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## Healthy Design’s Exersides® Refraint® System Enables ICUs to Lessen Restraint and Sedation Practices to Allow Better Outcomes



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**Interview conducted by:**  
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**CEOCFO: *Dr. Pavini, what led you to found Healthy Design?***

**Dr. Pavini:** I have been an intensive care unit physician for a couple of decades, and that put me right on the front line to see the unresolved issues that we face today. It seemed that no one was fixing these problems, so I decided to do it myself.

**CEOCFO: *What problems are you addressing?***

**Dr. Pavini:** The first problem that we are addressing is the issue that when people get sick and they end up in the hospital with vital tubes and lines, often they will get tied to their beds, so they will not pull these things out. If you are tied to the bed, of course you are going to get very agitated, and you are going to need sedation. So now you are going to be tied down and sedated, which causes hallucinations and delirium. This delirium can last even after you get home. It can actually last for years, or forever. It can lead to worsening dementia, it can uncover dementia, and it can lead to what is called Post Intensive Care Syndrome, or PICS. And you do not have to be in the ICU for this to happen. You can be anywhere in the hospital, or in rehab, so this is a real issue.

We can understand why staff are doing this. They do not want you to dislodge your tubes and lines, but really, it has to be the most barbaric way to bring this about, and it has just been kind of grandfathered in. We are all used to seeing it. It is the way it has been done, but it is the way it has been done since the dark ages, so it causes much more harm than good. it leads to worse outcomes.

Having seen this first-hand made me think that common sense has to prevail and this needs to be addressed. However, I did not see anyone else doing it. Therefore, one day I went to Home Depot and grabbed a few tools and started tinkering, and that led to getting an NIH award, and then several NIH awards, and eventually starting this company with the flagship product of our physical restraint alternative, The Exersides® Refraint® System.

**CEOCFO: *When did you decide to go to Home Depot? How did that come to you?***

**Dr. Pavini:** That is funny that you ask that question, because I have not publicized this. I think the turning point was when my brother got sick. He had a hemorrhagic stroke, and he was in the hospital that I trained in, a large academic

hospital. They were restraining and sedating him, and it is just the worst thing that you can do to a brain injury patient, for a couple of reasons. One is that you really need to keep that brain/muscle connection as intact as possible, in the very earliest stages. If your pathway has already been damaged when your brain tells your arm to move, then the last thing you want to do is make the arm that can move not be able to move by tying it down. If the affected arm moves even just a little bit when your brain tells it to, but the patient is being restrained, the pathway to healing may become delayed or even permanently damaged.

Going back to my brother's situation, they were restraining and sedating him, so I stayed by his bedside all day and all night, day after day, and refused restraint and sedation for him. Of course, he started getting better when the sedation was lifted. Unfortunately, one night I had to be out of his room and when I came back in the next day he was not moving. The overnight staff had not noticed it, but the morning staff just coming in saw that my brother was not responding and did an emergency MRI. We were all panicked and thought that he was gone. It turned out that they had just sedated him overnight and he could not wake up, even after they shut the sedation off, because it stays in the body.

This is such a bad thing to do to people. Even though my brother's situation was not the reason I started the project, that was the turning point that gave me the resolve to start making a prototype and finish developing the solution. No matter who helps me or works against me, I now have the resolve to keep going to the end.

**"We are all about a person's experience throughout their hospital stay, through to rehab and even home and hospice. There is not really another company doing this." Marie Pavini MD FCCM FCCP**

**CEO CFO: *Would you tell us about the Exersides® Refrains® System?***

**Dr. Pavini:** The Exersides® Refrains® System is a soft, lightweight device that goes on the arm to allow patients to move their arms in all directions. It does not have to be tied to the bed, and we entrain tubes, lines and cords with it. This allows the patient to move all around and not get tangled up in those vital tubes and lines, enabling them to stay safe. We do offer a couple of bed straps that can be used, because sometimes some people do need restraint. You can imagine maybe a drug withdrawal patient, or someone who has massive strength, along with severe agitation and confusion. Therefore, this device can turn into a restraint easily and quickly, so that the device can always be titrated to be the 'least restrictive intervention', which is a government mandate.

