

Curriculum Vitae

Date Prepared: August 2, 2022
Name: Michael S. Sinha, M.D., J.D., M.P.H.
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Place of Birth: Saint Louis, MO

Education

2015	M.P.H.	Law and Public Health	Harvard T.H. Chan School of Public Health, Boston, MA
2012	J.D. (<i>cum laude</i>)	Law	SIU School of Law, Carbondale, IL
2012	M.D.	Medicine	Southern Illinois University (SIU) School of Medicine, Springfield, IL
2003	B.A. (<i>cum laude</i>)	Biophysical Chemistry (Honors)	Dartmouth College, Hanover, NH

Postdoctoral Training

2018-2021	Regulatory Science Fellow	Harvard-MIT Center for Regulatory Science (HMCRS)	Harvard Program in Therapeutic Science (HiTS), Harvard Medical School, Boston, MA
2016-2018	Postdoctoral Fellow	Pharmaceutical Law and Health Services Research	Program On Regulation, Therapeutics, And Law (PORTAL), Brigham and Women's Hospital, Boston, MA
2015-2016	Medical Resident	Internal Medicine	Boston Medical Center, Boston, MA
2012-2014	Medical Resident	Internal Medicine / Preventive Medicine	Griffin Hospital, Derby, CT

Academic Appointments

2022-	Assistant Professor	Center for Health Law Studies	Saint Louis University School of Law, Saint Louis, MO
2022	Adjunct Faculty	Beazley Institute for Health Law and Policy	Loyola University Chicago School of Law, Chicago, IL
2020-2022	Lecturer	Health Sciences / Public Health	California State University East Bay, Hayward, CA
2020-2021	Teaching Faculty	Center for Bioethics	Harvard Medical School, Boston, MA
2019-2021	Adjunct Faculty	Health Law and Intellectual Property	Northeastern University School of Law, Boston, MA
2019-2021	Visiting Scholar	Center for Health Policy and Law	Northeastern University School of Law, Boston, MA
2018-2021	Research Fellow	Regulatory Science	Harvard Medical School, Boston, MA
2016-2018	Research Fellow	Pharmaceutical Law and Health Services Research	Harvard Medical School, Boston, MA

Other Professional Positions

2021-	Research Collaborator	HMCERS	Harvard Medical School, Boston, MA
2020-2021	Regulatory and Legal Team Lead	Greater Boston Pandemic Fabrication Team	HMCERS, Harvard Medical School, Boston, MA
2018-	Affiliated Researcher	PORTAL	Brigham and Women's Hospital, Boston, MA
2018-	Collaborating Researcher	Incentives for Antibiotic Development	Centre for Advanced Studies in Biomedical Innovation Law (CeBIL), University of Copenhagen, Denmark
2008	Summer Legal Intern	Office of Scientific and Regulatory Policy	Division of Global Medical, Regulatory and Safety, Eli Lilly & Co., Indianapolis, IN
2006-2007	Research Assistant	Health Law	SIU School of Law, Carbondale, IL
2004-2005	Research Technician II	Medical Oncology	Molecular Oncology Division, Department of Medicine, Washington University School of Medicine, St. Louis, MO
2003-2004	Research Assistant	Ocular Oncology	Department of Ophthalmology and Visual Sciences, Washington University School of Medicine, St. Louis, MO
2001-2003	Undergraduate Honor's Thesis Research	Organic Chemistry	Department of Chemistry, Dartmouth College, Hanover, NH

