

Patricia J. Zettler

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ACADEMIC EXPERIENCE

The Ohio State University Moritz College of Law

John W. Bricker Professor of Law, August 2023–present (on leave as of November 2023)

Professor (with tenure), May 2023–August 2023

Associate Professor (with tenure), June 2020–May 2023 Assistant Professor (tenure-track),
May 2019–June 2020 Faculty Member, Drug Enforcement & Policy Center (on leave as of
November 2023)

Faculty Member, Cancer Control Program, Comprehensive Cancer Center (on leave as of November 2023)

Georgia State University College of Law

Associate Professor (tenure-track), June 2015–May 2019

Faculty Member, Center for Law, Health & Society

Center for Law and the Biosciences, Stanford Law School

Fellow and Lecturer in Law, Aug. 2013–June 2015

PROFESSIONAL EXPERIENCE

Office of the General Counsel, U.S. Department of Health & Human Services

Deputy General Counsel, Nov. 2023–present

Office of the Chief Counsel, U.S. Food and Drug Administration

Associate Chief Counsel, Oct. 2012–July 2013

Assistant Chief Counsel, Sept. 2009–Oct. 2012

Department of Bioethics, Clinical Center, National Institutes of Health

Law Fellow, Sept. 2008–Dec. 2008

Program in Medical Ethics, University of California San Francisco

Greenwall Faculty Scholars Program Coordinator, July 2004–June 2006

Research Assistant to Bernard Lo, July 2004–June 2006

Research Assistant to Sara L. Swenson and Bernard Lo, July 2002–July 2004

EDUCATION

Stanford Law School, J.D. with distinction, June 2009

Features Articles Editor, *Stanford Law & Policy Review*

Stanford University, B.A. with distinction and departmental honors, Psychology, June 2002

Robert C. Byrd Honors Scholarship

Stanford Scholar-Athlete Honor Roll

Defensive Player, Stanford Varsity Lacrosse

SELECTED PUBLICATIONS

BOOKS

FOOD AND DRUG LAW: CASES AND MATERIALS (5th edition) (2022) (with Peter Barton Hutt, the late Richard A. Merrill, Lewis Grossman, Nathan Cortez & Erika Lietzan).

LAW JOURNALS

Rachel E. Sachs, W. Nicholson Price & **Patricia J. Zettler**, *Rethinking Innovation at FDA*, B.U. L. REV. (forthcoming 2024).

Greer Donley & **Patricia J. Zettler**, *Response to Listening to Mifepristone*, NYU ANN. SURV. AM. L. (forthcoming 2023).

Patricia J. Zettler, Annamarie Beckmeyer, Beatrice L. Brown & Ameet Sarpatwari, *Mifepristone, Preemption, and Public Health Federalism*, 9 J.L. & BIOSCIENCES 1 (2022) (peer-reviewed).

Jacob S. Sherkow & **Patricia J. Zettler**, *EpiPen, Patents, and Life and Death*, 96 NYU L. REV. ONLINE 164 (2021).

Efthimios Parasidis, Micah L. Berman & **Patricia J. Zettler**, *Assessing COVID-19 Emergency Use Authorizations*, 76 FOOD & DRUG L.J. 441 (2021) (peer-reviewed).

Patricia J. Zettler, *The FDA's Power Over Non-Therapeutic Uses of Drugs and Devices*, 78 WASH. & LEE L. REV. 379 (2021).

Louiza Kalokairinou, **Patricia J. Zettler**, Ashwini Nagappan, Moira A. Kywekuk & Anna Wexler, *The Promise of Direct-to-Consumer COVID-19 Testing: Ethical and Regulatory Issues*, 7 J.L. & BIOSCIENCES 1 (2020) (peer-reviewed).

Holly Fernandez Lynch, Neal W. Dickert, **Patricia J. Zettler**, Steven Joffe & Emily A. Largent, *Regulatory Flexibility for COVID-19 Research*, 7 J.L. & BIOSCIENCES 1 (2020) (peer-reviewed).

Christi J. Guerrini, Evan Spencer & **Patricia J. Zettler**, *DIY CRISPR*, 97 N.C. L. REV. 1399 (2019).

Amy Zarzeczny, Harold Atkins, Judy Illes, Jonathan Kimmelman, Zubin Master, Julie M. Robillard, Jeremy Snyder, Leigh Turner, **Patricia J. Zettler** & Timothy Caulfield, *The Stem Cell Market & Policy Options: A Call for Clarity*, 5 J.L. & BIOSCIENCES 743 (2018) (peer-reviewed).

Jacob S. Sherkow, **Patricia J. Zettler** & Henry T. Greely *Is It 'Gene Therapy'?*, 5 J.L. & BIOSCIENCES 786 (2018) (peer-reviewed).

Patricia J. Zettler, Natalie Hemmerich & Micah L. Berman, *Closing the Regulatory Gap for Synthetic Nicotine Products*, 59 B.C. L. REV. 1933 (2018).

Patricia J. Zettler, Margaret Foster Riley & Aaron S. Kesselheim, *Implementing a Public Health Perspective in FDA Drug Regulation*, 73 FOOD & DRUG L.J. 221 (2018) (peer-reviewed).

