EP.155 - Michelle Tarver

Narrator: You're listening to *BioTalk* with Rich Bendis, the only podcast focused on the BioHealth Capital Region. Each episode, we'll talk to leaders in the industry to break down the biggest topics happening today in BioHealth.

Rich Bendis: Hi, this is Rich Bendis, your host for *BioTalk.* As you know we generally have very interesting guests on the podcast and this isn't the first time, but we have a very interesting guest with one of our BioHealth Capital Region very important partners from the Food and Drug Administration. We have Dr. Michelle Tarver, who's Deputy Center Director and Chief Transformation Officer for the Center for Devices and Radiological Health—CDRH—for the USFDA. Dr. Tarver, welcome to *BioTalk*.

Dr. Michelle Tarver: Rich, thank you so much for the introduction.

Rich Bendis: I think that was the most difficult thing I'm gonna have during this interview. Dr. Tarver, do you mind if I call you Michelle during the podcast or would you prefer Dr. Tarver?

0:01:04

Dr. Michelle Tarver: Michelle is just fine.

Rich Bendis: Okay, great. Thank you. I wish everybody could see your big smile because they'd know why you're gonna let me use Michelle because you're just a very personable person representing us all at the FDA. Thank you for joining me today. Generally, instead of me reading your bio, which is very exciting, I'd rather have the guest introduce themselves because you can go into a little more detail than I could. The other thing is, with your role as a Chief Transformation Officer, that's a very good thing for people to learn about because we know CSOs and CSOs and CSOs and CCOs and CTOs, which are Chief Technology officers, but you're my first Chief Transformation Officer I've ever had on the podcast. In your introduction you can probably end with telling us about what that role is at the FDA.

Dr. Michelle Tarver: Absolutely. Again, I really appreciate the introduction, Rich. I guess I should start with saying that I often think of myself as a perpetually curious person.

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My parents and my children would probably use a different adjective, like nosy. But ever since I can remember, I've been interested in everything. I finished Spelman College in Atlanta and majored in biochemistry. I came to do my MD-PhD at Johns Hopkins, first starting off in Cell and Molecular Biology and then switching my doctoral degree into Clinical Epidemiology. I just enjoyed asking questions and seeing the application of the findings that I made. During the course of my graduate work I really looked at methods for many things—looked at rural data, epigenetic and molecular epidemiologic methods, laboratory studies as well as methods and tools to collect patients' perspectives. I also really enjoyed caring for people. I did a residency in Ophthalmology at the Wilmer Eye Institute then pursued a fellowship in Ocular Inflammation at Wilmer as well. I joined the faculty at Hopkins for a brief stint before being wooed to the public health world and the work done at FDA.

0:03:00 I've done everything here from benchtop to bedside, from pre-market to post-market, white papers to regulation. I've been in multiple leadership roles at the Center for Devices and Radiological Health and I just simply love the work that I do there. A lot of times when we talk about CDRH, people wonder, "What exactly is the work that you do?" We are the regulator of medical devices, which is everything that is used to diagnose, treat, monitor, manage and prevent health conditions. We are charged with protecting and promoting public health by assuring that patients and providers have timely and continued access to safe, effective and high-quality medical devices as well as safe, radiation-emitting products. These products are everything from contact lenses to pacemakers, defibrillators, MRI machines as well as the COVID tests that we are all familiar with. At the center, my role is focused on transformation.

0:04:00 That essentially is an executive who focuses on innovation and our center's future ability to gain forward momentum through executive, personnel, process and technological changes. I look at my role as to inspire, model and implement lasting changes in the organization. I'm always willing to roll up my sleeves—armed with problem-solving and leadership skills—to help set the goals and tone for each transformative effort that we undertake at the agency. I also see my role as an

integrator, helping to build CDRH's capacity for change and help cultivate leadership behaviors that ensure sustainable results.

Rich Bendis: Well, that's quite a mouthful Michelle. But I love the word innovation in your role because we are part of BioHealth innovation and that's one of the things that we try to do in the whole BioHealth industry: helping entrepreneurs, scientists and researchers try to commercialize their technologies and actually get them to the stage where they're ready to come to the FDA for regulatory approval. So, we are one of your partners that tries to help prepare them properly before they come to see you.

