Jordan K. Paradise, J.D.
Curriculum Vitae

Georgia Reithal Professor of Law
Co-Director, Beazley Institute for Health Law & Policy
Loyola University Chicago School of Law
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PROFESSIONAL EXPERIENCE

Loyola University Chicago School of Law, Chicago, IL, July 2016-present

- Georgia Reithal Professor of Law, March 2018-present
- Co-Director, Beazley Institute for Health Law & Policy, January 2020-present
- Co-Academic Director, Beazley Institute for Health Law & Policy, July 2018-December 2019
- Professor of Law, July 2016-March 2018
- Advisory Board, Institute for Consumer Antitrust Studies, July 2016-present

Seton Hall University School of Law, Newark, NJ, July 2009-June 2016

- Schering-Plough Professor of Health Care Law and Enforcement, September 2014-June 2016 (Endowed)
- Associate Professor of Law, July 2009-August 2014
- Faculty, Center for Health and Pharmaceutical Law, July 2009-June 2016
- Faculty, Gibbons Institute of Law, Science & Technology, July 2009-June 2016

University of Minnesota Law School, Minneapolis, MN, June 2005-June 2009

- Associate Director of Research and Education, Joint Degree Program in Law, Health & the Life Sciences and Consortium on Law and Values in Health, Environment & the Life Sciences
- Adjunct Associate Professor of Law
- Minnesota Journal of Law, Science and Technology: Faculty Editor-in-Chief, December 2006-June 2009; Faculty Managing Editor, April 2006-December 2006; Faculty Editorial Advisory Board Member, June 2005-April 2006

University of Minnesota, Minneapolis, MN, June 2005-June 2009

- Associate Researcher (joint appointment), Center for Bioethics, University of Minnesota Academic Health Center
- Adjunct Professor (joint appointment), Hubert H. Humphrey Institute of Public Affairs, September 2008-December 2008

Illinois Institute of Technology/Chicago-Kent College of Law, Chicago, IL, January 2001-May 2005

- Legal Fellow, Institute for Science, Law and Technology, August 2003-May 2005
- Policy Analyst, Institute on Biotechnology and the Human Future, March 2004-May 2005
- Research Assistant, Professor Lori Andrews, January 2001-August 2003

University of Michigan, Ann Arbor, MI, March 1999-August 2000

- Laboratory Technician, Dr. Kent Berridge (Neuroscience Department)

ADMISSIONS

State Bar of Illinois, November 2003

EDUCATION

Chicago-Kent College of Law, Chicago, Illinois
Juris Doctor, May 2003; Intellectual Property Law Certificate
Merit Scholarship, Legal Fellowship, Dean's List
1st Place, Food & Drug Law Institute H. Thomas Austern Student Writing Competition 2003

University of Michigan, Ann Arbor, Michigan
Bachelor of Science, Biological Psychology & Cognitive Science, April 1999
Campbell Foundation Scholarship
Cook Family Foundation Scholarship
College of Literature, Science & the Arts, Dean's List

TEACHING

Loyola University Chicago School of Law: Administrative Law, Administrative Health Law, Food & Drug Law, Genetics Law & Policy, Law & the Life Sciences, Property Law
Seton Hall University School of Law: Administrative Law, Biotechnology Law, Emerging Technologies Law, Food & Drug Law, Law & Genetics, Law & the Life Sciences
University of Minnesota Law School: Law, Health & the Life Sciences; Nanotechnology & Society; select lectures for Introduction to Bioethics (undergraduate course)

PUBLICATIONS

LAW REVIEW ARTICLES

From Emergency Use to Status Quo (in progress)

Public Health Effects of Medical Device Sterilization Processes (in progress)

Mifepristone Paternalism at the FDA, *forthcoming* J. L. MED.& ETHICS 2023.

The Complexities of Insulin Regulation and Access, forthcoming BELMONT HEALTH L. J. 2023.

Stumbling Over TRIPS: The International IP Waiver Petition and the U.S. Executive, 30 MSU INTERNATIONAL L. REV. 249 (2022)(with Christina Conroy).

Information Opacity in Biopharmaceutical Innovation Through the Lens of COVID-19, 47 AM. J. LAW & MED. 157 (2021).

Insulin Federalism, 27 BOSTON U. J. SCI. & TECH. L. 118 (2021).

Pandemic Politics, Public Health, and the FDA, 8 BELMONT L. REV. 301 (2021) (with Becky Bavlsik).

FDA Publicity and Enforcement in the COVID Era, 60 WASHBURN L. REV. 77 (2020) (with Elise Fester).

COVID-IP: Staring Down the Bayh-Dole Act with 2020 Vision, 7 J. L. & THE BIOSCIENCES 1 (2020), lsaa073. doi: 10.1093/jlb/lsaa073.

Three Framings of "Faster" at the FDA and the Federal Right to Try, 11 WAKE FOREST J. L. & POL'Y 53 (2020).

Public Health Preparedness & Response: An Exercise in Administrative Law, 20 DEPAUL J. HEALTH CARE L. 1 (2019) (with John Blum).

