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FOOD AND DRUG ADMINISTRATION

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CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

MEDICAL DEVICES ADVISORY COMMITTEE

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VIRTUAL PUBLIC WORKSHOP - 3D PRINTING IN HOSPITALS: VETERANS HEALTH ADMINISTRATION'S EXPERIENCES IN POINT OF CARE 3D PRINTING OF DEVICES AND IMPLEMENTING A QUALITY MANAGEMENT SYSTEM

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M E E T I N G

(12:00 p.m.)

CDR COBURN: Good morning, good afternoon, and good evening, everyone. My name is Commander James Coburn from the FDA's Office of Counterterrorism and Emerging Threats. I have the honor of introducing our opening speakers today.

The VHA and FDA have worked closely together for a long time on 3D printing endeavors, especially in the last 2 years, and we are pleased to be co-hosting this workshop on 3D printing in hospitals.

As attendees, you will have a chance to ask questions of our panelists for them to answer during the discussion. Just click the dialogue icon on the bottom of your screen for the streaming screen and enter your question. Please write them in the chat during the speaker's talk and we will raise them during that discussion time, that way they can be filtered in that order.

So we have a panoply of wonderful speakers today and without further ado, let's get started. We are very honored to present our opening speaker, Dr. Carolyn Clancy, the Department of Veterans Affairs' Assistant Undersecretary for Health, Discovery, Education and Affiliate Networks. For the last 9 years Dr. Clancy has been a part of the VHA's executive leadership, where she's been devoted to quality, performance, and safety, and she has seen 3D printing at the VHA expand rapidly in her tenure as Assistant Secretary and I'm excited to hear her perspective.

Dr. Clancy, over to you.

DR. CLANCY: Thank you so, so much, Commander Coburn, for that kind introduction. It is my great privilege to welcome all of you today to the FDA/VHA, that's Veterans Health Administration, public workshop on point-of-care 3D printing. But the most exciting part is being with a group that shares our passion and commitment to 3D printing. Together, our

shared vision for 3D-printing impacts how we think about and deliver care to our patients, to the veterans whom we serve, and health care overall across the nation. As hospitalists, researchers, regulatory staff, and business leaders, we're all on the front line of advancing innovation in 3D printing to continually improve care delivery and achieve better health outcomes. So today's workshop is really a true celebration of how we can unleash the full potential and impact of 3D printing when government, academia, and industry combine forces, especially our collective ingenuity, innovation, and creativity.

From the cardiac pacemaker and liver transplant to the nicotine patch, these all came out of VA research. We can add 3D printing to our legacy of producing breakthrough healthcare innovations.

The innovative spirit of 3D printing was on full display in the early days of the pandemic and one of the first groups that we heard from about this very early on was the FDA. When COVID hit, VA, in collaboration with FDA and the National institutes of Health, designed, tested, fabricated, and 3D-printed personal protective equipment, or PPE, and critical medical devices. The result, hold on to your seats, was more than 12 million diagnostic COVID nasal swabs, 38 million face shield parts, and hundreds of thousands of other items like mask and ventilator parts, all in 5 months. Fast forward to 2022 and VHA continues to build on those successes in several new and exciting areas such as additive manufacturing and pre-surgical planning meetings.

In the area of pre-surgical planning, VHA has been using 3D printing since 2017 to create surgical planning models, allowing veterans and their surgeons to make the most informed choices about their care. Just to give you a very quick visual of this, instead of having surgeons going to the OR and say "huh, whoa, this is trickier than I thought, who's going first," by having these 3D-printed models, you can have those conversations ahead of time and march into the OR with a plan in place.

Once such example of 3D printing is called the Geo-Stent. This is a medical first where the FDA approved VHA's request to prescribe an experimental 3D-printed device developed in-house by a 76-year-old patient facing a rare form of hearing loss. I should note, this is a 76-year-old veteran who is an engineer for his career.

Moving forward, we plan to continue to leverage this type of 3D-printing technology to address patient-specific medical needs that might not be yet met by off-the-shelf products.

In addition, VHA has been a pioneer in establishing point-of-care manufacturing labs, bringing medical device fabrication to the hospital campus, again, for the past 5 years. Our vision is for any of our nine million veterans to be able to walk into any VA and have access to personalized care and safe medical devices that fit the VHA's unique patient population's needs.

The Office of Advanced Manufacturing has been established as a national program office that brings capability and expertise from our VA medical centers across the country to support that common goal and harness the power of the 60-plus facilities with 3D printers on site. We want to assure that the office's, or OAM's, processes to produce medical devices that meet veterans' unique needs and comply with FDA quality standards, as well as our own policies, will ensure only safe, effective products are used in VHA patient care.

To that end, the new program office is being set up to achieve the same quality standards and good manufacturing practices of medical device manufacturers, including registering facilities and listing products produced there. In fact, late last year, OAM listed its first Class I product developed under our quality management system, which complies with FDA quality system regulations. The product need came from the National Center for Patient Safety and was a collaboration between our facilities in Pittsburgh and Seattle.

Over the next 2 days the experts in the Office of Advanced Manufacturing will be sharing with you the steps VHA has taken to meet these ambitious goals.

Point-of-care manufacturing and pre-surgical planning models are just two examples of how VHA is a leader in 3D-printing innovation, technology, and care delivery, but we know all too well we cannot do it alone. We need hospitalists, researchers, and clinicians like you who understand that the true power of harnessing 3D printing is a collaboration. For this reason, we've invited you to join us -- FDA, VHA -- to work in partnership with government, academia, and industry to ensure 3D printing is foundational to delivering the most accessible and best outcomes for our veterans. I wish you a very productive workshop and look forward to hearing about your discussions.

The one last visual I will leave you with, there was a kind of technology science fair, if you will, about 4 years ago. I think this was dreamed up by someone at the White House and originally, the plan was to have it at the -- what we used to refer to as the old executive office building we now call the Eisenhower Executive Office Building, a beautiful building, but for those of you who've had the pleasure of going to meetings there, you know you have to get in through security and so forth. So somewhere along the way somebody had a better idea, which was to use the Department of Labor, which had phenomenal, phenomenal space.

So if you can imagine people from all across the executive branch there to showcase, just like a science fair, their specific innovations and so forth, and in the middle of this is Dr. Beth Ripley, whom you will hear from today, with some of her models and so forth. I'm telling you, I was really sorry we didn't bring security to be with her because people were just mobbing this and asking lots and lots of questions for her and very, very excited.

So I think that this is very cutting edge; it's really, really important. Thanks to our work, you may not appreciate this now, we have a standard or FDA has a standard, but we

tested and evaluated this by working with our research partners for a nasal swab and that was very, very necessary so that they wouldn't break in people's noses. So I'm wishing you a phenomenal workshop and 5 minutes with Dr. Ripley. And many of you may be inclined to come join us at VHA, that would be okay.

Thanks very much, Commander Coburn.

CDR COBURN: Thank you very much, Dr. Clancy, it's really always inspiring to see the work that's going on in the VA and to see how much has gone on, especially during COVID with 3D printing. We appreciate it.

Our next speaker will be Dr. Matthew Di Prima, the CDRH or the Center for Devices and Radiological --

(Pause.)

CDR COBURN: Oh, I think I was muted. All right, wherever I was, our next speaker will be Dr. Matthew Di Prima, CDRH lead for 3D printing and co-chair of the FDA Advanced Manufacturing Working Group. He is a fixture of 3D printing at the FDA and has been leading the technical guidance and part of the discussion paper work that has come out, and he's been part of the 3D printing community for over 10 years, playing a leading role in all these activities, and he will be discussing the discussion paper in his overview.

Dr. Di Prima.

DR. DI PRIMA: Thank you so much, Commander Coburn. Next slide, please.

So this opens with our standard FDA disclaimer, but it's also very important to note that the discussion paper that I'm summarizing is a discussion paper, it's not representative of any draft or final guidance or other policy, and it's really designed to facilitate discussion, much like we're having here. And again, everything that is going to be discussed is still very much at that discussion stage. Next slide, please.

Some very just quick facts about the discussion paper. It was published back in

December. We present 16 questions at the end of the discussion paper to get a range of responses from industry and clinicians to understand the various concepts that were touched upon. The docket did close on February 8th, that just means that those are -- that any further comments we're not obligated to respond to, but if you have additional comments, those can always be submitted. We do have a link to the docket on the screen and we received comments from over 40 sources, and the vast majority of those comments are publicly available. So if you're interested to see what various industry sectors thought about the proposal, those can be checked. And of course, the paper can be found on the website mentioned on the slide. Next slide, please.

So it's very important to sort of emphasize that the scope of this is really only covering the products to which CDRH is the primary center with regulatory jurisdiction for premarket review and regulation. It does not apply to 3D-printed drugs, biologics, tissues, cells, or other products that would be regulated by other parts of the government. So this is really only focused on CDRH-regulated products. Next slide, please.

We do have three very important definitions in the discussion paper and I always want to emphasize, whenever I'm discussing this, what they are just to minimize any sort of confusion.

So the first one is the healthcare facility. So this is the facility whose primary responsibility is providing that clinical care and this is really important, because in some of the scenarios we need to differentiate sort of who owns what space.

And that immediately then sort of slides into the next point or the next definition, which is the 3D-printing facility at the point of care. So this is going to be the physical location where the 3D printing or additive manufacturing is taking place, and this is going to be differentiated because in some scenarios the healthcare facility may not be the one responsible for it.

And the last definition is from an IMDRF, that's the International Medical Regulatory Forum, guidance and it's called the MDPS. So this is essentially a collection of the raw equipment, software, digital files, production equipment, and post-processing equipment intended to make a specific product. And a complication, I will admit, with this definition is this also includes that final product to be made. So the best way to think about this would be it's a system that will make a specific product, and that product will have gone through all of the appropriate testing based on its classification and existing standards and requirements. Next slide, please.

So we have a number of key concepts that we're aiming for in the -- I should say, in the conceptual regulatory approach. So the first one is we really want this to be risk based. We understand that there's a range of risks for these products and I think this is something that the VHA is going to be presenting on today, to really understand the sort of range of applications of using 3D printing in the hospital setting and we want to be cognizant of that.

The next one is that the device specifications should not change based on the location of manufacture. So I think this is a very sort of FDA way of saying that a patient shouldn't have to wonder if a product is being printed at the hospital, versus at a traditional manufacturing location, the quality and performance of that won't change.

The next one is the capabilities available at a point-of-care healthcare facility can actually help mitigate some of these production risks. So there's a number of accreditation and existing requirements that healthcare providers are working under, and we expect that we can leverage some of those to sort of mitigate production risk and sort of account for some of the other requirements we may have.

I think one of the big ones here is that entities should understand theirs and the others' responsibilities. You know, as we get into this, and even as the discussion occurs today, there are lots of different people involved in this process and, from the regulatory

perspective, we want to make sure that everyone understands what they are responsible for to minimize and meet sort of issues or a necessary requirement being missed or not done because someone didn't understand it was their responsibility.

And the last one was leveraging existing controls, which are shown. Next slide, please.

So this is a fairly simple table talking through the sort of three main scenarios, and I'll have a number of slides on each one. But as a quick high level, Scenario 1 is where the healthcare facility is using the MDPS. So the person who's going to be designing and developing and testing the device would be a traditional manufacturer, the healthcare facility would be the one actually using the printers to make the product, and most of the regulatory burden would fall on the traditional manufacturer for complying with applicable regulatory requirements.

Scenario 2 is where we have a traditional manufacturer co-located at the point of care. I should also say this could potentially include a contract manufacturer. This is a really straightforward one and from the FDA perspective, you have a traditional manufacturer designing the product, a traditional manufacturer or a contract manufacturer is the one actually producing it at the point of care, and then you have the regulatory requirements that are already on the books for contract manufacturers or just manufacturers already applied (ph.).

And then Scenario 3, and we have sort of a sub-variant I'll talk about a little bit later, is where the healthcare facility is going to take on all of the requirements. Next slide, please.

So Scenario 1. So this is where the healthcare facility is then using the MDPS and here, the MDPS manufacturer is going to assume responsibilities for the FDA regulatory requirements and manufacturing of the devices printed at the healthcare facility using that

system. So the concept would be, let's say, the traditional manufacturer wants to have, let's say, a bone plate that could be manufactured at the point of care. They come to the FDA, do all the testing on the bone plate, show additional testing and the validation to show that their MDPS system can be used using their instructions, instructions for use, in a clinical setting with all of the controls to manufacture that product and then the healthcare facility then uses that product within its indications of use to produce that bone plate. Next slide, please.

Scenario 2. So this is where the traditional manufacturer is on or near the healthcare provider site. So here, the healthcare provider itself isn't actually engaged in the printing activity, the design or testing requirements. Here they are just going to be interacting as the customer to the traditional manufacturer and all the existing requirements are going to fall on the traditional manufacturer or that contract manufacturer. From a regulatory perspective, very neat and simple, it does sort of limit what can be manufactured at that location based on what clearances the company has. Next slide, please.

So the third scenario, again, is the healthcare provider is going to assume all the traditional responsibilities. They're going to be doing the design, the testing, they'll be getting the FDA clearance as appropriate, they'll be maintaining the quality management system and complying with all of the additional testing requirements. Next slide, please.

So a concept that FDA brought up in the discussion paper was this idea for a very low-risk device and that is a very nebulous concept, and certainly we're looking for a lot of feedback about it. But the idea here is that there's going to be some products that would pose a very low risk to patients and we can see that there is some ability for the regulatory flexibility when we're talking about these. So the discussion paper laid out a few thoughts on limitations. I think the big thing is going to be nothing implantable. Certainly, if it needs

to be sterilized, that's probably going to take it out of very low risk. But we're very interested in getting feedback on the discussion paper to help flesh this out because again, we think that there is a space where the risk to a patient is low enough that we can really allow this activity to occur under -- you know, again, under a space of regulatory flexibility. Next slide, please.

So this is just highlighting the range of questions and you can see, probably not surprisingly, that most questions the FDA gave to the public had to do with Scenario 3, the healthcare facility as manufacturer. But we did also have some questions about terminology and looking to understand people's experience with 3D printing at the point of care during the COVID pandemic.

So with that, I will hand it back to James, but I will say if there are any additional questions, you can always e-mail the AdditiveManufacturing@fda.hhs.gov e-mail. Thank you.

CDR COBURN: Thank you, Dr. Di Prima. And I know that many people were excited to see the discussion paper come out and to hear the overview that you just gave, so I hope that we see a lot of those questions come into AdditiveManufacturing@fda.hhs.gov, and to the chat when we have those discussions in the panels.

Now, from the VA, it is my pleasure to introduce Dr. Beth Ripley, another long-time 3D printing expert and Deputy Chief, Office of Healthcare Innovation and Learning, and the Acting Director of VA Ventures over in the Puget Sound VA Health Care System. Dr. Ripley is a radiologist who has worked and specialized in medical 3D printing for many years and has played a leading role in building, maintaining, and raising the level of 3D printing at the VHA, or Veterans Health Administration.

And with that, please, Dr. Ripley.

DR. RIPLEY: Thank you, Commander Coburn. Hope you all can hear me. And I'm

really excited to sort of set the stage for what's going on in VHA over the past few years and kind of bring you up to speed with what you're going to hear about today.

If we go to the next slide, this is just the government disclaimers, you will see this many times today. And again, we'll just go to the next slide. Excellent.

So I probably don't need to convince you all of this, but we really believe here, and I believe you probably do, too, that personalized medicine is truly the future of health care. Being able to understand what our patients need, their unique needs, you know, what makes them special and being able to provide for that is really the essence of what this is about. We know that there are small, medium, and large, but that doesn't fit everyone. And so back about 10 years ago in VA, a really industrious group started to realize this and this is a lot of our assistive technology devices that are coming out of a few hospitals within VA that really pioneered this work.

So what does that mean, assistive technology? So this is the idea of creating something that helps a veteran, a patient, interact better with his or her environment and get back to doing the things they love.

So imagine being an artist and not being able to grasp a pencil to draw. Now, we were able to use 3D printing to create custom solutions for each one of those artists to kind of unlock that potential again and get them back to doing what they love, things like being able to feed yourself with different manipulators that allow you to hold utensils better; a thumb, a thumb for a veteran who lost his thumb and was really into gaming, and I would say you got to have your thumbs for video gaming, so we are able to make that. So that's kind of where we started and it was really amazing, and it was in a few VAs and then people started to talk and realized they're doing this.

Around 2017 we also started working in the anatomical model space, so this is making pre-surgical planning models that take the veteran's data, their heart, their lungs,

their kidney, and translate it into the actual physical organ so that the veteran can hold it and he or she can understand what's wrong, they can have a really informed decision sitting down with the surgeon about what they're going to do. The surgeon can understand what kind of pitfalls they might be coming up against. Also, the surgeon can communicate with the rest of the care team that's going to be in the operating room. And then the gift keeps giving because then we can use these at post-surgery to educate the next group of emerging caregivers. So that's kind of where we were.

And again, in 2017, we're really trying to figure out how do we harness this technology, who has the expertise in the VA to do it. And so we kind of came together into this loose network where we're talking every couple weeks on the phone, you know, how do you solve this problem, have you hit this problem, what are you doing with your printer? Oh, I never thought of that. Like, what's next? And if we go to the next slide, we'll see how this keeps evolving.

So on the right is a map of the United States. Every one of those dots indicates a VHA hospital that has 3D-printing technology embedded in it. This is kind of where we were. Take away a few dots, in 2017 there were only eight dots and then it grew to 15 and then 20 and then to about 30 and right before the pandemic, we were sitting at about 30, 33 hospitals. Again, loose-knit network, but communicating back and forth, sharing best practices and really trying to grow this network within VHA, again, with a vision that every VA hospital could have access to additive manufacturing capabilities so that any veteran anywhere in the country could walk in the door with a need for a personalized device and we could get it to them.

Now, when the pandemic hit, everything went upside down, as we all know, and we really did pivot as fast as we could to try to figure out how we can leverage all of that networking and capabilities to start to drive forward on meeting supply chain gaps. And

this necessitated us to do a few things. First, we really had to focus in on just a few hospitals in order to really bring those hospitals up to the level that we needed to be able to put out certain devices. So those are the three stars you're seeing, the more yellow, dark yellow stars, and those were hub sites that we really kind of invested time and resources into spreading through. We have three more that are coming on. But this is really where we started to shift and think about when you have 30, 40, 60 hospitals, how do you figure out the same quality, the same processes across all of them?

And so what we've really been focusing on, and I think what you're going to see over the next few days, is us trying to drive this from kind of the grassroots to a really standardized approach to how we make sure that we turn out the best-quality product for our veterans regardless of where they are and regardless of where we're printing.

Now, this means scaling, which is always a challenge. The first model I ever made took me 40 hours to send that. Ridiculous, right? Totally not scalable, but I was teaching myself the segment, trying to learn anatomy, trying to understand it. Luckily, it doesn't take 40 hours now, it's like maybe 20 minutes, but again, this is the concept of scaling and I think what we want to figure out is what are the best practices, how do we test them across our network, make sure that they're robust and then be able to scale them out, not only into the VA but across the country, to any site, any hospital that has patients that could benefit from this technology.

You know, we see a lot of really important benefits, again, empowering our staff at the front lines to understand our patients best, to know and have in their hands the capabilities to create these new devices that they think of, the advocacy for the *n* of one's needs. You know, there are things that you can't buy, they're just not off the shelf. You know, the demand is maybe too small or somebody hasn't thought of it yet. These are the things that we really want to be able to make in the hospital for our patients.

Increasing our patient satisfaction is really important. When you're not feeling your best when you're going to the doctor, you want to know that you're getting the best care possible and we want our veterans to understand, when they're walking into the VHA, that we are giving them best-in-class care.

And also cost avoidance, the cost of healthcare is always rising, so if we can think of ways to provide better care at a more effective cost point, that means that we can care for more people with existing resources.

So with that, I've kind of brought you up to date through 5 to 10 years of the VHA history, and I'm really excited to be able to sit back with the rest of you and listen to the next 2 days of talks from government, industry, and academia about how we are going to be using additive manufacturing in hospitals to further the care of all patients. Thank you.

CDR COBURN: Thank you very much, Dr. Ripley. We always appreciate the VA's focus on patient-centered care, patient-centered 3D printing, and raising the quality of systems with 3D printing in clinics and hospitals. We've enjoyed, the FDA has enjoyed collaborating with the VA on 3D printing over the years and building the partnership we have today.

With that, and with your great transition, we will start our first panel today, which will give a point of view and perspective from three very experienced VA 3D-printing leaders. I will introduce them all now so that we can go straight through the presentations from one to another and then get to the panel with the moderated discussions. And please remember to ask your questions in the chat so that we can raise them with the panelists afterwards.

Our first speaker will be Dr. Dmitry Levin, the Clinical Director of Advanced Manufacturing at the VA Puget Sound Health Care System. And then we have Brian Layman, who is an orthotist and prosthetist in the Southeast Louisiana VA Health Care

System. And then lastly, to round off the panel, we'll have Dr. Peter Liacouras, Director of Services at the 3D Medical Application Center at the Walter Reed National Military Medical Center. And so we'll have each of them go in turn and then come to the panel afterwards.

And I will pass it to Dmitry Levin.

MR. LEVIN: Thank you, I appreciate it. Thank you for the invitation. And then what we're going to do over the next 20 minutes or so is spend a little bit of time talking about the point-of-care 3D printing and giving you a little bit of a perspective of how we feel about it and where we kind of see it standing at this point in time. We can go to the next slide, please.

These are the disclaimers. I will just give a couple of seconds for people to review those and then we'll go ahead and continue on to the next slide.

(Pause.)

MR. LEVIN: Next slide, please. Okay, so what I would like to do is set up, essentially, three goals for the talks so that people can better understand more about the point-of-care 3D printing. First of all, I would like to demonstrate the general approach that we're taking to the low-risk 3D printing at the point of care. Second, I would like to outline the steps that we are associating with 3D printing at the point of care. And lastly, I would also like to talk a little bit about what is the potential risk that could be there and how are we going about mitigating and addressing that risk. Next slide.

We're going to go ahead and start with the general approach. So really, the general approach is an overview of what we do in some of the low-risk applications. So there really is going to be two that we'll talk about primarily and mostly over the next -- today, and cover them a little bit. So next slide, please.

One of those applications is going to be assistive technology. I'm not going to spend too much time on this today, there's going to be two other speakers coming up behind me

who will jump in into much more detail. But essentially, assistive technology is something that we think can improve the functional capabilities for people coming in and really get something that we consider a low-risk category. Next slide.

Secondary to that, and this is what I will talk about mostly, is I will talk about the pre-procedural anatomical models at the point of care and sort of go a little bit through the overview of what they are, how we'll make them, and what is the general approach that we take to try to make sure that those are safe and effective and providing the most benefit both to clinicians, as well as to our patients. Next slide.

So let's go ahead and start with why we do 3D printing. If we can go ahead and move to the next slide.

I think what is the most important to remember is that sort of long gone are the days when it's just a surgeon in the OR doing their job by themselves. Now it is very much so a multidisciplinary team that's coming from a variety of backgrounds, it could be a surgeon, it could be a radiologist, it could be an interventional cardiologist, imager, nurse, it's the practitioner who is kind of organizing everything. So it is increasingly important to make sure that everyone is on the same page as they approach the patient and this multidisciplinary team knows what the anatomy is, knows what the device that's going to be used is, as well as really communicating effectively amongst each other.

So really, for us, the point of the anatomical models, as was mentioned by Dr. Ripley, is to think about how do we move the anatomical understanding across this team, how do we move the communication, and how do we improve clinical outcomes for the patients themselves? Next slide.

At the core of what we're trying to do, it does seem fairly simple, we are trying to take the images, usually a DICOM image that's coming from CT, MRI, or other datasets. We're trying to segment the anatomy of interest, so separate the things that we want

versus what we don't want, being able to create an STL file or a MESH file that the printer can actually recognize, and then being able to transfer it over to the printer itself and create that final model to be delivered. So with that, if we try to break it up a little bit more and think about things, let's go ahead to the next slide.

The main categories and the main imaging modalities that we have encountered over the last several years have been CT, all the way to the left, MRI followed by it, echocardiography and specifically, a three-dimensional echocardiography, and electrophysiology studies. All of those could be translated into the models. If we can go ahead and move to the next slide.

However, as we make and model, we really need to think about what type of data is being used and what are the limitations of the dataset. And I think most importantly is because these datasets are different and a different person is acquiring them and a different person is interpreting them, it's really important for us to remain in communication with --

(Audio feedback.)

MR. LEVIN: -- whether that be electrophysiologist, a radiologist, an echocardiographer or others, to really be able to understand what are we seeing on these images as we're trying to do that previous step of segmentation and transfer from one dataset to the next dataset. Next slide.

As you can see, and as most of you have already probably done, there are several dataset systems, there are several segmentation softwares out there, so it's important to recognize what the difference between those is, what the outcomes are, and where is the right understanding of which one needs to be used for an application, whether that be cardiovascular, orthopedic, neurological, neural or others. Next slide.

With that, I think it's also important to remember that there is a variety of 3D

printing technologies and picking the correct one for the correct application does make a difference, and each one of those also comes with its own challenges and understanding of not only how do you make an individual model for it, but also how do you place that model, how do you post-process that model, and how do you load it onto that printer so you come up with a successful outcome. Next slide.

So where do we end up? And I think if you've kind of looked over even those several slides, the position that you'll be in -- next slide -- is really going to be this, we're going to start asking a lot of questions, and I think a lot of questions need to be asked before people jump in and create an anatomical model for a patient.

