Centers for Medicare & Medicaid Services
Transitional Coverage for Emerging Technologies
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Eugene Freund: Welcome. I'm Dr. Eugene Freund with the CMS Office of Communications, and I'll be your moderator today. Today's listening session is an opportunity for CMS to hear public comments. As such, we're not gathering written comments today, we're taking questions through the Zoom platform. We will also not be responding individually to comments made or answering questions asked during the comments portion of the call. This session is being recorded and will be transcribed; please do not speak if you object to the recording. Also, everyone, press included, is 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.gov. We do have a closed captioning option available via the link in the chat. After some brief initial remarks, we will welcome the floor for comments; if you wish to speak, please raise your hand in the Zoom platform. We will do our best to get to as many speakers as possible, starting with those of you who indicated your interests upon registration. Each speaker will have no more than three minutes, and we're keeping an eye on the time, and we will politely ask those speaking to finish those remarks on time. And with that, I'll turn it over to Dr. Steve Farmer, the Chief Strategy Officer in the CCSQ's Coverage and Analysis Group (CAG).

Dr. Steve Farmer: Thank you, Eugene. Good afternoon. I'd like to thank all of you for taking the time today to join our listening session. As we mentioned before, CMS is committed to fostering innovation while ensuring that people with Medicare have faster and more consistent access to emerging technologies that will improve health outcomes. As part of this commitment, we recently announced a proposed Transitional Coverage for Emerging Technologies, or TCET, pathway through a procedural notice in the Federal Register. We also released three proposed guidance documents. Collectively, these documents propose a substantial transformation to our approach to coverage reviews and to evidence development. Based on our analysis of the Breakthrough pipeline, we believe that five topics per year will be sufficient to address the Breakthrough technologies that will have the highest impact on Medicare beneficiaries. I note that these additional reviews more than double the National Topic Review volume that CAG conducts each year. If our experience with TCET signals that additional reviews are needed, we'll explore opportunities to accommodate an increased number of technologies into the pathway as our resources allow. When developing the TCET pathway, CMS solicited extensive feedback from patient groups, medical professionals, device manufacturers, innovators, and other federal agencies. This feedback included requests for CMS to develop a more agile, iterative, evidence review process that considers fit-for-purpose study design, including those that make secondary use of real-world data. The proposed procedural notice outlines the new pathway that's expedited. The TCET pathway, which is voluntary and applies to certain FDA-designated Breakthrough Devices, supports innovation by providing an efficient, predictable, and

transparent coverage review process while developing robust safeguards for the Medicare population. The TCET pathway uses national coverage determination (NCD) and coverage with evidence development (CED) processes to expedite Medicare coverage of certain Breakthrough Devices. The new pathway provides the manufacturers with opportunities for increased pre-market engagement with CMS and a new and unprecedented level of flexibility to address any evidence gaps for coverage. TCET aims to reduce uncertainty about coverage options through pre-market evaluation of potential harms and benefits of technologies while identifying any important evidence gaps. The pathway allows manufacturers to address any evidence gaps through fit-for-purpose studies. A fit-for-purpose study is one where the study design, analysis plan, and study data are appropriate for the question that the study aims to answer.

In addition, the TCET pathway will help with coordinate benefit category determination, coding, and payment reviews. We believe that manufacturers will be better positioned for multiple product development stages if they anticipate both FDA and CMS requirements when developing clinical studies. To that end, CMS intends to publish a series of guidance documents that review health outcomes and their clinically meaningful differences within priority therapeutic areas. The proposed Clinical Endpoints Guidance for Knee Osteoarthritis is the first example in the series. CMS partnered with the Agency for Healthcare Research and Quality to develop a comprehensive approach that incorporates greater flexibility into the proposed CED paradigm. Accordingly, we have updated our CMS Evidence Review guidance to describe our review process more clearly, and we have updated our coverage with evidence development and study requirements to more clearly allow fit-for-purpose study designs. CMS will continue to engage with stakeholders to ensure that Medicare promotes access to emerging medical technologies while maintaining appropriate safeguards and rigorous evidence standards that are essential to the health of our beneficiaries. We appreciate the helpful feedback we've already received and look forward to hearing more of your thoughts during today's session. Again, thank you for your participation today, but please remember to submit your written comments. Now, I'll turn it over to Lori Ashby, who is a Senior Advisor in the Coverage Analysis Group.

Lori Ashby: Thank you, Steve. Thank you all for joining today's listening session. As you can tell, this is an important topic for CMS. 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. That being said, I'd like to remind everyone that written comments on the TCET Procedural Notice are due on August 28. Additionally, written comments on the three proposed guidance documents are due to CMS on August 21. During today's listening session, we would appreciate receiving feedback on the following questions: Question 1, the proposed procedural notice states that the appropriate time frame for manufacturers to self-nominate for the TCET pathway is approximately 12 months prior to an anticipated FDA decision on a submission as determined by the manufacturer. Is this an appropriate time frame? Question 2, in terms of the timing for post-market review, should CMS finalize its proposal to tie the duration of coverage under the TCET pathway to a date specified in the Evidence Development Plan, including conducting an updated evidence review within six months of the date noted in the evidence development plan? Question 3, how should CMS approach evidence development requirements for second and third-to-market devices following a Coverage with Evidence Development decision for Beakthrough Devices in

the TCET pathway? We appreciate your feedback and look forward to hearing from you. I'll now turn it over to Eugene, who will be moderating the comment period for today's session.

