Erika F. Lietzan

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ACADEMIC APPOINTMENT

University of Missouri School of Law — Columbia, MO

William H. Pittman Professor of Law & Timothy J. Heinsz Professor of Law — 2022–present

Associate Professor of Law (with tenure) — 2018–2022

Associate Professor of Law — 2014–2018

OTHER ACADEMIC AFFILIATIONS

Université de Bourgogne; Centre de Recherche sur le Droit Des Marchés et des Investissements Internationaux (CREDIMI) — Dijon, France

Member associé — 2021–present

Scalia Law School, George Mason University; Center for Intellectual Property x Innovation Policy (C-IP^2) — Arlington, VA

Senior Scholar — 2018–present

Affiliate Scholar — 2016–2018

HONORS AND AWARDS

American Law Institute (elected in 2006)

Best Lawyers in America

- FDA Law since 2013
- Biotechnology Law since 2007
- Washington Biotechnology Lawyer of the Year in 2013

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)

COURSES TAUGHT

Administrative Law; FDA Law; Regulation of Medical Products; Food Law and Policy; Health Law; Intellectual Property; Federal Courts; Property; Copyright

SCHOLARSHIP

Articles

User Fee Programs, 76 ADMIN. L. REV. __ (2024) (forthcoming)

Solutions Still Searching for a Problem: A Call for Relevant Data to Support "Evergreening" Allegations, 33 FORDHAM INTEL. PROP., MEDIA & ENT. L. J. 788 (2023) (with Kristina Acri)

The Case of the Missing Device Patents, or: Why Device Patents Matter, 33 FORDHAM INTEL. PROP., MEDIA & ENT. L. J. 409 (2023) (with Kristina Acri and Evan Weidner)

Ignoring Drug Trademarks, 56 WAKE FOREST L. REV. 101 (2021)

Lièvre ou tortue? Les accès anticipés au médicament à l'épreuve du dilemme entre précaution et "droit à l'espoir"des patients, REVUE DE DROIT SANITAIRE ET SOCIAL 289 (Mars–Avril 2021) (with Isabelle Moine–Dupuis)

Distorted Drug Patents, 95 WASH. L. REV. 1317 (2020) (with Kristina Acri)

The "Evergreening" Metaphor in Intellectual Property Scholarship, 53 AKRON L. REV. 805 (2020)

Vers une adaptation de la propriété intellectualle 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)

Access Before Evidence and the Cost of FDA's New Drug Authority, 53 U. RICH. L. REV. 1243 (2019)

The Surprising Reach of FDA Regulation of Cannabis, Even After Descheduling, 68 AM. U. L. REV. 101 (2019) (with Sean O'Connor)

The Innovation Paradox: Pharmaceutical Marketing Exclusivity and Incentives for Drug Development, J. PHARM. HEALTH SERV. RES. 1 (2019) (with Kristina Acri)

Paper Promises for Drug Innovation, 25 GEO. MASON L. REV. 168 (2018)

The History and Political Economy of the Hatch–Waxman Amendments, 49 SETON HALL L. REV. 53 (2018)

The Drug Innovation Paradox, 83 MO. L. REV. 39 (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. 883 (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)

While in Private Practice:

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 the Hon. Sarah E. 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)

Law and the Wisconsin Idea, 47 J. LEGAL EDUC. 297 (Sept. 1997) (with Paul Carrington)

While in Law School

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) (student note)

Books and Book Chapters

FOOD AND DRUG LAW AND REGULATION, 5th Ed. (forthcoming) (editor)

HUTT, MERRILL, GROSSMAN, CORTEZ, LIETZAN, AND ZETTLER'S FOOD AND DRUG LAW (5th ed. 2022) (chapters 6 and 8)

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, 2021) (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, 2021) (with Patricia Zettler)

Regulating Medicines in the United States, in OXFORD HANDBOOK OF COMPARATIVE HEALTH LAW (Orentlicher & Hervey, eds.) (Oxford University Press, 2021) (with Patricia Zettler)

Federal Regulation of Clinical Research, chapter 9 in BIOTECHNOLOGY & THE LAW (2d ed. 2019) (Wellons, Copple, & Wofford, editors) (with Afia Asamoah & Linda McCarty)

FDA Regulation of Biosimilars, 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)

While in Private Practice

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

User Fee Programs: Design Choices and Processes (Nov. 9, 2023) (report to the Admin. Conf. of the United States)

Various blog posts and essays on OBJECTIVE INTENT and YALE JOURNAL ON REGULATION: NOTICE AND COMMENT

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)

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)

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)

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)

Academic Workshops, Conferences, and Lectures

Our Bodies, Our Cells: When Courts and Regulators Collide, Food and Drug Law Journal Symposium (Nov. 8, 2023) (moderator)

Accountability by Petition, J. Reuben Clark Law School, Brigham Young University (Sept. 14, 2023)

Revising Generic Substitution Laws and Combination Medical Products, Food and Drug Law Journal 2022 Symposium on the Interconnected Regulatory Landscape (Nov. 4, 2022) (moderator)

The Case for Patents, Roundtable Hosted by Classical Liberal Institute, NYU School of Law (May 11, 2021) (roundtable participant)

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

Intellectual Property and the Constitution, Hudson Institute Forum for Intellectual Property (Dec. 3, 2020) (roundtable participant)

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 (CREDIMI), Universite de Bourgogne, Dijon, France (Nov. 10, 2020)

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

Public Health: Regulation, Innovation, and Preparation, C. Boyden Gray Center for the Study of the Administrative State Research Roundtable (Sept. 17–18, 2020) (paper discussant)

Intellectual Property Issues in Life Sciences R&D and Commercialization, WIPO–CPIP Summer School on Intellectual Property (June 12, 2020) (panelist)

