Ameet Sarpatwari, Ph.D., J.D., declares and states as follows:

1. I am an Assistant Professor of Medicine at Harvard Medical School and an Assistant Professor in the Department of Health Policy and Management at the Harvard T.H. Chan School of Public Health. I further serve as an Associate Epidemiologist and the Assistant Director of the Program on Regulation, Therapeutics, and Law (PORTAL) in the Division of Pharmacoepidemiology and Pharmacoconomics at Brigham and Women’s Hospital. I am also an Affiliated Faculty Member with the Center for Bioethics at Harvard Medical School; the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School; and the Behavioral Insights Group in the Center for Public Leadership at the Harvard Kennedy School.
2. I received my B.A. in Interdisciplinary Studies-International Health from the University of Virginia in 2003. I then pursued an M.Phil. and Ph.D. in epidemiology at the University of Cambridge, which I received in 2006 and 2010, respectively. In 2013, I received my J.D. with a Health Law Certificate from the University of Maryland and then completed a two-year Postdoctoral Research Fellowship in Pharmaceutical Law and Health Services Research with PORTAL.

3. My research lies at the intersection of pharmaceutical policy and pharmacoepidemiology, the study of the effects of prescription drugs, including patterns of utilization and adherence, safety signal detection, comparative effectiveness, and cost-benefit analyses. I have published numerous peer-reviewed research articles on a range of issues relating to drug risks and benefits, including FDA’s risk evaluation and mitigation strategy (“REMS”) programs. Among other projects, I am currently the Principle Investigator on a multi-year, multi-modal collaborative study with FDA to assess how REMS programs have impacted physician and patient burden, drug utilization, safety monitoring, and health outcomes.

4. I have testified on pharmaceutical policy before Congress, FDA, and multiple state legislatures. I also served as an expert panelist in an FDA-sponsored workshop on understanding and evaluating the impact of REMS programs on the health care delivery system and patient access.

5. I am a member of the International Society for Pharmacoepidemiology and serve as an ad-hoc peer reviewer for multiple medical journals, including the New England Journal of Medicine and the Journal of the American Medical Society.

6. Attached as Exhibit A and incorporated by reference in this declaration is a copy of my curriculum vitae.
Overview of Expert Opinion

7. I provide this expert declaration of facts and opinion based on my education, training, research, practical experience, knowledge of relevant literature and regulations, and conversations with other pharmacoepidemiologists, medical practitioners, and public health experts. I offer this declaration on my own behalf and not as a representative of Harvard University or any other professional organization with which I am affiliated.

8. I understand that Defendants seek to reinstate the mifepristone REMS in-person dispensing requirement during the public health emergency (“PHE”) first declared by the Secretary of the United States Department of Health and Human Services (“HHS”) on January 31, 2020, because they contend that (1) changed circumstances mitigate the viral risk of forcing mifepristone patients to travel to a health care facility just to pick up a pill and sign a form, and (2) geographic variation in viral rates and public health policies relating to in-person activities during the PHE counsel against maintaining nationwide relief for patients seeking medication abortion. Defendants make these arguments even though, as a part of their effort to limit the spread of SARS-CoV-2, the virus that causes Coronavirus Disease 2019 (“COVID-19”), Defendants have, on a nationwide basis and for the duration of the PHE, relaxed and suspended in-person requirements associated with other medications.

9. As explained in more detail below, it is my expert opinion that Defendants have suspended (or stated that they intend not to enforce) in-person requirements for drugs, many of which carry far greater risks than those presented by mifepristone. In addition, it is my expert opinion that, under the established framework for assessing the risks and benefits of approved medications in the United States, there is no sound clinical basis for HHS and FDA’s refusal to suspend the in-person requirements for patients who require treatment using mifepristone as they
have done for patients who require other far more dangerous medications. Indeed, it is my expert opinion that HHS and FDA’s insistence on enforcing the in-person requirements for mifepristone during the PHE runs counter to the purpose of the REMS system, which is to ensure that the benefits of a drug’s use outweigh the risks. Maintaining—or reinstating—the in-person requirements of the mifepristone REMS program would enhance patient risk rather than mitigate it and would do so in a manner inconsistent with how HHS and FDA have treated other medications posing greater health risks.

**Defendants’ Actions to Promote Telemedicine During the Public Health Emergency**

10. HHS Secretary Azar declared a nationwide PHE in January and has renewed that determination three times because of the “continued consequences” of the pandemic.\(^1\) Each time, including most recently on October 2, the Secretary exercised his discretion under section 319 of the Public Health Services Act to renew the PHE for the entire country because the public health emergency continues nationwide.\(^2\)

11. During the PHE, HHS has appropriately embraced the use of telemedicine to maximize patient access to health care while limiting in-person contact.\(^3\) It has promoted telemedicine by, among other things, announcing through the Centers for Medicare & Medicaid Services that it would expand Medicare coverage to include a broader range of telemedicine services under section 1135 waiver authority and the Coronavirus Preparedness and Response

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\(^2\) *Id.*

Supplemental Appropriations Act for the duration of the PHE. Secretary Azar appropriately expanded this coverage throughout the United States rather than limiting it to certain states or regions based on coronavirus rates at any given time or any other factors, because the COVID-19 pandemic has an ongoing nationwide impact. Similarly, HHS’s Office of Civil Rights announced in March that during the PHE, it would not enforce certain potential penalties for Health Insurance Portability and Accountability Act (“HIPAA”) violations against health care providers that serve patients through everyday communications technologies, such as FaceTime and Zoom. This policy also applies nationwide.

**Suspensions and Non-Enforcement of In-Person Drug Requirements**

12. As discussed in greater detail below, HHS and FDA have issued non-enforcement guidance and policies relaxing—on a nationwide basis and for the duration of the PHE—requirements that patients see their health care providers in person before they can be prescribed schedule II controlled substances; REMS requirements for laboratory testing and imaging studies before patients can be prescribed certain medications and for ongoing monitoring during use; and in-person visit requirements for drugs still undergoing clinical trials (i.e., drugs for

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6 Id.


which FDA has not yet determined whether to grant marketing approval at all or whether to impose a REMS as a condition of any such approval). For these drugs, HHS and FDA appropriately rely on the clinical judgment of practitioners to determine whether they can safely provide medications to patients without travel and in-person interaction in order to mitigate the risk of SARS-CoV-2 infection. They have issued these policies on a nationwide basis for the duration of the PHE, which, in my expert opinion, is appropriate in light of the critical need to stem the spread of deadly viral infection throughout the country. It is also my expert opinion that there is no justification for Defendants’ failure to issue similar guidance for mifepristone, a drug associated with far less risk than many of the drugs for which Defendants have issued non-enforcement policies.

