RACHEL E. SACHS

Washington University School of Law Campus Box 1120, One Brookings Drive St. Louis, MO 63130 rsachs@wustl.edu

ACADEMIC APPOINTMENTS

Washington University School of Law, St. Louis, MO	2016 – Present
Treiman Professor of Law	2021 - 2023
Professor of Law	2021 – Present
Faculty Scholar, Institute for Public Health	2016 – Present
Associate Professor of Law	2016 - 2021

NYU School of Law, New York, NY

Harvard Law School, Cambridge, MA

Visiting Professor of Law

Academic Fellow, Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics Lecturer on Law, Spring 2016

EDUCATION

Harvard Law School, Cambridge, MA

Juris Doctor, magna cum laude, 2013

Activities: Harvard Law Review, Articles Chair

Petrie-Flom Center Student Fellow in Health Law Policy, Biotechnology, and Bioethics

Spring 2022

2014 - 2016

John M. Olin Student Fellow in Law and Economics

Harvard School of Public Health, Cambridge, MA

Master of Public Health, 2013

Internship: United States Department of Health & Human Services, Centers for Medicare & Medicaid

Services, Region 1

Thesis: "The Impact of the Affordable Care Act's Medicaid Expansion on Region 1"

Princeton University, Princeton, NJ

Bachelor of Arts with High Honors in Bioethics, 2009

Honors: Phi Beta Kappa

Thesis: "Research Involving Human Biological Materials: Legal and Ethical Issues"

JUDICIAL CLERKSHIP

The Honorable Richard A. Posner, U.S. Court of Appeals for the Seventh Circuit, Chicago, IL Law Clerk, 2013–2014

PUBLICATIONS

Law Review Articles

The Role of State Attorneys General in Improving Prescription Drug Affordability (with Michelle Mello & Trish Riley), 95 S. CAL. L. REV. (forthcoming 2022).

New Innovation Models in Medical AI (with W. Nicholson Price II & Rebecca S. Eisenberg), WASH. U. L. REV. (forthcoming 2022).

Integrating Health Innovation Policy, 34 HARV. J. L. & TECH. 57 (2020).

The Medicare Innovation Subsidy (with Mark Lemley & Lisa Larrimore Quellette), 95 NYU L. REV. 75 (2020).

• Written up in *Jotwell*, https://health.jotwell.com/medicare-reimbursement-for-prescription-drugs-an-overlooked-policy-lever-for-innovation/

Regulating Intermediate Technologies, 37 YALE J. REG. 219 (2020).

The Uneasy Case for Patent Law, 117 MICH. L. REV. 499 (2018).

- Selected for inclusion in the Junior Faculty Forum for Law and STEM workshop
- Selected for inclusion in the BioIP junior faculty workshop

Delinking Reimbursement, 102 MINN. L. REV. 2307 (2018).

- Solicited for inclusion in the Law Review's 2017 Symposium
- Selected as one of the ten "Notable Employee Benefits Articles of 2018" by TAX NOTES

Administering Health Innovation, 39 CARDOZO L. REV. 1991 (2018).

- Selected for inclusion in the Health Law Scholars Workshop at St. Louis University School of Law
- Selected as one of eight finalists in the American Association of Law Schools' Scholarly Papers competition

Prizing Insurance: Prescription Drug Insurance as Innovation Incentive, 30 HARV. J. L. & TECH. 153 (2016).

• Written up in *Jotwell*, https://health.jotwell.com/health-insurance-as-innovation-incentive/

Innovation Law and Policy: Preserving the Future of Personalized Medicine, 49 U.C. DAVIS L. REV. 1881 (2016).

Rachel E. Sachs & Carolyn A. Edelstein, *Ensuring the Safe and Effective FDA Regulation of Fecal Microbiota Transplantation*, 2 J. L. & BIOSCIENCES 396 (2015) (peer reviewed).

The New Model of Interest Group Representation in Patent Law, 16 YALE J. L. & TECH. 344 (2014).

Anthony D. So & Rachel Sachs, *Making Intellectual Property Work for Global Health*, 53 HARV. INT'L L.J. ONLINE 106 (2012).

Shorter Pieces in Law Reviews

Encouraging Interagency Collaboration: Learning from COVID-19, J.L. & INNOVATION (forthcoming 2021) (invited).

Judge Posner's Reconstruction of Property Theory, 86 U. CHI. L. REV. 1201 (2019) (invited).

Addressing Pharmaceutical Price Spikes Through Generic Preclearance, 39 J. LEGAL MEDICINE 169 (2019) (invited).

