

PKA SoftTouch Microneedle poised to become a Global Medication Delivery Gamechanger



Dick Crawford
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Interview conducted by:
Lynn Fosse, Senior Editor
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CEOCFO: Mr. Crawford, would you tell us the focus behind PKA SoftTouch?

Mr. Crawford: Back in the year 2004, our Co-founder and Inventor, Dr. Pankaj Modi, worked in a company to build a pharmaceutical factory. He noticed my talent and approached me in 2004 and said that he had a device and he wanted me to make it work. He invented it, I made it work. That is our synergy for our endeavor here.

CEOCFO: Would you explain the device?

Mr. Crawford: The device is another form of a syringe and it is called a microneedle. The purpose of the device is to inject a drug into one's body. We do it differently in that we target the skin layer only and therefore this device can do a painless injection of the drug into the body. It has many different advantages over a syringe. The advantages are that first when you inject a drug into the skin layer, it is a painless injection because there are no nerves in the skin, the nerves are below the skin. All other applications of devices such as the syringes, pens and so on, inject a drug through the skin into the subcutaneous tissues, fatty tissues, muscular tissues, where nerve endings are, and there is the ouch or pain.

Secondly, because we target into the skin, and our target is the interstitial layer, which is a liquid between the epidermis or the outer skin, and the inner skin, called a dermis. In-between the liquid is constantly moving all the time. That brings the medication to the bloodstream twice as fast as does a subcutaneous injection by syringe or injection pen. Thirdly, because we inject into the skin, we can do that anywhere on the body. Syringes are limited to five different points of the

body which are the arms, legs or part of the stomach. With this device, anywhere on the body works.

CEO CFO: *Is it common knowledge that injecting into the skin could work better? Have people been looking to find a way?*

Mr. Crawford: People have been trying to do this for the last fifty years. I was involved in the initial writing of the patents in 2006. There are many different devices and a lot of them do not work. Some go on the market but they have drawbacks to them. We were able to get our device patented around the world. We are in twenty-three different countries and all the main countries of the world. We are able to protect our technology.

CEO CFO: *How does it work and why does it work?*

Mr. Crawford: This device is the size of a wine cork. When you get it, it will be in a plastic sterile wrapper. It has to be sterile because when the needle goes in the skin, it has to be sterile. You just lay it against the skin and we introduce a motion similar to a syringe where you use your first two fingers of your hand to hold the device and then your thumb to drive the small plunger. That pushes the liquid down into the skin layer via a very fine needle. When you let go of it the needle retracts and locks. The device does not require sharps disposal.

CEO CFO: *Why isn't there any pain?*

Mr. Crawford: Because the nerves are below the skin, not in the skin. We only touch the skin to lay the device against the skin. If you push hard, then it makes it difficult to get the liquid into the interstitial fluid, and if you push hard enough you may reach a nerve. Just lay it gently against the skin and it is a painless injection.

CEO CFO: *When did you recognize you accomplished what you wanted?*

Mr. Crawford: It was when we started writing the patents. When you look at patents, you look at everybody else's stuff that is on the market and you realize that this is very different. We knew we had a very novel discovery with many advantages on the market. From that point, after you patent a device you then have to prove it and that is what we spent the last fifteen years doing.

CEO CFO: *What types of drugs could benefit most?*

Mr. Crawford: This device can be used for most medications that need to be delivered to the body, not all. There are some that have to go into joints or some other things that are deeper. If it has to reach the bloodstream, this device can be used and it can be used for very liquid type drugs like insulin and can be used for more viscos type medications as well and if it can be forced down into a needle, it will work.

CEO CFO: *What would be involved in manufacturing and would there be a shelf life?*

Mr. Crawford: One of the things that is unique in the medical device industry and that is what we are in, is that we cannot buy the drug and nobody is going to sell it to us. We have to license our technology to a drug company so they can put the drug inside our device. We are not a

widget company; we cannot sell things but we have to license the technology.

We have to prove to the drug company that our device works and we prove that by doing what are called clinical trials. They are very standard clinical trials called proof of concept, so we take a known drug such as insulin and put it into the body. We do all of the pharma kinetics to note the drug's reaction to the body and if it is the same as a syringe, then that proves that the device works and that is what companies are looking for.

CEOCFO: *Is there a big market in syringe manufacturers who may somewhat fight against what you have developed?*

Mr. Crawford: The makers of the syringe are owned 80% by Becton, Dickinson and Company. However, we are not going to take them on directly. One of the things when you invent a novel technology, and there are many witnesses to this in the past, where some other company buys a technology, then because you challenge them, they put your technology on the shelf and they continue selling syringes or whatever they are selling.

We have devised a business plan where we go to the drug company and if the drug company is interested in the technology because of the many advantages to using it that they will gain market share. That is why they would want to do a license with us. That is the business model. Once we do a license with drug company A and then we do drug company B, C, and so on. That is how we are going to make our money, through license agreements.