First of all, how do you communicate with a clinician and what types of questions should you really be asking and asking effectively so you're creating the correct model for the correct application? You need to understand what type of data you're working with. What type of software do you want to use for a particular application? Again, how do we design the model so this way the model and the anatomy in question is really applicable to the procedure being performed? What kind of 3D printer should you be using, as those outcomes might change?

What's most important at times is what type of material should you use, and really a lot of that is also coming down to the proper communication with the clinician on the front end. I think the ways that you post-process that model is also going to create some challenges in a variety of things.

And importantly enough is how do you see the model? How do you really make sure that what you got in the very beginning from the imaging dataset is the same physical object that you're going to be delivering to a clinician?

And then lastly, how do you communicate back with a clinician to make sure that you effectively created the right model for the right reason and they're happy with the

outcomes, as well as the patient is truly understanding what is going on? Next slide, please.

And I think this is important to highlight, is if we start laying things out, it does become challenging, and challenging in a sense that there are a lot of steps to cover and then a lot of things to consider, and we need to remember all those things. Next slide, please.

I think we're kind of left in the scenario where we suddenly have a lot of information and we need to process it, we need to understand it, we need to know where do we go and what questions to ask, not in the beginning, but in the end. And next slide.

I think at times we kind of end up here, we just say okay, well, we don't really know what to do so let's figure it out and let's go somewhere. But I think what's important is not to end up in this last comment where we just give up. Next slide.

We have answers, we have lots of them, we have things that we've experienced on our side that we would love to transfer over that knowledge to the rest of the people interested in 3D printing. So let's go ahead and move forward to the next slide one more time.

So the next thing that we really need to do is recognize what are the potential risks and how do we mitigate it. Next slide.

If we come back to this diagram that I just showed you with lots of different steps, lots of inputs, outputs, different software, risks, what are the tracking points and things like that, the next point becomes is how can we simplify it, how can we make it a little bit better? Next slide.

So if we remove all those auxiliary points and just try to really understand the workflow and where we're going from Point A to Point B, frankly, from the intake of when we are able to talk to clinicians and then to delivery of that model and final assessment, we kind of end up with this diagram.

I think if we go even further, to the next slide, and we use just some of the bullet points and some of the infrastructure that we're trying to use and trying to understand where do we land with which different processes, we sort of end up at the next step over here. Next slide.

So separating things into three categories: the digital workflow, the physical workflow, and the quality control.

The digital workflow is really about what are we doing on the digital side of things? So we'll intake that model, we're going to segment it, we're going to, in this scenario, look at it or design it so that the model is correct, and we're going to go ahead and do some of the print prep work to be able to load it up onto the printer. So this could be considered one of the categories and questions that need to be addressed.

The next one is the physical workflow. The physical workflow will be to print, to post-process, to sterilize, if necessary -- and we'll come back to that little point later -- to do the final inspection, as well.

And that is the last step of the quality control, to do the final inspection to make sure the final report is created and then being able to deliver that model and the report to a clinician, and what we like to do is we really like to maintain communication at this point in time so we're not just dropping off the model and letting the clinician know "here, you have it," but we're really coming down, communicating with them, delivering it in person so they can better understand what is the anatomy that's gotten delivered, because a lot of the times, if you remember, our surgeons and our interventionalists are really looking at different types of imaging. They're not looking at the actual physical model themselves until -- unless you're a surgeon and you're cutting down and you're kind of seeing the real anatomy, so making sure there's an understanding between the digital, the intake part of things where we're looking at CTs, MRIs and other clinical datasets, to the final model. Next

slide, please.

So then what we're able to do is, if we sort of take that original diagram with a lot of information on it and break it down into individual points and areas of interest, really we can break it down into five different categories at each one of the steps and this is the example of the intake step, there's our inputs, our software, our potential failure points, so the risks that we're trying to understand, our solutions and our outputs.

So in this scenario, if we go through the step of the intake, our input is really going to be mostly a text dataset or images. So what does a clinician want and what type of images are we going to be working with?

Our software is going to be a VHA tracking system, so this is something that we're going to use to essentially make sure that we know what a request is for, what type of data is coming in and things like that.

But we're also going to identify what are the failure points that we might not be able to proceed forward after that. So we might not have sufficient datasets, the datasets might be wrong. We might have other problems such as the clinician is looking for the model tomorrow and really, it takes 48 hours to try to create and print it even in a best-case scenario.

Then we end up with the solutions. So for every one of those failure points we're identifying, how can we resolve those? Let's say can the model be substituted for a virtual model or are we able to go back and ask the clinician for a different dataset and then resolve it in order to be able to move and continue on with their request?

And then we have our outputs which, again, in this step would be the text data. Next step.

Similar to that, this is an example of the segmentation. So in this scenario we have our input of the text dataset and the DICOM data, we have our FDA-cleared segmentation

software that we'll be using, we have our failure points. So let's say the segmentation is incorrect and we have to adjust it and then we do that segmentation as part of our solution or if it's a challenging segmentation, again, this is where we're constantly remaining in communication, not with just the clinician themselves who is doing the request, but also having the oversight of several of our radiologists or other imagers who might be more familiar and properly trained on those datasets. And then in this example, our outputs are going to be our surface MESH file or that STL file that we talked about. Next slide.

So with that being said, what we end up with if we take that, frankly, somewhat variable diagram that was started in the very beginning and having a lot of inputs and outputs in there and trying to understand what's going on, we can simplify it a bit by essentially creating a straight pathway between the requesting physician and the case clinician and really having them to follow the main steps in here.

First of all, we're going to do the intake, then we're going to be doing the segmentation, we're going to be doing the model, editing the design, we're going to do the print prep, 3D printing, post-processing, possible sterilization step and again, like I mentioned, we'll come back to that in a couple of slides over here. We'll also be doing a final inspection and then we'll go on to deliver that to our clinician at the end of the day.

Now, I think what's important to highlight in this diagram is at every step there could be some risk associated with it, so we want to make sure we identify it and we can better understand what are the challenges that will either prevent this from going to the next step and how do we address it, or if that challenge is significant enough that we're not able to move on to the next step, then recognizing that maybe this is not a good pathway for a 3D printed model and we might have to start from the beginning or go back to the clinician and better explain to them what's going on and how do we want to address that. And with all of these steps, I think, again, it gives us an opportunity to ask questions along the way, so

let's go ahead on to the next slide.

During the intake process and understanding of what the case is, we usually and always want to communicate with the clinician directly themselves. We want to ask them questions about what type of model and what type of procedure are you looking for, because just printing out a nice anatomical model is not always going to be good enough for the clinical application that's really being asked. So what type of procedure are you doing, maybe what type of device are you going to be using, and what type of approach are you going to have in the anatomy become very, very critical questions for us to answer even before being able to take up the imaging dataset and start doing the processing. Next step. Sorry, next slide.

So what are some other questions for the intake that we would like to ask? As we already talked about, a lot of the times it is just an anatomical model, so it's here to be able to improve the anatomical understanding, improve the communication, and improve the clinical outcomes.

But a lot of the times -- next slide, please -- we also have requests from physicians who don't just want to look at the anatomy themselves, they also want to be able to practice with that anatomy so if you would cut down or essentially do a pre-procedure before they even go in, or they want to deploy a particular device to better understand how it will sit and what will happen to the relational anatomy surrounding it, or they might want to take that model and sterilize it and take it into the OR or cath labs.

So this is where a bench sterilization step comes in and frankly, the thing about that step is remembering what is it for, is this going to be something that will maybe take us out of that low-risk category and make it into something different that we might want to consider as a potential high risk? And again, these are the questions that we want to ask in the very beginning during the intake process so we can identify them early on. Next slide.

The other steps are questions about the segmentation. If this is a significant enough and a challenging enough anatomy, we want to make sure that we're recognizing this early on and involving the right people along the way, whether that be a radiologist or a clinician who's seen that patient before, and better understand maybe what type of procedure has been done or what type of devices have already been implanted, and it's very important to be able to do the proper segmentation of the proper anatomy. Next slide.

With that, one of the very, very important points about 3D printing, and specifically in the anatomical 3D printing or pre-procedural anatomical 3D printing, is the ongoing training. The earlier we can recognize the need for 3D printing, the earlier we can involve the right clinicians, the right experts, and as well as maybe even industry partners to better explain how does the technology work and what to watch out for as we try to go through the process of 3D printing.

And doing this across different divisions is also important. This is not just a radiology thing, this is not just a surgery thing, it's really something that broadcasts across all different divisions of surgery, cardiology, neurology, urology, radiology and others, to be able to really have the clinician better communicate and be that expert, as well, so they can communicate to you, as the person creating that model, what is it that they really want and how do we want to address that. Next step. Next slide, apologies.

The other questions we want to ask is during the design. If this is a type of a model or again, the type of technology and materials that we can just use and create a single model, are there going to be any challenges in putting that model together and making sure that we truly can address it and have a good model at the end of the day? Next slide.

And then similar, what are questions that we want to ask during the post-processing and what are the challenges that we might encounter during different technologies and use of those technologies that might affect that model in a negative way or change the

dimensions or the properties of it? Next slide.

And this is probably one of the last questions that you want to ask as well, and this is a question that you want to ask yourself, is how are you going to check that model, whether that be a physical measurement, such as indicated on these images or -- next slide -- or digital imaging where you're able to take that 3D printed model and overlay that on the original anatomy to be able to basically check it and make sure that everything has been verified properly. Those are the types of questions and answers that you want to be looking for even before you start the 3D-printing process. Next slide.

And lastly, this is sort of putting it all together and giving you a little bit more of a perspective of what it might take to go and create a 3D-printed model. So it will start at the requesting physician and it will end up with the case clinician who is actually performing the case, with a lot of steps in the middle, but also a lot of things that we want to consider as potential risk and how to mitigate that risk along the way. This should be serving essentially as a good starting step and a good summary for considerations of the anatomical 3D printing. Next slide.

And I want to thank you for your time and thank you for including me today during this presentation.

DR. DI PRIMA: Thank you so much, Dmitry.

Our next speaker is Brian.

MR. LAYMAN: Thank you very much for the introduction. My name is Brian Layman and I'm here today to talk to you about additive manufacturing of orthotics and prosthetic devices. Next slide, please. Next slide.

This is our standard disclaimer. Next slide.

And before I get started, I would like to thank the FDA for hosting such a platform and look forward to sharing my opinions, as well as answering any questions. With that

said, in order to give you my perspective, here is a quick chronicle of over the last decade of personal experience. I'll try to keep it short and not put you to sleep before lunch.

I'm an orthotist/prosthetist with the New Orleans VA Hospital. My journey started early, at an early age, working for the family business. My father is a traumatic transtibial amputee as well as a certified orthotist/prosthetist. We were early adapters of 3D scanner software and CNC carvers. Around 2008-2009, I stumbled onto additive manufacturing and the bug didn't just bite, it left an everlasting mark. Shortly after, I started collaborating with the additive manufacturing industry.

In about 2013 we invested in our first industrial printing, bringing the research and development in-house. Somewhere around along the right way we also had a patent filed and the pictures shown here are some of the early work of my father and I designing and developing, using ULTEM and nylon 12 along with some of the unique distal attachments.

Two thousand sixteen, there was a pivotal moment in my professional career and it was an unexpected opportunity to come to the New Orleans VA Hospital, and at this time the VA was set for a grand opening of a new facility and along with a top-rated O&P lab, so quite naturally I was excited to be considered for this position.

And shortly after that, around 2017, I was privileged to be part of a new group made of likeminded individuals from different professions with the passion of additive manufacturing and the fortitude of bringing this technology into their fold of their respective field, all with sharing a common goal of providing point of care to our patients. And, as they say, the rest is history. Next slide, please.

This is the New Orleans VA lab, it consists of two FDM printers, one multi-jet fusion, a handheld scanner, structural scanner, CNC carvers, O&P software, design software, full-functioning O&P lab, laminating machine and plaster runs, a wonderful workspace and naturally, a dedicated and motivated clinical and administrative staff. With that said, I'd

like to take the time, really to take the time to give credit to my colleagues, and they're truly a wonderful group of people to work with. We also have Tulane University BME interns. Over the last 4 years I've had an eager group of young minds come into the lab to assist and learn about orthotic and prosthetic devices. Typically, the students come with advanced levels of understanding CAD design, which fits well with what we're trying to offer here. I'm proud of the work that we've accomplished and look forward to continuing some of the efforts that they provide. Next slide, please.

This is the VA orthotic and prosthetic network, this 50,000-foot view. Currently we have 25 3D printers in the VA O&P clinics, they span from every entry level, desktop, pro, consumer, and industrial. We have around 350 to 400 practitioners throughout the nation and overall, printers in the VA network, as Dr. Ripley had led to be, is well over 200, which includes research as well as clinical.

Primary use for 3D P and O&P, we notice prosthetic test sockets are very common, orthotic AFOs, foot orthotics, upper extremity O&P devices.

Some of the benefits is going to be practitioner time, cost savings, data referencing or replication, unique design possibilities.

And then some of the facility participation, quite naturally, New Orleans, St. Louis, Cleveland, Orlando, Pittsburgh, San Antonio, and Long Beach, just to name a few. Next slide, please.

So I understand this may be a high-level presentation for -- so forgive me for dragging us through the weeds, but digital manufacturing workflow, as most of you know, you can't talk about additive manufacturing without discussing the digital workflow. We start off with scanning. Naturally, there are different entry levels of scanners such as printers, basic image capturing of anatomical structures, as the picture shown here was a dual limb. Some practitioners may still use traditional methods such as casting, where they

can then scan the negative mold into the software and then start their digital process. If there's one thing about the practitioner we can all agree upon is capturing the residual limb is a crucial part of the fit, and if you ever get more than one in a room, you'll be in for a lengthy discussion.

This next little clip here is the digital modification. The practitioner involvement is key at this stage, allowing the bony prominences and soft tissue compressions and other key anatomical structures. CNC carvers, I give acknowledgement to the CNC progression; however, the train does stop here in the digital process. Considering the digital workflow as a whole, this is a valuable resource and it does complement nicely as a suitable tool in the shed.

Design software, well, we're back on track. This is where art meets science. At this stage, it is important to understand the freedom of design, such as lattice structures, wall thicknesses, or even color patterns. Unique design nuances will need consideration and understanding in order to accurately choose what type of additive manufacturing process and outcome is desired in the following steps.

Preprocessing. In this case of using FDM, one will need to generate a G-code by using slicing software. In my opinion, this could be considered an in-depth course. Regarding O&P, this technique is typically acquired by the enthusiast or champion to whom may interact with the printer. However, this process could also simply be understanding part orientation and the benefits that may result in such a manner when using specific AM processes.

Additive manufacturing, however, it goes without saying, there are different entry levels of printers, desktop, pro, consumers, and industrial, which all come with their own learning curve and understanding. The most common current in orthotics and prosthetics is going to be FDM, your fused deposition modeling or your powder-based SLS or multi-jet

fusion.

Post-processing, depending on the additive process, the key step could be considered the removal of raw material using techniques such as bead blasting or simply cleaning up the trim lines of a device recently printed. There are several types of techniques, from hand-sanding, vapor-smoothing, sterilization, and even automation. There is still much to learn in this part of the process and just to help us with better outcomes and desired results. Next slide, please.

Validation. So currently, in the clinical setting, monitoring and reviewing the equipment as well as quality of the printed device is up to the O&P clinician or technician, as they would be using traditional orthotic or prosthetic standardized equipment for their fabrication and quality control. With that said, the new process which requires us to further educate ourselves on a different set of design controls that would check off the boxes to ensure device quality.

Justification along the digital workflow could easily start with techniques such as test coupons when printing to compare results or possibly monitoring the process during the print and understanding the optimal specs of your AM equipment. Simple things such as checking the quality of the part, is there any notable stepping? When using FDM, is there any Z-line binding problems? When using -- referring to a G-code, were there any indications of air gaps? Is the physical part a good representation of the CAD drawing? Did the post-processing affect the outcomes or did you just simply print the correct file? The point here is when considering a new fabrication technique, we should check the boxes. Next slide, please.

This is a SWOT analysis of the digital workflow, just to touch on a few points here, collecting the metrics. Scanning allows cross-referencing imaging of anatomical structures from previous scans. For one, it helps educate the patient's progress, such as volume or

limb-maturing and atrophy; (2) it helps the practitioner make better decisions for better outcomes of future device designs.

Remote capabilities, the potential to collaborate with other professionals with different skill sets, such as designing a device or sending files back to a central location.

Industry involvement regarding the digital workflow, there are established O&P companies that are rooted in the software and manufacturing process. Regarding additive manufacturing, less than 10 years ago I didn't see much involvement from the O&P manufacturing companies trying to streamline the workflow of scanner software and printers. However, recently, as our profession has adapted to this manufacturing technique, I've seen a push in this direction and the collaboration between O&P and additive manufacturing working together.

Continuing with the text service, continuity with the text service, this is primarily for your large facilities and not a smaller business; however, currently a weakness. I do believe that this could possibly be a strength in the future. Some of the difficulties are having these devices on a secure network.

On-boarding new equipment can be a task in itself at large facilities, as well as a small operation. Some equipment may require to be networked, as well as a dedicated space or possibly a power source such as three-phase.

Lack of education and training is always a concern when understanding new equipment. I've on-boarded a handful of printers at different stages in my career and there was always something that was overlooked by either parties' lack of experience or by just someone assuming. I'd advise to get the handbook or a hold of the user manual or the prep guide as soon as you can, so you can allow to have better-defined questions leading up to your purchase and more profound experience on-boarding the equipment.

New tech advancements. Over the last decade or so I've seen advancements in

technology. Like most tech, it's become faster, stronger, more cost efficient, so driven by the market and also research development.

O&P-related MDPS, medical device production systems, that was talked earlier, the opportunity of the unique processes such as scanners, softwares, and printers specific to O&P and really streamlining that process.

PHI and PI. Patient information is always a concern and offers a potential threat. Next slide, please.

So what we have here is, the point of this slide is to really just give you a brief visual of how things are broken up regarding printers and patient devices in orthotics and prosthetics. What it breaks down to is the current -- the two most common ones are going to be FDM and powder base. This truly comes down to what is the final intended purpose of the device. Both processes have their strengths and weaknesses. I see a benefit for FDA in in-house printing for check sockets; however, it's limited when considering certain devices that may be load-bearing. Next slide, please.

Clinical implementation. This is where I see clinicians finding the most use for this technology. Benefits: potential standardized and consistent methods, controlling wall thicknesses versus traditional fabrication sockets, consistent temperature regulations, time management, reduced waste, cost efficient, things of that nature.

And the picture at the bottom is just to kind of really show you the consistence of the thickness or the wall thickness where, in traditional methods, when you bubble-pull a socket you could have different wall thicknesses, thin or thick, depending on temperature and whatnot. So this process would also offer more of a standardized process. Next slide.

This is the clinical benefits, this is based on my own experience and what I have currently been doing at the VA, multiple prints with significant turnaround times for patients with volume fluctuation or design iterations. Time saved while devices are being

printed allow for practitioner time for other job duties. Use for prepatorial sockets, limb-shaping, shower or aqua therapy.

The use for the PDI printer pictured on the right-hand side is copolymer pellet extruder. It is used primarily for AK and BK prints and roughly about two to two and a half hours on a BK print. So it is a combination of material, software, and printer. The consumables are purchased through the company, along with distal attachments, locks, lanyards, and other O&P-related products.

Illustrated in Picture 1 and 3 are of this process. The first picture is of a patient that is a bilateral BK that we were able to get up quickly in rehab due to in-house printing capabilities. And Picture 3 is of a shower prosthesis which we find to be a useful option, as well.

The PVA printer is pictured on the left-hand side, by the manufacturing company that is known for automation, and has brought its own knowledge to the process. They also have a combination of tech that streamlines the process using scanners as well as their own software that would produce a G-code, keeping the room for error very low and as well as a printer that works in unison.

This is in my opinion, but I could see these systems becoming considered the classification under Scenario 1 in the FDA discussion, as a medical device production system. That would be unique to O&P. I would like to emphasize, this is a prime example of the shift that has been seen over the last several years, it hasn't spread like wildfire yet, but when I first started, there was no intent for or interest in this, but now today I'm talking to you about this process. So it has evolved over the past several years. Next slide.

This is also a continuation of the clinical benefits, this is a few more pictures here and process with the multi-jet fusion. Very common with custom bracing. I do quite a bit of AFOs, upper extremity O&P devices, custom foot orthotics. The patient story is a quick

story here about the gentleman in the wheelchair. I designed a flange off the distal aspect of the socket. At this time he could not acquire a power mobility device, so this was our attempt to service a need and help him propel himself forward. I can't say it was a homerun; however, this technology gave me the option to explore solutions and truly felt we were headed in the right direction. As a provider, I can honestly say our veterans deserve at least the consideration of all possibilities. Next slide, please.

The areas of precaution, it's the elephant in the room, load-bearing prosthetics, creative design features, distal attachment variations, post-processing techniques, these are all areas of concern when producing a definitive lower-extremity device. Historically, O&P devices are considered a Class I device; however, I do understand the level of concern when using additive manufacturing as a process. Simply put, there is more to learn regarding load-bearing prosthetic devices. I do see a possibility of gaining more knowledge using software such as FEA, finite element analysis, more structural testing comparing different AM processes to the traditional methods, and we can talk on that shortly, as well. Next slide, please.

Education. The workforce is being developed. O&P student enrollment with prior digital skills or engineering backgrounds are on the rise. I had the pleasure of talking to some of the leading programs and they see the benefit of offering education that would encompass scanning software, CNC, printers, and post-processing.

With that said, residents can have an immediate impact to companies and facilities that have transitioned to the digital workflow. Students are setting -- they're starting earlier on using these tools. They come to the programs already with their software and printers in hand, wanting to learn more about it. So with this transition, it eliminates initial learning curves that involves software and technical processes. And let's face it, today students are not acquiring the hand skills that were once taught in schools and may not

until they enter the residency, and acquiring such skills often do take years to develop. I'd like to make myself clear, though, I am still a strong advocate for understanding the traditional techniques and craftsmanship which will lead to being a well-rounded practitioner. Next slide, please.

Industry acknowledgement of additive manufacturing. Please excuse the misspelling, I was misguided thinking a spell-check would be my friend. Due to the time restraints, though, I will not dive deep into it; however, this is just highlighting the orthotic and prosthetic organizations such as AOPA, ISPO Academy, and their awareness of this technology and support of their practitioners providing proper care to their patients; however, I would encourage everyone to take the time to review their stance. Next slide.

And we round it up with socket testing. ISO 10328 is one of the major contributors of testing prosthetic devices, typically, prosthetics knees and feet; however, there is not a pure standard for testing prosthetic sockets, 10328 only touches on a very distal aspect of the socket when considering the process.

I'm privileged to sit on the AOPA work group that has partnered with the VA and the ISO committee in searching to establish better methods of demonstrating the structural strength of novel prosthetic sockets technology, including 3D-printed sockets. So as this technology advances and the demand increases, the goal is to have a standardized approach and understanding the forces within the socket to better help design the process for the future in lower extremity prosthetic devices.

And I'll leave you with this. As the future of orthotic and prosthetic workflow is educated in the art of digital workflow, along with the advancements of machine and materials and software integration into the desired isotropic state of existence, I believe that the door has opened to a wonderful world of design capabilities, unlocking personal-matched devices for patients and individuals alike, to not hide from their circumstances, but

to embrace and inspire others. Thank you.

DR. DI PRIMA: Thank you so much, Brian.

Our next speaker is Dr. Pete Liacouras, who's the director of the 3D printing facility at Walter Reed National Military Medical Center. I always get those M's switched.

DR. LIACOURAS: All right, thank you, Matthew. I'm happy to be here, excited to see that the FDA and VHA have combined to put on this conference to give us some guidance on future 3D printing in hospitals. I'm here to discuss some of the applications we've done over the years at Walter Reed National Military Medical Center in the prosthetics and orthotics arena. Hold on a sec. There we go.

As with all other slides and all other presenters today, you can see that I do have the official government disclaimer right here. So if I mention any companies, this is not an endorsement and these are my views, not the views of the government.

Three-D printing has a long history within military medicine, and starting early in the late 1990s with the 3D-medical application center, our additive manufacturing facility primarily, and we're located in the Department of Radiology at Walter Reed National Military Medical Center.

Early on, they did some skull models and then later on -- that was at National Navy. Later on, at Walter Reed, that progressed to other anatomical models. They purchased a large-frame stereo lithography machine in about 2003 and then later, a 3D print, the first 3D print of the anatomical model was created.

The program was transferred to the Department of Radiology and in 2007, the National Navy Postgraduate Dental School started to really invest in 3D printing and began to utilize some 3D printing there, too. They utilized Walter Reed at first and then advanced to buy some of their own equipment. What we did is we looked to some printing for molds for maxillofacial prosthetics.

By 2019 we invested in another large-frame stereo lithography machine and a photogrammetry system. Along those same lines, in 2007-2008 we saw an expansion at National Navy. They purchased some equipment and began some imaging research. By 2011 Walter Reed and National Navy merged together and it was decided that 3D MAC will remain in the Department of Radiology.

And then, since then there's been a rapid expansion of 3D printing at Walter Reed. We brought in titanium in 2011, brought in another material jetting machine in 2012. That was two materials at the time. We just replaced that with a new one that allows us to print six materials at a time.

Prosthetics actually reached out and used their gift fund to buy us a material extrusion machine so we could print ABS plastic because we were taking some of these models directly to titanium and we had no material in between.

