



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

*Annual Report, Fiscal Year 2021  
July 2021–June 2022*

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## **Introduction and Executive Summary**

The most significant highlight of Fiscal Year (FY22) for the Petrie-Flom Center was the successful first years of two fully funded three-year signature initiatives, one on diagnostic digital health and another on the law and regulation of psychedelics. Both projects released a tremendous amount of scholarship in high profile journals such as *JAMA*, *Nature Medicine*, and *Harvard Law Review Forum*. Each project hosted successful public events, such as *Should Alexa Diagnose Alzheimer's?* and *a Macro View of Microdosing*. Our psychedelics work is so unique that noted author Michael Pollan stated that there is nothing like it at any other American university.

Other areas of specific pride for the Petrie-Flom Center also include increased digital media and event presence, our maintained connection to Harvard Law School students, and the robust inclusion of the Center's experts in policy in media coverage. We continue to grow our digital media, including our successful digital symposia program, which hosted explorations on the interplay of adoption and abortion and international pandemic lawmaking. Our blog received over a million unique visitors this year and was quoted or linked to by outlets such as the *Los Angeles Times*, *Washington Post*, and the *New York Review of Books*. Center affiliates were also quoted and interviewed by leading media outlets including the *New York Times*, *Fox News*, *Bloomberg News*, *Time*, and *STAT*. We anticipate a similar high-profile year in FY23 as health issues, especially around reproductive rights, remain front and center.

As we chart our post-pandemic approach to engaging with our multiple audiences, FY22 was a dynamic and rewarding year for the Petrie-Flom Center. We hosted our first in person event since the start of the COVID-19 pandemic, welcoming over twenty scholars for a writers' workshop on digital at home health products. At the end of FY22, the Center quickly responded to *Dobbs v. Jackson Women's Whole Health*, the Supreme Court case overturning *Roe v. Wade*. Within days of the announcement, we hosted a panel for over 800 attendees to unpack the landmark decision. Lastly, we organized several successful private working groups, such as one gathering state Medicaid leaders to discuss supporting palliative care at home. Overall, FY22 was a year of successful launches and exciting work for the Petrie-Flom Center, in terms of projects, events, structure, and communications.

## **Accomplishments and Challenges**

Thought leadership at a time of significant ferment in health law and policy, engagement of HLS students despite the all virtual setting, and connections to the community and profession are central pillars of the Center's FY22 work. We are also proud of our research projects, including the two new projects that were launched in late FY21 and continued making great progress in FY22. Our diverse research portfolio, despite our small size, allows us to remain one of the leading health law and bioethics programs in the country.

### **Thought Leadership During a Public Health Crisis**

The Petrie-Flom Center had a prolific year, in part because public health law, policy, and ethics was foremost in most minds due to the on-going COVID-19 pandemic and Supreme Court Legislation on reproductive rights. As a result, we were well placed to influence the conversation from publishing cutting-edge scholarship, to presenting on policy choices to the National Governors Association, to being quoted in the country's leading newspapers and other media outlets.

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

#### **Scholarship:**

David A. Simon, ***Off-Label Innovation***, 56 GEORGIA LAW REVIEW 2 (August 18, 2022).

I. Glenn Cohen, Judith Daar, and Eli Y. Adashi, ***What Overturning Roe v Wade May Mean for Assisted Reproductive Technologies in the US***, 328 JAMA 1 (June 6, 2022).

I. Glenn Cohen and Mason Marks, ***Patents on Psychedelics: The Next Legal Battlefield of Drug Development***, HARVARD LAW REVIEW FORUM (February 20, 2022).

Boris Babic, Sara Gerle, Theodoros Evgeniou, and I. Glenn Cohen, ***Beware explanations from AI in health care***, 373 SCIENCE 6552 (July 16, 2021).

David A. Simon and Carmel Shachar, ***Telehealth to Address Health Disparities: Potential, Pitfalls, and Paths Ahead***, 49 JOURNAL OF LAW, MEDICINE & ETHICS 3 (Fall 2021).

A full list of our extensive media commentary in FY22 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 Marshall Project*, *the New York Times*, *Politico*, *Reuters*, *STAT*, *US News & World Report*, *the Washington Post*, *Vox*, and more. Selected highlights in which Center affiliates authored or were featured in COVID-19 related commentary are highlighted below:

## **Commentary:**

***Why a growing number of Latin American countries are legalizing abortion***, featuring Alicia Ely Yamin, PBS NEWSHOUSE (May 14, 2022).