Report of Scholarship

Legal Scholarship

Law Journal Publications

1. *EACH Person's Right: The Importance of Federal Abortion Care Funding to Health Care Reform* (with Cassandra LaRose), 48 AM. J. L. & MED. ____ (forthcoming) (symposium)
2. *Costly Gadgets: Barriers to Market Entry and Price Competition for Generic Drug-Device Combinations in the United States*, 23 MINN. J. L. SCI. & TECH. 293 (2022).
3. *The Other Three Waves: Re-assessing the Impact of Industry-Prescriber Relations on the Opioid Crisis* (with Jessica Bresler), 41 J. LEGAL MED. 47 (2021).
4. *Neither Ethical Nor Effective: The False Promise of Involuntary Commitment to Address the Overdose Crisis* (with John C. Messinger and Leo Beletsky). 48 J. L. MED. & ETHICS 741 (2020).
5. *Applying the Proportionality Principle to COVID-19 Antibody Testing* (with Hrefna D. Gunnarsdottir, Sara Gerke, & Timo Minssen). 7 J. L. BIOSCIENCES Isaa058 (2020).
6. *Generic But Expensive: Why Prices Can Remain High for Off-Patent Drugs* (with Aaron S. Kesselheim & Frazer A. Tessema), 71 HASTINGS L. J. 101 (2020).
7. *Pharmaceutical Policy in the United States in 2019: An Overview of the Landscape and Avenues for Improvement* (with Aaron S. Kesselheim, Jerry Avorn & Ameet Sarpatwari), 30 STAN. L. & POL'Y REV. 421 (2019).
8. *The Tax Cuts and Jobs Act of 2017 and the Pharmaceutical Industry* (with Aaron S. Kesselheim), 46 J. L. MED. & ETHICS 806 (2018).
 - Discussed in two BIOPHARMA DIVE articles

9. *Expansion of the Priority Review Voucher Program under the 21st Century Cures Act: Implications for Innovation and Public Health* (with Nina Jain, Thomas J. Hwang & Aaron S. Kesselheim), 44 AM. J. L. & MED. 329 (2018). (symposium)
 - Cited by the Government Accountability Office (January 2020, GAO-20-251) and in testimony to the U.S. House Committee on Energy and Commerce (July 2020).
10. *When Markets Fail: Patents and Infectious Disease Products* (with Jonathan J. Darrow & Aaron S. Kesselheim), 73 FOOD & DRUG L. J. 361 (2018).
 - Discussed in RAPS REGULATORY FOCUS article
11. *The Opioid Epidemic: Fixing a Broken Pharmaceutical Market* (with Ameet Sarpatwari & Aaron S. Kesselheim), 11 HARV. L. & POL'Y REV. 463 (2017).
12. *The Perils of Panic Ebola, HIV, and the Intersection of Global Health and Law* (with Wendy E. Parmet), 42 AM. J. L. & MED. 223 (2016) (symposium)
13. *Barking Up the Wrong Tree: The FDA's Misguided Attempt to Waive Informed Consent in Public Health Emergencies*, 28 J. LEGAL MED. 397 (2007). (student comment)
 - Nominated for the Scribes Law Review Award

Federal Comments

1. *COVID-19 Emergency Temporary Standard Rulemaking; Occupational Safety and Health Administration* (with David Michaels, Peg Seminario, and more than 100 cosigned experts in occupational safety and health, medicine, epidemiology, industrial hygiene, aerosol science, public health law and other relevant fields), April 22, 2022, <https://www.regulations.gov/comment/OSHA-2020-0004-2033>.
2. *Phased Approach to the Resumption of Cruise Ship Passenger Operations 2021-09094* (revised and contributed to 20 law student submissions as part of the Summer 2021 Problems in Public Health Law course at NUSL), June 30, 2021, <https://www.regulations.gov/document/CDC-2021-0011-0001>.
3. *Listing of Patent Information in the Orange Book; Establishment of a Public Docket; Request for Comments; Reopening of Comment Period* (with Reed F. Beall), April 15, 2021, <https://www.regulations.gov/comment/FDA-2020-N-1127-0028>.
4. *National Institute of Standards and Technology (NIST) Request for Comments; Rights to Federally Funded Inventions and Licensing of Government Owned Inventions*, April 6, 2021, <https://www.regulations.gov/comment/NIST-2021-0001-15844>.
5. *Treatment of E-Cigarettes in the Mail* (revised and contributed to 10 law student submissions as part of the Spring 2021 Problems in Public Health Law course at NUSL), March 22, 2021, <https://www.regulations.gov/document/USPS-2021-0027-0001>.
6. *FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic; Guidance for Industry, Investigators, and Institutional Review Boards* (with Deborah Plana & Andrea Arfé), July 13, 2020, <https://www.regulations.gov/document?D=FDA-2020-D-1106-0139>.
7. *Tobacco Products; Required Warnings for Cigarette Packages and Advertisements* (revised and contributed to 7 law student submissions as part of the Fall 2019 Drug Law & Policy course at NUSL), November 27, 2019, <https://www.regulations.gov/document/FDA-2019-N-3065-0001>.
8. *FDA Solicits Input on Potential Role for Abuse-Deterrent Formulations of Central Nervous System Stimulants; Establishment of a Public Docket; Request for Comments*, November 18, 2019, <https://www.regulations.gov/document?D=FDA-2019-N-3403-0886>.
9. *Standards for Future Opioid Analgesic Approvals and Incentives for New Therapeutics to Treat Pain and Addiction; Public Hearing*, November 18, 2019, <https://www.regulations.gov/document?D=FDA-2019-N-2514-0396>.
10. *Comments on Public Meeting: Responsible Innovation in Dietary Supplements*, July 17, 2019, <https://www.regulations.gov/document?D=FDA-2019-N-1388-0064>.

