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

U.S. House of Representatives
Witness Disclosure Requirement – "Truth in Testimony"
Required by House Rule XI, Clause 2(g)(5)

1. Your Name: Michelle Mello		
2. Your Title: Professor of Health Policy and of Law, Stanford University		
3. The Entity(ies) You are Representing: Stanford University School of Med Stanford Law School, and Stanford University's Institute for Human-Cer Artificial Intelligence.		
4. Are you testifying on behalf of the Federal, or a State or local government entity? (If "Yes," skip Item 5 and Item 6.)	Yes	No X
5. Grants, Contracts, and Payments		
a. Please list any <u>Federal grants or contracts</u> that you or the entity(ie represent have received <u>on or after January 1, 2023</u> . Only grants, payments related to the subject matter of the hearing must be liste	contrac	ts, or
I am unable to timely obtain a list of all federal grants and contracts received by Stanford University School of Medicine and Stanford Law School relating to artificial intelligence. If that is needed, I will need to refer you to financial administrators in each of those units of Stanford University.		
b. Please list any <u>contracts or payments originating with a foreign go</u> you or the entity(ies) you represent have received <u>on or after Janu</u> Only grants, contracts, or payments related to the subject matter of must be listed.	ary 1, 20	<u>)23</u> .
6. Are you a fiduciary (i.e., authorized to act on behalf of or for the benefit of) for any entity that has an interest in the subject matter of the hearing?		
7. Please attach your curriculum vitae to your completed disclosure form.		

CURRICULUM VITAE

Michelle M. Mello

Stanford Law School 559 Nathan Abbott Way, Stanford, CA 94305-8610

Tel. _____, Fax ________, Email:

EDUCATION:

2000	Law	J.D.	Yale Law School New Haven, CT
1999	Health Policy and Administration	Ph.D.	University of North Carolina at Chapel Hill, NC
1995	Comparative Social Research	M.Phil.	New College, University of Oxford, Oxford, England
1993	Political Science, Applied Ethics	B.A.	Stanford University, Stanford, CA

LICENSURE AND CERTIFICATION:

2001- Massachusetts State Bar

ACADEMIC APPOINTMENTS:

2021-	Professor of Law, Stanford Law School, and Professor of Health Policy, Department of Health Policy, Stanford University School of Medicine
2019-21	Professor of Law, Stanford Law School, and Professor of Medicine, Center for Health Policy / Primary Care and Outcomes Research, Department of Medicine, Stanford University School of Medicine
2014-19	Professor of Law, Stanford Law School, and Professor of Health Research and Policy, Stanford University School of Medicine
2014-17	Adjunct Professor of Law and Public Health, Department of Health Policy and Management, Harvard T.H. Chan School of Public Health

2008-14	Professor of Law and Public Health, Department of Health Policy and Management, Harvard School of Public Health
2006-08	C. Boyden Gray Associate Professor of Health Policy and Law, Department of Health Policy and Management, Harvard School of Public Health
2005-06	Associate Professor of Health Policy and Law, Department of Health Policy and Management, Harvard School of Public Health
2006	Visiting Lecturer, Faculty of Law, University of Otago, Dunedin, New Zealand
2000-05	Assistant Professor of Health Policy and Law, Department of Health Policy and Management, Harvard School of Public Health
<u>ACADEMIC</u>	CAFFILIATIONS:
2022-23	Faculty Research Fellow, Clayman Institute for Gender Research, Stanford University
2021-	Institute Faculty, Institute for Human Centered Artificial Intelligence, Stanford University
2020-	Faculty Affiliate, Freeman Spogli Institute for International Studies, Stanford University
2020-	Executive Committee, Center for Open and Reproducible Science (CORES), Stanford University
2017-	Faculty Fellow, Center for Innovation in Global Health, Stanford University
2014-	Affiliated Faculty, Meta-Research Innovation Center at Stanford (METRICS)
2014-	Affiliated Faculty, McCoy Family Center for Ethics in Society, Stanford University
2014-	Core Faculty, Health Policy PhD Program, Stanford University School of Medicine
2013-14	Residential Lab Fellow, Edmond J. Safra Center for Ethics, Harvard University
2013-14	Faculty Affiliate, Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School
HONORS A	ND DISTINCTIONS:
2024	Barbara Allen Babcock Award for Excellence in Teaching, Stanford Law School
2022	Ronald C. and Nancy V. Bishop Lecture in Bioethics, University of Michigan.
2022	John A. Benson Jr., MD Professionalism Article Prize, ABIM Foundation.
2021	Open Science Champion Prize, Center for Open and Reproducible Science (CORES), Stanford University
2018	David Barap Brin Visiting Professorship in Medical Ethics, Johns Hopkins University School of Medicine

