Centers for Medicare & Medicaid Services
Transitional Coverage for Emerging Technologies Listening Session
March 31, 2022
3:00pm-4:30pm

Webinar recording:
https://cms.zoomgov.com/rec/share/bSOTBxaodwHTbZkxcl4hMk4otd208mI_8uTRDdaD6obW6ONtSw09j0W8QqkmL_c.qd_RlI2gftZydsKD Passcode: Y19flc&6

(For questions please email MCIT@cms.hhs.gov)

Stefanie Costello: We'll just give it a moment as folks enter the room and we'll get started. There we go. Welcome, I am Stefanie Costello, Director of the Partner Relations Group in the CMS Office of Communications and I will be your moderator today. Today's listening session is an opportunity for CMS to obtain feedback from stakeholders to help inform coverage process improvements, including our development of an alternative coverage pathway to provide transitional coverage for emerging technologies. As such, we are not gathering written comments or taking questions through the Zoom platform. We will not be responding individually to comments made or answering questions asked during the comment portion of this call. The Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's disease NCD will not be addressed on today's call. The public comment period for that NCD is now closed and the final NCD is due on or before April 11, 2022. This session is being recorded and will be transcribed. Please do not speak if you object to the recording. Also, this call is not for press. Like everyone, press are welcome to listen to the call but press questions need to be directed to the press office's resource on the cms.hhs.gov website or sent to press@cms.hhs.gov. After some brief initial remarks, we will open the floor for comments. If you wish to speak, please raise your hand in the Zoom platform. We will do our best to get as many speakers as possible. Each speaker will have no more than three minutes. We are keeping an eye on the time and will politely ask those speaking to finish remarks at time. And with that, I will turn it over to Dr. Lee Fleisher, CMS Chief Medical Officer and Director, Center for Clinical Standards and Quality, CCSQ. Lee?

Lee Fleisher: Good afternoon. I would like to thank all of you for joining our listening session today. As I've mentioned before, improving and modernizing the Medicare coverage process continues to be very important to us and we remain committed to providing stakeholders with more transparent and predictable coverage pathways. CMS is working as quickly as possible to advance multiple coverage process improvements that provide an appropriate balance of access to new technologies with necessary patient protections. As part of this effort, we are conducting several listening sessions to learn about stakeholders' most pressing challenges and to receive feedback from stakeholders about which coverage process improvements would be most valuable and I would ask you to be specific. We appreciate the helpful feedback we received during the first listening session on February 17 which highlighted a wide range of stakeholder concerns. During that call, stakeholders expressed support for coverage process improvements and a new pathway that is more flexible,

transparent, predictable and collaborative. Additionally, we heard that stakeholders would like for CMS to develop a more agile, iterative evidence review process that considers real-world evidence and fit-for-purpose evidence study designs. Stakeholders also asked that any new coverage pathway should coordinate coding, payment and benefit category determinations. This feedback from the first listening session informed the agenda and framework for today's session. We look forward to hearing more of your thoughts today on how we can better achieve coverage process improvements. Thank you again for your participation today. Now I will turn it over to Lori Ashby, Senior Advisor, Coverage and Analysis Group.

Lori Ashby: Thank you, Lee. And thank you all for being here today. As Lee mentioned, this is an important topic for CMS and we value your feedback. During today's listening session, we would appreciate receiving feedback on the following questions, which you'll also see in a slightly abbreviated version on your screen. The first question is, do stakeholders find CMS guidance on acceptable outcomes and duration of follow-up useful within specific therapeutic areas? Question two, engagement with CMS should occur after the results of pivotal clinical trials are available, but early enough to expedite coverage after FDA market authorization. As we streamline the coverage review process, what is the appropriate timing of stakeholder engagement with CMS? Question three, as we work to provide a more collaborative evidence development process, what are stakeholders thoughts on: A) Should CMS provide early feedback on strengths and weaknesses of the available evidence based on a preliminary systematic literature review? B) should manufacturers propose a fit-for-purpose evidence development plan to resolve any evidence gaps identified during the preliminary systematic literature review as part of the national coverage determination process? Question four, how should CMS approach evidence development requirements for similar devices that are FDA market authorized after a Coverage with Evidence Development decision is finalized? As mentioned, today's listening session is an opportunity for CMS to hear stakeholder feedback and we will not be responding to the comments made or answering specific questions asked during the comment portion of this call. We appreciate your feedback and look forward to hearing from you. And with that, I'll turn it back over to Stefanie.

Stefanie Costello: Great, thank you Lori. We will begin the listening session portion of the call. Please use the raise hand function and I will call on individuals and you will be unmuted to make your comments. Again, please limit the comments to three minutes or less. We will provide time reminders in the chat box. And with that, I will call on those with hands raised and the moderator will unmute your phone line. We will start with Joseph McTernan.

Joseph McTernan: Good afternoon. Nothing like going first, so hopefully I will set the bar relatively high. My name is Joe McTernan, I am the Director of Coding and Reimbursement Services, Education, and Programming for the American Orthotic and Prosthetic Association. AOPA for short. AOPA represents over 2000 providers of orthotic and prosthetic patient care as well as various manufacturers and suppliers of orthotic and prosthetic product components. My comments will actually be very similar to those made by a colleague of

mine, Peter Thomas, who represented a group called the O&P Alliance during the first listening session, and that is really tied to the desire and the feeling that CMS should really examine processes that will allow new technology to enter the marketplace in the most efficient way possible to expand and allow Medicare beneficiaries crucial access to new technologies. For prosthetics and orthotics especially, things develop very quickly. Technology is moving and new procedures, new products are coming to the market all the time. One of the things that we are finding is that not only are there delays, year long delays often times, not only in coding decisions but also coverage decisions but often times frankly in benefit category decisions where technology may be coming to the market and before a coding decision can even be made and even a coverage decision can be made at the CMS level, there are delays in figuring out exactly where it falls in the scope of the Medicare benefits program. An example of some recent technology that's come to the market involves some upper extremity orthoses, where CMS has spent two to three years now in a feedback loop of trying to figure out if it's an orthosis or not an orthosis because they are trying to figure out whether it actually supports a body point or body part or weakened member or does it move a body part or weakened member. While this is all being done behind the scenes, unfortunately Medicare beneficiaries do not have access to this technology. Not only does it affect Medicare beneficiaries, but because so many private insurers are reliant on Medicare coverage guidelines, often times there is no benefits, no coverage decisions that happen in the private sector as well. We really urge, we know the MCIT rule was withdrawn but there were some very, very good parts to the MCIT rule that we felt were going to help improve this process so, so we would strongly encourage CMS to take the best parts of that rule and maybe build on that rule moving forward as you consider coverage of innovative technology moving forward. I will yield any remaining time. I very much appreciate the opportunity to speak today.

Stefanie Costello: Thank you very much. Rita Redberg. Rita, can you unmute?

