Home as a Healthcare Hub Stakeholder Listening Session
July 25, 2024
Transcript

Ankurita Datta: Hello, everyone! I'm Ankurita Datta, and it is my pleasure to welcome you all to this public meeting for the recently launched home as a healthcare hub initiative. We're delighted to have folks attending from several sectors, including healthcare, architecture and the medical device industry. As a reminder to you, this presentation is being recorded, and a transcript will be available on the home as a healthcare hub virtual public meeting website in one week. Throughout the meeting and the course of this initiative, we welcome your feedback and suggestions. In addition to the QA box which will be available to you during the meeting, please submit any thoughts or comments you may have to the docket listed on the virtual public meeting website. We're also giving you all another opportunity to participate during the meeting by responding to our poll. Some of you may have seen this poll as you were joining the meeting, and we'll reintroduce it during the break, but it'll only be open for 15 min, so we encourage you all to respond before stepping away. Now let's get started, to start us off, w will hear from Commissioner Califf.

Robert Califf: Thank you, Ankurita, and CDRH for the invitation to be with you today for this important meeting on Home as a Health Care Hub. I'm sorry I can't join you in person. I'm truly excited by this initiative, which is designed to help reimagine the home environment as an integral part of the health care system. We believe this program is an integral component of a broader goal of advancing health equity for all people in the U.S. I want to thank CDRH for their leadership on this issue and for the collaboration of patient groups, clinicians and provider organizations, the medical device industry, and housing design experts. The need to fill this gap has come into focus in recent years, thanks in part to public health crises like the pandemic. One of the most troubling health issues that I've been concerned about for some time now is our nation's decreasing life expectancy. 2021 marked the lowest life expectancy level in the US since 1996. And while we see signals this year of a small improvement, there is a long way to go to achieve pre-pandemic levels. To give you an idea of the impact, despite the change in trajectory, people in some communities in the US are, on average, dying 25 years earlier than others. One of the leading drivers of this drop in life expectancy is the increasing prevalence of certain chronic diseases -- heart, vascular, metabolic, lung and kidney disease; mental health issues, as well as depression and suicide and drug use disorder. Additionally, and certainly related to the mental health issues, gun violence is now the leading cause of death in children, as highlighted by the surgeon general's recent report. These negative health trends are occurring as we develop a better understanding of how much of health outcomes are driven by inequities and are, at least in part, the result of social determinants. Data shows that people most impacted by these trends have lower household income, lower educational attainment, and face barriers to health care access, including a growing chasm between people in rural and urban areas. The CDC estimates that 6 in 10 adults in the US currently live with a chronic disease such as cancer, heart disease or diabetes and these diseases are increasingly

concentrated in populations with lower incomes, less education and less access to high quality food and healthcare. Although many chronic diseases are the result of individual health behaviors, such as excessive poor nutrition, sedentary lifestyles, and tobacco use and excessive use of alcohol and drugs, along with poor adherence to basic medications for common problems like hypertension, hyperlipidemia and diabetes, these individual behaviors occur in the context of profound structural socioeconomic and environmental factors. Specifically, the environment in which a person lives influences that person's ability to engage in healthy behaviors that prevent these diseases and helps manage them. Once a chronic condition develops, management of the disease requires the ability to afford health care and have physical access to it. Yet research increasingly shows that even when medically necessary, people often forgo costly treatments and health care, hindering their ability to manage their disease and resulting in poor health outcomes.
Unfortunately, we are witnessing the decay of the healthcare system as we know it, a system that already has demonstrated large gaps in care outcomes and access for historical minorities and other socially and economically disadvantaged people in the US. In addition to structural social and economic issues, we have a basic supply and demand problem. Currently, it is estimated that 84 million people live in primary care health deserts and the AMA and the AAMC projects that the US will be facing persistent physician shortages. Compounding this shortage is the rate of hospital and clinic closures or truncated service offerings which is particularly felt by rural America. The same disparities we see in many communities are often mirrored by disparate inclusion in the evidence generation process for medical products. Last month, the FDA issued draft guidance describing diversity action plans which are intended to increase enrollment of participants who are members of historically underrepresented populations in clinical studies. The goal was to help improve the strength and generalizability of the evidence for the intended use population. While Congress has expanded our authority to require diversity action plans by manufacturers of medical products, innovative approaches to meet patients where they are will be needed to markedly improve clinical trial representation. Equally problematic and adding to this is challenge is the growing distrust of many of our societal institutions and lack of regard for expertise, particularly in science, coupled with dispersion of misinformation, which may create barriers to healthcare utilization and clinical trial enrollment. At the FDA, it is one of our central responsibilities to communicate trustworthy scientific information to the public and industry. But as we know, misinformation is being used today to undermine public confidence in science generally, and biomedical science, and to subvert the credibility of our agency's work. Collectively, we will need strategies that repair this trust and build on collaborative, trusted relationships. One area that will play a key role is the home, which increasingly is becoming the place where some care and clinical evidence generation must move. Consequently, medical devices in the home will have a more prominent presence in preventing, diagnosing, monitoring, managing, and treating health conditions. These devices will increasingly leverage digital capabilities and integrate with multiple other systems to connect care and wellness.

