



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

*Annual Report, Fiscal Year 2021  
July 2020–June 2021*

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## **Introduction and Executive Summary**

The most significant highlight of Fiscal Year (FY21) for the Petrie-Flom Center was the launch of two fully funded three-year signature initiatives, one on diagnostic digital health and another on the law and regulation of psychedelics. The Center has a history of launching research projects right before the topic becomes “hot,” such as when we launched our exploration into health artificial intelligence right before that became one of the most popular health law topics. We hope to continue that trend with our two new projects and to further build out our research portfolio in FY22.

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. Most notably, FY21 was a year in which the Center demonstrated national thought leadership, especially on public health law and ethics questions relating to the COVID-19 pandemic. Center affiliates published COVID-19 related scholarship in many high profile journals, such as *JAMA* and *NEJM*. Center affiliates were also quoted and interviewed by leading media outlets including the *New York Times*, *Washington Post*, *BBC*, and *CNN*. We anticipate a similar high profile year in FY22 as COVID-19 continues to raise health law, policy, and ethical questions.

In light of the changes necessitated by the COVID-19 pandemic, FY21 was a dynamic and rewarding year for the Petrie-Flom Center. Building on the lessons learned in Fiscal Year 2020, the Center was able to successfully translate our robust portfolio of events, publications, and research to virtual settings for the entirety of FY21 in addition to growing our sponsored project portfolio. Overall, FY21 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 FY21 work. We are also proud of our research projects, including the two new projects launched in FY21. 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 COVID-19 pandemic. 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:**

Sara Gerke, Gali Katznelson, Dorit Reiss, and Carmel Shachar, ***COVID-19 Antibody Testing as a Precondition for Employment: Ethical and Legal Considerations***, 49 JOURNAL OF LAW, MEDICINE & ETHICS 2 (June 29, 2021).

Alicia Ely Yamin, ***Future Directions for Human Rights Praxis in Health: The Imperative of (Re)claiming the Public***, 21 LA REVUE DES JURISTES DE SCIENCES PO 27 (June 2021).

Mason Marks, ***Emergent Medical Data: Health Information Inferred by Artificial Intelligence***, 11 U.C. IRVINE L. REV (May 2021).

Boris Babic, I. Glenn Cohen, Theodoros Evgeniou, Sara Gerke, and Nikos Trichakis, ***Can AI Fairly Decide Who Gets an Organ Transplant?***, HARVARD BUSINESS REVIEW (December 1, 2020).

Carmel Shachar and Gregory Curfman, ***Reconsidering Health Care Fraud and Abuse Laws***, 324 JAMA 17 (November 3, 2020).

Sara Gerke, Carmel Shachar, Peter R. Chai, and I. Glenn Cohen, ***Regulatory, safety, and privacy concerns of home monitoring technologies during COVID-19***, 26 NATURE MEDICINE (August 7, 2020).

A full list of our extensive media commentary in FY21 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:**

I. Glenn Cohen and Christopher T. Robertson, ***Cruise ship vaccine mandates are great. The latest ruling for them wasn't,*** THE WASHINGTON POST (August 11 2021).

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

Boris Babic and Sara Gerke, ***Explaining medical AI is easier said than done,*** STAT NEWS (July 21, 2021).

Health Murphy, quoting Carmel Shachar, ***A Look at Covid-19 Vaccine 'Passports,' Passes and Apps Around the Globe,*** THE NEW YORK TIMES (August 4, 2021).

Ashley Fetters Maloy, quoting Carmel Shachar, ***Some people are lying to get vaccinated, and it's testing their friendships,*** THE WASHINGTON POST (March 25, 2021).

Maria Chen and Lori Hinnant, quoting Alicia Ely Yamin, ***Push to bring coronavirus vaccines to the poor faces trouble,*** AP NEWS (October 1, 2020).

Overall, FY21 was a successful year for generating thought leadership by the Center.