Requiring Regulatory Approval of Medical Products: Tradeoffs in a Time of Crisis, Isolated By The Law, Part 2, An Asynchronous Symposium, Wake Forest University Center for Bioethics, Health, & Society (Apr. 2020)

The Assault on Drug Patents, University of Akron School of Law (Oct. 28, 2019)

Ending Exclusivity: The Role of the Orange Book, Pharmaceutical Innovation, Patent Protection, and Regulatory Exclusivities Symposium, Texas A&M School of Law (Oct. 25, 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)

The Cannabis Legal Landscape Today, Food and Drug Law Journal 2018 Symposium (Nov. 2, 2018)

History and Political Economy of the Hatch–Waxman Amendments, FDA: Past, Present, and Future, American University Washington College of Law (Oct. 19, 2018); Scalia Law School, George Mason University (Mar. 28, 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)

Direct–to–Consumer (DTC) Genetic Testing and Population Health, Frontiers in Precision Medicine III, University of Utah (Mar. 16, 2018) (panelist)

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) (panelist)

Regulation of Pharmaceuticals in the United States, UFR Droit et Sciences Économique et Politique, l'Université de Bourgogne (Dec. 10, 2017) (panelist)

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) (panelist)

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)

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) (presenter); St. Louis University School of Law Faculty Workshop (Nov. 16, 2016)

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)

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)

While in private practice

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, 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

The Hatch–Waxman Amendments and Generic Drugs, The Legal, Economic, and Regulatory Environment of the Pharmaceutical Industry, Mason Judicial Education Program (April 15, 2019)

While in private practice

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)

Other Speaking Engagements

Drug Patents and Evidence–Based Policymaking in Patent Law, Hudson Institute (April 15, 2022)

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)

Eagle v. Azar, Top Cases of 2018 Panel, Food & Drug Law Institute Annual Meeting (May 3, 2019)

Sandoz v. Amgen, Top Cases of 2017 Panel, Food & Drug Law Institute Annual Meeting (May 4, 2018)

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)

While in private practice

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)

FELLOWSHIPS AND GRANTS

Thomas Edison Innovation Fellowships (Center for the Protection of Intellectual Property, George Mason University) (2016–2018)

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

PROFESSIONAL ACTIVITIES

Administrative Conference of the United States

Public Member 2020–present

Committee on Regulation

Ad Hoc Committee on Regulation of Representatives (2021)

Ad Hoc Committee on Disclosure of Legal Materials (2023)

American Bar Association

Section of Administrative Law & Regulatory Practice 2020–present
2001–2017

Chair of FDA Committee 2020–present

Section of Science & Technology 2020–present
2001–2017

Section Council (four years)

Chair of the Life Sciences Division (five years)

Chair of the Biotechnology Committee (five years)

Food & Drug Law Institute

75th Anniversary Advisory Committee	2023
FOOD & DRUG LAW J. Editorial Advisory Board Chair	2022
Annual Conference Co–Chair	2021
Annual Conference Planning Committee	2020
Cannabis–Derived Products Committee	2019
Academic Programs Committee	2018
Drug and Biologics Committee	2014–2017
Austern Writing Awards Committee	2013–2014
Board of Directors	2008–2012
Food and Drug Law Journal Editorial Advisory Board	2004–2008

SERVICE ACTIVITIES

Professional Service

Distinguished Commentator, Thomas Edison Innovation Law and Policy Fellowship Program of the Center for Intellectual Property x Innovation Policy (C–IP²) (2024–2025)

Distinguished Commentator, Thomas Edison Innovation Law and Policy Fellowship Program of the Center for Intellectual Property x Innovation Policy (C–IP²) (2023–2024)

Assistance as requested (for staff and occasionally for member–level meetings) to Senate HELP Committee, House Judiciary Committee, and others in the U.S. Congress on issues relating to FDA law and proposed legislative reforms (examples available)

Peer review provided, on request, including to Yale Journal of Health Policy Law and Ethics, Stanford Law Review, New England Journal of Medicine, American Journal of Law and Medicine, Jurimetrics, Columbia Law Review, Journal of Law and Biosciences, and others (and as requested directly by other law professors)

Law School Service

Honor Code (Chair, 2023–2024); Promotion & Tenure Committee (2022–present); Policy Committee (2022–present, 2019–2021); Clerkship Committee (Chair, 2019–2022, Member 2014–2022); Curriculum Committee (2018–2022); Law Library

Committee (2018–2020); Diversity Committee (2017–2018); Career Services Committee (2016–2018); Dean Search Committee (2016–2017)

University Service

Institutional Review Board (2018–present); Chair, Campus Faculty Committee on Tenure (2021–2022); Committee on Residency for Tuition Purposes (2016–2018)

PROFESSIONAL EXPERIENCE

Covington & Burling LLP — Washington, DC

Partner (Food and Drug Group) — 2006–2014

Special Counsel — 2005–2006

Associate — 1996–2002

Pharmaceutical Research and Manufacturers of America — Washington, DC

Assistant General Counsel — 2002–2005

United States Court of Appeals for the 11th Circuit — Jacksonville, FL

Law Clerk for the Honorable Gerald B. Tjoflat — 1995–1996

EDUCATION

Duke Law School — Durham, NC

Juris Doctorate, with High Honors — 1995

Order of the Coif

Senior Editor, LAW & CONTEMPORARY PROBLEMS

University of California–Los Angeles — Los Angeles, CA

Master's Degree in History — 1992

University of North Carolina — Chapel Hill, NC

Bachelor of Arts in History, with Honors — 1990

Phi Beta Kappa

BAR MEMBERSHIPS AND 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