



**The Petrie-Flom Center for Health Law Policy,
Biotechnology, and Bioethics at Harvard Law School**

*Annual Report, Fiscal Year 2023
July 2022–June 2023*

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Introduction

In Fiscal Year 2023 (FY23), the Petrie-Flom Center took on a wide range of health law policy, biotechnology, and bioethics issues, including several fully-funded research initiatives on artificial intelligence in health care, digital home health, and psychedelics and the law. We also significantly contributed to the public conversation about access to reproductive health care after the United States Supreme Court's decision in *Dobbs v. Jackson*. Our work continues to be published in numerous high-profile journals, and we provide expertise and commentary on a wide range of health law policy topics.

Executive Director **Carmel Shachar** moved to an exciting new role as Assistant Clinical Professor of Law and Faculty Director of the Health Law and Policy Clinic at the Center for Health Law and Policy Innovation at Harvard Law School (CHLPI) and our new Executive Director, **Susannah Baruch**, joined Petrie-Flom in June 2023.

The Petrie-Flom Center has produced significant scholarly research while also growing our digital media impact, including our successful blog, *Bill of Health*, and its digital symposia program. We maintain an expansive webinar schedule and with the worst of the COVID-19 pandemic behind us, we are committed to providing in-person programming and hosting impactful convenings at Harvard Law School.

I. Accomplishments

Despite our small size, our diverse research portfolio allows us to remain one of the leading health law and bioethics programs in the country.

The Petrie-Flom Center’s focus on law, policy, and ethics could not be more relevant to the issues of our time. Our cutting-edge scholarship, presentations to a range of audiences, and commentary in the country’s leading media outlets brought our expertise to a range of public health issues, from the waning COVID-19 pandemic, to the impact of the Supreme Court decision in *Dobbs v. Jackson*. Petrie-Flom Center faculty and affiliates provided analysis of the Dobbs ruling and its implications through public events and media commentary including our June 29th webinar event, “[Dobbs v. Jackson: Understanding the Post-Roe Landscape](#).”

We also continue to break new ground with fully-funded work on cutting-edge issues including artificial intelligence in health care, digital home health, and the legal and ethical issues associated with psychedelic medicine.

A full list of our scholarship can be found [here](#). Highlights of Center affiliate scholarship and commentary are listed below:

Scholarship

David A. Simon, Carmel Shachar, and I. Glenn Cohen, ***Skating the Line between General Wellness Products and Regulated Devices: Strategies and Implications***, 9 JOURNAL OF LAW & THE BIOSCIENCES 1 (July 26, 2023).

I. Glenn Cohen, Eli Y. Adashi, and Mary Ziegler, ***The New Threat to Abortion Access in the United States—The Comstock Act***, 330 JAMA 5 (July 13, 2023).

Alicia Ely Yamin and Agustina Ramón Michel, ***Chapter 20: Engendering democracy and rights: the legalization of abortion in Argentina***, RESEARCH HANDBOOK ON INTERNATIONAL ABORTION LAW (March 21, 2023).

James René Jolin, Carmel Shachar, and Eli Y. Adashi, ***Future Directions For Delivering Contraceptive Healthcare Services Via Telehealth***, HEALTH AFFAIRS FOREFRONT (May 12, 2023).

Media

A full list of our extensive media commentary in FY23 can be found [here](#), covering the gamut of leading press outlets, including *ABC News*, *CNN*, *NPR*, *NBC*, *AIMed*, *the BBC*, *Bloomberg*, *Forbes*, *Health Affairs*, *the New York Times*, *Politico*, *Reuters*, *STAT*, *US News & World Report*, *the Washington Post*, *Vox*, and more. Selected highlights which Center affiliates authored or were featured in are highlighted below:

Commentary

Telehealth laws need to be updated for a post-COVID health system, by Carmel Shachar, Sean McBride, and Shannon MacDonald, THE BOSTON GLOBE (June 26, 2023).

US could soon approve MDMA therapy — opening an era of psychedelic medicine, featuring Mason Marks, NATURE (April 19, 2023).

The Latest Attack on the Abortion Pill Is Forty Years in the Making, featuring I. Glenn Cohen, THE NEW YORKER (March 9, 2023).

Lesson from Latin America for U.S. abortion rights movement, featuring Alicia Ely Yamin, THE HARVARD GAZETTE (October 26, 2023).

The sound of your voice might diagnose diseases, featuring David A. Simon, THE VERGE (September 13, 2022).

Digital media was another area of growth for the Center for FY23. Our blog, *Bill of Health*, received over 1,000,000 visits in the past year, due in part to our agile coverage of the COVID-19 pandemic, reproductive rights, and other timely health law matters. Our digital symposia included The End of Public Health, organized with Jennifer S. Bard, and Health Law and Policy in an Era of Mass Suffering, co-edited by Chloe Reichel and Benjamin A. Barsky.