2017	Dean's Distinguished Scholar in Law, Washington University School of Law
2015	Department of Health Policy and Management Alumni Leadership Award, Gillings School of Public Health, University of North Carolina at Chapel Hill
2013	Elected to National Academy of Medicine (formerly the Institute of Medicine)
2008-13	Robert Wood Johnson Foundation Investigator Award in Health Policy Research
2010	Roger L. Nichols Excellence in Teaching Award, Harvard School of Public Health
2006	Alice S. Hersh New Investigator Award, AcademyHealth
2005-09	Greenwall Faculty Scholar in Bioethics
2005	Citation for Excellence in Teaching, Harvard School of Public Health
2004	Citation for Excellence in Teaching, Harvard School of Public Health
2000	Delta Omega Honorary Public Health Society, Theta Chapter
1997-99	Beinecke Scholar
1995-97	Kenan Fellow, University of North Carolina
1997	Harry T. Phillips Award for Teaching, University of North Carolina
1995	Graduation with Distinction, Oxford University
1993-95	Marshall Scholar
1993	Lyle and Olive Cook Prize, Stanford University
1993	Graduation with Honors and Distinction, Stanford University
1991	Phi Beta Kappa
1990	Cottrell Prize for Political Science, Stanford University
SELECTED	EXTERNAL PROFESSIONAL SERVICE:
2023	NIH Clinical Center Board of Scientific Counselors
2022-24	Committee on Community Wastewater-based Infectious Disease Surveillance, National Academies of Sciences, Engineering and Medicine
2021-23	Mentor, Emerging Leaders in Health and Medicine Scholars Program, National Academy of Medicine
2020	Report Reviewer, National Academies of Sciences, Medicine and Medicine
2019	Report Review Monitor and Coordinator, National Academies of Sciences, Medicine and Medicine
2016-17	Committee on Ensuring Patient Access to Affordable Drug Therapies, National Academies of Sciences, Engineering and Medicine
2016-	Open Science Expert Panel, Patient-Centered Outcomes Research Institute (PCORI)
2016-17	Committee on Clinical Trials During the 2014-15 Ebola Outbreak, National

Academies of Sciences, Engineering, and Medicine

2015-24	Advisory Board, McCoy Family Center for Ethics in Society, Stanford University
2014-19	Technical Expert Panel, Agency for Healthcare Research and Quality Patient Safety Net (AHRQ PSNet)
2014-16	Expert Advisory Group, Patient Safety in Genome Medicine Project (NHGRI ELSI R21 project)
2013	Co-Chair, Working Group on Data Sharing, Multi-Regional Clinical Trials Center at Harvard University
2010-12	Committee on Ethical and Scientific Issues in Studying the Safety of Approved Drugs, Institute of Medicine
2010-11	Study Section, Research on Research Integrity, NIH / DHHS Office of Research Integrity
2009	National Advisory Council Subcommittee on Patient Safety and Medical Liability Reform Demonstrations, Agency for Healthcare Research and Quality
2009-11	Board of Directors, Coalition for Health Services Research
2008-09	Special Emphasis Panel, Research on Ethical Issues in Human Studies, National Institutes of Health
2007-11	Board of Directors, AcademyHealth
2007	Bioethics Ad Hoc Study Section, National Institutes of Health
2003-06	Links with Academia Advisory Group, American Health Lawyers Association
2003	Study Section, National Institute of Neurological Disorders and Stroke
2001-04	Ethics Advisory Committee, Children's Hospital, Boston
2000-14	Institutional Review Board, Harvard School of Public Health

PROFESSIONAL SOCIETIES:

American Society of Law, Medicine and Ethics

SELECTED OTHER PUBLIC SERVICE:

2023-	Committee Member and Volunteer, Young Men's Service League
2004-09	Executive Committee, Yale Law School
2003-09	Executive Committee, Yale Law School Association of New England
2000-08	Volunteer, Boston Cares

<u>SELECTED ADMINISTRATIVE RESPONSIBILITIES:</u>

2025- Chair, Health Policy Steering Committee, Human Centered Artificial Intelligence Initiative, Stanford University (Member, 2022-2025)

2025-	Chair, Environmental Health and Safety Committee, Stanford University (Member, 2023-2025)
2022-25	Co-Director, Stanford Health Policy Summer Internship Program
2022-23	Member, Strategic Planning Committee, Department of Health Policy, Stanford University School of Medicine
2021-22	Chair, Appointments Committee, Stanford Law School (Member, 2018-2019)
2017	Member, University Long Range Planning Committee, Stanford University
2014-17	Member, Committee on Joint Degrees, Stanford Law School
2009-15	Key Consultant and Methods Core member, National Program Office, Public Health Law Research Program, Robert Wood Johnson Foundation
2015-	Member, PhD Program Executive Committee, Stanford Health Policy
2009-14	Member, University-wide Committee on Conflicts of Interest, Harvard University
2008-14	Member, Committee on Higher Degrees in Health Policy, Harvard University
2006-14	Chair, Institutional Review Board, Harvard School of Public Health (Member, 2000-2006)
2006-14	Director, Program in Law and Public Health, Harvard School of Public Health (Associate Director, 2001-2006)
2000-14	Member, Master of Public Health Steering Committee, Harvard School of Public Health
2012-13	Co-chair, Standing Committee on Appointments, Reappointments and Promotions, Harvard School of Public Health (Member, 2011-2012)
2006-08	Vice Chair, Faculty Council, Harvard School of Public Health
2006-07	Member, Standing Committee on Ethics and Conflict of Interest in Continuing Education, Harvard Medical School
BUSINESS	AND CONSULTING EXPERIENCE:
2024	Expert witness on behalf of health insurers in litigation against Indivior, Inc. relating to Indivior's pharmaceutical marketing practices
2023-24	Advisor to AVIA Health, LLC Generative AI Collaborative and AI Collaborative 2.0
2022-23	Expert witness on behalf of Humana (health insurer) in litigation against Celgene Corporation relating to Celgene's off-label promotion of prescription drugs
2021-	Consultant to National Academy for State Health Policy on prescription drug affordability issues
2020-24	Expert witness on behalf of pharmacy retailers and health plan in Glumetza antitrust litigation
2020-22	Advisor to Verily Life Sciences LLC on product designed to facilitate safe return to

