MARGARET FOSTER RILEY
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EXPERIENCE:

July 1992 - Present **UNIVERSITY OF VIRGINIA SCHOOL OF LAW**, Charlottesville, Virginia.

Professor of Law

Secondary Appointments:
University of Virginia School of Medicine: Public Health Science, Division of Public Health Policy and Practice
Batten School of Leadership and Public Policy

Director, Program in Animal Law 2008-Present

Teaching includes: "Food and Drug Law," "Law and Bioethics," "Germs & Justice, Public Health Law and Infectious Disease," "Legal and Moral Dimensions of Policy Making," "Public Health Law and Chronic Disease," "Law and Ethics in Research in Biomedicine and Public Health," "Health Law Survey," "Law and Business in the Healthcare Sector," "Law and Ethics of Biotechnology," "Environmental Ethics" and "Animal Law."

Member: NExTRAC, NIH Novel and Exceptional Technology and Research Advisory Committee; a federal advisory committee that provides recommendations to the NIH Director and a public forum for the discussion of the scientific, safety, and ethical issues associated with emerging biotechnologies
Co-Chair: Working group on institutional development of NExTRAC framework

Present-July 2023.

Member, National Academies Science, Engineering Medicine; Committee on Assessment of the Care and Use of Dogs in

Biomedical Research Funded by or Conducted at the U.S. Department of Veterans Affairs 2019-2020

Consultant, National Academies Science, Engineering, Medicine, Committee on Pain Management and Regulatory Strategies to Address Prescription Opioid Abuse 2016-2017

Member, National Research Council Study Committee on Controlled Human Exposure Studies at EPA 2015-2016

Member, National Research Council, Committee on Revisions to the Common Rule for the Protection of Human Subjects in Research in the Behavioral and Social Sciences 2013-2014

Member, Food and Drug Law Institute (FDLI) Board of Directors, Washington, DC (2017-present)

Member, U. Penn ODC Ethics Working Group: addresses the topic of compassionate use as it relates to cell and gene therapy for rare diseases

Chair, UVA ESCRO (Embryonic Stem Cell Oversight Committee)

Member and Legal Advisor to the UVA Institutional Review Board for Biomedical Sciences; assisted in implementation of Revisions to Common Rule, HI-TECH, HIPAA regulations in research sector of health sciences; GWAS review; gene xfer.

Member, UVA Committee on Financial Conflicts of Interest in Research

Faculty Associate, Center for Biomedical Ethics

Fellow, University of Virginia Center for Health Policy (to 2020—Center under re-organization)

Peer Review: Journal of Law and Biosciences
Journal of the American Association for Laboratory Animal Science
Cambridge University Press
AJLM
National Institutes of Health

Advisor: International Society of Stem Cell Researchers

Chair, UVA Faculty Senate 2016-2017

Faculty Member, UVA Board of Visitors 2017-2019

Member, UVA Special Committee on the Nomination of a President

Member, UVA Strategic Investment Evaluation Committee

Member, UVA Bicentennial Steering Committee

Member, UVA Strategic Planning Committee (2019)

Advisory Committee: Religion, Ethics and the Environment (2012-14)

September 1988 - June 1992 **PEPPER HAMILTON & SCHEETZ,**
Philadelphia, Pennsylvania.

September 1985 - June 1988 **ROGERS & WELLS, (now Clifford Chance)**
New York, New York

EDUCATION:

J.D. May 1985 **COLUMBIA UNIVERSITY SCHOOL OF LAW**
New York, New York

A.B. May 1981 **DUKE UNIVERSITY**
Durham, North Carolina

Graduated *cum laude* in history and political science; elected to *Phi Beta Kappa*.

ADMISSION TO PRACTICE: New York, 1986 (on hiatus); Pennsylvania 1988 (on hiatus); also admitted to Third Circuit, the Eastern District of Pennsylvania and the Southern and Eastern Districts of New York.