Moving forward, we have 2019, we've done some educational videos and our lab video. By 2020, Dr. Ripley and I applied for JIF project to expand, educate, and implement a QMS system within the DoD and VA.

So if we look at the 3D printing in prosthetics, you can see here that there's a lot of different applications that we've done over the years. About 2013 was the first device. In the military you're dealing with a different type of patient, you have these young, active individuals that want to take a place in complex activities. They just don't want to be able to walk down the street, they want to be able to run, they want to be able to climb mountains, climb rock walls, play ice hockey, play sled hockey. Whatever they want to do, the DoD feels that they should be able to take part in these activities and along the way you may need some specialty attachments for these custom devices. So additive manufacturing has proved to be able to provide some of this flexibility and aid in the solution to these products.

These are just some of the numbers from the previous conflicts we've had, but you can see that they have a lot of amputees and one thing that we're looking at is the care of these amputees. So these amputees are within the DoD, then they go on to the Veterans Affairs healthcare system and over time, you want to deal with all of the amputees and so it's not just a one-day event, you have to deal with these amputees for the rest of their lives. Some of these individuals are very young, twenties, thirties, and they want to take place in these complex activities for many more years. So you have to look at that when you're looking at all of these different applications.

One of the medical models we do for our amputees -- and I say amputees, but no patient at our center can request the model, the model has to be requested by a surgeon or a clinician at our center. But one of the models that we do, that's a bone model in prosthetics and orthotics, are these heterotopic ossification models. This is bone growth outside the normal bony area.

From this, we took this data from a CT scan and reconstructed it and this all may impinge on the fitting of the prosthetic socket. Some of this HO could be between the fascial layers of the muscle and really prevent the muscles from contracting, causing pain. Some of these bony prominences could pinch when they're in the socket. So the prosthetist can get a feeling of where they may have to put relief in the socket.

Our first device that we made with prosthetics was what we call the Shorty Feet. This device, 2013, they came up to us with the picture up in your upper left-hand corner, it was a piece of carbon fiber with their inverted pyramid adapter and they said it would be really nice if we could manufacture a foot that they could use right on the end of their socket to walk. You might ask why they want to do this, but they start their patients out low and then they'll build them up higher. Some of these patients actually want to be on the ground to play with their kids or get up in the middle of the night and use the restroom.

This is a lot less cumbersome than putting on a full prosthetic socket.

In this video you can see here the patient walking, ambulating, almost like they're walking on their knees. He was within those parallel bars for probably 5 minutes before he was running down the hall. This particular patient just wanted to hang out at the pool on his honeymoon without getting his full prosthetics wet.

Here is another case where we had a custom gun-holder design. This isn't completely custom, but in the past, what they were doing was they were taking the gun, encasing the whole handle in thermoplastic with their half-inch 20 bolt sticking out of the thermoplastic. This gives them a nice, solid base for their gun, they can still use the thermoplastic, create that insert for the gun, put a strap across the front and it's countersunk for the half-inch 20 bolt out of the back.

And I apologize, this video isn't the best quality. Later on, we had a variation of the Shorty Feet. One patient really wanted to work under his car, he worked on his car all the time and his problem was two full prosthetics, it was hard to get under the car, hard to maneuver, and he wanted to get up and down from any angle. So we created these things called the mechanic's feet. It kind of looks like a bread bowl, but serves the purpose well. He can get up and down from any angle, he can get under his car. Later on, we also printed several of these for people who like to use the gym a lot and the cross-fitters. So they'll wear two of these at a time. This was the first trial.

We've done a lot of work with climbing gear for rock-climbing walls, because there's one in the rehab center right at Walter Reed, and ice climbing. They were using this device featured in the lower right-hand corner to hold this ice pick. Now, this is when I say the hardware store meets prosthetics, you can see this huge bolt coming out. We were really able to streamline that device and reduce the weight to one-third.

Here you see a hockey stick hand. This was used because the patient was playing

hockey one handed. What he wanted to do was really hold that stick with two hands, get in and out, skate down the ice, attempt his slap shot. So here you can see he slipped into the hockey stick and he can take that shot again.

Then down the line we created a hockey skate adapter. We felt this would be a one-off device. Now we probably manufactured and designed six of these. Here you see it's three components and then you have the normal prosthetic ankle joint, we made a component, we made a holder for that and those little lips resist the side-to-side shear of that device on the skate.

I think the next slide kind of shows the workflow. We have software to reconstruct the CT scans, but it also works for other items. If you can take other items down to your CT scanner in radiology, you can pool and reconstruct the data from these items. So we did that and then we used that scan as our starting point, created those organic shapes and then merged that with CAD elements and then finally, we 3D printed the end result.

Here's the end result. This patient was absolutely amazing, very happy to get out there and skate again.

So they have a device in the military called the IDEO brace and this is a device, a foot-ankle orthotic for foot drop. But we also had an ice skater who needed a similar thing for their ice skate. So here we call this one the ICEDEO, this was just a one-off device, a foot-angle orthotic for an ice skate.

So these we don't use anymore, but one of the problems along the way, that they were having, were these vents. So when they stick their residual limb within a socket, it creates a vacuum and to release some of this vacuum, they have to click on this vent, except these vents come out at almost a 90-degree angle from the socket. So we manufactured several of these as a padding for around the vent. We could build in the O-ring and print this in a flexible material.

Here you can see a picture of a steering wheel adapter. This was used to place the residual limb within the component which connected to the steering wheel instead of having your prosthetic connected and then connect somehow to the steering wheel. So this really makes driving safer, reduces the connections between yourself and the steering wheel. What they were using in the past was this old steering wheel adapter up in your left-hand corner; basically, a piece of carbon fiber formed around a three-prong adapter for a steering wheel. You can see this is our first prototype.

We've had a lot of upper extremity amputees that wanted to take part in normal day activities like fishing. This is a little different because there was a device on the market, but that device did not allow them to wear their prosthetic hook. So what we wanted to do was allow them to wear their hook while they're holding their rod and you might ask why they want to do this, but imagine trying to bait a fishing hook one handed, you really lose a lot of functionality without that other hand.

This guy was really happy. He actually said something that really resonated with me at the time, he said, "I don't want to be known for losing the limbs, I want to be known for what I do with what I have."

So he actually shared this video with us and I'm thankful he did because I think this makes a great point along the way. It's not only that they can do these activities now, but it also helps mentally. They are not limited by what they have.

We had a hand amputee who wanted to lift weights again. This one's also a little different, this one was custom at first. Here you see the titanium piece that was laminated into a carbon fiber socket. And then the prosthetist put this ratchet system that went around their elbow, this was done for the pull-up part.

So here he uses the pull-ups and the bench press, so this could be used for both pull-ups and bench press. Easy in and easy out. There was another device on the market, but

you had to screw your hand into the bar.

Now, you can see that elbow on the right-hand side is a little lower, so the biomechanics here are not perfect. So we also came up with a secondary design, this is called our turnkey weightlifting adapter, so you can go in at an angle and then turn. This really shrinks up the hand toward the prosthetic device so it mimics the human hand. You'll do your pull-ups at your fingers and your bench press with the palm of your hand.

A lot of simple things come up along the way. We had an upper extremity amputee who just wanted to take part in drinking a glass of wine without fear of breaking the stem. These prosthetic hooks are very powerful, so we made an adapter and this adapter was 3D printed. Eventually, we did go to a silicone mold for these. But this, you can grab the adapter instead of the glass and hold your glass of wine.

This was a device that was, again, made at first from pieces you can buy at a camera store or a hardware store and it kept breaking. So it kept breaking because they had this kayak paddle attached to a camera holder and some hose clamps. So we basically got all of those pieces in-house, were able to get some measurements taken and reproduce this piece in titanium so this device would be a lot safer.

So now we'll switch out a lot of the direct 3D printing applications and go into some of the silicone molding applications here. So this particular patient, his toe was fused in an upright position. You don't actually realize how much your big toe plays into balancing until you don't have access to that. Now, on a shoe they can create a custom orthotic, but when he's barefoot and wants to take part in yoga, he ended up just falling over. So what we did is we took that 3D scan. One nice thing is all these prosthetic molds and casts they make, that plaster scans beautifully, we end up having no problems scanning that plaster. We scan that in and we do the digital design. We make a final prototype, test that prototype out and if that prototype works well, what we'll do is we'll take that and create a mold.

We'll actually 3D print the mold. We use silicone rated for tissue contact. And you can see the picture of him doing his yoga on the foot that his toe is fused. Sometimes you end up having a little time and you can be a little creative, so we put the little Zen lion on the front of his yoga toe.

A similar prosthetic or orthotic piece here was for a second-toe amputee and what happens over time, the big toe and the third toe end up getting closer and closer together. So to maintain that space and maintain the patient's balance, what you want to do is create some kind of spacer in there. Again, they can create something with the materials they have, but the problem that the prosthetist was seeing is it would slip. The same with the toe yoga orthotic, it would slip and it wouldn't create the balance they wanted. So we created this spacer piece here.

There's also a lot going on with osteo-integrated prosthetics at Walter Reed. We don't deal with the prosthetic as much, but we have made what we call these, like, silicone umbrellas. Now, the only interface they have and the only function they have is to hold gauze up against the tissue-implant interface. That interface never quite heals against the implant and it does leak some fluid over time, so they have to wrap gauze and the old way was to wrap to gauze, tape, rubber bands, but we're able to make these silicone pieces that you can put the gauze around and then push up against your residual limb.

We also make one with a hard cap, you can see in the lower right corner, that they use during sleeping or to protect the sheets or their partner if they are to move their residual limb and you have this metal abutment sticking out.

Here's another example, this was a triathlete taking part in triathlons with a fused elbow and wrist. They made a carbon fiber piece, but this was not breathable and in the water it retained water, of course, so they wanted something breathable, they wanted something lightweight, so this was one of our first nylon products or projects that we did

for the triathlete. Every time he was riding his bike and he would go over a bump, it would send pain up his arm without a brace on. I know I'm moving fast, I have a lot in here.

And this is a totally different project, one of my last slides. Here, this was a clarinet adapter and hopefully you'll be able to hear the video. But what happened was this patient was bit by a tick, Lyme disease, suffered from Bell's palsy, which is partial paralysis of one side of the face. So what we wanted to do was make the prosthetic piece up from the clarinet, we used some digital imaging, were able to take this piece up to the cheek. So you can see here, when she was playing, you can hear that air escape. Again, afterwards, she's playing well.

Another case was a custom-protective face mask where we printed the layup for them, we printed the layup where they could lay up their thermoplastic or carbon fiber.

And then along the way you have all the different little things that just make a difference, from deodorant holders to toothbrush holders, a Segway steering device, to a lot of different clamps and brackets for assistive technology for phones and tablets that they need.

The last slide I have just shows a little bit of research that we've done with the prosthetics department and MIT Lincoln Lab, really analyzing the Shorty Feet, doing that finite element analysis and making sure this is a safe and effective device.

With that, I know I'm over time. Future work is going to include further integration of scanning and printing and looking more at custom liners along the way of the use of our nylon machine in-house.

The last thing I will mention is that the inter-professional collaboration between you and the providers and your facility is essential to the success. So I'll turn it back to Matthew.

DR. DI PRIMA: Thank you so much, Dr. Liacouras.

I'd like to introduce our moderator for this discussion session, Laura Gilmour of LG Strategies Consulting. She's the chief consultant at the VA for additive manufacturing, and as I always like to embarrass her, she was one of the founding members of the FDA for additive manufacturing working group.

You know, audience, please continue to submit your questions, we are following them for Laura as quickly as we can. And I should also note, this is being recorded and there will be a recording available after the workshop, as well as the transcript.

MS. GILMOUR: Great. Thank you, Matthew. Do we have everybody? Great. So thank you all for such wonderful and inspiring talks this morning, afternoon, evening, I guess, depending on where you are in the world watching.

One of the things that I wanted to start with is Matthew discussed the idea of considering a risk-based approach when thinking about point-of-care 3D printing, and also the typical framework for medical device regulation employs this risk-benefit concept. In your opinion, what do you see as the biggest benefit for these types of applications? Let's start there. And whoever wants to go first.

MR. LAYMAN: Well, for myself, a lot of the benefit is the design capabilities and to adapt to the patient's needs. I think that's really one of the major benefits of additive manufacturing and the design capabilities. You can't necessarily do some of the designs, creative designs, traditionally. And so additive manufacturing offers and opens up the door for that. I do see a huge benefit there.

MS. GILMOUR: Great. Dmitry.

MR. LEVIN: Yes, thank you, Laura. I think the opportunities from the pre-procedural planning in the clinical environment is the fact that, as I alluded to in my talk, there's a lot of opportunity to create better outcomes for our patients, but also there's an opportunity at times to even change the course of care where, after looking at the anatomy in three

dimensions instead of the traditional two-dimensional imaging, there are some adjustments that the physicians can make and say okay, maybe this is not an open procedure, maybe this is now changing into more of a minimally invasive procedure because I do have access and I do have enough space for me to do my work.

DR. LIACOURAS: Yeah, I agree with both of them. I think, for the medical models, you have the surgeons that say they feel like they've been there before. And for the major benefits, I mean, that's a huge benefit, they know what they're doing and they know what they're going to do or they can plan the surgery around that.

For the prosthetics and orthotics, I think it comes to speed and availability and what's on the market and what's not on the market. If there's a simple assistive device that's on the market, I'd say just go buy it. I mean, don't utilize us. If it's a complex item or has unique characteristics, that's where you really can use 3D printing and have the benefits of it.

MS. GILMOUR: Great, thank you all. There were a lot of questions about software and since this is a digital workflow for each of your topic areas, what software are you using either for segmentation or design software?

MR. LEVIN: So I will start that question since there is a segmentation question there. So a lot of the times --

(Audio feedback.)

MR. LEVIN: -- we're sort of breaking things down into several categories, whether that is a digital category or a physical category. Within the digital category we're using FDA-cleared software for segmentation. An example of those could be the 3D systems --

(Audio feedback.)

MR. LEVIN: -- and things like that. And that is sort of the initial steps that we take in order to be able to get from the clinical datasets, which are DICOM, to more of a three-

dimensional datasets such as the MESH models, STLs. And then from that point on, the software is really taken over by what are the other needs of that three-dimensional model, so this could be traditional CAD software, so it could be rated design software or any kind of printer-specific software that will actually allow us to load it onto the printer and run a successful print.

MS. GILMOUR: Pete, Brian, what is your software experience so far?

MR. LAYMAN: So, for orthotics and prosthetics, there are unique softwares to help the practitioner modify the actual design of the socket or the fit of the socket. And then after that, I would take it into more of a design software. There's free software out there, such as Meshmixer and things of that nature, but I use free-form geometrics and I have had a lot of success with that one, too. But there are a whole bunch of softwares out there when it comes down to it. In orthotics and prosthetics, the workflow, you have to kind of use a whole bunch of different softwares to get the outcome that you're really looking for.

DR. LIACOURAS: Yeah, I think it really depends where you're starting from, I mean, if you're starting from that CT or MRI imaging, you're going to want to use that FDA-cleared software for reconstruction all the way to printing. They have cleared systems where if you use specific printers with your cleared system for specific indications with specific materials, that it's a cleared system. Along with the prosthetics and the other applications, too, we do have CAD software in-house and we do have the clay modeling, the same software Brian has in-house, too.

MS. GILMOUR: Great, thanks. So in addition on the inputs to the digital workflow, Pete and Brian, the audience has observed you use multiple white light scanning technologies. Do you have any that you prefer for anatomical scanning in your current workflow or that you've investigated so far?

MR. LAYMAN: So I've used a variety of handheld scanners, structural scanners.

Truly, I've adapted to the structural scanners for that organic global shape, but you are limited when you're trying to do something more. Trying to capture fingers or things of that nature, you may need a better resolution or scanner that's going to pick up the detail. There are some O&P softwares that come with scanners and that's also what I have, as well. So when it comes to one versus the other, they all have their pluses and minuses depending on the size that you're trying to capture plays a big part, or the detail.

DR. LIACOURAS: Yeah, I'm going to completely agree with Brian there. Over the years we've used different scanning techniques. For the face models, we used to have a photogrammetry system in-house which was a lot easier than a handheld scanner because you could just set the patient down and it would take pictures from multiple angles and triangulate all that data for you and it was within, I think, 4 ms you would have that scan of the face done. But for the other applications, we use different scanners depending on the accuracy that we'll need. Usually, for the prosthetic applications, right now I think our scanner is about a half a millimeter inaccurate at a standard definition.

MS. GILMOUR: Great. So similarly, the imaging requirement for your models, for you, Pete, what are those imaging requirements? Do you communicate those requirements prior to patient imaging? And Dmitry, I'd like you to answer that question, too, now that you're back. So what types of imaging requirement and how do you communicate that before the scans.

DR. LIACOURAS: Luckily, most of the providers know what we need right now, but for the most part, they know around a millimeter slice thickness. When exported from the scanner, soft tissue protocol or kernel, depending on your MRI or CT scanner, the protocols could be named differently, but that's what we prefer for the scanning. And radiology usually takes care of that. They know when they're doing a skull, they want to capture it from under the mandible to above the apex of the skull. I will mention some other things. I

think this also depends on the critical feature you're trying to model. I always give the example that some of this could change. If you have an aneurysm within the skull that's 2 mm, you don't want a 1 mm slice exported from the scanner, you may want to reduce that. So if we have an aneurysm, you're going to want to reduce that to the highest resolution you can pull out from the scanner, which is usually about 0.5 to 0.625.

MR. LEVIN: I'll go ahead and echo what Pete said and just build on that even a little bit further. So all of those points are critical and I think one of the things to think about is sometimes it's beneficial if you talk to clinicians even before they do their scanning protocols and kind of explaining what is it that you're looking for on the pre-printing side of things and how could they adjust that protocol eventually, if possible, to be able to do it. And I think the other thing that was mentioned is the idea behind the soft tissue or bony tissue anatomy, that protocol doesn't need to change. And then further than that, say if it's something like a cardiac study, then you do need to consider what phase of the cardiac cycle you're going to be printing from.

So all of this comes down to outlining those protocols ahead of time depending on the types of cases that you're doing, and then doing that communication with your radiology department and giving them that as much ahead of time as you can to make sure you get them properly assessed and then essentially standardize them across different cases so it's always the same when it comes to clinical site and 3D printing type.

MS. GILMOUR: So along the same lines, you are -- Dmitry, you especially talked about the data and the conversion of data over the different steps of the process. So how do you ensure that there's consistency in the use of the conversion software, for example, from DICOM to STL? And are those in certain environments? The audience is observing that the tools that are utilized are arbitrary, so how do you determine what tools to use there?

MR. LEVIN: So I think we like to think about that kind of like a linear process since there is not necessarily demand and conversion to --

(Audio feedback.)

MR. LEVIN: And what I mean by this is, in the very beginning, as we start doing the intake and identifying what types of cases and what type of case this is, we're going to, at the same time, identify what type of technology were going to be used and what types of material were going to be used. To some degree this will get data from the very beginning, what type of file we're going to be essentially outputting.

A lot of it has to do with what type of information that file needs to contain, so an example being the STL files don't really contain a lot of information within them versus other files such as 3MF or X3D or others do contain a lot of information in it, such as the type of material you want to use, maybe the type of color you want to add to it and again, this is adjusted for by the beginning conversation of what type of technology you're going to use.

And then as far as the tools go, really there is only, frankly, two tools for us, one of them being the segmentation tool, and most of those tools are limited to probably only the STL file export, so that would be our first format. And then after that it will be the format from a computer-aided design, such as CAD software, that will, as I mentioned, be dictated by what type of printer am I going to use and what type of input can that printer take in order for me to produce a successful model.

MS. GILMOUR: Pete, Brian, anything to add to software or data conversion from one step of the process to the next?

MR. LAYMAN: I can agree with Dmitry, I mean, different files, STL files or 3DMF, depending on the overall process and what machine you're downloading your files into or what software you're going to use. So yeah, I think Dmitry hit it right there on the head.

DR. LIACOURAS: The other thing I would add is you can actually, when you're done with your model and you've taken it through the other program, you can also bring the images back in and -- or the STL back in and overlay and look at your contours just for a V and V step on the digital side.

MS. GILMOUR: Great. Changing gears a little bit, you all brought up post-processing in your workflow. How do you standardize procedures for post-processing, reprocessing, etc., especially when you scale up from doing a few cases to many?

MR. LEVIN: I can start that conversation. So a lot of it will have to be done on the front end and a lot of it again will come down to what types of cases and what types of material you're using. That will dictate the work instructions and the standard operation procedures that you're going to attach to those cases. So if it's a cardiac case or an ortho case or a neuro case, then you're going to right away understand what type of material you're using, what type of bench are you using, and then dictate those work instructions.

And those work instructions is something that you're going to translate over and transmit over to the next location that will potentially be picking up that task, and part of this is to be not just the on-boarding and the training in the beginning, but also the proficiency testing on a biyearly basis or anything like that where you're checking off your stuff to make sure that they're still following work instructions, they understand those work instructions, and then if they have any questions, comments or concerns, they are able to bring them back to you and kind of reevaluate if we need to change anything.

MS. GILMOUR: Pete, Brian, any other --

DR. LIACOURAS: I mean, I was going to say almost exactly the same thing and he said it in way more detail than I was going to say it.

MR. LAYMAN: I'll agree.

DR. LIACOURAS: I'm also going to mention the work instructions and write down

everything. You might think it's insignificant, but write it down and record any changes, of course, in those work instructions over time, that's very important to do. So that's the only thing I would add to Dmitry's comment right there.

MR. LAYMAN: Yeah, I would do the same.

MS. GILMOUR: Great. There was a question around materials and folks experiencing challenges in cooling time after printing. Have you ever experienced that in your workflows and what did you do to resolve it?

DR. LIACOURAS: Usually cooling time refers to powder bed fusion processes. I haven't really heard of cooling time referring at all to material extrusion. I don't think it's something we can get around. There's some things you can do especially on the nylon side to minimize some of the detrimental effects you may have from the cooling process. Some of the nylon parts can warp a little. The way you set those up within the platform to make sure they don't retain heat, that's one thing you can do. You can also put a cage around the part and this will help basically the thermodynamics as the part builds and cools down. We usually, for our nylon parts, we let them cool down naturally, which is the slowest process in our printer, but it's what yields the best results. So when you're dealing with cooling times, you might just be essentially increasing your risk if you don't let them cool down naturally.

MS. GILMOUR: Great. Any other thoughts?

(No response.)

MS. GILMOUR: Okay. On the same lines of materials, there are some audience members who are new to additive manufacturing and are looking for recommendations on how you started, especially around material properties, where would you look in articles, websites, things of that nature? It's overwhelming, right, to look through all the materials that are available and what to use, where did you start with that?

MR. LAYMAN: I started basically with the printer offered, right, so it's FDM and then you start looking at the different materials and powder base, you have it there. So you have your spec sheets and you can do your comparisons between different filament companies and as well as what the industry or the manufacturer provides. So yeah, it's a lot of paper-shifting and really kind of going back and forth and analyzing those properties and the flexural strengths or the tensile strengths and kind of comparing those to understand the detail and the nuances of it.

DR. LIACOURAS: Yeah, I believe before you even get to the material properties and everything, you really have to decide what you're going to focus on because if you don't know what you're going to focus on, there's not one material that fits every purpose that you want to deal. If it's just a medical model, I mean, you're going to be able to get away with a lot of different material choices than if you have something that you're going to actually use for a splint. Or sometimes maybe the answer is not even 3D printing as a whole, maybe you're just using 3D printing as the tool to get to a silicone part or maybe you don't have to use 3D printing at all. So you really have to just weigh in your whole purpose and overlying issues before you get into the specific material properties.

MR. LEVIN: I think that the bad news is that materials are changing every week. I think the good news is materials are changing every week. So there's lots of opportunities to explore over there and to just second what Pete said, is to identify the task at hand that you want to actually deal with and then backtrack from there, because it will be really helpful to know does it need to be rigid, does it need to be flexible, do I need to clean it, do I not need to clean it and things like that, that will help you better understand what types of materials you're going to use. But also, I think another little point to throw in there is you also want to understand the cost that's going to be included in there because there could be materials that are $50 and there could be materials that are a thousand dollars. What is

it that you're trying to do with them?

MS. GILMOUR: Great, all good advice. Thank you all. So there's a question -- oh, go ahead, Pete.

DR. LIACOURAS: Just one more thing, the last thing you also want to look at when you're looking at materials is the steps, you know, your post-processing procedures, because depending on what steps you do, that could change the material properties. So like Brian mentioned, vapor smoothing. Now, vapor smoothing can have an effect to change the material properties of your nylon, which actually is better material properties from vapor smoothing and actually seals it. So you want to look at your whole step all the way through each step and what other things you may be introducing to your parts.

MS. GILMOUR: Yeah, that's also great advice, Pete, thanks for adding that.

This question is multi-parts and so I'm going to go through it and if you need me to repeat something, let me know. Do you currently have a centralized 3D-printed model-ordering capability that prompts a consultation for an imaging protocol for the model? So is there some workflow that you're using and having a consultation in there? And then is there a full-time radiologist managing the process? And then are those cases, the third part of the question, entered into the current ACR/RSNA 3D-printing registry? Did you get all of that?