work and school during COVID-19

2020-	Consultant to National Academy for State Health Policy on pharmaceutical price regulation	
2018-22	Consultant to CVS/Caremark on value-based formulary	
2015-16	Consultant to the Medicare Payment Advisory Commission (MedPAC) on medical liability issues	
2014	Consultant to CVS/Caremark on tobacco-free pharmacies	
2011-12	Consultant to Oregon Health Authority on medical liability reform issues	
2010-11	Consultant to James Bell Associates, Inc. on evaluation of AHRQ demonstration project program for medical liability and patient safety	
2009-10	Consultant to the Medicare Payment Advisory Commission (MedPAC) on medical liability reform issues	
2007-09	Consultant to Common Good on technical assistance to states considering medical liability reform	
2007-08	Consultant to New York State Medical Liability Task Force	
2006-07	Consultant to American Cancer Society on study of impact of laws relating to breast cancer screening	
2006-07	Consultant to American Medical Risk Insurance Company on design of innovative professional liability insurance product	
2005-06	Consultant to Robert Wood Johnson Foundation Policy Synthesis Project	
2005	Consultant to Washington State Noneconomic Damages Task Force on study of noneconomic damages schedules	
2004-05	Consultant to American Hospital Association Task Force on Health Care Liability Reform	
2004-05	Consultant to Wyoming Health Care Commission on study of medical liability and patient safety reform commissioned by the Wyoming legislature	
2001	Consultant to plaintiffs' attorneys in <i>Simon v. Philip Morris Inc.</i> (consolidated tobacco litigation in the Eastern District of New York).	
1999	Summer Associate, Perkins Coie LLP, Seattle, WA	
1999	Summer Associate, Miller, Cassidy, Larroca & Lewin, LLP, Washington, DC	
1999	Intern, United States Attorney's Office, New Haven, CT	
1998-99	Intern, New Haven Legal Assistance Association, New Haven, CT	
IOUDNAL ROLES.		

JOURNAL ROLES:

2022-	Editorial Board, JAMA Health Forum
2021-25	Editorial Board, Journal of Health Politics, Policy and Law
2021-	Contributing Writer, JAMA Health Forum
2020-	Editorial Advisory Board, The Milbank Quarterly
2015-2020	Editorial Board, The Milbank Quarterly

2012-13	Guest Editor, Theme Issue on Public Health Law Research, Journal of Health
	Politics, Policy and Law
2005-	Advisory Board on Publication Ethics, <i>PLOS Medicine</i> journal
2004-05	Guest Editor, Symposium Issue on Medical Malpractice, Journal of Law, Medicine &
	Ethics
1999-00	Essays Chair, Yale Law Journal
1999-00	Editor, Yale Journal of Health Policy, Law, & Ethics
1998-99	Editor, Yale Law Journal
1997-98	Editor, Yale Journal on Regulation

MAJOR RESEARCH INTERESTS:

- 1. Artificial intelligence
- 2. Medical malpractice litigation, medical errors, and patient safety
- 3. Public health law
- 4. Pharmaceuticals
- 5. Bioethics

RESEARCH SUPPORT:

PAST FUNDING:

2022-24	Commonwealth Fund Public Health Powers After COVID-19 (Principal Investigator)
2019-23	Greenwall Foundation Ethical and Policy Issues for University Data Sharing in the Age of Big Data (Principal Investigator)
2019-23	Laura and John Arnold Foundation / Johns Hopkins Bloomberg School of Public Health Johns Hopkins Drug Access and Affordability Initiative (Co-investigator)
2022-23	Institute for Human-Centered Artificial Intelligence, Stanford University Tort Liability for Harms Arising from Healthcare AI (Principal Investigator)
2022-23	Institute for Human-Centered Artificial Intelligence, Stanford University Identifying and Communicating Ethical Challenges Bringing AI into Healthcare (Co-investigator)
2020-22	Greenwall Foundation Late Career Practitioners: Balancing Patient Safety and Physician Autonomy (Co-investigator)
2019-22	Arnold Ventures / Bioethics International