11. *Comments on Regulatory Provisions: 'Inadmissibility on Public Charge Grounds'* (with Public Health Law Watch), December 7, 2018, <https://www.regulations.gov/docket?D=USCIS-2010-0012>.
12. *A Response to "Unintended Consequences: Medicaid and the Opioid Crisis"* (with Public Health Law Watch), February 14, 2018, <https://www.publichealthlawwatch.org/blog/2018/2/14/a-response-to-unintended-consequences-medicare-and-the-opioid-crisis>.
13. *Comments on Public Meeting: 'Administering the Hatch-Waxman Amendments: Ensuring a Balance Between Innovation and Access'* (with Ameet Sarpatwari & Aaron Kesselheim), Nov 10, 2017, <https://www.regulations.gov/document?D=FDA-2017-N-3615-0092>.
14. *Comments on Public Workshop: 'Generic Drug User Fee Amendment of 2012'* (with Aaron S. Kesselheim), Jun 2, 2017, <https://www.regulations.gov/document?D=FDA-2013-N-0402-0034>.

Book Chapters

1. *Addressing Regulatory Exclusivity Issues During the COVID-19 Pandemic* (with Sven J.R. Bostyn & Timo Minssen), in *COVID-19 AND THE LAW: DISRUPTION, IMPACT, AND LEGACY* (I. Glenn Cohen, Abbe D. Gluck, Katherine Kraschel & Carmel Shachar, eds.) (forthcoming 2022). Available on SSRN: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3889894.
2. *Identifying and Eradicating Gender Discrimination and Sexual Harassment of Women Physicians in the United States* (with Christine A. Heisler, Melissa Blaker, Elizabeth H. Stephens, Kate Walsh, Pringl Miller & Sarah M. Temkin), in *GLOBAL PERSPECTIVES ON SEXUAL HARASSMENT IN MEDICINE* (Louise Stone, ed.) (forthcoming 2022)
3. *Strategies to Address the Chronic Shortage of N95 Masks and Other Filtering Facepiece Respirators During the COVID-19 Pandemic*, in *COVID-19 POLICY PLAYBOOK: LEGAL RECOMMENDATIONS FOR A SAFER, MORE EQUITABLE FUTURE* (Scott Burris, Sarah de Guia, Lance Gable, Donna E. Levin, Wendy E. Parmet, Nicolas P. Terry, eds.) Boston: Public Health Law Watch, 2021. Available on SSRN: <https://ssrn.com/abstract=3808308>.
4. *COVID-19: State and Local Responses to PPE Shortages*, in *ASSESSING LEGAL RESPONSES TO COVID-19* (Scott Burris, Sarah de Guia, Lance Gable, Donna E. Levin, Wendy E. Parmet, Nicolas P. Terry, eds.) Boston: Public Health Law Watch, 2020. Available on SSRN: <https://ssrn.com/abstract=3675861>.
5. *Chapter 28 - Mental Health Issues* (with Ross D. Silverman), in *ILLINOIS PRACTICE SERIES, VOLS. 21 & 22: THE LAW OF MEDICAL PRACTICE IN ILLINOIS* (Robert J. Kane, Ross D. Silverman & Larry E. Singer, eds., Supp. 2011).

