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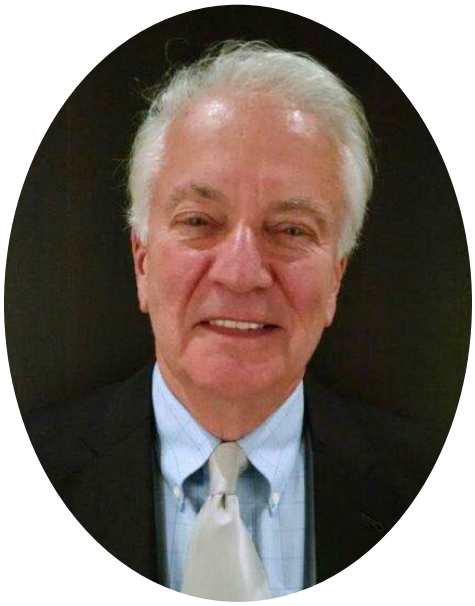
Q&A with Dr. Leonard Schultz, Founder and CEO of Nascent Surgical, LLC providing Smoke, Bioaerosol and Nanoparticles Capture devices to Clean the Air in Operating Rooms and Other Areas of Contamination



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CEOCFO: ***Dr. Schultz, what is the concept for Nascent Surgical, LLC™?***
Dr. Schultz: The concept is to provide smoke and bioaerosol capture devices to clean up the air in our operating rooms and other areas of contamination. The purpose would be to provide products for removal of surgical smoke and bioaerosols from the operative environment.

CEOCFO: ***How are these removed today or are they not considered a problem?***
Dr. Schultz: First of all, the development of these particulates in the air that the operating room team and patients should not have to breathe in on a chronic basis is produced by cauterization of the tissue. When you cut and coagulate, the end result is smoke production and the release of materials from the human body into the air; the air that the perioperative team and their patients have to breathe in during the surgery. Currently, until the need for smoke evacuation is fully recognized, most of these impurities, are not removed and are allowed to linger in the operating room until filtered by whole room filtration systems that do not really do a very good job of getting rid of these impurities.

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CEOCFO: ***Has the medical community not recognized the problem? Has there just not been a solution? Why has this been allowed to happen?***
Dr. Schultz: That is the ideal question! I have tried to understand myself, for what is now a thirty-five (35) year history of interest. For the most part I think it has to do with the coal mine mentality. That is, "This is where I have to be to earn my salary and if I have to breathe in some smoke and who knows what else; then I guess I have to." Now, what we know is that the masks that are customarily used are ineffective for filtering out and trapping particulates in the air that should not be breathed in. We know that. We have always known it. However, people put up with it and I think they put up with it simply because, like the coal miner who has to breathe in coal dust to make a living, they have got to breathe in smoke to make a living. Number two; it has been a hard fight to try to get them to realize that what they breathe in is potentially harmful to them; not just irritating and not just something that makes their eyes tear or their throats dry, but can actually have significant systemic effects following chronic inhalation. Number three; the effects that it would have on any one individual are highly variable and therefore not predictable. For example, what happens to you after ten or twenty to thirty

years in the operation room of breathing this junk in will be dependent upon the dose and duration of exposure. It will be dependent in part upon your genetics and in part upon any preexisting illnesses. The obvious example would be that someone with asthma would not want to be breathing in surgical smoke.

CEOCFO: ***Is there any way to prevent some of the smoke, some of the potential damage or is it a given that that is part of the procedure and there is no way around that aspect?***
Dr. Schultz: Actually, modern day technology does allow for adequate capture of surgical smoke so that it does not have to be chronically inhaled. Not only that, but additional research is indicating that not only do we capture the real harmful aspects of smoke, which include nanoparticles which are eighty percent of surgical smoke, but also the bioaerosols, which mean potentially infective viable bacteria present in surgical smoke. All of those can be captured satisfactorily by today's technology.

