### Lars Noah

# **EMPLOYMENT**:

- July 1994 present: University of Florida Levin College of Law (Gainesville, FL)
  Chesterfield Smith Eminent Scholar (since 2019); O'Connell Chair (2017-19);
  Univ. Term Professor (2016-19); UF Research Found. Professor (2002-05).
  Professor (since 1999); Assoc. Professor (1997-99); Asst. Professor (1994-97).
  Courses taught: Torts (x27); Medical Technology (x18); Public Health Law (x5);
  Administrative Law (x8); Products Liability (x6); Medical Malpractice (x4);
  Bioethics (x1); Conflict of Laws (x3); Civil Procedure (x1); seminars (x3).
  Named "Teacher of the Year" (1995, 1998, 2004).
- Aug. 2007 May 2008: <u>Vanderbilt University Law School</u> (Nashville, TN) Visiting Professor—taught *Torts* (x2) and *Medical Technology*.
- Aug. Dec. 2004: <u>George Washington University Law School</u> (Washington, DC) Visiting Professor—taught *Torts* and *Medical Technology*.
- Aug. Dec. 2001: <u>Georgetown University Law Center</u> (Washington, DC) Visiting Professor—taught *Administrative Law* and *Conflict of Laws*.
- Aug. Dec. 2000: <u>University of Texas School of Law</u> (Austin, TX) Visiting Professor—taught *Torts* (integrated w/ writing) and *Products Liability*.
- Jan. May 1999: <u>Washington & Lee University School of Law</u> (Lexington, VA) Visiting Professor—taught *American Public Law Process* (integrated w/ writing).
- July 1991 June 1994: <u>Covington & Burling</u> (Washington, DC)
  Associate specializing in food and drug law (FDA regulatory practice).
- July 1990 July 1991: <u>United States Court of Appeals</u> (Washington, DC) Law clerk to Chief Judge Abner J. Mikva, D.C. Circuit.

#### **EDUCATION:**

- Harvard Law School (1987-90): J.D., magna cum laude
  Recipient of Sears Prize (for highest first year grades)
  Editor, Harvard Law Review (articles/developments)
  Instructor, Legal Methods (civil procedure seminar)
- Harvard College (1983-86): B.A., Government, *magna cum laude*John Harvard Scholarship; Phi Beta Kappa
  Vice President, Harvard University Debate Council
  Undergraduate associate, Center for International Affairs

### **PUBLICATIONS:**

### **Books**:

- LAW AND THE PUBLIC'S HEALTH: CASES, CONTROVERSIES & COVID-19 [892 pp.] (Carolina Academic Press 2023), with Teacher's Manual [266 pp.].
- LAW, MEDICINE, AND MEDICAL TECHNOLOGY: CASES & MATERIALS [1352 pp.] (Foundation Press 5th ed. 2022), with Teacher's Manual [266 pp.].
- LAW, MEDICINE, AND MEDICAL TECHNOLOGY: CASES & MATERIALS (Foundation Press 4th ed. 2017), with Teacher's Manual.
- LAW, MEDICINE, AND MEDICAL TECHNOLOGY: CASES & MATERIALS (Foundation Press 3d ed. 2012), with Teacher's Manual.
- LAW, MEDICINE, AND MEDICAL TECHNOLOGY: CASES & MATERIALS (Foundation Press 2d ed. 2007), with Teacher's Manual.
- LAW, MEDICINE, AND MEDICAL TECHNOLOGY: CASES & MATERIALS (Foundation Press 2002), with Teacher's Manual.

# **Chapters**:

- Confronting the Inevitability of Diagnostic Uncertainty Across Multiple Legal Domains, in Diagnoses Without Names 59-68 (Michael D. Lockshin et al. eds., 2022).
- Legal Aspects of the Food Additive Approval Process, in Enhancing the Regulatory . . . Process for Direct Food Ingredient Technologies 13-110 (NAS Press 1999).

