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Device Makers Are Bucking Decades-Long Trend Of Launching Products In EU. Here's Why

Study finds more device makers are bringing new products to the US first

by Shawn M. Schmitt

In this *Medtech Insight* Q&A, two UCLA-backed study authors argue that the US FDA "has emerged as the global regulatory agency most successful in promoting access to novel medtech products, especially digitally enabled or software-driven ones."

Most medical device manufacturers are launching new product in the US first, upending a decades-long tradition of companies going to Europe first for a CE mark.

So says a recent study from UCLA Biodesign – the health care technology innovation hub at the University of California Los Angeles – and Boston Consulting Group, "*Interstates and Autobahns: Global Medtech Innovation and Regulation in the Digital Age*." (Also see "*Sea Change In Medtech As Industry Leans To US For New Innovation*" - Medtech Insight, 23 Mar, 2022.)

In it, study authors Jennifer McCaney, Kwame Ulmer, Christian Johnson, Meghna Eichelberger, Pete Lawyer, Gunnar Trommer and Barry Rosenberg argue that the US Food and Drug Administration "has emerged as the global regulatory agency most successful in promoting access to novel medtech products, especially digitally enabled or software-driven ones."

They go on: "Whereas a decade ago medtech companies strongly preferred to launch products in the EU due to a perception that the pathway to market was simpler and more predictable, the situation has reversed. In part, this reversal can be attributed to the EU's new MDR [Medical Device Regulation] legislation and the challenges associated with Brexit.

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"However, it is also clear that respondents hold a favorable view of several core FDA programs that promote innovation: de novo granting, breakthrough device designation, and the Digital Health Center of Excellence."

Study findings were based on a "survey of 104 company leaders who provided commentary and data on 105 novel medical devices, technologies and software of any risk class that have achieved regulatory clearance or approval within the FDA," the authors write. "Many of these products also sought EU CE mark."

Medtech Insight recently sat down with two of the study's authors – Jennifer McCaney, executive director of UCLA Biodesign, and Kwame Ulmer, principal consultant at Ulmer Ventures and cofounder of *MedTech Color* – to learn more about their work and some of the more surprising things they discovered in their data.

The Q&A below was edited for content and clarity.

Q **Medtech Insight: First off, let's talk about how long it took to put this study together, what type of work went into it. I know it's been at least a year. Just give a bit of background please.**

A Kwame Ulmer: Well, this has been for me a professional labor of love. Jennifer has been a great partner because really the research has been conducted by UCLA. It has taken over a year. And the original idea was – we started talking about this, it must have been in 2020 – the original idea was to do research to really understand, have all the reforms the FDA has put in place … taken hold.

And so, we set about doing what we thought was a comprehensive study. We interviewed over 105 companies. And we wanted to know not how long does it take to get through the regulatory process, but how long does it take to go from concept to commercialization? So it's an expansive report. And it touches on CMS [the Centers for Medicare and Medicaid Services], which prior research did not.

A Jennifer McCaney: Our real focus in doing this was to get to the bottom of first-in-class innovation. So, what's truly pushing the needle on transforming the state of care? Some of the products that tick the box are, of course, breakthrough designated devices, devices that incorporate digital technology and are interconnected, as well

as those that are incorporating AI and machine learning into their product features.

Q **Your survey respondents – you do lean heavily on US companies. One of the big themes is that new products are being launched more in the US. Well, if most of the companies, a majority of them who responded, are in the US, isn't that usually where they would start anyway because they want to sell here? If they want to sell here, they have to be authorized, cleared or approved by the FDA.**

A Ulmer: The whole feeling and the research in the 2000s was that if companies had a choice, they would get the CE mark first. And what we discovered was companies are opting now to go for the US clearance – the PMA and de novo first. That was, quite candidly, [FDA device center director] Jeff Shuren's emphasis and focus to put in reforms to encourage people to do the pilot, pivotal clinical study for the US first, and go for the US clearance, for de novo first.