	Pharma Integrity Index Project (Co-investigator)
2018-19	Stanford University School of Medicine Discovery Innovation Fund Application of Big Data to Medical Malpractice Policy Questions (Principal Investigator)
2018-19	California Tobacco Control Program / Change Lab Solutions Diffusion of Model Ordinances for Local Tobacco Control in California (Co-investigator)
2018-19	Laura and John Arnold Foundation / Johns Hopkins Bloomberg School of Public Health Johns Hopkins Drug Access and Affordability Initiative (Co-investigator)
2016-19	Alfred P. Sloan Foundation Stanford Data Center for Population and Social Science Research: A Model Data Core (Co-investigator)
2016-19	Laura and John Arnold Foundation / Bioethics International Pharma Integrity Index Project (Co-investigator)
2016-17	SUMIT Insurance Company Ltd. Practice Changes Among Physicians Who Incur Paid Claims and Disciplinary Actions (Co-investigator)
2016-17	Stanford University Cybersecurity and Health Information Exchanges (Co-investigator)
2015-16	Greenwall Foundation Clinical Trial Participants' Attitudes Toward Participant-Level Clinical Trial Data Sharing (Principal Investigator)
2012-16	Beth Israel Deaconess Medical Center Disclosure, Apology and Offer (Co-investigator)
2010-16	National Institutes of Health / DHHS Office of Research Integrity Accountability and the Role of the Principal Investigator in Multicenter Trials (Co-investigator)
2010-16	Agency for Healthcare Research and Quality

	New York State Medical Liability Reform and Patient Safety Demonstration Project (Co-investigator)
2014-15	Greenwall Foundation Understanding the Lifecycle of Public Opinion of Public Health Laws (Principal Investigator)
2013-15	Agency for Healthcare Research and Quality Comprehensive Patient Safety and Medical Liability Communication and Program Resolution Education Toolkit (Co-investigator)
2008-14	Robert Wood Johnson Foundation Responding Justly to Patients Harmed by Medical Care: Disclosure, Compensation, and Litigation (Co-Principal Investigator) (Investigator Award)
2013-14	Edmond J. Safra Center for Ethics, Harvard University Institutional Oversight of Faculty Consulting Relationships (Residential Lab Fellowship)
2010-14	Agency for Healthcare Research and Quality Communication to Prevent and Respond to Medical Injuries: Washington State Collaborative (Co-investigator)
2010-13	National Institutes of Health / National Center for Research Resources Restrictive Provisions in Faculty Consulting Agreements (Principal Investigator)
2011-13	Greenwall Foundation Moral Legitimacy in Public Health Practice (Principal Investigator)
2008-13	National Institutes of Health Harvard Catalyst (Clinical and Translational Science Award) (Co-Investigator, Ethics Core)
2010-11	Agency for Healthcare Research and Quality Removing Barriers to Disclosure-and-Offer Models (Co-investigator)
2010	Robert Wood Johnson Foundation An Empirical Evaluation of Public Health Law Approaches to Obesity Prevention - Phase II (Principal Investigator)
2009-10	Robert Wood Johnson Foundation

An Empirical Evaluation of Public Health Law Approaches to Obesity Prevention -Phase I (Principal Investigator) 2007-10 Robert Wood Johnson Foundation State Policy Approaches to Fostering Uptake of the Human Papillomavirus Vaccine (Principal Investigator) 2005-10 Greenwall Faculty Scholars Program Ethical Issues in the Pharmaceutical Industry (Investigator Award) 2007-09 Robert Wood Johnson Foundation Preventing Childhood Obesity: Restricting Advertising and Promotion of Foods and Beverages to Children (Subcontract from Public Health Law & Policy/Yale University) (Principal Investigator) 2004-08 Robert Wood Johnson Foundation Design of a Reliable System of Medical Justice (Principal Investigator) 2003-06 National Institute of Neurological Disorders and Stroke Industry-Sponsored Research Contracts: An Empirical Study of Policies and Practices at Academic Medical Centers (Phase II) (Principal Investigator) 2005 Harvard Interfaculty Program for Health Systems Improvement Constitutionality of Administrative Compensation Systems (Co-Principal Investigator) 2005 Commonwealth Fund Alternative Approaches to Compensating Medical Injury: Lessons from International Models (Co-investigator) 2004-05 Harvard/Kennedy School Health Care Delivery Policy Program Adverse Event Disclosure Evaluation Project Planning Grant (Principal Investigator) 2001-05 Agency for Healthcare Research and Quality Malpractice Insurers Medical Error Prevention Study (Co-investigator) 2004 US Agency for International Development Health Enhancing Local Partnerships – Local Government Units Project (Co-investigator)

2004 Harvard Interfaculty Program for Health Systems Improvement Caps on Noneconomic Damages: Efficacy and Equity (Co-Principal Investigator) **Pew Charitable Trusts** 2002-04 An Empirical Investigation of the Pennsylvania Malpractice Environment (Principal Investigator) 2002-04 National Institute of Neurological Disorders and Stroke Industry-Sponsored Research Contracts: An Empirical Study of Policies and Practices at Academic Medical Centers (Phase I) (Principal Investigator) 2002-03 Commonwealth Fund Legal Approaches to Improving the Business Case for Quality (Principal Investigator) 2001-02 Harris Interactive/Anderson Consulting Strategic Health Perspectives (Co-investigator) 2001 Harvard Risk Management Foundation Malpractice Insurers Medical Error Prevention Study (Co-investigator) 2000-01 National Science Foundation Public Valuation of Lifesaving: The Controllability Issue (Co-investigator) 1998-99 Health Care Financing Administration (Dissertation Grant) Market Penetration, Biased Selection, and Utilization in Medicare HMOs (Principal Investigator) 1996-97 New College, University of Oxford (Thesis Grant) Ethical Issues in "Do-Not-Resuscitate" Decisions (Principal Investigator)

