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Q&A: Meet DHCOE Acting Chief Brendan O'Leary, FDA's New Digital Health Guru

by Shawn M. Schmitt

In this revealing interview, the new acting director of the US FDA's Digital Health Center of Excellence talks about his new role at the DHCOE, the big shoes he'll have to fill now that former center head Bakul Patel is gone, the need for new regulatory frameworks for digital health – and how he helped repair the Hubble Space Telescope.

The US Food and Drug Administration's Brendan O'Leary was passionate about technology from an early age.

"I first started learning how to program as a kid," said O'Leary, the new acting director of the agency's *Digital Health Center of Excellence* (DHCOE). "My mother is a computer scientist, and she's taught me a lot. So it's been a theme in my life for many years."

He later pursued an education in mechanical engineering, a field he was drawn to "because what you learn there is really useful across many fields and disciplines. But along the way, whenever I've had an opportunity to make the computer do the hard work, that's always been my preference."

Notably, before coming to the FDA, O'Leary joined an aerospace firm where he designed and developed tools used during spacewalks to repair the Hubble Space Telescope. "It was an amazing opportunity to be a part of extending the lifespan of the Hubble because it was such a consequential scientific instrument," he said.

O'Leary took the reins of the DHCOE from former director Bakul Patel earlier this year. Patel left the FDA in May after 13 years to take a job as Google's senior director for global digital health strategy and regulatory affairs. (Also see "*Google Taps Former FDA Digital Health Leader*" - Medtech Insight, 17 May, 2022.)

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Medtech Insight sat down with O'Leary on 9 June to ask him about his new role at the DHCOE, the big shoes he'll have to fill now that Patel is gone, the need for new regulatory frameworks for digital health, what he hopes to accomplish as acting head of the DHCOE – and more.

The Q&A below has been lightly edited for content and clarity.

BRENDAN O'LEARY

Q **Medtech Insight: So let's talk about when you began work at the FDA. This is post-Hubble, correct?**

A Brendan O'Leary: That's right. As the work with Hubble wrapped up, I ended up with the opportunity to do a fellowship in FDA. And I was drawn to the idea of continuing to support scientific advancements. But I did have some concerns. You know, I can't say that I came into FDA expecting regulatory work in general to be long-term fit, because of my passion for building things. I just didn't know that [the agency] would be seen as a place where you can still do that. But I knew that I could do some good work, I could learn a lot. I was interested in seeing where I could take that. It's now been 13 years. So I think it's safe to say my concerns were very much misplaced. FDA is an amazing place to learn things, a wonderful place..

At FDA I got my start in radiological devices at CDRH [the Center for Devices and Radiological Health]. And because of my software experience, I reviewed a range of devices, everything from ultrasound elastography devices to MRI-guided radiation therapy, robotic biopsy, and ultimately the first cell phone tablet apps for diagnostic radiology. You know, I got an upgrade with digital health. I was heavily involved in the policy working on mobile apps and everything we later came to call digital health.

Ultimately I went on to a series of management roles, overseeing a range of policy operations working in the Office of In Vitro Diagnostics and Radiological Health. But

in each case, I did keep my digital health specialization and had the opportunity to oversee the establishment there of CDRH's first digital health team. And cut to about three years ago, I was asked to come here and help launch and scale the Digital Health Center of Excellence – another opportunity to build, and I joined the group as the deputy director.

Q **It's quite the resume. So it seems like when you joined the FDA, you had the digital side down, but it's maybe more the regulatory side of things where there was a baptism by fire, if you will.**

A O'Leary: Certainly, yeah, I came from a different field. So coming into FDA, without regulatory experience, it was it was something that I learned on the job.

Speaking Of Medtech, Ep. 4: FDA's Regulation Of Digital Devices

By Steve Silverman and Shawn M. Schmitt

19 Nov 2021
On this episode of Speaking Of Medtech we discuss the regulatory side of digital health – that is, the US FDA side of digital – and some of the more important related policies and activities that are going on at the agency right now.

Read the full article here

Q **Talk a bit about your learning experience with the regulatory side when you were new at the FDA.**

A O'Leary: One of the keys is reading. Even back at the time, I was reading *The Gray Sheet* and spending a lot of time with those articles.

Q **The Gray Sheet – that, of course, was the name of Medtech Insight before we went through rebranding in 2016. You're taking me back... It's nice to know you read us, even back in the day. What else did you read?**

A O'Leary: Well, I jumped into the CFR [Code of Federal Regulations], read the guidance documents and read the submissions, and kept up to date on the on the literature – FDA has an amazing library; it's a tremendous resource.

Q **So why do you think you were to the pick to fill Bakul Patel's shoes, even if on an acting basis?**

A O'Leary: Well, I think digital health is a team sport here at FDA. And over the last few years we've really put a strong team in place that can carry this work forward. And I certainly I was honored to be asked to help provide continuity in the role. I'm enjoying this work and I'm enjoying continuing to work with the team across the agency.

Q **What do you hope to achieve, even on an acting basis, as DHCOE director? And are there any activities or initiatives that Bakul started that you're keen on seeing through?**

A O'Leary: It's been said that the digital health team and the center of excellence is here to prepare FDA for the digital health future. And that's true. What's been particularly meaningful, though, is seeing this team taking an increasing role in helping FDA to shape that future to benefit patients. And we have a number of efforts firing up and underway on that. Things we're doing to help ensure that these technologies are designed, studied, deployed and maintained in a way that's going to meet the needs of diverse patient populations.