# **Articles**:

- Eliding Consent in the Case of Pandemic Countermeasures Authorized for Emergency Use, 58 Ind. L. Rev. (forthcoming Sept. 2024).
- Does Federal Preemption Inoculate Us Against the Alarming Prospect of State Vaccine Bans?, 100 Ind. L.J. Supp. (forthcoming Sept. 2024).
- "Major Questions" Malarkey: An Arbitrary and Capricious New Doctrine for Vetoing Rules, 97 St. John's L. Rev. (forthcoming June 2024).
- Preempting Red State Restrictions on the Use of Approved Drugs in Gender-Affirming Care?, 2024 Utah L. Rev. 833-51 (2024).

- Must Courts Recalibrate Tort Law Governing Firearms in Light of the Second Amendment?, 92 U. Cin. L. Rev. 412-54 (2023).
- Listening to Mifepristone, 80 N.Y.U. Ann. Surv. Am. L. 33-62 (2023).
- Time to Bite the Bullet? How an Emboldened FDA Could Take Aim at the Firearms Industry, 53 Conn. L. Rev. 787-834 (2022).
- Censorship Is So Last Century: Therapeutic Products, Propaganda, and Compelled Speech, 66 St. Louis U. L.J. 79-97 (2021).
- Banning Off-Label Drug Promotion Offends the U.S. Constitution: Making the Strongest Case, 83 Alb. L. Rev. 301-12 (2020).
- State Regulatory Responses to the Prescription Opioid Crisis: Too Much to Bear?, 124 Dick. L. Rev. 633-67 (2020).
- Federal Regulatory Responses to the Prescription Opioid Crisis: Too Little, Too Late?, 2019 Utah L. Rev. 757-84 (2019).
- Giving Personal Injury Attys. Who Run Misleading Drug Ads a Dose of Their Own Medicine, 2019 U. Ill. L. Rev. 701-42 (2019).
- Does the U.S. Constitution Constrain State Products Liability Doctrine?, 92 Temp. L. Rev. 189-224 (2019).
- "Go Sue Yourself!" Imagining Intrapersonal Liability for Negligently Self-Inflicted Harms, 70 Fla. L. Rev. 649-93 (2018).
- Doctors on the Take: Aligning Tort Law to Address Drug Company Payments to Prescribers, 66 Buff. L. Rev. 855-907 (2018).
- Reversal of Fortune: Moving Pharmaceuticals from Over-the-Counter to Prescription Status?, 63 VILL. L. REV. 355-93 (2018).
- When Constitutional Tailoring Demands the Impossible: Unrealistic Scrutiny of Agencies?, 85 Geo. Wash. L. Rev. 1462-83 (2017).
- State Affronts to Federal Primacy in the Licensure of Pharmaceutical Products, 2016 Mich. St. L. Rev. 1-54 (2016).
- Growing Organs in the Lab: Tissue Engineers Confront Institutional "Immune" Responses, 55 Jurimetrics J. 297-338 (2015).
- Product Hopping 2.0: Getting the FDA to Yank Your Original License Beats Stacking Patents, 19 Marq. Intell. Prop. L. Rev. 161-79 (2015).

- Genetic Modification and Food Irradiation: Are Those Strictly on a Need-to-Know Basis?, 118 Penn St. L. Rev. 759-88 (2014).
- Governance by the Backdoor: Administrative Law(lessness?) at the FDA, 93 Neb. L. Rev. 89-138 (2014).
- Permission to Speak Freely?, and The Whole "Truthiness," 162 U. Pa. L. Rev. Online 248-54, 261-67 (2014).
- Turn the Beat Around?: Deactivating Implanted Cardiac-Assist Devices, 39 Wm. MITCHELL L. Rev. 1229-86 (2013).
- Whatever Happened to the "Frankenfish"?: The FDA's Foot-Dragging on Transgenic Salmon, 65 Me. L. Rev. 606-25 (2013).
- Truth or Consequences?: Commercial Free Speech vs. Public Health Promotion (at the FDA), 21 Health Matrix 31-95 (2011).
- Coerced Participation in Clinical Trials: Conscripting Human Research Subjects, 62 Admin. L. Rev. 329-66 (2010).
- Adding Insult to Injury: Paying for Harms Caused by a Competitor's Copycat Product, 45 Tort Trial & Ins. Prac. L.J. 673-95 (2010).
- Comfortably Numb: Medicalizing (and Mitigating) Pain-and-Suffering Damages, 42 U. Mich. J.L. Reform 431-80 (2009).
- This Is Your Products Liability Restatement on Drugs, 74 Brook. L. Rev. 839-926 (2009).
- Platitudes About "Product Stewardship" in Torts: Continuing Drug Research and Education, 15 Mich. Tel. & Tech. L. Rev. 359-91 (2009).
- The Little Agency That Could (Act with Indifference to Constitutional and Statutory Strictures), 93 Cornell L. Rev. 901-25 (2008).
- Too High a Price for Some Drugs?: The FDA Burdens Reproductive Choice, 44 SAN DIEGO L. REV. 231-58 (2007).
- Treat Yourself: Is Self-Medication the Prescription for What Ails American Health Care?, 19 Harv. J.L. & Tech. 359-92 (2006).
- Managing Biotechnology's [R] evolution: Has Guarded Enthusiasm Become Benign Neglect?, 11 VA. J.L. & Tech. 4 [63 pp.] (2006).

