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Getting Personal With Edwards' Mike Mussallem: Hard Work, Giving Back And Changing The Practice Of Medicine

'Let's be givers, let's give back to the communities more than we ever take. Let's have the communities that we live and work in say, boy, I'm glad Edwards is here. They make us stronger.'

by Marion Webb

In this new series titled Getting Personal, we talk to new and veteran senior executives about their journeys to corporate leadership, their motivations, passions, and the peaks and valleys of running a medtech company. *Medtech Insight* sat down with Mike Mussallem, CEO of Edwards Lifesciences, the leading seller of transcatheter aortic valve replacement (TAVR) devices, at the company's Irvine, CA-based headquarters.

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With 22 years at the helm of *Edwards Lifesciences Corp.*, Mike Mussallem vies for the longest-standing CEO in medtech.

Much has changed in two decades, certainly in the global heart valve space that Edwards Lifesciences leads, but also in the prominence of social inequality issues in political discourse and public consciousness around the globe.

Headquartered in Irvine, California, where the median property value of a home in 2020 was \$861,700 and median household income \$108,318, according to DataUSA, Mussallem is keenly

aware that while Edwards' growing campus offers tremendous opportunities for many, its benefits may not be equally distributed across populations. He and other medtech leaders will address health inequities and their causes at the upcoming AdvaMed Medtech Conference in Boston. (Also see "*CEO Perspectives: COVID Impacts On Supply Chain, Digital, At-Home Care, And Medtech's Place In 'Food Chain'*" - Medtech Insight, 4 Nov, 2021.)

Mussallem grew up in Gary, Indiana, famously known for being Michael Jackson's birthplace and home to U.S. Steel's Gary Works, where he spent summers earning money for college. He was raised in a warm, loving family and looked up to his older brother, George, who was born with Down syndrome. Mussallem's wife, Linda, coincidentally also grew up with an older brother with Down syndrome. The couple is known for donating time and money to related charitable causes, among others.



Source: Edwards Lifesciences

Giving back is also a cornerstone of Edwards' culture. Edwards invested more than \$30m and employee hours in an initiative called Every Heartbeat Matters, which aims to improve the lives of an additional 2.5 million underserved structural heart and critical care patients by the end of 2025. The Edwards Lifesciences Foundation has gifted almost \$130m to non-profit organizations worldwide.

One of the biggest challenges for Mussallem is to maintain the company's culture, including a vibrant spirit of innovation, as Edwards grows. See our full interview below which has been lightly edited for content and brevity.

Q Medtech Insight: How has your upbringing shaped your career and where you are today?

A Mike Mussallem: I grew up in Gary, Indiana. It was a steel mill town. I spent my summer working in the steel mills to help pay for my college education. I'm very fortunate to come from a family that was a very warm, loving family. I also had an older brother with Down syndrome and so I learned a lot about achieving your

potential regardless of where you're from and appreciating others and some of the obstacles that they had to overcome to achieve what they have.

Q You are very active in philanthropic causes and charitable giving, and that's also a leading element of Edwards Lifesciences' culture. Can you talk about some of the causes you and your employees support?

Mussallem: I just feel very fortunate to have a career where I've been able to earn money and be successful beyond what I ever imagined or ever dreamed.
Coincidentally, my wife also had an older brother with Down Syndrome, and one of the centerpieces of our philanthropy is to give back to those with Down syndrome, particularly adult Down syndrome that need some independent life, need better health care and need a better life, frankly.

Beyond that, we're also engaged in organizations that relate to the help that I got when I was growing up, whether it's trying to do something nice for places like Gary, Indiana, or do something nice for the college where I was able to get an engineering degree [bachelor's degree in chemical engineering and honorary doctorate from the Rose-Hulman Institute of Technology] and generally support those that have a willingness to work hard and move up and need a little bit of a break in life.

[At Edwards] We think about trying to do big things to change the practice of medicine and give better futures for patients and try to have extraordinary quality and extraordinary integrity and a great place to work where all employees are respected. But this other part of giving back to the communities is something that we take very seriously.

Q Can you talk about some of your efforts to support the local community?

A Mussallem: Yeah, it's been rewarding. People may not understand that there are some parts of Orange County that are very successful and other parts of Orange County that really need a hand up. And so trying to make a difference in our local community is something that we're also quite engaged in. We particularly have taken this on

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from an Edwards perspective.

Here we have Edwards with a beautiful headquarters in beautiful Irvine, California, but not very far from here are families and schools that have communities where they're food-insecure and they don't end up graduating from even high school, let alone college, and they don't end up having bright futures. We work very strongly with United Way and the American Heart Association – the list is quite long of all the charities that we support in the local area.

One that I'm most proud of actually is Washington Elementary School, which is an elementary school not far from here where, boy, it's really tough. I want to say 70 to 80% of the kids are food-insecure and they don't have secure homes. Our employee base here has just embraced them, and they do things that are charitable for them.

