Erika Lietzan
Curriculum Vitae

Associate Professor of Law
University of Missouri School of Law
313 Hulston Hall
Columbia, MO 65203
Email: lietzane@missouri.edu
Phone: 573.882.6753

APPOINTMENT

University of Missouri School of Law
Associate Professor of Law
2014 –

PUBLICATIONS

Law Journals

• The Myths of Data Exclusivity, 20 LEWIS & CLARK L. R. ___ (2016)

• 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 JOURNAL OF HEALTH CARE LAW
& POLICY 226 (2010) (with Sarah Pitlyk)

• Advisory Committees at FDA: The Hinchey Amendment and “Conflict of Interest” Waivers,
39 JOURNAL OF HEALTH LAW 415 (Fall 2006)

• Tax Exemptions and the Establishment Clause, 49 SYRACUSE LAW REVIEW 971 (1999)

• Law and the Wisconsin Idea, 47 JOURNAL OF LEGAL EDUCATION 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)

Peer–Reviewed Law Journals and Scientific Journals

• An Unofficial Legislative History of the Biologics Price Competition and Innovation Act of
2009, 65 FOOD AND DRUG LAW JOURNAL 671 (2010) (with Krista Carver and others)
• A New History and Discussion of 180–Day Exclusivity, 64 FOOD & DRUG LAW JOURNAL 335 (2009) (with David Korn and others)


• Issues in the Interpretation of 180–Day Exclusivity, 62 FOOD & DRUG LAW JOURNAL 49 (2007) (with David Korn and others)


• An Overview of Canada’s Personal Information Protection and Documentation Act for Pharmaceutical and Device Manufacturers, 57 FOOD & DRUG LAW JOURNAL 205 (2002) (with John Fuson)

Books, Book Chapters, and Monographs


• “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)

• “Biosimilars,” chapter 15 in FOOD & DRUG LAW & REGULATION, 2d Ed. (FDLI, 2012) (with Emily Alexander)


• 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)

Shorter Publications

• Pharmacy Compounding after the DQSA, 26:4 Health Lawyer (2014) (co–authored)
• The Evolving Regulation of Medical Device Clinical Trials in the USA, Journal of Medical Device Regulation (May 2013) (co–authored)
• The U.S. Biosimilar Pathway Nearly Three Years Later, GxP Lifeline (Dec. 2012) (co–authored)
• Biosimilar regulation: important considerations and global developments, PLC Life Sciences Handbook (Cross–border) (2011) (co–authored)
• FDA in Federal Court: The Agency’s Ten–Year Record, FDLI Update (Feb. 2008) (co–authored)
• Learned Intermediary Doctrine: Required by Law?, Law360 (July 17, 2007) (co–authored)
• 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) (co–authored)
• The Medicine Equity and Drug Safety Act of 2000, FDLI Update (March/April 2001)
Current Projects

- An examination of the law and FDA policies relating to 180-day exclusivity, as it has developed since 1984, focusing on the post-2003 scheme, forfeiture of exclusivity, and parking of exclusivity.

- An examination of the biological medicines system as a whole (evolving regulatory expectations, intellectual property considerations, emerging state laws, expected means of market penetration, and reimbursement laws and emerging coverage policies and practices) for purposes of appropriately understanding and contextualizing the patent settlements and settlement terms that may arise

- An examination of the impact of the caps on and other statutory limitations to patent term extension for biopharmaceuticals

AWARDS AND HONORS

- Thomas Edison Innovation Fellowship
  Center for the Protection of Intellectual Property
  George Mason University School of Law
  2016 – 2017

- Best Lawyers in America, FDA Law
  2013 – present

- Best Lawyers in America, Biotechnology Law
  2007 – present

- American Law Institute, elected member
  2006 – present

GRANT INVOLVEMENT

- NIH/NIAID Grant: R21 AI119633–01
  Microbiota Transplantation: Recommendations for a Regulatory Framework, PI: Diane Hoffmann
  Role: Working Group Member
  2015 – present

SERVICE TO UNIVERSITY AND LAW SCHOOL

- Clerkship Committee
  2014 – present

PROFESSIONAL SERVICE

- ABA, Science and Technology Law Section
  Chair of the Life Sciences Division
  2013 – present
  2007 – 2009
  Editor, SciTech Lawyer
  2008 – 2009
  Section Council
  2004 – 2008
Chair of Biotechnology Committee 2005 – 2008
2002 – 2003
Vice Chair of Biotechnology Committee 2001 – 2002