Eugene Freund: Thank you very much. We will now begin the listening session portion of this call. Please, use the raise hand function. I see some hands are already raised. I will call on individuals, and you'll be unmuted to make your comments. Please limit the comments to three minutes or less. We'll provide time reminder comments in the chat box, and with that, I'll call on those with hands raised, and the moderator will unmute your phones. The first hand raised is Dr. Paul Rudolph.

Marvelyn Davis: Paul Rudolph, your line is unmuted.

Dr. Paul Rudolph: Can you hear me now? That was a mistake. I don't know how my hand got raised. I apologize for that.

Eugene Freund: Sorry about that. Okay. We can move on to Christine Jackson.

Christine Jackson: Thank you so much. Can you hear me?

Marvelyn Davis: Yes.

Christine Jackson: Ok, great. Good afternoon. My name is Christine Jackson. I'm Vice President of Global Health Policy and Health Law Counsel at Medtronic. Medtronic appreciates the opportunity and also CMS' efforts in coordinating the stakeholder forum, and again I appreciate the opportunity to speak here today. Medtronic scientists, engineers, and other research professionals are deep experts in evidence, generation, and trial design, and we have a strong history of working with CMS to generate meaningful evidence evaluating the effectiveness of our devices in the Medicare population. It's this history and experience, along with our ongoing commitment to evidence generation that informs our comments here today. Medtronic strongly supports CMS' goals to facilitate early, predictable, and safe beneficiary access to FDA-designated Breakthrough Devices to reduce manufacturers uncertainty about coverage and to encourage flexible and fit-for-purpose evidence development if evidence gaps exist. Specific to the TCET pathway, we believe the operational framework and pre- and post-market activities proposed by CMS offer a timely and predictable coverage review process for Breakthrough Devices, and it's a strong foundation on which to achieve CMS' express goal of establishing coverage for these important innovations within six months of commercialization.

Our comments related to the questions posed by CMS for the stakeholder's forum are as follows: Related to question 1, Medtronic believes early engagement between a manufacturer and CMS is critical to success under the TCET pathway. Therefore, the 12-month self-nomination time frame prior to commercialization is appropriate. Nevertheless, for self-nominations that are submitted within the first year after TCET is finalized, CMS should maintain some flexibility to ensure that eligible devices that receive regulatory approval shortly after the pathway is finalized will not be [no audio].

Marvelyn Davis: Eugene, I think we've lost our caller.

Eugene Freund: Yeah, I think we have. We can return to her afterwards. Next up is Katie Meyer.

Katie Meyer: Hello my name is Katie Meyer, and I am the Vice President 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 treated field. Our device is indicated to treat glioblastoma, a severe form of brain cancer, and mesothelioma, and we are now studying use of the technology in other cancers like lung, ovarian, and pancreatic. In fact, we recently announced results from a phase 3 trial in non-small cell lung cancer which showed a statistically significant improvement in overall survival when our technologies were added to standard-of-care therapies in comparison to standard-care therapies alone. Novocure thanks you for the opportunity to participate in this stakeholder call. We appreciate that CMS is interested in making innovative medical technologies more available to Medicare beneficiaries. However, we are disappointed in the overall approach CMS is taking with TCET.

TCET, as proposed, is relatively limited in scope, and as a result, many patients will continue to face challenges when attempting to access potentially life-saving technologies. First, eligibility is restricted only to those devices with FDA Breakthrough designations. There are several technologies in clinical development that do not have Breakthrough designation but do have the potential to meaningfully extend the lives of Medicare beneficiaries and improve their health outcomes. Manufacturers, for example, may elect not to pursue a Breakthrough designation for their device if they have experienced regulatory teams with large clinical trial results underway and, therefore, have already initiated pre-market engagement with the FDA. It is disheartening that these innovative devices that have the potential to extend survival but do not have Breakthrough designations are not eligible for TCET.

Second, TCET is focused on providing coverage through Coverage with Evidence Development (CED); while some devices may need additional evidence, there are others with robust clinical data sets that should not have to go through additional data collection via CED to secure coverage under TCET. TCET should create a pathway for devices with robust clinical data sets that allows for clear expedited coverage without additional data collection. Without this option, Medicare beneficiaries, unfortunately, will continue to face challenges accessing new treatments that can save their lives and improve their overall health and well-being. Novocure respectfully urges CMS to refine the TCET policy to ensure patients can access new medical technologies with robust clinical data sets without applying CED requirements. Thank you again for holding this stakeholder call and for allowing Novocure to participate today on behalf of the more than 27,000 patients we have served.

Eugene Freund: Thank you very much. Christine Jackson, you can resume. I'm sorry you got cut off.