21st Century Citizen Pharma, 44 AM. J. L. & MED. 309 (2018).

Regulatory Silence at the FDA, 102 MINN. L. REV. 2383 (2018).

Exploring Precision FDA, an Online Crowdsourcing Platform for Genomics, 58 JURIMETRICS 267 (2018).

Revisiting Regulatory Evasion, 2018 ILL. L. REV. ONLINE 93 (2018).

Cultivating Innovation in Precision Medicine through Regulatory Flexibility at the FDA, 11 NYU J. L. & LIBERTY 672 (2017).

A Profile of Bio-Pharma Consolidation Activity, 25 ANNALS HEALTH L. 34 (2016).

REMS as a Competitive Tactic: Is Big Pharma Hijacking Drug Access and Patient Safety?, 15 HOUS. J. HEALTH L. & POL'Y 43-82 (2015).

The Legal and Regulatory Status of Biosimilars: How Product Naming and State Substitution Laws May Impact the United States Healthcare System, 41 AM. J. L. & MED. 49-84 (2015).

No Sisyphean Task: How the FDA Can Regulate Electronic Cigarettes, 13 YALE J. HEALTH POL'Y, L. & ETHICS 326 (2013).

Synthetic Biology: Does Re-writing Nature Require Re-writing Regulation?, 117 PENN. ST. L. REV. 53 (2012)(with Ethan Fitzpatrick).

Reassessing 'Safety' for Nanotechnology Combination Products: What Do 'Biosimilars' Add to Regulatory Challenges for the FDA?, 56 ST. LOUIS U. L. J. 1 (2012).

Claiming Nanotechnology: Improving USPTO Efforts at Classification of Emerging Nano-Enabled Pharmaceutical Technologies, 10(3) NW. J. TECHNOL. & INTELL. PROP. 169 (2012).

The Devil is in the Details: Health Care Reform, Biosimilars, and Implementation Challenges for the Food and Drug Administration, 51 JURIMETRICS 279 (2011).

Follow-On Biologics: Implementation Challenges and Opportunities, 41 SETON HALL L. REV. 501 (2011).

Exploring Emerging Nanobiotechnology Drugs and Medical Devices, 63(2) FOOD & DRUG L. J. 407 (2008)(with Gail M. Diliberto, Alison W. Tisdale & Efrosini Kokkoli).

Developing Oversight Frameworks for Nanobiotechnology, 9(1) MINN. J. L. SCI. & TECH. 187 (2008)(with Susan M. Wolf, Gurumurthy Ramachandran, Efrosini Kokkoli, Ralph Hall & Jennifer Kuzma).

Tales from the Crypt: Scientific, Ethical, and Legal Considerations for Biohistorical Analysis of Deceased Historical Figures, 26 TEMPLE J. SCI., TECH. & ENV'TL L. 223 (Fall 2007)(with Lori B. Andrews).

Gene Patents: The Need for Bioethics Scrutiny and Legal Change, 5 YALE J. HEALTH POL'Y, L. & ETHICS 403 (2005)(with Lori B. Andrews).

Lessons from the European Union: The Need for a Post-Grant Mechanism for Third Party Challenge to U.S. Patents, 7(1) MINN. J. L. SCI. & TECH. 315 (2005).

European Opposition to Exclusive Control Over Predictive Breast Cancer Testing and the Inherent Implications for United States Patent Law and Public Policy: A Case Study of the Myriad Genetics' BRCA Patent Controversy, 59(1) FOOD & DRUG L. J. 133 (2004).

PEER-REVIEWED ARTICLES

The CRISPR Patent Ruling and Implications for Medicine, 329 JAMA 461 (2023).

The Status of California's Pay-for-Delay Legislation & Litigation, FDLI UPDATE, Fall 2022.

Nanomedicine & the FDA, 21(4) AMA J. ETHICS E347 (2019).

Regulatory Frameworks for Precision Medicine, 15(1) ABA SCITECH LAWYER 12 (2018).

U.S. Regulatory Challenges for Gene Editing, 13 ABA SCITECH LAWYER 10 (2016).

Electronic Cigarettes: Smoke-Free Laws, Use Restrictions, and the Public Health, 104 AM. J. PUB. HEALTH e17 (2014).

Recommendations for Oversight of Nanobiotechnology: Dynamic Oversight for Complex and Convergent Technologies, 13(4) J. NANOPARTICLE RES. 1345 (APRIL 2011)(with Gurumurthy Ramachandran, Susan M. Wolf, Jennifer Kuzma, Ralph Hall, Efrosini Kokkoli, & Leili Fatehi).

The Challenge of Developing Oversight Approaches to Nanobiotechnology, 37(4) J. L., MED. & ETHICS 543 (2009)(with Susan M. Wolf, Jennifer Kuzma, Gurumurthy Ramachandran & Efrosini Kokkoli).

Evaluating Oversight of Human Drugs and Medical Devices: A Case Study of the FDA and Implications for Nanobiotechnology, 37(4) J. L., MED. & ETHICS 598 (2009)(with Alison W. Tisdale, Ralph Hall & Efrosini Kokkoli).