CURRENT FUNDING:

2024-2027 Stanford Impact Labs

Proactive Ethical Assessment of Healthcare AI

(Principal Investigator)

2024-2027 Patient-Centered Outcomes Research Institute

Development of a Scalable Method for Identifying Ethical Issues Arising from

Healthcare AI (Co-investigator)

2023-2027 NIH

Identifying Barriers to Optimizing Data Sharing and Accelerate Discovery in Alzheimer's Disease and Related Dementia Research (Co-investigator)

2024-2025 Stanford Health Care FURM Assessments for Healthcare AI Tools (Co-investigator)

TEACHING EXPERIENCE:		
2015-	Torts. Stanford Law School. Course Director.	
2015-	Health Law: Improving Public Health. Stanford Law School and Stanford University School of Medicine. Course Director.	
2021-24	Health Policy Graduate Student Tutorial II. Stanford University School of Medicine. Course Director.	
2002-14	Public Health Law. Harvard School of Public Health. Course Director.	
2002-14	Ethical Issues in International Health Research. Harvard School of Public Health. Member of course faculty.	
2014	<i>United States Health Policy</i> . Harvard School of Public Health / EdX. Member of course faculty.	
2000-13	Ethical Basis of the Practice of Public Health: Health Care Delivery. Harvard School of Public Health. Course Director.	
2007-08	Law and Public Health. Harvard Law School. Course Director.	
2001-03	Capstone Course in Law and Public Health. Harvard School of Public Health. Coinstructor.	
2000	Democracy: Conflict, Collective Action, and the State. Yale University. Teaching Assistant.	
1997	Statistical Methods. University of North Carolina at Chapel Hill. Course Director.	

BIBLIOGRAPHY:

Assistant.

ARTICLES:

1997

1996

1. Mello MM, Jenkinson C. Comparison of medical and nursing attitudes to resuscitation between a British and an American teaching hospital. Soc Sci Med 1998;46:415-24.

Linear Regression. University of North Carolina at Chapel Hill. Teaching Assistant.

Health Politics and Policy. University of North Carolina at Chapel Hill. Teaching

- 2. **Mello MM**. Death, life, and uncertainty: allocating the risk of error in the decision to terminate life support. Yale Law J 1999;109:635-42.
- 3. **Mello MM**. Of swords and shields: the use of clinical practice guidelines in medical malpractice litigation. Univ Penn Law Rev 2001;149:645-710.
- 4. **Mello MM**, Brennan TA. The controversy over high-dose chemotherapy with autologous bone marrow transplant for breast cancer. Health Aff 2001;20:101-17.
- 5. **Mello MM**, Brennan TA. Demystifying the law/science disconnect. J Health Polit Pol'y Law 2001;26:429-38.
- 6. **Mello MM**, Stearns SC, Norton EC. Do Medicare HMOs still reduce health services use after controlling for selection bias? Health Econ 2002;11:323-40.
- 7. **Mello MM**. Policing Medicaid and Medicare managed care: the role of courts and administrative agencies. J Health Polit Pol'y Law 2002;27:465-94.
- 8. **Mello MM**, Brennan TA. Deterrence of medical errors: theory and evidence for malpractice reform. Texas Law Rev 2002;80(7):1595-1637.
- 9. **Mello MM**. Using statistical evidence to prove the malpractice standard of care: bridging legal, clinical, and statistical thinking. Wake Forest Law Rev 2002;37:821-59.
- 10. **Mello MM**, Rosenthal M, Neumann PJ. Direct-to-consumer advertising and shared liability for pharmaceutical manufacturers. JAMA 2003;289:477-81.
- 11. Studdert DM, **Mello MM**, Brennan TA. Medical monitoring for pharmaceutical injuries: tort law for the public's health? JAMA 2003;289:889-94.
- 12. **Mello MM**, Studdert DM, Brennan TA. The Leapfrog standards: ready to jump from marketplace to courtroom? Health Aff 2003;22:46-59.
- 13. Whang E, **Mello MM**, Ashley SW, Zinner MJ. Implementing resident work hour limitations: lessons from the New York experience. Ann Surg 2003;237:449-455.
- 14. Ransom SB, Studdert DM, Dombrowski MP, **Mello MM**, Brennan TA. Reduced medicolegal risk by compliance with obstetric clinical pathways: a case-control study. Obstet Gynecol 2003;101:751-755.
- 15. **Mello MM**, Studdert DM, Brennan TA. The new medical malpractice crisis. N Engl J Med 2003;348:2281-84.
- 16. **Mello MM,** Stearns SC, Norton EC, Ricketts TC. Understanding biased selection in Medicare HMOs. Health Serv Res 2003;38:961-92.
- 17. **Mello MM**, Studdert DM, Brennan TA. The rise of litigation in human subjects research. Ann Intern Med 2003;139:40-45.