Christine Jackson: Thank you so much, Eugene. I'll begin with my comments on question 2. Those are that we believe conducting an updated evidence review within six months of the date noted in the evidence development plan is reasonable for the manufacturer and CMS. However,

we strongly encourage CMS as part of this systematic review to allow manufacturers to submit materials in support of the evaluation including any unpublished evidence and also to allow manufacturers to review the results of the contractors' literature review and provide feedback so that would be similar to the process that's laid out for the evidence preview. Related to question 3, FDA Breakthrough Devices that are second and third to market should also qualify for coverage under the TCET pathway. However, the manufacturer for the follow-on technology should be required to invest in comparable studies as the first applicant. Given the efficiencies gained from this approach, we think that CMS should not count coverage that's extended to the follow-on devices against the agency's proposed five applicants that are accepted into the TCET pathway annually. We appreciate the opportunity to speak here today and CMS' efforts in establishing a path to transitional coverage for emerging technologies, and we look forward to continuing to work constructively with the agency to shape the development of this pathway. Thank you so much.

Eugene Freund: Thank you very much. Next hand raised is Brian Scarpelli.

Brian Scarpelli: Hello! Can you hear me?

Eugene Freund: Yes.

Brian Scarpelli: Yeah, wonderful. Thank you so much Eugene. Hi. My name is Brian Scarpelli—I'm the Executive Director of the Connected Health Initiative. The Connected Health Initiative appreciates the opportunity to provide views during today's stakeholder call to help inform the development of TCET. CHI is a leading digital health advocacy effort that's based on a consensus that we identify across the diversity of stakeholders in the health care ecosystem, which seeks to responsibly encourage the use of digital health innovation and support an environment in which patients and consumers can see improvement in their health. Data and clinical evidence from a variety of use cases continues to demonstrate how our digital and connected health technologies available today improve patient care, prevent hospitalization, reduce complications, and improve patient engagement, particularly for the chronically ill, while also reducing costs. Digital and connected health tools offer the potential to fundamentally improve and transform American health care, particularly for the Medicare population.

Unfortunately, despite the proven benefits of digital health technology to the American health care system, a range of statutory and agency-level restrictions inhibit their use. As a result, digital health innovations are quite underutilized today, in our view, which ultimately harms patients and results in unnecessary visits, including to clinics, emergency departments, and rehospitalizations. So, CHI first notes its support for the FDA Breakthrough Device Program and the TCET concept. There are steps CMS should take to provide fair and reasonable access to the TCET pathway as well. For example, CMS suggested in the notice that diagnostic products may not be appropriate for inclusion in the TCET pathway, but we recommend that devices and diagnostics both be considered equitably for inclusion in TCET as emerging digital health care technologies are under development in both areas of industry and are both subject to the same criteria and evaluation in the FDA's Breakthrough Device Program. CHI intends to elaborate on this issue and to make further recommendations in our forthcoming comment. But I thought we'd raise that here. We also urge CMS to recognize that most cutting-edge medical technology

today is or includes digital and connected health solutions, some of which meet the definition of medical device under the FD&C Act. While further efficacious, digital health solutions that stand to benefit patients and Medicare programs may not and, regardless of where a digital health product falls between these two areas, because the vast majority of software and medical device does not fall within an existing benefit category, it will be excluded from a TCET pathway as proposed, precluding countless Medicare beneficiaries from realizing the improved outcomes and reduced costs they bring.

From a coverage standpoint, CHI agrees with CMS' own assessment in its proposed role, which illustrates that the disjointed and complex pathways to device coverage in today's regulatory environment should be improved on. CHI is supportive of CMS' goal to realize innovation and value in Medicare, which can be and should be accomplished through regulatory changes that will appropriately encourage the responsible deployment and utilization of digital health technology that will add value in Medicare and help realize value-based care goals. In this respect, the proposed TCET pathway should be viewed as an important but incremental step towards much-needed modernizations for Medicare coverage, including synchronization of clinical evidentiary standards for FDA approval and CMS coverage focused on the clinical meaningfulness of the output from the digital device. So, while we're supportive of the TCET concept, CHI believes that CMS must take much broader steps at the policy level to enable larger support for digital health products. CMS should exercise flexibility when determining whether a potential device or diagnostic falls within a Medicare benefit category by considering how a solution may already be eligible for inclusion in an existing benefit category, even if it's not explicitly outlined in the statute. For instance, CMS can and should bring eligible digital health innovations into the Medicare beneficiaries' care continuum by clarifying the digital medical devices, such as software and medical device, are included in existing benefit categories like DME, and this is a determination we think is necessary to make long overdue updates to CMS rules. We stand ready to work with CMS, FDA, Congress, and others. Thank you for letting me make these comments. Sorry about running a little over there, Eugene. Thanks.

Eugene Freund: Understood. Up next is Tara Burke.

Tara Burke: Good afternoon. Can you hear me?

Eugene Freund: Yup.