Developing U.S. Oversight Strategies for Nanobiotechnology: Learning from Past Oversight Experiences, 37(4) J. L., MED. & ETHICS 688 (2009)(with Susan M. Wolf, Jennifer Kuzma, Aliya Kuzhabekova, Alison W. Tisdale, Gurumurthy Ramachandran & Efrosini Kokkoli).

Patient Advocacy Group Collaboration in Genetic Research and The Scope of Joint Inventorship under U.S. Patent Law, 3(2) INTERNAT'L J. INTELL. PROP. MANAGEMENT 97 (2009).

An Integrated Approach to Oversight Assessment for Emerging Technologies, 28(5) RISK ANALYSIS 1197 (2008) (with Jennifer Kuzma, Gurumurthy Ramachandran, Jee-Ae Kim, Adam Kokotovich & Susan M. Wolf).

The Law of Incidental Findings in Human Subjects Research, 36(2) J. L., MED. & ETHICS 361 (2008)(with Susan M. Wolf & Charlisse Caga-anan).

Managing Incidental Findings in Human Subjects Research: Analysis and Recommendations, 36(2) J. L., MED. & ETHICS 219 (2008)(with Susan M. Wolf, Frances P. Lawrenz, Charles A. Nelson, Jeffrey P. Kahn, Mildred K. Cho, Ellen Wright Clayton, Joel G. Fletcher, Michael K. Georgieff, Dale Hammerschmidt, Kathy Hudson, Judy Illes, Vivek Kapur, Moira A. Keane, Barbara A. Koenig, Bonnie S. LeRoy, Elizabeth G. McFarland, Lisa S. Parker, Sharon F. Terry, Brian Van Ness & Benjamin S. Wilfond).

When Patents Threaten Science, 314 SCI. 1395 (2006)(with Lori B. Andrews, Timothy Holbrook & Danielle Bochneak).

Decoding the Research Exemption, 7(2) NAT. REV. GENET. 148 (2006)(with Christopher Janson).

Response to Kate H. Mursahige and Joseph J. Rolla, 308 SCI. 1868 (2005)(with Lori B. Andrews & Timothy Holbrook).

Problems in Patenting Human Genes, 307 SCI. 1566 (2005)(with Lori B. Andrews & Timothy Holbrook).

Call for Biohistory Guidelines, 2 PLOS MED. e192 (2005).

Patents on Human Genes: An Analysis of Scope and Claims, 307 SCI. 1566 (2005)(with Lori B. Andrews & Timothy Holbrook).

Constructing Ethical Guidelines for Biohistory, 304 SCI. 214 (2004)(with Lori B. Andrews, Nancy Buenger, Jennifer Bridge, Laurie Rosenow, David Stoney, R.E. Gaensslen, Theodore Karamanski, Russell Lewis, Amy Inlander & David Gonen).

SHORT ARTICLES & BOOK REVIEWS

Inaugural Wiet Life Science Law Scholars Conference, 6 FDLI UPDATE 44 (November/December 2017).

Case Note: Sandoz v. Amgen, FDLI UPDATE 32 (July/August 2017).

Foreword: Innovations and Incentives in Law & the Life Sciences, 26 ANNALS HEALTH L. i (2017).

Reflection Essay, *Where Are They Now?,* FDLI UPDATE MAGAZINE, at 36-37 (November/December 2015).

Human Genome Research and Return of Research Results, ENCYCLOPEDIA OF BIOETHICS, 4th Ed., Bruce Jennings, Ed. (Macmillan, 2014).

Book Review of PRABUDDHA GANGULI & SIDDHARTH JABADE, NANOTECHNOLOGY INTELLECTUAL PROPERTY RIGHTS: RESEARCH, DESIGN, AND COMMERCIALIZATION, 34(4) WORLD PATENT INFORMATION 319 (2012).
Nanobiotechnology and the FDA, FDLI UPDATE MAGAZINE (March/April 2010).

Banning Gene Patents Can Bring Benefits, 1(39) BIOWORLD TODAY, September 20, 2007(with Lori B. Andrews).

National Conference on Research Cloning, PERSPECTIVES: THE MAGAZINE FOR THE UNIVERSITY OF MINNESOTA LAW SCHOOL (Spring 2007).

The Risks Posed by New Biomedical Technologies: How Do We Analyze, Communicate & Regulate Risk?, 13(3) LAHEY CLINIC MED. ETHICS J. 5 (Fall 2006)(with Susan M. Wolf, Eds.).

BOOK CHAPTERS & REPORTS
Biopharmaceutical Compliance Trends, in D. DANIEL SOKOL AND BENJAMIN VAN ROOJI, EDS., CAMBRIDGE HANDBOOK OF COMPLIANCE (Cambridge University Press 2021).

Academic Reading Group Contributor, *ABA Standing Committee to Federal Judiciary Report on the Honorable Merrick B. Garland to be an Associate Justice of the Supreme Court of the United States to Committee on the Judiciary U.S. Senate,* June 2016.

Introduction to Biologics, Chapter 3 in THE FUNDAMENTALS OF LIFE SCIENCES LAW: DRUGS, DEVICES, AND BIOTECH, 2nd Ed. *(*American Health Lawyers Association, 2014).

