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AdvaMed CEO: Less Optimistic On Full Device Tax Repeal By Deadline

by Ferdous Al-Faruque

In an exclusive sit-down with Scott Whitaker, the head of the largest medical device lobby group tells *Medtech Insight* why pharmaceutical companies should be concerned about Trump HHS Secretary nominee Alex Azar, his frustration with Congress' device tax repeal efforts, the growing likelihood of another temporary device tax moratorium and more. Listen to the podcast.

AdvaMed and other medtech lobby groups have been going to the mat over the past year to permanently repeal the 2.3% medical device excise that industry argues is stymieing innovation and preventing new hires. Despite their efforts and wide bi-partisan support for the repeal, AdvaMed CEO Scott Whitaker says he's frustrated with the lack of progress in Congress.

While he is optimistic the tax will not come into effect as scheduled in January, Whitaker says he's not as optimistic about being able to get a permanent repeal by the Jan. 1 deadline. Another temporary moratorium may be the deal they have to accept, he says, though they will continue to fight for the permanent repeal.

"I feel very good about the strategy we have in place on getting the device tax fully repealed," Whitaker said in an interview with *Medtech Insight*. " What I don't feel as good about is the urgency that we have is not reflected by those in Congress who need to pass it right now."

In the interview, Whitaker also talked about advising his friend Alex Azar, a former Eli Lily executive and HHS official, who has been nominated by President Trump to be the next HHS secretary, in advance of his confirmation hearing. While critics argue Azar's work with Lily creates a significant conflict-of-interest, Whitaker says Azar is a dedicated public servant, and pharmaceutical companies should "not be celebrating his nomination.

"I suspect the policies that he works on will be try to drive down cost and bring some transparency to the process at HHS," Whitaker said. "For those who want to make that a political issue, they are making a mistake, because he is not going to be a lap dog for anybody."

Whitaker also spoke about some of AdvaMed's 2018 priorities, including more focus on reimbursement reforms.

"One of the legislative proposals we're going to be focusing on next year is to make sure that if FDA approves a breakthrough product, that there's some type of expedited pathway for reimbursement for those products as well, whether it's a temporary code or a temporary-to-permanent code," he said.

Listen to our full interview via the player below, followed by a lightly edited transcript.

Scott Whitaker Discusses Alex Azar, Device Tax And More

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Q ***Medtech* Insight: We'd spoken just a few weeks ago when Alex Azar's name was floated as a potential nominee to lead HHS, and you threw your support behind him. Since then, the two of you have had a chance to talk. Could you tell me a little bit about what you talked about and how those talks went?**

A Scott Whitaker: Yeah, Alex Azar is kind of a long-time friend of mine, dates back to when we worked together at HHS. He was the general counsel, I was assistant secretary chief of staff, so we worked through a lot during that period of time, '01 to '05 when I was at HHS. Some pretty tough times politically and also policy wise. And so, we have a fairly long history.

He is a really good guy and a good friend of mine, I would say. One of the reasons why I threw my support behind him is because he understands that department and the issues that they deal with in a way that very few people do. As general counsel and then as deputy secretary, he has a breadth of experience and knowledge that I think in many ways is unprecedented for a new secretary coming in.

"Most of my conversations have been focused on trying to help [Azar] understand what the confirmation process is going to be like this time around and what I can do as a friend to help him through that, and I'll continue to do that."

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And I feel like from my perspective and the perspective of the medtech industry, you want a secretary who understands the issues well, and I think Alex will understand those very, very well. I've had a number of conversations with him before and afterwards. Most of my conversations have been focused on trying to help him understand what the confirmation process is going to be like this time around and what I can do as a friend to help him through that, and I'll continue to do that.

We've also talked in general terms about the job of secretary and some of the things he's going to face, and I think I can probably project a little bit forward on what he might see, if you want to talk about that a little bit further. But we're excited about him coming into the job, and I hope the confirmation process goes smoothly for him.

Q **I'm interested in what you think he might see moving forward in his job. And on top of that, if you would talk a little about in terms of the conversation you had, was there anything in particular that he said in response to the conversations that you've had where you felt, yeah, he gave you the right answer, he's going to do a good job?**

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Whitaker: Yeah, I think in general terms, I would say this about Alex: Alex wants to make sure that the department works well for the American people and for the industries that interact with the department. He understands the value of good government, and he understands the value of good private industry, and we're one of those very important industries.

As you know as well as anybody, we touch everybody's life from birth until the end of life. We're in the hospital room for the birth of children. We're in the hospital room all the way through life and at the end of life as well. It's our industry that impacts people.

And I think Alex understands that. His experience at HHS, then his experience in the private sector, I think gives him a unique understanding of the need to listen to industry before you make rash decisions about policies that could impact the industry because at the end of the day, government and the private sector need to work very closely together. Whether it's on Medicare policy, for example, or CMS reimbursement policy or in the FDA regulatory world, all of those areas I think he'll have a very open-door policy with industry in an appropriate way, not an inappropriate way, but to make sure he understands what policies they have that will impact the industry and how it could impact the patients we serve.