PUBLICATIONS IN PROGRESS:

"One Health Pandemic Prevention and Mitigation: The Role of FDA" forthcoming, Food and Drug Law Journal, expected September 2021

RECENT PUBLICATIONS:

"A RAT by Another Name: 21st Century Cures Act and Stem Cell Therapies" 44 AJLM 291-308 (2018)

"Big Data, HIPAA and the Common Rule: Time for Big Change?," Book Chapter, Big Data, Health Law and Bioethics, I. Glenn Cohen (Faculty Director), Holly Fernandez Lynch, Urs Gasser, and Effy Vayena, eds. Cambridge University Press (2018)

IMPLEMENTING A PUBLIC HEALTH PERSPECTIVE IN FDA DRUG REGULATION, with Patricia J. Zettler and Aaron S. Kesselheim, 73 FDLJ 222 (2018)

"CRISPR Creations and Human Rights," 11 LEHR 225-252 (2017)

Pain Management and the Opioid Epidemic: Balancing Individual and Societal Risks and Benefits, Report of the National Academies of Science Committee on Pain Management and Regulatory Strategies to Address Prescription Opioid Abuse (2017)

Kenneth Oye, Maureen O'Leary and Margaret Riley, Editorial, Revisit NIH Biosafety Guidelines, 357 SCIENCE 627, August 18, 2017

Controlled Human Inhalation Exposure Studies at EPA
Report of the National Research Council Study Committee on Controlled Human Exposure Studies at EPA 2015-2016, March 28, 2017.

Margaret F. Riley and Bernat Olle, "FDA's Pathway for Regulation of FMT: Not so Fraught," Peer Commentary, *Journal of Law & Biosciences* 2015

Margaret F. Riley, *Twenty-first Century Technology with Twentieth Century Baggage, FDA Regulation of Regenerative Medicine*, in FDA IN THE 21ST CENTURY (Holly F. Lynch & I. Glenn Cohen eds, 2015)

"An Unfulfilled Promise: Changes Needed to the Drug Approval Process to Make Personalized Medicine a Reality," 70 Food Drug L. J. 289 (2015)

"Whole-Genome Sequencing in Outbreak Analysis,"*Clinical Microbiology Reviews* Vol. 28 N. 3 July 2015
Carol A. Gilchrist, Stephen D. Turner, Margaret F. Riley, William A. Petri, Jr., Erik L. Hewlett

Selected Comments submitted by panelists for the August 6, 2013 Public Workshop for the IOM RAC, 25 Human Gene Therapy 27-30 (2014)

"Harnessing Next-Generation Sequencing Capabilities for Microbial Forensics" (with Stephen Turner, Carol Gilchrist, Erik Hewlett and William Petrie) White Paper for U.S. Department of Defense, September 2013

"In Plain Sight: A Solution to a Fundamental Challenge in Human Research" (with Lois Shepherd), *Journal of Law Medicine and Ethics*, 40 JLME 970 (2013)

"FDA Regulation of Antibiotic Use in Agricultural Animals," *Jurist,* (May 2012)

"Federal Funding and the Institutional Evolution of Federal Regulation of Biomedical Research," 5 *Harvard Law and Policy Review* 265 (2011)

"How Should Ethics Affect FDA Regulation Of Genetically Engineered Animals?" *Food & Drug Policy Forum*, Vol. 1, No. 15 (August 2011)

Council for Agricultural Science and Technology (CAST). 2010 **"**Ethical Implications of Animal Biotechnology: Considerations for Animal Welfare Decisionmaking," Paul B. Thompson, Fuller D. Bazer, Edna F. Einsiedel, Margaret Foster Riley. Issue Paper No. 46. CAST, Ames Iowa

"Regulating Reproductive Genetics: A Review of American Bioethics Commissions and Comparison to the British Human Fertilisation and Embyology Authority" (with Richard Merrill), 6 *Colum. Sci. & Tech. L. Rev.* <http://www.stlr.org/cite.cgi?volume=6&article=1> (2005).

"A Critique of Human Cloning and Human Dignity: The Report of the President's Council on Bioethics," 20 *J.L. & Pol.* 463 (2004).