FDA Regulation of Microbes Modified Using Synthetic Biology in Drugs and Cosmetics, commissioned by the J. Craig Venter Institute Policy Center, Rockville, MD, 2013.

Genetic Sequence Patents: Historical Justification and Current Impacts, in Jean-Paul Gaudillière, Daniel J. Kevles, Hand-Jörg Rheinberger, eds., LIVING PROPERTIES: MAKING KNOWLEDGE AND CONTROLLING OWNERSHIP IN THE HISTORY OF BIOLOGY 137- 163(Max Planck Institute for the History of Science: Paris 2009)(with Lori B. Andrews).

DEVELOPING OVERSIGHT APPROACHES TO NANOBIOTECHNOLOGY: THE LESSONS OF HISTORY, 37(4) J. LAW, MED. & ETHICS (2009)(with Susan M. Wolf, Gurumurthy Ramachandran & Jennifer Kuzma, Eds.).

INCIDENTAL FINDINGS IN HUMAN SUBJECTS RESEARCH: FROM IMAGING TO GENOMICS, 36(2) J. LAW, MED. & ETHICS 216-383 (2008)(with Susan M. Wolf, Charles A. Nelson, Jeffrey P. Kahn & Francis Lawrenz, Eds.).

Gene Patents and Bioethics in TOWARDS A DECLARATION ON UNIVERSAL NORMS ON BIOETHICS EXTRAORDINARY SESSION OF THE INTERNATIONAL BIOETHICS COMMITTEE, Paris, April 27-29, 2004 (with Lori B. Andrews).

BLOGS @ HEALTH REFORM WATCH.COM
LDTs, Genomic Research, and FDA Regulation, A Question of Intent, Apr. 29, 2015.

FDA Guidance to Industry Streamlines Physician Compassionate Use Request, Feb. 10, 2015.

New Disclosure Law Shines Light on Prescribing Practices, Dec. 11, 2014.

Battle Lines Drawn over Biosimilar Application and Patent Disclosure Process, Nov. 17, 2014. [Cross-posted at HEALTHAFFAIRS.ORG]

REMS as A New Competitive Sword?, Aug. 6, 2014.

Another Victory for Laws of Nature, Abstract Ideas, and Natural Phenomenon, June 19, 2014.

FDA Debuts OpenFDA Database, June 18, 2014.

What the FDA's Deeming Regulations Mean for E-Cigarettes, May 21, 2014.

State's Tackle Biosimilar Substitution, Mar. 19, 2014.

FDA's Proposed Changes to Generic Drug Label Rules Questioned by Members of Congress, Jan. 29, 2014.

The Trans Fat Smackdown, Nov. 11, 2013.

Funding, and Ethics, for the BRAIN Initiative, Oct. 1, 2013.

FDA is Taking Baby Steps toward Regulating Nanotechnology, June 13, 2011.

PRESENTATIONS

INVITED PRESENTATIONS

Discussant, *Regulating on Shifting Sands: Analyzing the Impact of Recent and Upcoming Federal Court Decisions on FDA's Authority,* Food and Drug Law Journal 2023 Symposium, virtual Nov. 8, 2023.

Access to Medicines and Medical Countermeasures, The Future of Human Rights and Justice-Centered Ethics in Epidemic Response, UCLA School of Law, Los Angeles, CA, Nov. 3, 2023.

Clashing Court Orders on Mifepristone Access: Implications for FDA and Stakeholders, Food and Drug Law Institute (FDLI), virtual May 4, 2023.

Information Opacity in Biopharmaceutical Innovation Through the Lens of COVID-19, Northwestern Journal of Technology and Intellectual Property Symposium, Pandemic Preparation After COVID-19: Rethinking Technology and IP Paradigms, Northwestern University School of Law, Chicago, IL, Mar. 10, 2023.

Hot Topics in Drug and Biologic Law, Chicago Bar Association, Section on Food and Drug Law, virtual Jan. 27, 2023.

Panelist, *Pharmaceutical IP and Antitrust,* New York State Bar Association Annual Meeting; Food, Drug & Cosmetic Law Section, virtual Jan. 24, 2023.

The Complexities of Insulin Regulation and Access, Belmont University Law School, Belmont Health Law Journal Symposium, Nashville, TN, Nov. 4, 2022.

Discussant, *The Interconnected Regulatory Landscape: Exploring FDA's Relationship with Other Domestic Regulators*, Food & Drug Journal 2022 Symposium, virtual, Nov. 3, 2022.

The State of the Law: Dobbs v. Jackson Women's Health, Chicago Bar Association, Young Lawyers Section, virtual Sept. 29, 2022.

Moderator & Organizer, Wiet Life Science Law Scholars Workshop, Loyola University Chicago School of Law, Chicago, IL, Sept. 16, 2022.

Discussant, Seton Hall University School of Law Health Law Scholars Retreat, virtual, Feb. 11, 2022.

Drug Pricing Debates and Public Health, University of Chicago Medical School, Chicago, IL, Nov. 30, 2021.