Rita Redberg: Thanks very much. I am Rita Redberg. I am a cardiologist and Professor of Medicine at the University of California San Francisco. I have served on and as chairperson of the Medicare Evidence Development and Coverage Advisory Committee and am a former Medicare MedPAC commissioner. I am speaking now as a cardiologist and on behalf of patients. I take care of Medicare beneficiaries. It is absolutely essential to have new technology on the market that is helping patients but I think the key point that hasn't been addressed by other comments that I have heard in the last listening session is that a lot of the Breakthrough technologies and Breakthrough devices have not actually been shown to be safe and effective. There is a lot of emphasis on getting things on the market quickly but this unfortunately has come at the price of not demonstrating safety and not demonstrating effectiveness. And that the increased use of surrogate markers, very small trials, and all kinds of other issues mean that they don't meet the criteria of safety and effectiveness. As you know, Medicare's duty is to provide reasonable and necessary treatments to Medicare beneficiaries so that is the obligation of Medicare and it absolutely would be remiss not to assure reasonable and necessary which means there has to be evidence that the new technology

benefits patients. Just being a new technology is not a reason for Medicare coverage and so I think it is incredibly important to keep the criteria in mind and then work with stakeholders so that when new technology is being developed and is being considered for Medicare that there is evidence of clinical outcomes benefit in the Medicare population. There is talk about post marketing requirements but unfortunately from multiple studies I have done with colleagues at UCSF and others, post marketing studies don't happen and when they do happen, they take many, many years and there has never been an instance when the FDA has then revoked an approval even when a post marketing study has shown not just lack of effectiveness but danger for Medicare beneficiaries. And I will also note that the speeding up of the process is really shifting the costs of clinical trial development from the sponsor which generally is the one that should be doing the randomized controlled trials before FDA approval to taxpayers because now Medicare is covering these very expensive devices that haven't been shown to be safe and effective. I will note that the coverage with evidence pathway which I believe is a good middle ground towards getting things on the market quickly but still getting randomized controlled trial evidence does assure that we will have trials that look like Medicare beneficiaries because a continued problem for the last 20, 30 years or more is that Medicare coverage is based on trials in people that are much younger, much healthier, because they have been excluding people with comorbidities are eliminated and therefore the data does not reflect the Medicare population. Medicare has to make decisions based on the Medicare population. I think it is important to get new technology on the market and definitely to be flexible, to be transparent, and to be collaborative. It is also incumbent upon Medicare to make sure it is reasonable and necessary for Medicare beneficiaries and that means improving clinical outcomes. My concern, and this is my last comment, is with real-world evidence, is that real world evidence doesn't tell me anything with my patient who would have been better off not getting this technology. Real world evidence cannot substitute for randomized control trials. It can add to data if we already have randomized controlled trial data showing benefit but it cannot substitute for it. Thanks very much. Really appreciate your attention and your work.

Stefanie Costello: Thank you for the comments. Next, we have Daniel Waldmann.

Dan: Thank you and good afternoon. My name is Dan Waldmann and I'm Executive Vice President for Health Policy and Reimbursement for the Medical Device Manufacturers Association. On behalf of the members of MDMA, thank you for another opportunity to engage with CMS on accelerating beneficiary access to new life-saving and life changing medical technologies. We appreciate the Agency's commitment to moving forward with the transitional coverage for emerging technologies rulemaking and its outreach to stakeholders in advance of the proposed rule that includes not only the second listening session but also includes Dr. Fleisher's participation at the TCET webinar held earlier this week by Stanford Byers Center for Biodesign and the Duke Margolis Center for Health Policy. Thank you also for distributing the questions that highlight the specific areas for which CMS is currently seeking stakeholder feedback. We'll be discussing these questions with our members and plan to provide feedback as a follow-up to this meeting. Today I want to make two important points. As we have stated

previously, MDMA strongly supports the creation of a dedicated coverage pathway for emerging medical technologies, meaning a pathway that is separate from and additive to the currently available coverage pathways. Creation of a Breakthrough technology coverage pathway is the subject of bipartisan legislative proposals in Congress. It also enjoys strong support from Medicare stakeholders. That support reflects the belief that the currently available pathways have been inadequate to speed access to new medical advances for Medicare beneficiaries whose medical needs are not adequately addressed by existing therapies. During the webinar this week, an industry representative presented a potential framework for a designated TCET pathway. That framework was developed specifically to address perceived shortcomings of the MCIT rule. we encourage CMS to carefully consider that framework as a starting point for developing a TCET proposed rule. Of course, MDMA also supports efforts to improve the currently available coverage pathways to make them more efficient but those improvements can and should be considered in parallel to the development of a designated TCET pathway. Second, the questions published by the Agency earlier this week explicitly state that the earliest that CMS would engage with the manufacturers of an emerging technology would be after the results of the pivotal clinical trials are available. We believe that both the manufacturer and the Medicare program would benefit from engagement earlier in the process. Again, we encourage the Agency to consider the potential framework discussed at the Stanford Duke webinar and to remain open to working with the industry and other stakeholders on mechanisms for engagement with innovators earlier in the technology development process. Thank you again for the opportunity to speak today.

Stefanie Costello: Thank you for your comments. Up next we have Kurt Imhof.

Kurt Imhof: Good afternoon and thank you CMS for the opportunity to provide comments on transitional coverage for emerging technologies. My name is Kurt Imhof and I'm the Vice President for Policy and Public Affairs at Life Sciences Pennsylvania. Life Sciences Pennsylvania is the state-wide trade association for the Commonwealth life sciences community. The Commonwealth is home to more than 330 medical device and diagnostics establishments. Over the course of the previous year, many of our med tech members expressed support for a coverage pathway that would provide transitional coverage for emerging technologies. While we understand the concerns expressed by CMS in repealing the previous rule, this will be a major step forward in addressing the delay that Medicare beneficiaries often face in accessing new medical devices. The change will provide patients with access to innovative medical technologies and ensure medical technology companies, many of whom are pre-revenue, have a market through which to disperse their technology a key component to generate continued investment in their research and development of innovative medical technologies. I recently spoke with a growing med tech member of Life Sciences Pennsylvania, Active Protective, that is developing a completely novel device for seniors that deploys an airbag to prevent hip fractures when the device senses its wearer is falling. This company is pursuing Breakthrough designation and is hopeful transitional coverage for emerging technologies moves ahead quickly. In response to question two from the questions on the screen, they believe would

be most helpful to engage with CMS at the same time they begin the process with FDA if that inclusion does not further delay the process. Engaging CMS during the pre-submission meeting with the FDA or Breakthrough designation meeting would be ideal. As for question three on early feedback and fit-for-purpose, generally speaking, they're compiling this information anyway for Breakthrough Device designation and believe team feedback from all stakeholders would be worthwhile and efficient. We wish to reaffirm our collective support for improving and modernizing CMS' coverage pathway and look forward to working with the Agency to move expeditiously on a new rule to create a reimbursement pathway for novel medical technologies. Again, thank you.

