From Interventional Radiologist to Medtech CEO: Interview with Dr. Bob Smouse, Founder of BrightWater Medical

Dr. Bob Smouse has over 20 years of experience in interventional radiology, endovascular surgery and clinical research. In addition to acting as CEO and CMO of BrightWater Medical and teaching at the University of Illinois College of Medicine, he provides interventional medical services to local hospitals through Central Illinois Radiology Associates.

Dr. Smouse is a medical consultant and scientific advisory board member for a host of medical device companies including Boston Scientific, Cook Medical, Endotronics, Novate Medical, Crocks Biomedical, Endoshape, the Medicines Company, and Varian Medical. Dr. Smouse has been involved in more than 30 international and national clinical research trials as the Global, National, and Local Principle Investigator and is the author of nearly 150 scientific publications and presentations.

Here are a few of the things we're going to learn in this conversation with Dr. Smouse:

- The time when Dr. Smouse and his team first believed they had a winner on their hands with the ConvertX System.
- How Dr. Smouse and his team built out their first prototype.
- His approach to raising money for BrightWater Medical, which involved a partnership with the venture arm of OSF, a large hospital system in the Midwest.
- The regulatory pathway that Dr. Smouse followed for the ConvertX System and what he learned through that process.
- How Dr. Smouse and his team are approaching value-based healthcare with respect to the ConvertX System.
- Dr. Smouse's favorite business book, the CEO he most admires, and the advice he'd give to his 30-year-old self.

Scott Nelson: Dr. Bob Smouse, welcome to the program. I appreciate you coming on.

Bob Smouse: Hey Scott, I appreciate the invitation. I've been listening to your program for quite a while now.

Scott Nelson: This is a unique experience for me and I'm certainly thankful to have this conversation. Let's start with ConvertX. Now that it is FDA cleared, you are at a point now where you are probably ready to commercialize. Thinking back to how it started, do you remember that time when you thought, "Wow, I think this device really works. We've got a winner here."

Bob Smouse: Yeah, it's funny. There were quite a few things that we did, or at least I did, to figure out if we have something that was exciting. I would say the real "wow" moment came when we started our preclinical testing of the device. We had it drawn out and it was on the back of a napkin and developed into CAD drawings. We even had some prototypes but you just don't know until you know. When we started doing the preclinical testing and it went in slick, it went in easy and then it formed. You have to shape it on to a position inside the body and then we tested the disconnect, the transformable component of it where it went from device A into device B and wow, it worked immediately. Within minutes of insertion, we had no issue.

Then we extended the time further and further and eventually went out to a month and transformed it after it had been beaten up quite a bit and it worked. That was the time that we realized, "Wow, this technology works. The team is stoked about it. Looks like we do have a winner." I must say, even before that time, we pinged a lot of people. I asked a lot of interventional radiologists what they thought about the concept and got a lot of enthusiasm. We talked to the typical corporate strategics in the space, "Hey, this is what we have, what do you think?" We were getting positive feedback from that, but the wow moment came when we actually used the device and it worked.

Scott Nelson: Yeah, that's great. Let's level set things for the audience. Can you give us an overview of what ConvertX is, what it treats, and how it's different than you know, the current devices on the market or current procedures and how you are disrupting the current process right now?

Bob Smouse: Yeah, I'd be happy to. I'm going to step back just for a second. As you may know, interventional radiologists work side by side multiple physician groups. Medical docs, pediatrics, interventional oncology or oncologists, surgeons, neurologist, nephrologists, et cetera. Every so often we're called to push the ball across a line, as it were. That is, there is a really tough case and perhaps it can't be completed in the traditional fashion so we get the phone call and without angiography suite and our imaging equipment, we can thread the needle and get really tough cases done.

Well, the ConvertX applies to those tough cases. That is, when there's a blockage in the ureter — that's the muscular tube that connects the kidney to the bladder that drains the urine into the bladder — the majority of cases are treated by urologists and the standard treatment is to use a scope, go through the bladder, and put a plastic tube up, in a retrograde fashion, from the bladder into the kidney. That is a minimally invasive method and that's called a ureteral stent. They are very successful in about 85 to 90 percent of the time.