Review of I Contain Multitudes, J. L. & Biosciences (2017).

Mobile Health Innovation and Interagency Coordination, 26 ANNALS OF HEALTH LAW 1 (2017).

Prizes for Payers, J. L. & BIOSCIENCES (2017) (peer reviewed) (invited commentary on Rebecca S. Eisenberg & W. Nicholson Price, II, *Promoting Healthcare Innovation on the Demand Side*, J. L. & BIOSCIENCES (2017)).

Note, Diagnostic Method Patents and Harms to Follow-On Innovation, 126 HARV, L. REV, 1370 (2013).

The Supreme Court, 2011 Term—Leading Case, *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 126 HARV. L. REV. 347 (2012).

Recent Case, Federal Circuit Invalidates Diagnostic Method Claims as Drawn to "Abstract Mental Processes": Association for Molecular Pathology v. U.S. Patent & Trademark Office, 125 HARV. L. REV. 658 (2011).

Peer-Reviewed Journals

Rachel E. Sachs, Kyle A. Gavulic, Julie M. Donohue, & Stacie B. Dusetzina, *Changes in the Use of Hydroxyprogesterone Caproate Injection After Confirmatory Trial Failure*, J. AM. MED. ASS'N INTERNAL MEDICINE (published online 2021 ahead of print).

Rachel E. Sachs & Nicholas Bagley, *Medicare Coverage of Aducanumab – Implications for State Budgets*, 385 NEW ENG. J. MED. 2019 (2021).

Rachel E. Sachs, Kyle A. Gavulic, Julie M. Donohue, & Stacie B. Dusetzina, *Recent Trends in Medicaid Spending and Use of Drugs with US Food and Drug Administration Accelerated Approval*, 10 J. Am. MED. ASS'N HEALTH FORUM e213177 (2021).

Rachel E. Sachs, *The Rhetorical Transformations and Policy Failures of Prescription Drug Pricing Reform Under the Trump Administration*, 46 J. HEALTH POLITICS, POL'Y, & L. 1053 (2021).

Rachel E. Sachs, Julie M. Donohue, & Stacie B. Dusetzina, *Confronting State Medicaid Drug Spending Pressures*, 324 J. Am. MED. ASS'N 1831 (2020).

Rachel E. Sachs & Adam Sacarny, *Ensuring Access to Emerging COVID-19 Treatments Through Medicare Reimbursement Policy*, J. AM. MED. ASS'N HEALTH FORUM (Aug. 7, 2020), https://jamanetwork.com/channels/health-forum/fullarticle/2769378.

Rachel E. Sachs & Nicholas Bagley, *Importing Prescription Drugs from Canada – Legal and Practical Problems with the Trump Administration's Proposal*, 382 New Eng. J. Med. 1777 (2020).

Rena Conti, Stacie B. Dusetzina, & Rachel Sachs, *How the ACA Reframed the Prescription Drug Market and Set the Stage for Current Reform Efforts*, 39 HEALTH AFFAIRS 445 (2020).

Thomas J. Hwang, Kerstin N. Vokinger, & Rachel E. Sachs, *Evaluating New Rules on Transparency in Cancer Research and Drug Development*, 5 J. AM. MED. ASS'N ONCOLOGY 461 (2019).

Austin Frakt & Rachel E. Sachs, *A Smarter Way to Provide Epinephrine at School*, 173 J. Am. MED. ASS'N PEDIATRICS 130 (2019).

Peter B. Bach & Rachel E. Sachs, *Expansion of the Medicare 340B Payment Program: Hospital Participation, Prescribing Patterns and Reimbursement, and Legal Challenges*, 320 J. Am. MED. ASS'N 2311 (2018).

Nicholas Bagley & Rachel E. Sachs, *Limiting State Flexibility in Drug Pricing*, 379 New Eng. J. Med. 1002 (2018).

Rachel E. Sachs, Nicholas Bagley, & Darius N. Lakdawalla, *Innovative Contracting for Pharmaceuticals and Medicaid's Best-Price Rule*, 43 J. HEALTH POLITICS, POL'Y, & L. 5 (2018).

Rachel E. Sachs, Paul B. Ginsburg, & Dana P. Goldman, *Encouraging New Uses for Old Drugs*, 318 J. Am. MED. ASS'N 2421 (2017).

Thomas J. Hwang, Rachel E. Sachs, & Aaron S. Kesselheim, *Public Participation in Drafting of the 21*st *Century Cures Act*, 45 J. L. MED. & ETHICS 212 (2017).

Amitabh Chandra & Rachel E. Sachs, *An FDA Commissioner for the 21st Century*, 376 NEW ENG. J. MED. e31 (2017).