Tara Burke: Good afternoon. I'm Tara Burke, the VP of Payment and Healthcare Delivery Policy at the Advanced Medical Technology Association, or AdvaMed. AdvaMed is a national trade association representing manufacturers of medical devices and diagnostic products. We will be responding to all three questions with more substantial comments submitted in writing by the comment deadline. For the first question, in general, we support starting the pre-market process early to allow time to complete all steps. Achievement of a timely process is dependent upon clearly defined timelines with a commitment from CMS to meet those established timelines. To that end, AdvaMed recommends that all steps be clearly defined, including timelines for key activities and public-facing guidance documents. For example, CMS should be held to an established time frame in which a definitive and not interim benefit category determination is made in a timely manner. Additionally, the pre-market process should outline

with clear timelines review of coding and payment for the device to ensure they're in place. We encourage CMS to finalize TCET quickly, recognizing that additional refinement may be needed in the future, and we encourage CMS to commit to routine evaluation and ongoing refinement. With regards to the second question, we support the approach to tie the timing for post-market review to a date established within the EDP. When developing the timelines during the pre-market process, CMS, together with the manufacturer, should establish a reasonable and mutually agreed upon collection period with an emphasis on establishing timelines that allows the collection of the most meaningful data points to demonstrate values for the Medicare population.

AdvaMed recognizes that CMS intends to utilize a third-party contractor for the updated evidence review, and we strongly recommend that the process include an open dialogue engagement with the manufacturer to aid the contractor in their review. Additionally, we encourage CMS to allow the manufacturer to extend the date if additional time is needed to complete data collection. Finally, we generally support the proposal that similar devices will be subject to the same coverage conditions, including a requirement to propose an EDP. This would provide similar recently approved products with the opportunity to leverage the TCET pathway and provide Medicare beneficiaries with faster access. However, more clarity on how CMS defines similar devices, as well as the process of establishing an EDP, and the timing associated with that, is needed. Our written comments will provide detailed recommendations related to the definition and process for similar devices. AdvaMed and CMS share a common goal—the establishment of a clear and expeditious process based on scientifically sound clinical evidence with appropriate safeguards for emerging technologies that will benefit Medicare-eligible patients. Thank you for the opportunity to speak today, and thank you for your continued collaboration.

Eugene Freund: Thank you very much. Next up is Mary Coppage. You may go.

Mary Coppage: Good afternoon. My name is Mary Coppage. I'm Vice President of Healthcare Policy at Edwards Lifesciences. Edwards is the global leader in patient-focused innovations for structural heart disease and critical care monitoring. Thank you for the opportunity to comment today. The proposed TCET guidance is a positive step forward and holds promise to address the needs of patients through access to Breakthrough therapies. We also believe that it holds a promise of providing more predictability of the process. We recognize that predictability is not necessarily certainty of outcome. However, there is a benefit to having more predictability around concepts CMS describes, including evidence preview, evidence review, evidence development plans, and agency timelines, as well as revisiting the coverage policy in three to five years, as proposed by CMS. Edwards is encouraged by CMS' openness to incorporating robust, fit-for-purpose evidence development into TCET and we look forward to the agency’s forthcoming guidance. While registries might be needed in some cases, routinely collected real-world data could replace the need for extensive clinical data outside the scope of CMS' key questions. We believe fit-for-purpose data collection should be designed with patients and their needs in mind. It should be streamlined to minimize administrative burden and limited to the data necessary to demonstrate to CMS that innovation is reasonable and necessary to cover. The process of identifying the core essential data could involve CMS working with stakeholders to outline data requirements. Edwards has concerns with the CMS proposal to share TCET

evidence preview with Medicare Administrative Contractors (MAC), recognizing the previews would be conducted to identify material evidence gaps that will require further evidence development during transitional coverage. We are concerned that they may not reflect the current state of the evidence when reviewed by the MAC. And while Edwards believes there is a need for more resources in the CMS Coverage and Analysis Group, we understand the need to prioritize. As such, we urge CMS to establish clearly defined and transparent criteria, including is this device a life-saving medical technology, will the device have is a significant, not incremental, impact on the lives of Medicare beneficiaries their families and community? Will the technology address unmet patient needs, and does it demonstrate potential for significant clinical benefits? How does consideration of this device's additional coverage contribute to addressing health disparities by expanding access and improving health outcomes?

With regard to follow-on devices, TCET should create opportunities for follow-on technologies to pursue transitional coverage that includes comparable studies. Following the conclusion of the transitional coverage period, any post-TCET national coverage determination for the first device should apply to other medical technologies within the same coverage category. We look forward to continuing to work with the agency to shape the development of a transitional coverage pathway. Thank you.

Eugene Freund: Thank you very much. Next is Dan Waldmann.

Dan Waldman: Thank you. Good afternoon. I am here speaking on behalf of the Medical Device Manufacturers Association. For 30 years, MDMA has advocated for policies that promote the development of innovative medical technologies that improve health care delivery and patient outcomes. We appreciate CMS' commitment to accelerating access to novel medical devices and diagnostics for Medicare beneficiaries and their physicians, especially when other treatment options are unavailable or inadequate. CMS has proposed a number of reforms to enhance the existing coverage with evidence-development pathway, many of which are improvements. With that said, we are concerned about the limited number of devices CMS projects will be accepted into the accelerated CED program. The proposal reflects how we believe CED should work for any product that is only eligible for coverage under the agency's CED authority as compared to its general authority to cover devices that are reasonable and necessary. We also intend to comment on a number of specific areas of the proposal, including the need for alignment of coding and payment determinations with the issuance of the final coverage determination. Unfortunately, being limited solely to an accelerated CED program, the current proposal represents a missed opportunity to meaningfully accelerate access and foster innovation. While developing its TCET proposal, CMS officials have frequently used a graphic to illustrate the Medicare coverage process, which divides items and services into three categories: those that clearly meet the reasonable criteria under general conditions of use and are therefore appropriate subjects for a national coverage determination, those that are promising but for which there are gaps in evidence relevant to the Medicare population that are significant enough that it does not meet the reasonable and necessary standard and thus can only be covered under CED. Finally, those that are reasonable and necessary but for which there is limited context, meaning that additional data from real-world use of the technology is needed to formulate a long-term national coverage policy. CMS currently defers coverage decision-making on items and services in this latter category to its local Medicare Administrative Contractors, or