However, in the really tough cases — cancer, a large impact of stones — we get the call. They either can't go up from below or they feel they will not be successful going up from below. So we take over the case. The way we do this is we do a more invasive procedure, but our mechanical advantage is greater. Our success rate in crossing the really tough blockages of the ureter to put the stent in is really around 99 percent of the time. I think the number is 98.6

percent but it comes at the cost of a more invasive procedure. That is, we have to work directly through the kidney itself and when we do that, we go through blood vessels.

We have a staged procedure to put this internal tubing, called the ureteral stent. That is, we bring the patient in, they're under sedation, they're on their stomach and we directly work through the flank of the patient, through the kidney, into the urine collecting system. We get a guide-wire into that area and we know that we cannot put that internal stent in on day one because we have a hole in the kidney. That is, if we don't have something blocking up that access, there's going to be internal bleeding. Or at least a high risk of internal bleeding.

On day one, and we've done this for 40 years, we simply put a drainage catheter in the kidney called a nephrostomy tube, we leave it in from three to 14 days until the blood vessels have had a chance to heal up. Then we bring the patient back and we swap that tube out for the internal stent. Now we don't need anything blocking up that hole in the kidney because they're not going to bleed.

That's worked great. Don't get me wrong, it's worked great but is two separate, invasive, one hour long procedures in the room that requires sedation, time off from work, radiation from the fluoro and the risk and pain associated with it. So about 15 years ago, I thought, "Well, it would be nice if we could combine two devices with one and convert it from an internal-external drain into a simple internal drain and that's what the ConvertX does.

On day one, the physician accesses the kidney like we normally would, the IR, through the flank. We put the ConvertX in that extends all the way to the bladder, it looks like the ureteral stent with an external component attached to it. Now, the interesting thing about the ConvertX is that this external component can be detached at the bedside or in the doctor's office in three to 14 days, whenever the physician feels it's time.

You put it in, takes about an hour to put in the patient, the patient is discharged either that day or the next day and instead of returning to the hospital to have the internal ureteral stent swapped out for the drainage catheter, the patient simply comes back to the office, the device is inspected and under 30 seconds, the external part is detached, leaving the internal double J pigtail in place, eliminating that second procedure.

Scott Nelson: That's a great overview and if I have this right, you are taking two procedures that a patient would have to come to the hospital, to the IR suite to have done, to a roughly one-hour procedure. I think everyone knows, when you go to a hospital, it's definitely more than just one hour. It's getting there a few hours in advance, the post work up, all that stuff.

You are basically combining two procedures into one where that patient, for the second time around, doesn't have to come back to the hospital per se. They can just go to the office to have that drainage device attached, correct?

Bob Smouse: Yeah, that's right. You are right about that. When I talk to patients, it is never a one-hour procedure, they have to be admitted, they have to come in and get the IV setup and every one of those patients for the second procedure that the ConvertX eliminates, every one of those patients has to bring a caregiver with them because they're going to be under IV sedation so they can't drive that date and they can't drive for 24 hours.

If they're on any blood thinners, Warfarin or any others, they have to stop that for five days before they come in. They have to NPO after midnight, the day before. All of that is eliminated with the ConvertX. When they come into the doctor's office, to have that external catheter detached, they don't have to stop their anticoagulation, they don't have to have any type of anesthesia, local or general, or IV sedation. They don't have to bring a caregiver with them, they can just stop them for a 15-minute office visit, a 30-second detachment and boom, they're done, they're ready to go back.

Scott Nelson: It almost seems so straightforward. That's a great overview. On that note, you mentioned earlier in our conversation some clinical work that went into getting your 510(k) clearance. Can you speak to that a little bit more in detail?

Bob Smouse: Yeah, there was no human clinical work. This is a traditional 510(k) device. There are predicate devices so the FDA, they certainly had a lot of testing that we had to go through like any other medical device. We cleared those quite nicely, but no human clinical trials were required. Now, having said that, a typical ureteral stent does not require animal studies but, as a physician, I wanted that preclinical testing. So I discussed that with the FDA ahead of time. Even though the form and function of the device is very similar, I knew there was a detachment mechanism.

