Committee on Energy and Commerce
U.S. House of Representatives

Witness Disclosure Requirement - "Truth in Testimony"
Required by House Rule XI, Clause 2(g)(5)

1. Your Name: **Aaron Kesselheim**		
2. Your Title: **Assoc. Professor of Medicine**		
3. The Entity(ies) You are Representing: **N/A**		
4. Are you testifying on behalf of the Federal, or a State or local government entity?	**Yes**	**No** X
5. Please list any Federal grants or contracts, or contracts or payments originating with a foreign government, that you or the entity(ies) you represent have received on or after January 1, 2015. Only grants, contracts, or payments related to the subject matter of the hearing must be listed. **None**		
6. Please attach your curriculum vitae to your completed disclosure form.		

Signature:_____ [redacted] _____**Date:**_____**July 10, 2017**___

Curriculum Vitae

Date Prepared: March 20, 2017
Name: Aaron Seth Kesselheim, M.D., J.D., M.P.H.
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Work Fax: [redacted]
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, Boston, MA

Postdoctoral Training

6/02-6/03	Intern	Internal Medicine	Brigham and Women's Hospital, Boston, MA
7/03-6/05	Resident	Internal Medicine	Brigham and Women's Hospital
7/05-6/07	Fellow	General Medicine and Health Care Policy Research	Division of Pharmacoepidemiology and Pharmacoeconomics, Brigham and Women's Hospital and Harvard Medical School, and Department of Health Policy and Management, Harvard School of Public Health

Faculty Academic Appointments

7/07-6/10	Instructor	Medicine	Harvard Medical School, Boston, MA
7/08-	Research Associate	Health Policy and Management	Harvard School of Public Health
7/10-6/14	Assistant Professor	Medicine	Harvard Medical School

7/14-	Associate Professor	Medicine	Harvard Medical School
7/14-7/15, 7/16-7/18	Visiting Associate Professor of Law	Law	Yale Law School

Appointments at Hospitals/Affiliated Institutions

6/02-6/05	Associate Physician	Medicine (General Internal Medicine)	Brigham and Women's Hospital
7/05-7/17	Staff Physician	Medicine	Dana-Farber Cancer Institute, Boston, MA
7/05-	Associate Physician	Medicine (Pharmacoepidemiology and Pharmacoeconomics)	Brigham and Women's Hospital
7/05-	Staff Physician	Medicine	Faulkner Hospital, Jamaica Plain, MA

Other Professional Positions

2010-2011	Consultant	Robert Wood Johnson Foundation Public Health Law Research program	Temple University, Philadelphia, PA
2010-2015	Research Associate	Law, public health, and ethics	Edmond J. Safra Center for Ethics at Harvard University
2013-	Faculty Supervisor	Petrie-Flom Center for Health Law Policy, Biotechnology and Bioethics	Harvard Law School
2014-	Faculty Member	Center for Bioethics	Harvard Medical School
2016-2017	Distinguished Visitor	Solomon Center for Health Law and Policy	Yale Law School

Major Administrative Leadership Positions

Local

2003-2005	Course director, Medico-Legal and Health Policy Curriculum for Internal Medicine Residents	Brigham and Women's Hospital (Internal Medicine)
2010-2011	Admissions chair, Law and Public Health Concentration	Harvard School of Public Health
2012-	Site director, HMS Fellowship in General Medicine and Primary Care	Division of Pharmacoepidemiology and Pharmacoeconomics, Brigham and Women's Hospital
2013-	Director, Program On Regulation, Therapeutics, And Law (PORTAL)	Division of Pharmacoepidemiology and Pharmacoeconomics, Brigham and Women's Hospital

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-	Governance Board	Innovative Medicines Initiative DRIVE-AB consortium

Committee Service

Local

2003-2004	Resident work hours committee, Department of Medicine	Brigham and Women's Hospital Member
2004-2006	Hospital work committee, Division of Pharmacoepidemiology and Pharmacoeconomics	Brigham and Women's Hospital Member
2004-	Faculty committee, Division of Pharmacoepidemiology and Pharmacoeconomics	Brigham and Women's Hospital Member
2009-2013	Research Ethics Working Group, Harvard Clinical and Translational Science Center	Harvard Medical School Member
2011-2013	Admissions committee, Law and Public Health Concentration	Harvard School of Public Health Member
2011-2012	Harvard Interfaculty Working Group on Government Management of Pharmaceutical Products	Harvard University Member
2012, 2015	Honors thesis program expert reader	Harvard Medical School Member
2013-	Regulatory Science Advisory Board	Harvard Medical School Associate 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
2015-2017	American Society of Law, Medicine, and Ethics	Board of Directors
2015-2016	Food and Drug Administration (FDA) Peripheral and Central Nervous System Advisory Committee	Voting Member
2016-	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

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-	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

Grant Review Activities

2010, 2013	Grant proposal reviewer	Robert Wood Johnson Foundation Public Health Law Research Program
2011	Grant proposal reviewer	Robert Wood Johnson Foundation Investigator Award in Health Policy Research
2013	Grant proposal reviewer	Alzheimer's Association

