The Most Critical Considerations for Selling Medical Devices in China

China is one of the largest and fastest-growing medical device markets in the world. Given the sheer size of the market, the fragmented nature of distribution, and the cultural differences from one province to the next, it is important to consider a number of implications unique to the China market. First, do you even meet the requirements to enter the market in China? If you do in fact meet the stipulations, should you even enter? What other steps must be considered? There are a ton of questions that need to be answered.

Enter Landon Lack, the President, and CEO of China MedConnect. Lack is a veteran of the healthcare, medical device, and high tech industries in the US and China. He has helped companies develop and execute sales strategies, developed highly successful strategic partnerships and channel strategies, and helped position companies for M&A exit.

In this interview, Landon reveals fascinating insights that will help in your medical device decisions regarding the China market. More specifically, here are some of the points we'll cover:

- Best practices employed by the multi-national corporations that are currently operating in China.
- The real risks vs perceived risks when considering whether to enter the China market.
- How to maintain licensing control without completely screwing yourself in years to come.
- How China's renewed interest in innovation impacts IP protection.

Scott Nelson: Hello everyone and welcome to another edition of Medsider. This is, of course, Scott Nelson, your host. For those of you who are experienced veterans of the program, you know what the show is all about, but for those who are just picking this up on iTunes or maybe this is the first Medsider interview you've listened to, this is a show where I interview interesting, dynamic medical device/medtech stakeholders, folks who are doing ambitious things in that space, and the goal is to bring them on the program, do a back and forth sort of interview, glean some insights, pick up on a few key takeaways that we can bring back to our world to further advance our career, to further advance our business, etc., the end goal being to become that linchpin, that sought-after medical device/med tech linchpin. So, our special guest on this show is Landon Lack. He is the President and CEO of China MedConnect. So welcome to Medsider, Landon. Appreciate you coming on.

Landon Lack: Thanks, Scott. Nice to be with you.

Scott Nelson: So, I will hand the baton to you to give the audience a brief overview of yourself as well as China MedConnect.

Landon Lack: Sure. So, I guess, by way of background, it would be good to mention that I started off in 1991 in medical devices, that was after a brief stint in the military, after West Point, and my first medical device company, McGaw, was infusion pumps and IV solutions. Had a short stint at Boston Scientific with their vascular graft division, and then I left the medical device field for a short while and moved into the Internet sector. About six years ago came back to medical devices and I've been in China working for medical device companies since then.

About four years ago, I started this company, China MedConnect, really with the sole purpose of supporting small to medium US medical device companies on the ground in China. We're a small team. We're 12 people right now. All of my colleagues other than myself and one US person are Chinese and have extensive backgrounds in China supporting US medical device companies. So, that's really our mission, is really just to be an on-the-ground resource for medical device companies who don't have resources on the ground.

Scott Nelson: Sure. Okay. That's a great overview, and presuming we have a few minutes, in the end, I'd love to get some background into how you ended up in Beijing in this world going from the medical device space to the high-tech world in Silicon Valley, and then over in Beijing, but we'll jump back to that if we have time.

So, the focus here is obviously on China. For those medical device companies that are interested in potentially launching and gaining a footprint in China. That's obviously a hot space, but it's also kind of fragmented. I mean, I think I probably echo a lot of the comments from those listening to this interview right now that China could be overwhelming to think about all that needs to be done to begin to launch and sell a device in that part of the world.

So, we're going to go into what a typical medical device company should consider upon entering the space over there in China, whether or not they even should enter when's the right time, and then also some best practices in regards to launching and selling devices over there. So, those are the kinds of topics that we'll discuss. So, let's start out with the first one, Landon. From the view of a medical device company, can they enter the China market? Let's address that one first.

Landon Lack: Okay, yeah, and that's a good first gating question because really it's binary. There's a new requirement in China. They've mimicked other countries which have a home country approval requirement. So previously, prior to 2010, you just had to have a CE Mark or a 510(k) to enter the China market, but since 2010, if you're a US medical device company, you have to have US regulatory approval to even start the process in China. If you don't have it, you can't even start, which brings up the great point because we're starting to talk to more and more US device companies who are finding the US FDA process quite challenging, and they're looking at OUS strategies and starting with Europe.