As a doctor, I just really wanted to make sure that there was no internal harm during the detachment period. I wanted to make sure that the internal stent did not shift or move, not even a millimeter when I detached the device. In the event that you know, I did not want to detach the internal stent, I wanted to take the whole thing out. I wanted to make sure in an actual model that I could take the device out without causing harm or without the device falling apart. So human clinical is not done, but a lot of preclinical testing was performed.

Scott Nelson: Yeah, that's interesting. I didn't realize traditional ureteral stents are a fast track to the 510(k) process without human clinical work. It speaks to your diligence and obviously your experience as an interventional radiologist wanting to make sure that you checked that box twice even though it may not have been required per the FDA guidelines.

Let's use this opportunity to go back in time and learn a little bit more about how ConvertX came to life. You are a practicing interventional radiologist in central Illinois, and if anyone looked at your background, you are an adviser to the "who's who" within the medtech space. Name your company that plays in the interventional radiology space, I'm sure you've done some advising to those companies in the past.

Now you are CEO also of ELGCO, the incubator that ConvertX was born out of. Can you speak to us or tell us a little bit more about how ConvertX came to life and maybe take us back to the time when you were evaluating other technologies and why you decided to really go down the path that led you to ConvertX?

Bob Smouse: Yeah, I'd be happy to. Physicians are tinkerers by design. We like better mouse traps, especially interventional radiologists. We're always thinking about "how can we make something better?" and that's no different for me. I remember I had this different ideas and thoughts about different devices that may or may not have an impact and what I should do with that.

To keep them organized and to get a formal process in place, I started an incubator called ELGCO with an investor. I put all the ideas in there and started a little bit more of a methodical process to determine which rabbit hole we would go down. Even though a device may be cool, I can tell you that the first device I ever designed and got a patent on had 28 moving parts so it was absolutely complex and challenging.

Early on I realized after reaching out and talking to friends who were CEO's that docs are good at coming up with new mouse traps and we tend to spend a lot of time and effort and even money trying to build these new mouse traps without looking at the market. Is there interest, is there an unmet clinical need? Will there be physician adoption? Do corporations like it? Will hospitals like it? What's the reimbursement pathway, what's the regulatory pathway?

So with ELGCO, it was nice. We were actually studying three different devices, two of which we have patents on, and we started this really rudimentary market analysis. We looked at the market potential and identified the unmet clinical need. I am a novice at this and not a serial entrepreneur at this point. I haven't done multiple companies. I needed to restrict my playing field. I didn't want to get into too deep of water.

So I set some boundaries early on. I said, "Let's look at those devices that are 510(k) nonclinical. Because a PMA device that requires a 300 man clinical trial is probably beyond my ability as a new CEO to do that. I wanted something that was restricted to the 510(k) space. This all goes into ELGCO. Also, I wanted something that was transformational and disruptive that is really highly differentiated and at the same time had a benign regulatory pathway, relatively speaking, with a reimbursement pathway.

I looked into the CMS pathway to go for additional coding and that's incredibly challenging, I didn't want to go that way. When we did that, it was myself and Dan Heilbrunn who is my VP of marketing and BD and then Ken Stalker came in and he's my VP of manufacturing and R&D. These guys have really a lot of depth in the space, so we looked at that and the device that really kind of rose to the top that had the best play was the ConvertX.

It was a very thoughtful process going after the ConvertX devices. To me, it ticked all the boxes and then we spent quite a bit of time getting that validation talking to companies, talking to

physicians, doing surveys. Me, talking to my own partners and then talking to the value assessment committee. Kind of getting a handle on this and that's what we've been doing for the last two and a half, three years.

Scott Nelson: That's a great overview. A couple of things that really stand out to me as you described sort of that early thought process, and this is probably more specific to early stage entrepreneurs that are out there, just the idea of falling too much in love with an idea or device that that may be overly complex and won't ever be adopted in the healthcare environment. So I love the fact that you evaluated all of those downstream issues too; the regulatory pathways, how much clinical data is going to be needed? Is there an existing path to reimbursement? Will someone get paid to use the device? They seem like relatively simple questions, but I love the fact that you evaluated and considered a lot of different things early on. It speaks to your experience in the healthcare arenas as a physician but also just your experience in dealing with large strategics as well.