2015	Grant proposal reviewer	Harvard Clinical and Translational Science Center

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
Pharmacoeconomics
Pharmacoepidemiology & Drug Safety
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	London School of Economics review of antibiotic incentive policy
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
2012-	Editorial Board	Expert Opinion on Orphan Drugs
2012-	Advisory Board, Perspectives section	New England Journal of Medicine
2013-2015	Editorial Board	Edmond J. Safra Center for Ethics at Harvard University Working Paper series
2013-2016	Health Policy Brief external editor	Health Affairs
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
2014, 2017	Faculty reviewer	Yale Journal of Health Policy Law and Ethics
2017-	Editor-in-Chief	Journal of Law, Medicine, 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	Brigham and Women's Hospital	Excellence in delivery of primary care
2008	Young Alumnus of the Year	University of Pennsylvania School of Medicine	Career excellence, dedication to school
2009	Top 10% of peer reviewers	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
2010	Top peer reviewer	Annals of Internal Medicine	Excellence in contributions to editorial decisions
2011	Top peer reviewer	Pharmacoepidemiology and Drug Safety	Excellence in contributions to editorial decisions
2012	Keynote speaker, 18th Annual Thomas Langfitt Symposium on Health Care Policy	Colleges of Physicians of Philadelphia and University of Pennsylvania	National recognition in health policy
2012	Visiting scholar	Yale School of Management	2-day program of interdisciplinary teaching
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
2013	Top peer reviewer	Annals of Internal Medicine	Excellence in contributions to editorial decisions
2014	Chair's Research Award	Brigham and Women's Hospital Department of Medicine	Skill in obtaining grant funding
2015	Top peer reviewer	Annals of Internal Medicine	Excellence in contributions to editorial decisions
2015-16	Young Mentor Award	Harvard Medical School	Excellence in developing quality mentoring relationships that lead to professional development and career advancement in basic/clinical medicine
2016	Visiting scholar	Center for Drug Safety and Effectiveness, Johns Hopkins Bloomberg School of Public	1-day guest expert to discuss drug innovation

2016	Research Leadership Award	Health Brigham and Women's Hospital	Awarded to investigators who have demonstrated outstanding research leadership of new or existing programs

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 ($10,000)
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 ($2,000)
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 ($1,500)
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 ($4,500)
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 ($60,000)
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

Project manager ($385,502)
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 ($225,000)
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 ($5,000)
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 ($4,000)
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 ($50,000)
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.

2010 Current trends in orphan drug development
Institute of Medicine Committee on Rare Disease and Orphan Product Development / Commissioned study
Principal investigator ($5,000)
Study of the characteristics of the drug development and FDA review process for a selection of orphan drugs.

2011 Medical device regulation in the US and EU
Center for Devices and Radiological Health, Food and Drug Administration / Commissioned study (HHSF223201111374P)
Principal investigator ($10,000)
Comparative analysis of device approval and post-market surveillance and systematic review of studies of device regulatory outcomes in the US and EU.

2010-2012 Remedies for financial distortions 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.

2012-2013 Post-market surveillance of medical devices in the US and EU
Pew Charitable Trust / Individual investigator initiated grant
Principal investigator ($31,575)
Cross-national comparison of systems of post-market surveillance for medical devices.

2009-2014 Off-label prescribing: Comparative evidence, regulation, and utilization
Agency for Healthcare Research & Quality K-08 Award/Training grant (5K08HS18465-04)
Principal investigator ($799,782)
Investigation of off-label prescribing and time series analysis of how legal, regulatory, and market forces affect these uses.

2012-2014 Novel methods to study the safety and efficacy of drugs approved to treat rare diseases on limited data
Agency for Healthcare Quality and Research/DEcIDE-2 Request for Task Order
Principal investigator ($558,819)
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 ($313,922)
Leading conduct and analysis of patient and provider focus groups intended to inform development of tool to promote patient adherence to antihypertensive medications

2010-2014 Sources of transformative innovation in drug development
Robert Wood Johnson Foundation Investigator Award in Health Policy Research / Individual investigator initiated grant (67487)
Principal investigator ($333,339)
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.

2013-2015 Assessing clinical equivalence for generic drugs approved using innovative methods
Food and Drug Administration (1U01FD004856-01)
Principal Investigator ($247,696)
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 Access to drugs and devices that have limited supporting data: ethical implications for patients and physicians
Greenwall Foundation Faculty Scholar Program
Principal Investigator ($414,568)
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

2013-2016 New methods for evaluation of impact of FDA Drug Safety Communications
Food and Drug Administration (HHSF22301001T)
Principal Investigator ($1,276,295)
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.

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 ($149,401) (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 ($49,694)
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.) ($71,000)
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.) ($36,752)
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 ($748,445)
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

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 ($749,892)
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.