It's a great thing to consider early on, and that is if you are going to start with a European approval, the CE Mark, you might want to consider tying that to a European subsidiary of your US company, so that way you have some sort of home country approval and then enter China as a European company tied to a CE Mark.

Scott Nelson: Okay. The rationale behind that change back in 2010. Can I have a brief background in regards to why China created that new requirement?

Landon Lack: Yeah. I don't know all of the details but my understanding is that they started looking at other countries and other regulatory requirements they had, and the SFDA previously, prior to 2007, was relatively lax in a number of ways, Since 2007 they've been trying to become more rigorous in their approval process to make sure that they don't have any issues. That was one of the things that they looked at in other countries and said, hey, if it's easier for a company to get regulatory approval outside their country, maybe it's not as strenuous. So, therefore, we're going to require this home country approval. Wherever you're manufactured, wherever you're owned, you have to get the approval there first.

Scott Nelson: Okay.

Landon Lack: I think other countries, I think Brazil has done that, Japan has done that. I don't know if the other countries still have that requirement, but right now that's the requirement in China.

Scott Nelson: Okay. Okay. You hit a rather hot topic in that a lot of device companies are seeking European... We'll see if that PIP breast implant scandal kind of changes things over in Europe, but it seems like most medical device companies are at least strongly considering pursuing a CE mark before US approval, before the daunting task of an FDA approval. So, are you saying like early on, if you're considering a CE mark, definitely consider pursuing China at the same time or at least think about your options earlier rather than later? Can you explain that in a little more detail?

Landon Lack: Yeah. Actually, my point was that if you are considering what I would call an outside US strategy, so it comes back to the US later. In doing that most companies look to Europe first and go through the CE mark approval process. If in fact, they are going to go OUS strategy, they can open up a lot more countries in terms of being able to operate in those countries if they do the CE mark tied to a European entity…

Scott Nelson: Okay.

Landon Lack: …so maybe having a German subsidiary or another European subsidiary and getting the CE mark tied to that European subsidiary.

Scott Nelson: Okay. Okay.

Landon Lack: That'll enable them then to execute in China and other countries, not that they have to, it just gives them the ability to.

Scott Nelson: Got you. Okay. Very good. Okay. So, if we could address even the next question of should a medical device company even enter it? So, say I followed those steps that you just outlined. I may have created some sort of allegiances to a European entity. Should I even enter the Chinese market? What are the things that a medical device company needs to consider when thinking about that question?

Landon Lack: Yeah, so should you enter is another really good question, and we'll tackle that. I just wanted to go back to that first point for a second, which is if you're a US company, you've got your 510(k) approval. A 510(k) is not too difficult to get for some devices. If you got the 510(k), then no problem. You don't even need to worry about anything else because as a US company with 510(k) you're free to start the regulatory process in China. I would suggest that if a company finds it challenging to get the 510(k) or have to do a PMA, then tying it to a CE mark might make sense.

Scott Nelson: Got you. Okay.

Landon Lack: So then, should you enter? I think, historically, US device companies have said, hey, let's operate in our home country first. That's our blocking and tackling, bread and butter stuff. They've said, okay, what's another easy country for us to enter? It's probably one of the European countries. Then, if they're looking at another big medical device market, they'll look at Japan. Japan's got a dozen challenges, but previously companies didn't look to China, but with China's current growth rate and their spending on the healthcare system, generally speaking, it's tough not to pay attention to it.

I think as we're interacting with small and medium US medical device companies, they all are thinking, hey, China's interesting. It's growing fast. There's a lot of spending on healthcare. Should we be there? or we want to be there, but how do we do it? But I think that it's important to recognize that you can't just look at the size of China and the growth rate and say it's a great place to be, because there are a lot of challenges and there are a lot of risks, and it's not for every medical device company.

We've suggested a number of device companies not even bother pursuing the market for a variety of reasons. So, 1.3 billion people, yes, but that's not necessarily the population for any particular medical device. If you're selling something that can be afforded by that size of the population, great. But a lot of the companies that we interact with have more expensive, more sophisticated devices, not necessarily a 1.3-billion market. It might be a fraction of that, whether it's one-tenth or one-quarter of that. But regardless, it's still a really big population.