Q **So you feel comfortable that at least 90 of the respondents being US companies had absolutely no effect on where they chose to launch their product first?**

A Ulmer: That could be a limitation of the study, for sure. By default, we needed to talk to people who had gone through the US process. And quite candidly, we're based in the US. So for sure there may be – I think we call this selection bias. That may be a factor. But Jennifer, what do you think?

A McCaney: Yeah, it's a good question. And certainly, I would echo what Kwame said about the limitations of the study. When you look at the global regulatory experience we measured, you can see that almost half of the companies have EU CE-mark experience.

Q **I'm wondering about the size of the companies you interviewed. When it comes to small, medium and large companies, how did you determine where those lines were?**

A McCaney: It's by head count. We looked at head count to do small, medium, large. We took a range, obviously, because it's a little bit fluid. But we did look at head count...

Q **I'm just curious because obviously the big players, I don't know if – let's say Medtronic, I don't know, maybe they responded to this. They, obviously, would have a totally different view of what's difficult and what isn't difficult than a start-up or a mom-and-pop situation.**

A McCaney: You're exactly right. And that's why we used not only a survey instrument, but also a guided interview. Of course, it takes a lot more time, but it enables you to capture the nuances of the experiences of a Medtronic versus a series A venture-backed start-up that's got $5m to burn and they have to make very careful choices.

Q **You also point out the roles of the people you interviewed. Sixty-five were CEOs, far and away the most respondents. And then regulatory leaders came in second with 30 respondents. Did you consider how that affected things? A typical CEO probably doesn't know as much about what's going on with the regulatory side of things as a reg leader would. I think if you would have interviewed all regulatory or quality officials, they probably would have complained about things like, say, the EU's MDR, a bit more.**

A McCaney: That's a good question.

A Ulmer: I've participated in a certain portion of the interviews. And I remember, we gave them the choice of who we could talk to. And I think Jennifer just said it's a good question. What if we had mandated that we must talk to the regulatory leader? But these CEOs are early-stage CEOs and they had actually been through the regulatory process. I would say they skewed toward CEOs of early-stage companies that are shoulder to shoulder and intimately involved in the regulatory process. That's why they felt comfortable talking about it.

A McCaney: I think you're spot on, Kwame. You and I both having worked with multiple early-stage companies, as a CEO of an early-stage medtech company, you've got your hands on a little bit of everything, right? So, I found the CEOs we talked to extremely

knowledgeable about the regulatory process. Some referred us to the regulatory consultant. And some did it themselves.

At a large multinational, however, sometimes there were three or four folks on the call representing the different parts of the regulatory vertical. So it depends. It was actually harder to schedule meetings with bigger companies because more people needed to be on the call.

Q **Speaking of the MDR, one of the quotes you highlight in your report says that the EU regulation is "killing innovation." Can you speak to that? Is that the sense you got, basically, across the board?**

A McCaney: There has been a lot of uncertainty across the industry with respect to the MDR. The implementation was postponed because of the pandemic. So, in terms of timing and product planning when we're looking at long product development timelines, the MDR has always been looming. But we've never known quite what the impact will be.

But the EU market is not as attractive a market as the US market. So, if you're going to have to choose, you choose the bigger market with the higher reimbursement first. Which is driving some of that shift to the US.

A Ulmer: And to add to that, what I think is to the credit of the FDA is, they promulgated new programs to facilitate more innovation from the breakthrough designation program to clarifying the de novo program. I remember when de novo was such an opaque, misunderstood program and no one really used it. Now, it's definitely increased in use. So it's a combination of, the FDA put out programs and guidances, and user fees allowed the FDA to ramp up. So there's more staff. You put those factors in concert with the EU MDR reforms, and it makes the choice to start with the US that much easier.

Q **Do you foresee the pendulum swinging back the other way?**

A Ulmer: I really don't know. It seems like there is so much "little P" political and "big P" political interest in the breakthrough program. It seems like, one, that the FDA program will stay. But the question is, will the reimbursement stay? If I had to wager a guess, there's a fair amount of interest in still incentivizing funding for reimbursement for breakthrough programs, even in this climate. And I'm hopeful that it does happen because I do think it's been a stimulatory effect on innovation.

