Or 20 years, the Stanford Byers Center for Biodesign has been the flagship academic program for training future generations of medtech innovators and entrepreneurs. The program has literally written the book and pioneered the curriculum combining the clinical, scientific, engineering, and business components necessary to develop innovative medical devices and launch successful start-up companies. It is a formula that has not only been successful in Palo Alto, but has also spawned similar programs worldwide.

When Biodesign co-founder Paul Yock, MD, retired in 2021 as the program’s director, and was succeeded by fellow co-founder, Josh Makower, MD, one of the questions that Stanford deans posed to Makower during the interview process was, “What changes would you like to see Biodesign make to keep the program on the cutting edge of innovation?” For Makower, the answer was clear: expand Biodesign to include a policy module to teach future entrepreneurs about the essential elements of the regulatory, reimbursement, and legislative processes. In his view, an equally important goal was to train the next generation of healthcare policymakers and deploy them to Washington, DC, and beyond as part of the overall policymaking ecosystem, both public and private. No such program existed anywhere. The idea was a hit with the administration and, upon taking the helm in August 2021, one of Makower’s first projects was to launch this policy module as part of the Biodesign curriculum, making Stanford’s the first policy program exclusively devoted to healthcare technology innovation broadly defined, including biotech, medtech, diagnostics, and digital health.

Having broken that ground, Makower then looked to take things one step further. As part of the policy program, Stanford Biodesign has created a fellowship designed to provide
Why Policy?

Makower’s promoting of the understanding of policy issues as important to the success of healthcare technology innovation is not an academic concern. His championing of the need for current device executives, as well as future generations of entrepreneurs, to better understand and contribute to the ongoing healthcare policy debate is borne out of the scars he earned while launching many of the start-ups that emerged from his Exploramed incubator, with Acclarent (which developed sinusplasty, the catheter-based treatment for sinusitis, and was sold to Johnson & Johnson in 2010) and NeoTract (treatment for benign prostatic hyperplasia [BPH], which was acquired by Teleflex in 2017) being two of the prime examples. NeoTract, in particular, was trapped for three years in what Makower calls “an opaque and shifting review process” as it tried to get an IDE approved, which cost the company years of development time and tens of millions of dollars.

In the mid-2000s when Makower was building those companies, the biggest challenge facing the industry was the slow and uncertain regulatory process at FDA. Getting CE mark approval in Europe was a much faster and more clearly defined pathway, leading many US companies to begin commercializing in the EU where they could generate early revenue and clinical data. (The situation has since been reversed due to both improvements at FDA and complications from the new Medical Device Regulation, MDR, in Europe.)

The device industry’s frustration with FDA not only led companies to go to Europe first, where patients and clinicians had access to innovative technologies several years before their counterparts in the US, but it also discouraged investors generally from looking at medtech companies given the uncertain and lengthy road to regulatory approval, thereby further slowing innovation. This overall depressed state of the device regulatory landscape drove Makower to spearhead, along with partners including trade groups and industry leaders, a study of the FDA’s medtech regulatory process that was published in 2010 called “FDA Impact on US Medical Technology Innovation” and has since come to be known as the Makower report.

The study relied heavily on information collected from surveying more than 250 stakeholders, including large and small companies, as well as investors, to generate a wealth of data documenting the issues the industry faced. The information generated by the report produced tangible results, not only sparking similar studies by FDA and others, but most importantly spurring bipartisan efforts to develop and pass the Food and Drug Administration Safety and Innovation Act into law in 2012. This law provided FDA a framework to improve the process by making it more transparent and accountable, resulting in significantly reduced product time to market. The outcome has been that the device approval process in the US and relations between industry and the FDA/CDRH have improved over the past decade to the point where regulatory issues no longer constitute the biggest challenge facing device companies.

In Makower’s view, the key to the success of the 2010 report was the data. “It came down to the power of data. In Washington, there are lots of opinions; all we need to do is turn on the news every night to see that,” he points out. “Data from a reliable source is ultimately the way to resolve differences of opinion and to refocus the discussion on how we solve the problem, rather than whether the problem exists or not.”

Breaking New Ground

Reaching a successful outcome with the regulatory project didn’t quell Makower’s interest in the important role that policy issues play in the innovation process. If anything, it fueled his interest in the area generally, looking beyond just FDA matters to the point where, when he assumed the leadership of the Biodesign program last year, one of his first undertakings was to launch an initiative dedicated to health technology policy issues generally.

