Executive Summary

Fiscal Year 2019 was a year of successful launches and exciting work for the Petrie-Flom Center, in terms of projects, events, structure, and communications. FY19 marked a year of high-profile work in an important new area of biotechnology, the application of artificial intelligence in health care, as well as development of work in an increasingly important health policy topic, delivery of health care to an aging population. We also were careful about maximizing the impact of our many events, exploring a model in which we were better able to host and influence important thought leadership at several events through use of roundtables. We were equally thoughtful regarding our own structure, launching a Health Care General Counsel Roundtable, and laying the groundwork for an Advisory Board. Reflecting our commitment to changing to meet new demands, FY19 marked a year in which we focused on our communications strategy, including relaunching our successful blog and improving our digital media presence.

Faculty Director Professor I. Glenn Cohen and Executive Director Carmel Shachar continue to work closely to promote our many ongoing initiatives and launch new projects at the intersection of health law policy, biotechnology, and bioethics. This task keeps them busy, as our sponsored research portfolio is also in an exciting state of flux. Most notably, this year marked the first full year of our Project on Precision Medicine, Artificial Intelligence, and the Law (PMAIL), a five-year project funded by the University of Copenhagen’s CeBiL, the Collaborative Research Program in Biomedical Innovation Law. Our work on PMAIL was especially productive due to the hard work of our Research Fellow in Precision Medicine, Artificial Intelligence, and the Law, Sara Gerke. Artificial intelligence, especially as applied to health care, is increasingly becoming an important topic in legal and ethical work, so we are proud to establish ourselves as thought leaders on this key biotechnology topic. PMAIL continues to flourish, with increasingly high-profile potential collaborators around Harvard University and in other institutions such as Stanford University and the Massachusetts Institute of Technology asking to work with the Petrie-Flom Center on projects relating to artificial intelligence in health care.
Reflecting our commitment to health care issues that have an international impact, the Petrie-Flom Center launched the Global Health Rights Project (GHRP) in FY19. Led by Senior Fellow Alicia Ely Yamin, and in collaboration with the Global Health Education and Learning Incubator (GHELI) at Harvard University, GHRP 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 Project will also explore the relationship between global economic and health governance. Yamin’s involvement with GHRP adds an important international health policy expertise to the resources available to HLS students. GHRP had a great start, with several events in FY19 and generating significant scholarship, and will bring two Mexican Supreme Court Justices to campus in Fall 2019 in addition to adding to the HLS curriculum by adding a reading group on sexual and reproductive rights.

Our other research projects also had a strong year. Our Innovative Funding Models in Translational Research Project, led by Senior Fellow Douglas Eby, brought representatives of leading research institutions such as the Broad Institute and the Dana-Farber Cancer Institute to campus in October 2018 for a sophisticated discussion of problems and opportunities created by the influx of for-profit funding and corresponding decrease of governmental funding for research. The Innovative Funding Models Project will next focus on producing a whitepaper summarizing the discussions of the working group and hosting a special event to mark the 75th anniversary of the report that created the modern American framework for biomedical research, with Eric Lander of the Broad Institute and President Emerita of MIT Susan Hockfield tentatively committed to participating. Our Project on Law and Applied Neuroscience capped another great year with a workshop cosponsored by the Federal Judicial Center on “Science-Informed Decision Making,” which was designed to help federal criminal justice practitioners develop improved collaborative responses to individuals with mental health and substance use disorders. Our FY19 Senior Fellow on the Project, Francis X. Shen, also organized some very topical events, including panels on the Neuroscience of Hate and Trauma at the Border, while also establishing ties with the Harvard Immigration and Refugee Clinic. The Center’s strong ties in the legal and medical fields positions us to be an important leader in this field and to help influence policy to better reflect the experience of older Americans. We hope to continue to grow our law and dementia work in the coming year.

Our Project on Advanced Care and Health Policy, led by Senior Fellow Mark Sterling, has helped contribute to the regulatory framework around advanced care and illness. The project hosted an important conversation on the newly announced by the U.S. Department of Health and Human Services payment models for advanced care. One of our hopes for the coming year, and a focus of planning during FY19, is to knit together our work on law and neuroscience and advanced care to look at improving the care models for patients with dementia. Considering the aging demographic of the United States, it is important to revisit the way that American delivers care for dementia patients, who are notoriously challenging and expensive for the health care system to address. We are currently searching for funders for this important work.

The Petrie-Flom Center is known for its extensive, busy, and strong events calendar and FY19 was no exception. We hosted leadership from the current Presidential Administration at our events, including the Chief Counsel of the Food and Drug Administration (and HLS alumna) at our Seventh Annual Year in P/Review and the Associate Director of Health Programs at the Office of Management and Budget at our conference, Drug Pricing Policies in the United States and Globally. The Center’s increased profile was also reflected in invitations to Center leadership and
staff to join roundtables and events hosted in Washington D.C. by various federal agencies. This year we also explored an event model in which part of the day would be open to the public and part of the day would be reserved for invitation-only smaller group sessions. We used this format at events such as our collaboration with former Acting Administrator for the Centers for Medicare and Medicaid Services, Andy Slavitt, on Medicaid buy-in programs, our roundtable on American mitochondrial replacement therapy policy, and our event on payment models for advanced care. We believe this events structure allows us to serve the public by bringing them interesting programming on health law policy and bioethics issues while also directly influencing important conversations by convening key thought leaders on the subjects. We are looking forward to experimenting more with this model in FY20. Our more traditional events were also successful, with our annual conference this year focusing on consumer genetic technologies and drawing a record crowd of close to 300 attendees. The American Academy of Arts and Sciences hosted the pre-conference dinner for that event, which reflects the value that people working on biotechnology and bioethics place on the Petrie-Flom Center’s thought leadership in our field.

The Petrie-Flom Center is always looking for opportunities to strengthen the ties between HLS alumni working in health law and the HLS community, especially students. As part of our efforts to bring health care practitioners to campus, in FY19 we launched our Health Care General Counsel Roundtable, a forum for ten to fifteen leading health lawyers to come together for peer conversations and education. This Roundtable provides the opportunity for Harvard University faculty, including HLS faculty, to have small group discussions with leadership at important health care entities such as Merck Pharmaceuticals and the Memorial Sloan Kettering Cancer Center. It also provides the Petrie-Flom Center a better sense of which health law policy issues are impacting real world practice, which in turn informs our research priorities. We hope that the lessons learned in creating our Roundtable will inform our next structural project, which will be to launch an Advisory Board in FY20.

FY19 was also a year in which the Center focused on its communications strategy. To reflect our increased commitment to digital media and outreach, we changed our staffing, bringing in a Communications Manager with significant experience in digital media to replace our previous Project Coordinator. Our blog, Bill of Health, continues to be a leading forum for health law policy and bioethical perspectives from thought leaders across the country and in Europe. In particular, entries relating to the opioid epidemic and a symposium that arose from our 2019 annual conference on consumer genetic technologies have recently sparked conversations and debate. Since our major relaunch in Fall 2018, our readership has more than doubled to roughly 27,000 unique users each month. We anticipate that Bill of Health will continue to host insightful analysis from contributors at Harvard and beyond, but will build its reputation in the wider digital landscape. This refresh reflects our commitment to expanding our online presence, to allow more people to engage with us than ever before.

This year we have also been very busy in the scholarship department, publishing an array of articles in legal, medical, and bioethics journals, including in the Journal of the American Medical
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Association, the Lancet, and the American Journal of Bioethics. Additionally, this was a full year for our edited volumes, as we released:

- **TRANSPARENCY IN HEALTH AND HEALTH CARE IN THE UNITED STATES** (Cambridge University Press, June 2019).

We have also just submitted the final manuscript for DISABILITY, LAW, HEALTH, AND BIOETHICS, stemming from our 2018 annual conference, which will be released in the coming year. We are excited to see where our scholarship goes next, especially with our focus on artificial intelligence in health care.

Our excellent Student Fellows joined the Center from across campus and pursued projects related to the need for greater attention to scientific knowledge when shaping HIV criminalization laws, the role of face-to-face pharmaceutical advertising to doctors in the opioid epidemic, the role of public-sector research in new drug discovery, the possibility of Medicaid coverage for doula services and the potential impact on post-natal outcomes, a reconsideration of the doctrine of legal capacity as it applies to seniors, and rethinking bioethics to account for human intellectual and moral frailty. 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 believe great things are in store for the Center in Fiscal Year 2020. We are well positioned to continue our position as thought leaders on increasingly high-profile topics such as the use of big data and artificial intelligence in health care. We also are looking to launch the Center’s work in an increasingly important health policy topic, namely, the challenges of meeting the health care needs of our aging population. We are excited to be a venue for furthering important policy conversations through our new events model of mixing public and invitation-only sessions. We are working to build connections between legal scholars and health law practitioners, both at Harvard and beyond, through our event programming and our Health Care General Counsel Roundtable. Our commitment to refreshing our digital media presence was reflected the successful relaunch of our blog, Bill of Health, and we hope to continue to build our unique digital outreach through better use of our video archives and perhaps even podcasting in the future. To support all of these projects and programming, and to secure the future of the Center, we hope to have a successful year in fundraising and to build the Center’s base of support through an Advisory Board. The Center’s work remains strong and we are looking forward to sharing it widely through these initiatives.

With sincere thanks to everyone who supports our work,
I. Glenn Cohen
Carmel Shachar

Faculty Director & James A. Attwood and Leslie Williams
Professor of Law, HLS

Executive Director

August 2019
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The Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School was founded in 2005 through a generous gift from Joseph H. Flom and the Carroll and Milton Petrie Foundation. The Center’s founding mission was to promote interdisciplinary analysis and legal scholarship in these fields. Today, the Center has grown into a leading research program dedicated to the unbiased legal and ethical analysis of pressing questions facing health policymakers, medical professionals, patients, families, and others who influence and are influenced by health care and the health care system. To achieve this goal, the Center fosters a community of leading intellectuals, practitioners, and policymakers from a variety of backgrounds at all stages in their careers, across Harvard University and the world.

The Center’s work generally falls into the following categories:

1. **Public engagement**, including frequent conferences and other events; extensive media commentary; our popular health policy and bioethics blog, Bill of Health, boasting a substantially increased average of roughly 27,000 unique monthly users since our relaunch in fall 2018; and our website featuring Center news, scholarship, and events, as well as health law policy and bioethics opportunities and other resources for the public.

2. **Academic programs**, including programs for visitors and senior scholars; a range of curricular contributions, most notably the Health Law, Policy, Bioethics, and Biotechnology Workshop; and various mentorship and writing opportunities for Harvard students, including a coveted graduate fellowship.

3. **Sponsored research** collaborations across the university and its affiliated hospitals, and elsewhere, with projects addressing the use of big data in health care diagnostics, innovative funding models in translational research, human subjects research regulation and ethics, and more, alongside additional collaborations covering law and neuroscience and care for advanced illness.

4. **Independent scholarship** and publications by our affiliates, including the peer-reviewed, open-access Journal of Law and the Biosciences with partners at Stanford and Duke universities, and books on cutting edge topics in health policy and bioethics.

Topically, our work spans the entire range of issues at the intersection of law and health policy, biotechnology, and bioethics. Among the many issues the Center’s work has covered are artificial intelligence in health care, health care reform and economics, human
subjects research regulation, medical tourism, the fragmentation of American health care, conflicts of interest in medicine, religion and health policy, reproductive technology, law and neuroscience, health law and behavioral economics, pharmaceutical and device regulation, and more.

**Leadership**

During FY19, the Center continued to be led by Faculty Director Professor I. Glenn Cohen and Executive Director Carmel Shachar.

**Research, Project Activities, and Scholarship**

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.

**Sponsored Research**

The Center was engaged in several sponsored research projects in FY19, one of which, the Patient-Centered Outcomes Research Oversight Study (PCOROS), came to a close in August 2018. The Project on Precision Medicine, Artificial Intelligence, and the Law – launched in January 2018 – has produced substantial scholarship, and we are in the process of planning two major conferences touching on the Project’s work for Spring 2020, including one that will bring participants from across the globe. We have launched the new Global Health and Rights Project, a collaboration with the Global Health Education and Learning Incubator (GHELI) at Harvard University. We also continue to seek additional funding opportunities, and submitted several letters of interest, proposals, and applications for additional funding.

**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.

PMAIL is led by I. Glenn Cohen, with support from Carmel Shachar and contributions from CeBIL Director Timo Minssen and Nicholson Price, Associate Professor of Law at the University of Michigan and a former Petrie-Flom Academic Fellow. Sara Gerke joined the PMAIL team in August 2018 as the Research Fellow in Medicine, Artificial Intelligence, and Law, undertaking primary responsibility for advancing the various projects on a day-to-day basis, including conducting law, policy, and ethics research; drafting reports and recommendations; and coordinating the Center’s efforts with collaborators at the Center for Advanced Studies in Biomedical Innovation Law (CeBIL) at the University of Copenhagen as well as other partners. PMAIL also collaborated with Harvard Law School’s Cyberlaw Clinic to provide opportunities to students interested in the intersection of regulation, health data, and biotechnology.

Research published by the PMAIL team covers a variety of topics, including:

- Ethical and legal challenges of AI-driven health care (e.g., AI in cardiology);
- Legal and ethical issues of ingestible electronic sensors (“smart pills”);
- Data protection and privacy in the age of medical big data in the U.S. and Europe, especially focusing on the Health Insurance Portability and Accountability Act (HIPAA), the EU’s General Data Protection Regulation (GDPR), and the California Consumer Privacy Act of 2018 (CCPA);
- Patent case law in the U.S. and Europe and how it affects precision medicine;
- Ethical and legal challenges of machine learning in medicine, including black-box medical algorithms;
- Contextual bias; and
- AI and liability.

While PMAIL does not have a formal collaboration with the Berkman Klein Center for Internet & Society, which also focuses on the impact that AI will have on our legal and regulatory systems, we are in close communications with our colleagues at Berkman Klein. In FY19 we began to develop a potential project on digital health that would have touched on issues related to AI implementation, but that project development stalled due to some family issues for the donor identified.

Greenwall Foundation Law and Bioethics Seminar Series

In FY19, the Center successfully completed the bulk of the activities associated with a Greenwall-funded seminar series led by Faculty Director I. Glenn Cohen. The seminar was designed to empower Greenwall Faculty Scholars to become better consumers of legal materials. This Law and Bioethics Boot Camp created a space where participants
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could make headway on legal issues related to the bioethical topics they work on, as well as become generally more comfortable with legal materials. Too often the law is used to “shut down” interesting conversation that is important to bioethics. The boot camp sought to enhance leading bioethicists’ ability to resist such force majeure and invite them to be part of the conversation.

The seminar series was held from September 2018 to March 2019. Selected scholars met for a total of eight discussion sessions – four in-person sessions and four web-based sessions – for which they prepared with pre-reading and legal materials.

The Law and Bioethics Boot Camp was a success. The course developed a unique curriculum for bioethics scholars seeking to improve their legal knowledge, including direct interaction with experts in the field of bioethics and law. Responses collected from participants at the beginning and the end of the course showed that it was a great success. Petrie-Flom Faculty Affiliate Aaron Kesselheim (HMS) and Kimani Paul-Emile (Fordham University School of Law) each led a seminar session, with Faculty Director I. Glenn Cohen leading the rest of the sessions and meeting individually with participants to discuss their projects.

Harvard Catalyst
Regulatory Foundations, Ethics, and Law Program

Harvard Catalyst | The Harvard Clinical and Translational Science Center at Harvard Medical School was established in 2008 to improve human health by enabling collaboration and providing tools, training, and technologies to clinical and translational investigators. It is funded by the National Institutes of Health (NIH) Clinical and Translational Science Award (CTSA) program (grant 1UL1 TR001102-01), and by contributions from a number of Harvard schools and affiliated institutions.

The Petrie-Flom Center has collaborated with Harvard Catalyst’s Regulatory Foundations, Ethics, and Law Program since December 2013, and has continued into the beginning of FY19. Our work may continue, pending the reorganization and reprioritization of Harvard Catalyst after their successful renewal of the CTSA for another 5-year term.

The Center’s work on this project has been co-led by I. Glenn Cohen and Carmel Shachar. Luke Gelinas joined the program in August 2015 as the Petrie Flom-Harvard Catalyst Fellow in Clinical Research Ethics, undertaking primary responsibility for advancing the various projects on a day-to-day basis. As of July 2017, Luke’s title shifted to Senior Researcher to reflect his work on other sponsored research projects at the Center. He remained involved in the project until Spring 2018, when he transitioned away from full time work at the Petrie-Flom Center to serve as the Chairperson at Advarra IRB.
The Center’s main focus for this collaboration has traditionally been to develop practical solutions to key legal and ethical barriers affecting participant recruitment to and retention in clinical research studies.

Projects

The Center successfully completed its inquiry into evaluating offers of payment to research participants as well as its work on social media as a recruitment tool for clinical trials in Spring 2018. The Center and Harvard Catalyst leadership have been exploring further topics for the Project, such as considering the impact of new Right to Try legislation on research as well as structuring informed consent to reflect use of artificial intelligence algorithms in clinical research. We also explored hosting an event around the implementation of the GDPR, but ultimately decided that this event was better suited for a different venue. Executive Director Carmel Shachar was a frequent presence at the monthly Harvard Catalyst Regulatory Foundations, Ethics, and Law meetings. The Center and Harvard Catalyst remain in discussions for the most productive path moving forward.

Publications

Luke Gelinas and Barbara E. Bierer, Social Media as an Ethical Tool for Retention in Clinical Trials, 19 AMERICAN JOURNAL OF BIOETHICS 6 (May 28, 2019).


The Patient-Centered Outcomes Research Oversight Study (PCOROS)

From September 2015 to August 2018, the Petrie-Flom Center was part of a collaborative project funded by the Patient-Centered Outcomes Research Institute (PCORI) called the “Patient-Centered Outcomes Research Oversight Study,” or PCOROS, led by Principal Investigator Joel Weissman. The Petrie-Flom Center’s work on PCOROS has been led by I. Glenn Cohen. From March 2017 to the conclusion of the project, Luke Gelinas supported the work as a Senior Researcher at the Center.

The primary focus of this project was to identify and address any novel or prevalent ethical and regulatory challenges posed by Patient-Centered outcomes research (PCOR) as relevant to human subjects protection and oversight. The first phase of the project was a qualitative research study (including interviews, focus groups, and case
studies) to catalogue the practical and ethical challenges encountered by IRB members, patient research partners, and other stakeholders dealing with PCOR. The second phase of this project was a national survey of IRB members on PCOR and human subjects protection and oversight. In Spring 2018 we completed the third and final phase of the project, consisting in a Delphi panel that established consensus among expert stakeholders on key recommendations for oversight of PCOR. The work from this project was further disseminated at a national Public Responsibility in Medicine and Research (PRIM&R) presentation and at a symposium entitled *Putting Patients at the Center of Research: Opportunities and Challenges for Ethical and Regulatory Oversight*, hosted by the Petrie-Flom Center in June 2018, which brought together a diverse group of patients and community members, policymakers, bioethicists, and regulatory officials to address oversight challenges with PCOR.

At the conclusion of the project, the results were published, along with an introduction from Joe V. Selby, Executive Director and Acting Chief Science Officer of PCORI:


**The Football Players Health Study (FPHS)**

All research activities related to the Petrie-Flom Center’s collaboration with the Football Players Health Study at Harvard Medical School concluded in May 2017. This year Petrie-Flom staff worked with staff at HMS and in the HLS Finance Office to close out all financial accounts related to the collaboration.