Developments in Drug Policy Research, Harvard University PORTAL program, virtual Oct. 18, 2021.

Expert Commentator, *Wiet Life Science Law Scholars Workshop*, Loyola University Chicago School of Law, Beazley Institute for Health Law & Policy, virtual Sept. 10, 2021.

U.S. Oversight of Nanotechnology in Medical Products, Emerging Nanomedicine: Innovation and Future Values, Asian Institute for Bioethics and Health Law, Institute for Legal Studies, Yonsei University, virtual May 26, 2021.

Pandemic Administration: The FDA, Vaccine Innovation, and The Public Health, Michigan State University College of Law, International Law Review Symposium, virtual Feb. 26, 2021.

Patent Opacity in Biopharmaceutical Innovation, Legal Innovations in Response to Public Health Crisis, 2021 American Journal of Law & Medicine Symposium, Boston University School of Law, virtual Feb. 5, 2021.

Pandemic Politics, Public Health, and the FDA, Contemporary Issues in Administrative Law Symposium, Belmont University College of Law, virtual Jan. 15, 2021.

Comparing Domestic Regulatory Regimes in Big Data and AI in Healthcare, Hastings Center and NYU Langone Health, virtual Dec. 14, 2020.

Faculty Panelist, *Together in Loyola Faculty Webinar Series: Ethical Issues in Science and Technology Innovation*, via Zoom webinar, Oct. 22, 2020.

Expert Commentator, *Wiet Life Science Law Scholars Workshop*, Loyola University Chicago School of Law, Beazley Institute for Health Law & Policy, virtual Sept. 18, 2020.

Finding A Cure for COVID: Regulatory and IP Issues, Loyola University Chicago School of Law, virtual July 16, 2020.

Health Law and the COVID-19 Pandemic, Loyola University Chicago School of Law, Beazley Institute for Health Law & Policy, virtual Apr. 28, 2020.

Three Framings of "Faster" at the FDA and the Federal Right to Try Act, Pennsylvania State University Law School, University Park, PA, Mar. 5, 2020.

Moderator, *Legal and Regulatory Issues in Life Sciences Law 2020*, AAL Biolaw section, Washington, D.C., Jan. 2020.

Patient Perspectives in FDA Regulation, Right to Try Laws: The Benefits and Burdens of Balancing Protection with Access in Human Subject Research, Wake Forest School of Law, Nov. 1, 2019.

Law & Ethics of Citizen Science, Participant-Driven Research, and Precision Medicine, Democratizing Medicine in Data and Tech-Driven World, DePaul University, Chicago, IL, Mar. 14, 2019.

Regulation of Biosimilars at the FDA: Current Trends and Challenges, Biosimilar Innovation, University of California Irvine School of Law, Feb. 8, 2019.

21st Century Citizen Pharma, FDA: Past, Present & Future, American University Washington School of Law, Washington, D.C., Oct. 19, 2018.

Health Law Grand Rounds, Indiana University Robert H. McKinney School of Law, Indianapolis, IN, Oct. 4, 2018.

FDA Medical Countermeasures, Jaharis Symposium on Health Law and Intellectual Property: Technological and Emergency Responses to Pandemic Diseases, DePaul University School of Law, Chicago, IL, Feb. 22, 2018.

21st Century Citizen Pharma, The 21st Century Cures Act: A Cure for the 21st Century?, Boston University School of Law, Boston, MA, Jan. 26, 2018.

Regulatory Silence at the FDA, University of Minnesota Law Review Symposium, Minneapolis, MN, Oct. 27, 2017.

Panel Member, *FDA Challenges for a New Century,* Medical Innovation and the Law, New York University School of Law, New York, NY, Feb. 22, 2017.

First Amendment Update: Reconciling Case Law and FDA Policy, Pharmaceutical Compliance Forum (PCF) Spring Meeting, Boston, MA, Apr. 13, 2016.

Consolidation in the Life Sciences, Ninth Annual Symposium on Health Law & Policy: Consolidation and its Impact on Quality, Accessibility, and Cost, Loyola University Chicago School of Law, Chicago, IL, Nov. 13, 2015.

Panelist, *Protecting Drug Franchises*, Life Sciences Symposium, Mayer Brown, Newark, NJ, Oct. 30, 2015.

Biotech and Biopharma Law & Regulation, Innovations in Health Law & Policy: Legal Challenges & Strategies, University of New Hampshire Law School, Concord, NH, Oct. 26, 2015.

Introduction to New Drug Development and Approval, Seton Hall Health Care Compliance Program, Newark, NJ, Oct. 13, 2015.

Introduction to New Drug Development and Approval, Seton Hall Health Care Compliance Program, Newark, NJ, June 9, 2015.

Panel Member, *FDA Hot Topics,* Sidley Austin Life Sciences College, New York, NY, May 7, 2015.

REMS as a Competitive Tactic: Is Big Pharma Hijacking Drug Access and Patient Safety?, Hofstra Law School Faculty Workshop, Hempstead, NY, Oct. 29, 2014.