So, should you enter? A couple of points on that. One is it makes sense to do some sort of market assessment to find out if there's a need for the product. The latest and greatest product in the US isn't necessarily right for the China market. It might be just an average product in the US market which is a great product for the China market, and everyone needs to look at it and assess it individually.

The other thing I would say is a lot of US companies are very used to looking at reimbursement models whether or not their business is going to be successful. That's not necessarily the same in China. There is a reimbursement mechanism in place in China but it's nothing like in the US tied to DRGs and so forth. It's a very small amount. So, the personal savings rate of individuals in China is extremely high, and it's high because they know that there's no safety net for their healthcare and they've got to pay cash. So, you generally consider that a cash pay situation. There is reimbursement for certain procedures, but all for intents and purposes, US device companies wouldn't factor that in too much into whether or not it's a good market for them.

Scott Nelson: Okay. So, two follow-up questions, but while we're on this reimbursement topic, being cash pay, are Chinese consumers more active participants in the healthcare space then because it's coming out of their pocket?

Landon Lack: Yeah, absolutely. So, generally speaking, I'm generalizing this because there are always exceptions, but generally speaking, if someone has some sort of health issue, what they'll do is they'll talk to their friends or others who they might think are experts in healthcare and find out for their particular ailment which hospital should they go to. They might be in Central China or Southern China, and their advice might be you need to go to this hospital in Shanghai or you need to go to this hospital in Beijing because that's the best hospital for this. Then when they get there to that hospital, they'll find out, okay, who's the best doctor for this? Then they'll wait to see that doctor and assuming they can afford the services, they'll wait. If they can't, then they'll find an alternative which might be a less well-known hospital and a less well-known doctor.

Scott Nelson: Okay.

Landon Lack: For all intents and purposes, it is cash pay. Now, when there is reimbursement, that is reimbursed back to the patient. So, for example, for a stent placement or something like that, there is some level of government coverage for that, it's cash out of the pocket first and then reimbursement later.

Scott Nelson: Okay. So, almost like, if I were to use the analogy of if I use a healthcare debit card or this is maybe not the best analogy, but if I use some sort of healthcare account here in the US I may have to pay out of pocket for that upfront until my healthcare savings account kicks in and reimburses me for that somehow.

Landon Lack: Yes, actually.

Scott Nelson: That's somewhat how that works?

Landon Lack: Yeah.

Scott Nelson: Okay, that's really interesting. Our Chinese patients more actively engage in the healthcare decisions because that's maybe why healthcare, it's somewhat challenging here in the US. Most consumers are like, oh, I've got health insurance. I don't need to really dig in and really find out what's the best alternative or best decision for me here in the States. Healthcare is a huge safety net. It's a huge golden parachute as you just mentioned. So that's an interesting side point, I guess, that I would have never known about the Chinese market.

Landon Lack: Yeah. No, it actually goes a little bit further than that. I've heard examples of a patient who has elected to get a hip replacement or a knee replacement and the doctor actually giving them a choice of a domestic Chinese-made product, which is a much lower cost, or a US- or European-made product which has a brand name and quality recognition at a much higher cost. For that procedure, there might be a dollar amount set by the government that the government will reimburse, and it might totally cover the domestic product and cover just half or a fraction of the foreign-made product. If the patient has the ability to pay for it, they may in fact choose to pay for what likely is and is certainly perceived as a higher-quality product. So, that takes it to a whole new level in terms of patient involvement or participation in the process.

Scott Nelson: Yeah. That's fascinating. That's a great example. Jumping back to that first point, the market need, do you have an example of when maybe a medical device company, let's pretend they had a CE mark or even maybe a 510(k) for example. So, they meet the requirement to enter China at that point but maybe they say, the market is huge, but maybe for our particular device or our particular disease state that we're going after it really doesn't make sense for us or maybe vice-versa. Maybe you another example where it really made a ton of sense to enter the Chinese market versus the Japanese market or some other country.

Landon Lack: Yeah, there are too many examples to go over, but I'll touch on a couple of points. One of the companies that we've suggested not to enter the market was a lower-cost disposable that could have easily been made in China. I mean, there was nothing terribly sophisticated about it. It can easily be made or manufactured in China and sold at a much lower cost. It didn't make sense. There was no differentiator for them to come into the market.

