

Inventing Success

Interviews and insights from some of the biggest hitters of all time!

BY PAUL GIANNESCHI

As a kid, I was a big baseball fan. Growing up in the city, you could always find me playing ball in some no-name parking lot. Staring down fastballs from my childhood friends, I stood in front of a spray-painted batter's box pretending to be one of history's great sluggers. Babe Ruth, Mickey Mantle, and Hank Aaron—I had hoped to someday join their ranks. Fortunately, I came to the realization fairly early on that I couldn't hit a curveball to save my life, and sadly would have to find another vocation that would enable me to pay the bills.

Through dumb luck, or perhaps divine intervention, I ended up in the medical device industry. Having enjoyed the past 15 years, I have found my work to be quite gratifying. As a result, the medical device industry has become the "baseball" of my adulthood. I now spend most of my time trying to understand new technologies, rather than trying to hit elusive curveballs. Much like the sluggers of my youth, I admire those device inventors and entrepreneurs who, against formidable odds, find success. I have replaced the heroes of my childhood. By definition, they are still "sluggers" like Ruth, Mantle, and Aaron, yet, they ply their craft in operating rooms, angiographic suites, and cath labs, rather than ballparks.

Having the pleasure of working with physician inventors on a daily basis, I can tell you that I have never met a doctor who didn't have an idea for a new "widget." Yet, only a handful of inventors ever truly find success. Why? Perhaps the device industry throws a pretty mean "curveball" that most physician inventors can't hit. The only way to get real answers would be to speak with a few big league inventors and ask them the questions everyone would like to know. How did they do it? What inspired them? And, what advice would they have for fellow physician inventors who have trouble hitting that proverbial "curveball"? Thankfully, some of the most successful modern-day physician inventors were gracious enough to share their views and experiences on this topic. Sluggers in their own right, each of these inventors has found great success in the device industry, and as a group, broadly represent endovascular medicine. Our group of accomplished entrepreneurs and inventors includes Thomas Fogarty, MD, Mark Wholey, MD, and Jay Yadav, MD.



Thomas Fogarty, MD

"An idea has no value unless it is implemented."

What was the first, or most important, device concept that you successfully commercialized?

Dr. Fogarty: The embolectomy catheter (Edwards Fogarty Embolectomy Catheters, Edwards Lifesciences Corporation, Irvine, CA).

Dr. Wholey: As a co-founder of Medrad, we developed what we thought was a better angiographic injection system (Mark V, Medrad, Inc., Indianola, Pennsylvania).

Dr. Yadav: The AngioGuard distal protection system (Cordis Endovascular, a Johnson & Johnson company, Miami, FL).

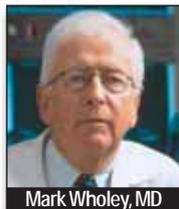
What inspired you? How did you come up with the idea?

Dr. Fogarty: Primarily through my own observations and the mentoring of Jack Cranley, MD. As a scrub tech working with Dr. Cranley in the 1960s, the amputation and mortality rates were around 50%. I thought that if you could make a small incision and insert a balloon to remove a clot, it just might work. The first time we used it, it worked immediately.

You have to remember that at the time, most people believed that manipulating an artery was the cause for thrombosis. It was the encouragement of Dr. Cranley, along with staying persistent, that finally caused things to change. I was making devices as a medical student, and then returned to Cincinnati after an internship to work as a first-year fellow for Dr. Cranley. I was making thrombectomy catheters and sending them out to Dr. Cranley's friends, who would try them and say, "Holy cow, it worked!" Yet, I couldn't get articles published on the procedure, and in fact, was turned down by five journals. I wondered if it would ever happen.

Dr. Wholey: When I returned from my fellowship in Sweden, the angiographic injectors that were available at that time were unreasonably large, not user friendly, and lacked the necessary mobility. Steven Heilman, MD, and I co-founded Medrad Inc. We developed the first flow rate control angiographic injector in the US. The Medrad injec-

tor became, and remains, the most dominant angiographic injector in the world market today.



"It is important to stay focused on the problem, and not to get too complex with your solution."

Dr. Yadav: Carotid stenting. I was concerned with emboli and thought that improvements in technique would help. We had found that we still had substantial embolization, and I wanted to solve this problem. How could we protect the brain and not make it ischemic in the process? We felt that a filter represented the best option. We talked with experienced people in the industry and were told by some engineers that it was not feasible. We even spoke with a large device company that had expressed some interest, yet their advisors told them it was not needed. We had no other options, so we made it ourselves. We could either quit or do it ourselves.

What motivated you to pursue your idea commercially?

Dr. Fogarty: I could only make so many of them myself.

Dr. Wholey: Back then, I pursued it more for the "science" than any commercial gain, yet my partner Steve was willing to quit his job and pursue it full-time. Andreas R. Gruntzig, MD, set the pattern for commercialization among doctors in this area.

Dr. Yadav: There was a clinical need, and we couldn't get anyone else to do it.

Did you have any help with the device concept's commercialization? If so, who helped you, and in what form?

Dr. Fogarty: On the commercial end, it took us 2 years to find someone to produce it. Al Starr, MD, was working on heart valves with an engineer by the name of Miles "Lowell" Edwards, who started Edwards Lifesciences (Irvine, CA). Charles Dotter, MD, knew that I made catheters and also knew Edwards and put the two of us together.

Dr. Wholey: We brought in a sophisticated board of directors with very talented people. It was the board that brought in business people that changed everything. Sophisticated management attracted venture capital investors, and through these investments the company grew. We had a great product and great management, which was critical. Management is everything!