On that note, it's interesting that you said that you're evaluating three or so different technologies at the same time. I remember a conversation I had recently with Ted Lamson and he was speaking to his experience before NeoTract came to life. He mentioned the same thing, that they were actually evaluating two or three different technologies at the same time. That evaluation process may extend the six, nine, 12 months before they narrow down to one particular opportunity. It seems like that's sort of a best practice when it comes to some of these early stage technologies.

Bob Smouse: Yeah, I agree completely. I've seen it too often and I've done it myself. I get enthusiastic about something and then as you try to start checking out the boxes, you really want to ignore the fact that something's not quite fitting. But it's important to listen to those things and look for the red flags and to make the internal pivots. One thing we did with Brightwater in general—and we think we have a little bit of a platform technology we can apply to other devices as well—but early on, we consistently reached out to our physician advisors. Even though I'm a physician and I advise other companies, I know I can get blinders on.

It's always good to hear from other physicians, and as a matter of fact, I called a couple of them yesterday getting their opinion on some modifications perhaps going forward. Some second generation and third generation modifications. Internal pivots are common, they're appropriate, and it's good to do it when you haven't invested the entire farm in it. It's been a very fluid process and I can tell you, we reached out to corporations early and continually over the last two and a half to three years to get their input, to ping them to find out what's in their strategic wheelhouse, what isn't. We actually engaged other experts early in the process to help steer us in the right direction.

I wish I could say it was all me, it wasn't. It was a group effort, and it was having a really good team. I can tell you this, I tell this to other friends and colleagues that have a similar bent in interest and have taken their device to market, I can tell you really the least expensive help you can get is really the most expensive. I found out very early on, trying to cut corners and not get

the appropriate management team or workers behind your devices is really a very expensive way to do it.

Early on I got people I had known for years who really been in the business for at least 15 years and many times 25 and 30 years and my director of manufacturing had 22 years with Abbott. My process engineer is 20 years with Abbott. My finance officer is more than 20 years with Abbott and others. My director of manufacturing and R&D is 15 years with Guidance and an additional 10 years elsewhere with ACS and just having a real seasoned pool of management team and even physicians who have domain expertise is invaluable.

Scott Nelson: That's a great anecdote because I think it would be easy for most people to look at your background and say, "Oh, Dr. Smouse probably didn't need to build out a team for this. He can answer most of the questions or make most of the decisions with relative ease along the way." But it's interesting that you say that's definitely the more expensive way to go about it and that you instead built out a solid team early on to help guide the direction of Brightwater and see ConvertX come to life.

On that note, speaking of that team, you've got, as you mentioned a lot of people with really great backgrounds as well. Look at your clinical advisors, Dr. Barry Katzen, Dr. Alan Matsumoto, Dr. Rod Raabe, let's spend a little bit of time discussing that. How are you able to coalesce a group of high-powered individuals to join what you were doing with Brightwater?

Bob Smouse: Those physicians I have known for many years and we would interface at meetings. I'd talk at a few meetings here and there and just got to know them and really respected their opinion. For example, Barry Katzen, he has a lot of depth in healthcare economics and the ConvertX really has a nice niche in that space with the Affordable Care Act and the change in the healthcare economics landscape as it were and the fact that we can eliminate an entire procedure, that certainly saves lot of healthcare dollars.

Barry was just a natural choice to bring on early as a medical adviser and so it was one of those things where I'd reach out to different physicians. The ones you mentioned, we also have Brett Wiechmann and Lindsay Machan out of Vancouver. Every one of them saw the vision. I mean, they got it. It was one of those things where I would start to go down the ConvertX pathway and they would stop me after just a few minutes and say, "Hey Bob, you had me at hello. This makes sense, it's something that eliminates a kind of cumbersome procedure," and I can tell you, it really rang solid with them even for a simple thing like the insertion of the normal ureteral stent that we insert.

This is something I don't really talk about to corporations or hospitals, but when we take a urology stent that's made to go from the bladder up to the kidney and we put it in backward — we have to actually turn it upside down and put it in — that's a very challenging procedure. It's rare that I'll let my fellow for example or any of my fellows do this solo on their own. I'll be next to them in the IR suite because it's a challenging procedure. To a person on the MAB, when I

told them about the ConvertX, they go, “Wow. That’s going to make the ureteral stent so much easier to put in and it’s better for patient care.”

