Harvard Medical School
Curriculum Vitae

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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-	Associate Professor	Medicine	HMS
7/14-7/15, 7/16-7/19	Irving S. Ribicoff Visiting Associate Professor of Law	Law	Yale Law School
8/14-	Faculty Member	Center for Bioethics	HMS

	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-	Jonathan J. Darrow, J.D., M.B.A., S.J.D. / Instructor in Medicine, Division of Pharmacoepidemiology and Pharmacoeconomics, Boston, 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 11 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. / Internal medicine resident, Stanford, 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. student, HMS and Harvard Business School, Boston, MA 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 / Research Assistant, Division of Pharmacoepidemiology and Pharmacoeconomics, Boston, MA Career stage: undergraduate (Harvard) and research associate (BWH). Oversight of coursework and thesis research on Food and Drug Administration rulemaking, regulation, and biopharmaceutical innovation, leading to 14 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. / Resident, BWH, Boston, MA 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. / Instructor in Medicine, Division of Pharmacoepidemiology and Pharmacoeconomics, Boston, MA
Career stage: post-doctoral fellow and junior faculty (BWH). Oversight of post-doctoral research program on law and public health topics, leading to 7 publications.

2013- Ben Rome, M.D. / Resident, BWH, Boston, MA
Career stage: medical student (HMS) and resident (BWH). Oversight of HMS/HSDM Scholars in Medicine-funded research internship on US high-risk medical device regulation, leading to 3 publications.

2014 Prashant Rajan / 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 Prof, Worcester State University, Worcester, MA
Career stage: post-doctoral fellow (BWH). Oversight of project on adaptive design clinical trials, leading to 2 peer-reviewed publications.

2014- Jing Luo, M.D. / Instructor in Medicine, Division of Pharmacoepidemiology and Pharmacoeconomics, Boston, MA
Career stage: post-doctoral fellow and junior faculty (BWH). Oversight of post-residency general medicine fellowship in health services research, leading to 10 publications.

2015 Audrey D. Zhang / Student, New York University School of Medicine, New York, NY
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, 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, M.P.H. / Law student, Harvard Law School, Cambridge, MA
Career stage: masters student (HSPH) and law student (Harvard Law School). 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- Spencer Phillips Hey, Ph.D. / Research Scientist, Division of Pharmacoepidemiology and Pharmacoeconomics, Boston, MA
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 8 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 3 peer-reviewed publications.

2016- Kerstin N. Vokinger, M.D., J.D., Ph.D., LL.M. / Instructor in Medicine, University of Zurich, Switzerland
Career stage: post-doctoral fellow (BWH). Oversight of projects on differences between U.S. and European drug regulation, market exclusivity and second-generation brand-name drugs, leading to 2 peer-reviewed publications.

2016- Michael S. Sinha, M.D., J.D., M.P.H. / Research Fellow, Division of Pharmacoepidemiology and Pharmacoeconomics, Boston, MA
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 6 peer-reviewed publications.

2016- Emily Jung / Research Assistant, Division of Pharmacoepidemiology and Pharmacoeconomics, Boston, MA
Career stage: undergraduate (Harvard). Oversight of projects on racial, ethnic, and gender diversity in pivotal clinical trials used for FDA drug approval, leading to 1 peer-reviewed publication.

2016- Nina Jain, M.D., M.B.A., M.Sc. / Resident, BWH, Boston, MA
Career stage: medical student (HMS) and resident (BWH). Oversight of projects on incentives for drug innovation, leading to 2 peer-reviewed publications.

2016-2018 Michael Fralick, M.D., M.P.H. / Clinician Scientist Training Program, 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 12 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 5 peer-reviewed publications.

2017- Chintan Dave, Pharm.D., Ph.D. / Research Fellow, Division of Pharmacoepidemiology and Pharmacoeconomics, Boston, MA
Career stage: post-doctoral fellow (BWH). Oversight of projects on prescription drug pricing, generic drug availability, drug shortages, and pharmacoepidemiology, leading to 2 publications.

2017- Elvira D'Andrea, M.D., M.P.H. / Research Fellow, 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 1 peer-reviewed publication.

