EXHIBIT 4

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, *et al*.,

Plaintiffs,

vs.

UNITED STATES FOOD AND DRUG ADMINISTRATION, *et al*.,

Defendants.

CIV. NO. TDC-20-1320

DECLARATION OF AMEET SARPATWARI, PH.D., J.D., IN OPPOSITION TO DEFENDANTS' RENEWED MOTION TO STAY THE PRELIMINARY INJUCTION AND FOR AN INDICATIVE RULING DISSOLVING THE PRELIMINARY INJUNCTION

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 Pharmacoeconomics 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

[1] U.S. Dep't of Health & Hum. Servs., Assistant Sec'y for Preparedness and Response, Renewal of Determination that a Public Health Emergency Exists (Oct. 2, 2020), https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-2Oct2020.aspx.
[2] *Id*.
[3] *See* Ctrs. for Disease Control & Prevention, Coronavirus Disease 2019 (COVID-19), Doctor Visits and Getting Medicines (Sept. 11, 2020), https://www.cdc.gov/coronavirus/2019-ncov/daily-life-coping/doctor-visits-medicine.html.

Supplemental Appropriations Act for the duration of the PHE.[4] 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.[5] This policy also applies nationwide.[6]

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;[7] REMS requirements for laboratory testing and imaging studies before patients can be prescribed certain medications and for ongoing monitoring during use;[8] and in-person visit requirements for drugs still undergoing clinical trials (*i.e.*, drugs for

[4] Ctrs. for Medicare & Medicaid Servs., President Trump Expands Telehealth Benefits for Medicare Beneficiaries During COVID-19 Outbreak (Mar. 17, 2020), https://www.cms.gov/newsroom/press-releases/president-trump-expands-telehealth-benefits-medicare-beneficiaries-during-covid-19-outbreak; Ctrs. For Medicare & Medicaid Servs., Medicare Telemedicine Health Care Provider Fact Sheet (Mar. 17, 2020), https://www.cms.gov/newsroom/fact-sheets/medicare-telemedicine-health-care-provider-fact-sheet.

[5] U.S. Dep't of Health & Hum. Servs., OCR Announces Notification of Enforcement Discretion for Telehealth Remote Communications During the COVID-19 Nationwide Public Health Emergency (Mar. 30, 2020), https://www.hhs.gov/hipaa/for-professionals/special-topics/emergency-preparedness/notification-enforcement-discretion-telehealth/index.html.

[6] *Id*.

[7] U.S. Dep't of Justice, Drug Enforcement Admin., COVID-19 Information Page: Telemedicine, https://www.deadiversion.usdoj.gov/coronavirus.html#TELE (last visited Nov. 10, 2020).

[8] U.S. Food & Drug Admin., Policy for Certain REMS Requirements During the COVID-19 Public Health Emergency: Guidance for Industry and Health Care Professionals 1, 7 (Mar. 2020), https://www.fda.gov/media/136317/download.

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).[9] 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

[9] U.S. Food & Drug Admin., FDA Guidance on Conduct of Clinical Trials of Medical Products During the COVID-19 Public Health Emergency 1, 6 (2020) [hereinafter FDA Clinical Trials Guidance], https://www.fda.gov/media/136238/download. FDA has also permitted drug manufacturers to distribute drug samples directly to patients at home. U.S. Food & Drug Admin., Temporary Policy on Prescription Drug Marketing Act Requirements for Distribution of Drug Samples During COVID-19 Public Health Emergency 1, 5 (June 2020), https://www.fda.gov/media/138697/download.

[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."[11]

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.[12] 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).[13] 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,[14] to the point that "overdoses from prescription opioids . . . [have] reduc[ed] life expectancy in the United States."[15] The societal "[c]osts for opioid use disorder and fatal opioid overdose in 2017 were estimated to be $1.02 trillion."[16] As a result, "[o]ne of the highest priorities of the FDA is advancing efforts to address