CMS, the Center for Medicare and Medicaid Services has a mandate that says you must use the least restrictive intervention, and all of the other devices out there are either on or off. This device can be titrated, so there is a bed strap that is a flexible strap, and you can titrate the length of that strap. You can titrate from restraint, to intermediate resistance settings from strict to liberal, to no bed strap at all, which is the goal for everybody. Addressing a patient's agitation from being strapped to a bed then allows the clinician to reduce sedation which reduces delirium and other complications.

There is just so much clinical evidence that links immobility and sedation to delirium. There are also complications from not moving such as getting secretions stuck in your lungs, having gut dysmotility, pressure injuries and things like that.

**CEO CFO: *Where are you in the development process?***

**Dr. Pavini:** We just finished our randomized control trial. We did a pilot study, a Phase 1 study, and now a Phase 2 multi-site randomized control trial, which was done at Johns Hopkins, University of Vermont Medical Center, and University of California San Diego. Those Phase 2 data are currently being analyzed, but I can say that the device is safe and effective. Basically, that means that the device will not hurt the patient, it will not hurt staff members, so we now know that you can have a patient untied from the bed with the Exersides® Refrains® System and they will be safe from vital tube and line dislodgement.

Clinicians can do whatever they want with that. They can now reduce sedation, they can instate more mobility programs, and hopefully patients will be able to interact more and be able to have decision-making power in their own care as it is happening. They can convey symptoms. We have had patients who were writing down for us that a certain medication affected them negatively, or that they were having trouble breathing, or that they needed to be suctioned, and things like

that. I think that the Refrains<sup>®</sup> is now the only clinically trialed all-in-one device that is compliant with that CMS mandate of 'least restrictive intervention'.

**CEOFCO: *When you show this to medical professionals, do their eyes open wide? Does everyone say, "Wow, this is wonderful?" Are people skeptical? What has been the response?***

**Dr. Pavini:** There is going to be a 'yes' and a 'no' answer here. People do come by and say, "Wow, this is a game-changer," "where was this before," and "yes, we have been doing crazy things, and this is wonderful!" The flip side is that trying to get this into their institutions is so difficult. We have been to medical conferences and people come by and they have that great reaction, but then say, "but I will never be able to get it into my hospital," or "it will have to go through so many committees and they are not going to want to spend any more money than they have to." Even though this device saves a ton of money and pays for itself over and over again we still hear this.

Another issue is that with the way medicine has become, we are spending much less time with patients. We have to document much more. We are busy. There is a nursing shortage, so they are trying to take care of many patients who are very sick, and they do not have time to think about something new right now. These are the two forces pulling against each other: clinicians wanting the device but feeling they cannot make it happen. What we are going to be doing to help that situation is to do more to let the public know a solution exists.

It is kind of a hidden thing that happens in the hospital. When you go visit a loved one in the hospital you figure that the hospital staff are just doing the best thing, and there is always an answer for why they are doing things, and you do not know if that is right. Therefore, it is better if you understand the problem before you get sick, or before you go visit your loved one, to make sure that your hospital has this option.

**CEOFCO: *Are there associations or committees that cover some of the main areas where people are likely to be restrained, that you could approach or try to work with in some way?***

**Dr. Pavini:** I have actually been on committees in some of those organizations, like the Society of Critical Care Medicine, the American College of Chest Physicians, and the American Medical Extended Reality Association. However, they are not allowed to mingle too much with industry, so they cannot support one company's product. That said, they definitely support research that has shown over and over again that restraint and sedation lead to delirium and other complications.

The government also supports that message, and they make regulations that say that we have to try to minimize restraint and harmful sedation, but since there was no device on the market, we could not do it, so it went unchecked. That is going to change now.

There is a strange thing that I have encountered, going from being a 100% clinician, to being in industry. It is like I have gone from being a COVID hero to being a capitalist pig. The same people that I was working alongside, researching with, and innovating around, now see me differently. Now that I have a company and a product for purchase, it becomes a very different thing, and some of my fellow clinicians and researchers now look at me askew. It is a very difficult landscape to navigate.

