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

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

1. **Your Name:** Aaron Kesselheim			
2. **Are you testifying on behalf of the Federal, or a State or local government entity?**		Yes	No (circled)
3. **Are you testifying on behalf of an entity that is not a government entity?**		Yes	No (circled)
4. **Other than yourself, please list which entity or entities you are representing:** None			
5. **Please list any Federal grants or contracts (including subgrants or subcontracts) that you or the entity you represent have received on or after October 1, 2011:** I have received grants from AHRQ and the FDA Office of Generic Drugs			
6. **If your answer to the question in item 3 in this form is "yes," please describe your position or representational capacity with the entity or entities you are representing:**			
7. **If your answer to the question in item 3 is "yes," do any of the entities disclosed in item 4 have parent organizations, subsidiaries, or partnerships that you are not representing in your testimony?**		Yes	No
8. **If the answer to the question in item 3 is "yes," please list any Federal grants or contracts (including subgrants or subcontracts) that were received by the entities listed under the question in item 4 on or after October 1, 2011, that exceed 10 percent of the revenue of the entities in the year received, including the source and amount of each grant or contract to be listed:**			
9. **Please attach your curriculum vitae to your completed disclosure form.** Attached.			

Signature: [redacted] **Date:** 7/8/14

Curriculum Vitae

Date Prepared: July 8, 2014
Name: Aaron Seth Kesselheim, M.D., J.D., M.P.H.
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[redacted] [redacted]

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
7/10-	Assistant Professor	Medicine	Harvard Medical School
7/08-	Research Associate	Health Policy and Management	Harvard School of Public Health

7/14-7/15	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-	Associate Physician	Medicine (Pharmacoepidemiology and Pharmacoeconomics)	Brigham and Women's Hospital
7/05-	Staff Physician	Medicine	Faulkner Hospital, Jamaica Plain, MA
7/05-	Staff Physician	Medicine	Dana-Farber Cancer Institute, Boston, MA

Other Professional Positions

2010-2011	Consultant	Robert Wood Johnson Foundation Public Health Law Research program	Temple University, Philadelphia, PA
2010-	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

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-	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)

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-	Admissions committee, Law and Public Health Concentration	Harvard School of Public Health Member
2011-	Harvard Interfaculty Working Group on Government Management of Pharmaceutical Products	Harvard University Member
2012-	Honors thesis program expert reader	Harvard Medical School Member
2013-	Regulatory Science Advisory Board	Harvard Medical School Member
2013-	Clinical trial data sharing working groups	Multi-Regional Clinical Trial Center, Harvard Global Health Institute Member

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-	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 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-present: Quality and Value Interest Group Advisory Committee 2012-2013: Annual Research Meeting Planning Committee	Member
2011-	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

Editorial Activities

Ad hoc peer reviewer

American Heart Journal
American Journal of Respiratory and Critical Care Medicine
Annals of Internal Medicine
BioMed Central (BMC) Medical Ethics
BMC Medical Research Methodology
British Medical Journal (BMJ)
BMJ Quality & Safety
Circulation
Clinical Pharmacology and Therapeutics
Current Medical Research and Opinion
Drug Discovery Today
Expert Review of Molecular Diagnostics
Expert Review of Pharmacoeconomics & Outcomes Research
Genome Biology
Health Affairs
Health Policy
Journal of the American Medical Association (JAMA)
JAMA Internal Medicine
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
Milbank Quarterly
Nature
New England Journal of Medicine
Pharmacoeconomics
Pharmacoepidemiology & Drug Safety
Public Library of Science (PLoS) Medicine
PLoS One
Science
Science Translational Medicine

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 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, appointed to 3-year term	PLoS Medicine
2012-	Editorial Board, appointed to 3-year term	Expert Opinion on Orphan Drugs
2012-	Advisory Board, Perspectives section	New England Journal of Medicine
2013-	Editorial Board	Edmond J. Safra Center for Ethics at Harvard University Working Paper series
2013	Health Policy Brief external editor	Health Affairs

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

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.

2008-2009 Mind the gap: efficacy versus effectiveness of colorectal cancer chemotherapy
AHRQ Developing Evidence to Inform Decisions about Effectiveness (DEcIDE) Network / Individual investigator initiated grant
Contributing investigator ($700,000)
Analysis of patterns of use of chemotherapy drugs after approval, including comparative effectiveness of different alternative therapies.