That’s where the Home as a Health Care Initiative launched by CDRH comes in. Grounded on the principles of health access and health democratization, it is an effort to further this conversation, build on this need, connect multiple stakeholders, identify barriers, and collectively develop solutions that meet the needs of all patients in the US. You will hear more about the home prototypes that we are developing with health equity in mind that we envision will facilitate this shifting care paradigm. Considering the overall picture I’ve described already, it’s clear that whether it involves staying healthy and preventing a disease, or managing a health problem or disease, the outcomes are heavily affected by repetitive decisions about what we eat, how we stay active, whether we take or medications and whether we can avoid use of tobacco, drugs or excess alcohol. While clinic visits are important, it only makes sense that reinforcement of healthy choices at home can make a huge difference. In my experience in the “big tech” sector, I saw so many potentially useful individual apps with no coherent place to connect, or that simply added another challenge for overwhelmed clinicians trying to care for patients. These would be much more manageable and effective at the household level. It's important to understand that these challenges cannot be solved by the FDA alone. One of the goals of this initiative is to make sure the conversation considers the perspectives of the many people who will be impacted and who can have an impact. That is where all of you come in. Over the course of this meeting, we want to hear from you and get your perspectives. We welcome your ideas and understand that while our aspirations are lofty, we are series about being pragmatic and effective. We must take deliberate steps together in the development of care and evidence generation in our homes. The FDA’s mission is to protect and promote public health, and it is a responsibility we take very seriously. We can’t do that appropriately if we don’t or aren’t able to consider the needs and characteristics of all people and populations in the policies we advance, the science we support, as well as the workplace in which we operate. So whether it involves access to clinical trials, the availability of new approaches for treating chronic diseases, or other work we do, we are committed to reimagining ways to achieve greater success. By building in care options that consider the structural and critical elements of the home is an important and forward looking way to get people the care they need, when they need it. I thank you for joining us today, and look forward to your input. Julianne Lally: Hello, good morning and good afternoon. My name is Julianne Lally. I am the Associate Director of community screening and clinical trial education for Breakthrough T1D. Breakthrough T1D, formerly, JDRF is the leading global type one diabetes research and advocacy organization. We invest in research to turn ideas into life-changing realities and work hard to break through barriers that limit access to care. Our vision is to make every day with type one diabetes better today and tomorrow. We believe the FDA serves an irreplaceable role in protecting the health of the public while promoting health, equity, and ensuring innovations are available to all. We are very excited to learn about the FDA's initiative, to reimagine the patient's home as a healthcare hub though the concept of care at home is not necessarily new. In fact, this dates back quite a long time ago, much before modern technology. Our world has since experienced numerous breakthroughs in science and tech. allowing innovation to accelerate the evolving healthcare landscape. Not to

mention the breakthroughs that have yet to come. Thanks to efforts such as this. We are pleased for diabetes to be selected as the focus for the initial phase of this important project. As many of you already know, the incidence and prevalence of diabetes continues to rise across the globe. Thanks to significant breakthroughs in recent decades, people living with type one diabetes are able to become connected to devices to monitor their health like continuous glucose monitors or insulin pumps. While these devices bring better ability to manage type one, they also come with significant challenges, and have not removed the full burden of this condition. The FDA's strategy to nurture innovation and health and wellness, solutions at home will without a doubt, help to address unmet needs of people with type one diabetes to enhance quality of life and further maximize impact. Most importantly, this initiative not only takes into consideration the perspective of the healthcare provider and the needs of the medical device companies but incorporates firsthand experience directly provided by the source which is the patient voice by exploring home barriers provided by patients themselves and understanding the actual reality of the home experience. This platform will serve as an ideal lab, to better connect patients to their health in the setting where they spend most of their time home. This initiative, without a doubt, mirrors our vision to make every day better, regardless of the health, condition, or conditions facing the patient and certainly for individuals living with type one diabetes. We appreciate the agency's patient-centric approach and look forward to future impacts and advancements kindled by this initiative.

Mark Leahy: Thank you. Good afternoon. My name is Mark Leahy, and I'm the President and CEO of the Medical Device Manufactures Association. MDMA represents hundreds of innovative medical technology companies, and our mission is to ensure that patients have timely access to safe and effective products. I truly appreciate the invitation from Dr. Tarver to take a few minutes to share some thoughts around CDRH's home in the healthcare initiative. This is something that, again, I know is critically important to patients, physicians, innovators, and the fact that FDA is facilitating this 1st meeting of one of many is a great 1st step. , MDMA is proud to be a member of the steering committee, and looks forward to working with everybody in a collaborative fashion. As we all know, we have an aging population with increasing healthcare needs, yet at the same time we are facing a shortage of medical professionals to care for these patients. We also know that the more acute the care setting is, the more costly the care typically is due to the labor component. So again, I want to applaud FDA for being proactive and understanding the needs of the patients and bringing together all the key stakeholders to explore ways to enhance and accelerate opportunities to meet patients where they are, and that's in the home as it relates to patient access and health equity. The two are related. The home is a healthcare hub initiative provides a wonderful opportunity to not only provide care in a more comfortable and cost-effective setting, it will accelerate patient access to those who may be in areas where health care facilities and professionals are limited. And so again, as we look at this, not just from a technology standpoint, but from an access

standpoint, this really does have a chance to level the playing field and provide every patient, the tools, and the technologies. They need to manage their healthcare in a more effective way and when one looks at innovation in our industry too. I think it's important to understand the dynamics, often very different than the pharmaceutical industry, where there's a smaller concentration of players here the medical device industry is really driven by smaller companies on the forefront of innovation. According to the Department of Commerce, 80% of medical technology companies have fewer than 50 employees, and 98% of medical technology companies have fewer than 500 employees. So again, it is small businesses that are the engine of innovation within our industry. That's in large part due to physicians, innovators, engineers working together, identifying the needs of the patient and developing technologies to meet those needs. And there have been significant advances over the years to improve patient care in a variety of healthcare settings. But I think Covid has certainly brought to light some unique challenges as well, and Joe Kiani, the CEO and inventor at Massimo, his safety net platform, I think, was a great example. We're allowed patient monitoring of hospital grade back to physicians so they could track a patient's performance, and when we had an issue of but not enough beds during Covid, this safety net product allowed huge flex in the capacity, because you put the monitoring device on the patients who could go home, and all that information was sent to the hospital in real time, and if a reading got out of range, it was immediately identified. An ambulance was called and helped bring that patient back in. But it was an amazing tool that allowed the healthcare system to flex enhanced capacity and deliver better outcomes for patients. MDMA's chair, Leslie Trigg, is the CEO of Outset Medical, another incredibly innovative technology tableau which is a home hemodialysis technology, again, allowing patients to receive the necessary treatments and care in their comfort in their own home. So you know, these examples demonstrate innovations for patient care in the home exists. And our hope is that this new initiative and focus in these areas and these efforts will be accelerated to have a greater impact on patient care. Again, close collaboration and coordination will be critical to the success in this initiative, and MDMA looks forward to working with FDA patients, providers and innovators to improve patient care in the US and beyond. So look forward to a great discussion today and again engaging to really move the needle and improve patient care, and really enhance the robustness of these technologies, as again, they treat the patient where they are, and that's in the home. So thanks very much, and I hope you have a great day.

