

# The MedTech STRATEGIST

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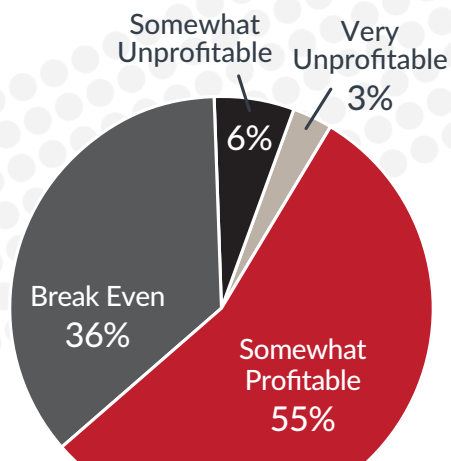
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# BIODESIGN

## at Fifteen

### KEY POINTS

- Fifteen years ago, Stanford's Biodesign program was launched with the idea of creating within an academic setting a means of training people how to be innovators in medical devices.
- Over the years, the program has expanded beyond that initial mandate and today plays a leading role not just in the medical device community around Palo Alto, but around the globe as well and has long attracted medtech companies and venture capitalists in its orbit.
- Indeed, the program's influence is felt around the world, in Biodesign's own programs in China, India, and Singapore and in programs hosted by other universities, such as NUIG's BioInnovate program in Ireland.
- Given all of the changes the medical device industry has seen over the years—from regulatory and reimbursement challenges to funding booms and busts—Biodesign has often found itself reconciling fundamental principles of innovation, most notably its focus on the critical role of needs identification, with shifting industry dynamics, whether in the form of new influences, such as the importance of health economics, or new technology horizons, like digital health.

by  
DAVID CASSAK



So many academic and university based medtech development programs have surfaced over the past several years that it's easy to forget how seminal a role Stanford University's Biodesign program has played in such efforts. Neither a tech transfer program in the conventional sense of the term nor an incubator in any sense, Biodesign started a decade and a half ago, the brainchild of two physicians who had already established significant *bona fides* as innovators in cardiovascular devices: Paul Yock, MD, the legendary interventional cardiologist who had developed breakthrough technologies such as rapid exchange catheters used in angioplasty and intravascular ultrasound (IVUS), and Josh Makower, MD, a physician by training who had earlier founded one of the first medical device incubators, ExploraMed, which in turn was responsible for, among other ventures, TransVascular, the developer of revascularization devices, and Acclarent, which pioneered a novel, percutaneous approach to sinusitis.

Yock and Makower began with a simple question: Can you teach people to be medical device innovators? From that beginning has come not just the Biodesign fellowship program, but university courses, books, and other publications, and, perhaps just as importantly, an influence that is now far-ranging and global in scope. Biodesign itself has spawned satellite programs in places like China, Singapore, and India and has inspired similar programs elsewhere around the globe: at universities in the US and in Ireland, whose BioInnovate program at the National University of Ireland, Galway (NUIG) was explicitly modeled after Biodesign.



Even more, Biodesign's influence has long been felt in the dozens of medtech industry executives the program has trained and the dozens of medtech start-ups that have come about as a direct or indirect result of the program. (For one such company, see *"Gauss Surgical: The Transforming Power of Digital Health in the OR,"* in this issue of *The MedTech Strategist*.)

The big, multinational strategists, too, have recognized the value and importance of Biodesign as a source of important new technology. Indeed, it is the rare CEO of a major medtech multinational who hasn't spent a day touring the Biodesign facilities and talking with the fellows. (Full disclosure: From its inception, I've been a part of the Biodesign program's Inno-

erator's Workbench program, an interview series that seeks to bring insights from physician entrepreneurs and industry executives to the Biodesign fellows and the surrounding medtech community.)

Yock and Makower insist Biodesign has always been about training young talent, not about company creation, and both argue for a kind of timeless approach to medtech innovation, a search for core principles and concepts, most notably the critical starting point of needs identification, that are integral to the process. Still, fifteen years ago when the program first launched, no one, neither Makower nor Yock nor anyone in the medtech industry for that matter, could have envisioned the changes that would soon begin to

roil the medical device industry and continue to do so for the next decade and a half. From major regulatory and reimbursement challenges to continuing healthcare reform and economic pressures to a cycle of boom and bust in early-stage capital, as well as the emergence of new technology areas, including neuromodulation and digital health, Biodesign has proven to be not only capable of adapting, but of helping a new generation of device developers keep ahead of those changes.

Now, as it celebrates its 15<sup>th</sup> anniversary, Biodesign is itself changing—if only in finding a new funding source and taking on a new name (see sidebar *"Biodesign Gets a New Name and a More Secure Future"*).

In the following interview, adapted from an Innovator's Workbench program held earlier this year, we spoke with six people who've played a key role in Biodesign over the years: Paul Yock, Director, Stanford Biodesign and Martha Meier Weiland Professor of Medicine, Stanford University; Josh Makower, Co-Founder, Stanford Biodesign, Chairman and Founder, ExploraMed Development LLC, and General Partner, NEA; Todd Brinton, MD, Fellowship Director, Stanford Biodesign and Clinical Associate Professor of Medicine, Stanford University; Lyn Denend, Director, Academic Programs at Stanford Biodesign; Tom Krummel, MD, Co-Director, Stanford Biodesign and Emile Holman Professor and Chair Emeritus, Department of Surgery, Stanford University School of Medicine, Susan B. Ford Surgeon-in-Chief, Lucile Packard Children's Hospital Stanford; and Uday Kumar, MD, Director, Strategy, Stanford Biodesign and Consulting Associate Professor of Bioengineering, Stanford University, and Founder, President & CEO, Element Science Inc. These teachers, mentors, clinicians and innovators discuss where Biodesign has come from, where it stands today, and where it is headed in the future.



