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Dean Kamen, who invented the Segway almost 20 years ago, is still busy inventing. Now, at the age of 69, he is working on the most ambitious project of his career: manufacturing organs. Photos: Tony Luong

The Segway's Inventor Has a New Project: Manufacturing Human Organs

When the FDA approves lab-grown human organs for patients, Dean Kamen wants to be ready to mass-produce them

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This past January, the umpteenth version of the Segway Personal Transporter whisked attendees around in its white, egg-shaped seat at CES, the huge annual consumer electronics show in Las Vegas. Called the Segway S-Pod, it drew comparisons to the hover-chairs in *Wall-E* that shuttled around people so out of shape and blob-like, they'd forgotten how to stand.
This is not how Dean Kamen, who invented the Segway almost 20 years ago, imagined his legacy.

Kamen was inspired to create a device like the Segway in the early '90s, when he noticed a young man who'd lost his legs in a wheelchair at the mall. It seemed like everywhere Kamen went that night, he bumped into the guy, seeing him unable to get over a curb or reach a high shelf at Radio Shack, too low to be noticed in line at the ice cream counter. Kamen had already been thinking about how to help the disabled. "And I just decided, you know what?" he says. "I'm going to solve that problem."

It took Kamen years to create a wheelchair with gyroscopic stabilizers, computer chips, tilt sensors, and special wheel clusters that could rear the chair on its hind wheels, allowing users to "walk" at eye-level with the able-bodied. Then, when he realized he could apply the same technology to the standing masses, his ambition grew. He believed the new device, which he called Ginger (after Ginger Rogers) and eventually renamed the Segway, would transform cities, replacing cars and their pollution with residents gliding down green streets, each one on a Segway. By the time the device actually launched, in December 2001, on a *Good Morning America* special, hype around Kamen and this vision reached a peak, complete with rumors from a leaked book proposal that Jeff Bezos and Steve Jobs both expected the Segway would be the next big thing. Shortly before its release, Kamen told *Time* magazine the device would "be to the car what the car was to the horse and buggy."

That never happened. Instead, the Segway became a regular feature of no-longer-walking tours and mall security, and Kamen moved on. In 2009, he sold the company to James Heselden, who accidentally drove his own Segway off a cliff and died. Today, the company is owned by Ninebot, a global brand headquartered in China that has found a new consumer market and will release at least three new Segway models this year.

Meanwhile, Kamen is still busy inventing. His company, DEKA (for DEan KAmen) Research & Development, in Manchester, New Hampshire, employs nearly 800 engineers. Since his first commercial invention — a wearable infusion pump that he built in high school — he has innovated a number of medical pumps and stents; a futuristic prosthetic robotic arm for amputee soldiers; a "Man Cannon" that launches SWAT personnel onto a roof; and the Slingshot, a purifying machine that brings clean water to villages in developing countries. And new ideas keep coming, whether that's building a Coca-Cola fountain vending machine that can make different 150 drinks, or an at-home dialysis unit that means patients won't have to go to clinics. He started a nonprofit, FIRST Robotics, to encourage kids to start inventing. And when the Covid-19 crisis hit, he refocused his firm's attention on manufacturing sterile solution for IV bags, which he believes will be in short supply, and inventing better mask materials.

But none of these many inventions — including the Segway — has an impact that comes close to what could be accomplished by the most ambitious project of Kamen's career: building human organ factories.

In December 2016, at the age of 65, he and his collaborators won an $80 million Department of Defense contract to manufacture replacement tissue and organs on-demand. Wounded soldiers need body parts, the DoD explained at the time. And so do Americans on organ transplant waiting lists — 111,000 people, at last count.
Kamen used the grant to help start the Advanced Regenerative Manufacturing Institute (ARMI), a nonprofit consortium of some 170 companies, research institutions, and

organizations from across the country that pay an annual fee, provide equipment, or contribute in other ways in exchange for sharing research and resources. Including the DoD grant, the project is funded to the tune of about $300 million.

Plenty of scientists are trying to grow organs. But what sets Kamen's group apart is that he's working a step ahead: He's making the tools and machinery to mass-produce those organs, if and when the Food and Drug Administration (FDA) approves them for patients. He wants to pump out hearts and kidneys much the same way factories produce smartphones: in high-tech assembly lines.
Kamen, now 69, says ARMI will start to get there — "whether it's an organ or piece of organ" — within a decade.