On the other hand, I'm thinking about a topical vessel closure. So, after an interventional procedure, you have either a mechanical vessel closure or in China what they do is they basically just hold for 30 minutes. So, this product actually was a hemostatic product that would only require a 5 to 8 minute hold time, which is a huge saving in terms of turnover and costs in the US, but in China the nurse's cost to hold it for 30 minutes really was insignificant. So, there were no real cost savings there even though there was a time saving, and it didn't have any appeal to the China market.

Scott Nelson: Okay.

Landon Lack: So each product is really unique and each one needs to be assessed at least taking a number of data points both from the doctors, which are important, and whether or not they see value in it, but then also hospital administration and whether or not they can include that into the [22:52 inaudible] cost to the patient. Then in some cases, it also makes sense to get patient acceptance because oftentimes they can be involved in the process. So, I have to say they're not that involved in the process, so it's more important to get both the doctors and the hospital administrators, and then in a number of cases you want to also get feedback from really the guys who are selling the products, which are the distributors in China.

Scott Nelson: Right.

Landon Lack: We'll talk more about the distributors and the China practices when we talk about best practices.

Scott Nelson: Sure. Okay. Maybe that's a good segue to jump to our next point. If you have nothing else to add, Landon, we can jump to that, the timing. When is the right time to actually enter the Chinese market?

Landon Lack: Yeah. So, from a timing perspective, if a company is a US device company and they want to sell in the US market, the 510(k) process can be relatively quick. It could be a half year or so.

Scott Nelson: Yeah.

Landon Lack: There is no 510(k) process in China. The process in China is pretty well-defined these days and more so than it has ever been, and it's becoming more structured, which is both good from safe products coming out the back end and being approved for sale, but it's also challenging because it's more onerous for device companies to get through it. So, the time to enter, if you have a class II or class III device. One point there is that if you have a class II device in the US, it may be a class III device in China, and a class III will likely be a class III, but if you have a class II or class III device, the process will take roughly 15 to 18 months, so you can count on almost a year and a half before you can start selling the product.

That regulatory timeline is about a month or two to get the paperwork together. Then you have to send test samples to a test center. That takes about four months for you to get a certificate of test approval. Then you submit to the SFDA and it goes through a seven to eight-month process. That's assuming you don't have any additional follow-up questions from the SFDA and then about a month after that you get your certificate.

Scott Nelson: Okay.

Landon Lack: So, it takes quite a while. Now, the good thing is it's not that expensive. So if in fact, you said, hey, we can enter the market and we believe we should enter the market, then it makes sense to get the clock ticking because until you start you're never going to get the approval, and if it's going to take 15 to 18 months, better to start sooner than later and there is value in it. Not to say probably five years ago or earlier than that companies didn't even look to China, but because of the size and because of the growth rate now, it's hard to not look at it. So, when to enter? If you've decided that it's a good place to be or you should participate, then start the regulatory process sooner rather than later.

Scott Nelson: Sure.

Landon Lack: But there's a got you there. So, in order to start the regulatory process, we talked about having own-country approval, but in order to start the regulatory process, you have to pick a regulatory agent or registration agent to do that work for you. You also, unless you have a legal entity in China, generally in the form of a wholly-owned foreign entity or WOFE, unless you have that legal entity you also have to pick a legal agent to represent you and you have to pick a service agent, really an after-service sales agent to represent you in China, You have to pick all of these at the beginning of the process.

This is a really, really important point because there are probably 10,000 or more distributors in China who could help foreign medical device companies, and those distributors all have the approval to play all those roles. That's common practice. A US device company will pick a partner in China who's typically a distributor, and that distributor will be their legal agent in China. But the got you is only the legal agent can ever authorize a change in a legal agent. So, if you have selected a distributor who obviously has their own agenda in the market, and it might be a great distributor and it might work out great, but if there's ever any conflict in that relationship, they're the only ones who can authorize a change of the US medical device company's legal agent in China. So, that can pose problems, obviously.