- A Drug by Any Other Name . . . ?: Paradoxes in Dietary Supplement Risk Regulation, 17 Stan. L. & Pol'y Rev. 165-96 (2006).
- An Inventory of Mathematical Blunders in Applying the Loss-of-a-Chance Doctrine, 24 Rev. Litig. 369-408 (2005).
- Medical Education & Malprac.: What's the Connection?, 15 HEALTH MATRIX 149-63 (2005).
- Ambivalent Commitments to Federalism in Controlling the Practice of Medicine, 53 U. Kan. L. Rev. 149-93 (2004).
- A Postmodernist Take on the Human Embryo Research Debate, 36 Conn. L. Rev. 1133-61 (2004).
- Deputizing Institutional Review Boards to Police (Audit?) Biomedical Research, 25 J. Legal Med. 267-93 (2004).
- Assisted Reproductive Technologies and the Pitfalls of Unregulated Biomedical Innovation, 55 Fla. L. Rev. 603-65 (2003).
- Challenges in the Federal Regulation of Pain Management Technologies, 31 J.L. Med. & Ethics 55-74 (2003).
- *Triage in the Nation's Medicine Cabinet: The Puzzling Scarcity of Vaccines and Other Drugs*, 54 S.C. L. Rev. 741-71 (2003).
- Medicine's Epistemology: Mapping the Diffusion of Knowledge in the Biomedical Community, 44 Ariz. L. Rev. 373-466 (2002).
- The Coming Pharmacogenomics Revolution: Tailoring Drugs to Fit Patients' Genetic Profiles, 43 Jurimetrics J. 1-28 (2002).
- Informed Consent and the Elusive Dichotomy Between Standard and Experimental Therapy, 28 Am. J.L. & Med. 361-408 (2002).
- Civil Jury Nullification, 86 IOWA L. REV. 1601-58 (2001).
- A Miscarriage in the Drug Approval Process?: Mifeprex Embroils FDA in Abortion Politics, 36 Wake Forest L. Rev. 571-603 (2001).
- Rewarding Regulatory Compliance: The Pursuit of Symmetry in Products Liability, 88 Geo. L.J. 2147-65 (2000).
- Divining Regulatory Intent: The Place for a "Legislative History" of Agency Rules, 51 HASTINGS L.J. 255-323 (2000).