2017- 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 1 peer-reviewed publication.

2018- Bishal Gyawali, M.D., Ph.D. / Research Fellow, Division of Pharmacoepidemiology and Pharmacoeconomics, Boston, MA
Career stage: post-doctoral fellow (BWH). Oversight of projects on biomarkers and their use in oncology drug development, leading to 3 peer-reviewed publications.

2018- William B. Feldman, M.D. / Fellow, Division of Pulmonary and Critical Care, BWH, Boston, MA

Career stage: fellow (BWH). Oversight of projects on 'exceptions from informed consent' clinical trials and evidence-based use and cost of pulmonary disease medications, leading to 1 peer-reviewed publication.

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

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

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 University 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 University School of Law Conference on the 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

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 Award 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 Award in Health Policy Research Annual 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

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

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*, 15 Nov 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*. 28 Jun 2011. Available 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*. 21 Jun 2013. Available 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*. 8 Apr 2014. Available 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*. 1 July 2014. Available 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*. 20 Aug 2014. Available 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*. 12 Nov 2014. Available 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*. 17 Dec 2014. Available 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*. 24 March 2015. Available 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*. 30 April 2015. Available 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* 10 September 2015. Available 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 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*. 2015 Sept 17. 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*. 2015 Oct 23. 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*. 2015 Nov 20. 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*. 2015 Dec 11. Available on-line at: https://theforum.sph.harvard.edu/events/medical-tests/.
18. **Kesselheim AS**. Why are we years away from a Zika vaccine? [Webcast] Health Affairs. 2016 Feb 11. Available on-line at: http://healthaffairs.org/blog/2016/02/11/why-are-we-years-away-from-a-zika-vaccine/.
19. Engelberg AB, Avorn J, **Kesselheim AS**. Addressing generic drug unaffordability and shortages by globalizing the market for old drugs. [Invited commentary] *Health Affairs Blog*. 2016 Feb 23. Available on-line at: http://healthaffairs.org/blog/2016/02/23/addressing-generic-drug-unaffordability-and-shortages-by-globalizing-the-market-for-old-drugs/
20. Sperling R, **Kesselheim A,** Tenaerts P, Goldstein J. Drug trials: challenges for Alzheimer's and other urgent needs. [Webcast] *The Forum at the Harvard T.H. Chan School of Public Health*. 2016 April 18. Available on-line at: https://theforum.sph.harvard.edu/events/drug-trials/.
21. Rizvi Z, Kapczynski A, **Kesselheim A**. A simple way for the government to curb inflated drug prices. [Op-Ed] *Washington Post*. 13 May 2016. Available at: https://www.washingtonpost.com/opinions/a-simple-way-for-the-government-to-curb-inflated-drug-prices/2016/05/12/ed89c9b4-16fc-11e6-aa55-670cabef46e0_story.html.
22. Luo J, **Kesselheim AS**. Setting prescription drug prices: a comparison of strategies in the US, UK, Canada, Australia, and Germany. *Harvard Health Policy Review* 2016;15(2):4-9.
23. **Kesselheim A**, Hey SP, Deak D, Lo B. Ethical tensions in expedited regulatory approval of new prescription drugs. [Invited commentary] *Health Affairs Blog*. 2016 June 23. Available on-line at: http://healthaffairs.org/blog/2016/06/23/four-ways-to-address-the-ethical-tensions-around-expedited-approval-of-new-prescription-drugs/
24. Goldman AS, **Kesselheim AS**, Davis MH, Sachs RE, Singhroy D, Basey M, Maybarduk P. NIH patent policy. [Conference call] *Knowledge Ecology International IP Health Policy Update*. 2016 June 29. Available on-line at: http://keionline.org/node/2608.
25. Pollack HA, Rector B, **Kesselheim AS**, Conti R. Drug Pricing: Value, Affordability, and Advocacy. [Webinar] *Doctors for America Expert Policy Webinar*. June 29, 2016.
26. Court E, **Kesselheim AS**. Drugs that could cut billions from health costs. [Podcast] *Wall Street Journal Money, Markets, and More*. 2016 July 21. Available on-line at: http://www.wsj.com/podcasts/drugs-that-could-cut-billions-from-health-costs/CA501FCE-5C22-41B2-A18B-294271722CDA.html
27. **Kesselheim AS**. The newest antibiotics on the block. [Podcast] NEJM Journal Watch. 15 Jul 2016. Available on-line at: www.audiodigest.org/NEJMJWinterviews.
28. Hey SP, **Kesselheim AS**. Imprecise research threatens precision medicine. [Invited commentary] *STAT: First Opinion*. 2016 Aug 11. Available at: https://www.statnews.com/2016/08/11/precision-medicine-research/.
29. **Kesselheim AS**. Featured expert: NEJM Group Open Forum "Drug pricing: de-mystifying the

