Harvard Medical School
Curriculum Vitae

Date Prepared:	January 8, 2024
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Place of Birth:	Cherry Hill, NJ

Education

1996	A.B. *(summa cum laude)*	History and Science	Harvard University, Cambridge, MA
2002	M.D.	Medicine	University of Pennsylvania School of Medicine, Philadelphia, PA
2002	J.D. *(magna cum laude)*	Law	University of Pennsylvania Law School, Philadelphia, PA
2007	M.P.H.	Clinical Effectiveness	Harvard School of Public Health (HSPH), Boston, MA

Postdoctoral Training

6/02-6/03	Intern	Internal Medicine	Brigham and Women's Hospital (BWH), Boston, MA
7/03-6/05	Resident	Internal Medicine	BWH
7/05-6/07	Fellow	General Medicine and Health Care Policy Research	BWH / Harvard Medical School (HMS) / HSPH, Boston, MA

Faculty Academic Appointments

7/07-6/10	Instructor	Medicine	HMS
7/08-	Research Associate	Health Policy and Management	HSPH
7/10-6/14	Assistant Professor	Medicine	HMS
7/14-4/19	Associate Professor	Medicine	HMS
5/19-	Professor	Medicine	HMS
7/14-7/15	Visiting Associate Professor of Law	Law	Yale Law School
7/16-7/19	Irving S. Ribicoff Visiting Associate Professor of Law	Law	Yale Law School
7/19-	Sidley Austin-Robert	Law	Yale Law School

8/14- 7/22-	D. McLean Visiting Professor of Law Faculty Member Director, Health Policy and Bioethics	Center for Bioethics	HMS

Appointments at Hospitals/Affiliated Institutions

7/05-6/07	Associate Physician	General Internal Medicine	BWH
7/05-11/13	Associate Physician	Medicine	Harvard Vanguard Medical Associates
7/05-7/17	Staff Physician	Medicine	Dana-Farber Cancer Institute, Boston, MA
1/06-7/12	Courtesy staff	Medicine	Faulkner Hospital, Jamaica Plain, MA
7/07-	Associate Physician (research)	Pharmacoepidemiology and Pharmacoeconomics	BWH
8/10-7/15	Research Associate	Law, public health, and ethics	Edmond J. Safra Center for Ethics at Harvard University
7/12-	Staff Physician	Medicine	Faulkner Hospital
5/13-	Faculty Supervisor	Petrie-Flom Center for Health Law Policy, Biotechnology and Bioethics	Harvard Law School
9/16-	Distinguished Visitor	Solomon Center for Health Law and Policy	Yale Law School

Other Professional Positions

2006-2007	Expert witness	Testimony in *IMS v. Ayotte* on behalf of state of New Hampshire	Concord, NH
2008-2009	Expert witness	Testimony on drug promotion	State of Texas
2008-2009	Expert witness	Testimony in *IMS v. Sorrell* on behalf of state of Vermont	Montpelier, VT
2008-2011	Consultant	Alosa Foundation	Boston, MA
2010-2011	Consultant	Robert Wood Johnson Foundation Public Health Law Research program	Temple University, Philadelphia, PA
2011, 2013-2016	Expert witness	Testimony on expert witness ethics review proceedings on behalf of American Academy of Orthopedic Surgeons	Chicago, IL
2016	Ethics review	Medical Quality Assurance Commission, Department of Health, State of Washington	Olympia, WA
2018	Outside expert	Northern District of Ohio, Judge Dan Aaron Polster, Multidistrict Litigation 2804: National Prescription Opiate Litigation	Cleveland, OH
2018	Consultant	Review of Pew Charitable Trusts' drug pricing portfolio	Washington, D.C.

Major Administrative Leadership Positions

Local

2003-2005	Course director, Medico-Legal and Health Policy Curriculum for Internal Medicine Residents	BWH
2010-2011	Admissions chair, Law and Public Health Concentration	HSPH
2012-	Site director, HMS Fellowship in General Medicine and Primary Care	Division of Pharmacoepidemiology and Pharmacoeconomics, BWH
2013-	Director, Program On Regulation, Therapeutics, And Law (PORTAL)	Division of Pharmacoepidemiology and Pharmacoeconomics, BWH
2016-	Leader, Health Policy and Bioethics Consortium monthly lecture series	HMS
2018-	Co-director, Harvard-MIT Center for Regulatory Science	HMS

National

2009-2017	Chair, Council of Recent Graduates	University of Pennsylvania School of Medicine
2011	Co-organizer, national conference on conflicts of interest in medicine	American Society of Law, Medicine and Ethics, University of Pittsburgh Law School
2013	Co-organizer, national conference on blinding in biomedical research and the law	Safra Center for Ethics at Harvard University, Harvard Law School Petrie-Flom Center
2014	Co-organizer, national conference on essential evidence for new drugs and medical devices	Harvard Medical School/Brigham and Women's Hospital, American Association for the Advancement of Science (AAAS), National Center for Health Research (NCHR)

International

2015-2017	Governance Board	Innovative Medicines Initiative DRIVE-AB consortium

Committee Service

Local

2003-2004	Resident work hours committee, Department of Medicine	BWH Member
2004-2006	Hospital work committee, Division of Pharmacoepidemiology and Pharmacoeconomics	BWH Member
2004-	Faculty committee, Division of Pharmacoepidemiology and Pharmacoeconomics	BWH Member
2009-2013	Research Ethics Working Group, Harvard Clinical and Translational Science Center	HMS Member
2011-2013	Admissions committee, Law and Public Health Concentration	HSPH Member
2011-2012	Harvard Interfaculty Working Group on	Harvard University

	Government Management of Pharmaceutical Products	Member
2012, 2015, 2019	Honors thesis program expert reader	HMS Member
2013-2018 2018	Regulatory Science Advisory Board	HMS Deputy Director
2013-2014	Clinical trial data sharing working groups	Multi-Regional Clinical Trial Center, Harvard Global Health Institute Member
2016	Precision Trials Challenge	Harvard Business School Judge

Regional

2011-2012	Master's thesis overseer, Julia Kay Preis	Harvard-MIT Division of Health Sciences and Technology (HST) Biomedical Enterprise Program
2012-2013	S.J.D. thesis committee, Jonathan J. Darrow	Harvard Law School

National

2007, 2012	Alumni reunion committee	University of Pennsylvania School of Med Member
2007-2008	Expert Advisory Committee	ClinicalTrials.gov Member
2008-	Medical Alumni Advisory Council	University of Pennsylvania School of Med Member
2008-	Penn Law Alumni Society of Boston	University of Pennsylvania Law School Member
2010	Task Force on Generic Immunosuppressants in Hematopoietic Cell Transplantation	American Society for Blood and Bone Marrow Transplantation Member
2011-2013	Patents for Humanity	United States Patent and Trademark Office Development Consultant and Judge
2013	Tenure review committee, Joanna K. Sax	California Western School of Law
2014	Chatham House working group on antibiotic delinkage	Observer
2015-	American Society of Law, Medicine and Ethics	Board of Directors
2015-2018	Food and Drug Administration (FDA) Peripheral and Central Nervous System Advisory Committee	Temporary Voting Member
2016-2018	Drugs and Biologics Committee, Food and Drug Law Institute	Member
2016-2017	Committee on Pain Management and Regulatory Strategies to Address Prescription Opioid Abuse, National Academies of Sciences, Engineering and Medicine	Member
2018-2021	Food and Drug Administration (FDA)	Permanent Member

	Peripheral and Central Nervous System Advisory Committee	
2019-2020	Committee on Clinical Utility of Treating Patients with Compounded "Bioidentical Hormone Replacement Therapy," National Academies of Sciences, National Academies of Sciences, Engineering and Medicine	Member

Professional Societies

1999-2006	American College of Legal Medicine 2003-2006: Student Awards Committee	Member
2003-	New York State Bar Association	Member
2004-2007, 2011-2013	Society of General Internal Medicine	Member
2004-2010	International Society for Pharmacoepidemiology	Member
2009-2017	AcademyHealth 2011-2013: Quality and Value Interest Group Advisory Committee 2012-2013: Annual Research Meeting Planning Committee 2015-2017: Alice B. Hersh Award selection committee	Member
2011-2012, 2015-	American Society of Law, Medicine & Ethics	Member
2020-	National Academy of Medicine	Elected member

Grant Review Activities

2010, 2013	Grant proposal reviewer (*ad hoc*)	Robert Wood Johnson Foundation Public Health Law Research Program
2011	Grant proposal reviewer (*ad hoc*)	Robert Wood Johnson Foundation Investigator Award in Health Policy Research
2013	Grant proposal reviewer (*ad hoc*)	Alzheimer's Association
2015	Grant proposal reviewer (*ad hoc*)	Harvard Clinical and Translational Science Center
2017-2022	External grant proposal reviewer	Greenwall Foundation Making a Difference

Editorial Activities

Ad hoc peer reviewer

American Heart Journal
American Journal of Bioethics
American Journal of Respiratory and Critical Care Medicine
American Journal of Tropical Medicine & Hygiene
Annals of Internal Medicine
BioMed Central (BMC) Medical Ethics
BMC Medical Research Methodology

British Medical Journal (BMJ)
BMJ Quality & Safety
Canadian Medical Association Journal Open
Circulation
Clinical Pharmacology and Therapeutics
Current Medical Research and Opinion
Drug Discovery Today
Drug Testing and Analysis
Expert Review of Molecular Diagnostics
Expert Review of Pharmacoeconomics & Outcomes Research
Family Practice Essentials
Genome Biology
Health Affairs
Health Policy
Journal of the American Medical Association (JAMA)
JAMA Cardiology
JAMA Internal Medicine
JAMA Oncology
Journal of General Internal Medicine
Journal of Health Politics, Policy, and Law
Journal of Law and Biosciences
Journal of Law, Medicine, and Ethics
Kennedy Institute of Ethics Journal
Medical Letter
Milbank Quarterly
Nature
New England Journal of Medicine (NEJM)
Pharmacoeconomics
Pharmacoepidemiology & Drug Safety
Pharmacy & Therapeutics
Public Library of Science (PLoS) Biology
PLoS Medicine
PLoS One
Science
Science Translational Medicine
Social Science & Medicine
Yale Journal on Regulation

Other Editorial Roles

1999-2000	Associate Editor	University of Pennsylvania Law Review
2000-2002	Senior Editor	University of Pennsylvania Law Review
2008	Faculty articles reviewer	Harvard Law Review
2009	Executive Board, review of antibiotic incentive policy	London School of Economics
2012	Guest co-editor, Journal of Law, Medicine, and Ethics, Volume 40, Issue 3 (title: "Conflict of Interest in the Practice of Medicine")	American Society of Law, Medicine, and Ethics

2012-	Academic Editor, PLoS Medicine	Public Library of Science
2012-	Editorial Board, Expert Opinion on Orphan Drugs	Taylor & Francis Online
2012-2021	Advisory Board, Perspectives section, New England Journal of Medicine	Massachusetts Medical Society
2013-2015	Editorial Board, working paper series	Edmond J. Safra Center for Ethics at Harvard University
2013-2016	Health Policy Brief external editor, Health Affairs	Project Hope
2014	Co-editor, Journal of General Internal Medicine, Volume 29, Suppl 3 (title: "Research Methods for Evaluating Patient Health Outcomes in Rare Diseases")	Society for General Internal Medicine, Agency for Healthcare Research and Quality
2014-	Editorial Board, Clinical Pharmacology and Therapeutics	American Society for Clinical Pharmacology and Therapeutics
2014, 2017	Faculty reviewer	Yale Journal of Health Policy Law and Ethics
2017	Prescription Drug Pricing Health Policy Brief series external editor, Health Affairs	Project Hope
2017	External editor, "Promoting Value, Affordability, and Innovation in Cancer Drug Treatment"	President's Cancer Panel, National Institutes of Health
2017-	Editor-in-Chief, Journal of Law, Medicine, and Ethics	American Society of Law, Medicine, and Ethics
2018	Co-editor, Journal of Law, Medicine, and Ethics, Volume 45, Suppl 2 (title: "Transparency at the US Food and Drug Administration")	American Society of Law, Medicine, and Ethics
2018	Invited contributor, annual editorial board meeting	JAMA
2021-	Advisory Board	Yale Journal of Health Policy Law and Ethics

Honors and Prizes

1992	Detur Book Prize	Harvard College	Academic excellence
1992	National Scholar	Harvard College	Academic excellence
1995	Harvard / Ford Foundation Samuel H. Abramson Memorial Fellowship	Harvard College	Thesis research proposal
1996	Phi Beta Kappa honor society	Harvard College	Academic excellence
1996-2002	Ben Franklin Fellow	University of Pennsylvania School of Medicine	Academic excellence
1998	History of Medicine Prize	University of Pennsylvania School of Medicine	History of science writing competition
1998-2002	James Wilson Scholar	University of Pennsylvania Law School	Academic excellence