- Interpreting Agency Enabling Acts: Misplaced Metaphors in Administrative Law, 41 Wm. & Mary L. Rev. 1463-530 (2000).
- Scientific "Republicanism": Expert Peer Review and the Quest for Regulatory Deliberation, 49 Emory L.J. 1033-83 (2000).
- What's Wrong with "Constitutionalizing Food & Drug Law"?, 75 Tul. L. Rev. 137-48 (2000).
- Regulatory Improvement Legislation: Risk Assessment, Cost-Benefit Analysis, Judicial Review, 11 Duke Envil. L. & Pol'y F. 89-138 (2000) (w/ several co-authors).
- Comments on the Rest. (Third) of Torts, 10 KAN. J.L. & Pub. Pol'y 98-101, 162-65 (2000).
- Pigeonholing Illness: Medical Diagnosis as a Legal Construct, 50 Hastings L.J. 241-307 (1999).
- Doubts About Direct Final Rulemaking, 51 ADMIN. L. REV. 401-28 (1999).
- The Executive Line Item Veto and the Judicial Power to Sever: What's the Difference?, 56 Wash. & Lee L. Rev. 235-46 (1999).
- Starting from Scratch?: Reinventing the Food Additive Approval Process, 78 B.U. L. REV. 329-443 (1998) (w/ Richard A. Merrill).
- Sanctifying Scientific Peer Review: Publication as a Proxy for Regulatory Decisionmaking, 59 U. Pitt. L. Rev. 677-717 (1998).
- Authors, Publishers, and Products Liability: Remedies for Defective Information in Books, 77 Or. L. Rev. 1195-228 (1998).
- Regulating Cigarettes: (Non)sense and Sensibility, 22 S. ILL. U. L.J. 677-92 (1998).
- Administrative Arm-Twisting in the Shadow of Congressional Delegations of Authority, 1997 Wis. L. Rev. 873-941 (1997).
- Advertising Prescription Drugs to Consumers: Assessing the Regulatory and Liability Issues, 32 Ga. L. Rev. 141-80 (1997).
- The FDA's New Policy on Guidelines: Having Your Cake and Eating It Too, 47 CATH. U. L. REV. 113-42 (1997).
- NAFTA's Impact on the Trade in Pharmaceuticals, 33 Hous. L. Rev. 1293-326 (1997).
- Reconceptualizing Federal Preemption of Tort Claims as the Government Standards Defense, 37 Wm. & Mary L. Rev. 903-78 (1996).

- Nicotine Withdrawal: Assessing the FDA's Effort to Regulate Tobacco Products, 48 Ala. L. Rev. 1-63 (1996).
- Sham Petitioning as a Threat to the Integrity of the Regulatory Process, 74 N.C. L. Rev. 1-73 (1995).
- *Liberating Commercial Speech: Product Labeling Controls and the First Amendment*, 47 Fla. L. Rev. 63-112 (1995).
- The Imperative to Warn: Disentangling the "Right to Know" from the "Need to Know," 11 Yale J. on Reg. 293-400 (1994).
- Constraints on the Off-Label Uses of Prescription Drug Products, 16 J. Prods. & Toxics Liab. 139-65 (1994).
- Amplification of Federal Preemption in Medical Device Cases, 49 Food & Drug L.J. 183-211 (1994).
- Death of a Salesman: To What Extent Can the FDA Regulate Promotional Statements?, 47 FOOD & DRUG L.J. 309-34 (1992).
- Note, The Politics of En Banc Review, 102 HARV. L. REV. 864-84 (1989).

### Other (selected):

- BDSM in Administrative Procedure: Using Agency Guidance for Bondage and Discipline, YALE J. ON REG.: NOTICE & COMMENT (posted May 7, 2019; removed May 20, 2019), https://papers.ssrn.com/sol3/papers.cfm?abstract\_id=3391569
- The Problem with the "Disease" Label, N.Y. TIMES, Nov. 28, 2011 (invited commentary for an online "Room for Debate" forum about employment discrimination related to obesity).

Supervising Research with Human Subjects, ADMIN. & REG. L. NEWS, Summer 2004, at 8.

Correspondence published in biomedical journals:

- Trends in Assisted Reproductive Technology, 351 New Eng. J. Med. 398 (2004).
- Pharmacogenetics, 348 New Eng. J. Med. 2042 (2003).
- Attorney General's Intrusion into Clinical Practice, 346 New Eng. J. Med. 1918 (2002).
- Standards for Medical Expert Testimony, 288 JAMA 2971 (2002).

Peer Review and Regulatory Reform, 30 Envtl. L. Rep. 10,606-14 (2000).

Statutory "Smoke" and Mirrors, 51 FOOD & DRUG L.J. 481-86 (1996).

# PRESENTATIONS (SELECTED):

[Participated in the "Market Share Liability Research Roundtable" sponsored by the Henry G. Manne Program in Law & Economics Studies, Chicago, IL, Aug. 6-8, 2024.]