The Petrie-Flom Center plans to continue this trend into FY22. To complete existing scholarship and commentary, in the coming year the Center plans to launch a podcast, as well as digital symposiums on international pandemic lawmaking in partnership with Verfassungsblog and on health justice. 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. Due to the move to remote learning for FY21, the Center missed in-person engagement with the PFC community, especially HLS students; however, the Center was able to maintain 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 – five of whom were HLS students:

**Jenna Becker**

Harvard Law School, JD ‘22;

**Paper: “Risk Scores and Resource Allocation: Governing Health Care AI Outside the FDA’s Authority”**

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

**Sravva Chary**

Harvard Medical School, MBE ‘21

**Paper: “Emergency Use of Hydroxychloroquine and Chloroquine During the COVID-19 Pandemic: Helpful or Harmful?”**

Industry Mentor: Sara Gerke, Assistant Professor of Law, Penn State Dickinson Law; and Former Research Fellow, Medicine, Artificial Intelligence, and Law, Petrie-Flom Center

**Vrushab Gowda**

Harvard Law School, JD ‘21; University of North Carolina, MD ‘22

**Paper: “Tuning Up Telemedicine: Post-Pandemic Pathways Toward a National Framework”**

Industry Mentor: Rina K. Spence, Former President and CEO, Emerson Hospital, Concord, MA; advisor to the Precision Medicine, Artificial Intelligence, and the Law Project, Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School; and Member, Petrie-Flom Center Advisory Board

**Laura Karas**

Harvard Law School, JD ‘22

**Paper: “The Hidden Costs of Drug Company-Sponsored Patient Support Programs”**

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

**Sunnie Ning**

Harvard Law School, JD ‘21

**Paper: “Follow-on Vaccines? A Case for Reforming the Regulatory Exclusivity for Vaccines”**

Industry Mentor: Claire Laporte, HLS '89, Head of Intellectual Property at Ginkgo Bioworks, Inc.

**Abraham Sutton**

Harvard Law School, JD '22

**Paper: “Approaches to make living organ donors whole”**

Industry Mentor: James Lytle, HLS '78, Senior Counsel, Manatt, Phelps & Phillips, LLP; Fellow, Harvard Advanced Leadership Initiative; Adjunct Professor, NYU Law School; and Member, Petrie-Flom Center Advisory Board

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:

- *The Future of Race-Based Clinical Algorithms*, by Jenna Becker, JD '22
- *Duplicate Discounts Threaten the 340B Program During COVID-19*, by Sravya Chary MBE '21
- *Can We Expect Legislation on Surprise Medical Billing? I'd Be Surprised*, by Abe Sutton JD '22

**Other Opportunities for Students**

The Center was also proud to maintain our ability to employ interns and RAs virtually through FY21. 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 projects as assigned. Our 2020-2021 intern was: Taylor Goss, HMS MBE '22.

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 four Harvard Law RAs to assist with line-editing our upcoming volume, *Innovation and Protection: The Future of Medical Device Regulation*. 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 FY22 and adding experience to their resumes. We will continue to use the lessons learned from FY21 to create strong virtual programming and connections for the fellows and other HLS students. An example of our programming aimed at students for FY22 is our event, "The Future of Abortion in America: A Virtual Townhall Discussion for Students," which will offer Harvard Law students a chance to ask experts their questions about recent developments in abortion jurisprudence.

### **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 FY21 Petrie-Flom affiliates offered the following full courses for credit:

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

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

Fall 2020

The Health Law, Policy, Bioethics, and Biotechnology Workshop is offered annually at HLS for enrollment by graduate students from across the university, and is a required course for Petrie-Flom Center Student Fellows. In FY20 and previous years, attendance was open to all interested parties; however, for FY21, this course was only open to Harvard graduate students as it is being taught virtually.

The workshop is a preeminent venue for leading scholars in health law, biotechnology, and bioethics to launch, discuss, and improve their newest ideas. During two-hour sessions, presenters engage in extensive Q&A with the audience, and students enrolled in the course also offer written suggestions and responses. Workshop presentations are usually followed by a small dinner in which Harvard students, fellows, and faculty continue the discussion and have the opportunity to engage more closely with the speaker.