MR. LEVIN: I think so. So let's start with is there a capability to do it in an order? The answer is yes, and it's built into our system and it's also built into an opportunity that it's not just localized to one facility, but it's at multiple facilities and we're looking to on-board more facilities as we go, that are either interested in doing the 3D printing as part of our different sites, but are also interested in just requesting a consult so someone else can do the model for them, that is also built into the system, as well as it's broken out for us by different types of templates depending on what type of case you're requesting based on

our experience with those cases so they can better have a request that actually makes sense for them, because something for prosthetics is different for something for anatomical models, it's different for something for dental, and we have an opportunity to do a close-out of that consult so everything is recorded within the patient record as well, to say this was the request and this is what was done based on that request.

I think the second question was is there a radiologist involved or is there -- I would even actually maybe even change it to is there an imager involved, and the answer is yes. Obviously, the involvement of that imager is going to depend on the type of complexity of the case and how much they're getting to participate and actually do this, but the answer is yes, the imager is involved in the process. And are those types of cases that we're able to enter into the 3D-printing registry, then the answer is also yes.

MS. GILMOUR: Pete, at your facility. Do you remember all the questions or do you want me to --

DR. LIACOURAS: Yeah, we do have an ordering system that the provider basically, I mean, writes the prescription for their medical model or device, that's essentially what it is, which they basically cite the imaging file or the session number so we can pull that imaging down and start the request. We have a traveler that goes along with the model which kind of tracks it at every stage along the process, too. So that's a physical folder. But we do have that upfront, centralized ordering system.

For the radiologist involvement, that really depends on the case. We kind of do it on a case-by-case basis. A lot of the just bone segmentation cases, a bone's pretty simple to segment. It's a lot less risky than some of the other cases. I always give another example of a soft tissue tumor case with surrounding bone. Now, tumors are not our specialty at all, we don't study 8 years to be able to identify the margins of a tumor. So that's when we will place a call to radiology and say hey, we need a radiologist to come up and look at our

segmentation. We'll do our segmentation first, but then we also want a radiologist to sign off saying yes, you have the margins, this is the exact same margins I would've segmented out or no, maybe this tumor flares a little bit into this section. So that's another area where we used to really mitigate that risk down, is call radiology.

Unfortunately, we are not involved in the registry right now. I tried, but I didn't get clearance for the registry, so that's the third question.

MS. GILMOUR: Got you. And Pete, by "we," you mean an engineer, is that right?

DR. LIACOURAS: An engineer or we have, well, three engineers at the lab, two CT technicians, a dental technician, and administrative staff. So it would either be one of the engineers or the CT technicians who work as engineering technicians right now.

MS. GILMOUR: Got you, yeah. Thanks.

So I think the last question for today, as we know in the medical device industry, the responsibility doesn't end when you provide the product to the patient, there is a postmarket surveillance that's needed after. Do any of you have experience with postmarket surveillance perspective? Any controls you might have in place for the devices that are made in your facilities?

MR. LAYMAN: Well, as a clinician, all the devices that I've ever made, we always do a follow-up, of course, and within the VA system of care those follow-ups actually happen more than outside, I would say, because they're either here for some other service and they may stop in and we may chat and come across "so you need a new strap" or "you need this" or maybe there's fatigue here or wear or whatever it may be. So the follow-up with a patient is always available here at the VA hospital. So that is the main thing, I think, that we're constantly checking on these devices and as they mature and as the individual wears into them and actually, sometimes there are breakages, but that's traditional and that's also throughout our manufacturing. But as a clinician, yes, we have our eyes on our patients

and the devices that we custom make quite often.

MS. GILMOUR: Pete, Dmitry, do you want to tackle that question?

DR. LIACOURAS: We do try and follow up with most of the medical models. Now, if we receive an answer to the e-mail, that's a different story, but we do try and follow up for each of them and make sure everything went as planned.

MR. LEVIN: I think similar here that this is the reason that we always do a hand delivery of our anatomical models, so to make sure that there's a clear understanding what the clinician asked for is what they get and if it's not what they asked for, then there's an opportunity for us to adjust and learn from that and understand how to better do it next time.

MS. GILMOUR: Great. Thank you all for your time and your answers to these great questions. I'll turn it back over to Matthew to tell us what's next in the day.

DR. DI PRIMA: Thank you so much, Laura, and the great panel. We are going to take the 5-minute break now and at about 2:10 Eastern we will resume for the next session. Thank you, all.

(Off the record at 2:05 p.m.)

(On the record at 2:15 p.m.)

CDR COBURN: Welcome back. Thank you for coming back after the break. We have our second panel for the day, which will be on the clinical ideas and applications of 3D printing in critical situations, and again we have three wonderful speakers from Veterans Affairs here, which I'll go through quickly with the introductions and then we can do the transitions in between more quickly.

So we have Nikki Beitenman from the South Carolina, Charleston, South Carolina VA and she's the Advanced Manufacturing Site Lead there. We have Dr. Michael Amendola, Professor of Surgery at the VCU School of Medicine and he is director of the 3D Printing

Fellowship Program. And we also have Dr. Diana Otoya, who is Chief Resident in Quality and recently started the new 3D printing fellowship at the Central Virginia VA system there. So with that, I will throw it to Nikki Beitenman to start her presentation.

(Pause.)

CDR COBURN: You're on mute.

MS. BEITENMAN: Sorry about that. All right, hi, everyone. Like he said, I'm Nikki, so I'm going to be doing a little bit of discussion about dental applications for 3D printing. And I am battling a cold, so please don't mind me, I'll be drinking water the whole time. So next slide, please, let's get started.

I'll give everyone a minute to go over the disclaimers.

(Pause.)

MS. BEITENMAN: Okay, next slide.

So during this presentation I'm going to be discussing some of our current dental use cases and products being manufactured here -- VHA. So the top left photo shows a site (ph.) of copy dentures, a dental protector, and also a custom impression tray. The top right is a 3D-printed model. The bottom left is a stack of PMMA bridges. The top one is actually milled, the middle one was made with an SLA printer, and the bottom with a DLP printer. The bottom middle photo is actually printed castable wax used to make crowns. And the last photo is a surgical guide, also on a 3D-printed model. Next slide.

So through this, we're going to go through some of the processes for developing some of the different items we just showed. So here it shows the process for developing custom impression trays, so the dental CAD softwares are very intuitive and they really walk you step by step through the process of creating any type of dental application. So for our work flow, the dentists will see their patients, they'll take the standard impression of the patient's mouth, and then we have two pathways we can really go from there. We can

either scan that initial impression and use an analog-to-digital scanner to create a digital model from that, or the dental lab tech will take the impression and create a stone model off of it and then we will take that stone model and scan it in the same analog-to-digital scanner. Either way we're going to end up with a digital model to do our design off of.

So once we have that, in the CAD software we create a new order for the patient and for this application we select a custom tray work flow and as you can see, we create an outline based on where the dental tech has marked for us, and then the third photo shows the software generating that custom tray. Give me one second.

(Pause.)

MS. BEITENMAN: All right, sorry, had to take a water break. So from here there are different options that the design software will do for you based on the 3D printer that you're using. So your 3D-printing material and printer will actually dictate your retentioning or your relief or what you can build into your parts that you're creating so that accuracy of your printer is really important for these types of applications.

After designing your appliance, you'll then print it, we deliver it over to the dental lab tech who makes any manual adjustments if needed, and then they provide it to the dentist to give to the patients. Next slide.

So dental protectors are a very similar process to custom impression trays. However, our facility completes these all digitally. So instead of taking an initial impression, the dentist utilizes an intraoral digital scanner to create the digital model straight from the get-go. From there, that scan is uploaded into our dental CAD software and we do the same work flow that I just discussed for the custom trays. So again, it's the same situation that, depending on which printer you're using, that's what's going to dictate your thickness, your retention, your relief, or whatever you're trying to apply to the device that you're creating. So for dental protectors, after the design the product is again printed, passed back to the

dental technician, he'll make any manual adjustments if he needs to and then provides it to the dentist. These are a little more unique because the dentist will then make adjustments after they're tried on the patients. So if the occlusal needs to be grinded down a little bit to make sure they're having a nice, good grip between the tooth and the guard, they can do that with dental tools and they just do it manually with the patient in the chair. Next slide.

So this is something new that we are actually working on here. So these are copy dentures and we often have situations where our patients will come in with either a broken or a damaged denture. If we reorder one from an external lab, it will be weeks before we get it back and therefore the patient is going without having teeth, so we obviously don't want that and we want to get it to them as quickly as we possibly can. So by collaborating with the dental team, we've been able to make this workflow where we can produce these copy dentures the same day, if possible, or we do them within a couple days.

So this is showing the clinical side. So the first picture is the pre-procedure denture, so that would be the damaged denture. They take a functional impression with hydrocast, they trim the flash to prepare the scan, they idealize the contours, they add dimples to assist with the scanner, and then they're currently using the intraoral scanner to scan that denture which will then give them the digital image. Next slide.

And this slide highlights the engineering side. So once the dentist does their step to give us the digital file, we then go through the process to create the copy denture. So once we receive that scan, that scan still has those dimples on it that they did in the first step, so we digitally remove the dimples, we number the teeth in the software so that the software understands what's what, it finalizes the layout, you add any aesthetics. We get a final approval from the dentist before we actually send it to the printer to make sure we're not wasting any time or material. We slice it for printing and then go ahead and print the pieces off and then we assemble it and cure it all together. Next slide.

So what are the benefits of doing all of this in-house versus sending this out? Well, the number one benefit is we're reducing patient wait time. Normally, when we send out guards it can be anywhere from 3 to 4 weeks before we get it back. A copy denture can be up to 6 weeks before we get that back. And then when we're doing it in-house, we can do guards within a week, copy dentures in 3 to 4 days, and we can also do same-day delivery for emergent cases.

Decreased cost. So the average third-party cost is between a hundred to a hundred and ninety for a guard depending on what type you're looking at, if it's hard or it's soft or athletic. A denture can be around a hundred and fourteen dollars to have that made. And then the 3D-printed material cost for guards are only 3 to $4. It's about the same for custom trays, I know I don't have that listed on here. The only difference on the custom tray is you're normally always having a top and a bottom instead of just one. Then the denture is between 14 and $16. I have a couple other items listed there, it's just the surgical guides, models, and the patterns for casting. So these are all material costs, keep that in mind.

You also will have a labor cost on top of that. For us, it can range anywhere between 14 to $20 depending on who's working on it. So a dental lab tech is a different salary versus what an engineer salary is versus what the dentist salary is, so it all kind of depends on which person's cost you want to contribute into that. So we took some averages, we came up between 14 to 20. So if you're looking at a guard, per se, and let's say it was $4 and $20 of labor, so it's just $24 as opposed to the hundred to a hundred and ninety.

Then by doing it in-house you are able to reduce errors and reduce repeat orders. So by having the dentist directly involved in the design work of the items that you're making, they're getting exactly what they want, they know what's coming to them ahead of time. We also have the ownership of the digital file, so if we make a copy denture and God

forbid that one gets broken, we can just go ahead and print another one really quickly because we already have the file. Then we also have control of manufacturing processes including the quality management for the end-use product, so we know what is going on to making this product and we're following it step by step through the entire pathway. Next slide, please.

So this is where some of the questions come in and I'm going to talk a little bit about gray areas of regulations, particularly going for practice of medicine versus scope of practice.

So engineers typically have education in CAD design, modeling, and more recently, 3D printing while they're still earning their degrees. Biomedical engineers take courses involving medical device development including device regulations, classifications, and steps for clearances. Dental lab technicians earn their certificates learning all things dental appliances and focusing on working in an actual traditional dental lab.

Some dental technician programs have started to implement 3D printing into their educations but many still have not, meaning that the majority of dental lab technicians out in the field right now are left to learn the 3D printing technology in the field only if their lab offers it. So if a dental lab doesn't have a printer at all, then obviously this isn't something they're going to be focusing on.

I know, particularly, a lot of our -- the job descriptions for our dental technicians just consider 3D printing a tool that they offer to use for their job. So they don't necessarily have to know it, it's just once they get hired, that's a tool that they'll teach them to use once they're there. So if a facility doesn't have a printer, then it's not something they're going to learn.

So one of the major benefits of having this multidisciplinary team work together to develop these types of products is we have engineers who understand the regulations and

they can assist with designing and printing; the dental lab technicians advise on the dental terminology, specifics of dental appliances being produced, and the final polishing and refinement of the product all before it's going back to the dentist. And of course, this is all being seen as all being completed by a dentist. So we take orders based on what the dentist thinks the patient needs, therefore I've never seen a patient, I'm not making any clinical decisions for that patient, I'm taking orders directly from a dentist.

And the nice part about having that dental lab tech mixed in there is engineers obviously are not trained in dental, so we don't have the proper terminology, education for the most part, so a lot of times we're really heavily relying on the dental lab tech to be assisting us to make sure that we know okay, we're doing -- you know, we're designing correctly based on the terminology we're being told and things of that nature.

So in-house dental labs are exempt from registration under 21 C.F.R. 807.65 Part 1. Even though a dental lab would not be expected to be inspected by the FDA, it's possible that they still could be. Best practice is always to develop and maintain a quality system regardless of registration status, therefore VHA Office of Advanced Manufacturing is moving in this direction.

We hear phrases "scope of practice" and "practice of medicine" used very frequently in regards to dental devices being produced at dental practices; however, there's not really a clear indication on who all is covered under these topics. So if I'm an engineer and I'm producing a dental appliance under the direction of a dentist who is dispensing the final product to their patient, is that still considered scope of practice if the engineer is the one who's actually utilizing the printer and designing it? Next slide, please.

So a little -- a couple more topics about gray areas and understanding the 510(k) clearances and different exemptions out there. Once we began digging into these regulations, I asked one of our dentists if they had learned about 510(k) clearances and

product codes while they were in dental school and he literally looked at me and laughed and told me he had no idea what I was talking about. So in my opinion, this is one of the largest confusions and misunderstandings amongst the dental field when it comes to 3D printing these products.

Terminology is used very fluently, so a dental protector is also called a night guard which is also known as an occlusal guard, which is also called a splint. And sometimes it's even just deemed a mouth guard, regardless of what it actually is, they just call it a mouth guard.

So when looking into the regulations on these types of products, there's multiple different product codes and different use cases based on the title of the device, but your typical dentist is not trained, nor is the dental lab technician, on what those different product code options are, so they don't really understand that they might be calling one thing something else.

So a typical dental lab is relying upon information provided and advertised to them from many of the 3D-printing companies who promote their products for these different use cases. So if a dentist is running their private practice and they purchase a printer under the impression that they can produce splints on this printer and in their mind the splint is the same thing as a night guard, they may be producing night guards for the bruxism product code, but the resin isn't really cleared for that product code. So there are many differences amongst the actual diagnoses going along with each product code versus what 510(k) clearance has actually done on that resin being utilized. So the 3D printing company may have obtained a 510(k) clearance for their product to be used as a splint, but if the dentist is actually treating bruxism, that would be a different product code and therefore a different 510(k) would be needed.

Another difficulty is the open-source printers that can use multiple different

materials. There are several instances where material companies have only obtained clearances for their products to be used on specific printers but you might have an open-source printer that you could put any material into, but that doesn't necessarily mean that material is cleared to be used on that printer but you may never know that if you didn't know that you had to dig into the regulation.

So although some products may be listed as 510(k) exempt, they still require GMP, so this goes back to the lack of understanding of what is GMP, what's a QMS system, how do you even go about establishing these processes and what do they mean, so this is something we're going to get into in a lot of the presentations later to come today. But even though there's confusion amongst a lot of these topics, it is clear that these materials have been developed under GMP and there has been testing completed on these products for use cases.

So we know engineers have experience in CAD, a dentist is overseeing the design, a dental lab tech is assisting in the final development, and a dentist is administering the final device to the patient at their appointment and appropriately sizing them and fitting the item on the patient. Therefore, we're comfortable considering dental appliances a low-risk device at point of care. Next slide.

So these are a couple of things that I wanted to highlight between GMP and QMS, so I'm going to talk a little bit about IQ/OQ/PQ, a little bit about the manufacturers, and then also biocompatibility.

So when I had my first experience with IQ/OQ/PQ, I thought to myself okay, this is easy, I can just do this in a couple days and we'll be good to go, but I was very, very wrong, I learned the hard way. The truth of the matter is the majority of people looking to explore utilizing 3D printers for medical applications don't actually know what IQ/OQ/PQ is or know that it even exists. So to further complicate things, many of the printer manufacturers also

have a lack of understanding or experience with these processes and they're unable to provide guidance on following through with these processes for their machines.

IQ is typically pretty straightforward, it's just how do you install the printer, how do you set it up, do you have the right space requirements.

However, OQ is where things get really complicated. If you're working with a proprietary print company, you're very limited based on the proprietary slicing software for challenges that you can implement on the printer to test its capabilities.

For PQ, a question that comes across our minds multiple times is performing tests to validate a material specifically or strictly doing one product at a time. And of course, if you only do PQ on one product at a time, you're going to have a very lengthy testing process and you're going to be doing a lot of repeat testing.

So there's a lot of confusion in the field, in the healthcare field, specifically, about when it's even necessary to perform IQ, OQ, and PQ.

One thing that we've learned along the way is that many 3D printing manufacturers are actually utilizing the same resin manufacturers, they're just relabeling their resin for their own reso (ph.). Typically, we wouldn't think anything of this until we start asking for biocompatibility reports.

So once we found this was an issue, we started questioning what was the process followed when they did the biocompatibility testing. So they might give you a document that says yes, this material is biocompatible, but okay, what were the steps that were taken when that test was run? So am I doing it exactly the way they're doing it when they ran that report to ensure that it is really biocompatible? So we would like to see something more than just a letter stating it's biocompatible, we would like to know what the process is, we'd like to see the actual data of those reports so we have all the information that we can need to know that we're mimicking the correct process when making these products.

We've also run into scenarios where the reseller has recommended supplies for post-processing that don't align with what's printed on the resin bottle itself, so for example, using isopropyl alcohol versus ethanol for rinsing parts. We had one bottle that had an IFU with it that was labeled of using the ethanol, but then the 3D print company, in their IFU on their website, recommended using isopropyl alcohol. So from here, these are my two situations in front of me, how do I know what was actually used in the biocompatibility testing to know that I'm matching the exact process that they did.

We're looking for some way for the end user to be confident in knowing that the process that they're doing will not negatively affect the biocompatibility of that material. So one suggestion we would put out here is to get more stringent regulation on labeling of these products. Next slide.

That is actually my end of all I have today to talk about dental, so I thank everyone for listening and I'm happy that I was able to share this information and be part of this workshop today.

CDR COBURN: Thank you very much, Nikki. It was great to hear your perspective on dental and I always love it when somebody says IQ/OQ/PQ in a presentation, so that was music to my ears.

And next, we will go to Dr. Amendola to hear a vascular, cardiovascular perspective from the clinical side.

Dr. Amendola.

DR. AMENDOLA: Thanks, Commander Coburn. Thanks to the FDA and to VHA for allowing me to speak with you today. I'm Mike Amendola, I'm with the Richmond VA, now known as the Central Virginia VA Health Care System. And go ahead to the next slide, please.

These are the standard disclosures you all have seen, I won't reiterate those here.

Next slide, please.

So I'm going to talk about point-of-care 3D printing, I'm going to talk about surgeon as advocate, I'm going to tell you how I got here, why I'm here, and what I'm trying to teach other surgeons in terms of the technology and approach. And I'm going to go through some quick case examples from the Richmond VA and also others from our system and talk about what the clinically relevant pieces were as it pertains to 3D printing or pre-surgical planning angle. Go ahead, next slide, please.

So next slide.

So what is the point of care, what is the setting? So we all know this, this was the beginning of our history in VA was from Lincoln's second inaugural address where he established basically the tenets of what we do in VA and taking care of our veterans. We have now grown into a system of roughly a hundred and thirty-four medical centers with affiliations with medical schools, allopathic and osteopathic, with the majority of faculty members such as myself having an association with these other medical centers. Next slide, please.

So point of care at VA, we're looking -- this is what our clinical practice is. We have several learner types that our in our practice, we have providers and we also have patients. Next slide, please.

This is a breakdown of who is in the VA in terms of learners and medical students, residents and fellows. You can see roughly one in four of every medical student in the United States gets some aspects of training in VA. Our medical residents, roughly just under half get also training in the VA and fellows with a minority of training positions in VA. Next slide, please.

This is a breakdown of how our VAs -- our eight million veterans get their care throughout what they call Veteran Integrated Service Networks, we reside in six here in

Virginia. Next slide, please.

And this is roughly the providers, just over 300,000 providers in the United States within VA. Next slide.

Point-of-care 3D printing, as we have published and others have also reported in the literature, its clinical- or hospital-based models can be quickly manufactured and allows for the creation of individual patient-specific models. This is a picture from our Puget Sound site, looking at their point-of-care 3D printing. Next slide.

So we're going to focus -- next slide -- we're going to focus on learners and providers, and at the end I'm going to follow up on the patient angle in terms of individual cases. Next slide, please.

This is all part of VHA's innovation network, trying to discover, test, replicate things that work and work well, scale them into our system for ultimate success, not only at individual VAs, but across the system as a whole. Next slide, please.

Next slide.

So how did I get here? That should be a question in each and every person's mind listening to this webinar. So this is me on the left in 2018, I was in Seattle at the Association for VA Surgeons meeting, I was asked to meet with this talented radiologist to the right, Beth Ripley, for a 30-minute meeting. Next slide, please.

I came to her office, this is a picture of Beth Ripley's office, as you can see, it is an office of someone with great vision and intellect, there are lots of things going on. The original 30-minute meeting resulted in a 4-hour conversation about what 3D printing was, where it's going, and what surgeons, what part we potentially have within it in terms of pre-surgical planning. Next slide, please.

You're a surgeon and you should be involved in this technology, that's what I left -- when I left that room, that really stuck in my mind. And Dr. Ripley uses this example, which

I'm going to walk through with you, that helped really crystallize in my mind the power of this technology at the point of care but also in surgeons' hands and surgeons' involvement. Next slide, please.

So you're a radiologist. Someone's been into your reading room and they have messed up all of the CT scan files and you're asked to try to figure out what is going on with this patient or who do these images really belong to. Next slide.

So there's the first set of images that you see and these are axial cuts, so these are top-down cuts, looking at the top down. Next slide.

Then the radiologist says I think these are saggital cuts side to side, still trying to figure out am I looking at a shoulder, am I looking at a long bone of a leg. Next slide, please.

And then lastly, these are coronals from front to back. So Dr. Ripley showed me these images and said what do you think you're looking at? I had no idea at the time until she showed me the next picture. Next slide.

So what am I looking at here? Next slide.

So this is called the alligator problem. So this is a CT scan of an alligator. So only by having in my mind's eye the three-dimensional reality of something that I've known since I'm a boy, of what an alligator looks like, was I able to piece together the two-dimensional representations of that reality. Next slide, please.

So looking back here, you can see an eye, you can see the jaw and even a tooth. These things now in retrospect, because you have the three-dimensional reality in your mind, are easy to ascertain. Next slide, please.

So I really need you to do this, is what Beth left me with, and this has now been a 4-year, really, a big journey for me and also part of my fellowship and the innovation fellowship within VA. Next slide, please.

So 3D printing certainly basically kind of resides in a couple different realms: pre-surgical modeling on the far left; creating surgical instruments in the center there, in that case an Army-Navy retractor; and then on the far right, advanced surgical planning or cut guides, in this case from aortic graft. Next slide, please.

Why are surgeons different? We are different because we live in a three-dimensional reality. We are commonly dealing with three-dimensional things and objects, in this case this is an aortic aneurysm that's being dissected and on the right shows the graft that's been sewn into place. Next slide, please.

So again, two-dimensional, three-dimensional, our surgeons are constantly using this translation back and forth and that's the inherent power from the models once it's in the hands of surgeons. Next slide, please.

More than manufacturing, 3D printing is an additive technology, but it's a unique way for us, as surgeons, to look at surgical problems prior to going to the operating room, but also afterwards in terms of training. Next slide.

So this is the traditional model. We've always had providers who've seen a patient, ordered an imaging X-ray, for example, and gotten it back and just made some clinical decisions based on the imaging. Next slide.

Now with 3D printing, we're able to take that and create a model, which we're able to feed back -- next slide -- to the provider. Next slide.

The issue is, and I think where surgical advocates come into play is do we need the model, asking some serious questions about the technology, how we can push it forward, do we even need a real model, could it be a virtual model? Next slide, please.

So these are several of the questions that I ask every day within my VA when I'm advocating for this technology. Who needs it? What's the limitation of a model? Do we need to do a virtual model? So you can see multiple questions feeding back as a surgical

advocate for all this technology. Next slide.

So who should be the surgical advocate? It should be ideally someone broadly trained in surgery and understanding of the technology and understanding of 3D printing as engineers apply it at the point of care. Next slide.

So the educational problem, we are using it increasingly in surgical practice, there is an emerging role for surgeon advocates and there's no curriculum currently that trains surgeons in this technology. Next slide.

So we establish here to provide our surgical trainees an extensive exposure to 3D printing as it applies in the clinical environment. Dr. Otoya will walk you through what our fellowship is currently in Richmond, but I wanted to set up kind of the background in terms of this training. Next slide.

So here's some case examples. Next slide.

I start with this, this is George Box, who's a famous economics thought professor who said, "All models are wrong, but some are useful," and I think this is a key thing to think about, especially in serving and applying this technology. Next slide.

So we start with a 56-year-old, had a history of a previous ganglioma, you can see here in the red and the green crosshairs, planning for a second resection of that tumor which recurred; the neurosurgeons asked, based on CT and MR imaging, if we could create a model. Next slide.

