The Art of Medical Device Reimbursement: Interview with Randel Richner, Founder of Neocure Group

Scott Nelson: Hello everyone, it's Scott Nelson and welcome to Medsider, home for ambitious medical device and med-tech upstarts. For those of you who are new to the program, this is a show where I interview interesting and dynamic people in the med-tech and medical device arena, and on today's call, we have Randel Richner. She is the founder of Neocure Group, which is a consulting firm specializing in health policy, reimbursement strategy, health economics in global planning for biopharma and med-tech companies. So, welcome to the call, Randel. Appreciate your taking some time this morning.

Randel Richner: Great. Wonderful. Thank you, Scott.

Scott Nelson: Okay. So I definitely want to get into what Neocure is, I want to learn about your background as well because I think it's very interesting, but let's start with a recent case study of how you helped one of your clients because that will give the audience kind of snapshot or at least a peek into what you do at Neocure.

Randel Richner: Okay, a small cardiovascular company just called me about six months ago and showed me a policy, a local coverage policy in the Northeast and asked me if it was going to essentially affect their technology would they be at risk of being carved out of the market with this local coverage policy? There was a big player. There are essentially two or three players in this space and the bigger cardiovascular company had essentially worked with the local carrier and carved out their indication in this small policy. So, within a week I had to work with this small company and say indeed, this was a very serious problem, and rally the societies, physician groups, and others to write in immediately to the local carrier to say that carving out this one indication would have severe ramifications to the patients and to treatment if this technology wasn't available.

So, we fast-forward two months and, fortunately, because of that major effort we were able to get that local policy changed to include the indication for this. But if they hadn't called, and this is showing again sort of some naïveté about local coverage policies and monitoring and how important that is that one policy can lead to other policies and can essentially be shut right out of the market. So, it was great that they called, and we tried to react to that, but again this is not how you want to work…

Scott Nelson: Sure.

Randel Richner: …when you have a small company.

Scott Nelson: Right.

Randel Richner: So that was, but again, because of our connections and my long experience in the cardiovascular space, I was able to make some phone calls and get this done, but it was a real education for this small cardiovascular company.

Scott Nelson: Okay, great. That's a really interesting story. And I don't want to really go into a lot of details, but I think that helps paint a little bit of a picture for the audience of what you do at Neocure. So, starting there, can you provide just a brief overview first of what you folks do at Neocure? I know it's a lot, but just a brief overview, and then we're going to do a little bit about your background.

Randel Richner: We make sure that products are paid. We essentially follow the money. So, whether it's in the US or globally, it's important to understand the food chain, the dollars. So, any technology at various points may have barriers or opportunities to payment, so we look at what those are based on the stakeholder, the physician, the hospital, the payers, and those are the primary markets. So, we look at all of those stakeholders and where they see the value and essentially who gets paid what along that continuum.

Scott Nelson: Okay.

Randel Richner: So, that requires a whole set of skills, especially in the US, given the complexity of our healthcare system, that you often find the monetary incentives are different depending upon the physician payment or the hospital payment or whether or not there's value to the overall payer, which would be Medicare or the commercial payers in the US. So, there are many nuances associated with all of that, and so I need to have a group of technical experts that know all of those various stakeholder payment systems in order to provide the right information to the technology.

Scott Nelson: Sure. Okay. I like your 10-second little elevator pitch at the very beginning when you said, "We help med-tech or medical device companies get paid."

Randel Richner: Yes.

Scott Nelson: And obviously, it entails a lot more than that, but that's a great little intro because that's the truth.

Randel Richner: Right.

Scott Nelson: That's really the truth.

Randel Richner: Yeah, we'll often find that I get somebody—I love med-tech, I love medical technology inventors and they often will come to me with great ideas, great technology and I can almost do like 5-second dating and say, well, that's a wonderful product but you're never going to get paid for it.

Scott Nelson: Mm-hmm.

Randel Richner: So, that's the kind of advice that we give early on as well as to investors as to what we think the payment systems will support or not for any of these technologies. Looking at it in a global fashion as well, recognizing that there are so many barriers and hurdles now in the US that many of the technologies are starting in Europe. We still take that into account and look at what it might mean to them when they try to market in the US ultimately.