MACs. CMS has not proposed to take any steps to accelerate access to technologies in a reasonable and necessary limited context guide, many of which languish for years as manufacturers, especially small innovative companies that comprise the majority of MDMA membership, struggle to navigate the opaque, inconsistent, and undefined procedures that the MAC uses to make coverage decisions. If CMS is truly committed to accelerating beneficiary and physician access to promising new technologies, CMS must, in addition to the proposed CED improvements, focus on creating similar but separate pathways for technologies that meet a minimum, reasonably necessary threshold but limited context on real-world use. Adopting a temporary transitional national coverage policy for important new technologies in this category would have dual benefits, accelerating access and, when necessary, organizing the collection and evaluation of additional real-world evidence to support development of a permanent coverage policy. Predicates for such a pathway might be found in previous CMS initiatives that were discontinued, such as coverage study participation and coverage with appropriateness and determination. MDMA looks forward to working with CMS to finalize a more robust and meaningful TCET program that includes both CED improvements and a separate non-CED coverage pathway. Thank you again for the opportunity to speak today.

Eugene Freund: Thank you very much for your comments. Next up is Larry Anderson.

Cody Simmons: Hi. Hello. I think my colleague may have checked that off. My name is Cody Simmons. I'm the CEO of DermaSensor. DermaSensor is a 10-person medical device company with our one product, an FDA Breakthrough skin cancer detection device for PCPs currently under review by FDA, and the device is already CE marked as well. We've spent 10 years and over $20 million developing this product and conducting 12 clinical studies with industry awards in 2023 alone, including the Edison Award, MedTech Breakthrough Award for best innovation in dermatology, and our recent acceptance into the AFP Foundation program. We expect to be the first automated skin cancer device authorized by the FDA for use by PCPs and the first such skin cancer device as indicated for use for all skin cancers, not just melanoma. Our company, as well as our physician leader, collaborators, and advisors, are appreciative of the agency's efforts to address the coverage gap for innovative technologies by issuing the TCET notice. In my forthcoming comments, I'm providing feedback limited to only the first question that CMS is receiving and put out today. With our company's leadership and Board of Directors having founded and invested in dozens of early-stage medical device companies, including Intuitive Surgical, Insightec, Eco Surgical, and OrthoSensor. We have three concerns with the current proposed TCET procedure, all three of which pertain to necessary resource burdens for CMS and also for companies, and again, this is for the first question.

Companies, especially start-ups, often inherent optimistic and unrealistic submission timeline expectations and also often knowingly pursue activities just to support financing efforts—for example, applying to TCET to help with fundraising regardless of the company's actual FDA submission time. Thus, whether intentional or not, we are confident that many TCET submissions, if not the majority of them, would be submitted well before their one-year authorization decision counter to CMS' intention. Number 2, even after submission, authorization timelines can be unpredictable and vary greatly since 510(k) and De Novo typically range from at least five months to well over 12 months to receive clearance, and many PMAs has been taking two or three years, for FDA approval, as has recently been reported

publicly. Lastly, FDA authorization ultimately does not occur for many De Novo and PMA submissions.

While the authorization rates for FDA Breakthrough Devices is not shared publicly by FDA, we suggest CMS continue to work with FDA to consider those authorization rates and the resulting waste of resources that would occur if CMS were to conduct their proposed robust assessment of devices that may not ultimately even be authorized. All of these considerations with the proposed procedural notice would ultimately result in waste of substantial CMS resources—resources that could be better directed toward timely and effective reviews for devices nearing FDA authorization or were recently authorized. Thus, we believe there are opportunities to improve upon this proposed procedural notice that would ultimately allow for more efficient use of CMS resources to more quickly cover Breakthrough Devices that are actively on the market and actually able to benefit Medicare patients.

Therefore, our feedback is that CMS consider a procedural notice change that would only allow for companies to apply to TCET that have (a) already submitted to FDA for authorization, or (b) that were recently authorized by FDA. Allowing recently authorized devices would align with the MCIT rule in which manufacturers could submit MCIT program within two years of FDA authorization. Our regulatory experts believe this approach would still result in the large majority of Breakthrough Device submissions being at least six months before FDA authorization and that the majority would still be at least a year before FDA authorization. Accordingly, this timing would be in line with CMS' desired timeline for the majority of preauthorized devices while also greatly lessening the number of TCET submissions that are prematurely submitted since companies would not be able to submit for TCET prior to submitting to the FDA. In place of those many premature TCET submissions, CMS can then accept Breakthrough Devices recently authorized by FDA and therefore fully avoid wasting CMS and manufacturers' resources due to unpredictable FDA timelines and unpredictable FDA authorization risks.