## **Health Care Rights in the Twenty-First Century**

**Carmel Shachar**

Fall 2020

Underlying the current health care debate engulfing Washington is the fundamental question whether Americans enjoy a basic entitlement to health care. This course briefly traced the history of the American conception of health care rights through the last half-century of administrative and political cycles, contrasting a diverse array of ideological perspectives over this progression to understand the context of the current climate.

The seminar was designed to be limited lecture, incorporating debates, role-plays, and other interactive sessions, culminating in a student-chosen project arising from the course materials – students wrote rights-enforcing instruments, which could include an administrative filing, a federal court complaint, or a regulatory comment.

## **Bioethics and Health Law: Selected Topics**

**I. Glenn Cohen**

Winter 2021

This class covers selected topics in health care law, public health law, and (especially) bioethics. Among the topics that may be covered are: informed consent, medical confidentiality (including issues pertaining to medical big data), the duty to treat, conscientious objection in health care, ownership and patenting of human tissue, organ donation and allocation, abortion, reproductive technologies, end of life decision-making, the definition of death, and mandatory testing for diseases.

## **Reproductive Technology and Genetics: Legal and Ethical Issues**

**I. Glenn Cohen**

Spring 2021

Should individuals be able to sell reproductive materials like sperm and ova, or reproductive services like surrogacy? Should the law require individuals diagnosed with diseases like Huntingtons diseases to disclose to family members that they too are at risk for the disease? Should prenatal sex selection be a crime? Should federal funds be used for stem cell research? Should law enforcement be able to bank DNA samples collected from suspects and perpetrators? Should we allow Gene editing? Should doctors be able to patent cell lines developed from their patients bodies?

Since Watson and Cricks discovery of the double helix structure of DNA in 1953, and the 1978 birth of Louis Brown, the first child conceived through in vitro fertilization, pressing questions like these have propagated. This course cut across doctrinal categories to examine how well the law and medical ethics have kept up, and plot directions for fruitful development. Topics covered included: \* Prenatal genetic screening and sex selection \* Genetic enhancement \* The sale of sperm and ova and access to reproductive technology

\* Surrogacy \* Cloning \* Preembryo disposition disputes \* Wrongful birth, wrongful conception, and wrongful life torts \* The parentage and anonymity of gamete donors. \* Imposition of criminal liability on mothers and third parties for harm to fetuses \* The use of genetic information by insurers and employers \* The collection of genetic information by the state and the criminal justice system \* Biobanking \* Chimeras (human-animal hybrids) \* Uterus Transplants\* \* stem cells and embryo destruction\* The patenting of genes and their derivatives \* Research ethics issues involving fetuses and embryos \* Pharmacogenomics and Race.

## **Pandemic Inequalities: Human Rights and Global Health**

**Alicia Yamin**

Spring 2021

The staggering toll of COVID-19 has laid bare and exacerbated structural injustices within and between countries, which call for profound reflection on the societies and world we had inhabited pre-pandemic-- as well as the role of human rights praxis in creating transformative change. In this context, how should we understand the suffering we and/or others are experiencing, and the dramatically disparate health and social impacts of this novel coronavirus on diverse groups across our societies and the globe? Further, how can we catalyze transformative legal, political and programmatic responses?

This seminar provided historical context for understanding the profound inequalities that COVID-19 has revealed in the United States, and around the world, and critically examines the role of international human rights law and strategies in creating progressive social change. Looking forward, the seminar explored how human rights, together with other movements, can be deployed now and beyond the pandemic, to address other global threats such as climate crisis, as well as broader political economy questions. Guest speakers, emphasis on personal narratives, readings from multiple disciplinary perspectives, and class debates regarding legal and policy issues sharply revealed by the pandemic were intended to encourage critical reflection on prevalent national and global discourses in relation to when misfortune becomes injustice, in health and beyond.

## **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 FY21 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 400 unique live views per event and our events often draw a national or international audience.