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[11] U.S. Dep't of Justice, Drug Enforcement Admin., How to Prescribe Controlled Substances to Patients During the COVID-19 Public Health Emergency, https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-023)(DEA075)Decision_Tree_(Final)_33120_2007.pdf (last visited Nov. 10, 2020).
[12] U.S. Dep't of Justice, Drug Enforcement Admin., Drug Scheduling, https://www.dea.gov/drug-scheduling (last visited Nov. 10, 2020).
[13] Mark J. Edlund et al., *The Role of Opioid Prescription in Incident Opioid Abuse and Dependence Among Individuals with Chronic Noncancer Pain: The Role of Opioid Prescription*, 30 Clin. J. Pain 557, 559 (2014).
[14] Nana Wilson et al., *Drug and Opioid-Involved Overdose Deaths – United States, 2017-2018*, 69 Morbidity & Mortality Wkly. Rep. 290, 291 (2020).
[15] U. S. Food & Drug Admin., Opioid Medications (Aug. 4, 2020), https://www.fda.gov/drugs/information-drug-class/opioid-medications.
[16] Curtis Florence et al., *The Economic Burden of Opioid Use Disorder and Fatal Opioid Overdose in the United States, 2017*, Drug & Alcohol Dependence 1, 1 (2020).

misuse and abuse of opioid drugs harming families."[17]

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.[18] 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."[19] According to FDA's 2016 medical review of mifepristone, major adverse events including death, hospitalization, serious infection, severe

[17] U. S. Food & Drug Admin., *supra* note 15.
[18] U.S. Dep't of Justice, *supra* note 11.
[19] Jane E. Henney & Helene D. Gayle, *Time to Reevaluate U.S. Mifepristone Restrictions*, 381 New Engl. J. Med. 597, 597 (2019); *see also* Nat'l Acads. Of Scis., Eng'g & Med., *The Safety and Quality of Abortion Care in the United States* 1, 54-55 (2018).

bleeding, and ectopic pregnancy are "exceedingly rare"—"generally far below 0.1% for any individual adverse event."[20]

17. In light of mifepristone's well established record of safety and efficacy,[21] 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":[22] "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."[23] 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,

[20] U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Res., Medical Review of Mifeprex 1, 47 (Mar. 29, 2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020MedR.pdf; *see also* U.S. Food & Drug Admin., Full Prescribing Information for Mifeprex 1,7-8, Tables 1 & 2 (Mar. 2016) [hereinafter FDA Full Prescribing Information for Mifeprex], https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf.
[21] Henney & Gayle, *supra* note 19.
[22] U.S. Food & Drug Admin., REMS: FDA's Application of Statutory Factors in Determining when a REMS Is Necessary Guidance for Industry 1, 5 (April 2019), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/rems-fdas-application-statutory-factors-determining-when-rems-necessary-guidance-industry.
[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

[24] *See* American College of Obstetricians and Gynecologists, COVID-19 FAQs for Obstetrician-Gynecologists, Gynecology (2020), https://www.acog.org/en/clinical-information/physician-faqs/COVID19-FAQs-for-Ob-Gyns-Gynecology.
[25] U.S. Food & Drug Admin., *supra* note 8, at 7.
[26] *Id*.
[27] *Id*.

in elderly patients with dementia-related psychosis).[28] 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.[29] A separate investigation of 163 identified cases of clozapine-induced severe neutropenia in Finland found a 3.1% case fatality rate.[30] Owing to these potential substantial harms, the REMS program for clozapine requires routine monitoring and reporting of patients' absolute neutrophil count ("ANC").[31] 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.

20. 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

[28] U.S. Food & Drug Admin., Full Prescribing Information for Clozaril 1,1 (1989), https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/019758s095lbl.pdf.
[29] Janet Munro et al., *Active Monitoring of 12760 Clozapine Recipients in the UK and Ireland*, 175 Brit. J. Psych. 576, 577 (1999).
[30] Liisa Lahdelma & Björn Appelberg, *Clozapine-Induced Agranulocytosis in Finland, 1982-2007: Long-Term Monitoring of Patients Is Still Warranted*, 73 J. Clin. Psychiatry 837, 840 (2012).
[31] U.S. Food & Drug Admin., Approved Risk Evaluation and Mitigation Strategies for Clozapine (Nov. 12, 2019), https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=351.

an increased risk of infection or death."[32] 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." [33] 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"[34] and "concern about risk of exposure to COVID-19."[35] 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.
[33] U.S. Food & Drug Admin., *supra* note 22, at 5; *see also* 21 U.S.C. § 355-1.
[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] *I*d. 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).

credible 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

[41] Mifeprex REMS Study Group et al., *Sixteen Years of Overregulation: Time to Unburden Mifeprex*, 376 New Engl. J. Med. 790, 791 (2017); FDA Full Prescribing Information for Mifeprex, *supra* note 20.

