**Further Together: The ORAU Podcast**

**New Day Diagnostics**

**March 26, 2024**

I mean, the negative impact of this cancer is profound as you started the conversation off with. We don't want to stop at one option or two options or even three options.

We have got to, as a scientific community and as a public health community, keep coming at this problem from every possible direction with every possible solution.

There are just... too many people at risk that are not willing to get screened or don't know that they need to get screened and then they just think we need options.

We need everything possible out there. - You're listening to "Further Together," the ORAU podcast. Join Michael Holtz and his guests for conversations about all things ORAU.

They'll talk about ORAU's story history, our impact on an ever -changing world, our innovative scientific and technical solutions for our customers, and our commitment to the communities where we do business.

Welcome to Further Together, the ORAU podcast. As ever, it is me, your host, Michael Holtz, from the Communications and Marketing Department at ORAU. And it is Colorectal Cancer Awareness Month.

As a colorectal cancer survivor myself, this would be the high holy days of cancer awareness for me. And I am thrilled to have a couple of friends with me on the ORAU podcast.

the podcast this episode. Um, talking about new technology and new detection methods for colorectal cancer and other cancers. Um,

my friends, Eric Mayer and Jessica Ethridge from New Day Diagnostics are with me. Eric and Jessica, welcome so much for being here. Oh, thank you for having us,

Michael. It's a pleasure. It's great to be here. I'm sorry. so excited to be talking to you I've We've known each other for a few years through a name change of the company or two,

whatever but there are exciting days ahead for Early detection and prevention of cancer new day is on the front lines of that and hopefully we get to talk about a little bit of what's going on,

but first Eric if you would talk about what new day diagnostics is No, that's a great question new day diagnostics is a cancer diagnostics company We believe wholeheartedly that if you catch diseases early There's a bright new day ahead of you That's the name,

you know. We want to empower patients with more accessible options, starting with colorectal cancer screening. We can find this disease earlier and get the correct patients to go to a confirmatory colonoscopy or get the correct patients into a treatment if they need it.

And give that physician and that individual an empowering tool. that they don't currently have or new option that they don't currently have. New Day as a company,

you know, has a deep history in colorectal cancer research and research in other disease areas. We have a pipeline, a robust pipeline of other diagnostics in oncology,

in infectious disease, in moving into women's health and in digestive disease. The goal is to get as close to the patient as you can, and make sure that there are great options for those individuals to live healthier lives.

I love it. And of course, if you detect cancer earlier, treatment is easier. You actually live and live longer, all of those great things. So,

I love, love, love what New Day is doing. and what you all stand for. And I'm actually, I understand that I was,

when I was diagnosed, I was part of an early research trial, I guess, of the blood test 'cause my sample was used in the early days of the development of your blood.

blood test. So that's also exciting. - That's absolutely correct, Michael. You kind of introduced that we've known each other as people for the last few years,

but we actually knew you as a number. We didn't know it was you, but it has a blood tube sample for sitting in the freezer about 10, 12 years ago. And these things take a long time to research,

to develop. develop, to go through the clinical studies to prove safety, to prove effectiveness. And we're on the cutting edge, but that started 10 plus years ago to get to this point.

Absolutely. And it's really exciting and so necessary. I mean, the numbers, the latest statistics around colorectal cancer are alarming and astounding,

right? I mean, when you think about... the fact that colorectal cancer is the number one cancer killer of people under the age of 50 under the age of 50 colorectal cancer used to be an old person's disease that's not true anymore I should sorry I should correct that it's the number one cancer killer of men under the age of 50 number two among women but on the fast track to be be really the number one cancer killer

overall we we have been talking about in cancer advocacy world the number one cancer killer people under 50 by 2030 but here we are it's 2024 it's happening much faster than even experts have predicted so it's a little scary out there.

It's happening here in the United States with younger and younger individuals it's happening globally as lifestyles and diets change even in developing nations.

They're seeing high incidence of colorectal cancer continuing to spike. And you're absolutely right. Right now, the guidelines for screening are to start at 45. Used to start at 50,

and we're very pleased and happy that the needle is moving earlier and earlier. That said, folks that are here today, you know, I just turned 40. I had a colonoscopy performed three years ago.

