



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

*Annual Report, Fiscal Year 2020
July 2019–June 2020*

Introduction and Executive Summary

In light of the changes necessitated by the COVID-19 pandemic, Fiscal Year 2020 was a dynamic and rewarding year for the Petrie-Flom Center. Following a productive and successful Fall, the Center was able to quickly pivot their robust Spring calendar of events, publications, and fellows to virtual settings. Overall, FY20 was a year of successful launches and exciting work for the Petrie-Flom Center, in terms of projects, events, structure, and communications.

Areas of specific pride for the Petrie-Flom Center, in light of the events in spring 2020, include our 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. These will also be our areas of focus for FY21. Upcoming highlights include: the launch of our Advisory Board, the start of a fully funded three-year initiative on diagnostic digital health, and the beginning of a podcast aimed to bring the Center's work to a general audience.

Increased Digital Media and Event Presence

A central focus of the Center in FY20 was its communications strategy, especially in relation to providing our audiences accurate and impactful information on the COVID-19 pandemic and its interaction with health law policy and bioethics. Our blog, *Bill of Health*, which continues to be a leading forum for health law policy and bioethical perspectives from thought leaders across the country and in Europe, experienced an explosion in readership in May and June, reaching over 120,000 visits monthly, due to our coverage of the COVID-19 pandemic. We anticipate that *Bill of Health* will continue to host insightful analysis, especially as the Pandemic evolves, from contributors at Harvard and beyond.

In Spring of 2020, the Petrie-Flom Center was able to quickly pivot our extensive event calendar to virtual settings. Our Annual Conference, "Innovation and Protection: The Future of Medical Device Regulation", was transitioned into a series of podcasts with an average of 1,200 listeners

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per episode, and is currently in process of becoming a published book with Cambridge University Press. In addition to transitioning our existing events to virtual settings, the Center also produced additional events that explored COVID-19 and the policy and legal impacts of the Pandemic. Our attendance has been very strong with up to 450 unique live views per event. A full list of our FY20 events can be found [here](#). Highlights from our virtual event calendar included:

Disability, COVID-19, and Triage: Exploring Resource Allocation and the Framing of Disability

April 14, 2020

Attendance: 321 unique views

Disability, COVID-19, and Triage: Exploring Resource Allocation and the Framing of Disability

Featuring: Michael Ashley Stein HLS '88, Executive Director, Harvard Law School Project On Disability, Visiting Professor, Harvard Law School

Ethical Dilemmas in Mask and Equipment Shortages: Health Care During the COVID-19 Pandemic*

April 22, 2020

Attendance: 450 unique views

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

Featuring: Stephen Wood, Visiting Fellow, Petrie-Flom Center

Incarcerated Populations and COVID-19: Public Health, Ethical, and Legal Concerns*

May 20, 2020

Attendance: 209 unique views

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

Featuring: Stephen Wood, Visiting Fellow, Petrie-Flom Center; Joel Thompson HLS '97, Staff Attorney, Prisoners' Legal Services of Massachusetts and Clinical Instructor, Harvard Prison Legal Assistance Project; Jessie Rossman HLS '07, Staff Attorney, ACLU Massachusetts

Data and COVID-19*

June 2, 2020

Attendance: 323 unique views

Sponsored by the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School and the Berkman Klein Center for Internet and Society at Harvard University.

The Petrie-Flom Center plans to continue its superb digital media and event presence into FY21. In the coming year, the Center plans to launch a podcast, as well as a semester-long symposium on Race and Health. 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.

Maintained Connection to HLS Students

Due to the move to remote learning, the Center has 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, intern, and research assistant (RA) programs.

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Our excellent Student Fellows joined the Center from across campus and pursued projects related to public health contracting and agency problems; the rise of assisted reproductive technology disputes focused in New Zealand; the Constitutional right to physician assisted suicide; a comparison of cellular and gene therapy regulations in China and the United States; ethical considerations of voice assistant devices in in-home aging care; and affirmative consent in childbirth. 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. As a new component to our Student Fellow program in FY20, we paired each Student Fellow with a mentor from a related industry. The Center was especially grateful to be joined by Law School alumna, **Susan Galli JD '84**, Partner at Ropes & Gray LLP who acted as industry mentor for Student Fellow, **Sarah Alawi**, and her project on the enforceability and interpretation of preconception agreements after relationship breakdowns.