- **Food & Drug Law Institute**
  Drug and Biologics Committee 2014 – present
  FDLI’s Austern Writing Awards Committee, Long Papers 2013 – 2014
  Board of Directors 2008 – 2012

- **Institute of Medicine**
  Comm. on Strategies for Responsible Sharing of Clinical Trial Data 2014
  Consultant

- **Generics and Biosimilars Initiative Journal (GaBi)**
  International Editorial Advisory Board 2014 – present

- **ABA, Health Law Section**

- **ABA, Special Committee on Bioethics & the Law** 2006 – 2009

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

- **FDA Alumni Association**
  General Counsel (*pro bono*) 2007 – 2011

- **ALI–ABA**
  Advisor on IP Law, Board of Directors Program Committee 2008 – 2014

- **AAAS–ABA National Conference of Lawyers and Scientists**
  Co–Chair 2006 – 2009
  Member 2003 – 2009

**PROFESSIONAL AFFILIATIONS**

- ABA: Science and Technology Law Section, Health Law Section, Intellectual Property Law Section

- Food & Drug Law Institute

- American Intellectual Property Law Association

- American Health Lawyers Association
• American Society of Law, Medicine, and Ethics

**COURSES TAUGHT**

• Regulation of Drugs and Medical Devices
• Intellectual Property
• Administrative Law
• Copyright

**PRESENTATIONS**

**Academic Workshops, Lectures, and Conferences**

• “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)


• “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


• Eli Lilly & Co. et al. v. 8 PM Chemist Limited et al., HC07C No. 02877 (UK High Court of Justice, Chancery Division, Intellectual Property) (2009–2010) (expert witness on a wide range of FDA and state law issues)

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 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)

Professional Conferences, Workshops, and Webinars


• “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)

• “Interchangeability of Biosimilars: the Legal Perspective,” DIA/FDA Biosimilars Conference: Guidances, Science, and BsUFA (Sept. 12, 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)


• “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)

• “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)


• “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)


• “The Nature of the Drug & Biologic Approval Processes” and Conference Chair, American Conference Institute, FDA Boot Camp (Mar. 31 – Apr. 1, 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)


• “The Nature of the Drug & Biologic Approval Processes” and Conference Chair, American Conference Institute, FDA Boot Camp (Sept. 25 – 26, 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)

• “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)


• “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)


• “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)


• “Counterfeit Pharmaceuticals: The Dangers of Importation,” American Conference Institute Conference on Importation, Reimportation, and Counterfeiting (Nov. 9, 2004)


• “Working at the Frontiers of Law & Science: Applications of the Human Genome” (ABA, AMA, AALS) (Oct. 2003) (program committee)


Private Workshops and Invited Talks

• “Pliva v. Mensing: Consequences for FDA Labeling and Product Liability,” Presentation to BIO General Counsels Committee (Oct. 2012)

• “Track & Trace / Pedigree,” Presentation to the PhRMA Law Section Executive Committee (Feb. 2012)


• “Expanded Access to Investigational Drugs: Legal Overview,” Presentation to BIO General Counsels’ Committee (Nov. 2, 2007)

• “European Regulation of Biosimilars,” National Consumers League Stakeholder Forum, Biologics: The Pathway to Biosimilar Products (Sept. 18, 2007)

• “Regulatory Climate, Developments, and Challenges in the Pharmaceutical/Biotech Industry,” Utah Life Sciences Symposium (May 17, 2007)

• 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)

• “The OxyContin ‘Crisis’ – Who’s To Blame?,” Health Policy Discussion, American Enterprise Institute (Feb. 7, 2002)

OTHER PROFESSIONAL EXPERIENCE

Covington & Burling, LLP 2005 – 2014

Pharmaceutical Research and Manufacturers of America 2002 – 2005
Assistant General Counsel

The Hon. Gerald B. Tjoflat, U.S. Court of Appeals, 11th Cir. 1995 – 1996
Law Clerk

EDUCATION

Duke Law School, J.D., with High Honors 1995

University of California, M.A., Intellectual History 1992

University of North Carolina, B.A., History, with Honors 1990

BAR MEMBERSHIPS

• District of Columbia

• North Carolina

ADMISSIONS

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