Based on that, we were able to set up a model here, as you can see. The yellow stars there are actually what's kept the cranial vault in place from the previous resection. So our surgeons are trying to figure out exactly where they have to enter into that previous resection to get to the tumor. Next slide.

Here you can see the tumor in green with a lot of -- with the brain removed, the parenchyma of the brain removed. This is incredibly powerful to a surgeon to figure out

from terms of the angulation and approach exactly how you can reenter to the brain to get to the tumor and its recurrence. Next slide, please.

So this was the model here that was created here in the Richmond VA to get down to that tumor. Next slide.

So I think the power here is not all structures have to be printed; relationships or key questions for the surgeon should drive the model creation and listening to the requesting surgeon, exactly what are you trying to get at, in this case, how much more of the cranium did I have to remove to get down to that mass. In this case it's the top part of the previous resection. Next slide, please.

This is a 64-year-old that came to us from consultation from our neighbors just south of us at the Charleston VA. Looking at a left kidney mass, we were asked to segment this and to print this model in a consultation by a team, so this is actually one of the shots of the segmentation of us going through the model after we had segmented it. Next slide, please.

So typically, tumors -- and this is a picture from our Seattle site from part of our Office of Advanced Manufacturing. Typically, we print tumors so there's a pacification (ph.) so we can see the tumor, like I just showed you in the previous example. In this case, the surgeons did not want that, they wanted to not be able to see the tumor. Why? Because they wanted to see if they could directly palpate the kidney by an approach, an operative approach, to see what they could actually resect based on the tactile feedback. So it made some huge implications in terms of what the incision was and in this case, printing something that was opaque was more valuable than something that was visible. Next slide, please.

You get to print it all at the same time. This is a 16-year-old female that came from our academic affiliate. She had previous spine hardware, which you can see there in blue, and it needed to be revised. She's a bedbound 16-year-old with severe cerebral palsy. The

question was how much of this did we have to remove in terms of getting this hardware out? Next slide.

Part of any time that you image metal is that you will get artifact. You can go to the next slide, please.

In this case here, you can see the metal which we printed in red, but we also printed the sacrum in this case clear so again, giving some clear guidance to orthopedic surgeons to figure out exactly what their approach needed to be. Next slide.

This is a 50-year-old female that we just actually saw in the vascular surgery clinic yesterday here in Richmond, left lower extremity edema. She had a duplex and CT scans which revealed a cyst on her femoral vein. Next slide.

Here you can see the breakdown of the ultrasound on the left of the vein with aliasing on duplex but also on the right, the occurrence of the cyst, which is the dark gray, is the dark gray structure, and then the vein. Next slide.

So in discussing with the patient, we went ahead and printed this for her, to put it in her hand. She has an incredible amount of anxiety, but we were able to put that in her hand so she could make the ultimate decision that she did not want the operation in this case. Next slide, please.

So again, helping the patient decide by having the anatomy actually in her hand was crucial for her decision making and decide in this case not to get an operation. Next slide, please.

I talk about education a lot. This is what I call simulating the rare. We, in medical education, figure if you're in residency for a certain amount of time or training, that you're going to run into rare pathologies. The question is can we simulate those rare pathologies and make them more common? Next slide, please.

In this case, this is a picture of an endarterectomy of a carotid artery, so undergoing

this operation and simulation, which we just did in this hospital today, so figuring out how we can train surgeons on this particular approach. Next slide, please.

In this case you can see these are 3D printed simulation models that we are using. The red arrow shows you the suture that I put in, this is where we come and we do to tack down residual disease that we cannot remove to prevent it from causing a complication down the road. Next slide, please.

So we're trying to get iterative change in our models to get them more and more accurate and represent what we actually see in the operating room, and creating a high-fidelity simulation is the goal here and that's where this model's going here. Next slide, please.

The last thing I want to talk about, three-dimensional, 3D printing consultations. This is a 62-year-old female with a previous pituitary adenoma that was removed. Now she had a recurrence, the surgeon was asking for help in surgical planning. This is one of the first models that we printed here. Next slide, please.

So here is the tumor that is printed in clear. The surgeon wanted to do this, she wanted to be able to put the tumor directly in the sella where the tumor exists in terms of the pituitary. Next slide, please.

This is us delivering the model to her. This is a crucial part of what we do or what I do as a surgical advocate, is to meet with surgeons and watch how they interface with the models and capture, not only in notes also from them, but what they're doing with the models. Next slide, please.

So in this case, one of the key things that we figured out was she wanted to see the operative approach with a transsphenoidal approach or via the nose up towards the mass, so this blue arrow shows you what she's typically looking at when she's operating on the patient. So figuring out how much of the mass is visible, where it's visible, why it's not

visible, those kinds of key questions before you get to the operating room are crucial. Next slide, please.

This is one of the segmentation sessions we did. We actually gave the surgeon control of the segmentation so she could actually help guide what we were segmenting in terms of this tumor. Next slide, please.

And then finally, we took her a model, she said here, I want you to do this, she actually wrote on our model. This is a key thing, this is the ultimate set of crib notes for us, as model generators, to say okay, now we take this and how are we going to create this model? She said let's cut the skull off here, I want to see it from here. Next slide, please.

And based on that, we came up with this, this is a top version of the model, again, the tumor's in green, and in the bottom -- next slide, please -- and you can see it pulled apart here. So here, by virtue of magnets (ph.), we're able to pull it apart and when you see surgeons work with models and translate them in space, it's pretty amazing because again, the vernacular of surgeons is 3D space. Next slide, please.

And you can see again here the tumor. Next slide.

Next slide, please.

So we are at the beginning of personalized medicine. Dr. Ripley had mentioned that at the very beginning of this session. Next slide, please.

Three-D printing is a tool and surgeons are going to use it more and more at point of care and push the boundaries. Next slide, please.

We need to help surgeons use 3D printing in their daily activities. Part of that is getting stakeholders, explain the technology, but in this case, a consultative kind of aspect of using the technology. Next slide, please.

Surgeon advocates will be needed at the point of care, as I just mentioned before, from the points above. Next slide.

And the next generation of surgeons will need to understand this consultative aspect of the technology as it applies to pre-surgical planning. Next slide.

And VA is in a unique position in its history and its continued investment in 3D printing to lead the way in terms of this technology and its application at point of care. Next slide, please.

Thank you for your time. I look forward to the discussion and again, thanks to FDA. Commander Coburn, thank you very much for your leadership here, as well as Matthew for his leadership, as well. Have a good day.

CDR COBURN: Thank you very much, Dr. Amendola. It's great to hear the clinical perspective and the examples you gave. I'm definitely going to use the alligator example, if I can, in the future.

Next, we have Dr. Otoya, who will be coming to us from Central Virginia.

Dr. Otoya.

DR. OTOYA: Hi, my name is Diana Otoya, I'm a general surgery resident at Virginia Commonwealth University and one of the 3D printing fellows at the Central Virginia VA Chapter. I also serve as a VA chief resident in quality and patient safety. Next slide.

I have no disclosures, but my slides reflect my experiences working with the Office of Advanced Manufacturing. Next slide.

A little background on Richmond and our facilities. Next slide.

The Richmond VA is a complex 1A facility that offers all practices of surgery and surgical subspecialty care. Currently, there is a longstanding and academic affiliation with Virginia Commonwealth University School of Medicine and VCU Health Systems. This affiliation has extended across departments and programs and includes general surgery as well as other practices in medicine. Next slide.

For over a decade, 3D printing has been done within the PM&R department by

assistive technologies which works primarily with physical therapy to adapt rehabilitation devices for specific patient needs. In 2020, Dr. Amendola was recruited by Dr. Ripley, and his surgical expertise helped expand pre-surgical modeling for various departments. In 2021, we officially became affiliated with the Office of Advanced Manufacturing coordinated by Dr. Ripley and our program was able to secure funding for our fellowship. Next slide.

Next slide.

As Dr. Amendola mentioned in the previous talk, 3D printing is becoming more common in surgical practice. With the growth of this technology, there's an emerging role and need for a clinical champion to aid in this practice. Next slide.

Given that no current curriculum exists to train surgeons in the use of 3D printing, the Office of Advanced Manufacturing sought to bridge this gap in training. The goal of our program is to provide surgical trainees an extensive exposure to 3D printing as it applies in the clinical environment. Next slide.

These are current 3D printing fellows and their respective funding sources. Dr. Boyd and I have a strong interest in vascular surgery and Dr. Keller-Biehl has a strong interest in minimally invasive surgery. Next slide.

And none of this would be possible without great mentors. At the national level, we have Dr. Ripley and Dr. Vega, who have been instrumental in implementing us into the larger Office of Advanced Manufacturing. Next slide.

And we also have local mentors that have taught us greatly about the engineering aspects of 3D printing. In our program, we cannot function without these connections. Next slide.

And lastly, we have additional local mentors and users of 3D printing that have worked closely with us through projects. Without these local mentors accepting and

applying this technology, our program would not be successful. Next slide.

Our local curriculum includes dedicated readings in 3D printing and our duties include pre-surgical model creation, segmentation training to create those models, and simulation model creation. We've received medical and scanner imaging training. Next slide.

Each fellow has a specialty project they manage and three times a week we meet with the national group to go through workflow and upcoming projects. Next slide.

This is a 12-month full-time clinical program that includes clinical exposure, structured and self-guided education courses, and candidates for this fellowship must be enrolled in an accredited residency training program in the field of surgery. Additionally, fellows must have an active, unrestricted license to practice in the U.S. and be appropriately credentialed for clinical practice at a local VA facility, as well as demonstrating an interest in 3D printing and research. Next slide.

Our training focuses on these three core areas: engineering principles; 3D printing, imaging processing and segmentation; and application in surgical planning. Next slide.

There are five central objectives for a fellowship. Objective 1 is recognizing the essential materials in 3D printing. Objective 2 is understanding the common types of 3D printers. Objective 3 is appreciating the essential steps in 3D model segmentation. Next slide.

Recognizing the positive and negative aspects of patient imaging approaches as it pertains to 3D model creation. And Objective 5 is applying those essential steps in communicating with surgeons regarding 3D-printed modes. Next slide.

In order to learn the essential materials needed, we work closely and have an apprenticeship with engineering. During model creation we learn about different material integrity, ability to be sterilized, and what type of support structures are needed. We also

learn about the cost of these materials. Pictured here is Brian Burkhart, one of our key engineers who is instrumental in teaching us the basic engineer principles. Next slide.

Similarly, the engineering department has been crucial in teaching us the common types of 3D printers. We've also had to complete TMS module training and a mini-series YouTube session on these different types of printers. Next slide.

To learn how to make patient individualized pre-surgical models, we've had official segmentation training. It would just come from patients' charts and we work closely with one another and Brian to segment each model. Next slide.

We've had ample opportunities to recognize the positive and negative aspects of patient-imaging approaches. We've come to learn the different CT protocols and slice thickness needed to separate from different organs. Most importantly, reviewing local and national medical imaging as part of the national consult workflow has been the most beneficial. Next slide.

And this last objective, which has probably been the easiest to achieve, given our surgical background and communicating with other surgeons about their model needs, has been most natural to us. We've had several outreach opportunities to other departments as our fellows have given various talks at different departments' educational conferences. We each have ongoing research projects and contribute to the curriculum by identifying current literature and its applications to 3D printing and assume authorship in at least one manuscript submission. Next slide.

Our local duties focus on supporting pre-surgical model creation and each fellow has been responsible for reaching out to various surgical subspecialties in order to get buy-in. Dr. Boyd has given talks to the Department of Vascular Surgery and Neurology and many more to inform surgeons on how this technology applies to them. We review current literature through didactic lectures, journal clubs, and case presentations, and we do this all

while still working 1 or 2 days clinically covering ICU and floor patients at both our academic institution and the VA. Next slide.

As mentioned before, we work closely with our national cohort and have participated in national projects. For example, we'll present relevant clinical materials to explain clinical scenarios and give clinical context to the group. Our background helps triage and understand different lists necessary for the Office of Advanced Manufacturing. For example, we have interfaced with the National Center for Patient Safety in problem-solving patient hemodialysis bleeding events. We've participated in several project management including OMFS cutting guides and left atrial appendage projects.

Lastly, in the past year we have learned greatly about policy development. As surgical trainees, business modeling is a thing we rarely get exposed to and working with the financial consulting group this year has given us some real-world understanding of what it's like to implement such a change in medicine from both an economic standpoint but also a policy standpoint. And working with the FDA has been extremely educational and has given us special insight into product development, which a lot of our peers don't get exposed to. Next slide.

This last year has been an incredible learning experience for me and the other fellows as this program is the only official 3D printing fellowship offered to surgical residents. It has given us new perspective on how to problem solve and how we think of anatomy. Now when I look at a CT scan in my brain, it is slowly reprogramming me to view it in 3D. And learning how to segment those CT scans will also be an invaluable skill as we move forward and start new projects.

Lastly, we have applied 3D printing to help train surgical residents by creating cost-effective surgical simulation models. The use of 3D-printed surgical simulation models has been shown in the literature to improve surgical skills and improve training confidence.

Next slide.

Next slide. Sorry, one more slide.

As part of this program, we have taken the lead on discussion and introduced new projects to the team as well as lead literature reviews for official project documents. We are able to act as liaisons between the 3D printing team and surgical subspecialties to introduce the concept of 3D printing and demonstrate its usefulness in the pre-surgical planning. Presenting across a virtual platform across different states and specialties has also given us invaluable leadership skills and improved our confidence in presenting and leading. Next slide.

This experience has taught us how to communicate medical terminology to a nonclinical audience by allowing us to discuss what is important clinically and what is feasible from a materials and operational standpoint, and we have learned so much in how to collaborate not only locally, but across different states.

As previously mentioned, our experience this year was exposure to a consulting group and viewing the business model things has allowed me to set realistic goals and learn how to appreciate that certain projects require bigger lists. The Office of Advanced Manufacturing has helped me understand how to break up projects into achievable steps and milestones and how to document those milestones in order to build on conversations and team collaboration. Next slide.

As a surgical trainee, we've been able to help bridge the gap between medical and clinical and anatomical aspects of a project and the engineering aspects. We can provide a context for the surgical side to help complete projects successfully. Conversely, this has also provided us trainees with insight from both the radiology and engineering teams that we would not otherwise have been exposed to, and we have also gained an appreciation for different site capabilities and troubleshooting issues across an interdisciplinary team. Next

slide.

As we continue to work on projects, we've been exposed to new anatomy that we were not intimately familiar with, like cardiac models which required expert-level segmentation. This has allowed us to work with new areas that as general surgeons we are not commonly exposed to, which further expands our clinical knowledge. We've also learned how to engage stakeholders doing need-based analysis. Lastly, we have constantly felt like our opinions and expertise are valued despite our training level. Next slide.

So thank you for your time today, I look forward to the panel and I'm happy to take any questions.

CDR COBURN: Thank you very much, Dr. Otoya. It's amazing to see what you've already accomplished in this fellowship, what you're learning with this program and what you're using it to do, and I'm looking forward to seeing how that grows and develops in the future.

So now we will go over to our moderator, Bill Corcuera, who is the Innovations Program Coordinator and 3D printing lab manager at the Northeast Ohio VA Health Care System, and to have a wonderful discussion with all of our panelists and your questions that you provided.

Bill.

MR. CORCUERA: Thank you, Commander.

So the first question is for Dr. Amendola. When working with a 3D printed anatomical model, what other tools would a surgeon be utilizing in the pre-planning of a surgical intervention?

DR. AMENDOLA: Yeah, so I think the answer to that is we commonly use imaging as kind of our bookmark of what, in our mind, we think we're going to be doing in the operating room. We constantly refer back to that. What I think the model does in a lot of

these cases is take surgeons and think about things differently, and so it might have changed the approach to what we potentially would be doing. Well, we are constantly relying on fixed imaging that we've had for several, several decades.

The next step will be how three-dimensional modeling or models that we could give the surgeon at point of care in an expedited fashion to really get them to have that anatomy in their hands, having the anatomy in their hands and being able to translate it with our hands, when you give these models to surgeons you commonly see that because like, as had been mentioned before, we are constantly working in this 3D world, we're operating in it, we're solving three-dimensional problems, so really the reality of the anatomy should be presented in its ideal sense in a three-dimensional fashion, which will be the model. But to answer your question, two-dimensional imaging with an augmented sense with 3D modeling.

MR. CORCUERA: Thank you.

This next question is for Ms. Beitenman. In your experience, what dental products have been most successful or most adopted at the Charleston VA? Also, what products have been the most challenging to implement?

MS. BEITENMAN: So just from our experience alone here in Charleston, we rolled out the custom impression trays actually very quickly, those are very basic. As you saw from the design work, it's really drawing an outline and the software kind of does it for you, so then from there it's just printing and you're good to go.

Making the dental protectors took a little bit more work. We had to work with the dentist a lot to figure out exactly what they wanted and really truly understand how the teeth hit those and you want a certain ramp on them, so there's a lot of detail that goes into those you wouldn't really think otherwise. Those two we rolled out quickly and we make many, many of them.

The copy dentures is something new, and dentures are going to take a lot more time for us because there's a lot more dental knowledge needed and there's a lot more aesthetics that go into that. So even some of the 3D printed dentures on the market right now, some dentists don't like the aesthetic look, they feel like they still look very fake and they look very plastic. So there are some post-processing techniques you can do and there are different products that you can apply to the 3D-printed resin after the fact to make them look a little more realistic, so that's something we're going to be trialing to see if we can get, you know, a more real feel.

We do have some dentists that straight up tell us we don't care how real it looks, some of our patients just want to have teeth and they don't care. So if that's the case, then great, that's easy, but otherwise we're having a lot more go into the backend of the dentures, so that's really where we started with those copy dentures first is "okay, take a broken one and literally just duplicate it, that's easy." Now trying to make a denture completely from scratch, that's going to take some time.

MR. CORCUERA: Awesome, thank you.

This next question is regarding the fellowship program. The 3D printing fellowship program for surgical residents sounds incredible. Do you foresee a potential and benefits of expanding this fellowship to radiology trainees, as well?

DR. OTOYA: Yeah, absolutely. And we've done some literature review on if some more fellowships are available to not only radiology but engineers, as well, and there is definitely more literature out there of engineering getting more exposure to the medical aspect of 3D printing. But radiology, we actually did a needs assessment research of our own and we have found that radiology departments in and of itself is lagging behind surgery in these particular fellowships or at least integrating these into their official curriculum. So when we did this needs assessment, we looked at every single radiology program here that

is accredited by the American College of -- Board of Education and we found that it is lagging in their official -- like official, having any official curriculum to be able to teach their trainees in comparison to surgical subspecialties. Granted, there are a vast more -- like, there's a lot more surgical subspecialties than there are radiology departments, but it is something that should be expanded. I think it would help a lot of the communication across teams, especially in the future moving forward with this technology becoming more common.

MR. CORCUERA: Thank you.

So this is for the group. What are some determining factors when deciding which interventions 3D printing is appropriate for and which ones are not?

DR. AMENDOLA: You want me to start? I'll start. Yeah, it's not -- there is a general ignorance of what 3D printing is in the healthcare system, that's part of why when we started, one of the initial tasks to me was to help spearhead a national kind of TMS module, which is our educational program within VA, to be able to point providers -- but everyone within our environment to kind of educate them broadly on what is three-dimensional printing.

There are some things that are not and that's part of what -- you know, a lot of things that we do as a surgical advocate is to try to narrow down what the clinical question is but also sometimes say to people who are asking for help in the use of technology, it's just not applicable. We can't create a model between now and tomorrow, for example, or we can't create a model based on imaging that doesn't have the appropriate thickness or slice thickness that we need. So those are kind of key questions that a lot of times we, as clinicians, step in to kind of give power to the engineer to say hey, you know what, we can't really create this or if we did, it would not necessarily answer the key clinical question.

MS. BEITENMAN: To add on to what Dr. Amendola is saying, I think a lot of times -- I

mean, obviously, of course, we always want to consider risk, so what is the risk to the patient if I develop something and then I 3D print it, you know, we always look at risk factors and then what are the mitigation factors for those risks. So sometimes when we're doing patient specific products, there might be nothing available that worked for that patient on the market so now you're creating something totally customized which, if you're doing that and you're able to do it, that's absolutely amazing because you're giving this patient something they couldn't have gotten otherwise and increasing their quality of life.

So if I'm able to increase a patient's quality of life in a very low-risk fashion, then absolutely it's worth it. But if I'm thinking like oh, I'm going to develop something but this might be pretty risky and if I give this to the patient and it breaks with the patient using it and the patient's going to get hurt, well, is that worth it?

And you have to make sure you always have these conversations with the patient when providing them a 3D printed product so they have to know okay, this item was 3D printed, these are potential risks based on utilizing a 3D-printed item and everything might work out perfectly and there might never be an issue, but I think making sure you're communicating with the patient and letting them know hey, this could be something that could potentially happen, then that's a very important piece to it, as well.

MR. CORCUERA: So speaking of working with the patient and keeping the patient in mind, and again, this is for the group, what feedback have you received from patients and/or clinicians regarding the introduction of 3D printing and anatomical modeling and its impact on their practice of medicine?

DR. AMENDOLA: So I'll start with that. So there were more examples that I had that I actually cut from this talk, one of them was from the Seattle -- the Puget Sound VA, where a patient had a kidney tumor and his quote was, "It all looks like gobbledygook to me, doesn't look like anything, but when you print it and put in my hand, then I understand

inherently." So there's an incredible power that patients get.

And there's another component of this which is in surgery we commonly get consent for an operation, informed consent, and a lot of that is we're informing patients based on what we're verbally telling them about their disease state. We are moving to the next step of ultimate personalized medicine where we say this is what your tumor looks like, this is how I plan to take it out, and this is going to be the recovery.

So there's a lot of power there and there's also the value-based calculation that VA has made to say this technology has inherent value for our patients and when you put it in patients' hands, you just see it, it's an instantaneous kind of return just based on patient satisfaction. So I think that's one of the key things is the ability of patients to see their anatomy, see what's going on, but more importantly, for us as surgeons to effectively communicate what kind of operation and/or non-operation in some cases, we would potentially undertake to help treatment.

DR. OTOYA: I agree, I go with what Dr. Amendola said. I think it's always surprising when we go to consent patients, which us, as residents, often do, how little patients understand about what they're having done and having these models and being able to have a physical representation and be able to show these adds a lot of value, and for trainees and for attendings, as well, the requesting surgeon, I think these models are adding a lot of value in being able to hold something, be able to physically manipulate something, I think that's pretty invaluable.

MS. BEITENMAN: Adding to the topic of not only just anatomical modeling, but just creating different devices for patients, so we just recently have been working with one of our amputee patients who is in a wheelchair and we made a couple of different attachment pieces for his wheelchair. So we got the order from PT to reach out to the patient, so I called him and I said hey, they let me know that you're looking for a tray and a basket

attachment and a couple other things to go on the front of your wheelchair and he was like well, no, I think it has to go on the back and I was like okay, well, let's meet up and like, we'll go over some options. So when we met with him, we had shown him a device we had developed for another patient that had his exact wheelchair, so we had already built this for another patient, we knew we could do it for him, so we said hey, like it will insert here and this is how it's going to work and this is how we're going to design it and we can make it for you real quick and we'll get it to you right away and he looked at us and he was like oh, I didn't think you were going to be able to do that, I would've never thought that you could install something on that part of my wheelchair by making something with a 3D printer.

So I really love the -- patients get really excited as soon as they see like oh, there's options outside of other things on the market, like there's options besides normal things that I would've thought of. So that's my favorite part is you see their excitement and then they realize like oh, well, what about this, maybe I have a new idea that I want and maybe they can make it for me and as soon as the wheels start turning and they start throwing other ideas at you, that's where I think they truly love getting involved.

MR. CORCUERA: So Nikki, in working with Geo Stent, like walk us through that collaboration with the patient.

MS. BEITENMAN: So the Geo Stent, I'm going to talk a little bit about the Geo Stent in my -- I'm doing a presentation right after this, so everyone stay tuned for that, for the whole pathway on the Geo Stent. But just working with the patient on that, so for those that don't know, it was a custom designed ear stent that we made for one of our patients in tandem with an audiologist at our facility. So the patient was actually an engineer by background, so that made it a lot easier because he truly -- he actually worked in the medical device industry, so he understood the whole process. When we said we had to submit over to the FDA, he was like okay, great, like no questions, but he really challenged

us in a very good way because we printed it initially one way and he would run his fingernail down it and he was like I can feel layers and I tell you, we sanded that with thousand-grit sandpaper, like it was smooth, and this patient still was telling us he was feeling layers on it. So he was so good about really challenging us in a way of "I know you can do it better, I know you can do it better," so he was the perfect patient to work with, especially for our first compassionate use 3D-printed item that was -- we couldn't have asked for someone better.

MR. CORCUERA: So Dr. Amendola, so in staying in line with collaboration, can you talk about a specific interaction with a fellow surgeon that just was like it blew your mind?

DR. AMENDOLA: Well, you know, those in the neurosurgical model I showed you, we've done several neurosurgical models here in Richmond and working with our neurosurgeon here, she really kind of -- it kind of like clicked when we were segmenting the model and she said "now I get why this, this, this, this, and this and this," and it just all of a sudden you could see, as a fellow surgeon, all of the tick marks happening, you could see the processing happening, and that was with a virtual representation of a model. And so in a lot of ways, that really -- you know, I have several videos of the interactions I've had with her where she pulls the model apart and she looks at it from different angles, it's all things that we do in surgery all the time.