Sharmila Sandhu: Good afternoon. My name is Sharmila Sandhu, and I'm the Chief Operating Officer at the American Occupational Therapy Association. I am honored to have been invited to represent the American Occupational Therapy Association in this FDA stakeholder listening session. AOTA is also excited to participate alongside our member, Sabrena McCarley, who is an occupational therapist and Director of clinical reimbursement and transitional care management. Ms. McCarley was chosen to participate as an occupational therapy practitioner expert on the FDA's home as a healthcare hub initiative's steering committee. Occupational therapists and occupational therapy assistants are skilled clinicians who focus on

the things you want and need to do in your daily life. If you are recovering from an acute illness, accident, or injury, or managing a chronic medical condition, your valued occupations or daily activities may be disrupted. Occupational therapy incorporates skilled evidence-based evaluations and interventions to meet your goals in the therapeutic process. Your life is made up of occupations, meaningful everyday activities. Occupational therapy practitioners serve clients and their caregivers of diverse backgrounds and needs across the lifespan in their homes, through various programs available to them to provide home health care services. Clients who seek occupational therapy span all Americans, including Medicare and Medicaid beneficiaries, our service members and veterans, and those on commercial insurance, as well as those who may have no health insurance at all. In addition, occupational therapy practitioners have a critical understanding of the supports or barriers to occupation that exist in the home environmental context. As such, occupational therapy practitioners provide consultation and advice to builders, designers of homes, hospitals, schools, communities, playgrounds, and almost any lived or community space that you can imagine based on their expertise in analyzing the fit between environments and occupations. Occupational therapy is a critical service and is targeted to optimize health and function while achieving and maintaining independence and safety. Occupational therapy practitioners assess not only the physical function, but also the cognitive and psychosocial function of clients. Occupational therapy practitioners view cognition as such a critical component of function that we use the term functional cognition to encapsulate the relationship between an individual's cognition and their ability to perform activities of daily living healthcare. Providers need to understand how a client safely and effectively participates in essential activities of daily living, such as personal hygiene behaviors, and dressing, as well as instrumental activities of daily living, such as medication, management to guide post-acute care, transition, placement, discharge decisions and client and caregiver training. An example might be a client that has an acute crisis related to the diagnoses of diabetes. This results in a change in their medication regimen, including the increased frequency of self-administered insulin shots. Occupational therapy will help the client and the care team understand if there are motor skill, cognitive or visual deficits that could interfere with safe and effective medication management, post-discharge and develop compensatory strategies to mitigate these challenges in the home. In addition, our nation is in a mental health crisis. Prior to the pandemic 1 in 5 adults reported having mental illness, and deaths due to drug overdose were 4 times higher in 2018 than 10 years prior, as of January 2021. As a result, in part to the COVID-19 pandemic, 41% of US adults reported symptoms of anxiety or depressive disorder occurring nearly every day. At the same time, there's the documented shortage of mental health professionals with at least 152 million Americans living in a mental health professional shortage area. Occupational therapy can have a direct, positive impact on psychosocial functioning and behavioral health. Finally, I want to touch upon the community aging in place, advancing better living for elders program, which is also known as the Capable Program. Capable is a program developed by the Johns Hopkins School of Nursing that employs an occupational therapist, a registered nurse, and a handy person working in concert to address client difficulties in home safety, fall, risk and

prevention, while addressing activities of daily living and instrumental activities of daily living. The program has evolved through a series of evidence-based studies that clearly demonstrate the importance of addressing Medicare and Medicaid beneficiary problems related to everyday functioning in the home environment. The capable program has resulted in reduced disability, healthcare cost savings, and the promotion of aging in place services. services which are increasingly desired by elders and their families or caregivers as the baby boomer population continues to age. The program is an example of how we can make the home a healthcare hub and the key contributions that occupational therapy makes to optimizing healthcare outcomes. As a national professional organization representing occupational therapy, AOTA asserts that the need for these types of targeted coordinated services for the population will only continue to grow. The inclusion of housing and home modification considerations is critical at a time when payers, policymakers, and quality experts are recognizing the importance of social determinants of health or social risk in the overall risk, profile, and recovery trajectory for patients. AOTA continues to believe it is critical to incorporate key social determinants of health in particular housing status into the fabric of health, care, coverage, and payment. If we truly wish to be more responsive to the needs and wishes of our chronically ill and elderly population. Thank you for the opportunity to contribute to this critical discussion. AOTA stands ready to continue to contribute to this and future FDA initiatives and recognizes the home environment as an integral part of the healthcare system for all people in the United States.

Charles Henderson: Thank you. I'm Chuck Henderson and I have the privilege of serving as the CEO of the American Diabetes Association. I very much appreciate this opportunity to share a few words with you regarding the FDA's home as a health care hub initiative. At the ADA, we absolutely believe that health equity is a human right. Health equity is an underpinning of everything we do, so that we can ensure that more than 136 million Americans live with diabetes and prediabetes along with the millions more who are at higher risk for diabetes, no matter their race, income, zip, code, age, education, or gender get equal access to the most basic of human rights which is their health. One of the barriers to accessing care that we see is related to visiting a healthcare professional's office. Whether there's a transportation issue or inability to get away from work during the day. Some individuals may not always be able to have in-person visits with their healthcare professionals thus providing opportunities for their home to be a place where they can receive some of the most basic care they need, which is very important for people living with diabetes. This includes access to technology such as continuous glucose monitors, so that their healthcare professional can see their numbers is extremely important. At the ADA, we're proud to have led efforts that have resulted in greater access to CGMs for people with diabetes enrolled in Medicare veterans, affairs, benefits, and more than 10 State Medicaid programs, including the most populous states in the US. Ensuring a person living with diabetes has consistent and secure access to Wi-fi services, so that they can communicate with their clinicians if they're unable to visit them in

person is another aspect of making healthcare at home accessible to everyone. There's certainly more work that we can do, and it will take all of us to achieve health equity, which is why initiatives like this are so very, very important. Thank you for your time. Thank you so much and have a great day.