The Center is moving forward with Student Fellowships for FY21. We are converting the program into a virtual setting and are excited to continue to mentor Harvard Law School Students. An example of our programming aimed at students for FY21 is to connect students with inspirational women judges in the wake of the death of Justice Ruth Bader Ginsburg. In November 2020, our Global Health Rights Project (GHRP) will host a one-on-one conversation with **Justice Mumbi Ngugi** of the High Court of Kenya, which will both address the enforcement of health rights in the Kenyan Constitution, and highlight the role of Judge Ngugi as a role model for women in the law, as well as persons with disabilities.

Center affiliated interns and RAs also transitioned to online in the spring of 2020. Our student internship program employs paid interns (undergraduates and graduate students at Harvard and elsewhere) 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 2018–2019 interns were:

- Danielle Pacia, HMS MBE '20
- Jonathan Chernoguz, HMS MBE '20

The Center also engaged an RA, Tara Boghosian, JD '20, 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.

For FY20, GHRP, led by Yamin and assisted Boghosian, presented the following well-attended events:

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- Book Talk: When Misfortune Becomes Injustice: Evolving Human Rights Struggles for Health and Social Equality
February 7, 2020
- Debt, Dignity, and Health Care: Guaranteeing Health Rights and Universal Health Coverage
March 27, 2020
- Digital Symposium: Global Responses to COVID-19: Rights, Democracy, and the Law
May 2020

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. Boghosian co-published with Yamin:

- *Democracy and Health: Situating Health Rights within a Republic of Reasons*, 19 YALE J. HEALTH POLICY, LAW AND ETHICS (2020): 87-123
- *The Right to Health: Contesting the Bounds of the Natural, the Normal and the Political* in OXFORD HANDBOOK ON ECONOMIC, SOCIAL AND CULTURAL RIGHTS (Malcolm Langford and Katherine Young eds., forthcoming 2020).

As in previous year, the Center also engaged RAs to assist with line-editing our upcoming volume, *Consuming Genetics: Ethical and Legal Considerations of New Technologies*. This work was easily transitioned to a remote setting, and due to the RAs' excellent work, this volume will be shortly going to our publisher, Cambridge University Press.

The *Project on Law and Applied Neuroscience* also engaged HLS students through its work under the guidance of **Francis Shen**, Senior Fellow in Law and Applied Neuroscience. HLS student Fenella McLuskie, JD '22, along with two Harvard College research assistants, published an OpEd in The Harvard Crimson on "The Forgotten: Juveniles In Detention During COVID-19". McLuskie and Erin Shortell, JD '21, are also working with Shen on a paper exploring the use of neuroscience in legal cases arguing for extension of constitutional protections for juveniles to young adults ages 18-21. In FY20, Shen provided extensive mentoring to HLS students McLuskie and Shortell, meeting with them weekly and collaborating on multiple writing projects as described above.

Robust Inclusion of the Center's Experts in Policy in Media Coverage

The Petrie-Flom Center's leadership, fellows, and other affiliates have once again enjoyed a prolific year, producing cutting-edge scholarship in the areas of disability and health, artificial intelligence in health care, reproductive technologies, human subjects research, and, timeliest, the COVID-19 pandemic. These publications (some of which remain pending) have generated academic conversation, invitations to events, inquiries from the press, and a great deal of positive attention to our Center. A full list of our scholarship can be found here. Highlights of Center Affiliate scholarship are listed below:

Scholarship:

Carmel Shachar, Sara Gerke, Eli Y. Adashi, ***AI Surveillance during Pandemics: Ethical Implementation Imperatives***, 50 THE HASTINGS CENTER REPORT 3 (June 29 1, 2020).