REMS as a Competitive Tactic: Is Big Pharma Hijacking Drug Access and Patient Safety?, University of Houston, Houston, TX, Oct. 16, 2014.

Introduction to New Drug Development and Approval, Seton Hall Health Care Compliance Program, Newark, NJ, Oct. 14, 2014.

Keynote Address: Three Challenges to Pharmacovigilance, Sidley Austin Pharmacovigilance (pv) Legal, Whippany, NJ, July 16, 2014.

Nanotechnology Law & Policy, Earth Justice, New York, NY, June 11, 2014.

Emerging Life Sciences, Lafayette College, Easton, PA, Apr. 29, 2014.

Panel Member, *FDA Hot Topics,* Sidley Austin Life Science College, New York, NY, Apr. 3, 2014.

The BRAIN Initiative: Law, Policy, Ethics, Lehigh University, Bethlehem, PA, Nov. 21, 2013.

The BRAIN Initiative: Law, Policy, Ethics, New Jersey Institute of Technology, Newark, NJ, Nov. 6, 2013.

Working in the Food and Drug Law Space: Challenges and Opportunities, Food and Drug Law Institute Annual Conference, Washington, D.C., Apr. 24, 2013.

Gene Patents at the Supreme Court, New Jersey Institute of Technology, Newark, NJ, Apr. 17, 2013.
FDA I & II: Pharmaceutical Regulatory and Compliance Fundamentals, Sidley Austin Life Sciences College, New York, NY, Feb. 26, 2013.

Implementation of the Biologics Price Competition and Innovation Act, Gibbons PC and Institute for Law, Science & Technology, Newark, NJ, Feb. 19, 2013.

An Overview of the Food & Drug Administration, Seton Hall MSJ Open House, Newark, NJ, Oct. 20, 2012.

Panel Moderator, CBER Developments, Food & Drug Law Institute, 55th Annual Conference, Washington, D.C., Apr. 24, 2012.

Assessing FDA Regulation of New Drugs, Animal Drugs, and Cosmetics As Applied to Microbes Modified Using Synthetic Biology, J. Craig Venter Institute, Rockville, MD, Jan. 31, 2012.

The Devil is in the Details: Health Care Reform, Biosimilars, and Implementation Challenges for the Food and Drug Administration, 3rd Annual Pharmaceutical Reimbursement & Market Access Conference, Philadelphia, PA, Oct. 28, 2011.

Sottera v. FDA: Electronic Cigarettes and the Tobacco Control Act of 2009, Food & Drug Law Institute, 54th Annual Conference, Washington, D.C., Apr. 6, 2011.

Panel Member, *Synthetic Biology Meets the Law,* AALS Annual Meeting, Biolaw Section, San Francisco, CA, Jan. 5, 2011.

The Biologics Price Competition and Innovation Act: FDA and Biosimilars, Seton Hall University School of Law, Follow-On Biologics: Implementation Challenges and Opportunities Roundtable, Newark, NJ, Oct. 29, 2010.

Health Care Reform Challenges for FDA -- Follow-On Biologics, Seton Hall MSJ Open House, Newark, NJ, Oct. 23, 2010.

Developing Oversight for Nanobiotechnology: Human Drugs and Medical Devices, University of Massachusetts, Nanotechnology & Society: Emerging Organizations, Oversight, and Public Policy Systems Conference, Amherst, MA, Sept. 24, 2010.

Consensus Recommendations on Nanobiotechnology Oversight, Governing Nanobiotechnology: Reinventing Oversight in the 21st Century Conference, University of Minnesota, Minneapolis, MN, Apr. 15, 2010.

Joe Camel, The Marlboro Man, and the FDA: Implementing the 2009 Tobacco Legislation, Seton Hall MSJ Open House, Newark, NJ, Mar. 6, 2010.

Regulating Nanotechnology, Panel member, Food and Drug Law Institute Second Annual Nanotechnology Conference, Washington, D.C., Feb. 19, 2009.

Intellectual Property, Innovation, and Genetics, University of Minnesota, GCD 8914: Ethical & Legal Issues in Genetic Counseling, Minneapolis, MN, Feb. 13, 2009.

Nanotechnology in the Life Sciences, Biology, Society & Environment 3305: Introduction to Bioethics, Minneapolis, MN, Nov. 18, 2008.

Patent Implications for Genetic Counseling, Minnesota Genetic Counselors, Landscape Arboretum, Chaska, MN, Nov. 7, 2008.

Synthetic Biology: Balance Between Scientific Innovation and Security, Commentator, Lecture Series in Law, Health & the Life Sciences, Minneapolis, MN, Nov. 4, 2008.

What's the Problem with Gene Patents? Biology, Society & Environment 3305: Introduction to Bioethics, Minneapolis, MN, Oct. 16, 2008.

Intellectual Property and the U.S. Constitution, Public Affairs 5701: Science & State, Minneapolis, MN, Oct. 6, 2008.

Scientific and Regulatory Issues in Nanobiotechnology: Exploring Nanodrugs and Nanodevices, University of Minnesota, Materials Research Science and Engineering Center, Research Experience for Undergraduates, Minneapolis, MN, July 23, 2008.

