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Q&A: AFDO And RAPS Are Breathing New – Yet Familiar – Life Into Industry's Beloved MedCon

by Shawn M. Schmitt

The medtech-focused MedCon Conference, which was unceremoniously flushed by Cincinnati's Xavier University at the end of 2021, is back. The new AFDO/RAPS MedCon will be held virtually on 4-6 May, with plans to make it an in-person event once again in 2023.

Many in industry were caught off-guard when Cincinnati's Xavier University abruptly shut down the work of its Xavier Health unit in late 2021.

After all, Xavier Health put on several highly regarded and apparently successful annual shows, including the MedCon Conference, the AI Summit, the PharmaLink Conference and the Combination Products Summit.

But a few months ago the Association of Food and Drug Officials (AFDO) and the Regulatory Affairs Professionals Society (RAPS) announced that they had picked up the work of the now-defunct Xavier Health to continue those events.

The medtech-focused MedCon, which appeared to be dead in the water last December, is back on. *The new AFDO/RAPS MedCon will be held virtually on 4-6 May*, with plans to make it an inperson event once again in 2023.

Medtech Insight sat down with Marla Phillips, the former director of Xavier Health who's now CEO and president of *Pathway for Patient Health*; Brian Savoie, VP for education & professional development at RAPS; and Steve Mandernach, executive director for AFDO, for some insight on what went down with Xavier University and how AFDO and RAPS plan to keep the spirit of the aforementioned conferences intact.

The Q&A below is the result of blending two separate interviews, and was edited for content and clarity.

- Medtech Insight: As you know, Marla, I've attended every single MedCon. So I have to say, I was super surprised late last year when I got an email from Xavier Health that basically said, "MedCon is over." That seemed so bizarre to me given the meeting's popularity. So let's chat about that but first, maybe talk with me a bit about MedCon's beginnings.
 - Marla Phillips: Of course. As you know, we had our first conference in 2010, and we had 263 people who showed up, and it was because we had industry experts on stage, and just phenomenal [US Food and Drug Administration] support and involvement. I think one of the key aspects was that FDA came to attend, and creating our roundtables, where people would sit with the FDA at the table. "We're all here and in this together" is the atmosphere we created.
- You know, that was one of the differences between MedCon and other events that I've been to over the years is that MedCon had so many FDA speakers there was so much FDA involvement. You know, you go to other conferences, and they'll just have consultants, consultants, consultants, consultants talking, and people want to know what the FDA is thinking, not what a consultant necessarily is thinking. So I always found that to be super helpful, and it was why I was there every year.
 - Phillips: Yes, and you were a big part of getting us on the map, and I know I've told you that. When you came and covered it, that gave MedCon credibility. So it had the FDA name. We had legitimate industry trade press coverage, and it put us on the map.
- Yes, I was more than happy to help. OK, you said the first meeting had 263 attendees. But what about that last in-person conference before COVID-19, in 2019. How many were attending by that point?
 - A Phillips: We actually sold out for several years. Our maximum was 420, because we

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were committed to having the roundtables and staying on Xavier's campus. Many people asked us if we could move off campus to a bigger venue, and we said, "No, this really is a part of what we're doing, is bringing people here to this experience."

- Q OK, so let's talk about the big surprise of what happened with Xavier University and Xavier Health.
 - Phillips: I don't want to speak for Xavier and what they were thinking, but I decided to resign last September because the company I'm leading, Pathway for Patient Health, is exploding in growth. And I was really running two full-time jobs and would have loved to have dedicated more time to what we're doing with students and universities and companies. And I felt that the Xavier Health team was in a very mature situation, where I could leave, and they could hire someone to take my place, and it could keep running. But Xavier decided to not go forward.

"One of the things we wanted was for this to be a seamless transition for the community that Marla and the Xavier Health team built." – Brian Savoie

- Q Did the university scrap the entire Xavier Health program?
 - Phillips: Everything. Everything's done. AFDO and RAPS are adopting everything we were doing artificial intelligence, combination products, pharma, devices. All of it. But this is an opportunity for the Xavier Health work to expand way beyond what the Xavier Health team could have done because of the size and resources and experiences of two very respected organizations, AFDO and RAPS, combined together to take this forward.
- Q Brian, I might be getting ahead of myself a little bit here, but it sounds like you're still interacting with Xavier to transfer knowledge about the

conferences. Obviously you're taking on more than MedCon. So what kind of relationship do you have with Xavier at this point? What's their role?