Scott Nelson: Got you. I was reading this a little bit more on your website, chinamedconnect.com, a little bit more about this process, and it sounded definitely interesting. But just to review because it's such an important point, as you just mentioned, you need to have really three agents – the regulatory agent, the legal agent, and the service/sales agent, for lack of better distribution. What you're saying is you have to choose. So, right when you start this regulatory SFDA approval process, you need to pick all agents upfront right away?

Landon Lack: That's correct.

Scott Nelson: The legal agent is the only one; you're fully captive to them almost at that point where if you ever want to pivot or make a different move later on down the road, they have to authorize that.

Landon Lack: That's right.

Scott Nelson: Okay. Okay.

Landon Lack: So, it absolutely makes sense to have a line in between whoever your distribution partner is going to be. So, the one selling the product and the one who's holding your license as the legal agent...

Scott Nelson: Okay.

Landon Lack: …and ensuring that that entity holding your license or that legal agent is not a distributor or doesn't have any conflict of interest with regard to changing distribution partners or commercialization partners in the future.

Scott Nelson: Okay. Okay. Yeah, I can see. I think it's safe to say how risky that could be if you don't strongly consider that or at least try to understand the implications of that looking two, three, four, or five years down the road. But just to take even a further step back.

Landon Lack: Yeah.

Scott Nelson: We're mentioning these agents, but you mentioned the wholly-owned subsidiaries, is that what you mentioned before?

Landon Lack: Yes, it's called a WOFE. It's a wholly-owned foreign entity…

Scott Nelson: Okay.

Landon Lack: …and really anyone could set one of these up, but what you have to do, you have to have an office in China.

Scott Nelson: Okay.

Landon Lack: You have employees with certain qualifications in China. You have to have a certain amount of storage space for your products. After you've established your presence and gotten your business license, then you have to go through the SFDA and get your SFDA license as well.

Scott Nelson: Okay.

Landon Lack: So, that costs time and money.

Scott Nelson: Yup.

Landon Lack: There are companies like ours who are set up to do that on behalf of US device companies, and that's one of the largest values that we provide for US device companies, which is really doing the regulatory work, and then, more importantly, holding their licenses for them or on behalf of them so they can make a change whenever they want.

Scott Nelson: Okay.

Landon Lack: Our vision is that we help a company get started in the market. As they start to have commercial success, they might say, okay, well, now we're ready to add our own resources on the ground, and at that time they can set up a WOFE or we can help them set up a WOFE and transfer the licenses back to them. Basically, they move into their phase of life in China. So, we help them get started on the right track, make sure that they didn't hit the knee of the potential land mines or pitfalls that are here, and then when they're ready to take over we transition it back to them.

Scott Nelson: Okay. Okay. So, if I don't fit in the category of the Medtronics, the Covidiens, the J&Js of the world, I don't have the capacity nor do I want to have the capacity to pursue a WOFE in China. I'm more bootstrapped, more nimble, my model's more lean, I want to go more kind of the regulatory agent/legal agent/sales service agent in China, and basically you act as almost my WOFE at that point, kind of.

Landon Lack: Yeah, that's right. I mean, the way that we see ourselves is we're an extension of our client in the US. So, basically, if our client in the US says, hey, we're a virtual medical device company, which there are more and more of, right?

Scott Nelson: Right.

Landon Lack: We just become one more aspect of their virtual team.

Scott Nelson: Got you.

Landon Lack: So, we're their virtual team in China helping them execute on a China strategy. Hopefully, one, if a product should be in China, we help them get the product to China faster. It might never get to China or it might be three to five or more years before it gets to China. So, it's good for China, it's good for the medical device company, and then with success, if they decide, hey, we want to now put our own feet on the street, that's great.

Scott Nelson: Yup. Okay. Now, after you explained that, that seems so obvious like that's the obvious choice that I want to make if I'm the President or CEO of a small, kind of nimble medtech company that wants to enter the China market. Why wouldn't you go that route? Is it just ignorance, just lack of knowledge about that market and not thinking it through?

Landon Lack: Yeah. I think that because, as I was mentioning before, most companies say, well, we focus on the US, and then we focus on a couple of countries in Europe. It makes a lot of sense. Let's pick Germany, for example, to pick one distributor to handle Germany, and then you say, "Well, you know what? We also think we want to be in France or Italy. We'll pick one distributor for France, maybe two distributors for Italy because of the new ups in that market." But when you look to China, it's really not the best practices to pick that same strategy for the reasons we've already discussed, but furthermore because China is so large and so complex and it's not a homogenous country.