In FY21, 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 healthcare workers' pandemic experiences, to medical racism, to the legalization of psychedelics. Our Annual Conference, "COVID-19 and the Law: Disruption, Impact, and Legacy", was held as a virtual seminar series bringing together top legal and medical scholars on the impact of COVID-19 across topics, including its legacy and evolving legal doctrines, the role of health justice in the pandemic, the use of biotech in the pandemic, the disparate burdens of COVID-19 and varying communities, and its impact on the health care system. Reaching up to 196 unique views per event, it 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 FY21 events can be found [here](#).

In the Fall, the Center was specifically excited to be able to include preeminent government officials in our events and enable HLS student opportunities to connect with them. Events included:

**Enforcing Constitutional Commitments to Health and Social Equality in Kenya: A Conversation with Justice Mumbi Ngugi**  
**November 19, 2020**

*This event was cosponsored by the Global Health and Rights Project (GHRP), a collaboration between the Petrie-Flom Center for Health Law Policy, Biotechnology, Harvard University Center for African Studies, and The Hutchins Center for African & African American Research.*

**Constitutional Democracy and the Role of High Courts in Times of Crisis: The Case of Mexico**  
**October 23, 2020**

*This event was cosponsored by the Global Health and Rights Project (GHRP), a collaboration between the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School, the Global Health Education and Learning Incubator (GHELI) at Harvard University, and the David Rockefeller Center for Latin American Studies at Harvard University.*

This event, headed by **Alicia Ely Yamin**, brought together Mexican Supreme Court, Justice Gutiérrez Ortiz Mena LLM '89 in conversation with Director of the Undergraduate Law Program, Full time Professor, Instituto Tecnológico Autónomo de México (ITAM), Sofia Charvel, for a discussion of how modern constitutional democracies preserve the rule of law during crises and states of exception or emergency. Following the event, both speakers met with students from the Mexican Association at Harvard Law.

Other highlights from our virtual event calendar included:

**Can Psychedelics Help Save America?**  
**October 28, 2020**

Attendance: 255 unique views

*Sponsored by the Edmond J. Safra Center for Ethics at Harvard University and the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School.*

Featuring: 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

## **IVF Add-Ons: Scientific, Ethical, Regulatory, and Legal Considerations**

**November 10, 2020**

Attendance: 235 unique views

*Sponsored by the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School.*

## **Medical Stereotypes: Confronting Racism and Disparities in US Health Care: A Health Policy and Bioethics Consortium**

**February 12, 2021**

Attendance: 396 unique views

*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.*

## **Other Avenues of Connection**

In our new virtual setting, the Center is also excited to position itself as a virtual meeting and convening place in FY21 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.

On September 9, 2020, we convened our first virtual meeting of our Office of General Counsels (OGC) Roundtable, which featured **Provost Alan Garber** who led a discussion on institutional leadership during the pandemic. Our Roundtable allows us to serve the HLS alumni community by connecting our alumni back to each other and Harvard experts. During FY21, 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 had its inaugural meeting on December 11, 2020. 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 sunsetting funded work. During FY21 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 at some point to bring both of these groups to the HLS campus 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 FY21, the Project began the general literature review and regulatory scan. The literature identified key areas in ethics, law, and medicine that implicated the project. Additionally, Simon co-authored several draft papers with **I. Glenn Cohen**, **Carmel Shachar**, Anaeze Offodile, and Celynne Balatbat on legal and ethical issues relating to digital home diagnostics and diagnosis in the hospital-at-home system. Simon also organized a blog series on *Bill of Health* entitled *Innovation and Incentives in Digital Health*, some of which was published in FY22.

For FY22, the Project will further work and publish on issues at the cutting edge of medical development, especially the ethics and law of new diagnostic technologies outside the traditional confines of the clinic, imaging room, or hospital. In addition, the Diagnosing in the Home Project will produce a Regulatory Scan, which will identify the central federal laws implicated by emerging digital home diagnostics as well as conduct a Delphi panel to develop a framework for analyzing and addressing issues in the Project. The Project will also organize, in collaboration with partners across Harvard, several events on digital home health and related topics, such as “Should Alexa Diagnose Alzheimer’s?” and other topics, such as on racial and equity issues related to mobile magnetic resonance imaging (MRI) technology.