Paul Yock



Josh Makower



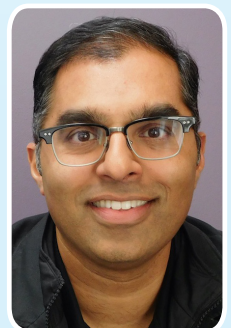
Todd Brinton



Lyn Denend



Tom Krummel



Uday Kumar

**The MedTech Strategist:** *Paul and Josh, let me begin by asking you to give us a sense of what you were trying to accomplish before the actual launch of the Biodesign program? Where did the idea come from and what was the thinking behind the project? I know Josh had created an innovation-focused program when he was at Pfizer.*

▶ **Paul Yock:** I guess I'll start because I have the gray hair on the panel. When I joined the faculty at Stanford in the mid-1990s I had a debt to pay back: as a fellow in cardiology at Stanford, I had the amazing good luck to be mentored by Tom Fogarty and John Simpson on some early inventions of mine. I just fell into that situation haphazardly and it was an incredibly valuable experience. When I came back to Stanford I had the notion that we should set up a mentoring program that was more organized and broad-reaching. We started with a group of faculty that included Mike Dake, Scott Delp, Steve Oesterle, Bobby Robbins and others—in a program we called the Medical Device Network. We developed some early education and training initiatives. But the real origin of what would become the fellowship program came from a breakfast at Il Fornaio with Josh Makower—where he mentioned that he had created a program in industry that was a training initiative for medtech innovators.

▶ **Josh Makower:** That was the Pfizer program. Back when I was leaving medical school and was an engineer looking for a job, I was very fortunate to have my resume picked out of the stack by the CFO of Pfizer at the time, Hank McKinnell. Hank brought me in and basically created a job for me. One of his primary assignments for me was to try to figure out why it was that Pfizer kept on acquiring these great start-up companies that then would stop innovating when they became part of the larger organization. His question was 'How do we actually innovate here at Pfizer? How do we keep that innovation going?'

So I set about the task of understanding the history of all these founders from companies that Pfizer had acquired and understanding the processes that they went through. I tried to understand the similarities and read as much as I could about innovation, et cetera. In the process, I realized that the best of these start-up companies fundamentally started with a patient need, and that their founders took the time to understand that need independent of a technology. They actually built the technology to meet the need rather than the other way around. And this is one of the reasons these companies became successful businesses.

Another one of my roles in this position was to be a part of an R&D review process within Pfizer. When I looked at what was actually going on within its medical device units, everything was iterative. It was just the same technology getting iterated over and over. My observation was they weren't going back to fundamental principles and looking at needs and therefore they weren't really innovating. So we started a training program we called Pfreshtech to teach people a process for needs-driven innovation.

Over many years we worked to perfect this process, which became the foundation of my own career as an entrepreneur [through the incubator ExploraMed]. And when I left Pfizer, I started to experiment with using these tools to create companies.

**MTS:** *Given the roots of the idea in the Pfizer program, why did you launch the program in an academic setting and at Stanford? Was there ever any temptation to create a kind of separate, quasi-industrial program not necessarily rooted in academia?*

▶ **Josh Makower:** As I think Paul mentioned, we're sitting here in the middle of the most vibrant medical device network in the world, and Stanford's right in the middle of it. It was a natural opportunity to capitalize on the best of academia and the best of industry. It was the perfect time for his peanut butter and my chocolate to come together to create this first-of-its kind training program in innovation.

**MTS:** *What were the early days like? And can you share who was in the first class?*

▶ **Paul Yock:** We had a great group that included Asha Nayak who's now the Chief Medical Officer at Intel and Chris Eversull who went on to form AuST Engineering in Mountain View. Nick Mourlas, who founded Acumen Medical, is now Senior Director for New Ventures at the J&J Innovation Center. We had David Miller, who is a senior engineer at a device company called ArthroCare in Texas, and Amir Belson, who was a specialty fellow that year. He has gone on to found multiple companies in the medtech space.

**MTS:** *Before we get to what their experience was like, what criteria did you use early on in accepting fellows? Were there a lot of applicants? Or did most people not*

*yet understand what you were doing and why they might benefit from the Biodesign program?*

▶ **Paul Yock:** The main criterion back then was somebody who was willing to do something this crazy! But seriously, we were then—as now—looking for people who had the ambition and talent to be leaders in medtech innovation, and who were interested in a training process and a pathway for doing that.

**MTS:** *There seems to be an implicit entrepreneurial bent to Biodesign—a goal to create something that will make someone money rather than just develop technology for its own sake or the benefit of patients. What was the reaction or reception from your academic colleagues? Was there any skepticism about the entrepreneurial nature of the program?*

▶ **Paul Yock:** Well, let me start by saying that the whole point of Biodesign is to provide better health technologies to patients—and having a workable business or entrepreneurial model is critically important for this. But the main goal is not to make money. Having said this, yes, there was some initial suspicion of what we were doing from a conflict-of-interest standpoint. We were careful from the start not to take any financial interest in the companies coming out of the program. I should also point out that, in the past 15 years, the landscape with respect to entrepreneurship in universities—and in particular, in medical centers—has changed profoundly. Now there are many entrepreneurship programs at medical centers around the country and internationally.