In conclusion, our company believes that FDA submission should be the earliest timing for companies to submit to TCET. This would avoid both CMS and companies wasting valuable resources working on Breakthrough Devices that prematurely applied to TCET or that will ultimately not even be authorized by the FDA. Those resources could be redirected to working on submissions of recently authorized FDA Breakthrough Devices that could still greatly benefit from the TCET program, similar to the MCIT program approach. Thank you for your consideration of DermaSensor's feedback.

Eugene Freund: Thank you for your feedback. Next up is Yajuan Lu.

Yajuan Lu: Thank you, Eugene. Good afternoon, everyone. My name is Yajuan Lu, Director of Health Policy of Boston Scientific. We appreciate CMS' continued effort on the TCET pathway, and thank you for the opportunity to give input to the proposed notice. Our comments will respond directly to the three questions CMS posted, but before then, we would like to encourage CMS to consider and confirm the eligibility of the following technologies under TCET. First, this new indication for approved technologies that have FDA Breakthrough designation and second, software as a medical device with FDA Breakthrough designation. We would also like

CMS to provide additional clarity around how technologies will be prioritized for inclusion under TCET, as illustrated by my colleagues that have spoken in the call.

To respond to CMS' first question regarding the time frame for self-nomination. We consider the 12 months prior to the anticipated FDA approval actually appropriate. Based on our experience, we believe that manufacturers can reasonably estimate when they are approximately 12 months away from full market approval, and this is also the right amount of time to complete the pre-market approval tasks outlined in the notice. For example, from our experience when CMS established the for left atrial appendage inclusion, it took CMS 10 months to finalize the NCD in February 2016, since we submitted the application in April 2015. So, 12 months seems to us the right amount of time for self-nomination. To CMS' second question regarding the duration of coverage under the TCET pathway, we believe the definitive timeline or process to decide when sufficient data has been collected to reach a coverage or an uncovered decision is critical. This could be achieved either by specifying in that date in the Evidence Development Plan if visible during the pre-EDP stakeholders meetings, while also providing an opportunity to reassess within six months of that date, as CMS proposed, or if determining that end date for TCET data collection and coverage is not feasible when the EDP is developed, then CMS should establish a series of predefined check-in points to determine the most appropriate end date.

Additionally, it is important that the duration of the coverage under the TCET pathway should also be extended if necessary to ensure sufficient data collection. To the third question regarding the evidence development requirements for a follow-on product, we believe it would be appropriate for the follow-on products to be subject to a comparable level of requirements as initial applicant. Following the conclusion of the transitional coverage period, Medicare coverage should generally be class-specific, agnostic to individual devices, consistent with standard NCD and LCDs. As such, any post-TCET national coverage determination for the first device would also be applicable for follow-on devices. This concludes my remarks. Thank you again for the opportunity to provide input. Boston Scientific looks forward to continued partnership with CMS to advance the TCET pathway.

Eugene Freund: Thank you very much. Next up is Leah Amir.

Leah Amir: Thank you very much. Can you hear me?

Eugene Freund: Yup.

Leah Amir: Great. So, I am the Executive Director of the Institute for Quality Resource Management. In that role, we commercialize medical products through clinical analysis outcomes methods, looking at cost effectiveness as well. We welcome CMS uptake to the TCET pathway. This is an opportunity to accelerate patient access to beneficial medical products while generating evidence, and as stakeholders, we welcome these improvements to a new pathway that is flexible, transparent, predictable, and collaborative. To that end, relative to question number 1, I am agreeing with my colleagues, in that timing is critical when aligning FDA clearances as well as NCD development based upon clinical evidence. The new device that is in question may be marketed for at least a year before final NCD development. This may not be favorable. Please consider increasing the time—as we have said, making that time more flexible

for the coverage based upon the date of the FDA clearance, and the actual date the provider is billing for this new technology. So, aligning FDA clinical evidence as well as sales on the market. When doing the clinical trials under CED to achieve the NCD, enrolling patients that meet the inclusion and exclusion criteria, as these must be controlled, randomized studies, and collecting the relevant outcome information that is specific to this particular product, answering the recent question, can frequently take over a year on that alone. So, flexibility between FDA, stakeholders, and CMS is absolutely critical for this to succeed and actually get this technology into the hands of the physicians and patients. Because Medicare is a defined benefit program and based upon our experience over the years working with new medical technology if the new medical technology is highly innovative, definitely going through the Breakthrough or De Novo pathway, we find once in a while these technologies did not meet a benefit category although the outcome data is very clear. So, we ask CMS to consider what would be the appropriate pathway in the case of a Breakthrough technology that does bring significant benefit to the patient population, what could be done to update, modify, or edit the benefit categories that are relevant. We also ask that Medicare while providing this TCET program that will result in NCDs that there be some in relationship such that a commercial Medicare Advantage Plans would recognize the CMS fee-for-service payment process that it's gone through rigorous clinical evidence and the NCD so that they might comply as well as they do not. We welcome this opportunity to communicate with you in an ongoing fashion and respond to the guidance in a timely manner. Thank you very much.