- 18. Brennan TA, **Mello MM**. Patient safety and medical malpractice: a case study. Ann Intern Med 2003;139:267-273.
- 19. Burns JP, **Mello MM**, Studdert DM, Puopolo AL, Truog RD, Brennan TA. Results of a controlled clinical trial on care improvement for the critically ill. Crit Care Med 2003;31:2107-2117.
- 20. Studdert DM, Burns JP, **Mello MM**, Puopolo AL, Truog RD, Brennan TA. Nature of conflict in the care of pediatric intensive care patients with prolonged stay. Pediatrics 2003;112:553-558.
- 21. Studdert DM, **Mello MM**, Burns JP, Puopolo AL, Galper BZ, Cook EF, Truog RD, Brennan TA. Conflict in the care of patients with prolonged stay in the ICU: types, sources, and predictors. Intensive Care Med 2003;29:1489-1497.
- 22. **Mello MM**, Brennan TA. Due process in investigations of research misconduct. N Engl J Med 2003;349:1280-1286.
- 23. Whang EE, Perez A, Ito H, **Mello MM**, Ashley SW, Zinner MJ. Work hours reform: perceptions and desires of contemporary surgical residents. J Am Coll Surg 2003;197:624-30.
- 24. **Mello MM**, Kelly CN, Studdert DM, Brennan TA, Sage WM. Hospitals' behavior in a tort crisis: observations from Pennsylvania. Health Aff 2003;22:225-233.
- 25. **Mello MM**, Rimm EB, Studdert DM. The McLawsuit: the fast food industry and legal accountability for obesity. Health Aff 2003;22:207-216.
- 26. **Mello MM**, Burns JP, Truog RD, Studdert DM, Puopolo AL, Brennan TA. Decision making and satisfaction with care in the pediatric ICU: findings from a controlled clinical trial. Ped Crit Care Med 2004;5:40-47.
- 27. Studdert DM, **Mello MM**, Brennan TA. Medical malpractice. N Engl J Med 2004;350:283-292.
- 28. **Mello MM**, Studdert DM, Brennan TA. The pharmaceutical industry versus Medicaid: limits on state initiatives to control prescription drug costs. N Engl J Med 2004;350:608-613.
- 29. **Mello MM**, Hemenway D. Medical malpractice as an epidemiological problem. Soc Sci Med 2004;59:39-46.
- 30. Studdert DM, Yang YT, **Mello MM**. Are damages caps regressive? A study of malpractice jury verdicts in California. Health Aff 2004;23:54-67.
- 31. **Mello MM**, Studdert DM, DesRoches CM, Peugh J, Zapert K, Brennan TA, Sage WM. Caring for patients in a malpractice crisis: physician satisfaction and quality of care. Health Aff 2004;23:42-53.

- 32. Studdert DM, **Mello MM**, Brennan TA. Financial conflicts of interest in physician relationships with the pharmaceutical industry: self-regulation in the shadow of federal prosecution. New Engl J Med 2004;351:1891-1900.
- 33. **Mello MM.** The experience of a community representative on an ethics consult team. J Clin Ethics 2004;15:296-301.
- 34. **Mello MM**, Kelly CN, Brennan TA. Fostering rational regulation of patient safety. J Health Polit Pol'y Law 2005;30:375-426.
- 35. **Mello MM**, Kelly CN. Effects of a professional liability crisis on residents' practice decisions. Obstet Gynec 2005;105:1287-1295.
- 36. **Mello MM**, Clarridge BR, Studdert DM. Academic medical centers' standards for clinical-trial agreements with industry. N Engl J Med 2005;352:2202-2210.
- 37. Studdert DM, **Mello MM**, Sage WM, DesRoches CM, Peugh J, Zapert K, Brennan TA. Defensive medicine among high-risk specialist physicians in a volatile malpractice environment. JAMA 2005;293:2609-2617.
- 38. Entwistle VE, **Mello MM**, Brennan TA. Advising patients about patient safety: current initiatives risk shifting responsibility. Joint Commission J Qual Patient Safety 2005;31:483-494.
- 39. **Mello MM**. Managing malpractice crises. J Law Med Ethics 2005;33:414-415.
- 40. Kelly CN, **Mello MM**. Are medical malpractice damages caps constitutional? An overview of state litigation. J Law Med & Ethics 2005;33:515-534.
- 41. Irani JL, **Mello MM**, Ashley SW, Whang EE, Zinner MJ, Breen E. Surgical residents' perceptions of the effects of the ACGME duty hour requirements one year after implementation. Surgery 2005;138:246-253.
- 42. Breen E, Irani JL, **Mello MM**, Whang EE, Zinner MJ, Ashley SW. The future of surgery: today's residents speak. Curr Surg 2005;62:543-546.
- 43. **Mello MM**, Studdert DM, DesRoches CM, Peugh J, Zapert K, Brennan TA, Sage WM. Effects of the malpractice crisis on specialist supply and access to care. Ann Surg 2005;242:621-628.
- 44. **Mello MM**, Clarridge BR, Studdert DM. Researchers' views of the acceptability of restrictive provisions in clinical trial agreements with industry sponsors. Accountability in Res 2005;12:163-191.
- 45. **Mello MM**, Brennan TA. Legal concerns and the influenza vaccine shortage. JAMA 2005;294:1817-1820.