Dr. Yadav: We brought in an engineer, Greg Sutton, and worked on it ourselves—basically on a shoestring budget. At the time, I was also giving various lectures, and that created visibility and exposure for me. After a speaking engagement, I

met Raul Esquivel, who was the head of research at an investment firm. He, along with several of his contacts and some individual investors, participated in our early funding.

Physicians have device ideas every day. Going back to when you first started working on device concepts, what do you think differentiated you from those who were unable to find success with their device ideas?

Dr. Fogarty: Basically, I implemented the idea. An idea has no value unless it is implemented. I had the mechanical skills and made all kinds of things. I used the baby finger of a #5 glove and a ureteral catheter tied off with surgical silk, using fly-tying techniques to make my first device.

Dr. Wholey: You must have "stick-to-it-iveness" to succeed. It is important to stay focused on the problem, and not to get too complex with your solution. In addition to my successes, I have also been a part of quite a few losers, and that always seems to be one of the problems. A solution can get too complicated (over-engineered), and as a result, people give up.

Dr. Yadav: Persistence. I think you need to have confidence in your idea, but solving a clinical problem is what is most important. Your device concept has to be "need" or "problem" driven. The market is efficient and fairly demanding, and those concepts that don't solve a need will not survive.

How have things changed for physician inventors over the years?

Dr. Fogarty: It has gotten extremely more difficult than when I first started. There are regulations at all levels, and the costs have been multiplied a hundred times. In addition, there are more patents being challenged legally, and the IP (intellectual property) is more complex. More people are working on stuff.

Dr. Wholey: Things are much easier now than when I first started. Physicians are more sophisticated and have a better understanding of business and markets. There are tiers of more knowledgeable physicians and everybody starts out at the same level. Although I must say that the final outcome has gotten more difficult due in part to the regulatory hurdles.

Dr. Yadav: I think things have gotten easier now with the various resources that are available, such as incubators. People are aware that it is possible when they see other physician inventors succeeding, and as long as patients don't do well, there will be problems to solve.

What advice would you give to any would-be physician inventor looking to develop their device concepts today? How might this be different from when you

first got your start?

Dr. Fogarty: It is virtually impossible to do it alone. You need experts in engineering, regulatory affairs, intellectual property, and operations. Physicians often come up with the idea. However, the real work starts after the idea. You need to allocate value to those who assist you. An idea has no value unless it is implemented. Physicians need mentorship to understand the process, and how to do it. You can't go from practicing medicine to device development.

Dr. Wholey: Make sure that there is a need for your product before you get started—you can't create a need. Be sure to thoroughly evaluate the IP space and perform a prior art search. Your IP coverage is critical. I would also suggest that you work with an engineering team to design and develop functional prototypes of your product. You will need to raise some serious money to get things off the ground. You can't do much without \$600,000 to \$700,000 and help from a management team, especially if you are inexperienced. A management team is more skillful, and a team approach often works best.

Dr. Yadav: It's important to remember that this is a marathon, not a sprint. We had been performing carotid angioplasty since 1987, and you can see how long it has taken. It is often a labor of love for inventors. Realize that it is not easy and that most times you will not succeed. A few years back, we saw several vanity companies that had significant financial backing, but the ideas were not very good. However, you can succeed if you can solve life-or-death issues (eg, stroke), big, noncritical problems (eg, restenosis), or identify ways to improve a procedure (eg, Monorail).

Given your experience and expertise in the device industry, which single device, or technology, has had the greatest impact on the way you practice medicine? What would you say to the inventor of this device, if you could?

Dr. Fogarty: The emergence of endovascular techniques and the balloon catheter. The harder you work, the luckier you get!

Dr. Wholey: Endovascular stents and the technologies associated with them. Stents have changed the way we manage patients and have improved the lives of so many people.

Dr. Yadav: Andreas Gruntzig, MD, and over-the-wire PTCA. Without balloon angioplasty, we would not have the Gianturco/Palmaz concept of stents. I would thank him for his foresight, creativity, and persistence. As I understand it, Dr. Gruntzig did his first case when his chairman was out of town.

Looking out into the future, and assuming you would still be practicing medicine, what technologies do you think will have the greatest impact on the way you practice medicine?



Jay Yadav, MD

"The market is efficient and fairly demanding, and those concepts that don't solve a need will not survive."

Dr. Fogarty: I would have to say drug and cell delivery techniques that actually work and manipulate genes.

Dr. Wholey: I expect that we will begin to see us treating disease at the molecular level—utilizing broad-based vaccines, genetic transfer, and systemic treatments to help patients.

Dr. Yadav: Further applications of micro-electro-mechanical systems and nano technologies will enable us to have much better technology, allowing us to produce much smaller and more reliable devices. I would also expect to see better integration of information technology along with better integration of devices and drugs. Pharmacogenomics, the ability to tailor medications to fit your genetic composition, also holds great promise.

Do you have any last words of wisdom that you would like to share with fellow physician inventors?

Dr. Fogarty: You don't know it all. Be humble and listen to others!

Dr. Wholey: I think as the inventor, you must have a genuine interest in your concept; from there, it takes patience, creativity, and tenacity. If you have an idea, you must stay with it!

Dr. Yadav: If you can solve a significant clinical problem, you will be in a position to succeed. However, as Thomas Edison once said, "Genius is 1% inspiration and 99% perspiration."

These gentlemen have created companies, invented devices, and advanced medicine. And like all big hitters, command respect when they step up to the plate. Truly, they are all pioneers who have changed the medical device industry, and have done so while practicing medicine. Perhaps it is your turn to step up to the plate. There is no better time than the present, and as they say, you can't hit a home run if you never take the bat off of your shoulder. ■

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Note: The preceding interviews were conducted separately.