**A. In-Person Requirements Suspended for Controlled Substances**

13. On March 16, 2020, HHS Secretary Azar, working with the Drug Enforcement Agency (“DEA”), designated that the telemedicine allowance under section 802(54)(D) of the Controlled Substances Act, 21 U.S.C. 802, involving the use of telemedicine during a public health emergency, extends to all schedule II-V controlled substances in all areas of the United States. Thus, “[a]s of March 16, 2020, and continuing for as long as the Secretary’s designation of a public health emergency remains in effect, DEA-registered practitioners in all areas of the United States may issue prescriptions for all schedule II-V controlled substances to patients for whom they have not conducted an in-person medical evaluation.”10 In issuing a prescription in

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10. U.S. Dep’t of Justice, supra note 7.
accordance with this policy, practitioners must use their “sound judgment to determine” that they have “sufficient information to conclude that the issuance of the prescription is for a bona fide medical purpose.”

14. The medications covered by this policy include opioids, such as fentanyl-containing products, extended-release oxycodone (OxyContin®), and other schedule II controlled substances—the most restricted class of controlled substances that have an accepted medical use. Among the risks associated with these medications are misuse and abuse, which can result in addiction, overdose, and death. For example, in a study of 568,640 adults with a newly diagnosed chronic non-cancer pain condition, researchers found that 1.3% and 6.1% of those issued a medium- or high-dose chronic opioid prescription, respectively, developed opioid use disorder (characterized by abuse of or dependence on opioids). The population-level impact of opioid misuse and abuse has been staggering, with over 45,000 opioid-involved overdose deaths in the U.S. recorded in 2018 alone, to the point that “overdoses from prescription opioids . . . [have] reduc[ed] life expectancy in the United States.” The societal costs for opioid use disorder and fatal opioid overdose in 2017 were estimated to be $1.02 trillion. As a result, “[o]ne of the highest priorities of the FDA is advancing efforts to address

misuse and abuse of opioid drugs harming families.”

15. Because schedule II drugs like opioids pose a serious risk of misuse and abuse, with high rates of addiction and tens of thousands of lethal overdoses each year, prior to the pandemic, practitioners could not prescribe these medications without first conducting an in-person evaluation to, among other things, assess whether the patient has a legitimate need for the drug. However, because of the risk of SARS CoV-2 infection, during the PHE, HHS and DEA have waived this requirement, and health care providers are now free to rely on remote practitioner-patient interactions to determine whether the patient can safely receive these controlled substances in a manner that protects against the risks of misuse and abuse without requiring the patient to travel during the pandemic to a medical facility. In my expert opinion, this decision was appropriate: through telehealth technologies, practitioners can conduct comprehensive clinical assessments and engage in effective counseling, enabling safe, remote prescribing of schedule II controlled substances for eligible patients.

16. In comparison to the risk of misuse and abuse from schedule II opioids, the risks of bleeding and infection—the stated justification for the mifepristone REMS program—are miniscule at both a patient and population level. As former FDA Commissioner Jane Henney, M.D., has explained in advocating for FDA to entirely reevaluate and lift the mifepristone REMS, “[m]ost adverse effects [of the drug] are mild, such as cramping or abdominal pain, and the rate of severe adverse events is very low.” According to FDA’s 2016 medical review of mifepristone, major adverse events including death, hospitalization, serious infection, severe

18 U.S. Dep’t of Justice, supra note 11.
bleeding, and ectopic pregnancy are “exceedingly rare”—“generally far below 0.1% for any individual adverse event.”

17. In light of mifepristone’s well established record of safety and efficacy, FDA’s retention of the mifepristone in-person dispensing requirement during the pandemic is exceedingly difficult to square with the first factor FDA is required to consider in deciding “whether a REMS is required for a particular drug and what type of REMS might be necessary”: “The seriousness of any known or potential adverse events that may be related to the drug and the background incidence of such events in the population likely to use the drug.”

Indeed, during the pandemic, retaining the mifepristone in-person requirements undermines, rather than advances, safety. Mandating that patients visit a medical facility to pick up a pill their clinician would otherwise mail or deliver to them at home needlessly exposes the patient, those they encounter as they travel to the facility or when they return home, and health care staff, to the risk of SARS-CoV-2 infection, a growing threat as we approach the winter months. Additionally, as with the HHS-DEA PHE policy for controlled substances, lifting the mifepristone in-person dispensing requirement does not preclude practitioners from conducting an in-person assessment for any patient for whom it is clinically appropriate based on their individual circumstances. But allowing patients to receive the medication by delivery or mail, where medically appropriate,

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21 Henney & Gayle, supra note 19.


23 Id.; see also 21 U.S.C. §355-1.
substantially reduces unnecessary COVID-19 risks for the many patients who do not require in-person medical care.24

**B. In-Person Requirements Suspended for Drugs with REMS Programs Requiring Laboratory Testing and Imaging Study Requirements**

18. In March 2020, FDA issued a Guidance for Industry and Health Care Professionals, announcing that, during the PHE, it did not intend to enforce REMS program requirements that mandate laboratory testing or magnetic resonance imaging (“MRI”) studies before prescribing or dispensing certain drugs that carry serious risks, “provided that such accommodations were made based on the judgment of a health care professional.”25 In so doing, FDA recognized that, during the PHE, “undergoing laboratory testing or imaging studies in order to obtain a drug subject to a REMS program can put patients and others at risk for transmission of the coronavirus.”26 Accordingly, FDA determined that health care practitioners should “use their best medical judgment in weighing the benefits and risks of continuing treatment in the absence of laboratory testing and imaging studies.”27

19. One medication covered by this policy is the antipsychotic clozapine (Clozaril®). FDA required a REMS program for the drug owing to its risk of inducing neutropenia (an abnormally low number of a certain kind of white blood cells known as neutrophils), which, in severe cases, can result in lethal infection. The black box warning for clozapine states that it “can lead to serious and fatal infections” (and additional risks highlighted in the warning include orthostatic hypotension, bradycardia, and syncope; seizure; myocarditis; and increased mortality

26 Id.
27 Id.
in elderly patients with dementia-related psychosis). A registry-based study of 12,760 patients receiving clozapine in the United Kingdom and Ireland between January 1990 and April 1997 found that 2.7% of patients were forced to discontinue treatment due to neutropenia and that 0.7% of patients developed severe neutropenia. A separate investigation of 163 identified cases of clozapine-induced severe neutropenia in Finland found a 3.1% case fatality rate. Owing to these potential substantial harms, the REMS program for clozapine requires routine monitoring and reporting of patients’ absolute neutrophil count (“ANC”). Yet despite these serious risks, because of the dangers inherent in traveling to a health care facility for testing, FDA issued a nationwide non-enforcement guidance that covers the clozapine REMS program’s requirement of routine ANC testing for the duration of the PHE.