2000	William Osler Medal	American Association of the History of Medicine	History of science writing competition
2001	Alpha Omega Alpha honor society	University of Pennsylvania School of Medicine	Academic excellence
2002	Order of the Coif honor society	University of Pennsylvania Law School	Academic excellence
2002	Burton Award	The Burton Foundation	National excellence in legal writing
2002	Schwartz Award	American College of Legal Medicine	Health law writing competition
2002	First Place	Epstein, Becker, and Green Health Law Writing Competition	Health law writing competition
2005	Karen Kaufman Memorial Book Award	BWH	Excellence in delivery of primary care
2008	Young Alumnus of the Year	University of Pennsylvania School of Medicine	Career excellence, dedication to school
2009, 2010, 2013, 2015, 2020, 2022	Top peer reviewer	Annals of Internal Medicine	Excellence in contributions to editorial decisions
2010	Alice S. Hersh New Investigator Award	AcademyHealth	Exceptional promise for future contributions to health policy research
2011	Top peer reviewer	Pharmacoepidemiology and Drug Safety	Excellence in contributions to editorial decisions
2013	30th Anniversary Award	Center for Excellence in Education's Research Science Institute	Excellence and achievement in science, technology, engineering, math and business
2013	Second place prize	Eighth Annual Massachusetts Medical Society Research Poster Symposium (health policy/medical education category)	Senior author of research poster
2014	Chair's Research Award	BWH Department of Medicine	Skill in obtaining grant funding
2015-16	Young Mentor Award	HMS	Excellence in developing quality mentoring relationships that lead to professional development and career advancement in basic/clinical medicine
2016	Research Leadership Award	BWH	Awarded to investigators who have demonstrated outstanding research leadership of new or existing programs
2017	Power List 100: Masters of the Bench	The Medicine Maker	National trade publication list of top individuals "involved in bettering the

			pharma industry"
2017	Leonard M. Rosen Memorial Research Award	Children's Cause Cancer Advocacy	Outstanding contribution of research to childhood cancer policy and advocacy
2018	Thought Leader	NEJM Catalyst	Demonstrating credentials, expertise, and knowledge related to the health care marketplace
2018	#2 Most-Cited Health Law Scholar, 2013-17	Web of Science	Acknowledgement of wide impact of research on field
2018	#8 Most-Cited Health Law Scholar, 2013-17	WestLaw	Acknowledgement of wide impact of research on field
2020	Elected to membership	National Academy of Medicine	Outstanding professional achievement and commitment to service
2021	#3 Most-Cited Health Law Scholar, 2016-20	WestLaw	Acknowledgement of wide impact of research on field
2021	#2 Most-Cited Health Law Scholar, 2016-20	GoogleScholar	Acknowledgement of wide impact of research on field
2023	Senator Joseph I. Lieberman Award	Center for Excellence in Education	Excellence in science, technology, engineering and mathematics leadership
2024	Top tier peer reviewer of 2023	JAMA	Excellence in contributions to editorial decisions
2024	Top tier peer reviewer of 2023	JAMA Internal Medicine	Excellence in contributions to editorial decisions

Report of Funded and Unfunded Projects

Funding Information

Past

1999
Health care delivery systems for terminal cancer patients
National Cancer Policy Board, Washington, DC / Research fellowship
Co-investigator
Review of current state of end-of-life care for cancer patients, including trials, physician education and patient knowledge about care options.

2000-2001
Adapting the 25th Amendment to provide for presidential health oversight
Philadelphia College of Physicians and Surgeons, Philadelphia, PA / Research project
Co-principal investigator
Organization of expert working panel to develop recommendations for health of President of the United States and role of 25th Amendment in ensuring proper oversight. Studied history of presidential health.

2003-2005
Developing a health policy curriculum for medical residents
Brigham and Women's Hospital Support for Excellence in Educational Development / Educational project
Principal investigator

Organization of curriculum of guest lectures to expose internal medicine residents to pressing national health policy issues; empirical analysis of reaction to curriculum.

2004-2005 Investigation of health policy issues in the U.S. Senate Health, Education, Labor, and Pensions Committee
Martin P. Solomon Medical Education Scholarship / Educational project
Principal investigator
Full-time externship with office of Sen. Christopher Dodd (D-CT) to contribute to considerations of current health-related legislation and development of national health information technology infrastructure development bill.

2007-2008 Research in drug and health law policy
Agency for Healthcare Research & Quality (AHRQ) Post-Doctoral Fellowship in Health Services Research / Mentored training grant
Principal investigator
Using empirical research techniques, investigated US intellectual property policies and studied how management of intellectual property rights influences worldwide access to essential medications.

2007-2008 Educational outreach to improve prescribing practices
Attorney General Prescriber and Consumer Education Grant Program / Educational project
Co-Investigator (PI: Jerry Avorn, M.D.)
Development of an innovative series of curricula, interactive web-based programs, and educational outreach activities to equip prescribers and prescribers-in-training with the cognitive and attitudinal tools they need to make optimal drug-use decisions.

2007-2010 Design of a national educational curriculum, "Generics are powerful medicines"
Cy pres award distribution from court settlement / Educational project
Program director
Organization of consumer education materials and website describing the safety and efficacy of generic drugs, including developing partnerships with local public health outreach organizations through a national request for proposals.

2008-2009 Assessment of strategies for development of novel antimicrobial products
Resources for the Future / Commissioned study
Co-principal investigator (Co-PI: Kevin Outterson, J.D., LL.M.)
Descriptive analysis of current proposals to encourage antibiotic drug development, and discussion of a novel alternative, the Antibiotic Conservation and Effectiveness program, which would combine incentives for development with reimbursement for rational drug use.

2009 Using market exclusivity incentives to promote pharmaceutical innovation
Robert Wood Johnson Foundation Public Health Law Research / Commissioned study
Principal investigator
Study of the effect on medical innovation of statutes that provide additional intellectual property rights or related incentives to pharmaceutical developers in the US.

2009-2010 Patterns of use of newly approved orphan drugs for rare diseases
Harvard Clinical and Translational Science Center / Individual investigator initiated grant

Principal investigator
Analysis of effectiveness of Orphan Drug Act as means of incentivizing drug development to generate treatments for rare diseases, and expansion of use of those drugs after approval.

2009-2014 Off-label prescribing: Comparative evidence, regulation, and utilization
Agency for Healthcare Research & Quality K-08 Award/Training grant (5K08HS18465-04)
Principal investigator
Investigation of off-label prescribing and time series analysis of how legal, regulatory, and market forces affect these uses.

2010 Current trends in orphan drug development
Institute of Medicine Committee on Rare Disease and Orphan Product Development / Commissioned study
Principal investigator
Study of the characteristics of the drug development and FDA review process for a selection of orphan drugs.

2010-2012 Varying disclosure policy for biomedical journal articles: a randomized controlled trial for remedies for financial disclosure of science
Edmund J. Safra Center for Ethics at Harvard University / Investigator initiated grant
Co-principal investigator ($60,582) [with Christopher Robertson, J.D., Ph.D.]
Randomized controlled study to test solutions to presentations of conflicts of interest in the medical literature.

2010-2014 Researching ways to overcome obstacles to creation of breakthrough new drugs
Robert Wood Johnson Foundation Investigator Award in Health Policy Research / Individual investigator initiated grant (67487)
Principal investigator
Investigation of how basic, translational, and product-development research combine to create breakthrough new drugs and role of patents in facilitating or impeding this process.

2011 Medical device regulation in the US and EU
Center for Devices and Radiological Health, Food and Drug Administration / Commissioned study (HHSF223201111374P)
Principal investigator
Comparative analysis of device approval and post-market surveillance and systematic review of studies of device regulatory outcomes in the US and EU.

2012-2013 Post-market surveillance of medical devices in the US and EU
Pew Charitable Trust / Individual investigator initiated grant
Principal investigator
Cross-national comparison of systems of post-market surveillance for medical devices.

2012-2014 Research methods for evaluating patient health outcomes in rare diseases: symposium and journal supplement Agency for Healthcare Quality and Research/DEcIDE-2 Request for Task Order HHSA290201000006I - TO4
Principal investigator
Organization of expert advisory group, literature review and stakeholder focus group

addressing the application of research methods to studying outcomes for patients with rare diseases, and experiences with newly approved orphan drugs

2012-2014 Developing and testing a decision support tool for primary medication adherence
Patient-Centered Outcomes Research Institute (PCORI)/PI-12-001
Contributing investigator (PI: Jennifer Polinski, Ph.D.)
Leading conduct and analysis of patient and provider focus groups intended to inform development of tool to promote patient adherence to antihypertensive medications

2013-2015 Assessing clinical equivalence for generic drugs approved using innovative methods
Food and Drug Administration (1U01FD004856-01)
Principal Investigator
Study of 6 generic drugs approved using non-traditional methods for determining bioequivalence, including surveys of patients and physicians, a secondary data analysis of their use, and a systematic review of published studies of the drugs.

2013-2016 New methods for evaluation of impact of FDA Drug Safety Communications
Food and Drug Administration (HHSF22301001T)
Principal Investigator
Combined methodological approach to understanding the impact of information disseminated by FDA about prescription drug safety using qualitative analyses of traditional and social media, surveys of patients, interview of patients and physicians, and pharmacoepidemiologic analyses of drug prescribing and patient outcome trends.

2013-2016 Access to drugs and devices that have limited supporting data: ethical implications for patients and physicians
Greenwall Foundation Faculty Scholar Program
Principal Investigator
Using orphan drugs for rare diseases and early access programs as empirical studies to build normative ethical conclusions relevant to patients, physicians, manufacturers, and payers when regulators approve experimental drugs and devices on limited premarket data

2013-2017 Does variation in the physical characteristics of generic drugs affect patients' experiences: A survey of pharmacists and patients
Food and Drug Administration (HHSF223201310232C)
Principal Investigator
National surveys of patients and pharmacists to determine their experiences with generic medications that change shape or color during routine refills, and the association of these episodes with nonadherence and confusion.

2014-2021 Examining the Impact of FDA Regulatory Policies on Therapeutic Approval
Harvard-MIT Center for Regulatory Science
Principal Investigator ($1,037,525)
Conduct of research in the field of "regulatory science" evaluating the impact of FDA-imposed Risk Evaluation and Mitigation Strategies and evaluating how the FDA applies its existing rules to novel technologies.

2014-2016 Studying the impact on public health of variations among states in laws regulating substitution of generic for brand-name drugs
Robert Wood Johnson Foundation Public Health Law Research Program
Co-investigator (Principal Investigator: Ameet Sarpatwari, J.D., Ph.D.)
Mapping of state drug product selection laws affecting generic substitution and observational and direct national survey studies assessing the implications of these laws on access to generic drugs

2016 Use of patents and FDA regulatory exclusivities to set and extend brand-name drug market exclusivity: a review of the evidence
Commonwealth Fund
Principal Investigator
Description of the state of the law relating to pharmaceutical market exclusivities and a review of the evidence relating to the strategies used to delay entry of generic drugs.

2016-2017 A Study of Pharmaceutical Pay for Outcomes Contracts in the US and their Implications for Pharmaceutical Spending
Commonwealth Fund
Co-Principal Investigator (with Elizabeth Seeley, Ph.D.)
Qualitative interview-based analysis of payors, policymakers, and pharmaceutical manufacturers involved in pay-for-outcomes contracts of high-priced drugs.

2016-2017 Reviewing the Legal, Political and Public Health Parameters of Increasing Transparency at the Food and Drug Administration
Laura and John Arnold Foundation
Co-investigator (Principal Investigator: Joshua Sharfstein, M.D.)
Review of the current status of the transparency of FDA decision-making and the potential for enhancing the public availability of key regulatory information.

2016-2017 Impact of Drug Innovation Incentive Strategies on Drug Development and Costs
Laura and John Arnold Foundation
Principal Investigator
To examine the outcomes of programs intended to incentivize drug innovation, to identify the most successful aspects of these programs, and to determine how efficiently these programs facilitate the introduction of important new products by grading the innovativeness, efficacy, and safety of the products whose approval they have facilitated

2016-2018 Development of Educational Boot Camp in Methods Used in Empirical Bioethics Research
Greenwall Foundation
Consultant (PI: Eric Campbell, Ph.D.)
To develop a recurring, year-long educational program for Greenwall fellows to introduce them to qualitative and quantitative data collection and analysis, along with pre- and post-testing, and then expand the educational program more broadly to the bioethics community

2017-2020 Creation of the PORTAL Biomarker Research Consortium
Laura and John Arnold Foundation

Principal Investigator
To systematically review and meta-analyze the validity of biomarkers used in drug development and treatment in cardiovascular medicine, cancer, Alzheimer's disease, and tuberculosis, as well as to develop additional studies and reviews of biomarker and surrogate measure policy.

2017-2020 Prescription Drug Innovation, Availability, and Affordability: The Impact of Drug Innovation Incentive Strategies on Drug Development and Costs
Laura and John Arnold Foundation
Principal Investigator
To document the impact of policy levers on innovation, access, and affordability of prescription drugs, identify how they work well, how they work sub-optimally, and what specific policy options could be implemented to improve them, characterize and critically assess key trends at each stage of the drug product life-cycle that impact expense and innovation, and develop and assess specific possible alternatives to existing policies.