Rachel E. Sachs & Austin B. Frakt, *Innovation-Innovation Tradeoffs in Drug Pricing*, 165 ANNALS OF INTERNAL MEDICINE 871 (2016).

Book Chapters

Innovation Law and COVID-19: Promoting Incentives and Access for New Healthcare Technologies (with Lisa Larrimore Ouellette, Nicholson Price, & Jacob Sherkow), in COVID-19 AND THE LAW: DISRUPTION, IMPACT AND LEGACY (eds.I. Glenn Cohen, Abbe Gluck, Katherine Kraschel, & Carmel Shachar) (Cambridge University Press 2022, forthcoming).

The Impact of the ACA on the Debate Over Drug Pricing Regulation (with Steven D. Pearson), in The Trillion Dollar Revolution: How the Affordable Care Act Transformed Politics, Law, and Health Care In America (eds. Ezekiel J. Emanuel & Abbe R. Gluck) (PublicAffairs 2020).

Increasing FDA Transparency as Enhancing the Innovation Process (with Thomas J. Hwang), in TRANSPARENCY IN HEALTH AND HEALTH CARE (eds. I. Glenn Cohen, Barbara Evans, & Holly Fernandez Lynch) (Cambridge University Press 2019).

Introduction: Intellectual Property Rights for Health Big Data, in BIG DATA, HEALTH LAW, AND BIOETHICS (eds. I. Glenn Cohen, Holly Fernandez Lynch, Effy Vayena, & Urs Gasser) (Cambridge University Press 2018).

Human Tissue Samples: Balancing Autonomy vs. Justice (with David E. Korn), in Specimen Science: Ethics and Policy Implications (eds. Barbara E. Bierer, I. Glenn Cohen, Holly Fernandez Lynch, & Suzanne M. Rivera) (MIT Press 2017).

Religious Exemptions to the Individual Mandate: Health Care Sharing Ministries and the Affordable Care Act, in LAW, RELIGION, AND HEALTH IN AMERICA (eds. I. Glenn Cohen, Holly Fernandez Lynch, & Elizabeth Sepper) (Cambridge University Press 2017).

Additional Written Work

Testimony before the United States House of Representatives Committee on Energy & Commerce, Subcommittee on Health, Hearing on Negotiating a Better Deal: Legislation to Lower the Cost of Prescription Drugs, May 4, 2021.

Testimony before the United States House of Representatives Committee on Ways & Means, Hearing on the Cost of Rising Prescription Drug Prices, February 12, 2019.

Additional Online Publications

Multiple contributions at:

- Bill of Health, http://blog.petrieflom.law.harvard.edu/category/contributors/rachel-sachs/
 - o These blog posts have been cited in briefs before the United States Court of Appeals for the Federal Circuit, as well as letters from Congressional Committees.
- Health Affairs Blog, http://healthaffairs.org/blog/author/sachs/
 - o These blog posts have been cited in reports and letters from Congressional Committees.
- STAT, https://www.statnews.com/category/the-regulars/analysis-rachel-sachs/
- Written Description, https://writtendescription.blogspot.com/

A Framework for Categorizing and Analyzing Prescription Drug Pricing Reform Options (with Loren Adler & Paul B. Ginsburg), BROOKINGS (Aug. 31, 2021), https://www.brookings.edu/essay/a-framework-for-categorizing-and-analyzing-prescription-drug-pricing-reform-options/.

The Drug That Could Break American Health Care (with Nicholas Bagley), THE ATLANTIC (June 11, 2021), https://www.theatlantic.com/ideas/archive/2021/06/aduhelm-drug-alzheimers-cost-medicare/619169/.

Update on Regulatory Withdrawals of Drug Pricing Rules (with Bridget C.E. Dooling), NOTICE & COMMENT (March 19, 2021), https://www.yaleireg.com/nc/update on regulatory withdrawals/.

Prescription Drug Affordability: A Bipartisan Goal?, HUMAN RIGHTS (Sept. 8, 2020), https://www.americanbar.org/groups/crsj/publications/human_rights_magazine_home/health-matters-in-elections/prescription-drug-affordability/.

Prescription Drug Affordability, THE REGULATORY REVIEW (April 30, 2019), https://www.theregreview.org/2019/04/30/sachs-prescription-drug-affordability/.

Drug Prices: Where Do We Go After the Election?, THE CONVERSATION (Oct. 30, 2016), https://theconversation.com/drug-prices-where-do-we-go-after-the-election-67812.

• This piece was reprinted in a number of other media outlets, including in *Scientific American*.