Gary Shapiro: The CEO of the Consumer Technology Association. CTA is a National Trade Association of some 1,300 American companies focused on innovation and making the world better for people. And one of the major areas is definitely healthcare. Because that's where technology is moving so quickly. I want to thank the US Food and Drug Administration for inviting me to speak today. And I want to welcome you over to this very important task you've embarked upon of ensuring that Americans can get health care and benefit from technology, especially when there's such a shortage of healthcare professionals. Of course, that's the way it is today. We have seen at our big trade show, which is held each January in Las Vegas, the CES, where we get basically 140,000 media investors, innovators from around the world who are focused on technology where healthcare has probably been our fastest growing segment. And it really accelerated with COVID because people are looking for solutions where they could cut back from going in to see a doctor, they could do different things. They can have more personalized, accessible, and intelligent healthcare, but also use technology to connect them more closely to their healthcare providers. And we're seeing new innovations so quickly that are empowering patients and giving them more options to understand and imagine their own home. But there's a challenge because we know more is possible. I hear it directly from my wife Mal, who is a well-known retina surgeon, and works at the national level on the boards of her subspecialty. But this shortage of doctors, the shortage of healthcare professionals and nurses, the difficulty in getting patients back and forth with caregivers. There's an opportunity here with technology which will allow better and home healthcare. In fact, in a survey that the Consumer Technology Association did last year, we found that fewer than half of healthcare professionals said that healthcare technology is living up to its potential. So even the healthcare world sees the potential of healthcare technology. But we're just not there yet. And it's especially a problem for the United States, because we spend more than any other country per capita on healthcare by a tremendous amount. We all know that it's affecting our debt. It's contributing to our annual deficit and it's something that we are passing on to our next generation of healthcare system, which is not only super expensive, but growing in cost. And it's something where we know technology can make not only things better, but actually can save money. So what's the solution. Here let's talk about the solutions. Obviously, technology can make doctor more efficient and can reduce paperwork. That's something we saw with Obamacare introduced the concept of electronic medical records. And it's starting to be realized now as more and more doctors are using it. And they realize they can go to research in that area and see what works and what doesn't. But more importantly, for us, for this initiative, is that technology can help people get out of hospitals and other facilities quicker, and know when they should go in, and it should also allow people to manage their care from home. And that was something clearly which COVID taught us. We have to learn how to

do that. We have to take advantage of the fact that people at home people are more comfortable in their homes. There's a lot of issues in hospitals with disease generation and getting sick in hospitals. And what we're also seeing at the same time is tremendous growth, not only in artificial intelligence, but generative AI. Specifically, where there's a promise that we could do even more. We saw this at CS 2024 in January, in Las Vegas, where there's AI-driven healthcare tools that help monitor patients' vitals at home, reduce pain, and even reduce the risk of infections after the surgery. As a trade association, we have a role. We're the voice of the tech industry. We have the most innovative health tech companies in the world as our members, and we have all sorts of participants from the entire health ecosystem. Some of the health technology companies are pioneering great things in remote patient monitoring, digital therapeutics, precision medicine, and other AI tools. And what binds us together is that these companies and the people that are working for them full time, want to achieve the same type of goal which is healthcare at any address, recognizing the shift from the care and health facilities to care and home and other environments. So on behalf of our membership, I want to thank and congratulate the work of the FDA is doing on this very innovative initiative which is helping to make that shift possible. So how we're doing our part is something I want to talk about, because we are also doing our part when it comes to digital health. CTA wears many hats. We're a standard sitting organization that's American National Standards Institute certified. We've actually already published 30. That's actually 30. We just got the 30th digital health standards covering areas like over-the-counter hearing Aids and Health AI on Capitol Hill, we helped launch the Congressional digital Health Caucus. This past February, and we've also launched a consortium of associations to educate policymakers on health AI policy issues. We also do a lot of original research in the past year alone we published reports on women's digital health solutions, mental health, and the adoption of digital health tools. And last, but certainly not least, we convene leaders in the healthcare community. At CTA 2024, we hosted our 1st health leaders, industry forum, and throughout the year we have events like our Health AI plus Conference series. So I want to thank you for everyone who has partnered with us and worked with us in these efforts. And I believe that together, we're moving things forward. We're moving innovation forward. We're moving healthcare forward. And we're solving some of the biggest and most fundamental challenges that make a difference in the lives of the people around the globe. Thank you, good luck, and let us know how we can help further. Good afternoon. Thank you for inviting me to speak today on behalf of the medical technology industry.

Scott Whitaker: I'm Scott Whitaker. I'm President and CEO of AdvaMed,the Med Tech Association. AdvaMed represents more than 500 companies, from the largest MedTech developer to the smallest startup in every category of care, devices, diagnostics, imaging, and even the emerging AI tools. In many ways. MedTech is the backbone of our healthcare system. We develop all the life-saving and life-enhancing medical technologies that require FDA review in every healthcare setting from the clinic, to the hospital, to the home. So, we're excited to be a part of the home as a