Though industrializing human organ production may sound like a moonshot, Kamen has a track record of unlikely adventures into which this goal seems to fit. In 1986, he became Lord Dumpling — Dumpie to his friends — after he bought a two-acre island off the Connecticut coast called North Dumpling. He tricked it out with its own constitution and currency (dumplings, naturally), and ran it on solar and wind power. His main home 20 minutes outside Manchester, too, is befitting of a man with an outsize imagination. A huge hexagonal acropolis, the house is built around a multistory steam boat engine that once belonged to Henry Ford, has a few secret doorways, and a wall that opens onto a hanger where his helicopter awaits. The flying time between his home and DEKA's roof is three minutes, he says.

The BioAssemblyBot. Photo: Courtesy of Advanced Solutions.

Kamen turned to the artificial organ project about four years ago. That's when he met Martine Rothblatt, a fellow eccentric visionary who co-founded Sirius XM. After Rothtblatt's daughter was diagnosed with a rare condition called pulmonary arterial hypertension, she started United Therapeutics, a biotechnology company, to develop drugs to treat it. Rothblatt told Kamen that in addition to pharmaceuticals, her R&D team was working on growing artificial lungs from patients' stem cells that are seeded on scaffolds. He went to visit UT's labs in Silver Spring, Maryland, and Research Triangle Park, North Carolina, to see for himself. There, he was struck by how dated the equipment was — "borrowed from Madame Curie," as he describes it. He told Rothblatt he could add sensors and systems to improve accuracy and keep things sterile. The two had already begun collaborating when they heard that the Department of Defense was calling for proposals on a scalable process of manufacturing human organs.

There's been exciting progress growing organs in the lab over the last 15 years. One of the most exciting developments has come out of Wake Forest University School of Medicine's Institute for Regenerative Medicine. There, in 1999, Anthony Atala, MD, grew a bladder and implanted it in a patient. Since then he's improved the technique, which like UT's artificial lungs, involves creating a scaffold of a bladder and infusing it with the patient's cells so the organ is not rejected.
Many internal organs, however, have yet to be grown in a lab, much less put into a patient; even the bioengineering of most tissues like muscles and ligaments is still in the early research stage.

Still, Kamen could see the potential of engineering systems with data-measuring and quality control capabilities — not only to speed up bringing all this science into clinical practice, but to then speed up scaling it. Eventually, he saw, the field would need special 3D bioprinters that, instead of using plastic or metal, print living cells and produce organ scaffolds. It would need equipment like bioreactors to grow and cultivate the stem cells that are eventually implanted on these scaffolds. And it would need custom technology to measure and monitor in real time what's happening with those cells on the way to becoming an organ. He could get a head start on building these tools.

Betting on success for growing organs, Kamen compares scaling their manufacturing to the way Silicon Valley turned an understanding of semiconductors into creating transistors so small and cheap that the tech industry now churns out phones by billions. *"So I thought, why don't we do the same thing for living tissues,"* he says. *"There ought to be a way to make a high quantity of them, a high quality of them, and at a realistic cost for the American public that's in desperate need when they have an organ failure."*

When Kamen and Rothblatt saw the Department of Defense's call for just those solutions, it felt like the DOD "were a fly on the wall to our conversations," marvels Kamen. "And we said, this is a major opportunity."

During the process of applying for the grant, Kamen had several meetings with the DOD. *"I told them that I'm going to collect extraordinary people that have different backgrounds, that probably don't interact now,"* he says*, "but if they did would dramatically accelerate the path to a major breakthrough."*

To form ARMI and BioFabUSA, the entity within it that will eventually carry out the work of manufacturing these organs, Kamen attracted members like Rockwell Automation, which put in $10 million, and universities like MIT and UCLA. Then he went about recruiting the most cutting-edge companies in the field to join them. He hired a staff that's now around 25 people, including two former FDA officials Richard McFarland, MD, PhD and Becky Robinson-Zeigler, PhD, who run the regulatory program. He also won the support of New Hampshire's governor Christopher Sununu and U.S. Senator Jeanne Shaheen. Executives from Microsoft and Boston Scientific are on the board. So is Rothblatt.

The historic Amoskeag Millyard, which winds along both sides of New Hampshire's Merrimack River, once produced nearly 500 miles of fabric a day, and dates back to the 1830s. Now Kamen owns about a million square feet of the hulking red brick factories. This is where both his company and his human organ projects are based. Teams from ARMI's member companies and research institutions have set up shop in Millyard buildings, and they're working on different approaches to the same goal side by side. Someday Kamen hopes these old textile factories will become a hub of organ manufacturing**.**

The historic Amoskeag Millyard, where DEKA and ARMI/BioFabUSA are based. DEKA employs nearly 800 engineers.