- 46. **Mello MM**, Powlowski MP, Nañagas JMP, Bossert T. The role of law in public health: the case of family planning in the Philippines. Soc Sci Med 2006;63:384-396.
- 47. Studdert DM, **Mello MM**, Gawande AA, Gandhi TK, Kachalia A, Yoon C, Puopolo AL, Brennan TA. Claims, errors, and compensation payments in medical malpractice litigation. N Engl J Med 2006;354:2024-2033.
- 48. **Mello MM,** Studdert DM, Brennan TA. Obesity--the new frontier of public health law. N Engl J Med 2006;354(24):2601-2610.
- 49. Samanta A, **Mello MM**, Foster C, Tingle J, Samanta J. The role of clinical guidelines in medical negligence litigation: a shift from the *Bolam* standard? Med Law Rev 2006;14:321-366.
- 50. **Mello MM,** Studdert DM, Kachalia A, Brennan TA. "Health courts" and accountability for patient safety. Milbank Q 2006;84:459-492.
- 51. Kesselheim AS, **Mello MM.** Medical process patents—monopolizing the delivery of health care. N Engl J Med 2006;355:2036-2041.
- 52. Studdert DM, **Mello MM**, Gawande AA, Brennan TA, Wang YC. Disclosure of medical injury: an improbable risk management strategy. Health Aff 2007;26:215-226.
- 53. Joffe S, **Mello MM**, Cook EF, Lee SJ. Advance care planning among patients undergoing hematopoietic cell transplantation. Biol Blood & Marrow Transpl 2007;13:65-73.
- 54. Studdert DM, **Mello MM**, Jedrey CM, Brennan TA. Regulatory and judicial oversight of nonprofit hospitals. N Engl J Med 2007;356:625-631.
- 55. Kesselheim AS, **Mello MM**. Confidentiality laws and secrecy in medical research: improving access to data on drug safety. Health Aff 2007;26:483-491.
- 56. **Mello MM**, Studdert DM, Schumi J, Brennan TA, Sage WM. Changes in physician supply and scope of practice during a malpractice crisis: evidence from Pennsylvania. Health Aff 2007;26:w425-w435 (web exclusive).
- 57. Studdert DM, **Mello MM**, Levy MK, Gruen RL, Dunn EJ, Orav EJ, Brennan TA. Geographic variation in informed consent law: two standards for disclosure of treatment risks. J Empirical Leg Stud 2007;4:103-124.
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- 54. Burris S, Wagenaar AC, Swanson W, Ibrahim JK, Wood J, **Mello MM**. A framework for public health law research. In: A.C. Wagenaar, R.L. Pacula, and S. Burris (eds.), *Legal Epidemiology: Theory and Methods* (2d edition) (Hoboken, New Jersey: John Wiley & Sons, 2023).
- 55. Yishak-Sade M, Kachalia A, Novack V, Mello MM. Reply to LeCraw, Montanera, and Mroz on hospitals' malpractice claims and costs. Econ J Watch. 2023;20(2):349-356.

SELECTED PRESENTATIONS, LAST 3 YEARS:

- "Tort Liability as a Compensation System for Injured Research Participants," Invited presentation to NASEM Committee on Developing a Framework to Address Legal, Ethical, Regulatory, and Policy Issues for Research Specific to Pregnant and Lactating Persons (online).
- 2023 "Prescription Drug Costs and Access to Care," Santa Clara University High Technology Law Journal Symposium on Diversity, Inclusion, and Wellness in the Tech and Law Fields, Santa Clara, CA.
- "Public Health Modernization 2.0: Rebalancing Public Health Powers and Individual Liberty in the Age of COVID-19," Health Law Professors Conference, Baltimore, MD.
- 2023 "Publishing in High-Impact Medical Journals," Health Law Professors Conference, Baltimore, MD.
- "Opportunities and Challenges in Implementing the Inflation Reduction Act," Office of the Assistant Secretary for Planning and Evaluation (ASPE) Visiting Scholar Seminar (online).
- "Understanding Liability Risk from Health Care AI Tools," Anesthesia Grand Rounds, Department of Anesthesiology, Perioperative and Pain Medicine, Stanford University School of Medicine, Stanford, CA.
- 2023 "Understanding Liability Risk from Health Care AI Tools," Research Colloquium, Stanford Center for Biomedical Informatics Research, Stanford University School of Medicine, Stanford, CA.