Pharmaceutical Transparency Bills: Targeting Disclosure Purposefully, THE HASTINGS CENTER BIOETHICS FORUM (April 15, 2016), http://www.thehastingscenter.org/Bioethicsforum/Post.aspx?id=7844&blogid=140.

Happy About the Supreme Court's ACA Decision? Thank a Law Professor, THE CONVERSATION (June 26, 2015), https://theconversation.com/happy-about-the-supreme-courts-aca-decision-thank-a-law-professor-43889.

How Law Professors Helped the Supreme Court Understand the Affordable Care Act, THE CONVERSATION (June 16, 2015), https://theconversation.com/how-law-professors-helped-the-supreme-court-understand-the-affordable-care-act-39982.

FDA Proposal for Regulating Laboratory Diagnostics Could Improve Patient Care, THE HASTINGS CENTER BIOETHICS FORUM (Sept. 4, 2014), http://www.thehastingscenter.org/Bioethicsforum/Post.aspx?id=7018&blogid=140.

GRANTS

Principal Investigator, Arnold Ventures award to study state Medicaid programs and the FDA accelerated approval pathway (2020-present)

ADDITIONAL PROFESSIONAL EXPERIENCE

Gibson, Dunn & Crutcher, Palo Alto, CA

Summer Associate, Summer 2012

Drafted legal memoranda and other documents primarily related to intellectual property law.

Duke University, Program on Global Health and Technology Access, Durham, NC

Associate in Research, 2009–2010

Wrote a strategy paper for the United Nations Development Programme. Researched patent pools for neglected tropical diseases. Helped manage the Program's extensive portfolio of grants. Organized the Global Health Fellows Program for graduate students, which featured a health policy internship and intensive course.

SELECTED ACADEMIC LECTURES AND PRESENTATIONS

The Role of State Attorneys General in Improving Prescription Drug Affordability WashULaw Faculty Workshop, St. Louis, MO (July 2021 – Virtual)

The Accidental Innovation Policymakers

WashULaw Faculty Workshop, St. Louis, MO (December 2020 – Virtual)

Works-in-Progress Intellectual Property Colloquium (February 2021 – Virtual)

Regulation and Innovation in the Biosciences (May 2021 – Virtual)

American Society of Law, Medicine, & Ethics Annual Conference (June 2021 – Virtual)

Intellectual Property Scholars Conference (August 2021 – Virtual)

Junior Faculty Forum for Law and STEM, Philadelphia, PA (October 2021)

Northeastern Law School Faculty Workshop, Boston, MA (November 2021 – Virtual)

New Innovation Models in Medical AI

Intellectual Property Scholars Conference (August 2020 – Virtual)

Northwestern Law School Faculty Workshop (March 2021 – Virtual)

Encouraging Interagency Collaboration: Learning from COVID-19

University of Pennsylvania Journal of Law and Innovation Symposium (February 2020 - Virtual)

Fordham Law School Faculty Workshop (March 2021 – Virtual)

Integrating Health Innovation Policy

Center for Health Economics and Policy, St. Louis, MO (December 2019)

WashULaw Faculty Workshop, St. Louis, MO (May 2020 – Virtual)

Health Law Scholars Virtual Workshop (July 2020 – Virtual)

Regulating Intermediate Technologies

Regulation and Innovation in the Biosciences, St. Louis, MO (April 2018)

American Society of Law, Medicine, & Ethics Annual Conference, Cleveland, OH (June 2018)

Intellectual Property Scholars Conference, Berkeley, CA (August 2018) (plenary presentation)

University of Copenhagen Symposium, Copenhagen, Denmark (October 2018)

FDA: Past, Present, and Future, American University, Washington, DC (October 2018)

University of Texas-Austin Law School Intellectual Property Workshop, Austin, TX (November 2018)

Works-in-Progress Intellectual Property Colloquium, Houston, TX (February 2019)

Cardozo Law School IP Colloquium, New York, NY (February 2019)

St. John's Law School IP Colloquium, New York, NY (February 2019)

University of Illinois Law School Faculty Workshop, Urbana-Champaign, IL (February 2019)

Delinking Reimbursement

Regulation and Innovation in the Biosciences, Ann Arbor, MI (April 2017)

American Society of Law, Medicine, & Ethics Annual Conference, Atlanta, GA (June 2017)

Wiet Life Science Law Conference, Loyola University, Chicago, IL (October 2017)

Minnesota Law Review Symposium, Minneapolis, MN (October 2017)

Harvard Law School, Petrie-Flom Center Workshop, Cambridge, MA (December 2017)