health care Hub initiative launched by FDA earlier this year. The vision of all patients enjoying their best health, regardless of zip, code or circumstance, is one we share. There are so many ways that medical technology improves patients' lives, especially in the home healthcare setting, whether through diagnostics or home monitoring care management, new technologies, connected care and many other means. You know, I was reflecting recently on the progress we've made over the last 50 years, thanks to the work of MedTech companies, and of course, the partnership we have with the FDA. And one of the best examples of this is in the diabetes space. 50 years ago, a complete diabetes system was like wheeling around a computer monitor on a shopping cart. Now, today, many of the technologies used to manage diabetes can fit in the palm of your hand and are much more accurate and much more powerful in managing this disease. My daughter Eva was diagnosed with type one diabetes 14 years ago and the innovations we have seen to help make diabetes more manageable, have been truly remarkable and life-changing, not only for her, but for our whole family. From insulin pumps to continuous glucose monitors, and now connected devices that often don't require human intervention. Those living with type one diabetes have more control than ever over their health care decisions and the innovations just keep coming. For example, both Abbott and Dexcom recently launched the 1st over the counter CGMs. Those products will help diagnose and monitor blood sugar levels for those who are pre-diabetic and type 2 diabetic, including those who just want to better understand how diet and exercise may affect their blood sugar levels. Consider a patient who's been told recently that they're pre-diabetic. They want to take better care of their health and prevent developing diabetes. They may live in a rural area, and their access to doctors. may be lacking. The ability to buy a CGM at a local drugstore or order online could be a game changer for their health. A recent project by Dexcom, found that mostly rural Hancock County, Ohio, participants in this project, using a CGM, achieved dramatic improvements in their blood sugar levels, and most of them wanted to continue using the device after the project was over. With an estimated 98 million Americans living with Prediabetes. A simple change like wearing a CGM, could prevent them from developing a lifelong condition. Whether the company is Avid or Dexcom, or Insolent, Medtronic, Bekta Ascension, Lily or Roche, or many other MedTech companies. We see that medical technology, when it's accessible, easy to use, makes a huge difference in people's lives and they will embrace it. MedTech innovators wake up every day motivated to find solutions that ensure as many people as possible can achieve better health. The next essential question then becomes, how to break down barriers to access. And the barriers are diverse. People are uninsured. They don't have access to a doctor because they live in a rural area. They lack access because of provider shortages, or they're underinsured and can't afford expensive copays. Medical technology can help break down those barriers. The FDA recognizes this fact, and the real-world examples prove it. So my call to action is this, let's leverage the hard-won lessons of recent history, including those from the Covid crisis, to break down barriers to access. We have evidence that home-based health care works. We know telehealth works and in-home diagnostic testing works, CGMs work, automated insulin delivery systems work. The home of the future holds tremendous promise for patients of all kinds, suffering from any number of ailments, not just diabetes. Every patient who could benefit from safe and effective medical

technologies and treatments should have access, period. I'm fortunate in my role to know many MedTech innovators and patients from all backgrounds. And I love hearing the stories about their technologies and how those technologies have changed their lives. And the FDA plays an incredible role in helping patients get access to these technologies that save and change lives. FDA represents the best of Federal agencies. We're grateful to the regulators who are dedicating so much of their time and their lives to MedTech innovation and helping patients live better and longer lives. So, on behalf of Advamed and our member companies, we're excited to see what we can accomplish for patients here at home, in your home and around the world. So, thank you for having me thank you for the work you're doing, and have a great day.

Ankurita Datta: Thank you all. To set the stage for why we're all here. CDRH Director, Dr. Jeff Shuren will provide remarks.

Jeff Shuren: Welcome everyone. And thank you to all the organizations that are participating with us on shaping this new initiative. I invite you to take a journey with me and imagine the typical person who lives with diabetes. They have many appointments each year with their primary care, provider, their endocrinologists, their podiatrists, their ophthalmologist, and that list can go on and on. However much of the care happens at home, and the outcomes are largely impacted by aspects of their daily lives. Now consider those individuals who live in rural locations, or those with few resources facing the absence of clinics or healthcare providers near where they live, pressing work commitments or childcare, elder care, responsibilities, making it difficult to even schedule appointments or attend them. And rising healthcare costs, forcing many to choose between managing their disease or keeping the lights on in their homes. You can clearly see how difficult it may be for them to experience good healthcare outcomes. Healthcare in our country has been designed around the needs of the healthcare system, which maybe made sense years ago. But today can lead and has led to problems with access to care, adequacy of care, and cost of care. It's critical that we transform how we deliver care and broaden it to include wellness and prevention, beginning with centering care around the person and not the healthcare system. Even the terminology we use – patient - can be disempowering and limits and confines a person’s identity to their disease. With respect to the healthcare system, this conceptualization ignores so many of the complexities that comprise the entire human lived experience, which directly impacts health outcomes. A model of healthcare that is focused on the system and healthcare providers squarely puts the burden of care and the coordination of care, the screening for complications and the prevention of poor outcomes more and more on the backs of the person who is already managing a complicated condition. The Home as a Healthcare Hub initiative stems from efforts by the Center over the years to improve access to healthcare, as well as facilitate the participation of diverse populations in clinical evidence generation. One approach to accomplish this objective is by helping to bring elements of care and clinical trials to the home, as well as to other non-traditional settings. This approach was described in our CDRH Strategic Priority for 2022 -2025 to advance health equity. We opened a public docket on home use devices in June 2023, and we received many comments from the public, including patient organizations. We also held a meeting of a Patient

Engagement Advisory Committee (PEAC) in September 2023, where we heard the importance of considering the homes of people where the devices will ultimately be used. In particular, the PEAC members stressed the criticality of not only ensuring devices will work well in the home when used by people living with a health condition, but also the importance of considering where people live and the challenges they may face at home. The Hub initiative is a step towards addressing these concerns for many people. Home is where they spend time with family and friends, where they build a life, and where they can have some privacy and be themselves. Home should not lose its charm or warmth, nor should care encroach on patient's privacy and personal agency. Hence health and wellness solutions that come into the home should not undermine or interfere with the prevailing concept of home. We have a contract with HKS, a company skilled in designing homes and clinical care sites with health equity in mind. You'll hear more details about this work from Dr. Nanda, the perspectives of people from different communities about the prospect of having healthcare and wellness delivered at home. Working with the FDA's Office of Minority Health and Health Equity's (OMHHE) REACH consortium, we spoke to leaders from African American, Hispanic, Native American, Asian, Hawaiian, and Pacific Islander communities about the concept, even as their perspectives on what we would call the hub we are planning to develop. Their comments coupled with neurocognitive testing helped us land on the newly minted name of LilyPad. To describe the prototype LilyPad allows for screening, diagnosis, monitoring and treatment plus prevention and wellness, and the opportunity to participate in clinical studies in the comfort of the home. It provides people with intuitive to operate privacy, protected technology that puts people and their families at the center of the latest care. You'll have a chance to view the new LilyPad logo at the end of the meeting. As I hope you can see, we designed the initiative, including the name, by starting with all people and equity in mind. Now, you may be asking, why did we just start with the condition of diabetes. It's a condition that currently plagues over 38 million people of all ages in the US. Which is about 11% of the US population, and that number is growing in 2021. Roughly 1.2 million new cases were diagnosed according to the CDC. And the groups most affected are rural residents, poorer populations, and those in the American Indian, Alaskan, Native, Black, Hispanic, and Asian communities. It comes with a financial cost of over 300 billion dollars in medical costs, with that number anticipated to increase with the rise in prevalence. These costs are attributed in part to the impact. The disease takes on so many organ systems resulting in significant morbidity and mortality. It's a leading cause of blindness, lower limb amputations and end-stage kidney disease, all of which can be disabling conditions. Diabetes is also a condition with mobilized, patient organizations and provided groups that are well positioned to contribute to the solution. And lastly, it's a condition where lifestyle factors, such as what you eat daily and how active you are in your sleep patterns to name a few, can impact your health outcomes. We are committed to centering on the person living with the condition and insisting the perspectives of the people with diabetes be considered at the start rather than at the end of this conversation. We're setting the stage to build integrative solutions and not silo development. We hope to move from retrospecting hospital devices to work in the home, to creating devices at the outset for the home ensuring they are truly interoperable, accessible, intuitive to use, non-intrusive to