Nanotechnology: Ethical, Social and Legal Issues, University of Minnesota, Life Sciences Summer Undergraduate Research Program, Minneapolis, MN, July 14, 2008.

Tales from the Crypt: Scientific, Ethical, and Legal Considerations for Biohistorical Analysis of Deceased Historical Figures, Case Western Reserve University, Center for Genetics Research Ethics and Law, Translating ELSI: Ethical, Legal and Social Implications of Genomics conference, Cleveland, OH, May 1, 2008.

Patent Pending: Rights and Roles of Patients and Human Subjects in Commercialization of Genetics Research, University of Minnesota, BTHX5325/Phil 5325: Biomedical Ethics, Minneapolis, MN, Apr. 29, 2008.

Gene Patents & Biobanks: Law & Policy, University of Minnesota, GCD 8914: Ethical & Legal Issues in Genetic Counseling, Minneapolis, MN, Feb. 22, 2008.

Developing Oversight Mechanisms for Nanobiotechnology, National Science Foundation, NIRT Investigators meeting, Arlington, VA, Dec. 3, 2007.

Article 1: The Basis of Intellectual Property Rights, Public Affairs 5701: Science & State, Minneapolis, MN, Oct. 8, 2007.

FDA & Nanomedicine: Nanodrugs & Nanodevices, Nanoscale Interdisciplinary Research Team (NIRT) Working Group Meeting, Minneapolis, MN, Oct. 4, 2007.

Patent Law & Policy in Genetics, University of Minnesota, BIOC8401: Careers, Policy & Ethics in Biomedicine, Minneapolis, MN, Mar. 19, 2007.

FDA and Nanobiotechnology: Regulatory Issues & Capacity, National Science Foundation Investigators Meeting, Arlington, VA, Mar. 16, 2007.

Gene Patents & Biobanks: Law & Policy, University of Minnesota, GCD 8914: Ethical & Legal Issues in Genetic Counseling, Minneapolis, MN, Feb. 16, 2007.

Food & Drug Administration: Oversight of Drugs and Medical Devices, Nanoscale Interdisciplinary Research Team (NIRT) Working Group Meeting, Minneapolis, MN, Jan. 16, 2007.

Patent Law and Policy in Human Genetics, University of Minnesota, GCD 8073: Advanced Human Genetics, Minneapolis, MN, May 5, 2006.

Intellectual Property & Genetics, University of Minnesota, BIOC8401: Careers, Policy & Ethics in Biomedicine, Minneapolis, MN, Mar. 27, 2006.

Gene Patents & Biobanks: Law, Policy, Problems, University of Minnesota, GCD 8914: Ethical & Legal Issues in Genetic Counseling, Minneapolis, MN, Mar. 10, 2006.

Problems with Gene Patents, University of Minnesota Law School, Law 6875: Law, Health & the Life Sciences, Minneapolis, MN, Sept. 7, 2005.

Genetic Modifications: Ethical, Legal and Social Implications, Chicago-Kent College of Law, Reproductive Technology Seminar, Chicago, IL, Apr. 7, 2005.
Gene Patents and Intellectual Property, University of Minnesota Law School, Minneapolis, MN, Jan. 27, 2005.

COMPETITIVELY SELECTED PRESENTATIONS
From Emergency Use to Status Quo, AALS Annual Conference, Section on Law, Medicine and Health, Washington, D.C., Jan. 5, 2024.

Public Health and Medical Device Sterilization, American Society of Law, Medicine & Ethics 45th Annual Health Law Professors Conference, Baltimore, MD, June 8, 2023.

Patent Opacity in Biopharmaceutical Innovation, American Society of Law, Medicine, and Ethics, 44th Annual Health Law Professors Conference, Northeastern School of Law, virtual June 2021.

21st Century Citizen Pharma, American Society of Law, Medicine & Ethics 41st Annual Health Law Professors Conference, Cleveland, OH, June 9, 2018.

Crowdsourcing Genomics, Loyola University Chicago Law School, Wiet Life Science Law Scholars Conference, Chicago, IL, Oct. 13, 2017.

Crowdsourcing Genomics, Pennsylvania State University & AALS Property Law section, Property Law in the Sharing Economy, State College, PA, Oct. 6, 2017.

Cultivating Innovation in Precision Medicine through Regulatory Flexibility at the FDA, American Society of Law, Medicine & Ethics 40th Annual Health Law Professors Conference, Atlanta, GA, June 10, 2017.

Cultivating Innovation in Precision Medicine through Regulatory Flexibility at the FDA, Arizona State University Sandra Day O'Connor School of Law, 5th Annual Governance of Emerging Technologies: Law, Policy, and Ethics, Phoenix, AZ, May 18, 2017.

The Precision Medicine Initiative, American Society of Law, Medicine & Ethics 39th Annual Health Law Professors Conference, Boston, MA, June 3, 2016.

Companion Diagnostics and the Precision Medicine Initiative, AALS Annual Meeting, Biolaw section, New York, NY, Jan. 8, 2016.