We plan to continue this momentum in FY24. Upcoming symposia focus on topics including reproductive technologies and workplace equality, the recently published Principles and Guidelines on Human Rights and Public Health Emergencies, technoableism, and critical psychedelic studies.

We also created a **podcast**: Season 1 of the Petrie-Flom Center’s podcast “Petrie Dishes” focuses on legal and ethical concerns relating to health AI, as explained and interrogated by the show host, **Faculty Director I. Glenn Cohen**, and key stakeholders in the digital health ecosystem.

II. On-Campus Programs

Student engagement is a key component of the Center’s academic focus, which we achieve through our programming (often in collaboration with student groups), curricular offerings, internships, research assistantships on the scholarship of Center affiliates as well as the Center’s sponsored research and book projects, availability of affiliates for mentoring and professional advice, and, most importantly, our Student Fellowship.

Student Fellowship Program

The Petrie-Flom Center’s Student Fellowship program is an integral component of our contribution to student development. Open to any graduate student at Harvard, the fellowship is designed to support mentored scholarship in health law policy, biotechnology, and bioethics. As

part of our increased commitment to digital outreach, we trained our Student Fellows extensively on how to write intellectual yet accessible pieces for digital media outlets, such as our blog. We also continued to pair each Student Fellow with a mentor from a related industry (including several HLS alumni).

This year's cohort of Student Fellows was strong, with four students – three of whom were HLS students:

Matthew Chun

Harvard Law School, JD'24

Paper: “Artificial Intelligence for Drug Discovery: A New Frontier for Patent Law”

Industry Mentor: Niven Narain, Cofounder, President, and CEO, BERG, LLC and Member, Petrie-Flom Center Advisory Board

Sarah Gabriele

Harvard Medical School, MBE'23

Paper: “Rethinking the Use of Flexibilities under the Trips Agreement: Challenges and Solutions”

Industry Mentor: David Simon, Research Fellow, Digital Home Health, Petrie-Flom Center

Katie Gu

Harvard Law School, JD'24

Paper “The Post-Dobbs Health Data Inquisition”

Industry Mentor: Julia Hesse, Partner, Choate, Hall & Stewart LLP and Member, Petrie-Flom Center Advisory Board

Aparajita Lath

Harvard Law School, LLM'23

Paper “Commercialising MRNA: A Patent Law and Policy Perspective”

Industry Mentor: Aaron Kesselheim, Professor of Medicine and Member, Center for Bioethics, Harvard Medical School and Lead and Founder of the Program On Regulation, Therapeutics, And Law

We transitioned our Student Fellowship to blend in-person with hybrid settings in FY23. Virtual activities included onboarding, blog training, and mentor meet-ups, and in-person activities included student fellow lunches, writing and reading groups, and end of the year presentations. We were also able to welcome our Student Fellows into the PFC offices where they could work and network informally throughout the year.

Periodic surveying of Student Fellows has indicated that blogging was the strength of our virtual programming, while the strengths of our in-person programming included the writing and reading group and the ability to make connections with Center affiliates. Student Fellows have noted difficulty in forging connections with their industry mentors, which provides valuable feedback to prioritize more structured connection and networking opportunities as we move forward with the Student Fellowship program in FY24.

Every year we require our Student Fellows to contribute to our blog, *Bill of Health*. Communications Manager **Chloe Reichel** guides the fellows in blogging throughout the year. Student Fellows know that social media and non-traditional internet media outlets are becoming increasingly important in building a thought leader's reputation, and her mentorship gave the Fellows a deeper understanding of how to hone a digital presence, write for lay readership, grow an audience, and avoid common pitfalls in online communication.

Some of the work published by Student Fellows on *Bill of Health* this year includes:

- *How Artificial Intelligence is Revolutionizing Drug Discovery*, Matthew Chun, JD'24
- *The New Search for Reproductive Justice in Old Laws*, by Katie Gu, JD'24
- *Should TikTok Doctors Owe Any Duty of Care Toward Their Followers?* by Sarah Gabriele, MBE'23
- *The Supreme Court of India's Landmark Abortion Ruling. Explained*, by Aparajita Lath, LLM'23

Other Opportunities for Students

The Center also was proud to continue our work with interns and RAs through FY23. Our student internship program employs paid interns (undergraduates and graduate students at Harvard) who assist with various Center projects while gaining experience with the work of the Center. Intern projects this year included: developing our biweekly newsletter; updating the website and social media as needed; advertising and preparing materials for Petrie-Flom Center events; collecting and formatting materials for drafts of Center reports; and research and writing projects as assigned. Our 2022-2023 interns were: **James Jolin AB'24** and **Minsoo Kwon AB'24**. Their work includes:

- *Future Directions for Delivering Contraceptive Healthcare Services via Telehealth*, by James Jolin AB'24, Carmel Shachar, and Eli Y. Adashi, HEALTH AFFAIRS FOREFRONT (May 12, 2023).
- *Losing Control of Controlled Substances? The Case of Telehealth Prescriptions*, by Minsoo Kwon AB'24, BILL OF HEALTH (January 30, 2023).