their lives and develop with affordability and value in mind. We're not naive to think that these changes will be immediate nor seamless. Organizational changes take time and, definitely more than 6 months when we hope to have a prototype. This prototype, we hope, will serve as an idea lab. An initiative of conversations where all interested parties can work together to drive this opportunity forward and develop solutions that ultimately improve the health of all people and transform how we deliver care, wellness, and prevention. I look forward to the discussion today, as well as what comes afterwards, new partnerships, deliberate activities, and inclusive efforts to foster health and wellness at home. Back to you, Ankurita.

Ankurita Datta: Thank you, Dr. Shuren. Next, we will hear from Joanna Frank, the President, and CEO for the Center for Active Design.

Joanna Frank: Hi, everybody! I'm Joanna Frank, CEO of the Center for Active Design, and the operator of Fitwell, which is a healthy building standard. I'm really privileged to address you today about the transformative power of our homes as a healthcare hub. I've been in the real estate industry for 3 decades. So get to bring a slightly different perspective to today's discussion. I have learned that as architects and developers, we aren't just in the brick and mortar business building buildings, which is how I would have described my work a couple of decades ago. But we are actually in the people business, creating places where people live, work and play. And it is only when we understand, demand from that people perspective that you can maximize the value of buildings and future proof our communities from risk. And let me turn to history to illustrate this point, because this is not a new idea, as with most things in the built environment, it's been going on for a very long time. When my ancestors were fighting one another in Scotland, the basic priority of the people of the time was survival, so shelter, food, and safety. So the highest value for the location of a building was at the top of a hill, a defensible space, preferably with a large wall around it, and enough land inside to feed the people. But with times changing and more stable. Society expectations for quality of life evolves, and our built environment has always been key to addressing that changing demand. If we look at the 1900s in New York City, which is my hometown today. New York transformed its built environment to address the greatest priority of the day, which was infectious disease, and New York used the built environment in order to address that disease infrastructure investments in parks. New York City was actually the first city to create a park's department, including Central Park, which was described as the working man's lung. In the papers of the time, we created piped water from reservoirs. The subway system was used to alleviate overcrowding and policy and design standards also resulted in the Tenement House Act, which set minimum standards for homes around light and air. These really were some of those 1st design standards for healthy buildings, which I'm going to very much be talking about today. And then if we fast forward to New York City. In 2010, I actually started working for Mayor Michael Bloomberg, leading something called the Active Design Initiative, and for this we use the precedent from the 1900s to really convince ourselves and other lawmakers and agencies that we could transform New York City from a car centric environment into a people centric place that addressed the risk factors of chronic disease and met the demand for quality of life in

the 21st century. To achieve this transformation, we had to break down silos across agencies. I was running a multi-agency program in active design across the Health Department, Transportation Department, housing, design and construction, and we were working both across the public and the private sector. To make this happen and to do this we had to translate public health research, which is not written for real estate developers. We had to translate that into practical and scalable strategies that could be used when designing buildings, whether it be housing, public buildings, or infrastructure that create our communities and streetscapes. All of that was used to then better understand, how is this impacting the business case for health in New York City. So very important - we were measuring impact at the same time as implementing these design solutions. So, we could really make the business case for health and growth. This work which we were able to do, brings us to the next kind of 10 years. So since the end of that administration which is crazy, I think it's actually almost probably 15 years. At this point we have continued this work with something called Fitwell. Fitwell is the global standard for health promoting environments. Fitwell was actually first created by the US Centers for Disease Control and Prevention. I usually have to explain to my real estate audience what it is the CDC does, I'm not sure that I have to do that today. We have worked with the CDC over the last 6 years to translate more than 7,000 peer reviewed research studies published by academic institutions all around the world, to understand what facets of our buildings and our neighborhoods are directly impacting health - physical health, mental health and community health. And how can we use this knowledge to really influence and transform our built environment by working with the real estate industry to actually change the way that we design and build our buildings, really focusing first on how do we look at our existing buildings, our existing homes? How do we understand? What is the status quo of today? What is our housing stock like? What are the design and operational aspects of our existing homes? And how do we use this knowledge to really transform these homes into places that are optimized for the health of the occupants and the community at large. Because we know from this evidence base that housing is a core determinant of health, as we have heard already today from many folks. Housing profoundly influences, physical, mental, and social wellbeing. And the research can really underscore our approach to continuing to make investments in our home and ensure that everybody has access to homes that have been optimized for their health. Both in ways that prevent the onset of chronic disease in the first place, and then today, very much talking about, how do we look into the future and start using our homes as a way to actually treat health conditions, and not just as a preventative and management strategy. Diabetes. I am not qualified to speak about diabetes. I can talk about real estate, but diabetes is a complex condition, as you all know, and necessitates a comprehensive strategy extending beyond medical intervention. The built environment plays a pivotal role here, influencing factors like physical activity levels, dietary choices. We can even use our physical environment to limit the amount of smoking through policies and through messaging and signage, and so on. And this is evidence-based that it is successful in limiting smoking. So, we can use our built environment to measurably impact health behavior, which in turn reduces the risk of diabetes. Specifically, we know from that same evidence base that when we create walkable neighborhoods that have