I do have family history of many cancers on my mom's side of the family. I know early detection is how you get ahead of these things, but I was not in the screening guidelines. That procedure was not reimbursed.

I had to pay for that out of pocket. And folks that are our age need an option. They need something they can do effectively, efficiently, and efficiently. and that they'll do every year so that we can catch something as early as possible.

Absolutely, and not be gaslighted, right, about, you know, your symptoms could be this or it could be that, you know, and like just do this,

do the screening test, whatever that is, you know, hopefully it's eventually a blood test that makes it easy, but do the test so that we... we can at least,

at the very least, rub it out. Yeah, you're absolutely right. This is a, this is a cancer that grows fairly slowly over time. By the time you have symptoms,

it's already in typically later stage and that's not always the first thing that a primary care doc is gonna think. They're gonna think let's look at IBS, let's look at IBD,

let's look at other reasons that you may be having you know gastro symptoms and you know those kinds of things in our opinion are our standard of care that's exactly what the physician should be doing but if we can have a better option earlier and it's not a hope anymore it's happening right now.

The new day blood test colo health is launching in March for colorectal cancer awareness month so this will be accessible. to patients and individuals by the end of the month. That is exciting.

I love hearing that, and it's kind of breaking news. This is the first announcement. So that's exciting.

Eric, how long has it taken to get here? I know you've mentioned years, but I mean, it's clearly been over. a decade, 12 years in the works to get to the point that we are here.

It has been, and prior to that, the company that started in Knoxville was called EDP Biotech Early Detection Products. That company was founded in 2005,

so we're going on nearly 20 years of underlying primary research. I came to the company in in 2015, so almost ten years of moving the direction of going from research into development into clinical practice very soon here.

So how did you how did you get to become part of EDP and now New Day? Well personally it was a bit of an accident.

I came from Raleigh, North Carolina. I was in cancer research at UNC Chapel Hill at the Weinberger Comprehensive Cancer Center. I did my undergraduate research there,

went into diagnostics in Research Triangle Park, and then my wife, girlfriend at the time, wife now, got an opportunity at the University of Tennessee,

Knoxville. Go Vols, and we packed up and moved to Knoxville, Tennessee in 2011. I met the company founder here at EDP Biotech within the first week of boots on the ground in Tennessee.

The gentleman had started the cancer research company in '05, had spun out a veterinary genetics company in '08, and I actually started working on both right away and just continued my journey since then.

- Awesome. And then our paths met crossed five or six years ago. It's been a minute for sure. - Slept a few nights since then.

- That's exactly right. But it's been exciting to follow and watch the progress and, you know, it's been great. as You know great work is being done to make these tests more accessible easier to do You know,

we know we know people love that colonoscopy, right? Hear the nightmares about the prep and they don't want to they don't want to have to endure that and you know while prep has has certainly gotten easier,

you know, the easier choice isn't a choice that everyone gets, um, at least not yet. And, um, you know, it's still an invasive procedure and, um,

a blood test is definitely much, much easier to do. So, um, the easier we can make it, the more accessible we can make those tasks. Um,

and that's our philosophy. philosophy, right? - Absolutely, the best screener is one that somebody will take, and colonoscopy is the gold standard. It will remain the gold standard.

A trained physician with his two eyes will find small masses and small polyps and colorectal cancers and then can begin treatment. Our job is to raise the red flag in early screening and say these are the people that need to go to colonoscopy.

And that's exactly the way we're going to create that accessibility and drive better patient outcomes, reduce mortality, reduce incidence rates is by finding those polyps in their earliest state,

sending those patients to confirmatory colonoscopy where the physician can resect and cut those polyps out before they progress to cancer. This is a preventable cancer,

one of the few preventable cancers. So let's get on the forefront of it. Absolutely and you know if we detect it early, if we you know get folks taking care of early,

it's less expensive, it's you know more people live, you know all of those things. You know I as you know spend a lot of time in the cancer.

community with other advocates and other cancer survivors. In my experience, I was lucky. I was diagnosed at 43. I did first -line treatment,

first -line treatment works. I was diagnosed States 3B, rectal cancer, and first -line treatment worked for me, but I know so many people who they are incurable.

