JUST BECAUSE YOU'VE BUILT A BETTER MOUSETRAP, DON'T ASSUME THE WORLD WILL BEAT A PATH TO YOUR DOOR.

From Mind to Market

Every invention starts with a problem. For Jim Geiger, M.D. — a young pediatric surgeon at the U-M Health System in the late 1990s — it was an unwieldy surgical clamp. Geiger often operated on infants with pyloric stenosis — an obstruction in the pyloric muscle that connects the stomach to the small intestine. In the beginning of his career, Geiger had to make a large abdominal incision to reach the pyloric muscle, but with the development of laparoscopic surgery, only a small incision was required. Less invasive surgery was better for the baby, but made it impossible for the surgeon to reach inside and hold the pyloric muscle steady before cutting it. To make it even more cumbersome, the surgical instruments used for the procedure were made for adults.

BY SALLY POBOJEWSKI · PHOTOGRAPHS BY SCOTT SODERBERG

Jim Geiger

The more Geiger tried to fit an adult-sized surgical clamp through a tiny incision in a newborn baby, the more he thought there must be a better way to do this.

Geiger sketched out some designs for new pyloric clamps to use on his tiny patients. He shopped them around, but his ideas went nowhere. It takes time and money to develop new medical devices, and Geiger had neither. The market for instruments used in pediatric surgery was too small for companies to justify the investment in new technology.

Then, in 2004, Jim Geiger met Albert Shih, Ph.D., a professor of mechanical engineering who was making a career transition to biomedical engineering. It was a fortuitous match: Shih wanted to collaborate with Medical School faculty who were interested in new medical devices; Geiger needed engineering expertise to develop his pyloric clamp.

Shih assigned the project to a team of senior engineering students enrolled in his design and manufacturing class. Geiger spent a lot of time working with the students to perfect the design for the clamp. He invited them into the operating room to see the surgery. And he came up with money to cover the cost of making a prototype.

With a working prototype and engineering specifications in hand, Shih and Geiger were able to interest executives at a medical device company. The U-M Office of Technology Transfer (OTT) licensed the device to the firm in 2008. Now, more than 10 years after Geiger first came up with the idea for a better surgical clamp, it is finally available to pediatric surgeons around the world.

The story of the pyloric clamp illustrates how difficult and time-consuming it can be to bridge the gap from mind to market, especially when the mind belongs to someone who works at a university.

Even if a faculty member has a terrific idea for a new invention, he or she might need help or have questions about the next steps in the process. Questions like: How do I create a prototype? Is there a manufacturer willing to make my device? Where do I go to connect with the right collaborators?

"We call it the fuzzy front end," explains Geiger, an associate professor of surgery and executive director of the U-M's Medical Innovation Center. "It's the very early stage of a project where it's still just an idea."

To help U-M faculty negotiate the "fuzzy front end" of the medical device innovation process, Geiger and Shih created the Medical Innovation Center, or MIC. The center was established in 2008 with nearly $2 million in start-up funding contributed by the Medical School and Department of Surgery, the College of Engineering, School of Dentistry, Office of the Vice President for Research and the Michigan Institute for Clinical and Health Research (MICHR).

"Our mission is to positively impact health by encouraging medical innovations that will actually be adopted — made by someone, bought by someone, used by someone," explains Geiger. "To accomplish this, we work closely with the Office of Technology Transfer. MIC has been characterized as a 'feeder' for OTT. By stimulating cross-campus collaboration, advancing innovative concepts and providing early stage technology development, we help supply quality medical innovations for OTT."

Though it's less than two years old, MIC has already had some success at soliciting external funding and is looking for more, according to Brenda Jones, the center's managing director. Warren "Bud" P. Williamson III — a U-M alumnus and chairman of Skye Management in Loveland, Ohio — is MIC's first private donor. With matching internal funding from MICHR, Williamson established an innovation fund to pay for initial product market assessments and prototype development.

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"At U-M, we have a ton of invention and discovery," says Geiger. "But in most cases, discovery does not directly impact health. That's one of the fundamental parts of MIC's mission. We want to be one of the agents that help move that discovery into a commercialized product that can impact people's lives. It isn't always a home run on the money-making front."

A DAUNTING PROCESS

When you talk about innovations in medical care, most people think of new therapeutic drugs developed by pharmaceutical or biotechnology companies. But there's another segment of the health care industry that is just as important. It's the $85-billion medical device and diagnostics market. More than 10,000 medical devices are now on the U.S. market, including everything from implantable heart-assist pumps to Band-Aids.

University inventors who have ideas for new medical devices face many barriers, but the most immediate is a lack of time. It takes a tremendous amount of time and sustained effort to nurture ideas through the initial steps of creating a prototype, perfecting the product design, identifying market potential, finding resources for funding and managing the project.

"We're all professors or clinicians and we are incredibly busy," says Geiger. "We are basically on the treadmill at full-speed already. You have an exciting idea, but where are you going to find the time? For many of these products, there is a limited window of opportunity. The market may only be good for five years. If you move too slowly, you're going to be bypassed. Let's face it. We are not the only ones with good ideas, so speed is of the essence."