Participated in the "Information as Medicine" workshop sponsored by the Univ. of Arizona's TechLaw Program with the Johns Hopkins Univ. Sch. of Med., Washington, DC, Nov. 4, 2022.

Spoke at the "Privatizing the Gun Debate" conference held at Duke University School of Law, Durham, NC, Mar. 18, 2022 (constitutional constraints on tort liability).

Spoke at a virtual conference ("When the Illness Has No Name") hosted by the Volcker Center at New York's Hospital for Special Surgery, Weill Cornell Medical College, Apr. 27-28, 2021.

Spoke at GW law school's virtual conference on "First Amendment Values in Health Care," Mar. 12, 2021: https://www.youtube.com/watch?v=tAtGFyZwJ5A [##3:48-19:00, 51:19-59:12]

Interviewed for scholarship highlight series, Duke Univ. Ctr. for Firearms Law, Dec. 21, 2020: https://firearmslaw.duke.edu/2021/01/scholarship-highlight-interview-noah-on-fda-gun-regulation/

Spoke at a conference on the opioid crisis held at Penn St. University's Dickinson Law School, Carlisle, PA, Nov. 8, 2019 (state regulation and constitutional constraints).

Spoke at the 13th Annual Judicial Symposium on Civil Justice (by GMU's Law & Econ. Ctr.), Arlington, VA, May 7, 2019 (opioid litigation): https://vimeo.com/337291863 [##45:25-58:55]

Spoke at a conference on the opioid crisis at the Univ. of Utah, Salt Lake City, UT, Nov. 30, 2018 (fed. regulation): https://www.youtube.com/watch?v=LqEn 2lvcZ0&t=20s [##22:00-39:00]

Spoke at the "FDA: Past, Present and Future" conference at the Washington College of Law, American Univ., Washington, DC, Oct. 19, 2018 (OTC-to-Rx switches).

Spoke at the fall meeting of the ABA Section on Administrative Law & Regulatory Practice, Washington, DC, Dec. 9, 2016 (constitutional review of agency action).

Spoke at the Food Law Colloquium sponsored by the Univ. of Maine School of Law, Portland, ME, Feb. 23, 2013 (federal regulation of genetically engineered livestock).

Spoke at a health law conference at the Univ. of Texas School of Law, Austin, TX, June 4, 2010 (tension between commercial free speech doctrine and public health promotion).

Presented a paper for a seminar series on health law, ethics & policy at the Univ. of Toronto, Ontario, Canada, Mar. 11, 2010 (coerced participation in biomedical research).

Spoke on a panel at the annual meeting of the Law & Society Ass'n, Denver, CO, May 30, 2009 (coerced participation in biomedical research).

Testified by invitation at a workshop on food safety sponsored by the Institute of Medicine (NAS), Washington, DC, Mar. 24, 2009 (FDA's legal authority).

Spoke at a conference on the law & economics of drug development at the Univ. of Michigan Law School, Ann Arbor, MI, Nov. 7, 2008 (liability issues).

Spoke at a conference celebrating the tenth anniversary of the *Products Liability Restatement* at the Brooklyn Law School, NYC, Nov. 13, 2008 (pharmaceutical issues).

Presented a paper to the faculty at the Vanderbilt Univ. Law School, Nashville, TN, Feb. 7, 2008 (mitigating pain and suffering damages).

Spoke at a program of the ABA Section on Administrative Law & Regulatory Practice, Washington, DC, Apr. 26, 2007 (FDA enforcement and dietary supplement regulation).

Presented a paper at a conference held at the Univ. of Minnesota Law School (co-sponsored by the Life Sciences Consortium), Minneapolis, MN, May 20, 2005 (law, ethics & biotechnology).

Presented a paper to the faculty at the Univ. of Utah College of Law, Salt Lake City, UT, Feb. 3, 2005 (computational errors in loss-of-a-chance cases).

Presented a paper to the faculty at the George Washington Univ. Law School, Washington, DC, Oct. 22, 2004 (computational errors in loss-of-a-chance cases).

Spoke on a panel at a Federalist Society program on controlling drug prices, Washington, DC, Oct. 6, 2004 (involuntary switches of prescription drugs to over-the-counter status).