Ovetta Wiggins, ***Grocery store employee Leilani Jordan died of covid-19 at the start of the pandemic. Her mom wants justice***, featuring Carmel Shachar, THE WASHINGTON POST (January 11, 2022).

Carmel Shachar and I. Glenn Cohen, ***The Danger of the Supreme Court Undercutting Biden's Vaccination Rules***, TIME (January 10, 2022).

Jennifer S. Bard and Chloe Reichel, ***Covid-19 booster shot distribution must learn from vaccine roll-out mistakes***, STAT (August 20, 2021).

Aishvarya Kavi, ***How the HIPAA Law Works and Why People Get It Wrong***, featuring I. Glenn Cohen, THE NEW YORK TIMES (July 24, 2021).

Overall, FY22 was a successful year for generating thought leadership by the Center.

The Petrie-Flom Center plans to continue this trend into FY23. To complete existing scholarship and commentary, in the coming year the Center plans to launch a podcast, as well as digital symposiums on COVID-19 and tort liability and the role of health law and policy in shaping, and at times catalyzing, the impact that the pandemic. Season 1 of the Petrie-Flom Center's podcast will focus 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.

## **Participation of HLS Students in Program Activities**

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, research assistantships on the individual 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 Fellowships. The Center moved to hybrid student programming for FY22, and we were thrilled to once again foster our connection to HLS students through our student fellowship, internships, and research assistant (RA) programs.

## **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), an increasingly important component of the fellowship as connections to the industry are harder to form in the remote setting.

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

**Matt Bauer**

Harvard Biological and Biomedical Sciences program, PhD

Harvard Law School, incoming JD'25

**Paper: " Public Health Emergency Preparedness: A Framework For Accessing Trade Secrets For Biologics Within The Biopharmaceutical Industry "**

Industry Mentor: Michael Rosenblatt, Senior Partner, Flagship Pioneering and Member, Petrie-Flom Center Advisory Board

**Jack Becker**

Harvard Law School, JD'22

**Paper: "Military Service Members and (In)vulnerable Status in Medical Research"**

Industry Mentor: Wade Ackerman, JD'04, Partner, Covington and Member, Petrie-Flom Center Advisory Board

**Bailey Kennedy**

Harvard Law School, JD'22

**Paper: "Coercion, Vaccines, and Organ Transplants: For the Greater Good?"**

Industry Mentor: Jorge Lopez, JD'84, Executive Vice President and General Counsel, Memorial Sloan Kettering Cancer Center and Member, Petrie-Flom Center Advisory Board

**Kaitlynn Milvert**

Harvard Law School, JD'22

**Paper: "The Right to Refuse Psychiatric Treatment, Revisited"**

Industry Mentor: Mason Marks, Senior Fellow and Project Lead on the Project on Psychedelics Law and Regulation at the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School

**Leah Pierson**

Harvard Medical School, MD-PhD

**Paper: "Accounting for future populations in health research"**

Industry Mentor: Alicia Ely Yamin, Lecturer on Law and the Senior Fellow on Global Health and Rights, Petrie-Flom Center; Adjunct Senior Lecturer on Health Policy and Management, Harvard TH Chan School of Public Health; and Senior Advisor on Human Rights and Health Policy, Partners In Health

**Cathy Zhang**

Harvard Law School, JD'23

**Paper: "Medicare Reimbursement of Telehealth Services for Mental Health Care: Lessons for the United States from Australia and Canada"**

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

Our Student Fellows participated in their fellowship virtually for FY21, which was a learning experience for the Center. Virtual activities included onboarding and blog training, mentor meet-ups, PFC student fellow lunches, and end of the year presentations. Periodic surveying of Student Fellows indicated that strengths of our virtual programming included blogging, end of the year presentations, and engagement with the Center and writing portion of the fellowship. Student Fellows did note the difficulty in forging connections with their peer fellows and their industry mentors, which provides valuable feedback for more structured connection and networking opportunities for future virtual programming as we move forward with the Student Fellowship program in FY22.