I mean, there are 34 different provinces. Previously all of them had their own dialect, they still have their own dialect. They have their own provincial or regional influences, and if you're a typical medical device distributor in China, you're quite small with a small footprint, and if you're sitting in Beijing, you're just not going to be successful if you go down to Shanghai or an Eastern province or in the center of China. So, when you look to China, you have to look at it like the big guys do, like the Medtronics and others, and say, "You know, we can't have one distributor cover the whole country because there is no distributor who covers the whole country."

So, as a smaller company, you should look at either starting with at least three distributors, one in North China, one in Eastern China, one in Southern China where most of the wealth is and most of the best hospitals are, and that's a great starting point. But you can't do that unless you're controlling your own destiny and you maintain control of your licenses, because if you've bequeathed that to one distributor, then that distributor controls what you're going to do in China to control your strategy in China.

Scott Nelson: Yeah.

Landon Lack: So, I think the reason why people look at China and think of it as, "Hey, we'll enter that country like we entered every other country. We'll pick a partner." That partner is invariably a distributor who invariably has a very small footprint and who a lot of times will say, "Hey, we're your resource to cover all of China," but that's not the best practices.

Scott Nelson: Okay.

Landon Lack: If you look at, for example, Stryker, Stryker has multiple divisions. If you just take one division of Stryker in China, for example, their spine trauma. This is just an example, they might have 100 distributors that they manage, first-level distributors, and a little company doesn't need to do that but they need to follow that model, which controls your licenses and have the flexibility to choose the right distributor for the right market, realizing that there are lots of different markets in China.

Scott Nelson: Got you. Okay. No, that's a great, almost like two really key takeaways, is make sure you've got control on that end that allows the flexibility to pursue different markets with different distributors. So that's great stuff. For the sake of time, let's jump to some of these best practices. You probably already mentioned some of them, and even that distribution model, at least start with maybe three distributors based on the geography you want to enter. But what are some other best practices versus other common practices that you see, whether it relates to partnering, investment, M&A activity, etc.?

Landon Lack: Yeah, so in actual fact, we've covered a lot of the best practices, but it makes sense to recap them because they're really important.

Scott Nelson: Yeah.

Landon Lack: One is, make sure that you control the licenses by selecting a neutral party to be your legal agent in China or, if you want to actually create your own WOFE in China, it's not hard to do. It just takes some money, and it takes some time.

Scott Nelson: Yup.

Landon Lack: So, either way, is great, and that way you preserve your options to change your strategy at any point in time in China. That's probably the first best practice. The other best practices are ones that you would know anyways if you had multiple distributors or multiple sales reps in the US or another country, which is just closely defining the distributors' footprint and area of responsibilities area assuming that you have more than one distributor. Then maintaining price parity amongst all the distributors because we see many examples where a distributor in one province will say, our province is not as wealthy as that province, so you have to give us a lower price, and that causes all kinds of conflict because the product will move across border immediately…

Scott Nelson: Okay.

Landon Lack: …across province to province. The other one is the Foreign Corrupt Practices Act. So, the FCPA or the Foreign Corrupt Practices Act is something that you have to pay attention to in the China market. FCPA essentially says a government employee can't get financial gain for making a purchasing position essentially. It's basically giving money to someone to buy something.

Scott Nelson: Okay.

Landon Lack: For all intents and purposes, every doctor and every hospital administrator in China is a government employee. So over 95% of the hospitals are state-owned or state-controlled. So, you have to put in place a policy to ensure that your distribution partners and anyone else working for you in the market knows what FCPA is, understands the implications of the Foreign Corrupt Practices Act, and agrees to abide by the FCPA. It's not just a one-time thing, it's an ongoing practice, and all the multinationals have these policies and practices in place to make sure they have a proactive program.

The other thing I'd mention, we haven't mentioned it yet and it's the elephant sitting on the table, which is intellectual property and IP protection. Virtually every conversation with have with a medical device company in the US, their first concern is IP. I think that five years ago or more, companies weren't really that interested in the China market or they weren't looking at it as a place to get active in right away. A lot of law firms and IP firms basically said, "Hey, don't worry about covering if you have patents or other IP. Yeah, don't worry about protecting China because it just doesn't matter there anymore.