It's still early days. But a prototype manufacturing platform is already taking shape in BioFabUSA's offices.

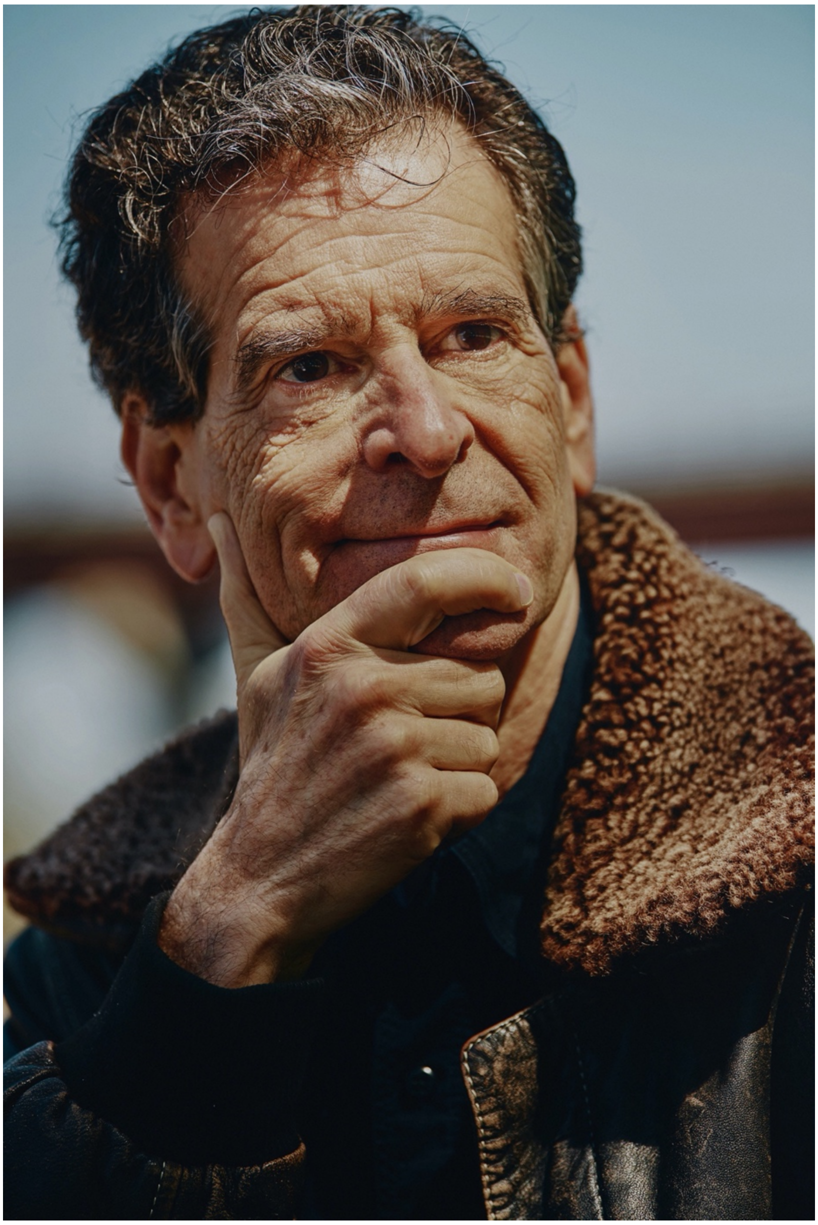
ARMI member STEL Technologies is developing bioengineered anterior cruciate ligaments (ACLs), a key stabilizing tissue in the knee that is often torn or overstretched. Based in Michigan, they're doing it all by hand and working with McFarland, one of the former FDA officials on ARMI's staff, on getting FDA approval. Meanwhile, BioFabUSA has innovated a "line" of equipment that can automate the process. It starts with a frozen vial of stem cells pulled out of a patient's bone marrow. The cells are thawed and pumped into a broth, where they multiply for about a week. Then they're nudged by chemicals in a second medium to start making tissue; finally they go into a bioreactor to form the 7-centimeter segment of bone-to-ligament-to-bone that is the person's new ACL.
The whole process takes 45 days, as it does by hand. But the BioFabUSA automated prototype doesn't require a cleanroom or technicians coming in and out working with the cells — reducing both cost and error.
"When you're in this industry and you're thinking about scale, you can't go to Home Depot," says Michael Lehmicke, director of science and industry affairs at the Alliance for Regenerative Medicine, a nonprofit that advocates for the commercialization of tissue engineering and gene and cell therapies. "It has to be medical-grade materials. What's unique about ARMI, is they're thinking of how you would actually scale the system when it is fully commercialized."