In contrast to the mifepristone in-person dispensing requirement, which is irrelevant to the risks the mifepristone REMS purportedly guard against—since no medical care or counseling is required to occur at the time of dispensing, and relevant counseling can happen via telehealth—the clozapine in-person testing requirement is directly related to mitigating the risk of infection from severe neutropenia. Moreover, whereas taking clozapine can cause severe neutropenia leading to lethal infection, the FDA-approved labeling for mifepristone acknowledges that “there is no evidence of a causal relationship between use of mifepristone and

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an increased risk of infection or death.” Mifepristone is simply a safer drug than clozapine. Yet the FDA has relaxed in-person testing requirements for clozapine while insisting on maintaining the requirement that mifepristone patients travel during the pandemic to pick up a pill.

21. As with the controlled substances discussed above, this differential treatment reveals troubling inconsistencies in the FDA’s evaluation of the “seriousness of any known or potential adverse events that may be related to the drug and the background incidence of such events in the population likely to use the drug.” Indeed, as noted, FDA’s refusal to lift the mifepristone in-person requirements increases rather than mitigates risk, by unnecessarily subjecting patients, their health care providers, and their communities to risk of viral exposure in contradiction to the statutory purpose of the REMS program.

C. In-Person Requirements Suspended for Clinical Trials

22. In March 2020, FDA issued a Guidance for Industry, Investigators, and Institutional Review Boards, which was updated in September 2020 and permits modifications of FDA-approved protocols in clinical trials during the PHE because of difficulties “adhering to protocol mandated visits and laboratory/diagnostic testing” and “concern about risk of exposure to COVID-19.” For ongoing trials, the FDA stated in relevant part:

Since trial participants may not be able to come to the investigational site for protocol-specified visits, sponsors should evaluate whether alternative methods for safety assessments (e.g., phone contact, virtual visit, alternative location for assessment, including local labs or imaging centers) could be implemented when necessary and feasible, and would be sufficient to assure the safety of trial participants. Sponsors should determine if in-person visits are necessary to fully assure the safety of trial participants (for

32 Nat’l Acads. Of Scis., Eng’g & Med., supra note 19, at 55; see also FDA Full Prescribing Information for Mifeprex, supra note 20, at 2.
34 FDA Clinical Trials Guidance, supra note 9, at 5.
35 Id. at 15.
example to carry out procedures necessary to assess safety or the safe use of the investigational product appropriately); in making the decision to continue use or administration of the investigational product, the sponsor should consider whether the safety of trial participants can be assured with the implementation of the altered monitoring approach.36

In addition, because of concerns about viral exposure, the FDA advised that health care professionals conducting trials consider whether “certain investigational products, such as those that are typically distributed for self-administration, may be amenable to alternative secure delivery methods,”37 including home delivery “to protect patients from coming to clinical trial sites.”38

23. This guidance applies to investigational products that are under study and have not been determined to be safe and effective. Notably, only 6-7%, 11-15%, and 49-62% of investigational drugs that initiate Phase I, II, and III testing, respectively, ultimately launch.39 The reasons for failure often include safety. For example, an assessment of 640 investigational drugs entering Phase III clinical testing between 1998 and 2008 found that 17% failed because of safety concerns.40

24. The Defendants’ argument that the COVID-19 risks are now so minimal that the injunction should be lifted cannot be squared with their recently updated guidance relaxing mandatory protocols for in-person visits even in the context of clinical trials of drugs whose safety remains an open question. If the FDA deems it appropriate to maintain this kind of flexibility during the PHE even for unapproved drugs under study, there simply can be no

36 Id. at 6 (emphasis added).
37 Id. at 7.
38 Id. at 15.
39 Helen Dowden & Jamie Munro, Trends in Clinical Success Rates and Therapeutic Focus, 18 Nature Revs. 495, 495 (2019).
40 Thomas J. Hwang et al., Failure of Investigational Drugs in Late-Stage Clinical Development and Publication of Trial Results, 176 JAMA Internal Med. 1826, 1829 (2016).
creditable justification for reinstating in-person requirements for mifepristone, a medication whose safety and efficacy is well-established based on two decades of use in the United States (and beyond).41

25. It is my expert opinion that Defendants’ request to reinstate the mifepristone REMS in-person requirements during the COVID-19 pandemic turns the purpose of the REMS system on its head—imposing unnecessary risk on patients and the public, rather than mitigating risk and promoting access to a safe medication. This is even more so when one considers that Defendants have suspended other in-person requirements, on a nationwide basis, for the duration of the PHE, for drugs that carry far greater risks than mifepristone.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on November 12, 2020.

Ameet Sarpatwari, Ph.D., J.D

Sarpatwari Declaration
Exhibit A
Harvard Medical School
Curriculum Vitae

Date Prepared: November 9, 2020
Name: Ameet Sarpatwari, Ph.D., J.D.
Office Address: Division of Pharmacoepidemiology and Pharmacoeconomics
Department of Medicine, Brigham and Women’s Hospital
1620 Tremont Street, Suite 3030
Boston, MA 02120

Home Address: 11 Monmouth Court, Apartment 6
Brookline, MA 02446

Work Phone: (617) 278-0930
Work E-mail: asarpatwari@bwh.harvard.edu
Work Website: www.portalresearch.org
Work Fax: (617) 232-8602

Place of Birth: Louisville, KY

Education

2003  B.A. (with distinction)  Interdisciplinary Studies-
      International Health  University of Virginia,
      Charlottesville, VA

2006  M.Phil.  Epidemiology  University of Cambridge,
      Cambridge, UK

2010  Ph.D.  Epidemiology  University of Cambridge

2013  J.D. (cum laude)  Law-
      Health Law Certificate  University of Maryland
      School of Law, Baltimore, MD

Postdoctoral Training

08/13-07/15  Research Fellow  Pharmaceutical Law and
      Health Services Research  Program On Regulation,
      Therapeutics, And Law (PORTAL), Division of
      Pharmacoepidemiology and Pharmacoeconomics,
      Brigham and Women’s Hospital, Boston MA /
      Harvard Medical School, Boston, MA