They'll be doing chemo for the rest of their lives, you know, whatever that looks like. And if we can avoid that with, you know,

a simple blood test with catching it early so that it's not progressed. And at younger age, you know, if we can give these tests to people in their 20s and their 30s so that they don't have to inculcate.

long treatments and 144 keynote sessions and all of that, it's the quality of life and the quantity of life and the expense that can be spared if we can get this thing under control.

That's right and, you know, we we always think of cancers in general as very complex Biological systems. There's never gonna be one single magic bullet cure.

You know, these are many diseases by many different You know genetic and environmental and behavioral factors that cause them in many different organs So,

you know, we want to focus on the one that we believe is gonna make the biggest impact to start off As you said, with the colorectal cancer incidences rising in certain populations with here in the Appalachia region of Tennessee,

we have higher than the rest of the United States incidences of colorectal cancer. And there's data showing that this annual blood test, this specific annual blood test went done annually,

avert more CRC cases and avert more CRC patients. per thousand people screened than other modalities. So as a screening tool, we believe this is going to make a humongous human impact and the economic impact that follows as health care costs are rising.

Let's figure out how to get those down. A simple cost -effective blood test is one such solution. It's amazing. It really is. In terms of of,

of course, you know, insurance drives everything in coverage. What do people need to know about coverage for the test? So right now we are working on coverage.

It is going to be an out -of -pocket, but we wanted to make the out -of -pocket pay acceptable to most people. So we are going to launch this test at all.

$199 to start off. We know there are other blood tests out there that are $500 to $1 ,000. You know, those are not, in our opinion, accessible to most patients.

But we are working with private payers, the Medicare Medicaid, there is a CPT code, we're working to get that reinstated. So,

you know, hang with us a couple more months. months hopefully we'll have the coverage but to start off to get this out to the patient population that needs it here in the Appalachia and the sort of Knoxville and regional you know Nashville Atlanta Charlotte etc.

you know the Southeast region we're gonna start off here in March under the self -pay model. For those of us who are answer advocates and spend a lot of time working on policy,

which I have spent years, what can we do to help get this test covered and make sure that it's truly accessible to everyone?

Well, I will turn that over to Jessica. She just spent most of this week in Nashville on Day on the Hill with Life Science Tennessee meeting with policy makers and legislators.

Yeah, it was a really interesting experience. It was very impactful to sit down and talk with the legislators,

one after the other with a group of us from Life Science Tennessee. Tennessee, just highlighting the bills that we're coming through that were related to the work that we were doing.

And so early diagnosis is a really big one, just bringing it to their awareness that these are things that we're doing in Tennessee. We're developing tests to diagnose things earlier,

to identify them earlier, and pointing out where the possible... funding issues are or things with Medicare and Medicaid.

I think that the cutoff for sensitivity, the sensitivity is where we are right now is just beneath the threshold,

just beneath it for what their standard acceptability is in terms of what they'll cover. You know, many, many, many, many, many, many, many, many advocating for more due diligence and whether or not that that is the number to be at.

Diagnostics are a, diagnostics are a place where we can really, really, really make an impact in disease, you know, we're catching it before it's needing cures,

it's needing treatment, and I think just generally having the awareness to our lawmakers that the diagnostic space is one to be paying attention to,

supporting and advocating for on all fronts is really where we need to be having the conversation to begin with. Awesome. Well,

I know for patients like me, if there's anything I can do to raise my voice. to help make any of that happen. I'm happy to do it.

I have no doubt there are others that I can bring to the table as well. I just believe in my heart and soul that early detection and prevention is critical.

You know, I know too many people who are who have. passed away, who are, you know, fighting this long term, and all of that is unacceptable,

personally unacceptable to me. It shouldn't be that way in, you know, the world that we're living in today. So the fact that that there is a test that,

you know, is epically beneficial, that that can catch, you know, this early that can save lives, is incredibly heartening, and I think will be exciting for a lot of people to learn about.

I look forward to you learning more and seeing results as things move along and as the test becomes available. - That's right,

we're starting right here in our hometown of Knoxville, Tennessee. We're expanding out, you know, regionally. in the Southeast. And then we are also working with,

you know, several partners nationwide. Can't mention any names yet, but over the next six to 12 months, this will be available throughout the United States.