Scott Nelson: Okay. Okay. And that's interesting because I think, from my standpoint and maybe from the standpoint of most of my audience, they think, "Okay, I've got this new device. Either it's not currently being offered in this space today or the other providers are not adequate enough, so hey, this makes sense." But what you're saying is even though it may make sense, or it may seem obvious, the bigger question is, how are you going to get paid for that? How are you going to get reimbursed for that? So, that's kind of a paradigm shift, I guess, probably for me as well as most of my audience. So, that's great. I think that gives me a little bit better understanding of what Neocure Group is, but can you provide us a little bit of a background to how you came up through the ranks and now the founder and president of Neocure?

Randel Richner: Right. Well, you know, originally I was a nurse, so I have the background of knowing how the technology works on patients. So, it gives me a unique perspective. So, I did that for many years and then went on to the pharmaceutical industry where I was very interested in terms of patient outcomes with drugs and essentially worked with a variety of different pharmaceutical companies, worked overseas, worked in Europe on showing how drugs were cost-effective or important to the government. In the beginning, I actually worked with the authors of NICE and looked at what comparative effectiveness meant, or cost-effectiveness meant to the UK in developing those guidelines that are now referenced all the time for technology and drugs. So, I did that for several years but got very bored with just studying asthma or just studying one particular disease area…

Scott Nelson: Mm-hmm.

Randel Richner: …and found out about Boston Scientific in 1997, which I thought was fantastic in terms of understanding the impact of new technologies quickly and how it was replacing standard therapy, and it was very exciting as a researcher to be able to look at those opportunities and advantages of impact on value and payment. So, it was a great experience at BSC because they had so many novel products that were really changing care.

Scott Nelson: Mm-hmm.

Randel Richner: So, within that role, I built infrastructure in the company on a global basis that really thought about what the outcomes were on patients. We built the data capabilities, the health economic capabilities, the reimbursement and payment capabilities as well as the government advocacy group that all are necessary for achieving success in payment for a technology. So, we built that internally and were essentially an internal consulting firm to the company.

At the end of 2006, I decided to go off on my own and have almost replicated that with Neocure where we have a group of people that I trust and appreciate because most of them have backgrounds in companies and understand how important it is to develop a strategy that's based on a return on investment to the company. So, we understand that we know all of the components of getting that done, and not one person has the expertise to be able to shepherd something through. You need to have a whole range of skill sets, data analytics, and health economics. The key area that's critical though is understanding the payment systems and what that means for achieving success for your product and make sure it's got the right payment attributes that will get it through the system…

Scott Nelson: Okay.

Randel Richner: …so that you can sell to the hospital or that so the physician gets paid sufficiently for doing the procedure, or that the payer recognizes that if they adopt something that might be more expensive that it pays off in the long run because of the impact it has on patient adverse events or in the improvement in health.

Scott Nelson: Okay.

Randel Richner: So, with that in mind, Neocure includes experts in all of those different areas.

Scott Nelson: Okay. You mentioned that some of your team or maybe most of your team has experience in the corporate world. So, how big of a difference does that make when you're consulting and you're working with your clients now?

Randel Richner: Well, I find that if you look over the reimbursement firms across the US, I mean, they're usually brought up as consultants and they understand certain aspects of what it means to develop a product from birth to commercialization…

Scott Nelson: Sure.

Randel Richner: …and they don't understand that whole continuum, all the issues that you have with R&D, the interplay between FDA and your regulatory strategy, and how that's so intimately linked to the premium payment. So, having the corporate experience, I know what it takes to do all of that and how important it is to have that group of perspectives from clinical, regulatory, and marketing and reimbursement. To have all of that together is critical for success. So, I often find consulting firms that specialize in reimbursement really don't understand all of those intricacies and interplay between those specialties and how it needs to be orchestrated.

So, I often give the example that, with Neocure. What we have is we build essentially an orchestra score and we know that we have to bring in the percussion at certain times or the strings, that we know that we have to bring in. That it's important at the early stages to have a full understanding of the research and development of the product and what kind and how it's going to be used in the body and where and how that's so important, because ultimately how you get

paid matters about how it's actually introduced into the body and how it may or may not be used in the body.

So, all of that matters, again, in terms of your regulatory strategy too, whether or not you have the right predicate device, because often the predicate device is referenced in terms of payment. So, there is a real disconnect between what I see in terms of the reimbursement firms that give advice that don't understand that relationship, as well as my team, does.