Current

2014-2017 Examining the Impact of FDA Regulatory Policies on Therapeutic Approval
Harvard Program in Therapeutic Science
Principal Investigator ($608,329)
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.

2016-2018 Development of Educational Boot Camp in Methods Used in Empirical Bioethics Research
Greenwall Foundation
Consultant (Principal Investigator: 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

2017-2019 An International Comparison of Regulatory Risk Communication on Medicines
National Health and Medical Research Council (NHMRC)
Co-Investigator (Principal Investigator: Barbara Mintzes, Ph.D.) ($95,000)
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

2017-2020 Creation of the PORTAL Biomarker Research Consortium
Laura and John Arnold Foundation
Principal Investigator ($2,024,093)
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
Principal Investigator ($3,268,850)
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.

Report of Local Teaching and Training

Teaching of Students in Harvard Medical School Courses

Teaching prior to start of current Harvard appointment:

2002-2005	Core Medicine Clerkship I	Harvard Medical School
	Third- and fourth-year medical students	9 hrs per day for 12 wks per year
2002-2005	Core Medicine Clerkship II	Harvard Medical School
	Third- and fourth-year medical students	9 hrs per day for 12 wks per year

Teaching during current Harvard appointment:

2005-2009	Core Medicine Clerkship I	Harvard Medical School
	Third- and fourth-year medical students	13 hrs per wk for 4 wks per year
2005-2009	Core Medicine Clerkship II	Harvard Medical School
	Medical students	13 hrs per wk for 4 wks per year
2009	Health Care Policy	Harvard Medical School
	Second-year medical students	6 hrs per lecture for guest lecture
2009-2014	Health Care Policy	Harvard Medical School
	First-year medical students	3 hrs per lecture for annual guest lecture
2015	HMS Health Policy Student Interest Group	Harvard Medical School
	50 first-year medical students	3 hrs per lecture for guest lecture
2016	HMS BCMP 311qc: Unmet Medical Needs and Translational Solutions	6 hrs per lecture for guest lecture
	25 medical and PhD students	
2017	Essentials of the Profession: Health care policy	Harvard Medical School
	First-year medical students	3 hrs per lecture for guest lecture

Teaching of Students in Non-Harvard Medical School Courses

Teaching prior to start of current Harvard appointment:

2005	Public Health Law	Harvard School of Public Health
	Masters students	8 hrs per wk for 1 semester
2006	Law and Public Health	Harvard School of Public Health
	Masters students	5.5 hrs per lecture for 2 lectures

Teaching during current Harvard appointment:

2007-2009	Public Health Law	Harvard Law School
	Law students	5.5 hrs for annual guest lecture
2008-2014	Advanced Pharmacoepidemiology	Harvard School of Public Health
	Masters students	4 hrs for annual guest lecture
2012-2013	GHHP 91r Seminar	Harvard Faculty of Arts and Sciences
	Undergraduate student independent study	25 hrs per semester for 2 semesters
2013	Law and Public Health (HPM 213)	Harvard School of Public Health
	Masters students	6 hrs for 1 guest lecture
2013	7.015 Introductory Biology	Massachusetts Institute of Technology
	Undergraduate students	4 hrs for 1 guest lecture
2013	EP748 Drug Epidemiology	Boston University School of Public Health
	Masters students	4 hrs for 1 guest lecture
2014	EPI 502 Antibiotic Epidemiology	Harvard School of Public Health
	Masters students	4 hrs for 1 guest lecture
2014	Law 7606 Health Law	Northeastern University School of Law
	Law students	4 hrs for 1 guest lecture
2015	Law 21767 FDA Law	Yale Law School
	Law students	2 credit semester-long seminar (16 students)

2016	Bioethics 706.0 Health Law, Policy, and Bioethics (Co-taught with H.F. Lynch) Masters students	HMS Center for Bioethics 4 credit semester-long seminar (8 students)
2016	HPM 213 Public Health Law Masters students	Harvard School of Public Health 4 hrs for 1 guest lecture
2016	Law 20616 FDA Law Law students	Yale Law School 2 credit semester-long seminar (12 students)
2016	Bioethics 742: Policy Ethics Consortium Masters students	HMS Center for Bioethics 2 credit year-long tutorial (10 students)
2016	Navigating the American Pharmaceutical Sector Executive education students	Executive and Continuing Professional Education, Harvard T.H. Chan School of Public Health 4 hrs for 1 guest lecture (30 students)
2017	Bioethics 706.0 Health Law, Policy, and Bioethics (Co-taught with H.F. Lynch) Masters students	HMS Center for Bioethics 4 credit semester-long seminar (18 students)

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

Teaching prior to start of current Harvard appointment:

2004	Primary care in the White House 30-50 residents	Brigham and Women's Hospital and Faulkner Hospital Guest lecture, 5 hrs
2005	The health care of our political leaders 30-50 residents	Brigham and Women's Hospital and Faulkner Hospital Guest lecture, 3 hrs

Teaching during current Harvard appointment:

