ERIKA LIETZAN
William H. Pittman Professor of Law
Timothy J. Heinsz Professor of Law
University of Missouri School of Law

PUBLICATIONS

Academic Law Reviews and Peer-Reviewed Journals

Trademark Erasure, 56 WAKE FOREST L. REV. __ (2021) (forthcoming)
Distorted Drug Patents, 95 WASH. L. REV. 1317 (2020) (with Kristina Acri)
Vers une adaptation de la propriété intellectuelle à des stratégies de recherche et de développement: perspectives américaines: Réflexion sur le paradoxe de l’innovation en matière de médicaments, 54 LE DROIT DES AFFAIRES PHARMACEUTIQUES 71 & 79 (2020)
Early Access to Unapproved Medicines in the United States and France, 19 YALE J. HEALTH POL’Y, LAW, & ETHICS 1 (2020) (with Isabelle Moine-Dupuis)
A Special Exception for CBD in Foods and Supplements, 25 DRUG DISC. TODAY 467 (2019) (with Patricia Zettler)
The Surprising Reach of FDA Regulation of Cannabis, Even After Descheduling, 68 AM. U. L. REV. 101 (2019) (with Sean O’Connor)
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. 883 (2017)
The Myths of Data Exclusivity, 20 LEWIS & CLARK L. R. 91 (2016)

Written while in private practice:


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)


Outpatient Civil Commitment in North Carolina: Constitutional and Policy Concerns, 58 LAW & CONTEMP. PROBS. 251 (Spring 1995)

Books and Book Chapters

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

Introduction to Medical Products Law, in OXFORD HANDBOOK OF COMPARATIVE HEALTH LAW (Orentlicher & Hervey, eds.) (Oxford University Press, 2020) (with Patricia Zettler and Aurélie Mahalatchimy)

Regulating Medical Devices in the United States, in OXFORD HANDBOOK OF COMPARATIVE HEALTH LAW (Orentlicher & Hervey, eds.) (Oxford University Press, 2020) (with Patricia Zettler)

Regulating Medicines in the United States, in OXFORD HANDBOOK OF COMPARATIVE HEALTH LAW (Orentlicher & Hervey, eds.) (Oxford University Press, 2020) (with Patricia Zettler)
Written while in private practice:


*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)


**Other Publications**


*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)

Written while in private practice:

*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)


*Biosimilar regulation: important considerations and global developments*, PLC Life Sciences Handbook 2011 (Thomson Reuters) (with Peter Bogaert and Laura Sim)

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)


ACADEMIC APPOINTMENTS

University of Missouri School of Law

William H. Pittman Professor of Law and Timothy J. Heinsz Professor of Law (2020- )

Associate Professor of Law (with tenure) (2018-2020)

Associate Professor of Law (2014-2018)

Centre de Recherche Sur le Droit des Marches et des Investissements Internationaux (CREDIMI), Faculté de droit, sciences économique et politique de Dijon, Université de Bourgogne

Membre associé (2021- )

EDUCATION

Duke Law School (JD with High Honors)

Order of the Coif

Senior Editor, LAW & CONTEMPORARY PROBLEMS

University of California - Los Angeles (MA, History)

Area of focus: intellectual history

University of North Carolina - Chapel Hill (BA, History with Honors)

Phi Beta Kappa

TALKS AND 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)
Paper and Research Presentations

Direct-to-Consumer Genetic Testing, Genetics & Medicine: Ethical, Legal & Social Issues (S.J. Quinney College of Law, University of Utah) (Feb. 24, 2021)

Le marché des médicaments face à l’insatisfaction des besoins des populations: des adaptations d’urgence ou une réforme aux fondements juridiques pérennes?, Centre de Recherche Sur le Droit des Marches et des Investissements Internationaux (CREDSII), Universite de Bourgogne, Dijon, France (Nov. 10, 2020)


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)

The Political Economy of the Hatch-Waxman Amendments, Scalia Law School, George Mason University (Mar. 28, 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, Le droit des affaires pharmaceutiques, Maison des Sciences de l’Homme, Universite de Bourgogne, Dijon, France (Dec. 8, 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 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)

Other Academic Programs


Inventing and ‘Reinventing’ Under Patent Law, webinar hosted by Notre Dame Law School’s IP & Tech Law Center (Sept. 17, 2020) (panel moderator)


The New Role of the Administrative State in the Innovation Economy, 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)


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 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, Testimony before West Virginia Cost Containment Council (Oct. 20, 2005)

Selected Other Public Speaking Since 2014

The Race for a Coronavirus Vaccine: The Intersection of Science and IP Policy, MorningsideIP (Sept. 22, 2020)

Don’t Let a Good Crisis Go to Waste, Federalist Society COVID-19 & The Law Virtual Conference (June 12, 2020)


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)

HONORS AND AWARDS

American Law Institute (elected 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)

PROFESSIONAL SERVICE

Administrative Conference of the United States

Public Member and Committee on Regulation (2020- )

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

NIH/NIAID Grant: R21 AI119633-01, PI: Diane Hoffmann (Microbiota Transplantation: Recommendations for a Regulatory Framework)
Working group member (2015-2018)

American Bar Association
Section of Science and Technology: membership and leadership 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)
Section of Administrative Law & Regulatory Practice: membership from 2001 to 2017, chair of FDA Committee 2020-

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
Campus Faculty Committee on Tenure (starting fall 2021 - )
Institutional Review Board (2018 - )
Committee on Residency for Tuition Purposes (2016-2018)

University of Missouri School of Law
Policy Committee (Fall 2019 - )
Clerkship Committee (2014 - ) (Chair January 2019 - )
Curriculum Committee (2018 - )
Law Library Committee (2018-2020)
Diversity Committee (2017-2018)
Career Services Committee (2016-2018)
Dean Search Committee (2016-2017)

COMMUNITY SERVICE
University of Missouri’s University Hospital Wags Therapy Dog Program
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

LEGAL EXPERIENCE
Covington & Burling, LLP, Washington, DC
Partner (2006-2014), Special Counsel (2005-2006), and Associate (1996-2002)
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, and North Carolina bars (all inactive)
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