Faculty Academic Appointments

08/15-06/19  Instructor  Medicine  Harvard Medical School

08/15-  Affiliated Faculty  Behavioral Insights Group,
      Center for Public Leadership  Harvard Kennedy School,
      Cambridge, MA
08/15- Affiliated Faculty Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics Harvard Law School, Cambridge, MA

05/16-11/19 Instructor Health Policy and Management Harvard T.H. Chan School of Public Health Boston, MA

05/18-09/20 Affiliated Faculty Center for Bioethics Harvard Medical School

07/19- Assistant Professor Medicine Harvard Medical School

12/19- Assistant Professor Health Policy and Management Harvard T.H. Chan School of Public Health

10/20- Faculty Member Center for Bioethics Harvard Medical School

**Appointments at Hospitals/Affiliated Institutions**

01/07-06/11 Lead Epidemiologist United Kingdom Adult Immune Thrombocytopenia (ITP) Registry Royal London Hospital, London, UK

08/15- Associate Epidemiologist Division of Pharmacoepidemiology and Pharmacoeconomics Brigham and Women’s Hospital

**Other Professional Positions**

2010-2013 Honorary Fellow Centre for Haematology, Barts and the London School of Medicine, London, UK


2017-2018 Member Advisory Board, Drew Quality Group (Non-Profit Generic Drug Manufacturer)

2019- Member West Health Drug Spending Expert Panel

**Major Administrative Leadership Positions**

Local
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<th>Year(s)</th>
<th>Role</th>
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<td>2015-</td>
<td>Assistant Director, Program on Regulation, Therapeutics, and Law (PORTAL), Division of Pharmacoepidemiology and Pharmacoeconomics</td>
<td>Brigham and Women’s Hospital</td>
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<tr>
<td>2016-</td>
<td>Course Director, Public Health Law</td>
<td>Harvard T.H. Chan School of Public Health</td>
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<td><strong>Committee Service</strong></td>
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<tr>
<td>2005-2006</td>
<td>Student Representative, Administrative Committee, M.Phil. Epidemiology Course, Department of Public Health and Primary Care</td>
<td>University of Cambridge</td>
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<tr>
<td>2013-</td>
<td>Member, Program Management Committee, PORTAL, Division of Pharmacoepidemiology and Pharmacoeconomics</td>
<td>Brigham and Women’s Hospital</td>
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<tr>
<td>2019-</td>
<td>Member, MPH-45 Admissions Committee</td>
<td>Harvard T.H. Chan School of Public Health</td>
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<tr>
<td>2019-</td>
<td>Faculty Wellness Representative</td>
<td>Division of Pharmacoepidemiology and Pharmacoeconomics, Brigham and Women’s Hospital</td>
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<td>2011-2013</td>
<td>Member, Maryland Regional Selection Committee</td>
<td>Jefferson Scholars Program, University of Virginia</td>
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<td>Member, Boston Regional Selection Committee</td>
<td>Jefferson Scholars Program, University of Virginia</td>
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<td>2019</td>
<td>Member, Planning Committee, The Role of NIH in Drug Development Innovation and its Impact on Patient Access</td>
<td>The National Academies of Science, Engineering, and Medicine</td>
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<td>2019-</td>
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<td>International Society for</td>
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Pharmacoepidemiology
2014, 2018, 2019, 2020
2015
Member, Abstract Reviewing Panel
Member, Abstract Organizing Committee
Moderator, Session: Measured Policy

Grant Review Activities
2013 Grant Proposal Reviewer, Patient Powered Research Networks,
Patient Centered Research Outcomes Research Institute
Ad hoc Member

Editorial Activities
Ad Hoc Peer Reviewer
Arthritis and Rheumatology
BMJ Case Reports
Cambridge University Press (Books)
Haematologica
Health Affairs
Health Economics
Journal of the American Medical Association
Journal of General Internal Medicine
JAMA Internal Medicine
Johns Hopkins University Press (Books)
Journal of Health Politics, Policy, and Law
Journal of Law and Biosciences
Journal of Law, Medicine, and Ethics
Journal of Thrombosis and Haemostasis
New England Journal of Medicine
PLOS Medicine
Pharmacoepidemiology and Drug Safety
Tissue Antigens
Value in Health

Other Editorial Roles
2011-2012 Staff Editor University of Maryland Law Journal of Race, Religion, Gender, and Class
2012-2013 Editor-in-Chief University of Maryland Law Journal of Race, Religion, Gender, and Class
2014- Ad-Hoc Faculty Reviewer Yale Journal of Health Law, Policy, and Ethics

Honors and Prizes
1999 Echols Scholarship University of Virginia Academic Excellence
1999 Jefferson Scholarship University of Virginia Leadership, Scholarship
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<td>2003</td>
<td>Phi Beta Kappa Society</td>
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<td>Academic Excellence</td>
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<td>2005</td>
<td>Woodward Award</td>
<td>Groton School</td>
<td>Service Beyond Call of Duty</td>
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<td>2010</td>
<td>John L. Thomas Leadership Scholarship</td>
<td>University of Maryland School of Law</td>
<td>Leadership, Scholarship (Full-Merit Award)</td>
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<td>2013</td>
<td>Joseph Bernstein Award</td>
<td>University of Maryland School of Law</td>
<td>Excellence in Legal Writing</td>
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<td>2013</td>
<td>Cunningham Award</td>
<td>University of Maryland School of Law</td>
<td>Citizenship, Leadership</td>
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<td>2016</td>
<td>Partners in Excellence Award</td>
<td>Partners HealthCare, Boston, MA</td>
<td>Leadership and Innovation</td>
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**Report of Funded Projects**

**Past**

- **2014-2016** State pharmacy laws affecting generic prescription drug substitution: their effect on public health
  - Principal Investigator
  - An evaluation of the impact of variation in state drug product selection laws on public health outcomes, including a survey examination of the frequency with which pharmacists in states with permissive drug product selection laws exercise their discretion to substitute generic for brand-name drugs

- **2014-2017** Does variation in the physical characteristics of generic drugs affect patients’ experiences: a survey of pharmacists and patients
  - Food and Drug Administration (HHSF223201310232C)
  - Co-Investigator (Principal Investigator: Aaron S. Kesselheim, M.D., J.D., M.P.H.)
  - National surveys of patients and pharmacists to determine their experiences with generic medications that change appearance during routine refills, and the association of these episodes with non-adherence and confusion