2004-2009	Medico-legal issues for medicine residents 30-50 residents	Brigham and Women's Hospital 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-	Partners Center of Expertise in Health Policy and Management: Health Policy Certificate Course 30-50 residents	Harvard Medical School-affiliated teaching hospitals Annual guest lecture, 3 hrs
2015	What do we know about diabetes drugs? 60 residents	Brigham and Women's Hospital Guest lecture, 2 hrs
2017	Harvard Graduate School of Arts and Sciences Science Policy Group 40 graduate students	Harvard Graduate School of Arts and Sciences Guest lecture, 3 hrs
2017	Understanding Biomarker Science: From Molecules to Images 120 graduate students	Harvard Catalyst 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 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	Close mentorship on daily basis, weekly lab meetings, lasting from a few months to several years.

Formally Supervised Trainees

2005-2009	Rahul Rajkumar, M.D., J.D. / Senior vice president/Chief Medical Officer at CareFirst BlueCross BlueShield, Baltimore, MD 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. / Assistant Professor of Medicine, New York University Langone Medical Center, New York, NY 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. / Resident, Massachusetts General Hospital, Boston, MA 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. / Resident, Massachusetts General Hospital, Boston, MA Oversight of research project in effect of various legal, social, and medical market events on off-label use of Neurontin, leading to 1 publication.
2010-2011	Kirsten E. Austad, M.D. / Women's Health fellow, Brigham and Women's Hospital, Boston, MA 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 Oversight of honors master thesis on innovation in influenza vaccine development.
2011-2014	Jonathan J. Darrow, J.D., M.B.A., S.J.D. / Instructor in Medicine, Division of Pharmacoepidemiology and Pharmacoeconomics, Boston, MA Supervision of thesis and post-doctoral work on history of drug efficacy study and regulation, leading to S.J.D. thesis and 11 publications.
2011-2012	Adam Licurse, M.D. / Assistant Medical Director, Brigham and Women's Physician's

Organization, Brigham and Women's Hospital, Boston, MA
Oversight of research on conflicts of interest and physician disclosure of industry relationships, leading to 1 publication.

2011-2014 Shuai Xu, M.D., M.Sc. / Resident in dermatology, Chicago, IL
Oversight of HMS/HSDM Scholars in Medicine-funded research internship and honors thesis work 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. / Resident in internal medicine, Stanford, Palo Alto, CA
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.

2012-2015 Yongtian T. Tan / Combined M.D./M.B.A. student, Harvard Medical School and Harvard Business School, Boston, MA
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.
Investigation of sources of innovation leading to development of vascular endothelial growth factor inhibitors for use in ophthalmologic disease, leading to 1 publication.

2012 Kyle D. Checchi, M.Sc., M.D. / Resident, San Diego, CA
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.
Oversight of research on development of transformative HIV drugs (zidovudine and protease inhibitors)

2012- Thomas J. Hwang / Post-Baccalaureate student, Boston, MA
Oversight of coursework and thesis research on Food and Drug Administration rulemaking, regulation, and biopharmaceutical innovation, leading to 14 publications.

2013-2016 Carolyn Treasure, M.D. / Resident, Brigham and Women's Hospital, Boston, MA
Oversight of HMS/HSDM Scholars in Medicine-funded research internship on university patenting and government march-in rights, leading to 4 publications.

2013-2016 Ben Rome, M.D. / Resident, Brigham and Women's Hospital, Boston, MA
Oversight of HMS/HSDM Scholars in Medicine-funded research internship on US high-risk medical device regulation, leading to 3 publications.

2013 Nathan Shiu, J.D., M.P.H. / Lawyer at FDA
Oversight of summer research fellowship on adjudication of truth and scientific certainty in the federal courts, leading to 2 publications.

2013-2015 Ameet Sarpatwari, Ph.D., J.D. / Instructor in Medicine, Division of Pharmacoepidemiology and Pharmacoeconomics, Boston, MA
Oversight of post-doctoral research program on law and public health topics, leading to 7 publications.

2013-2015 James S. Yeh, M.D. / Internal medicine specialist, Massachusetts General Hospital, Boston, MA
Oversight of post-residency general medicine fellowship in health services research, leading to 6 publications.