Amicus Briefs

1. *Brief of Amici Curiae 6 Former CDC Directors, 20 Leading Public Health Organizations, and 231 Public Health Experts in Support of Defendants-Appellants and Reversal*, Health Freedom Defense Fund v. President of the United States (U.S. Court of Appeals for the Eleventh Circuit), 2022.
2. *Motion of American Public Health Association, Association of Schools and Programs of Public Health, 12 Leading Public Health and Health Care Organizations, 30 Deans of Leading Academic Programs, and 109 Leading Public Health and Health Policy Scholars for Leave to File Attached Brief as Amici Curiae in Support of Respondents*, In re MCP No. 165, Occupational Safety & Health Administration, Interim Final Rule: COVID-19 Vaccination & Testing, 86 Fed. Reg. 61402 (U.S. Supreme Court), 2021, https://www.supremecourt.gov/DocketPDF/21/21A244/206948/20211230132243997_21A244%20-247%20bsac%20American%20Public%20Health%20Assoc.pdf.

3. *Brief of Amici Curiae Professors of Health Law and Policy in Support of Petitioner*, Ruan v. United States (U.S. Supreme Court), 2021, https://www.supremecourt.gov/DocketPDF/20/20-1410/206387/20211223153256418_Ruan%20Amici%20-%20Professors%20of%20Health%20Law%20and%20Policy%20-%20Brief%20-%202012-23-2021.pdf.
4. *Motion of American Public Health Association, Association of American Medical Colleges, 22 Deans of Leading Academic Programs, and 126 Leading Public Health and Health Policy Scholars for Leave to File Attached Brief as Amici Curiae in Support of Applicants*, Biden v. State of Missouri (U.S. Court of Appeals for the Eighth Circuit) and Becerra v. State of Louisiana (U.S. Court of Appeals for the Fifth Circuit), 2021, https://www.supremecourt.gov/DocketPDF/21/21A240/206355/20211223134535380_21A240%20-241%20Amici%20Brief%20American%20Public%20Health%20Assoc.pdf.
5. *Motion to File Brief Amicus Curiae by Public Health Associations and Public Health Scholars Supporting Respondents*, We The Patriots, et al. v. Hochul, U.S. Supreme Court, 2021, https://www.supremecourt.gov/DocketPDF/21/21A125/199645/20211110205927191_2021.11.06%20-%20Vaccine%20Mandates%20Public%20Health%20Scholars%20MOTION%20FINAL.pdf
6. *Brief of Public Health Scholars and Practitioners Supporting Respondents*, John Doe, et al. v. Mills (U.S. Supreme Court), 2021, https://www.supremecourt.gov/DocketPDF/21/21A90/198025/20211028141652778_2021.10.28%20-%20Vaccine%20Mandates%20Public%20Health%20Scholars.pdf
7. *Amici Curiae Brief of 547 Deans, Chairs, Scholars and Public Health Professionals, the American Public Health Association, and the Guttmacher Institute, the Center for U.S. Policy, in Support of Respondents*, Dobbs v. Jackson Women’s Health Organization (U.S. Supreme Court), 2021, https://www.supremecourt.gov/DocketPDF/19/19-1392/193052/20210920164243798_19-1392%20Brief.pdf.
8. *Brief of Amici Curiae Professors of Health Law and Policy in Support of Practitioner*, Ruan v. United States (U.S. Court of Appeals for the Eleventh Circuit), 2021, https://www.supremecourt.gov/DocketPDF/20/20-1410/178631/20210507164642254_Ruan%20Amici%20Brief%20-%20Final%20for%20Filing%20-%202020-05-07-2021.pdf.
9. *Brief of Amici Curiae in Support of the Defendants*, Terkel v. Centers for Disease Control and Prevention (U.S. Court of Appeals for the Fifth Circuit), 2021.
10. *Brief of Amici Curiae in Support of the Defendants*, Chambless v. Centers for Disease Control and Prevention (U.S. Court of Appeals for the Fifth Circuit), 2021, <https://pacificlegal.org/wp-content/uploads/2020/10/Chambless-Enterprises-LLC-v.-CDC-PLF-Opening-Brief.pdf>.
11. *Public Health Amici Curiae Brief in Support of the Centers for Disease Control and Prevention Eviction Moratorium*, Brown v. Azar (U.S. District Court for the Northern District of Georgia, Atlanta Division), 2020, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3708504
12. *Brief of Amici Curiae 57 Law, Economics, Business, Health, and Medicine Professors in Support of Cross-Appellant's Petition for Rehearing En Banc*, GlaxoSmithKline v. Teva Pharmaceuticals (U.S. Court of Appeals for the Federal Circuit), 2020, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3750396.
13. *Amici Curiae Brief of 66 Law, Economics, Business, and Medical Professors in Support of Plaintiffs-Appellants*, UFCW Local 1500 Welfare Fund v. AbbVie (U.S. Court of Appeals for the Seventh Circuit), 2020, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3708338.
14. *Motion for Leave to File Amicus Brief of Proposed Amici Curiae Health Law Advocates, Health Care for All, and the Public Health Law Watch in Opposition to Plaintiff's Motion for Preliminary Injunction*, Matorin v. Commonwealth of Massachusetts (Suffolk County Superior Court, Commonwealth of Massachusetts), 2020, <https://www.healthlawadvocates.org/pdfs/2020.07.24-HLA-Matorin-Amicus-Motion-for-Leave-and-Exhibit-1-FINAL.pdf>