Brian Savoie: One of the things we wanted was for this to be a seamless transition for the community that Marla and the Xavier Health team built. So when I heard about this in mid-December, I started putting together a list, and I was like, "In our dreams, Xavier University is going to be helpful and supportive." And I think that is what we've received, is help and support. They are anxious to see the programs continue and have given us website access, website assets, just insights into approaches and overall support.

So I'm not sure it's much beyond that, but I think it's just a feeling of goodwill as far as how this transition is going. They want to see these programs succeed. They want to see that the 13 years of work that Xavier Health successfully did in creating something that was very valuable to the community continues.

- So the new MedCon, will it be a mirror of its former self? Or are there going to be tweaks? I'm thinking pre-pandemic, also, if that helps.
 - A Savoie: For 2022 we are going to be in a pandemic mode still. We're still going to be a virtual event. This was a consensus decision by the MedCon Program Committee, in consultation with the AFDO/RAPS staff. I think our desire was for the event in its first year to be in-person, but it was viewed as impractical for this go-round, unfortunately. Our objective is a return to in-person, for us to mirror the event design as much as possible. We are trying to mirror the approach as much as possible because we value the place that MedCon had for the community.

There was a feeling that was created. It wasn't simply about knowledge acquisition, so having that emotional feel when people return to MedCon is very important to us and very important to the collaborative as a whole. I'd say every member of the committee has reflected that the culture is important to continue. We've heard that, and that's something we're committed to.

- So there's optimism for next year that you will have that in-person element again.
 - A Savoie: I think that's where we're looking, that 2023 is going to be a return to inperson. We're going to plan in that direction. We've already started talking about sourcing for locations with the Program Committee, as well as with the AFDO team.
 - A Phillips: And one of the keys about having AFDO involved is it has cooperative agreements with FDA, so FDA is on stage; FDA is in the audience. And so you can still get that same feel that we were able to create at Xavier.
 - A Steve Mandernach: AFDO does have a history of doing co-sponsorship agreements with FDA. We have several different events that we've historically done co-sponsorship agreements on. We also produce a lot of events directly for them, particularly with the state and local regulatory community where we're under cooperative agreement and essentially produce the FDA event. So we have a great deal of experience in this area.
- Interesting. One of my questions for Brian was, why team with AFDO on this?

 Couldn't RAPS run this alone? I'm always seeing events for RAPS. You do it all the time. So I was wondering what kind of component AFDO is providing. But I guess that kind of answers it.
 - Savoie: I think it does. I have worked in collaboration with a lot of different organizations. I've been very impressed with the AFDO team and think our teams actually mesh together very well. I think we are much stronger to get together on this because our approaches to an aligned mission are a little bit different. So we actually fill each other's areas of weakness, and we augment each other's strengths.

So it has been actually really delightful to find them. So it's not a situation where we both approach the same problem in the same way. We actually approach things in different ways that I think are going to help further these programs a great deal.

Q And I have the same question for you, Steve: Couldn't AFDO have taken this on

by itself? Why the strategic alliance with RAPS? What do you bring? What do they bring?

Mandernach: Each of us brings a few different key things. First, I'll talk about us and then I'll talk about some of the strengths I see with RAPS. AFDO's strength is really that we have experience working in co-partnering and co-sponsoring with the FDA all the time. We do it particularly with the Office of Regulatory Affairs, but also with the various centers. We just have such a strong relationship with the agency.

In addition, we're really good at doing events, particularly those where FDA is a key speaker [or] has lots of speakers. And those could be somewhat challenging at times – just because you may not know until the week before if people are actually going to be able to travel, and things like that. All those sorts of uniquely government things. We also understand the concept of a continued resolution. We also know the IT. So, if we're going to have to bring someone virtual, we know how to get in there – how to get them into a virtual event and be successful. We've done that with hundreds of FDA speakers over the last several years, so we know that process.