RECENT PRESENTATIONS:

"The Biden administration inherits the Covid-19 crisis" Panel Discussion with Guian McKee and J. Stephen Morrison, The Miller Center, University of Virginia, Charlottesville, Virginia January 22, 2021 (Virtual Event)

"Introducing the Novel and Exceptional Technology and Research Advisory Committee "NExTRAC," Presentation to the NASEM Committee on Ethical, Legal and Regulatory Issues Associated with Neural Chimeras and Organoids, November 13, 2020 (Virtual Event)

FDLI Academic Symposium, "This Teachable Moment: How COVID-19 Provides Lessons from FDA's Past and Present That Will Benefit Its Future Preparedness," Presentation: "One Health Pandemic Prevention and Mitigation: The Role of FDA" November 13, 2020 (Virtual Event)

Co-Chair Presentation, "NExTRAC Framework Working Group", Meeting of the NExTRAC, November 10, 2020 (Virtual Event)

FDLI Annual Meeting, CVM Center Director Q&A, moderator, October 2020 (Virtual Event)

"Exploring Beauchamp and DeGrazia's Principles of Animal Research Ethics," AALAS Annual Meeting, October 2020 (Virtual Event)

Moderator: "Fostering Rigorous Research: Lessons Learned from NHP Models and Charting the Path Forward," Workshop at the National Institutes of Health, Bethesda, MD, February 18-19, 2020

Keynote, Challenges Faced by IACUCs: Balancing Advancing Technology And Animal Welfare, SCAW, San Antonio, TX December 9, 2019

Moderator, SESSION III: PROACTIVELY ADDRESSING SCIENTIFIC AND SOCIETAL IMPLICATIONS OF EMERGING BIOTECHNOLOGIES;*Define the specific risks, benefits, and implications of emerging biotechnologies and discuss strategies for anticipating these issues proactively.* Inaugural meeting of the NExTRAC, National Institutes of Health, Rockville MD, December 5-6, 2019

"Rights, Ethics and Regulatory Systems: How Law and Ethics Interact in Animal Research" AALAS Annual Meeting, October 17, 2019, Denver CO

FDA Drug Development and Bioethics, Charm City Bioethics Colloquium, University of Maryland School of Law, September 29, 2019

Comments on Behalf of Authors of NASEM Consensus Report on Pain Management and the Opioid Epidemic (2017) with Richard Bonnie, FDA Standards for Future Opioid Therapy Approvals Part 15 Meeting, FDA White Oak Campus, September 17, 2019

Keynote, Ethical Animal Use and Advanced Technologies, Rocky Mountain Reproductive Sciences Symposium, Fort Collins, CO, May 3, 2019

Future Ethical Challenges for IACUCS: Balancing Advanced Technologies and Animal Welfare, SCAW, San Antonio, TX December 4, 2018

Law & Ethics in the use of Genomics in Medical Care, Virginia Bar Association, The Homestead, Hot Springs, VA, July 21, 2018

CRISPR Quandaries, Ethics in Genetic Engineering of Large Animals, Large Animal Genetic Engineering Summit, Park City, Utah, June 4, 2018

Regulating RATS, 21 Century Cures Act and Stem Cell Therapies, AJLM, Boston, MA, January 26, 2018

Humane Care and Use of Laboratory Animals, Federal Regulation of Use of Laboratory Animals for Research, National Academy of Sciences, Institute for Laboratory Animal Research, Webinar, January 2018.

"Rights, Regulatory Systems and Legal Revolution," Webinar, OLAW, Office of Laboratory Animal Welfare, National Institutes of Health. September 21, 2017

"Future of Health Care Reform," Russell Senate Office Building, Washington D.C., November 18, 2016.

Keynote Speaker: "Regulation of Neuro-Oncology Research and Clinical Care in the Era of Big Data," 21st Annual Meeting and Education Day of the Society for Neuro-Oncology, Scottsdale, AZ, November 17, 2016

"Agency Policymaking in Animal Biotech," Animal Biotech Summit, BIO, Bethesda, MD, September 22, 2016

Moderator, "Ensuring the Continued Responsible Oversight of Research with Non-Human Primates" National Institutes of Health, Bethesda, Maryland, September 7, 2016.