2014 Prashant Rajan / Medical student, Harvard Medical School, Boston, MA
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	Jing Luo, M.D. / Instructor in Medicine, Division of Pharmacoepidemiology and Pharmacoeconomics, Boston, MA Oversight of post-residency general medicine fellowship in health services research, leading to 10 publications.
2014-2016	Laura E. Bothwell, Ph.D. / Adjunct Fellow, Division of Pharmacoepidemiology and Pharmacoeconomics, Boston, MA Oversight of project on adaptive design clinical trials.
2015	Audrey D. Zhang / Student, New York University School of Medicine, New York, NY 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. / Student, University of New Hampshire Law School, Concord, 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 Oversight of project examining characteristics of clinical trials used to evaluate drugs moving through the Accelerated Approval pathway at FDA, leading to 1 publication
2015-2016	Dalia M. Deak, M.P.H. / Law student, Harvard Law School, Cambridge, MA 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-	Spencer Phillips Hey, Ph.D. / Research Fellow, Division of Pharmacoepidemiology and Pharmacoeconomics, Boston, MA Oversight of projects at intersection of ethics and regulation involving personalized medicine and biomarker, leading to 3 publications.
2015-	Mallika L. Mundkur, M.D. / Research Fellow, Division of Pharmacoepidemiology and Pharmacoeconomics, Boston, MA Oversight of projects on trends in high-risk medication use, including antibiotics and opioids
2016-	Emily Jung / Undergraduate student, Harvard College, Cambridge, MA Oversight of projects on racial, ethnic, and gender diversity in pivotal clinical trials used for FDA drug approval
2016-	Nina Jain, M.Sc. / M.D./M.B.A. student, Harvard Medical School, Boston, MA Oversight of projects on incentives for drug innovation
2016-	Michael Fralick, M.D. / Research Fellow, Division of Pharmacoepidemiology and Pharmacoeconomics, Boston, MA, leading to 2 publications Oversight of projects on drug safety monitoring and evaluation of drug clinical trials
2016-	Chana A. Sacks, M.D. / Research Fellow, Division of Pharmacoepidemiology and Pharmacoeconomics, Boston, MA Oversight of projects on drug prices and off-label use of drugs for rare diseases
2016-	Sana Mostaghim / Dr.P.H. student, Harvard Chan School of Public Health, Boston, MA Oversight of projects on regulatory approval pathways and prescription drug safety, leading to 1 publication
2016-	Kerstin Noëlle Vokinger, M.D., J.D., Ph.D., LL.M. / Research Fellow, Division of

Pharmacoepidemiology and Pharmacoeconomics, Boston, MA
Oversight of projects on differences between U.S. and European drug regulation, market exclusivity and second-generation brand-name drugs

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

2017- Reed Beall, M.A., Ph.D. / Research Fellow, Division of Pharmacoepidemiology and Pharmacoeconomics, Boston, MA
Oversight of projects on impact of patents and market exclusivity on availability of essential medical products

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, Brigham and Women's Hospital

2004 Patents, academic research, and drug discovery / Research Rounds
Department of Medicine (Division of Pharmacoepidemiology and Pharmacoeconomics), Brigham and Women's Hospital

2006 Characteristics of physicians who frequently act as expert witnesses in neurological birth injury litigation / Research Rounds
Department of Medicine, Brigham and Women's Hospital

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

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, Brigham and Women's Hospital

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

2011 Patents and public health: what are the limits / Invited Lecture
Department of Biostatistics, Harvard School of Public Health

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, Harvard Medical School, Boston MA

2014 Hepatitis C drugs: what price progress? / Medicine Grand Rounds (with Paul E. Sax)
Department of Medicine, Brigham and Women's Hospital

2015 Updating the Harvard Medical School conflicts of interest policy / Invited speaker
Harvard Medical School 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
Harvard Medical School 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, Harvard Medical School, 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
Harvard Medical School Center for Bioethics, Boston 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, Brigham and Women's Hospital

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

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

2016 Current Legal and Ethical Issues Affecting Prescription Drugs / Featured speaker
Harvard Medical School 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, Harvard Medical School, Boston MA

2016 Regulatory science and precision medicine: the tale of eteplirsen / Invited lecture
Regulatory Science Advisory Council Meeting, Harvard Medical School, 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 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

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

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

2011 Legal ecology of resistance / Invited Speaker
Antimicrobial resistance: biology, population dynamics and policy options, Harvard School of Public Health Center for Communicable Disease Dynamics annual symposium, 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]

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
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

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 Annual 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 Annual 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 FDA's restrictions on promoting flawed 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 Speaker
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 Law Review 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 speaker
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 [national attendees]

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 The promise and pitfalls of 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 current health policy topics/Invited Speaker
National Physician's Alliance FDA task force, Boston, MA [national attendees]

2015 Managing uncertainty and reproductive rights in the context of 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 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 [national attendees]

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

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

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

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, Brigham and Women's Hospital	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-	Attending physician	Phyllis Jen Center for Primary Care, Brigham and Women's Hospital	1 half-day session per week / 4 hours per week
2011-2013	Attending physician	Hospitalist Service, Brigham and Women's Hospital	20 hours per month / 12 months per year

Report of Education of Patients and Service to the Community

No activities or materials below were sponsored by outside entities.