Every year we require our Student Fellows to contribute to our blog, *Bill of Health*, and this year we significantly strengthened our digital media training for the Student Fellows. Communications Associate, **Chloe Reichel**, guided the fellows for their Blog Posts 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 the digital sessions 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:

- *Disclosing Pain: The Case for Greater Transparency*, by Leah Pierson MD-PhD
- *Vaccine Mandates in the Military: Litigation Over Religious Exemptions*, by Kaitlynn Milvert JD'22
- *Addressing Distracted Driving: The Problem is Bigger than Texting*, by Jack Becker JD'22

### **Other Opportunities for Students**

The Center was also proud to maintain our ability to employ interns and RAs virtually through FY22. 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 material for drafts of Center reports; and research and writing projects as assigned. Our 2021-2022 intern was: James Jolin AB'24. Some highlights of James' work include:

- *Weathering the Climate Crisis: The Health Benefits and Policy Challenges of Home Weatherization*, by James Jolin AB'24

The Center also engaged an RA, Alison Roberts, JD '22, to work with the Global Health Rights Project (GHRP), led by **Alicia Ely Yamin**. This Research Assistantship enabled GHRP to continue to organize its robust array of activities and research collaborations relating to global

health rights, especially during this pandemic period when such issues are of pressing importance. Furthermore, this Research Assistantship position benefited from the ability to work closely with Yamin, a highly regarded scholar in the global health rights field, on cutting edge research, and publications. Roberts co-published with Yamin: *Medical Research and Human Rights*, Edward Elgar Encyclopedia of Human Rights (Forthcoming 2022).

As in previous years, the Center also engaged two Harvard Law RAs to assist with line-editing our upcoming volume, *COVID-19 and the Law: Disruption, Impact, and Legacy*. This work was easily continued in a remote setting, and due to the RAs' excellent work, this volume will be shortly going to our publisher, Cambridge University Press.

The Center remains strongly committed to working with and mentoring HLS and Harvard students through our various programs, ensuring that Harvard students have the ability to continue meaningful work for FY23 and adding experience to their resumes. We will continue to use the lessons learned from FY22 to create strong virtual programming and connections for the fellows and other HLS students.

### **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 FY22 Petrie-Flom affiliates offered the following full courses for credit:

#### **Health Law, Policy, Bioethics, and Biotechnology Workshop**

##### **I. Glenn Cohen**

Fall 2021

This seminar will feature the presentation and discussion of cutting edge scholarship on health law, health policy, biotechnology and bioethics. The evaluation mechanism is that students must submit 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 will come from a wide range of disciplines and departments, and papers may feature doctrinal, economics, philosophical, political science, or other methods, but students need not have prior training in these disciplines.

#### **Civil Procedure 4**

##### **I. Glenn Cohen**

Fall 2022

This course examines 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 include 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 2021

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

## **Contested Domains: Comparative and International Legal Struggles over Sexual and Reproductive Health and Rights**

**Alicia Ely Yamin**

Spring 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. The pandemic revealed the precariousness of advances in reproductive justice and SRHR, which had been forged in significant measure through legal mobilization and the use of international human rights standards. However, pre-pandemic, it was already evident that a wave of ethnonationalism and populism had created backlash against reproductive justice under the umbrella of anti- “gender ideology”. Drawing on case examples from multiple regions, as well as in supra-national human rights forums, the course will explore: the origins and evolution of asserting international legal claims to SRHR; challenges to advancing reproductive justice and SRHR in diverse lived realities; and contested narratives about health, sexuality and rights embedded in SRHR claims.

## **Connections to the Community and Professions**

The Center’s regular programming focuses on policy issues of interest to both academic and lay communities, and is almost always 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**

The Petrie-Flom Center is known for its extensive, busy, and strong events calendar and FY22 was no exception. Indeed, the virtual setting allowed us to offer a vast array of events to the public around the world. Our attendance has been very strong with up to 777 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 to make our events more accessible. Our online recordings have garnered up to 25,000 views per video.