But things are changing, and the government in China is very powerful, and when they decide to do something it generally happens, and what they have decided at a macro level is they don't want to be the manufacturing hub of the world anymore. They've said, we want to return to innovation rather than just copy, and it's gotten at a point now where that makes sense. So, they're moving back towards innovation, and in order to enable innovators, they've got to protect IP. They're starting to do that, and we're seeing cases where there's been Chinese infringement on foreign IP and the foreign IP had been upheld in China.

So, I'm not trying to suggest that IP is as protected as in the US. It's not even close. But it's moving in that direction and we've seen recently even Chinese entities who've become less interested in US products for the China market if they don't have their IP protected in the China market. So, best practices now include, hey, if you've got some sort of patent or IP that you're protecting in the US, cover this with international patent and include China, and you've only got a window of it's like a year and a half to protect it in China also using a PCT.

Scott Nelson: Okay.

Landon Lack: Well, definitely that is a best practice now, and it's not expensive but you have to proactively do that.

Scott Nelson: Okay. Is that something where, looking five years ago, was it somewhat of the Wild West that China didn't even really pay attention to those patent issues but now they are because of their focus on innovation?

Landon Lack: That's right.

Scott Nelson: Okay. Okay.

Landon Lack: Yeah, that's exactly right. Actually, I think there are more patents, I don't know the exact numbers, but my understanding is there were more patents filed in China last year than any other country. Certainly, they want to protect their own IP, but in order to do that they have to protect others' IP also. So, they can't pick and choose. They've got to protect. But that said, it's still not to the level of maturity as in the US, not even close, but it's moving in that direction. So, generally, when I have companies ask about that, that's information that I share with them quite readily. Yes, protect your IP legally. You might have practical barriers but also protect it legally because that is important to your partners in China as well.

Scott Nelson: Okay.

Landon Lack: Then the other thing, there's, you know, will your product get copied whether it has protection or not? That certainly can happen anywhere, and it can happen whether or not you enter a foreign market. So, you might not ever go to China or to some other foreign country. You can still have your product copied. I think that issue in itself is bigger for probably pharmaceutical companies where it's really easy to copy something. For a lot of medical devices, it's not as easy to make something of the same quality and with the same clinical efficacy. If your target market is the top hospitals and the top doctors, they're not generally in the practice of buying knocked-off products. They want the high-quality product because that's their reputation as well.

Scott Nelson: Okay.

Landon Lack: So, it comes up on everyone's mind. Every medical device you have to look at independently in terms of what the risks are, but generally, we don't see it as big an issue as the perception is with a lot of the companies we talk to.

Scott Nelson: Got you. Okay. To your point about the top doctors, the top hospitals, and if I'm looking to try to get on their radar, if I'm entering the China market and I've got a device that I think they'd be interested in, looking at those upper echelons of hospitals and physicians. In the US, as you know, it's highly relationship-driven. You've got your podium guys, your KOL guys across the country based on their specialty. Is it the same thing in China or does that FCPA, does that create a little bit of a barrier between those really strong relationships that we see here in the US between a physician and a certain company?

Landon Lack: I would say that the doctors in China, and really the key opinion leaders in China, are like the doctors and key opinion leaders in the US and they have the same things that drive them, and they like to be courted, they like relationships to be built. They like becoming aware of new products. They like to participate in studies where they can publish papers and get recognized. If you look at a particular therapeutic area and who the leaders are, there are invariably Chinese leaders in with the US and other European leaders as well, and the world's becoming closer in that regard.

Scott Nelson: Yeah.

Landon Lack: So, as a result of the Internet and the multi-nationals also present in the China market for the last couple of decades, it's actually quite close to the US in that regard or European doctors.

Scott Nelson: Okay. Got you. Okay. Very cool. Anything else we missed that you wanted to add in there in regards to best practices before we reach towards a conclusion here?

Landon Lack: No, I think that's it. I think we covered most of the salient points. I think we could go on talking for a day but those are some of the high points and some of the takeaways that are most important.