2017-2019 The US Government's Contribution to Transformative Drug Development
Open Society Foundation
Co-Principal Investigator (Co-PI: Ameet Sarpatwari, Ph.D., J.D. ($125,000)
To study the amount of support that the US government has provided for the discovery and development of specific highly innovative and clinically important pharmaceutical products.

2017-2019 The Impact of Intra-Class Competition on Drug Prices
Anthem Public Policy Institute
Co-Investigator (PI: Ameet Sarpatwari, Ph.D., J.D.)
To assess the impact of new drug market entry on the prices of older drugs and investigate the conditions needed for prices to fall.

2017-2020 An International Comparison of Regulatory Risk Communication on Medicines
National Health and Medical Research Council (NHMRC)
Co-Investigator (Principal Investigator: Barbara Mintzes, Ph.D.)
To understand of how regulatory warnings are related to medication safety impact health care delivery, and identify a set of 'best practices' contributing to effectiveness, by comparing medication safety advisories in Australia, Canada, the US, and Europe

2019-2020 Evaluating the Modern Generic Drug Market
Anthem Public Policy Institute
Principal Investigator
To assess the uptake and predictors of new generic drug prescribing and to study the effect of drug coupons on generic substitution.

2020-2023 Prescription Drug Innovation, Access, and Affordability: Key Issues in Drug Costs and Development
Arnold Ventures
Principal Investigator

To inform decisions on medication use and access in the public and private sectors by studying drug market exclusivity and competition, improving regulatory approaches throughout a drug's lifecycle, evaluating public and private contributions to drug development, defining value for drugs and gene therapies, and optimizing the role of biosimilars.

Current

2018-2023 Incentivizing the Development of Effective and Safe Antibiotics
Collaborative Research Programme in Biomedical Innovation Law at the University of Copenhagen (supported by grant NNF17SA027784 from the Novo Nordisk Foundation)
Subcontract Principal Investigator ($348,456)
To study effects of intellectual property laws and regulatory policies on pharmaceutical development, drug approval processes, and the costs, availability, and use of prescription drugs, with a particular focus on antibiotic drug development.

2020-2024 Risk Evaluation and Mitigation Strategy (REMS) Programs to Promote Appropriate Medication Use and Knowledge: A Multimodal Analysis
Food and Drug Administration
Co-Principal Investigator (with Ameet Sarpatwari) ($4,418,854)
To understand the impact of REMS, we are conducting observational studies to evaluate trends in the use of REMS-covered drugs, surveys of physicians and structured interviews with patients to understand individual experiences using REMS-covered drugs, and textual analyses of REMS educational materials.

2020-2023 Establishing a Process for Evaluating High-Priced Drugs
Massachusetts Health Policy Commission
Principal Investigator ($300,000/yr)
Hired through competitive bidding process to help Commission in its statutory responsibility to set up a system to receive recommendations from MassHealth for drugs that appear to be excessively priced and then evaluate whether those drugs offer clinical benefits that are commensurate to the prices charged.

2021-2023 Development of Prescription Drug Policy Ideas to Inform PDUFA Reauthorization
Kaiser Permanente Institute of Health Policy
Principal Investigator ($400,000)
To review the characteristics of pivotal trials, completion of post-market commitments/requirements, and comparative analysis of drug value for recently approved drugs for inclusion into policy recommendations to inform PDUFA reauthorization.

2022-2023 Interpreting Colorado's Upper Payment Limit Legislation
Colorado Department of Regulatory Agencies
Principal Investigator ($100,000)
Hired through competitive bidding process to help state regulators interpret its new law setting up a prescription drug affordability board and implementing an upper payment limit for qualifying drugs.

2023-2026 Shaping a New Era for US Prescription Drug Policy: Optimizing Evidence, Accessibility, Regulation, and Innovation
Arnold Ventures ($7,500,000)
Principal investigator
A series of research and outreach activities intended to inform policymaking that will improve the functioning of several aspects of the US prescription drug market, including providing incentives for investment in development of useful new medicine; optimizing evidence generation, regulatory review and oversight to ensure generation of high-quality information about drug benefits and risks; and re-thinking drug pricing and access to most effectively benefit the patients who need them.

Report of Local Teaching and Training

Teaching of Students in Courses at HMS/HSDM/DMS

2002-2005	Core Medicine Clerkship I Third- and fourth-year medical students	HMS 9 hrs per day for 12 wks per year
2002-2005	Core Medicine Clerkship II Third- and fourth-year medical students	HMS 9 hrs per day for 12 wks per year
2005-2009	Core Medicine Clerkship I Third- and fourth-year medical students	HMS 13 hrs per wk for 4 wks per year
2005-2009	Core Medicine Clerkship II Medical students	HMS 13 hrs per wk for 4 wks per year
2009	Health Care Policy All second-year medical students	HMS 6 hrs per lecture for 1 guest lecture
2009-2014	Health Care Policy All first-year medical students	HMS 3 hrs per lecture for annual guest lecture
2015	Health Policy Student Interest Group 50 first-year medical students	HMS 3 hrs per lecture for 1 guest lecture
2016	BCMP 311qc: Unmet Medical Needs and Translational Solutions 25 medical and PhD students	HMS 6 hrs per lecture for 1 guest lecture
2017-2019	Essentials of Professions: Health care policy All first-year medical students	HMS 3 hrs per lecture for 1 guest lecture
2018-2019	Essentials of the Professions II: Everything you need to know about prescription drug policy in 60 minutes 25 medical and PhD students	HMS 3 hrs per lecture for 1 guest lecture
2019	AISC 604.0: Translational Pharmacology 60 medical, Masters, and PhD students	HMS 3 hrs per lecture for 4 guest lectures
2019-2021	HST 150: Pharmacoepidemiology 30 medical students	HMS 3 hrs per lecture for 1 guest lecture
2020	AISC 624.0: Medications and Evidence: Understanding the Effectiveness, Risks, Outcomes, Costs, and Regulation of Prescription Drugs [lead faculty with J. Avorn, M.D., S. Schneeweiss, M.D., Sc.D., M.A. Fischer, M.D., N.K. Choudhry, M.D., Ph.D.] 24 medical students	HMS 1 credit January-term course (2020: offered a second time in May)

2020-2021	Essentials of the Professions II: Prescription Drug Regulation and Economics: 5 Key Controversies 35 medical and PhD students	HMS 3 hrs per lecture for 1 guest lecture
2021	AISC 626: Sex- and Gender-Informed Medicine	HMS 4 hrs for 1 guest lecture

Other Harvard University Courses

2005	Public Health Law Masters students	HSPH 8 hrs per wk for 1 semester
2006	Law and Public Health Masters students	HSPH 5.5 hrs per lecture for 2 lectures
2007-2009	Public Health Law Law students	Harvard Law School 5.5 hrs for annual guest lecture
2008-2014	Advanced Pharmacoepidemiology Masters students	HSPH 4 hrs for annual guest lecture
2012-2013	GHHP 91r Seminar Undergraduate student independent study	Harvard Faculty of Arts and Sciences 25 hrs per semester for 2 semesters
2013	Law and Public Health (HPM 213) Masters students	HSPH 6 hrs for 1 guest lecture
2014	EPI 502 Antibiotic Epidemiology Masters students	HSPH 4 hrs for 1 guest lecture
2016-2021	HPM 213 Public Health Law Masters students	HSPH 4 hrs for 1 guest lecture
2016	Navigating the US Pharmaceutical Sector Executive education students	Executive and Continuing Professional Education, Harvard T.H. Chan School of Public Health 4 hrs for 1 guest lecture
2016-2021	Bioethics 706.0 Health Law, Policy, and Bioethics (Co-taught with H.F. Lynch, J.D., M.B.E. [2016-17] and Brendan Abel, J.D. [2018-21]) Masters students	HMS Center for Bioethics 4 credit spring semester-long seminar
2016-2021	Bioethics 742: Policy & Ethics Consortium Masters students	HMS Center for Bioethics 2 credit year-long tutorial
2019	Massive Open Online Course: The FDA and Prescription Drugs: Current Controversies in Context [lead faculty with A. Sarpatwari, Ph.D., J.D., and J.J. Darrow, J.D., S.J.D., M.B.A.]	HarvardX 6 sessions, 3-5 hours per session
2021	HPM 538: Pharmaceutical Development and Pharmacy Distribution: Markets and Policy Masters students	HSPH 4 hrs for 1 guest lecture

Courses Taught While Appointed as Visiting Professor of Law at Yale

2015	Law 21767 FDA Law Law students	Yale Law School 2 credit semester-long seminar

2016	Law 20616 FDA Law Law students	Yale Law School 2 credit semester-long seminar
2017-2021	Law 20616/HPM 595 FDA Law and Policy Law and School of Public Health students	Yale Law School and separately with Yale School of Public Health 2 credit semester-long seminar

Formal Teaching of Residents, Clinical Fellows and Research Fellows (post-docs)

2004	Primary care in the White House 30-50 residents	BWH and Faulkner Hospital Guest lecture, 5 hrs
2005	The health care of our political leaders 30-50 residents	BWH and Faulkner Hospital Guest lecture, 3 hrs
2004-2009	Medico-legal issues for medicine residents 30-50 residents	BWH and Faulkner Hospital Annual guest lecture, 5 hrs
2005-2008	Ambulatory care rotation Residents	Massachusetts General Hospital, Boston 4 hrs per wk for 3 wks per year
2011-2017, 2019-2020	Partners Center of Expertise in Health Policy and Management: Health Policy Certificate Course 30-50 residents	HMS-affiliated teaching hospitals Guest lecture, 3 hrs
2015	What do we know about diabetes drugs? 60 residents	BWH Guest lecture, 2 hrs
2017-2020	Understanding Biomarker Science: From Molecules to Images 120 graduate students	Harvard Catalyst Guest lecture, 2 hrs
2021	Drug Prices and Oncology Drug Policy 15 oncology fellows	Dana-Farber Cancer Institute Guest lecture, 2 hrs

Clinical Supervisory and Training Responsibilities

2005-2009	General Medical Service Attending / Brigham and Women's Hospital	5 hrs per day for 4 wks per year

Laboratory and Other Research Supervisory and Training Responsibilities

2008-	Supervision of college students, medical students, medical and neurology interns/residents, post-doctoral fellows, visiting scholars, and junior faculty members on intersections between law and medicine, pharmaceutical and medical device law and policy, legal research methodology, qualitative data collection, manuscript preparation, career development. Brigham and Women's Hospital	Varied levels of mentorship, from daily to weekly, lasting from a few months to several years.
2013-	Initiated Program On Regulation, Therapeutics, And Law (PORTAL) to bring together post-doctoral fellows trained in law and medicine, along with students	Close mentorship on daily basis, weekly lab meetings, lasting from a few months to several years.

with law, public health, and/or public policy interest, to study questions related to regulatory and drug development and delivery. Brigham and Women's Hospital

Mentored Trainees and Faculty

2005-2009	Rahul Rajkumar, M.D., J.D. / Senior vice president/Chief Medical Officer at CareFirst BlueCross BlueShield, Baltimore, MD Career stage: medical resident (BWH). Oversight of research program in intellectual property issues affecting availability of drugs in resource-poor settings, leading to 3 publications.
2006-2012	Dave A. Chokshi, M.D., M.Sc. / Former Chief Population Health Officer, New York City Health & Hospitals, New York, NY Career stage: medical student (University of Pennsylvania) and resident (BWH). Oversight of research program in access to and study of drugs and vaccines, leading to 2 publications. Dave served as 2012-2013 White House Fellow.
2008-2013	Alex Misono, M.D., M.B.A. / Interventional Radiologist, Newport Harbor Radiology Associates, Newport Beach, CA Career stage: medical student (HMS). Research on generic and brand-name drug policy, including evidence of relative efficacy of generic and brand-name drugs and study of effect of generic/brand color changes on medication adherence, leading to 3 publications.
2009-2010	Devan D. Bartels, M.D., M.P.H. / Instructor in Anesthesia, Massachusetts General Hospital, Boston, MA Career stage: medical student (HMS). Oversight of research project in effect of legal, social, and medical market events on off-label use of Neurontin, leading to 1 publication.
2010-2011	Kirsten E. Austad, M.D. / Attending physician, BWH, Boston, MA Career stage: medical student (HMS). Oversight of Safra Center-funded fellowship on medical school education and changes in attitudes about the pharmaceutical industry, leading to 8 publications.
2010-2012	Julia Kay Preis, S.M., M.B.A. / Consultant, The Frankel Group, Boston, MA Career stage: masters student (HMS). Oversight of honors master thesis on innovation in influenza vaccine development.
2010-	Daniel B. Kramer, M.D., M.P.H. / Associate Professor of Medicine, Division of Cardiovascular Medicine, Beth Israel-Deaconess Medical Center, Boston, MA Career stage: Junior faculty. Supervision of series of projects relating to medical device regulation and ethics, leading to 14 publications.
2011-2012	Adam Licurse, M.D. / Assistant Medical Director, Brigham and Women's Physician's Organization, BWH, Boston, MA Career stage: medical resident (BWH). Oversight of research on conflicts of interest and physician disclosure of industry relationships, leading to 1 publication.
2011-2014, 2016-2022	Jonathan J. Darrow, J.D., M.B.A., S.J.D. / Associate Professor of Law and Taxation, Bentley University, Waltham, MA Career stage: S.J.D. student (Harvard Law School) and post-doctoral fellow and junior faculty (BWH). Supervision of thesis and post-doctoral work on history of drug efficacy study and regulation, leading to S.J.D. thesis and 52 publications.
2011-2014	Shuai Xu, M.D., M.Sc. / Instructor in Dermatology, Northwestern Feinberg School of Medicine, Chicago, IL Career stage: medical student (HMS). Oversight of HMS/HSDM Scholars in Medicine-