▶ **Josh Makower:** There was a lot of skepticism, especially because we were doing something medical. The idea of juxtaposing company creation with that was very controversial. Our philosophy was that if you really want to change the world and do something good for patients on a major scale, it actually has to be a great business in order to succeed. That principle is relatively well understood today, but at the time, at least in academia, some people perceived it as a conflict of interest. But we knew that new therapies would never get developed and touch so many patient lives if no one would invest in them.

▶ **Paul Yock:** I should have mentioned earlier that, at the time we started Biodesign, Stanford was probably the only university that would have tolerated this type of program. Over the years, the University wound up nurturing us in many respects, so we were lucky to be in the right spot.

**MTS:** *Was there any temptation just to turn the program over to Stanford's tech transfer office and make it part of that office?*

▶ **Paul Yock:** Not especially. Our focus from the start was on education and training, and the tech transfer office is more transactional in terms of licensing technologies out. As it turns out, we have had a nicely synergistic relationship between Biodesign and the Stanford OTL.

**"The whole point of Biodesign is to provide better health technologies to patients—and having a workable business or entrepreneurial model is critically important for this. But the main goal is not to make money."**

—Paul Yock

**MTS:** *The reason I asked that is because you launched the program with the idea of engaging in a process of thinking about what innovation is and how you develop great technology as a purely academic exercise. But to what degree was the goal always to take the next step and actually launch a new company around that innovation?*

▶ **Paul Yock:** Training has always been our goal. The companies are a byproduct of our program, not a goal.

**MTS:** *So you can go through the program and not start a company and that would still be a successful outcome in your mind?*

▶ **Josh Makower:** Absolutely. We want trainees to fail as much as possible when they're with us at Stanford so that they can go out in the real world and actually get it right.

▶ **Paul Yock:** It's important to note that most of our alums do not go directly into their own start-ups. There are some great early career stories from these other folks. A number of our graduates have gone on to join big companies—and have had a significant impact there. We also have many alums in faculty positions in universities around the country—in fact nine of our alums are on faculty at Stanford alone.



**MTS:** *At some point, Biodesign began to expand beyond the confines of Stanford and to be embraced by the larger medical device community here. How did that come about, and to what extent do you think Biodesign has helped shaped the culture of that community?*

▶ **Josh Makower:** I'll say that we started off with the idea that Paul and I are not the experts. The experts were all around us in the valley. So we realized that to do it right we had to draw from the community and actually make Biodesign about the community, taught by the community. Biodesign has benefitted greatly from the riches of all of these talented people who are experts in their various fields and who bring all this relevant experience to our trainees. And to this day, they participate very actively in training our students and our fellows. It's a community effort.

**MTS:** *I've spoken with a lot of CEOs and senior executives in this industry, not just in the context of the Innovators Workbench program, but in independent conversations with them, and I've noticed over the course of the years a significant ramp up in awareness about in the program. You must see that as well. At what point did that begin to gel for you?*

▶ **Paul Yock:** We had good support even at the outset. We had a couple of large companies who provided start-up gifts just based on the idea. So even for the first year of the program we had official funding.

**MTS:** *What about the investor community out here?*

▶ **Josh Makower:** Same story. Right away, we had good support from a number of venture groups.

**MTS:** *Do you think your interests and their interests have always been aligned? Are they looking for the same things from the program that you are?*

▶ **Josh Makower:** Absolutely. They were looking for the talent that was being created here. They're looking for the ideas, the companies. We had venture capitalists sit on the panels at the end of the class. We had them come in, interact with our students and fellows. It was great.

**MTS:** *The medical device industry has faced a lot of challenges over the years and has changed in significant*

*ways as a result. Has the approach or the goal, the fundamental principles of the program, changed over the course of last 15 years as well? Are you still trying to accomplish the same things now as you did then? You talked about needs-identification being a big part of the curriculum from the beginning. But have there been major changes from the original vision?*

▶ **Josh Makower:** From my perspective, the process is timeless and our focus on needs as a primary basis for creating innovative solutions is fundamental. What's changed is the selection criteria—the constraints that the ideas need to navigate to be successful—and those change constantly in relation to the external environment.

**MTS:** *You mean the kinds of technology that come out of the needs identification process?*

▶ **Josh Makower:** Actually, I mean that you have to consider factors such as how much money is available and to what extent you can take on projects with what degree of risk and be successful. I think that's changed dramatically over time. But the fundamental idea—that you should initiate the innovation process by really focusing on the patient and understanding what they're going through and the caregiver experience and trying to figure out what's working and not working—that's still the same and I think will be true forever.

▶ **Paul Yock:** If I can just add two things to that: I agree completely with what Josh said. But I want to be clear that the needs finding process is evolving, based on the changing environment. We are now adding 'economic needs finding' to 'clinical needs finding.' The question now becomes: where is the best opportunity to provide value with a health technology innovation—both for the patient and for the system at large? Best case: is there an opportunity to take cost out of the system without compromising care? The second change we've brought to the process is this: we are now looking for needs outside of the hospital. We are focusing on intervening earlier, before the disease process is so far along that it requires hospitalization. This is where there can be real cost savings, and obviously, great benefit for the patients.