Patricia J. Zettler, *The Indirect Consequences of Expanded Off-Label Promotion*, 78 OHIO STATE L.J. 1053 (2017).

Patricia J. Zettler, *Pharmaceutical Federalism*, 92 IND. L.J. 845 (2017).

Patricia J. Zettler, *What Lies Ahead for FDA Regulation of tDCS Products?*, 3 J.L. & BIOSCIENCES 318 (2016) (peer-reviewed).

Patricia J. Zettler, *Regulating Drug Promotion to Promote the Public Health: A Response to Bennett et al.*, 2 J.L. & BIOSCIENCES 712 (2015) (peer-reviewed).

Patricia J. Zettler, *Toward Coherent Federal Oversight of Medicine*, 52 SAN DIEGO L. REV. 427 (2015).

Seema Shah & **Patricia J. Zettler**, *From a Constitutional Right to a Policy of Exceptions: Abigail Alliance and the Future of Access to Experimental Therapy*, 10 YALE J. HEALTH POL'Y, L. & ETHICS 135 (2010) (peer-reviewed).

Patricia J. Zettler, *Is It Cheating to Use Cheetahs? The Implications of Technologically Innovative Prostheses for Sports Values and Rules*, 27 B.U. INT'L L.J. 367 (2009).

SCIENTIFIC AND MEDICAL JOURNALS

Patricia J. Zettler, Lewis A. Grossman, Eli Y. Adashi & I. Glenn Cohen, *The Mifepristone Litigation: Untangling the Implications of the Fifth Circuit's Decision for Abortion Access and the U.S. Food and Drug Administration*, ANN. INTERNAL MED. (published online 2023, forthcoming in print).

Nathan Richards, Martin Fried, Larisa Svirsky, Nicole Thomas, **Patricia J. Zettler** & Dana Howard, *Clinician Perspectives on Opioid Treatment Agreements: A Qualitative Analysis of Focus Groups*, AJOB EMPIRICAL BIOETHICS (forthcoming 2023).

Patricia J. Zettler, Eli Y. Adashi & I. Glenn Cohen, *Alliance for Hippocratic Medicine v. FDA — Dobbs's Collateral Consequences for Pharmaceutical Regulation*, 388 N. ENGL. J. MED. E29 (2023).

Laertis Ikonomidou et al, *Key Considerations to Support Evidence-Based Cell and Gene Therapies and Oppose Marketing of Unproven Products*, 25 CYTOTHERAPY 920 (2023) (position paper of the ISCT Committee on the Ethics of Cell and Gene Therapy).

Patricia J. Zettler, Laertis Ikonomidou, Aaron D. Levine, Leigh Turner, Bambi Grilley & Beth Roxland, *An ISCT Expanded Access Working Group Short Report on The Future of Expanded Access to Unapproved Cell and Gene Therapies*, 25 CYTOTHERAPY 712 (2023).

Megan E. Roberts, Joanne G. Patterson, Brittney L. Keller-Hamilton, Amy K. Ferketich, Jill M. Singer & **Patricia J. Zettler**, *JUUL and its 'Action Network' Attempt to Prevent a Local Flavour Ban*, TOBACCO CONTROL (2023).

Brittney Keller-Hamilton, Hayley Curran, Elise M. Stevens, **Patricia J. Zettler**, Darren Mays & Amy K. Ferketich, *Effects of "Tobacco Free" Language in Warning Labels on Perceptions of Electronic Cigarettes and Nicotine Pouches among Young Adult Men: A Randomized Trial*, 58 SUBSTANCE USE & MISUSE 1302 (2023).

Patricia J. Zettler, *State Regulation of Biomedical Citizen Science*, 7 CITIZEN SCIENCE: THEORY & PRACTICE 43 (2022).

Alexis R. Miranda, Joanne G. Patterson, Devin LaPolt, Ruva P. Rumano, Alexa M. Reynoso, Micah L. Berman, Brittney L. Keller-Hamilton, Megan E. Roberts, Amy Ferketich & **Patricia J. Zettler**, *A Call for Regulatory Clarity: “Switch” and “Quit Smoking” Marketing among Online Disposable E-Cigarette Sellers*, 61 HARV. PUB. HEALTH REV. 56 (2022).

Patricia J. Zettler & Ameet Sarpatwari, *State Restrictions on Mifepristone Access—The Case for Federal Preemption*, 386 N. ENGL. J. MED. 705 (2022).

Natividad Cuende, Rachele Ciccocioppo, Miguel Forte, Jacques Galipeau, Laertis Ikononou, Bruce L. Levine, Alok Srivastava, **Patricia J. Zettler**, *Patient Access to and Ethical Considerations of the Application of the European Union Hospital Exemption Rule for Advanced Therapy Medicinal Products*, 24 CYTOTHERAPY 686 (2022).

Govind Persad, **Patricia J. Zettler** & Holly Fernandez Lynch, *Flexible Administration Of COVID-19 Vaccines and Therapeutics—Clarifying Legality, Liability, And Compensation*, HEALTH AFFAIRS FOREFRONT (2022).