- **2014-2017** Assessing the post-marketing safety of authorized generic drug products
  - Food and Drug Administration (U01-FD-14-013)
  - Co-Investigator (Principal Investigator: Joshua J. Gagne, Pharm.D., Sc.D.)
  - A study of authorized generics—brand-name drugs that are marketed, sold, or distributed as generic medications—to examine the extent to which negative perceptions of generic drugs affect patient acceptance and utilization of these products
2015-2018 Novel approaches for confounding control in observational studies of generic drugs
Food and Drug Administration (1U01FD005555-01)
Co-Investigator (Co-Principal Investigators: Rishi J. Desai, M.S., Ph.D. / Joshua J. Gagne, Sc.D., Ph.D.)
A study of strategies of confounder selection in comparative studies of generic drugs

2016 Use of patents and regulatory exclusivities to set and extend brand-name drug market exclusivity: a review of the evidence
Commonwealth Fund
Co-Investigator (Principal Investigator: Aaron S. Kesselheim, M.D., J.D., M.P.H.)
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 center for the empirical study of therapeutic regulation and innovation
The Laura and John Arnold Foundation
Co-Investigator (Principal Investigator: Aaron S. Kesselheim, M.D., J.D., M.P.H.)
A project to create and run a center focused on how laws and regulations influence the development, utilization, and affordability of therapeutics, as well as the ethical questions that current and proposed policies raise for patients, physicians, policymakers, and payors

2016-2017 Ethical issues in prescription drug access under restricted distribution programs
Greenwall Foundation
Principal Investigator
A project to develop an ethical framework for the use of risk evaluation and mitigation strategies with elements to assure safe use based on quantitative and qualitative investigations of the benefits and limitations of such programs for patients, prescribers, manufacturers, and regulators

2018-2019 The US government’s contribution to transformative drug development
Open Society Foundations
Principal Investigator
A study analyzing the amount of support that the US government has provided for the discovery and development of two highly innovative and clinically important pharmaceutical products, and the ways in which that investment can be leveraged with respect to the price of the products

2018-2019 The impact of intra-class competition on drug prices
Anthem Public Policy Institute
Principal Investigator
A study assessing the impact of new drug market entry on the prices of older drugs to identify the conditions needed for prices to fall

2018-2020 Transformative reforms for US pharmaceutical policy
Open Society Foundations
Principal Investigator ($96,862)
A study critiquing proposed US pharmaceutical policy reforms to promote the development of and access to medicines meeting public health needs

**Current**

2014-2020  Examining the impact of FDA regulatory policies on therapeutic approval
Harvard-MIT Center for Regulatory Science
(formerly: Harvard Program in Therapeutic Science)
Co-Investigator (Principal Investigator: Aaron S. Kesselheim, M.D., J.D., M.P.H.)
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

2017-2020  An International Comparison of Regulatory Risk Communication on Medicines
Australian Government National Health and Medical Research Council
Site Principal Investigator ($72,867) (Principal Investigator: Barbara Mintzes, Ph.D.)
To understand 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 United States, and Europe

2017-2023  Prescription drug innovation, availability, and affordability
Arnold Ventures
Co-Investigator (Principal Investigator: Aaron S. Kesselheim, M.D., J.D., M.P.H.)
A series of studies characterizing and critically assessing key trends at each stage of the drug product lifecycle that affect cost and innovation as well as proposed alternatives to existing policies

2019-2021  Promoting a competitive market for high-cost biologic drugs
Arnold Ventures
Principal Investigator ($409,032)
A study examining the characteristics of pivotal trials for follow-on biologics, the follow-on biologic pipeline, and the scope and impact of biologic patenting

2020-2024  Risk evaluation and mitigation strategy programs to promote appropriate medication use and knowledge: a multimodal analysis
US Food and Drug Administration
Principal Investigator ($4.4 million)
A study assessing how risk evaluation and mitigation strategy (REMS) programs have impacted drug utilization, health outcomes, and physician and patient experiences, and how effectively REMS programs translate important benefit-risk information to physicians and patients.

**Report of Local Teaching and Training**

**Teaching of Students in Courses**
Teaching prior to start of current Harvard appointment
2007  Introduction to the cardiorespiratory system, Problem-Based Learning Facilitator, Barts and the London School of Medicine, first-year medical students 3 hours per session for 5 sessions

2008  Introduction to metabolism, Problem-Based Learning Facilitator, Barts and the London School of Medicine, first-year medical students 3 hours per session for 4 sessions

2009  Risk measures, M.Phil. epidemiology and public health students Lecturer, University of Cambridge 2 hours

HMS/HSDM/DMS Courses
2016- Health privacy, health law, policy, and bioethics class Faculty, Harvard Medical School 3 hours / year

2018- Medicines and Evidence Faculty, Harvard Medical School 3 hours / year

Other Harvard University Courses
2015- Data privacy, security, and use agreements; effectiveness research with longitudinal databases class Faculty, Harvard T.H. Chan School of Public Health 1 hour / year

2015- Data privacy, security, and use agreements; database analytics in pharmacoepidemiology class Faculty, Harvard T.H. Chan School of Public Health 1 hour / year

2016- Public health law class Sole Course Instructor, Harvard T.H. Chan School of Public Health 3 hours per session for 8 sessions / year

Formal Teaching of Residents, Clinical Fellows, and Research Fellows (Post-Docs)
Teaching prior to start of current Harvard appointment
2007  Fundamentals of epidemiology, haematology fellows, Royal London Hospital, London, UK 3 hours

Laboratory and Other Research Supervisory and Training Responsibilities
2008-2010  Supervision of data extraction from medical records, Royal London Hospital
records by medical students for registry study. Varied levels of mentorship, from daily to weekly, lasting months.

2015-2016
Supervision of students and post-doctoral fellows, 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 months.

Formally Mentored Harvard Medical, Dental, and Graduate Students

2016-2017
Vijay Raghavan, M.Sc. / M.Bioethics Student (2018) / Harvard Medical School
Oversight of capstone project on ethical, legal, and pragmatic differences between traditional and network models for conducting multi-center biomedical research.

2016-2017
Seán Finnan / L.L.M. Student (2017) / Harvard Law School
Oversight on student paper tracing the application and merits of Article 53(a) of the Convention on the Grant of European Patents.

