STANFORD BYERS CENTER FOR BIO DESIGN POLICY PROGRAM

2023 ANNUAL REPORT
A Message from
Josh Makower & Kavita Patel

The Stanford Biodesign Policy Program is fully operational and we could not be more pleased to give you an update on our activities in the last year. Our ultimate objective at the Stanford Byers Center for Biodesign is to advance health outcomes and health equity through innovation education, translation and our latest endeavor: policy. We created the Policy Program to build a bridge between innovators and policymakers, because we recognized the complexities of the landscape innovators confront in their quest to bring life-changing inventions to patient care. The program hinges on three pillars — education, research, and engagement — and across all three, we had a very successful year.

Our first cohort of Policy Fellows arrived on campus in August to commence the first phase of their two-year experience. Through the stellar guidance of our teaching team, they are fully immersed in understanding the interconnectedness of innovation and policy and are undertaking individual research projects that explore timely policy issues within the health technology landscape.

We continued to publish influential research on critical health policy issues such as the time required to achieve Medicare coverage for novel technologies, and are seeing the results in real time in DC. In a demonstration of the power of such data-backed studies, Josh was invited to testify before the Health Subcommittee of the House Committee on Ways and Means in May 2023 on policies that inhibit innovation and patient access. Additionally, our team has continued to be a resource on both sides of the aisle and with multiple government agencies as they evaluate ideas for advancing innovation in health in the United States. This is clear validation that our research is making an impact and we’ve successfully elevated the needs of the health technology innovation ecosystem into the discussions on Capitol Hill and leading government agencies.

We also have capitalized on our unique purview to drive conversations among stakeholders from different sectors of the health ecosystem by organizing multiple well-attended webinars on the vital topics we research, as well as other relevant issues of importance to innovators, patients, and policymakers. This webinar content continues to be viewed many times after the fact, further broadening our influence.
Looking Forward

We are committed to having a meaningful impact on innovation-related health policies through this burgeoning program. On May 8, 2024, we will be hosting our inaugural Health Technology Innovation Policy Conference in Washington DC. This convening will bring together healthcare innovators and entrepreneurs, policymakers, researchers, funders, patient advocates, and other thought leaders to conceive and deliberate solutions to challenges and opportunities at the intersection of health technology and policy. Registration to attend this event in person or online can be found here: https://bit.ly/SBD-HTIPConference. In the fall, our first class of fellows will proceed to the second year of their training in applied policy positions while we welcome the new cohort — the 2024-26 fellows — to campus. Our research efforts also are ongoing and we look forward to sharing new insights this year.

Kavita has been instrumental in working with us to help forge this program. She will transition out of the director role at the end of the 2023-24 academic year however, to enable the appointment of a new director who can be more physically present on campus. A search for a new director has already begun and we welcome any suggestions or recommendations you may have. Our excitement and optimism about the future of this endeavor is unchanged and Kavita remains core to the execution of our plans for the rest of the academic year. I want to take this opportunity to thank her for her exceptional work that’s helped to put the program “on the map.”

Thank You

Perhaps most importantly, we must thank you all for your help. We could not do this work without you, our donors and supporters. Your confidence in our vision has facilitated our accomplishments thus far. We hope we can continue to earn your trust and support as we work to enable current and future policymakers to better understand how health policies impact innovation.

Josh Makower, MD
Director and Co-Founder,
Stanford Byers Center for Biodesign
The Yock Family Professor of Medicine and Bioengineering,
Stanford University

Kavita Patel, MD
Director, Policy Program,
Stanford Byers Center for Biodesign
Professor of Medicine,
Stanford University School of Medicine
The two-year Policy Fellowship is a cornerstone of the Policy Program. It aims to develop future health policy leaders with a deep understanding of how health technologies can be leveraged to improve patient outcomes, expand access to care, and reduce healthcare costs. From the start of the year, the program team laid the groundwork for the fellowship, working with our seven appointed domain directors to build a comprehensive curriculum to give the fellows a deep and substantive understanding of the complexities of health policy.

The 2023-25 cohort is made up of four accomplished fellows. Together with their counterparts in the Innovation Fellowship, they began their learning on August 1 with a one-month bootcamp that grounded them in the biodesign innovation process, laying the foundation for what would follow. Throughout the fall, they participated in lectures and interactive sessions with the domain directors, many featuring other guest speakers who helped provide additional real-world context for the discussions at hand.