0:05:04 I don't know if we do a good job all the time but some come a little prematurely and some of 'em aren't ready—or will never be ready. But your job as a regulator is to give the appropriate feedback to them based on what they present to you. So, one of the things I'd like to talk about is how the definition of medical devices and devices in general has changed in the FDA over years. Because I would imagine you're regulating things today that never existed before, as well as other things they didn't know what category to put 'em into and they end up in CDRH. Is that true?

Dr. Michelle Tarver: Honestly, CDRH hasn't always existed. We came about in the 1970's. And if you think of the regulation—the regulation that governs drugs is very, very broad. Devices are unique. They are those products that do not operate through a chemical action. Instead, they have a mechanical or structural impact on a person.

0:06:03 And they are—as I've mentioned—prevent, diagnose, manage, monitor and treat health conditions. It can also be—not only in humans—but also in animals. Because devices are used across the board in caring for living beings. So, that's what we regulate. There are new technologies that you've already alluded to—like digital health technologies—that have come into the marketplace that we never imagined, probably, back in the 1970's. Some of the imaging devices that we have available now exceed our expectations of what we thought would be our reality now. And so, I would say that the definition of the device has stayed relatively the same but the products that fit under that have expanded exponentially.

Rich Bendis: You mentioned digital health but one of the other things that's very hot

right now is artificial intelligence, machine learning, quantum computing and it's all being integrated into healthcare and products and services or technology.

0:07:01 How do you keep track of all of this and how does that fit into the regulatory process?

Dr. Michelle Tarver: Well, I think that agility is critical. These technologies are changing at a rapid pace and the regulation has to also change with it and be adaptable. We've got a number of new guidances that we've put out acknowledging that rapid iteration cycle that happens for many devices in the virtual reality space and the artificial intelligence space. So, those devices predetermine change control plans. One of the guidances that came out talks specifically about that; how can you make changes to your product in a way that doesn't slow the innovation cycles but also maintains the safety and the effectiveness of that particular product when it's on the U.S. market? So, you're absolutely right, agility is critical. But also understanding that there are many different players that can be very helpful in understanding the impact of those devices when they are in use.

0:08:00 Not only is it the medical devices industry, the consumer health tech industry is increasingly coming into the healthcare arena. We're also seeing patients and providers taking a more active and proactive role in helping to define their needs as these devices are being developed.

Rich Bendis: Well, thank god we have a watch guard like yourself because there's so much going on in AI going on right now and sometimes you don't know what to believe. So, I would imagine that's one of the challenges you might incur as well as to what's real and what's not real in that world based on things that are evolving all over the world around all this new artificial intelligence.

Dr. Michelle Tarver: Well, it is definitely changing how we're looking at the world and what we need to consider and think about. So, I think pragmatic, well-grounded approaches are gonna be important, and important is also standards in that process. And we've got a number of great minds working on that at the agency and across federal government writ large.

Rich Bendis: And basically as you're looking at the world right now, one of the things that has been identified as a priority for the FDA, is the importance of diversity, equity and inclusion in evaluating medical devices—especially as it relates to underserved and underrepresented populations.

0:09:13 And I know that's something that you're passionate about. Please elaborate on that a little bit.

Dr. Michelle Tarver: I think we all have seen that life expectancy in the United States has been declining. We've seen it in many periodicals over the past year. Even when we look at Maryland. Maryland has one of the highest median incomes in the country but yet, in certain counties we see more than a decade life expectancy difference. That is astronomical and we can't continue to ignore those things. COVID-19 also put a bold spotlight on these health disparities that we're seeing across the population. We're seeing them between different racial and ethnic groups, in rural and urban locations, across the age spectrum and different genders. So, it really is important that we pay attention because we're gonna see that difference widen over time if we don't.

0:10:06 One of the things that we have launched is our strategic priority in 2022 which focuses on ways in which we could advance health equity. We believe that no person should be left behind in healthcare and that we should afford opportunities for everyone to participate fully, not only in the evidence generation process but also in actually having better healthcare outcomes. They should have access to those technologies as well as diagnostic and interventions that could change their life expectancy and the quality of life that they're living from day to day. Not only that, we believe that the information that people are using to make their decisions should be interpretable, accessible and culturally relevant to them so that they can see themselves in the information that we as an agency are sharing with them about the performance of medical devices.