Scott Nelson: Yup. If I'm listening in the audience, obviously there's been some really interesting key things learned, and I'll ask you for your one or two big takeaways, but if I'm listening it's pretty obvious that you need someone that's in the trenches over in China. I mean, if you're outside China trying to do this, it would seem to be a monumental sort of project. But for those listening that want to reach out to you, Landon, that want to learn about potentially partnering with you when looking at the China market, what avenues would you have them pursue? Is it email, check out your website, etc.? Go ahead and mention those.

Landon Lack: Yeah, website, email, all are okay, and always happy to just field questions and share information. A lot of our role is to help educate, and that was one of the reasons that I was so interested in talking to you, is just to get the word out and help educate and help answer some questions proactively that invariably come up. But always happy to talk to anyone anytime, and you have my email, landon.lack@chinamedconnect.net, not dot com…

Scott Nelson: Okay.

Landon Lack: …and then chinamedconnect.net.

Scott Nelson: Okay, so china…

Landon Lack: Happy to talk anytime.

Scott Nelson: Okay. Just real quick, chinamedconnect.net is the website?

Landon Lack: Right.

Scott Nelson: Chinamedconnect.net, and for the transcriber, I just wanted to make sure that was clear for the transcriber and then landon.lack@chinamedconnect.net is the email?

Landon Lack: That's right.

Scott Nelson: Got you. Okay.

Landon Lack: I happen to be in the US today, but 12 months out of the year, I'm in Beijing, so email is usually the easiest.

Scott Nelson: Yeah. Okay. Very good. Very good. Yeah. Do you carry that US cell when you're in Beijing?

Landon Lack: I don't, no.

Scott Nelson: You don't? Okay. Okay. I noticed you had two cell phones and…

Landon Lack: Yeah, it just goes to voicemail, which then gets forwarded to me.

Scott Nelson: Got you. Got you. Very good. Alright, so if I'm listening, I always the one or two big takeaways. You obviously threw a lot of information at the audience, and a lot of it was fantastic information pertaining to entering the China market, but are there one or two big takeaways that you'd like to leave people with?

Landon Lack: Yeah, I mean, I think one of the things that we've run into with younger companies is they just say, "Hey, we don't have the time or resources to look at the China market." But it's too big to ignore. So, if you take a little bit of time to determine whether or not China is interested in your product, there are ways to do it that don't take a lot of money or time in terms of resources that you have to expend, and there's a lot of value in doing it if you do it right.

Scott Nelson: Okay. Very good. Alright, so it's worth at least reaching out to you and maybe at least somewhat digging into that to get a feel for whether you should take that next step. So, really cool. Well, thanks a ton, Landon, for coming on. Just out of side-topic, pure curiosity, you mentioned you've been in Beijing, that's where you live pretty much full-time. What are the next steps for China MedConnect then?

Landon Lack: We're going to continue to do what we do and our mission all along. I've been there six years now and we'll be there for the foreseeable future. I think at some point in time we'll come back to the San Francisco Bay Area because we have three young daughters who just know China right now and they need to come back and know America. So, we'll be there for the next probably three years at least Our mission remains to really just be the on-the-ground resource and support for device companies from the US who don't have their own resources on the ground.

Scott Nelson: Yup. Very good. Very good. So, there you have it folks, chinamedconnect.net or hit up Landon at the email, landon.lack@chinamedconnect.net. Well, thanks again, Landon, for coming on. I really appreciate you taking the time to educate the Medsider and MD and DI audience.

Landon Lack: Thank you, Scott. Great to talk to you.

Scott Nelson: Alright. I'll have you hold on the line real quick, but that's it, folks. Again, if you're new to this program and you haven't discovered the Medsider interviews on iTunes, we are on iTunes, just search Medsider. Go to the iTunes search bar, search for Medsider, or "medical device," it shows up, and then subscribe to the podcast for free. That way all the new interviews are automatically just downloaded into your iTunes account, syncs with your iPhone or your iPad, or your iPod. It's really easy to consume the interviews that way if you're on a drive or an airplane flight or whatever, wherever life has you. So, anyway, can't thank you enough for listening. Thanks for your time and attention, and until the next episode of Medsider, everyone take care.