15. *Brief in Support of Appellant by Amici Curiae the Health in Justice Action Lab at Northeastern University School of Law and the Center for Public Health Research at Temple University School of Law, Joined by Several Law Professors, Public Health Organizations, and Affected Families Working to Reduce Overdose Deaths*, United States v. Semler (U.S. Court of Appeals for the Third Circuit), 2020, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3717117.
16. *Brief of Biomedical Ethicists Ruth R. Faden, Ph.D., M.P.H. et al., as Amici Curiae in Support of Petitioners*, EMW Women's Surgical Center v. Meier (U.S. Supreme Court), 2019, https://www.supremecourt.gov/DocketPDF/19/19-417/120523/20191028162658319_19-417_Amici%20Brief%20in%20Support%20of%20Petitioners.pdf.
17. *Brief of Amici Curiae Health Law Advocates in Support of Plaintiffs' Motion for Preliminary Injunction*, State of Washington v. U.S. Department of Homeland Security (U.S. Court of Appeals for the Fourth Circuit), 2019, <https://www.healthlawadvocates.org/pdfs/90.1-Exhibit-1-Amicus-Brief.pdf>.
18. *Brief Amici Curiae of 82 Law, Economics, Business, and Medical Professors in Support of Respondent*, Impax Laboratories v. Federal Trade Commission (U.S. Court of Appeals for the Fifth Circuit), 2019, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3504773.