Seattle University Law School Faculty Workshop, Seattle, WA (February 2018)

Bio Law Conference, Stanford Law School, Palo Alto, CA (March 2018)

Administering Health Innovation

Central States Law School Association Scholarship Conference, Grand Forks, ND (September 2016)

Health Law Scholars Workshop, St. Louis, MO (selected through blind review) (September 2016)

Notre Dame Law School Faculty Workshop, South Bend, IN (February 2017)

Bio Law Conference, Stanford Law School, Palo Alto, CA (April 2017)

Innovative Contracting for Pharmaceuticals and Medicaid's Best-Price Rule

University of Chicago Health Economics Workshop, Chicago, IL (March 2017)

Divided Infringement and the Doctor-Patient Relationship
Works-in-Progress Intellectual Property Colloquium, Boston, MA (February 2017)

Mobile Health Innovation and Interagency Coordination

American Society of Law, Medicine, & Ethics Annual Conference, Boston, MA (June 2016) Loyola University Chicago Tenth Annual Symposium on Health Law & Policy, Chicago, IL (Oct. 2016)

CRISPR: Are We Ready to Rewrite the Human Genome?
Instituto Cervantes at Harvard University, Cambridge, MA (March 2016)

The Progress of the Affordable Care Act's Medicaid Expansion
Petrie-Flom Center Annual Health Law Year in P/Review, Cambridge, MA (January 2016)

The Current Regulatory Framework for Fecal Microbiota Transplantation
NIH Microbiota Transplantation Working Group Meeting, Baltimore, MD (December 2015)

Health Law Frameworks Affecting Research with Big Data
PRIM&R Advancing Ethical Research (AER) Conference, Boston, MA (November 2015)

Human Tissue Samples: Balancing Autonomy vs. Justice
Petrie-Flom Center Conference on Specimen Science, Cambridge, MA (November 2015)

Patent Law and Microbiome-Based Technologies
MIT Translational Microbiome Workshop, Cambridge, MA (November 2015)

Prizing Insurance: Prescription Drug Insurance as Innovation Incentive
Harvard Law School, Petrie-Flom Center Workshop, Cambridge, MA (April 2015)
American Society of Law, Medicine, & Ethics Annual Conference, St. Louis, MO (May 2015)
Intellectual Property Scholars Conference, Chicago, IL (August 2015)
Case Western Spangenberg Center Innovation & IP Speaker Series (March 2016)

Health Care Sharing Ministries and the Purposes of the Affordable Care Act
Petrie-Flom Center Annual Conference on Law, Religion, and Health in America (May 2015)

King v. Burwell and the Future of the Affordable Care Act Harvard Law School, Cambridge, MA (Conference Organizer and Panelist, April 2015)

Outbreak: Developing New Medical Products for Epidemics Harvard Law School, Cambridge, MA (January 2015)

Innovation Law and Policy: Preserving the Future of Personalized Medicine
Works-in-Progress Intellectual Property Colloquium, Alexandria, VA (February 2015)

The Future Society at Harvard Kennedy School (January 2015)

University of New Hampshire Law School Intellectual Property Roundtable (November 2014)

Boston University Law School Conference on Personalized Medicine & Intellectual Property (August 2014)

Intellectual Property Scholars Conference, Berkeley, CA (August 2014)

The Changing Regulation of Laboratory-Developed Tests: New Challenges and New Opportunities Massachusetts General Hospital, Genomic Medicine Case Conference (November 2014) Petrie-Flom Center Annual Health Law Year in P/Review (January 2015)

The New Model of Interest Group Representation in Patent Law Intellectual Property Scholars Conference, New York, NY (August 2013)

SELECTED ACADEMIC AND PROFESSIONAL SERVICE

Washington University School of Law Clerkship Committee, 2016 — 2018, spring 2020 — 2021 Washington University School of Law Appointments Committee, 2018 — 2019 (entry-level), spring 2022 (lateral)

Washington University School of Law Promotion & Tenure Committee, 2021 — present

Washington University in St. Louis Global Health Visiting Speaker Series Committee, 2018 — 2020 Washington University in St. Louis Faculty Committee on Technology Transfer, 2019 — 2021 Washington University in St. Louis Strategic Planning: Committee on the Research Enterprise, 2021 — present

Institute for Clinical and Economic Review, Member, Midwest Comparative Effectiveness Public Advisory Council, 2016 — Present

West Health, Member, Council for Informed Drug Spending Analysis, 2020 — Present National Academy for State Health Policy, 2020 — Present Journal of Health Policy, Politics, & Law, Editorial Board Member, 2021 — Present