I. Glenn Cohen, Lawrence Gostin, and Daniel Weitzner, ***Digital Smartphone Tracking for COVID-19: Public Health and Civil Liberties in Tension***, 323 JAMA 23 (May 27, 2020).

Carmel Shachar, Jaclyn Engel, and Glyn Elwyn, ***Implication for Telehealth in a Postpandemic Future: Regulatory and Privacy Issue***, 323 JAMA 23 (May 18, 2020).

Danielle Allen, Anne-Marie Slaughter, Josh Simons, and Carmel Shachar, ***Federalism Is an Asset: How to Activate It to Build a National Pandemic Testing Program***, EDMOND J. SAFRA CENTER FOR ETHICS' COVID-19 RAPID RESPONSE IMPACT INITIATIVE (April 28, 2020).

I. Glenn Cohen, Andrew M. Crespo, and Douglas B. White, ***Viewpoint: Potential Legal Liability for Withdrawing or Withholding Ventilators During COVID-19: Assessing the Risks and Identifying Needed Reforms***, 323 JAMA 19 (April 1, 2020).

Alicia Ely Yamin, and Roojin Habibi, ***Human Rights and Coronavirus: What's at Stake for Truth, Trust, and Democracy?***, HEALTH AND HUMAN RIGHTS JOURNAL (March 1, 2020).

Roojin Habibi, Gian Luca Burci, Thana C de Campos, Danwood Chirwa, Margherita Cinà, Stéphanie Dagron, Mark Eccleston-Turner, Lisa Forman, Lawrence O Gostin, Benjamin Mason Meier, Stefania Negri, Gorik Ooms, Sharifah Sekalala, Allyn Taylor, Alicia Ely Yamin, Steven J Hoffman, ***Do not violate the International Health Regulations during the COVID-19 outbreak***, LANCET (February 13, 2020).

A full list of our extensive media commentary in FY20 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:

Joanne Kene, quoting Carmel Shachar, ***Immunity passports' won't reopen America***, POLITICO (May 18, 2020).

Alicia Ely Yamin, ***Post-pandemic collective action for health rights and social justice is essential***, OPENGLOBALRIGHTS (May 18, 2020).

Jacob Ward and Chiara Sottile, interview I. Glenn Cohen, ***A Facial Recognition Company Wants to Help with Contact Tracing. A Senator Has Questions***, NBC NEWS (April 30, 2020).

Dave Biscobing, interviewing I. Glenn Cohen, ***Experts: Arizona Officials Unlawfully Holding COVID-19 Information***, ABC 15 (April 27, 2020).

Jacob Ward, interviewing I. Glenn Cohen, ***Controversial Tech Company Pitches Facial Recognition to Track COVID-19***, NBC NEWS (April 27, 2020).

Katie Brigham, interviewing I. Glenn Cohen, ***Privacy Concerns Arise as Big Tech Unites to Fight Coronavirus***, CNBC (April 23, 2020).

NBC's Today Show, interviewing I. Glenn Cohen. ***Coronavirus-detecting Drones Stir Privacy Concerns***, NBC'S TODAY SHOW (April 23, 2020).

Casey Ross, quoting I. Glenn Cohen, ***After 9/11, we gave up privacy for security. Will we make the same trade-off after Covid-19?***, STAT NEWS (April 8, 2020).

Shira Springer, interviewing I. Glenn Cohen, ***Injured Athletes, Sports Leaders Face Ethical Issues Amid Pandemic***, WBUR (April 8, 2020).

Alicia Ely Yamin, ***Truths and Lies about this Pandemic: What are the lessons for health rights and social justice?***, THE GLOBAL INITIATIVE FOR ECONOMIC, SOCIAL AND CULTURAL RIGHTS (April 3, 2020).

I. Glenn Cohen, Andrew M. Crespo, and Douglas B. White, ***Protect the Doctors and Nurses Who Are Protecting Us: They need immunity from lawsuits and prosecution for triage decisions***, NEW YORK TIMES (April 1, 2020).

Nicholas Florko, quoting I. Glenn Cohen, ***Explaining a mass quarantine: What does it mean to 'shelter in place'? And who has the power to call for it?***, STAT (March 17, 2020).