Eugene Freund: Thank you very much. Next up is Rita Redberg.

Rita Redberg: Hi, thanks. Can you hear me?

Eugene Freund: Yup.

Rita Redberg: Thanks. I'm Rita Redberg. I'm a Professor of Medicine and a cardiologist at University of California, San Francisco, where I take care of lots of patients with various medical devices, particularly Kardia. I'm also a former member of the Medicare Evidence Development Coverage Advisory Committee for over eight years, of which four of those were as chairperson. So, I want to note first that CMS has a robust process already in place for determining what procedures meet reasonable and necessary criteria for Medicare beneficiaries. I certainly favor continued robust evidence development, but I do have concerns about some of the assets of this new proposal. Firstly, I think it's really important that transparency be a principle of the program and that all data collected, particularly using Medicare resources, is transparent and accessible to all patients as well as providers. I'm concerned about the cost of this program, which is aimed at the FDA Breakthrough Devices. As we know, FDA allows Breakthrough criteria and devices on the market with potential, but more uncertainty than the usual pathway, which means that we don't know if they're by the FDA's definition safe and effective, and we don't know for sure if they meet Medicare's criteria of reasonable and necessary. So while I think there are appropriate times for coverage with evidence development, it does shift the cost from the sponsor, which would usually have to do a clinical trial to show reasonable and necessary to Medicare, and essentially taxpayers to now cover devices that we're not sure they're absolutely going improve the outcomes for Medicare beneficiaries. So, that is a big financial burden.

There are particular issues with Breakthrough Devices because they tend not to include people in their pre-market trials that represent the Medicare population—in particular they often exclude older persons, they exclude more women, and they exclude more persons of color, and that is not reflective of the Medicare population. I think there are issues also with registries as Jay Crosson, former Chair of the Medicare Payment Advisory Commission, and I wrote in an editorial in *JAMA Internal Medicine* that came out on Friday. Registries have not had a good track record at identifying dangerous or ineffective devices and helping to remove them from the market, and the reliance of registries to replace randomized clinical trials means that dangerous devices can get on the market inside Medicare beneficiaries, and they are very dangerous or impossible to remove. Particularly, for example, in cardiology, when we're talking about implanted devices, and there have been numerous examples of this, where after approval and widespread use, we discover that these are actually more likely to harm than to be good. Other issues, for example, is that early and unrestrictive adoption of devices often occurs after widespread Medicare coverage, and it's very hard to change practice once people have bought the equipment, have done the training, and start believing in a procedure even if it's totally ineffective. For example, we're still doing lots of stenting for percutaneous coronary intervention in people who would be better off with medical therapy just because we started doing it that way and, for a lot of reasons we continue to believe in it even though trial after trial shows no benefit. Cardiac CTA was another example. I sat on the Medicare Coverage Committee in 2004 where we found absolutely no evidence of improved outcomes with cardiac CT. Medicare declined to issue a coverage decision at that, at that time. They were considering a CED. There was widespread lobbying by the manufacturer as well as professional groups and there was widespread adoption by regional carriers. Two years later, when CMS was concerned that the enthusiasm for the technology had way overtaken the evidence, it was impossible to roll it back. So, I think that it's important to offer necessary and reasonable technologies, but we really have to be careful not to unroll them before they're ready. Thank you.

Eugene Freund: Thank you very much. Next up is Josh Makower.

Josh Makower: Thank you very much. I really appreciate Dr. Farmer, Dr. Freund, and Ms. Ashby for giving me the opportunity to make some comments today. Our team will be submitting comments to the specific questions asked in our written comments, but I wanted to make more general comments now to share our overall perspective. My name is Josh Makower, I have dedicated the past 34 years of my life to developing therapies and technologies to improve patient care. In addition to being a physician, innovator, and entrepreneur at Stanford University, I'm a Professor of Medicine and Bioengineering. I'm also the Co-Founder and Director of Stanford Byers Center for Biodesign Policy Program. The opinions I express today are my own and do not represent the opinions of the organizations that I'm affiliated with.

Increasingly, medical technology innovators are being confronted with the valley of death, where technologies have received FDA authorization but often no CMS or insurance coverage is in place to allow patients to gain access to them. American seniors and patients across the country are often not getting timely access to critical medical technologies for many years, if ever. Being science- and data-driven, my colleagues and I at Stanford have taken some time to study just how difficult the environment has become, and we hope to publish the results in our work very shortly. To summarize, here are some of our findings. Using publicly available information, we

discovered that only 44% of novel or Breakthrough technologies authorized by the FDA between 2016 through 2019 achieved even the most nominal degree of Medicare coverage by the end of 2022, and the median time to achieve this nominal coverage was actually 5.7 years. This is too long to wait, especially for Breakthrough medical technologies that have been determined to be safe and effective by the FDA. A broad and robust transitional coverage program should ideally provide coverage shortly after FDA authorization, allowing for continued evidence collection as the process begins adoption and be much broader. If, in fact, issues are discovered that did not reveal themselves during the pivotal studies, FDA already has the authority to quickly remove them from the market, and CMS could remove transitional coverage as well. As a physician and innovator, I remain concerned that the current TCET proposal from CMS is extremely limited to minor enhancements of the existing Coverage with Evidence Development program (CED) versus establishing a new pathway. Furthermore, the current proposal is very narrow in scope, only applying to a small handful of Breakthrough Devices each year. Five devices a year is really not sufficient to truly enhance and improve Medicare beneficiary access. There are many novel technologies, such as digital health technologies, novel diagnostics, and new advanced therapies that are reasonable and necessary where additional data collection focused on real world use would help inform the development of a long-term coverage policy. The current TCET proposal does not appear large enough in scope to be able to address many of these technologies.