As in previous years, the Center also engaged four Harvard Law RAs, **Shing-Shing Cao JD'24**, **Noah Delwiche JD'24**, **Olivia Staff JD'24**, and **Scott Wang JD'24** to assist with line-editing our upcoming volume, *Digital Health Care Outside of Traditional Clinical Settings: Ethical, Legal, and Regulatory Challenges and Opportunities*. This volume is forthcoming from Cambridge University Press in 2024. Additionally, the Center hired **Brenna Phillips JD'24** to support Center visiting scholar **Kathleen Boozang**, former Dean at Seton Hall, whose current scholarship reimagines the application of informed consent and negligence law to the athlete-college relationship in light of NIL, legalization of betting on college sports, and the possibility of treating college athletes as employees.

In addition to these line editors, the Center engaged eight Harvard Law students for research project-based work. RAs worked closely with Center affiliates to support research and publications as well as receive mentorship.

The Center remains strongly committed to working with and mentoring HLS and Harvard students through our various programs in FY24.

Courses Taught by Center Affiliates

Petrie-Flom Center affiliates make substantial contributions to the university's health law curriculum through various courses and frequent guest lectures. In FY23, Petrie-Flom affiliates offered the following courses for credit:

Health Law, Policy, Bioethics, and Biotechnology Workshop

I. Glenn Cohen

Fall 2022

This seminar featured the presentation and discussion of cutting edge scholarship on health law, health policy, biotechnology, and bioethics. The evaluation mechanism was that students submitted brief written comments on a number of the papers during the course. Because the papers are different every term, students can take the class as many times as they wish. Presenters came from a wide range of disciplines and departments, and papers featured doctrinal, economics, philosophical, political science, or other methods.

Civil Procedure 4

I. Glenn Cohen

Fall 2022

This course examined the theory and practice of civil litigation, and the rules and statutes that govern the process by which substantive rights and duties are enforced in federal and state courts (with a focus on the federal courts). Topics included the proper reach of judicial authority, personal and subject matter jurisdiction, pleading, motions practice, joinder of parties and claims, pretrial discovery, the relationship of procedure to substantive law, the Erie doctrine, post-trial procedure, and claim and issue preclusion.

Writing Group: Health Law/Bioethics/Pharmaceuticals and the Law

I. Glenn Cohen

Fall-Spring 2022

This was a small group writing workshop led by Professor Cohen to help students advance work in the fields of health law, bioethics, and pharmaceuticals and the law.

Comparative and International Legal Struggles Over Sexual and Reproductive Health and Rights

Alicia Ely Yamin

Fall 2022

At the intersection of debates about religion, private morality, and public policy, sexual and reproductive health and rights (SRHR) are lightning rods of controversy in most societies. While the pandemic revealed the precariousness of some advances, a wave of

ethno-nationalism and conservative populism has brought a sharp backlash against SRHR in many countries across the globe. Drawing on case examples from multiple regions, as well as in supra-national human rights forums, the reading group critically explored: strategies used to assert legal claims relating to involuntary sterilization; abortion; maternal health care; and other SRHR issues under international law; strengths and challenges to advancing reproductive justice through human rights law; and contested narratives about health, sexuality, and dignity embedded in SRHR claims.

III. Connections to the Community

The Center's work focuses on legal and policy issues of interest to both academic and lay communities and typically is free and open to the public. Nearly all of our events are also video-recorded in full and posted online with links on our website, thereby permitting the broader community the opportunity to take advantage of our offerings.

Events

Holding virtual events has enabled us to offer a vast array of events to the public around the world, a lesson learned from our COVID-19 programming. Our virtual event attendance has remained very strong, with up to 200 unique live views per event, and our events often draw a national or international audience. Following each event, we caption the recording and post it to our YouTube channel to make our events more accessible. Our online recordings have garnered up to 1,800 views per video.

In FY23, we were also able to start bringing some of our events back to campus, like Abortion Rights and Reproductive Justice in Latin America: Recent Landmark Decisions from Mexico and Colombia, on October 21, 2022, which brought two sitting Latin American Supreme Court Justices, **Alfredo Gutierrez Ortiz Mena**, Justice of the Supreme Court of Mexico and **Natalia Ángel Cabo**, Justice of the Constitutional Court of Colombia to HLS Campus for an in-person presentation and Q&A on the decriminalization of abortion in Mexico and Columbia. Following the event, which was also livestreamed for virtual audiences, both Justices joined us for a lunch and closed discussion with approximately 30 HLS students. Hundreds of virtual viewers were also able to learn from the event through the livestream and YouTube recording of the event.

We also brought our annual conference back to campus in a hybrid setting in FY23. Our 2023 Petrie-Flom Center Annual Conference: Health Law as Private Law, held on June 23, 2023 was organized by Faculty Director I. Glenn Cohen, Executive Director Carmel Shachar, N. Neal Pike Scholar and Professor of Law at Boston University School of Law **Christopher Robertson**, and Professor of Law and Associate Dean of Research and Faculty Professional Development at DePaul University College of Law and Visiting Professor at Arizona Law **Wendy Netter Epstein**. We welcomed 21 scholars to HLS campus for an invite-only writers' workshop to explore the intersection of private law and health care. The workshop was also livestreamed and recorded to allow the public to engage with the conference.