In FY22, the Petrie-Flom Center was able to continue our virtual event momentum by hosting at minimum one event per week through the Fall and Spring covering a variety of topics from media coverage of the COVID-19 pandemic, the neuroscience of substance use disorder, to Alexa’s ability to diagnose Alzheimer’s. Our Annual Conference, “Diagnosing in the Home: The

Ethical, Legal, and Regulatory Challenges and Opportunities of Digital Diagnostics and Therapeutics Outside of Traditional Clinical Settings”, was held as a hybrid writers’ workshop on HLS campus with a Zoom call-in option and was livestreamed so virtual audiences could watch the day’s proceedings. As our first hybrid event, and first on-campus event presence since spring 2020, the day a great success with much enthusiastic participation from our guests, and we have learned many valuable lessons in implementing hybrid events for FY23. This workshop brought together top legal and medical scholars to reflect on the 2020-21 explosion of at-home digital health care and to think through the ethical and legal challenges and opportunities of this shift, finally leaving the 20th century focus on the clinic and the hospital for a more modern model. The work from this workshop is currently in process of becoming a published book with Cambridge University Press. In addition to our events focusing on the pandemic, the Center also produced additional events that explored timely health policy and bioethics questions. A full list of our FY22 events can be found [here](#).

In the year, the Center was proud to be able offer discussion forums for HLS students to learn more about and process current events including:

### **Dobbs v. Jackson: Understanding the Post-Roe Landscape**

**June 29, 2022**

*This event is sponsored by the [Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School](#) with the support of the [Harvard Medical School Center for Bioethics](#) and the [Edmond & Lily Safra Center for Ethics](#) at Harvard University.*

### **The Future of Abortion in America: A Virtual Townhall Discussion for Students**

**November 10, 2021**

Other highlights from our virtual event calendar included:

### **Should Alexa Diagnose Alzheimer’s?: A Health Policy and Bioethics Consortium**

**February 11, 2022**

Virtual attendance: 330 unique views; YouTube views: 1,738 as of August 2022

*The Health Policy and Bioethics Consortia is a monthly series that convenes two international experts from different fields or vantage points to discuss how biomedical innovation and health care delivery are affected by various ethical norms, laws, and regulations. They are organized by the [Harvard Medical School Center for Bioethics](#) and the [Program on Regulation, Therapeutics, and Law \(PORTAL\)](#) at [Brigham and Women's Hospital](#), in collaboration with the [Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School](#). Support provided by the [Oswald DeN. Cammann Fund](#) at Harvard University.*

Moderated by: David A. Simon, Research Fellow, Digital Home Health, Petrie-Flom Center

### **A Macro View of Microdosing**

**April 13, 2022**

Virtual attendance: 104 unique views; YouTube views: 25,291 as of August 2022

*Accompanied by a digital symposium on the [Bill of Health](#)*

### **Dobbs v. Jackson: Understanding the Post-Roe Landscape**

**June 29, 2022**

Virtual attendance: 777 unique views; YouTube views: 8,757 as of August 2022

*Sponsored by the [Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School](#) with the support of the [Harvard Medical School Center for Bioethics](#) and the [Edmond & Lily Safra Center for Ethics](#) at Harvard University.*

Featured: Noah Feldman, Felix Frankfurter Professor of Law, Harvard Law School; Jeannie Suk Gersen, John H. Watson Jr. Professor of Law, Harvard Law School; and I. Glenn Cohen, Petrie-Flom Center Faculty Director, James A. Attwood and Leslie Williams Professor of Law, and Deputy Dean, Harvard Law School

### **Other Avenues of Connection**

Building on our experiences from FY21, the Center was also excited to continue our role in serving as a virtual meeting and convening for the HLS alumni and student communities, and the health law policy and bioethics professional community. The Center is working hard to leverage the Harvard name and the Petrie-Flom Center reputation to serve as a virtual meeting space and to strengthen relationships with HLS alumni working in health care and biotechnology.

In FY22, we engaged our Office of General Counsels (OGC) Roundtable, in topical conversations from handling social media crises, the impact of climate change on healthcare environments, supply chain and labor and staff shortages, to developments in medical devices and AI with guests, such as Sharon Block, Professor of Practice and Executive Director, Labor & Worklife Program at Harvard Law School. Our Roundtable allows us to serve the HLS alumni community by connecting our alumni back to each other and Harvard experts. During FY22, we developed closer relationships with the following HLS alumni, by engaging them with our Health Care 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 are all active members of our Roundtable.
- **Jennifer Zachary** HLS'04, Executive Vice President and General Counsel, Merck

Our Advisory Board, which was launched in December 2020, met for quarterly virtual meetings throughout FY22. This Board 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 FY22 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

We hope to bring both of these groups to the HLS campus in Fall 2022 in order to provide students further mentorship opportunities.

## Research

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 also took steps in some new directions. These accomplishments are described in more detail below.