sidewalks and street trees and lots of visual interests and amenities, that are within a 5 or 10 minute walk of where you live, like parks and subways and shops, we know that that increases the amount of physical activity everybody gets. We also know that it's correlated with more positive mental health outcomes and actually alleviates some social isolation, as well. So, all of these things obviously contribute to the overall health and wellness, as well as risk factors for chronic disease. Similarly, our neighborhoods are really the source of the food that we eat. So having neighborhoods that have fresh food are demonstrated to have lower related rates of diseases related to diet. I actually used to run the fresh program in New York City, where we were providing zoning incentives and financial incentives to building grocery stores at that time in New York City, which was also very effective. Sleep quality is something that I'd also like to talk about again. The design of your homes really does affect the quality of the sleep that you are able to get, and we know that poor sleep patterns really disrupt your metabolic function, your insulin sensitivity, and immune response exacerbates diabetes, heart disease, obesity, etc. It impacts mental health. We all know that disrupted sleep has a really profound impact on overall health outcomes, and your home design can really make a difference in those sleep patterns, reducing noise, providing you with the ability to set optimal temperature ranges so that you can sleep in the cool or the warm depending on who you are. Adjustable lighting, also. Things as simple as blinds, so that you can effectively block out daylight or lighting from the streets. And then it's maybe counterintuitive, but having access to adequate daylight during the day, actually helps to set your circadian rhythm, and therefore allow you to have a proper restorative night's sleep. All of these sleep hygiene issues can really impact your overall rest, and therefore risk of chronic disease. And for individuals who are already managing diabetes, the built environment really serves as a critical support system - providing accessible infrastructure, supportive neighborhoods, and well-designed homes that can alleviate barriers to self-care, which both improve quality of life and also prevent complications. So the home has a really big impact on preventing and managing. Today, our focus is extending beyond prevention and management. How do we now explore how homes can actively treat chronic disease which will mark a pivotal shift in the way that we think of holistic healthcare delivered in your home environment. Covid-19. It's already been mentioned a few times, but it has had a profound impact on all of us in basically every aspect of our life. Our homes very much were part of that conversation. We all spent unprecedented amounts of times at home, and we've now, really, we felt firsthand how the design, the location, the maintenance of our homes, is affecting our physical health and our mental health. And this evolution hasn't just really increased the demand for healthy homes. It has actually changed the demand to the point where we now see investment in healthy homes actually having a direct return on investment. And this is a really important part to talk about, and that is that, because of this increased demand from society, because this is now a priority of society. There is a strong business case to be made for health promoting environments. We can show, using the evidence base and data again, that there is a co-benefit to having a healthy home. Yes, it impacts health, but it also impacts economic outcomes, including return on investment, including reducing the cost it takes to actually operate a home - both for the developer and for individuals living in that home. We

can reduce maintenance costs. We can increase satisfaction. You can use these health promoting ideas to actually differentiate your properties in a marketplace and command higher rents. A more stable tenant base that is a healthier tenant base also is more likely to pay rent on time or pay mortgage. So you see, less disruption and more tenant stability, all of which obviously then reduces the financial risk of the owners of that real estate and the developers. All of this is essential, because, just like you see, in those historic precedents, we need to extend the folks that are in the room to everybody that is involved in creating the ecosystem in which we live in order to promote health. So work that we have been doing, that I have been doing over a very long time now is, how do we translate between all of the different people involved in making these decisions, to understand the motivation, understand when decisions are made and understand the business case from all of the different players who will go together to make these healthy homes of the future and really understand what is the business case from each of those perspectives. So that we can have significant investment from both public and private side of our institutions in order to really develop this healthy housing of the future in a way that remains affordable for all people, because it isn't good enough to create a few fancy condos that have amazing tech installed in them, that is not interesting. That is not going to impact public health. We really need to be looking at solutions that are available to everybody, and that we can actually put into existing homes and really use as a way to optimize our existing homes, as well as obviously use to inform how we design homes in the future. So I urge everybody here and everybody that you know that is involved in this. I'm going to bring a lot of folks that I know into this conversation. So architects, developers, medical device manufacturers, the policymakers. the healthcare, the investors, the insurers as well. Everybody that has a stake in the outcome of people's health needs to be part of this paradigm shift, and I really encourage everybody collectively to make the business case for this. So that we can really scale quickly to really address this amazing opportunity that the FDA is spearheading. So thank you all.

Ankurita Datta: Thank you, Joanna. Next up is Dr. Upali, Nanda, Global Sector Director and Innovation Partner at HKS.

Upali Nanda: Thank you. I'm Ankurita. I'm going to go ahead and share my screen.

Upali Nanda: Perfect. Well, thank you everyone. You know, in every career there's this one project that is a milestone project that you feel, this is the project of my career, and for me and my team we fully believe that this is this project that we're doing is so poised to move the needle. We're very privileged to be here today to lead this conversation and participate and listen. This treaty is about unlocking the potential of the home to achieve better health outcomes equitably. And it's an incredible case that has been made so far on how we do it. We are a large design, firm HKS. We represent a sector in the firm for innovation, which is about envisioning new futures within, through and beyond the built environment. And that is exactly what we are trying to do through this project today. We're trying to bridge the gap. Dr. Shuren laid out both the need and so many of the speakers earlier laid out the opportunity. We