It wasn’t a big sales pitch I had to give them. They got it, they understood it, they thought it would be a nice bolt on technology to what they have already on their shelves that they can use. I think it was just reaching out, explaining what the concept was and we’re planning on doing and they jumped on board, it was pretty simple.

Scott Nelson: There’s a quote, “the best marketing starts with the product” and so it’s hard to do really good marketing or have a really good commercialization strategy if your product is mediocre or substandard. So listening to you explain that, it sounds that you were able to solve a lot of pain points in this traditional process and so it made it easy for a lot of those well-known folks, people with a lot of experience in health care and in medtech to join the team, so good to know.

Let’s go back to the early thought process of ConvertX and at that point, you’ve got the idea narrowed down and at some point you’re going to have to raise money to take this to the next step and I noticed that you raised a round with OSF Ventures I think was part of that syndicate. So could you help us understand a little bit more about your approach to raising money and how you went about that?

Bob Smouse: Yeah and there was some stumbling, there is no doubt. When you’re doing this for the first time, you learn by trial and error what works and doesn’t work. Mel Schatz is on my board, he’s a serial entrepreneur and CEO with Tom Fogerty and he was a lot of help. I remember Mel early on in the process saying, “Bob, you’ve got to put the story together. A simple PowerPoint deck to put it together, make sure it says what the need is and how you’re going to solve the problem out there and really make a nice story.”

So early on, I put the pieces of this story together what the ConvertX means. I did a lot of Google searching, a lot of literature searching, and I wanted to understand what type of an impact the ConvertX may have for your urethral blockages. Am I in a super niche area or as a more significant area? I talked with a lot of physicians and once I had what I thought was a pretty good story, together that's when Dan Heilbrunn, he’s my VP of BD and Marketing and I’ve known Dan for many years.

When I consulted for Guidant, Dan was the marketing and BD expert at Guidant so we interfaced. Once we had a nice rounded out presentation, then we went to friends and family. Very typical of most startups. I called physician friends and physician colleagues that I knew. I talked to a local angel investor group, high net worth individuals, and also some other physicians. Then through Dan's connections and some of mine who are industry insiders, other MBA’s that do consulting for medtech startups.

Other CEO’s that actually have run and are presently running medtech startups really liked the idea and they invested and we didn’t get a lot of money, but we got enough to keep us moving

forward to developing the product. What was nice on day one when we started the company, this was in March of 2014, not too long ago, we had our IP issued. Our foundational patent was already issued, which was really nice. Then we built out the story and the market validation, the physician adoption, and sent out a survey.

By putting those pieces together, when we started giving the pitch to different groups, it became more and more refined. We eliminated unnecessary slides and augmented areas that we would have questions in and had backup slides and so was the friends and family push and with that, we were able to raise around $2.2 million and that was almost like the seed funding.

Now I'd put in money in the beginning. I had a silent investor who is an interventional radiologist, Karl Weingarten, who also put in some money and we were able to get the ball rolling. Then St. Francis really came into the mix later on after we had developed prototypes, we had done some bench working we'd used up, to be honest, most of the $2.2 million. Then we went and we said, "Well to get us to the point where we can get regulatory submission and approval, it is probably going to take another $3 million or so."

That's when I reached out to OSF Ventures, which is a healthcare VC group that's actually affiliated with my hospital system and that took about four months of diligence but they ended up becoming our lead investor and they've been a really good investor. Just for other early entrepreneurs, once we had that cornerstone, that lead investor, it's amazing how people just followed on very quickly.

Scott Nelson: That's great to hear about the effort that went into building the story and what ConvertX could become with adoption in the health care space is really important. Sometimes there is this mystique with early stage, raising money for early stage companies but it really comes down to honing in on your story and being able to convince others that it makes sense and that there's a lot of opportunities.

Before we go on, I'm going to read a quote from Dr. James Benenati. He said, "The ConvertX System is the kind of technology advance that we require to meet the dual goals of improving patient care and reducing the financial burden to the health care system."

I'm curious to get your thoughts on once you began to build out the commercialization strategy for ConvertX, how are you going to tell that story to hospitals and other healthcare providers that maybe are a little bit skeptical at first?