Peer-Reviewed Scientific or Medical Publications

Research investigations

1. *Differences in Prescription Drug Utilization and Costs among Patients with Diabetes Enrolled in Marketplace and Medicaid Plans* (with Peggah Khorrami, Aditi Bhanja, Heidi L. Allen, Aaron S. Kesselheim & Benjamin D. Sommers), 5 JAMA NETWORK OPEN e2140371.
 - Discussed in ENDOCRINOLOGY ADVISOR, MD MAGAZINE, AMERICAN JOURNAL OF MANAGED CARE, and MEDPAGE TODAY articles
2. *De novo Powered Air-Purifying Respirator Design and Fabrication for Pandemic Response* (with Akshay Kothakanda, Lyla Atta, Deborah Plana, Ferrous Ward, Chris Davis, Avilash Cramer, Robert Moran, Jacob Freake, Enze Tian, Ofer Mazor, Pavel Gorelik, Christopher Van, Christopher Hansen, Helen Yang, Ju Li, Sherry H. Yu, Nicole R. LeBoeuf & Peter K. Sorger) FRONTIERS IN BIOTECHNOLOGY (BIOSAFETY AND BIOSECURITY) (2021, <https://www.frontiersin.org/articles/10.3389/fbioe.2021.690905/>).
3. *Assessing the quality of nontraditional N95 filtering face-piece respirators available during the COVID-19 pandemic* (with Deborah Plana, Enze Tian, Avilash K. Cramer, Helen Yang, Mary M. Carmack, Florence T. Bourgeois, Sherry H. Yu, Peter Masse, Jon Boyer, Minjune Kim, Jinhan Mo, Nicole R. LeBoeuf, Ju Li, and Peter K. Sorger). 21 BMC INFECTIOUS DISEASES 712 (2021).
4. *A Crisis-Responsive Framework for Medical Device Development during the COVID-19 Pandemic* (with Marc-Joseph Antonini, Deborah Plana, Shriya Srinivasan, Lyla Atta, Aditya Achanta, Helen Yang, Avilash Cramer, Jacob Freake, Sherry H. Yu, Nicole R. LeBoeuf, Ben Linville-Engler, and Peter K. Sorger). FRONTIERS IN DIGITAL HEALTH (HEALTH TECHNOLOGY INNOVATION) (2021: <https://www.frontiersin.org/articles/10.3389/fdgth.2021.617106/abstract>).
5. *Factors affecting buprenorphine utilization and spending in Medicaid, 2002-2018* (with Rachel E. Barenie & Aaron S. Kesselheim). 24 VALUE IN HEALTH 182 (2021).
6. *Addressing the surgical shortage: revisiting residency training requirements for international medical graduates* (with Karim W. Sadik), 2 CLINICAL SURGERY J. 1 (2021).