Q **Let's talk about breakthrough devices. I haven't heard a bad thing about the FDA's program. You can ask me about any other program, and I could tell you I've talked to someone who was unhappy with it. But I don't know, it seems like a very quickly beloved program.**

A Ulmer: The question will be, is if reimbursement goes away, will people still apply for breakthrough? And that's just because we heard from companies that said if there's no reimbursement, breakthrough is much less interesting.

Q **Was there anything that surprised you in your survey results? Was there anything that was unexpected?**

A Ulmer: I'm just going to touch on one thing that really surprised me: the reporting from companies of how much time and money it took to go from concept to commercialization for a 510(k). It is roughly $5m and two-and-a-half years. And I thought it was going to be longer for a 510(k). And I thought it was going to be more expensive. Now, there is a wide delta – and there are some critiques about, is that number right? But even in the median and the average, it's not super expensive to get a 510(k) product to market.

And then the de novo cost on average, even the median, is not as big a number as I thought it was going to be. The time did not surprise me. But the amount of millions of dollars for de novo came in somewhere around $20m, which was – I thought it was going to come in at twice that amount. But it didn't. That's my big "ah-ha."

Q **OK. Jennifer?**

A McCaney: I would add a note about what Kwame said with just respect to the overall study. Every product is unique. That's something about medtech. It is a little bit more challenging and perhaps a little bit different from that regard from biopharma regarding study design and many of the other aspects.

One of the things to answer your question specifically about what surprised me, and this goes to a little bit of the reimbursement component of our findings with respect to reimbursement emerging as a barrier – more so of a barrier according to the study results – than regulatory would previously seem to be. And that kind of gets to that market access component, with the tradeoffs associated with breakthrough.

Now, one of the things that surprised me specifically was that I heard from several founders and executives in interviews that there are a lot of products out there that they want to develop that could be developed, but there is such uncertainty about who would pay for it that they're not getting explored. That they're not getting developed.

And when we're thinking about the importance of safety and efficacy, and the role of the regulatory process, and of course reimbursement is looking at ensuring that it's reasonable and medically necessary, the question begs, what reforms are needed with respect to the reimbursement process if there are innovators out there who feel they can do more and develop more products, but couldn't find a way to pay for them, so they're not exploring those opportunities? That, to me, was surprising.

And so, from a health system perspective, from a practitioner perspective, I would love to see more of those devices and those ideas come out into sort of the mainstream so we can explore them all as an industry and brainstorm how to pay for them, and how to get them to market.

Q **Were there any trends in your survey results that concerned you?**

A McCaney: Probably two things. We saw that innovators and our survey respondents still consider the regulatory pathway for more traditional medtech products – and

> when I say “traditional,” I mean those that aren't digitally connected, interoperable, SAM-D [software as a medical device], so, really kind of your bread-and-butter catheter tools, those types of products – are seen as more predictable in terms of understanding the regulatory path and what's expected.
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> That's less so the case for digital. We've made improvements. We've made strides. But we're not where we need to be yet. That's certainly the trend. The voice in the industry has said that the FDA is emerging as a global leader for digital products in comparison to the rest of the global landscape. So, I think that's certainly encouraging. And as a forward-looking trend with respect to all the work that the FDA's been doing to build up the Digital Health Center of Excellence, to try to bring in that in-house expertise, I would say there's still more to be done, but we're moving in the right direction.

Q **So what are you going to be looking at next? Is it going to be something tied to this? Maybe taking it a step further?**

A McCaney: We’ll be looking specifically at the innovation fast lane, if you will. When I think of the innovation fast lane, I'm thinking about breakthrough designation products. I'm thinking about AI/ML products. We have some research currently in the pipeline focusing on those specific product categories because, you know, from my own perspective, I'm very interested in that first-in-class innovation. Product line extensions and incremental features additions, that's a different strategy and a different kind of study. My interest is around those products that are in that innovation fast lane and how do we get that technology to patients, such that it's safe and effective.