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)
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.

Current

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.

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

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

2013-2014 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.

2013-2015 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.

2014-2015 Examining the impact of FDA regulatory policies on therapeutic approval
Harvard Program in Therapeutic Science
Principal Investigator ($106,604)
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.

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
2009-2013	Health Care Policy	Harvard Medical School
	First-year medical students	6 hrs per lecture for annual 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
	Graduate students	8 hrs per wk for 1 semester
2006	Law and Public Health	Harvard School of Public Health
	Graduate 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 per lecture for annual guest lecture
2008-	Advanced Pharmacoepidemiology	Harvard School of Public Health
	Graduate students	4 hrs per lecture for annual guest lecture
2012-2013	GHHP 91r Seminar	Harvard Faculty of Arts and Sciences
	Undergraduate student independent study	25 hrs per semester
2013	Law and Public Health (HPM 213)	Harvard School of Public Health
	Graduate students	6 hrs per lecture for guest lecture
2013	7.015 Introductory Biology	Massachusetts Institute of Technology
	Undergraduate students	4 hrs per lecture for guest lecture
2013	EP748 Drug Epidemiology	Boston University School of Public Health
	Graduate students	4 hrs per lecture for guest lecture
2014	EPI 502 Antibiotic Epidemiology	Harvard School of Public Health
	Graduate students	4 hrs per lecture for guest lecture
2014	Law 7606	Northeastern University School of Law
	Graduate students	4 hrs per lecture for guest lecture

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 Residents	Brigham and Women's Hospital and Faulkner Hospital, 5 hrs
2005	The health care of our political leaders Residents	Brigham and Women's Hospital and Faulkner Hospital, 3 hrs

Teaching during current Harvard appointment:

2004-2009	Medico-legal issues for medicine residents Residents	Brigham and Women's Hospital and Faulkner Hospital, 5 hrs per year
2005-2008	Ambulatory care rotation Residents	Massachusetts General Hospital, Boston 4 hrs per wk for 3 wks per year

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 advisor, Center for Medicare and Medicaid Innovation, Baltimore, MD Oversight of research program in intellectual property issues affecting availability of drugs in resource-poor settings, leading to two peer-reviewed 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 two peer-reviewed publications. 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 three peer-reviewed publications.
2009-	Jonathan J. Darrow, J.D., M.B.A., S.J.D. / Federal Circuit law clerk, Washington, D.C. Supervision of thesis and post-doctoral work on history of drug efficacy study and regulation, leading to S.J.D. thesis, and 1 peer-reviewed publication
2009-2010	Devan L. Darby, 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 one peer-reviewed publication.
2010-2011	Kirsten E. Austad / Family medicine resident, Boston Medical Center, Boston, MA Oversight of Safra Center-funded fellowship on medical school education and changes in attitudes about the pharmaceutical industry, leading to five peer-reviewed 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.
2011-2012	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 one peer-reviewed publication
2011-	Shuai Xu, M.Sc. / Resident, Chicago, IL Oversight of HMS/HSDM Scholars in Medicine-funded research internship and honors thesis work on medical device innovation, leading to four peer-reviewed publications and 2012 Soma Weiss Research day finalist
2011-	Bo Wang, Pharm.D. / Medical student, Harvard Medical School, Boston, MA Oversight of course of research related to drug policy issues, leading to four peer-reviewed publications
2012-	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 2 peer-reviewed publications
2012	Evan Caplan / Combined M.D./M.B.A. student, Harvard Medical School and Harvard Business School, Boston, MA Investigation of sources of innovation leading to development of vascular endothelial growth factor inhibitors for use in ophthalmologic disease.
2012	Kyle Checchi, M.Sc. / Medical student, Harvard Medical School, Boston, MA Oversight of HMS/HSDM Scholars in Medicine-funded research internship on use of pill bottle-related medical device innovation to improve medication adherence.
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 Hwang / Blackstone Group, London, England, UK Oversight of coursework and thesis research on Food and Drug Administration rulemaking, regulation, and biopharmaceutical innovation, leading to 5 peer-reviewed articles
2013	Carolyn Treasure / Medical student, Harvard Medical School, Boston, MA Oversight of HMS/HSDM Scholars in Medicine-funded research internship on university patenting and government march-in rights, leading to 1 peer-reviewed publication.
2013	Ben Rome / Medical student, Harvard Medical School, Boston, MA