2023	"Liability and Ethical Risk Assessment for Healthcare AI Tools," AVIA Generative AI Collaborative Meeting (online).
2024	"Understanding Liability Risk from Health Care AI Tools," Stanford Institute for Human-Centered Artificial Intelligence Seminar, Stanford University, Stanford, CA.
2024	"Investigating Ethical Concerns in AI Implementation: The Case of Nursing Notes Summarization via LLMs," Coalition on Health AI Meeting (online).
2024	"Facilitating Responsible Governance of Healthcare AI Tools," Testimony Before the Senate Committee on Finance, Washington, DC.
2024	"Institutional Governance of Health Care AI Tools," American Board of Family Medicine EnAIBL Learning Collaborative Convening (online).
2024	"The Legal Infrastructure and COVID-19 Response," Duke Global Health Institute Seminar on U.S. Pandemic Response: What Will It Take to Do Better?, Duke University, Durham, NC.
2024	"Stanford's Approach to Ethical Assessment of AI Tools," Coalition for Health AI Convening, Stanford, CA.
2024	"Looking to the Future: Where Do We Go From Here?" National Academies of Sciences, Engineering and Medicine Workshop on Optimizing Federal, State, and Local Response to Public Health Emergencies (online).
2024	"Judicial Decisions Constraining Public Health Powers During COVID-19: Implications For Public Health Policy Making," Health Affairs Briefing on Reimagining Public Health (online).
2024	"Liability Risk From Using AI Tools in Patient Care," Pediatrics Grand Rounds, Stanford University School of Medicine, Stanford, CA.
2024	"GenAI Governance at Stanford," AVIA Generative AI Collaborative Meeting (online).
2024	"Liability Risk From Using AI Tools in Patient Care," Virginia Health Medical Grand Rounds (online).
2024	"Liability and Ethics Issues Arising From Use of GenAI Tools in Healthcare," Augmedix AI Council Meeting (online).
2024	"Transforming Healthcare Through Innovation," Congressional Boot Camp on AI, Stanford HAI, Stanford, CA.
2024	"Understanding Liability Risk From Healthcare AI Tools," Ethics Grand Rounds, UT Southwestern Medical Center (online).

2024	The Regulatory Landscape For AI in Healthcare," JAMA Summit on Healthcare AI, Chicago, IL.
2024	"Bridging the Gap: Generative AI and Pediatrics," AMIA 2024 Annual Symposium, San Francisco, CA.
2024	"AI Governance: Federal, State, and Private Roles," National Conference of State Legislatures Health Innovation Task Force Meeting, Palo Alto, CA.
2025	"Augmented Intelligence – Balancing Interests and Identifying Appropriate State Guardrails," American Medical Association State Advocacy Summit, Carlsbad, CA.
2025	"Understanding Liability Risk from AI Tools," Medicine Grand Rounds, Methodist Dallas Medical Center (online).
2025	"Liability Risk from Using AI Tools in Pediatric Care," Stanford Medicine Pediatric & Maternal Innovation Showcase, Stanford, CA.
2025	"Ethical Issues Arising from Implementation of AI Tools in Healthcare," Stanford Center for Biomedical Ethics Seminar, Stanford, CA.
2025	"System-Level Ethical Issues Arising from AI Adoption," AAMC-Manatt Digital Health and AI Learning Collaborative Retreat, Stanford, CA.
2025	"Understanding Liability Risk from Using Healthcare AI Tools," Guy Carpenter Medical Professional Liability Forum, Cary, NC.
2025	"The Real Hurdle for AI Adoption: Liability," STAT Breakthrough Summit West, San Francisco, CA.
2025	"Challenges in Resolving Claims for AI-Related Injuries to Patients," Continuing Judicial Education Program on Telemedicine and Medical Malpractice: Legal Complexities and Evolving Standards of Care, Thomas R. Kline Center for Judicial Education (online).
2025	"Private Regulation to Ensure Safe Practice by Aging Physicians," BioLawPalooza, Stanford Law School, Stanford, CA.
2025	"Generative AI in Healthcare: Challenges and Policy Implications," Testimony before the California State Assembly Health and Privacy & Consumer Protection Committees, Sacramento, CA.
2025	"Stanford Ethics Work and Patient Engagement," Coalition for Health AI Summer Convening, Stanford, CA.
2025	"Legal Liability in the Age of Medical AI," AI in Medical Education Symposium, Stanford, CA.

2025	"Insights From Listening to Patients," Institute for Human-Centered Artificial Intelligence Health Policy Workshop, Stanford, CA
2025	"Moving Clinical AI Forward: A Policy Perspective," Center for Artificial Intelligence in Medicine and Imaging Symposium, Stanford, CA.
2025	"Using Generative AI Tools in Clinical Practice: Benefits and Legal Risk Management," ISMIE Risk Management Webinar (online).
2025	"Transforming Healthcare Through Innovation," Congressional Boot Camp on AI, Stanford HAI, Stanford, CA.
2025	"Roundtable: AI in Health Technology," Health Technology Innovation Congressional Bootcamp, Stanford Biodesign, Stanford, CA.
2025	"Regulatory and Policy Considerations in Healthcare AI Use," Alignment Health Executive Education Session, Stanford Law School, Stanford, CA.