Govind Persad, **Patricia J. Zettler** & Holly Fernandez Lynch, *Off-Label Prescription of COVID-19 Vaccines in Children: Clinical, Ethical, and Legal Issues*, 149 PEDIATRICS e2021054578 (2022).

Patricia J. Zettler, Eli Y. Adashi & I. Glenn Cohen, *A Divisive Ruling on Devices—Genus Medical Technologies v. FDA*, 385 N. ENGL. J. MED. 2409 (2021).

Patricia J. Zettler & Seema K. Shah, *Broader Implications of Eliminating FDA Jurisdiction Over Execution Drugs*, 111 AM. J. PUB. HEALTH 1764 (2021).

Joanne G Patterson, Devin T LaPolt, Alexis R Miranda, **Patricia J. Zettler**, Micah L. Berman, Megan E Roberts, Brittney Keller-Hamilton, Amy K. Ferketich, *Switching Stories: User Testimonials on Juul.com Continue to Contradict JUUL’s Switch ≠ Cessation Narrative*, 30 TOBACCO CONTROL e37 (2021).

Robin Lovell-Badge et al., *ISSCR Guidelines for Stem Cell Research and Clinical Translation: The 2021 Update* 16 STEM CELL REPORTS 1398 (2021) (reporting on updates to the International Society of Stem Cell Research’s guidelines).

Christi J. Guerrini, Jacob S. Sherkow, Michelle N. Meyer, **Patricia J. Zettler**, *Self-experimentation, Ethics, and Regulation of Vaccines*, 369 SCIENCE 1570 (2020).

Christi J. Guerrini, Jacob S. Sherkow, Michelle N. Meyer, **Patricia J. Zettler**, *Transparency is Key to Ethical Vaccine Research—Response*, 370 SCIENCE 6523 (2020).

Lisa M. Rasmussen, Christi J. Guerrini, Todd Kuiken, Camille Nebeker, Alex Pearlman, Sarah B. Ware, Anna Wexler, **Patricia J. Zettler**, *Realizing Present and Future Promise of DIY Biology and Medicine through a Trust Architecture*, 50 HASTINGS CENTER REPORT 10 (2020).

Micah L. Berman, **Patricia J. Zettler**, Efthimios Parasidis, *Law and Ethics During a Public Health Crisis*, 3 OHIO J. PUB. HEALTH 3 (2020).

Patricia J. Zettler & Erika Lietzan, *A Special Exception for CBD in Foods and Supplements?*, 25 DRUG DISCOVERY TODAY 467 (2020).

Y. Tony Yang, **Patricia J. Zettler** & Theodore Wagener, *New Graphic Tobacco Warnings and the First Amendment*, 6 JAMA ONCOLOGY 473 (2020).

Patricia J. Zettler, Christi J. Guerrini & Jacob S. Sherkow, *Regulating Genetic Biohacking*, 365 SCIENCE 34 (2019).

Holly Fernandez Lynch, Ameet Sarpatwari, Robert H. Vonderheide & **Patricia J. Zettler**, *Right to Try Requests and Oncologists' Gatekeeping Obligations*, 38 J. CLINICAL ONCOLOGY 111 (2019).

Christi J. Guerrini, Anna Wexler, **Patricia J. Zettler** & Amy L. McGuire, *Biomedical Citizen Science of Something Else? Reflections on Terms and Definitions*, 19 AM. J. BIOETHICS 17 (2019).

Y. Tony Yang & **Patricia J. Zettler**, *FDA's Regulatory Shift on Direct-to-Consumer Genetic Tests for Cancer Risk*, 125 CANCER 12 (2019).

Holly Fernandez Lynch, **Patricia J. Zettler** & Ameet Sarpatwari, *Promoting Patient Interests in Implementing the Federal Right to Try Act*, 320 JAMA 869 (2018).

Micah L. Berman, **Patricia J. Zettler** & David Ashley *Anticipating Industry Arguments: The FDA's Authority to Reduce Nicotine Levels in Cigarettes*, 133 PUB. HEALTH REP. 502 (2018).

Emily Jung, **Patricia J. Zettler** & Aaron S. Kesselheim *Prevalence of Publicly Available Expanded Access Policies*, CLINICAL PHARMACOLOGY & THERAPEUTICS (2018).

Patricia J. Zettler, *tDCS Research in a World with FDA Regulation*, 8 AM. J. BIOETHICS NEUROSCIENCE 1 (2017).

Patricia J. Zettler & Erin Fuse Brown, *The Challenge of Paying for Cost-Effective Cures*, 23 AM. J. MANAGED CARE 62 (2017).

Patricia J. Zettler, *Compassionate Use of Experimental Medicines: Who Should Decide?*, 7 EMBO MOLECULAR MED. 1248 (2015).

Patricia J. Zettler & Henry T. Greely, *The Strange Allure of State Right-to-Try Laws*, 174 JAMA INTERNAL MED. 1885 (2014).

Patricia J. Zettler, Jacob S. Sherkow & Henry T. Greely, *23andMe, the Food and Drug Administration, and the Future of Genetic Testing*, 174 JAMA INTERNAL MED. 403 (2014).

Patricia J. Zettler, Leslie E. Wolf & Bernard Lo, *Establishing Procedures for Institutional Oversight of Stem Cell Research*, 82 ACADEMIC MED. 6 (2007).