Spoke on a panel at the National Academy of Sciences (sponsored by its Science, Technology, and Law Program), Washington, DC, Sept. 13, 2004 (regulatory compliance defense).

Spoke on a panel at the mid-year meeting of the ABA Tax Section, Kissimmee, FL, Jan. 30, 2004 (challenging overly generous agency regulations).

Presented a paper at a workshop held at the St. Louis Univ. School of Law (co-sponsored by ASLME), St. Louis, MO, Mar. 23, 2002 (regulating pain management technologies).

Spoke on a panel at the annual AALS meeting (co-sponsored by the health law and intellectual property law sections), New Orleans, LA, Jan. 4, 2002 (biotechnology innovation and access).

Presented a paper to the faculty at the College of William & Mary Marshall-Wythe School of Law, Williamsburg, VA, Oct. 23, 2001 (biomedical knowledge).

Presented a paper to the faculty at the Georgetown Univ. Law Center (Sloan Interdisciplinary Workshop series), Washington, DC, Sept. 21, 2001 (biomedical knowledge).

Presented a paper to the faculty at the Univ. of Texas School of Law, Austin, TX, Sept. 15, 2000 (civil jury nullification).

Spoke at a conference on the *Restatement (3d) of Torts* at the Univ. of Kansas School of Law (sponsored by its Law & Organizational Economics Center), Lawrence, KS, June 1-3, 2000.

Spoke at a conference on FDA regulation at Stanford Law School (sponsored by its Program in Law, Sci. & Tech.), Palo Alto, CA, Mar. 23-24, 2000 (panels on jurisdiction, speech, devices).

Delivered a lecture at the ASU College of Law (sponsored by its Law, Sci. & Tech. Ctr.), and presented a paper to the faculty, Tempe, AZ, Mar. 6-7, 2000 (reg. peer review/agency intent).

Presented a paper to the faculty at the Univ. of California Hastings College of the Law, San Francisco, CA, Oct. 29, 1999 (interpreting agency rules).

Spoke at a symposium on the regulatory compliance defense at the Georgetown Univ. Law Center, Washington, DC, Oct. 8, 1999.

Testified by invitation before the Subcommittee on Commercial & Administrative Law of the House Judiciary Comm., Washington, DC, May 25, 1999 (arm-twisting by the FCC).

Presented a work-in-progress to the faculty at the Washington & Lee Univ. School of Law, Lexington, VA, Mar. 22, 1999 (interpreting agency statutes).

Participated in a workshop sponsored by the Harvard Center for Risk Analysis (School of Public Health), Washington, DC, Dec. 17, 1998 (peer review of agency risk assessments).

Spoke at the fall meeting of the ABA Section on Administrative Law & Regulatory Practice, Washington, DC, Oct. 9, 1998 (led a panel on agency arm-twisting).

Presented a paper at a Food Forum workshop sponsored by the Institute of Medicine (NAS), Washington, DC, May 6, 1997 (food additives).

Testified by invitation at an FDA public hearing on the labeling of nonprescription products, Rockville, MD, Sept. 29, 1995 (60 Fed. Reg. 42,578).

Presented a paper to the faculty at the Harvard Law School, Cambridge, MA, Mar. 17, 1994 (consumer product warnings).

# PROFESSIONAL ACKNOWLEDGMENT AND ACTIVITIES (SELECTED):

National recognition for scholarly impact (based on citation surveys):

- Top 10 in Administrative Law (#7) over a five-year span (Leiter, 2010)
- Top 20 in Health Law (#5) over a five-year span (Hall & Cohen, 2018)
- Top 250 among legal academics (#186) overall (HeinOnline, Mar. 2019)

Served as a referee for JAMA (x9); JAMA Network Open (x6); Alzheimer's & Dementia (x1); AMA J. Ethics (x2); Law Probability & Risk (x1); Yale J. Health Pol'y L. & Ethics (x5); J.L. Med. & Ethics (x1); Colum. L. Rev. (x4); Stan. L. Rev. (x3); Harv. L. Rev. (x1); Yale L.J. (x1); academic presses (Cambridge, Chicago, Columbia, Oxford, Vanderbilt); etc.