Stefanie Costello: Thank you for your comments. Up next we have Leslie Levin.

Leslie Levin: Hello, can you hear me?

Stefanie Costello: Yes.

Leslie Levin: Okay, thank you very much for this opportunity. I applaud CMS' review of its approach to the accelerated adoption of Breakthrough medical technologies to TCET. My name is Leslie Levin. I'm the Chief Executive and Scientific Officer of a nonprofit organization called The Excite International. I have been at the evidence to policy interface to de-risk and expedite access to my patients to new impactful health technologies for 25 years and completed in 2011 that the approach of assuming downstream evidence expectations without a clear understanding of these expectations about payers and end users increases the risk of late rejection. Others came to similar conclusion. A streamlined path from regulatory approval to coverage determination was needed and this would require the direct engagement with payers and expert end users from the early stage in technology development. This was the basis behind our formation of Excite International a nonprofit organization which has facilitated early direct engagement of payers and expert end users of non-drug technology companies since its inception in 2016. It is invested mostly in the U.S. would interact closely with representatives from six of the largest payers but also interact with other payers and health systems internationally. Approaches more likely to lead to positive coverage determination by allowing companies to address expectations earlier instead of trying to shoehorn their way into health systems at the back end. TCET has the potential of becoming one of the most important examples of expediting the passage of emerging and Breakthrough technologies to early engagement and could become a leading transformational example of early evidence development to guide coverage and adoption. This would be a very positive development. Excite has demonstrated the feasibility of implementing this constructive approach which I wish to share with you. This is underpinned by an early evidence review that informs six panel meetings, comprising payers, expert end users, methodologists and company representatives. All proceedings are evidence based and objective while maintaining complete confidentiality to protect proprietary information. The working with the panels is guided by an agreed to framework of expectations and an optional economic analysis. This process takes 16 weeks to complete and forms a comprehensive platform on which to build clinical trials that meet the expectations of payers and experts. Clinical trial development based on the evidence-based process described is undertaken by the nonprofit Harvard-based BAIM Institute for

Clinical Research through a special relationship with Excite. This is a recent development. The continuum between evidence and clinical trial development is needed to bridge the gap between regulatory clearance and coverage determinations. TCET and Excite international share common objective. We look forward to sharing our experience with TCET should CMS choose to go down this path. We also look forward to learning from TCET's approach and experience. CMS leadership in this transformational change could substantially improve patient access to and outcomes from Breakthrough technologies. Thank you.

Stefanie Costello: Great, thank you for your comments up next we have Chandra Branham.

Chandra Branham: Hi, this is Chandra Branham. I'm Senior VP and Head of Payment and Healthcare Delivery Policy at the Advanced Medical Technology Association, or AdvaMed. And I'm going to address the four questions that CMS posed, but just to note at the outset, our sort of primary and recurring comment today is that we really are urging CMS to create a new process for transitional coverage for emerging technologies that is separate and apart from the national coverage determination process. So, I'm going to the questions, the first one regarding CMS guidance. We do know that manufacturers are able to request informal guidance now, sometimes referred to as informal parallel review. And this guidance can be very useful. CMS can and has provided helpful signals to device companies. And more formalized guidance by therapy area could also be helpful, but we just think that CMS should retain some flexibility there given the potential range of medical devices and therapy areas. For the second question regarding timing of engagement with CMS, we believe that voluntary engagement should occur earlier and certainly well before the results of the pivotal clinical trials are available. This early engagement with the opportunity to receive feedback from CMS on the evidence developed today would enable companies and CMS together to proactively address outstanding questions around the evidence of the impact on Medicare beneficiaries and any known disparities and other questions. The third question, and we've already stated early feedback on the available evidence base is a good idea, but we also think it's really important to allow manufacturers to be able to respond, for example, to an evidence review or literature summary and provide additional information when necessary. And manufacturers, yes, should be able to propose and collaborate with CMS to develop fit-for-purpose evidence development plans to resolve any evidence gaps. But the question that is posed here by CMS is whether this should be part of the national coverage determination process. And in response to that, we do believe that, you know, improvements could be made to the NCD process. But CMS really only issues three to five NCDs every year, and so the NCD process may not be a good fit for many new emerging technologies. So again, we're urging CMS to develop a separate process for transitional coverage for emerging technologies that's distinct from the NCD process. And finally, the last question regarding second to market devices after a CED decision is finalized. This is a good question we really look forward to working with CMS to think through the issues that are associated with that question. But again, this question assumes an NCD with CED would be in place, and so we, you know, urge CMS to move forward on a separate process. I'm a little bit over, but my last comment is just we stated during the last listening session that any new program should ensure all the appropriate safeguards for beneficiaries. And that there should be transparency and

opportunities for public input, as well as adequate time to ensure that all of the other surrounding systems are ready, proper coding, payment levels, instructions to the MACs and other issues. And so, we thank you very much, and we look forward to working with CMS on all of these issues. Thanks.

Stefanie Costello: Thank you for your comments. Next, we have Sarah Thibault-Sennett.

Sarah Thibault-Sennett: Hello, this is Sarah Thibault-Sennett, the Senior Manager of Public Policy and Advocacy at the Association for Molecular Pathology, or AMP. As experts in molecular diagnostics, AMP is committed to protecting patient access to high quality care, including access to new Breakthrough Devices. We provided comments to CMS on the Medicare Coverage of Innovative Technologies (MCIT) and definition of reasonable and necessary (R&N) rule during the rulemaking process and welcome the opportunity to provide feedback today. AMP believe that current Medicare coverage policies have led to challenges that hamper national coverage and limit patient access to molecular diagnostic tests in certain circumstances. For this reason, AMP supported the MCIT pathway, as originally envisioned by CMS that would provide immediate national coverage for Breakthrough Devices beginning with the date of the FDA market authorization and continue for up to four years. However, AMP had been, and continues to be, concerned with the original policy's changes to the definition of reasonable and necessary, and had submitted multiple comments outlining these concerns. Specifically, AMP is concerned with how CMS' regulation codified the program integrity manual or PIM definition of reasonable and necessary. As envisioned, the definition would have been applied more broadly than the MCIT and will be used in national coverage determinations and other coverage decisions. CMS' definition included in the regulation had three main elements: an item or service must be safe and effective, not experimental or investigational, and appropriate for Medicare patients. AMP believes strongly that the inclusion and codification of the term, safe and effective within the definition of reasonable and necessary does not appropriately apply to all items and services considered for coverage under Medicare as safe and effective strongly equates with FDA clearance or approval. However, not all laboratory services are regulated under FDA. Laboratory developed testing procedures, also known as LDPs or LDTs our services regulated under the CLIA program at CMS. Since these procedures are regulated separately from FDA, AMP is concerned that the inclusion of safe and effective within the definition may lead to inappropriately restricting coverage and the potential exclusion of LDPs from coverage and requests that the PIM definition of reasonable and necessary not be codified in future regulation. Should there be a need to codify the definition of reasonable and necessary, AMP asks that the safe and effective requirement not be included. Should this terminology not be removed from the definition, AMP alternatively would ask for explicit clarification that use of safe and effective is not intended to suggest a necessary role for the FDA in determining reasonable and necessary. Codifying this language in regulation may ultimately limit innovation and patient access. On behalf of AMP, thank you for your consideration.