2017-2018
Oversight on research comparing adherence to inhaled corticosteroids in adolescents, children, and adults with asthma.

2017-2018
Farhad Udwadia / M.Bioethics Student (2018) / Harvard Medical School
Oversight on capstone project on the ethics of compulsory treatment for opioid use disorders.

2017-2018
Oversight on research on brand-brand drug competition, leading to 1 publication.

2018-2019
Rotimi Adigun / M.Bioethics Student (2019) / Harvard Medical School
Oversight on capstone project on the ethics of orphan drug policies.

2019-2020
Thalia Nikoglou / M.Bioethics Student (2019) / Harvard Medical School
Oversight on capstone project on an ethical framework for pricing and paying for gene therapies.

2019-2020
Melissa Barber / Ph.D. Student (2019) / Harvard T.H. Chan School of Public Health and Harvard Graduate School of Arts and Sciences
Oversight on research modeling impact of biosimilar competition and antitrust enforcement on drug prices, and research characterizing product lifecycle management strategies.

2020-2020
Paul Pouzet / M.Bioethics Student (2020) / Harvard Medical School
Oversight on capstone project on the bioethical considerations in sharing deidentified genetic data.
Other Mentored Trainees and Faculty
*All below co-mentored with Aaron S. Kesselheim, M.D., J.D., M.P.H.

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 on post-approval surveillance of biologics, leading to 1 publication

2016-2017  Kerstin N. Vokinger, M.D., J.D., Ph.D., LL.M. / Assistant professor, University of Zurich
Oversight of project on strategies to extend market exclusivity, leading to 1 publication

Oversight of project on contributing factors to the opioid crisis, leading to 1 publication

2017-2018  Reed Beall, M.A., Ph.D. / Assistant professor, University of Calgary, Calgary, Canada
Oversight of projects on impact of patents and market exclusivity on availability of medical products, leading to 2 publications

2018-2020 Rachel E. Barenie, Pharm.D., J.D., M.P.H. / Research fellow, Division of Pharmacoepidemiology and Pharmacoeconomics, Brigham and Women’s Hospital
Oversight of projects on follow-on biologics and the impact of pill appearance changes on medication adherence, leading to 2 publications

2019- Victor Van de Wiele, LL.B., LL.M. / Research fellow, Division of Pharmacoepidemiology and Pharmacoeconomics, Brigham and Women’s Hospital
Oversight of projects on state drug product selection laws and the Biologics Price Competition and Innovation Act, leading to 1 publication

2020- Bryan S. Walsh, J.D. / Research fellow, Division of Pharmacoepidemiology and Pharmacoeconomics, Brigham and Women’s Hospital
Oversight of project on “skinny labeling”

Local Invited Presentations
No presentations below were sponsored by outside entities.

2012 On scholarly writing: a guide for incoming law journal staff editors / Lecture
Journal of Health Care Law and Policy, University of Maryland School of Law, Baltimore, MD

2014 Regulation of new drugs with important safety risks: evaluating the role of safety risk evaluation and mitigation strategies (with Aaron S. Kesselheim, M.D., J.D., M.P.H.) / Lecture
Harvard Program in Therapeutic Science, Harvard Medical School, Boston, MA

2014 Behavioral economics and physician prescribing practices: legal and ethical considerations in the use of “nudges” to promote generic drug use / Speaker
2015
Paying physicians to promote generic drugs and follow-on biologics in the United States 
Lecture
Behavioral Insights Group, Center for Public Leadership, Harvard Kennedy School of 
Government, Cambridge, MA

2015
Book launch, FDA in the Twenty-First Century: The Challenges of Regulating Drugs 
Moderator
Harvard Law School, Boston, MA

2016
Data sharing that enables post-approval drug and device research and protects patient 
privacy: best practice recommendations
Speaker
Petrie Flom Center for Health Law Policy, Biotechnology, and Bioethics Annual 
Conference, Harvard Law School, Cambridge, MA

2016
From rare disease to legal epidemiology: the case of immune thrombocytopenia 
Lecture
International Society for Pharmacoepidemiology and International Society for 
Pharmacoconomic and Outcomes Research Student Chapter, Harvard T.H. Chan School 
of Public Health, Boston, MA

2016
Clinical trial data sharing and reproducibility
Moderator
Health Policy and Bioethics Consortium, Harvard Medical School, Boston, MA

2017
Drug pricing and costs
Speaker
5th Annual Health Law Year in P/Review; Petrie Flom Center for Health Law Policy, 
Biotechnology, and Bioethics; Harvard Law School, Cambridge, MA

2017
Transparency on prescription drug expenditures: a lever for restraining pricing?
Speaker
Petrie Flom Center for Health Law Policy, Biotechnology, and Bioethics Annual 
Conference, Harvard Law School, Cambridge, MA

2018
Book launch, FDA in the Twenty-First Century: The Challenges of Regulating Drugs 
Gasser)
Speaker
Harvard Law School, Boston, MA

2018
Patients perceptions of and responses to changes in pill appearance 
Lecture
Behavioral Insights Student Group, Harvard Kennedy School of Government, 
Cambridge, MA

2018
The US biosimilar market: stunted growth and possible reforms
Lecture
Health Law Workshop, Harvard Law School, Boston, MA
2018 When is a medical treatment worth $850,000? The value of Luxturna and gene therapy treatments / Moderator
Health Policy and Bioethics Consortium, Harvard Medical School, Boston, MA

2018 The US government’s contribution to transformative drug development / Host
Radcliffe Institute for Advanced Study Exploratory Seminar, Cambridge, MA

Harvard Law School, Boston, MA

2020 Private funding of drug discovery: ethical issues and practical alternatives / Moderator
Health Policy and Bioethics Consortium, Harvard Medical School, Virtual

2020 The US biosimilar market: progress, challenges, and possible reforms / Lecture
Division of Pharmacoepidemiology and Pharmacoeconomics, Brigham and Women’s Hospital, Virtual

2020 Drug shortages: managing prioritization and improving the supply chain / Moderator
Health Policy and Bioethics Consortium, Harvard Medical School, Virtual

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 identified.