0:11:02 The last thing that I would suggest is that there's an opportunity for us to do innovation in new ways. There are approaches that we've taken in the past that we may need to rethink and look at different approaches to, not

only addressing some of the differences we're seeing in clinical trial enrollment in different populations, but also in terms of, how do we get healthcare into communities that often are not able to access that healthcare?

Rich Bendis: And as you're looking at new things that come in for regulatory review and approval, is DEI one of the areas that is reviewed as you're going through that regulatory approval process?

Dr. Michelle Tarver: At the end of 2022 the Congress passed FDORA, which is legislation that spoke specifically about the importance of having diversity in clinical trials, they spoke specifically about racial and ethnic diversity, as well as age and sex diversity.

0:12:01 And they encourage both the medical device industry, drug industry and biological industry that you design a trial with a plan in place for how you're going to enroll people from those various populations. That is law, it will be required for those clinical studies. We're trying to help create tools that can help the industry be prepared for when that does happen. We're also trying to understand: what're the barriers and challenges to that enrollment? That was discussed at a workshop that we had in November of 2023. Specifically tacking: what're the barriers for different racial method groups, those who may have cognitive challenges, those who are pregnant and lactating women and children? What're the ways we can encourage them to participate in trials and can we get rid of some of the barriers? Should we use community health centers to be a part of the clinical trial enterprise more prominently than has been in the past?

0:13:02 And particularly for devices studies—where centers—particularly tertiary-care centers are where a lot of these novel and innovative surgical approaches may be employed—it is a little bit more challenging. We might have to be more creative about how we look and tap into community networks to get patients from various racial and ethnic groups to participate in clinical studies.

Rich Bendis: I think one of the overall goals the FDA as well as others have is really increasing the quality of life for *everybody* and one of the challenges is access. And I think that from an access standpoint—I had an opportunity

to listen to you speak at a recent Life Sciences Advisory Board meeting for the state of Maryland and you talked about a brand new program that is called “Home as a Healthcare Hub”, which will be introduced soon by the FDA and I anxiously await that, Michelle. But, let’s talk to the listeners a little bit about the concept around Home as a Healthcare Hub, since so much healthcare occurs within the home and how do we increase the quality of care and access of care at the home?

0:14:06

Dr. Michelle Tarver: Well, we’re hoping by bringing healthcare into the home that we will further democratize healthcare. Our initiative, Home as a Healthcare Hub, is reimagining how the locus of care is being delivered. Centering on the person and not the system. Focusing on what’re the different touchpoints on which the person is going to have to access the healthcare system and can we integrate those, synthesize them and decrease the burden on a person who is living with a health condition so that they don't have to find time in their day to sit in a clinic or be relegated to hospital settings that may have them waiting in emergency rooms for hours and hours on end when their issue or question could be answered at home in a more seamless way? And we’re thinking beyond a telehealth solution. We’re actually thinking of: are there devices that can be designed, that can be intuitive, not necessarily require a lot of activities and actions on the part of the patient, where they can just live their daily life and information can be collected about how they are feeling and living and communicate it with their provider and then tailored solutions can be developed in a personalized manner that allow them to have better healthcare outcomes?

0:15:21 But in order for us to do that, we’ve gotta think about the home itself. How is the home designed? Is it designed in a manner that will encourage health and wellness? Is it designed in a manner that allows it to contribute to the evidence generation process? And if not, are there ways that we can reimagine or redesign elements of the home that it can better facilitate healthcare moving there? That being said, we’re baking in the health equity component as well. We’re thinking: what’s the smallest footprint of a home? Looking at a single family home—an apartment, a mobile home—what’re the critical elements of those

homes—a bathroom, a bedroom, a kitchen?

0:16:03 And can we consider those who have the lowest amount of resources, those homes, and design with that in mind? It's easy to build a solution when you're building it for the penthouse, but it's harder, but critically important that we build a solution for those people who are often left out of those solutions.

Rich Bendis: Based on the traditional role for FDA, it sounds like when you talk about innovation and transformation, it's not that it's out of the scope, it just seems like it's out of the box a little bit from what traditionally is done by the FDA. How did you and the FDA come up with this as a potential need and why should the FDA be leading an initiative like this?