### **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.

The Project includes a Research Fellow, **David A. Simon**, and conduct a literature review of legal and ethical works on digital health; complete a regulatory scan to identify which regulatory statutes are relevant to the implementation of digital home health; use an interdisciplinary Delphi panel to generate ethical guiding principles and best practices for diagnostic digital home health; articulating model regulation to support diagnostic digital home health; engage with key stakeholders and thought leaders on this subject through our steering committee, events, and the Delphi panel; and educate scholars, policymakers, providers, patient advocates, and the public via virtual events, conferences, podcasts, and digital symposia.

In FY22, worked continued on the Diagnosing in the Home project. Simon completed drafting for the project's regulatory, which surveyed all significant federal laws and regulations that apply to digital diagnostics and will be published on the Petrie-Flom Center website. **Jackson Xu JD'23** provided research assistance for this project by performing research on some regulatory issues, cite-checking, and editing portions of early-stage drafts. Simon also co-authored publications with, **I. Glenn Cohen**, **Carmel Shachar**, Barbara Evans, Anaeze Offodile, and Celynne Balatbat, and contributed to white papers and the *Bill of Health* blog.

The Diagnosing in the Home project was also the focus of the 2022 Petrie-Flom Center Annual conference: Diagnosing in the Home: The Ethical, Legal, and Regulatory Challenges and Opportunities of Digital Diagnostics and Therapeutics Outside of Traditional Clinical Settings.

This hybrid writers' workshop gave us the opportunity reflect on the 2020-21 explosion of at-home digital health care and to think through the ethical and legal challenges and opportunities of this shift, finally leaving the 20th century focus on the clinic and the hospital for a more modern model.

For FY22, the project will be initiating and running a Delphi panel designed to build consensus around ethical and legal standards for Diagnosing in the Home. Project leadership will continue to produce scholarship on cutting-edge legal and ethical issues, collaborating with a variety of partners and retaining contacts in the public and private sectors.

### **The Project on Psychedelics Law and Regulation (POPLAR)**

Launched in June 2021, the Project on Psychedelics Law and Regulation (POPLAR) seeks to advance evidence-based psychedelics law and policy. This three-year project will promote safety, innovation, and equity in psychedelics research, commerce, and therapeutics. In addition to developing the field of psychedelics law and policy, this innovative work will have broad implications for drug policy, pharmaceutical development, and intellectual property law more generally.

POPLAR is led by **I. Glenn Cohen** and **Mason Marks**, Senior Fellow and Project Lead on the Project on Psychedelics Law and Regulation at the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School, Assistant Professor of Law at the University of New Hampshire Franklin Pierce School of Law (starting Fall 2021), and Affiliated Fellow at the Information Society Project at Yale Law School. Professor Marks, an authority on controlled substance regulation, also teaches Drug Law and Pharmaceutical Innovation at the UNH Franklin Pierce School of Law and serves on the Oregon Psilocybin Advisory Board, which advises the Oregon Health Authority on creating the first statewide industry for psilocybin services. Additionally, **Jeannie Suk Gersen**, John H. Watson, Jr. Professor of Law, Harvard Law School will provide leadership in one area of inquiry. In FY22 the Center will hire a Research Fellow to contribute to POPLAR's work.

During the 2021 – 2022 academic year, POPLAR published a series of high impact articles in leading academic journals of law and medicine including Nature Medicine, Scientific American, the Harvard Law Review Forum, and the Duke Law Journal. POPLAR researchers also placed a law review article for spring 2023 publication in the Boston University Law Review. Marks secured a publishing agreement with Yale University Press for a forthcoming book on psychedelics law. This spring, the Ninth Circuit cited his article *Controlled Substance Regulation for the COVID-19 Mental Health Crisis* in the high-profile psychedelics case *AIMS Institute v. Garland*.

POPLAR's research and commentary was featured by numerous national outlets such as the *New York Times*, *Fox News*, *Bloomberg News*, *the Economist*, *Brookings*, and *Vice News*. POPLAR researchers provided expert commentary for leading government and academic organizations such as the U.S. Food and Drug Administration, the Washington State Senate, the Seattle City Council, Harvard Medical School, Mount Sinai School of Medicine, Yale Law School, Howard University, and the offices of several Members of Congress. Marks was featured in the *Vice*

News documentary *The Battle Over Psychedelic Therapy's Future*, which aired on cable television and has been streamed over 1.2 million times on YouTube.