Stefanie Costello: Thank you for the comments. Up next we have Christine Jackson.

Christine Jackson: Thank you. Good afternoon, my name is Christine Jackson. I am the Vice President of Global Health Policy at Medtronic. And I'm speaking here today on behalf of the work of five companies that include Boston Scientific, Edwards Lifesciences, Johnson & Johnson, Medtronic and ViewRay. We appreciate CMS' efforts and posting the questions in advance of this listening session and the opportunity to speak here today. Each of our companies have ongoing commitments to clinical research and support the creation of a voluntary, timely, and predictable coverage process for emerging technologies that provides for continued high quality evidence development when it is necessary to better understand the benefits that these technologies bring to Medicare beneficiaries. For the sake of time, our remarks here today will focus solely on responding to question two, and we will submit responses to the remainder of the questions directly to CMS in writing. Related to question two, we believe early engagement between a manufacturer and CMS is critical to minimize the gap in time between FDA market authorization and Medicare coverage. Therefore, CMS should maintain flexibility in the timeframe surrounding manufacturer engagement prior to FDA authorization. In select instances for particularly complex technologies and disease states the initial meetings between a manufacturer and CMS could begin before the pivotal trials have started and this would allow CMS and the manufacturer to work together to align on requirements for pre or post market evidence development. After this initial meeting, CMS could provide further guidance to the manufacturer on the expected timeframes for follow on discussions. Emerging technologies are unique products and the necessary processes that must be undertaken for a technology to achieve full reimbursement through appropriate coverage, coding, and payment can often be lengthy and highly variable and this variability is due to a number of factors, including the existing evidence base supporting the technology or disease state, the availability of appropriate coding, and potential payment assignments. Flexibility surrounding the timing for early engagement with the Agency is key and accommodating this variability and ensuring that alignment between CMS and the manufacturer on efficient fit-for-purpose evidence generation is achieved through the TCET process. Flexibility in the timeframes for manufacturer engagement ensures that the TCET process will result in suitable decisions surrounding the evidence needs for a particular technology and provide early certainty that the technology will be covered by the Medicare program as quickly as possible after FDA market authorization. This early certainty surrounding coverage and potentially other aspects of reimbursement under the TCET process will provide even more powerful incentives for innovators to tackle some of the most pressing health care issues facing Medicare beneficiaries today. Again, we appreciate the opportunity to speak here today and CMS' efforts in establishing a path to transitional coverage for emerging technologies. We look forward to continuing to work constructively with the Agency to shape the development of this pathway. Thank you.

Stefanie Costello: Thank you for your comments. Up next we have Jeffrey Salzman.

Jeffrey M Salzman: Hi there. Thank you for the opportunity to speak with you this afternoon. My name is Jeff Salzman and I'm with Geneoscopy Incorporated based in St. Louis, Missouri. Geneoscopy's mission is to transform gastrointestinal health through innovative diagnostics., We thank you for holding these listening sessions and providing an opportunity to share our views.

We appreciate the Agency's commitment to exploring other policy options and statutory authorities for coverage that better suits the needs of Medicare beneficiaries and other stakeholders when the items or services are supported by adequate evidence. Geneoscopy believes it is in the best interest of Medicare beneficiaries to have policies and practices in place that close the gap between FDA approval and Medicare coverage and reimbursement. To ensure that Medicare beneficiaries have timely access to new technologies and can benefit from innovation, we believe CMS should have a streamlined pathway to coverage and payment. And, in particular, we believe such a pathway should be available as an option for products and services that have earned FDA Breakthrough Device designation. We were initially pleased with the MCIT that helped minimize the time between FDA approval and the availability of Medicare coverage, however, we were concerned that it was unclear whether the MCIT would have applied to both diagnostic and screening tests. There's ambiguity as to whether MCIT would have applied to screening tests broadly or only defined benefit screening tests or none at all. Now, with the possibility of a new transitional coverage policy, we urge the Agency to ensure that the new approach applies to diagnostic and screening tests that have received FDA Breakthrough Device designation and to make that clear from the outset. Further, we also appreciate the Agency's taking an interest in data that illustrates how the technology and innovations perform in the 65 and over population. As noted in the November 15, 2021 MCIT final rule, we agree that it is important to require manufacturers participating in an innovative coverage pathway such as MCIT to produce evidence that demonstrates health benefits the device and the related services for patients with demographics, similar to that of the Medicare population. It is essential that the impact of the new technology and health and well-being and Medicare beneficiaries is understood and demonstrated. In closing, we stand to collaborate with you and support the Agency and its efforts to develop a new opt-in transitional coverage and payment pathway for FDA Breakthrough Device designated tests so Medicare beneficiaries have timely access to new technologies that are safe and effective, address an unmet need, and deliver a benefit to Medicare beneficiaries. Please consider Geneoscopy to be a partner in this important effort, thank you.

Stefanie Costello: Thank you for those comments. Up next we have Josh Makower.

Josh Makower: Thank you very much. My name is Josh Makower. I'm a Professor of Medicine and Bioengineering at Stanford University and the Co-founder and Director of Stanford Byers Center for Biodesign. We focus on training innovators and are developing a new policy program which would concern issues like TCET and transitional coverage. We're very fortunate and very thankful to CMS and Dr. Fleisher for participating in the webinar that we held on Monday. For those that did not get a chance to attend, it is available on our website biodesign.stanford.edu and will be available very shortly, and we partnered with Duke Margolis Center for Policy on that event as well. I think the takeaway from the paper that we published several months ago in Health Management Policy and Innovation Journal which is also available for free online at hmpi.org revealed the comments from over 300 innovators both innovators and investors on the state of the innovation ecosystem and the degree to which it is currently under threat from and I would say, patients access primarily is under threat due to primarily issues associated with access