Dr. Michelle Tarver: I would say for the past decade or more we have been talking about the importance of home as a part of a healthcare enterprise. But COVID—as I said—thrust this into the spotlight.

0:17:00 We heard at a couple of different public meetings in recent years, including our Patient Engagement Advisory Committee meeting, that we can talk about devices coming into the home but until we actually talk about the home we're not gonna really address the challenges or barriers to that happening. And we heard that loud and clear, both during that public meeting—the Patient Engagement Advisory Committee meeting—as well as on our docket. So we took those findings and decided somebody's gotta tackle the home. Now, the funny thing about it is that if somebody is tackling the home, well, we're not architects, we're not designers but we know that sometimes the FDA having the conversation brings those interested parties to the table. And so, we decided to launch the initiative. We're working with an architectural firm to create a home prototype that is a virtual reality experience for folks to be able to put on the headset and see what it's like to navigate in a home of somebody who's got fewer resources so as we're creating and designing devices, they will be designed in a way that they will work in those homes too.

0:18:06 We're talking with consumer technology companies, we're talking with the medical devices industry, patients, providers. We're setting the stage for a true conversation— it's an idea lab where folks can talk about these

challenges and opportunities, develop new frameworks and maybe develop new solutions that are different than the ones that we currently are using. It's an experiment.

Rich Bendis: Yeah and it sounds like a very interesting pilot project and I guess, the key to the success of this would be innovators that you can partner with that have ideas that people have not thought about. And then, how do you really engage with them—or how do you even identify them—and more importantly how do the innovators know that there is an opportunity for them to engage with the FDA on this interesting new project?

Dr. Michelle Tarver: Absolutely, we've issued a statement and we have been trying to amplify that message.

0:19:01 And venues like this—really appreciate this opportunity to also get that message out to a wide audience. We are planning to have a public meeting coming up in the next few months, I would say.

Rich Bendis: Breaking news!

Dr. Michelle Tarver: Yeah, we'll hopefully have an announcement out that you'll be able to see soon. But, we expect for the public to come tell us what those needs are. We're having a listening session and we expect the industry will come share with us the opportunities they see and the challenges they may have identified with their particular technologies. And then we want people to sign up and say, "I'll try it out. Give it to me. I wanna play with it." Because we're going to make this prototype publicly available for anyone to use. It is not gonna be a static prototype, it'll be one that'll be iterative. So people can take it, modify it, change it and use it in a way that it'll be useful. We understand that when you're developing something new—when you're reimagining something—you may not get it right the first time.

0:20:01 And we're willing to have that conversation. But we know that if we don't try we'll be right where we are right now.

Rich Bendis: And so, what do you think the critical factors are? And we're talking to Dr. Michelle Tarver, who's Deputy Center Director, Chief Transformation Officer with CDRH. And I left out the big names there Michelle, and

everybody knows CDRH by now. But anyway. But at the end of the day what are the critical factors that are needed to transform the healthcare system to leave no one behind? I mean, you can talk about all of these different elements, but what do you see as the top two or three critical factors that're necessary?

Dr. Michelle Tarver: Well, I mean, one: the environment and understanding the environment that we exist in—one. That many homes in rural locations do not have access to clinics anymore. They don't have access to hospitals. We're seeing a decrease in the number of available clinical providers with not having them replaced at the same rate that they're leaving the healthcare industry. We're also seeing a rise in cost for healthcare services, which is a challenge.

0:21:03 When we look at that entire constellation, the solutions that we develop have to be sensitive to those needs. We don't want devices and technologies that're gonna further burden the healthcare providers. We just talked about burnout being a huge driver of people leaving healthcare. We can't burn them out even more with the solutions that we're developing. We also have to look at affordability and accessibility. The technologies have to work in the homes in which we're expecting them to go into. That means there's an infrastructure element that we need to consider in terms of Wi-Fi or cellular capabilities that're available to those particular patient groups. As well as, other infrastructure like community health workers and other care extenders. And then lastly, it's gotta be within the price point that people who most need it can get it. And so that may be that we have to look at what're the value-based care considerations? Can we collect evidence in the real world that'll help support payment models?