A full list of our FY23 events can be found here.

Other highlights from our virtual event calendar included:

Comparing Legal Approaches to Accessing Psychedelics

December 7, 2022

Virtual attendance: 43 unique views; YouTube views: 523 as of September 2023

Moderated by: Mason Marks, MD, Senior Fellow and Project Lead on the Project on Psychedelics Law and Regulation, Petrie-Flom Center

What Magic Can Teach Us About Misinformation

January 13, 2023

Virtual attendance: 196 unique views; YouTube views: 1.8K as of September 2023

Moderated by: Stephen P. Wood, Visiting Fellow, Petrie-Flom Center

Neuroscience and Cannabis: Implications for Law and Policy

April 20, 2023

Virtual attendance: 143 unique views; YouTube views: 131 as of September 2023

Moderated by: Stephanie Tabashneck, Senior Fellow in Law and Applied Neuroscience, Petrie-Flom Center

HLS Community

Our event calendar in FY23 also included convening opportunities for HLS alumni and student communities.

In October of 2022, we invited our Office of the General Counsel (OGC) Roundtable and Advisory Board to campus for our fall meetings. Following the meetings, we hosted a dinner for members and invited PFC student fellows and affiliates to join as a networking opportunity. We also offered a virtual option for the meetings and hosted a fully virtual meeting of each group in the spring.

Our Roundtable allows us to serve the HLS alumni community by connecting our alumni back to each other and Harvard experts. During FY23, we developed closer relationships with the following HLS alumni by engaging them with our General Counsel Roundtable:

- **Afia Asamoah** HLS'05, Head of Legal for Google Health
- **Danielle Gray** HLS'03, Senior Vice President, Chief Legal Officer and Corporate Secretary for Blue Cross Blue Shield North Carolina
- **Hank Greenberg** HLS'11, General Counsel for Oscar Health
- **Mary C. Hennessey** HLS'89, General Counsel for PCORI
- **Brad Lerman** HLS'81, Senior Vice President, General Counsel and Corporate Secretary for Medtronic
- **Jorge Lopez** HLS'84, Executive VP and General Counsel for Memorial Sloan Kettering Cancer Center
- **Cathy O'Rourke** HLS'99, Chief Legal and Compliance Officer for Smith & Nephew
- **Ellen Weinstein** HLS'06, Chief Legal Officer for Boston Medical Center Health Net Plan
- **Jennifer Zachary** HLS'04, Executive Vice President and General Counsel, Merck

Our Advisory Board, which was launched in December 2020, allows us to bring together industry leaders with HLS alumni who will help to shape the Center's work. The Board involves a wider range of stakeholders in the workings of the Center, including industry leaders from the health care

and life sciences fields, community advocates, and experts in health law policy and bioethics within and outside Harvard University. The Board has provided insights on Center projects at all stages of the life cycle: shaping project proposals, launching projects, and sunseting funded work. During FY23 we developed closer relationships with the following HLS alumni through our Advisory Board:

- **Wade Ackerman** HLS'04, Partner at Covington & Burling
- **Jorge Lopez** HLS'84, Executive VP and General Counsel for Memorial Sloan Kettering Cancer Center
- **James Lytle** HLS'79, Senior Counsel for Manatt, Phelps & Phillips, LLP; Fellow for Harvard Advanced Leadership Initiative; and Adjunct Professor for NYU Law School

IV. Research Programs

Our research programs also experienced a successful year. The Petrie-Flom Center has developed a strong reputation for leading scholarship at the forefront of health law policy, biotechnology, and bioethics. This year our affiliates again published top-rate scholarship and served as commentators for major media outlets, as well as invited lecturers, panelists, and presenters at a wide variety of events. We continued several sponsored research projects and other collaborations and took steps in some new directions, including receiving funding for two short-term event-based research projects. These accomplishments are described in more detail below.

Achieving Telehealth's Potential: Navigating Licensure Barriers

This initiative, which ran from November 2022 – July 2023 and was funded by the Commonwealth Fund, focused on alternative policy solutions for reforming state-based medical licensure to promote national telehealth practices without undermining quality assurance, patient safety, and oversight of physician practices.

In spring 2023, to kick off this project, the Center successfully hosted three virtual, public events on achieving telehealth's potential. These events were designed to both brief working group members on the regulatory and policy landscape and be accessible to the broad lay audience.

Achieving Telehealth's Potential: The Policy Landscape's Impact on Specialty Care

February 23, 2023

This event, the first of three in a series, mapped out the impact of our current physician licensure framework on the delivery of specialty care to patients through the patient, provider, and health system perspective.