Thomas Fuller, quoting I. Glenn Cohen, ***How Much Should the Public Know About Who Has Coronavirus?***, THE NEW YORK TIMES (March 28, 2020).

Jonathan Chernoguz, featuring I. Glenn Cohen, Carmel Shachar, Alicia Ely Yamin, and Sara Gerke, ***Protecting rights in a global crisis: HLS scholars raise important legal and ethical questions about health care delivery and the enactment of extraordinary public health measures***, HARVARD LAW TODAY (March 25, 2020).

Nicholas Florko, quoting I. Glenn Cohen, ***Explaining a Mass Quarantine: What Does It Mean to 'Shelter In Place'? And Who Has the Power to Call for It?***, STAT News (March 17, 2020).

Overall, FY20 was a year of change for the Petrie-Flom Center and beyond. With our ability to agilely pivot our program and activities, the Center has continued to fulfill our core mission in a virtual setting, which we carry on into FY21.

Accomplishments and Challenges

Contributions to the HLS teaching program, participation of HLS students, connections to the community and professions, and thought leadership at an important time of health law policy ferment are central pillars of the Center's FY20 work. In light of the Pandemic and in light of staffing changes throughout the fiscal year, the Center was rarely at full staffing capacity, making our robust contributions to the HLS community and beyond even more of an accomplishment for the Center.

Contributions to the HLS Teaching Program

Petrie-Flom Center affiliates make substantial contributions to the university's health law curriculum through various courses and frequent guest lectures.

This year, Petrie-Flom affiliates offered the following full courses for credit:

Health Law, Policy, Bioethics, and Biotechnology Workshop

I. Glenn Cohen

Fall 2019

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 is 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

Kevin Costello

Fall 2019

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.

***Carmel Shachar** normally co-teaches this course with Kevin Costello, but could not during FY20 due to family leave. She has resumed teaching this course for FY21 and anticipates teaching it for FY22.*

Bioethics and Health Law: Selected Topics

I. Glenn Cohen

Winter 2020

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.

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

Alicia Ely Yamin

Spring 2020

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. Political polarization has been particularly pronounced with regard to abortion rights, but is also evident in an array of other SRHR issues. Issues of SRHR present an opportunity to extend thinking on judicial review across contexts of varying levels of democratic consolidation, as well as to critically examine the effectiveness of international human rights law in changing “lived realities.” This course explored lessons with respect to how engaging with different SRHR issues can affect the sociological legitimacy of tribunals at domestic and international levels, as well as public attitudes and the dynamics of social conflict.

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.

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.

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

Daniel Aaron

Harvard Law School, JD '20;

Boston University School of Medicine MD '20

Paper: "The Biggest Agency Problem of All: Public Health in the Opioid Litigation"

Industry Mentor: Tom Lee, Chief Medical Officer, Press Ganey

Sarah Alawi

Harvard Law School, LLM '20

Paper: "Posthumous Medical Data Donation: Guiding Elements For A Legal Framework"

Industry Mentor: Susan Galli HLS '84, Partner, Ropes & Gray LLP

Beatrice Brown

Harvard Medical School, MBioethics '20

Paper: "Redefining Healing: Arriving at a New Argument for a Constitutional Right to Physician-Assisted Death"

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

Phebe Hong

Harvard Law School, JD '21

Paper: "CAR T-cell Therapy Innovation & Regulation: China and the United States Compared"

Industry Mentor: Robert Urban, Global Head, Johnson & Johnson Innovation

Adriana Krasniansky

Harvard Divinity School, MTS '21

Paper: "Ethical Dimensions of Voice Assistant Devices for In-Home Healthcare"

Industry Mentor: Cynthia Bero, Vice President, Information Systems at Mass General Brigham

Alexa Richardson

Harvard Law School, JD '21

Paper: "The Case for Affirmative Consent in Childbirth"

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

Our Student Fellows finished out their fellowship virtually, presenting their independent research projects over Zoom to an audience of their peers, industry mentors, and Center staff and affiliates. The event was covered by Harvard Law Today, highlighting the accomplishments of our FY20 Fellows.