CEOCFO: ***What have you developed at Nascent?***
Dr. Schultz: We developed the product that can actually capture those nanoparticles and capture the bioaerosols and get rid of them. That is the beauty of the product! Of course this whole topic begins in the 1960s with the advent of electric current for surgical cutting and coagulation. Therefore, the famous Bovie is the product that was put out by Bovie Medical back in the 1960s, which introduced electrocautery or electrosurgical current to the operating room.. Before that it was all clamps and ties, clamps and ties, which took way too long! Therefore, the people were starting to get into this electric current, because it was quick! It really shortened the operating room time, which was important to everyone, in terms of cost as well as fatigue and so forth. Therefore, it caught on very quickly. However, the problem was that it created smoke that nobody had any idea how to get rid of. Then along came Wyman Stackhouse® in the 1980s, prompted by laser surgery which produced twice as much, three times as much smoke into the air, than did electric current. Now it became literally impossible to do major laser surgery; for example tumor surgery, the removal of big tumors from people, without having something to capture the smoke. That was the advent of smoke evacuation, which was initially a modified vacuum cleaner and a seven-eights inch plastic hose that was sterilized so that it could be used in the surgical field. Then someone had to hold the end of that tube and follow the column of smoke before it escaped. That is because smoke is hot and it has what is known as Brownian motion. Therefore, it wants to rise and go in all directions quickly. If you wanted to capture it the hose did not really do a great job unless it was right on top of the source of the smoke. Plus the fact that as the years went by it was too expensive to have someone dedicated to go running after a column of smoke to get rid of it. Therefore, we had to come up with a product that would do a better job of capturing smoke over a larger area, so that we could have the assistant do what assistants do, which is help the surgeon with the surgery and not to worry about smoke capture. That is what led us to the development of our product, the miniSQUAIR®. You can think of the miniSQUAIR® as kind of a smoke hood. When you are cooking on a range and you are cooking onions and things that may not smell so good, you turn on the Jenn-Air and all the smoke goes to the Jenn-Air. That is exactly how this product works.

CEOCFO: ***Would you describe the physical product and how it works?***
Dr. Schultz: The miniSQUAIR®, as its name implies, is a smaller version of a larger device, because the original name was SQUAIR because of its square shape that promised clean air in the operating room. Therefore, it was spelled, "SQUAIR". The original idea was that it would be reticulated cell foam, which resembles honeycomb, sandwiched between two layers of non-porous, medical grade material, so that anything that the foam captured could not escape. The capture device, is placed close to where the smoke is produced which then entered a flexible tube greater than one (1) inch in diameter. The wider the tube the more air and smoke that you have taken away from the surgical field. The smoke in the tube then goes to a filter where particulates and odors are removed. The filter standard used today is called an ULPA or an ultra low particulate air filter. They remove particulates down to one hundred nanometers or a tenth of a micron in diameter. They are also called, "ultra fine" particles. Let us just say the particles are pretty small and it filters out certain bacteria. This passive system is made active with a turbine. This turbine is also referred to as a smoke evacuator, which is a turbine in a box. You turn it on and it creates a suction which is transferred to the smoke source. Therefore, the smoke is literally sucked, like a vacuum cleaner away from the operative field so it is not inhaled by the operative participants. It is sucked right into the capture device and travels down the tube and through the filter and then comes out the other end and it is nice and clean and fresh. At least that is what they tell you. That is not quite true, but that is another story. Suffice it to say you can do a pretty good job in cleaning up the air when using an ULPA filter with current technology. The next step will be to take that smoke and particulates and the bad stuff in it and put it into a central vacuum system, which will bring all of the contaminates to a remote site, where they will undergo ultraviolet light treatment for sterilization as they exit the hospital.

CEOCFO: ***Where are you in commercialization and in getting hospitals, doctors and the public to pay attention?***
Dr. Schultz: The product has been around now for about three years. It has entered into a field which has been pretty much owned by another alternative technology called an electrosurgical unit "pencil". That pencil, which has been around

now for almost twenty years, consists of a single electrode through which the electric current does the cutting and the coagulation. Imbedded in that electrode is a three-eights inch wide flexible tube, the end of which has to be very close to the tip of the electrode so that it can collect the smoke. Our product has been tested at the University of Minnesota Particle Calibration Lab against the competition. The people who tested it found it to have a ninety-nine point five percent (99.5%) capture efficiency verses the tube with the pencil, which has about half that. The other reason why we are excited about it is that it allows for the capture of the nanoparticles, which, with chronic exposure, can cause serious systemic illnesses, some of which include multiple cancers, heart disease, collagen diseases; and the list goes on and on, including Alzheimer's and Parkinson's.