Sara L. Swenson, **Patricia J. Zettler** & Bernard Lo, *'She Gave It Her Best Shot Right Away': Patient Experiences of Patient-Centered and Biomedical Communication*, 61 PATIENT EDUC. & COUNSELING 200 (2006).

Bernard Lo, **Patricia J. Zettler**, Marcelle I. Cedars, Elena Gates, Arnold R. Kriegstein, Michelle Oberman, Richard Wagner, Leslie E. Wolf, Mary T. Wuerth & Keith R. Yamamoto, *A New Era in the Ethics of Human Embryonic Stem Cell Research*, 23 STEM CELLS 1454 (2005).

Sara L. Swenson, Stephanie Buell, **Patricia J. Zettler**, Martha White, Delaney C. Ruston & Bernard Lo, *Patient-Centered Communication: Do Patients Really Prefer It?*, 19 J. GEN. INTERNAL MED. 1069 (2004).

REPORT AND BOOK CHAPTERS

Micah L. Berman, **Patricia J. Zettler** & Sven E. Jordt, *Synthetic Nicotine: Science, Global Legal Landscape, and Regulatory Considerations*, in World Health Organization Study Group on Tobacco Product Regulation Technical Report (Aug. 23, 2023).

Patricia J. Zettler, Micah L. Berman & Efthimios Parasidis, *Drug and Vaccine Development and Access*, in ASSESSING LEGAL RESPONSES TO COVID-19 (Burris, S., de Guia, S., Gable, L., Levin, D.E., Parmet, W.E., Terry, N.P. eds., 2020) (updated version also published in 2021).

Patricia J. Zettler, Christi J. Guerrini & Jacob S. Sherkow, *Finding a Regulatory Balance for Genetic Biohacking*, in CONSUMING GENETICS: ETHICAL AND LEGAL CONSIDERATIONS OF NEW TECHNOLOGIES (Cambridge University Press, I. Glenn Cohen, Nita Farahany, Henry T. Greely & Carmel Shachar eds., 2021).

Erika Lietzan & **Patricia J. Zettler**, *Regulating Medicines in the United States*, in OXFORD HANDBOOK ON COMPARATIVE HEALTH LAW (Oxford University Press, David Orentlicher & Tamara Hervey, eds., 2020).

Patricia J. Zettler & Erika Lietzan, *Regulating Medical Devices in the United States*, in OXFORD HANDBOOK ON COMPARATIVE HEALTH LAW (Oxford University Press, David Orentlicher & Tamara Hervey, eds., 2020).

Timothy D. Lytton & **Patricia J. Zettler**, *Regulation of Chemicals in Food*, in CHEMICALS AND THE LAW (Edward Elgar Publishing Ltd., Lucas Bergkamp et al., eds., forthcoming).

Erika Lietzan & **Patricia J. Zettler**, *Regulation of Medicines*, in CHEMICALS AND THE LAW (Edward Elgar Publishing Ltd., Lucas Bergkamp et al., eds., forthcoming).

Michelle Oberman, **Patricia J. Zettler** & Leslie E. Wolf, *Where Stem Cell Research Meets Abortion Politics: Limits on Buying and Selling Human Oocytes*, in BABY MARKETS: MONEY AND THE NEW POLITICS OF CREATING FAMILIES (Cambridge University Press, Michele Goodwin, ed., 2010).

OTHER

The Case Against Medication Abortion Rejects Science and Embraces Falsehoods, THE HILL (Nov. 27, 2022) (with Greer Donley), <https://thehill.com/opinion/healthcare/3751672-the-case-against-medical-abortion-rejects-science-and-embraces-falsehoods/>.

Should Vaccinating Children Off-Label Against COVID-19 Be Universally Prohibited? BILL OF HEALTH (Oct. 6, 2021) (with Govind Persad & Holly Fernandez Lynch), <https://blog.petrieflom.law.harvard.edu/2021/10/06/vaccinating-children-off-label-covid/>

The Biden-Harris FDA Should Make Friends with Independent Researchers, STAT (Jan. 26, 2021) (with Christi Guerrini & Alex Pearlman), <https://www.statnews.com/2021/01/26/the-biden-harris-fda-should-make-friends-with-independent-researchers/>

It's Time to Add Graphic Warnings to Cigarettes THE HILL (Feb. 21, 2020) (with Y. Tony Yang & Theodore L. Wagener), <https://thehill.com/opinion/healthcare/484101-its-time-to-add-graphic-warnings-to-cigarettes>

Regulating Genetic Self-Experimentation as Biomedical Research, REGULATORY REVIEW (July 30, 2019) (with Jacob S. Sherkow & Christi J. Guerrini), <https://www.theregreview.org/2019/07/30/zettler-sherkow-guerrini-regulating-genetic-self-experimentation-biomedical-research/>

The Logical Outgrowth Doctrine and FDA's Intended Use Revisions, NOTICE & COMMENT (July 18, 2017), <https://www.yalejreg.com/nc/the-logical-outgrowth-doctrine-and-fdas-intended-use-revisions/>

FDA Advisory Committees and Industry-Funded Patient Advocacy, NOTICE & COMMENT (June 23, 2017), <https://www.yalejreg.com/nc/fda-advisory-committees-and-industry-funded-patient-advocacy/>