In addition to academic publishing and providing expert commentary, POPLAR organized ten publicly accessible educational events, both independently and in collaboration with leading research institutions such as Yale Law School, Duke Law School, Harvard's McLean Hospital, and the Center for the Neuroscience of Psychedelics at Massachusetts General Hospital.

In 2021, POPLAR welcomed post-doctoral fellow **David Angelatos** and research assistants **Jack Kelly AB'23**, a Harvard University undergraduate student, and **Daniel Albert-Rozenberg JD'24**. Angelatos conducted legal research on a variety of topics and co-authored several articles. Kelly and Albert-Rozenberg conducted research for an upcoming article on biopiracy. POPLAR also assembled its first cohort of affiliate researchers from other institutions to support and diversify the project's academic scholarship and educational programming. The first cohort 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-Reyvin**, a second-year student at Yale Law School; and **Dustin Marlan**, a law professor at the University of North Carolina at Chapel Hill. To further diversify its educational programming, POPLAR formed an educational collaboration with **Chacruna**, a non-profit organization focused on psychedelic equity and the protection of psychedelic plants and Indigenous practices.

In FY23, POPLAR will continue publishing high impact scholarship in academic legal and medical journals and providing expert commentary in national news outlets. The team has active research pipelines focused on psychedelic intellectual property and biopiracy, federal rescheduling of psychedelic substances, trends in state and federal psychedelics legislation, safety and psychedelic harm reduction, and the licensing of psychedelic professionals. POPLAR recently welcomed two additional research assistants to the team, **Logan Fahrenkopf JD'24** and **Lexo Walker JD'23**, who will support these research projects. The team will launch a POPLAR podcast and continue offering timely educational events for students, practitioners, government officials, and the public. POPLAR staff will represent the team at academic and industry conferences like Wonderland Miami, South by Southwest, and Psychedelic Science 2023.

### **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. This research is supported by a Novo Nordisk Foundation-grant for a scientifically independent Collaborative Research Programme in Biomedical Innovation Law (grant agreement number NNF17SA0027784). PMAIL will run until the end of December 2022.

PMAIL aims to provide a comparative analysis of the ethics and law of AI in healthcare in the U.S. and Europe, as well as digital health in general, such as the ethics and law of ingestible electronic sensors.

PMAIL is led by **I. Glenn Cohen**, with support from **Carmel Shachar**, and contributions from **Timo Minssen** and former Academic Fellow **Nicholson Price**. Our work on PMAIL was

especially productive due to the hard work of our Research Fellow in Medicine, Artificial Intelligence, and the Law, **Sara Gerke**.

In FY22, PMAIL continued to publish several articles on a variety of topics, including

- Regulatory Issues of AI in Health Care,
- Impact of COVID-19,
- Digital Health,
- Health AI Ethics,
- Privacy,
- Home Monitoring Technologies,
- AI & Liability,
- Direct-to-Consumer Apps,
- Medical Devices.

In its final year, PMAIL will further work and publish on issues at the cutting edge of medical development, especially the ethics and law of health AI, digital health, and big data. PMAIL will continue to collaborate with various stakeholders (e.g., INSEAD Business School, AIMed, Stanford Medicine, University of Pennsylvania, Harvard Business School, and Harvard Medical School) in the field of AI and digital health, as well as with our core partners at the Center for Advanced Studies in Biomedical Innovation Law (CeBIL) at the University of Copenhagen, University of Michigan, and University of Cambridge in England.

### **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 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 that is refracted in disparities in health status and access to care, and face a series of 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.

The Global Health and Rights Project is a collaboration with the Global Health Education and Learning Incubator (GHELI) at Harvard University. **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. She currently serves on the WHO’s Technical Advisory Group on ‘Health Technology Assessments’; the joint World Bank/Norwegian Institute for Public Health/Bergen Centre on Ethics and Priority Setting project on ‘Health Financing for Universal Health Coverage’; the Lancet Commission on Arctic

Health; and as Vice-Chair of the Transitional Council of Global Public Investment (2021-2022, co-chair , Transitional Council; 2020-2021, member, Steering Committee and Expert Working Group).