Regional
2013 Overdose Response Program-Senate Bill 610 / Testimony
Maryland General Assembly, Annapolis, MD

2015 Forbidden and permitted statements about medication uses and effects / Lecture
Drug Policy Class, Northeastern Law School, Boston, MA

2015 From prescriptions to addiction / Panelist
Students for a Sensible Drug Policy, Northeastern Law School, Boston, MA

2015 Law, government, and public health / Lecture
Principles and History of Urban Public Health Class, Bouve College of Health Sciences, Northeastern University, Boston, MA

2015 Big data ethics in comparative effectiveness research / Panelist
Ethics Forum, Massachusetts Medical Society, Waltham, MA

2016 Sticker shock: navigating clinical care in an era of skyrocketing drug prices / Grand Rounds
Emerson Hospital, Concord, MA
2016 Prescription drug prices / Testimony (with Michael A. Fischer, M.D., M.Sc.)
	House Committee on Health Care, Vermont General Assembly, Montpelier, VT

2016 A prescription for insight: understanding the cost and value of pharmaceutical drugs / Testimony
	Joint Committee on Health Care Financing, Massachusetts General Assembly, Marblehead, MA

2017 States and rising prescription drug costs: origins and prospects for reform / Testimony
	Connecticut Health Care Cabinet, Hartford, CT

2017 Rising drug prices and prospects for reform / Speaker
	Health Law Symposium, Massachusetts Bar Association, Boston, MA

2017 Pharmaceutical transparency and price gouging / Testimony
	Joint Committee on Health Care Financing, Massachusetts General Assembly, Boston, MA

2017 Is there a research agenda here in law, public health, health services, economics, policy? / Moderator and Speaker
	Ensuring Safety, Efficacy, and Access to Medicinal Products in the Age of Global Deregulation Conference, Yale University, New Haven, CT

2018 Market dynamics and intellectual property / Lecture
	FDA Law Class, Northeastern Law School, Boston, MA

2018 The rising price of prescription drugs in the United States: reasons and possible solutions / Speaker
	University of Rhode Island College of Pharmacy Seminar by the Sea 2018, Newport, RI

2019 FDA regulation of drugs and devices / Lecture
	Drug Epidemiology Class, Boston University School of Public Health, Boston, MA

National

2007 Disease progression, treatment effectiveness, and co-morbidities among adult patients with ITP in a UK cohort / Speaker
	ITP Support Association National Convention, Oxford, UK

2008 Analysis of the ITP Support Association lifestyle survey / Speaker
	ITP Support Association National Convention, London, UK

2013 Reinforcing a public health response to the opioid epidemic: on the merits of the reclassification of buprenorphine / Lecture
	Division of Pharmacoconomics and Pharmacoepidemiology, Brigham and Women’s Hospital, Boston, MA
2014 The use of field experiments for public health law research / Speaker (with Christopher T. Robertson)
Robert Wood Johnson Foundation Public Health Law Research Annual Conference, Atlanta, GA

2014 Inroads into immune thrombocytopenia: the path of an epidemiologist-lawyer / Lecture
Epidemiology of Aging Training Program, University of Maryland School of Medicine, Baltimore, MD

2015 The impact of risk evaluation and mitigation strategies on generic market entry and off-label prescribing / Lecture
Center for Drug Safety and Effectiveness, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD

2015 State pharmacy laws affecting generic drug substitution: their effect on public health / Speaker
Robert Wood Johnson Foundation Public Health Law Research Annual Conference, San Juan, Puerto Rico

2015 Assessing the impact of risk evaluation and mitigation strategies with elements to assure safe use on patient access / Panelist
Public Workshop on Risk Evaluation and Mitigation Strategies, Food and Drug Administration, White Oak, MD

2016 A call to action on pharmacy prices / Plenary Session
National Academy for State Health Policy Annual Meeting, Pittsburgh, PA

2016 High cost drugs: origins, impact, and prospects for reform / Speaker
Council of State Governments National Meeting, Williamsburg, VA

2016 1-800-bad-drug advertisements / Speaker
Organized Systems of Anticoagulation Care Summit, American College of Cardiology, Washington, DC

2016 Changing physician and patient perceptions about generic drugs / Speaker
Substitutability of Generic Drugs Conference, Johns Hopkins Center for Excellence in Regulatory Science and Innovation & Food and Drug Administration, White Oak, MD

2016 Does variation in the physical characteristics of generic drugs affect patients’ experiences? Results from a national survey of pharmacists and patients / Speaker
Substitutability of Generic Drugs Conference, Johns Hopkins Center for Excellence in Regulatory Science and Innovation & Food and Drug Administration, White Oak, MD

2016 Tackling high drug costs in the Trump era / Working Group Member
Politico, Washington, DC
2017  Ensuring patients’ access to high-value cancer drugs / Workshop Participant
President’s Cancer Panel, Pittsburgh, PA

2017  The opioid epidemic: fixing a broken pharmaceutical market / Speaker
Health Law Professors Conference, Atlanta, GA

2017  Administering the Hatch-Waxman amendments: ensuring a balance between innovation
and access / Speaker
Food and Drug Administration, White Oak, MD

2017  FDA efforts to balance innovation and access & state efforts to control rising drug prices:
transparency and 28 USC §1498 / Speaker
Convening of Organizations Working on Drug Prices and Affordability, Doctors for
America & Center for American Progress, Washington, DC

2017  Data sharing that enables post-approval drug and device research and protects patient
privacy: best practice recommendations / Speaker
Data Privacy in the Digital Age Meeting, Department of Health and Human Services,
Washington, DC

2018  Requesting NIH revisit its position on pricing for drugs developed with taxpayer funding
/ Participant in meeting with NIH
Patients for Affordable Drugs, Washington, DC

2018  An update on biologics and the BPCIA / Speaker
Antitrust Practice Group, NY State Bar Association, Albany, NY

2018  Roundtable discussion on value-based drug pricing / Organizer
Center for American Progress and Doctors for America, Washington, DC

2018  Addressing public health crises: identifying state approaches to effectively purchase and
safeguard access to evidence-based pharmaceutical interventions / Workshop Participant
National Governors Association, Washington, DC

2018  2018 Rome lecture: drug pricing: problems and prospects / Panelist
University of Maryland Law School, Baltimore, MD

2018  Addressing bias and potential conflicts of interest / Speaker
American Diabetes Association Annual Meeting, Orlando, Florida

2018  Impact of variation in the physical characteristics of generic drugs on adherence and
patient experiences / Faculty Speaker
American College of Clinical Pharmacology Symposium, Bethesda, MD

2018  Rising drug prices: addressing a national crisis to protect public health / Speaker
American Society of Health-System Pharmacists Leaders Conference, Dallas, TX

2019 Promoting competition to lower Medicare drug prices / Witness
U.S. House Ways and Means Subcommittee on Health, Washington, DC