**Publications**

Additional Efforts

In FY19, we submitted five applications for sponsored research projects, two of which were successful and one of which is still outstanding. This reflects a fairly typical return on competitive research funding applications. We also explored potential projects relating to topics such as the medicalization of the social determinants of health and the regulation of digital health, although we have not yet submitted grant applications for those projects.

Gilead Sciences, Inc.
Drug Pricing Policies in the United States and Globally: From Development to Delivery

This award supported a one-day conference held on October 24, 2018, at Harvard Law School. The event explored the current pharmaceutical pricing landscape by bringing together leaders from the pharmaceutical industry, policymakers, legal practitioners, and scholars to engage in novel, interdisciplinary discussions to better understand current challenges and articulate best practices to address these issues. Participants assessed the current challenges presented in drug pricing policy, from development to delivery, in both the United States and international context. Participants also explored and articulated best practices to expand access to medicines and worked toward developing a plan for disseminating these practices more widely. The award also supported the work of an HLS student research assistant who worked with Petrie-Flom Executive Director Carmel Shachar and Global Access in Action Fellow Ashveena Gajeelee to develop a whitepaper summarizing the discussions held at the October conference. This event was coorganized by the Petrie-Flom Center, Global Access in Action at the Berkman Klein Center for Internet and Society at Harvard University, and the student-run Harvard Health Law Society at Harvard Law School.

Amount Received: $10,000

The Dean’s Initiative Award Program for Planning Activities for Future Innovation Grants in Healthy Aging, Harvard Medical School
Models to Address the Gap in Care for Advanced Illness

We have received support to hold planning sessions to design a larger project for the Harvard Initiative on Aging (HIA). The aims of the larger project will be to develop, and ultimately pilot and test, one or more variants on the Advanced Care Model developed by the Coalition to Transform Advanced Care, the Petrie-Flom Center’s partner in our ongoing Project for Advanced Care and Health Policy, for aging individuals who are not yet in the last year of life. Participants in the planning sessions will determine the target population(s) and care model, and work to identify potential pilot sites. We will seek to include a payor, which may provide an opportunity to test the model on a broader regional or statewide basis. Faculty
Director **I. Glenn Cohen** and Senior Fellow in Advanced Care and Health Policy **Mark Sterling** will co-lead this project with Susan Mitchell (HMS, Hebrew Senior Life), with substantial support from Executive Director **Carmel Shachar**.

We have postponed the implementation of this award until we receive a response regarding our more recent proposal to the Harvard Initiative on Aging (see below), as the shape of these planning sessions would have been impacted significantly by whether or not we receive funding to move forward with that specific project. We expect to carry out this work in FY20.

**Amount Received: $8,715**

**Harvard Initiative on Aging at Harvard Medical School**

**Redesigning Dementia Care: Developing a Roadmap for Coordinated Care**

Building on our successful planning grant proposal on the topic of Advanced Care Models (ACM) (see above), this grant submission proposed to explore how the ACM can be adapted to innovatively redesign dementia care and provide more coordinated and cost-effective services. Dementia is an ideal target for the ACM approach because it is difficult for health care delivery systems to cost-effectively meet patient needs. Current spending levels in the U.S. health care system are unsustainable, especially considering the limited success and quality of the care provided. On a more individual level, dementia often results in suffering, both for the affected individuals and their caregivers. Providers report ethical challenges to working with patients who require complex care management but are often unable to participate in shared decision-making.

This project was designed to bring together resources developed under the Petrie-Flom Center’s existing Project on Advanced Care and Health Policy and Project on Law and Applied Neuroscience under the co-leadership of Faculty Director **I. Glenn Cohen** and **Dr. Bruce Price** of the Center for Law, Brain & Behavior at MGH. Petrie-Flom Senior Fellow for Advanced Care and Health Policy **Mark Sterling** and Senior Fellow for Law and Applied Neuroscience **Francis X. Shen** would have performed the bulk of the research, with support from Petrie-Flom Executive Director **Carmel Shachar** and Center for Law, Brain & Behavior co-Faculty Director **Dr. Judith Edersheim**. A post-doctoral fellow was planned to provide support and capacity. As part of the grant application process, we invited leaders in aging and gerontology from across Harvard University, including faculty from HSPH, HBS, HKS, and HMS, along with leading D.C. policymakers to join an advisory committee to steer the work of this project.
Although Harvard Medical School declined to fund this project, we hope to find a funder for it. Since the end of FY19 we have reached out to contacts at the Milbank Fund and the Peterson Foundation.

**Amount Requested: $153,679**

**Greenwall Foundation Making a Difference in Real-World Bioethics Dilemmas Grants Program**

**Informed Consent in Health Artificial Intelligence Applications**

This grant submission proposed a two-year project focused on how best to promote patient autonomy in the context of health artificial intelligence (AI) applications, both in and outside of the clinic, by exploring whether informed consent must be updated to reflect challenges unique to health AI. It aimed to contribute to a better understanding of how the bioethical concept of informed consent should apply to health AI applications, as used by clinicians as well as patients and consumers themselves. Such an understanding would empower patients and consumers to make voluntary and informed decisions in health AI. The project would have been led by Faculty Director [I. Glenn Cohen](#), with support from Research Fellow [Sara Gerke](#). Although we were invited to submit a full proposal on the basis of our Letter of Intent, the proposal was ultimately not selected for funding. We are currently exploring alternative avenues for funding, possibly from the McGovern Foundation.

**Amount Requested: $182,142**

**Social Sciences and Humanities Research Council (Canada)**

**Art, Bioethics & Artificial Intelligence: ‘AI-ship’ or the New States of Being**

The Petrie-Flom Center submitted a letter of support for this proposal, led by Visiting Researcher [Jean-Christophe Belisle-Pipon](#), which committed engagement from Faculty Director [I. Glenn Cohen](#), in-kind administrative and technical support, and a small financial contribution. This one-year multidisciplinary project would have sought to engage the public in exploring – through the mingling of arts and bioethics – the complex ethical, legal and societal considerations underlying AI in health. The project would have brought together the general public, bioethicists, artists, and members of the AI community in dialogue about the bioethical issues of AI developments in health. While this proposal did not receive funding, [Jean-Christophe Belisle-Pipon](#) has since secured funding from the government of Québec for a more modest proposal that does not include direct support from the Petrie-Flom Center. We continue to explore ways in which the Center can support this work and bring the exhibition to Boston.
The Commonwealth Fund
The Legal Barriers to Value-Based Health Care Project

In collaboration with HBS’s Institute for Strategy and Competiveness, we submitted an inquiry to the Commonwealth Fund regarding a proposed project exploring the legal and regulatory barriers to implementing value-based health care. The purpose of this project would be develop scholarship around the real and perceived legal challenges to implementing value-based health care, with the ultimate goal of developing solutions to the actual challenges and supporting the education of stakeholders around the perceived challenges. The project would have been led by Faculty Director I. Glenn Cohen, with support from Executive Director Carmel Shachar. This project would have also supported the work of a post-doctoral fellow. Although the Commonwealth Fund considered our initial project proposal summary, we were not invited to submit a fuller, more formal application.

Amount Requested: $828,565.34

Projects in Development

At the end of FY19, the Petrie-Flom Center had several project proposals that were in development but were not yet submitted to a potential funder. One project, the Building Community Responses to the Opioid Epidemic for High-Risk Workers, will bring in HMS Fellow in Bioethics Stephen Wood and the Fishing Partnership Support Services to examine the responses of blue-collar communities uniquely vulnerable to substance abuse to the opioid epidemic. We also developed a project focusing on issues in digital health with the Berkman Klein Center for Internet and Society and began initial discussions with funders for this project. We have continued to develop these projects, and other proposals, and would welcome guidance from Harvard Law School Alumni Center as to which funders might be best suited to support these efforts.
Project Activities

In addition to sponsored research, the Petrie-Flom Center is involved in a number of projects that seek to advance cutting-edge scholarship and policymaking in our fields, including a collaborative, peer-reviewed journal that offers a unique opportunity outside of traditional law reviews for publications at the intersection of law and the biosciences, as well as programs on law and neuroscience and law and advanced care planning.

Global Health and 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. She is also currently an Adjunct Lecturer at the Harvard T. H. Chan School of Public Health.

During this early phase of her fellowship, Yamin has pursued original research, mentoring, and public engagement related to issues of global health governance, sexual and reproductive rights, and international human rights. She has also organized multiple expert symposia and public events.

On March 11, 2019, GHRP hosted a panel at Harvard Law School on “Global Health Justice and Governance,” which brought together Professor Jennifer Prah Ruger from the University of Pennsylvania to discuss her latest book with Professor Michael Ashley Stein of HLS, as well as Yamin. The event was moderated by Petrie-Flom Center Executive Director Carmel Shachar.

This event led indirectly to Yamin’s collaboration and participation in a multi-disciplinary working meeting, which Professor Stein and Professor Vikram Patel of the Harvard T. H. Chan School of Public Health are co-hosting in conjunction with the Weatherhead Center, on September 12 and 13, 2019: “Whose Health Is It Anyway? Mental Health and Decision Making in the CRPD Era.”

Yamin organized a second event in conjunction with the Petrie-Flom Center’s 2019 annual conference on the topic of consumer genetic technologies. The event, entitled “Gene Editing: Human Rights, Social Justice and Health Equity Issues” was a two-hour discussion and dinner hosted at GHELI on May 16, 2019, which included presentations by Marcy Darnovsky and Katie Hasson from the Center for Genetic and Society, as well as discussions with both students and local academics and activists who are interested in learning more about this topic. Yamin and Harvard Medical School Center for Bioethics student Jonathan Chernoguz wrote about the meeting for the Bill of Health. GHELI also posted a description of the discussion on its website.
This event generated sufficient interest that Yamin will be leading a reading group on human rights and genetic technologies for students from HMS and the DRPH program at the Harvard T. H. Chan School of Public Health during AY2019–2020.

**Health Care General Counsel Roundtable**

In addition to our public events, this year we launched a new semesterly closed round table to bring together general counsels of leading health care entities for peer discussion and conversations led by experts from around Harvard University. The purpose of the Health Care General Counsel Roundtable is to gather lawyers who represent leading health care entities in a small peer group to facilitate discussions around the challenges facing health care in-house counsels today. The Roundtable explores the unique position of in-house counsel in guiding health care entities in today’s regulatory environment. The Roundtable consists of ten to fifteen general counsels of companies from across the spectrum of health care entities, including providers, pharmaceutical companies, device manufacturers, insurers, and digital health companies.

The Roundtable benefits the HLS community by bringing these industry leaders to campus, allowing for their participation in Center public events such as our *Annual Year in P/Review* and mentoring students. It also affords HLS and other Harvard University faculty opportunities to engage with industry leaders. The Center benefits by having a dialog with leading industry practitioners about important trends in health law and policy and developing its network. While there are other roundtables operating in this space, our Roundtable is the only one operated by an academic research center at a leading law school.

Led by Faculty Director **I. Glenn Cohen** and Executive Director **Carmel Shachar**, the Roundtable had its first successful year with meetings in December 2018 and May 2019. Interest in the Roundtable has only continued to grow, with several members added to the group in between each session. Participants come from government, research and teaching hospitals, and industry, and including the general counsels of such organizations:

- **Jorge Lopez,** *Memorial Sloan Kettering Cancer Center* (unofficial Chair)
- **Dan Esrick,** PillPack
- **Andrew Fuqua,** Cambridge Health Alliance
- **Jeffrey Kahn,** Children’s Hospital of Philadelphia
- **Brad Lerman,** *Medtronic*
- **Joshua Murphy,** Mayo Clinic
- **Catheryn O’Rourke,** *Smith & Nephew*
- **Michael Regier,** Vanderbilt University Medical Center
- **Thomas Sabatino,** Aetna
- **Donald Savery,** Blue Cross Blue Shield of Massachusetts
Drew Staniewski, State of Tennessee Medicaid
Michael Ullman, Johnson & Johnson Pharmaceuticals
Sandy van der Vaart, Lab Corp.
Robin Walker, Casebia Therapeutics
Kathleen Waters, Davita
Jennifer Zachary, * Merck Pharmaceuticals

* HLS alumna/us

The group met twice in FY19:

**December 6, 2018**
Topics covered included:
- Artificial Intelligence, Big Data, and Health: Presented by Faculty Director I. Glenn Cohen
- The Future of Stem Cell and Other Cutting Edge Technologies: Presented by Brock Reeve, Executive Director, Harvard Stem Cell Institute
- Developments in Fraud and Abuse: Presented by Michael Loucks (COL '77), Partner, Skadden, Arps, Slate, Meagher & Flom, LLP
- Innovative Structures in Value-Based Care: Presented by Michael E. Porter, Harvard Business School

**May 8, 2019**
Topics covered included:
- Health Care Consolidation: Presented by Leemore Dafny, Harvard Business School
- Regulatory Sprint in Fraud and Abuse: Presented by Kelly Cleary, Deputy General Counsel and Chief Legal Officer, Centers for Medicare and Medicaid Services, U.S. Department of Health and Human Services
- Challenges Facing General Counsels: Presented by David Wilkins, Harvard Law School
- Leadership and Crisis Management: Presented by Scott Westfahl, Harvard Law School

**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 2018, Francis X. Shen continued for a second year as the third Senior Fellow in Law and Neuroscience. Francis is currently an Associate Professor, McKnight...
President Fellow, and Member of the Graduate Program on Neuroscience at the University of Minnesota; the newly named Executive Director at the Center for Law, Brain and Behavior at Massachusetts General Hospital; and Executive Director of Education and Outreach for the MacArthur Foundation Research Network on Law and Neuroscience. During FY19, 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. “Trauma at the Border” brought together Professor Charles Nelson III (HMS) and Clinical Instructor Cindy Zapata (HLS, Harvard Immigration and Refugee Clinic) to explore the intersection of neuroscience, trauma, and immigration law. “The Neuroscience of Hate,” which featured remarks by Professor Jon Hanson (HLS) and Professor Rebecca Saxe (MIT), explored structures in the brain and in the law that foster hate.

Building on the previous year’s work on the aging brain, Shen led several efforts in FY19 to engage the legal and medical communities on dementia, including a working group on dementia and the law. Shen also developed several writing projects in collaboration with the Petrie-Flom Center and CLBB. The first, titled Aging Judges, was completed and is forthcoming in the Ohio State Law Journal. The article argues that in light of neuroscientific understandings of the aging brain, neither life-time appointments with no cognitive health review, nor mandatory retirement ages, are optimal. The article builds on an event hosted by the Project at Harvard Law School in 2017, “Dementia and Democracy: America’s Aging Judges and Politicians.”

Reaching beyond the Project on Law and Applied Neuroscience, Shen also contributed to a joint effort with the Project on Advanced Care and Health Policy, the Petrie-Flom Center’s joint project with the Coalition to Transform Advanced Care (C-TAC), to explore new opportunities for collaboration around the development of and Advanced Care Model (ACM) for a pre-hospice population with a high one-year mortality risk (see Sponsored Research, Additional Efforts). He also mentored Petrie-Flom Student Fellow James Toomey (JD ‘19), as Toomey completed an article on legal assessment of capacity for dementia patients. Shen was also a guest lecturer in the Law and Neuroscience seminar.

In addition to the work on dementia and the law, during the Fellowship year, Shen led a new engagement around issues of trauma, neuroscience, and immigration law. Building on the event, “Trauma at the Border,” Shen laid the groundwork with the Harvard Immigration and Refugee Clinical Program to develop new, neuroscience-informed resources for advocates working on immigration and asylum cases. The expert affidavit research will focus on three intersections of neuroscience and law: (1) neurobiology of trauma; (2) effect of trauma on memory, with an emphasis on credibility; and (3) traumatic brain injury in clients with trauma history. During the Fellowship year, Shen drafted an initial grant proposal around this intersection of trauma and immigration law.
Events

The Project on Law and Applied Neuroscience hosted the following events this year:

**Trauma at the Border**
March 4, 2019

**The Neuroscience of Hate**
April 13, 2019

June 25–27, 2019
Cosponsored by the Federal Judicial Center.

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.

Recognizing that current health care policy and regulation, developed largely in a fee-for-service environment with siloed providers, creates barriers that may impede widespread adoption of improved models of care for those with advanced illness, 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.

**Senior Fellow**

**Mark Sterling, MPP, JD**, served as the Senior Fellow in Advanced Care and Health Policy for FY19 and will continue to do so for FY20. He is a senior strategic advisor to C-TAC, and recently was a Senior Fellow at Harvard University’s Advanced Leadership Initiative. Sterling has built connections throughout Harvard University, as evidenced by his invitation to present at the Harvard Initiative on Aging symposium on January 3-4, 2019. He was, along with Executive Director
**Carmel Shachar**, one of two invited attendees from HLS to this event organized by the HMS Dean’s office to bring together leading experts on aging from around Harvard University (see below for more information).

**Events**

The Project regularly hosts public events and workshops with business leaders, policymakers, and legal scholars. In FY19 we focused on convening leaders to consider opportunities to redesign care delivery for people with serious illness, given the shifting landscape to value-based care. This is in keeping with the Center’s increasing interest in value-based health care.

In April 2019, we hosted a conference featuring thought leaders who identified key challenges and shared their visions for a future where new payment models align with improved advanced illness care. Featured speakers for the event, titled “Providing Value and Redesigning Care for Serious Illness,” included Diane Meier, MD, Director of the Center to Advance Palliative Care and Thomas W. Feeley, MD, Senior Fellow at Harvard Business School’s Institute for Strategy and Competitiveness. Drs. Meier and Feeley provided their insights on the recently-announced “Primary Cares Initiative” of the Centers for Medicare and Medicaid Services, which Dr. Meier described as a profound step forward. Dr. Meier also underscored the value of palliative care and its ability to reduce avoidable spending and utilization in all settings, while improving quality of life and symptom management. Dr. Feeley, focused on defining value for health care and how to address value-based care for people with advanced illness. Executive Director **Carmel Shachar** and Senior Fellow **Mark Sterling** introduced the conference.

Also in April 2019, we hosted an executive roundtable focused on opportunities presented by the new value-based payment models under the Primary Cares Initiative. Roundtable participants discussed promising developments in their regions, and highlighted key drivers to successful system change. The participants also reviewed and provided feedback on the roll-out of a new state-based index to measure progress in improving advanced illness care. Forty healthcare leaders participated in the roundtable discussions, including executives from health systems and health plans, academia, foundations, as well as other thought leaders.

**Policy and Research Projects**

Current regulatory frameworks can impose obstacles to adoption of innovative models of caring for those with advanced illness. As the Project moves forward, it will continue to engage in policy and research projects that identify and analyze these obstacles, and propose policy solutions that promote development and scaling of successful programs. This likely will include a focus on state statutory and regulatory barriers and ways to overcome them.
In FY19, the Project actively participated in the early stages of the Harvard Initiative on Aging (HIA), a new Harvard-wide initiative. The goal of this initiative is to inspire and engage members of the Harvard community to address issues in global aging and healthy longevity and to build capacity for scholars, researchers, innovators, program builders, and policymakers to address the most pressing challenges in aging and healthy longevity worldwide. HMS Dean George Daley, with support from the Dr. M. Lee Pearce Foundation, Inc., has committed to funding of planning and pilot grants to catalyze collaborations and to generate preliminary work that can lead to future larger initiatives (including the National Academy of Medicine Grand Challenge prizes, the MacArthur Foundation $100M award, NIH or foundation grants), or other sustained follow-up activity.