So again, 3D modeling, it gives us -- it's a vernacular that we understand as surgeons, so when we put forth models that -- and again, we've talked about the patient centered model but also the provider centered model, when we do that and they use it, it really just -- you just see inherent value when you put that model in the hands of the clinician. But again, giving them the right model, again, which models are useful, all of them are wrong but some of them are very useful. Figuring out what's useful to that surgeon or more broadly, to that clinician, is really the big lift here.

And I think the other lift here for three-dimensional printing in general for VA is extending it outside of the layers of providers but, in general, in our whole healthcare system. We have nurses every day that deal with patients that deal with problems. We need to democratize this approach and get them and pull them in and say what potentially could we do to help you on a day-to-day basis.

And I guess the other thing is in terms of creating solutions at the point of care and that's the real key here, is 3D printing at point of care and advocating for not only clinicians, but engineers and imaging experts at the point of care to use these models but create them, but also solve some key questions that are personalized and kind of the case that Nikki was saying, but also personalized in terms of some of these operative approaches.

MR. CORCUERA: Those are -- I mean, those are really -- I mean, it's so exciting to be a part of all of this, but speaking of the point of care and keeping in line with that, the digital workflow opens the door for 3D-printing solutions at the point of care. What other benefits could the digital workflow bring to point-of-care applications?

DR. AMENDOLA: Well, I think the pandemic has taught us -- within VA, we do a lot of workflows, digital workflows now. We work on a lot of projects across VAs and across VISNs and across our system. That's a good thing because we can utilize expertise in different places. The lift becomes trying to figure out how, when a solution works in Richmond, for example, how do we get it to Seattle in terms of a practical application and vice versa, how do we exchange that information, how do we exchange imaging files?

So we're trying to figure that out in terms of kind of a national response or consult for utilization of these different technologies and I think that's part of what we have figured out in terms of the digital workflow. The other thing is VA has been the leader in telemedicine, we have that backbone, we had it before the pandemic, we utilized a lot of that expertise in the midst of the pandemic and it's helped us and been crucial, I think, in

the growth of the Office of Advanced Manufacturing and also in the education of our future leaders, say for example, Dr. Otoya, Boyd, and Keller-Biehl. They are the leaders, they are the future, and they're interfacing across the whole system. So I think there's incredible value in terms of the workflows that this technology lends itself to.

MS. BEITENMAN: And on top of what Dr. Amendola just said, it also opens up the door to be able to benefit the other facilities across the country. So like he was kind of saying, we're trying to set up where we can consult at one facility and we can have that printed on a totally different coast of the country and then have that sent back so we can provide a product to anyone anywhere, that's what digital really gives you. So I don't have to have that patient right in front of me to be able to provide them a product.

And the other thing about digital is there are people all over the place that have learned CAD, they do it as a hobby, they do it at home, they have small printers at home, so we've had a couple of instances where people have reached out to us here in Charleston and have been like hey, I have this idea for a product that I need to use at my facility, maybe it's like a bracket, as an example.

We did an endoscope leak tester bracket, they didn't sell them anymore and we needed to get it up off the counter. So the person at the hospital that reached out to me was actually a biomed and he had designed it by himself, he's like "I know a little bit about CAD, so I did this drawing, if I send it to you can you print it off for me?" So yeah, of course. So we ran it off, sent it to him and he sent me pictures of the leak tester sitting up on the bracket. So that's the other nice thing about digital is it doesn't have to be designed where it's being printed and then vice versa, the person reviewing it doesn't have to be sitting there. So we've done consults with Dr. Amendola where we've just done everything virtual and he's looking at our segmentations and making sure that we're doing things correctly and we're multiple states away. So that's really what that visual workflow opens up to you.

Also, I mentioned a little bit in my presentation, holding those digital files, so if you ever need another one of anything, you have the digital file so you can just go ahead and make another one. So I know in dental, for instance, the stone models, they store those for years. So they have them like stacked up in the dental lab, hundreds of them, but we can just scan those all in and then now they're digital and we have that same exact file, but we don't have stacks and stacks and stacks of models somewhere, so that's another huge benefit, as well.

MR. CORCUERA: Excellent. This next question --

DR. OTOYA: Can I add to that?

MR. CORCUERA: Oh, yeah, please. Absolutely.

DR. OTOYA: I think in terms of training, it has helped greatly, as well, like we've been able to get training from Dmitry, who is probably our expert in cardiac with modeling and segmentation, and being able to interface with him virtually and have him walk us through segmentation training, that's not something that we would've been -- you know, had an opportunity to do without this whole virtual database and being able to connect virtually. So in terms of training it opens up the world, really, for anyone to be able to learn how to do these 3D-printing models and how to segment because you can get training from across the country.

MR. CORCUERA: And speaking with training, Dr. Otoya, this next question is for you, do the fellows have to add a year to their training?

DR. OTOYA: So part of the general surgery, the way general surgery training is set up is it's a 5-year clinical training program with two added years for research. I would say the majority of surgical trainees take those extra 2 years to be able to do research. At certain academic centers those two extra years are mandatory as part of the training program and certain other training, like training programs don't have that be mandatory at all. At VCU

it's not mandatory, but we have the support system at our academic program to be able to go do training not only at our VCU and do research with our attendings, but be able to go elsewhere, as well. So those 2 years are kind of already built into our program and allows us great flexibility to be able to find what we're passionate about and all three of us that are doing this fellowship this year, we're really interested in 3D printing and its applications, and we're really, really interested in research. So that's the great part of about being able to have those 2 years as an option, it gives us a lot of flexibility and lets us really dive into our passions. But yes, it does.

MR. CORCUERA: Thank you.

This next question is for the group. A lot of presenters have mentioned risk and assessing risk to patients. When assessing risk, is there a clinical risk assessment tool used to ensure the consistency from among these decisions?

DR. AMENDOLA: So we in VA are -- we've seen the guidance from FDA in terms of what kind of low risks, the pre-surgical modeling, non-sterilized, low risk, we're still trying to figure out where that is on the continuum and I think what the question really is, is are you doing something risky even though it's considered low risk. And I think we in VA think that we need to be very thoughtful in how we approach this technology, we have to make sure that it's being done consistently within our centers, we have to make sure that the experts within our walls and, quite frankly, without our walls are part of the process, to make sure that we have an accurate representation of what's going on in terms of anatomical representation for a patient, for example, pre-surgical modeling. But again, part of that, as a surgical advocate, is to remind clinicians of full-time limitations with some of these imaging approaches as well as segmentations for these models. And so I think that's part of the consultative component of the three-dimensional modeling as it applies to point of care.

MR. CORCUERA: Keeping in line with risk assessments, this next question is in regards to dental or orthopedic applications and are there any considerations for polymer debris?

MS. BEITENMAN: So I can answer that one. I think when you're talking -- so when you're talking dental, the items, when we're post-processing we're removing all of that debris. So specifically, the dental items, they're being washed before they're cured, they're being cleaned again after they're cured to remove any support marks on them and then we're cleaning them again before we polish them, before we send them over to dental who then will make any adjustments to them and polish them again. So these things are being cleaned to a crazy extent and there is not going to be any debris left on them when they're all said and done and made.

Now, that being said, when they're being used in the mouth, of course, if you're grinding on something with your teeth or if you're wearing something in your mouth that could break if you're eating something, something like that, of course you have a risk for debris, but that's where the importance of those biocompatibility reports come in and this is where the importance of knowing what material you're using and knowing that they've gone through the proper clearances, that's really important.

This is why we don't want any dental practice to just pick up any printer and start using it because oh, it was sold to them as something that they can make these products on. Okay, well, we need to make sure that people understand okay, I may be using this product but is it cleared for this, for what I'm using it for, and on top of has it been cleared, do I have the data that shows it has gone through the proper testing and it is safe for use for the patient and if there is some minor debris that comes off, is it going to be okay. So those are the questions that we really need to get clinical practices to be asking and to know to ask those questions to make sure that the items that they're purchasing are safe

for the patients.

MR. CORCUERA: Staying in line with dental, Nikki, these next two questions are specifically for you. You mentioned that you use intraoral scanners, which ones are they? And do you also use CBCT data?

MS. BEITENMAN: We do use the intraoral scanners, we use the Dentsply Primescan, is the one that we have. We do not use that second data, that I know of, that you asked, but we use the intraoral scanner and then we do use the 3Shape CAD software and the 3Shape analog-to-digital scanner so if we take an impression, we're scanning it in the 3Shape box. So we have done some with exocad, as well, they're very, very similar. I think it's just user preference, honestly.

MR. CORCUERA: All right, the next question is, is there data available for comparison of life span of 3D-printed denture versus a traditionally manufactured one?

MS. BEITENMAN: So I'm sure there is and there's also the same data that -- I've been asked the question about the dental protectors, as well, anything that you're wearing long term in your mouth, so 3D printed versus traditional. That being said, a lot of traditional products are made of different acrylics or also different resins which are very, very similar to the same products they're being -- the same materials they're being 3D printed off of.

So you're going to have similar material properties and a lot of it really boils down to the patient. So if a patient's grinding really bad, obviously theirs isn't going to last as long. And the same like, for dentures as well, depending on -- you know, if someone eats apples every day that's going to be different than someone who doesn't. So it's really dependent on the patient themselves. I personally cannot direct you to any specific data, I haven't done research on it, I'm sure it's out there, though, but the material properties are so similar it really boils down to how the patient treats their products.

MR. CORCUERA: So this looks like the last question that has come in. Are there

requirements around data security and integrity? There is quite a bit of data going back and forth, so it would be necessary to have checks and balances in place.

MS. BEITENMAN: So --

DR. AMENDOLA: I'll take that.

Go ahead, Nikki. Go ahead.

MS. BEITENMAN: I'll just say from the IT side, so the way we have our printer set up is they're all on a VA network's view-in (ph.) which is locked down by an ACL. So when we're pulling data, everything is going behind an ACL and then also being uploaded to the printer that's behind an ACL. So as far as security from the networking side, we are locked down. Of course, government internet, we are locked down. But I'll let Dr. Amendola talk a little bit more about the other side.

DR. AMENDOLA: So we have kind of a robust way that we document the models, we place them into the patient medical record. There's no identifying aspects to the patient's name, their date of birth, for example, on the actual model, the models actually have their own unique serial number. And then also, like Nikki had mentioned, in terms of kind of data security, the IT security side, we try to keep all of our printers on that VA kind of IT back, kind of firewall, in terms of that.

In terms of consent for additional imaging, we have traditional medical imaging. So if clinicians have made the decision to get some imaging based on that, we are able to create the models based on imaging that has already been obtained. But if additional imaging is needed for the model, we will obtain a separate consent. We haven’t done that as of yet because most all of our models are based on what's traditionally obtained for individual cases. And then this is also, just as a general point, this is also part of what we're doing internally with our legal group in terms of deciding kind of the legal checks and balances, as well, in terms of informed consent for that matter, but also in terms of privacy

and then health information and privileged information within the VA for taking care of these patients with this technology.

MR. CORCUERA: So we have one, actually one more question. What elements should a clinician consider when deciding to order 3D-printing services?

DR. OTOYA: Yeah, that's a great question. I think it depends what you're trying to -- like what your goal for that pre-surgical modeling is. So if you're trying to look at arteries, then you have to make sure that the contrast is present, that it's appropriately timed, that the slice thicknesses are small enough. But if you're trying to segment bone or if your question is really more about bony anatomy, so the CT scan has to be different.

It really depends, and I think that's one of the most aspects of having a clinician on your team is really honing in on that question so then you can really identify what imaging needs are present because there's a lot of different protocols out there and most surgeons or most clinicians will know what type of protocol they need to say view a liver or view a pancreas, etc., but really understanding what anatomy they're interested in is important.

DR. AMENDOLA: I think establishing the key clinical question. I tell the fellows all the time 3D printing is not putting pinstripes on a car, it might look nice, but what's the real functionality of it? We have to push the clinicians and say what's the key clinical question you're trying to answer and then how can we use the technology to help answer that? And again, sometimes clinicians will come to us with those requests and we'll say the technology's not going to help you answer that question, so we're not going to necessarily create that model for you. We might create a virtual model for you, we might point you in a different direction but again, is the model appropriate for asking that key -- or answering that key clinical question. But again, getting to that, you have to ask it and that is, I think, that's kind of the threshold to say okay, you have a question, let's see if we can answer it with this model.

MR. CORCUERA: Well, I want to take an opportunity to thank the panel for not only answering questions today and presenting, but also for what they do every day for our patients at VA. With that being said, I want to hand it back over to the moderators.

CDR COBURN: Thank you very much, Bill. And it's been a great panel discussion, thank you for all the great questions to do that and then also the great answers, we appreciate it.

We finished a couple minutes early, so we will reconvene at 3:50 p.m., which is Eastern Time or 12:50 Pacific Time, it's 8 minutes from now, so see you all in 8 minutes.

(Off the record at 3:42 p.m.)

(On the record at 3:51 p.m.)

CDR COBURN: Welcome back, everybody. I hope you had a nice short break there. Before we begin the next session, I would like to remind everybody or just mention that these sessions are being recorded so that we can have a record of these in the future. They will be available online after the workshop for 1 year after the time and we hope that people would take advantage of that, as well, because we've had some really amazing discussion so far.

Our next session will be Outstanding Challenges, so what are the things that we are still addressing, still looking for and wanting to address in the future. Our three speakers for this panel will be a return of Nikki Beitenman from the South Carolina VA Health Care System; then Melissa Oliver, who is the assistant technology program director and the AT design lab director in the Central Virginia VA Health Care System; and our first industry speaker, Henry Pinchbeck, who is the CEO of 3D LifePrints.

And with that, I will throw it to Nikki again to start us off.

MS. BEITENMAN: Thank you, James.

Okay. So for this one, I'm going to be discussing gaps and challenges with 3D

printing at point of care, so this is based on our experience and things that we came across so far. So next slide.

I'll give everyone a second to look over the disclaimer slide.

(Pause.)

MS. BEITENMAN: All right, next slide.

So for this presentation, I'm going to talk through some topics of concern that we came across within the industry. So we're unique in the sense that we have access to people helping us work through many of the regulatory standards, but we also work daily with our clinical staff at our medical centers.

So a couple of the things that I am going to highlight in this talk, number one, utilizing readily available design files. So for that, I'm going to address pulling an STL or a CAD file from the Internet and utilizing it on a patient.

The second thing is addressing individual patient specific needs, meaning when a patient has a unique issue how can we go about developing a solution for them in an appropriate manner.

The third thing is clinical training versus understanding of regulations, and I'm going to talk about the gaps of knowledge between clinical staff versus engineering staff and how the benefit of merging the two really helps us.

The fourth thing is knowing when, where, and how to navigate regulations. Navigating through the website structure of searching for regulations can cause a lot of confusion for a new person trying to get answers; for example, 510(k) exempts but not GMP exempts or 510(k) exempts and also GMP exempts, knowing the different combinations of what's out there and what's required.

And then the fifth thing is miscommunications from sales reps, so we've run into a couple of times where the company tells you all the great things -- hold on one second.

(Pause.)

MS. BEITENMAN: Okay, sorry. I'm battling through a cold, so work with me here. So last thing, working through how these machines are sold to you.

So let's dive into utilizing readily available design files. So as 3D printing has grown substantially, there are many websites being developed that offer free downloads of STL files and object files, and things can be easily obtained and just thrown on any 3D printer. So many clinical staff members don't have CAD training, but having these types of websites available to them offers easy access to find something that they may be looking to provide to their patient that they wouldn't then have to design themselves.

So although this is very beneficial in some situations, it generates a new risk that we need to consider and there also needs to be an understanding that a 3D printed product is not always equivalent to the product that you may have purchased otherwise.

So first thing, many of these websites are based on hobbyist level printing. There are many limitations on hobby-style printers, including materials and software. For example, someone may think that they can use PLA to print a small part; spools of PLA are very cheap and they're very easily accessible and it's probably the most used and recommended material on most of these free websites, but PLA is very weak and it's very highly permeable to moisture and it will deform on a hot summer day. So for example, here in Charleston, South Carolina we have had things deform when we tried to mail them somewhere else. So is PLA great for prototyping? Yes. Is it great for an end-use product for a patient? No.

So second, there has not been testing performed on the item that may be selected off of one of these websites. So many files may suggest that a material to use to print this free file with is great, but that doesn't mean that it's really the material you should be choosing, and let's go to the next slide.

So without proper testing and validating of the part being made with that specific material, it puts these devices at risk of failure, and the last thing that we really want in health care is to make a device for a patient and then have that device fail when the patient is utilizing it. That type of failure would not only potentially harm the patient, but it would also reduce the trust that patient has in you to be providing the care for them.

There should be defined lines between prototyping and testing versus providing a device to a patient for them to go home with and use without being supervised. The developer of the device may not always be an engineer but rather a clinical team member who maybe saw an ad for a 3D printer and decided to bring that printer into their clinic and use it based on someone's recommendation, but that clinical team member may have no further knowledge of the types of materials that are available or the software that's available other than that they just saw an advertisement for it, then they can go and grab the free file from the Internet and away they go and they just are making products.

There really needs to be better education available for the clinical staff members utilizing this equipment, but all staff utilizing the equipment need to understand the risk associated with providing a 3D printed product to a patient. Clinicians need to be able to inform and consent their patients of any type of potential risk that could come along with the product that they're providing. Next slide.

So in the medical field you never know what you're going to get. One of our clinical teams runs into scenarios with patients where they try everything that they possibly have access to on the market but they're still not meeting that patient's unique need and the patient isn't satisfied with the results that they're getting. So no healthcare provider ever wants to be in the situation to tell their patient that they're completely out of options for them. This is where 3D printing can really benefit the healthcare field at point of care. So last year we utilized the expanded access pathway to develop an ear stent for one of our

veterans. It was the first time a 3D-printed product had gone down this pathway for VHA and now that we have done it, we have a better understanding of the process. However, initially navigating the process took us some time. The audiologist at our healthcare facility came to us with the idea to 3D print the stent based on the patient's initial concept for the design. Our goal was to design the product that was going to improve the patient's hearing. It was noninvasive, it could be removed whenever the patient needed to take it in and out, and based on his health history, it was extremely low risk for him. Luckily, we have a great team of people that backed us and they said hey, it looks like you're potentially about to make a medical device.

So we had no idea that we were into that territory, but since we have this national work group, we were kind of hey, red flag, need to look at these regulations. So from there, we started with notifying our IRB and we let them know what our plan was. They initially denied our request, but we really felt like it was just due to a lack of understanding of how we were actually developing and manufacturing this product. Give me one second for a water break.

(Pause.)

MS. BEITENMAN: Okay, sorry for the pause. So once we defined our process a little more to the IRB, they still came back with us and they said what does the FDA have to say about this? So from there, we were really trying to determine what pathway we fell under, so we looked at humanitarian use versus compassionate use, we gathered data and we submitted our proposal through the expanded access pathway for compassionate use. We got the response that we were cleared to move forward, but part of moving forward was that we needed concurrence from our IRB. So once we got the letter from the FDA, we then went back to the IRB again and this third time we did get all the final signoff and they concurred with us moving forward with the patient.

So there were many learning experiences from this, some of which we're still trying to navigate. Healthcare facilities need to know when, that they're developing products, it gets to the point that they need to submit it for one of these pathways and they also need to understand that these pathways exist. And knowing that is something that doesn't come to them in their normal clinical training, which is where there's a lot of lack of communication in this field.

So most importantly, the people in the healthcare facilities that are utilizing the equipment to manufacture these types of devices need to know that IRBs exist, expanded access pathways exist. I can assure you, me, as an engineer, I was unaware of any of these pathways until we got to this point of making this product for our patient and luckily we had people within the VA that could guide us in the right direction. Clinicians are medically trained to provide for their patients but they're definitely not regulatory experts.

So this is where merging together and having a group of people that know how to look to the regulations, but also your clinical team who knows what's best for the patient and knows what's risky for that patient or not, when we're all working together, that's how we can really take care of patients at point of care utilizing this technology.

So in addition to knowing that these pathways exist, the healthcare facilities need to have people on their teams that are knowledgeable of C.F.R. Title 21 and again, until this project came along we didn't know that our products fell into this category, so we didn't know about 21 C.F.R. 812.5 for labeling of investigational devices and we didn't know about the labeling requirements that were in C.F.R. 801.1, so navigating those took some time and took a lot of learning and that's the topic I'm going to address in my next slide.

So as I keep touching upon, medical professionals do not spend time learning about these regulations in regard to medical device manufacturing, especially not quality system regulations while doing clinical training. Rather, they're fully focused on using solutions

available on the market or potentially off-label uses for products to resolve their patients' issues. So 3D printing is not the only medical device fabrication technique that can be used at a healthcare facility and it's not even the most complicated piece of equipment that's being used in healthcare facilities. For example, you have MRIs and CTs that are way more complicated pieces of equipment than a little 3D printer, but there are also several healthcare facilities that have machine shops within them and they utilize subtractive manufacturing or actual manufacturing equipment. So therefore we feel like it might not be the 3D printer itself that introduces the risk, but rather the flexibility and the approachability of a digital to physical workflow that makes personalized medicine directly available to clinicians.

Additional risk could be introduced if clinicians wish to enhance the practice of medicine or scope of practice with new tools such as 3D printing without understanding or appreciating when they may be crossing the line into what might become a high-risk scenario. It's unclear exactly where practice of medicine stops and medical device manufacturing begins, so it would be very beneficial for healthcare facilities to understand where exactly the FDA is thinking on practice of medicine versus medical device manufacturing and utilizing 3D printers for this manner. Next slide.

So one thing I always preach to people when I am talking to peers about 3D printing is just because you can make something doesn't mean you should make it, especially when it comes to healthcare. So a large piece of utilizing 3D printing for healthcare relies on the user of the system knowing when to say no. So sometimes a product is extremely simple to design and there are numerous materials that you can make that product out of; however, just because you can doesn't mean you should. There are many scenarios in a healthcare facility that the healthcare facility community does not really have a clear understanding of within medical device regulations or if those regulations even apply. So they may exist for a

certain medical device out on the field, but if I'm going to try to duplicate something similar with a 3D printer do I still have to follow all of these same regulations? Healthcare facilities already act within a regulated environment that seeks to reduce risk, so we are never trying to make something high risk and we never want to put anyone in a situation where they could potentially be hurt. Despite the similarity to medical device regulation, the difference between the environments are so large -- the environments I'm referring to is healthcare environment versus manufacturing environment -- you can't take a clinician and put them into a manufacturing role and you couldn't take a machinist and put them into an operating room without thoroughly preparing and training both of them.

Therefore, we would really like to see a defined and clear educational campaign on regulations. The navigation of the regulations is also oftentimes confusing. Sometimes you may look up something and you see 510(k) exempt, so you would assume you don't have to follow any regulation. However, a product classification listed as 510(k) exempt doesn't necessarily mean its GMP exempt and many healthcare facilities don't even know where to start when it comes to establishing and implementing a QMS system or let alone what all even goes into GMP in the first place.

So we would really like to see some advisement from 3D printing system manufacturers to make it clear to the healthcare facilities and their customers to let them know hey, if you want to utilize these machines to make these products there are regulations that you need to meet moving forward, especially if you're going to provide products at point of care. Next slide.

So I hate to bring up the topic of COVID-19, as we are all aware of the unfortunate outcomes of the pandemic. However, the pandemic did showcase the capabilities of 3D printers, especially in the time of crisis. So in 2020, the sales of 3D printers to medical facilities skyrocketed when people started producing things such as face shields, ear

protectors, masks, and the COVID swabs. But what did not come along with the sales of all those machines was any information in regard to the regulations that go along with producing medical devices. We did see several companies that stated that you would need to establish a registration with the FDA before they would provide you the design file for the swab. However, there was also communication going around that it was okay to produce the devices under some of the 3D printing companies' FDA registrations, which was not actually accurate.

Lack of medical terminology amongst 3D printing manufacturers seems to be an issue when it comes to understanding regulations. As I spoke about a little bit earlier, in the dental world, I highlighted that a night guard is also known as an occlusal guard, also known as a splint, also known as a mouth guard. So therefore, a typical dental lab, relying upon information provided and advertised to them from a 3D-printing company promoting this product needs to include all of the regulations and all of the clearances that are required. A dentist running his own private practice may purchase a printer under the impression that he can produce guards for bruxism on a printer and in his mind, he was told he could make a splint, so he thinks a splint is the same thing as a night guard.

However, the clearances are not the same. Every sales rep that I have personally ever asked about IQ/OQ/PQ always has the same response to me and that response is always "Let me get back to you." So typically, the ones who are actually trying to sell you the product don't have that deep of information and they need to go back to either the technical side or the people who are actually working on the regulatory side within the company to get you that right information. So to further complicate things, it's not openly presented from the 3D-printing manufacturers that they are not the actual manufacturers of the materials that they are providing to be used into their printers and I'm really specifically talking about a lot of the resins that are available.

So the label on the bottle might read that 3D-printing manufacturer's name, so you just assume that they are the ones that make that resin, right? Wrong. You go and you try to navigate the FDA's website for clearances for that resin that you're going to be using and you're looking for specific product codes based on that 3D-printing manufacturer's name but you're not finding that 3D-printing manufacturer's name anywhere on the FDA's website for any clearances. So then you think this resin has no clearances when really the clearances are there, they're just listed under the actual manufacturer of the resin itself, not the reseller of the resin. But without extensively digging and trying to pry from the people at the company, you're never -- you don't know to look for what you don't know.