	funded research and honors thesis on medical device innovation, leading to 5 publications, a *cum laude* medical school thesis, and 2012 Soma Weiss Research day finalist.
2011-2016	Bo Wang, M.D., Pharm.D. / Chief Medical Officer, Health IQ, Palo Alto, CA Career stage: medical student (HMS). Oversight of course of research related to drug policy issues, leading to 17 publications. Bo won the 2015 Robert Wood Johnson Foundation Public Health Law Research Program Young Investigator Award.
2012	Kyle D. Checchi, M.Sc., M.D. / Resident, San Diego, CA Career stage: medical student (HMS). Oversight of HMS/HSDM Scholars in Medicine-funded research internship on use of pill bottle-related medical device innovation to improve medication adherence, leading to 1 publication.
2012-2013	Colin Schwartz / Senior Associate for Policy and Advocacy, American Association of People with Disabilities, Washington, D.C. Career stage: masters student (Harvard Kennedy School). Oversight of research on development of transformative HIV drugs (zidovudine and protease inhibitors)
2012-2015	Yongtian T. Tan, M.D., M.B.A. / Resident, UCSF Benioff Children's Hospital, San Francisco, CA Career stage: medical student (HMS). Oversight of research on medical device innovation in resource-poor settings and comparison of medical device regulation in China and US, leading to 5 publications.
2012-2015	Evan S. Caplan, M.D., M.B.A. / Consultant, McKinsey & Co. Career stage: medical student (HMS). Investigation of sources of innovation leading to development of vascular endothelial growth factor inhibitors for use in ophthalmologic disease, leading to 1 publication.
2012-	Thomas J. Hwang, M.D. / Urology resident, Brigham and Women's Hospital/Dana-Farber Cancer Institute, Boston, MA Career stage: undergraduate (Harvard), research associate (BWH), medical student (HMS). Oversight of coursework and thesis research on Food and Drug Administration rulemaking, regulation, and biopharmaceutical innovation, leading to 46 publications.
2013	Nathan Shiu, J.D., M.P.H. / Lawyer at FDA Career stage: law student (University of California-Los Angeles). Oversight of summer research fellowship on adjudication of truth and scientific certainty in the federal courts, leading to 2 publications.
2013-2015	James S. Yeh, M.D. / Instructor in Medicine, Massachusetts General Hospital, Boston, MA Career stage: post-doctoral fellow (BWH). Oversight of post-residency general medicine fellowship in health services research, leading to 6 publications.
2013-2016	Carolyn Treasure, M.D. / Co-founder, Peachy, New York City, NY Career stage: medical student (HMS) and resident (BWH). Oversight of HMS/HSDM Scholars in Medicine-funded research internship on university patenting and government march-in rights, leading to 4 publications.
2013-	Ameet Sarpatwari, Ph.D., J.D. / Assistant Professor of Medicine, Division of Pharmacoepidemiology and Pharmacoeconomics, Boston, MA Career stage: post-doctoral fellow and junior faculty (BWH). Oversight of research program on law and public health topics, leading to 80 publications.
2013-	Ben Rome, M.D. / Instructor in Medicine, Division of Pharmacoepidemiology and Pharmacoeconomics, BWH, Boston, MA Career stage: medical student (HMS) and resident/fellow/junior faculty (BWH). Oversight of projects on evidence-based medicine use, device regulation, drug pricing, and pharmacoepidemiology, leading to 54 publications.

2014	Prashant Rajan, M.D. / Orthopedic surgery resident, Cleveland Clinic, Cleveland, OH Career stage: medical student (HMS). Oversight of project on current and future prospects for FDA postmarket regulation of medical devices, and the FDA regulation of medical device approval, leading to 2 publications.
2014-2016	Laura E. Bothwell, Ph.D. / Assistant Professor, Yale University School of Public Health, New Haven, CT Career stage: post-doctoral fellow (BWH). Oversight of project on adaptive design clinical trials, leading to 2 peer-reviewed publications.
2014-2019	Jing Luo, M.D., M.P.H. / Assistant Professor of Medicine, University of Pittsburgh School of Medicine, Pittsburgh, Pennsylvania Career stage: post-doctoral fellow and junior faculty (BWH). Oversight of post-residency general medicine fellowship in health services research, leading to 19 publications.
2015	Audrey D. Zhang, M.D. / Internal Medicine Resident, Duke University, Durham NC Career stage: undergraduate (Harvard). Oversight of projects on use of biomarkers in FDA decision-making about investigational drugs, and tracing their conceptual evolution as shaped by academia, industry, and regulatory agencies.
2015	Vincent C. Capati, J.D., Pharm.D., M.S. / Associate, Wiley Rein LLP, Washington, D.C. Career stage: law student (University of New Hampshire) Oversight of project examining interaction of antitrust law and pharmaceutical manufacturer marketing behavior, leading to 1 publication.
2015-2016	Nicole L. Levidow, J.D., M.P.H. / Compliance administrator, Massachusetts Institute of Technology Office of Sponsored Programs, Cambridge, MA Career stage: post-doctoral fellow (BWH). Oversight of project examining characteristics of clinical trials used to evaluate drugs moving through the Accelerated Approval pathway at FDA, leading to 2 publications.
2015-2017	Dalia M. Deak, J.D., M.P.H. / Associate, Covington & Burling, Washington, D.C. Career stage: masters student (HSPH ‘16) and law student (Harvard Law School ‘19). Oversight of projects examining, drug rediscovery and repurposing, the state of antibiotic development, the ethics of FDA approval pathways, and the history of biotechnology innovation, leading to 2 publications.
2015-2017	Mallika L. Mundkur, M.D., M.P.H. / Medical Officer, FDA, White Oak, MD Career stage: post-doctoral fellow (BWH). Oversight of projects on trends in high-risk medication use, including antibiotics and opioids, leading to 1 peer-reviewed publication.
2015-2020	Spencer Phillips Hey, Ph.D. / Co-founder, Prism Analytic Technologies Career stage: post-doctoral fellow (BWH) and staff (HMS). Oversight of projects at intersection of ethics and regulation involving personalized medicine and biomarker, leading to 20 peer-reviewed publications.
2016-2017	Sana Mostaghim, Dr.P.H. / Vaccines Business Unit, Takeda, Cambridge MA Career stage: doctoral student (HSPH). Oversight of projects on regulatory approval pathways and prescription drug safety, leading to 2 publications.
2016-2018	Chana A. Sacks, M.D., M.P.H. / Instructor in Medicine, Massachusetts General Hospital Career stage: post-doctoral fellow (BWH). Oversight of projects on drug prices and off-label use of drugs for rare diseases, leading to 7 peer-reviewed publications.
2016-2023	Kerstin N. Vokinger, M.D., J.D., Ph.D., LL.M. / Professor for Public Law and Digitalization, Health Law and Regulatory Sciences, University of Zurich, Switzerland Career stage: post-doctoral fellow (BWH), junior faculty (Zurich). Oversight of projects on differences between U.S. and European drug regulation, market exclusivity and second-generation brand-name drugs, leading to 12 peer-reviewed publications.

2016-2022 Michael S. Sinha, M.D., J.D., M.P.H. / Assistant Professor of Law, St. Louis University
Career stage: post-doctoral fellow (BWH). Oversight of projects on market exclusivity extensions applied to drugs studied in pediatric trials, use of social media in communicating about drug safety, leading to 18 peer-reviewed publications.

2016-2019 Emily Jung, M.D. / Ophthalmology resident, Duke University, Durham NC
Career stage: undergraduate (Harvard). Oversight of projects on racial, ethnic, and gender diversity in pivotal clinical trials used for FDA drug approval, leading to 9 peer-reviewed publications.

2016-2018 Nina Jain, M.D., M.B.A., M.Sc. / Medical director of value-based care, Brigham and Women's Hospital
Career stage: medical student (HMS) and resident (BWH). Oversight of projects on incentives for drug innovation, leading to 5 peer-reviewed publications.

2016-2018 Michael Fralick, M.D., Ph.D. / Clinician Scientist and Assistant Professor, Department of Medicine, University of Toronto, Canada
Career stage: post-doctoral fellow (BWH). Oversight of projects on drug safety monitoring and evaluation of drug clinical trials, leading to 18 peer-reviewed publications.

2017-2018 Reed F. Beall, M.A., Ph.D. / Assistant Professor, University of Calgary, Alberta, Canada
Career stage: post-doctoral fellow (BWH). Oversight of projects on impact of patents and market exclusivity on availability of essential medical products, leading to 8 peer-reviewed publications.

2017-2019 Chintan Dave, Pharm.D., Ph.D. / Assistant Professor of Epidemiology, Rutgers University, New Brunswick, NJ
Career stage: post-doctoral fellow (BWH). Oversight of projects on prescription drug pricing, generic drug availability, drug shortages, and pharmacoepidemiology, leading to 7 publications.

2017-2019 Elvira D'Andrea, M.D., M.P.H. / Research Scientist, Division of Pharmacoepidemiology and Pharmacoeconomics, Boston, MA
Career stage: post-doctoral fellow (BWH). Oversight of projects on biomarkers and their use in drug development, leading to 8 peer-reviewed publications.

2017-2019 Huseyin Naci, Ph.D., M.H.S. / Assistant Professor, London School of Economics, UK
Career stage: Harkness fellow (BWH). Oversight of projects on FDA expedited approval pathways and insurance coverage of high-priced drugs, leading to 2 peer-reviewed publications.

2017-2019, 2022-2023 Frazer Tessema / Medical student, University of Chicago, Chicago, IL
Career stage: research assistant and medical student (BWH). Oversight of projects on prescription drug pricing, generic drug availability, drug shortages, and pharmacoepidemiology, leading to 14 publications.

2018-2019 Bishal Gyawali, M.D., Ph.D. / Assistant Professor of Public Health Science, Queen's University Cancer Research Institute, Kingston, Ontario, Canada
Career stage: post-doctoral fellow (BWH). Oversight of projects on biomarkers and their use in oncology drug development, leading to 20 peer-reviewed publications.

2018- William B. Feldman, M.D., Ph.D., M.P.H. / Instructor in Medicine, Division of Pharmacoepidemiology and Pharmacoeconomics, BWH, Boston, MA
Career stage: medical subspecialty fellow (BWH). Oversight of projects on 'exceptions from informed consent' clinical trials and evidence-based use and cost of pulmonary disease medications, leading to 31 peer-reviewed publications.

2018-2020 Rachel E. Barenie, Pharm.D., J.D., M.P.H. / Assistant Professor, University of Tennessee, Memphis, TN

Career stage: post-doctoral fellow (BWH). Oversight of projects on opioid regulation and use, leading to 13 peer-reviewed publications.

2018-2020 Sheng Liu, M.Sc., J.D. / Associate, ReedSmith LLP
Career stage: post-doctoral fellow (BWH). Oversight of projects on regulatory pathways for new drugs and rules relating to pharmaceutical promotion, leading to 2 peer-reviewed publications.

2019 Rick A. Vreman, Pharm.D., Ph.D. / Patient Access manager and policy lead, Roche
Career stage: visiting Ph.D. student (BWH). Oversight of qualitative research project comparing features of the deliberative process of Health Technology Assessment organizations in the US and Europe, leading to 2 peer-reviewed publications.

2019-2020 Veroníque Raimond, Ph.D. / Senior project manager, French National Authority for Health
Career stage: Harkness fellow (BWH). Oversight of projects on drug pricing and regulation comparisons between France and the US, leading to 2 peer-reviewed publications.

2019- Leah Z. Rand, Ph.D. / Research Scientist, Division of Pharmacoepidemiology and Pharmacoeconomics, BWH, Boston, MA
Career stage: post-doctoral fellow (BWH). Oversight of projects on ethics and comparative drug evaluation and regulation, leading to 16 peer-reviewed publications.

2019- Victor van de Wiele, LL.B., LL.M. / Ph.D. candidate, University of Cambridge, UK
Career stage: post-doctoral fellow (BWH). Oversight of projects on generic drugs, biosimilars, and state drug regulatory laws, leading to 9 peer-reviewed publications.

2019-2021 Brooke Raunig, B.S.N., J.D. / Attorney in private practice
Career stage: post-doctoral fellow (BWH). Oversight of projects on regulation of addictive medicines and intellectual property law, leading to 1 peer-reviewed publication.

2020-2022 Bryan Walsh, J.D. / Associate, Hogan Lovells, Washington, D.C.
Career stage: post-doctoral fellow (BWH). Oversight of projects on FDA regulation of generic drugs and health insurance policy, leading to 8 peer-reviewed publications.