At a HIA planning meeting in September 2018, Senior Fellow Mark Sterling presented on new care models for advanced illness, and proposed that this topic be a selected area of focus for this initiative. Mark Sterling and Executive Director Carmel Shachar were subsequently both invited to participate in a two-day private Scientific Symposium for the HIA, held at the Medical School in early January 2019. At the Symposium, Mark Sterling presented on the topic of “Advanced Illness: Emerging Models to Address the Gap in Care”, and Carmel Shachar presented the results of a workgroup on the topic of “Innovations in Health Care Policy and Delivery.”

As an outgrowth of the Symposium, Mark Sterling and Carmel Shachar were asked, together with others, to develop and submit a proposal for a project now entitled, “Redesigning Dementia Care: Developing a Roadmap for Coordinated Care”. The proposal notes that many individuals with dementia receive care that is fragmented, uncoordinated, or inadequate. The project proposes to adapt the “Advanced Care Model” (ACM) to redesign dementia care and provide coordinated cost-effective care that aligns with patient goals and values. While HMS ultimately chose not to fund this project, we are eager to identify alternate funders for this important work (see above, Sponsored Research, Additional Efforts for more information).

Additional Collaboration

Since the Project launched, it has (through the stewardship of Senior Fellow Mark Sterling) become a member of the Massachusetts Coalition on Serious Illness Care. The Coalition has over 100 members (led by Blue Cross Blue Shield of Massachusetts) with a goal of ensuring that all Massachusetts residents receive care that is in accordance with their goals, values, and preferences. As a result of the Project, Muriel Gillick, M.D., became a panelist and an important contributor to the work, funded by the Gordon and Betty Moore Foundation, to develop a guiding framework for improved community-based care for serious illness. Dr. Gillick is Director, Program in Aging, Harvard Pilgrim Health Care Institute, and Professor of Population Medicine at Harvard Medical School.
During FY19, Executive Director Carmel Shachar began holding discussions with Fellow in Harvard University’s Advanced Leadership Initiative Chairman of Newton-Wellesley Hospital’s Board of Trustees, and Partners Healthcare Innovation Advisory Board Member Earl “Duke” Collier regarding the application of value-based care to dementia and other conditions of aging. The hope is to support Collier’s work in this area, while developing collaborations with the Project on Law and Advanced Care and Health Policy.

Events

The Project on Law and Advanced Care and Health Policy hosted the following events this year:

**Providing Value and Redesigning Care for Serious Illness**
April 26, 2019

**Innovative Funding Models in Translational Research Project**

Launched in early 2018, the Innovative Funding Models in Translational Research Project explores the bioethical, legal, and risk management challenges of translational research in the context of a shift from governmental funding to private funding for cutting edge biomedical research. The purpose of the Project is to investigate the ethical safeguards necessary to accelerate the development and application of new health care technologies through intelligent and thoughtful private for-profit investment and support. The goal of the Project is to articulate the best ethical practices for for-profit involvement in early stage health care startups and translational research.

A major focus of the Innovative Funding Models Project this year was to host a one-day working group exploring the challenges in pursuing for-profit private funding for early stage translational research. This working group, whose discussions were made open to the public, including Professor William “Terry” Fisher (HLS), Professor Robert Langer (MIT), and Chief Innovation Officer Chris Coburn (Partners Healthcare) among other leaders in Boston biotechnology from Harvard, MIT, the Broad Institute, and the Whitehead Institute. Faculty Director I. Glenn Cohen led a discussion section of the event. In keeping with the Center’s commitment to engaging HLS students as often as possible. Helena Ferreira Matos do Carmo (LLM ’19) was hired as a research assistant to translate the discussion of the working group into a whitepaper for broader consumption.

While not strictly the efforts of the Innovative Funding Models Project, Senior Fellow Douglas Eby also worked with Center staff to bring John Carreyrou, investigative report and author of New York Times bestseller Bad Blood: Secrets and Lies in a Silicon Valley Startup to campus. Eby moderated a panel of respondents, including Faculty Director I. Glenn Cohen, Dean Rakesh Khurana (COL and HBS), and Rachel
Wang (JD ‘19) before Carreyrou spoke to a crowd of approximately 400 HLS and Harvard students and affiliates.

Senior Fellow

Leading the Innovative Funding Models Project for the Center is inaugural Senior Fellow, Douglas Eby. As a 2017 Fellow in Harvard University’s Advanced Leadership Initiative, Doug’s efforts have been focused on innovative financing models to meet the unprecedented gap that currently exists in translational research. His work at Harvard led to the formation of Cambridge Science Corporation, where Doug serves as the Chief Executive Officer. Cambridge Science Corporation’s mission is to improve global health by accelerating the pace of medical technology innovation.

Steering Committee

The Project is led by Executive Director Carmel Shachar and the Senior Fellow, and is guided by a steering committee of thought leaders in this area, including:

- Irit Ben-Chelouche, Executive Director, Harvard University Office of Technology Development
- Susan Korsmeyer, Senior Managing Director for Institutional Management, The Whitehead Institute
- Adam Landman, Chief Information Office, Brigham and Women’s Hospital
- Lesley Millar-Nicholson, Director, MIT Technology Licensing Office
- Scott Orchard, Senior Counsel, Johnson & Johnson Innovation
- Gregory Raskin, Vice President of Technology Development, Memorial Sloan Kettering Cancer Center
- Issi Rozen, Chief Business Officer, The Broad Institute

Events

The Project on Innovative Funding Models for Translational Research hosted the following events this year:

New Funding Frontiers: Innovative Funding Models for Translational Research
October 1, 2018

HLS alumni who participated in the event:

- Susan Galli, Ropes & Gray (ret.)
The Journal of Law and the Biosciences (JLB) is a collaboration between the Petrie-Flom Center and colleagues at Duke and Stanford Universities, published by Oxford University Press. I. Glenn Cohen serves as co-Editor-in-Chief, alongside Nita Farahany (Duke) and Hank Greely (Stanford). In FY19 visiting researcher Jean-Christophe Belisle Pipon continued as managing editor on behalf of the Center. JLB is now in its sixth volume, and we are currently working on the agreement to extend the project for another three-year term.

JLB is the first fully Open Access peer-reviewed legal journal focused on advances at the intersection of law and the biosciences. An online, interdisciplinary academic journal, JLB publishes cutting-edge scholarship, including original and response articles, essays, and commentaries on a wide range of topics, including bioethics, neuroethics, genetics, reproductive technologies, stem cells, enhancement, patent law, and food and drug regulation.

The journal is freely available to readers and without publication fees to authors, making it one of the most accessible journals in the field. The journal continues to experience extraordinary growth.

In June 2019, the JLB received its first impact factor, an impressive 2.431. It was ranked in the following categories:

**Social Sciences Citation Index:**
- Law – Ranked 14 of 148 journals
- Ethics – Ranked 6 of 54

**Science Citation Index Expanded:**
- Medical Ethics – 3 of 16
- Medicine, Legal – 3 of 16

This is an exceptional impact factor for such a young journal, and surpasses those of many of its more established peer journals. It reflects the strong leadership provided by Profs. Cohen, Farahany, and Greely, along with the hard work of Center and other staff. We anticipate that the research published in JLB will only continue to grow in profile and impact now that it has such a strong impact factor.
Scholarship

One of the central missions of the Petrie-Flom Center is to support emerging, transitioning, and senior scholars making critical contributions to the ways in which the law can and should shape health law and policy, biotechnology, and bioethics.

Postdoctoral Fellows

Although the Academic Fellowship has been a cornerstone of the Center since its inception in 2006, we have temporarily discontinued the program as we pursue new funding opportunities and Topical Programs. We hope to reinitiate the Academic Fellowship as soon as possible, as the Fellowship has established the Petrie-Flom Center and HLS as leaders in the field of health law policy and biotechnology law.

While the Academic Fellowship is currently on hold, the Center continues to host postdoctoral fellows in conjunction with ongoing sponsored research projects as well as through a new collaboration with the Edmond J. Safra Center for Ethics. We are also actively seeking funding and cultivating new partnerships that would enable us to host additional fellows.

Two postdoctoral fellows were involved with the Center in FY19:

Sara Gerke, August 2018–August 2021

Sara is the Research Fellow in Medicine, Artificial Intelligence, and Law under the Project on Precision Medicine, Artificial Intelligence, and the Law (PMAIL), where she oversees the day-to-day work of the Center’s component of this collaborative project. Sara’s work includes conducting law, policy, and ethics research; drafting reports and recommendations; and coordinating the Center’s efforts with collaborators at the Center for Advanced Studies in Biomedical Innovation Law (CeBIL) at the University of Copenhagen as well as other partners.

Jacob S. Sherkow, September 2019–May 2020

Jacob was accepted from among a stellar group of applicants in Spring 2019 as the first Edmond J. Safra Center for Ethics and Petrie-Flom Center joint fellow focused on legal implications of the Ethics of Technological and Biomedical Innovation. He is currently a Professor of Law at the Innovation Center for Law and Technology at New York Law School, where he teaches a variety of courses related to intellectual property and the life sciences. His research focuses on how scientific developments, especially in the biosciences, affect patent law, regulation, and bioethics.

Jacob has already been engaged with the Center, participating in the 2019 annual conference on “Consuming Genetics: Law and Ethics of New Technologies” as the
co-author of a paper that will become a chapter in the edited volume of the conference proceedings.

Visitors

Although the Center does not actively solicit applications for Visiting Scholars and Researchers, it is a sign of our national and international influence that we receive numerous requests to visit with us each year. We welcome Visitors to our Center who have demonstrated academic success in our areas of interest, have a current project that would benefit from collaboration with our affiliates, and have a perspective that may be of value to our students, fellows, and faculty.

Visitors are expected to pursue their own independent academic projects related to our areas of focus, attend any Center events that take place during their visit, and share their expertise with students and colleagues. We sometimes invite them to present on the topic of their research at a public lecture and/or blog about their work at Bill of Health.

We hosted several outstanding visitors whose terms extended into FY19:

Jean-Christophe Belisle Pipon, September 2017–October 2020

Jean-Christophe Belisle Pipon completed his PhD in Bioethics at the University of Montreal in Fall 2017. He is supported as a Visiting Researcher at the Petrie-Flom Center with funding from the Canadian Institutes of Health Research. During his three years at the Center, Jean-Christophe is pursuing independent research on issues surrounding direct-to-consumer marketing in the pharmaceutical industry. This year, he developed and submitted a successful funding proposal on the topic “Art, Bioethics & Artificial Intelligence: ‘AI-ship’ or the New States of Being.” He is also serving as managing editor of the Journal of Law and the Biosciences on behalf of the Center, and continues to collaborate with Faculty Director I. Glenn Cohen and Executive Director Carmel Shachar in the development and execution of research that falls within his areas of expertise.

John Tingle, November 2018

John Tingle, currently a Visiting Lecturer in Law at Birmingham Law School, University of Birmingham (UK) and Visiting Professor of Law at the School of Law at Loyola University Chicago, had a brief but busy visit at the Petrie-Flom Center. He delivered a workshop presentation as part of the “Health Law, Policy, Biotechnology, and Bioethics Workshop” taught by Faculty Director I. Glenn Cohen at Harvard Law School, discussing his chapter on patient safety in England from Global Patient Safety Law, Policy and Practice (edited with Clayton Ó Néill, Morgan Shimwell; Routledge, August 2018). A key theme of the session was the extent to which communication errors between health care staff and patients
cause errors. He also spent time connecting in person with colleagues at the Petrie-Flom Center. Some of these discussions have translated into contributions for the Center’s Bill of Health blog.

During his stay Professor Tingle presented a keynote paper at Western New England University School of Law (Springfield, MA) on “Global Patient Safety Law, Policy, and Practice” as part of the Clason Speaker Series. He also delivered a lecture on “Global Patient Safety” at the ECRI Institute in Plymouth Meeting.

Jennifer S. Bard, Spring 2019

During her time at the Petrie-Flom Center Jennifer Bard was a professor of law at the University of Cincinnati College of Law, where she also held an appointment as professor in the Department of Internal Medicine at the University of Cincinnati College of Medicine. Prior to joining the University of Cincinnati, Bard was associate vice provost for academic engagement at Texas Tech University and was the Alvin R. Allison Professor of Law and director of the Health Law and JD/MD program at Texas Tech University School of Law. From 2012 to 2013, she served as associate dean for faculty research and development at Texas Tech Law.

During her time at the Center, Professor Bard worked with faculty affiliate Mark Barnes (Ropes & Gray LLP) to make considerable progress on their project “Nutshell in Human Subject Research,” with a particular focus on issues involving vulnerable populations such as prisoners, asylum seekers, and those detained for violation of immigration laws. Professor Bard’s work addresses the fact that the current review of the Common Rule for the protection of human subjects does not address the Appendixes to 45 CFR 46, which have been largely untouched since the 1990s and therefore do not reflect what we know today about issues such as genetic privacy, vulnerability, stigma, and intersectionality.

Two highlights of her visit were:

- Interviewing Shannon Seward, Harvard’s Director of IRB Administration
- Attend Harvard’s Committee on the Use of Human Subjects in Research (CUHS) Institutional Review Board (IRB). The Harvard University-Area (HUA) CUHS, reviews projects from FAS, GSE, HKS, HBS, HLS, SEAS, GSD, HDS, and the Radcliffe Institute.

This was especially exciting since the new revision to the Common Rule is likely to affect particularly social and behavioral research which are the focus of the CUHS.

She also published two in a series of posts on Human Subject Research to Bill of Health and will continue the series into the fall.
The Petrie-Flom Center
Annual Report, August 2019

- Regulating Human Subject Research: Like Being an Unwilling Participant in a Very Nerdy Version of Groundhog Day
- The ‘Nazi Problem’ in Human Subject Research Regulation

She looks forward to continuing the relationship with the IRB and the Center.

Jennifer D. Oliva, Spring 2019

Jennifer Oliva joined the Petrie-Flom Center from her position as Associate Professor at the West Virginia University College of Law and School of Public Health. In the College of Law, she taught torts, evidence, and public health law courses and directs the Veterans Advocacy Clinic. She is a recognized expert on veterans health and public health issues including addiction and mental health. In Fall 2019, she will take up the position of Associate Professor of Law at Seton Hall Law School.

During her time at the Petrie-Flom Center, Professor Oliva researched a variety of works-in-progress, including articles entitled Waging Class Warfare: The Battle Against Privatization of the Veteran Health Care Delivery System, an article entitled Public Health Policing, a co-authored article entitled Regulating Expert Evidence, and an interdisciplinary, mixed-methods empirical project, entitled the Justice-Involved Veterans Research Study (JIVRS).

In addition, Professor Oliva was a prolific contributor to the Bill of Health blog, and presented as part of a public panel discussion hosted by the Petrie-Flom Center on “Public Health Approaches to the Opioid Crisis: Overcoming Obstacles to Community-Driven Solutions.”

Dagim Belay, February–April 2019

Dagim Belay joined the Center as a Visiting Researcher as part of our Precision Medicine, Artificial Intelligence, and the Law (PMAIL) Project, a collaboration with the Center for Biomedical Innovation Law at the University of Copenhagen. At the University of Copenhagen, Mr. Belay is a Postdoctoral Fellow in the Section for Production, Markets, and Policy in the Department of Food and Resource Economics.

During his time at the Center, Mr. Belay met with colleagues at Harvard Law School and the Program on Regulation, Therapeutics, and Law at Brigham and Women’s Hospital to advance his research.
**Faculty Summer Research Support**

The Center contributes summer support for HLS faculty research projects related to our areas of interest. In Summer 2018, we supported the following:

**I. Glenn Cohen** worked on several books, articles, and book chapters including:

**Disability, Health, Law, and Bioethics** (edited with Carmel Shachar, Michael Ashley Stein, and Anita Silvers) (Cambridge University Press, forthcoming 2020).

**Einer Elhauge**, the Petrie-Flom Center’s founding faculty director, continued research and writing on his book about what limits are appropriate for re-engineering human biology, extending the project to include not only medical, genetic and mechanical changes but also going beyond humans to create new nonhuman entities that have attributes entitling them to personhood rights. He also wrote an article on the anticompetitive effects of horizontal shareholding and co-authored an article on how best to model horizontal shareholding effects on corporate decision-making.

**2018–2019 Affiliate Scholarship**

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 more. 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.

Publications from Center faculty, staff, fellows, and visitors are listed below. The work of Student Fellows is discussed in the section of this report on the Student Fellowship Program.

**Publications from Sponsored Research**

**Precision Medicine, Artificial Intelligence, and the Law (PMAIL)**


W. Nicholson Price, Big Data and Black-Box Medical Algorithms, 10 SCIENCE TRANSLATIONAL MEDICINE 471 (December 12, 2018).


**Patient-Centered Outcomes Research Oversight Study (PCOROS)**


**Harvard Catalyst**


**The Football Players Health Study (FPHS)**


**Center-Edited Volumes**


Affiliate Scholarship

I. Glenn Cohen

Books

**Health Care Law and Ethics** (Wolters Kluwer, 9th ed. 2018) (co-authored with Mark A. Hall, David Orentlicher, Mary Anne Bobinski, and Nicholas Bagley).


**Medical Liability and Treatment Relationships** (Wolters Kluwer, 4th ed. 2018) (co-authored with Mark A. Hall, David Orentlicher, Mary Anne Bobinski, and Nicholas Bagley).

Chapters and Articles

*A Troubling Court Decision for Reproductive Rights: Legal Recognition of FetalStanding to Sue*, JAMA (May 22, 2019) (co-authored with Dov Fox and Eli Y. Adashi).


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1 Publications included above under sponsored research or edited volumes are not repeated for each individual affiliate.


Regulation of Stem Cell Therapy Travel, CURRENT STEM CELL REPORTS (July 2018) (co-authored with Shelly Simana).

Carmel Shachar

Chapters and Articles

Are Fraud and Abuse Laws Stifling Value-Based Care?, NEW ENGLAND JOURNAL OF MEDICINE CATALYST (Sept. 12, 2018).

In Whose Best Interests: The Impact of Globalised Medicine on Withdrawal of Treatment Decisions in the UK, NEW LAW JOURNAL (Sept. 7, 2018) (co-authored with David Locke).

Sara Gerke

Books

Chapters and Articles


Eine rechtsvergleichende Analyse der klinischen Translation von hiPS-Zellen in Deutschland und Österreich / A Comparative Legal Analysis of the Clinical Translation of hiPSCs in Germany and Austria, in Sara Gerke, Jochen Taupitz, Claudia Wiesemann, Christian Kopetzki, and Heiko Zimmermann (eds.), DIE KLINISCHE ANWENDUNG VON HUMANEN INDUZERTEN PLURIPOTENTEN STAMMZELLEN – EIN STAKEHOLDER-SAMMELBAND [THE CLINICAL APPLICATION OF HUMAN INDUCED PLURIPOTENT STEM CELLS: A STAKEHOLDER ANTHOLOGY], (Berlin, Heidelberg: Springer, forthcoming) (with Christian Kopetzki, Verena Christine Blum, Danielle Noe und Claudia Steinböck).

Alicia Yamin

Books


Chapters and Articles

Strategies for Promoting Justice through Health Rights Litigation, in RESEARCH HANDBOOK ON ECONOMIC, SOCIAL AND CULTURAL RIGHTS (Jackie Dugard, Bruce Porter, and Daniela Ikawa eds, forthcoming 2019).