7. *Fentanyl panic goes viral: The spread of misinformation about overdose risk from casual contact with fentanyl in mainstream and social media* (with Leo Beletsky, Sarah Seymour, Sunyou Kang, Zachary Siegel, Ryan Marino, Aashka Dave & Clark Freifeld). 16 INT'L. J. DRUG POL'Y. 102951 (2020).
 - Discussed in MIAMI HERALD, VICE, PHILADELPHIA INQUIRER, NEW YORK TIMES, LOS ANGELES TIMES, and ABC NEWS articles
8. *Analysis of the SteraMist ionized hydrogen peroxide fogging system as a method to sterilize N95 masks and other PPE* (with Avilash K. Cramer, Deborah Plana, Helen Yang, Enze Tian, Mary M. Carmack, David Krikorian, David Turner, Ju Li, Rajiv Gupta, Heather Manning, Florence T. Bourgeois, Sherry H. Yu, Peter K. Sorger & Nicole R. LeBoeuf). SCIENTIFIC REPORTS. 2020.
9. *Regulatory and safety considerations in deploying a locally-fabricated, reusable, face shield in a hospital responding to the COVID-19 pandemic* (with Arash Mostaghimi, Marc-Joseph Antonini, Deborah Plana, Philip D. Anderson, Brandon Beller, Edward W. Boyer, Amber Fannin, Jacob Freake, Richard Oakley, Leanne Smith, Christopher Van, Helen Yang, Peter K. Sorger, Nicole R. LeBoeuf & Sherry H. Yu). MED. (2020, <https://doi.org/10.1016/j.medj.2020.06.003>).
10. *Estimating the Cost of Delayed Generic Drug Entry to Medicaid* (with Chintan V. Dave, Reed F. Beall & Aaron S. Kesselheim), 39 HEALTH AFFAIRS (MILLWOOD) 1011 (2020).
11. *FDA and EMA Biosimilar Approvals* (with Emily H. Jung, Ameet Sarpatwari & Aaron S. Kesselheim), 35 J. GEN. INTERNAL MED. 1908 (2020).
12. *Prescription Opioid Epidemic and Trends in the Clinical Development of New Pain Medications* (with Thomas J. Hwang, Chintan V. Dave & Aaron S. Kesselheim), 94 MAYO CLINIC PROCEEDINGS 2437 (2019).
13. *Multimodal Analysis of FDA Drug Safety Communications: Lessons from Zolpidem* (with Aaron S. Kesselheim, Eric G. Campbell, Sebastian Schneeweiss, Paula Rausch, Brian M. Lappin, Esther H. Zhou, Jerry Avorn & Gerald J. Dal Pan), 42 DRUG SAFETY 1287 (2019).
14. *Patients' Knowledge of Key Messaging in Drug Safety Communications for Zolpidem and Eszopiclone: A National Survey* (with Aaron S. Kesselheim, Paula Rausch, Zhigang Lu, Frazer A. Tessema, Brian M. Lappin, Esther H. Zhou, Gerald J. Dal Pan, Lee Zwanziger, Amy Ramanadham, Cheryl Enger, Jerry Avorn & Eric G. Campbell), 47 J. L. MED. & ETHICS 430 (2019).
15. *Labeling Changes and Costs for Clinical Trials Performed under the US Food and Drug Administration Pediatric Exclusivity Extension, 2007 to 2012* (with Mehdi Najafadeh, Elizabeth K. Rajasingh, James Love & Aaron S. Kesselheim), 178 JAMA INTERNAL MED. 1458 (2018).
 - Discussed in RAPS REGULATORY FOCUS, STAT NEWS, MEDSCAPE MEDICAL NEWS, PHARMACO-ECONOMICS & OUTCOMES NEWS, and POLITICO PRESCRIPTION PULSE articles
16. *Uptake of FDA Drug Safety Communication Messages about Zolpidem in Social Media* (with Clark C. Freifeld, John S. Brownstein, Macarius Donneyong, Paula Rausch, Brian M. Lappin, Esther H. Zhou, Gerald J. Dal Pan, Ajinkya M. Pawar, Thomas J. Hwang, Jerry Avorn & Aaron S. Kesselheim), 4 JMIR PUB. HEALTH & SURVEILLANCE e1 (2018).
 - Discussed in RAPS REGULATORY FOCUS, FDANEWS, FORTUNE, MEDI:GATE NEWS, and MEDSHADOW articles
17. *Determinants of Market Exclusivity for Prescription Drugs in the United States* (with Aaron S. Kesselheim & Jerry Avorn), 177 JAMA INTERNAL MED. 1658 (2017).
18. *Regulatory Incentives for Antibiotic Drug Development: A Review of Recent Proposals* (with Aaron S. Kesselheim), 24 BIOORGANIC & MEDICINAL CHEMISTRY 6446 (2016).
19. *Physicians and Insider Trading* (with Aaron S. Kesselheim & Steven Joffe), 175 JAMA INTERNAL MED. 1955 (2015).

20. *The Impact of Tort Reform and Quality Improvements on Medical Liability Claims: A Tale of 2 States* (with Kenneth D. Illingworth, Steven H. Shaha, Tony H. Tzeng & Khaled J. Saleh), 30 AM. J. MED. QUALITY 263 (2015).
21. *Novel Indole Chemistry in the Synthesis of Heterocycles* (with Gordon W. Gribble, et al.), 9 CURR. ORGANIC CHEMISTRY 1493 (2005).