and reimbursement. So, this area of transitional coverage is exceptionally important and it's a huge opportunity for patients, especially Medicare patients that really do not have the time to wait, as various new technologies that might offer real benefit to their suffering sort of go through a fairly lengthy and difficult process. Elements of the proposal that I'd like to put forward, some of this was discussed on Monday, is I do get the feeling that we're sort of moving away from a Breakthrough Designation as affiliated with the access into the program. What I put forward was that we should consider, you know, technologies deserving of transitional coverage be those that could really offer significant benefit above and beyond the standard of care for treatment and diagnosis of particular, you know, life threatening or irreversible debilitating disease state or condition and also where there's really no pathway for coding, coverage, and or payment that exists today, or the existing pathway is insufficient. In those situations, and really for many exceptionally important new medical technologies, those pathways don't exist and it's a very long process to establish it as was revealed by our paper. Some of the questions that were put forward for this listening session do sort of indicate a little bit more of a trend towards what exists already today and there are challenges with the existing system, the national coverage decision element of the existing coverage with evidence development pathways is challenging for many, many innovators. The idea that after all of this work one could at one moment be determined to not have coverage is sort of the kiss of death of a technology, and it would be very difficult for that innovator to sell their products afterwards. So, I really encourage the folks at CMS to rethink and really consider developing a completely new pathway that does not require an NCD as part of its ultimate determination. Also, very important is to engage with the sponsor and CMS before the pivotal occurs. The great opportunity there is that many of the evidence that is desired could be potentially acquired during the pivotal period, and then it could also be determined what pieces of evidence might not be reasonably obtained during that pivotal period with through FDA's process and then that could be a part of the real world evidence phase and post market after approval is obtained and during the time that coverage is being offered in exchange for basically obtaining that evidence. You know FDA's job is to assure reasonable safety and efficacy of devices and technologies, they do a very good job of that and so any technology that would be covered would obviously have to be approved by the FDA for it to be used in the United States. I will just conclude by saying that this is exceptionally important innovation is an exceptionally important program for innovators and we should really think carefully to make sure that it provides the incentives for innovators, as well as investors, to continue to support technologies which are incredibly risky going after very large and unsolved disease states. Thank you very much for considering my comments. Thank you. Bye bye.

Stefanie Costello: Great, thank you very much. Up next we have Marijke Annis.

Marijke Annis: Thank you, Stefanie. This is Marijke Annis. I am Senior Director of Health Policy for Exact Sciences and I appreciate the opportunity to speak today. As a leader in cancer screening and diagnostic testing, Exact Sciences is committed to changing the way we detect and treat cancer. Americans 65 and older are seven times more likely than younger Americans to be diagnosed with cancer. Accordingly, Medicare coverage for new cancer detection technologies and diagnostic tests that guide better treatment decisions represents an important policy

opportunity to improve cancer survival in the Medicare population. We appreciate the opportunity for this continued engagement with the Agency on transitional coverage for emerging technologies. We would like to highlight the following considerations that we believe are critical for CMS to address as it develops a new alternative coverage pathway for these emerging technologies. Exact Sciences is in support of the development of a new transitional coverage pathway for emerging technologies. We believe the pathway should be voluntary to allow manufacturers that meet the criteria for this pathway to pursue the flexibility to choose to pursue this pathway or other existing coverage pathways. In response to questions two and three, we support a framework that would allow for early engagement between CMS and manufacturers to review the existing evidence and to align on a strategy to generate evidence in the Medicare population during the transitional coverage period. As mentioned by other commenters today, we believe this early engagement can happen prior to the completion of the pivotal studies. We also believe there should be an opportunity for manufacturers to respond to any early feedback provided by CMS as that evidence strategy is created. To the extent that CMS is concerned about Medicare population specific evidence for these innovative devices and diagnostics, the Agency could achieve its objectives by formally requiring in regulation that CMS approve evidence and evidence collection plans for transitional coverage applicants before such coverage is operative. Any application process and associated review criteria that CMS designs for Medicare transitional coverage and any future changes to such processes or criteria should be promulgated via notice and comment rulemaking and be clearly described in those resulting regulations. Regarding question number four, we support the creation of a new alternative pathway to transitional coverage of emerging technologies that is different from the national coverage determination and coverage with evidence development processes as this would allow innovative technologies to reach appropriate Medicare populations more quickly. Lastly, we believe that if a candidate device or diagnostic for a transitional coverage pathway is not successful in its application that noncoverage decision for the transitional pathway should not result in a broader definitive noncoverage determination for other coverage pathways. Otherwise, many emerging technology manufacturers likely would not take the risk of engaging in the transitional coverage application process. We thank CMS for the opportunity to provide our comments today and we look forward to providing more detailed written comments and in engaging further with CMS and stakeholders as this new coverage pathway is developed. Thank you.

Stefanie Costello: Thank you for those comments. Up next we have Peter Thomas.

Peter Thomas: Hi, can you hear me?

Stefanie Costello: Yes.

Peter Thomas: Thank you. Peter Thomas here with the Powers Law Firm in Washington, DC. I represent the Orthotic and Prosthetic Alliance which is five national organizations all working on orthotic and prosthetic policy. I spoke last time so I won't repeat my comments, but I wanted to offer a few additional comments today. The first being that we certainly support evidence sufficient to support Breakthrough technologies at the FDA in response to a comment that was

made earlier to demonstrate safety and effectiveness. On the other hand, with respect to orthotics and prosthetics, you know most O&P devices and components are class one FDA devices. Some are class two, but most are class one. And frankly, you simply don't have the same level of infrastructure and funding available for the kinds of studies, the kinds of evidence development that is present in say the area of drugs and medications or other kinds of invasive internal implants and things of that nature. We hope that CMS recognizes that because, frankly, we have been to CMS on a number of occasions and oftentimes were met with when we put evidence on the table we're met with statements that the sample sizes are too small or you know the Medicare population, not enough study participants were above 65 years of age, despite the fact that nine million beneficiaries are below age 65 and who benefit from the Medicare program people qualified based on disability status. So, we do hope that the level of evidence is taken into account when with respect to assessing the coverage and the evidence base for various types of new technologies, or even existing technologies that currently don't have coverage under the program. And we're hopeful that there is some kind of a sliding scale. We're not asking for a less rigorous standard per se, we're not saying that you don't need as much evidence, but frankly, there are some things in orthotics and prosthetics and even in durable medical equipment and DMEPOS generally that are pretty self-evident In terms of their benefit to a particular patient population and requiring double blinded trials for many of these technologies is simply potentially undoable in many instances it's just not possible., Where there are capabilities for double blinded trials. we do hope CMS will take into account the fact that you just can't get the study sample sizes that you get with much larger drug trials or other kinds of trials that have very deep pocketed backers that are supporting that research and that have a huge payoff in the end. With respect to orthotics and prosthetics, it's a much smaller population that benefits from new technologies, and we hope that that's taken into account. We do, therefore support fit-to-purpose evidence development by manufacturers to fill evidence gaps. We hope that that's a partial answer in response to that question. We also support the transitional coverage process as separate from the NCD process. We also wanted to make one last point that we made the first time around, and that is that the current coding, coverage and payment determination process with respect to durable medical equipment, prosthetics, and orthotics and supplies continues to need improvement, and we do hope that CMS will not omit that in consideration when you're looking at coverage of new technologies or innovations in the area of DMEPOS. We'd be happy to continue to talk with CMS about those improvements moving out over time., Thanks so much for the opportunity to comment.