power, politics, and practice behind today's pharmaceutical economy." 2016 Oct 12-22. [Web discussion] Available at: https://medstro.com/groups/nejm-group-open-forum/discussions/300

30. **Kesselheim AS**. Juno trial deaths underscore need for greater transparency by FDA. [Invited commentary] *STAT: First Opinion*. 2016 Nov 24. Available at: https://www.statnews.com/2016/11/24/deaths-juno-trial-transparency-fda/
31. Darrow J, **Kesselheim A**, Laskey-Su J. The future of precision medicine: great promise, significant challenges. [Invited commentary] *Health Affairs Blog*. 2017 Feb 28. Available at: http://healthaffairs.org/blog/2017/02/28/the-future-of-precision-medicine-great-promise-significant-challenges/
32. Klitzman RL, **Kesselheim AS**, Holcombe K, Dehoney E. Implications of the 21st Century Cures Act: a webinar. *Columbia University Bioethics Program.* 2017 April 20. Available on-line at: http://sps.columbia.edu/bioethics/events/04-20-2017-webinar-implications-of-the-21st-century-cures-act.
33. Hwang TJ, **Kesselheim AS**. Taxing drug price spikes: assessing the impact. [Invited commentary] *Health Affairs Blog*. 2017 May 12. Available on-line at: http://healthaffairs.org/blog/2017/05/12/taxing-drug-price-spikes-assessing-the-potential-impact/.
34. Sarpatwari A, **Kesselheim AS**. Get generics to market faster. [Op-Ed] *Bloomberg View*. 2017 June 20. Available on-line at: https://www.bloomberg.com/view/articles/2017-06-20/get-generic-drugs-to-market-faster.
35. **Kesselheim AS**, Lacey P. Fast-tracked drugs can save lives, but are they safe? [Televised roundtable] *Greater Boston with Jim Braude*. WGBH News. 2017 July 18. Available on-line at: http://news.wgbh.org/2017/07/18/local-news/fast-tracked-drugs-can-save-lives-are-they-safe
36. Sinha MS, **Kesselheim AS**. The future of American science and medicine. [Blog post] *The Spoke*. 2017 July 25. Available on-line at: http://www.wellesley.edu/albright/about/blog/3516-future-american-science-and-medicine
37. Terry NP, Pasquale F, **Kesselheim AS**, Sarpatwari A. Episode 107: Prescription Drug Price Metrics. [Podcast] *This Week in Health Law Podcast*. 2017 August 4. Available on-line at: https://www.podbean.com/media/share/pb-vjp26-6db941
38. **Kesselheim AS**. The complexities behind high prescription prices: a conversation with Dr Aaron Kesselheim. [Podcast] *Medscape Cardiology: The Bob Harrington Show*. 2017 Aug14. Available on-line at: http://www.medscape.com/viewarticle/883281.
39. Redberg RF, **Kesselheim AS** Califf RM. Are they safe? Drugs and devices receiving accelerated approval by the FDA. [Podcast] *JAMA Podcast*. 2017 Aug 15. Available on-line at: http://jamanetwork.com/learning/audio-player/14650592
40. Darrow J, **Kesselheim A**. Nearly One-third of new drugs are no better than older drugs, and some are worse. [Invited commentary] *Health Affairs Blog*. 2017 Oct 6. Available on-line at: http://healthaffairs.org/blog/2017/10/06/nearly-one-third-of-new-drugs-are-no-better-than-older-drugs-and-some-are-worse/.
41. Sherman M, Chandra A, **Kesselheim AS**. Navigating Payment Reform for Providers, Payors, and Pharma. [Web series] *NEJM Catalyst*. 2017 Nov 2. Available on-line at: https://catalyst.nejm.org/events/navigating-payment-reform-providers-payers-pharma/.
42. Kapczynski A, **Kesselheim AS**. Three things Trump can do to bring drug price 'way down.' [Op-Ed] *Washington Post*. 2017 Nov 21. Available on-line at: https://www.washingtonpost.com/opinions/what-trump-should-do-if-he-actually-wants-to-cut-drug-prices/2017/11/21/f7522422-be4f-11e7-8444-a0d4f04b89eb_story.html?utm_term=.3ef061b32123.