Policy Fellow Profiles

Rebekah Dailey, DNP
Rebekah is a patient safety manager, who coaches and empowers teams to achieve zero-harm through continuous improvement. A former nurse manager in vascular surgery, she helped introduce innovative vascular treatments to the Northern Virginia market and has also lobbied for mental health legislation on the Hill. Rebekah is a community ambassador for the AARP and a former board member of the National Board of Certification for Medical Interpreters.

Rory Thompson, MD, MPH, MSc
Rory is an internal medicine physician with a background in health policy and a passion for improving population health through value-based healthcare transformation. Before medical school, he developed a bottom-up view of healthcare with experiences ranging from delivering basic patient care as a nurse’s aid, to analyzing pharmaceutical trial data for a clinical research organization, to implementing national healthcare reforms for the Brookings Institution.

Erika Modina, Msc
Erika is the president of Epimetrics Inc., a Philippines-based entity focused on achieving health equity through research. She also is the co-founder of Fort Health Data Systems where she designed a digital health tool that reduced their clients’ COVID-19 testing-related costs by 87%. Her studies have been integral to increasing access to medicines, institutionalizing health promotion strategies, and developing key legislations, such as the Philippines’ Universal Health Care Law.

Leana Silverberg, MS, MPH, MBA
Leana co-founded EMet Nanotech, a nanoimaging drug discovery tools company, and served as CEO. She has consulted for over 50 startup teams, co-developed a new SARs-CoV-2 screening technique, worked on tech transfer for a Nobel Laureate, and created and implemented strategies for pharmaceutical companies.
Educação

Rohini Kosoglu, former deputy assistant to President Biden and domestic policy advisor to Vice President Kamala Harris, and Jay Khosla, former chief economic counsel for Senate Majority Leader Mitch McConnell, taught sessions on the art of policymaking. They crafted exercises that challenged the fellows to develop policy briefs on decisions making headlines in the present-day.

Nancy Issac, regulatory counsel and VP of quality at Moximed, Inc., lectured on the step-by-step phases in device and therapeutic product development, the realities of navigating the regulatory environment, pre-clinical and clinical proof of principles, and how and when to seek guidance from the FDA.

Eb Bright, a patent attorney and the president and general counsel of medical device incubator ExploraMed, gave the fellows a primer on intellectual property - the fundamentals of IP, the history of US innovation policy and the connection to national security, and the impact of IP policies on investment, technology development, and economic development.

Stella Safo, an HIV primary care physician and founder of healthcare improvement company Just Equity for Health, delivered sessions introducing the principles of health equity, why it matters, considerations in different contexts, and equitable care model design.

Jan Pietzsch, CEO of technology consulting firm Wing Tech Inc., who has also taught the Stanford Biodesign course Technology Assessment and Regulation of Medical Devices since 2005, introduced the fellows to reimbursement data tools and also took them through a case study on evaluating the cost-effectiveness of new inventions.

Piper Su, an expert on market strategy and on policy issues related to healthcare payment and delivery, gave the fellows an introduction to Medicare and Medicaid, the current state of play in payments, and a view of what may come in the future.

“Lectures with the Domain Directors

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“The fellows are AMAZING and had the best questions ever. It was so fun to see them synthesize the information in real-time and ask important questions about regulatory policy in the US and globally. These people are going to change the world.”

- Carrie Kuehn, Clinical and Regulatory Affairs Professional

Guest lecturer on real world data and real world evidence
In our 2022 publication, “The Need for Accelerated Medicare Coverage of Innovative Technologies: Impact on Patient Access and the Innovation Ecosystem,” we reported that innovators and investors estimate that it takes 4.7 years (±2.8 years) to establish nationwide Medicare coverage for breakthrough technologies. In 2023, in JAMA Health Forum, we published “Time From Authorization by the US Food and Drug Administration to Medicare Coverage for Novel Technologies.” This time, we assessed 64 novel technologies that had been authorized by the FDA between January 1, 2016 and December 31, 2019, that were seeking new coverage or codes.
Policy research director Sandra Waugh Ruggles’ diligent stewardship of the research and writing process had a tremendous impact on the quality of both papers. Following the publication of the 2023 analysis, we organized a webinar in August, which featured a presentation of the research findings by Ruggles and another senior author Kevin Schulman, a professor of medicine and senior advisor to the program. Kavita Patel then moderated a discussion on the implications of the findings with Josh Makower and industry professionals Leslie Trigg, CEO of Outset Medical, and Parashar Patel, vice president at McDermott+Consulting.

With the explosion of interest in artificial intelligence in 2023, we also published a viewpoint article in JAMA Network, “AI Alone Will Not Reduce the Administrative Burden of Health Care,” where we discussed some of the complexities of the US healthcare system which must be better understood before automation can be applied efficiently.

