

Forces Affecting Medical Device Innovation in the United States

A perspective from one of the field's foremost physician-inventors, Thomas J. Fogarty, MD.



The regulatory environment in the United States is more restrictive than in many other countries, with European systems being the most frequent comparison. The data needed to prove safety and efficacy by the US Food and Drug Administration (FDA)'s standards often require more extensive clinical trial testing, which has added benefits in ensuring safe outcomes for patients. However, some feel the environment is too restrictive and unpredictable, and that the cost in dollars and time of bringing innovative devices to market can be prohibitive.

Vascular surgeon Thomas J. Fogarty, MD, first worked to bring a medical device to market in the early 1960s. His homemade balloon catheter would become the Fogarty Embolectomy Catheter (Edwards Lifesciences, Irvine, CA)—a precursor to the angioplasty balloon. This was an innovative, “game-changing” technology, and the platform is still in use today. Since then, he’s worked to bring numerous other vascular devices to market (most recently the Crux IVC filter [Crux Biomedical, Inc., Menlo Park, CA] in 2012) and founded the Fogarty Institute for Innovation. He has also consulted with the FDA on new initiatives the agency is implementing. We’ve asked Dr. Fogarty to share his unique perspectives as a prolific physician-inventor on the current state of medical device innovation and how it has changed over the course of his career.

What was the most challenging aspect of getting the embolectomy balloon concept from your attic to ORs across the country?

One of the biggest challenges was finding a company to manufacture the device. In my situation, because I was so young, I can understand why industry had questions about whether the device had any significance or utility. They should have. They wanted to make sure they’d get a good product, and a good product usually comes from senior people, not kids still in school. Having said that, it was also interesting that the academic community was really skeptical. As it has been in the past and continues to be, some academics do not recognize the value of some new technologies. However, Dr. Albert Starr (originator of the first successful prosthetic valve and chairman of the Department of Cardiac Surgery at the University of Oregon) did. Through Dr. Starr, I was introduced to Edwards Lifesciences, the company that continues to manufacture and sell the balloon catheter.

An additional challenge was getting our work published, because it was so outlandish. The concept that existed at the time was that touching the endothelium would result in thrombosis of the vessel, and we were scraping the endothelium off the vessel wall. The embolectomy catheter article was turned down by three major medical journals before finally being accepted by *SG&O (Surgery, Gynecology & Obstetrics)*, in a section called *Surgeon at Work*. It con-

PERSPECTIVE:

Physician/Inventor

sisted of two pages with illustrations. It was only through the influence of my mentor, Dr. Jack Cranley, that the article was published. He insisted that my name be first.

It seems as though you would say some of these elements are still challenging in bringing a device to market here in 2013. What are some of the current hurdles?

That is certainly true—the discouraging old elements are still challenges. A newer significant challenge is maneuvering through the regulatory and reimbursement process. The regulatory and reimbursement process can now take 5 to 8 years. By that time, the device could be, and often is, replaced by a newer technology.

Displacing the old is another significant challenge. “Old” is not limited to chronological age. If that were the case, I would be long gone. Old includes old concepts, old relationships, old traditions and habits.

Of the devices you have worked on to develop that didn’t make it to market, were most due to the technology itself having some issue, or were more due to regulatory hurdles that could not be overcome?

It is hard to characterize them as one or the other; it’s been a combination of both. When you’re developing a technology, you start off with one concept that will address an issue, and if you find out it doesn’t work, based on the experience of a failure, you come up with something that has a better chance. We have learned that failure is often a preamble to success. One fails when you fail numerous times, run out of money, and have many regulatory problems.

Is there another side to the regulatory coin, whereby the FDA’s policies on regulation—which certainly come with delays, especially when compared to the European market—can also lead to true innovation by actually proving that the technology works? Or, is it mostly just a restrictive process?

I truly think it’s primarily a restrictive process. I’m not saying that everybody is exerting restrictions, but when you’re delayed by inappropriate requests, excessive numbers of animals, and unrealistic bench testing requirements—if you add all the expenses up, the barrier now becomes significant enough to lead to bankruptcy.

What are your overall impressions of the current venture capital environment with respect to the medical device industry? Do you see any opportunity for this to improve in the future?

It used to be that the venture capital community

would support early-stage startups, but that is declining. I do not see it improving in the near future.

What’s holding them back—is it the federal legislation that guides their overall goals?

Everything is multifactorial. But, there’s a public opinion that has been promoted by the press that new things are not tested adequately, and these technologies are being developed for the wrong reasons—primarily greed. Sometimes they are, but it’s very unusual. It’s not sensible to think that a company or the FDA would want to put out a bad product. If an approved product fails, they immediately think it’s the FDA’s or industry’s fault. This is not always the case. Postapproval failures can be the result of many things, such as using a technology in an area where it’s not appropriate, or when people who do not know how to use a device don’t take the steps to find out how best to use it.

How would you define “innovation”?

Something is innovative when it is new, better, and can be applied to a large patient population. In the field of medicine, it has to be easier, accessible, and inexpensive to patients.

What would you say is the ideal role of the physician in device innovation?

It’s a critical role. Physicians are the ones who recognize the need, and very often, the physician is capable of conceiving what may satisfy that need. But he or she can’t do it without industry, nor without a regulatory body that is efficient and effective. The physician plays a key role, followed by the engineer and other specialties who have knowledge in the development of technology related to the medical field. Again, when you look at what’s going on in the United States, it’s not just the FDA. All of us, in some way, have to share some of that blame—including physicians.

What led you to start the Fogarty Institute for Innovation?

Frustration with getting products to the marketplace that are safe and effective. Currently, we are not able to do that in a cost-efficient way. It’s been extremely difficult, because the people who had money in the industry have come to the conclusion that it’s not economically possible to do, so they all go offshore. We’re trying to influence them to stay within the United States. It can be done, but is more and more difficult. The thought of failure is onerous and bad for patients. Change is our only option.

Something is innovative when it is new, better, and can be applied to a large patient population.

What are the Institute's goals?

We try to review technologies that have very wide and broad applications. One of our objectives is to take very promising technologies and individuals and put them in an environment where the deterrents to innovation that we currently face are minimized. That doesn't mean we don't follow rules or we're not concerned about safety—we are, and we need rules and regulation. But we want the rules to be reasonable. We want to reward success as much as we can, encourage them as best we can, and surround them with people who have been part of the process of innovation, and that includes many different individuals from different backgrounds. We do relate to many academics who understand that technology is very important and is

closely related to, but is different than, basic science.

We involve experienced people who, on a pro bono basis, give their time and money to support our not-for-profit institution. We have engaged CEOs of companies big and small to serve as consultants, as well as intellectual property attorneys, regulatory people, tax attorneys, and accountants, who are all supportive of our efforts. The interactions occur in an environment where people understand the big clinical problems. At El Camino Hospital, our administration understands the issues surrounding innovation, and they know and believe that through innovation, patients will be better served.

Every patient wants the best doctor and the best hospital. In the field of medicine, "best" means newer, better, and less expensive. There is a lack of understanding that innovation, when designed properly and used appropriately, will serve to reduce cost, not increase cost. We are convinced that this is the case.

Now, we can't address all these problems, but we can start working on them. ■

For more information about the Fogarty Institute for Innovation, visit www.fogartyinstitute.org.