Workshop on the Microbiome and Compassionate Use, New York University, New York, NY, September 8, 2016

"Big Data, HIPAA and the Common Rule: Time for Big Change?" Big Data, Health Law, and Bioethics, Petrie Flom Center, Harvard University, Cambridge MA, May 6, 2016

"CRISPR Creations and Human Rights," Human Rights and the Rights of Non-Humans workshop, College of Law and Business, Ramat Gan, Israel, January 2016,

"A Discussion of the Supreme Court's Upcoming Decision in *King v. Burwell,*" with Timothy Jost, University of Virginia School of Law, Charlottesville Virginia, March 23, 2015

"Where's the Beef? The Future of Bioengineered Meat," Center for Law and Biosciences, Stanford University School of Law, Palo Alto, CA February 3, 2015

"Deciphering Quality Improvement from Research: Implications for Informed Consent," Eighth Annual Virginia IRB Consortium Conference: Lifting the Fog: Issues of Informed Consent, Data Protection and Oversight in QI/Institutional Assessments and Research, University of Virginia, Charlottesville, VA, November 14, 2014

Big Data, HIPAA and the Common Rule: Time for Big Change? Human Subjects Protection in the Digital Age, George Mason University, November 9, 2014

"Can FDA be an Effective Regulator for Personalized Medicine," The Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School and the Food and Drug Law Institute, Emerging Issues and New Frontiers for FDA Regulation; October 20, 2014; Washington, DC

"Health Policy and the Constitution," Panel Discussion, Batten School, University of Virginia, Charlottesville, VA, September 17, 2014

"Consensus Study: Proposed Revisions to the Common Rule for the Protection of Human Subjects in the Behavioral and Social Sciences," ASLME Health Law Professors Conference, San Francisco, CA June, 2014

"The Evolution of Animal Law," Ross University School of Veterinary Medicine, St. Kitts, May 13, 2014

"Rights, Regulatory Systems and Regulation," Ross University School of Veterinary Medicine, St. Kitts, May 12, 2014

"Top 20 Cases in Food and Drug Law in 2013 and Cases to Watch in 2014," Panelist, Food Drug Law Institute Annual Meeting, Washington, D.C., April 24, 2014

"United States v. Regenerative Sciences, Implications for Regulation of Stem Cell Therapies in the United States (and the World)", Webinar, International Society for Stem Cell Research, March 19, 2014

"Regulatory and Legal Frameworks for Offering Stem Cell Therapies in the United States," Stem Cell Therapies: Opportunities for Assuring the Quality and Safety of Unregulated Clinical Offerings—A Workshop, Institute of Medicine and the National Academy of Sciences, Washington, D.C. November 18, 2013

"Rights, Regulatory Systems and Regulation," Special Session, AALAS Annual Meeting, Baltimore, MD October 29, 2013

"State of Gene Transfer Research Oversight," testimony before the Institute of Medicine Committee Evaluating the RAC, National Academies, Washington, DC, August 4, 2013

"Can FDA Serve As An Effective Gatekeeper For Personalized Medicine?,"Workshop Paper; "FDA Regulation of Genetic Testing and Direct to Consumer Marketing and FDA, Plenary Session, Third National Conference on Genetics, Ethics and the Law, Charlottesville, VA, May 23-24, 2013.

"Legal Issues Regarding Animal Activism and Research," ARVO Annual Meeting, Seattle, WA, May 5, 2013

"Twenty-First Century Technology with Twentieth Century Baggage: FDA Regulation of Regenerative Medicine," The Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School 2013 Annual Conference,

The Food and Drug Administration In The 21st Century, Cambridge, MA, May 2-3, 2013

"Top 20 Cases in Food and Drug Law in 2012 and Cases to Watch in 2013," Panelist, Food Drug Law Institute Annual Meeting, Washington, D.C., April 23, 2013

"Rights, Regulatory Systems and Regulation," *Research Animal Welfare: What's Current, New and Changing,* SCAW, San Antonio, TX, December 3, 2012

NFIB v. Sibelius: Supreme Court Round Up, University of Virginia School of Law, September 20, 2012

"EFIC Research: Concerns, New Methods And Thinking About The Future (Especially The Internet)" NIEHS/OHRP SANC Conference, Raleigh, NC March 21, 2012

"Legal Conundrums in the Hunt to Cure Cancer," January 20, 2012, Virginia Bar Association Annual Meeting, Williamsburg, VA.

"Rights, Regulatory Systems and Regulation: How the Interplay of Different Concepts of Rights Within Different Regulatory Systems Affects Regulation of Biomedical Use of Animals, " U.S. Institute of Medicine and the UK Home Office, July 25, 2011, Kavli Royal International Centre, Buckinghamshire, UK.

"Public Attitudes Towards Genomic Data Sharing," Genetic Alliance 25th Anniversary Annual Conference: *25 Years of Innovation***,** June 25, 2011, North Bethesda, MD.