Do You Need a Medical Degree to Crowdsource Medicine?, THE HEALTH CARE BLOG (June 19, 2015), <http://thehealthcareblog.com/blog/2015/06/19/do-you-need-a-medical-degree-to-crowdsource-medicine>

OBJECTIVE INTENT (blog about FDA law and policy), Co-Founder and Contributor, <https://objectiveintent.wordpress.com/author/pzettler/>

STANFORD LAW AND BIOSCIENCES BLOG, Contributor, https://law.stanford.edu/blog/?tax_and_terms=3140&page=1&primary_author=Patti%20Zettler

ACADEMIC HONORS AND GRANTS

The Ohio State University Early Career Distinguished Scholar Award (2023)

Patricia T. Morgan Award for Outstanding Scholarship, Georgia State University College of Law (2018)

Wiet Life Sciences Law Scholar, Loyola University Chicago Beazley Institute for Health Law & Policy (2018)

Health Law Scholar, American Society of Law, Medicine, and Ethics (2015)

Co-Investigator, Ohio State Addiction Innovation Fund (2021-2022), *Stigma, Trust, and the Physician-Patient Relationship: A Mixed Methods Study of How Physicians Use and Perceive Opioid Treatment Agreements for Long-Term Opioid Therapy*

Principal Investigator, Ohio State Cancer Control Program Award GR118331 (FY2020), *Bait and Switch: Do JUUL Testimonials Constitute Switching or Cessation Claims?*

SELECTED PRESENTATIONS

Federal Administrative Law Update

Ohio State Bar Association Administrative Law Seminar (Sept. 1, 2023)

Ohio State Bar Association Administrative Law Seminar (Sept. 9, 2022)

ISCT Expanded Access Working Group

Stem Cells, Cell Therapies, and Bioengineering in Lung Biology and Diseases, University of Vermont (July 19, 2023)

Federal Advisory Committee Act “101”

Yale Collaboration for Regulatory Rigor, Integrity, and Transparency (CRRIT) (June 8, 2023)

Administering Execution Drugs

Stanford Law School (May 19, 2023)

FDA Under Fire

Food and Drug Law Institute Annual Meeting (May 17, 2023)

Mifepristone, Preemption, and Public Health Federalism

Solomon Center for Health Law & Policy, Yale Law School (Apr. 4, 2023)

Jaharis Health Law Symposium, DePaul College of Law (Mar. 1, 2023)

University of Pennsylvania Carey School of Law (Nov. 9, 2022)

The Public Health Administrative State Under Fire: Restoring Trust in the CDC and FDA

Georgia State University College of Law (Mar. 24, 2023)

The Global Legal Landscape for Synthetic Nicotine Products

World Health Organization (WHO) Study Group on Tobacco Product Regulation (TobReg) (Dec. 12-15, 2022)

Sixth Meeting of the Global Tobacco Regulators Forum (June 13, 2022)

Federal Tobacco Control Policy Updates

6th Annual Maryland Tobacco Control Conference (June 7, 2022)

Stigma, Trust, and the Physician-Patient Relationship: The Legal Landscape for Opioid Treatment Agreements

American Society of Law, Medicine, and Ethics (ASLME) 2022 Health Law Professors Conference (June 2, 2022)

Moderator, Expanded Access and Hospital Exemption: Understanding Investigational Treatment Pathways

Panelist, Ethical Considerations and Consent in Novel Therapies

International Society for Cell & Gene Therapy 2022 Annual Meeting (May 4 and 5, 2022)

A Right to Try Psychedelics? Pathways for Treatment Use of Unapproved Psychedelics

NYU Langone Medical Center Working Group on Compassionate Use and Preapproval Access (Dec. 9, 2021)

COVID-19 Drug and Vaccine Development and Access

National Academies of Sciences, Engineering, and Medicine Workshop on The Food and Drug Administration's Emergency Use Authorization: Lessons Learned from the Past to Guide the Future (Oct. 6, 2021)
Ewha Institute for Biomedical Law & Ethics, South Korea (Nov. 16, 2020)
National Governors Association (Oct. 20, 2020) (with Efthimios Parasidis & Micah L. Berman)
Gonzaga University School of Law (Oct. 9, 2020)
Public Health Law Virtual Summit: COVID-19 Response and Recovery (Sept. 17, 2020) (with Micah L. Berman)
Alliance for Regenerative Medicine, ARM Foundation, and International Society for Cell & Gene Therapy (July 7, 2020)
University of Regina and University of Saskatchewan, Canada (June 25, 2020)
Wake Forest Journal of Law and Policy Symposium, Isolated by the Law Part 2 (recorded June 2020)

Invited Participant, FDA-PTO Roundtable on Innovation

George Washington University (Jan. 21, 2022)

Creative Chemistry: Addressing Industry Evasion and Synthetic Nicotine Products

Public Health Law Center Webinar (December 15, 2021)
Program on Regulation, Therapeutics, and Law, Harvard Medical school and Brigham and Women's Hospital (June 17, 2021)