2020-2022 Beatrice Brown, M.Be. / Student, Yale Law School, New Haven, CT
Career stage: research assistant (BWH). Oversight of projects on FDA regulation, women's health, drug prices leading to 19 peer-reviewed publications.

2020-2021 Doni Bloomfield, J.D. / Judicial clerk, District of Columbia Court of Appeals
Career stage: post-doctoral fellow (BWH). Oversight of projects on patents and antitrust policy affecting drugs, leading to 6 peer-reviewed publications.

2021-2022 Anjali Deshmukh, M.D., J.D. / Assistant Professor of Law, Georgia State University, Atlanta, GA
Career stage: post-doctoral fellow (BWH). Oversight of projects on FDA regulation and prescription drug use in children.

2021- Hussain Lalani, M.D., M.P.H., M.Sc. / Research Fellow, Division of Pharmacoepidemiology and Pharmacoeconomics, Boston, MA
Career stage: post-doctoral fellow (BWH). Oversight of projects on drug pricing, drug development, medical communication, and out-of-pocket spending on prescription drugs leading to 4 peer-reviewed publications.

2021- Joseph R. Daval, J.D. / Research Fellow, Division of Pharmacoepidemiology and Pharmacoeconomics, Boston, MA
Career stage: post-doctoral fellow (BWH). Oversight of projects on FDA organization, advisory committees, and administrative law.

2021-2023 Caroline Horrow, J.D. / Research Fellow, Division of Pharmacoepidemiology and Pharmacoeconomics, Boston, MA

Career stage: post-doctoral fellow (BWH). Oversight of projects on pharmacogenomics and drug pricing for gene therapies.

2021- Alex Egilman / Research Assistant, Division of Pharmacoepidemiology and Pharmacoeconomics, Boston, MA
Career stage: research trainee (BWH). Oversight of projects on drug pricing, drug evaluation and drug benefits-risk balance.

2022- Catherine Hwang, M.D., M.P.H. / Research Fellow, Division of Pharmacoepidemiology and Pharmacoeconomics, Boston, MA
Career stage: post-doctoral fellow (BWH). Oversight of projects on medication adherence and impact of novel regulatory changes on drug use.

2022- Dongzhe Hong, Ph.D. / Research Fellow, Division of Pharmacoepidemiology and Pharmacoeconomics, Boston, MA
Career stage: post-doctoral fellow (BWH). Oversight of projects on pharmaceutical use and spending using large databases.

2022- Jacob Madden, J.D. / Research Fellow, Boston University School of Law
Career stage: post-doctoral fellow (BUSL). Oversight with Kevin Outterson, J.D., LL.M., of projects on antibiotic and antiviral pricing, use, and development incentives.

2022- Edward R. S. Cliff, M.B.B.S., B.Med.Sc., M.P.H. / Research Fellow, Division of Pharmacoepidemiology and Pharmacoeconomics, Boston, MA
Career stage: post-doctoral fellow (BWH). Oversight of projects on cancer drug use and policy leading to 4 peer-reviewed publications.

2022- Sarah Gabriele, J.D., LL.M., M.Be. / Research scientist, Division of Pharmacoepidemiology and Pharmacoeconomics, Boston, MA
Career stage: research scientist (BWH). Oversight of projects on intellectual property law, drug regulation, and international comparative law.

Local Invited Presentations

Those presentations below sponsored by outside entities are so noted and the sponsor(s) is (are) identified.

2004 Two medico-legal cases / Medicine Grand Rounds (with James T. Hilliard)
Department of Medicine, BWH

2004 Patents, academic research, and drug discovery / Research Rounds
Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine, BWH

2006 Characteristics of physicians who frequently act as expert witnesses in neurological birth injury litigation / Research Rounds
Department of Medicine, BWH

2007 Patent extensions and public health: an empirical analysis / Research Rounds
Department of Health Care Policy and Management, HSPH

2007 Patents and public health: balancing innovation and access / Research Rounds
Center for Outcomes and Policy Research, Dana-Farber Cancer Institute

2008 Balancing drug development and public health / Invited Lecture
Department of Medicine, Massachusetts General Hospital

2008 The insiders: a decade of health care whistleblowers and Department of Justice investigations of health care fraud / Research Rounds
Department of Medicine, BWH

2008 Industry sponsorship in medicine and medical research / Grand Rounds
Department of Geriatric Medicine, Hebrew Rehabilitation Center, Jamaica Plain, MA

2008 Patents and public health: balancing access and incentives for innovation / Plenary Talk

Harvard Interfaculty Initiative for Medicines and Society conference, Harvard University

2009 Patents and cancer drug development / Research Rounds
Center for Outcomes and Policy Research, Dana-Farber Cancer Institute

2009 Patents, innovation, and public health / Invited Lecture
Department of Medicine, Massachusetts General Hospital

2009 Intellectual property issues limiting access to essential medicines / Panel
Journal of Law and Technology annual symposium, Harvard Law School

2009 Health metrics evaluation workshop / Panel
Petrie-Flom Center for Health Policy, Biotechnology, and Bioethics, Harvard Law School

2010 Intellectual property and health care delivery / Invited Speaker
Harvard Law School Conference on Intellectual Property Law, Cambridge, MA

2010 Market exclusivity incentives for drug development: perils and promise / Invited Lecture
Department of Medicine, Massachusetts General Hospital

2011 Legal ecology of resistance / Invited Speaker
Antimicrobial resistance: biology, population dynamics and policy options, HSPH Center for Communicable Disease Dynamics annual symposium, Boston, MA

2011 Patents and public health: what are the limits / Invited Lecture
Department of Biostatistics, HSPH

2011 The Orphan Drug Act and transformative drug development in oncology / Research rounds
Center for Outcomes and Policy Research, Dana-Farber Cancer Institute

2011 Medical malpractice as a health policy issue / Invited Lecture
Department of Medicine, Massachusetts General Hospital

2011 Legislative incentives for pharmaceutical innovation / Invited Lecture
Department of Medicine, Massachusetts General Hospital

2011 Making drug approval and surveillance less scary / Invited Lecture
Harvard Interfaculty Initiative on Drug Development, Harvard University

2012 Legislative incentives for pharmaceutical innovation / Invited Lecture
Health Policy Certificate Program, Partners Graduate Medical Education

2012 Influence of conflict of interest disclosure on physicians' interpretation of clinical research: a randomized controlled trial / Research Rounds
Center for Outcomes and Policy Research, Dana-Farber Cancer Institute

2013 Association for Molecular Pathology v. Myriad Genetics, the Supreme Court, and the ongoing fight over breast cancer patents / Research Rounds
Center for Outcomes and Policy Research, Dana-Farber Cancer Institute

2013 Health law year in p/review: gene patents / Invited Speaker
Harvard Law School Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics, Cambridge, MA

2013 Legal and ethical issues in therapeutic development and regulation / Invited Speaker
Harvard Program in Therapeutic Science, Boston, MA

2013 Bayh-Dole march-in rights and the public's access to medical products based on federally-funded research / Invited Speaker
Harvard Law School Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics Health Law Policy and Bioethics Workshop, Cambridge, MA

2014 Second Annual Health law year in p/review: breakthrough drugs / Invited Speaker
Harvard Law School Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics, Cambridge, MA

2014 Patents without patents / Moderator
Harvard Law School Petrie-Flom Center for Health Law Policy, Biotechnology, and

Bioethics, Cambridge, MA

2014 Overview of current issues facing biosimilar regulation / Featured Speaker
Mini-Course to Visiting Members of Chinese FDA, Boston, MA (sponsored by Charles Institute of Management)

2014 Accelerated FDA approval of new drugs and devices: what are the medical, legal, and ethical risks? / Grand Rounds
Beth Israel Deaconess Medical Center Department of General Medicine and Primary Care, Boston MA

2014 Are stem cells patentable? / Invited lecture
Harvard Department of Stem Cell and Regenerative Biology-Laboratory of Systems Pharmacology Research Day, Cambridge, MA

2014 Studies in regulatory science / Invited lecture
Therapeutic Science Advisory Council Meeting, HMS, Boston MA

2014 Hepatitis C drugs: what price progress? / Medicine Grand Rounds (with Paul E. Sax)
Department of Medicine, BWH

2015 Updating the HMS conflicts of interest policy / Invited speaker
HMS Standing Committee on Conflicts of Interest and Commitment, Boston MA

2015 Brain hacking to boost your A-game: the ethics of cognitive enhancement in gaming and competition / Invited Speaker
HMS Center for Bioethics neuroethics seminar series, Boston MA

2015 FDA in the 21st Century / Invited panelist
Harvard Law School, Cambridge MA

2015 Regulatory science and the 21st Century Cures Act / Invited lecture
Therapeutic Science Advisory Council Meeting, HMS, Boston MA

2015 Specimen science: background and foundations / Invited panel moderator
Harvard Law School, Cambridge MA

2015 Ethical issues in expanded access to investigational drugs / Invited discussant
HMS Center for Bioethics, Boston MA

2015 Institutional corruption and public health: the case of FDA expedited review and development programs/Invited speaker
Edmond J. Safra Center for Ethics at Harvard University, Cambridge, MA

2016 Health law year in p/review: 21st Century Cures Act / Invited Speaker
Harvard Law School Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics, Cambridge, MA

2016 High-cost drugs: origins, impacts, prospects for reform / Cardiovascular Grand Rounds
Division of Cardiovascular Medicine, BWH

2016 Should cost matter in the care of patients with advanced cancer? / Featured discussant
Harvard Center for Bioethics Clinical Ethics Consortium, HMS

2016 Regulatory environment around cancer drug development / Featured speaker
HMS External Education: Cancer Care in 2025, Boston MA

2016 Current Legal and Ethical Issues Affecting Prescription Drugs / Featured speaker
HMS Media Fellowship on Bioethics, Boston MA

2016 Fostering innovation in early stage bio-pharma / Featured speaker
Harvard Business School Health Care Initiative and Harvard Kennedy School Healthcare Policy Program, Cambridge MA

2016 FDA regulation, innovation, and the 21st Century Cures Act / Featured speaker
Pharmaceutical Policy Research Seminar, Department of Population Medicine, HMS and the Harvard Pilgrim Health Care Institute, Boston MA

2016 Patient involvement with the FDA / Discussant and Moderator
Health Policy and Bioethics Consortium, HMS, Boston MA

2016 Regulatory science and precision medicine: the tale of eteplirsen / Invited lecture
Regulatory Science Advisory Council Meeting, HMS, Boston MA

2016 What is the proper role of patient advocacy in FDA approval decisions? / Grand Rounds
Henry Hardy Lecture in Bioethics and Public Policy, Beth Israel Deaconess Medical Center, Boston MA

2017 Prescription drug policy: The past, present and future / Invited Lecture
Harvard Graduate School of Arts and Sciences Science Policy Group, Cambridge, MA

2017 Looking forward: the next generation of biosimilars / Moderator
Harvard Law School Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics, Cambridge, MA

2017 The future of the FDA / Medicine Grand Rounds
Department of Medicine, Brigham and Women's Faulkner Hospital, Boston, MA

2017 Global health challenge: 2017 and beyond / Panelist
Harvard Kennedy School Global Development Conference, Cambridge, MA

2017 Prescription drug prices: controversies and potential solutions / Grand Rounds
Department of Medicine, BWH, Boston MA

2017 The Cost of Medications: Current Realities and the Future of Pharmaceutical Pricing Regulations in the United States / Invited Speaker
Harvard Law School Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics, Cambridge, MA

2017 Health law year in p/review: Prescription Drug Pricing / Invited Speaker
Harvard Law School Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics, Cambridge, MA

2018 Prescription Drug Prices and "Value" / Invited Speaker
Harvard Law School Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics, Cambridge, MA

2018 Patients' Role in FDA Drug Approval Decisions / Ethics Grand Rounds
Dana-Farber Cancer Institute, Boston, MA

2019 Health law year in p/review: Prescription Drug Pricing / Invited Speaker
Harvard Law School Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics, Cambridge, MA

2020 Prescription Drug Pricing: Where We Are and Where We Are Going / Visiting Speaker
Richard A. and Susan F. Smith Center for Outcomes Research in Cardiology**,** Beth Israel Deaconess Medical Center, Boston, MA

2020 Seeking value in our health care system / Featured speaker
Research Fellow Economics Seminar, BWH Division of Hospital Medicine, Boston, MA

2021 Contribution of Public Funding to the Development of Transformative Drugs and Covid-19 Products / Featured speaker
Boston Children's Hospital Department of Pediatrics Grand Rounds, Boston, MA

Report of Regional, National and International Invited Teaching and Presentations

Invited Presentations and Courses

Those presentations below sponsored by outside entities are so noted and the sponsor(s) is (are) identified.