Q And what does RAPS bring to the table?

A Mandernach: RAPS, once again, knows the space well and is very good at doing events also. I think we complement each other nicely. But what they bring to the table also is a lot more experience on things like sponsorship. They have a more robust ability in registration and some of those areas that, frankly, if you asked me my pain points today, those are two pain points that we don't do as well as they do. And knowing the Xavier history, they've done very well with them, with particularly sponsorships and helping to defray the cost through sponsorships. That was something that we really saw that RAPS could bring to the table. Not to mention they have a whole host of professional staff. And what we've really seen is the two staffs are working together like one. It's a very seamless transition.

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AFDO and RAPS "are very committed to taking the great work Xavier Health had done and, hopefully, maybe we can even make it a little better over time." – Steve Mandernach

- I know all of you want this to be seamless, but come early May when MedCon happens, will there be anything that participants will notice that's different in approach?
 - A Savoie: Well, our approach toward systems is going to be a little bit different, so when people go on the website, registration will look a little bit different. The event platform is going to be new. But from a content perspective, the program committees have been empowered. They own the events that we're going to be putting together. They own the Xavier Health events. They own the AFDO/RAPS collaborative events, MedCon foremost in that. So from a content perspective, they shouldn't see a difference.
- Q Brian, does RAPS team with AFDO on anything else?
 - A Savoie: No, this is the first time.
 - A Phillips: A committee member had reached out to AFDO, and I was familiar with them because I've presented for AFDO for a few years. And I thought an AFDO/RAPS team-up would be great. Both of them seemed very viable, and the two of them coming together is just really powerful. They're going to be able to take this so far beyond where our tiny Xavier Health team ever could have taken it.

And so we brought them together. Well, first we asked them individually, "Would you be interested in having a discussion with AFDO?" And "AFDO, would you be interested in having a discussion with RAPS about collaborating together and partnering on this?" And both instantly said yes. It was very collaborative from the first minute.

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- A Mandernach: Yes, Marla brought us together.
- Q She does that.
 - Mandernach: She does. That's her technique. And I know one day she just said, "Well, is there any chance you'd guys be willing to partner?" And I was like, "Of course, why wouldn't we? You know RAPS. You know what they do. We're happy to partner. It's a great opportunity for us to work together. Yes." And RAPS said the same thing. So, within a matter of a 20-minute conversation we had agreed, why *wouldn't* we move together on this project?
- Will having the involvement of AFDO and RAPS bring in more attendees? Have you kind of projected that out, what that might be for future conferences?
 - A Savoie: Will it be more attendees? I think that's yet to be determined. Again, it may be marginally more. But I think the entire focus is continuing the culture of MedCon through this process. I think that growth has to be measured with that culture in mind. I think there are other ways that you can measure growth. I think that you measure growth in influence, in the ability for us to be seen as a relevant, well-positioned event, which MedCon already is.

So I think that's one of the pieces. But how do we further some of the findings that come out of the event and the meetings? How do we make sure that it's seen as a place where you can find answers, where you can connect with vital peers in the process and continue that? So I think right now, our goal is to be seen as the collaborative that is continuing to bring the magic.

Q Any parting thoughts?

A Phillips: I can only add that I have been just so impressed with the reception and the openness and willingness of both AFDO and RAPS in this collaboration that they've formed in adopting the culture and learning from the Xavier Health team, as well as from each other.

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I barely even remember who is from AFDO and RAPS anymore when we're all coming together to talk, so it has really been an amazing transformation, and I am so extremely excited for seeing the future of each and every one of the conferences and the initiatives. So it has been a great experience.

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Mandernach: I just think that both of us [AFDO and RAPS] are very committed to taking the great work Xavier Health had done and, hopefully, maybe we can even make it a little better over time. If we can do that, it's a winner for all of us. Again, we're both with that mission of helping to improve public health overall. Both organizations are very committed to that. So, I think this just fits nicely with both groups' missions and so we're excited. Couldn't be more excited to be part of this event.