And, you know, and you and Jessica perfectly hit the nail on the head. You know, there is a disconnect, I think at the federal level, when the FDA approved something and says, "Yes." yes,

this is safe. Yes, this is effective. This works. It's FDA approved. But yeah, we cannot create accessibility by allowing individuals to actually get reimbursed for taking the screening test.

That is an unfortunate disconnect that we need to work on together with the advocacy groups. And let's just keep... pushing for early detection. We know that's gonna save people's lives.

Well, wherever, again, wherever I can help, wherever I can bring folks to the table, happy to do that because accessibility is important.

You know, we know that, you know, there are certain populations, you know, black and brown people who have, you know, are disproportionate. disproportionately at higher risk and particularly higher risk of death from colorectal cancer.

But they also don't have the same level of accessibility to the gold standard colonoscopy. So, you know, whatever we can do to level the playing field,

and this test does that, you know, it levels the playing field. field and can get into the hands of everybody. Then let's do everything we can to make that happen.

Well, Michael, this right here helps. This is awareness. This sends the message out. You know, Jessica's been working diligently on our awareness campaigns that will go direct to consumer as well as to physicians and providers.

So stay tuned. The month of March, we're going to get a lot of of info out and that's the whole goal We can raise awareness so that individuals out there know to advocate for themselves even when they go into their annual physical Hey,

let's talk about this. This is not something that we should be embarrassed to talk about just because it's our rear ends, you know absolutely Let's get that awareness out and And yeah, you know keep an eye out weekend meet the patient where they are so social media campaigns,

Jessica's promoting, you know, we're going to be on Facebook. We're going to be on LinkedIn. We're going to be where the patients go to get the information. - You know, you touch on an important point 'cause there is such a stigma around colorectal cancer and the body parts that are involved,

right? We don't like to talk about the fact that, you know, literally everybody. poops, everybody. We all do. We all have butts. We all have, you know,

we all have colons, we all have rectums, you know, mine looks a little different now because I have a permanent colostomy, but it still works just, you know, the same way everyone else's does,

and but we have, there's this inherent fear and embarrassment of talking about. about what happens in the bathroom and We need to get over that.

We need to You know be able to say, you know, there's blood in my stool. There's you know, I'm not Feeling well, but you know, I'm bloated.

I have cramps. I have you know, and a lot of those symptoms You know our signs of late -stage, you know diagnosis unfortunately, but we need to be able to talk about the fact that there's stuff going on in our bodies that we are not going to be aware of.

And if getting a blood test makes you live longer because you're detecting something early, by all means, let's make that happen.

But, you know, I think, again, we have to... stop being ashamed of talking about, you know, what happens in our underwear areas,

as they say. Yeah. Hopefully, hopefully really even just having another option, blood test as an option, makes the conversation more approachable. The,

you know, what we are seeing in a lot of research out there is just for patients to have multiple options. in ways that they can test in screen, opens them up to the possibility.

And I think this idea even lends itself to what you're saying about having uncomfortable discussions. Maybe it's easier for me to go into my doctor and say, "I'm having stomach problems and I noticed there was a blood test for colorectal cancer screening." Like,

it's just an easier conversation than... this really overwhelming idea. You know, we hear so many difficult stories about the colonoscopy.

We know there's other alternatives, but they also involve stool. So we're still, that's still involving these uncomfortable conversations and these uncomfortable body parts and whatnot.

Maybe those two. are still the best one, you know, your your your physician might still say no I think you need to do this test or I think you need to do the colonoscopy but if the the knowledge that there is an option that they're comfortable with at least starts the discussion then you something like this begins to help the landscape in softer ways.

ways, not just having an option that, you know, it's more accessible in so many ways. Geography, you don't have to be close to big facilities.

More comfortable with the idea of donating blood. It can be done every year. You could potentially make it part of screening for younger and younger...

people. There's a lot, a lot, a lot of opportunities with this, but some of them are things that are soft, like we're talking about here, just the conversation.

- And we make some jokes every once in a while. It's okay to, you know, have some fun jokes and put the new one. - Absolutely. - We make everything colo healthy around here with colo health. - Yeah, colo healthy and you don't.

have to ship it in a box. - I can't do the jokes. I'm the worst joke teller ever. I'm like, I'll just mess it up. Just forget I said that.