CEOCFO: *Does this work on animals as well as humans?*

Mr. Crawford: Yes, actually we did initial animal trials with dogs at the Ontario Veterinary College of the University of Guelph Animal Clinic years ago to prove our technology works. When we do our first clinical trials, we will again go to the University of Guelph using research dogs again. We do this under the auspices of Health Canada, so it is an approved trial. After that, we then do a clinical trial on humans and most likely at Lakeridge Regional Health Center in Newmarket, Ontario.

CEOCFO: *I could see this as being a big game-changer for so many people. Is the public aware of what you are doing?*

Mr. Crawford: I think this is going to be a market interrupter or game-changer. We are not very well-known yet, we are a small company. We have had quite a bit of success with two equity crowd funding campaigns, so our word is getting out. I have had many calls from people saying they needed this device now, because their aunt has to take three insulin shots every day and they are painful.

The big thing with our device is it is easy to use. We can train an eight-year-old or an eighty-year-old to use it. It does not look threatening, there are no needles sticking out, you use it and throw away. There is no sharp disposal because the needle retracts, locks inside and does not come out anymore or injure anybody.

CEOCFO: *How do you deal on a personal level with frustration in how long it takes to get there?*

Mr. Crawford: First of all, in the pharmaceutical industry, and I have been in the industry for fifty years, any new technology takes a long time to incubate and develop before it gets on the market. We are on par with other technologies in the pharmaceutical field. Our fifteen years is normal because we have to conquer a lot of different things along the way and we have to make our device fool-proof, it has to work 100% of the time, and it has to be easy to use.

It is also inexpensive; we are in the same price range with a syringe which is the lowest cost device on the market. We expect that once a company picks us up, other companies will want to pick us up to because they can see that this thing really works and is going to change the way we do inoculations around the world.

CEOCFO: *Would you tell us about your recognition as one of the Top Ten Best Innovations at the ICAN?*

Mr. Crawford: I belong to the Inventors Circle in Toronto. I joined them about five years ago. The head guy heard about our technology and then I gave a presentation there and he has been a real backer for us. He submitted us to ICAN and ICAN responded with an award, a gold medal, and then we came out 2nd in the world. We are the only Canadian one that won the award in the Top Ten. I think other people are now beginning to recognize the uniqueness of this technology. I am a pharmaceutical engineer and Dr. Modi is a medical doctor, PhD, chemical engineer. The guy is a walking book, he never writes anything down and he is brilliant.

One of the reasons I went with him is because he has invented other unusual technologies that work. For example Botox, you have to inject Botox in somebody's skin to reduce wrinkles. He has reformulated molecules into a lotion that you just put on in that case. He has invented a wafer that can put a drug in your body in two seconds. You put it under your tongue and it dissolves in two seconds because under your tongue is very close access to the bloodstream. He has invented another salve that if you have a knife cut or something, you put this on it and it heals twice as fast. It brings more oxygen to the site to heal the tissues.

Another one I worked with him on is insulin in a puffer. You blow it into your mouth to put insulin in your body. Dr. Modi invented this process and I built a factory to make the puffer device with the insulin. That is how we got together. He saw what I did and said he wanted me to join him.

CEOCFO: *What, if anything, might people miss when they are looking at PKA Soft Touch and what you have developed?*

Mr. Crawford: Our device is really a platform technology because it is versatile with many different kinds of medications but also with different kinds of situations. We had a company in North Carolina that contacted us and said they dealt with peoples' warts. They wanted to inject a drug into the roots of the wart as it grows in the skin, but they use a syringe and they cannot see inside, so they would be almost there or right there or too far.

With our device we put a little acorn at the bottom, come in from a 45-degree angle and we can target that root structure every single time 100%. They love that. When we deal with a large animal, cow, horse or pig, we can make our device a little larger and we have a larger volume of drug inside the device. We can make our needle longer to reach so we can do many different kinds of things with this device.

CEO CFO: *Lots of opportunity?*

Mr. Crawford: Yes, a lot of opportunity. That is why we think it is going to end up changing the world. The syringe has been around for 170 years and it is still the same.

CEO CFO: *Do you have a global vision for your product?*

Mr. Crawford: We have a vision here and that is because as unique as the device is, there is no sharp disposal, it can be used anywhere on the body. We see this being used in Africa, Asia, and underserved countries of the world where we have to inoculate populations against Ebola, dengue fever, diphtheria, cholera, all those things. We envision long lines of people coming up and when they see a syringe, they all know the thing is going to hurt and people are crying or they do not want to take it. Our device looks so safe and simple. They get inoculated, they come out of the tent and they are smiling, other people see they are smiling, so it is going to encourage people to reduce the fear of getting inoculations.

When you are doing this in the bush, you have the problem with sharp disposals and with our device it goes into the ordinary garbage. Therefore, it is ideal for that kind of situation. We did have some preliminary contacts with the WHO (World Health Organization), and they are interested. We also contacted twenty major pharmaceutical companies in North America. They are also interested in our device but they are waiting for our clinical trials and then that will get the ball rolling back to these companies.