Achieving Telehealth's Potential: The Federal Policy Landscape for Interstate Telehealth Practices

March 9, 2023

This event, the second of three in a series, mapped out the current and potential federal initiatives to facilitate interstate telehealth practices.

Achieving Telehealth's Potential: The State Policy Landscape for Interstate Telehealth Practices

March 13, 2023

This event, the final of three in a series, explored some of the state leadership, challenges, and opportunities to build interstate telehealth practices.

The project also hosted an in-person working group on professional licensure and telehealth at Harvard Law School on June 2, 2023. The working group aimed to synthesize current perspectives on the regulation of telehealth and to propose concrete policy recommendations. The working group, which consisted of an interdisciplinary group of leading regulatory scholars, physicians, telehealth advocates, and state leaders, was organized and hosted by **Carmel Shachar**, Harvard Law School, **Ateev Mehrotra**, Harvard Medical School, and **Barak Richman**, Duke Law School.

There were several written deliverables for this project. The first is a regulatory landscape of the barriers and potential solutions to interstate telehealth for specialty care services. The second significant deliverable is the consensus statement of the group.

Our dissemination efforts began before the in-person meeting of the working group and are ongoing. Project leadership worked on two key pieces summarizing the current landscape of interstate telehealth, one for the academic audience and one for the general public.

- Carmel Shachar, Barak Richman, and Ateev Mehrotra, [*Providing Responsible Health Care for Out-of-State Patients*](#), 330 JAMA 6 (Aug. 8, 2023): This article discusses why the legality of calling patients located in another state (a common practice pre-pandemic) has been suddenly called into question by hospital leadership, legal counsels, and state regulators. This was an issue that was brought up in our many discussions with physicians regarding the provision of telehealth services and was not documented in the academic literature. We were glad to be well placed to flag this barrier in access to care for patients.
- Carmel Shachar, Shannon MacDonald, and Sean McBride, [*Telehealth Laws Need to be Updated for a Post-COVID Health System*](#), Boston Globe (June 26, 2023): This op-ed translated some of the barriers to interstate telehealth licensure for a general audience. Prof. Shachar worked with two physician members of the working group to write an article reflecting their experiences providing care to cancer patients located across the country. Profs. Mehrotra and Richman consulted on the article.

Our project, which we consider a success, in many ways can be considered the “tip of the iceberg” when it comes to studying access to telehealth and working with stakeholders to identify avenues of reform. The project lead, Carmel Shachar, remains committed to working on telehealth policy and physician licensure reform.

2023 Petrie-Flom Center Annual Conference: Health Law as Private Law

The Lynde and Harry Bradley Foundation provided partial funding for our 2023 annual conference, which sought to explore the intersection of private law and health care, especially regarding how private law can be a tool for achieving health care reform or addressing a significant health care or public health problem. The purpose of this project was both to commission interdisciplinary, quality scholarship focusing on the potential role of private law in health care, but also to foster connections and collaborations between thought leaders and to spark additional interest in this topic.

Diagnosing in the Home: The Ethical, Legal, and Regulatory Challenges and Opportunities of Digital Home Health

In March 2021, we began a three-year initiative that examines the ethical, social, and legal challenges of digital home health products, with a focus on home diagnosis of infectious and chronic conditions. Supported by the Gordon and Betty Moore Foundation, Diagnosing in the Home: The Ethical, Legal, and Regulatory Challenges and Opportunities of Digital Home Health seeks to develop scholarship, guidelines, and proposed regulations for the ethical implementation of digital products that support clinical diagnosis in patients' homes.

In FY23, the project made substantial progress on all remaining deliverables. We developed public-facing documents, a Regulatory Scan, which provides a comprehensive review of all federal regulation digital diagnostic technologies implicate, and a Regulatory Roadmap, which is designed to highlight for policymakers the key challenges digital diagnostics pose and the potential ways of responding to these challenges. The project completed work on the Delphi Panel and corresponding publication, which is forthcoming in FY24 in *Nature Digital Medicine*. Finally, the project launched our podcast "Petrie Dishes," an exploration of biotechnology, ethics, medical law, and health care policy. Over the span of seven episodes, host I. Glenn Cohen provides an accessible analysis of a single digital health technology – such as digital pills, social robots, and digital health apps – through the lens of ethical concerns like informed consent, liability, and privacy.

In addition, the project produced:

- *Digital At-Home Diagnostics: Ethical, Legal, and Regulatory Issues*, Julia Adler-Milstein, I. Glenn Cohen, Daniel Kramer, and Carmel Shachar, eds., Cambridge University Press, (forthcoming 2024)
- *Skating the Line Between Wellness Products and Regulated Devices: Strategies and Implications*, David A. Simon, Carmel Shachar, I. Glenn Cohen 9 *JOURNAL OF LAW & BIOSCIENCES* 1 (2022) (peer reviewed)
- *Should Alexa Diagnose Alzheimer's?: Legal and Ethical Issues With At-Home Consumer Devices*, David A. Simon, Barbara J. Evans, Carmel Shachar, and I. Glenn Cohen, 3 *CELL REPORTS MEDICINE* 1 (2022) (peer reviewed)

The Project included a Research Fellow, **David A. Simon**, who oversaw the day-to-day work of this project, including conducting law, policy, and ethics research; drafting reports and recommendations; and coordinating the Center's world-wide collaboration with stakeholders from academia, non-profits, private industry, and the public sector. He also worked closely with two HLS RAs, **Katie Kelleher JD'24** and **Sara Raza LLM'23**. Kelleher supported research and publication work, while Raza helped to organize the Delphi Panel and its deliverables.