“While there are a lot of policy groups looking at all sorts of healthcare questions, I saw that there really is no university-based policy group that is primarily focused on health technology innovation, so I thought, ‘There is no better place for us other than Biodesign,’” Makower recalls. “We’re all about innovation, we train innovators, that is our mission.”

Makower has several goals in mind for the Biodesign policy program. “Number one is we’re going to produce research and data similar to what I did back in 2010 on the regulatory process, but we’re going to focus on all policy questions and issues,” he explains. Another aim is to try to align themselves with where the legislative agenda is going, so they can get relevant data to policymakers when they need to make decisions, whether that is FDA, CMS, or Congress. “We want to try to be
“WE LEARNED THAT INNOVATION IS A PROCESS. IT CAN BE LEARNED AND WE CAN TEACH IT TO OTHERS, AND IF WE DO THAT EFFECTIVELY, THEN WE CAN EFFECT REAL CHANGE,” HE SAYS. IN MAKOWER’S VIEW, THE SAME CAN BE TRUE FOR HEALTH TECHNOLOGY INNOVATION POLICY: “IF IT IS A PROCESS AND YOU CAN LEARN IT, THEN YOU CAN TEACH IT AND PEOPLE CAN GET GOOD AT IT.”

Launching a Fellowship

Beyond those goals for Biodesign’s new policy module, Makower has decided to take this project one step further by launching a new fellowship dedicated exclusively to health technology innovation policy. To play a senior role in this new effort, Makower recruited Kavita Patel, MD, a health policy expert who may be best known currently for her stints on NBC. She previously worked for Senator Ted Kennedy and in the Obama White House on the Affordable Care Act, as well as at the Brookings Institution. Makower met Patel at the venture firm NEA, where they both still work.

The genesis for the fellowship, Makower explains, comes from the fact that for the many fellows and students that Biodesign has trained over its 20-year history, although they have gone on to play diverse roles in the global healthcare system, “they all have faced some very similar challenges, which involve getting their products through the regulatory process, especially the ones that are the most innovative, and also getting their products paid for—it drains resources and delays patient access.” Moreover, he adds that these policy drags on the system discourage innovation and disincentivize investment.

Makower believes that the policy program has a lot in common with Biodesign at its launch. “We learned that innovation is a process. It can be learned and we can teach it to others, and if we do that effectively, then we can effect real change,” he says. In Makower’s view, the same can be true for health technology innovation policy: “If it is a process and you can learn it, then you can teach it and people can get good at it.” However, he acknowledges, “Right now, the thought of ‘How do you change things in DC?’ seems insurmountable, but it’s not. What I learned is that there is a way to do it and that’s what we need to train people how to do, in order to really train policymakers of the future.”

Bringing Kavita Patel on board was essential, Makower says. Having gotten to know her at NEA, he lauds her domain knowledge built from experience in Washington, DC, along with her established relationships in both the legislative and executive branches, which enable her to credibly share the inner workings of policy processes.

Makower also points out that for this new fellowship, the program will be looking for candidates who differ from those for a traditional Biodesign fellowship. In his view, there is very little overlap between the two. He characterizes the difference this way: “For Biodesign fellows, we look for people who want to be innovators and create technologies by inventing things that change the world by helping improve patients’ health. With the policy fellowship, we are looking for people who want to change the world by leading with policy.”
Market Pathways: Let’s start with a little bit of background because it’s not immediately obvious why you would pursue a career in health policy after medical school. Were you always interested in policy and, if not, what drew you to this area?

Kavita Patel, MD: No, if you’d asked my younger medical self what I was going to be when I grew up, I would have told you I had this incredibly elaborate plan to start a clinic for uninsured people. I’m from South Texas, and especially at that time before the ACA [Affordable Care Act], there were a ton of uninsured people. So I wanted to start what I guess would be now called kind of like a community health center aimed at uninsured people. That was all I wanted to focus on. It’s actually why I went into primary care medicine.

My interest in policy came when I learned that the rubber hits the road in medicine when you have to talk about who pays for all this. What I realized is that nobody in medical school taught me anything about that, and they still don’t, by the way; still to this day, we don’t teach med students about how healthcare is paid for, how doctors are paid, how even the Band-Aids that I give to a patient in the clinic are paid for.