Unfortunately, although I am pleased to see CMS making an effort to address innovation for patient care and within the constraints of its existing programs, it's important to note that CED itself has not lived up to expectations because of the way it has been structured and resourced. And today, even with this TCET modification, CED is too limited to really encourage the advancement of innovation for patient care. CMS must expand the current proposal and establish a new dedicated pathway to capture these technologies and allow for more streamlined coverage and coding payment pathway if they really hope to bring patient care into the future. Lastly, as I read the document, there was consistent use of the words "CMS may," leaving open, of course, to the possibility that CMS also may *not*, makes me wonder what in the proposal was really being committed to and what is just a possible suggested approach. As innovators, the work we've invested in inventing and developing cures, therapies, and diagnostics are only beneficial when patients and providers can have access to them. I look forward to working you, Congress, and with all stakeholders to achieve our common goal of improving patient care by establishing a new, robust, and broad transitional coverage pathway that is not constrained by the limitations of prior programs. Thank you for considering these comments.

Eugene Freund: Thank you for your comments. Next up is Diana Zuckerman.

Diana Zuckerman: Hi. Can you hear me now?

Eugene Freund: Yup.

Diana Zuckerman: I'm Dr. Diana Zuckerman, President of the National Center for Health Research. Our center is a public health think tank that focuses on policies and programs that increase the safety and effectiveness of medical products. We support the goals of the TCET program but see an enormous disconnect between the types of evidence that the FDA requires for Breakthrough Devices, especially 510(k) devices, and the CED standards that CMS requires

for coverage. We hear a lot about flexibility from FDA and from industry but not enough about scientific evidence of safety or effectiveness. Innovation and devices and other products should be defined to require that the product is proven to be better, not just newer. We urge CMS to work with industry to make it clear that CMS evidence standards of clinical benefit are very different from the standards required by Center for Device and Radiological Health (CDRH), and we urge CMS to urge companies to provide the evidence needed to be worthy of CMS coverage. I just want to mention that the standard for FDA devices is not proven safety or effectiveness. It's a reasonable assurance of safety and effectiveness and many times not so reasonable. I also do want to reiterate what was said earlier about how often when there are studies that FDA has used as a basis for approval, it does have a tendency to have fewer older people, fewer people of color, and fewer women. So again, we thank CMS for this effort to improve access to safe and effective medical devices and urge CMS to stick with their very important standards of what is reasonable and necessary. Thank you very much.

Eugene Freund: Thank you very much. Next up is Lea Kaydus.

Lea Kaydus: Hello. I am an end user, I'm a grandmother and the only comment that I have to keep this simple is that when a device has been approved for use by some members of a population, that rather than having to go through the entire process again for the remainder of that population, would it not be to everyone's advantage if the work was done between the physician and the patient to determine the correct prescribing information? Thank you for your time.

Eugene Freund: Thank you for your comment. At this point I am not seeing further hands raised, so I'm going to give some time for others to ask to be recognized. I see Leah Amir has raised her hand.

Leah Amir: There's been a lot of discussion relative to the second and third generation devices that come subsequent to the Breakthrough Device going through the FDA pathway. I welcome all the comments we've had, particularly with the huge divergence between FDA criteria for safety and effective, or safe and effective, not effectiveness, and the CED requirements. I do agree that it would be appropriate for the second and third generation devices to go through Clinical Evidence Development as the primary for the main purpose that it will be well-defined. The patients to be enrolled would be defined and depending upon the importance of that particular device to a specific patient population, and the need at the time of coverage can be determined while it's going through the clinical trial process. But given the importance of this and the cost and the importance to be safe with the patients, I do think they should go through a Clinical Evidence Development, thank you.

Eugene Freund: Thank you and seeing no further hands raised, I think this concludes our comment period. Dr. Farmer, do you have any final words for us?

Dr. Steve Farmer: Yes, thank you, Eugene. I want to again thank everybody for your thoughtful comments today. We'll consider them carefully as we finalize the pathway and the associated guidance documents. We tried to get in a diversity of comments today and thankfully were able to get through to everybody that wished to speak. We want to remind you to submit your written

comments before the comment period is closed. The comments on the three proposed guidance documents are due by August 21, and the comments on the proposed TCET procedural notice are due by August 28. Thank you so much for your thoughtful comments, and we look forward to reviewing your comments as you submit them.

Eugene Freund: This ends the session, and again, thanks so much for attending.