### **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. It is supported by a generous grant from the Saisei Foundation.

Despite a longstanding prohibition on psychedelics dating back to the 1970s, scientific and public interest in these substances is growing. Clinical trials repeatedly demonstrate their promise for treating mood, anxiety, and substance use disorders. In 2017, the FDA designated MDMA a breakthrough therapy for post-traumatic stress disorder, and in 2018 the agency recognized psilocybin as a breakthrough for treatment-resistant depression. These designations indicate that psychedelics may be substantial improvements over existing treatments for mental illness. While psychedelic therapies make their way through the drug development pipeline, seven U.S. cities and the state of Oregon have decriminalized them, and last November, Oregon voters legalized the supervised administration of psilocybin. At least eight other states are considering similar legislation to legalize or decriminalize psychedelics. Due to their therapeutic and commercial potential, the U.S. market for psychedelics is projected to reach \$6.85 billion by 2027, attracting a significant number of for-profit companies and investors. However, despite the proliferation of clinical research centers, increasing private investment in psychedelic drug development, and widespread state and local decriminalization, there is a relative lack of research on the ethical, legal, and social implications of psychedelics research, commerce, and therapeutics.

POPLAR is the first academic initiative focused on psychedelics law and policy, positioned to be a global leader for research and education in this space. Currently, there are a handful of psychedelics research centers at universities around the country. However, they are focused on

clinical research. There is no systematic research being done on psychedelics law, and POPLAR will fill this gap. The POPLAR team will advance evidence-based psychedelics regulation through research in five key areas: ethics in psychedelics research and therapeutics, challenges at the intersection of psychedelics and intellectual property law, opportunities for federal support of psychedelics research, access to psychedelic therapies and equity in emerging psychedelics industries, and the role of psychedelics in healing trauma. The project will address these areas by publishing academic research; hosting academic events and roundtables with experts from industry, government, and academia; educating courts, legislators, government agencies, and the public; partnering with clinical researchers to help them navigate legal and ethical roadblocks in their work; and training the next generation of thought leaders in this emerging field.

Shortly after its launch at the end of FY21, POPLAR received wide press coverage, including:

Shayla Love, *Harvard Lawyers Will Study the Legal Questions Around Psychedelic Treatment*, VICE (June 30, 2021).

Chloe Reichel, *A Q&A with Mason Marks on new psychedelics law and regulation initiative*, VICE (July 7, 2021).

Audrey Conklin, *Harvard to study psychedelics and the law as decriminalization gains steam*, FOX NEWS (July 10, 2021).

*"Legalizing PSYCHEDELICS?" Rising* by THE HILL (July 12, 2021).

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.

### **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 FY21, 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. 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. Yamin also joined Partners in Health as a Senior Advisor on Human Rights in FY20.

COVID-19 created an imperative to address multiple aspects of the pandemic on democracy, rights and the rule of law not just in the United States but around the globe. In FY21, through a broad range of publications and events, mentioned in the introduction, GHRP has contributed to policy-relevant scholarship on the International Health Regulations and global health law, as well as to examining the impacts of the pandemic on specific populations, health systems and the rule of law more broadly, across a wide range of countries.

In FY22, 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, such as the jointly organized and hosted International Pandemic Law Making Symposium with Verfassungsblog and



the Max Planck Institute (September-November, 2021), and accompanying webinar and working paper series.

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 FY21, the Project on Advance Care and Health Policy, by inaugural Senior Fellow **Mark Sterling** (through January 2021) and Senior Fellow **Cheryl Matheis** (since January 2021), continued to contribute to public policy on care for people with advanced illness. In July 2020, the project hosted an insightful conversation around advance care planning in the age of COVID. In April 2021, as a part of CTAC's Trends Transforming Advanced Illness Care, the Project hosted a virtual seminar examining the promise of technology, from the perspective of three experts who approach care delivery from different vantage points.