Addressing Harm: Opioid Settlement Background and Historical Context

The Ohio State University Drug Enforcement and Policy Center (Nov. 10, 2021)

Regulating Emerging Non-Nicotine Vaping Products

Public Health Law Center Webinar (Sept. 28, 2021)

Regulating Psychedelics

College of Social Work, The Ohio State University (Sept. 27, 2021)
Higher Education Center for Alcohol and Drug Misuse Prevention and Recovery (Apr. 7, 2021)
Elon University Law School (guest lecture in Addiction Law and Policy) (Nov. 4, 2021)
Can Psychedelics Save America?, The Petrie Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School (Oct. 28, 2020)

Understanding FDA Regulation of Opioids

Panel on Empowering Public Health to Influence Federal Regulation, 2021 Public Health Law Conference, Baltimore, MD (Sept 22, 2021)
Pain, Profits, Plaintiffs, Prison: A Prescription for Addressing the Opioid Epidemic in Georgia, Georgia State University College of Law (CLE course Feb. 16, 2018)

Direct-to-Consumer Cell-Based Interventions for Respiratory Disease: Stratagems and Countermeasures

Stem Cells, Cell Therapies, and Bioengineering in Lung Biology and Disease, University of Vermont (July 13, 2021)

Phishing for Cell Therapies—Therapeutic Deception

International Society of Cell & Gene Therapy 2021 Annual Meeting (May 26, 2021)

Citizen Science Federalism

Washington University St. Louis (guest lecture in Biotechnology Law and Policy) (Mar. 8, 2021)

Cannabis, CBD, and FDA

George Mason University Law & Economics Center's Cannabis Symposium for State Attorneys General and State and Federal Judges (Oct. 13, 2020)

University of Michigan Law School, Health Law Students Association (Mar. 9, 2020)

Marijuana Reform Panel (Paper Reviewer), The Controlled Substances Act at 50 Years, Arizona State University Sandra Day O'Connor College of Law (Feb. 22, 2020)

Cannabiz Roundtable, The Ohio State University (Jan. 24, 2020)

The Ethics and Regulation of Clinical Trials for COVID-19 Treatments

University of Michigan School of Law (guest lecture in Food and Drug Law) (Sept. 18, 2020)

The Ohio State University Center for Ethics and Human Values (webinar May 20, 2020)

Situating Stem Cells within the Regulatory Environment for Patient-Driven Access

International Society for Cell & Gene Therapy 2020 Annual Meeting (recorded May 11, 2020)

Stem Cell Network, Ottawa, Canada (Oct. 27, 2017)

Approving Opioids

Indiana University Robert H. McKinney School of Law (CLE webinar April 30, 2020)

New York University Journal of Law & Business and Classical Liberal Institute Symposium (Sept. 26, 2019)

Utah Law Review Symposium (Nov. 30, 2018)

FDA's Power Over Non-Therapeutic Uses of Drugs and Devices

Stanford Law School (Feb. 11, 2020)

The Ohio State University Medical Ethics Conference (Oct. 3, 2020)

Public Policy Conference, Antonin Scalia Law School, George Mason University (Oct. 24, 2018)

FDA: Past, Present, and Future, American University Washington College of Law (Oct. 19, 2018)

University of North Carolina School of Law (Oct. 4, 2018)

Wiet Life Sciences Law Conference, Loyola University Chicago School of Law (Sept. 7, 2018)

Research Roundtable on Permits, Licenses, and the Administrative State, Antonin Scalia Law School, George Mason University (Apr. 13, 2018)

Ethical and Legal Challenges in a "Right to Try" World

American Society of Bioethics & Humanities 2019 Annual Meeting (Oct. 24, 2019)

University of Copenhagen (June 12, 2019)

ASLME 2019 Health Law Professors Conference (June 5, 2019)

Society for Clinical Trials 2019 Annual Meeting (May 22, 2019)

Keynote, University of Florida College of Pharmacy Seminar (Mar. 9, 2019)

DIA Medical Affairs and Scientific Communication 2017 Annual Forum (Mar. 15, 2017)

Federal and State Oversight of Direct-to-Consumer Health Products, Reconceptualizing the Challenges of Direct-to-Consumer Health Products

The Banbury Center, Lloyd Harbor, New York (Oct. 14-16, 2019)

Panelist, Forecasting the Future of the Cannabis Industry and Regulations

Buckeyes in Cannabis, The Ohio State University Moritz College of Law (Sept. 6, 2019)

Regulating Genetic Biohacking

Consuming Genetics, Harvard Law School (May 17, 2019)

Promises and Perils of Emerging Health Innovations, Northeastern University School of Law (Apr. 12, 2019)

“Democratizing” Medicine, DePaul University College of Law (Mar. 14, 2019)

U.S. Special Operations Command Legal Conference, MacDill Air Force Base (Mar. 29, 2018)

Invited Speaker, Biohack the Planet

Omni Commons, Oakland, CA (Sept. 1, 2018)

Panelist, Comparative Health Law

ASLME 2018 Health Law Professors Conference (June 8, 2018)

Implementing a Public Health Perspective in FDA Drug Regulation

2018 BioLawlapalooza, Stanford Law School (Mar. 22, 2018)

Symposium on FDA and Health Behavior Regulation, Georgetown University Law Center and the Food and Drug Law Institute (Oct. 20, 2017)