Why Accountability Matters for Universal Health Coverage and Meeting the SDGs, 393 LANCET (March 16, 2019) (co-authored with Elizabeth Mason on behalf of the UN Secretary General’s Independent Accountability Panel).


Compounded Injustice and Cautionary Notes for “Progress” in the Sustainable Development Era: Considering the Case of Sterilization of Women Living with HIV, 41 HARV. J. L. & GENDER 2 (Summer 2018) (co-authored with Corey Prachniak-Rincón).

Jean-Christophe Bélisle-Pipon

Chapters and Articles


Conflicts of interest and the (in)dependence of experts advising government on immunization policies, VACCINE (Nov. 26, 2018) (co-authored with Louise Ringuette, Anne-Isabelle Cloutier, Victoria Doudenkova, Bryn Williams-Jones).


Jennifer D. Oliva

Chapters and Articles


2018–2019 Affiliate Commentary

Our affiliates are highly sought after for their expert opinions on a number of pressing news items, including issues related to health reform, football player health, reproductive technology, human subjects (and biospecimens) research, organ transplantation, intellectual property, and more. Center affiliates also authored editorial pieces and gave extended interviews, and several are also regular bloggers at the Petrie-Flom Center’s collaborative blog, Bill of Health, as well as other high-profile blogs, including Health Affairs. These contributions to the media, lay press, and more informal online outlets help advance the Center’s goal of reaching beyond academic circles on critical policy issues.

A full list of our extensive media commentary in FY19 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 commentary or were extensively interviewed are featured below:

Commentary co-authored by members of the Petrie-Flom team

Smart Pills Can Transmit Data to Your Doctors, But What about Privacy?, NEW SCIENTIST (Sept. 19, 2018) (co-authored with Alex Pearlman).
Health as a Human Right, Medicare for All, and the Evolution of the American Health Care Debate, TAKE CARE BLOG (Dec. 11, 2018) (co-authored with Carmel Shachar and Alex Pearlman).

Carmel Shachar


Sara Gerke


Rise of AI in Healthcare Raises Important Questions About Safety, Liability and Privacy, quoted and mentioned by Megan Diamond, HARVARD GLOBAL HEALTH INSTITUTE (October 24, 2018). Available at:

Alicia Ely Yamin

Silencing the Drama: Do the SDGs Expose the Limitations on Women’s Sexual and Reproductive Rights?, OPEN GLOBAL RIGHTS (March 27, 2019).


Francis X. Shen

Sex Robots Are Here, But Laws Aren’t Keeping Up With the Ethical and Privacy Issues They Raise, THE CONVERSATION (February 12, 2019).
Public Events Programming and Conferences

In addition to a variety of invited presentations given by Center affiliates around the world, the Petrie-Flom Center hosted a number of fantastic events again this year. It was a very busy year: our public events included ten conferences and multiple panel events. We also provided support for a range of events hosted by partners at Harvard Law School, Harvard Medical School, and elsewhere.

The Center continued its shift in focus away from panel events to larger, often cosponsored conference events. This Center continued to build relationships with government agencies, industry partners, and scholarly centers within and outside of Harvard. We continue to leverage the Center’s broad expertise in health law and policy to address a diversity of topics and intended audiences. Examples this year included a collaboration with the Global Access in Action (GAIA) at the Berkman Klein Center for Internet and Technology at Harvard to host a conference that brought together leaders from the pharmaceutical industry, policymakers, legal practitioners, and scholars to engage in novel, interdisciplinary discussions to better understand current challenges and articulate best practices to address issues in pharmaceutical pricing policy. We also partnered and with the American Academy of Arts and Sciences to host a working meeting on the night before our annual conference that brought together our scheduled speakers – experts on legal and policy issues relating to consumer genetic technologies – with area scientists and medical researchers in a discussion that will help guide the American Academy’s priorities in this area. Our continued goal is to raise the profile of the Center with leading scholars, policymakers, and practitioners while delivering quality programming to the Harvard community.

The Center experimented with two innovations in its events programming this year. First, we moved to hosting events that had a mix of public and invitation only sessions. This was most notably highlighted in our April 2019 conference, “Mitochondrial Replacement Therapy: Considering the Future of U.S. Policy on ‘Three-Parent IVF.’” This event opened with a panel of leading scientists and ethicists discussing mitochondrial replacement therapy and then led into a half day roundtable with leading scientists, policymakers, and patient advocates discussing next steps in American MRT policy. The event was notable enough to inspire an editorial on the topic in the New York Times, which explicitly mentioned the work of the Center. We anticipate that this public/private hybrid model will allow us to better influence key stakeholders on the topics we cover as it did for our MRT event. This year we also began livestreaming our major events online for leading scholars, practitioners, and journalists who are interested in our content but unable to travel to Cambridge to participate in events in person.

Our programming allows the Center to form partnerships with and to learn from other research programs, to offer students and other interested participants direct contact with key opinion leaders and exposure to cutting-edge issues in health policy and bioethics, and to bring our scholarship to life through in-person discussion and debate. These events
continue to be the backbone of the Center and we look forward to continuing to prioritize this service in the coming years.

Below is a condensed list of our events from the past year, with hyperlinks for additional information regarding topic descriptions and speakers:

**Major Events/Conferences**

**Outbreak Week**
Organized by the Harvard Global Health Institute (HGHI), in partnership with the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School, with support from the Center for Bioethics at Harvard Medical School and the Oswald DeN. Cammann Fund at Harvard University; the Harvard T. H. Chan School of Public Health; the Shorenstein Center on Media, Politics and Public Policy at the Harvard Kennedy School; the Department of Global Health and Social Medicine at Harvard Medical School; Common Spaces | the Richard A. and Susan F. Smith Campus Center at Harvard University; the Harvard Museums of Science and Culture; the Center for the History of Medicine at Countway Library of Medicine; the Lakshmi Mittal and Family South Asia Institute at Harvard University; and the Center for Communicable Disease Dynamics at the Harvard T. H. Chan School of Public Health.

**Media in the Age of Contagions**
**September 26, 2018**
This session was sponsored by the Harvard Global Health Institute (HGHI); the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School; and the Shorenstein Center on Media, Politics and Public Policy at the Harvard Kennedy School.

**Vaccines for Outbreaks in the Modern World**
**September 27, 2018**
This session was sponsored by the Harvard Global Health Institute (HGHI); the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School; and the Center for Communicable Disease Dynamics at the Harvard T. H. Chan School of Public Health.

**Preventing Epidemics in a Connected World**
**September 28, 2018**
This session was sponsored by the Harvard Global Health Institute (HGHI); the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School; the Lakshmi Mittal and Family South Asia Institute at Harvard University; and the Center for Communicable Disease Dynamics at the Harvard T. H. Chan School of Public Health.

**New Funding Frontiers: Innovative Funding Models for Translational Research**
**October 1, 2018**
Part of the Innovative Funding Models in Translational Research Project. This event received support from the Center for Bioethics at Harvard Medical School and the Oswald DeN. Cammann Fund at Harvard University.
Drug Pricing Policies in the United States and Globally: From Development to Delivery
October 24, 2018
Sponsored by the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School, Global Access in Action at the Berkman Klein Center for Internet and Society at Harvard University, and the Harvard Health Law Society, with support from Gilead Sciences, Inc. and the Center for Bioethics at Harvard Medical School and the Oswald DeN. Cammann Fund at Harvard University.

Seventh Annual Health Law Year in P/Review
December 7, 2018
Sponsored by the Petrie-Flom Center in Health Law Policy, Biotechnology, and Bioethics at Harvard Law School, with support from the Center for Bioethics at Harvard Medical School and the Oswald DeN. Cammann Fund.

The Future of Health Care? Medicaid Buy-In and State Trailblazing in Health Care
March 15, 2019
Two hours of public presentations followed by an afternoon of closed round table discussion among invited scholars, researchers, and practitioners.
Sponsored by the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School, with support from the Center for Bioethics at Harvard Medical School and the Oswald DeN. Cammann Fund. Harvard University, and United States of Care.

Harvard Medical School Annual Bioethics Conference 2019
Controlling Death: The Policies, Practices, and Ethics of Choosing When We Die
April 11–12, 2019
Hosted and organized by the Center for Bioethics at Harvard Medical School and cosponsored by the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School, with support from the Oswald DeN. Cammann Fund at Harvard University.

Mitochondrial Replacement Therapy: Considering the Future of U.S. Policy on “Three-Parent IVF”
April 17, 2019
Two hours of public presentations followed by an afternoon of closed round table discussion among invited scholars, researchers, and practitioners.
Sponsored by the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School, with support from the Center for Bioethics at Harvard Medical School and the Oswald DeN. Cammann Fund at Harvard University.

Providing Value and Redesigning Care for Serious Illness
April 26, 2019
Two hours of public presentations followed by an afternoon of closed round table discussion among invited scholars, researchers, and practitioners.
This event is part of the Project for Advanced Care and Health Policy, a collaboration between the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School and the Coalition to Transform Advanced Care (C-TAC), 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.
Consuming Genetics: Pre-Conference Discussion  
May 16, 2019  
*Hosted by the American Academy of Arts and Sciences.*

2019 Petrie-Flom Center Annual Conference  
**Consuming Genetics: The Ethical and Legal Considerations of Consumer Genetic Technologies**  
May 17, 2019  
*Sponsored by the Petrie-Flom Center in Health Law Policy, Biotechnology, and Bioethics at Harvard Law School, with support from the Center for Bioethics at Harvard Medical School and the Oswald DeN. Cammann Fund.*

June 25–27, 2019  
*Cosponsored by the Federal Judicial Center and the Center for Law, Brain and Behavior at MGH.*

**Lectures and Panels**

**Book Launch: Big Data, Health Law, and Bioethics**  
September 12, 2018  
*Sponsored by the Harvard Law School Library, the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School, and the Berkman Klein Center for Internet & Society at Harvard University.*

2018 Petrie-Flom Center Open House  
September 12, 2018  
*Sponsored by the Petrie-Flom Center in Health Law Policy, Biotechnology, and Bioethics at Harvard Law School, with support from the Center for Bioethics at Harvard Medical School and the Oswald DeN. Cammann Fund.*

**Bad Blood: Secrets and Lies in a Silicon Valley Startup: A Special Evening with Author John Carreyrou**  
October 2, 2019  
*This event was hosted by Cambridge Science, Harvard College Cabot House, and the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School.*

**Trauma at the Border**  
March 4, 2019  
*Part of the Project on Law and Applied Neuroscience, a collaboration between the Center for Law, Brain & Behavior at Massachusetts General Hospital and the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School.*
Book Talk: Global Health Justice and Governance
March 11, 2019
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 Center for Bioethics at Harvard Medical School and the Oswald DeN. Cammann Fund at Harvard University.

Public Health Approaches to the Opioid Crisis: Overcoming Obstacles to Community-Driven Solutions
April 1, 2019
Sponsored by the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School, with support from the Center for Bioethics at Harvard Medical School and the Oswald DeN. Cammann Fund at Harvard University.

The Neuroscience of Hate
April 10, 2019
The Part of the Project on Law and Applied Neuroscience, a collaboration between the Center for Law, Brain & Behavior at Massachusetts General Hospital and the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School.

The Science and Ethics of Chimera Research: Part of the Ethics Frontiers Seminar Series
May 16, 2019
This series is hosted and organized by the Center for Bioethics at Harvard Medical School and cosponsored by the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School with support from the Oswald DeN. Cammann Fund at Harvard University.

Event Series

Digital Health @ Harvard

The Digital Health @ Harvard series features speakers from Harvard as well as collaborators and colleagues from other institutions who research the intersection between health and digital technology. The series is cosponsored by the Berkman Klein Center for Internet & Society at Harvard University and the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School. The goal of the series is to discuss ongoing research in this research area, share new developments, identify opportunities for collaboration, and explore the digital health ecosystem more generally.

Sessions in 2018–2019:

Medicaid Work Requirements: Limitations in Digitally Identifying Individuals for Exemption Due to Disability
October 16, 2018
A lecture by Rachel Gershon (JD/MPH ‘10), Center for Health Law and Economics, UMass Medical School.
Simulation and Deliberation to Prepare for Clinical Trials in Infectious Disease Emergencies
November 27, 2018
A lecture by Marc Lipsitch, Professor of Epidemiology, Harvard T. H. School of Public Health.

What Should Happen to Our Medical Records When We Die?
April 3, 2019
A lecture by Jon Cornwall, Senior Lecturer in the Centre for Early Learning in Medicine, Otago Medical School, at the University of Otago (Dunedin, New Zealand)

Health Policy and Bioethics Consortia

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 Center for Bioethics at Harvard Medical School 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 for the Consortia is provided by the Oswald DeN. Cammann Fund at Harvard University. While most of the sessions were hosted on the Harvard Medical School campus, on February 8, 2019, the Petrie-Flom Center hosted a session at Harvard Law School on Black-Box Medicine: Legal and Ethical Issues: A Health Policy and Bioethics Consortium.

For a full listing of consortium topics, visit the website.
Additional Events with Petrie-Flom Co-Sponsorship and/or Participation

In addition to events the Petrie-Flom Center played a leading role in organizing, we also collaborated on several other events organized by our Harvard colleagues:

**Achieving Equitable Access to Vaccines: From Policies to Provisions**
October 17, 2018
Organized by Global Access in Action, a project at the Berkman Klein Center for Internet & Society at Harvard University.

**Antibiotic Resistance: What Collaboration and Policy Can Do For Our Future**
November 15, 2018

**An MD’s Take on Single-Payer Health Care**
November 16, 2018
Organized by the Harvard Health Law Society at Harvard Law School. Cosponsored by the Student Mental Health Association, the DOS Grant Fund, the HLS Democrats, and the Center for Health Law and Policy Innovation, all at Harvard Law School.

**Inequity in Mental Health Care Access**
February 20, 2019

**Accelerating Alternatives to Animal Experimentation**
March 1, 2019
Part of Animal Law Week at Harvard Law School, sponsored by the Animal Law & Policy Program.

**Health Law Careers in the Public Sector**
March 28, 2019

**On Life and Death in Rikers with Dr. Homer Venters**
April 16, 2019

**Gene Editing of Babies and Universal Human Rights: Hot Topics in Health Law**
April 19, 2019
Organized by the Harvard Health Law Society at Harvard Law School. Cosponsored by the Dean of Students Grant Fund, the American Constitution Society, the Center for Health Law Policy and Innovation at Harvard Law School.
April 23, 2019
Organized by the Animal Law & Policy Program at Harvard Law School. Cosponsored by the Animal Law Society, the Food Law and Policy Clinic, the Harvard Food Law Society, HLS Effective Altruism, and the Dean of Students Grant Fund at Harvard Law School.

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. In addition to contributions to regular university courses, I. Glenn Cohen’s HarvardX course, “Bioethics: The Law, Medicine, and Ethics of Reproductive Technologies and Genetics” remains a popular offering on the HarvardX website, with the most recent session running in Fall 2018. Over the life of the course over 35,000 learners have enrolled, with more than 1,000 paying associated fees to receive a verified certificate of completion. The course is scheduled to re-open in July 2019. He also lectured online and in person in other offerings around Harvard University. Among his lectures at Harvard was “Implementation Research in Health and Health Care” at the Harvard T. H. Chan School of Public Health, which he reprised in Summer 2019.

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

Health Law, Policy, Bioethics, and Biotechnology Workshop
I. Glenn Cohen
Fall 2018

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. However, attendance is open to all interested parties, and the workshop audience often includes faculty, fellows, and students from across Harvard and surrounding universities, as well as local practitioners and the general public.

The workshop – the content of which varies every year – has become one of the preeminent venues for leading scholars in health law, biotechnology, and bioethics to launch, discuss, and improve their newest ideas. During two-hour sessions that take place over the course of the full academic year, 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.
The 2018–2019 workshop welcomed the following scholars:

- **Zack Buck**, Assistant Professor of Law and Wilkinson Junior Research Professor, University of Tennessee at Knoxville College of Law
  “The Price of Universality: Sustainable Access and the Twilight of the ACA”

- **Timothy Caulfield**, Canada Research Chair in Health Law and Policy, Professor in the Faculty of Law and the School of Public Health, and Research Director of the Health Law Institute, University of Alberta (Canada)
  “Health Misinformation and the Power of Narrative Messaging in the Public Sphere”

- **Christina S. Ho**, Professor of Law, Rutgers Law School
  “Health Impact Assessment: A Negative Right to Health”

- **James Hodge**, Professor of Law, Sandra Day O’Connor College of Law, Arizona State University
  “Constitutional Cohesion and Public Health Promotion”

- **Craig Konnoth**, Associate Professor of Law, Colorado Law
  “Medical Civil Rights”

- **Matthew J. B. Lawrence**, Assistant Professor of Law, Penn State Dickinson Law
  “The Social Consequences Problem in Health Insurance and How to Solve It”

- **S. Matthew Liao**, Director of Center for Bioethics and Arthur Zitrin Professor of Bioethics, NYU College of Global Public Health
  “The Moral Status and Rights of Artificial Intelligence”

- **Anya Prince**, Associate Professor of Law at the University of Iowa College of Law and Member of the University of Iowa Genetics Cluster
  “Gene Therapy’s Field of Dreams: If You Build It, Will We Pay?”

- **Natalie Ram**, Assistant Professor of Law at the University of Baltimore School of Law and Associate Director of the University of Baltimore’s Center for Medicine and Law
  “Rebuilding Privacy Practices after Carpenter”

- **Ameet Sarpatwari**, Instructor in Medicine, Harvard Medical School; Associate Epidemiologist, Brigham and Women’s Hospital; and Assistant Director, Program On Regulation, Therapeutics, And Law (PORTAL), Division of Pharmacoepidemiology and Pharmacoeconomics, Brigham and Women’s Hospital
  “The U.S. Follow-On Biologic Market”

- **John Tingle**, Associate Professor, Nottingham Law School, Nottingham Trent University (UK)
  “Patient Safety Policy Development in the NHS in England”

- **Kristen Underhill**, Associate Professor of Law, Columbia Law School
  “Perceptions of Protection under Nondiscrimination Laws”
Health Care Rights in the 21st Century
Carmel Shachar (co-taught with Kevin Costello)
Fall 2018

Health care has become a dominant political issue in contemporary America – to the point of swaying national elections and consuming congressional calendars. Underlying this political debate is the fundamental question whether Americans enjoy a basic entitlement to health care. This course will briefly trace the history of the American conception of health care rights through the last half-century of administrative and political cycles. We will contrast a diverse array of ideological perspectives over this progression to understand the context of the current climate.

Building on this background, this course considers a broad range of rights-affording sources across the landscape of the modern American health care system: Federal civil rights statutes; the laws and agreements that govern public and private health insurance arrangements; data privacy and ownership rights; and other state and federal statutes that govern health care consumers, insurers, institutions and spending. We will also consider negative rights in the context of the now defunct individual mandate of the Affordable Care Act and relevant Religious Freedom Restoration Act developments. We will place congressional and common law health care rights provisions in the broader context of civil rights jurisprudence, including anti-discrimination regimes. Applying a lens of civil rights and enforcement to these sources of law, the course considers differing avenues available to achieve enforcement of health care rights, including through administrative and policy-based advocacy, as well as more formalized litigation.

The seminar is designed to be limited lecture, incorporating debates, role-plays, and other interactive sessions. Class participation is expected. The seminar will culminate in a student project arising from the course materials. Students will have the option of further honing their health care rights skills by participating in the Health Law and Policy Clinic in conjunction with this seminar.