Tom Bollenbach, ARMI's Chief Technology Officer, says teams are now at work on five new lines, including muscle, bone, insulin-making beta cells and islets. According to Giuseppe Orlando, MD, PhD, a regenerative medicine researcher and transplant surgeon at Wake Forest Medical School who is not involved with ARMI, producing the last two to treat Type 1 diabetes will probably be the next major breakthrough in medicine.

ARMI is also collaborating with the Texas Heart Institute to develop a manufacturing line for a children's heart, the platform's first attempt at a whole organ.
The ACL prototype line has been built to accommodate a 3D bioprinter to make a scaffold, say, of a heart or kidney, which it will then impregnate with the patient's own cultivated stem cells for an exact match. UT's team has now set up shop in the Millyard to continue researching how

to 3D-print its own lung scaffolds, complete with the bronchi and nearly 500 million alveoli, then mature each with a patient's cells for transplant. The need for lungs is critical: "At times you don't even bother matching because there's such a shortage," says Luis Alvarez, PhD, UT's director of organ manufacturing. "After five years, a significant fraction of people haven't made it, a lot of it due to immunosuppression."

Advanced Solutions in Louisville KY, another ARMI member that has also opened a branch in the Millyard, is focused on the manufacturing side. "BAB," their BioAssembly Bot, 3D-prints human cells and has a six-axis robot arm that makes structures, holds tools, and does assembly. With BAB, engineers at Advanced Solutions have used cells from belly fat to create blood vessels, and they're currently working on vascularizing a liver with another ARMI member. "In a lot of cases we have moved beyond scaffolds," says engineer and CEO Michael Golway. "BAB is so flexible she really allows us to do design tissue structures in a way that we can add the cells, so that it can be 100% living."



Kamen stands by his bet that "within 10 years it will be as common as a lot of standard medical procedures to have a defective organ or piece of an organ replaced."

This year, ARMI is building a new facility to focus on quality control — perhaps one of the most important pieces of an organ production line. So far, says Bollenbach, "that's been a shot in the dark. Because what does quality mean? It means it's going to work in the patient and it's safe, right? So if you're making a lipid, it's got length, width, height, but what do you measure that's important? And those are the questions we're going to answer definitively."
Between creating quality control, fostering collaboration in the field, building the manufacturing platform, and working on data gathering, Lehmicke says, "There's no individual company that's really doing what [Kamen is] doing. If you talk about trying to build tissues, I'm not aware of anybody else who's shooting at that target as actively as they are."

Not everyone is as optimistic as Kamen about a timeline toward mass-produced organs. Wake Forest's Orlando thinks we're still about 50 years away from what Kamen is promising. But all it takes to make it sooner is a single person having "an intuition that can change completely the way we do things." He points to 2012 Nobel Prize winner Shinya Yamanaka, who upended the status quo that stem cells only come from embryos, by discovering that you can actually make adult cells act the same way. Orlando suggests that such leaps of thought are often fostered by the kind of environment we have now with regenerative medicine, which 12 years ago was "like a few players in a club for fanatics who were following some belief" and has become a booming field based on hard science.

Kamen knows there are doubters. Throughout his career he's paid little attention to them. "Will it take 50 years? Absolutely not,"' he says. "Will it be 25? Five? It's not going to be a bright line." He stands by his bet that "within 10 years it will be as common as a lot of standard medical procedures to have a defective organ or piece of an organ replaced."
Of course, he was just as bullish 20 years ago with the Segway. But he's learned a lot since then about the art of collaboration and about inspiring the kind of power players who can push his concepts and bring them to life. If anything, the Segway only reinforced his itch to reach for seemingly impossible goals. "If a project doesn't pass the threshold of 'wow, if it works, that's a really big idea,' we don't do it," he says. "We never do a project because, oh, couldn't we make a buck?" he says. "Life's too short for that."

Advanced Solutions' Golway says he was sold on ARMI halfway through dinner with Kaman in 2017. Now he's partnering with other members, evolving BAB to work on various organs. However the Segway panned out, he suggests, perhaps it was the segue that carried Kamen forward on the path to what might truly change the world. "If this project was brought to him early in his career would he be as effective as he is now, with all those years of experience, all the political clout that he's been able to gain, all the credibility?" Golway asks. "Dean has been training for this moment his entire career. This is the project. This is it."