43. Bollyky TJ, **Kesselheim AS**, Sharfstein JM. What Trump should actually do about the high cost of drugs. [Op-Ed] *New York Times*. 2018 May 14. Available on-line at: https://www.nytimes.com/2018/05/14/opinion/trump-costs-drugs-pricing.html.
44. **Kesselheim AS,** Mitchell D, Thomas K. Runaway train: America's drug price problem. [Webcast] *The Center for Health Journalism at the USC Annenberg School of Journalism*. 2018 May 17. Available on-line at: https://www.centerforhealthjournalism.org/content/runaway-train-americas-drug-price-problem.
45. Dafny L, Frank R, **Kesselheim AS,** Pearson S. U.S. drug prices: why are they so high? [Webcast] *The Forum at the Harvard T.H. Chan School of Public Health*. September 26, 2018. Available on-line at: https://theforum.sph.harvard.edu/events/u-s-drug-prices/.

Patient educational materials

1. **Kesselheim AS**, Avorn J. True or false: common myths about generic drugs. [Patient monograph] September 2008. Available at: http://www.mmcpho.org/resource/d/13754/commonmythsaboutgenericdrugs.pdf.
2. **Kesselheim AS**, Avorn J. What are generic drugs? How can they help me? [Patient monograph] September 2008. Available at: http://www.mmcpho.org/resource/d/60045/whataregenericdrugs.pdf.
3. **Kesselheim AS**, Avorn J. Generics are powerful medicines. [Patient monograph] September 2008. Available at: http://www.mmcpho.org/resource/d/68289/Genericsarepowerfulmeds.pdf.
4. **Kesselheim AS**, Avorn J. Frequently asked questions about generic drugs. [Patient monograph] September 2008. Available at: http://www.mmcpho.org/resource/d/48358/faqgenericdrugs.pdf.
5. **Kesselheim AS**, Avorn J. What brand-name drug companies don't want you to know: how they keep generics off the market. [Patient monograph] September 2008. Available at: http://www.usaindiana.org/document/generics/Dont_want.pdfhttp://www.genericsarepowerful.org/learn?d=0002

There are numerous articles, interviews, and information products in the national and global popular media (on-line, in print, broadcast news, etc.) related to my work or for which I have served as a contributor, including the following selected samples:

1. Press M. Interview with Aaron Kesselheim, M.D., J.D., M.P.H: patent attorney, general internist and health services researcher from Harvard Medical School. *RWJF Clinical Scholars Health Policy Broadcast.* Broadcast May 17, 2010. Available at: http://rwjcsp.unc.edu/resources/podcast/archive.html
2. Rooney E. Antibiotics reform. *The Emily Rooney Show*. Broadcast November 30, 2010. Available at: http://www.wgbh.org/programs/The-Emily-Rooney-Show-Podcast-1162/episodes/Airport-Security-Boston-Accent-Reduction-Antibiotics-Reform-22067.
3. Kolata G. Pills morph as patients try to cope. *New York Times*. July 11, 2011. Available on-line at: http://www.nytimes.com/2011/07/12/health/12pills.html?_r=1&
4. Song S. Lipitor vs. Crestor: cholesterol drugs on a par. *Time Magazine*. November 16, 2011. Available on-line at: http://healthland.time.com/2011/11/16/lipitor-vs-crestor-cholesterol-drugs-are-on-a-par/
5. Understanding how 'the system' can be made to work better for patients. *Health Affairs*. December 2011.
6. Investigator examines path to more affordable and effective drugs. *Robert Wood Johnson Foundation*. January 30, 2012. Available at: http://www.rwjf.org/content/rwjf/en/about-rwjf/newsroom/newsroom-content/2011/12/breaking-new-ground-in-research/investigator-examines-path-to-more-affordable-and-effective-drug.html?cid=XEM_205596