**CEOFCO: *Are there companies that make the current restraint systems, that are likely to not want you around? Do you see partnering as a possibility?***

**Dr. Pavini:** As far as the current restraint companies, sure they do not want reduction in their sales, but there is enormous partnering opportunity. We have just finished our clinical trials, and we are getting ready to take over the market now. However, there is a lot of opportunity for partnering, not only with the other restraint companies, but also with companies that want early mobilization, delirium prevention, and sedation reduction as part of their own product, such as the hospital bed companies.

Bed companies are very invested in early mobilization and sedation minimization. Their beds can now verticalize, so that we can get patients in a better position, and try to get them moving. Therefore, this product fits in perfectly with those types of companies. If we end up partnering with one of them, that company would have the very earliest mobilization device to add to their product portfolio, so there is a lot of opportunity.

**CEOFCO: *Are you seeking investments, or funding of any kind?***

**Dr. Pavini:** We are, but the type of investment we would be looking for is not just money. It would have to be something that could help us to spread across the market more widely and quickly. It would have to be money that talks, let's say.

**CEOFCO: *Do you see areas outside of the United State as perhaps better possibilities to begin?***

**Dr. Pavini:** That is kind of an interesting point. I think Germany is one of the countries that is having the largest problem with restraint and sedation. They seem to be really looking for answers. They have expressed interest, so that would be an interesting country to go into. There are other countries, like the Scandinavian countries, that do not use physical restraints, but they over-sedate patients so that they do not move, and that causes just as many problems as being tied to the bed. Or they have more one-to-one staff to patient ratios. Those staff have reported that they are burning out more, because they are always in the room with a patient who is not tied to the bed, and could easily, in an instant, just pull out a breathing tube. Therefore, that is not a good model either.

There are different countries that would be really ripe for this market, and we will get there. We are ISO 13485 compliant. We manufacture our own devices here in Vermont and once we have ISO certification we will get a CE Mark, and then distribute globally.

**CEOFCO: *What have you learned throughout this process, both on getting the device to where it is ready, and as well as the business side?***

**Dr. Pavini:** I was just a doctor. I did not know anything about any of this stuff. Therefore, I have been going through an incredible on-the-job entrepreneurship training! I have been so lucky that the NIH has provided me with mentors to help me to learn. They are really an incredible group of people. I have worked very closely with them to understand the commercialization landscape.

Certainly, just learning about business is something that has taken place. The other part is that I have been kind of sheltered where I was a clinician in a small community hospital, and everyone was happy, friendly, the patients were our neighbors, and we worked together very well. However, that model does not exist everywhere, so it is really disheartening to learn that there are institutions that will not exert the extra effort to help their patients, but there are still some that do, and that is where we are going to start.

**CEOFCO: *Why does Healthy Design stand apart? Why should people pay attention?***

**Dr. Pavini:** Much of the advancement that has been going on lately has been digital. Like apps, there is an app for everything. These things that are supposed to help reduce the time that it takes to deliver care, to try to get more people in and out, and high-tech solutions, like different types of implantables and things like that. However, the thing that has been missing is the humanity, dignity, and quality of life of the person going into the hospital. They are no longer treated like people. They become widgets once inside, and it is really difficult if you are not a medical person, to see that it could be different.

Healthy Design is aimed at bringing the humanity and dignity back to the person who gets sick and ends up in the hospital. We are congruent with the Social Justice Movement, because it is the black older adult who is at higher risk of being restrained and sedated. Since product development is coming from me, and I do not answer to someone telling me to change the device to serve the bottom line, I can focus on what I have always focused on, which is making people's lives better. I want my family to have a good experience in the hospital. I want everybody to have a good experience in the hospital, patients and staff.

We have other products coming out for the same patient population, such as an agitation monitor, a platform that gives patients a safe way to have mobilization on their own while they are in the bed, and we even have Virtual Reality staff training experiences, so that they can better understand what it is like to be the patient. They can actually put a headset on and get in the body of the patient, to understand what it is like. Then they can get into the body of the caregiver and learn how to deal with the issues. We are all about a person's experience throughout their hospital stay, through to rehab and even home and hospice. There is not really another company doing this.