0:22:02 Those are things that we definitely need to work on putting in place in order to really support this transformation of healthcare.

Rich Bendis: And you talk about payment and reimbursement in other areas right now, which is a critical factor—we're fortunate to have the CMS, located right in Baltimore. Are they one of the partners you're working with when you're looking at cost and how to keep cost as low as possible?

Dr. Michelle Tarver: So, I would say this, for the healthcare hub itself we are working with patients and providers. We're working with the medical device and consumer technology industry. We're also working with the architectural firms. That's to put the prototype out. But, for the conversations that're gonna need to take place afterwards, obviously CMS is an entity, an agency that we are committed to having conversations with but other payers as well, other providers as well, hospital systems as well. I mean, this is something that will expand way beyond our prototype build. We plan to do this within a short span.

0:23:01 It'll be by the end of this calendar year we hope to have the prototype up and available. And that's why I said, it is a starting point for some of these conversations that we're alluding to.

Rich Bendis: And anything that's innovative within a new federal agency or that a federal agency requires, I would say, sustainable budget and long term financial support in order to keep programs going. Do you see a commitment within the FDA and the administration to make this a priority to continue to sustain the Home as a Healthcare Hub project?

Dr. Michelle Tarver: I see a commitment to help reimagine healthcare. I think innovation has been a priority that you have seen our center speak very loudly about. We put out a report earlier this year about the innovation work that we are doing at CDRH as well as a safety report. 'Cause we're committed to both pillars and the work that we do. What we're hoping will happen is that this won't be something that one agency would have to carry alone.

0:24:03 That this is something that the community will carry and move forward. Where we see value is where we see investment. And so, as we continue to show that this moves the needle in a direction that is going to allow for the healthcare system to be more sustainable, to help shore up some of the cracks that we're seeing right now and allow people to live a better and fuller life, we're hoping that people will continue to come to the table and invest in the effort.

Rich Bendis: We're working with another relatively new entity within the federal government called ARPA-H and they love funding innovative things. So, I would imagine they might be a potential future partner you could work

with.

Dr. Michelle Tarver: We definitely talk with ARPA-H so we will see what the future holds. [Laughs]

Rich Bendis: Right. Super! As the Chief Transformation Officer for the CDRH, I would imagine there's more things than just the healthcare at home project you're engaged with. Can you talk a little bit about some of the other things that're transformative going on within your division of FDA right now?

0:25:04

Dr. Michelle Tarver: We're working on a lot of things. One of the things that we are committed to—the Home as a Healthcare Hub is one part of our strategic priority related to advancing health equity. You heard me speak about clinical trial changes that we will be seeing as part of our efforts again to advance health equity. We're also looking at how we can be more transparent and clear in our communication to different communities. We have websites and social media presence, but sometimes they're not always accessible to the communities that need those messages the most, so we're doing some work on that. Particularly in the recall space. We're looking at, how can we better communicate when there are safety challenges with medical devices? 'Cause that's the information that people need in order to make informed decisions. So those are some of the efforts that we've got underway. We're also looking at: how can we more transparently show, to the public, who participated in the trials that supported a marketing authorization and are there approaches that can make that tangible and accessible to people so that when a provider is sitting with a patient, they can have a very fluid conversation about, "You were or were not studied in this particular study?"

0:26:12 And, "I don't know or I do know how well this device will work for you." That's the information we wanna empower patients and providers with. The last thing that I wanna touch on with respect to the health equity work, is that—I spoke about Home as a Healthcare Hub, I've spoken about the different trial approaches, I've spoken about communication—but I also have heard about partnerships. Over and over again we are

looking at ways to better partner with various communities. We have our strategic priority from years ago, which was the Collaborative Community initiative, and that has exponentially grown with many of those collaborative communities saying, “We want to take on health equity. It’s an important principle for us.” That blew my mind.

0:27:01 Because we don’t control or run those collaborative communities. That is really a grassroot effort from communities that’re tackling different topics like digital pathology or artificial intelligence or wound care. But many of them are saying, “Health equity is a priority for us.” And we wanna have a specific effort in that space. So, all of it to say that this is not something FDA does alone. We are a part of a larger ecosystem and we are trying to do our part to help move the needle forward with respect to health equity. But we know that it’s by holding hands across the ecosystem that we really do make a significant and lasting change.