- Because stool is messy, and we mess it up. - That's right. - That's right, exactly. And on the one hand,

the statement's understandable, but on the other hand, it's understandable. hand, it's, you know, like this can save your life. So I love the idea of Jessica making it softer, making it a softer approach to say, let's do a blood test.

And then if we have to move to you, you know, confirmatory colonoscopy, then we have the more uncomfortable conversation. But let's start with just sitting on the couch,

right? right? We can, we can move elsewhere after that, right? That's right. And, you know, the doctor is gonna know the best route and they're gonna be able to take the information and the result and make the best decision for their patient and consult with their patient properly.

And it's all about getting info out there, you know, this is another tool in the toolbox. It's not the only tool, you you know, and that's the whole goal. As Jessica said,

more options gives that patient some comfort level that there is something I can do about these symptoms I'm feeling, you know, and it's not necessarily something that's going to be gross or uncomfortable.

There are other options out there, and that's the whole goal. Create accessibility. If it's our test, great. If it's not our test, great. We want people to get screened. That's the whole goal.

I mean the negative impact of this cancer is profound as you as you started the conversation off with we don't want to stop at one option or two options or even three options we have got to as a scientific community and as a public health community keep coming at this problem from every possible.

direction with every possible solution. There are just too many people at risk that are not willing to get screened or don't know that they need to get screened.

And then they just think we need options. We need everything possible out there. - That is so awesome.

- Yeah, someday we'll have that little Star Trek, you know, screened. and we'll be able to do everything. But that's a couple hundred years in the future. So until then, we keep innovating and we keep iterating and we keep making improvements.

Jessica mentioned the threshold level. It's FDA reviewed it and said, safe and effective, well, we're going to make some improvements and we're actually working on those already in our laboratories and in our research facilities to get.

far above that threshold, an extra 10, 20 % above that threshold can. So it's always about getting better results, getting better patient outcomes and making better tools for the patient and the physician.

- And not to jump backwards too much, but you just gave me a thought. You're making it clear that this is deemed safe and effective by the FDA, where...

where the threshold cutoff that is not allowing it to be reimbursable is actually CMS. So the FDA and the CMS, you know,

their guidelines and their expectations, like there's a little -- A misalignment. A misalignment. Thank you, that's the word that I was looking for. And so that could be a really important thing to identify.

and go after is this 1 % or 2 % difference between these two things is how many people are prevented from having a solution that they're comfortable with because of this small misalignment when the test has been deemed safe and effective by the FDA.

That sounds like a place where advocate voices can be heard. in. Hmm. Hmm. See, that's why we have these conversations.

It's raising awareness overall, right? That's right. So, yeah, I think that we need to fix that misalignment and straighten that road a little bit.

So, I'll take that under advisement. Hmm. How about that? Is there anything we have not talked about that you want to make sure that we cover in this?

I would just say, you know, keep on the lookout, especially if you're here in sort of the East Tennessee region over the month of March. There's going to be news stories,

social media stories, you know, keep your ear to the ground. because this is coming in March, newdaydiagnostics .com, Colo Health, right, colohealthdx .com,

is that the website? And let's make this happen. Yeah. I love it. There'll be lots of information and it should be published any day now on our website. Certainly you'll be able to follow us on our social media and find out more if you're interested in actually coming and getting screened with this test.

test. - Awesome, I'll post links and all that in the show notes. So folks will be able to find it who are listening. - Perfect. - Hopefully they'll take you up on the test and get it done 'cause it could,

the life that you save could be your own, quite frankly. - That's right. Exactly. - Get the test done. Eric and Jessica, thank you so much for spending this time with me today. I really appreciate it. appreciate it and I look forward to you letting people hear more about Call of Health and hopefully getting tested,

but I know it meets a specific desire for me to spread the word about awareness and early detection and prevention. So, I'm so happy we can have this conversation.

- Well, thank you for having us. We always enjoyed, Michael, cool, all right. our conversations with you, and we will continue this one because this one's really important. Absolutely.

Absolutely. Thank you, Michael. Thank you. Thank you for listening to Further Together, the ORAU podcast. To learn more about any of the topics discussed by our experts, visit www .orau .org.

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