But probably the thing that's most impressive is just the way that they engage with them and try and open their eyes to a future of science, technology, engineering and math that would stimulate them to get excited. So whether it's little lectures in the classroom or building model rockets together, or have them come to campus and experience what life is like here, just a chance to try and inspire these kids for a better life.

Q What are Edwards' biggest accomplishments?

A Mussallem: I'm very proud of the culture here. I think it starts with culture, this idea of really declaring that we're here because of patients. That's why we exist. Helping patients is our life's work. That it's always patients first, that it's our priority, is something that's ingrained with our team, and in many cases, that's why they come to Edwards.

We also have a culture that prioritizes innovation and picking chances to do something big, like change the practice of medicine and then backing it up with evidence. I'm so proud of what we've done, for example, in areas like transcatheter aortic valve replacement. To actually be able to routinely replace valves around the world in under an hour and have patients go home in a day or two has just turned out to be a remarkably positive development for patients with aortic stenosis.

- Q In September, Edwards announced that its Pascal Precision transcatheter valve repair system for transcatheter edge-to-edge repair (TEER) was approved by the US Food and Drug Administration. What does that mean for Edwards on the competitive landscape?
 - A Mussallem: Yes, so TAVR really went after one of the biggest structural heart diseases out there called aortic stenosis. This is where your aortic valve fails because of circulating calcium. But there are many patients – and some would argue more patients – that suffer from mitral regurgitation or leaky mitral valves or leaky tricuspid valves.

And those have turned out to be very difficult engineering problems to be able to address the leaks of those valves. We feel like the time is right now to be able to apply technology to be able to repair and replace mitral and tricuspid valves. The Pascal is the first US approval of a system that is commercially available to address mitral valves that leak. There is one other competitor that's already done this [Abbott] and we're very pleased to be able to bring Pascal on the scene, and we think it will be welcomed by the customers that are there. (Also see "<u>TCT 2022: Edwards Ready To</u> <u>Take On Abbott In Mitral Repair Market With 'Premium' Device</u>" - Medtech Insight, 22 Sep, 2022.)

We also think though these kinds of patients with these diseases are not going to be addressed by one technology. It's going to take a toolbox. We're not just bringing Pascal, but we're going to bring replacement technologies as well. And then we also have a bunch lined up for the tricuspid valve. So we have, I think, just in the area of mitral and tricuspid, probably six or seven pivotal trials going on right now.

Q Can you talk about the EARLY TAVR trial, which examines the safety and effectiveness of the Edwards SAPIEN 3/SAPIEN 3 Ultra Transcatheter Heart Valve versus careful observation in patients with severe aortic stenosis, and

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where you see the growth of TAVR?

A Mussallem: TAVR today is indicated for people that have severe aortic stenosis and symptoms. We would argue that's an outdated notion. Now that there is a minimally invasive procedure like TAVR, the idea of symptoms doesn't make any sense. It would be like telling a cancer patient, 'Oh, you have cancer ... we'll treat it when you feel bad.' Aortic stenosis is what's going to cost you your life if you're not careful.

So you should treat people when their aortic valve closes to one-square centimeter, which is the current indication, and not wait for symptoms. We've run this large clinical trial where patients with symptoms or without symptoms are being randomized to either being watchfully waited, which is the current standard, or get TAVR and we'll see what group is doing better at the end of two years.

That's the study that we look forward to seeing results in 2024. We think it'll be groundbreaking because we think it confuses both patients and physicians when you introduce this idea of 'Oh, you also have to have symptoms,' because it's difficult to know. Is that symptom because I'm just getting older or do I have something else wrong with me or is it related to my aortic stenosis? We can take that confusion out of the system. (Also see "*TCT 2022: Edwards' Pascal Matches Abbott's MitraClip In CLASP IID*" - Medtech Insight, 22 Sep, 2022.)

Q What have been some of your biggest challenges leading Edwards?

A Mussallem: Well, we've been fortunate that we've been growing. One of the things that we always talk about and we think about as a board and as a company is how do we maintain this culture of staying innovative and staying patient-focused as we get bigger.

As you get larger, do you let systems creep into the company that causes people to get more conservative and not really reach for big innovations? And what goes along with these big innovations is also failing. Do you decrease your tolerance for failure? And, you know, if you're going to be a bold innovator, then failure is part of it.

Maintaining culture is one of the greatest challenges.

Q What has been the toughest decision in leading Edwards?

A Mussallem: The decision to spin out of Baxter was a big decision, because we weren't a particularly successful business. But we had big eyes and big hopes and big dreams that we were going to build a special company.

Acquiring PVT [privately held medical technology firm Percutaneous Valve Technologies for \$125m in cash] back in 2004 was a little scary. That was a lot of money for us. But as big as those [decisions] were, just the smaller decisions along the way on whether we should discontinue a program are the kinds of things that challenge me on a regular basis.

Because for every time you hear a program that should have been canceled two or three years ago, I also know that there are winning projects that faced adversity and could have been shut down several times, but people decided to persevere, and they found a way through the problems and solved them.