So since you're making medical devices, you should be asking for biocompatibility reports on your resin. Given that the 3D printing manufacturer didn't produce the resin themselves, they don't always have the full data on those reports to provide to you. I've been provided letters from companies that just says that they, as a company, are vouching that this resin is biocompatible and it has passed testing, but really we should be saying that's not good enough, show me the data. And on top of show me the data, show me the process that you used to run the test to get that data. It would be very beneficial to see more distinguished labeling requirements, as well as requirements to provide that data to the facilities or the healthcare providers that want to be making any type of products that there would be a biocompatibility concern for. Next slide.

That concludes my presentation on some of the gaps and challenges that we've had so far trying to implement at point of care, and I'll be happy to answer any questions at the panel following this discussion.

DR. DI PRIMA: Thank you so much, Nikki.

Our next speaker is Melissa Oliver.

MS. OLIVER: Thank you, Matthew, I appreciate that.

So today I'm going to be talking about managing very low-risk 3D-printed devices. I am an occupational therapist by background and have been working at the Central VA Health Care System in assistive technology and implementing the use of 3D printing for the past 12-plus years. Next slide.

So this is the disclaimer, I'll give you just a few seconds to review those.

(Pause.)

MS. OLIVER: Next slide.

So as Nikki mentioned, healthcare systems culture is to regulate and manage as much risk as possible, they seek reduction in risk, and they do this through quality management programs or departments that they might have. They run tracers, both internal and external; there are audits that are done on a regular basis; there are regulatory agencies that have specific standards around quality management and healthcare systems; and there are annual trainings for all employees at all different levels. The types of trainings that might occur around quality management will vary depending on where you work within a healthcare system. And then there's also reporting mechanisms that are built into healthcare systems where you can report when risk occurs, when potential risks may happen, and there's annual analysis of those reports that then continue to seek the reduction on risk based on what is found throughout the year. Next slide, please.

So these are just a few examples of regulatory agencies that do exist. OSHA exists around safety in all different types of environments, but especially in health care. There's the Joint Commission that has regulatory standards around running hospitals, inpatient and outpatient care, all different aspects of the facility. And then there's also, an example is CARF International, that's a rehabilitation agency that provides certain standards around certain healthcares with different populations that might be served. None of these organizations currently have very specific -- don't have very specific standards related to 3D

printing or advanced manufacturing. Next slide.

So how can healthcare centers manage risk, what are they currently doing with very low-risk device development? So professional accrediting organizations are starting to look at their scope of practice and how this modality might be utilized within their scope of services. So as a rehab therapist, how can 3D printing be built into your scope of practice, so that's being looked at, at different levels of different professional organizations.

Sometimes it's clinicians' special knowledge, so they may take on, as Dr. Ripley mentioned, you know, she learned on her own how to do segmentation. Brian Layman mentioned about how he took the time to really learn that new technology that was coming out to fit his needs for prosthetics. And so sometimes it's based on experience and trial and error and they learn how things are working for them.

There's also clinical training, so clinical training or opportunities where there might be working with manufacturers, working with the software companies, that they may learn the specific technology that's out there, different CAD design that's out there, and so they're getting specialized training. There are also certifications that exist for advanced manufacturing that individual clinicians can look into.

And then we're also looking to our professional organizations for guidelines, you know, are they coming out with their own guidelines on how to use advanced manufacturing technology within their scope of practice, where do they stand, how does that protect you with your registration, certification, or licensing? So we're looking to those organizations for input and feedback.

And then within a clinical environment, within the hospital itself, there are protocols that might be developed for equipment use and those are going to be very specific to that hospital, maybe even to that department that may set up certain ways to minimize risk as much as possible.

There's also defined technology competencies. I know here, when I was in the occupational therapy department, we had certain competencies on specific equipment that we had to pass on an annual basis. So certain programs or departments within a healthcare system are setting up competencies just internally so that they're helping to continue to minimize risk, increase knowledge and expertise in the use of that technology.

And then there's always safety measures. So healthcare facilities have safety departments, quality management departments, engineering departments that implement and require certain safety measures that might be followed by OSHA, might be followed by the Joint Commission, but also might be internally specific to that facility that you're working at. Next slide, please.

So some examples of professional guidance and oversight that we're starting to see emerge. The American Occupational Therapy Association, actually, their accreditation council for occupational therapy education in 2018, they came out with their wanting occupational therapy students to become competent in various aspects of assistive technology, including the fabrication, application, fit, and training of use of equipment for clients that might be specific to assistive technology.

In that they include emerging technology which encompasses 3D printing, 3D scanning, and they look at it as a modality, a clinical modality that can help them meet the goals of our clients. It is a clinical decision that's within their scope of practice to utilize that technology if they so choose, it's kind of one of the tools in the toolbox that they might choose to use, but they do need to have that training and expertise. There are certifying organizations for dental laboratories that are providing some guidance around the use of fabrication tools including 3D printing, as Nikki mentioned earlier in her presentation around dental. And then there's also the American Board for Certification in Orthotics, Prosthetics & Pedorthics. They're providing oversight, recommendations of resources and

training to help to expand the knowledge and skill set of the professionals within that organization. Next slide.

So now I'm going to go over a couple examples that we've seen in assistive technology or within rehabilitation that have been fairly low risk. And so the first example is a mahl stick holder, so this is for an individual with a spinal cord injury. Our occupational therapists that we work with, you can see the blue foam there, she basically took foam, traditional material that's available in occupation therapy, she sliced it in half and took duct tape and if anyone knows occupational therapists, duct tapes are our best friend, and she just took, duct taped it to a mounting system in hopes that the patient would be able to put the mahl stick in that holder, so that would help to reduce caregiver burden and allow independence for that patient.

With the implementation and availability of 3D printing as a new tool, it added a lot of value to what this one option and solution for this veteran was, which is to increase durability, you know, the risk of the foam is falling and breaking, it was unsanitary after several uses, so this improved infection control. We also wanted -- one of the risks is -- you know, it was going on to a mounting system that could be mounted to the bedside table, it could be mounted to a wheelchair, so it had to be something that was going to be securely applied to that mounting system, so that had to be part of our design because obviously duct tape wouldn't last for a very long time. It's very reproducible. And it ended up being something that wasn't just going to be one individual's need and this could mean a multiple population who had this particular desire to use a mahl stick for touch screens or turning pages in a book and it was fairly low cost and probably even less than the $15 that we have printed there. The next slide, please.

So our next example is with hand splints. So this would be the use of 3D printing for hand splints is more for a chronic need, acute need using traditional tools such as

thermoplastic, splinting -- splint pans and a heat gun would be more cost effective for an individual that just had an acute need, maybe temporary relief from carpal tunnel or something that needed to be applied right after surgery, but someone who had chronic spasticity in their wrist who needed a splint to help with extension looking at new "splinting tools" such as 3D scanning and printing is a viable option.

Some of the risks that we needed to take into account was skin contact, making sure the materials that we use, what the risks were around that, and we wanted to make sure that they were safe, also reducing the risk of skin breakdown. So this is where we included not only the veteran and the engineer, but we also included the occupational therapist that worked with that individual. And so the reason we wanted to do that is we wanted to make sure there were no pressure points so that we could ensure that there would be no skin breakdown, no redness to that individual.

By going this route, the value that was added, it increased the durability, it was reproducible, and so if they broke, which they did initially because we never get it right the first time, we always say this is -- you know, we're going to give it a try and see what works and fix it if we need to and we already have the file, so the patient just has to call us and we can print it again, we can do a telehealth visit and we can figure out what the issues were, why did it break, and decrease the clinician's time which increases their productivity because they don't have to spend multiple hours reproducing, through traditional methods, the hand splint. This is very patient specific, which is why 3D scanning is really important in this process. Next slide, please.

So this example here is really interesting, this is a cane clip holder for a scooter, it actually came to us from the patient advocate's office. We had a veteran who got his scooter and he wanted to be able to safely get his cane when he was ready to walk and to ambulate. The only thing that was available was a bag that attached to the back of the

scooter and every time the patient would reach for it, he became a risk of falling, he had a lot of balance issues, and so we wanted to be able to minimize that risk for him, as the patient. And so some of the risk considerations that we had is we needed to make sure it was going to be securely mounted to a mobile device. Since the scooter was mobile and motorized, we wanted to make sure that when we secured it, it wasn't swinging, hitting anybody, risking to fall off. We also wanted to make sure that the material that we selected was going to be able to tolerate, have that tolerance, of having the cane snapping in and out of it, and so that was really important in the material selection.

You can see our design process here, we started out with one clip, we thought that would be a straightforward solution, we found that that still added a lot of swing to the cane as the scooter was moving, so we added two clips to hold it in place, that made it more secure, and if you'll notice, in the last design, it has three different sizes. As we worked with the physical therapist, we learned that canes come in different sizes and we wanted to make sure it would accommodate multiple cane users and that way it was more universal. Next slide, please.

So our next slide was one of our earlier designs that we did, this was a diabetes test strip dispenser. We had a veteran who had a stroke, he was only able to use one hand, he also was an extreme diabetic, but one of his rehab goals was to be able to do his own test. And so his wife actually had the idea of can we just turn it into something like a toothpick dispenser and I said oh yeah, sure, no problem, that would be pretty easy.

But one of the risks that we needed to take into consideration was would it be a test invalidation and if he poured out too many, what kind of exposure would that do based on heat, cold, or just damage to the strips itself. And so we wanted to make sure that it minimized the number of strips that came out to lessen the risk of exposure and damaging the test strips. And so you can see here in our picture, evolution in our design and we

finally ended up with kind of a half-funnel where the veteran is able to shake out one, sometimes two might come out, and it met his needs and it minimized that risk of multiple strips being exposed. Next slide.

So this example here is for a lip bumper. So we're working with a veteran out of a VA in Pittsburgh and they're wanting to protect his lip, he has involuntary lip biting due to a severe brain injury and it is really damaging his lower lip. And there are some existing solutions and some require a dental procedure that are already FDA approved; however, sedation is not an option for this individual or it puts him at extremely high risk and it's one that the family and clinicians would like to prevent.

We also want to ensure, because he also has some tongue thrashing, anything that we recommend, he could be potentially at a choke risk, so we don't want him to actually have the device that we designed to go into the throat and be a potential choking risk. We want to make sure it's also something that's not easily dislodged.

So we're still analyzing the risk in this situation, we want to minimize as much risk to this patient as possible, we're also looking at types of materials that would be safe to use around the mouth area, and we want to make sure we are protecting that lip as much as possible. Next slide.

So the last example I have is a one-handed blood pressure cuff. So this is a holder for a home telemedicine noninvasive blood pressure cuff monitor for individuals who only have one functional hand or arm. And so some of the things that we have to take into account when we're looking at risk is, you know, is there any safety concerns with modifying a blood pressure cuff even if we utilize this type of holding mechanism or do we need to look at something different than what's pictured here, and does this change the function of the device? So is there any risk of test invalidation based on how the design would be around holding a blood pressure cuff for a one-handed individual? And would

there be any danger to the patient? So we want to make sure that the patient isn't overly squeezed or the pinching of the device or closing of the holder that might be holding the blood pressure cuff, so we want to make sure we look at all different aspects to minimize the risk as much as possible. Next slide, please.

So some additional examples of how you can look at minimizing and managing low-risk devices. When external certifying bodies such as CARF International, which certifies rehabilitation programs, come to facilities, we share best practices about the use of 3D printing both from a patient/person sort of perspective but also from the clinician side and the engineering side. So this is a way to engage communication, look at where standards might be needed and met, and also potentially looking at collaboration and opportunities for advanced manufacturing with accrediting organizations.

Also, we've worked to update job descriptions, so here with the clinical rehab engineers we've outlined very specific technical roles that they have for specific skill sets that are needed around 3D printing and other aspects of advanced manufacturing. Next slide.

So some additional examples. As I mentioned earlier, professional competencies and demonstrating skills are critical. So within rehabilitation, whether you're an occupational therapist, physical therapist, speech therapist, there are specific modalities and tools that are utilized that require annual competencies and demonstrations. For us in occupational therapy, it was utilizing industrial sewing machines, drilling presses, splinting pans, fluidotherapy machines, etc. The same would be said for any skills that are required around advanced manufacturing. And then engineering departments, on a regular basis, are providing safety and maintenance checks. They come around to different areas that are required to have safety checks. Here, we see them walking around on a monthly basis; sometimes it's quarterly and sometimes it's annually, it just depends on the healthcare

organization and the standards that they're following. Next slide.

So recommendations and continued need. You'll start to notice a theme from the presenters that have already presented today. We do need to define a continuum of risk even in the very low-risk category. As you could see from my examples, there's a wide range of low-risk devices that are being designed and produced, but we need to define that continuum of risk. We also need to answer how can we continue to provide immediate patient needs if we're an FDA-registered or a point-of-care medical device manufacturer? It's a question that needs to be continued to be asked in order that patient care can continue to be the first and foremost important reason why we're here in the healthcare setting.

And then a huge educational campaign. Nikki mentioned a few areas, these are some additional areas of education that I think need to be addressed. Medical professional societies could provide educational opportunities around regulatory uses for medical device manufacturing and how that can be implemented in a clinical workforce setting. Also, perhaps the FDA could advise 3D printing system manufacturers to make it clear to healthcare facility customers that there are regulations which need to be met if they are going to use 3D-printing machines to make certain products at point of care.

So in other words, to be clearer in the use of their materials, their printers, and what it actually means in the FDA regulatory process and not just assume; as Nikki said, the language is not the same. And then higher education institutions provide academic training and certification in the use of advanced manufacturing for 3D printing within healthcare as well as around regulatory needs and understanding in the healthcare setting and different avenues that you can follow for medical device development. Next slide.

Thank you for your time and I look forward to answering your questions at the end. I'll turn it over to Matthew.

DR. DI PRIMA: Thank you so much, Melissa.

Our next speaker is going to be Henry and before he starts, I just want to remind everyone that yes, this is being recorded and two, if you have questions for the panel, please submit them through the bubble on the -- I believe it's the center of -- lower part of the screen. And I will say there are lots of questions about very low risk printing and I think this is a great time to talk to people who are engaging in that space.

MR. PINCHBECK: Okay, thank you. Thank you for the introduction there and my name is Henry Pinchbeck, I'm the CEO of 3D LifePrints, and also thank you to the FDA and the veterans association for inviting me to be here today. I think, as you said, I'm the first commercial entity who is talking to you and it's quite an honor. I'm going to talk to you today about our company, 3D LifePrints, and why it's relevant for me to talk to you today about it. I'm then going to describe what we do, which is all to do at point of care. I'll then give you a bit of an overview of where we work in the UK and in the EU and the regulations, and the way that point of care has developed over there. And then I'll flip back a little bit and talk a little bit about your proposals the FDA put together for point of care in the States. But first, let's start with 3D LifePrints. So next slide, please.

So what do we do? We are a designer and manufacturer of patient specific medical devices. You can see one example on the right-hand side there, that is an anatomical model, so a copy of the patient's anatomy. We also make surgical guides and also custom 3D-printed titanium implants. So those are three types of devices, categories of devices, if you will, that we provide.

Just looking at that anatomical model on the right-hand side, that was actually developed from three different types of imaging modalities, you know, from -- that's got CT, MRI, and PET scan have been merged together to make that model and I'm not sure anyone would think that that's not a medical device. The surgeons that were using that to operate

on that little girl to remove that 3 mm (ph.) tumor from her chest, which by the way, was on the BBC and is on the website of the hospital, as well. It was integral to their care of that patient, and as I talk through the next 20 minutes, I think I'll try and explain to you why we think it's so important that these categories of devices are regulated and have a quality system approach, because they very much do influence outcomes.

So a bit more about 3D LifePrints. As I said, we're a UK company, we're set up at the point of care, which means that we embed our engineers within hospitals, I'll describe exactly how on the next slide or two. We also provide remote services. So if we're embedded in a hospital, we can provide our services at point of care, but if there's a surgeon at a remote hospital, we also have a digital platform which I'll try and show you later on, where a surgeon can get in touch and we can interact with them virtually and give them the design files and then send them the devices.

So that's our digital platform, it's called Embedmed; again, I'll try and show you it later on. We work with lots of hospitals across the EU, around 50 on a regular basis, providing these types of medical devices. Most importantly, the last two points I've got here, we are ISO certified, that's a quality certification, and that quality certification covers everything from the moment that a surgeon gets in touch with us and wants to upload some scans to us, all the way through to the point where a medical device is delivered.

Everything within there is covered by our quality management system, which means it's tested, verified, and validated against standards, so we know that exactly that scan that comes to the door is going to be replicated either in a device, as a model, or as a guide or as an implant. And so I said we're a UK company, just opened in the U.S., we opened our first embedded facility in a Texas medical center, we're working very closely with Houston Methodist. We don't have FDA clearance yet for our products; like I said, these are medical devices, I wouldn't want or wish to sell any products in this country until I have that, so it's

currently being reviewed by the FDA and hopefully, within a couple of months we'll be putting our first few products on the market. Okay, next slide, please.

So I've actually stolen this slide here, I'm not sure if you can see the reference at the bottom of it. I've stolen it from Brigitte de Vet, who is an industry leader in custom-made medical devices from Materialise, and I stole this from a meeting that she presented at 2 or 3 years ago in London that I attended and I spoke to her afterwards and asked her for her slides and what she's done here, she's put the three categories that I consider the major categories of medical device, models, guides, and implants, and she said what she thought or Materialise thinks, where should the line be drawn as to who should be manufacturing, designing and manufacturing these devices. She put the line slightly to the left of patient-specific guides.

I think it's my job to move that line a little bit to the right. I want to include patient specific guides into the point-of-care manufacturing in hospitals. And the reason I want to do that are the reasons she's put on the left- and right-hand side here. There's lots of benefits of producing things at the point of care. Access to the data, access to the clinicians, quick turnaround times, all these things are very important, especially if you're working on something like trauma surgery or cancer surgery.

On the right-hand side you can see there's patient specific implants. There are companies out there who want to bring implants to the point of care, as well. I think that's a little bit premature, perhaps, but it's being worked on and we are doing it and I know of another company, too. So I think this will come in time and obviously, we have to balance the regulatory concerns especially about the technical complexity. You're putting metal 3D printers into hospitals, you've got to think about the implications of that.

Okay, so I'll go on and talk about point of care and how 3D LifePrints considers that it can be run. Okay, so next slide, please.

Okay, so this is basically a description of our business model. When we set up the company 5 or 6 years ago, we looked at point of care and medical 3D printing and thought amazing technology, terrible delivery, how can we increase and improve the way that these amazing products can be delivered to surgeons? So what we do is we provide a service to a hospital where we provide them with some staffing; biomedical engineers, generally. We provide them with a whole suite of hardware and we provide them with a whole suite of software. The hospital doesn't pay for those, we provide those. What the hospital does is it buys the products from us.

So what we've done basically is we've set up a medical device company at the point of care either in or very close to a hospital. Sometimes hospitals are comfortable with us being inside, sometimes like at Texas Medical Center, we're just outside of range of hospitals but we're close enough that we can talk to the clinicians, they can drop into our facility, we can pick up the patient data very easily, and we can deliver the product very quickly. And so this is my model that we set up several years ago and this is how we deliver these amazing devices.

On the right-hand side you can see another one of these different types of devices, that's an anatomical model, obviously. You can see the white thing on here is a cutting guide that's designed to cut out that sarcoma as picked out in red. And again, I'll try and show you some more details about those later on. Okay, next slide, please.

So what do we do differently from other medical device companies and why does it involve you guys? So if you're a hospital and you're working in a setting of a point-of-care facility, you're presented with a lot of choices and we'd like one of the choices to be don't do it yourself. If you think this is too big a bridge to cross, you're not comfortable about certain things, we want to be able to provide a full service to a hospital that gives them all of the assets that they need in order to get a great service. Like, if you look at some of the

great hospitals we talked about here, or the Mayo Clinic, they generally don't need what we have to provide, they have a great service already, but a lot of hospitals are still working out how to do this, that's what we do. So we need to provide a point-of-care service by providing an engineer to the hospital, that he works within the hospital, gets to know the hospital really well, or we have this thing like a remote service where a hospital will just order from us on a one-off basis. A big thing for most, we treat every product as a medical device.

Now I'll talk a lot more about the regulations as we go through these slides. The medical device regulations, every presenter has talked about this that I've listened to so far, they are absolutely critical. We cannot ignore the fact that we're making things that either are or are close to being medical devices and they should be treated with the due respect that that means, that that deserves.

Alongside medical devices and the regulatory compliance there's quality control, slightly separate to regulation compliance, you can have one without the other. All of these devices should be created in a quality controlled environment. Ours is ISO 13485, there are different systems available, but that's a very, very rigorous system to ensure high quality and reproducibility of our products. I need to know that a product, that the scans that come through the door, are absolutely going to be represented by the products that go out to the surgeon.

And the last point here is using validated hardware and software. We very much narrowed down the type of hardware and the type of software we use. We validate each piece ourselves, as part of our QMS. We only use reliable and regulated, and in the UK, CE-marked pieces of hardware and software. Okay, next slide, please.

A quick description of one particular type of device that we make. These are custom-made medical devices for surgical guides. So surgical guides are used in either

orthopedic surgery or craniofacial surgery, they attach to the patient for about 20 minutes to half an hour during the surgery and they determine the planes that the surgeon cuts it on or they can determine a line of drilling. And under my rules, in the UK and the EU, these are called Class 2a custom-made medical devices and therefore they have a certain amount of regulation that's required for each one.

We manufacture these in a controlled environment, yes, at the point of care. You can see that gentleman there is our head of engineering, Mike, he is working in a hospital inside a controlled environment manufacturing surgical guides. He's using a Formlabs printer, which we love, they're excellent printers, we've validated the processes and the resins ourselves, but Formlabs has done a lot of that themselves, as well, and we use Simpleware, another excellent piece of validated software.

I cannot drill down how important it is for this verification and validation. Each one of our devices and each one of our pieces of hardware and each piece of software is fully validated so we know what we're going to get. And because we're at the point of care, we can provide these services really fast. We have a 5-day turnaround, we've done it in three sometimes, but that really puts my engineers under some pressure. We have a 5-day standard turnaround, let's say, on delivery of urgent guides. Now, that is much, much faster than you will find a traditional manufacturer doing. It's probably comparable with some of the hospitals and I'd like to think that is the same thing, really. We run the system within the hospital. Okay, let's click on one more slide, as well, please.

Okay, this is an example of some of the surgical guides. Now, we use some of our surgical guides in oncology surgery, so these are osteosarcomas and on the right-hand side here, you can see a model and some guides that are used to cut out an enormous tumor that was present in this poor patient's lower anatomy. I'm going to try to share screens with you and show you this as a digital model which will give you a really good look at it. So

if this goes wrong, please excuse me, but -- here we go. I'm going to share screen and see if that's going to work. That worked. I'm going to assume it has. So here we go, here is our platform, Embedmed, and you can see here is this case that we were working on before. The pink thing is obviously the tumor and the blue things are the cutting guides. Let me see if I can go a bit closer here, yeah. And here's the cutting guides in the back, here's the tumor, the surgeon obviously wants to remove this large -- very, very large -- sarcoma here, which is integral into the bone.

So they have to cut through past the pelvis, so we basically designed these guides with them, you can see them here a bit more clearly at that point, so those are the two products we make. The surgeon then uses those. You can see they've got cutting lines on them to cut through the bone here and here in order to remove an enormous part of bone but also all of the tumor. And again, nobody's going to think that these are not medical devices, these are clearly, clearly medical devices. But in the UK, they're custom-made medical devices. In the U.S., in your system, they'll be a 510(k) because these are available. We make these at the point of care. I think that's the point here, we make these at the point of care and can deliver them in 5 days. That is an achievable target, if you get to the end game with your point-of-care setup. Okay, I'm going to stop sharing and hopefully go back to my -- yeah, I think that worked.

Okay, so you can see that we merged the various results of scan and through this, the CT picks up the bone very well, MRI picks up the soft tissue and the other vasculature, the PET obviously shows the tumor very well, as well. We then make a model alongside it, as well as these, the surgeon gets a bit of a practice go to simulate the removal of the tumor first. Okay, so that's about our oncology. Perhaps you can click one more slide, as well. Here's just another couple of pictures of these guides in use. You can see this guide here has been manufactured in something called -- excuse me, BioMed Clear, which is the

material that we validated, which is a Formlabs material, excellent. It also allows the surgeon to see through the guide to see exactly where it is they're cutting. And you can see here's a surgeon, and I think this is in the Royal National Orthopaedic in Stanmore, here's a surgeon discussing the case, with the model, and I have to say the surgeons find the models almost as useful as the guides. So here they're talking about what they're going to do and this is kind of the implementation of the plan. And again, I think the pictures tell a thousand words. Okay, that's the part about the company covered. If you can click on to the next slide, we'll have a quick chat about the rules, basically, the rules in the UK and the EU.

Well, first of all, thank you to Mr. Boris, we have left the EU, which is a complete disaster, from my point of view, but what can we do about it? That means that the UK has not adopted the medical device regulations, we're still stuck on the old rules, the Medical Device Directive, which is vastly inferior and not up to date. However, the UK government is bringing in a new piece of legislation soon, I'm assured, because I'm in touch with them all the time, and it will replicate many parts of the MDR. The part that I'm going to really concentrate on in the MDR is the part about in-house manufacture or the health exemption, health institution exemption, which basically is very much about point of care.

When we knew about Brexit in our company, we decided to go for MDR level, anyway. Despite the fact that the rules say you have to get MDD, we went to MDR because we want to sell into the EU and also we know sooner or later that we're going to have something in the UK of this level. And also it helps, actually, that a lot of the quality systems within our quality management system also enables us to meet these regulatory standards. But rewind a bit. How does medical 3D printing work in the UK and the EU? Well, a big difference from the States is that we have a big difference between custom-made devices, a description of what they are, and patient-matched devices.