Stefanie Costello: Great, thank you for your comments. Next, we have Katie Meyer.

Katie Meyer: Thank you. Hi my name is Katie Meyer and I'm Head of Government Affairs for Novocure, a global oncology and medical device company striving to extend survival in some of the most aggressive forms of cancer with our innovative therapy tumor treating fields. Through Optune, a wearable portable FDA approved medical device designed for at home patient use, electric fields are delivered to disrupt the cancer cell division and cause cancer cell deaths. Optune is currently indicated to treat glioblastoma in combination with chemotherapy and we are studying use of the technology in other cancers, including lung, ovarian, and pancreatic cancer.

Novocure thanks you for your commitment to improving the Medicare coverage process for innovative medical devices. We applaud CMS for holding this series of listening sessions and urge the Agency to continue actively engaging with affected and impacted stakeholders throughout the policy development process. This continued engagement is critical to understanding key issues that must be addressed in order to effectively implement the TCET rule for Medicare beneficiaries. Novocure also requests that CMS adheres to the October 2022 scheduled release of the TCET rule listed on the HHS Unified Agenda. As you continue this work, Novocure again wishes to emphasize the importance of using existing CMS authority to establish a clear and predictable pathway for Medicare coverage of medical devices with some clinical evidence. An established pathway with consistent and expedited coverage is paramount to ensuring that Medicare beneficiaries with serious illnesses do not face unnecessary hurdles to accessing lifesaving medical devices once they have FDA approval. This pathway should include a formal process for premarket engagement between manufacturers and CMS that begins at very early device development stages to discuss clinical trial design and the evidence necessary to support Medicare coverage. Conducting these meetings before pivotal clinical trials begin will meaningfully help to preemptively address any issues that could prevent or delay Medicare coverage upon market entry particularly for innovative devices with clear evidence of clinical effectiveness. Thank you again for holding this listening session and for allowing Novocure to participate today on behalf of the more than 22,000 patients we've served. We are excited to contribute to the future of Medicare coverage for innovative medical technology and look forward to the continued discussions going forward. Thank you.

Stefanie Costello: Great, thank you for those comments. Up next we have Brock Schroeder.

Maude Champagne: Hi, my name is Maude Champagne. I'll speak on behalf of Brock here. I'm in Market Access, Strategy and Operations at Illumina. Illumina is a leading developer and manufacturer of next generation sequencing tools for both research and clinical use. We appreciate the opportunity to provide comments in today's session. We would like to thank you for all the work on defining the transitional pathway to expedite coverage of innovative technology following Breakthrough designation, FDA clearance or approval. Illumina supported the effort to develop the MCIT pathway and look forward to working with the Agency on the TCET pathway. We would like to highlight a few items for your consideration. Clinical laboratory testing and diagnostic technologies, especially genomic testing for constitutional and cancer mutations contribute to innovation in healthcare, and it would benefit the Medicare population to include genetic testing innovation in this new TCET pathway. Genetic tests used for disease screening purposes shows promise and the way that cancer could be detected earlier in the future and would benefit from [inaudible] that would have covered under this new tool. To answer your first question, establishing clear and transparent criteria to qualify for coverage under TCET would remove uncertainties and benefit access to innovation. Guidance on acceptable outcomes and duration of follow up would be useful. Answering your second question, the coverage review process discussion should start in parallel to the pre-submission meeting. From a regulatory perspective definitely much earlier in the process. Regarding question three, during their coverage review process CMS feedback on available evidence with

the literature review would be helpful. The manufacturer would benefit from suggesting an evidence development plan to resolve the gaps and have a discussion. Finally, answering your fourth question, TCET could serve as a way to generate real world evidence of utility in the Medicare population in parallel to working with FDA. Defining what is a similar device and whether or not such similar device should be included in an NCD plan should be discussed in a case by case scenario TCET should be a voluntary pathway, of course. So, to reiterate, we believe that a transitional pathway is necessary to eliminate the coverage gap following FDA approval. And we hope that the Agency will be able to expedite the rulemaking to accelerate access to innovative technology for the Medicare population. So again, thank you for all your efforts and we look forward to working with you on the strategy.

Stefanie Costello: Great, thank you for the comments. Up next we have Juli Goldstein.

Juli Goldstein: Can you hear me?

Stefanie Costello: Yes.

Juli Goldstein: Hi, this is Juli Goldstein and I am Vice President of Government Affairs and Market Access at Digital Diagnostics. Digital Diagnostics is formerly IDx Technologies and we are a pioneering AI diagnostic company on a mission to transform the quality, accessibility and affordability of health care. We are founded and led by Dr Michael Abramoff who's a fellowship trained retina specialist, ophthalmologist, neuroscientist and [inaudible] engineer. Digital Diagnostics developed the patents and biomarker-based approach to build autonomous AI that makes simple decisions without human intervention. Digital Diagnostics and its flagship product IDx-DR, an autonomous AI system with FDA De Novo authorization to diagnose diabetic retinopathy and diabetic macular edema, has proven that intelligent diagnostic platforms can be used safely, efficiently and equitably to improve patient outcomes. Today Digital Diagnostics has three FDA Breakthrough designated devices. To our knowledge, this is more than any other innovator in the United States. We are grateful for the opportunity to respond to questions regarding the transitional coverage of emerging technologies, including innovative validated healthcare AI for all patients. We suggest the following: Number one, we strongly support a coverage pathway for emerging and developing technologies, especially those medical advances that have been defined as Breakthrough by the FDA. Number two, we suggest just permitting all FDA cleared Breakthrough devices that have been based on evidence that validated evidence from the Medicare population eligibility to participate in the pathway. Number three, allow the FDA market authorized Breakthrough technologies that do not squarely fit within an existing Medicare benefit category to be covered in instances when all other eligibility criteria has been met. And number four, permit any earlier engagement with medical device companies during the pre-submission process with the FDA Thank you.

Stefanie Costello: Great, thank you for the comments. Next, we have James Vavricek.

James Vavricek: Stefanie, can you hear me?

Stefanie Costello: Yes.