Activities

2000-2001 Pennsylvania Health Law Project / Volunteer

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*. 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/.
18. **Kesselheim AS**. Why are we years away from a Zika vaccine? [Webcast] Health Affairs. February 11, 2016. 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*. February 23, 2016. 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*. April 18, 2016. 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, 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*. June 23, 2016. 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*. June 29, 2016. 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*. July 21, 2016. 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 from: www.audiodigest.org/NEJMJWinterviews.
28. Kapczynski A, **Kesselheim AS**. Why government patent use to lower drug costs won't stifle innovation. [Invited commentary] *Health Affairs Blog*. July 28, 2016. Available at: http://healthaffairs.org/blog/2016/07/28/why-government-patent-use-to-lower-drug-costs-wont-stifle-innovation/
29. Hey SP, **Kesselheim AS**. Imprecise research threatens precision medicine. [Invited commentary] *STAT: First Opinion*. August 11, 2016. Available at: https://www.statnews.com/2016/08/11/precision-medicine-research/.
30. **Kesselheim AS**. Featured expert: NEJM Group Open Forum "Drug pricing: de-mystifying the power, politics, and practice behind today's pharmaceutical economy." October 12-22, 2016. [Web discussion] Available at: https://medstro.com/groups/nejm-group-open-forum/discussions/300
31. **Kesselheim AS**. Juno trial deaths underscore need for greater transparency by FDA. [Invited commentary] *STAT: First Opinion*. November 24, 2016. Available at: https://www.statnews.com/2016/11/24/deaths-juno-trial-transparency-fda/
32. Darrow J, **Kesselheim A**, Laskey-Su J. The future of precision medicine: great promise, significant challenges. [Invited commentary] *Health Affairs Blog*. February 28, 2017. Available at: http://healthaffairs.org/blog/2017/02/28/the-future-of-precision-medicine-great-promise-significant-challenges/
33. Klitzman RL, **Kesselheim AS**, olcombe K, Dehoney E. Implications of the 21st Century Cures Act: A Webinar. *Columbia University Bioethics Program.* April 20, 2017. Available on-line at: http://sps.columbia.edu/bioethics/events/04-20-2017-webinar-implications-of-the-21st-century-cures-act.
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35. Sarpatwari A, **Kesselheim AS**. Get generics to market faster. [Op-Ed] *Bloomberg View*. June 20, 2017. Available on-line at: https://www.bloomberg.com/view/articles/2017-06-20/get-generic-drugs-to-market-faster.

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.pdf

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
18. Britt R. Will drug makers see other nations challenge drug patents? *Wall Street Journal MarketWatch*. April 1, 2013. Available on-line at: http://blogs.marketwatch.com/health-exchange/2013/04/01/will-drug-makers-see-other-nations-challenge-drug-patents/.
19. Conaboy C. 1 in 4 Mass. physicians received industry gifts, payments. *Boston Globe.* May 1, 2013. Available on-line at: http://www.boston.com/lifestyle/health/blogs/white-coat-notes/2013/05/01/mass-physicians-received-industry-gifts-payments/RbxWq4YEevJMwk0Xt6N0QL/blog.html
20. Rabin RC. Doctors' lucrative industry ties. *New York Times*. May 13, 2013. Available on-line at: http://well.blogs.nytimes.com/2013/05/13/doctors-lucrative-industry-ties/
21. Chen P. For med students, love from the drug rep. *New York Times*. October 4, 2013. Available on-line at: http://well.blogs.nytimes.com/2013/10/03/for-med-students-love-from-the-drug-rep/?_r=0
22. Schwarz A. The selling of attention deficit disorder. *New York Times*. December 15, 2013. Available on-line at: http://www.nytimes.com/2013/12/15/health/the-selling-of-attention-deficit-disorder.html?_r=1&
23. New York Times Video. *How drug companies sell A.D.H.D*. New York Times website. Posted December 15, 2013. Available on-line at http://www.nytimes.com/2013/12/15/health/the-selling-of-attention-deficit-disorder.html?_r=1&#videoModal.
24. Rabin RC. The device maker's shortcut. *New York Times*. April 1, 2014, at D4. Available on-line at: http://well.blogs.nytimes.com/2014/03/31/the-device-makers-shortcut/?_php=true&_type=blogs&hpw&rref=health&_r=0
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28. Thomas K. Financial ties between doctors and health care firms detailed. *New York Times*. October 2, 2014 at B1.

29. LaPook J [video]. Why some generic drug prices are skyrocketing. *CBS Evening News*. November 12, 2014. Available on-line at: http://www.cbsnews.com/news/generic-drug-prices-skyrocketing/
30. Godman H. Best tips to stay on your medication and stay healthy. *Harvard Health Letter*. 2015;40(6):1,7.
31. Perrone M. Obama nominates Dr. Robert Califf, cardiologist and FDA deputy, to be next FDA commissioner. Associated Press/*US News & World Report*. Sept. 15, 2015. Available on-line at: http://www.usnews.com/news/business/articles/2015/09/15/obama-to-nominate-fdas-no-2-official-to-lead-agency.
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33. Flatow I [radio segment]. Why generic doesn't mean cheap. *PRI's The World Science Friday*. September 25, 2015. Available on-line at: http://www.sciencefriday.com/#path/segment/09/25/2015/why-generic-doesn-t-mean-cheap.html
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Report of Scholarship