I should also say that I was an activist, not a policy activist, but a student activist. I took a year off in med school between third and fourth years to run the American Medical Student Association. It’s not the AMA [American Medical Association] student chapter. It’s actually an independent student organization. I went to DC to run that organization. It’s an elected position. A lot of now famous physicians also had that same job, so it’s kind of a breeding ground for student/doctor activists, but again, not policy-focused. But I was exposed to policy in my time in DC, and it bored me to pieces; I thought, “This is incredibly boring to think about how bills become law and how laws are interpreted.”

But when I was in residency, I learned the phrase “No margin, no mission.” You can’t do anything unless you actually think about the financing. Then I did a fellowship at UCLA, where I actually wanted to understand a little bit more about healthcare financing, and I wanted to do research in this area because I thought, “Surely, if I published a New England Journal of Medicine article on the topic, that would have an impact.” So I pursued a career in research and was able to get grants from the National Science Foundation, looking at various aspects of mental health, such as how do we fund better care in mental health? How do we fund better care for people after Hurricane Katrina? And every road I pursued in research led to policy, every single road, and so I published papers, and presented abstracts and research around the policy impacts of not having a safety net, not having insurance, that type of thing.

Then, thanks to Google and some mutual colleagues I got noticed by somebody on Senator Ted Kennedy’s staff, who contacted me and asked me to present to Committee leadership on my findings on mental health care. And then the rest was history. Once I interacted more with his staff—they had a job opening at the time in the Senate—and they offered me a job, I picked up my stuff from Los Angeles and moved to DC and haven’t left.

Since you were initially bored by policy, what caused the switch to flip to get you interested in making a career out of it?

Initially, I had the same assumption as I think most Americans do, which is that people who work in healthcare policy really understand our healthcare system. It just was an assumption I made. And then lo and behold, I’m a 32-year-old doctor and I get to Capitol Hill only to find out that these people have no idea what actually goes on inside the healthcare system for which they’re creating policies, and they’re well-intentioned people of both parties. Nobody actually understood the healthcare system. They would talk about things like access to dialysis or trying to get home health visits and none of them understood the process the way I did, such as what actually happens when a patient gets dialysis and how does that feel.

That’s when I realized we needed to have more doctors working on healthcare policy. To be candid, there’s one answer: it just doesn’t pay. I mean, I was one of Ted Kennedy’s most senior staff and I was getting paid $105,000, which I thought was great at the time, but I could have been working at a Kaiser practice in California and easily making $250,000.

And in the interests of full disclosure, Senator Kennedy paid his staff better than did most members of Congress.

He reminded me of that every now and then when I annoyed him, which I frequently did. He reminded me that he paid for my moving costs, which they rarely do.
“IT’S INTERESTING BECAUSE I WENT TO CAPITAL HILL THINKING THESE PEOPLE UNDERSTAND HEALTHCARE, AND THEY CAN TEACH ME SO MUCH, BUT I QUICKLY REALIZED THAT I’M THE ONE WHO CAN ACTUALLY OFFER THEM SOMETHING. I RECOGNIZED THAT MY ABILITY TO TAKE THESE COMPLEX CONSTRUCTS LIKE CHILDREN’S HEALTH INSURANCE, MENTAL HEALTH PARITY—ALL THESE THINGS THAT WE TALKED ABOUT IN POLICY CIRCLES— AND QUICKLY TRANSLATE THEM TO WHAT WOULD IMPACT PATIENTS, THAT WAS MY SUPERPOWER.

But that’s when I realized that they just didn’t understand healthcare. They were mostly young staffers who barely had any healthcare themselves. In fact, many of them weren’t old enough to have had to help their parent die or deal with their own diagnosis of a chronic disease, or watch their child go in and out of an ER.

It’s interesting because I went to Capitol Hill thinking these people understand healthcare, and they can teach me so much, but I quickly realized that I’m the one who can actually offer them something. I recognized that my ability to take these complex constructs like children’s health insurance, mental health parity—all these things that we talked about in policy circles—and quickly translate them to what would impact patients, that was my superpower.

Interestingly, you eventually went from the policy circles of DC to the venture capital world of Silicon Valley when you joined NEA, with which you still are affiliated, before you started working with Stanford. How did that transition happen?