Bob Smouse: Yeah, that's really a good question and it's something we certainly chewed on for a long time. We've been looking at that for probably a year and a half now and doing a lot of analysis, reimbursement, and hospital expenses. It really comes down to getting your ducks in order. As a physician, I know this. The mandates that we're having, there are several. One is that we've gone from a patient outcomes basis to include a patient satisfaction. So that's important and that plays significantly in the medical value proposition of the ConvertX. I think we certainly will improve patient satisfaction.

Then from a more corporate level, hospital economic level, we're really tasked with two things. That's to improve patient care while at the same time decreasing the healthcare expenditures. That's where the whole thing with the Affordable Care Act comes in and so there are processes set up within the hospital and certainly 20 years ago there wasn't, for the most part, value assessment committees. They just didn't exist.

As a physician, I wanted something and even though I have perhaps two other brands on the shelf, I could ask my purchasing department to bring it in and we can do that. But those days are long past in the majority of hospital practices and so the device has to go through the value assessment committee and nowadays, we know we need a couple of things. We need to be able to show the clinical value proposition, that's number one. I pinged my own VA committee and I said, "Hey, I've heard of this device that does X, Y and Z." I didn't identify this with my company and they were really taken by the fact that we had eliminated an entire procedure.

So that resonated clearly with them, but usually, the follow-on question is, "Well what does it cost and what products are they going to eliminate and what's your healthcare economic message?" So it's really a dual one. I think with the physicians they don't get into the economics too much and they really shouldn't. They understand the clinical value proposition, so I think finding a physician champion to get behind this device is going to be very simple. Getting that physician champion is incredibly important. Anytime you have a medical device that comes into a hospital system, you need somebody to back it.

Because a vendor, which I'm not, but if my sales guy came in to show that he's not going to sit on the VA committee. He won't be there. He's going to need to have somebody who believes in the products. So getting that position championed will be really important for us and that has really shown not to be an issue. Physicians get it, they understand it. If they like it, they want it. The next thing is to show them what type of economic improvements there will be at the hospital level by eliminating that procedure.

We're certainly still sorting through those numbers but sometimes when you have to get that ball across the line and you have to use a very expensive angiography suite, reimbursements may not cover expenditures. We're sorting that out but there certainly is a very strong, they call it "HCE message" or "Health Care Economic Message", by eliminating that procedure.

So that's our pathway. We're going to have to make sure we dial in on the physicians to make sure they really understand it and see the benefit to it and then also, on the other side, show how this impacts positively the healthcare expenditures.

Scott Nelson: That's a great description. I think most people that would learn more about ConvertX would probably have similar responses if they are familiar with the intervention radiology space. You're reducing an entire procedure and of course, that's a great health care economic story but I love the fact that you guys are still taking a pretty methodical, diligent approach.

I think that maybe the lesson there is that even if your product or your story is pretty obvious, you still need that support inside the hospital system. If it's a physician or some other sort of decision maker that's going to really help to tell your story when you're not there. So I think that's a really good lesson learned.

Before we wrap up the conversation, anything else you want to share about Brightwater in terms of next steps for either ConvertX or other technologies that you guys are thinking of?

Bob Smouse: Yeah, when I look at ConvertX and it was to eliminate that catheter to stent exchange procedure and all the benefits that would go along with that in the kidney, one I'm very familiar with. When I started training in physicians on this almost to a person they would say, "Well what about the biliary system?" That kept coming back and we are laser focused for two years plus on the ureteral device, but now that we had issued patents we have proprietary materials, we've gone through all the testing of the FDA about compatibility etcetera.

Then the team sat down and said, "You know, Bob we're still hearing this from multiple physician groups, what about the biliary product? This are biliary play?" Our MAB brought that up very early too that we do internal-external biliary drainages for bile duct blockages in a similar fashion. For example, a patient may have pancreatic cancer that blocks the common bile duct or may have an internal cancer of the liver or the bile duct itself and gastroenterologists are incredibly successful at doing ERCP's and putting stents up in what we call a retrograde fashion. But every so often, and this is around 10 percent maybe 8 percent of the time, the blockage is just too big and too strong and they can't get across it.

