

The Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School and the Center for Advanced Studies in Biomedical Innovation Law (CeBIL) at the University of Copenhagen (UCPH) have announced a second generous five-year grant from the Novo Nordisk Foundation that enables the Petrie-Flom Center's Project on Precision Medicine, Artificial Intelligence, and the Law (PMAIL) to continue its close collaboration with the International Collaborative Bioscience Innovation & Law Programme (Inter-CeBIL).

Launched in 2018 upon the award of the first NNF grant, PMAIL and its partner projects at the University of Copenhagen and the University of Cambridge provide analysis of the law and ethics of AI-driven precision medicine, explaining the shortcomings of the current innovation policy landscape in Europe and the U.S., and providing a comprehensive examination of policy options to better harness its potential by analyzing legal challenges to innovation and patient care.

Thus far, PMAIL has produced scholarly articles for publication in high-impact outlets including *JAMA*; *Science*; *The American Journal of Bioethics*; the *Oxford Handbook of AI Governance*; the *Journal of Law and the Biosciences*; the *Cambridge Journal of Law, Medicine, and Ethics*; *Milbank Quarterly*; *Nature Machine Intelligence*; *Lancet Digital Health*; and *Nature Medicine*. PMAIL affiliates have also written for or provided comment in multiple media outlets, including *WBUR*, the *Wall Street Journal*, the *Harvard Business Review, Medscape News*, *STAT*, and *Vice*. This scholarship and commentary cover topics such as algorithmic bias, informed consent and AI, the applicability of AI in specific clinical areas such as ophthalmology and organ transplantation, and the challenges associated with explainable AI. The group has addressed and been cited by major regulatory groups including the United States Food and Drug Administration, the World Health Organization, and the Organisation for Economic Co-operation and Development.

Bringing innovation in patient care from the laboratory to the market is dependent on complex laws and regulatory processes. With the Novo Nordisk Foundation's renewed commitment, PMAIL, as part of the Inter-CeBIL, will continue to investigate legal, regulatory, and ethical challenges in the rapidly growing fields of precision medicine and artificial intelligence. With the new grant, the scope of the project will further extend to new collaborative studies on emerging regulatory challenges in other areas, including polygenic risk scores and advanced medical computing, such as quantum technology. The Petrie-Flom Center expects to hire a post-doctoral fellow to assist on PMAIL and collaborate with post-docs at the University of Copenhagen.

Spotlight on Scholarship



Regulatory Roadmap for Digital Diagnostics

In-home digital diagnostic technologies raise difficult questions for patients and regulators alike. With an eye toward policymakers interested in supporting the benefits of moving health care to the home and preventing possible harms, this Regulatory Roadmap – the result of a multi-year project – dives in to the legal, regulatory, and policy issues linked to home delivery of care.

Read the full roadmap here.

Upcoming Events

The Quantified Worker: Book Talk

DATE

November 13, 2023,12:30 PM EST, Hybrid

Register for "The Quantified Worker: Book Talk"

Event Recordings

Psychedelic Law and U.S. Military Veterans

DATE

October 25, 2023

Watch "Psychedelic Law and U.S. Military Veterans"

Toward a More Effective, Equitable Pandemic Response

DATE October 16, 2023

Watch "Toward a More Effective, Equitable Pandemic Response"

<u>Affiliate News and Scholarship</u>



Recently on Bill of Health:

"Introduction to the Symposium: From Principles to Practice: Human Rights and Public Health Emergencies," by Roojin Habibi, Timothy Fish Hodgson, and Alicia Ely Yamin.

"Non-State Actors and Public Health Emergencies," by Rossella De Falco.

"Taking Abortion to the Polls: What To Expect in Ohio," by Joelle Boxer.

"Making Explicit a Rights-Based Approach to Infodemic in a Public Health Emergency," by Calvin Wai-Loon Ho.

<u>"Emoji Laws in Health Care ♥☆、"</u> by Bobby Stroup.

<u>"Protecting Consumer Privacy in DTC Tissue Testing,"</u> by Adithi Iyer.

<u>"COVID-19 Showcased Failed Global Cooperation,"</u> by Kayum Ahmed, Julia Bleckner, and Kyle Knight.

"A Pseudo-Nonprofit Model for Psychedelic Clinical Trial Funding," by Vincent Joralemon.

<u>"Despite Legal Exceptions, Access to Abortion Denied in Peru,"</u> by Camila Gianella.

"Organ Transplant Candidates Who Use Medical Cannabis Face Discrimination," by Hannah Rahim.



I. Glenn Cohen (Faculty Director) @CohenProf

NEW SCHOLARSHIP

"Preimplantation Polygenic Risk Score Testing Is Unvalidated And Unregulated," by Eli Y. Adashi, Daniel P. O'Mahony, and I. Glenn Cohen in Health Affairs Forefront.

NEW COMMENTARY

"Harvard Announces Study of Psychedelics in Society and Culture Following \$16M Donation," by Elyse C. Goncalves and Matan H. Josephy, featuring I. Glenn Cohen in *The Harvard*



Holly Fernandez Lynch (Former Executive Director)
@HollyLynchez

PROFESSIONAL UPDATE

Served as a witness at the Senate Special Committee on Aging Hearing on October 26, 2023, "Unlocking Hope: Access to Therapies for People with Rare, Progressive, and Serious Diseases".

NEW COMMENTARY

"ALS patients support bill that could help patients with other rare diseases," by John Wilkerson, featuring Holly Fernandez Lynch in *STAT*.



Mason Marks (Senior Fellow and Project Lead on POPLAR)
@MasonMarksMD

NEW COMMENTARY

"An Air Force Academy Cadet Pleaded Guilty to Using Magic Mushrooms. Is DoD Ready for the Drug's Legal Rise?" by Thomas Novelly, featuring Mason Marks in *Military.com*.

"Inside the movement to legalize magic mushrooms in Massachusetts," by Chris Serres, featuring Mason Marks in *The Boston Globe*.

"Medical or Recreational? States Debate Where Psychedelics Belong," featuring Mason Marks on Tradeoffs.

"Veteran Access To Psychedelics Requires Balance Of Speed And Caution, Says Panel With VA And Former CDC Officials," by Ben Adlin, featuring Mason Marks in Marijuana Moment.



Frances X. Shen (Former Senior Fellow in Law and Applied Neuroscience)

NEW COMMENTARY

"REACH for BRAIN: Improving Recruitment, Engagement, and Access for Community Health Equity for Human Neuroimaging Research," by Gary Boas, featuring Francis X. Shen in Athinoula A. Martinos Center.



David A. Simon (Research Fellow, Digital Home Health)
@david simon

NEW SCHOLARSHIP

<u>"Off-Label Preemption,"</u> by David A. Simon in *Wisconsin Law Review*.

W. Nicholson Price II (Former Academic Fellow) @WNicholsonPrice

NEW SCHOLARSHIP



<u>"Translating Commercial Health Data Privacy Ethics into Change,"</u> by Kayte Spector-Bagdady and W. Nicholson Price in *The American Journal of Bioethics*.

Selected Opportunity Listings

We choose a few upcoming opportunities to feature each week. To see <u>the full list, check our site</u>. To post your own, <u>get in touch!</u>







<u>Call for Applications:</u> Graduate Teaching Fellow and Part-time Postdoctoral Researcher



New Events: Health Policy & Bioethics Consortia

Petrie-Flom Center | Harvard Law School, 23 Everett Street, Cambridge, MA 02138

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