Reviewing the Regulatory History of DTC Health Products, Workshop on the Evolving Phenomenon of Direct-to-Consumer Neuroscience

The Banbury Center, Lloyd Harbor, New York (Feb. 6, 2018)

Closing the Regulatory Gap for Synthetic Nicotine Products

ASLME 2017 Health Law Professors Conference (June 10, 2017)

2017 BioLawlapalooza, Stanford Law School (Apr. 21, 2017)

The Indirect Consequences of Expanded Off-Label Promotion

University of Tennessee College of Law (Mar. 2, 2017)

Law and the Biosciences Workshop, Stanford Law School (Nov. 29, 2016)

First Amendment Symposium, Ohio State Law Journal (Nov. 18, 2016)

Chase College of Law, Northern Kentucky University (Nov. 17, 2016)

Pharmaceutical Federalism

Harvard Law School (Sept. 12, 2016)

University of Kentucky College of Law (Mar. 24, 2016)

ASLME Health Law Scholars Workshop, St. Louis University School of Law (Oct. 9, 2015)

ASLME 2015 Health Law Professors Conference (June 5, 2015)

Invited Participant, Microbiome Science and Ethics Workshop

New York University Langone Medical Center (Sept. 8, 2016)

State of the Data: The Legal and Ethical Divide Between Biospecimens and Derived Data

ASLME 2016 Health Law Professors Conference (June 4, 2016)

Biotech-Driven Change in Prescription Drugs: Regulation and Prevalence of Bio-Tech Drugs
National Press Foundation (webinar recorded Sept. 17, 2015)

Regulating Direct-to-Consumer Genetic Testing

Guest Lecturer, Stanford Department of Genetics, Online Course (recorded Oct. 24, 2014)
Oxbridge Biotech Roundtable, University of California San Francisco (Apr. 7, 2014)
Stanford Center for Law and the Biosciences (Feb. 20, 2014)

Toward Coherent Federal Oversight of Medicine

Stanford Center for Law and the Biosciences (Oct. 7, 2014)
Stanford Center for Biomedical Ethics (Mar. 26, 2014)

Invited Participant and Moderator of the Genetic Testing Session, Workshop on Personalised Medicine
Centre for Law and Genetics, Faculty of Law, University of Tasmania (July 11-12, 2014)

SELECTED SERVICE

ACADEMIC AND PROFESSIONAL

Food and Drug Law Institute

Member, Board of Directors (2022-2023)
Member, Black Lives Matter Advisory Committee (2020-2021)
Member, *Food and Drug Law Journal*, Editorial Advisory Board (2015–2020)

International Society of Cell & Gene Therapy

Chair, Committee on the Ethics of Cell and Gene Therapy (2023)
Chair, Working Group on Expanded Access (2022-2023)
Member, Committee on the Ethics of Cell and Gene Therapy (2020-2022)

National Academies of Sciences, Engineering, and Medicine

Member, Board on Health Science Policy (2023)
Member, Planning Committee for a public workshop on in-home opioid disposal systems (2023)
Member, Committee on Reviewing the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) (2021)
Consultant, Committee on Pain Management and Regulatory Strategies to Address Prescription Opioid Abuse (2016-2017)

Ohio State Bar Association

Member, Administrative Agency Law Specialty Board (2023)

World Health Organization

Consultant, Synthetic Nicotine: Properties, Marketing, Challenges, and Regulatory Considerations (2021-2023)

Regulation and Innovation in the Biosciences (workshop for junior faculty)

Co-Founder and Steering Committee Member (2016-2022)

International Society for Stem Cell Research

Task Force to Revise Guidelines, Working Group on Regulatory, Pricing & Access Issues
(2019-2021)

Ad Hoc Peer Reviewer, New England Journal of Medicine, Science, JAMA, JAMA Internal Medicine, JAMA Health Forum, American Journal of Public Health, Health Affairs, Regenerative Medicine, The Oncologist, Yale Journal of Health Policy, Law, and Ethics, Social Science & Medicine, Food and Drug Law Journal, Journal of Law and the Biosciences, American Journal of Law & Medicine, Journal of Law, Medicine & Ethics, Dalhousie Law Journal, Journal of Business Ethics, Journal of Legal Medicine, Journal of Health Politics, Policy & Law, Expert Opinion on Orphan Drugs, Therapeutic Innovation & Regulatory Science, BMC Medical Ethics, Clinical Pharmacology in Drug Development, Biosocieties, Citizen Science: Theory & Practice, Milbank Quarterly, Cytotherapy

UNIVERSITY AND COLLEGE OF LAW SERVICE

Chair, Ohio State Academic Affairs Committee (2023-2024)
Ohio State Graduate Studies Committee (2022-2023)
Ohio State Administration Committee (2019-2020; 2021-2022)
Ohio State Appointments Committee (2020-2021)
Ohio State Junior Lightning Rounds (Summer 2020; Summer 2021)
Ohio State Workshop Committee (2019-2020)