Oversight of HMS/HSDM Scholars in Medicine-funded research internship on US high-risk medical device regulation, leading to 2 peer-reviewed publications

2013 Nathan Shiu, M.P.H. / Law student, University of California-Los Angeles, Los Angeles, CA
Oversight of summer research fellowship on adjudication of truth and scientific certainty in the federal courts, leading to 2 publications

2013- Ameet Sarpatwari, Ph.D., J.D. / Post-doctoral research fellow, Program On Regulation, Therapeutics, And Law (PORTAL), Division of Pharmacoepidemiology and Pharmacoeconomics, Boston, MA
Oversight of post-doctoral research program on law and public health topics

2013- James Yeh, M.D. / Harvard Medical School fellow in general medicine and primary care, Division of Pharmacoepidemiology and Pharmacoeconomics, Boston, MA
Oversight of post-residency general medicine fellowship in health services research

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

2014- Jing Luo, M.D. / Fellow in medication use and outcomes, Division of Pharmacoepidemiology and Pharmacoeconomics, Boston, MA
Oversight of post-residency general medicine fellowship in health services research

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 / Grand Rounds
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

2006 Nesiritide: drug policy lessons / Research Rounds
Department of Medicine (Division of Pharmacoepidemiology and Pharmacoeconomics), 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)

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)

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

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

2005 Economic impact of patent extension on Medicaid drug expenditures / Invited Lecture
International Society for Pharmacoepidemiology annual meeting, Nashville, TN

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 Food and Drug Administration (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 has authority to restrict promotion of 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? / Invited 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, Cambridge, MA [national attendees]

2013 Patient-centered outcomes research in rare diseases / Keynote Speaker
14th North American Genzyme 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 Intersection of market exclusivity and access to medicines / Roundtable Participant
University of Melbourne-Vanderbilt University International Roundtable Meeting, Honolulu, HI

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 Second 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 / Invited 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? The 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 Institute, 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.

International

2007 The patentability of pharmacoepidemiology methods / Invited Lecture
International Society for Pharmacoepidemiology 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 annual meeting, Brighton, England, UK

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

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

Books, 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. **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/.
5. 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/

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. The Forum at the Harvard School of Public Health. *Battling Drug-Resistant Superbugs: Can We Win?* Post February 5, 2014. Available on-line at http://theforum.sph.harvard.edu/events/battling-drug-resistant-superbugs/.
25. 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
26. Silverman E. Can pharma sales reps influence prescribing for unapproved uses? *Wall Street Journal*. June 9, 2014. Available on-line at: http://blogs.wsj.com/pharmalot/2014/06/09/can-pharma-sales-reps-influence-prescibing-for-unapproved-uses