The seminar appeals to law students interested in working across the spectrum of the health care field generally, to those interested in the intersection between law and health care, and to those who aspire to be civil rights lawyers.

Law and Neuroscience
Nancy Gertner
Spring 2019

This seminar examines cutting edge and even controversial linkages between law and neuroscience. We seek to highlight neuroscientific basis for behavior patterns with legal implication including how neuroscience intersects with criminal law, its normative assumptions and criminal punishment, evidentiary rules, memory bias and enhancement, lie and deception detection, adolescent brains and juvenile law.
We will look critically at efforts to use neuroimaging in court in connection with in the prediction of criminality and predispositions towards mental illness and addiction, as well as efforts to identify neurobiological influences on the brain. Is there such a thing as a criminally violent brain? Does it make sense to speak of the neurobiology of violence or the psychopathology of crime, and how are (or should) such concepts translated into criminal law. The seminar will necessarily consider the relationship between law and science, more generally, and neuroscience in particular. Speakers will provide insights into their work and research.

**Bioethics: The Law, Medicine, and Ethics of Reproductive Technologies and Genetics**

I. Glenn Cohen (HarvardX)

Most recent (self-paced) session launched on June 1, 2018, and concluded in December 2018. Slated to relaunch a new session in July 2019.

Bioethics provides an overview of the legal, medical, and ethical questions around reproduction and human genetics and how to apply legal reasoning to these questions. This course includes interviews with individuals who have used surrogacy and sperm donation, with medical professionals who are experts in current reproductive technologies like In Vitro Fertilization and Preimplantation Genetic Diagnosis, and bioethicists and journalists who study the ownership and use of genetic information within human tissue. Additional Harvard colleagues will also share their thoughts on topics such as disability law as it relates to reproductive technology.

While the law and ethics surrounding these technologies are a central component to this course, it will also provide examples of the deeply personal and human side of these issues. Throughout the course, students will discuss leading legal cases in this field, which will illuminate the types of questions the law has struggled with – stretching and evolving over time. From the famous Baby M surrogacy case, to cases on the paternity of sperm donors, to a case related to the ownership of human tissue turned into a commercial product, and others. The course will explore the ethical, legal, and rhetorical underpinnings that have served as the basis for various court decisions over the past 20-30 years. It will also explore potential future technologies and their implications for society: genetic enhancements to increase our intelligence, let us live a hundred years longer, or make us immune to diseases – and the possibility of creating animal-human hybrids, for example a mouse with a humanized brain.

The content within this course is intended to be instructive, and show how legal reasoning has been applied, or could be applied, to questions related to parenthood, reproduction, and other issues surrounding human genetic material. The material organized within this course should be considered an authoritative overview, but is not intended to serve as medical or legal advice.
This course is designed for a diverse audience including, but not limited to, law students, prospective law students, medical professionals, as well as members of the general public interested in questions and topics related to surrogacy, parenthood, genetic and reproductive technology, ownership of genetic material, and more.

**Bioethics and Health Law: Selected Topics**  
*I. Glenn Cohen*  
Winter 2019

This class covers selected topics in health care law, public health law, and (especially) bioethics. Among the topics that 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.
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.

Under Executive Director Carmel Shachar’s leadership, we have actively sought to increase opportunities for student engagement at the Petrie-Flom Center. This has been evident in FY19 as we have increased our outreach to admitted and incoming students through participation in Admitted Students Weekend activities in the spring and the Student Activities Fair in the fall; expanded collaborations with student organizations, most notably the Harvard Health Law Society; and increased opportunities for students to participate in ongoing research. Shachar also works alongside Faculty Director I. Glenn Cohen to oversee the joint JD/MPH program, and to advise students interested in pursuing education and/or careers in health law and policy.

The Center was particularly engaged in the admitted students programming during Spring 2018, hosting two full tables at two luncheons for incoming students. We were encouraged to find that at least four of the attendees later matriculated at HLS and told us that the Petrie-Flom Center was a decisive factor in making that decision. This group includes incoming 2019–2020 Student Fellow Alexa Richardson (JD ‘21). Unfortunately, due to a shift in the admitted students programming for Spring 2019 we were unable able to repeat our successful outreach. We hope moving forward to work closely with the team that organizes the admitted students programming to be better involved.

We also joined the student-run Harvard Health Law Society at a jointly run table at the HLS Student Activities Fair in September 2018, where Administrative Director Cristine Hutchison-Jones engaged with dozens of students to share information about the Center’s Student Fellowship, public events, sponsored research projects, and opportunities for engagement.

We are also making efforts to give students more prominent roles as participants in Petrie-Flom events. In FY19, students were active participants in the following events:

- **Daniel Aaron** (JD ‘20; Boston University School of Medicine, MD ‘20), President of the Harvard Health Law Society, delivered welcome remarks at the conference “Drug Pricing Policies in the United States and Globally: From Development to Delivery.”
- **Clio Koller** (HMS, MBioethics ‘19), an intern at the Center throughout the academic year, served as a notetaker and discussant at “Consuming Genetics: A Pre-Conference Discussion,” hosted by the American Academy of Arts and Sciences in conjunction with the Petrie-Flom Center’s 2019 Annual Conference.
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- **Shelly Simana** (SJD expected ‘20) served as a notetaker and discussant during the private afternoon session at “Mitochondrial Replacement Therapy: Considering the Future of US Policy on ‘Three-Parent IVF’.”
- **Rachel Wang** (JD ‘19) served as a respondent to author John Carreyrou at the book event “Bad Blood: Secrets and Lies in a Silicon Valley Startup.”

Outreach to HLS alumni was also a priority during FY19. We believe that outreach to HLS alumni not only benefits the Center, but also reinforces ties between past and present HLS students by reengaging alumni in campus events and life. During FY19 we developed closer relationships with the following HLS alumni, by engaging them with our Health Care General Counsel Roundtable or asking them to speak at our events:

- **Stacy Cline Amin**, Chief Counsel of the Food and Drug Administration
- **Susan Galli**, Partner, Ropes & Gray (ret.)
- **Jorge Lopez**, Executive Vice President and General Counsel of Memorial Sloan Kettering Cancer Center
- **Brad Lerman**, Senior Vice President, General Counsel, and Corporate Secretary, Medtronic
- **Catheryn O’Rourke**, Chief Legal and Compliance Officer, Smith & Nephew
- **Jennifer Zachary**, Executive Vice President and General Counsel, Merck Pharmaceuticals

**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:

- **Rebecca Friedman**
  Harvard Law School, JD ‘19
  **Paper:** “Feasibility and Potential Impact of Broader Medicaid Coverage of Doula Services on Racial and Socioeconomic Disparities in Birth Outcomes”

- **Rahul Nayak**
  Harvard Medical School, MD ‘19
  **Paper:** “Public Support for Late-Stage New Drug Discovery”
Mark Robinson
Harvard Medical School, MBioethics ‘19

Mark Satta
Harvard Law School, JD ‘19
Paper: “Spitting at Science: HIV Criminalization Laws and the Duty to Legislate in Accordance with Current Scientific Knowledge”

Alexandra Slessarev
Harvard Law School, JD ‘19
Harvard T. H. Chan School of Public Health, MPH ‘19

James Toomey
Harvard Law School, JD ‘19
Paper: “How to End our Stories: Dementia, Narrative Personal Identity and Seniors’ Theories of Legal Capacity”

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 Manager Alex Pearlman supported the Fellows with an hour-long digital training session in the fall, followed by one-on-one meetings with Fellows over the course of 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:

- **Spitting at Science: The Unjustified Criminalization of Spitting While HIV-Positive**, by Mark Satta, JD ‘19
- **On Social Suicide Prevention, Don’t Let the Perfect be the Enemy of the Good**, by James Toomey, JD ‘19
- **The Troubling Prevalence of Medical Record Errors**, by Rebecca Friedman, JD ‘19
Research Assistants

Petrie-Flom affiliates routinely work directly with Harvard graduate students as Research Assistants (RAs) on particular projects. We have engaged RAs to help identify topics, develop book proposals, and edit manuscripts for our conference volumes; conduct literature reviews and draft memos; prepare for media interviews; assist with development and submission of research protocols to Institutional Review Boards; and collaborate on empirical research projects. In FY19 we particularly prioritized placing students on every Petrie-Flom project possible, including hiring students to translate our events into whitepapers.

In particular, we enjoyed the excellent work of the following students this year:

**Disability, Health, Law, and Bioethics**
- Rosie Bichell, JD ‘19
- Grant Glovin, JD ‘20
- Margaret Mattes, JD ‘20
- Andrew Skaras, JD ‘20

**Drug Pricing Policies in the United States and Globally**
- Jennifer Esch, JD ‘20

**Global Health and Rights Project**
- Tara Boghosian, JD ‘20
- Ava Liu, JD ‘20

**Innovative Funding Models in Translational Research**
- Helena Ferreira Matos do Carmo, LLM ‘19

**Transparency in Health and Health Law**
- Gali Katznelson, HMS ‘18

**Advanced Care and Health Policy**
- Gali Katznelson, HMS ‘18
Other Petrie-Flom Projects

- Ramon Gonzalez, JD ‘19 / HBS ‘19
- John Hylton, JD ‘20

Student Bloggers

In addition to our Student Fellows, Bill of Health is home to a number of graduate student bloggers from HLS and around Harvard. With the relaunch of the blog in October 2018, we invited our affiliates to suggest potential student bloggers. In addition to a number of excellent Harvard graduate student contributors, we accepted submissions on a case-by-case basis for students outside the Harvard community.

Some of our most notable student blog posts in FY19 were:

- **Ohio’s “Fetal Heartbeat” Bill and the Effort to Restrict Abortion Access**, by Hailey Cleek (Wake Forest University, ‘19)
- **US Legislators Take a Scattered Approach to Neonatal Abstinence Syndrome**, by J. Alexander Short (Penn State University Dickinson School of Law, ‘19)

Student Interns

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 events;
- Collecting and formatting material for drafts of Center reports; and
- Research projects as assigned.

Our 2018–2019 interns were:

- Clio Koller, HMS ‘19
- Margaret Wilson, COL ‘19
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; Michael Stein of the Harvard Law School Project on Disability co-edited the volume Disability, Health, Law, and Bioethics, based on the 2018 Petrie-Flom Center Annual Conference that he also co-organized; we have increasingly engaged with the leadership at the Center on the Legal Profession, including welcoming Faculty Director David Wilkins as a speaker at one of our Health Care General Counsel Roundtable meeting and working closely with Executive Director Derek Davis on mutual programming; and we have continued to collaborate regularly on events with our colleagues at the Animal Law and Policy Program. 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. 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 multiple sessions of the “Digital Health @ Harvard” lecture series and our fall conference on “Drug Pricing Policies in the United States and Globally: From Development to Delivery.”

Other faculty members from around the university have been involved in Petrie-Flom events and research, including:

- Brendan Abel, HMS
- Danielle Allen, University Professor and Edmond J. Safra Center for Ethics
- William P. Alford, HLS
- Satchit Balsari, HMS
- Barbara E. Bierer, HMS
- Phillip Boiselle, HMS and Dean, Florida Atlantic University Charles E. Schmidt College of Medicine
- Rebecca Brendel, HMS
- Caroline Buckee, HSPH
- Eric Campbell, HMS
- Amitabh Chandra, HKS/HBS
- Kevin Costello, HLS
- Leemore Dafny, HBS
- Jonathan Darrow, HMS
- Judith G. Edersheim, HMS
- Nir Eyal, HMS
- Thomas W. Feeley, HBS
- Alan M. Garber, Provost
- Jon Hanson, HLS
- Omar Sultan Haque, HMS
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.
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.

Affiliate Engagement

In addition, our affiliates are regularly sought after to provide media commentary on news stories in our fields, to serve as expert witnesses and legal consultants, and perform other types of public service, such as committee membership, amicus curiae briefs, peer review for academic publications, and the like. Representative examples of such engagement are included below:

I. Glenn Cohen

Faculty Director I. Glenn Cohen serves on the Ethics Committee for the American Congress of Obstetricians and Gynecologists (ACOG), the Ethics Committee for the Organ Procurement and Transplantation Network (OPTN), and the Research Oversight Committee of Genome British Columbia. He also serves as a reviewer for most of the major bioethics and medical journals.

Carmel Shachar

Executive Director Carmel Shachar serves as a board member for the Fishing Partnership Support Services, a non-profit organization devoted to improving the health, well-being, and safety of fishing communities of New England. She serves on the admissions committee for the Center for Bioethics at Harvard Medical School. She also serves on the leadership team for the recently launched Scientific Citizenship Initiative at Harvard Medical School.

Additionally, she presented on topics such as the right to health and universal coverage, including:


Sara Gerke

Since 2017, Gerke has been the initiator of the Strategic Working Group ELSA (Ethical, Legal and Social Aspects of the Modern Life Sciences) of the German Stem Cell Network. She also serves as a member of Durham CELLS (Center for Ethics and Law in the Life Sciences), United Kingdom, a member of the ISSCR (International Society for Stem Cell Research), Skokie, United States, and a member of the Association for the Promotion of German, European and International Medical Law, Health Law and Bioethics in Mannheim and Heidelberg, Germany.

Gerke is also a reviewer of the *Journal of Law and the Biosciences*.

From May 2019 to June 2019, Gerke spent six weeks as a Visiting Researcher at the Center for Advanced Studies in Biomedical Innovation Law (CeBIL) at the University of Copenhagen. During her research stay at CeBIL, she pursued various PMAIL/CeBIL projects on legal and ethical issues with AI and medicine, including working on comparative approaches, cardiac devices as well as data protection and privacy.

Gerke also delivered numerous national and international public presentations related to her work with the *Project on Precision Medicine, Artificial Intelligence, and the Law* (PMAIL) to audiences that included students, legal and medical practitioners, judges, international legal, ethical, and medical scholars, AI startups/developers, and data scientists. Selected presentations include:

- **Ethical and Legal Challenges of AI in Cardiology**, AIMEd CARDIOLOGY (Chicago, IL) (2019).


- **A Smart Pill to Swallow: Legal and Ethical Issues of Ingestible Electronic Sensors** (with Timo Minssen), THE 2019 DIGITAL MEDICINE SYMPOSIUM, HARVARD BUSINESS SCHOOL AND THE HARVARD MIT CENTER FOR REGULATORY SCIENCES (Boston, MA) (2019).

Precision Medicine: Future Trends & Challenges, Promises and Perils of Emerging Health Innovations, 2019 Annual Health Law Conference, Center for Health Policy and Law, Northeastern University, School of Law (Boston, MA) (2019).

Panel Discussion: Experience the Future of AI in Radiology, AIMed (Boston, MA) (2019).

Ingestible Electronic Sensors: Cutting Edge Medicine, and Their Ethical & Legal Issues (with Timo Minssen), BioLawLapalooza, Center for Law and the Biosciences, Stanford Law School, (Palo Alto, CA) (2019).

How Will AI Transform Healthcare? CELLS (Center for Ethics and Law in the Life Sciences) 10 Year Anniversary Celebration, Leibniz University Hannover (Hannover, Germany) (2018).


Ethical and Legal Challenges of AI-Driven Health Care in the U.S. and Europe, invited presentation at the U.S. Department of Health & Human Services (June 2019).

Alicia Ely Yamin

Senior Fellow in Global Health and Rights Alicia Ely Yamin continues to serve on the UN Secretary General’s Independent Accountability Panel for the Global Strategy on Women’s Children’s and Adolescents’ Health in the SDGs. In 2019, Yamin was named to the “Lancet-Dartmouth Commission on Arctic Health,” as well as the “WHO Technical Advisory Group on Heath Technology Assessments in Universal Health Coverage.” Yamin also served on the Lancet-Georgetown/O’Neill Institute Commission on Global Health and the Law, which released its report on May 1, 2019.

In March 2019, Dr. Sofia Charvel, Professor of Law at the Instituto Tecnológico Autónomo de México, came to the Global Health Education and Learning Initiative (GHELI) at Harvard University as a Visiting Scholar to work with Yamin on the constitutionalization of health rights in Latin America and priority-setting in Mexico. As a follow-up to this visit, Yamin is organizing an event to be hosted by the Petrie-Flom Center on October 4, 2019. Two sitting justices of the Supreme Judicial Court of Mexico, Justice Gutiérrez Ortiz Mena (LLM) and Justice Gonzalez Alcántara, will speak on abortion jurisprudence in that country, and a recent landmark decision authored by Justice Gutiérrez Ortiz Mena.

In April 2019, Yamin was one of 16 scholars invited to the Global Health Law Consensus Consultation in Stellenbosch, South Africa. The meeting, funded by research grants from the Canadian Institutes of Health Research and the Research Council of Norway, aimed at providing clarity on the obligations imposed by Articles 43-44 International Health Regulations. Sixteen scholars participated in the conference, and will collaborate on two articles published in different international law journals as well as other projects.

Yamin also delivered numerous public presentations related to her work with the Global Health and Rights Project to audiences that included undergraduate and graduate courses, legal and medical practitioners, policymakers and international legal and medical scholars. Selected presentations during this period include:


The Relevance of Human Rights to Clinical Practice, lecture to Harvard-McGill Medical Student Exchange, Cambridge Health Alliance, Cambridge, MA (May 10, 2019).

Reflections on Advances in Global Health Law, GLOBAL HEALTH LAW INTERNATIONAL CONFERENCE, Faculty of Law, University of Capetown, South Africa (April 8, 2019).
Health and Social Justice, Seminar in International Masters’ Program on Human Rights and Democratization in Africa, Faculty of Law, University of Pretoria, Pretoria, South Africa (April 2-5, 2019).

Is Human Rights Relevant to Advancing Global Health Anymore? DrPH Colloquium Lecture, Harvard T. H. Chan School of Public Health, Boston, MA (March 26, 2019).


El Derecho a la salud, los sistemas de salud y el reto de fijar límites justos con enfermedades raras y costosas [The Right to Health, Health Systems, and the Challenge of Setting Fair Limits in Cases of Rare and Expensive Diseases], First Regional Conference on Hereditary Angioedema: Medical, Ethical and Public Health Perspectives, University of Costa Rica, San Jose, Costa Rica (Feb 18, 2019).

Knowledge and Politics in the Setting of the SDGs, launch event, New School of International Affairs, New York (February 7, 2019).

Sexual Violence: Survival Stories, Gender-based Discrimination and Social Change, Keynote Speech, Martin Luther King Day Celebration, Geisel School of Medicine, Dartmouth University, Hanover, NH (January 19, 2019).

Evaluating Alston’s Contribution to Economic and Social Rights through the Lens of Health, International Conference in Honor of Professor Philip Alston, New York University School of Law, New York (January 17, 2019).

Francis Shen

Senior Fellow in Law and Applied Neuroscience Francis Shen served on the Neuroethics Subgroup of the National Institutes of Health Advisory Committee to the Director BRAIN Initiative Working Group. Shen also delivered numerous public presentations related to his work with the Project on Law and Applied Neuroscience to audiences that included undergraduate student organizations, legal and medical practitioners, judges, and international legal and medical scholars. Selected presentations include:

Neuroscience and the Law, Virginia Tech Carilion School of Medicine and Research Institute (Roanoke, VA) (2019).
A Fresh Look at Youth Sports Concussion Policy in Minnesota (with Sydney Diekmann), MINNESOTA BRAIN INJURY ALLIANCE, 34TH ANNUAL CONFERENCE FOR PROFESSIONALS IN BRAIN INJURY (Brooklyn Park, MN) (2019).