James Vavricek: Hi, James Vavricek, I'm Director of Regulatory Affairs at the American College of Cardiology. Thank you for hosting this session, and you and Lori and the rest of the Coverage Group. We're frequent flyers, as it were, with a lot of new technology and coverage with evidence sorts of decisions in the past, so I'm not going to go through all the comments we've submitted previously over the proposal and the reconsideration, and the withdrawal. You know all that we've been talking about an issue like this, since 21st Century Cures when that was just a discussion draft legislation, so this is not new ground in a lot of ways, but we wanted to go through your questions and hope that that we could be a little bit helpful. So, for the first one there, just yes, you know, probably, as we're thinking of the sorts of evidence development questions we see in CED policies that type of guidance would be helpful. On number two, early stakeholder engagement makes sense. I've heard people on this call saying even before the PMA and the trials get underway. I mean as early as make sense for the applicants, as it were. For number three, certainly that could be helpful. To get that feedback from the Agency in advance. Also, as we were looking at the questions there could be some amount of redundancy in terms of what FDA might be directing people to do in their premarket studies. Or maybe also in post market studies as you're looking at the number, the excuse me, you know some of the sorts of things that are going to be identified by FDA for post market studies would probably be some of the same sorts of things that CMS we want to see. And then finally we've talked, I think we talked about this in our comment letter previously, that the evidence development requirements for follow on devices, you know we wouldn't want to see any sorts of odd competitive advantages by not being the first to market if people get one coverage pathway versus another. So, at least on its face, it seems to us that it would make sense for them to be the same. And then, finally, you know, thanks again for offering this you know thing that we thought about along the way through the whole consideration of how to get the coverage there faster. Services aren't noncovered on the day that they're approved by the FDA they just don't have the structure, so I appreciate the desire to get to there. And then, finally, you know, one thing we had offered way back at one point I don't even know if it was in CMS' proposal at that point but you know, even a version of like accelerated CED that kicks off the day something is FDA approved depending how that is structured could be preferable to what people seem to find challenging right now, so thank you.

Stefanie Costello: Great, thank you very much, I just want to be aware of the time. It is 4:05 and we have about four folks left. So, if you can, please make sure to keep your remarks to three minutes. Hopefully we can get through everybody. Up next we have Michael Plick.

Michael Plick: I apologize. [inaudible].

Stefanie Costello: Yes, you don't wish to make a comment? [Pause]

Stefanie Costello: Okay, I'm moving on, we have Julie Piriano.

Julie Piriano: I want to thank you all for the opportunity to speak today. My name is Julie Piriano. I'm the Vice President of Clinical Education, Industry Affairs and Compliance for Pride Mobility Products Corporation, a leading manufacturer of seating and wheeled mobility products including complex rehab power wheelchairs that are individually configured to meet the unique

needs of the one person it's recommended for. I'm also a physical therapist, assistive technology professional, and seating and wheeled mobility specialist that has been practicing for the last 38 years and I can say without hesitation that the seating and wheeled mobility needs of the disability community are distinctly different from the typical needs of Medicare beneficiaries with mobility challenges that age in to the benefit. Currently Medicare has deemed a basic power seat elevation system defined by HCPCS code E2300 as noncovered, stating that it does not serve a medical purpose. Subsequently, a seat elevation system that has a limit of six inches of elevation or rise doesn't meet the definition of DME and can't be considered as a covered benefit. What I'd like to bring to your attention today is the innovation of a complex rehab seat elevation system, or elevated motion seating, used in conjunction with group three complex rehab power wheelchairs that received a new FDA 510(k) premarket clearance distinction on July 23, 2015. Elevated motion seating allows individuals with disabilities that meet the coverage criteria for the group three complex rehab power wheelchair the ability to remain in the seated position and access the vertical environment by elevating the seat at least 10 inches. It also lets the person raise and lower the seat while driving their chair to perform or participate in activities of daily living as well as drive the chair in an elevated position as at a speed of at least 2.8 miles an hour which is the average walking speed of ambulatory individuals. Since the innovation of elevated motion seating there have been numerous research studies that have validated the medical benefits of a complex rehab seat elevation system, including but not limited to improving transfer biomechanics, safety and independence, facilitating reached biomechanics safety and range, enhancing visual orientation in line of sight, support of physiological health, safety and well-being and improving safety in the performance or participation in activities of daily living. And so, we would fully encourage and support a streamlined transitional coverage review process. Early feedback on the strengths and weaknesses of the evidence in support of emerging and enabling technologies and most importantly, a mechanism that allows new technologies that have been deemed distinctly different by the FDA from products that are viewed as similar and noncovered when seeking coding, coverage, and reimbursement consideration for the new and enabling technologies for disabled Medicare beneficiaries. We feel that safe, independent access to the vertical environment is directly in line with the mandate of the national coverage determination for mobility assistive equipment and the American Disabilities Act. Yet, we've run into roadblock after roadblock under the current process to date and fully support change in a positive direction. Thank you.

Stefanie Costello: Great Thank you very much. Up next we have John Chi.

John Chi: Hi, can you hear me?

Stefanie Costello: Yes.

John Chi: Okay, great. Hi, I'm John Chi and I'm the CEO of Synova Life Sciences and we make a device that gets stem cells out of fat and we're a small company. Small companies make up the majority of innovation, so for a small company time and funding are incredibly important. And as developments have been progressing with CMS and TCET, the trend seems to be moving more and more towards lengthier and more expensive processes. And you just want to first for

CMS to keep in mind that this, an accelerated process, would greatly benefit the small companies from where most of the innovations are coming from. On top of that, the low frequency and length of time to reach an NCD issuance really highlights the need for as many as mentioned, a separate process and pathway that accelerates the path to coverage. So maybe something like a transitional coverage determination or a TCD instead of an NCD. So then, with that separate designation, it would also be much easier to sunset or revoke if our evidence didn't meet what was needed. And then, with the first question with the CMS guidance on outcomes and durations, I think input could be useful with the caveat that an entity that's working in that specific therapeutic area might have much deeper knowledge about what would be a good outcome or duration of follow up. So, even though CMS guidance might be useful it shouldn't be issued as a requirement, like the way that an FDA guidance is so that it pretty much just becomes the rule So, it may be more appropriate for the company to have more input on an acceptable outcome and follow up so companies' input should definitely be considered in this kind of determination. For the second question, stakeholder engagement should definitely happen earlier. Certainly prior to the pivotal trial as such late engagement could create another delay in the implement of transitional coverage which defeats the purpose of accelerating access to the treatment or therapy or whatever the modality is., And that also delays, a company's ability to respond earlier to what would be needed to be received to receive a transitional coverage determination so that it would be possible to have coverage from day one following an FDA clearance or approval. And then to the third point about review and providing feedback for that, some questions like how long would it take to provide this kind of feedback and evidence doing it, the gap in literature review. So, a manufacturer might opt into the TCET program and then have to wait for CMS to provide feedback and then have to propose an evidence development plan following that feedback it sounds like a significant and time-consuming amount of work. However, if this does mean that transitional coverage can be provided or guaranteed if the company met these gaps, then it would be very useful. So, just on behalf of small companies, really, we thank CMS for this opportunity to provide our feedback and look forward to the further developments.

Stefanie Costello: Great. Thank you very much. Up next we have James Love.