Regional

2008 Pressing issues in health care and pharmaceutical policy / Invited Lecture

Massachusetts Attorney General Health Care Division offices, Boston, MA

2009 Access to human papillomavirus vaccines: human rights and global health / Plenary talk
American Journal of Law and Medicine annual symposium, Boston University School of Law, Boston, MA

2009 Clinical and policy rationales for legislation banning the commercial sale of physician-identified prescription data / Invited Lecture
Massachusetts state legislature Joint Committee on Health Care Financing, Boston, MA

2011 Public health goals and commercial speech in off-label drug promotion / Plenary talk
American Journal of Law and Medicine annual symposium, Boston University School of Law, Boston, MA

2012 The past, present and future of pay-for-delay settlements between brand-name and generic manufacturers / Invited Speaker
Boston Intellectual Property Law Association, Antitrust Division, Boston, MA

2012 Incentivizing research in rare diseases / Invited Plenary Speaker
Pharmaceutical Research and Manufacturers of America Annual Meeting, Boston, MA

2012 Health policy visiting scholar / Invited Speaker
Yale College, Yale School of Management, and Robert Wood Johnson Clinical Scholars Program, New Haven, CT

2013 Implementing conflicts of interest policies at academic medical centers / Invited Speaker
New England Medical School and Academic Medical Center Roundtable, Community Catalyst, Boston, MA

2013 Public health implications of the Supreme Court's decision in *Federal Trade Commission v. Actavis* / Invited Speaker
Boston Intellectual Property Law Association, Antitrust Division, Boston, MA

2013 Opening up translational research / Featured Speaker
Universities Allied for Essential Medicines joint MIT-Harvard conference, Cambridge, MA

2013 Overview of current issues facing biosimilar regulation in the US / Featured Speaker
Days of Molecular Medicine Global Foundation, Boston, MA [sponsored by Sectoral Asset Management]

2013 Antibiotics: Issues in the Development and Evidence-Based Use / Guest Course Lecture
Massachusetts Institute of Technology Introductory Biology 7.015, Cambridge, MA

2013 Prescription Drugs: Intersections with Patents and Public Health / Guest Course Lecture
Boston Univ School of Public Health Epidemiology 748 Masters Seminar, Boston, MA

2014 Patents and public health / Guest Course Lecture
Northeastern University School of Law 7606: Health Law, Boston, MA

2015 Is there a myth of data exclusivity?/Invited speaker
2nd Annual BioIP conference, Boston University School of Law, Boston, MA

2016 The Future of Drug Promotion and Public Health / Invited Speaker
Northeastern Univ Law School Conference on Future of Public Health Law, Boston, MA

2016 Government Interventions to Address High Drug Prices / Invited Speaker
American Society of Law, Medicine, and Ethics' Health Law Professors' Conference, Boston, MA

2016 Developing Legal and Policy Responses to Drug-Resistant Bacteria / Panelist
Yale Global Health Justice Partnership Forum, New Haven, CT

2016 The Legal Causes of – and Solutions to – High Drug Prices / Panelist
Yale Global Health Justice Partnership Forum, New Haven, CT

2017 Myths and realities of FDA drug regulation / Featured speaker

Pharmaceuticals Certificate Program, Global Health Department at Boston University School of Public Health

2017 Physicians and Their Role in Reducing Drug Costs / Featured speaker
Massachusetts Medical Society Ethics Forum, Boston, MA

2017 Managing High Prescription Drug Prices / Featured speaker
Institute for Healthcare Improvement Leadership Conference, Boston, MA

2019 Current Topics in Prescription Drug Prices / Featured speaker
Department of Economics, University of Massachusetts-Amherst, Amherst, MA

2019 Prescription Drug Prices 2019 / Invited speaker
Innovations and New Practices in Internal Medicine, Boston, MA

2019 Prescription Drug Prices: A Day-Long Symposium / Speaker and Organizer
International Federation of Employee Benefit Plans, Boston, MA

2020 FDA and COVID-19 / Invited panelist
Yale Law School Faculty Symposium, New Haven, CT

2021 Pharmaceutical Competition Policy: What's Next on Patents and Market Entry and Exclusivity Reform / Panelist
Biopharmaceutical Innovation and Pricing Reform Conference, Boston University Institute for Health System Innovation and Policy, Boston, MA (virtual)

National

2000 End-of-life care report: information for patients and families / Invited Lecture
National Cancer Policy Board, Woods Hole, MA

2001 Gleevec (STI-571), a new treatment for chronic myelogenous leukemia: the science of drug discovery and FDA approval / Grand Rounds
M.D./Ph.D. program, University of Pennsylvania School of Medicine

2004 Deoxyribonucleic Acid (DNA) in civil litigation / Invited Lecture
American College of Legal Medicine annual meeting, Las Vegas, NV

2005 Financial impact of current drug patent policy on Medicaid drug spending / Invited Lecture
Society of General Internal Medicine annual meeting, New Orleans, LA

2006 Update on DNA in civil litigation / Invited Lecture
American College of Legal Medicine annual meeting, Las Vegas, NV

2006 The price of innovation: the effect of patents on medical practice / Plenary Lecture
American Association of Pharmaceutical Scientists annual meeting, San Antonio, TX

2007 Presenting truthful information to physicians / Invited Lecture
National State Attorney General Program at Columbia Law School, New York, NY

2008 Local prescribing practices and access to drugs in resource-poor settings / Plenary Talk
American Journal of Law and Medicine symposium, Boston University School of Law

2008 Free speech and pharmaceutical promotion to physicians / Invited Lecture
American University Washington College of Law Conference, Washington, DC

2008 Pharmaceutical policy issues and points of interest for Attorneys General / Invited Lecture
National Teleconference of Attorneys General

2008 Should FDA drug and device regulation bar liability claims? / Congressional Testimony
House of Representatives Committee on Oversight and Government Reform (Rep. Waxman, Chairman), Washington, DC

2008 Global Health Frontiers Workshop / Panel
Center for Global Development, Warrenton, VA

2008 Pharmaceutical development: innovation vs. public health / Invited Lecture
Leonard Davis Institute, University of Pennsylvania

2008 The priority review vouchers: questions and concerns / Invited Lecture
Knowledge Ecology International meeting on incentivizing drug development for neglected diseases, Washington, D.C.

2008 The risks and benefits of follow-on biologics legislation for Medicare / Panel
Medicare Payment Advisory Commission, Washington, DC

2010 Constitutional health law: pharmaceutical regulation and commercial speech / Panel
Association of American Law Schools Annual Meeting, New Orleans, LA

2010 Using market exclusivity to incentivize drug development / Invited Speaker
University of Pennsylvania Law School Center for Technology, Innovation, and Competition, Philadelphia, PA

2010 Implementation of and innovation within the Orphan Drug Act / Invited Speaker
Committee Accelerating Rare Disease Research and Orphan Product Development, Institute of Medicine, Washington, D.C.

2010 Legal issues in drug development and drug use / Invited Speaker
Robert Wood Johnson Clinical Scholars Policy Speaker Series, Philadelphia, PA

2010 Methodological issues in comparative effectiveness research / Invited Speaker
Health Affairs Comparative Effectiveness Research consortium, Washington, D.C.

2010 Sources of transformative innovation in drug development / Invited Plenary Speaker
Robert Wood Johnson Investigator Award in Health Policy Research Meeting, Itsaca, IL

2011 Insiders' perspectives on off-label drug promotion / Invited Speaker
Food and Drug Administration Drug Safety Oversight Board, White Springs, MD

2011 Transformative drug and device development / Invited Plenary Speaker
Robert Wood Johnson Investigator in Health Policy Research Meeting, Princeton, NJ

2011 Institutional challenges at the FDA / Invited Plenary Speaker
FDA at Crossroads National Meeting, Union of Concerned Scientists and GW School of Public Health, Washington, D.C.

2012 Asymmetry in the ability to communicate CER findings / Invited Speaker
National Pharmaceutical Council, Washington, DC

2012 Reauthorization of the Medical Device User Fees Amendments: what it means for jobs, innovation and patients / Congressional Testimony
House of Representatives Committee on Energy and Commerce Subcommittee on Health (Rep. Pitts, Chairman), Washington, DC

2012 Restrictions on promoting comparative effectiveness research (CER) / Invited Speaker
Health Affairs kick-off symposium on promotion of CER, Washington, D.C.

2012 The roles of academia, industry, and patents in transformative drug development in oncology / Invited Plenary Speaker
Robert Wood Johnson Investigator in Health Policy Research Meeting, Princeton, NJ

2012 Patents and market exclusivity: a lever for incentivizing drug development? / Keynote
18th Annual Thomas Langfitt Symposium on Health Care Policy, College of Physicians of Philadelphia and the University of Pennsylvania, Philadelphia, PA

2013 Research on COI: results from two national surveys / Invited Keynote Speaker
FOCI Academe Meeting, Association of American Medical Colleges, Baltimore, MD

2013 The Food and Drug Administration in the 21st century / Invited Speaker
Harvard Law School Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics, Cambridge, MA [national attendees]

2013 Issues and case studies in clinical trial data sharing: lessons and solutions / Invited Panelist
Multi-Regional Clinical Trial Center, Harvard Global Health Institute [national attendees]

2013 Patient-centered outcomes research in rare diseases / Keynote Speaker

14th Annual North American Lysosomal Storage Disease Registries Meeting, Chicago, IL

2013 Effect of drug detailing restrictions on prescribing of antidepressants and antipsychotics in children / Invited Lecture
AcademyHealth annual meeting, Baltimore, MD

2013 High Priority Research Topics in Regulatory Science Related to Generic Drugs / Featured Speaker [with William Shrank]
FDA Office of Generic Drugs Generic Drug User Fee Act (GDUFA) Regulatory Science Initiatives Public Meeting, Silver Spring, MD

2013 FDA Safety and Innovation Act (FDASIA) and the breakthrough drug designation: the risks of approving drugs on the basis of limited supporting data / Featured Speaker
Briefings for Senate and House of Representative Congressional Staff, Washington, D.C.

2013 The practices and perils of "non-traditional" drug promotion / Invited Panelist
Food and Drug Law Institute Advertising and Promotion for the Pharmaceutical, Medical Device, Biological, and Veterinary Medicine Industries, Washington, D.C.

2013 Prospects for regulation of off-label drug promotion in an era of expanding commercial speech protection / Featured Speaker
University of North Carolina School of Law Annual Symposium, Chapel Hill, NC

2013 Are biomarkers patentable? / Keynote Speaker
Global Biomarkers Consortium 2nd Annual Conference, Boston, MA [national attendees]

2013 Approval of new drugs on the basis of extremely limited data / Invited Speaker
Center for Excellence in Education's 30th Anniversary Celebration, Cambridge, MA [national attendees]

2013 Ethical implications of approval of drugs on the basis of limited data / Invited Speaker
Greenwall Foundation Scholar Annual Meeting, New York City, NY

2013 Alternative or additional incentives for drug development / Invited Speaker
Duke Law School Center for Innovation Policy Annual Meeting, Washington, D.C.

2014 Lessons for Follow-On Biologics from Generic Small Molecules / Speaker and Panelist
Federal Trade Commission Follow-On Biologics Workshop, Washington, D.C.

2014 Specialty pharmaceuticals / Round table discussant
Health Affairs Planning Meeting, Bethesda, MD

2014 Is sunshine the best disinfectant? Promise and perils of the Sunshine Act / Invited speaker
American College of Physicians Internal Medicine 2014 annual meeting, Orlando, FL

2014 Ethical approaches to expanded access of investigational drugs / Round table discussant
Engelberg Center for Health Care Reform, Brookings Institution, Washington, D.C.

2014 Tackling generic drug safety / Featured Speaker
FDA Office of Generic Drugs Generic Drug User Fee Act Regulatory Science Initiatives Public Meeting, Silver Spring, MD

2014 Using 'big data' to change policy: physician financial relationships and prescribing practices / Invited panelist
AcademyHealth Annual Research Meeting, San Diego, CA

2014 Generating evidence for use of new drugs and devices: what are the issues? / Keynote
PORTAL/AAAS/NCHR conference on evidence development and FDA policy, Washington, D.C.

2014 21st Century Cures: Modernizing Clinical Trials / Congressional Testimony
House of Representatives Committee on Energy and Commerce Subcommittee on Health (Rep. Pitts, Chairman), Washington, DC

2014 Lessons from the development of the most transformative drugs of the past 25 years / Invited speaker

Robert Wood Johnson Foundation Investigator Award in Health Policy Research Annual Meeting, Indianapolis, IN

2014 FDA regulation of specialty drugs/ Invited Speaker
Health Affairs kick-off symposium on specialty drugs, Washington, D.C.

2014 Health policy implications of FDA approval of new drugs and devices/ Grand Rounds
Department of Health Services, Policy & Practice, Brown University School of Public Health, Providence, RI

2014 Preparing for biosimilars in the U.S.: what are the controversies?/ Invited Speaker
Academy of Managed Care Pharmacy 2014 annual meeting, Boston, MA

2014 Regulation of off-label drug promotion and the First Amendment/ Invited Speaker
Public Health in the Shadow of the First Amendment symposium at Yale Law School, New Haven, CT

2014 Regulation of new technologies: vaccines for non-communicable diseases/ Invited Speaker
Emerging Issues and New Frontiers in FDA Regulation, Food and Drug Law Institute/Petrie-Flom Center Symposium, Washington, D.C.