Georgia State Faculty Hiring Committee (2016-2017; 2018-2019)
Georgia State Dean's Advisory Committee (2018-2019)
Georgia State Faculty Development Committee (2018)
Georgia State Workload Committee (2018)
Georgia State Scholarships Committee (2018)
Georgia State New Journal Task Force (2017-2018)

MEDIA

Quoted: New York Times, Wall Street Journal, Washington Post, LA Times, Vanity Fair, Reuters, The Atlantic, Wired, San Francisco Chronicle, Atlanta Journal Constitution, St. Louis Post-Dispatch, Slate, Forbes, NBCNews.com, BuzzFeed, STAT, Al Jazeera America, Politico, Politico Pro, Bloomberg News, Bloomberg BNA, LongReads, The Nation, Pacific Standard, Cincinnati Enquirer, Star Tribune, Scientific American, WebMD, The Verge, Fast Company, Mashable, Gizmodo, S&P Global, Genetic Expert News Service, GenomeWeb, MIT Technology Review, Nature, Nature Medicine, Science, ASCO Post, Pink Sheet, Healthline News, Biocentury, BioPharma Dive, The Niche, ScienceBlogs, Harvard Crimson, Stanford News, Georgia State News

Interviewed: NPR's All Things Considered, Bloomberg's Prognosis Podcast, New England Journal of Medicine Podcast, The Guardian's Science Weekly Podcast, Science Advisory Board, WSB-TV Atlanta, WOSU Public Media (Central Ohio), KNX1070 (Los Angeles), DarshanTalks (FDA-focused podcast), Ohio State Insights

Scholarship Cited: New York Times, LA Times, Wired, ABCNews.com, Time.com, Forbes, STAT, Weiner Zeitung, El País, Regulatory Affairs Professionals Society (RAPS), Inside Health Policy, Food and Drug Law Institute Update, Pink Sheet, Regulatory Review, WOSU Public Media (Central Ohio), Plenary Session Podcast (oncology and medicine podcast)

OTHER ACTIVITIES

AMICUS BRIEFS

Amicus Brief filed in the U.S. Supreme Court on behalf of Food and Drug Law Scholars, in *Alliance for Hippocratic Medicine v. FDA*, Case Nos. 23-235 & 23-236 on October 12, 2023.

Amicus Brief filed in the U.S. Court of Appeals for the Fifth Circuit on behalf of Food and Drug Law Scholars, in *Alliance for Hippocratic Medicine v. FDA*, Case No. 23-10362, on May 1, 2023.

Amicus Brief filed in the U.S. Supreme Court on behalf of Food and Drug Law Scholars, in *Alliance for Hippocratic Medicine v. FDA*, Case Nos. 22A902 & 22A901, on April 14, 2023.

Amicus Brief filed in the U.S. District Court for the Southern District of West Virginia on behalf of Food and Drug Law and Health Law Scholars, in *GenBioPro v. Sorsaia*, Civil Action No.: 3:23-cv-00058, Mar. 20, 2023.

Amicus Brief filed in the U.S. District Court for the Northern District of Texas on behalf of Food and Drug Law Scholars, in *Alliance for Hippocratic Medicine v. FDA*, Case No. 2:22-CV-00223-Z, on Feb. 10, 2023.

Amicus Brief filed in the U.S. Supreme Court on behalf of Pharmacy, Medicine, and Health Policy Experts, in *Bucklew v. Precythe*, Case No. 17-8151, on July 23, 2018.

CONSULTING AND EXPERT WITNESS WORK

External Review of FDA Regulation of Opioid Analgesics (Sept 2022-January 2023), <https://www.fda.gov/media/165238/download>.

Expert Witness retained by Direct Purchaser Class, End Payor Class, and Retailer Plaintiffs, *In re Opana Antitrust Litigation*, No. 14cv-10150 (N.D. Ill.) (January 2019-March 2022).

Expert Witness retained by the Direct Purchaser Class Plaintiffs, *In re: Suboxone Antitrust Litigation*, Case No. 2:13-md-2445-MSG (E.D. Pa.) (July 2019-October 2023).

COMMENTS

Comment, Vaccines and Related Biological Products Advisory Committee, Docket No. FDA-2020-N-1898 (Oct. 15, 2020) (with Efthimios Parasidis & Micah L. Berman).

Comment, Standards for Future Opioid Analgesic Approvals and Incentives for New Therapeutics to Treat Pain and Addiction, Docket No. FDA-2019-N-2514 (Nov. 18, 2019) (with Richard J. Bonnie, Aaron S. Kesselheim & Margaret Foster Riley).

Comment, Opioid Analgesic Drugs: Considerations for Benefit-Risk Assessment Framework; Draft Guidance for Industry, Docket No. FDA-2019-D-1536 (Aug. 20, 2019) (with Richard J. Bonnie, Aaron S. Kesselheim & Margaret Foster Riley).

Comment, Joint Meeting of the Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee, Docket No. FDA-2018-N-1797 (June 12, 2018) (with Richard J. Bonnie, Aaron S. Kesselheim & Margaret Foster Riley).

Comment, FDA's Approach to Evaluating Nicotine Replacement Therapies, Docket No. FDA-2017-N-6529 (Jan. 9, 2018) (with Micah L. Berman & Natalie Hemmerich).

BAR ADMISSION

Admitted to practice law in California