Peer reviewed publications in print or other media

Research investigations

1. **Kesselheim AS**. Deception and presidential disability: a historical analysis. Trans & Stud Coll Phys Phila 2001;23:87-98.
2. **Kesselheim AS**. What's the appeal? Trying to control managed care medical necessity decisionmaking through a system of external appeals. Univ of Penn Law Rev 2001;149:873-920.
3. **Kesselheim AS**. Privacy versus the public's right to know: presidential health and the White House physician. J Legal Med 2002;23:523-545.
4. Rudnick MR, **Kesselheim A**, Goldfarb S. Contrast-induced nephropathy: how it develops, how to prevent it. Cleveland Clinic J Med 2006;73:75-80, 83-87.
5. **Kesselheim AS** and Studdert DM. Characteristics of physicians who frequently act as expert witnesses in neurological birth injury litigation. Obstet & Gyn 2006;108:273-279.
6. **Kesselheim AS**, Fischer MA, Avorn J. Extensions of intellectual property rights and delayed adoption of generic drugs: effects on Medicaid spending. Health Affairs 2006;25:1637-1647.
7. **Kesselheim AS** and Avorn J. The role of litigation in defining drug risks. JAMA 2007;297:308-311.
8. Shrank WH, Agnew-Blais J, Choudhry NK, Wolf MS, **Kesselheim AS**, Avorn J, Shekelle P. The variability and quality of medication container labels. Archives of Internal Medicine 2007;167:1760-1765.

9. Outterson K and **Kesselheim AS**. Putting patients first: a market-based licensing proposal for HPV vaccines and other patented medical products in developing countries. Health Affairs 2008;27:130-139.
10. **Kesselheim AS** and Studdert DM. Whistleblower-initiated enforcement actions against health care fraud and abuse in the United States, 1996-2005. Annals of Internal Medicine 2008;149:342-349.
11. **Kesselheim AS**, Misono AS, Lee JL, Stedman MR, Brookhart MA, Choudhry NK, Shrank WH. The clinical equivalence of generic and brand-name drugs used in cardiovascular disease: a systematic review and meta-analysis. JAMA 2009;300:2514-2526.
12. **Kesselheim AS** and Studdert DM. Professional oversight of physician expert witnesses: an analysis of complaints to the Professional Conduct Committee of the American Association of Neurological Surgeons, 1992-2006. Annals of Surgery 2009;249:168-172.
13. **Kesselheim AS** and Avorn J. Using patent data to assess the value of pharmaceutical innovation. J Law Med Ethics 2009;37(2):176-183.
14. **Kesselheim AS**, Stedman MR, Bubrick EJ, Gagne JJ, Misono AS, Lee JL, Brookhart MA, Avorn J, Shrank WH. Seizure outcomes following use of generic vs. brand-name antiepileptic drugs: a systematic review and meta-analysis. Drugs 2010;70(5):605-621.
15. **Kesselheim AS**, Studdert DM, Mello MM. Whistle-blowers' experiences in fraud litigation against pharmaceutical companies. New England Journal of Medicine 2010;362:1832-1839.
16. Kramer DB, **Kesselheim AS**, Brock DW, Maisel WH. The ethical and legal views of physicians regarding deactivation of cardiac implantable electrical devices: a quantitative assessment. Heart Rhythm 2010;7(11):1537-1542.
17. **Kesselheim AS**, November MT, Lifford KL, McElrath TF, Puopolo AL, Orav EJ, Studdert DM. Risk factors for neurological impairment among infants following nonreassuring fetal heart rate patterns during labor. J Evaluation in Clin Prac 2010;16(3):476-483.
18. Shrank WH, Choudhry NK, Agnew-Blais J, Federman AD, Liberman JN, Liu J, **Kesselheim AS**, Brookhart MA, Fischer MA. State generic substitution laws can lower drug outlays under Medicaid. Health Affairs 2010;29(7):1383-1390.
19. Kramer DB, **Kesselheim AS**, Brock DW, Maisel WH. Ethical and legal views regarding deactivation of cardiac implantable electrical devices in patients with hypertrophic cardiomyopathy. American Journal of Cardiology 2011;107(7):1071-1075.
20. **Kesselheim AS**, Mello MM, Studdert DM. Strategies and practices in off-label marketing of pharmaceuticals: a retrospective analysis of whistleblower complaints. PLoS Medicine 2011;8(4):e1000431.
21. Shrank WH, Liberman JN, Fischer MA, Avorn J, Kilabuk E, Chang A, **Kesselheim AS**, Brennan TA, Choudhry NK. The consequences of requesting "dispense as written." American Journal of Medicine 2011;124(4):309-317.
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23. **Kesselheim AS**, Myers JA, Avorn J. Characteristics of clinical trials to support approval of orphan vs nonorphan drugs for cancer. JAMA 2011;305:2320-2326.
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oncology publications. Cancer 2012;118(1):188-195.
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1. Schrag D, Naughton M, **Kesselheim A**, Archer L, Niedzwiedcki D, Romanus D, Goldberg R,