Rich Bendis: There’s no question that leveraging private-public partnerships actually accelerates getting closer to an end goal. And also provides a more cost-effective way of looking for what the end result would be. So how do you determine who’s an ideal partner? Or someone listening to this podcast right now says, “I think I could be a partner to the FDA on a project,” how do you determine who’s appropriate and how does someone approach you about opportunities to work with the FDA?

0:28:11

Dr. Michelle Tarver: So for Collaborative Communities, it’s a community. And part of what we’ve described in that effort is that we’re looking to be a member like other members in communities where multiple stakeholders are at the table, not just one entity. But it takes a system-wide approach. And the importance of working together is critical because the challenge is so big, it’s multi-dimensional, it hits many different stakeholders and it’s gonna require a sustained, prolonged interaction in order to truly have impacts and deliver products that are going to be adoptable and implementable. So, those are some of the efforts that we tend to participate in, but we participate as members like anybody else participates.

0:29:00 In terms of companies—I mean there are obviously some ways in which

we can partner with people and ways in which we cannot partner with people because we are a regulator too. And we do take that into consideration. We have the Medical Device Innovation Consortium, which is a public-private partnership, whereby we work with companies that are part of this particular consortium and they do a number of different efforts in different areas, like our case for quality work or real world evidence work through NEST, which is a mechanism via healthcare providers, patients, industry all look at real-world data and see how it can impact regulatory decision making. We also have a number of different areas in cyber security and other pressing topics that we know as the device world are going to be—or have already been— issues for public health.

Rich Bendis: That's pretty exciting. So the question now is, are there things that you would like to discuss and our listeners should hear from you that we haven't talked about and that you should make them aware of right now?

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Dr. Michelle Tarver: I would just say that I hope that collaboration resonates with the listeners. That the FDA is here to help—we really are. We are committed to public health and we are committed to finding solutions that help advance public health and innovation is key to that. We are looking to be a partner and we want to encourage innovative solutions. So, we hope that you all are willing to take up our Home as a Healthcare Hub prototype, play with it, give us feedback, give us ideas, give us suggestions because we wanna make sure that what we're developing, this tool, will be helpful for all the folks who are developing solutions that will help improve our nation's health.

Rich Bendis: I'd be remiss if I didn't close by asking one more question, and that is—and I should've done this at the beginning but it might be a good way to close—and that is, public service requires different types of individuals who really have a passion for giving back and being involved in public service and through this interview over the last half-hour or so it's very clear that you have a great passion for what you're doing every day, Michelle.

0:31:16 So talk a little bit about what motivated you to get into the public service world and what keeps you motivated day in and day out.

Dr. Michelle Tarver: The mission. Hands down, the mission. I love caring for patients in clinic. I've done that—and I still do that! I love seeing people get better. But it's one person at a time. At the FDA, you have the opportunity to impact the entire nation's health. And that to me is so rewarding. To be able to serve in that capacity. To be able to help people who often don't get the opportunity to raise their hand for help or don't even know what help is available to them. That is what the agency offers. And we have—as a team, at our entire center—committed people who believe in the mission, who have come to FDA simply to serve the U.S. public.

0:32:06 So when I say we are here to help, we truly are! We have come from the private sector; we have come from all walks of life to serve and help move public health forward.

Rich Bendis: Well I think you're being on *BioTalk* today helped dispel some of those myths about the FDA and that you really are here to help. People who are listening, if you wanna get involved in the Home as a Healthcare Hub you hear that Dr. Tarver is looking for partners to be engaged in this as well as other engagements with the FDA in other projects and I'm sure she would open her doors for new discussions with people who have something innovative to bring to the table. So I wanna thank Dr. Michelle Tarver who's the Deputy Center Director, Chief Transformation Officer at the Center for Devices and Radiological Health, which is CDRH, at the U.S. Food and Drug Administration for being on *BioTalk* today.

Dr. Michelle Tarver: Thank you so much, Rich.

0:33:01

Narrator: Thanks for listening to *BioTalk* with Rich Bendis.

End of recording.