**MTS:** *Phrasing that question differently, as the years have gone by, to what extent are you focused on identifying those timeless core principles about innovation that you talked about and that are still relevant despite whatever is going on in the larger environment? And to what extent are you instead trying to adapt to the changes that take place in order to give would-be entrepreneurs a road map to deal with current industry conditions? For example, when this program started 15 years ago, it was very*

*difficult to raise capital for medtech start-ups. We then went through a period in the mid-2000s when it was easy; now, it's difficult again. Is that reflected in what goes on in the program?*

▶ **Josh Makower:** I think we've said that the fundamental principle of taking time up-front to understand and characterize a need before inventing a technology is incredibly robust. And we have the luxury of still being

## Biodesign Gets a New Name and a More Secure Future

Halfway into its second decade, the Biodesign program has a new name and new financial backing that should help the program both sustain and build on its success as a leading center for the training of medtech innovators.

This past May, Biodesign announced that going forward, the program will be called the Stanford Byers Center for Biodesign and will go from being a program within the University to having official status. "This is a pivotal moment for us," said Paul Yock, founder and director of the program, in making the announcement. "It's an acknowledgement by the University that Biodesign has an essential and on-going role in training health technology innovators—and in continuing to innovate this training process. We are very grateful to the Byers family for giving us a strong start toward financial sustainability of the program."

As Yock's comments suggest, funding for the newly named Center comes from Brooks Byers, the Byers in venture capital giant Kleiner, Perkins, Caufield, Byers, long a key figure in life science investing and a mentor to fellows in the program for years. In a press release issued by Biodesign upon the announcement, Byers commented, "This program is uniquely positioned to improve human health around the world. Their fellows and medical innovations change healthcare and have already directly benefited hundreds of thousands of patients. And they're inspir-

ing and empowering others by sharing best practices globally."

Until now, funding for Biodesign was provided by a combination of private donors and industry gifts, as well as foundation and grant support. In addition to Byers' contribution, Yock noted that the new Center's top funding priority looking ahead "is to be able to raise endowments for our fellowships. Our goal is to raise twelve of these endowments," with the first two, from the Cottrell Foundation and from Fred and Flora Khosravi, already secured.

Since its launch in 2001, the program has trained more than 1,000 graduate students and nearly 200 fellows. In turn, the fellows and students have gone on to found more than 40 companies and to create products used by well over a half-million patients, including products to forestall night terrors in children, prevent infections after surgery, relieve symptoms from an enlarged prostate, provide respiratory support in low-resource settings, as well as to treat dry eyes and female incontinence.

In the announcement about Biodesign's new funding source and sta-

tus, Lloyd Minor, MD, dean of the school of medicine, said, "Biodesign is a program that exemplifies the concept of precision health. Working at the intersection of medicine, engineering, and business, Biodesign fellows are delivering path-breaking solutions to the most pressing human health problems. Moreover, these innovative fellows go back out into the world, taking with them not just their first invention but their capacity to keep inventing—and to teach others how to invent—whether in their own start-ups, in existing companies or as faculty members in top universities. This is the multiplier effect: We seed the world with people who approach innovation using this proven, needs-based process." Persis Drell, PhD, dean of Stanford's School of Engineering, added, "Over the last 15 years, Stanford Biodesign has had an extraordinary impact on the world. It has done so in large part because its leadership recognized early on that solving big, complex problems requires teams of scholars from multiple backgrounds and disciplines to work together. Stanford engineers are very proud to be a part of this highly successful collaboration and look forward to continuing to do so."

—David Cassak

able to function in the current environment because that approach is so robust.

▶ **Paul Yock:** Absolutely. We're helping fellows and students develop the ability to see problems in a way that hasn't been considered before—that's a durable set of skills, whatever happens to the environment moving forward.

**"Our philosophy was that if you really want to change the world and do something good for patients on a major scale, it actually has to be a great business in order to succeed."**

—Josh Makower

**MTS:** *We're going to turn in just a second to the current state of the program with Todd and Lyn. One final question: as you think about what you wanted to accomplish at the very beginning and where the program is today, were there any major readjustments, recalibrations, or detours? Or is the program today very similar to what you had always envisioned?*

▶ **Paul Yock:** I would say that the overall outcome in terms of the careers of the fellows and students—what we'll hear about in just a second—has exceeded our expectations by far. We've certainly expanded the program well beyond what we originally anticipated, both in terms of the number of classes and the impact on faculty at Stanford, and in our global programs. And I would say we did not anticipate that this type of training approach would spread so widely to universities across the country and across the world. I believe it's fair to say that Stanford Biodesign has had a major influence here—and the scale is way beyond what we imagined.

**MTS:** *Let's turn now to Todd and Lyn. To set the stage for the next discussion: 168 fellows have gone through the Biodesign fellowship programs and more than 1,000 grad students have taken Biodesign courses in medtech development. Todd, as the director who is now running the fellowship program, can you give us some sense of who the fellows are today? Do they have a different profile than those who were in the program during its early days,*

*given the maturation of the program and the way it's taken hold in this community?*

▶ **Todd Brinton:** First, I echo what Josh said, which is that the fundamental process that we're teaching has not changed. It was the same when I was a fellow in the third or fourth year of the program as it is today. That said, I think some components of it have changed and, though the fundamentals are the same, I think we're learning how to teach a lot differently than we did and how to apply our insights differently. I think the type of people that were applying has changed and the type of the people we're taking into the fellowship has changed.

**MTS:** *In what way?*

▶ **Todd Brinton:** 15 years ago when Josh was a fellowship director, and even ten years ago when I got the opportunity to take over what Josh had started, we were looking for a traditional medtech person who was building surgical tools, some disposables, and maybe a few implantables. This idea of health tech and wireless and mobile didn't exist. We didn't have the iPhone, we didn't have any of those things that we have today. Now we're looking at people who are in computer science and other related fields. We consider people with a much broader range of professional and education experience and much more experience than fellows have had in the past. Before we were primarily recruiting clinicians and mechanical engineers. It's a lot different now.