And I think that's the best thing you can ask for from a secretary is to have that type of dialogue with folks who are impacted by that department.

Q **That brings up a really interesting issue, and you kind of touched on it; one of the big issues that Alex is likely to face during his confirmation is his ties to the pharma industry for lawmakers and critics who are concerned that there's a major conflict of interest here regarding his nomination. How do you respond not just as a friend and as a lobbyist but as an American citizen that Alex is the guy for the job?**

A Whitaker: I would say this: If I was pharma or those working in the pharmaceutical industry, I would not be celebrating his nomination. He's been at the department before. He knows how the department works. He's been inside a pharmaceutical company. He knows how a pharmaceutical company works. He also knows, going back into that job, his responsibility is the Department of Human Health and Services, not the companies he's worked for in the past.

I suspect the policies that he works on will be to try to drive down cost and bring

some transparency to the process at HHS. For those who want to make that a political issue, I think they're making a mistake because he's not going to be a lapdog for anybody.

Q **Speaking of the stuff that Alex is going to be dealing with, you guys have been dealing with the medical device tax issue. We've been covering it for the past year. But we're coming awfully close to hitting the deadline. How are you feeling about the legislative efforts that you have going on right now on getting a permanent repeal?**

A Whitaker: I feel very good about the strategy that we have in place on getting the device tax fully repealed. What I don't feel as good about is the urgency that we have is not reflected by those in Congress who need to pass it right now. As you know, we were in every piece of major health care legislation on ACA that moved, and unfortunately the votes weren't there, but it wasn't because of the device tax.

There is broad bipartisan support for this in the House, broad bipartisan support for it in the Senate. We've got more than 60 votes in the Senate I think to pass it. We've got 300-some-odd votes in the House if they were to bring it up. The reality is Congress just needs to lead. They've said the right thing about this issue for a long time and right now we're asking them just to actually do what they said they wanted to do.

If Congress does not pass permanent device-tax repeal this year, "we're going to go into an election year next year and we're going to remind folks of the urgency of this issue both in Washington and in their districts."

A So, from a process standpoint, it gets complicated and Congress gets easily wrapped around the axle. Whether it's ACA or tax reform or the end-of-the-year spending bill, they've said they want to take care of it in one of those vehicles, and so, I'm very

optimistic that the tax will not go back into effect next year. I'm not yet that optimistic that we can get it fully repealed this year.

So, I think right now we're likely looking at a one- or two-year delay, which is nice but not adequate. But we're continuing to push for a full repeal or a ten-year repeal so we can actually get back to doing what we do is creating innovative new products and getting them to market. Folks on the Hill listen, they say the right things, but at some point, we need to hold them to what they said. And if they don't get it done this year, we're going to go into an election year next year and we're going to remind folks of the urgency of this issue both in Washington and in their districts, and we expect if it doesn't get done this year, it will get done next. At least that's my hope.

Q **So, another two-year moratorium might be your plan B?**

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Whitaker: It's not my plan B. It may be their plan B. If that's where we end up, we'll end up there, but we're not going to consider that success and we're not going to consider that satisfactory. We're going to continue to push for it. I'm not giving up. I think there's a path to get full repeal this year, but if you listen to folks in Congress, that's not what they're saying right now.

Q **Now, beyond medical device tax, what are some major legislative efforts that are coming up for next year that the medical device industry should know about?**

A Whitaker: Yeah, let me back up for just a second and say we had a major legislative victory this past year, which was the enactment of MDUFA IV. A lot of our activities going forward in 2018 and beyond are going to be focused on making sure that the FDA implements that legislative agreement as it was constructed and intended. There's a lot of work that AdvaMed is going to do with its member companies to hold FDA accountable. We're also going to rely on Congress and the committees of jurisdiction to help us make sure FDA is held accountable to the standards that were set in this agreement.

Looking back just a little bit legislatively, that was a major success, but then if you look forward a little bit, making sure that's implemented correctly is a major priority of what we're going to do on the regulatory side.

The other bucket of work that we're very focused on is in the reimbursement space, CMS primarily. Public payers, because we have more interaction with public payers than we necessarily would with the private payers, but the broad landscape of reimbursement is really important to our industry. If you ask most CEOs, I think what they'll say is CMS today is what FDA was about six to ten years ago. It lacks clarity, it lacks transparency, there's not a good form of communication to understand how you get your products approved.

So, next year, we're going to be very focused on legislative and regulatory solutions to improve the performance of CMS. One of those that we've been focused on so far is the breakthrough pathways legislation. If you recall, in 21st Century Cures there was a breakthrough pathway for FDA. If it was designated a breakthrough product, it had an expedited pathway to get through the FDA.