"We're going to launch something called the Power Policy Navigator to make it easier for stakeholders to go through the various guidance documents that FDA has."

A We're working to implement our *artificial intelligence and machine learning action plan* and working to draft and finalize key policies – we need those so the developers can move forward more quickly and with more confidence. And then, specifically, working to support FDA decision-making on digital health technologies across the medical product space – not just medical devices – and continuing to engage with

our colleagues across government, across the country, and international counterparts in particular.

It reflects this opportunity that we have here, with these technologies, everything from the cloud to machine learning, to the increasingly ubiquitous sensors, computers – all of these technologies that are more and more a part of our day-to day lives – it really presents that opportunity more than ever before to bring health care, to bring the science that's going to improve health care and bring it to patients, and to help build more digital bridges to the folks who aren't so well served by the status quo that we have today. So there's a lot there and we're up against a lot. But I think the needs and the opportunities are becoming more clear. So here at FDA we're focused on doing our part in that ecosystem.

Q **What are some of the more interesting things you're working on right now?**

A O'Leary: Well, there are many things underway. Like I mentioned earlier, we're furthering our work on artificial intelligence and machine learning, and taking the steps that we outlined in our action plan. We're focused on issuing our final clinical decision support software guidance, the premarket software guidance. Also, we're going to launch something called the Policy Navigator to make it easier for stakeholders to go through the various guidance documents that FDA has, and find the parts that are most applicable to the situations they're finding themselves in.

And we're going to continue to advance cybersecurity, medical device interoperability – this is so critical to making all of these other elements work together. And I think we're really facing a moment of opportunity in this space. And working with MDIC [the Medical Device Innovation Consortium], that public-private partnership and others lead to advanced regulatory science and approaches. And, again, I'm really excited about some of the conversations we've been having with international regulators.

Q **OK, let's talk about regulatory frameworks for digital health. Last month *CDRH director Jeff Shuren said Congress desperately needs to act*. And I recently**

read a Medtech Insight article where you're quoted as saying roughly the same thing. So talk to that a bit. Why is this being slow-walked when it should be fast-walked?

A O'Leary: FDA appreciates the work that Congress does to support our programs. And that includes the digital health program. Congress has a long track record of passing legislation that supports medical device innovation and benefits public health. You know, one example of that is the de novo program established in 1997, and then streamlined in early 2010, maybe 2012. That provided a voluntary alternative pathway for novel products. And I believe it's resulted in somewhere north of 300 new device classifications, and it begs the question: How many of those might never have made it to patients if Congress hadn't taken the action to establish that alternative approach? That's just one example where when the framework that we had wasn't producing the public health results that it needed to, Congress took important steps to provide an alternative.

"Just like we would miss out on some really important innovations if we didn't have de novo, I think we have to consider the very real possibility that there's another piece of the puzzle that is still missing."

A Speaking from my own experience, it's true that we have a hardware-oriented framework here in the United States. And it's not well suited to modern DevOps approaches, and other software engineering best practices that can support more safe and more effective software development, testing, deployment, monitoring and updates. I'm not just talking about products that are fundamentally different in their intended use or in their technological characteristics. I'm talking about products that are built a different way, products that are built a better way. And they may otherwise fit under the classifications that FDA has today, but when you try to shove them into that framework, and when there isn't an alternative available, it's not going to take

full advantage of the extra engineering investment that people are making.

Again, in my own experience, some developers decide to soften, shorten and make that extra investment, and others decide it's not worth it to be in this business at all because of the approaches they would have to employ to align with the hardware-oriented framework. They don't align with what they know about how to best build software in their development environments.

And so I see that and I become concerned that it may not be good for innovation and competition, and really, ultimately for public health. And just like we would miss out on some really important innovations if we didn't have de novo, I think we have to consider the very real possibility that there's another piece of the puzzle that is still missing. And that if we had that piece, it might enable some really important advancements. So certainly, I'm hearing concerns like this from stakeholders; I'm sure others are too. And I think when that's happening, we owe it to the public, we've got to be thinking about how we might be able to address this sort of thing without disrupting the approaches that we have in place today.

So it's not about dismantling the other puzzle pieces, because they work well for a lot of devices. But what might be missing? And as you said, you know, FDA has explored a number of concepts along these lines, but to fully implement something like that requires legislation.

Q **OK, but even if you had all of the authority from Congress that you need, is the FDA fast enough to keep up with digital? You know, because sometimes it can take a while for things to move out the agency's door – we all know that's not a secret. Your thoughts?**

A O'Leary: Well, it is a fast-paced field. And we do need to have frameworks that can move at the speed of science. But this agency is more nimble than it's ever been before. This is something we have a lot of experience to move forward with, at a speed that's necessary for public health. But we're always looking for frameworks that can help us better meet that. I don't worry nearly as much about the speed of the

agency, necessarily, as I do about the processes themselves, the frameworks that we're tied to, and how we can improve that overall system.

Q **Moving forward, what's the biggest challenge for digital?**

A O'Leary: It's always rapid innovation cycles, much faster than were envisioned by the original regulatory frameworks, and continuing to ensure that these products are designed, validated, deployed and used in ways that are going to work across the diverse populations that they need to work for. So we can help build that bridge to patients who are and will serve today. And making sure that users, clinicians and the broader community have the transparency into the into the development and performance of these products.