Negotiating the U.S. Food and Drug Administration's regulatory approval process is another major hurdle in the way of faculty entrepreneurs with big ideas. Since 1976, to ensure the public's safety, all medical and diagnostic devices are legally required to be certified by the FDA as safe and effective for consumer use before being marketed or sold. It's a daunting process. The regulations are intricate and at times hard to understand; the paperwork is measured in feet, not inches; and the process is so complex that most academic inventors throw up their hands and abandon the idea of getting their invention onto the commercial market.

Academic institutions are in the education business, not the product development business. So, universities aren't likely to hire staff specialists who are knowledgeable about the arcane world of the FDA regulatory approval process. But the U-M is an exception.

Kay Fuller is the U-M's resident expert on working with

Adrienne Harris

the FDA to obtain pre-market approvals and conduct clinical trials testing for new drugs and medical devices. She is a MICHR project manager who joined the U-M in 2008, after a 30-year career in regulatory management for several global medical device manufacturers. Fuller works with faculty to manage paperwork and shepherd inventions through the FDA pre-market regulatory process. Private companies are much more likely to be interested in medical devices after they've received initial FDA approval, she says.

A member of the Medical Innovation Center Technical Advisory Group, part of Fuller's time is devoted to the center and its mission. One of her favorite parts of the job is advising and coaching five people with graduate degrees in medicine, engineering, science or business who have been selected for a Medical Innovation Center fellowship.

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MIC fellows spend a year studying how the innovation process works, identifying a need for new medical device technology, and developing a solution to fill that need. Along the way, they learn how to communicate and work together as a team to develop medical devices and get them on the market.

"Working in a multi-disciplinary group opened my eyes to the need for communication with business people and engineers," says Merrell Sami, M.D., who interrupted her residency in general surgery to spend a year as a MIC fellow. "It's like learning to speak a different language. But it's given me the tools to make something I feel is needed become a reality through industry."

One of the first things MIC fellows learn is that even the most promising new technology will go nowhere if it's designed in isolation without considering the preferences of the medical professionals who will be using it.

"As an engineer, something is either right or wrong," says Adrienne Harris — a 2008 MIC fellow who has a master's degree in biomedical engineering from the U-M. "In medicine, it's not that way. Go to one doctor or nurse and they'll say this is the right way to do it. Go two doors down and you'll get a different answer. It's based on personal experience — what they are comfortable with."

SECURE IDEAS

Check into any hospital or emergency room and the first thing that happens is someone shows up to stick a needle into a vein in your arm. It's part of what medical professionals call a peripheral intravenous catheter system — an integral part of health care delivery because it is the quickest way to get painkillers, fluids or medications into the patient's bloodstream. Every year, U.S. hospitals and clinics purchase about 275 million of these devices for about $6 apiece. That adds up to a $1.6 billion market.

Intravenous catheters have their problems. If the patient moves, it's easy for the needle to slip out of the vein, which cuts off the flow of medicine and can cause infections or blood clots. Many nurses were taught to tape the catheter to the patient's arm or hand to hold it in place, but that takes extra time, can be uncomfortable for the patient, and doesn't always work.

Adrienne Harris and the other MIC fellows think they have a better idea. It may not look like much to an outsider, but the little plastic device they've invented represents six months of hard work and could become the next blockbuster in the competitive catheter securement market.

"The downstream cost of treating a patient who has a complication from a misplaced IV catheter can be thousands or tens of thousands of dollars," says Fuller. "The fellows figured out the root cause of the problem: It's how you secure the device to the patient. They came up with four fabulous design solutions to solve the problem."

Toby Donajkowski

When they asked U-M nurses for feedback on their new catheter securement design, the fellows encountered another hurdle that's common in developing any new technology. Just seeing a sketch on paper, or an image on a computer monitor, is not good enough. People need to hold something in their hands to be able to imagine how well it will work.

That's where Toby Donajkowski, prototype specialist for the Medical Innovation Center, comes in. Instead of microscopes and centrifuges, his laboratory is filled with industrial drills, lathes and milling machines. Donajkowski's job is to create a working prototype of medical devices being developed at MIC. Building a prototype is a crucial step in the journey from idea to reality, and Donajkowski says communication skills are a major part of the job.

"There are a lot of unknowns when you start a prototyping project," he says. "I like to talk to the end-user first. If the person who's going to use this doesn't like it, it's not going to fly. The more information you can gather up front, the better it works."

Changing the culture of the Medical School to encourage and support the development of new technology will be the ultimate, and perhaps most difficult, obstacle MIC has to overcome. Time spent on entrepreneurial activity is generally not rewarded in the academic promotion process, according to Geiger, and universities don't appreciate how important it is to provide enough experienced staff support to keep projects moving through the process.

It takes time to create a culture of innovation within a large bureaucratic institution, but Geiger sees signs that the Medical Innovation Center has had a positive impact during its first year. And he has no intention of giving up now.

"With a top-ranked medical school, engineering school and business school, this university has so many opportunities and resources to develop new medical technology," he says. "If we can't do it here at the U-M, where can we do it?" [M]

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