One of my friends that I got close to when I worked for Senator Kennedy was a young Scott Gottlieb, who was then in the Bush administration. Actually, in the beginning, we were enemies because he was very snotty, and I called him out on it. Then we became close friends. I went from Senator Kennedy’s office to the Obama White House, and then actually moved to work at the Brookings Institution for his old boss, Mark McClellan. But all along the way, Scott and I worked closely together—we collaborated on papers and stayed in touch socially.

When he made the transition to run the FDA, he had to leave his role as a venture partner at NEA and he called me and asked if I would be interested. I had no clue about the world of venture capital but was very interested in learning a new vocabulary and meeting some very impressive people along the way.

What did you learn about venture capital and what did the NEA partners learn about policy that resulted in you joining the firm?

Scott introduced me to Josh Makower and some of the general partners and we had casual lunches where we talked about reimbursement and innovation. I learned that investors are not against innovation; what they are violently against is this notion that innovation has to come at a price that forces people to either go bankrupt or only adds to your profit lines and doesn’t actually contribute value back to society. But there was often a disconnect between why policymakers had to think much more broadly ensuring that there is a viable Medicare program to last generations, for example. These were great discussions, which resulted in me joining NEA as a venture partner, and it’s been five years now and I haven’t looked back; I’ve gotten more and more involved.

What I’ve found is that Josh is an outlier among investors; he’s an outlier in a lot of ways, but he’s an outlier, because he has this policy interest. Most entrepreneurs and investors, as you know since you interact with these executives, don’t really worry about how the sausage gets made, they just want to make sure that they find a better way to make the sausage in some way, or try to deliver the sausage in a more patient-friendly way. But at the end of the day, they don’t want to understand what’s actually in the sausage. I find that I can put some reality checks on companies. I tell companies that they can have incredible pivotal trials, and it might take them 10 years to get reimbursed, and that’s just the way life is. That is because, whether people want to admit this publicly or not, we ration care. We do it all the time. And that’s just how it works and then I go on to tell companies what they need to do to present a compelling case.
That’s a good segue to discuss your transition to Stanford, where you will be working with entrepreneurs and innovators who will be building the next generation of medtech companies. It’s instructive to frame the context for how device companies’ views of policy issues have changed over the years. Roughly a decade ago, the big issue was regulatory, but as things have improved under Jeff Shuren’s tenure at CDRH [Center for Device and Radiological Health], the device branch at FDA, the leading challenge, based on my discussions with company executives, has become reimbursement, which used to be an issue that companies would largely ignore, often saying that the large strategies would handle that post-acquisition. Now, both investors and potential acquirers expect start-ups to have at least general reimbursement strategies. You will be getting involved in the new policy module and fellowship within Stanford Biodesign; what do you see as the role of policy within the program and how will this fellowship differ from the many other academic healthcare policy programs that already exist?

That’s exactly right. There are many policy fellowships and programs out there. I think what’s unique about Stanford in particular, is not only that it is a world-class institution, but that integrating this with the Biodesign program offers people what I would say is kind of the missing leg on a stool, whether it’s entrepreneurs or inventors or executives or even patients. This is the exact kind of person who needs to understand how not only can you advocate on the policy side, but what is it that investors of all sizes are looking for, and a place like Stanford offers insight into all of these things—the inventor community, alongside the policy expert community, alongside these operators of multibillion-dollar companies. This is a chance to bring it all together.

The first few classes that come through this fellowship are going to be the proof that we’re not just cultivating people who quote, understand policy; these are going to be the people who shape it, who influence it, who lead it. I’m hoping that we have a future FDA commissioner, a future medtech innovator who also helps to establish IP law in new areas. That is who we hope to have in our classes.

There are people who might suggest that the natural constituency for Stanford Biodesign, the MDs and the biomedical engineers who typically would make up the program, that for them, policy is not a natural extension of that kind of entrepreneurial creative process and that this type of fellowship would fit more naturally into existing healthcare policy programs such as those at places like Harvard’s Kennedy School or at Duke or at Johns Hopkins. How do you respond to the suggestion that launching this within Biodesign might be trying to fit a square peg in a round hole?

No, I think it’s actually the opposite. It’s funny, every Biodesign fellow including alumni, as well as this current class of fellows, they have all expressed an interest in understanding policy. They don’t want to be policy experts, per se. But they all have understood that without a very solid understanding of nomenclature and the ability to advocate, they can’t accomplish even a fraction of what they’re trying to do. So for me, the square peg in a round hole analogy is quite the reverse where people are realizing that that round hole not only fits a square peg, it fits about 10 other square pegs because it’s so big, and people are so poorly equipped to understand it going back to my med school explanation because nobody teaches this.