We've also changed in the sense that we now conduct a huge international search of fellows. We're no longer just putting up posters at Stanford and saying let's take a couple of doctors and some engineers. Now through word of mouth and the other centers we've dealt with internationally, we have a much bigger pool of people than we had before. And it's a competitive process that's managed by an admissions committee. Each year, we get about 150 applicants for 12 spots so it's not an easy process.

**MTS:** *Have the criteria changed as the program has evolved? Are you now accepting more seasoned folks, people with more experience? Do they need to have spent time in industry or can they come right out of undergrad or grad school?*

▶ **Todd Brinton:** I think that has changed a lot, too. We used to get a lot of people right out of grad school. Now, we



tend to take people with more experience. They've gone to business school or gotten an MS or PhD in engineering and then they've worked for a few years. Or they've practiced as a clinician for a year or two, or at least doing most of their residency. They have enough experience to have seen how the healthcare system works and want to make a difference through the application of medical technology.

**MTS:** *I know that you recently did some focus groups with the fellowship alumni. Can you share some of the findings of your research?*

▶ **Lyn Denend:** Let's start with the curriculum. As Josh and Todd have indicated, the fundamentals of what we teach and the core of the process really is the same, but one of our big challenges is making sure that what we're teaching and how we're teaching it is adapting to the environment around us. Paul hit on a couple of the really big things that are changing. But we recently did some focus groups with fellowship alumni and asked them, "what do you wish you learned when you were here?" "What do you wish you had more of?" We gather that feedback and try to adapt the program in response.

Health economics is one of the big things that is really top of mind for everyone. So we're trying to do more to teach people how to look for value-rich opportunities and then estimate how great an improvement or a reduction in cost they would have to deliver with a new technology to get stakeholders interested in making a change. It's not just about constructing a downstream value proposition anymore, but really thinking about those things very early and continuously through the process so you come up with a solution that can really be successful in this very competitive, demanding, cost-sensitive marketplace.

**MTS:** *Todd, you went through the program it sounds like 10 years ago or so?*

▶ **Todd Brinton:** Twelve years ago, and Josh was the fellowship director.

**MTS:** *How is the experience for someone today different from the experience that you had?*

▶ **Todd Brinton:** There are two parts to that question. I think it is different. There are more teams. There were only four fellows when I was training, and now we have 12, so it's a bigger program. We have a suite of graduate and

undergraduate courses that we offer as well, so the culture here and the amount of drive and interest in Biodesign innovation is a lot more robust than it was in the fourth year. I think back then, the interest was in certain specific types of devices. Now people are really looking outside the box, really trying to change the way we do healthcare.

**"We're trying to do more to teach people how to look for value-rich opportunities and then estimate how great an improvement or a reduction in cost they would have to deliver with a new technology to get stakeholders interested in making a change."**

—Lyn Denend

Again, I think the focus on value has been a big change for us. It's no longer just about being better. You have to be better and you have to be more cost effective. You have to drive more value. We're grinding that into everybody, whether they like it or not. When you're developing a technology, you can kind of kid yourself that it's the coolest thing in the world, but if you can't find someone to pay for it in the new healthcare system, ten years of work doesn't matter.

For myself, I would say that the transition from being a fellow to having the opportunity to lead the fellowship and work with the fellows every week has been one of the most rewarding parts of my career. The theme that hopefully comes through tonight is that mentorship is probably the single biggest aspect that can make an impact in your career. We say here at Stanford that intelligence is a commodity, but it's what you do with it that matters. It's also the people that help get you there in training.

The things that Josh, Paul, Tom, and lots of other people, like Jay Watkins and many other people in this room, contribute to the fellowship and the other Biodesign training programs is remarkable. Being able to be part of that has been a big change in my career. I would never have anticipated being in this spot if you asked me ten years ago.

**MTS:** *Can you give us some sense of where the fellows go and what they do after they leave the program?*

▶ **Todd Brinton:** I would say that the big thing is there's no single trajectory. In fact, we have multiple different

pathways that our trainees follow. To name a few, there are clinical/academic innovators. These are people in clinical practice or academic practice. We have corporate innovators. These are people that have gone to large caps and are in leadership positions, changing the way that large caps think and innovate. The last group is the entrepreneur-innovators, which is our largest group. These are the folks who really want to start something on their own and develop a novel technology on their own.

**"I think back then, the interest was in certain specific types of devices. Now people are really looking outside the box, really trying to change the way we do healthcare."**

—Todd Brinton

**MTS:** *Of the three paths you've described, what's the approximate breakdown in terms of percentage of fellows that fall into each?*

▶ **Todd Brinton:** I would say it's probably 30%, 30%, and 40%, respectively. We get a pretty equal distribution. But even within these groups, the fellows are very heterogeneous. For example, we have clinicians who are practicing every day, clinicians who are academics, and clinicians who have trained clinically but are now in the industry as entrepreneurs.

**MTS:** *What's the value to someone who's going to back into clinical practice in understanding how the process of innovation works?*

▶ **Todd Brinton:** Tom likes to say that you can give someone a fish or you can teach them to fish. For clinicians, there is, of course, the ability to care for the person in front of them, one on one. But when they work in the medical technology sector, they can have an exponential impact on many patients.

