & Biologic Approval Processes," American Conference Institute, FDA Boot Camp (Sept. 22, 2008)
- "The Nature of the Drug & Biologic Approval Processes" and Conference Chair, American Conference Institute, FDA Boot Camp (Mar. 31 – Apr. 1, 2008)
- "Follow–on Biologics: Current Legislative Models," 2008 RAPS Horizons Conference (Mar. 28, 2008)
- "Clinical Trial Registries and Results Databases: State Law Developments," American Conference Institute, Managing Risks in Structuring and Conducting Clinical Trials (Feb. 26, 2008)
- "Follow–on Biologics: How the Current Legislative Models Could Change the Pharma Industry," The Center for Business Intelligence (Feb. 5, 2008)
- "Expanded Access to Investigational Drugs: Legal Overview," Presentation to BIO General Counsels' Committee (Nov. 2, 2007)
- "The FDA Revitalization Act and Related Legislative Proposals: Understanding Their Impact on Pharmaceutical Patent Life Cycles," American Conference Institute, Maximizing Pharmaceutical Patent Life Cycles (Oct. 24, 2007)
- "The FDA Amendments Act of 2007: How Will the Largest Changes to FDA in a Decade Affect You?" FDA News Teleconference (Oct. 17, 2007)
- "The Nature of the Drug & Biologic Approval Processes" and Conference Chair, American Conference Institute, FDA Boot Camp (Sept. 25 – 26, 2007)
- "Patent and Non–Patent Exclusivity," American Conference Institute, PhRMA/Biotech Patent Boot Camp (Sept. 19, 2007)
- "European Regulation of Biosimilars," National Consumers League Stakeholder Forum, Biologics: The Pathway to Biosimilar Products (Sept. 18, 2007)
- ALI–ABA, Emerging Issues in Biotechnology Law (Sept. 6 – 7, 2007) (conference chair)
- "Patent and Non–Patent Exclusivity," American Conference Institute, PhRMA/Biotech Patent Boot Camp (June 22, 2007)
- "Biotechnology and the Law: A Primer — Part Two," ABA CLE Teleconference (June 7, 2007)

- "Regulatory Climate, Developments, and Challenges in the Pharmaceutical/Biotech Industry," Utah Life Sciences Symposium (May 17, 2007)
- "The Nature of the Drug & Biologic Approval Processes," American Conference Institute, FDA Boot Camp (May 15, 2007)
- "Regulation of Biological Product Marketing," FDLI's Introduction to Biotechnology Law and Regulation Workshop (May 8, 2007)
- "The Nature of the Drug & Biologic Approval Processes," American Conference Institute, FDA Boot Camp (Mar. 26, 2007)
- "Clinical Trial Disclosure and Transparency: Ensuring Compliance With Current Law and Responding to Proposals for Reform," American Conference Institute, Managing Legal Risks in Structuring and Conducting Clinical Trials (Feb. 27, 2007)
- "The Nature of the Drug & Biologic Approval Processes," American Conference Institute, FDA Boot Camp (Sept. 18, 2006)
- "Drug and Device Recalls: Nuts, Bolts, and Consequences," AHLA Life Sciences Law Institute (May 2, 2006)
- "The Nature of the Drug & Biologic Approval Processes," American Conference Institute, FDA Boot Camp (Mar. 27, 2006)
- "Guidance from PhRMA: Clinical Trials," American Conference Institute, Managing Legal Risks in Conducting and Promoting Clinical Trials (Feb. 27, 2006)
- "Regulation of Drug Manufacturing," FDLI, Introduction to Drug Law and Manufacturing (Jan. 24, 2006)
- "PhRMA Code: Guiding Principles for Marketing Your Pharmaceutical or Biotech Products," BioWest (Nov. 8, 2005)
- "Using Intellectual Property to Combat Bioterrorism," 20th Annual Intellectual Property Law Conference, ABA (Apr. 15, 2005) (moderator)
- "Drug Importation Policy," Association of Clinical Research Professionals, Annual Meeting (Apr. 4, 2005)
- "Counterfeit Pharmaceuticals: The Dangers of Importation," American Conference Institute Conference on Importation, Reimportation, and Counterfeiting (Nov. 9, 2004)
- "Pharmaceutical Balance of Powers: Do the Hatch–Waxman Reforms Restore Equilibrium?" 19th Annual Intellectual Property Law Conference, ABA (Apr. 2, 2004)
- "Importation of Foreign Drugs: An Update," Drug Information Association (Mar. 24, 2004)
- "Working at the Frontiers of Law & Science: Applications of the Human Genome" (ABA, AMA, AALS) (Oct. 2003) (program committee)
- "The First Amendment and Commercial Speech," Regulatory Affairs Professionals Society (RAPS), Advertising, Promotion, and Labeling of Health Care Products (Feb. 2003)
- The Food and Drug Administration Confronts Homeland and National Security: A Workshop of the RAND Center for Domestic and International Health Security & the RAND Center for Military Health (Dec. 19, 2002)

- "Dry Powder Inhalers: An Attorney's View of the FDA Guidelines," 11th Annual Management Forum in London (June 28, 2002)
- "The OxyContin 'Crisis' – Who's To Blame?," Health Policy Discussion, American Enterprise Institute (Feb. 7, 2002)
- "Voluntary Children's Chemical Safety Testing Program," Half–Day Panel Discussion on Chemical Right–to–Know Initiatives (ABA, Section of Environment, Energy, and Resources) (Apr. 2000) (moderator)

BAR MEMBERSHIP

Missouri, District of Columbia, and North Carolina

ADMISSIONS

U.S. Supreme Court; U.S. Courts of Appeals for the Federal Circuit, D.C. Circuit, Eleventh Circuit, and Tenth Circuit; North Carolina Supreme Court; United States District Court, District of Columbia