Scott Nelson: Okay. Do you call that the orchestra score?

Randel Richner: Yes.

Scott Nelson: Okay.

Randel Richner: It's an orchestra score.

Scott Nelson: I'm just jotting down some notes. That's unique. I want to make sure I have that correctly.

Randel Richner: Right. Again, our "reimbursement strategy" includes a combination of building evidence, meaning working with the clinical group to establish what kinds of outcomes are necessary to collect within the trials to look at how again the physician gets paid, which means that you have to have what's called the CPT strategy. That has to be started early, early on before commercialization, and some of the elements that are necessary for getting the physician paid and getting the CPT code also include gathering evidence.

Scott Nelson: Okay.

Randel Richner: So, that also has to happen early on. But then we also have the issue of the hospitals, and they have a very unique understanding of payment and whether it's delivered, or the procedure is done in the inpatient versus the outpatient versus the ambulatory care setting versus the physician's office.

Scott Nelson: Sure.

Randel Richner: Any of those types of service all have different payment incentives and the hospital could lose money on the technology where the physician might make money, and so you have to understand that early on as well. Then, the final thing that's very critical is whether they're going to be primarily Medicare patients versus commercial pay, and Medicare is always an important part of any of the technologies that we deal with and you have to understand the important issues that Medicare is up against now. So, that's also included in any of our strategies. The biggest issue that we're facing right now, and that is also included in our orchestra score for any of the technologies, is the introduction of health reform.

Scott Nelson: Okay.

Randel Richner: In my experience over the last 30 years in healthcare is that about every 10 years there's some significant change in Medicare payment systems, starting with DRGs, and then around the year 2000, there was the introduction of APCs for the different payments for outpatient care. Now, fast-forward to 2010-11, they are implementing as we speak the Health Reform Bill, which will have massive implications for technology companies because of new payment systems that are being introduced for technology. So, all of that is happening as we speak, and again, all of that has to be considered in any strategy that we're looking at for new technologies.

Scott Nelson: Okay. Okay.

Randel Richner: Or even existing technologies. There are going to be some big changes in cardiology payment over the next few years that everyone needs to prepare for.

Scott Nelson: Okay. I interviewed Chris Seper recently, who is the President of MedCity News, and he mentioned one of the big things that he sees on the near-term horizon is the healthcare reform wildcard, and I'm hearing the same thing from you as well. So, I guess it'll be fascinating to see how that changes this industry. But based on what you just kind of outlined for us, it's easy for us to say reimbursement fits within this or takes up this small little pie of the entire med-tech picture, but really it affects so many different pieces of the puzzle. Because of your experience and almost creating a Neocure within Boston Sci, and now your team that also has corporate experience, that really helps build a good case for your orchestra score philosophy in helping achieve higher reimbursements, etc. Is that a pretty accurate statement?

Randel Richner: Yeah, and I think another unique attribute of Neocure is that we have very unique data capabilities. When I was at Boston Scientific, again, we built this data warehouse there that was particularly valuable in terms of looking at procedure trends and looking at actual hospital-level data on reimbursement and payment. It's unique in the sense that the algorithm that we put together is based on a technology experience and understanding the payment systems like no other. Oftentimes what we've noticed is that a lot of the data and forecasting of procedures and this kind of thing are inaccurate because they often misrepresent or misunderstand the algorithm that's necessary to accurately define what a procedure is…

Scott Nelson: Okay.

Randel Richner: …which is a combination of different kinds of codes and claims data. So, what we've done is we've built that internally and are now working with a variety of different companies to have this data available. It's very valuable for even defining for recruitment for clinical trials, for understanding what procedures are being done at different hospitals and accurately defining that. We had an instance at VSC where the clinical group used our data extensively because hospitals weren't enrolling. They were very slow. We couldn't figure it out.

We used our data to say, "Look, if you go across the street to St. Elizabeth's versus Mass General, you're going to find that the procedures are 10 times the number than they are at the other." So, we provided all of that data. That's the kind of capability we have now, plus we have the ability

to look at trends over time in terms of how much the hospital is reimbursed at the procedure level for our products, and you can do that by region of the country. So, that's incredibly valuable information.