I also think that for clinicians in particular it's a totally different type of training. Clinicians are generally fearful of making mistakes. Their careers will hopefully be defined by how few mistakes they make clinically. In innovation, you're hoping to have a big success. But every day involves learning from failure—getting up from failure and trying to turn it around and do it again so you can be successful. If you're

a clinician you need to have that cross training to be able to think outside the box.

**MTS:** *In the results from your focus groups, you asked the fellows both what they liked most about the program and also for a wish list of things they'd have liked to have seen from it. Can you share their thoughts as to what was most helpful to them and what they would have liked to see more and less of?*

▶ **Lyn Denend:** One of the things that people really enjoy is the multidisciplinary nature of the teams and the opportunity they have to work with clinicians and engineers, as well as interfacing with stakeholders across the ecosystem. This really does help prepare them to be successful whether they're inside a big company or starting their own organizations.

**MTS:** *A lot of the things the fellows put on their wish list were geared towards preparing them for success in the marketplace. Among the things they said: 'We need more help learning how to do technical de-risking so that we have trial results and other things that will convince investors that we know what we're doing.' Did you get the impression that later stage issues have become more important?*

▶ **Lyn Denend:** The environment for implementing these technologies is tough. So issues like finding funding, having a solid business plan, developing a good value , and getting prepared to implement new technologies are really critical.

**MTS:** *I'm glad you framed it that way because one of the things that stood out to me on the wish list was something characterized as 'downstream commercialization.' I would argue that 15 years ago, few small medtech companies worried about commercialization because they figured they'd get acquired before they had to confront that. Today, more and more exits are happening only after the company has demonstrated demand in the marketplace. If you go to centers of innovation like Ireland and Israel, the one thing everyone comments on is that, notwithstanding all of the technological innovation, there is a lack of marketing or commercial expertise. To what extent have those things become part of the curriculum now?*

▶ **Todd Brinton:** The commercialization issues ultimately come back to value, to understanding how to be compelling

when the healthcare system is changing all the time, and not just in the US, but in Europe and Asia as well—being able to understand how to build a true value proposition. The question is how to build a business and get to market, rather than just to develop a new technology.

**MTS:** *Lyn, in addition to the fellowship program and the Biodesign courses, you've been instrumental in the publication of a textbook that has come out of this program. Can you tell us a bit about the book and how it fits into the overall scheme of what Biodesign is trying to do?*

▶ **Lyn Denend:** We were actually all involved in writing the book and we had a lot of fun doing it. The Biodesign textbook stemmed from our graduate-level innovation class. There were no teaching materials available on how to do medtech innovation.

So we said, let's write ten papers, ten pages each. We'll just bang them out on the ten most important topics. As soon as we wrote those we discovered that they were really helpful to the students so we wrote ten more. Once we had the whole set, we decided to package them up and shop them to a publisher. We were able to get some interest in writing the textbook and 700 pages later we came out with our submission. The best part of this is that it broadens the scope of what we can do, because at Stanford we have a finite teaching team.

And the process we teach is very high-touch. As Todd said, it depends on mentorship. Writing the book at least gave us a way of spreading the Biodesign innovation process to programs across the country as well as around the world. The first edition of the book sold over 10,000 copies. Then we wrote a second edition. We thought we might update the 20% of the content that would give us 80% of the impact. But that didn't work out so well. We rewrote more than half of it, with more case studies and more value orientation and better information on commercialization planning and the globalization of the medtech field. But we feel that's an important way for us to give to the community as a whole.

**MTS:** *We'll pick up the theme of how the program is changing in just a minute, but let me end this part of the discussion by returning to a topic we discussed before: where do Biodesign's relationships with the medical device community stand today, with both industry executives and venture capitalists? As I said earlier, I sense there's a greater awareness today than there was even ten years ago, and I know many of them have come to participate in*

*mentoring programs. Has the relationship changed over time? Or is it pretty much the same as it was during the early days?*

▶ **Todd Brinton:** First of all, they're a critical part of the ecosystem. You need investors. You need the corporates, not just to put the money in, but as we said, as mentors. We have many executives and many of the venture people come in regularly to teach in the graduate class and meet with the fellows.

▶ **Paul Yock:** They've made a huge commitment to helping train the next generation of innovators in the health technology field.

**MTS:** *Let's turn now to talk about where the Biodesign program will and might go in the future. I want to start with an area that I think bridges both present and the future—the globalization of Biodesign. There are now Biodesign programs in places like China, India, Singapore and there are also programs outside the US that have modeled themselves after Biodesign, like Ireland's BioInnovate program. Can you tell us how those programs came about and how they build on what the Biodesign program is trying to do?*

▶ **Uday Kumar:** I was fortunate to be a fellow ten years ago myself and, like Todd, I really learned a lot from the program and wanted to give back. Around ten years ago, we realized that Stanford was interested in exploring global opportunities so we started a global fellowship in India and then more recently in Singapore. I was fortunate enough to lead the teaching of the Biodesign process to these global fellows for almost a decade.

A lot of what we've learned has a lot to do with value, which you've already heard a fair bit about. Many other countries have been thinking about value by default because they've had to. It wasn't a choice. They didn't have the luxury to spend 16-18% of GDP on healthcare. The nature and state of their economies just didn't give them that opportunity. So in the last eight years as we've learned a lot about other countries and other economies, that learning has translated to a lot of what we've done and what we've incorporated into our programs. In terms of your question, David, I think the global network is just as much about what we can learn from other countries as what we can teach them. This larger network has really helped shape how we intend to move forward.