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
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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
2014-2015	Research Affiliate	Behavioral Insights Group, Center for Public Leadership, Harvard Kennedy School, Cambridge, MA
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

2015-	Assistant Director, Program on Regulation, Therapeutics, and Law (PORTAL), Division of Pharmacoepidemiology and Pharmacoeconomics	Brigham and Women's Hospital
2016-	Course Director, Public Health Law	Harvard T.H. Chan School of Public Health

Committee Service

Local

2005-2006	Student Representative, Administrative Committee, M.Phil. Epidemiology Course, Department of Public Health and Primary Care	University of Cambridge
2013-	Member, Program Management Committee, PORTAL, Division of Pharmacoepidemiology and Pharmacoeconomics	Brigham and Women's Hospital
2019-	Member, MPH-45 Admissions Committee	Harvard T.H. Chan School of Public Health
2019-	Faculty Wellness Representative	Division of Pharmacoepidemiology and Pharmacoeconomics, Brigham and Women's Hospital

Regional

2011-2013	Member, Maryland Regional Selection Committee	Jefferson Scholars Program, University of Virginia
2013-2016, 2018-	Member, Boston Regional Selection Committee	Jefferson Scholars Program, University of Virginia

National

2019	Member, Planning Committee, The Role of NIH in Drug Development Innovation and its Impact on Patient Access	The National Academies of Science, Engineering, and Medicine
2019-	Member, Graduate Selection Committee	Jefferson Scholars Program, University of Virginia

Professional Societies

2013-2014	Maryland State Bar Association	Member
2013-	International Society for	

	Pharmacoepidemiology	
	2014, 2018, 2019, 2020	Member, Abstract Reviewing Panel
	2015	Member, Abstract Organizing Committee
	2015	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

			(Full-Merit Award)
2003	Phi Beta Kappa Society	University of Virginia	Academic Excellence
2005	Woodward Award	Groton School	Service Beyond Call of Duty
2010	John L. Thomas Leadership Scholarship	University of Maryland School of Law	Leadership, Scholarship (Full-Merit Award)
2013	Joseph Bernstein Award	University of Maryland School of Law	Excellence in Legal Writing
2013	Cunningham Award	University of Maryland School of Law	Citizenship, Leadership
2016	Partners in Excellence Award	Partners HealthCare, Boston, MA	Leadership and Innovation

Report of Funded Projects

Past

2014-2016 State pharmacy laws affecting generic prescription drug substitution: their effecton public health
Robert Wood Johnson Foundation Public Health Law Research (I.D. 72231)
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 of how regulatory warnings are related to medication safety impact health care delivery and identify a set of 'best practices' contributing to effectiveness, by comparing medication safety advisories in Australia, Canada, the 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, first-year medical students	Problem-Based Learning Facilitator Barts and the London School of Medicine 3 hours per session for 5 sessions
2008	Introduction to metabolism, first-year medical students	Problem-Based Learning Facilitator Barts and the London School of Medicine 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	Royal London Hospital

	records by medical students for registry study	Varied levels of mentorship, from daily to weekly, lasting months
2015-	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 Lara Bishay, M.D., M.P.H. / M.Sc. Student (2018) / Harvard T.H. Chan School of Public Health
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 Jonathan DiBello / M.P.H. Student (2018) / Harvard T.H. Chan School of Public Health
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- 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- 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

2016-2017 Michael S. Sinha, M.D., J.D., M.P.H. / Research fellow, Harvard-MIT Center for Regulatory Science
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 publication

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

Petrie Flom Center for Health Law Policy, Biotechnology, and Bioethics Annual Conference, Harvard Law School, Cambridge, MA

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 and New Technologies (2015) (Eds. Holly Fernandez Lynch & I. Glenn Cohen) / 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 Pharmacoeconomic 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 and New Technologies (2018) (Eds. I. Glenn Cohen, Holly Fernandez Lynch, Urs 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

2019 Book launch, Transparency in Health and Health Care in the United States (2019) (Eds. Holly Fernandez Lynch, I. Glenn Cohen, Carmel Shachar, Barbara J. Evans) / Speaker
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 Pharmacoeconomics 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 Prospects for IP incentives reform: orphan drugs as a case study / Speaker [Video Link]
US-Europe Access to Medicines Capacity Building and Strategy Meeting, Brussels, Belgium

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 (2017-2018) 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

(6) current debates over the scope of FDA regulation. Course site: https://bit.ly/2TZi9zq.