REMS as a Competitive Tactic: Is Big Pharma Hijacking Drug Access and Patient Safety?, American Society of Law, Medicine & Ethics 38th Annual Health Law Professors Conference, St. Louis, MO, June 6, 2015.

The Gen-Nano-Neuro Convergence, Food & Drug Law Institute and Harvard Law School, Emerging Issues and New Frontiers for FDA Regulation, Washington, D.C., Oct. 20, 2014.

Is One of These Things Not Like the Other?: Biosimilar Naming and Substitution Challenges, American Society of Law, Medicine & Ethics 37th Annual Health Law Professors Conference, San Francisco, CA, June 7, 2014.

Different Risk, Different Name?: The Debate over Nonproprietary Naming of Biosimilar Biologics, Arizona State University Sandra Day O'Connor School of Law, 1st Annual Governance of Emerging Technologies: Law, Policy, and Ethics, Phoenix, AZ, May 21, 2013.

No Sisyphean Task: How the FDA Can Effectively Utilize the Tobacco Control Act to Regulate Electronic Cigarettes, AALS Annual Meeting, New Voices in Administrative Law, New Orleans, LA, Jan. 5, 2013.

Is it Science? Is it Engineering? Is it Safe?, American Society of Law, Medicine & Ethics 35th Annual Health Law Professors Conference, Tempe, AZ, June 8, 2012.

Current Legal Status of Follow-On Biologics, American Society of Law, Medicine & Ethics 33d Annual Health Law Professors Conference, Austin, TX, June 4, 2010.

The FDA, Nanodrugs, and Implications for Healthcare, American Society of Law, Medicine & Ethics 32nd Annual Health Law Professors Conference, Cleveland, OH, June 5, 2009.

Oversight Challenges for Drugs and Medical Devices at the Nanoscale, Institute of Nanotechnology, 21st Century Medicine: Breakthroughs and Challenges, London, U.K., Nov. 26, 2008.

Tales from the Crypt: Scientific, Ethical, and Legal Considerations for Biohistorical Analysis of Deceased Historical Figures, Case Western Reserve University, Center for Genetics Research Ethics and Law, Translating ELSI: Ethical, Legal and Social Implications of Genomics Conference, Cleveland, OH, May 1, 2008.

Ethical, Legal & Scientific Issues with Incidental Findings in Human Subjects Research, Genetic Alliance 2007 Annual Conference, Bethesda, MD, July 28, 2007 (with Bonnie LeRoy & Suzanne Sobotka).

GRANT INVOLVEMENT

National Human Genome Research Institute, Grant # R01 HG005171, *Federal Regulation of Probiotics: An Analysis of Existing Regulatory Frameworks*, September 4, 2009-June 30, 2012 (PI: Diane Hoffmann). Role: Working Group Member.

National Institutes of Health & National Human Genome Research Institute, Grant # RC1 HG005338 01, *Nanodiagnostics and Nanotherapeutics: Building Research Ethics and Oversight*, September 30, 2009-July 31, 2012. (PI: Susan M. Wolf). Funded Role: Co-Investigator. [Project role declined after funding award as result of employment change.]

National Science Foundation, Grant # 0608791, *NIRT: Evaluating Oversight Models for Active Nanostructures and Nanosystems: Learning from Past Technologies in a Societal Context*, September 2006-August 2010. (PI: Susan M. Wolf). Role: Co-Principal Investigator.

The Greenwall Foundation, *Emerging Problems in Neurogenomics: Ethical, Legal & Policy Issues at the Intersection of Genomics & Neuroscience*, November 1, 2007-May 31, 2008. (I: Susan M. Wolf). Role: Co-Investigator.

National Institutes of Health, Grant 5R01HG003178, *Managing Incidental Findings in Human Subjects Research*, September 2005-July 2007 (PI: Susan M. Wolf). Role: Working Group Member.

Robert Wood Johnson Foundation, Grant 047723, *Impact of Gene Patents on the Delivery of Health Care Services*, September 2003-August 2005 (PI: Lori Andrews). Role: legal researcher and policy analyst.

Department of Energy, Grant DE-FG02-02ER63460, *Complex Genetic Disorders and Intellectual Property Rights*, September 2002-August 2005 (PI: Lori Andrews & Timothy Holbrook). Role: legal researcher and policy analyst.

National Science Foundation, Grant 0134850, *Ethical, Legal, and Technical Issues of Biohistorical Research*, June 2002-May 2004 (PI: Lori Andrews). Role: legal researcher and policy analyst.

PROFESSIONAL MEMBERSHIPS

Association of American Law Schools

- Biolaw Section: Chair 2018-2019; Vice-Chair, 2017-2018; Treasurer 2016-2017; Secretary 2015-2016
- Law, Medicine & Health Section

American Bar Association, Science and Technology Section
American Health Lawyers Association

- Editorial Board Member, AHLA Journal of Health Law & Life Sciences 2016-2021

American Society of Law, Medicine & Ethics
Food and Drug Law Institute

- Academic Programs Committee Member 2016-2019; 2022-23
- Thomas Austern Memorial Writing Competition Committee Member 2020-2021

PROFESSIONAL PEER REVIEW

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