James Love: Okay, thank you. I'll be brief. And thank you for allowing us to listen in on the session. We would, even though it's not specifically one of the four questions, I think in general it'd be helpful if there's disclosure and things public about the cost of the clinical trials that were used to support FDA registration. It goes to a couple of different areas where it'd be helpful for the public: one, it would help people who are just understanding a bit more the economics of development of products and technologies in this area and, secondly, would help people understand the kind of incentives, the best way to design some of these for people to invest in research, development, by having better more granular data on what these costs are. The World Health Organization adapted a resolution in 2019, WHA72.8, which goes to this issue of trying to enhance the transparency of the whole value chain in medical technologies. I just got off a call with another group of organizations who are working on these issues trying to enhance transparency of clinical trial costs. I know that there's actually a lot of different people working

on this issue, but I wanted to bring attention to it in this session, and thank you very much. That's it for me.

Stefanie Costello: Great, thank you very much. Next, we have Stephanie Woodward.

Stephanie Woodward: Hi, thank you so much. Good afternoon. Again, I'm Stephanie Woodward, I'm an attorney and I'm a proud wheelchair user. I'd like to start by reminding everyone that 'nothing about us without us' is the mantra of the disability community because historically society has made decisions for disabled people without ever inviting us to the table or even having us in the room for the discussion. So, I use a power wheelchair with power adjustable CI technology, which is the fancy way of saying that my chair can elevate to allow me to reach things in my environment that I traditionally would not be able to reach in a standard wheelchair. Because of this technology, I can independently cook in my kitchen because I can reach everything. I can reach the stove. I can reach my sink, my cupboards. Things that I cannot reach when I met a standard height. I can take care of all of my household chores and I am excited to say I am now in the process of a home study for adopting a child because I can reach everything in my environment. This is a critical piece in my life. Moreover, it is life changing technology that is being kept from wheelchair users across the nation because Medicare does not cover it. And by not covering this technology, Medicare is causing healthcare inequities and further marginalizing people with significant disabilities. Especially since private payers will consider paying for this technology but Medicare will not., And while you may believe that this is emerging technology it isn't. I have had this technology since 2015. And CMS has been making the disability community wait on this for years. I personally met with CMS about this technology on more than one occasion to express why this technology is medically necessary. Furthermore, the national coverage determination request was submitted to CMS over a year ago and it was deemed complete but there has still been no action taken. So, to answer your question about stakeholder engagement, the answer is immediately. Wheelchair users across the nation want to be able to provide their input about this important subject and they've been waiting years for the opportunity to do so. It should not be a privileged handful of people on an email chain engaging with CMS about the technology that allows us to live our lives. Disabled people across the nation should all have the ability to engage in these important conversations. For this reason. I urge CMS to release the national coverage determination for public comments of the coverage process can move forward, because until CMS does healthcare equities will continue and disabled people across the nation will suffer. Furthermore, for all coverage review processes impacting disabled people in the future, people with disabilities should be engaged from the very first stages because no one knows better about what we need in our lives than we do. I just need to remind you one more time 'nothing about us without us.' Thank you.

Stefanie Costello: Thank you for those comments. Our final comment today is going to go to Joseph Nahra.

Joseph Nahra: Hi everyone. My name is Joe Nahra. I'm a representative of the Independence Through Enhancement of Medicare and Medicaid, or the ITEM Coalition, which represents about 95 national organizations, all focused on increasing access to assistive technology

particularly for people with disabilities. And so, I'd like to really thank Stephanie for her comments just now, really powerful, and I hope CMS takes those into account. We appreciate the opportunity to give comment on this listening session and we spoke on the last session as well, so I'll try not to reiterate those same comments. I will say that the ITEM coalition strongly supports the CMS' efforts to develop a new alternative coverage pathway, and we do sincerely support the requirement of sufficient evidence to demonstrate safety and effectiveness for Medicare patients, as was stated earlier. I'll note we are also still seeing significant delays in reviewing evidence, even when there is sort of a significant clinical evidence base supporting the use of different technologies. And so, as was stated by a couple of other commenters today, we urge CMS to continue considering broader coding, coverage, and payment process improvements in addition to a specific dedicated pathway for emerging technologies. In terms of the future TCET pathway we do appreciate that CMS seems to be at least be open to considering eligible devices beyond just those receiving a Breakthrough designation. We note that there are many devices that are in need of alternative coverage that are innovative and emerging and patients need improved and expedited access to both the ones that are in development now and in the future. But also, innovations that have been created in more recent years still have found roadblocks in a traditional CMS coverage pathway and process. We've seen this often occurring without a lot of transparency from the Agency about what is actually causing these delays. And this of course limits the ability of manufacturers, consumers and other stakeholders to work to address any roadblocks to coding, coverage, and payment for these devices. Specifically, regarding question two, we agree with many of the other commenters today that early engagement is beneficial to both the Agency and stakeholders. We also suggest CMS consider instituting more firm and clear deadlines and timelines for stakeholder engagement and also actions within the Agency across various steps of the coding, coverage, and payment process. And again, that is something that should apply not just this new transitional process, but the broader coding, coverage and payment processes as well. A couple of other commenters already mentioned the NCD reconsideration request for seta elevation standing systems and I'll just reiterate that that's been at CMS without action for nearly 16 months after having been deemed complete. And regarding transparency, I'll remind the agency that the NCD dashboard covering all supposed to cover all pending NCD requests and sort of what's under review currently and what will be covered soon, has not been updated in near more than a year and a half ago. September 2020 was the last time that was updated. And then finally, just reiterating one of the points that was made earlier, this innovative emerging technology process should really look not just to things that have been you know added the market in the last year or so, but also things that have been emerging and available to consumer, but not available to Medicare beneficiaries for some time. So, for example, again, that wheelchair technology that's been actually on market for nearly 20 years now, the evidence base is strong. It's clearly providing a clinical benefit to consumers but Medicare beneficiaries have been unable to access that so we really appreciate your consideration of our comments and your time and attention to these issues and we look forward to continuing to work with the Agency as you develop these policies. Thank you very much.

Stefanie Costello: Great, thank you for that comment and thank everyone today for their comments. I'm going to flip it back over to Dr. Fleisher for some final remarks. Dr Fleisher?

Lee Fleisher: Yes, thank you so much. And thank you for hosting today, but also, I'd like to thank everyone for the comments and specifically for focusing on the questions that we put out. That really will help us as we think through this complex problem. As someone who still practices and provides care, both for Medicare and. non-Medicare beneficiaries while I give anesthesia a couple times a month, you know we're really focused and I am focused on bringing technologies that really improve patients' health to them in a quicker fashion and within our statutory authorities, which includes those technologies for which Medicare has a benefit category or which Congress has given the authority to actually provide as part of the benefits that Medicare beneficiaries can obtain so all this information is incredibly helpful and useful as we really try to do what's best for the patients in that we all want their health to improve. So, thank you again, and we look forward to interfacing in the future as we work through this, how we can resolve it, and really get to the best pathway. And with that I will turn it back to Stefanie.

Stefanie Costello: Thank you very much, and thank you to everyone today for all of your comments and those who just joined to listen in. We appreciate you spending the afternoon with us. This ends our session and again, thanks for attending.