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
2007-2008	The Platelet [Newsletter] / Contributing Writer
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	NEJM Podcast: Can transparency cut drug spending?	Guest	https://bit.ly/2HGyVLZ
2016	This Week in Health Law Podcast	Guest	https://bit.ly/2sNTtxx
2016	NEJM Group Open Forum: Big data meets big medicine	Expert	https://bit.ly/2emFARS
2017	National Academy for State Health Policy Webinar: A call to action	Co-Presenter	https://bit.ly/2JuhSmg
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	Boston Globe Op-Ed: Don't limit the powers of the FDA	Co-Author	https://bit.ly/2y0agTl
2017	AMA Journal of Ethics Discussion Forum: The ethical challenges of compassionate use in modern medical care.	Expert	https://bit.ly/2MjECTW
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

2008	Press mention of scholarship (Research Investigation #1): ASH: thrombosis risk increased in ITP. Medpage Today.	https://bit.ly/2JIMG1P
2016	Press mention of scholarship (Other Peer-Reviewed Publication #10): Drug price transparency laws may not drive down spiraling costs for consumers. KQED News.	https://bit.ly/2l2xBu1
2016	Press mention of scholarship (Other Publication #10): A new way to cut drug prices? Make big pharma show what it spends to bring drugs to market. Los Angeles Times.	https://lat.ms/28LVlyd
2016	Press mention of scholarship (Research Investigation #11): What drives high drug prices? Becker's Hospital Review.	https://bit.ly/2Mg6FmZ
2016	Regulatory Focus: Academics to follow on Twitter	https://bit.ly/2LJ0s6r
2017	Press mention of scholarship (Research Investigation #11): The unaffordable cost of M&A-driven drug prices. Modern Healthcare	https://bit.ly/2y0i3R5
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): Why the price of prescription drugs in the US is out of control. Business Insider.	https://read.bi/2cLLQ1R
2017	Press mention of scholarship (Research Investigation #11):	https://cbsn.ws/2coZ6vV

	What's behind the sharp rise in prescription drug prices? CBS.	
2017	Press mention of scholarship (Research Investigation #11): Without competition, drug prices soar. Boston Globe.	https://bit.ly/2y25btE
2018	Press mention of scholarship (Research Investigation #17): Market exclusivity is not what attracts orphan drug investment, research finds. Regulatory Focus.	https://bit.ly/2JCTuLl
2018	Press mention of scholarship (Other Peer Review Publication #18): 4 ambiguities FDA should address about right to try. Becker's Hospital Review.	https://bit.ly/2NKRPVe
2018	Press mention of scholarship (Research Investigation #20): Review addresses obstacles to US biosimilar entry and uptake. Regulatory Focus.	https://bit.ly/2swWLVy
2019	Press mention of scholarship (Other Peer Review Publication #21): Fentanyl REMS program falls short. Medscape.	https://wb.md/2Uj5VkA
2019	Press mention of scholarship (Research Investigation #26): Brand-brand competition is unlikely to reduce list prices of medicines. Science Daily.	https://bit.ly/2LHLQ5Q
2019	Press mention of scholarship (Research Investigation #26): Brand-brand competition is unlikely to reduce list prices of medicines. Harvard Business School Working Knowledge.	https://hbs.me/2LJSDMo
2020	Press mention of scholarship (Research Investigation #39): Calls for more transparency in gray area of post-approval drug studies. Medscape.	https://wb.md/38mZDu6
2020	Press mention of scholarship (Other Peer Review Publication #30): Revise remdesivir EUA to add registry, say researchers. Regulatory Focus.	https://bit.ly/3lbV4Gx
2020	Press mention of scholarship (Research Investigation #42): Aligning costs with benefit for cancer drugs: success in Germany. Medscape.	https://wb.md/3ld6UR1
2020	Press mention of scholarship (Research Investigation #41): Pharmacists say they tell patients about physical changes to pills, but consumers say that isn't always the case. Pharmalot.	https://bit.ly/32rcesz
2020	Press mention of scholarship (Research Investigation #45): Generic drug substitution laws vary greatly across US. Healio.	https://bit.ly/3n7ViPU

2020	Press mention of scholarship (Research Investigation #45): Pharmacists not required to substitute generics for brand-name drugs in most US states. Reuters.	https://wb.md/358s7pE
2020	Press mention of scholarship (Research Investigation #47): Testing requirements are likely slowing biosimilar entries in the US. Regulatory Focus.	https://bit.ly/35cvfAA

Report of Scholarship

Peer-Reviewed Publications in Print or Other Media

Research Investigations

1. Stasi R, **Sarpatwari A**, Segal JB, Osborn J, Evangelista ML, Cooper N, Provan D, Amadori S, Bussel JB. Effects of eradication of Helicobacter pylori infection in patients with immune thrombocytopenic purpura: a systematic review. Blood. 2009;113:1231-40.

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