Along these lines, as Stanford Biodesign moves to becoming a Center that's going to be on the Stanford campus indefinitely, we took our desire to understand how we move forward and focused on creating a clear vision. A few of us sat down and thought about what we've learned over the last 15 years. It's not just about the people. It's about what the people end up doing. We realized that we really wanted to bring everything back to the patients we serve. Ultimately a lot of what we do when we're dealing with a medical or health technology should help somebody.

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—Uday Kumar

After thinking about it at length, we decided on the vision statement "to be a global leader in advancing health technology innovation to improve lives everywhere." It's a very simple statement, but I think it captures the essence of what we've been doing abroad. We learned a lot, we've been able to teach a lot, but most importantly, we hope this network of people we've taught can help improve lives everywhere.

That was a great framework for thinking about what we want to be for the next ten, 15, 20 years and hopefully forever. For the last 15 years, our mission has really been to empower and educate innovators, so we really focus a lot on the fellows and what the fellows do. But it has to be broader than that. I think we've realized that our mandate now is also to take a leadership position, which is what we've been doing with our book and with our global network. It can't be just about teaching innovators; I think we also have a responsibility to lead based on where we are and what we've done and all the people we've trained.

**MTS:** *What does that broader vision look like?*

▶ **Uday Kumar:** We created the following mission statement: "educating and empowering health technology innovators, and leading the transition to a value-driven innovation ecosystem." Just like before, the first part is about educating, but now we believe it's important to also empower the innovators we touch. Part of empowering is using our network to allow these fellows

who have this education to take it to the next level and allow our teaching process and new innovations to reach more people.

Probably the biggest change is that we are actually accepting the position of leadership in the space. And we'd like to help lead a shift in to a more a value-driven healthcare system in the US and beyond.

Finally, something worth noting is that we realized the definition of medtech has changed. When I was a fellow, it was all about developing stents, implants, and pacemakers. But these days the toolbox of technologies for solving needs has changed. We also realized that cost has to be taken out of the system, so how we move to a lower cost of care—which means out of the hospital or into ambulatory settings or moving from acute episodes of sickness to prevention—becomes very important. Thus, we realized we're not just creating new medical devices. We are really innovating new health technologies in the broadest sense, from early prevention to late-stage disease, so that's why you see our mission statement focused on health technology moving forward.

**MTS:** *You frame globalization in a very large context. Let me ask a more specific question concerning how translatable the principles and training around innovation are to other countries. Do the Biodesign programs in Singapore and India have the same curriculum as the one in the US? Does the program look very similar? Or, given the important differences in the healthcare systems in those countries, is the content of those programs very different?*

▶ **Uday Kumar:** As you've heard, our process is very universal. But our global programs are focused on in-country innovators because it doesn't make sense for people from the US to parachute in and try to understand all of the cultural and societal norms or how healthcare is delivered, when they haven't experienced it themselves.

What we do is bring fellows here for six months to do the exact same program as our US fellows but in a condensed way. All the things that Todd teaches, we teach the exact same way to the global fellows. But the whole of that is a kind of a dry run, if you will, for when they go back to their home countries and repeat the process in that local context. Our goal is for them to use what they've learned to solve the problems of a developing world—in India or in Singapore and more broadly in Southeast Asia. Again, the principles are the same but the context is very different. Fellows from those countries understand this context and thus can come up with the correct constraints within which to solve a problem. Universal but applied.

**MTS:** *Tom, let me bring you in here. We've mentioned several times today that the medtech industry is facing new challenges and opportunities and that it's gone through cycles—at times it's been easier to raise capital, at others harder; the regulatory process has been challenging at times, at others less so. The physician component of the program has always been key. As a physician, how do you think the program has had to change? What's different about healthcare today for physicians that might shape what the Biodesign program is all about?*

▶ **Tom Krummel:** First of all, I'd make the observation that I think the principles of Biodesign make for better doctors because it makes you a better problem solver. Instead of jumping to a conclusion, it makes you try to understand the problem. I've encouraged our trainees to participate because I honestly think it makes you a better doctor. In the end, this is about taking care of patients and for us, I think it's about broadening the scope of the impact. If you are one doctor doing one thing, you get one RVU [relative value unit], but if you train the next generation to innovate, we think the scope and scale can be profound.

I think the other thing that's gotten more interesting as tools and technology have changed is that the nature of our partnerships has changed too. Who could imagine that Intel would have a CMO? Who could imagine that [Facebook CEO] Mark Zuckerberg would announce that he wants to cure all human disease within the century? Where else would we want to be but in the valley, and in particular, at Stanford?

I want to come back to a comment Paul made. I think at the average university, this would have been snuffed out in a heartbeat. The fact that we had John Hennessey as a president, who happened to mentor two grad students, Larry [Page] and Sergey [Brin], who now happen to be on the board of directors at Google, is critical. John talks about the porous walls of this university and I think our ability to be inside and outside, to have so many of you who are working in the real world here as colleagues, friends, coaches, teachers, and mentors is incredibly powerful. And I think there really is a new group of partners, whether it's Google, Apple, Facebook.