Law and Neuroscience, MINNESOTA CHAPTER OF THE FEDERAL BAR ASSOCIATION (Minneapolis, MN) (2019).


From Lab to Law: Neuroscience in the Courtroom, NATIONAL INSTITUTES OF HEALTH LabRoots (2019).

Brain-Based Memory Detection: From Lab to Law, DUKE UNIVERSITY SCHOOL OF LAW FORENSIC SCIENCE COLLOQUIUM (Durham, NC) (2019).

Introduction to Law and Neuroscience, HARVARD LAW SCHOOL, LAW AND NEUROSCIENCE SEMINAR (Cambridge, MA) (2019).


Mark Sterling

In addition to serving as Chief Strategy Officer of the Coalition to Transform Advanced Care (C-TAC), Mark Sterling provides strategic advice to C-TAC affiliate Respecting Choices®, an internationally recognized, evidence-based system for person-centered decision making that transforms the health care culture by honoring an individual’s goals and values.

Sterling also served on the planning committee for a proposal by C-TAC submitted to the Physician-focused Payment Technical Advisory Committee (PTAC), a panel of experts convened by HHS. C-TAC’s proposal was favorably recommended by P-TAC to the Secretary of the Department of Health and Human Services, and the Secretary commented that the new Primary Cares Initiative includes elements of the C-TAC proposal.
Sponsored and Other Research

The Center’s sponsored research and other projects described above have direct policy implications for the broader community. For example:

- The **Project on Precision Medicine, Artificial Intelligence, and the Law** has garnered significant interest from thought leaders including those in policy and industry. PMAIL provides a comparative analysis of the law and ethics of artificial intelligence and black-box precision medicine, explaining the shortcomings of the current innovation policy landscape in Europe and the U.S. and providing a comprehensive examination of various policy options to better harness the potential of these new health technologies.

- The **Greenwall Law and Bioethics Seminar** empowered leading bioethics scholars to become better consumers of legal materials by creating a space where participants could make headway on legal issues related to the bioethical topics they work on, as well as become generally more comfortable with legal materials. The seminar enhanced scholars’ ability to resist efforts to use the law to “shut down” conversations and empowered them to be part of the conversation.

- Through our work with Harvard Catalyst, we are directly engaging with researchers, institutional policymakers, industry leaders, regulators, patients, and others to advance clinical and translational research through improved recruitment to clinical trials.

- Our work on the **Patient-Centered Outcomes Research Oversight Study (PCOROS)** seeks to identify and address any novel or prevalent ethical and regulatory challenges posed by Patient-Centered outcomes research (PCOR) as relevant to human subjects protection and oversight.

- Our edited volume, **TRANSPARENCY IN HEALTH AND HEALTH LAW IN THE UNITED STATES**, which was published in June and will be featured in a book launch at Harvard Law School in September 2019, explores the extent to which transparency, a currently very popular concept in health policy circles, will address serious health policy concerns such as drug prices or medical waste.

- Our edited volume, **DISABILITY, HEALTH, LAW, AND BIOETHICS** (forthcoming 2020) considers the impact that different philosophical framings of disability have on medical and legal policies.

- Our new **Global Health and Rights Project** 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.

- Our **Project on Law and Applied Neuroscience** is devoted to bringing together the professions of law and neuroscience so that each discipline can inform the other.

- The **Project on Advanced Care and Health Policy** seeks to implement policy change to improve decision-making and care at the end of life, issues of dramatic importance to patients and their families.
• The Innovative Funding Models in Translational Research is gathering the leaders in the medical and scientific research community to articulate the challenges around for-profit funding of early stage research. We anticipate that this work will lead to significant policy recommendations in the area.

• Finally, the Journal of Law and the Biosciences is an open-access online journal freely available to anyone with an interest in its contents, providing an important resource to both professional and lay communities.
Communications

The Center this year focused on refreshing and expanding its communication efforts and digital offerings. Spearheading this initiative was Communications Manager and Research Associate, Alex Pearlman, who joined the Center in May 2018. Pearlman drew on her communications and bioethics expertise to support the Center’s mission to promote interdisciplinary scholarship and to grow the reach of the Center’s work through strategic digital growth and public outreach.

A major cornerstone of our refreshed communications strategy was amplifying the reach of Petrie-Flom initiatives and scholarship by drawing the attention of the mainstream media to the Center’s scholarship and events. Most notably, the New York Times ran an editorial, “This Editorial is Not About Designer Babies,” that was inspired by the Center’s work and explicitly highlighted an initiative spearheaded by the Petrie-Flom Center to bring advance attention to an important bioethics event. Other prominent examples include:

- Don’t Expect Brett Kavanaugh To Protect The Affordable Care Act, by Carmel Shachar on WBUR’s Cognoscenti
- Smart pills can transmit data to your doctors, but what about privacy? by I. Glenn Cohen and Alex Pearlman in New Scientist
- CRISPRbabies: What’s the Future of Gene Editing? Featuring I. Glenn Cohen and Alex Pearlman on Al Jazeera’s The Stream
- The first genome edited babies are here: What happens next? by Alex Pearlman, on PRI’s The World
- As opioid crisis rages, cost of overdose antidote spikes, by Kate Gibson, featuring work by Stephen Wood from Bill of Health on CBS News
- U.S. researcher says he’s ready to start four pregnancies with ‘three-parent’ embryos, by Emily Mullin, featuring a Petrie-Flom event on STAT.
- Patient advocates and scientists launch push to lift ban on ‘three-parent IVF’, by Emily Mullin, featuring a Petrie-Flom event on STAT.

Another area of new focus was expanding the reach of Petrie-Flom within Harvard Law School and in the wider Harvard network by working alongside other communications professionals across the university. At Harvard Law School, Petrie-Flom staff have become a fixture at the monthly Colocation Editorial meetings. Executive Director Carmel Shachar advised several other HLS programs, including the Animal Law and Policy Program regarding their communications strategies. Within the broader Harvard University Community, the Center assisted in building a website as part of the “Roadmap Team” for the new Harvard Health Innovation Network. The network, funded by the Harvard Presidential Administrative Innovation Fund, is a collaboration between over a dozen organizations across Harvard focused on health care, health policy, and innovation who have come together with a mission to share resources, opportunities for funding, mentoring, networking, careers, and continued learning across Harvard’s stakeholders.
Website and Social Media

The Petrie-Flom Center’s website is a critical component of promoting our public-facing work, offering users easy access to a wide array of information about the Center’s events, research, affiliate scholarship, fellowships, and other activities, as well as more general information about news and opportunities in the Center’s major research areas at the intersection of health law and policy, biotechnology, and bioethics.

The website is maintained by Center staff, who update it daily with new opportunities, breaking news, scholarship by our affiliates, and other resources related to upcoming and past events. The website is a central hub for all information related to the Center’s work, that of our larger community, and the broader fields of health law policy and bioethics.

In the past year, we have seen tremendous results from efforts to increase engagement on social media and drive traffic to the site. Overall traffic has increased across all platforms and, crucially, we have continued to see a steady flow of requests by partners to be included in our resource listings (e.g., opportunities and partner events), as well as strong attendance at our own events.

In FY19, the Center’s website averaged roughly 6,000 unique visitors per month, with usage spiking during the academic year to nearly 7,500 visitors in some months. Visitors to the site came from over 170 countries. This shows a steady increase in year-over-year traffic.

We continue to use our web presence to share our events, in particular, with a much broader community. Our Vimeo account, where we host videos of panels and lectures from our events, saw more than 5,000 plays this year, while our slide-sharing site received an average of over 1,500 views per month. Both of these indicate steady engagement of our core audience and the strength of our programming.

Our social media properties continue to grow, helping us reach new audiences. Our Facebook following increased 18 percent this year, and our Twitter following has also grown steadily, with our monthly impressions reaching into the hundreds of thousands. We continue to be a leading source for health law news, opportunities, and community on social media.

Newsletter

Our popular biweekly email newsletter underwent a radical transformation this year, as we sought a new, mobile-friendly design to better highlight the Center’s events, affiliate news and scholarship, and opportunities at the Petrie-Flom Center, across Harvard, and elsewhere.
At the beginning of FY19, an analysis of our subscribers and their habits showed that, on average, over 35% of our newsletter’s more than 6,000 subscribers read the biweekly email on their phones. We also found that there were weeks when there was no engagement, or clicks, on our newsletter at all, despite there being a steady open rate (30%, in line with the high side of industry averages). This suggested it was time to give the newsletter, which had previously not been in a mobile-friendly template, a new look and feel and a device-agnostic layout, meaning it would rearrange the content to fit on any screen. Communications Manager Alex Pearlman did a stakeholder analysis as preparation for updating not only the design of the email, but also the order and arrangement of the content, so as to balance the needs and interests of Petrie-Flom leadership with a user experience that would engage our readership.

We launched the new newsletter design at the beginning of the Fall 2018 semester, and since then have seen an uptick in both subscribers and engagement in the past year. User engagement is now very steady. While our open rate has stayed the same, the engagement and clicks on our stories is now between 12% and 16% every week, which is high. Clearly when our audience is able to easily read the newsletter, which 30% of readers could not prior to the redesign due to a lack of mobile-friendly formatting, they engage with our content and click generously.

In addition to updating the newsletter’s design, we also cleaned up our subscribers list. We asked our email client, Constant Contact, to erase all addresses on our list that were marked as “Undeliverable,” which happens when an email is no longer active (for example, when someone leaves their job and had used their work email to subscribe). As a result of this process, we lost nearly 1,000 subscribers. But within three months, we gained over 1,200 new subscribers, many of which came from manual sign-ups at events and the new Sign Up form on the redesigned Bill of Health.
These significant increases in user numbers and engagement demonstrate the success of our efforts to innovate our digital media products. By better responding to the needs and habits of our affiliates, we have dramatically increased our audience and audience engagement with the Center’s content.

**Bill of Health**

Bill of Health, our blog on health law policy, biotechnology, and bioethics, edited by Communications Manager Alex Pearlman since May 2018, continues to be a resounding success.

The blog, launched in 2012, has proven to be a successful venue for hosting news, commentary, and scholarship in the fields of health law policy, biotechnology, and bioethics. Since its launch, over 150 bloggers, including leading health law scholars and bioethicists from more than 50 different institution and from across the globe have contributed to build this platform. The community remains heavily active, with new bloggers joining us regularly. We publish between five and eight posts per week, and have hosted a number of successful blog symposia in conjunction with our events programming. Our blog has also become a recognized outlet for other health law programs and centers, many of whom regularly ask us to host symposia on their events and research.
In October 2018, we moved Bill of Health from its original home on the Harvard blog network. The blog network is slated to be retired at the end of 2019, and this move also enabled us to take Bill of Health to the next level, as befits its enormous growth since its launch in 2012. The move to an external server and to the Petrie-Flom sub-domain was undertaken in tandem with a full graphic redesign and visual update to the site. The re-launch of Bill of Health also met a specific goal of increasing mobile engagement. The previous version of the site was not formatted in responsive template, and thus was essentially inaccessible on mobile devices. With its new design, Bill of Health is device-agnostic so it is accessible and loads properly on any device, regardless of screen size. Since the launch of the redesign in Fall 2019, 35% of our readers access Bill of Health on mobile phones and tablets, which reflects the demographics of our audience: over 60% of current audience is between ages 18 and 35. This indicates that we are successfully reaching the next generation of health law and bioethics scholars and policymakers.

In the year before the redesign and relaunch of the blog, our page views averaged roughly 12,000 per month. Since the relaunch, Bill of Health has averaged over 27,000 views per month – indicating that the redesign more than doubled the size of the audience. We consistently see Bill of Health content shared across social media, and engagement is also very high. Bill of Health readers still see an average of about two pages per visit – a sign that the move and redesign maintained the site’s stable readership habits in the health law community: readers come for one article, and more often than not, they find something else that interests them on the site.

The increased traffic on the site has also caught the attention of larger media outlets. And because of the readability of Bill of Health’s content, which is aimed at a lay audience, many outlets have repurposed blog posts for an even wider audience. In the past year, Bill of Health content has been featured on outlets such as CBS and WBUR in FY19.

The most popular articles we published this year spanned subjects across the health law and bioethics spectrum, and demonstrate how Bill of Health is a home for thought leaders throughout these newsmaking and important fields.

Some of our most popular articles published this year include:

- How Scott Gottlieb is Wrong on the Gene Edited Baby Debacle, I. Glenn Cohen (Faculty Director, Petrie-Flom Center)
- Where Calls for Overturning Bruesewitz v. Wyeth Go Wrong, (Dorit Reiss, University of California Hastings College of Law)
- Addressing the Opioid Epidemic Starts with How We Treat Pain, Stephen Wood (HMS)
• **The Problem With Doctors Communicating via Robot is Attitudes About Technology, Not Poorly Communicating Doctors**, Evan Selinger (Rochester Institute of Technology)

We have also encouraged participants in our on-campus events to engage more with our digital community as a way to promote their events as well as novel scholarship. A selection of blog posts tied to events follows:

• **What Should Happen to our Medical Records When We Die?**, Jon Cornwall (Otago Medical School, Otago University, New Zealand)
• **The Future of Health Care? How States are Trailblazing Medicaid Buy-In Programs**, Alex Pearlman interviewing Emma Sandoe (FAS ‘19)
• **Gene Editing and Intellectual Property: A Useful Mix?**, Jacob S. Sherkow (New York Law School)
• **Trauma at the Border: Can Neuroscience Inform Legal Advocacy?**, Francis X. Shen (Senior Fellow, Petrie-Flom Center; University of Minnesota)
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Collaborations

As described throughout this report, the Petrie-Flom Center actively seeks out collaborators both within and beyond Harvard in order to extend our influence and capitalize on the expertise of others. We cosponsor events, work with affiliated faculty, co-teach classes, and participate in joint projects wherever appropriate.

This year, our major collaborative efforts included:

- Our blog, Bill of Health
- Our sponsored research project primarily based at Harvard Medical School, Harvard Catalyst (with collaborators at various Harvard-affiliated medical centers and colleagues at Emory University)
- The Patient-Centered Outcomes Research Oversight Study (PCOROS), based out of Brigham and Women’s Hospital
- Our new sponsored research project on Precision Medicine, Artificial Intelligence, and the Law, in collaboration with colleagues at the University of Michigan School of Law, under the leadership of the Center for Advanced Studies in Biomedical Innovation Law at the University of Copenhagen
- Our project on Innovative Funding Models in Translational Research includes a steering committee of representatives from the Broad Institute, the Whitehead Institute, Partners Health care, the Dana-Farber Cancer Institute, and Johnson & Johnson Innovation.
- Our Project on Law and Applied Neuroscience with the Center for Law, Brain, and Behavior at Massachusetts General Hospital
- A major conference, co-organized as part of the Project on Law and Applied Neuroscience, sponsored by the Federal Judicial Center in Washington, D.C.
- Our Project on Advanced Care and Health Policy, with the Coalition to Transform Advanced Care (C-TAC)
- Work on the Journal of Law and the Biosciences with colleagues at Duke and Stanford
- Participation on the leadership team of the Scientific Citizenship Initiative at Harvard Medical School through the efforts of Executive Director Carmel Shachar
- Book projects based on our conferences, with authors from a variety of institutions
- A variety of projects with the Berkman-Klein Center for Internet and Society at Harvard University, including the continuation of our Digital Health @ Harvard series, the ongoing development of a proposal seeking funding for a joint project on legal and ethics issues around digital health, and new collaborative work with the Global Access in Action project
- A series of events co-organized with the Center for Health Law and Policy Innovation, as well as early discussions on the development of a funding proposal to support a joint project on the medicalization of the social determinants of health
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- A conference – our second in as many years – co-organized with the Edmond J. Safra Center for Ethics at Harvard University, with whom we will share a fellow and with whom we are in discussions about further collaborative efforts in the future.
- Collaboration with the Harvard Medical School’s Center for Bioethics on events, conferences, and their Master’s program in bioethics

We collaborated with the following groups to pursue programming or other joint effort in areas of mutual interest:

- The Berkman-Klein Center for Internet & Society at Harvard University
- The Broad Institute at MIT and Harvard
- The Center for Advanced Studies in Biomedical Innovation Law at the University of Copenhagen
- The Center for Law, Brain and Behavior at Massachusetts General Hospital
- Countway Library of Medicine
- The Coalition to Transform Advanced Care (C-TAC)
- Edmond J. Safra Center for Ethics at Harvard University
- Global Access in Action, a project of the Berkman-Klein Center
- Harvard Catalyst
- Harvard Health Publications at Harvard Medical School
- Harvard Law School Project on Disability
- The Hastings Center
- Health Affairs
- The Health Ethics and Policy Lab, University of Zurich
- HLS 1200
- HLS American Constitution Society
- HLS Animal Law and Policy Program
- HLS Center for Health Law and Policy Innovation
- HLS Food Law Lab
- HLS Harvard Health Law Society
- HLS Human Rights Program
- HLS Lambda
- HLS Library
- HMS Center for Bioethics
- The Massachusetts Bar Association
- Northeastern University School of Law Center for Health Policy and Law
- The Program On Regulation, Therapeutics, And Law (PORTAL) at the Division of Pharmacoepidemiology and Pharmacoeconomics at Brigham and Women’s Hospital
- Public Responsibility in Medicine & Research (PRIM&R)
- Ropes & Gray LLP
2018–19 Plans for Activities
(Fiscal Year 2019: July 2018–June 2019)

During the coming year, the Petrie-Flom Center will have three areas of focus: developing new projects and collaborations, launching our advisory board, and further innovating our digital content. Additionally, we plan to continue our ongoing sponsored research projects and other collaborations, host a compelling slate of public events and conferences, offer a range of opportunities for students and visitors, and contribute to the HLS teaching program.

Research, Scholarship, and Project Activities

Sponsored Research

As described above, our sponsored research projects will be changing during FY20, with some kicking into high gear while others will sunset:

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

Our Project on Precision Medicine, Artificial Intelligence, and the Law (PMAIL) with the University of Copenhagen’s Center for Advanced Studies in Biomedical Innovation Law (CeBIL) entered a new phase when our Research Fellow in Medicine, Artificial Intelligence, and Law, Sara Gerke, joined the Center in August 2018. We experienced an uptick in publications and events around artificial intelligence during this new phase of PMAIL, and anticipate continuing on this impressively productive schedule for the coming year.

In the upcoming year, PMAIL will continue to collaborate with various stakeholders (e.g., INSEAD Business School, AIMed, Stanford Medicine, 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, the University of Michigan, and the University of Cambridge (UK). We are currently working on two events scheduled to take place at Harvard Law School in Spring 2020: a conference on AI and disability, in collaboration with the Harvard Project on Disability, and a regulatory roundtable on AI in healthcare, drawing regulators from across the globe, including Denmark, Singapore, Japan, India, China, and the US. We are also working to develop a curriculum on ethics in the application of AI in health care, to be used by Harvard Medical School and other institutions. Lastly, we are working on several grant proposals to expand our work on artificial intelligence, including seeking funders for work on informed consent in the use of AI and work on ethical interactions between humans and AI programs in the health care context.
Harvard Catalyst

Our collaboration with Harvard Catalyst’s Regulatory Foundations, Ethics, and Law Program continues. Because the priorities of Catalyst are changing with the start of their next grant, we are currently in discussions with Catalyst leadership as to the future of our collaboration with them. We have submitted several proposals for future work to Catalyst leadership and remain active participants of the monthly Regulatory Foundations, Ethics, and Law meetings.