Other peer-reviewed medical publications

1. *Realigning Incentives for Novel Pain Therapeutics* (with Kelly K. Dineen Gillespie) ____ ANESTHESIOLOGY ____ (forthcoming).
2. *AM Last Page: How Male Allies Can Support the Advancement of Women in Academic Medicine* (with Kristina Dzara and Stephanie K. Mueller) ____ ACADEMIC MED. ____ (forthcoming).
3. *Patient Assistance Programs and the Anti-Kickback Statute: Charting a Pathway Forward* (with Aaron S. Kesselheim and Christopher T. Robertson) 327 J. AM. MED. ASS'N 1231 (2022).
4. *Return to Work During COVID-19: Temperature Screening is No Panacea* (with David H. Slade). 42 INFECTION CONTROL & HOSPITAL EPIDEMIOLOGY 1166 (2021).
 - Discussed in THE INTERCEPT
5. *The Wrong Cure: Financial Incentives for Unimpressive New Antibiotics* (with John H. Powers, III and Aaron S. Kesselheim). 223 J. INFECTIOUS DISEASES 1506 (2021).
6. *Personal Protective Equipment for COVID-19: Distributed Fabrication and Additive Manufacturing* (with Florence T. Bourgeois and Peter K. Sorger). 110 AM. J. PUBLIC HEALTH 1162 (2020).
7. *Covid-19 – The Law and Limits of Quarantine* (with Wendy E. Parmet). 382 NEW ENGL. J. MED. e28 (2020).
8. *What Does It Mean to Be a Male Ally? Implementing Meaningful Change in Gender Representation in Medicine* (with Skihka Jain, Katayoun Madani, Lewis Flint, Mamta Swaroop, Howard Liu, Thomas Varghese, and Julie Silver). 230 J AM. COLLEGE SURGEONS 355 (2020).
9. *Sexual Harassment in Medicine: Toward Legal Clarity and Institutional Accountability* (with Julie K. Silver), 7 ECLINICALMEDICINE 3 (2019). (editorial)
10. *Micro-inequities in Medicine: Legal and Ethical Implications*, 10 PHYSICAL MED. & REHABILITATION 1106 (2018).
11. *Antitrust, Market Exclusivity, and Transparency in the Pharmaceutical Industry* (with Gregory D. Curfman & Michael A. Carrier), 319 J. AM. MED. ASS'N. 2271 (2018).
 - Nominated for the Best Business Article of the Year, Concurrences Antitrust Law Awards
12. *The Next Forum for Unraveling FDA Off-Label Marketing Rules: State and Federal Legislatures* (with Aaron S. Kesselheim), 15 PLOS MED. e1002564 (2018). (editorial)
 - Discussed in STAT NEWS, BLOOMBERG LAW, MEDSCAPE MEDICAL NEWS, and MANAGED CARE
13. *Pharmaceutical Advertising in Medical Journals: Revisiting an Old Relationship* (with Aaron S. Kesselheim & Jonathan J. Darrow), 153 CHEST 9 (2018). (editorial)
14. *The Effects of the Sunshine Act: What Can and Should We Expect?* (with Aaron S. Kesselheim), 17 AM. J. BIOETHICS 22 (2017).
15. *A Panic Foretold: Ebola in the United States* (with Wendy E. Parmet), 27 CRITICAL PUB. HEALTH 148 (2017).
16. *Disclosure of Errors in Surgical Procedures* (with Marsha G. Ryan & Michele Mekel), 2016, updated 2018. UPTODATE.COM.
17. *Informed Procedural Consent* (with Marsha G. Ryan), 2011, updated 2018. UPTODATE.COM.
18. *Rousseau at the Roundtable – The Social Contract and the Physician's Responsibility to Society*, 13 AMA J. ETHICS 703 (2011).

Non-Peer Reviewed Scientific or Medical Publications

Op-eds and Blogs

1. *Letter from Legal and Public Health Experts to Senator Elizabeth Warren*, April 20, 2022, <https://www.warren.senate.gov/imo/media/doc/2022.4.20%20Letter%20to%20Warren%20on%20Drug%20Pricing%20Executive%20Authorities.pdf>.
2. *Patient advocacy organizations and FDA drug approval: Lessons from aducanumab* (with Stephen Latham), STAT NEWS FIRST OPINION, July 23, 2021, <https://www.statnews.com/2021/07/23/patient-advocacy-organizations-lessons-from-aducanumab/>.
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