Simon left the Petrie-Flom Center at the end of FY23 to become an Associate Professor of Law at Northeastern University School of Law, and we have secured a subgrant so he can finish out the work on the project, which ends in May 2024.

The Project on Psychedelics Law and Regulation (POPLAR)

Launched in June 2021, the Project on Psychedelics Law and Regulation (POPLAR) was founded to advance evidence-based psychedelics law and policy. Based at the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School, this three-year project examines the ethical, legal, and social implications of psychedelics research, commerce, and therapeutics, promoting safety, innovation, and equity. While focused on the field of psychedelics law and policy, this project has implications for broader drug policy, pharmaceutical development, and intellectual property law more generally.

Highlights from this second year of the grant:

- We published an article on the role of psychedelic regulators in *Science*, one of the most prestigious journals in the world.
- We organized a conference at the Cold Spring Harbor Laboratories with representatives from the major pharmaceutical companies developing psychedelics, government representatives, leading researchers, veterans, and indigenous groups to work on an important new statement of principles.
- Our article in *Harvard Law Review Forum* on patenting psychedelics was featured on HBO's Last Week Tonight with John Oliver.

The work of this project would not be possible without the support of the Saisei Foundation, which has allowed us to launch this first of its kind project and produce groundbreaking scholarship as thought leaders in the field, just as a sea change in psychedelics law, policy, and medicine became imminent.

POPLAR is led by Professor and Deputy Dean **I. Glenn Cohen** and **Mason Marks**, Senior Fellow and Project Lead of POPLAR and the Florida Bar Health Law Section Professor at the Florida State University College of Law. Professor Marks, an authority on controlled substance regulation, teaches Drug Law and Psychedelic Law at Florida State University and was a founding member of the Oregon Psilocybin Advisory Board, which advises the Oregon Health Authority on creating the first statewide industry for psilocybin services. **Jeannie Suk Gersen**, the John H. Watson, Jr. Professor of Law at Harvard Law School also provides leadership in consideration of the use of psychedelics in recovery from trauma, such as war or rape.

In addition, the Petrie-Flom Center Executive Director devotes significant time to working substantively on the POPLAR project, collaborating and advising on research projects, taking a leadership role in our POPLAR events program, and engaging closely with our student research assistants and student fellows who are interested in learning more about psychedelic research. PFC's Executive Director also oversees the management of the grant. For the majority of FY23, **Carmel Shachar** was the Petrie-Flom Center's Executive Director, and the role transitioned to **Susannah Baruch** in June 2023.

POPLAR welcomed research assistants **Logan Fahrenkopf JD'24**, and **Lexo Walker JD'24**. Fahrenkopf conducted research on psychedelic community organizations and FDA regulation of psychedelics, and Walker conducted research on the use of psychedelics in end-of-life care.

POPLAR also welcomed **Leonard Pickard** as an affiliated researcher and continued working with its original cohort of affiliated researchers, which includes **Kwasi Adusei**, a psychiatric mental health nurse practitioner who developed a grassroots harm reduction project; **Ismail Lourido Ali**, Director of Policy and Advocacy at the Multidisciplinary Association for Psychedelic Studies (MAPS); **Jonathan Perez-Reyzin**, a second-year student at Yale Law School; and **Dustin Marlan**, a law professor at the University of North Carolina at Chapel Hill. The affiliated researchers meet monthly with POPLAR leadership.

In FY24, POPLAR will continue to engage with students and the Harvard community on this work. We will also host our 2024 Annual Conference on psychedelic medicine, which will convene scholars at HLS to explore the law and policy challenges and opportunities resulting from increased clinical research, private investment, and political interest in psychedelic medicines.

The Project on Precision Medicine, Artificial Intelligence, and the Law (PMAIL)

The Project on Precision Medicine, Artificial Intelligence, and the Law (PMAIL) was launched in January 2018, to provide a comparative analysis of the ethics and law of AI in health care in the U.S. and Europe, as well as digital health in general, such as the ethics and law of ingestible electronic sensors. This research has been supported by a Novo Nordisk Foundation grant for a scientifically independent Collaborative Research Programme in Biomedical Innovation Law (grant agreement number NNF17SA0027784).

Our work has been led by **I. Glenn Cohen**, with support from **Carmel Shachar**, and contributions from **Timo Minssen** and former Academic Fellow **Nicholson Price** and Research Fellow in Medicine, Artificial Intelligence, and the Law, **Sara Gerke**.