Yamin is also routinely sought after for interviews from foreign media- print, radio and TV as well as maintaining of deep connections to scholars and activist networks in the region and expertise. In addition to testifying in foreign legislatures or weighing in on Chile's new proposed constitution to Chileans, or submitting amicus to and advising high courts, and the like, GHRP plays a key role in interpreting US decisions and processes for Latin American audiences.

In FY22, GHRP convened and co-guest edited a digital Global Symposium on “International Pandemic Lawmaking: Conceptual and Practical Issues” with Pedro Villareal, Max Planck Institute of Comparative and Constitutional Law, and Joelle Grogan, Middlesex University. In addition to blog entries jointly published between Petrie-Flom and Verfassungsblog, the symposium included three webinars co-sponsored with Max Planck Institute of Comparative and Constitutional Law and Verfassungsblog.

In FY22, the Project also expanded its footprint significantly this year by adding four Affiliated Researchers, **Alma Luz Beltran**, Professor, Faculty of Law at University of El Rosario, **Natalia Echegovemberry**, Defender for Civil Association for Equality and Justice in the Access to Justice and Community Legal Action Program, **Luciano Bottini Filho**, Ph.D. Candidate, University of Bristol, Centre for Health, Law and Society, and **Ana Lorena Ruano**, Researcher for the Center for International Health, University of Bergen.

In FY23, GHRP will continue to address issues arising at the intersection of health policy, global development and international law (including both human rights and global health law). We will continue to provide spaces to critically debate current developments. GHRP will increasingly center its work around Latin America, which is already a heavy focus of its events and work. GHRP’s activities and work will seek to extend understanding of trends related to health and rights in the region, such as, major precedents in judicial enforcement of health rights; sexual and reproductive rights developments (including but not limited to abortion); and health and social protection reform in a post-pandemic future. GHRP will not seek merely to report on developments in the region, but to elevate thinking and perspectives on global health and rights issues from the region, working in collaboration with individual scholars and institutions across Latin America

### **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 FY22, the Project on Advance Care and Health Policy, led by Senior Fellow **Cheryl Matheis**, continued to contribute to public policy on care for people with advanced illness. As a part of CTAC's series, Trends Transforming Advanced Illness Care, the project hosted Emerging Policy Opportunities for Community-Based Serious Illness Care, a virtual public event on April 27<sup>th</sup> in which leading experts discussed the progress being made in community palliative care benefits for seriously ill persons in under the Medicaid program. Leading off that event was CMS' Chief Medical Officer for Medicaid, **Aditi Mallick, MD**.

There were several take-aways from this event to maximize likelihood of success. These included the need for extensive stakeholder buy-in upfront; the support of philanthropy to enable demonstration of cost savings sufficient to persuade payers to adopt changes; and the critical importance of establishing definitions—what is the benefit, who receives it, and standards for providers. Dr. Mallick identified federal programs that offer financial support and encouraged use of Medicaid Waivers and State Plan Amendments.

In early FY23, the Project will continue this work by convening several interested states in a workshop to explore how each state can make use of the guidance to accelerate the transformation of their Medicaid program. It is our objective to continue to build state capacity and expand the base of knowledge and experience of these trend setting states so that other states will be encouraged to act.

To further this objective, Petrie-Flom Center will co-host an event focused on state Medicaid policy initiatives at the C-TAC Summit in October with PFC Executive Director Carmel Shachar as moderator.

### **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 focused on the criminalization of addiction in criminal court and family court, the neuroscience of addiction, and considerations for public policy. The Project organized events with judges, medical professionals, and scientists who contributed to dismantling stigma and identified areas for improvement and innovation. Tabashneck gave talks in-person and virtually across the country and internationally, including in Alaska, Illinois, Massachusetts, Missouri, Minnesota and Indonesia as well as working on cases involving substance use and provided sought after legal testimony. Her scholarly writing focused on substance use issues, judicial bias, and other psycholegal topics.

The Project also employed and provided mentorship to a student RA, **Shruti Gautam AB**, who worked assisted Tabashneck on numerous projects including, line editing and formatting articles,

contributing to memos on gender bias and family court, research and pulling articles for Project events and presentations, and contributing to literature reviews on drug treatment, court participants, credibility determinations, and adoptive parent and biological parent contact and relationships.

For FY23, Tabashneck will continue as the Senior Fellow for the Project and will focus on neuroscience and juvenile and young adult justice and will focus on topics that include late adolescent brain development, the neuroscience of solitary confinement, and young adult justice innovations. The Project will also welcome an International Fellow for Law, Policy and Neuroscience, **Saul Glick**, who aims to improve the procedures used by frontlines agencies, such as the police, during their interactions with children and vulnerable young people.