So over 100,000 times a year in the US, the interventional radiologist will access the liver. Again, working through the side of the patient into the vial dock and in a basic procedure is just very similar to what we do in the kidney. We put an internal-external drain in and then we send the patient back later for gastroenterologists to use that drain as an access to put a retrograde stent in. So the MAB said, "Well why don't you make a ConvertX for the biliary system and internal-external drain that you can detach and leave a plastic stent in fanning the obstruction so you don't have to send the patient back for that second procedure in the ERCP."

So we're sorting that out. It's a nice platform technology to eliminate that. We're looking at potentially other procedures as well. Besides taking the urethral device further on, which we want to do, and building that space out and getting adoption for that, I think a nice follow-on product will be a ConvertX biliary but we have a lot of work to do. At this point, we do have prototypes now that we're testing but it's going to be a while before we'd be ready.

Scott Nelson: That built in platform approach, is that something you've realized early on through the incubation process with ConvertX?

Bob Smouse: Yeah, we realized it was there but it is a landmine you want to stay away from. It's really easy for green execs to spin off in multiple different directions, and I and my team, we

really control that. We were very laser focused on the ConvertX urethral and we still remain incredibly laser focused, but there's certainly an economy of scale. When we looked at the ConvertX biliary, we realized the value proposition was exactly the same. The health care economics are exactly the same.

We also know that the target user, that is interventional radiologists, are the same. We don't change referral patterns, we just give them a better tool to do what they're doing. So the similarities between the two were incredibly important and we all have stories of where somebody invents a stent for the heart for example and then they want to bring it out to a different part of the vascular bed and they end up going to a different target audience and it's just a nightmare.

The nice thing about the platform technology of the ConvertX, that is eliminating the catheter to stent exchange procedure, is that it really plays in the same sandbox. It's IR used, it's a device designed by an IR for an IR. So it just fits. The first device may have taken five million dollars to develop. We can leverage the IP, the materials, the similar regulatory pathway etcetera. That's what we're hoping and so there's certainly an economy scale with the platform technology that allows us to put another club in the bag without spending the same kind of funds and time that we did on the first product.

Scott Nelson: Such a good lesson there for every early stage medtech entrepreneur on the importance of doing your due diligence early on with the first product so that the opportunities are there for add-on devices or procedure related applications down the road.

I want to finish with the traditional last three rapid-fire questions that I've been including with most of my conversations. Looking back at your experience at ELGCO and then seeing ConvertX come to fruition with Brightwater, is there any other advice or things that maybe that you would have done differently? Or alternatively, something that you're really proud of? Like, "We really did it this way and I'm glad we did it because of XY and Z."

Bob Smouse: Yeah, I'm really proud in that we know the national average for getting in the traditional 510(k) device to clearance us around five and a half years and the team at Brightwater was able to do it in under three years. We were really tickled with that and I know traditional VC-backed companies are fewer than they used to be and ours was nontraditional. A lot of it, I would say 90 percent has been friends and family, non-industry investors, non-VC backed. We were able to really get this up by the bootstraps without having to go to large VC groups and it may not be a big VC group. That was part of our thought process.

Having Rod Raabe from Sapheon on board was really good because they did likewise. They raised significant capital without having to go to VC groups and we kind of did that. We were excited about that. The other thing is we're primarily a 1099 company. I do have some employees but the majority of employees are 1099 consultants. They're really dedicated to Brightwater without a doubt, but that's allowed us to really move quickly to make internal pivots to close down one aspect for example and augment another one. So that's made our

flexibility great and our responsiveness very quick. I'm really proud of that and incredibly proud that we're able to get the 510(k) with the first pass around.

I got some good advice early on from some of my other board members such as Chas Taylor, he's a CEO of Novate and Veryan and then other people too and I went to the FDA early and got into a really nice dialogue with the lead reviewer and the FDA was phenomenal. You hear a lot of stories, no doubt they're tough but they're in a tough position. They've got to protect the welfare of the patient at the same time they have to allow technologies to develop and improve and so I was really proud of the working relationship that I had with the FDA as we got in through the process of clearance.

Scott Nelson: Bill Facteau, who I recently interviewed, had mentioned something similar, that if you do your diligence right up front and make sure that you start to build that relationship with the FDA early on, it can be a relatively straightforward, easy process. It's good to hear that you had a similar experience, you took a nice approach seeing this through FDA clearance.