2014 Subcommittee Hearing Investigating Generic Drug Prices / Congressional Testimony
Senate Committee on Health, Education, Labor and Pensions Subcommittee on Primary Health and Aging (Sen. Sanders, Chairman), Washington, DC

2014 Ethical and clinical implications of expedited regulatory development and approval of new drugs and medical devices / Invited speaker
Arthur & Ilene Dalinka Penn Grand Rounds Series, Hospital of the University of Pennsylvania Department of Medicine, Philadelphia, PA

2015 Adjusting regulatory standards to promote development of new CNS drugs
Financial Incentives to Support Unmet Medical Needs for Nervous System Disorders: A Workshop*,* Institute of Medicine, Washington, D.C.

2015 Roles of academia, repurposing and orphan drugs in transformative drug development / Invited Speaker
Health Affairs kick-off symposium on innovation, Washington, D.C.

2015 Expanded access to investigational drugs and other health policy topics / Invited Speaker
National Physician's Alliance FDA task force, Boston, MA [national attendees]

2015 Managing uncertainty and reproductive rights with new technology / Invited speaker
Institute of Medicine Workshop: Ethical and Social Policy Considerations of Novel Techniques for Prevention of Maternal Transmission of Mitochondrial DNA Diseases, Washington, D.C.

2015 Prospects for use of march-in rights to affect pricing of drugs emerging from government-sponsored research/Invited speaker
Yale Health Law and Policy Society Guest Lecture Series, New Haven, CT

2015 Lessons from the most transformative drugs of the past 25 years / Invited speaker
Michael M. Davis Lecture Series, Center for Health Administration Studies, University of Chicago School of Social Service Administration, Chicago, IL

2015 Does controversy during generic drug approval affect outcomes? Results from observational data, a systematic review, and surveys of patients and physicians/Invited speaker [with Joshua Gagne]
FDA Office of Generic Drugs (OGD)/Office of Research & Standards, Rockville, MD

2015 Studying the post-market safety and rational use of generic drugs / Featured Speaker
FDA Office of Generic Drugs Generic Drug User Fee Act (GDUFA) Regulatory Science Initiatives Public Meeting, Silver Spring, MD

2015 Assessing PDUFA 2012: breakthrough therapy and other expedited review and approval

designations / Invited Speaker
FDA Center for Drug Evaluation and Research PDUFA Reauthorization Public Meeting, Silver Spring, MD

2015 Role of Public Funding in the Development of Transformative Drugs / Invited Speaker
Middle Class Prosperity Project Forum, U.S. Senate, Washington, D.C.

2016 Law and humanities: Blinding images in the law and other disciplines / Panel
Association of American Law Schools Annual Meeting, New York, NY

2016 Innovation, Safety, and Value: The 21st Century Cures Bill / Invited Speaker
Center for Drug Safety and Effectiveness, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD

2016 Prescription Drug Prices: Origins and Options for Reform / Plenary speaker
American Heart Association Quality of Care and Outcomes Research Annual Meeting, Phoenix, AZ

2016 Hospital administration and prescription drug prices / Plenary speaker
American Hospital Association Annual Meeting, Washington, D.C.

2016 Balancing speed vs. evidence in cancer drug development / Grand Rounds speaker
Memorial Sloan Kettering Cancer Center Survivorship, Outcomes, and Risk Seminar Series, New York, NY

2016 Pharma, Science, and Innovation: What Does the Future Hold for the Health Care Industry and for Patients? / Speaker and moderator (with Peggy Hamburg and Ken Frazier)
Yale Law School Solomon Health Law and Corporate Law Centers' Craig Wasserman '86/Wachtell, Lipton, Rosen & Katz Alumni Breakfast, New York, NY

2016 High Drug Prices: Sources and Solutions / Invited Speaker
American Medical Association Board of Delegates, Chicago, IL

2016 Regulatory Review Times and Adverse Event Reports in Cardiovascular Devices / Speaker
American Society of Health Economics Biannual Meeting, Philadelphia PA

2016 Transforming Data to Inform Value: Balancing Innovation with Access / Panelist
American Heart Association Corporate Forum Policy Dialogue, Washington, DC

2016 High Drug Prices and State-Based Solutions / Speaker
Council of State Governments Medicaid Leadership Policy Academy, Washington, D.C.

2016 High-Cost Drugs: Ensuring Access without Hampering Innovation / Speaker
Yale Law School, New Haven, CT

2016 Strategies for Ensuring Patient Access to Affordable Drug Therapies / Speaker
National Academies of Science, Engineering and Medicine, Washington, D.C.

2016 Limiting Off-Label Promotion is Needed to Protect Patients / Speaker
Part 15 Public Hearing: Manufacturer Communications Regarding Unapproved Uses of Approved or Cleared Medical Products, Food and Drug Administration, Silver Spring, MD

2016 Emerging Opportunities to Streamline Cancer Drug Development / Panelist
President's Cancer Panel, Arlington, VA

2017 Expedited FDA approval and stem cell therapies / Keynote speaker
International Society for Stem Cell Research Nucleus Forum, Berkeley, CA

2017 March-In Rights: Experiences and Prospects for Reducing Drug Prices / Speaker
Knowledge Ecology International, Washington, D.C.

2017 Prescription Drug Pricing / Featured Speaker
American Medical Association National Advocacy Conference, Washington, D.C.

2017 Right to Try and Expanded Access to Investigational Drugs / Featured speaker
Pew Prescription Project: Framing the Debate on Right to Try, Washington, D.C.

2017 Ensuring Availability of Innovation and Prescription Drugs to Patients / Featured speaker
America's Health Insurance Plans National Health Policy Conference, Washington, D.C.

2017 An Overview of the 21st Century Cures Act / Featured speaker
National Comprehensive Cancer Network Institutional Review Board Directors Forum, Orlando, FL

2017 The Future of Prescription Drug Prices / Keynote Speaker
Distinguished Lecture Series, Florida Hospital, Orlando, Florida

2017 Regenerative Medicine and the 21st Century Cures Act / Featured speaker
National Academies of Science, Engineering, and Medicine Forum on Regenerative Medicine, Washington, D.C.

2017 Physicians' Knowledge and Perceptions about FDA Approval Standards / Invited Speaker
Committee for Advanced Scientific Education Seminar, FDA, Silver Spring, MD

2017 Can Importation Address High Generic Drug Prices? / Featured Speaker [with Thomas J. Bollyky]
Brookings Institution "Reining in Prescription Drug Prices", Washington, D.C.

2017 What is the Price of a Drug? / Invited panelist
Financial Times US Healthcare & Life Sciences Summit, New York City, NY

2017 Prescriptions Drug Prices and Policy Reform Options / Keynote Speaker
340B Coalition Summer Conference, Washington D.C.

2017 Generic drug competition: understanding demand, price, and supply / Invited Speaker
Federal Trade Commission Workshop, Washington, D.C.

2017 An Interview with Rep. Henry Waxman / Interviewer
Next Steps in Health Reform Conference, Washington College of Law at American University, Washington, D.C.

2018 FDA's Breakthrough Therapy Designation: Origins, (Early) Outcomes / Guest speaker
Stanford Law School Law and Biosciences Workshop, Palo Alto, CA

2018 Prescription Drug Prices: Problems and Potential Solutions / 2018 Stuart Rome Lecture
University of Maryland Francis Carey King School of Law, Baltimore, MD

2018 Prescriptions for Lowering Drug Prices / 2018 Rodman Lecture
St. Jude Children's Research Hospital Grand Rounds, Memphis, TN

2018 Promoting Competition in the Prescription Drug Market / Invited speaker
House of Representatives Antitrust Caucus Briefing, Washington, D.C.

2018 The Breakthrough Therapy Pathway: Policy Goals and Outcomes / Invited speaker
The Commonwealth Fund Harkness Fellow Orientation Meeting, New York City, NY

2018 Ethical role of patients in FDA approval decisions / Invited speaker
Stanford Center for Biomedical Ethics, Palo Alto, CA

2019 Decoding the drug pricing debate: ask the experts panel / Invited panelist
House of Representatives Rayburn Office Building, Washington DC

2019 Patents and market exclusivity in the pharmaceutical market / Invited speaker
National Business Group on Health, Washington, D.C.

2019 Approaches to accounting for public funding of drug developing in pricing / Speaker
Workshop on the Role of NIH in Drug Development Innovation and its Impact on Patient Access, National Academies of Science, Engineering, and Medicine

2019 Prescription drug prices: issues and solutions
Samuel P. Martin Lecture, Leonard Davis Institute, University of Pennsylvania, Philadelphia, PA

2020 Hacking Coronavirus / Moderator
Center for Excellence in Education, Washington, D.C. (virtual, available at: https://youtu.be/46xDGCrKvIg)

2020 CDER OND Senior Leadership Retreat: Ideas for Strategic Objectives / Featured Speaker
Food and Drug Administration, White Oak, MD (virtual)

2021 Incentives for Drug Development / Featured Speaker
Improving the Evidence Base for Treatment Decision-Making in Older Adults, National Academy of Medicine Symposium, Washington DC (virtual)

2021 Drug Regulation in the 21st Century: The FDA, Politics, and Policy / Keynote speaker
Ray Symposium, Western University of Health Sciences, Pomona, CA (virtual)

2021 COVID-19 and the Future of Public Health: Respecting Science, Protecting Liberty, and Restoring Trust / Keynote speaker
UNLV Annual Health Law Conference, Las Vegas, NV (virtual)

2021 Prescription Drug Prices: Controversies and Potential Solutions / Invited speaker
Federal Employee Health Benefits pharmacy group, Washington, D.C. (virtual)

2021 Regulation of Off-label Drug Promotion and the Future of Rational Prescribing / Panelist
Pharmed Out Biannual Conference, Washington, D.C. (virtual)

2021 Hot topics: accelerated approval and aducanumab / Panelist
Annual Health Law Professors Conference, Northeastern University, Boston, MA (virtual)

2022 The Inflation Reduction Act and the Future of Pharma / Panelist
Council on Foreign Relations, Washington, D.C. (virtual)

2023 Accelerated approval: regulatory goals vs. real-world experience / Panelist
American Society of Cell and Gene Therapy Annual Meeting, Los Angeles, CA (virtual)

2023 An Overview of US Drug Pricing with Application to Cell and Gene Therapies/ Panelist
American Society of Cell and Gene Therapy Annual Meeting, Los Angeles, CA (virtual)

2023 Public trust and the FDA / Panelist
Yale Law School, New Haven, CT

2023 Uncertainty and the FDA approval process: from safety to efficacy / Invited speaker
Harvard Kennedy School, Cambridge MA

2023 The future of drug pricing / Panelist
America's Health Insurance Plans Annual Meeting, Phoenix, AZ

2023 Giving FDA flexibility to include optimal dosing on drug labels / Keynote speaker
Optimal Cancer Care Alliance Annual Meeting, Chicago, IL (virtual)

2023 Addressing reimbursement for innovative health technologies: considering cost vs. benefits / Invited speaker
Congressional Budget Office Panel of Health Advisers Annual Meeting, Washington, DC

2024 Should FDA advisory committees always vote? Yes / Invited speaker
UCSF-Stanford Center for Excellence in Regulatory Science Innovation Annual Meeting, San Francisco, CA

International

2005 Economic impact of patent extension on Medicaid drug expenditures / Invited Lecture
International Society for Pharmacoepidemiology 21st annual meeting, Nashville, TN [international attendees]

2007 The patentability of pharmacoepidemiology methods / Invited Lecture
International Society for Pharmacoepidemiology 23rd annual meeting, Quebec City, Canada

2007 Balancing drug innovation and cost-effective medical treatment in the US / Invited Lecture

European Science Foundation semiannual meeting, Kiel, Germany

2009 Roundtable on delinking research and development incentives from prices: designing innovation inducement prizes for tuberculosis diagnostics and new drugs for tuberculosis and Chagas disease / Invited Panelist
Knowledge Ecology International, Geneva, Switzerland

2010 The prevalence and cost of unapproved and non-evidence-based uses of selected orphan drugs / Invited Lecture
International Society for Pharmacoepidemiology 26th annual meeting, Brighton, England

2013 Five models of incentives for drug innovation: successes, collateral effects, and lessons / Invited Lecture
Médecins Sans Frontières, New York City, NY [international attendees]

2013 Intersection of market exclusivity and access to medicines / Roundtable Participant
University of Melbourne-Vanderbilt International Roundtable Meeting, Honolulu, HI

2015 Eye of the beholder: legal views on drugs risks and causation / Plenary lecture
International Society for Pharmacoepidemiology 31st annual meeting, Boston, MA [international attendees]

2015 Regulatory and legal issues for follow-on biologic drugs / Course faculty speaker
International Society for Pharmacoepidemiology 31st annual meeting, Boston, MA [international attendees]

2015 Rethinking the economics of pharmaceutical innovation / Roundtable participant
Open Society Foundations, New York, NY [international attendees]

2017 Drug regulation in the US: past, present, and future / Keynote speaker
London School of Economics International Health Policy Conference, London, England

2018 Generic Drug Price Changes: Should the US be Looking to Canada? / Guest speaker
York University, Toronto, Canada

2018 FDA's Breakthrough Therapy Designation: Origins, (Early) Outcomes / Keynote speaker
University of Toronto Faculty of Law Health Law, Ethics & Policy Seminar, Canada

2018 Antibiotics and Innovation / Invited speaker
Innovation Gaps and Life Sciences Frontiers, University of Copenhagen, Denmark

2019 Conserving and Producing New Antimicrobials / Keynote speaker
CeBIL Annual Symposium: Legal Innovation to Support Antibiotic Development, Cambridge, England

2021 Placing access conditions on incentives for innovation / Panelist
2021 Fair Pricing Forum, World Health Organization, Geneva, Switzerland (virtual)

2022 Drug repurposing: legal and regulatory issues in the US / Panelist
REPO4EU kick-off meeting, Maastricht, Netherlands (virtual)

2023 Recent advances in antimicrobial innovation policy / Panelist
CEBIL symposium, University of Copenhagen, Denmark

Report of Clinical Activities and Innovations

Current Licensure and Certification

2002 United States Patent and Trademark Office (Patent attorney license)
2004 National Board of Medical Examiners (Physician license)
2004 New York State Bar (Attorney license)
2005 American Board of Internal Medicine (Diplomate)
2005 Massachusetts Board of Registration in Medicine (License)

Practice Activities

2005-2009	Attending physician	Internal Medicine Inpatient Ward, BWH	15 hours per week / 4 weeks per year
2005-2011	Attending physician	Hospitalist Service, Harvard Vanguard Medical Associates	20 hours per month / 12 months per year
2005-	Ambulatory Care	Phyllis Jen Center for Primary Care, BWH	1 half-day session per week / 4 hours per week
2011-2013	Attending physician	Hospitalist Service, BWH	20 hours per month / 12 months per year

Report of Education of Patients and Service to the Community

Activities

No activities or materials below were sponsored by outside entities.