Project Activities

Global Health and Rights Project (GHRP)

Our collaboration with the Global Health Education and Learning Incubator (GHELI) at Harvard University will continue for a second year of the Global Health and Rights Project. Program activities will again include expert symposia and public events, as well as a seminar that Senior Fellow Alicia Ely Yamin will teach at HLS in Spring 2020: “Contested Domains: Comparative and International Legal Struggles over Sexual and Reproductive Health and Rights.”

2019–2020 Areas of Inquiry

In the coming year, Yamin will be focused on three principal strands of work: (1) the role of legal norms, ranging from constitutional rights to individual entitlements to regulation of private actors, in priority-setting for UHC; (2) critical analysis of global health governance institutions in relation to accountability for the SDGs; and (3) understanding ongoing legal mobilization and contestation regarding abortion and other SRHR, especially in Latin America and in supra-national forums.

GHRP plans to host two events at Harvard Law School in 2019–2020:

- October 4, 2019: Abortion Battles in Mexico and Beyond: The Role of Law and the Courts
- Spring 2020: A panel discussion of the burden of medical debt in a global health context. This event will explore the impact that private debt has on health. In the U.S., medical bills are still one of the primary drivers of bankruptcies. Globally, it is increasingly common practice for hospitals to detain patients for non-payment of health care bills. We will consider the chilling effect that debt can have on access to care and therefore health in both contexts.
The Project on Law and Applied Neuroscience

Our collaboration with Massachusetts General Hospital’s Center for Law, Brain and Behavior will continue for the seventh year of the Project on Law and Applied Neuroscience. Program activities will again include expert symposia and public events, as well as a Law and Neuroscience seminar taught by the Hon. Nancy Gertner.

The Project will also continue its work on dementia and the law. Specifically, the Project anticipates working closely with the Project on Advanced Care and Health Policy to help in the development of an Advanced Care Model (ACM) for patients with dementia. Together and in collaboration with Petrie-Flom leadership, the Projects have applied for grant funding from the Dean’s Initiative Award Program for Planning Activities for Future Innovation Grants in Healthy Aging at Harvard Medical School to: (1) create a roadmap for adapting ACM to patients with dementia, both those in programs focusing on memory care but also those within more general nursing and end of life facilities. This blueprint will be a guide for facilities and providers who serve dementia patients and are looking to implement ACM into their practices, although implementation itself at the pilot site stage will still involve tailoring the roadmap for the specific needs of each practice; (2) articulate the specific considerations and challenges for improving care for patients with dementia; and (3) identify the regulatory barriers that prevent the implementation of ACM and other similar models for improving care for this population. We will translate these regulatory barriers into recommendations for state policymakers looking to improve support for quality dementia care (see above, Sponsored Research, Additional Efforts).

If this grant application is unsuccessful, we anticipate seeking alternative funding for this project. Francis Shen, who will remain affiliated with CLBB as well as with the Petrie-Flom Center as a Senior Fellow in FY 20, and Petrie-Flom Executive Director Carmel Shachar, will work to develop the efforts described above and to further identify grant and funding opportunities for work on this topic. This work will include multiple CLBB faculty, including Judge Nancy Gertner, Judith Edersheim (both affiliated faculty of the Petrie-Flom Center), and Bruce Price.

2019–2020 Area of Inquiry: Neuroscience, Trauma, and the Law

Building on the successful event “Trauma at the Border,” which hosted an audience of nearly 100 during a snowstorm that closed area public schools on March 4, 2019, in FY20 the Project on Law and Applied Neuroscience will explore the role that neuroscience of trauma may play in the law.

With a steep rise in asylum claims, there is a shortage of affordable legal representation for those seeking to enter the United States. Even when an attorney is available, high caseloads and limited resources often mean that the requisite background research and client medical evaluations are not completed. Thus, there is an urgent need to provide attorneys and asylum seekers with new advocacy tools.
Utilizing the interdisciplinary expertise of the Petrie-Flom Center and its affiliates in trauma, fear, and memory, as well as the Harvard Law School Immigration and Refugee Clinical Program, the Project on Law and Applied Neuroscience will explore the development of neuroscience-informed advocacy tools for judges and attorneys. Neuroscience is poised to help in two primary ways. First, neuroscience can help to adjudicate credibility related to claims of “credible fear” and past trauma. Second, the neuroscience of memory can help to understand the impact of trauma on a client’s testimony, including their ability to recollect details and to tell a coherent narrative of their experiences, especially when that testimony may be perceived by the court as inconsistent.

**The Project on Advanced Care and Health Policy**

As noted above (see Sponsored Research, Additional Efforts), the Project on Advanced Care and Health Policy will focus on the development of an Advanced Care Model (ACM) for patients with dementia, although other activities will include an event and roundtable on the role of hope in palliative care. We are also in discussion with other supporters of this work, including former Fellow in Harvard University’s Advanced Leadership Initiative, Chairman of Newton-Wellesley Hospital’s Board of Trustees, and Partners Healthcare Innovation Advisory Board Member Earl “Duke” Collier regarding the application of value-based care to dementia and other conditions of aging. Lastly, we anticipate involving HLS students in a research opportunity to survey state policies around dementia and advanced care, including identifying regulatory barriers to optimal care.

**Mark Sterling, MPP, JD** will continue as the Senior Fellow on this Project.

People with advanced illness often face fragmented care, treatments they do not want or need, and an overly burdensome and costly health care experience. The Center for Medicare and Medicaid Innovation (CMMI) and others have tested several successful new models of advanced illness management and care. In April, CMMI announced a much-anticipated new payment model to support Americans living with advanced illness, which will operate under a new “Primary Cares Initiative.” The new model will include elements of the proposal our Project partner, the Coalition to Transform Advanced Care (C-TAC), submitted to the U.S. Department of Health and Human Services (HHS). Senior Fellow **Mark Sterling** served as a member of the planning committee for C-TAC’s proposal.

Preparing for the new serious illness payment environment, including related state and federal policy issues, remains an area of focus for the Project during the coming year. The Project aims to produce materials helpful to key stakeholders looking to improve the regulatory landscape around care for serious and advanced illness. HLS students will likely be engaged to assist with legal research. In addition, the Project is contemplating events on other topics related to advanced care. As before, these events are expected to lead to whitepapers and reports with recommendations for
policymakers and other stakeholders. The Project is also exploring potential funding opportunities for an Advanced Care Policy Fellowship.

**The Innovative Funding Models in Translational Research Project**

Translational research is vital, as targeted translational science can ensure that new treatments and research knowledge actually reach the patients or populations waiting for these breakthroughs. Nevertheless, in the age of frequent governmental budget crises and government spending cutbacks, relying on a government agency to promote such important developments may be problematic. An obvious solution to the funding gap that exists in current health care and biomedical research is the close investment and involvement of private, for-profit entities. The increased involvement of for-profit funding in early stage research is relatively new and therefore raises questions about the best practices for supporting research through these funding models. This event aims to explore the current funding landscape for translational research and develop a sense of whether best practices exist to address challenges or if additional research and work must be done to support innovative funding models for translational research.

The Project, led by Senior Fellow Douglas Eby and Executive Director Carmel Shachar, will focus on two initiatives. First, it will produce a report evaluating the extent to which utilizing non-governmental sources of funding for translational research, especially in the early stages, raises legal and ethical questions distinct from government-funded clinical and translational research. This report is intended to be a road map for ethicists and other scholars working in this area. Second, it will put together a 75th anniversary celebration of Vannevar Bush’s *Science, the Endless Frontier* report. This report laid the groundwork for the modern American scientific system, including the National Science Foundation and the National Institutes of Health. Susan Hockfield (President Emerita of MIT, the Koch Institute) has agreed to speak at this event and Eric Lander (the Broad Institute of MIT and Harvard, HLS) is tentatively committed as well. We anticipate that this will be a marquee event bringing together leading scientists, regulators, and industry players.

**Journal of Law and the Biosciences**

In January 2018, the Petrie-Flom Center took over the managing editorship of the journal. For FY19 and part of FY20, Visiting Researcher Jean-Christophe “J-C” Béisle Pipon will serve as Managing Editor. At the very end of FY19 we received JLB’s first impact factor score of 2.431. This is a very strong impact factor score, especially for such a new journal, placing JLB third out of medical ethics and medicine and legal journals with impact factor scores. More impressively, this places JLB as 14th out of 148 ranked law review and legal journals (including several HLS publications), and 6th out of 54 ethics journals. Supported by Petrie-Flom staff, we will launch a major marketing campaign in Summer 2019 to publicize our strong impact factor, in the hopes of attracting further strong submissions and building the reputation of the journal. We
are also working to develop a closer relationship between the journal and our blog, Bill of Health, to help promote the articles published in the journal.

Scholarship

Academic Fellows

For a variety of reasons, we have not accepted a new Academic Fellow to join the Center this year. Going forward, and discussed below, we are reconsidering our plans for the Academic Fellowship program and considering possible alternatives, including development of a policy or senior fellowship. Our goal is to reconfigure the Academic Fellowship program to broadly seed the fields of health law policy and bioethics, including placing future fellows at key non-profits and other thought leading institutions. We hope to relaunch the program when additional funding is secured in the near future.

Two postdoctoral fellows will continue their involvement with the Center in FY20:

**Sara Gerke**, August 2018–August 2021

Sara Gerke is the Research Fellow in Medicine, Artificial Intelligence, and Law under the Project on Precision Medicine, Artificial Intelligence, and the Law (PMAIL), where she oversees the day-to-day work of the Center’s component of this collaborative project. Sara’s work includes conducting law, policy, and ethics research; drafting reports and recommendations; and coordinating the Center’s efforts with collaborators at the Center for Advanced Studies in Biomedical Innovation Law (CeBIL) at the University of Copenhagen as well as other partners.

**Jacob S. Sherkow**, September 2019–May 2020

Jacob was accepted from among a stellar group of applicants in Spring 2019 as the first Edmond J. Safra Center for Ethics and Petrie-Flom Center joint fellow focused on legal implications of the Ethics of Technological and Biomedical Innovation. Jacob is currently a Professor of Law at the Innovation Center for Law and Technology at New York Law School, where he teaches a variety of courses related to intellectual property and the life sciences. His research focuses on how scientific developments, especially in the biosciences, affect patent law, regulation, and bioethics.
Faculty

In the summer of 2019, the Center will once again provide research support to Profs. Cohen and Elhauge.

**I. Glenn Cohen** will begin work on a new volume based on the Center’s 2019 annual conference, “Consuming Genetics: Ethical and Legal Considerations of New Technologies.” He also continues working on new versions of the law school’s online course “Zero-L: Introduction to American Law.”

Professor Cohen will be working on a number of other projects, including:

- A new book inspired by his Chair Talk “The Second Reproductive Revolution”
- Publications and other grant-related activities pertaining to the Petrie-Flom Center’s new project on Precision Medicine, Artificial Intelligence, and the Law (PMAIL)
- Work on a new casebook on Comparative Health Law and Bioethics
- Completion of the Center’s new edited volume on Disability, Health, Law, and Bioethics (forthcoming 2020)

**Einer Elhauge**, the Center’s founding faculty director, is continuing work on his book about the appropriate limits on re-engineering human biology, *A Little Lower Than God: Redesigning Humans – What Limits?* He also is finishing two new articles on horizontal shareholding, “The Causal Mechanisms of Horizontal Shareholding” and “How Horizontal Shareholding Harms Our Economy—And Why Antitrust Law Can Fix It.”

Visitors

The Center continues to receive a number of high-quality applications from potential Visiting Scholars, both international and domestic. The following have been accepted as Visiting Scholars in the 2018–2019 academic year. While additional Visitors may be added throughout the year, the following are confirmed:

- **Jean-Christophe Belisle Pipon**, who has been with the Center since September 2017, will continue his visit through August 2020.
- **Minerva Rivas Velarde**, Scientific Collaborator (FNS) at the Institute of Ethics, History, Humanities (IEH2) at the Geneva Faculty of Medicine for the Big Data-Ethics-Health-Framework (BEHALF) project at UNIGE and ETH Zurich, will visit the Center while researching ethical issues raised by the use and storage of residual dried blood samples collected without consent from state-mandated newborn screening in Switzerland commonly known as the Guthrie test. She will be resident at the Center in September and October 2019.
• **Miriam Bentwich**, Faculty of Medicine in the Galilee, Bar-Ilan University, will visit the Center while pursuing a research project entitled, “The ‘nudgability’ model for a more ethical healthcare provision and clinical research” from September 2019 to April 2020.

• **Mateo Aboy**, Senior Research Scholar at the LML (University of Cambridge, UK), an affiliated Professor & Fellow at the CeBIL (University of Copenhagen) and tenured Full Professor of Electrical Engineering and MSE Program Director in the EERE Department at the Oregon Institute of Technology (Oregon Tech), will visit the Center while pursuing research in the areas of innovation in biomedical engineering and intellectual property from September 2019 through July 2020.

• **Katie Hammond**, a recent BCL/LLB graduate of McGill University's Faculty of Law, will visit the Center to perform research on a book project entitled *What Money Can Buy: Tracing Transnational Egg Transactions*. She will be resident at the Center from September to November 2019.

• **Navraj Nagra**, a DPhil (PhD) candidate at the University of Oxford and Clinical Research Fellow, Royal College of Surgeons of England, will come to the Center on a Fulbright fellowship to pursue research in partnership with colleagues at HBS and BWH from October 2019 through April 2020.

• **Lucia Berro Pizarroassa**, a recent graduate of the Groningen Global Health Law Program, to work with Yamin in the Spring of 2020.

• **Anniek de Ruijter**, Associate Professor of European Law, Faculty of Law, University of Amsterdam, will pursue research on international and European risk and security regulation at the intersection of health and the environment during a term at the Center from January to June 2020.

**Book Projects**

We continue to pursue edited volumes out of a variety of Petrie-Flom Center events and collaborations:

• We have submitted the manuscript *Disability, Health, Law, and Bioethics* (co-edited by I. Glenn Cohen, Michael Ashley Stein, Anita Silvers, and Carmel Shachar), which stems from our 2018 annual conference. The book will be published by Cambridge University Press in 2020.

• We have received an offer from Cambridge University Press to publish an edited volume based on our 2019 annual conference, “Consuming Genetics: Ethical and Legal Considerations of New Technologies” to be co-edited by conference organizers I. Glenn Cohen, Nita Farahany, Hank Greely, and Carmel Shachar. We except that the book will be published in late 2020.
Events Programming and Conferences

Over the 2018–2019 academic year the Center will continue to host and co-sponsor a variety of exciting public events dealing with issues at the intersection of health law policy, biotechnology, and bioethics. We have a significant number of additional events currently under development, particularly under the banners of the Project on Law and Applied Neuroscience and the Project on Advanced Care and Health Policy, and potentially in collaboration with a leading health care law firm. The following events are confirmed to date:

Major Events/Conferences

**Abortion Battles in Mexico and Beyond: The Role of Law and the Courts**  
October 4, 2019  
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.

**15+ Years of PEPFAR: How US Action on HIV/AIDS Has Changed Global Health**  
October 7, 2019  
This event is 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.

**Eighth Annual Health Law Year in P/Review**  
December 6, 2019  
Sponsored by the Petrie-Flom Center in Health Law Policy, Biotechnology, and Bioethics at Harvard Law School, with support from the Center for Bioethics at Harvard Medical School and the Oswald DeN. Cammann Fund.

**2020 Petrie-Flom Annual Conference**  
**Innovation and Protection: The Future of Medical Device Innovation**  
May 8, 2020  
Sponsored by the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School, with support from the Oswald DeN. Cammann Fund at Harvard University. Co-sponsored by the University of Copenhagen’s Center for Advanced Studies in Biomedical Innovation Law (CeBIL) and the University of Arizona Health Law Program. This event is supported in part by a Novo Nordisk Foundation grant for a Collaborative Research Programme (grant agreement number NNF17SA027784).
We have also confirmed several additional conferences for the spring that are still in early planning stages:

- April 2020: A conference on hope in advanced care, part of the Center’s Project on Advanced Care and Health Policy.
- April 28, 2020: A roundtable for international regulators of AI technologies, cosponsored by the University of Copenhagen’s Center for Advanced Studies in Biomedical Innovation Law (CeBIL).
- May 2020: A symposium on the 75th anniversary of the US government’s landmark report Science: The Endless Frontier, featuring MIT President Emerita and Professor of Neuroscience Susan Hockfield and George Q. Daley, Dean of the Faculty of Medicine at HMS. The event will be hosted as part of the Center’s Innovative Funding Models in Translational Research Project.

**Lectures and Panels**

**Book Talk: Birth Rights and Wrongs: How Medicine and Technology Are Remaking American Reproduction and Law, with author Dov Fox**
September 10, 2019
Sponsored by the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics.

**2019 Petrie-Flom Center Open House**
September 10, 2019
Sponsored by the Petrie-Flom Center in Health Law Policy, Biotechnology, and Bioethics at Harvard Law School, with support from the Center for Bioethics at Harvard Medical School and the Oswald DeN. Cammann Fund.

**Book Launch: Transparency in Health and Health Care in the United States**
September 16, 2019

**Health Care General Counsel Roundtable**
November 8, 2019
Sponsored by the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics.

**Health Policy and Bioethics Consortium**
February 2020
Organized by the Program On Regulation, Therapeutics, And Law (PORTAL) in the Division of Pharmacoepidemiology and Pharmacoeconomics at Brigham and Women’s Hospital and hosted by the Center for Bioethics at Harvard Medical School, in collaboration with the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School and the Harvard Program in Therapeutic Science.
**February 2020**  
*Sponsored by the Harvard Law School Library and the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School.*

**Book Talk: Exposed: Why Our Health Insurance is Incomplete and What Can Be Done about It**, with author Christopher Robertson  
**February 21, 2020**  
*Sponsored by the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School.*

**Book Launch: Disability, Health, Law, and Bioethics**  
**April 14, 2020**  
*Sponsored by the Harvard Law School Library and the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School.*

**Health Care General Counsel Roundtable**  
**May 4, 2020**  
*Sponsored by the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics.*

We have also confirmed several additional panels that are still in early planning stages:

- **Spring 2020:** A panel discussion, hosted as part of the [Global Health and Rights Project](#), that will explore the burden of medical debt in a global health context. This event will explore the impact that private debt has on health. In the U.S., medical bills are still one of the primary drivers of bankruptcies. Globally, it is increasingly common practice for hospitals to detain patients for non-payment of health care bills. We will consider the chilling effect that debt can have on access to care and therefore health in both contexts.

- The [Project on Law and Applied Neuroscience](#) plans to hold three panel discussions – one in late fall and two in the spring.

**Event Series**

**Health Policy and Bioethics Consortia**  
**Monthly, September 2019–April 2020**  
Harvard Medical School  
*Organized by the Program On Regulation, Therapeutics, And Law (PORTAL) in the Division of Pharmacoepidemiology and Pharmacoeconomics at Brigham and Women’s Hospital and hosted by the Center for Bioethics at Harvard Medical School, in collaboration with the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School and the Harvard Program in Therapeutic Science.*
Digital Health @ Harvard Series
Dates TBD
Sponsored by the Berkman Klein Center for Internet & Society at Harvard University and the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School.
Contributions to HLS Teaching Program

Petrie-Flom affiliates will continue to make substantial contributions to the HLS health law curriculum this year, through workshops and seminars, as well as I. Glenn Cohen’s award-nominated Massive Open Online Course (MOOC), first launched in fall 2016, available to the public via HarvardX. Notably, Senior Fellow Alicia Ely Yamin will be leading a reading group, currently in development, at HMS and HSPH on “Gene Editing: Human Rights, Social Justice and Health Equity Issues,” which is based in part on the Petrie-Flom Center’s 2019 annual conference “Consuming Genetics: Ethical and Legal Considerations of New Technologies.”