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 Associates, **Katherine Dowling** and **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:

- COVID-19 Policies and Constitutional Violations, by Daniel Aaron, JD '20
One of the Bill of Health's Top 10 posts for FY20
- Staying Sane and Hopeful During the COVID-19 Pandemic, by Sarah Alawi, LLM'20
- Stopping the Pharmaceutical "Product Hop", by Phebe Hong, JD'21

The Center was also proud to maintain our ability to employ interns and RAs both in person and virtually through FY20. Their work helped to further important Center initiatives, such as communications, the Global Health and Right Project, and the Project on Law and Applied Neuroscience, as noted in the Introduction and Executive Summary. 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 FY21 and adding experience to their resumes.

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 FY20 was no exception, both in-person and virtually. During the spring, as highlighted in the Introduction and Executive Summary, the Center worked very hard to serve the HLS community by bringing reputable and useful COVID-19 information, such as "Ethical Dilemmas in Mask and Equipment Shortages: Health Care During the COVID-19 pandemic." Despite our virtual setting, the Center

remained committed to One Harvard, by maintaining and growing our relationships with our sister programs, such as collaborating Center for Bioethics and Edmond J. Safra for Ethics.

In the Fall, the Center was specifically excited to be able to bring preeminent government officials to Campus to interact with our students. Events included:

15+ Years of PEPFAR: How U.S. Action on HIV/AIDS Has Changed Global Health

October 7, 2019

This event was cosponsored by the Harvard Global Health Institute, the Harvard University Center for AIDS Research, the Center for Health Law Policy and Innovation at Harvard Law School, and the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School.

Featured speakers included: Ambassador-at-Large, **Deborah L. Birx**, Coordinator of the United States Government Activities to Combat HIV/AIDS and U.S. Special Representative for Global Health; **Anthony S. Fauci**, Director of the National Institute of Allergy and Infectious Disease (NIAID)

Abortion Battles in Mexico and Beyond: The Role of Law and the Courts

October 4, 2020

Part of 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 and the Global Health Education and Learning Incubator (GHELI) at Harvard University, with support from the Center for Bioethics at Harvard Medical School and the Oswald DeN. Cammann Fund at Harvard University.

This event, headed by **Alicia Ely Yamin**, brought together two sitting justices on the Mexican Supreme Court, Justice Gutiérrez Ortiz Mena LL.M. '89 and Justice González Alcántara, for an event, "Abortion Battles in Mexico and Beyond: The Role of Law and the Courts." The event discussed the holdings, implications, and context for two recent Mexican Supreme Court decisions, as well as the Court's evolving role in the area of sexual and reproductive health and rights, and in particular abortion. Following the event, both justices met with students from the Mexican Association at Harvard Law, which co-sponsored the event, as well as meeting with **Dean Manning**.

Faculty Participation

As noted throughout this report, HLS faculty participation in the Petrie-Flom Center is both strong and essential. In addition to the clear investment by Faculty Director **I. Glenn Cohen** and Founding Director **Einer Elhauge**, **Hon. Nancy Gertner**, Lecturer on Law, has continued to support our collaborative Program on Law and Applied Neuroscience. Under Executive Director **Carmel Shachar** – an alumna of the Center for Health Law Policy and Innovation – we have continued to build our relationships with **Robert Greenwald** and **Emily Broad Leib**, collaborating on events, such as "Soda Taxes and Other Policy Responses to the American Obesity Epidemic: A Health Policy and Bioethics Consortium," "Eighth Annual Health Law Year in P/Review," and "15+ Years of PEPFAR: How U.S. Action on HIV/AIDS Has Changed Global Health." Finally, we continued working with **Urs Gasser** and **Terry Fisher** of the Berkman Klein Center for Internet and Society to expand our collaborations, resulting this year in our virtual event on "Data and COVID-19," which took place in early FY21, but was planned in FY20.