Scott Nelson: Okay. That's one of the points I was going to ask you about is I looked on your website, and for those of you who are interested in checking this out, go to Neocure's website. It's n-e-o-c-u-r-e.com. Go to the website and check out the focus reports, because that at least gives you an idea of kind of the unique data that are outlined in graphs and different tables and whatnot. It's really quite fascinating. So yeah, that's interesting. So, I did want to get into a little bit about the common barriers to success that you often see when working with your med-tech and biotech clients. Are there some commonalities that you typically see when it comes to overall reimbursement or healthcare economic strategies?

Randel Richner: Oh yes. The common theme now is the challenges to get companies to understand how important it is to develop the information necessary to convince a payer of the value of the technology, and we find over and over again that the companies think that as long as the doctors get paid a certain amount that that is sufficient, and unfortunately that's just simply not the case anymore. So, we find this over and over again that there's a real lack of understanding of the difference between how physicians get paid and how the hospitals get paid.

Scott Nelson: Okay.

Randel Richner: And so, what often happens is they spend a whole lot of time just talking to doctors, and the doctors often really also don't have a complete understanding of how the facility gets paid versus how they get paid and they give the technology companies misinformation about that.

Scott Nelson: Okay.

Randel Richner: That's a theme that happens over and over and over again, and it's one that is very challenging for us to explain.

Scott Nelson: Okay.

Randel Richner: Also, I find that the investor community is very savvy now and the tech companies need to be as savvy in terms of understanding where and how things get paid, and so the kind of information that you have to have for reimbursement is critical in that it's accurate for the investors.

Scott Nelson: Okay.

Randel Richner: We find that oftentimes they want an overview that is not in-depth. It's sort of like coming to the doctor and saying, "Well, I only want to get one test and that will be good enough for me to say whether or not I have cancer."

Scott Nelson: Okay.

Randel Richner: “Or whether or not I’m safe to move ahead.” So, you really do have to do a lot of research in terms of understanding where the technology fits and who’s getting paid what and be very astute about that, and I find over and over again these companies are unwilling to invest in the research that it takes to do that.

Scott Nelson: Okay. When you refer to the investor community, are you talking about the VCs or are you talking about Wall Street?

Randel Richner: Both actually.

Scott Nelson: Okay. Okay.

Randel Richner: Yeah, and for the publicly-traded companies, they have to be right on top of their game and understand the nuances of payment. Generally, they all have more in-house capability to do that and they have whole reimbursement teams that are set up in the larger public companies. 80% I think of the medical device community is private and there are very few that are publicly traded. So, those privately-held companies, have a responsibility to their investors as well as when they’re trying to raise financing rounds.

Scott Nelson: Okay.

Randel Richner: They have to have accurate reimbursement data. I hear over and over again now from the investor side and from the company side that the number one barrier to getting financing now is reimbursement. It’s not regulatory and they need to have a clear pathway for that.

Scott Nelson: Okay. That's fascinating. Repeat that for me, because I think that's really important.

Randel Richner: Right. In fact, I've just heard this last week, again, that the number one concern of investors now is reimbursement and not regulatory.

Scott Nelson: Okay.

Randel Richner: They still are concerned about the regulatory environment because it’s becoming so onerous, but they are equally or more so concerned about reimbursement at this point.

Scott Nelson: Okay, because I hear so much hype in the media in regard to the slow FDA turn times and a host of other different reasons, but it really comes back to the regulatory. But what you’re saying is there's really a newfound and almost equal or perhaps greater concern amongst the investor community in identifying reimbursement.

Randel Richner: Yes, reimbursement pathways.

Scott Nelson: Okay. Okay.

Randel Richner: Yes.

Scott Nelson: That's fascinating. That's amazing.

Randel Richner: Yeah.

Scott Nelson: Okay, that's some really good stuff. One of the things I wanted to ask you about too is this idea of comparative effectiveness because it seems like that's becoming a much bigger deal in terms of regulatory approval. Is that becoming a big issue in terms of the pathway to reimbursement as well?

Randel Richner: Comparative effectiveness is a code word for cost-effectiveness and for technology assessment. There are many, many different labels about what comparative effectiveness is or means for what comparative effectiveness is.

Scott Nelson: Okay.