7. National Pharmaceutical Council. *CER & academic detailing: Harvard's Dr. Kesselheim explains*. YouTube. Posted February 16, 2012. Available on-line at http://www.youtube.com/watch?v=e0Xs4dH5F8U.
8. AJMCtv. *Dr. Aaron Kesselheim discusses comparative effectiveness research*. YouTube. Posted April 3, 2012. Available on-line at http://www.youtube.com/watch?v=vTdlZ0d934w.
9. Out of the mire?: The justice department may spoil the drugmaker's fresh start. *The Economist*. April 28, 2012. Available on-line at: http://www.economist.com/node/21553512
10. Krumholz H. A suggestion to restore faith in pharma studies. *Pharmalot*. September 20, 2012. Available at: www.pharmalot.com/2012/09/the-op-ed-a-suggestion-to-restore-faith-in-pharma-studies/
11. Conaboy C. Study: physicians give less credence to studies funded by pharmaceutical industry. *Boston Globe*. September 20, 2012. Available on-line at: http://www.boston.com/whitecoatnotes/2012/09/20/study-physicians-give-less-credence-studies-funded-pharmaceutical-industry/xd8MAnN5SqizUiBO6kTTOJ/story.html
12. Rehman J. Can the source of funding for medical research affect the results? *Scientific American*. September 23, 2012. Available at: http://blogs.scientificamerican.com/guest-blog/2012/09/23/can-the-source-of-funding-for-medical-research-affect-the-results/
13. Chen P. Are doctors too wary of drug companies? *New York Times*. October 18, 2012. Available on-line at: http://well.blogs.nytimes.com/2012/10/18/are-doctors-too-wary-of-drug-companies/
14. Lyons C. What's on your doctor's mind? *Boston Magazine*. December 2012. Available on-line at: http://www.bostonmagazine.com/articles/2012/11/boston-best-doctors-how-doctors-think-top-docs/
15. Tinker B. Don't judge that generic pill by its color. *CNN.com*. December 31, 2012. Available on-line at: http://thechart.blogs.cnn.com/2012/12/31/hfr-123112-4pet-dont-judge-your-generic-pill-by-its-color/
16. Bakalar N. The confusion of pill coloring. *New York Times*. December 31, 2012. Available on-line at: http://well.blogs.nytimes.com/2012/12/31/the-confusion-of-pill-coloring/
17. Conaboy C. Study authors: On medical school conflict of interest policies, more enforcement needed. *Boston Globe*. February 28, 2013. Available on-line at: http://www.boston.com/whitecoatnotes/2013/02/28/study-authors-medical-school-conflict-interest-policies-more-enforcement-needed/q06z6QUFQdyfUq36H8pahK/story.html
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   Teaching cases

   All written for medical students affiliated with Improvehealthcare.org, a student-run organization based at Harvard Medical School, with 19 affiliated chapters, that uses case-based learning to teach physicians-in-training about health policy issues. At the time it was developed, it was available to all interested medical students on integrated website.

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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.

In recognition of the impact of my research, 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.

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. As an outgrowth of my PORTAL work, I have become a Deputy Director of the HMS Regulatory Science initiative. I established a monthly Policy and Ethics Consortium series at HMS in 2016 that attracts experts in the field to wrestle with challenging current health policy topic; we routinely receive 100-150 audience members from the community at each public session.

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, 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 in 2016-2017, 2017-2018, and 2018-2019. Because of growing demand, we doubled the class size and opened it up to cross-registrants from Yale Medical School and Yale School of Public Health.