So this idea of should we stop, or should we keep going, I find very challenging, and it's one that we try not to delegate, but to keep it at the most senior levels of the company. If you're going to innovate, you constantly have these kinds of decisions.

Q What advice do you have for other CEOs who have to make these tough decisions?

A Mussallem: I don't think that you can make them alone. I think you owe it to yourself to listen to a lot of voices – the believers and the non-believers – and to personally get involved and not delegate those to somebody else, but actually own the decision.

The biggest thing when you discontinue a program is how you end up treating the team that was engaged in that program, because in many cases, they have put their heart and soul into that innovation, and to respect that, and not in any way to have

that team feel like they were failures.

Q What are you looking for when hiring talent?

A Mussallem: Yeah, so this idea of cultural fit is not something that we take lightly. So, of course, people must have the technical skills to be good at their job, but it's not sufficient for them to be able to fit in a culture where we really prioritize patients and innovation. I love people that are different than me.

It's really healthy to be surrounded by people that just are different and think differently. I especially value people that are learners. I also like people that are independent thinkers with their own original ideas and not just regurgitating those of others.

If you're looking for a leader, this idea of someone that brings others along, and they're less focused on themselves, but count as their accomplishment those that they have brought along, that is very special.

Q How has the pandemic affected the culture of the company?

A Mussallem: I considered it a culture test, and I was so proud of the way that our employees responded to this. They came in every day and they continued to produce. We're fortunate to be the global leader, in many cases by a large margin, so if we weren't there, supply would dry up and it would dry up fast.

And our employees knew that and they showed up. Now, obviously, we like everybody else have tried to learn how to operate more remotely and faster and so forth, and we've learned a lot of lessons that have carried over to today. But we're still dealing with the pandemic and I feel like we're still learning from that and still adjusting as a company and as a society to what life is going to be like living with COVID.

Q How has the pandemic redefined the workspace for your employees? Do you offer flexible work schedules?

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Mussallem: The tendency as a leader sometimes is to want to grab for more control. But I think in moments like this, we're almost better to be able to trust our leaders and trust our employees to come up with the right solution. So we said, 'You know what, why don't you think about what is the best way for you to accomplish your goals?'

Because we know it's so different if you're running a manufacturing operation in Singapore than if you're running an R&D project in Irvine or you're trying to support patients in a far-away hospital. I think we're still learning about what really works best. I don't know that we've really finished this project. It's one that we're still adapting on, but we have a wide variety of practices across the company.

Q How has the pandemic affected your own priorities in your personal life?

A Mussallem: Well, early on, I personally probably focused more on my own health than ever before. I found myself traveling less than I ever traveled, because typically I'm going somewhere every week. Now I was home, I was eating home cooking, which is very healthy. I was getting good sleep every night without any time-zone changes. I was doing regular exercise on a daily basis and probably got healthier than I've been in a very long time.

And it was a reminder about all those good habits that sometimes can go away. It also was a reminder to me of how much value that I get from personal interaction with people, because when we did have the chance to travel again, I found that the conversations that I had, the depth of the conversations, the relationships, the trusts, were stronger when we were back in person again, and so I personally have found that to be very rewarding to be re-engaging.

Q Speaking of diet and exercise, that are some of your favorite foods and exercise activities?

Mussallem: I have a Lebanese heritage. My grandparents came from Lebanon at the turn of the century, so I was very much raised on that kind of food, a Mediterranean

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diet. That would be my go-to. I do a variety of exercise. I'm fortunate to have a trainer I go to. But I also run and do some big hikes. I just stay active and outdoors. My wife tells me I never sit still.

Q Do you have any book recommendations for other CEOs?

A Mussallem: Yeah, it's a good question and this might be controversial, but I probably don't get most of my learning from books. I'm one of these people that learns by doing and learns by engaging directly with people.

Now, I won't say that I haven't learned a lot from books. I remember early on, when we were forming Edwards Lifesciences, I was inspired by Clayton Christensen's book "The Innovator's Dilemma." He was arguing why market leaders couldn't be the innovators and I was convinced to prove him wrong, even though I have tremendous respect for Clay

Q What are your priorities for the upcoming annual AdvaMed MedTech Conference in Boston?

A Mussallem: There is an Inclusion and Diversity Summit. We're having much more conversation about that at the industry level. For me, it starts with the patients. We know that we're leaving a lot of patients behind. There are groups that are underserved that maybe never get access to the technologies that come from the medtech industry.

And what are the reasons for that? Or is there something wrong with the system that serves those people? Are they being served by doctors that look like them and talk like them and they're comfortable having relationships with? Is there sufficient clinical data that's being generated by those groups?

There's a lot of really thought-provoking questions. We probably need to improve in terms of the way that we operate. So we'll talk about that. I'm going to be involved in a CEO unplugged session. Our Lifetime Achievement Award winner this year is going

to be Lester Knight [CEO of <u>Allegiance Corp.</u> and Lester is a long-time friend. We'll have some fun celebrating Lester. It's also the 10th anniversary of MedTech Innovator.