Randel Richner: What it means is that the person who is paying for this technology needs to know if there's a value compared to existing approaches to care. So, this is not new to the medical device industry. We've had to do it on a variety of different levels for many years. Blue Cross Blue Shield has their tech assessment committee which is essentially comparative effectiveness.

What's new is that this has been introduced into law now, which is called comparative effectiveness, but there is an entity that is going to attempt to do studies to validate whether or not the technology is worth it compared to something else, and I am less concerned about that in some aspects because it's still being formulated. It's still unclear as to whether through the health reform how much the comparative effectiveness studies will influence actual coverage decisions. So, there's still a slight gap between what it means for comparative effectiveness through the health reform initiative and what it means directly for medical technology. On the other hand, everybody, any entity, any peer even through CPT now is requiring information on the value of the technology.

So, that means that translates into doing studies. So, in publishable studies that is the evidence that they're looking for, publishable evidence of improvement in care. You can't just do an add-on. So, that means that if you have a new diagnostic, for instance, does that just mean it will add on to the cost of what we normally do, or is it something that's going to replace something along the way? That's what comparative effectiveness is.

Scott Nelson: Okay. Okay. So, it's not necessarily, is this stent better than the next one in terms of competing stent technologies? It's more so, does this stent lead to cost reductions in the overall treatment for this patient and not necessarily an add-on to the treatment of this patient?

Randel Richner: Right.

Scott Nelson: Okay.

Randel Richner: That's one way to look at it.

Scott Nelson: Okay.

Randel Richner: I think a greater concern and opportunity is what's different this year, again, in the health reform that hasn't been in the past, is this issue of quality metrics associated with payment. So, that to me is more interesting than anything else. The comparative effectiveness means to get all the top billing, but where the real money is associated with quality metrics, whether or not your technology reduces infection, whether it changes an embolism, whether it can lead to a change in detection of adenomas in the colon.

Scott Nelson: Okay.

Randel Richner: Quality metrics have been introduced now that will change the dynamic of payment for the doctor and for the hospital and for the payer. So, there's going to be a lot of negotiation and interest into what those quality metrics are because it will be linked directly to the payment in all three of those categories.

Scott Nelson: Okay. Okay.

Randel Richner: So, that's the one where we have an opportunity to play. If we can show that we're going to reduce an admission for CHF, for instance, within a global time period, that the hospital could win, or the physician could win. But again, we have to produce the evidence to do that.

Scott Nelson: Okay. Very good. Good. I know we're running really short on time, and I would like to end these interviews with maybe one piece of advice from you, Randel. So, looking back at your career thus far, is there one piece of advice that maybe you'd like to give the audience or maybe one thing that you know now that you wish you knew 10, 15, 20 years ago?

Randel Richner: A piece of advice would be to just understand, to just make it very simple about who gets paid along with the care…

Scott Nelson: Okay.

Randel Richner: …and to remember that it's all about the patient and it's about the patient and improving care. If you can show that, you've got a win.

Scott Nelson: Okay.

Randel Richner: I love this quote from Warren Buffett, "Show me the incentives and I'll show you the outcomes."

Scott Nelson: That's great. That's a great quote to end the interview. So, I know we're running really short on time, but I almost want you to repeat that. What's that quote again from Warren Buffett?

Randel Richner: From Warren Buffett, "Show me the incentives and I'll show you the outcomes."

Scott Nelson: Yeah, it's always the short, little quotes that are really profound. You almost laugh at how simple but, yeah, how true they are.

Randel Richner: Yeah.

Scott Nelson: So, that's great stuff. Thanks a lot for coming on the program, Randel. I really appreciate it. Where's the best place for people to find out about you, is it your website?

Randel Richner: Yes, and to correct what you had said earlier, it's neocuregroup.com.

Scott Nelson: Okay.

Randel Richner: So it's n-e-o-c-u-r-e-g-r-o-u-p.com.

Scott Nelson: Okay. n-e-o-c-u-r-e-g-r-o-u-p.com. Alright. Excellent.

Randel Richner: Yeah.

Scott Nelson: Very good. Well, thanks a ton for coming on the show, Randel. I really appreciate it.

Randel Richner: Okay, great. Wonderful.

Scott Nelson: Excellent. Thanks, everyone for listening. Take care.