Harvard faculty are also less formally involved with the Center through attendance and participation in the Center's Health Law, Policy, Bioethics, and Biotechnology Workshop and other programmed events. We continue to actively develop faculty involvement to help offer a centralized location within the university for faculty sharing a collective interest in our fields.

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.

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 by the Petrie-Flom Center and the Center for Advanced Studies in Biomedical Innovation Law (CeBIL) at the University of Copenhagen. This research is supported by a Novo Nordisk Foundation-grant for a scientifically independent Collaborative Research Programme in Biomedical Innovation Law (grant agreement number NNF17SA027784). PMAIL will run until the end of December 2022. PMAIL aims to provide a comparative analysis of the ethics and law of AI in health care in the U.S. and Europe, as well as digital health in general, such as the ethics and law of ingestible electronic sensors.

The Petrie-Flom Center organized (in collaboration with other partners) several events on PMAIL related topics, such as on Black-Box Medicine: Legal and Ethical Challenges and AI and Disability/Dependency: Equity, Access, and Interdependence. PMAIL had to postpone its international regulators' roundtable on health AI from spring 2020 to likely late 2021/early 2022 (when it will be safe to travel again). The roundtable had regulators from 20 different countries committed to coming to Harvard's campus for peer discussion and working groups with leading scholars. We anticipate a similar or larger size group when we are able to host it.

In FY21, The PMAIL project 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. In addition, PMAIL will also host virtual events and conferences and release a podcast on the challenges and opportunities of incorporating AI into health, including discussions of privacy, racial inequalities, and patient safety. The podcast will likely come out right after the new year 2021 and feature leading scholars, health lawyers, and industry leaders.

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.

Since February 2020, COVID-19 has 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. Through a broad range of publications and events, GHRP has contributed to policy-relevant scholarship on the International Health Regulations and global health law, as well as to issues of health and other rights and impacts on health systems, across a wide range of countries. In addition to an array of articles, commentaries and presentations, the PFC digital global symposium on COVID-19 and the Rule of Law compiled the reactions of 30 international health law experts on the reactions in their countries to the pandemic.

In FY21, GHRP has already sponsored two follow-up events to the PFC digital symposium, seeking to focus on: (1) the specific effects on sexual and reproductive health and rights; and (2) the social, economic and political impacts of governmental responses to the pandemic in South America, where the repercussions on democratic institutions and the rule of law have been particularly dramatic. GHRP has sponsored a third event related to themes of the digital symposium focusing on the role of high Courts in Times of Crisis” featuring Justice Gutierrez Ortiz Mena of the Mexican Supreme Court. Further activities and events, likely around global access to an eventual vaccine, are planned for spring, 2021.

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. It includes a Senior Fellowship, public symposia and events, and policy and research projects. **Mark Sterling, MPP, JD**, served as the Senior Fellow in Advanced Care and Health Policy for FY19 and FY20 and will continue to do so for FY201. He is a senior strategic advisor to C-TAC, and recently was a Senior Fellow at Harvard University’s Advanced Leadership Initiative.

In March 2020, we hosted a Conference entitled “The Evolution of Hope in Advanced Illness: A Key to Health System Transformation,” with thought leaders, innovators, and advocates exploring the nature, dynamics, and management of hope in the context of advanced illness and end-of-life care. The overarching goal was to suggest ways to measure, implement, test, and disseminate novel tools and national strategies to improve care and quality of life for the growing population of patients with advanced illness. In light of the pandemic, in June 2020 we hosted an

on-line panel discussion, attended by over 400 participants, on the topic, “Advance Care Planning in the Age of COVID: Lessons Learned and Policy Implications.”

In FY21, Mark Sterling will transition off this project and the Center hopes to engage Cheryl Matheis as the new Senior Fellow.