"Electronic Health Records and Family History: Ethical, Legal and Social Issues in Family Data-Sharing," ASLME Health Law Professor's Conference, June 9, 2011, Chicago, IL.

"Personalized Medicine, Direct to Consumer Marketing and FDA, " Second National Conference on Genetics, Ethics and the Law, June 1 - 2, Charlottesville, VA.

"GE Animals and Humans: FDA Regulation and Other Issues," Food & Drug Law Institute Annual Meeting, April 5, 2011, Washington, D.C.

"Electronic Health Records and Family History: Ethical, Legal and Social Issues in Family Data-Sharing," Fourth National Conference on Genomics and Public Health, December 8, 2010, Washington, D.C.

"Family Data Sharing and Ethical Norms" with Ruth Gaare Bernheim, APHA Annual Meeting, November 9, 2010, Denver, Colorado.

"Sharing Results with Participants in Large-Scale Genomic Studies: Pitfalls, Perils and Possibilities," with Donna Chen, GARNET Working Group, NIH, Rockville, Md., September 16, 2010.

"Ethics in Biotechnology: Genetically Engineered Animals" BIO Annual Meeting, Chicago, IL, May 4, 2010.

"A View from Academia: 'To SCRO or not to SCRO' Stem Cell Ethics and Justice Issues, The Role of Institutional Oversight," Panel on Cell Based Therapies, Food and Drug Law Institute Annual Meeting, Washington DC, April 23, 2010.

"A Cross Disciplinary Look at Ethics in Animal Biotechnology, *Burdens of Proof, Emerging Issues in Law and the Humanities,* University of Virginia, Charlottesville, VA, February 19, 2010.

"The Genome Information Nondiscrimination Act (GINA) of 2008" and "Regulatory Aspects of Genetic Research"; Virginia IRB Consortium, University of Virginia School of Medicine, PRIMR Charlottesville, VA, September 29, 2009.

Keynote Address: "Regulating Cloned and Genetically Engineered Animals: Opportunities, Perils and Pitfalls**" *Bio2Biz South Africa***, South Africa's annual national biotechnology meeting. Also "Challenges and Solutions in Commercializing Genetically Engineered Animals and their Products" breakout. Durban, South Africa, September 19-21, 2009.

Panelist, ABA TIPS/Animal Law Committee, "The Supreme Court and the Ownership of Life: An Oral Argument." ABA Annual Meeting, Chicago, IL, July 31, 2009.

"Personalized Medicine, Direct to Consumer Marketing and FDA," Genetics, Ethics and the Law, University of Virginia School of Law, May 30, 2009.

"Public Health Genomics," Genetics, Ethics and the Law, University of Virginia School of Law, May 30, 2009.

"Challenges and Solutions in Commercializing Genetically Engineered Animals and their Products: A Role for Practical Ethics," BIO Annual Meeting, Atlanta, GA, May 20, 2009.

"The Public Health Enterprise: Regulating Research and Producing Health Products – FDA," University of Virginia School of Medicine, January 13, 2009.

"Where Are We and Where Are We Going? Regulation and Oversight of Stem Cell Research**",** University of Virginia School of Medicine, January 8, 2009.

"Morality, Ethics and Law: Genetically Engineered Animals and the FDA," Food and Drug Administration, Center for Veterinary Medicine, November 7, 2008.

Communication and Collaboration: An International Forum for Animal Research Policy, Washington, D.C., June 23-25, 2008.

"The Public Environment in Which We Work," *2008 Annual IACUC Conference*, Ethics and Compliance in Animal Care and Use Programs: Current Challenges and Future Directions. Atlanta, Georgia, March 27, 2008.

"Abigail Alliance: Its Implications for IRBs," University of Virginia School of Medicine, January 22, 2008.

"Ethics and Law in Animal Biotechnology," Duke University Conference on Animals and Bioengineering: A Consideration of Ethics, Law and Science. Durham, North Carolina, November 9-10, 2007.

"Law and Ethics of Human Experimentation," University of Virginia School of Medicine, October 11, 2007.

IRB Consortium, "IRBs and Genetic Studies; Implications of Personalized Medicine," University of Virginia; Co-sponsored by Public Responsibility in Medicine & Research (PRIM&R), September 24, 2007.