The difference in comparing this program with Harvard’s and anywhere else, is that Biodesign has a 20-year track record now of creating successful curriculum, fellows, and experiences. They’ve had policy issues constantly coming up, but it’s always been like whack a mole, like, “Okay, here’s how we’ll deal with that,” or “Here are some issues to consider in your PowerPoint presentation,” whereas now we’re just kind of flipping it and putting it on the front burner instead of the back one.

I’d like to conclude by asking you to discuss your vision for the approach that will define this Biodesign policy fellowship and how to assess its ultimate success particularly given the current political climate, and in light of that, what strategy would you like the program to take? Specifically, the device industry has been successful by drawing on a heavily data-driven approach in addressing regulatory challenges at FDA, for example. I would cite the so-called Makower report from 2010 as helping to spearhead those efforts, and that was followed recently by a similar data-focused report from the UCLA Biodesign program. You are aware first-hand from your experience in DC of the fact that the current political climate has changed to one where fact- and data-driven arguments may not hold the same weight as they once did. How do you go about training the next generation of policy innovators and entrepreneurs in today’s environment of unprecedented skepticism toward science? What kinds of obstacles does that present and how can they be overcome?

Just as with my research, I don’t change my approach based on the times. I think the integrity and transparency of science data collection and reporting, which is what Josh has been doing for more than 10 years, is foundational. On top of this is putting it into the context of the state of where we are today: we have budgetary constraints, we have a Medicare trust fund that’s going to go bankrupt in the next few years, we have had all sorts of real fiscal constraints, particularly during COVID. I don’t think that science can be ignorant to those concerns, but at the same time, science must speak for itself.

For me as a policy expert, we have to present the context of that science in a way such that lawmakers see the urgent need, so
"I do not like to look at the scientific questions in a different way just because of policy constraints or context. I would much rather let the science stand as it is, and then have the discussion around the impact, and the policy effects, in addition to the science. That is the skill set that we’re hoping to teach people.

As you open the application process for year two of the fellowship, what did you learn from the first year and will you be doing anything differently this year both in terms of the program and its content and structure, and the application process and types of applicants you are seeking?

We are still trying to put the finishing touches on some of the details of the first year, but needless to say this will be engaging and exciting content taught by world-class policy experts. What I would do differently is to probably offer a much clearer understanding of what the Innovation Fellowship does and doesn’t do, and what the Policy Fellowship does and doesn’t do. The Policy Fellowship is meant to give anyone interested in policy—entrepreneurs, clinicians, and researchers alike—the tools they need to bring bold ideas forward and create actionable change.

At the end of the day, how would you like to see the Biodesign fellowship program contributing to the broader healthcare policy debate? Do you see this ultimately serving a front-line lobbying/advocacy role in shaping the discussion or is the goal more to generate a better understanding of healthcare as an added, but indirect resource?

I see three things. Number one: more presence in Washington, DC. You really just cannot have influence without having presence; that can be virtual, but it needs to be a thoughtful presence in Washington, DC, getting the people who make the decisions at the table, virtual or real, together with the best and brightest from Stanford Biodesign. Josh has started that, but we need to do more of it.

Number two is actually creating actionable policy briefs. My job at Brookings was to be able to take some of these complex concepts, put them into two to three pages, and then to be able to go to a staffer and say, “You need to do these three things.” And then, “Here, by the way, are actually experts who can speak to this substance, the science, the data.” That’s probably what you’re loosely calling the lobbying or the advocacy function.

And then the third is actually getting back to why I think this is so relevant for me and my interest in policy, and that is stories. I don’t know of any senior congressperson, or even the president of the United States, for that matter, who doesn’t think about a policy issue without thinking about a personal story. And we have to bring those stories forward. Who better to do that than the people who are actually on the front lines, but are also doing the design, doing the innovation, and doing the research. That’s what I know we need, and we can use this fellowship to help bring them forward.

For anyone interested in learning more about the Stanford Biodesign Policy Fellowship, please contact Antje Kirschner, Fellowships Coordinator, at Akirschner@stanford.edu. The application deadline for the coming academic year is August 25, 2023 at 11:59 p.m. Pacific time. More details can also be found on the FAQ page and the application instructions are on the Policy Fellowship website at biodesign.stanford.edu/programs/fellowships/policy-fellowship.