2000-2001 Pennsylvania Health Law Project / Volunteer

Educational Material for Patients and the Lay Community

Monographs, articles and presentations in other media

1. **Kesselheim A** and Outterson K. Super bugs call for super changes in drug-sale rules. [Op-Ed] *Boston Globe*, November 15, 2010, at A11.
2. **Kesselheim AS**. Does pharmaceutical industry marketing to medical students affect their prescribing choices as physicians? [Invited commentary] *Robert Wood Johnson Foundation Human Capital Blog*. June 28, 2011. Available on-line at: http://blog.rwjf.org/humancapital/?p=887.
3. **Kesselheim AS**, Shiu N. *FTC v. Actavis*: the Supreme Court issues a reversal on reverse payments. [Invited commentary] *Health Affairs Blog*. June 21, 2013. Available on-line at: http://healthaffairs.org/blog/2013/06/21/ftc-v-actavis-the-supreme-court-issues-a-reversal-on-reverse-payments/#more-32326
4. Lipsitch M, **Kesselheim AS,** Bell B, Levy S. Battling drug-resistant superbugs: can we win? [Webcast] *The Forum at the Harvard T.H. Chan School of Public Health*. February 5, 2014. Available on-line at: http://theforum.sph.harvard.edu/events/battling-drug-resistant-superbugs/.
5. **Kesselheim AS**, Tan YT. Accelerating Medicines Partnership: a new public-private collaboration for drug discovery. [Invited commentary] *Health Affairs Blog*. April 8, 2014. Available on-line at: http://healthaffairs.org/blog/2014/04/08/accelerating-medicines-partnership-a-new-public-private-collaboration-for-drug-discovery/.
6. Darrow JJ, **Kesselheim AS**. New drug and device approval: what is sufficient evidence? [Invited commentary] *Health Affairs Blog*. July 1, 2014. Available on-line at: http://healthaffairs.org/blog/2014/07/01/new-drug-and-device-approval-what-is-sufficient-evidence/
7. Maggs LR, **Kesselheim AS**. The role of Black Box Warnings in safe prescribing practices. [Invited commentary] *Health Affairs Blog*. August 20, 2014. Available on-line at: http://healthaffairs.org/blog/2014/08/20/the-role-of-black-box-warnings-in-safe-prescribing-practices/
8. Maggs LR, **Kesselheim AS**. The short-term and long-term outlook of drug coupons. [Invited commentary] *Health Affairs Blog*. November 12, 2014. Available on-line at: http://healthaffairs.org/blog/2014/11/12/the-short-term-and-long-term-outlook-of-drug-coupons/
9. Thacker PD, **Kesselheim AS**, Campbell EG. Will a new website empower patients to ask their

physicians about financial relationships with industry? *JAMA Forum*. December 17, 2014. Available on-line at: http://newsatjama.jama.com/2014/12/17/jama-forum-will-a-new-website-empower-patients-to-ask-their-physicians-about-financial-relationships-with-industry/

10. Sarpatwari A, **Kesselheim AS**. Ensuring timely approval of generic drugs. [Invited commentary] *Health Affairs Blog*. March 24, 2015. Available on-line at: http://healthaffairs.org/blog/2015/03/24/ensuring-timely-approval-of-generic-drugs/
11. **Kesselheim AS**, Sarpatwari A. To spur innovation, make corporate cheaters pay. [Invited commentary] *Health Affairs Blog*. April 30, 2015. Available on-line at: http://healthaffairs.org/blog/2015/04/30/to-spur-medical-innovation-make-corporate-cheaters-pay/
12. Greene J, **Kesselheim AS**. Selfie-medication: regulation of drug promotion in the Instagram era. *The Atlantic* September 10, 2015. Available on-line at: http://www.theatlantic.com/health/archive/2015/09/fda-drug-promotion-social-media/404563/
13. Carrier MA, **Kesselheim AS**. The Daraprim price hike and a role for antitrust. [Invited commentary] *Health Affairs Blog*. October 21, 2015. Available on-line at: http://healthaffairs.org/blog/2015/10/21/the-daraprim-price-hike-and-a-role-for-antitrust/.
14. Terry NP, Pasquale F, **Kesselheim AS**. Episode 26: EHR gag clauses, ACOs, the state of drug safety & price regulation & Kim Kardashian. [Podcast] *This Week in Health Law Podcast*. September 17, 2015. Available on-line at: http://twihl.podbean.com/e/26-guest-aaron-kesselheim-ehr-gag-clauses-acos-the-state-of-drug-safety-price-regulation-kim-kardashian/
15. Pearson S, **Kesselheim AS,** Rosenthal M, Schnipper L. Drug pricing: public health implications. [Webcast] *The Forum at the Harvard T.H. Chan School of Public Health*. October 23, 2015. Available on-line at: https://theforum.sph.harvard.edu/events/drug-pricing/.
16. Sax PE, Gallant JA, **Kesselheim AS**. Episode 8: Daraprim price hike. [Podcast] *Open Forum Infectious Diseases Podcast*. November 20, 2015. Available on-line at: http://www.oxfordjournals.org/our_journals/ofid/podcasts.html
17. **Kesselheim AS,** Leape L, Gutierrez A, Arnaout R. Medical tests: inaccuracies, risks, and the public's health. [Webcast] *The Forum at the Harvard T.H. Chan School of Public Health*. December 11, 2015. Available on-line at: https://theforum.sph.harvard.edu/events/medical-tests/.
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Thesis

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Narrative Report

I have established a program of research within the Division of Pharmacoepidemiology and Pharmacoeconomics at BWH and as a faculty member at HMS that combines the fields of medical practice, law and regulation, pharmacoepidemiology, and health services research. My work analyzes how prescribing and other aspects of medication use – and their resulting clinical outcomes – are shaped by drug and device policies, laws, and ethical norms. This work has four interrelated areas of focus.

The first is studying how laws and regulations affect access to and use of therapeutic interventions, as well as drug approval and promotion. This work has led to grant funding from the Laura and John Arnold Foundation to develop empirical research on drug development and the effects of patents and other forms of market exclusivity on medication access, prices, and utilization. Another component of this work studies the role of biomarkers and other surrogate measures in FDA drug approval. The FDA has implemented several policy proposals related to our work through these grants, including a) expediting the review of generic drugs when there are 3 or fewer manufacturers in the field to enhance competition and control costs; b) increasing generic drug competition by issuing guidances on generic drug interchangeability for complex products soon after their initial approval; and c) allowing greater therapeutic substitution across drugs within the same drug class when clinically appropriate.

Second, drawing on my training as a patent attorney, I have studied the effects of market exclusivity on drug innovation, development and use. I have reviewed the impact of patents and legislative incentive programs including the Orphan Drug Act to analyze their strengths and weaknesses in contributing to the discovery and approval of new drugs. Through this work, we have documented the strategies used to delay generic drug availability, and described the role that Orphan Drug Act and other incentives play in the development, evaluation, and approval of new drugs. In work funded by an Investigator Award in Health Policy Research from the Robert Wood Johnson Foundation, I examined the origins and development of the most transformative drugs and devices of the past 25 years. By mapping patents and conducting interviews with key inventors, I described the roles played by academic and private-sector researchers in moving innovation forward, and defined the contribution of patents and other incentives to this work. My studies on the contribution of government-funded research to the development of transformative drugs has been widely cited in the national debate on the proper level of public funding of science in the US.

Third, I have analyzed the clinical, ethical, and economic consequences of regulatory decisions that are based on limited pre-approval clinical studies, and considered the implications for patients, physicians, and payors of making such drugs and devices widely available. This work has examined the increasing use of expedited drug development and regulatory review pathways in the US as well as issues in post-approval followup and the risk-benefit tradeoffs for patients that these products and procedures can pose. In 2013, I was selected to join the Greenwall Faculty Scholar program in Bioethics to study the ethical considerations involved in regulatory determinations about new medications. I have continued pursuing this work through the Program On Regulation, Therapeutics, And Law (PORTAL) that I developed within the Division, which now encompasses a team of junior faculty members, post-doctoral fellows, and students focused on this area and a $1 million annual budget.

Finally, I have conducted empirical research into other intersections of public health, law, and medication use and outcomes, including showing that disclosures about funding directly influence the interpretation of clinical trial data, often counterproductively (*New England Journal of Medicine,* 2012), and how conflict of interest disclosure policies such as state and federal open payments legislation influence physician reporting and brand-name drug prescribing.

My administrative and institutional leadership has included several novel contributions to the BWH and HMS communities. The PORTAL program, which is among the largest independent research centers in the US focusing on drug policy issues, has attracted numerous talented trainees and faculty and is widely known as a center for expertise on drug regulatory science and policy. PORTAL was recognized

with a Pillar Award for research leadership in 2016. In 2020, I was elected as a member of the National Academy of Medicine in recognition of my "national leadership in studying how prescription drugs and medical devices interact with regulatory practices and the law to affect patient health outcomes. Blending rigorous empirical and policy analysis, his research shapes our understanding of how to improve the safety, effectiveness, and affordability of medical products."

The impact of my research has been broad. I was recognized as one of the top 3 most cited health law scholars in the US from 2013-2020 in Web of Science, Westlaw, and GoogleScholar. I have been invited to speak at numerous national and international meetings, and to consult for expert bodies such as the US Patent and Trademark Office and ClinicalTrials.Gov. In 2016, I was appointed to a committee of the National Academies of Science, Engineering, and Medicine and contributed expertise on prescription drug regulation to help shape recommendations on how FDA oversight of opioid medications can best promote public health goals. I currently serve as a Deputy Director of the HMS Regulatory Sciences Advisory Group, as a member of the *New England Journal of Medicine* Perspectives Advisory Board, as a faculty affiliate of the Harvard Law School Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics, and as a core faculty member of the HMS Center for Bioethics. In 2015, I was invited to serve on an FDA Advisory Committee and to join the Board of Directors of the American Society of Law, Medicine, and Ethics. In 2017, I was appointed editor-in-chief of its *Journal of Law, Medicine, and Ethics*.

Clinically, I practice internal medicine in the Phyllis Jen Center for Primary Care at BWH, where I manage a panel of primary care patients with a wide range of acute and chronic primary care problems. I have cared for many of these patients since my residency, and the ways that they have benefitted from new drug treatments, as well as struggled with issued related to drug costs and side effects, has inspired my work.

Finally, I have been committed to teaching throughout my career. As founder and director of PORTAL, I have been directly responsible for the oversight of numerous post-doctoral fellows, who have gone on to academic and government positions, as well as HMS students interested in prescription drug policy and law. I have consistently taught in the HMS Health Policy course as well as lectured on prescription drug policy issues in annual seminars for medical residents and fellows across the Harvard teaching hospitals. In 2015-2016, I originated a class on Health Law, Policy, and Bioethics for the HMS Center for Bioethics which I now co-lead, and in 2016-2017 I initiated a monthly health policy and bioethics seminar for the entire Harvard community that is also offered for class credit for Bioethics Masters students. In 2014-2015, I was first invited by Yale Law School to teach a class on FDA law. Receiving top student reviews, I was re-appointed as Irving S. Ribicoff Visiting Associate Professor of Law and have continued to teach there yearly since then. Because of growing demand, since 2020, I now teach another version of the class at the same time for the Yale School of Public Health.