ERIKA LIETZAN
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PUBLICATIONS

Academic Law Reviews and Peer–Reviewed Journals

- *A Special Exception for CBD in Foods and Supplements*, 25 DRUG DISC. TODAY 467 (2019) (with Patricia Zettler)
- *A Solution in Search of a Problem at the Biologics Frontier*, 2018 U. ILL. L. REV. ONLINE 19
- *The Myths of Data Exclusivity*, 20 LEWIS & CLARK L. R. 91 (2016)

• A New History and Discussion of 180–Day Exclusivity, 64 FOOD & DRUG L. J. 335 (2009) (with David Korn and Shaw Scott)


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


• 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

• Regulating Medical Devices in the United States, in OXFORD HANDBOOK OF COMPARATIVE HEALTH LAW (Orentlicher & Hervey, eds.) (Oxford University Press, forthcoming) (with Patricia Zettler)

• Regulation Medicines in the United States, in OXFORD HANDBOOK OF COMPARATIVE HEALTH LAW (Orentlicher & Hervey, eds.) (Oxford University Press, forthcoming) (with Patricia Zettler)

• Medicines, in CHEMICALS AND THE LAW (Abelkop et al., eds.) (Edward Elgar Publishing Ltd., forthcoming) (with Patricia Zettler)


• Federal Regulation of Clinical Research, in MEDICAL BIOTECHNOLOGY: PREMARKET AND POSTMARKET REGULATION (ABA, 2015) (with Afia Asamoah)

• MEDICAL BIOTECHNOLOGY: PREMARKET AND POSTMARKET REGULATION (editor) (ABA, 2015)

• Biosimilars, in FOOD AND DRUG LAW AND REGULATION, 3d Ed. (FDLI, 2015) (with Emily Alexander and Laura Sim)

- **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)


- **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 U.S.A.**, 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)


- **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)

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

HONORS AND AWARDS

American Law Institute (elected in 2006)

Shook Hardy Bacon LLP Excellence in Research Award (for The History and Political Economy of the Hatch–Waxman Amendments) (2019)

Husch Blackwell Distinguished Faculty Award (teaching award) (2018)

Best Lawyers in America (FDA Law since 2013, Biotechnology Law since 2007, Washington Biotechnology Lawyer of the Year in 2013)

SERVICE

PROFESSIONAL SERVICE

Food and Drug Law Institute


Peer Review

- Various, including Yale Journal of Health Law, Policy, and Ethics; Food and Drug Law Journal; Generics and Biosimilars Initiative Journal; Mercatus Center

Microbiota Transplantation: Recommendations for a Regulatory Framework (NIH/NIAID Grant: R21 AI119633–01, PI: Diane Hoffmann)


American Bar Association

- Leadership positions within the Section of Science and Technology between 2001 and 2017, including Chair of the Biotechnology Committee (five years), Chair of the Life Sciences Division (five years), and Section Council (four years)

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

- Institutional Review Board (since 2018)
- Committee on Residency for Tuition Purposes (2016–2018)

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University of Missouri School of Law

- Policy Committee (starting fall 2019)
- Clerkship Committee (since 2014) (chair effective January 2019)
- Curriculum Committee (since 2018)
- Law Library Committee (since 2018)
- Diversity Committee (2017–2018)
- Career Services Committee (2016–2018)
- Dean Search Committee (2016–2017)

COMMUNITY SERVICE

- University Hospital Wags Therapy Dog Program

FELLOWSHIPS & GRANTS


Leonardo Da Vinci Fellowship Research Grant (Center for the Protection of Intellectual Property, George Mason University) (2018)

TALKS AND PRESENTATIONS

Congressional Testimony


Academic Workshops, Conference, and Lectures

- “The Assault on Drug Patents,” University of Akron School of Law (Oct. 28, 2019)
- “When Access Precedes Evidence: The Cost of FDA’s New Drug Authority,” FIRST PRINCIPLES FOR OPTIMAL REGULATION SYMPOSIUM, University of Missouri School of Law (Feb. 8, 2019)
- “Fundamental Rights in U.S. Food and Drug Law,” UFR Droit et Sciences Économique et Politique, l'Université de Bourgogne (Dec. 7, 2018)

• “Drug Innovation Out of Order,” Sixth Annual Fall Conference, Center for Protection of Intellectual Property, Antonin Scalia Law School, George Mason University (Oct. 12, 2018)

• “Effective Incentives to Develop New Uses of Established Drugs,” Webcast for the NYS Science & Technology Law Center at Syracuse University College of Law (Mar. 29, 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 intellectuelle à des stratégies de recherche et développement – Perspective américaine,” Conférence on “Le droit des affaires pharmaceutiques” hosted Maison des Sciences de l'Homme, Université de Bourgogne, Dijon, France (Dec. 8, 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)


• “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)
• “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 Judicial/Agency Education Programs

• “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 Biologies,” 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)
• “DTC Advertising, the First Amendment & Learned Intermediary Doctrine: A General Introduction to the Legal Framework,” Testimony before West Virginia Cost Containment Council (Oct. 20, 2005)

Expert Witness Testimony (Deposition and Trial Testimony)

• Fera Pharmaceuticals, LLC v. Akorn, Inc., Case No. 12–cv–07694–LLS (S.D.N.Y.)


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)


• “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)


• “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)
• “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)


• “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)

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


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


• “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)
• 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)

PROFESSIONAL AFFILIATIONS
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

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
**LEGAL EXPERIENCE**

**Covington & Burling, LLP, Washington, DC**

**Pharmaceutical Research and Manufacturers of America, Washington, DC**
- Assistant General Counsel (2002–2005)

**United States Court of Appeals, 11th Circuit**

**BAR MEMBERSHIP & ADMISSIONS**

- Member of the Missouri, District of Columbia (inactive), and North Carolina (inactive) bars
- Admitted to practice before the 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; and United States District Court, District of Columbia