## **Upcoming Initiatives**

In FY23, we are looking forward to another productive and busy year at the Petrie-Flom Center. Among our FY23 plans, we anticipate 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.

### **Digital Media**

Digital media was an area of growth for the Center for FY22, and we plan to further build on this foundation to enhance our thought leadership in the health law policy and bioethics field. In FY22, our blog, *Bill of Health*, featured a significant increase in digital symposia and blog readership. *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. Our coverage has recently been cited in prominent, diverse outlets ranging from the *Los Angeles Times* to the *Washington Post* to the *New York Review of Books*. Our timely digital symposia also drove traffic to the blog throughout FY22. In May 2022, in response to the leaked Supreme Court opinion on Dobbs v. Jackson, we organized a digital symposium in collaboration with Gretchen Sisson on Adoption, Family Separation & Preservation, and Reproductive Justice, which gathered contributors reflections on reflect not only an array of scholarly disciplines, but a range of lived experiences related to adoption, including adopted people, birth/first parents, and adoptive parents. The blog also hosted, Build Back Better? Health, Disability, and the Future of Work Post-COVID, guest edited by Marissa Mery and Michael Ashley Stein, which addressed the critical junctures of health, disability, and work at the heart of the domestic policy response to COVID-19.

We plan to continue this momentum in FY23. We already have three digital symposia scheduled for FY23.

#### **Health Law and Policy in an Era of Mass Suffering**

Guest edited by Benjamin Barsky, this symposium will reckon with the role of health law and policy in shaping, and at times catalyzing, the impact that the pandemic has had on our loved ones and communities.

#### **COVID-19 and Tort Liability**

This symposium, guest edited by Valerie Gutmann Koch, will reinvigorate questions around whether and how individuals and entities might be held liable for the harms associated with SARS-CoV-2 infection.

#### **The End of Public Health?**

Over the past two years, the U.S. Supreme Court and federal courts have shown unprecedented hostility to efforts by both state and federal government to stop the spread of a deadly virus. With this symposium, Guest edited by Jennifer Bard and Jacqueline Fox, we aim to address this critical juncture: have we reached the end of public health? And where do we go from here?

We will view ourselves as successful in expanding our digital media presence if we work with media leaders to continue to grow the presence and audience of the *Bill of Health* as a resource on public health matters; and if we produce at least one season of the Petrie-Flom Center Podcast.

## **Research and Scholarship**

Our second central guiding pillar for FY23 is our commitment to scholarship and research. We remain deeply committed to continuing to being thought-leaders in the health policy and bioethics sphere, especially in light of the COVID-19 pandemic. In FY21, we identified digital health as the next “big” thing, and received funding from the Gordon and Betty Moore Foundation to fund a three year initiative on ethical implementation of digital products that support clinical diagnosis in patients’ homes, which will position us as thought-leaders in this area. At the very end of FY21 we received funding from the Saisei Foundation for a three-year initiative to examine the ethical, legal, and social implications of psychedelics research, commerce, and therapeutics, the Project on Psychedelics Law and Regulation (POPLAR) at the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School. Our focus in FY22 was growing and successfully launching these two major initiatives.

We hope to further expand our research program in FY23. Our funding for the Project on Precision Medicine, Artificial Intelligence, and the Law is up for renewal in FY23. We hope to use this as an opportunity to revisit our digital health and medical computing work and expand its scope. With the *Dobbs* decision, we have identified reproductive data governance and privacy as an area of unique competency for the Center and are anticipating building a project in collaboration with our colleagues at the Center for Health and Policy Innovation and the Berkman Klein Center for Internet and Society on this topic. Lastly, we are working with key members of our Advisory Board to develop a project proposal on the regulatory barriers to value based health care, in conjunction with our colleagues at Harvard Business School. Our hope is to find a funder in FY23 to support this project.

We are also 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 book on the impact that COVID-19 will have had on public policy and health law.

In FY23, we will consider ourselves successful in regards to our status as thought-leaders if we publish our joint book project on COVID-19 and public policy, grow our two new signature initiatives, launch at least one other significant sponsor funded research initiative, and continue to produce and support high profile scholarship.