Each Policy Fellow is also undertaking a research project with the guidance of Sandra Waugh Ruggles and a second senior author and research mentor. Their areas of focus are medicare coverage for emerging technologies; evidence supporting US FDA drug approvals; data interoperability; and artificial intelligence in healthcare innovation. By the end of their first year, they each will have produced an asset that will be useful for briefing policymakers and driving impact.
In various forums throughout the year, we had opportunities to engage with current and former officials from multiple government agencies, as well as with some elected officials, all of which generated increased visibility for the program.

As part of their experiential learning program, more than 100 staff members of the US Food and Drug Administration’s Center for Devices and Radiological Health joined us in April and May for a three-part online series aimed at fostering a deeper understanding of the challenges faced by non-traditional innovators. Led by Stanford Biodesign faculty, each session featured an engaging panel discussion that showcased alumni who founded companies from their fellowship and course projects, followed by breakout sessions with the attendees.

In April, two former directors of the US Patent and Trademark Office, Andrei Iancu and David Kappos, were joined by then chair of the Patent Public Advisory Committee, Suzanne Harrison, to discuss the role intellectual property law and policy play in supporting innovation and technological disruption, particularly in the healthcare sector. The conversation was moderated by the Policy Program’s intellectual property director, Eb Bright.

In May, Josh Makower was invited to testify before the Health Subcommittee of the House Committee on Ways and Means. Drawing on our research on the “valley of death” that confronts medical technology innovators as they await insurance coverage following FDA authorization of their technologies, he highlighted the risks to the continued development of breakthrough technologies without an expedited reimbursement pathway.

In August, Michelle Tarver, deputy center director and chief transformation officer at the FDA’s Center for Device and Radiological Health spent a day at Stanford Biodesign meeting with faculty, fellows, and staff to learn more about our programs. Later, she gave a talk to the Biodesign community on advancing health equity with medical devices.
Monthly Health Policy Webinar Series

Moderated by Kavita Patel, these monthly conversations offered the opportunity to deep-dive on significant and timely issues.

September - AI
Aneesh Chopra, former US chief technology officer, Jerome Adams, former US surgeon general, Rohini Kosoglu, former deputy assistant to the president, and Oliver Aalami, director of digital health at Stanford Biodesign, discussed the compelling ethical and equity challenges posed by the broad potential use of artificial intelligence in healthcare and healthcare decision-making.

October - Drug Pricing
Drug policy experts Allan Coukell, SVP of public policy at nonprofit generic drug manufacturer Civica Rx, Michelle McMurry-Heath, former president and CEO of the Biotechnology Innovation Organization, and Kevin Schulman, professor of medicine at Stanford University, shared lessons learned in leading efforts focused on balancing innovation and cost, and also highlighted policy gaps that need to be addressed.

November - Laboratory Developed Tests
ACLA president Susan Van Meter, physician executive Bruce Quinn, and Stanford Biodesign’s Sandra Waugh Ruggles discussed the Food and Drug Administration’s new proposed language on laboratory developed tests, and the potential impact on clinicians, patients, and innovators.

Following a break in December, the monthly series resumed in January 2024.
Program Team

Bringing all the components of the program together has required the efforts of a dedicated team.

Antje Kirschner
Fellowship Coordinator

Lyn Denend
Director, Academic Programs

Mollie Tiernan
Policy Program Coordinator

Sandra Waugh Ruggles
Director, Policy Research

Susie Spielman
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Deja Hill
Events Specialist
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Policy Fellows with Brook Byers, founder of Kleiner Perkins

Policy Fellows with Mike Mussallem, former CEO of Edwards Lifesciences, and Josh Makower

Policy Fellows with Andrew Cleeland, Tom Krummel, and Josh Makower at the 25th Thomas J. Fogarty MD Lecture

Get Involved!

For more information on how you can support the Stanford Biodesign Policy Program, please contact Debbie Drake Dunne (debbiedd@stanford.edu; (650) 497-2371). To learn more about Stanford Biodesign visit us at https://biodesign.stanford.edu.
The Stanford Biodesign Policy Program also benefits tremendously from the leverage provided by all other Stanford Biodesign programs. We deeply appreciate all our sponsors for their continued support of our mission.

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We also appreciate all of our individual donors, along with all those who are supporting our named fellowship endowments:
- The Cottrell Biodesign Innovation Fellow
- The Duerig Family Innovation Fellow
- The Khosravi Innovation Fellow
- The Lu Family Innovation Fellow
- The Stanford Biodesign Alumni Association Fellowship Fund
- The Paul Yock Biodesign Fellowship Fund