Bob Smouse: Can I just give you one story about the FDA?

Scott Nelson: Yeah, absolutely.

Bob Smouse: The lead reviewer is Dr. Timothy Martin and this is the type of thing that he did for us and I thought it was really good. I remember I took my wife to a pizza place to have a slice of pizza at lunch and we were getting towards the end of the timeframe to get the approval and then I get a call from Dr. Martin. He goes, "Hey Bob, you know, one of my reviewers has a question about this most recent response to the additional information that we requested."

The fact that he reached out on a telephone call just to ask a few questions and then within 15 minutes he put me on a voice call with the reviewer to discuss the concerns, was incredibly helpful. The bureaucracy of sending a formal letter and going through the whole process could have extended this out another six months I'm sure. At least. The fact that he was willing to pick up the phone and we obviously were willing to pick up the phone to engage in dialogue, cut through a lot of that red tape. I tell you, if the FDA is going on that pathway in the future, that's going to be very helpful to entrepreneurs like myself.

Scott Nelson: Yeah, no doubt. In my conversation with Bill Facteau, he had mentioned the same thing with Dr. Sheeran and that, to your point, the FDA gets pressure from both sides in their efforts. But he did mention that he personally is known as a big change in terms of trying to make the process a little bit more efficient for everyone. Great to hear and learn more about the story of ConvertX and Brightwater Medical. I know I've known you as a physician entrepreneur but it is great to see something come to life and here we are with FDA clearance and you're ready to start seeing this work in the healthcare setting across the US. Congratulations on that.

Bob Smouse: Thank you very much.

Scott Nelson: Let's finish off with the last three rapid fire questions. The questions are rapid fire nature but your answers don't necessarily have to follow suit. Let's start with the first one, what's your favorite business book?

Bob Smouse: It was *The 10 Day MBA*. That was pretty good. I don't know if I got through all 10 days but it got me charged up and I refer to it every so often when I run into a roadblock but yeah, *The 10 Day MBA.*

Scott Nelson: I actually never heard of that. I love the fact that it sounds like a pretty efficient way to get up to speed.

Bob Smouse: It's funny, I ask people and I say, "Hey, is it worth, as a physician, for me to go back and get an MBA?" They said, "Don't do it, you're crazy, hire an MBA and pick up a book and learn that way."

Scott Nelson: Yeah, sure. I completely appreciate that approach. Second question. Is there a CEO that you're following or one that has inspired you in the past?

Bob Smouse: Yes, there really is. He doesn't know this but it's Eamonn Hobbs. He is the founder and was the CEO of Angiodynamics and I interfaced very early with him when I was in my fellowship period with Dick Hawkins out of Gainesville, Florida at Shands Teaching Hospital and Eamonn used to come and I used to talk to him about different devices and products. So I've been tied to follow Eamonn Hobbs for a while.

Scott Nelson: Do you still keep in touch with him?

Bob Smouse: I really don't. Off and on, I see him in a meeting, once out of every blue moon and I'll say hi to him. But other than that, I probably should reach out. That's a good thought.

Scott Nelson: Yeah, I'm sure he'd probably love to see, if he hasn't heard about Brightwater and what you're doing now, I'm sure he would be thrilled to learn about what you are doing.

The last question is, take us back to your 30-year-old self, I imagine you're probably in residency or fellowship at that point. Any advice that you'd give yourself at that point in time?

Bob Smouse: Yeah, I'd probably say pull the trigger earlier. I've reinvented myself several times and I see a lot of people working towards retirement and stashing away funds and I think if I were to tell my 30-year-old self something different I'd say, stash away the funds but use it to go out and try something new.

Scott Nelson: Yeah, that's great advice. I don't think I would have expected you to answer in that fashion. That's great advice for anyone, even if you're outside of the healthcare space.

Well, I can't thank you enough, Dr. Smouse, for joining me. It was fun to learn more about your experience with Brightwater. I wish you nothing but the best with ConvertX and it will be exciting to see what you guys do with it.

Bob Smouse: Well Scott, I appreciate the invitation and it is always nice talking with you.