CEOCFO: ***Are there immediate reactions as well? Might it slow down a nurse or a surgeon while they are in the operating room, because they are breathing this in?***
Dr. Schultz: Absolutely! The study has actually been done by a past president of the Professional Organization of Nurses called the AORN; the American Organization of periOperative Nurses. They used to be called Operative, but now the are called periOperative Nurses. Her name is Kay Ball and she found that there are actually multiple acute changes that take place by breathing in this smoke. To give you an idea of the numbers the OR nurses exposed to smoke on a chronic basis had twice the incidence of respiratory illnesses than did the general US population. Therefore, there is an immediate issue. Also, illnesses represent absenteeism. Absenteeism represents an increased cost to the hospital. I should also point out, while we are talking about this, the known association, of exposure and later disease could represent a huge financial burden to the employer. We are into a phase of education, educating clinicians who have not received this education, especially surgeons. The nurses; yes, because they work in the environment, literally 24/7. Doctors; much, less, since they have a lot less exposure to the smoke. However, the nurses, when they come to realize that their chronic illnesses, upon retirement at fifty five or sixty, have been related to unprotected smoke inhalation despite OSHA guidelines, that make the employer responsible for a healthy environment, watch out!. When this information becomes available, think about the potential liability to workmen's compensation claims for the healthcare systems that now employ everybody; nurses, doctors, technicians and so forth. If you think asbestos was a problem with mesothelioma, the potential financial liability to healthcare systems is well beyond that.

CEOCFO: ***How are you making progress in getting into operating rooms?***
Dr. Schultz: We make progress slowly, but steadily. Over the past three years what we have found is that there will usually be a nurse or a doctor that gets in touch with us. Often-times it will be a Director of the O.R. or O.R. Nurse Educator who will get in touch with us and say, "We have seen your product on the internet, we have seen you at a trade show". There will be some point of contact of information. "Would you please send us more," and we do. Every claim we make has documentation in contrast to the competition that just says, "Use our product, we collect smoke." We tell you our smoke capture efficiency. We tell you about the nanoparticles and why you should get rid of them. We tell you that we also capture bioaerosols which are potentially infectious viable bacteria present in the operative area. This is very significant and will become more significant, because if anyone is interested in anything in the OR these days, it is the incidence of post-operative wound infections. Nobody wants to pay for them. Now that we have minimally invasive surgery, everybody gets a same day operation, is sent home and should the wound be contaminated, within a week when they finally go back to see the doctor, they have a frank infection that now needs hospitalization and special care to the tune of at least twenty-five to thirty thousand dollars per case, which the government insurers will not pay if it occurs within thirty days of surgery. Therefore, everyone is starting to pay attention. We believe that by capturing the bioaerosols we will ultimately show a significant decrease in the rate of post-operative infections. We are now writing up results of a preliminary study. It is the very first time that smoke capture has been considered as an infection control device, in this case with a clinical review of spine surgical cases. We chose spine because there is the implantation of a prosthetic. Other at risk operations would include heart valves, and orthopedic appliances; If these patients get a wound infection, it is a disaster and a significant cause of in-hospital mortality. Therefore, we chose a group where they do not have high infection rates, but they do have significant infections when they occur. We reviewed close to one thousand patients; half with and half without our product and we found a definite trend towards reduction in wound infections but the groups did not attain "P' value significance; that is where $p>0.05$ or better. Therefore, we are now expanding the study to try to get the numbers that we need (861 in each group) to gain the statistically significant differences. We believe that we will get them.

CEOCFO: ***Are you seeking funding, investments or partnerships?***
Dr. Schultz: Yes, we always do. I will tell you why. Our business plan has multiple stages. The first phase was to establish marketability of our miniSQUAIR® product and I think we have and are continuing to do that. We continue to add accounts and we have had increasing sales, usually at about thirteen percent a year since we introduced this product. However, we do not have enough penetration because we are a small company. In order to get a product really accepted

at a hospital, you need to have a presence there on a continuing basis. For a small company like ours, we have multiple advocates at different hospitals and therefore have sales at a wide swath of hospitals around the country, including by the way, Europe and Canada. We depend on surgical advocates to carry our product into the operating room, so we need investment to expand our sales network. We also need it to go onto the second phase of our company, which is to take our technology and put it into a surgical drape, because then the doctor is not asked, “Would you use this?” This is because eighty percent or more of physicians say no. Once declined, the nurses cannot say, “But I want you to protect my respiratory health,” and they back down at this stage. Our technology in a drape would remove the choice. The third phase is that we need to direct all smoke components into a central vacuum system, which also can double as a fluid management system. There is no difference between sucking up smoke and sucking up fluid. The technology for both is the same. All of a sudden the costs for both of these types of hospital requirements go down dramatically. Therefore, we are always looking for funding to carry us into the central vacuum system phase of our company, at which point we will have completed our business plan.