In FY23, PMAIL published on a variety of topics, including

- Regulatory Issues of AI in Health Care,
- Digital Health,
- Health AI Ethics,
- Privacy,
- Home Monitoring Technologies,
- AI & Liability,
- Direct-to-Consumer Apps,
- Medical Devices.

In the fall of 2024 Petrie-Flom learned that this grant has been renewed for another term.

Global Health Rights Project (GHRP)

Launched in January 2019, the Petrie-Flom Center's work on global health justice seeks to strengthen theorization of a "right to health" under international and applicable domestic law, as well as respond to the challenges to using human rights to advance global health justice. Since its inception, GHRP has maintained a particular focus on Latin America, and has sought to elevate the voices and perspectives of Latin American scholars and practitioners regarding global health issues. Although an extremely diverse region, Latin American countries share high degrees of

socio-economic inequality reflected in disparities in health status and access to care, and face common challenges. The pandemic highlighted the cumulative effects of transnational determinants of health on the region, including intellectual property regulation, sovereign debt, and multiple waves of austerity on institutional capacity and political economies. GHRP engages in policy and research projects that identify and critically analyze the use of distinct approaches for advancing systemic fairness in national health systems and across issues relating to global health equity, with a focus on reproductive justice.

Alicia Ely Yamin is the inaugural Senior Fellow in Global Health and Rights. In addition to her scholarly work at Harvard and advocacy as Senior Advisor on Human Rights and Health Policy at Partners In Health, Yamin continues to be engaged in many global initiatives and sits on a variety of steering committees and boards. During FY23, she was appointed to the WHO Global Advisory Committee, Maternal, Newborn, Child and Adolescent Health and Ageing, the global “Prevention Project” (regarding prevention of violations of human rights), and the editorial review committee of the *Journal of Global Health Law*. She finished her service on the joint World Bank/Norwegian Institute for Public Health/Bergen Centre on Ethics and Priority Setting project on “Health Financing for Universal Health Coverage,” as the report was launched officially. She continues to serve on the Global Health Law Consortium, the Lancet Commission on Arctic Health, and as Co-Chair of the International Steering Committee for Global Public Investment, as well as on the Board of Directors of Women in Global Health.

In 2022, Yamin was also named Series Editor for Global Health, Human Rights and Social Justice (Brill/Nijhoff). Yamin is also closely connected to reproductive justice and health rights networks in Latin America. She continues to sit on the Advisory Boards of Proyecto Mirar (Observatory on Implementation of Law 27.610 of 2020 in Argentina) and the Argentine Network for Safe Abortion Access (RedAAS). Yamin is also routinely sought after for interviews from foreign media — print, radio and TV — and maintains expertise and deep connections to scholars and activist networks in the region. In FY23, Yamin participated in drafting Expert Consensus “Principles and Guidelines on Human Rights and Public Health Emergencies,” and was one of the original endorsers of the “Maastricht IV Principles on the Rights of Future Generations.”

GHRP plays a key role in interpreting U.S. decisions and processes for Latin American audiences. The Project has continued to expanded its footprint significantly by working with four Affiliated Researchers, **Alma Beltrán v Puga**, Associate Professor, Faculty of Law at University of El Rosario, **Natalia Echegovemberry**, Associate, Civil Association for Equality and Justice in the Access to Justice and Community Legal Action Program (ACIJ, for its Spanish acronym), **Luciano Bottini Filho**, Lecturer, Sheffield University, and **Camila Gianella Malca**, Associate Professor at the Pontificia Universidad Católica del Perú. GHRP affiliated researchers have written a report on the right to health for the WHO Commission on the Economics of Health for All, participated in a process to arrive at Consensus Principles and Guidelines on Human Rights in Public Health Emergencies; given virtual talks at Harvard; and organized symposia and related events in their respective countries.

The Center also engaged two RAs, **Victoria Abut JD’25** and **Sabrina Ochoa JD’25**, to work with GHRP. These Research Assistantships enabled GHRP to continue to organize its robust array of activities and research collaborations relating to global health and health rights in comparative constitutional law. Ochoa worked closely with Yamin on an expert opinion for the Inter-American

Court of Human Rights in the *Beatriz v. El Salvador* case involving abortion rights, and co-published with Yamin: *What's at Stake in the Abortion Case before the Inter-American Court of Human Rights?* (2023) *EJIL:Talk!* Abut worked closely with Yamin on a book chapter and a separate article on maternal mortality and human rights, as well as an updated entry on the Colombian Constitutional Court for the Max Planck Encyclopedia of Comparative Constitutional Law.

Project on Advanced Care and Health Policy

In March 2016, the Petrie-Flom Center launched a collaboration with the Coalition to Transform Advanced Care (C-TAC). C-TAC is a non-partisan, non-profit alliance of over 140 national organizations dedicated to being a catalyst to change the health delivery system, empower consumers, enhance provider capacity, and improve public and private policies in advanced illness care. Our joint Project on Advanced Care and Health Policy seeks to study and foster development of improved models of care for individuals with serious, advanced illness nearing end-of-life, and to apply interdisciplinary analysis to important health law and policy issues raised by the adoption of new, person-centered approaches to care for this growing population.