Our affiliates will also lecture on an ad hoc basis around the university, primarily through partnerships and collaborations developed as part of our many ongoing research projects. I. Glenn Cohen also delivers an annual lecture for the Health Policy PhD program in FAS.

Health Law, Policy, Bioethics, and Biotechnology Workshop

I. Glenn Cohen
Fall 2019

This seminar will feature the presentation and discussion of cutting edge scholarship on health law, health policy, biotechnology, and bioethics. Because the papers are different every term, students can take the class as many times as they wish. Presenters will come from a wide range of disciplines and departments, and papers may feature doctrinal, economics, philosophical, political science, or other methods, but students need not have prior training in these disciplines.

The 2019–2020 workshop will host the following scholars:

- **Nicholas Bagley**, Professor of Law, University of Michigan Law School
- **Jacob T. Elberg**, Associate Professor of Law, Seton Hall Law School
- **Holly Fernandez Lynch**, John Russell Dickson, MD Presidential Assistant Professor of Medical Ethics and Health Policy, Assistant Faculty Director of Online Education, and Senior Fellow, Leonard Davis Institute of Health Economics, University of Pennsylvania Perelman School of Law
- **Dov Fox**, Herzog Endowed Scholar, Professor of Law, and Director, Center for Health Law Policy & Bioethics, University of San Diego School of Law
- **Lewis A. Grossman**, Professor of Law, American University Washington School of Law
- **Insoo Hyun**, Professor, Department of Bioethics, School of Medicine and Director, Undergraduate Bioethics Program Department of Bioethics, School of Medicine, Case Western Reserve University; Faculty Member, Center for Bioethics, Harvard Medical School
- **Alex John London**, Clara L. West Professor of Ethics and Philosophy, Carnegie Mellon University
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- **Davna Bowen Matthew**, William L. Matheson and Robert M. Morgenthau Distinguished Professor of Law, F. Palmer Weber Research Professor of Civil Liberties and Human Rights, and Professor of Public Health Sciences, University of Virginia School of Law
- **Michelle Mello**, Professor of Law, Stanford Law School and Professor of Health Research and Policy, Stanford School of Medicine
- **Kimani Paul-Emile**, Professor of Law, Fordham Law School
- **Jacob S. Sherkow**, Edmond J. Safra Center and Petrie-Flom Center Fellow in Ethics of Technological and Biomedical Innovation and Professor of Law, Innovation Center for Law and Technology, New York Law School
- **Michael Ashley Stein**, Visiting Assistant Professor of Law, Harvard Law School and Executive Director, Harvard Project on Disability

**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. Drawing on examples from constitutional and high courts in Latin America and Africa, as well as cases in various regional and international supra-national human rights forums, the course will explore: the historical origins of asserting international legal claims to SRHR; challenges and benefits of turning toward domestic courts and international forums to advance sexual and reproductive health; evolving narratives of women’s agency and state obligations; and power dynamics/conflicts within global SRHR advocacy. We will discuss the limitations of the autonomy narrative and adoption of “reproductive justice” paradigm in the US, and compare that with evolutions of SRHR in other national contexts, as well as in international law. Some of the topics to be covered include: gender-based violence; involuntary sterilization; abortion; access to care (obstetric care/LGBTQ access to care); disrespect and abuse/obstetric violence;
SRHR of persons with disabilities; assisted reproductive technologies; and SRHR in an era of conservative populism and backlash against so-called “gender ideology.”

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.” On the one hand, the marginalization of claimants suggests a place for counter-majoritarian rights protection. Similarly, advocates have sought to set standards in international human rights forums, as these spaces have been perceived as less “tainted” by the political power structures that inflect domestic law and institutions. On the other hand, the morally contested nature of SRHR norms often complicates the claims of courts and supra-national forums to special competence, limits their ability to catalyze the politics of implementation (including within health systems), and inspires backlash. This course will explore 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.

**Law and Neuroscience**

*Nancy Gertner*

*Spring 2020*

This seminar examines cutting edge and even controversial linkages between law and neuroscience. The course seeks to highlight the neuroscientific basis for behavior patterns with legal implications including how neuroscience intersects with criminal law, its normative assumptions and criminal punishment, evidentiary rules, memory bias and enhancement, lie and deception detection, adolescent brains and juvenile law. The course will look critically at efforts to use neuroimaging in court in connection with in the prediction of criminality and predispositions towards mental illness and addiction, as well as efforts to identify neurobiological influences on the brain. Is there such a thing as a criminally violent brain? Does it make sense to speak of the neurobiology of violence or the psychopathology of crime, and how are (or should) such concepts translated into criminal law. The seminar will necessarily lead to a consideration of the relationship between law and science, more generally, and neuroscience in particular. Speakers will provide insights into their work and research.

**Redesigning Humans: What Limits?**

*Einer Elhauge*

*Spring 2020*

Modern technology is increasingly making it possible to enhance human biology through medical, genetic, and biomechanical means. What regulatory limits should be imposed on such efforts? This seminar covered a range of literature on that topic.
Bioethics: The Law, Medicine, and Ethics of Reproductive Technologies and Genetics
I. Glenn Cohen (HarvardX)
Most recent session launched on July 16, 2019. Slated to relaunch a new session in late fall (exact date TBD).

Bioethics provides an overview of the legal, medical, and ethical questions around reproduction and human genetics and how to apply legal reasoning to these questions. This course includes interviews with individuals who have used surrogacy and sperm donation, with medical professionals who are experts in current reproductive technologies like In Vitro Fertilization and Preimplantation Genetic Diagnosis, and bioethicists and journalists who study the ownership and use of genetic information within human tissue. Additional Harvard colleagues will also share their thoughts on topics such as disability law as it relates to reproductive technology.

While the law and ethics surrounding these technologies are a central component to this course, it will also provide examples of the deeply personal and human side of these issues. Throughout the course, students will discuss leading legal cases in this field, which will illuminate the types of questions the law has struggled with – stretching and evolving over time. From the famous Baby M surrogacy case, to cases on the paternity of sperm donors, to a case related to the ownership of human tissue turned into a commercial product, and others. The course will explore the ethical, legal, and rhetorical underpinnings that have served as the basis for various court decisions over the past 20-30 years. It will also explore potential future technologies and their implications for society: genetic enhancements to increase our intelligence, let us live a hundred years longer, or make us immune to diseases – and the possibility of creating animal-human hybrids, for example a mouse with a humanized brain.

The content within this course is intended to be instructive, and show how legal reasoning has been applied, or could be applied, to questions related to parenthood, reproduction, and other issues surrounding human genetic material. The material organized within this course should be considered an authoritative overview, but is not intended to serve as medical or legal advice.

This course is designed for a diverse audience including, but not limited to, law students, prospective law students, medical professionals, as well as members of the general public interested in questions and topics related to surrogacy, parenthood, genetic and reproductive technology, ownership of genetic material, and more.
Participation of HLS Students in Program Activities

Student involvement is an important priority of the Petrie-Flom Center. We will continue to engage students in a variety of ways, through our event programming, courses, and other mechanisms. We will also continue to offer opportunities for selected students to work directly with the Petrie-Flom Center as Student Fellows, research assistants, and bloggers.

Student Fellowship Program

As we do each Fall, we will welcome a new crop of Harvard graduate Student Fellows this year who will pursue independent research under the supervision of Center faculty and fellows, regularly contribute to our blog, and enroll in the Health Law Policy, Bioethics, and Biotechnology Workshop. For the upcoming year we allowed Harvard Law School students to apply before other Harvard graduate students. As a result, we already have three Harvard Law Students selected as Fellows for FY20, with several more interested in applying during the general round of applications. The remaining Student Fellows will be selected in mid-August.

Every year we require our Student Fellows to contribute to our blog, Bill of Health. In the FY19 we significantly strengthened our digital media training for the Student Fellows. New Communications Associate Kaitlyn Dowling, who joined the Center in July 2019, will continue this in the coming year, supporting the Center’s Student Fellows with more digital training, drawing upon her background and expertise in digital media strategy. This additional training will continue in response to overwhelming positive feedback from AY2018–2019 Student Fellows, as well as in acknowledgement of the fact that social media and non-traditional internet media outlets are becoming increasingly important in building a thought leader’s reputation. We will also continue to support other HLS centers upon request, such as the Center for Health Law and Policy Innovation and the Berkman Klein Center for Internet and Society.

Research Assistants

We will continue to work with graduate student research assistants on our sponsored research projects, book projects, and other initiatives as needed. The Center is committed to placing student research assistants on all of our projects to better serve the HLS student population.

Student Bloggers

Bill of Health is home to a number of graduate student bloggers. In addition to our Student Fellows, who each year are required to blog regularly throughout their fellowship, we will continue to host graduate students at HLS and around Harvard, as well as graduate students nominated by senior scholars at other institutions, to be Student Contributors on the blog.
Like our Student Fellows, our student bloggers will continue to benefit from the support and expertise of our new communications staff person who provides increased social media and digital expertise through mentorship and editing help.

**Student Interns**

We plan to continue to work with a small number of paid interns, primarily Harvard students, who will contribute to a variety of Center projects (see Student Interns section above for details).
New Initiatives and Collaborations

The Petrie-Flom Center anticipates that Fiscal Year 2020 will build upon the successes of FY19 to expand our research portfolio, Center structure, and communications strategy. Our Project on Precision Medicine, Artificial Intelligence, and the Law (PMAIL) was fully launched in FY19 and was a runaway success, generating top-notch scholarship, invitations for further collaborations within and outside of Harvard, and reinforcing the Center’s position as a leading program on the regulation and ethics of biotechnology. We look forward to continuing to expand our expertise in this area, while also expanding our portfolio in health policy issues, such as value-based health care and challenges in aging. In order to expand our portfolio we work to further develop relationships with appropriate funders, think smartly about how to leverage existing collaborations and relationships, and use existing resources. We are also looking forward to further expanding the Center’s structure. FY19 saw the successful launch of our Health Care General Counsels Roundtable, which brings leading practitioners in the health care industry to campus twice a year. We hope to build upon the lessons learned growing and hosting this group to launch our Advisory Board. This Advisory Board will broaden the support base and network of the Center, in addition to providing valuable feedback to Center leadership about opportunities and priorities. Lastly, FY19 also saw a successful re-envisioning of our social media, communications and marketing strategies by bringing on a dedicated communications professional. Our hope is to continue to build upon our communications relaunch to broaden our public-facing offerings and continue to raise the profile of the Center outside of Harvard.

Expanding our Signature Projects

The Petrie-Flom Center is at the forefront of some exciting developments in biotechnology and health policy. The Petrie-Flom Center is uniquely positioned, as a longstanding collaborator of many leading scientists and medical providers, to identify important trends in health law policy, biotechnology, and bioethics. As such, our goal is for the Center to establish several new projects that will be funded, staffed, organized, and interacting substantively with policymakers at all levels, providing independent expert analysis, policy recommendations, empirical research, and practical solutions to pressing issues. If funded, these projects would pair an expert staff with faculty, students, and other collaborators at Harvard and beyond to generate policy briefs, white papers, model legislation, public commentary, and real-time responses to emerging issues and opportunities. In so doing, we will continue our central commitment to unbiased, non-partisan, expert analysis.

Artificial Intelligence and Health Care

As discussed above, the Center spent FY19 establishing itself as a leader on the important topic of artificial intelligence in health care through our Project on Precision Medicine, Artificial Intelligence, and the Law (PMAIL). We are planning to build upon the success of PMAIL in several respects. First, we are exploring collaborations with other thought leaders, such as programs at the Massachusetts Institute of Technology and Stanford.
University. In our potential collaboration with MIT, we will likely bring regulators from across the globe, including countries such as Japan, Singapore, India, the Emirates, Denmark, the United Kingdom, Canada, and the United States, to HLS to discuss the challenges of regulating artificial intelligence in health care. Our collaboration with Stanford, which will also include the Harvard Law School Project on Disability, will focus on encouraging the ethical application of health care artificial intelligence to the challenges faced by people with disabilities. Our hope is to locate funding to provide seed grants to developers, patient advocates, and other practitioners to further research and innovation in this field.

We are also pursuing funding to expand our artificial intelligence work, including developing a major initiative on promoting the ethical artificial intelligence and human collaboration. Our hope is to better understand how to train humans, particularly medical providers and patients, to ethically use, oversee, and interact with artificial intelligence programs, as well as to create best practices for shaping artificial intelligence in health care to be an “ethical actor.” While our informed consent and artificial intelligence grant application was unsuccessful, we are also considering whether other funders might be interested in this work. Lastly, we are exploring collaborations with Harvard Medical School researchers and practitioners, including the Brigham and Women’s Innovation Hub, to tie our research to real world challenges in implementing artificial intelligence in health care.

Aging Population and Health Care Delivery

The American population is aging, which presents significant challenges in health care delivery. Aging patients require more complex medical care management, consume more medical resources, and often present challenges in terms of competency and capacity to be active partners in their medical care. Mindful of the challenges that the American health care system will face as the baby boomer generation continues to age, the Petrie-Flom Center is developing a slate of projects to address these challenges. This priority comes at a time when there is an increased awareness of the challenges of aging across Harvard University, including the Harvard Initiative on Aging (HIA), spearheaded by HMS Dean George Daley. The Center hopes to build upon this interest to further strengthen our collaborations with other Harvard schools, such as HMS, HBS, and HSPH.

Our interest in aging is expressed in a variety of potential projects. Furthest along is our grant application on dementia and advanced care (see above, Sponsored Research), which would also knit together our longstanding Projects on Law and Neuroscience and Advanced Care. Unfortunately our initial grant application was unsuccessful, so we are considering other avenues of funding. Our Project on Advanced Care is also considering other aging work, including a research opportunity for HLS students to consider the regulatory challenges to providing coordinated care to older patients. In FY20 we will submit a grant application to the Administration for Community Living (ACL), with several high-profile disability rights partners, centered around the challenges facing aging patients with intellectual disabilities. This project would consider how to update best
practices for medical providers, such as gerontologists and institutional review boards, investigate organ transplantation protocols, and end of life decision-making. We will be the lead partners in investigating the approach that institutional review boards take to including subjects with intellectual and developmental disabilities in research protocols. This work will also contribute to our collaboration with Harvard Catalyst.

Other Research Areas

We continue to consider how best to pursue our interests in digital health, the opioid epidemic, and in value-based health care. These projects, and the ones discussed above, are in the exploratory phase and we are actively seeking funding to expand our capacity to undertake these projects and other, similar ones in the health law policy and bioethics space.

Expanding Our Structure

As the Petrie-Flom Center enters its newest chapter, we are also considering how to modify our structures to maximize the reach and impact of the Center. Drawing upon the lessons learned from launching the Health Care General Counsel Roundtable, we anticipate launching an Advisory Board to help shepherd the Center in FY20. Our hope will be that this Board will grow to provide significant guidance, networking, and financial support for the Center’s work. As always, we remain interested in reinvigorating one of the Center’s signature programs, the Academic Fellowship, pending interest and support.

Advisory Board

The Petrie-Flom Center’s leadership spent FY19 considering the challenges and opportunities in launching an Advisory Board. We appreciate the guidance of the HLS Dean and the Dean of Administration in considering the most appropriate way to establish an advisory board. Center leadership also spent some time in FY19 cultivating relationships with leading industry stakeholders and health law practitioners to develop future Advisory Board members. The Center was also mindful to pursue events that had appeal to audiences that might include potential Advisory Board members, although we did not compromise on our commitment to cutting edge scholarship and debate to achieve that goal. Now that we are confident that the Advisory Board would be a positive development for the Center, we are hoping to launch this Board with its first meeting in Spring 2020.

The purpose of this Board will be to secure the financial future of the Center and 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. Our goal for the Advisory Board will be to create a group that will provide input to the Center’s leadership as we decide our next steps and to increase the financial and intellectual resources and network of the Center. For example, in FY19 one of our potential members worked to bring FDA and HHS leadership to our events and encouraged us to host high profile events in
Washington D.C. to influence policymakers, although we did not ultimately host such an event due to resource limitations. Our hope is to begin to recruit appropriate potential members in Summer 2019, continue to build the Board through Fall 2019, and host our first meeting in Spring 2020.

**Academic Fellowship**

We are also interested in reinvigorating the Academic Fellowship program to include fellows who are interested in a career trajectory outside of academia. As discussed above, the Academic Fellowship is currently on hiatus for a variety of reasons. Increasingly, non-profit advocacy organizations are providing thought leadership on health law policy issues, including health care reform. Our goal for the remodeled fellowship would be to provide career development for individuals early to mid-career in health law policy, including people with a background in government and advocacy work. The Academic and Policy Fellowship would allow these individuals to leverage the incredible health law policy resources of Harvard to contribute and advance key health policy debates while providing the Center with additional capacity to take on health law policy projects. This fellowship program would also build the relationship of the Center with health law and policy organizations outside of academia. Revitalization of this program is dependent on securing additional funding, however.

**Expanding Communications and Digital Offerings**

FY19 marked the first year that the Petrie-Flom Center had a dedicated communications staff member. Our first person to serve in this role, Alex Pearlman, left the Center in May 2019 to pursue other opportunities. Our new communication associates, Kaitlyn Dowling, joined us in July 2019. Kaitlyn was previously the Senior Editor on the Disinformation Research Project, housed in the Shorenstein Center on Media, Politics, and Public Policy at the Harvard Kennedy School. She brings experience in journalism studies, marketing, and digital media to our Center. Our goals are to continue to be a leading forum for innovative ideas in the field while also expanding and diversifying our contributor base, improving our conversion of first-time readers into returning users, increasing engagement with our newsletters and social media presence, and serving as a conduit between mainstream outlets and scholars.

Building on the enormous success of the redesign and relaunch of the Bill of Health blog in FY19, in the coming year we will focus on expanding our blogging community through outreach to practitioners in fields related to health law, biotechnology, and bioethics. A truly interdisciplinary platform where all sides of health law policy and bioethical issues are considered and discussed. Some of the goals for our blog include expanding the audience beyond scholars and researchers to regulators, policymakers, and practitioners to further expand the Center’s influence. We also aim to become a popular option for hosting online symposia related to health law policy and bioethics events, both within Harvard and outside of the University. We spent FY19 investigating the challenges of launching a podcast to
support some of the Center’s work and are continuing to consider the right opportunities to do so. One of our upcoming grant applications, focusing on the AI/human collaboration, including a proposal to produce a series of podcasts on the impact of AI in health care for non-academics.

We will also focus on creating strategic publishing partnerships with mainstream outlets in order to reach audiences beyond the health law policy space and outside of the academy. An early example of these efforts was the *New York Times* editorial inspired by and covering our work on American mitochondrial replacement therapy policy. Our aim will be to place Center leadership, staff, events, and work in outlets such as the *New York Times*, *the Boston Globe*, *Stat*, *Kaiser Health News*. We believe this will help us cement our reputation as a leading health policy and bioethics program and help us locate further resources for our work.