For FY22, the Project will continue to host insightful events that further explore the forces driving care into the community. Potential topics include new delivery models of care, financial challenges with Medicare, Medicaid and private insurance reimbursement, and social issues to be addressed that together will determine our ability to provide individuals with care that enables quality of life in their advanced illness.

### **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 2021, **Elyssa Spitzer** HLS'17 joined as the Project's fourth Senior Fellow. As Senior Fellow, Spitzer was excited to return to HLS to conduct original research, mentoring, policy work, and public engagement on legal issues related to uses of force against juveniles. Under her leadership, the Project hosted several public events, including a panel on how neuroscience could contribute to police reform and one on the potential for a federally-funded mental health moonshot built around psychedelics and the obstacles to achieving it. Spitzer will continue her work into FY22, featuring an author talk with Daniel Schacter on his updated edition of *The Seven Sins of Memory: How the Mind Forgets and Remembers*.

In FY22, **Stephanie Tabashneck** will join the project as Senior Fellow in January 2022. Her work will focus on substance use and addiction within the context of judicial and legal education. She plans to explore the intersection of substance use and the law with leaders in the field of addiction in closed and public events.

## **Upcoming Initiatives**

In FY22, we are looking forward to another productive and busy year at the Petrie-Flom Center. Among our FY22 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 FY21, and we plan to further build on this foundation to enhance our thought leadership in the health law policy and bioethics field. In FY21, our blog, *Bill of Health*, featured a significant increase in digital symposia and blog readership. In the spring of FY21, the blog had over 100,000 unique views per month, peaking at 119,000 views in April. Stephen Wood, Visiting Fellow organized, in conjunction with Blog editor-in-chief, Chloe Reichel, a digital symposium on *In Their Own Words: COVID-19 and the Future of the Health Care Workforce* which shared reflections from a diverse range of health care workers, including ICU and ED nurses and physicians, medical and nursing students, emergency medical technicians, and leaders of professional groups within the health care sector, about their experiences on the front lines. The symposium received coverage in *Harvard Law Today* and was accompanied by a panel discussion featuring four of the contributors. We also built our audience of partners who want to deliver digital symposia and expect to continue to build on this momentum. For example, we hosted a digital symposium on health justice organized in collaboration with **Lindsay Wiley**, Professor of Law and Director, Health Law and Policy Program, American University Washington College of Law and **Ruqaiyah Yearby**, Professor, Center for Health Law Studies; William C. Wefel Center for Employment Law, School of Law Professor; and Executive Director and Co-Founder, Institute for Healing Justice and Equity, Saint Louis University, which will also include a companion event, *Health Justice: Engaging Critical Perspectives in Health Law and Policy*.

We plan to continue this momentum in FY22. Another focus for our digital media presence in FY22, is a podcast aimed at serving the broader HLS alumni community, by connecting them back to the health law policy and bioethics work being done at HLS, and the broader community through timely and dependable information sharing. Our first season will provide a thorough investigation into the state of digital health/health AI, and is underway. The Center has engaged a podcast producer to ensure that the Petrie-Flom Center podcast is polished and professional.

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 FY22 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. We anticipate that both of these projects will be signature areas of research for Petrie-Flom in the coming years. For more on each of these initiatives please see our research section.

We hope to further expand our research program in FY22. We anticipate receiving funding to hire a research fellow for our Innovative Funding Models in Translational Research project. This will allow us to greatly expand the work of that project. We have several grant applications outstanding, mostly focusing on expanding our work on artificial intelligence and digital health technologies. 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 FY22 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 FY22, we will host out 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 Conference will be is organized in collaboration with Julia Adler-Milstein, Professor of Medicine and Director of the Center for Clinical Informatics and Improvement Research at University of California San Francisco, and Daniel Kramer, Assistant Professor of Medicine at Beth Israel Deaconess Medical Center. This Conference, which will be held in June 2022, will engage with the vision for a 21st century health care system that embraces the potential of at-home digital products to support diagnoses, improve care, encourage caregivers, maximize pandemic resilience, and allow individuals to stay within the home when preferable. We will also publish an edited volume from the presentations of this Conference.

In FY22, 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.