For FY23, the Project on Advanced Care and Health Policy, led by Senior Fellow **Cheryl Matheis**, continued to contribute to public policy on care for people with advanced illness. A consortium of expert national advisors was convened to consider how to accelerate the transformation of care delivery. Consortium participants included senior executives from payers and providers, alongside academic researchers, consumer advocates, and national policy experts.

In May 2023, thought leaders Kristofer Smith (MD, MPP, Chief Medical Officer, Landmark Health) and Elizabeth Teisberg (PhD, Executive Director, Value Institute for Health and Care, University of Texas, Austin) presented issues on aligning evidence and practice to promote value-based care models that best meet the needs of people with serious illness. Discussants addressed the “value” concept — it begins with the goals of the patient.

In July 2023, Ravi Parikh (MD, MPP, FACP, Director of the Human Algorithm Collaboration Lab, University of Pennsylvania) and Sonoo Thadani-Israni (MBA, Executive Director, Presence and Program in Bedside Medicine, Stanford University School of Medicine) addressed the challenges and opportunities of using Artificial Intelligence and emerging technologies in serious illness care. The final session, in Washington, DC in October 2023, will bring together federal experts and policymakers to discuss legislative initiatives and to hear from Consortium members about their ideas for helpful federal policies to improve serious illness care for all patients.

Project on Law and Applied Neuroscience

Since Fall 2014, the Petrie-Flom Center has hosted the Project on Law and Applied Neuroscience, a collaboration with the Massachusetts General Hospital Center for Law, Brain and Behavior (CLBB). The collaboration has included a Senior Fellow, public symposia at Harvard Law School, and a Law and Neuroscience Seminar (taught by Petrie-Flom Center Faculty Affiliate **Hon. Nancy Gertner**).

In January 2022, **Stephanie Tabashneck** joined the project as Senior Fellow. Her work in her first year focused on the criminalization of addiction in criminal court and family court, the neuroscience of addiction, and considerations for public policy.

For FY23, Tabashneck focused on neuroscience and juvenile and young adult justice, and on topics that included late adolescent brain development, sentencing youth as adults, and substance use topics, including the neuroscience of cannabis. The Project organized events with judges, medical professionals, and scientists who contributed to litigation involving children and late adolescents with criminal sentences and with expertise in substance use disorder. Tabashneck gave talks in-person and virtually across the country and internationally, including for the Flaschner Judicial Institute, the Association of Family and Conciliation Courts, the Massachusetts Family Court Judges, the Supervised Visitation Network, Ontario Family Court Judges, and the Center for Law, Brain and Behavior. Her scholarly writing focused on substance use issues and drug policy.

The Project also employed and provided mentorship to a Harvard Medical School student RA, **Amanda Chen**, who assisted Tabashneck on numerous projects, including line editing and formatting article and chapter drafts, research and pulling articles for project events and presentations, contributing to literature reviews on topics that included relapse and recurrence, substance use and criminal court and family court, and co-authoring a chapter on neuroscience and drug policy for the book “Frontiers in NeuroJustice” (Oxford University Press UK).

In FY23, the Project also welcomed an International Fellow for Law, Policy, and Neuroscience, **Saul Glick**, who aims to improve the procedures used by frontline agencies, such as the police, during their interactions with children and vulnerable young people.

V. Preview of FY 2024

In FY24 we anticipate revitalizing our web presence, expanding our digital media presence, and continuing to build out our research portfolio while maintaining our position as thought leaders on health law policy and bioethics.

We are in the process of publishing an edited volume on “COVID-19 and the Law: Disruption, Impact, and Legacy,” in collaboration with Solomon Center for Health Law and Policy at Yale Law School. We believe this will be one of the first in-depth scholarly books on the impact of COVID-19 on public policy and health law.

We also expect publication of our volume Digital Health Care Outside of Traditional Clinical Settings: Ethical, Legal, and Regulatory Challenges and Opportunities, based on our 2022 annual conference, to be published in FY24. This volume reflects on the recent explosion of at-home digital health care and explores the ethical, legal, regulatory, and reimbursement challenges and opportunities of this shift away from the 20th century focus on clinics and hospitals towards a more modern model.

Our 2024 Annual Conference, as a part of the POPLAR project, will focus on the law and policy of psychedelic medicine. To further our work on psychedelics, the Center was able to secure

funding through the Gracias Family Foundation. We plan to host an annual three-day boot camp to train up-and-coming thought leaders in the legal, policy, and ethical issues surrounding the psychedelic field. A Harvard-wide interdisciplinary Study of Psychedelics in Society will include our work at Harvard Law School, the Faculty of Arts and Sciences, and Harvard Divinity School.