Media interviews—quoted in the following publications:

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N.Y. TIMES (x7); WASH. POST (x2); WALL St. J. (x2); L.A. TIMES (x2); BOS. GLOBE (x1); PHILA. INQUIRER (x1); BALT. SUN (x2); USA TODAY (x3); BUS. WK. (x3); NEWSWEEK (x2); NAT'L L.J. (x4); NEW ENG. J. MED. (x1); LANCET (x1); etc.; and on CNN (x1); NPR (x3).
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Named as a member of UF's Emerging Pathogens Institute (2024).

Invited to lead "Grand Rounds" at UF's Health Science Center: Family Med. (Apr. 2015); Cardiology (Dec. 2012); Dermatology (June 2010); Pharmacology (Mar. 2003).

Recipient of the Simonsmeier Award from the American Society for Pharmacy Law (2006).

Served as an external reviewer for the National Academy of Sciences on a draft report by the Institute of Medicine's Committee on Implications of Dioxin in the Food Supply (Mar. 2003).

Served as a member of an Institute of Medicine committee charged with developing a framework for conducting safety evaluations of dietary supplements (July 2001 - Jan. 2002).

Served as a member of the expert advisory panel for a National Institutes of Health technology assessment conference on the retrieval of implanted medical devices for biomaterials testing, Bethesda, MD, Jan. 10-12, 2000.

Member, Editorial Advisory Board, Food & Drug Law Journal (2000-04).

Selected to serve as the "Roger J. Traynor Summer Research Professor" (scholar in residence) at the Univ. of California Hastings College of the Law, San Francisco, CA, June-July 1999.

Served as an expert consultant to Senator Orrin Hatch's Judiciary Committee health staff in drafting proposed legislation to codify the nationwide tobacco settlement (Nov. 1997) and in analyzing the regulatory provisions of Senator John McCain's bill (Apr. 1998); and to Senator Ted Kennedy's staff in evaluating a medical device provision of FDA reform bill (Sept. 1997).

Co-taught *Food & Drug Law* as an adjunct professor at the Univ. of Maryland School of Law (Baltimore, MD), Jan.-May 1994.

### **BIBLIOMETRIC ASSESSMENT:**

Total citation counts [as of 6/7/24]:

- Google Scholar = 3,839
- HeinOnline (in articles) = 2,122
- Lexis (in law reviews) = 1,425
- Westlaw (in law reviews) = 1,419

Mapping scholarly work—approximate focus of publications (extremely rough estimates): Regulatory (30%), Constitutional Law (25%), Torts (20%), Administrative Law (15%), other (inc. antitrust, civ. pro., corps., crim., evid., insur., IP, PR) (10%).

- Within the largest of those categories, "Regulatory" (30%), the breakdown is as follows: FDA (60%), CDC (10%), CMS (10%), DEA (5%), EPA (5%), other (inc. non-federal) (10%); and within largest subcategory ("FDA"), the further breakdown is as follows: drugs (50%), devices (25%), food (15%), biologics (10%).
- Within the second largest category, "Constitutional Law" (25%), the breakdown is as follows: 1st Amend. (esp. speech) (40%), substantive due process (25%), proced'l due process (10%), commerce/supremacy/federalism (10%), takings (5%), separation of powers (5%), other (5%).
- Within the third largest category, "Torts" (20%), the breakdown is as follows: products liability (35%), med. mal. (15%), other claims (15%), preemption defense (10%), other defenses (10%), causation (10%), damages (5%).
- Within the fourth largest category, "Administrative Law" (15%), the breakdown is as follows: rulemaking (40%), adjudication/enforcement (30%), statutory interp. (20%), other (10%).

In non-doctrinal terms, roughly 40% relates to "S.T.E.M." subjects, and the further breakdown within that group is as follows: science (25%), technology (60%), engineering (10%), math (5%).

• Alternatively, approximately 30% falls within the "public health" category—including opioid abuse (20%), tobacco use (20%), food safety (15%), vaccines (10%), gun violence (10%), and misinformation (25%)—with another 10% falling into the "bioethics" category—including human research (50%), end-of-life care (20%), reproductive autonomy (20%), rationing (10%).