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1. Zerden M, Avorn J, **Kesselheim AS**. Pharmaceutical marketing practices towards physicians. Written for Improvehealthcare.org; 2008.
2. Gold L, Avorn J**, Kesselheim AS**. Postmarketing review and analysis of new drugs. Written for Improvehealthcare.org; 2008.
3. Wheeler LA, Avorn J, **Kesselheim AS**. The FDA and the drug approval process. Written for Improvehealthcare.org; 2008.
4. Rivara M, Mello MM, **Kesselheim AS**. Medical malpractice: Current issues and policies. Written for Improvehealthcare.org; 2008.
5. Song Z and **Kesselheim AS**. Conflicts of interest policies and federal antikickback and fraud laws. Written for Improvehealthcare.org; 2008.
   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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2. Choudhry NK, Fischer MA, Hoge E, **Kesselheim AS**, Parikh S, Shrank WH. The pursuit of happiness: management of depression in the elderly. Independent Drug Information Service; 2008: available at: www.rxfacts.org.
   Evidence-based care guidance document
   Written for physicians caring for elderly patients, for use in academic detailing programs in Pennsylvania and available via Internet website for all interested clinicians. Academic detailing program extending to other states, including New York, South Carolina, Washington D.C., and other countries including Canada and Brazil.
3. Jackowski L, Avorn J, Choudhry NK, Fischer M, **Kesselheim A**, May F, Parikh S, Rowett D, Shrank W. Preventing falls and enhancing mobility in the community dwelling elderly. Independent Drug Information Service; 2009: available at: www.rxfacts.org.
   Evidence-based care guidance document
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4. Jackowski L, Avorn J, Choudhry NK, Fischer M, **Kesselheim A**, Parikh S, Shrank W. Maximizing function in the patient with impaired cognition and behavior: What the primary care physician needs to know to help patients and caregivers. Independent Drug Information Service; 2009: available at: www.rxfacts.org.
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Written for physicians caring for elderly patients, for use in academic detailing programs in Pennsylvania and available via Internet website for all interested clinicians. Academic detailing program extending to other states, including New York, South Carolina, Washington D.C., and other countries including Canada and Brazil.

Thesis

1. **Kesselheim AS**. A method to their madness: Greek Methodism in its social context. [Honors undergraduate thesis]. On file, Department of History of Science, Cambridge, MA: Harvard University, 1996.

Narrative Report

Within the Division of Pharmacoepidemiology and Pharmacoeconomics of the Brigham and Women's Hospital Department of Medicine, I have established a program of research that combines the fields of law and regulation, pharmacoepidemiology, assessment of clinical practices, and health services research. My work analyzes how prescribing and other aspects of medication use are influenced by drug and device policies, laws, and ethical norms, with 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. 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. In work funded by an Investigator Award in Health Policy Research from the Robert Wood Johnson Foundation, I have examined the origins and development of our most transformative drugs and devices. By mapping patents and conducting interviews with key inventors, I have sought to define the roles played by academic and private-sector researchers in moving innovation forward, and to assess the contribution of patents and other incentives to their work.

Third, I have analyzed the clinical, ethical, and economic consequences of regulatory decisions made on the basis of limited premarket clinical studies, and considered the implications for patients, physicians, and payors of making such drugs and devices widely available. In 2013, I was selected as the single Harvard University applicant for the Greenwall Faculty Scholar program in Bioethics. I am using this support to study the ethical considerations involved in regulatory determinations about new medications. I am pursuing this work through the Program On Regulation, Therapeutics, And Law (PORTAL) that I developed within the Division, now encompasses a team of 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 how disclosures about funding influence the interpretation of clinical trial data, published in the *New England Journal of Medicine,* and how conflict of interest disclosure policies such as state and federal open payments legislation affect physician reporting and patient outcomes.

In recognition of my research, I have been invited to speak at numerous national and international meetings, and have served as a consultant for expert bodies such as the US Patent and Trademark Office, ClinicalTrials.gov, and the National Academy of Medicine. I was appointed to 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 at the Harvard Medical School Center for Bioethics. In 2015, I was invited to serve on an FDA Advisory Committee and joined the Board of Directors of the American Society of Law, Medicine, and Ethics.

In 2014-2015, I was a Visiting Associate Professor of Law at Yale Law School, where I taught a class on FDA law. I was invited to serve in this role again in 2016-2017. In 2015-2016, I originated a class on Health Law, Policy, and Bioethics for the Harvard Medical School Center for Bioethics, and in

2016-2017 I initiated a monthly health policy and bioethics seminar for the entire Harvard community (but which is also offered for class credit for masters students). I have supervised numerous Harvard medical, law, and public health students, as well as post-doctoral fellows, residents, and clinical fellows.

Clinically, I practice internal medicine in the Phyllis Jen Center for Primary Care at BWH, where I manage patients with acute and chronic problems, many of whom I have cared for since my residency.