**MTS:** *You raise one important change the medical device industry constantly faces: new technology horizons. Over the past 15 years, new technologies have frequently brought new capabilities and opportunities to medtech. Today, digital seems to be the best example; neuromodulation might be another. Where do you see the technology horizons going and does the program change more*

*fundamentally when you're talking about bringing to the fore digitally based or sensor-based technology than a more traditional catheter-based or implant technology? How are you preparing the Biodesign program for a world in which Google and Johnson & Johnson are now collaborating on a robotic system? (See, "Verb Surgical: Surgery in the Digital Age," *The MedTech Strategist*, May 13, 2016.)*

▶ **Tom Krummel:** One of the most compelling covers on *The Economist* magazine less than a year ago showed the globe with all of the countries made up of cell phones. By the year 2020, 80% of the world's adult population will have a super computer in their pocket. That makes you think very differently about distributed health. The patient is no longer

**"By the year 2020, 80% of the world's adult population will have a super computer in their pocket. That makes you think very differently about distributed health."**

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someone in the hospital. The ability to connect and be connected at any point in the globe becomes profound. It really changes the definitional piece. I will come back and say that I think the problem solving—the understanding of the problem and the need—doesn't change, but the tool box that we use to get there is now much more powerful.

**MTS:** *I'm intrigued that a fairly significant percentage of the fellows go back into clinical practice. What's the impact of a physician returning to clinical practice with a better perspective on needs identification, innovation, and, in particular, on the economics of innovation, which has become such an important part of the equation today?*

▶ **Tom Krummel:** If you talk to two guys that I give huge credit to as personal mentors, Tom Fogarty and Rodney Perkins, both of them have said that [understanding the innovation process] makes them better doctors; they understand the problems. They're not an administrator or a C-suite person, but rather a colleague who can talk to a urologist or a cardiologist on an even footing so that they can really come to understand what the problem is. Once you're out of the clinical world for five years, the world has changed by at least 50%. My message to the docs is that the Biodesign program doesn't necessarily mean you have to give up the practice of medicine.

**MTS:** *Let me ask one more question about health economics. When you think about the cost pressures and scrutiny around cost and value that we're seeing today, does that fundamentally change the kind of technology that comes out of a program like Biodesign or is it simply a screen against which technology has to be measured? Given the cost pressures today, is appropriate innovation about factoring cost/benefit analyses into the kinds of devices we would normally bring forward? Or are we talking about developing a whole new set of tools to address issues like cost, efficiency, and value?*

▶ **Uday Kumar:** I don't think it actually changes the technology. I think it's just become more of a focus. As you mentioned, ten years ago, people would ask about a new device, 'Do you have a good need and do you have a good solution?' That was it. Now, it's 'Do you have a good need, Do you have a good solution, Do you understand your regulatory pathway, Do you know how you're going to get paid and in the process deliver clinical and economic value?' There are a lot more questions today, and we're realizing that if you really want to do this right, you need to codify these questions at the time you're looking for your need. If you wait to ask these questions until after you've looked at your need and get to your solution, you're already too far down the road. That's when people have a tendency to try to rationalize how cost-effective their technology is when it actually might not be.

▶ **Josh Makower:** I think many of the investors around the valley routinely say: before you even know how you're solving a problem, tell me how this is going to actually improve clinical and economic outcomes. But I think we do tend to get enamored quite a bit with all of the technology that's out there. Again, we're fundamentally a program that says technology is good. We now have more things with which we can solve problems, but that's not what should drive the problem solving.

▶ **Paul Yock:** I think what's changed is that cost has become part of the need. Before, cost really wasn't something we thought too much about. We looked at the clinical problem, the physiology, et cetera. Now, we realize cost can limit the ability for technology to actually touch people's lives when it's too expensive or if they can't get coverage for it. The ability to now factor-in cost is a really big difference.

**MTS:** *As I said before, I hear so many people even outside Palo Alto talking about the program and it now has a global reach, not just through Biodesign programs but in programs run by others. I'd like to end by having you all weigh in on what, after 15 years, you think is the legacy of*

*the Biodesign Program? How close to your original vision is that legacy?*

▶ **Paul Yock:** I think both the process and the way we're approaching training the process is the legacy. And it makes me want to highlight one point, which is the fact that we get such enormous help from the community.

▶ **Josh Makower:** What's great is the fellows, the alumni, and the students who have been here, and to see the technologies they're creating. It's also gratifying to see their own commitment to training and mentoring the next generation of innovators who come behind them. I think we've really accomplished our goals through their accomplishments.

▶ **Tom Krummel:** The big legacy of any great university comes from the graduates and their contributions to the world for the rest of their lives. I think we've been able to move the needle on those that have come to work with us. I think we've taken some silver medalists and turned them into gold medalists. For the rest of their lives, they will make contributions, and to me, that is the gift that keeps on giving and why I get up every morning to play a role in this.

▶ **Uday Kumar:** Stanford Biodesign has become kind of the standard for how to think about biomedical innovation and, because of that, it's had a multiplier effect not just from fellows teaching students and students teaching when they graduate, but also now in programs teaching programs, and these new programs teaching their own fellows, their own fellows teaching students, and so on. If you were able to see this on a map, it would look viral and that's not easy to accomplish—it's rare and very special.

▶ **Lyn Denend:** I fundamentally agree. It's all about the people and that is really why I personally am so excited to be a part of Stanford Biodesign. But the other thing is that we go to different places around the world and attend conferences with other universities and they tell us that they're using our teaching materials. It's little things like that that show us the work that we're doing is being adopted and helping people train more innovators around the world. That's exciting.

▶ **Todd Brinton:** The brand is the people and the reason that the brand is getting recognition internationally is because of those people. It's hard to go someplace in this fairly small medtech community and not bump into Stanford Biodesign. You see this when people are looking for jobs or looking for support for their ideas. The alumni now are completely organized and structured. They have events. They help each other out. This thing has really exploded. 📦