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. NIHMS200394
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.e5.
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.
22. Austad KE, Avorn J, **Kesselheim AS**. Medical students' exposure to and attitudes about the pharmaceutical industry: a systematic review. PLoS Medicine 2011;8(5):e1001037. doi:10.1371/journal.pmed.1001037. (presents new data)
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.
24. Avorn J and **Kesselheim AS**. The NIH's new drug-development initiative: socialization of risk and privatization of gain? Nature Medicine 2011;17(10):20. (presents new data)
25. **Kesselheim AS**, Darby DL, Studdert DM, Glynn RJ, Levin RL, Avorn J. False Claims Act prosecution did not deter off-label drug use in the case of Neurontin. Health Affairs 2011;30(12):2318-2327.
26. **Kesselheim AS**. An empirical review of major legislation affecting drug development: past experiences, effects, and unintended consequences. Milbank Quarterly 2011;89(3):450-502.
27. **Kesselheim AS**, Lee JL, Avorn J, Servi A, Shrank WH, Choudhry NK. Conflict of interest in oncology publications. Cancer 2012;118(1):188-95.
28. **Kesselheim AS**, Myers JA, Solomon DH, Winkelmayer WC, Levin R, Avorn J. The prevalence and cost of unapproved uses of top-selling orphan drugs. PLoS One 2012;7(2):e31894.
29. Kramer DB, Xu S, **Kesselheim AS.** How does medical device regulation perform in the United States and the European Union? A systematic review. PLoS Medicine 2012;9(7): e1001276. doi:10.1371/journal.pmed.1001276. (presents new data)
30. **Kesselheim AS**, Wang B, Studdert DM, Avorn J. Conflict of interest reporting by authors involved in promotion of off-label drug use: an analysis of journal disclosures. PLoS Medicine 2012;9(8):e1001280.
31. Greene JA, Choudhry NK, **Kesselheim AS**, Brennan TA, Shrank WH. Changes in direct-to-consumer pharmaceutical advertising following Rx to OTC shift. JAMA 2012;308(10):973-975.
32. **Kesselheim AS**, Robertson CT, Myers JA, Rose SL, Gillet V, Ross KM, Glynn RJ, Joffe S, Avorn J. A randomized study of how physicians interpret research funding disclosures. New England Journal of Medicine 2012;367:1119-1127. NIHMS415947.
33. Amin T and **Kesselheim AS**. Secondary patenting could extend US market exclusivity of HIV drugs Norvir and Kaletra through 2028. Health Affairs 2012;31:2286-2294.
34. Robertson CT, Rose SL, **Kesselheim AS**. Effect of financial relationships on the behaviors of health care professionals: a review of the evidence. Journal of Law, Medicine & Ethics 2012;40(3):452-66. (presents new data)
35. Xu S, Avorn J, **Kesselheim AS**. Origins of medical innovation: the case of coronary artery stents. Circulation: Cardiovascular Quality and Outcomes 2012;5(6):743-749.
36. **Kesselheim AS**, Misono AS, Shrank WH, Greene JA, Doherty M, Avorn J, Choudhry NK. Variations in pill appearance of antiepileptic drugs and the risk of non-adherence. JAMA Internal Medicine 2013;173(3):202-208.
37. **Kesselheim AS**, Robertson CT, Siri K, Batra P, Franklin JM. Distributions of industry payments to Massachusetts physicians. New England Journal of Medicine 2013;368(22):2049-52.

38. **Kesselheim AS**, Avorn J. The most transformative drugs of the past 25 years: a survey of physicians. Nature Reviews: Drug Discovery 2013;12(6):425-431.
39. Austad KE, Avorn J, Franklin JM, Kowal MK, Campbell EG, **Kesselheim AS**. Changing interactions between physician trainees and the pharmaceutical industry: a national survey. Journal of General Internal Medicine 2013;28(8):1064-1071.
40. **Kesselheim AS**, Franklin JM, Avorn J, Duke JD. Speaking the same language?: International variations in the safety information accompanying top-selling prescription drugs. BMJ Quality & Safety 2013;22:727-734.
41. **Kesselheim AS**, Wang B, Avorn J. Defining 'innovativeness' in drug development: a systematic review. Clinical Pharmacology and Therapeutics 2013;94(3):336-48. (presents new data)
42. Wang B, Avorn J, **Kesselheim AS**. Clinical and regulatory features of drugs not initially approved by the FDA. Clinical Pharmacology and Therapeutics 2013;94(6):670-677.
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Abstracts, Poster Presentations and Exhibits Presented at Professional Meetings

1. Xu S and **Kesselheim AS.** Promoting medical technology innovation: lessons learned from the case of bare metal coronary stents. Therapeutic Innovation & Regulatory Science 2013;47:511. [Abstract and Poster]
2. Checchi K, Avorn J, **Kesselheim AS**. Technological innovations in medication packaging to improve patient adherence: a systematic review. Therapeutic Innovation & Regulatory Science 2013;47;509 [Abstract and Poster]

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. Last year, I was selected as the single Harvard University applicant for the Greenwall Faculty Scholar program in Bioethics, which I was awarded this past summer. I will use this support to study the ethical considerations involved in regulatory determinations about new medications. I am pursuing this work through the new Program On Regulation, Therapeutics, And Law (PORTAL) that I developed within the Division, which is building a team of post-doctoral fellows and students focused on this area.

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 Institute of Medicine. I was recently appointed to the *New England Journal of Medicine* Perspectives Advisory Board, and as a faculty supervisor of the Harvard Law School Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics.

I regularly teach in the first-year HMS health care policy course, and at HSPH in an advanced pharmacoepidemiology course and in law and public health courses. 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.