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 Fall 2019, **Francis X. Shen** continued for a third year as the third Senior Fellow in Law and Neuroscience. During his fellowship in 2019-20, he pursued original research, mentoring, and public engagement related to issues of neuroscience and law, with a focus on three areas: dementia and the law; trauma and immigration law; and juvenile justice. This work included two public events: *Computational Justice: How Artificial Intelligence and Digital Phenotyping Can Advance Social Good*, which examined the legal implications of computational methods in psychiatry; *The Next Frontier of Neuroscience and Juvenile Justice*, which explored the legal implications of advances in neuroscientific understanding of the developing brain, including development in emerging adulthood from ages 18 to 25. A third event, *Detecting Dementia: Technology, Aging Brains, and the Law*, was scheduled for April 1, 2020 but was postponed and rescheduled to Fall 2020 due to COVID-19.

Upcoming Initiatives and Collaborations

In FY21, we are looking forward to another productive and busy year at the Petrie-Flom Center. We plan to expand our digital media presence, serve as a virtual meeting place, and continue our authoritative and well-respected scholarship and research programs.

Digital Media

Digital media was an area of growth for the Center for FY20, and we plan to further build on this foundation to enhance our thought leadership in the health law policy and bioethics field. In FY20, our blog, *Bill of Health*, featured a significant increase in digital symposia and blog readership. **Alicia Ely Yamin**, Senior Fellow in Global Health Rights, organized, in conjunction with Blog editor-in-chief, Chloe Reichel, a digital symposium on “Reproductive Rights in 2020” in reaction to the Supreme Court decision on *June Medical Services v. Russo*, and the impact of the COVID-19 pandemic on access to abortion, sexual health, and reproductive health services. For FY21, we are already under way with a digital symposium co-organized by **Craig Konnoth**, Associate Professor of Law, Colorado Law, that asks leading scholars in law, public health, history, sociology, and other fields to explore how critical race theories and other strands of racial justice scholarship can inform health care, public health, and other areas of law to improve health

outcomes among minorities. We are also building an audience of partners who want to deliver digital symposia and expect to have more throughout FY21.

Another focus for our digital media presence in FY21, 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 in 2020, and is underway. Our second season will address the intersection of the opioid and COVID-19 pandemics. 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.

Virtual Connections

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. Already in FY21, the Center is working hard to leverage the Harvard name and the Petrie-Flom Center reputation to serve as a virtual meeting space. 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 FY20 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
- **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.

Our Advisory Board, which will have its augural meeting on December 11, 2020, will likewise allow us to bring together industry leaders with HLS alumni who will help to shape the Center's work. The Board will involve 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.

In FY21, we also plan to leverage our robust event schedule to convene experts on timely topics, and provide valuable information to our ever-growing audience. Highlights from our FY21 event

schedule include, “Understanding the Role of Race in Health: A Moderated Discussion,” and “Can Psychedelics Help Save America?” planned with Mason Marks, our joint Fellow in Ethics and Technological and Biomedical Innovation with the Edmond J. Safra Center. We are also planning a seminar series and 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.

Another avenue through which we plan to leverage our resources as a virtual meeting space is with our Student Fellows. Our Fellowship allows our student to connect with HLS faculty and peers who have similar academic and professional interests, and with members of the professional community, such as with their Industry Mentors. These opportunities to network and make connections are more important for us facilitate now more than ever due to our virtual setting.

We will consider ourselves successful in serving as a virtual meeting and convening space if we have quarterly meetings of our OGC Roundtable, host two sessions of our Advisory Board, continue to provide an event calendar that brings together top experts and provides relevant content for our audiences, and receive feedback from our 2020-2021 Student Fellows that our activities were helpful in developing their career goals.

Research and Scholarship

Our final central guiding pillar for FY21 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. Previously, through our Project on Precision Medicine, Artificial Intelligence, and the Law (PMAIL), we identified artificial intelligence as a research area about to explode. Our advance work allowed us to lead the scholarship and research on health AI, writing many of the defining pieces in the field. In the upcoming years, we see digital health as the next “big” thing, and are currently in the grant application process for three projects on digital home health and access to care and justice, as well as digital infrastructure, which will position us as thought-leaders in this area. Already in FY21, we have received support 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.

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 FY21, 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, begin serious work on our diagnostic digital home health initiative, and continue to produce and support high profile scholarship.