2019 Fulfilling our promise to lower prescription drug prices / Panelist
House Affordable Prescription Drug Task Force Briefing, Washington, DC

2019 Prescription drug regulation and reimbursement: research, development, and FDA policy / Speaker
Prescription Drug Regulation and Reimbursement Boot Camp, Washington, DC

2019 The Role of NIH in drug development innovation and its impact on patient access: a workshop / Speaker
The National Academies of Sciences, Engineering, and Medicine, Washington, DC

2019 Unpacking drug value: a path to fair pricing / Speaker
Kaiser Permanente Institute for Health Policy Forum, Washington, DC

2020 Vaccines – the COVID-19 case for public pharmaceutical research and development / Speaker
Democracy Collaborative, Virtual

2020 Roundtable on prescription drug patents / Panelist
Commonwealth Fund and Arnold Ventures, Virtual

2020 Why prices are not coming down? / Panelist
Why Americans are so worried about rising healthcare costs and what can be done about it? West Health and Gallup Webinar, Virtual

International

2008 The UK Adult ITP Registry: addressing unresolved epidemiological questions / Speaker
European ITP Support Group Meeting, London, UK (sponsored by GlaxoSmithKline)

2008 The UK Adult ITP Registry: a framework for addressing unresolved epidemiological questions / Speaker
ITP Annual Update Meeting (satellite session of the American Society of Hematology Annual Meeting and Exposition), San Francisco, CA

2009 Autologous In-labelled platelet sequestration studies in patients with primary ITP: a report from the UK Adult ITP Registry / Speaker
ITP Annual Update Meeting (satellite session of the American Society of Hematology Annual Meeting and Exposition), New Orleans, LA

2009 The epidemiology of autoimmune diseases and role of registry studies / Speaker
Haematological aspects of autoimmune diseases, European School of Haematology,
Mandelieu, France

2010 How useful are autologous In-labelled platelet sequestration studies in patients with ITP? / Speaker, Immune thrombocytopenia European School of Haematology, Lisbon, Portugal

2017 Medication use and criminality / Symposium Host International Conference on Pharmacoepidemiology and Therapeutic Risk Management, Montreal, Canada

2018 The affordability and access to medicines debate in Europe: challenges and opportunities to ensure medical research and development works for the public good / Speaker Open Society Foundations High-Level Policy Retreat, Salzburg, Austria

2018 Evidentiary requirements: are we asking pharmaceutical manufacturers the right questions when approving new drugs in Europe? / Speaker Open Society Foundations Workshop, Salzburg, Austria

2018 Impact of risk evaluation and mitigation strategies (REMS) on erythropoiesis stimulating agent use / Speaker International Conference on Pharmacoepidemiology and Therapeutic Risk Management, Prague, Czech Republic

2018 Assessing the quality of innovation / Speaker European Health Forum, Gastein, Austria


2019 Access to medicines and innovation in Europe / Speaker Open Medical Institute, Salzburg, Austria

**Report of Clinical Activities and Innovations**
**Current Licensure and Board Certification**
2013 Maryland Attorney License

**Report of Teaching and Education Innovations**
HarvardX Co-developed with Aaron S. Kesselheim, M.D. J.D., M.P.H. and Jonathan J. Darrow, J.D., S.J.D., M.B.A. a six-week online course “The FDA and Prescription Drugs: Current Controversies in Context,” which will cover: (1) the FDA—its history, public health role, and rules affecting the US prescription drug market; (2) the process of discovering, testing, and approving innovative drugs; (3) the cost of prescription drugs; (4) the promotion of prescription drugs by pharmaceutical manufacturers to physicians and patients; (5) post-approval safety evaluation of prescription drugs; and

**Report of Education of Patients and Service to the Community**

No activities or materials below were sponsored by outside entities.

**Activities**

- **2007-2008** UK Adult ITP Registry / Co-Host
- **2008-2010** UK Adult ITP Registry Patient Forum / Administrator
- **2014-** Petrie-Flom Center Bill of Health / Blogger
- **2015** Harvard Health Blog / Contributing Editor

**Educational material for patients and the law community**

- **2016** This Week in Health Law Podcast Guest https://bit.ly/2sNTtxx
- **2017** Bloomberg Op-Ed: Get generic drugs to market faster: one good way Congress can help lower the cost of prescription medicines Co-Author https://bloom.bg/2rN7ugI
- **2017** Reuters Q&A: REMS and generic competition Interviewee https://reut.rs/2JsmXLX
- **2017** 1A Radio Show: Experimenting with drugs while terminally ill Guest https://bit.ly/2t0mrK3
- **2017** This Week in Health Law Podcast: an exploration Guest https://bit.ly/2JCxAb4
of the reasons for high and increasing drug costs and a critical analysis of investment, transparency, value, and outcomes-based metrics being used to determine fair prescription drug costs

2018 NPR: Patients’ Drug Options Under Medicaid Heavily Influenced by Drugmakers Guest https://n.pr/2mYZLHt

2019 Plenary Session Podcast: a discussion of REMS, the Orphan Drug Act, and the role of the FDA Guest https://apple.co/2vcgB9O

2020 Plenary Session Podcast: remdesivir, cloth masks, and incentives for COVID-19 drug development Guest https://apple.co/3ld3Xjo

Recognition


2016 Regulatory Focus: Academics to follow on Twitter https://bit.ly/2LJ0s6r


2017 Press mention of scholarship (Research Investigation #11): Tighter patent rules could help lower drug prices, study shows. NPR. https://n.pr/2bsRO8P


2017 Press mention of scholarship (Research Investigation #11): https://cbsn.ws/2coZ6vV
What’s behind the sharp rise in prescription drug prices? CBS.


Press mention of scholarship (Research Investigation #45): Pharmacists not required to substitute generics for brand-name drugs in most US states. Reuters.

Press mention of scholarship (Research Investigation #47): Testing requirements are likely slowing biosimilar entries in the US. Regulatory Focus.

Report of Scholarship

Peer-Reviewed Publications in Print or Other Media

Research Investigations


49. **Sarpatwari A**, He M, Tessema FA, Gagne JJ, Kesselheim AS. Changes in erythropoiesis stimulating agent use under a risk evaluation and mitigation strategy (REMS) program. Drug Safety. [In Press]

Other Peer-Reviewed Publications


Non-Peer Reviewed Scientific or Medical Publications/Materials in Print or Other Media
Reviews, Chapters, Monographs, and Editorials


Amicus Briefs

Blogs


Rulemaking Comments


Theses