Now, custom-made devices, I'm going to talk about under the MDR, they are basically devices where you start from nothing. You start with a blank piece of paper, you design a device, and it is kind of a one-off custom pure -- it means exactly what it sounds, a custom-made device, custom made for particular patients, start from scratch. And the second thing that's similar is something called a patient-matched device.

Now, if you talk to Materialise, I believe, although obviously I haven't worked with Materialise, they have moved all of their devices into patient-matched devices other than custom-made devices. So they have a design inflow in which they have determined that particular product, anatomical model, guide, whatever it might be, should exist. So actually, they're moving much closer to the U.S. system, I think, where each type of product is regulated rather than the old MDD system, which we're still under, where actually, as long as you're in custom made, you can actually have quite a lot of latitude about what it is that you make.

Now, there's a big misconception that custom-made devices means you don't need any regulation. That is clearly not true -- I should have said at the start of this, I am a lawyer before I started running this company -- that is clearly not true, there is a lot of regulation where it relates to custom-made medical devices, even more so now under the MDR.

So the first thing you need is you need the prescription from a registered practitioner, which could be a surgeon, it doesn't have to be, and that prescription sets up the details of what is required for this custom device. All of 3D LifePrints devices, by the way, are custom devices. And we also need the prescription to set up -- instructing the clinician, and also determine that there is a single patient that this custom device is for. The custom device then needs a full technical pack which includes all the verification and validation, all the risk assessment, all the general safety regulations. There is a lot of documentation that has to sit alongside even a custom device in the EU and in the UK.

And last of all, you need a QMS. And you do only in ISO, I think, for Class 3 devices, but you can have any other form of QMS. But again, I think this is a really -- I'm not going to say it's essential, it's so important that the manufacturer of these devices, whether it be a hospital, whether it be a manufacturer, whether it be an individual or a university, has a really solid quality management system in place because otherwise, how do you know what you are getting? Okay, next slide, please.

Now, I promised you a little bit more detail about how the MDR deals with point of care. So they have some rules about how a hospital, a health institution, they call them, can manufacture custom devices and standard devices for themselves. So the first rule is this, if a hospital makes it for themselves, that can fall into the health institution exemption. I mean, the other points have to apply, as well. But as soon as a hospital or a university or someone else transfers a device, they're placing it on the market, they're treated just like any other manufacturer. So that means any university that's making models has to stop doing so or it has to meet all of the requirements of a medical device manufacturer. No transferal.

Number 2, a quality management system has to be in place if a hospital in the EU, not the UK yet, unfortunately, wants to make custom-made devices.

Three is my favorite point out of here, is no equivalent device on the market. I say favorite because I'm a company and when I read that I thought wow, that's amazing because a hospital wants to make itself an anatomical model or cutting guide, I make those, that's great for me, so therefore what they're doing is they're pushing the bar out -- so they're pushing the bar up so a hospital either has to meet the standards, and they're pushing the money budget out of hospitals, these are the regulators, so that medical device companies take on that responsibility. Very interesting. Next, they require that the device meets all of the MDR safety standards and also to the documentation of the device is made

and the justification is made. So the bar has been raised. The regulators in the EU are trying to put the requirements upon hospitals that they have the same-ish, almost the same requirements, as a medical device manufacturer, which from a patient's point of view, I don't think you get to argue it because this goes straight to risk, it goes straight to outputs, it goes straight to surgical outcomes. Okay, last slide. Excuse me a moment.

Thank you. Okay, for my last slide I'm just going to touch on the FDA discussion paper, which I read with interest, it came out a couple of months ago now, and a great paper. I was really impressed, I think it showed that the FDA is taking this really seriously, is looking at how point of care can be utilized in the best way, and so I picked out three particular points and the three points I picked out are the ways that the system a point-of-care company can implement.

Number one, this idea about a medical device production system, like the idea, it's pretty good. My issue with this is only that I think the people that put together the MDPS, the system, are not going to like the idea that they have the responsibility. So if you're talking about, I don't know, Simpleware, Synopsys, or any of the software companies, or Formlabs or whatever these companies are that are putting the hardware and software on the market, I think this points at that they have to take responsibility for that. They ain't going to like that at all but I think they should, by the way, I think they should. Somebody's got to take responsibility, correct, and I think it should be them. But you're going to get some pushback.

Number two, again, there were high fives from my office when we read this bit because it said that you can have a traditional manufacturer on the hospital site. That's what we do. That's amazing, that's fantastic, thank you very much. You basically wrote my business model 5 years after I did it. But that's what we do for a living.

And the last one is about the traditional manufacturer, the hospital basically taking

on all the responsibility. Again, super. There's some great hospitals, they should definitely do this themselves if they have the capability, if they have the QMS, if they have a tech, if they do all of their testing. And I think, as a last point, what I'd say is I'm new to this market, I don't know it very well. What I've seen, in the short time I've been around, is lots of universities manufacturing for hospitals and then some kind of an indemnity being provided them back and the hospital just saying okay, never mind, we indemnify you, Mr. University, but please make us those models for free. And they do, because it's nice. But I think that that is something you really have to look at because I think that is very, very common.

Okay. So that's me, that's 3D LifePrints and that's a quick whistle-stop tour for everyone, the UK, EU, and a bit about the U.S. regulations.

DR. DI PRIMA: Thanks so much, Henry.

It is my pleasure to introduce everyone to Dr. Nicole Wake, Regional Director of Medical and Scientific Affairs, GE Healthcare. I've known her for a while back when she was still not yet a doctor and this is going to be a great session. Just for some timekeeping, we're going to aim to close the Q&A at about 5:25, so we still have some time for some closing comments.

DR. WAKE: Thank you for having me and thanks for all the great talks in this session.

So I want to start out with asking you guys a question about risk, so there are many applications and you guys gave some really nice examples of really nice models. I think one of the challenges is defining risk and risk can be involved in the 3D-printing process or the use of the device, so how do you guys define risk?

MS. OLIVER: I can start. So I think it depends, you know, you have to take into account the scenario, the type of device that may need to be modified or developed. For us, we look at worst-case scenario and work from there. We look at the risk of the

materials that are out there and the purpose of that. We take into consideration during the design process the different risk scenarios that can occur, kind of "what if" types of things. So I think it is variable, but we all -- here, at least, we look at worst-case scenario but also looking at the materials and the printers themselves and the risk around those.

MS. BEITENMAN: I was going to add to that, from our side, we -- similar to what Melissa said, it really is dependent on the situation and dependent on what you're making and the type of material that you're using and, of course, for us, from the engineering side when we're working with clinicians, the first thing we always say is I want you to take that and I want you to try and break it, and they always look at us like we're crazy and we're like no, seriously, break it, because if you can break it, that means there's a problem. So that means we're going to turn around, try to make it better.

So we put everything we make through some abuse, literally, we've thrown pieces like on the floor, into the wall and tried to break them. So that's one way on the engineering side, we're looking at it to assess okay, did I make it good enough? And there are some situations like maybe you're making a soft -- something that's soft, so you're not printing a hard material, and then your question is more is it going to tear? So depending on how it's being used, it might be okay if it tears. So it's really, really scenario based and just working with the clinicians very closely and understanding exactly how the product is being used is what helps us work through the risk of that product.

MS. OLIVER: And one other quick thing I would want to add is you need to ask the question should we be printing anything at all.

MS. BEITENMAN: Um-hum.

MS. OLIVER: So a good example would be an axle for a wheelchair, should we really be 3D printing or manufacturing that or just going back to the manufacturer themselves with the 3D printer or the wheels to address that.

MR. PINCHBECK: Yeah, from my point of view, I actually know this absolutely, we have like a motto, it's first do no harm, right, first do no harm and once you've got past that hurdle, then let's think about what we can do. We turned down so many jobs during the COVID period where people wanted to fix something, do something, shortcut something, and we couldn't -- there were certain places where we weren't sure we weren't going to do more harm than good.

And so for example, somebody wants us to print a part for a ventilator, I was like whoa, we're not going to print a part for a ventilator, you need to speak to the manufacturer of the ventilator. Unless it's an absolutely life-threatening, critical situation, then we should not be 3D printing that, that is a part that should be manufactured by the manufacturer, otherwise you invalidate the warranty, who knows what's going to happen with that. So we need to go through the process. Each medical device you make, or if it's not a medical device, needs to have a complete thought process behind it and that doesn't happen just because you have a 3D printer. These are very dangerous to have lying around the place, I think, and I think that the thought process should be very clear and they should be kept in the hands of professionals. It terrifies me sometimes when I see them lying around on everyone's tables, just "oh, hey, we just made that" and stuck it into a patient. Okay, right. Well, I just don't think that's okay, but that's just one, I don't think that's okay. Full stop.

DR. WAKE: Yeah, no, thank you, I guess. And a follow-up question to that. For anatomic models, do you think that they are truly low risk? How would you characterize those? Like a medical model that you make from imaging data that you give to a physician for planning or for a trainee for education or even a patient for education.

MR. PINCHBECK: So I'm very happy to address that. I think the answer is no, I don't categorize them as low risk. I think when you categorize them low risk, you're devaluing

the model itself. I think the model should be useful and it should be relied upon, and the same as any other medical device, it should be. So if a surgeon's going to have something that doesn't mean anything, why are you making these in the first place? I think that a model should be representative of the anatomy and it should be useful.

One of the previous speakers said you should look up what the reason for the model is. If the reason's solid and the model's going to be useful, and yes, of course, it's going to be useful to the surgeon and it's not low risk, no. On the tumor model that I showed you, if we got the aorta in the wrong place in there and they cut the aorta, I mean, that's not low risk, that's life and death. So I think that if they use the communication, very different. I don't consider that to be a medical device. If they use it planning a surgery, in the surgery, you determine what the surgeon does, then I think I they are outside of the low risk.

DR. WAKE: Thank you.

Melissa, Nikki, anything to add?

MS. BEITENMAN: The add-in from the VA side, we do feel that you can take a lot of that risk away by having the trifecta of the imaging champion and the clinical champion involved with an engineer who might be making it. So I do agree with you, if it's in the wrong hands, yeah, you have a lot of risk there. If you make an error in segmentation, that is scary, of course.

However, how we're trying to work this is to set up the process where, at our facility, so an engineer is doing the segmentation; however, the surgeon initially asks the radiologist for the model, the radiologist comes to us, gives us the imaging and we go over the imaging with the radiologist first, then we do a segmentation. We then have the radiologist log in and look at what we segmented and verify that we did it correctly, and then we have a surgeon look at it and say yes, you hit all the anatomical features that I was looking for, and then we send it to the printer. So we're doing all of these double-checks before we even

print the model in the first place. So from there, we do feel like you take some of that risk off if you have all those people involved while making the model. But Henry, I do agree, if it's in the wrong hands, then you got problems.

MR. PINCHBECK: You know, I think what you're doing there is absolutely right, basically what you're doing is you're going through the steps for a quality system, you know, that's what you're doing. You're ensuring by those very different steps that the product that's going to come out the end is going to be representative of that, but I think that's all that's required here is there needs to be a system in place by whoever's making these products to ensure that the medical device that comes out the end is correct.

DR. WAKE: And would you guys be able to describe more about what those systems look like? Obviously, it's really important that these models are accurate and we want to ensure the best care of our patients. Like, what does the system look like? Like you did, Nikki, a really good explaining with the radiologist and the segmenter and checking. Henry, do you have any comparable systems in place that you could share with us?

MR. PINCHBECK: Yeah, absolutely. I mean, we have similar sort of systems honestly, in that we have internal checks, we have validation by the surgeon on the digital model before we print, we also go back to the scans each time. But also, we have verified pieces of software that you use on the way and the hardware that you use on the way.

So I've seen again another terrifying thing, you speak to some hospitals, a surgeon, and they say "oh, I got some software off the Internet, it's amazing, it's free and you just do segmentation and it works like a dream." That's nice, maybe it was good, maybe it wasn't, who knows? But that, I think, is what we need to do is make sure that the systems that we use are verified and the steps in there are consistent and are replicated for each one. So for example, when we make surgical guides, which are a slight category above models, there's a really distinct measuring step that goes on at the end. With models, yeah, we classify them

-- they're already classified as Class 1 in the UK and surgical guides are like Class 2a, so they're actually a class beneath them in terms of risk, and I think that's bad. I think they are less risky. But therefore, we have a different kind of measuring system at the end in order to verify the models as we do for the guides. So I think it's a risk-based approach and what we don't want to do is stop people making these things, right? We have to have a system in place that allows people to manufacture them in a safe environment. I think once you get through those steps, if you put an ISO in place, it will cover all of the steps that you need in order to produce an anatomical model safely. It's not rocket science, it just needs a process to be followed.

DR. WAKE: Yeah, and I guess adding to that, Melissa and Nikki, do you agree that it should be different based on risk? Like, do you guys have the same kind of system no matter what the model is or do you have it vary, based on what your level of risk assessment is?

MS. OLIVER: Yeah, are you talking specifically about medical modeling or any device?

DR. WAKE: Any device.

MS. OLIVER: So I would say it's similar. For example, for assistive technology, we may not have a radiologist involved but we're going to have the therapist that is treating the patient involved, we're going to have the patient involved, and we're going to have the engineer involved. And so we still try to follow that same model as well, it just doesn't include the imaging aspect of things unless it's 3D scanning around some orthotics and prosthetics, then we would include the prosthetist as well as the clinician, from a rehab perspective, and the engineer in that design, development, and testing process.

DR. WAKE: Nikki?

MS. BEITENMAN: I'll add to -- you know, I'm an engineer so I'm always going back to

the clinician and I've pretty much just taken the stance that myself and any of my staff that work in my area, we don't make clinical decisions because we are not clinicians. So that's where I stand, no questions asked, you need a clinician working with you for anything you're making for a patient. And I think that what is important is engineers need to have that mindset and have the understanding of you're treating a patient but you're not medically trained to treat that patient, so you need to be working with someone who is.

And going back to a little bit about what Henry said, too, even for the anatomical models, so what we're trying to work on within the VA is setting up a plan for okay, if we get a heart case, who are we going to assign that to, or if we get a kidney case or a neuro case. So we have people that are very specialized in certain areas and you want that, you want someone who really knows what they're looking at. So of course, we are all cross-trained, but we do have people on our staff that have really good little niches and they've done numerous things over and over. So if I get a heart case, I'm calling Dmitry; if I get a neuro or a spinal, I'm calling Brian Burkhart. So we know who to go to and having those resources with you and having those people who have the proper education is really what you need to have in place.

MR. PINCHBECK: I think that's really good, Nikki, we're the same, honestly. We have expertise within different sort of bonds within certain people within the company. And I think that the other thing that factors is that expert kind of builds a rapport not only knowing their subject, which is obviously very important, so they know cardiology, for example, but they build a rapport with the surgeon, they know what the surgeon wants. While they're not making clinical decisions, they can anticipate what is going to happen, which cuts down the time, makes it more efficient. So I think that another benefit of the point-of-care model is that the engineer and the surgeons get to know each other really well and that means that the whole process works better and faster, you know. So the first

one's a bit clunky because the engineer is still learning. Second one still, but by the tenth one that they do, they're flying, it cuts down the time by half. And one of the big issues that we're presented with is the amount of time engineers spend doing segmentation and design, and I believe there are some automatic software pieces out there that try and do the automatic segmentation, some of them are pretty good, but they're not all the way there yet. If we can bring the time down and segmentation down so the engineers can spend more time designing and doing the clever bits, then that's all the better for me. I just see the automatic segmentation as a tool to get us further down the line quicker.

(Cross-talk.)

DR. WAKE: Oh, sorry.

MS. BEITENMAN: So sorry. I totally agree those automatic segmentations are extremely beneficial, but I agree with you, they're not a hundred percent. So even if you use the automatic, you still have to go back and double-check the automatic. So you can't 100% rely on the software itself, you still have to go back and look and make sure it did it correctly.

MR. PINCHBECK: Like 50%-50%. You know, most of the time you need to -- almost in every case you have to go and fix something.

DR. WAKE: So training is definitely a challenge. And thanks for sharing those small details. What do you think that we could do better to train our engineering staff or even our medical professionals to better understand the risk associated with devices or even what type of clearance is needed for medical devices and how you started to address that at each of your places?

MS. BEITENMAN: I'll say for us, really when you're doing these, you learn them by way of experience and unfortunately, I feel like 3D printing is kind of like done as a whole because there is not a formal education for it, you can't go to school for it, you can't

possibly learn every 3D printer that's out there, every material that's out there. There are new materials coming out, it feels like weekly, honestly. So you learn all these things by practicing, especially with segmentations. Me, being an engineer, coming into this and trying to learn the anatomy and things of that nature, we have so many little, like cheat anatomy books that we're looking up to make sure we actually segmented the right anatomy, but that's what you need and you get there by practicing. And of course, you don't want to practice on true cases in the heat of the moment, that's not when you should be learning.

So VA is really trying to build this whole education structure behind segmentation, so we've put together a boot camp, we're going to have everyone get together, go through a ton of cases, look at cadavers, and really I know Dr. Amendola will be chiming into this. Melissa, you can chime into this.

MS. OLIVER: I will.

MS. BEITENMAN: Dr. Amendola is huge about putting engineers into the OR. So he wants the engineers to be in there and actually witnessing what is happening during that surgery so then the engineer can understand oh, that makes sense, that's why you want to see it in a model, so then I know better what to put into that model.

And Melissa, you work with him all the time, so I'm sure you can chime in more.

MS. OLIVER: And even kind of a bigger overview for VA, and Dr. Amendola really led this effort, is we created -- you know, it's an online course that's available to any employee at the VA about what is 3D printing, how is it being utilized, how is it being utilized for medical modeling, just for number one, awareness, knowledge is key. And so if you don't know that it's out there, it's happening in your healthcare system, then that's a disservice to our patients and our veterans. And then we are working, as Nikki talked about, developing educational opportunities within the VA for VA employees on different aspects of the use of

3D printing such as the segmentation boot camp. We'd like to continue to expand that in different areas of application for 3D printing and advanced manufacturing, and that's a process. In addition, most of the people that have presented today, I know, are working with their academic affiliates, with their universities, on training the next generation on the use of 3D printing and what is needed, working with our professional organizations on adding that to their educational curriculum and adding that to continuing education.

What I don't see happening as much, and which Nikki and Henry have talked about, is the education of regulatory guidance that's required. Whether it's in the EU or UK or here in the United States, you don't really get that training unless you went to school specifically for that and I think that's really a need that needs to go across the board. Whether you're a manufacturer, a medical manufacturer or a healthcare employee or an engineer, I think that's critical.

DR. WAKE: Thank you. When you guys are doing segmentation, let's say you're just starting cardiac or you're just starting orthopedic applications, do you have a minimum number of cases you think the engineer or the user should go through and then how do you grade their competence?

MR. PINCHBECK: Yeah, we have a rigorous system, actually, in 3D LifePrints which we've built over the last few years and we have -- I think we need -- I think it's 10, I mean, I'm not involved in the training, I'm the CEO, unfortunately, so I can't do that, but I think it's 10 cases before you get let up on and do one of your own.

So you have to shadow them, do cross-cases, just what Nikki was talking about. You can go back over previous cases and redo the segmentation and then you can compare it to the segmentation that the engineer did the first time. And I think once you've achieved that, it's not like you're left off on your own, you just run off to do your own cases, still checks and balances need to come in. Even the best segmenters can have a bad day, right?

It's a very, very detailed time consuming difficult job segmenting some anatomy. So therefore, we always have -- when something's been segmented, it's checked by a second engineer and it's checked by the surgeon in their group. Surgeons, obviously, quite often they just say yes because they're busy and they're not looking at things and you need proper engagement. We found the best way is to have a second pair of eyes within the company, go back to the original scans, check what segmentation has happened, then you can see, "Oh, look, isn't that something you missed?" "Yes." "Okay, fair enough." So that's how we do it and I think there has to be some check and balance in the segmentation and the training.

Just one more thing I was thinking as you were saying that, it used to be, when we started the company, we went out there and hired people who could 3D print and so who can do 3D printing, that was interesting, that was our first question. That's our last question now. Our question now is do you know anatomy, do you know anything about surgery, that's the first question, because teaching 3D printing is much easier than teaching anatomy and surgery and those are the things we look for first. If you can segment and know anatomy, I can teach you how to 3D print, so that's the way the skills like it.

MS. BEITENMAN: It's actually funny you say that because now my first question to everyone is do you know what CAD is?

(Cross-talk.)

MS. BEITENMAN: So if they say no, then I'm like --

MR. PINCHBECK: Yeah.

MS. BEITENMAN: Because like you said, I can teach the printer, but the CAD work and the segment work is where it really --

MR. PINCHBECK: Segmentation, you have to get to a certain level before you can be competent and that certain level is quite a lot of cases.

DR. WAKE: So we only have a few more minutes, so I'm just going to go to a couple of questions from the audience, so this one was for Melissa. You talked about both your clinical training and risk with each of the assistive device examples you shared. From your experience, was the consideration of risk-benefit a natural part of your design process before you had exposure to the quality system, good manufacturing practices of the Office of Advanced Manufacturing?

MS. OLIVER: Absolutely. As an occupational therapist, and as Henry mentioned, you do no harm. You know, any type of approach or treatment or modality that I use with my patients, risk is part of that and so that's just a natural evolution of my clinical decision making and processing that I do and so just adding 3D printing and a quality management system was natural for me. It wasn't something that I didn't think about, it's more now of getting used to having to do all the paperwork around quality management systems, that wasn't necessarily required for just basic medical documentation for what I was doing with the patient but yes, that's natural to what we do as clinicians.

DR. WAKE: Okay, thank you.

Another audience question and this one is for Henry. Are you currently embedded with and providing products to any hospitals that are also 3D printing products on their own in addition to the products you're providing? And if so, how are these activities balanced when in the healthcare facility and are any 3D printing or space resources shared between the two of you?

MR. PINCHBECK: Yeah. Yeah, we have done that a couple of times. It does get a bit complicated, obviously, because we either need to own it or not own it in terms of each product that's made. So for example, if the institution has a printer, then we can share the printer provided we validate the printer. But if we're going to make a model together and we couldn't have them do the segmentation and us do the printing or the other way around

unless we validate it all the way through. So that's the problem for our regs because if we're going to work together and like I say, we have done it on several occasions because for example, we can do some things that some hospitals can't. Merger of scans, certain types of models, certain types of cutting guides, custom implants, a lot of hospitals aren't going to be comfortable making those but they might be comfortable making models or maybe we can just help them with the regs, you know, we take them through the processes, help them set up their own quality management system, that kind of stuff. So yeah, we definitely can work with hospitals that are already printing, we just have to have some really clear lines about who's doing what.

DR. WAKE: Okay. Thank you so much and then with that, we are unfortunately out of time, but I'd like to thank all of our panelists for participating. I think this was a really engaging discussion and I really appreciate your time.

DR. DI PRIMA: Thank you, Nicole, and thank you to our panelists. And I actually want to thank a lot of people right now, it's been a highly successful Day 1 and I'm really looking forward to tomorrow where we can talk more about quality management systems, which I think is always a weird thing to say, but I think we've really set up a really interesting narrative here with what VHA's been doing.

And I also want to thank our non-VHA speakers, as well as our great moderators who have come in to really help communicate all of this. And there's another person I need to thank, you haven't seen her yet, but we have Kirstie Snodderly from the ASTM AM Center of Excellence working on the back end with my team to get all the questions from the -- the system where everyone's putting them into the system where the moderators can see them, so that's been a great help. And again, this has really been a huge labor for a lot of people, I mean VHA's been talking about this for a while. I don't know if people remember in some of the early press releases coming out in 2014 and 2015 where FDA was talking

about technical guidance as well as some sort of printing in a hospital policy, so this has been a long time coming and even from what we were presenting in 2019, there's been a lot of changes from what we initially presented to the discussion paper and that really came out of all those early conversations we had with you all. And this is a really key thing because there are lots of stakeholders in this space and we're going to have to get broad agreement across the clinicians, the traditional device manufacturers.

We're even hearing things from printer manufacturers and material suppliers. We're going to have some standards people talking, accreditation has been mentioned, so there's going to be a lot of work that we need to do to get this across the finish line. And as part of that, I do want to mention again that there is a docket for this workshop and if you have thoughts, comments, really any feedback that you want to give to FDA, please go to the docket and provide that for us.

And with that, I want to say that we are meeting at the same time tomorrow. There is a different link, so you should have received two links when you registered. Please don't use the same link for today, I'm pretty sure it's not going to work, so make sure tomorrow 12:00 Eastern, you're clicking on the right link and I'm excited to see everyone tomorrow.

(Whereupon, at 5:28 p.m., the meeting was adjourned, to be continued the following day, Thursday, March 17, 2022 at 12:00 p.m.)

C E R T I F I C A T E

This is to certify that the attached proceedings in the matter of:

VIRTUAL PUBLIC WORKSHOP - 3D PRINTING IN HOSPITALS: VETERANS HEALTH ADMINISTRATION'S EXPERIENCES IN POINT OF CARE 3D PRINTING OF DEVICE AND IMPLEMENTING A QUALITY MANAGEMENT SYSTEM

March 16, 2022

Via Microsoft Teams Videoconference

were held as herein appears, and that this is the original transcription thereof for the files of the Food and Drug Administration, Center for Devices and Radiological Health, Medical Devices Advisory Committee.

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