"I would say is if there's a way to increase the funding for CMS that results in a more clear, transparent and effective pathway at CMS, we'd be happy to have those conversations -- whether it's a user fee or whether it's some other form of funding."

A What doesn't exist, however, is for breakthrough products there's no pathway at CMS. So, one of the legislative proposals we're going to be focusing on next year is to make sure that if FDA approves a breakthrough product, that there's some type of expedited pathway for reimbursement for those products as well, whether it's a temporary code or a temporary-to-permanent code, to make sure these products get into the marketplace.

And that's going to be a major priority for us. We're also looking at some broader issues around CMS' performance, and I think next year you'll see from us some new proposals around that as well. So, CMS and the reimbursement space is going to be a major focus of our legislative activity next year.

Assuming they get device tax fully repealed this year, we won't have to worry about that next year. But if they don't, it's going to be CMS and device tax again.

Q **It's really interesting you brought up the reimbursement issue. I think during the past AdvaMed annual conference, there was some talk about potentially maybe a user fee associated with CMS reviews. Do you guys have a position on that?**

A Whitaker: Don't have a position on it. What I would say is if there's a way to increase the funding for CMS that results in a more clear, transparent and effective pathway at CMS, we'd be happy to have those conversations. Whether it's a user fee or whether it's some other form of funding, process improvements, whether it's propping up CMMI to be what the Innovation Center was supposed to be, which was about getting innovative products to patients, we'd be open to all those conversations.

Listen, we always have viewed CMS as a partner. And while there's frustrations between industry and CMS, while there's frustrations between industry and FDA, at the end of the day they're our partners. We create the products that we try to provide to the patients that they serve.

And so, whether it's a user fee or an increased funding model or increased changes to the regulatory structure to allow products to move more quickly or fundamental changes to CMMI, we're open to all of those things, I would say, but I wouldn't want to say we're for or against anything at this stage.

Anything that improves the process is good by us, and it's one of the reasons, back to Alex Azar, it's one of the reasons why having a secretary like him there who understands the industry, understands CMS, understands the need for reforms, is encouraging because I think with the right type of leadership at HHS, you can start to

make progress in the CMS space.

Q **Now, this year you guys have touted it as the year of digital health. I'm curious, what do you see next year being?**

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Whitaker: Hopefully next year will be a year without the device tax for good. That would be the ultimate goal I think for us is to get rid of that. And the reason why I say that, and we both chuckle when I say that—and we chuckle because it's been around for so long and the conversation never seems to go away—but if you can get rid of a tax like that, it frees up the industry to do so many important things around innovation.

I was talking to a few CEOs the other day with a member of Congress, and we were talking about the impact of that tax on next year and the following year's innovation cycle. They were articulating very clearly for the member of Congress what it will do for a specific, innovative new product line that they're working on and how they can't fund it if it doesn't go forward.

So, if you can fully get rid of that device tax, it frees up companies to do so much more over the next five or ten years, whether it's digital health or just transformational new medical devices. In either space, it's really, really important.

I'll come back—you say what do we see next year being? Hopefully we also see next year being of great progress with the payer community, getting some type of understanding between the industry and the payers so that payers understand that it's not just about budgets, it's about patients as well.

I've been trying to make that point as clearly as I can. You see this oftentimes in the public systems. Decisions are made about reimbursement primarily based on how they anticipate it will impact their budget the next year, not over the next ten years. And part of our conversation needs to be with the payers that innovation saves money over the long term and it also impacts people's lives in a positive way. So, that's going to be a really big part I think of what we focus on next year, to create a

better ecosystem, a better environment more broadly for companies to be successful.

Q **Well, before I close out, based on our conversation today and thinking about the year ahead, what would you like to say to the medical device industry? Any sort of advice for them? Any sort of pep talk you want to give them?**

A Whitaker: Yeah, first of all, to the device industry broadly I think I would say thank you. The work that the medical device and medical technology companies are doing for people in this country and around the world is remarkable. I see it in my own life with my daughter who's alive today because of medical technology. My story is not unique. There are millions of people in this country, there are millions of people all over the world, who are alive and healthier and prospering because of this industry. So, I always say to our industry, "Thank you for the work you do." It makes a huge difference in people's lives.

And then the second thing I would say is I'm optimistic about the future. I think the performance improvements that you've seen at FDA from a Washington perspective have been tremendously helpful to the innovation ecosystem. Looking forward, I'm still optimistic that if CMS can do what FDA has done—and I think there's a path toward that—the next five or ten years for this industry in a growing economy with the innovation cycles the way they are, with the convergence of IT and traditional medical device technology coming together, the future is really, really bright.

And so, I would say keep up the good fight. We are here to help the industry in whatever way we can be more successful, and if we get the environment right, the sky's the limit on what the future looks like for most of our companies in this industry more broadly. And a result of that is patients will be better off for it as well.

From the editors of The Gray Sheet