know there are provider shortages. There's delayed care. There's pressure on a maxed out system and the opportunity with emerging MedTech and healthcare, healthy environments, decentralizing care and bringing care to the home is so incredible. There is a lot of evidence that Joanna Frank just talked about, that leads design to outcomes that the built environment can actively promote health. And so we have this body of evidence around devices. We have a body of evidence around built environment. But these 2 domains of knowledge haven't met yet. This is an opportunity here today as well. Why did we choose diabetes again? Dr. Shuren laid out this case very compellingly. This is a complex condition, and if we can solve for complex conditions with comorbidities which really affects our entire life cycle, then we could solve for many other health conditions. This is why we started with diabetes. It allows us to look at a spectrum of needs all the way from clinical needs around mobility, commutability, comorbidities, sensory sensitivities to technology in terms of literacy and access to care, needs, and social support. Because not all of us have the same level of support that we need in our care. There's an emerging technology spectrum that we heard so much about from our partners in the beginning of the call, all the way from mobile apps to variables, to objects, smart objects in our environment, to home embedded technologies. And this emerging technology spectrum is embedded in an entire design continuum from our cities to our neighborhoods, to our buildings, to our homes, which could become a site of care. The opportunity to bring health care to the home is incredible. The evidence base is compelling. We can see decrease in A1C or days to optimal insulin levels, or just accuracy in predicting what blood glucose would be when we embed these technologies. So we know the opportunity exists. And yet when we start thinking about who really has access to this opportunity, we stumble. We have challenges today with integrating healthcare into the home, because our homes are not equitably designed. They're not designed for health. These are some of the images that we collected from our own field research, thanks to some incredible partners. And these are challenges that are basic that you and I, who are all on this zoom call together, won't even think about. Infrastructural challenges, like consistent access to power, to consistent heating and cooling, to internet. Things we take for granted are not affordable, not accessible in lower income households. Simple things like storage and organization, safety and accessibility. We always call out this image. It's incredible. This is in the room of an aging resident, an 85-year-old, who has a rug taped to her floor because the flow hurts her feet, which are so sensitive. And yet she's not asking more for homes. She doesn't know how to. And awareness and literacy which remain challenges today. So, in some ways our homes are not only not promoting health, they look to be actively inhibiting them. And that's the gap. This incredible technology available to us, an environment that is just neutral. How do we bridge that? That's the design question opportunity. And that's why we focused on affordable housing, just like diabetes, affords us the challenge of a clinical condition. Affordable housing affords us the challenge of home conditions that we have to design for. And we know statistically that there are higher mortality rates in affordable housing and low-income housing, especially the minority groups. So we took these 2 extreme conditions and are trying to design for them. Because if we design for the experience, we can benefit. We're thinking about the housing spectrum, all the way from mobile homes to single unit homes, to

multifamily buildings, because we want to think about the range of experiences. We want you to step back and imagine what it looks like when our home becomes the nexus of our health, to be equitably accessible for all. Imagine if our home environment, the medical devices within it and the healthcare system and providers worked like yours together, lock and step where we are sharing data and building trust and enhancing experience so that we can get to better outcomes for all. But to do that, we have to think and visualize our current conditions. So, imagine this, if you could visualize experiences, the true experience of the person that is dealing with the burden of the disease, and often the care and the care management before we build our products. If you could visualize the experience, then we could transform the experience in everything we desire and invest in. And that's really what this project is about. It's a virtual idea. All of us, for device developers and regulators and providers to understand the lived experience of people living with diabetes and their care partners within the context of performance. It has the voices of patients. The person who's thinking about how his insulin pump bumps into the door every day because there aren't enough clearances. The one who says, "I'm overwhelmed with all the technology. How do I make it simple?" The person who's figuring out where to put all of their stuff because they don't have enough space in our rooms, or the ones who are health conscious and want to live healthy lifestyles, but are not necessarily in environments that promotes nutrition, physical activity, clinical life, and clinical interventions. All of it. When it moves to the home, the home must be ready. and if we can have this, if we can have an idea lab where all of us get together and visualize what we could do in these experience-based environments. Then we could also envision what the future of this hyperconnected health care hub, which is really the home now, could be. So really, what we're trying to do is a platform for shared visualization building, deep empathy and a launch point forward, leaning towards what a home could be. We are very lucky that in this we have great guidance and advisors. We heard from many of them. In the beginning we have the Consumer Technology Association, Jo Kiana from Masimo, the American Diabetes Association, Sabrena McCarley as an occupational therapist, Susan Albert, who was a stalwart, and the field, and Julianne Lally, who, again, you heard from earlier. We have the FDA as a guide, and our own team is contained of researchers, clinicians and technology experts. And this is our process. It's really simple, deep discovery, with stakeholder engagement. Looking at the evidence going in the field, envisioning what the future could be, and developing not just design concepts, but experience concepts then developing the virtual models for the design concept itself and the Vl. And then developing this VR experience that we can all participate in. And through this idea lab and then testing it and trying to see what works before we launch into the future state. And we are here in this little blue dot. We are in the middle of our journey. And today we are here to listen. From you to learn from you, and to ask you to participate, to share perspectives, to share a commitment to proof. Because we need to build this evidence base together. And we're looking for partners, innovators, and all of you who are investing in impact. So thank you again from our team for this incredible opportunity. And we look forward to learning and transforming with you.

Ankurita Datta: Thank you, Dr. Nanda. We'd love to hear more from the organizations as to their vision and goals in participating in this effort. We will move to a panel discussion moderated by Dr. Matthew Diamond, Chief Medical Officer in the Digital Health Center of Excellence. The audience can also participate to contribute. Please enter your thoughts, questions, or ideas in the Zoom Q&A Box, and they will be shared with Dr. Diamond to raise to the group, as time allows.

Matthew Diamond: Thank you very much, Ankurita. I'm really delighted we have the opportunity to take a few minutes to speak with those who've been participating in this home as a healthcare hub initiative. I'd like to ask all of our panelists for this first panel to turn on their cameras. Today we have with us Julianne Lally of Breakthrough T1D, Renee Quashi representing the Consumer Technology Association or CTA, Sabrena McCarley from the American Occupational Therapy Association or AOTA, Dr. Susan Albert representing the Advanced Medical Technology Association or AdvaMed, Joe Kiani representing the Medical Device Manufacturers Association, MDMA, and Dr. Deborah Wingler from the architectural firm, HKS. First of all, I'd like to thank you all for your efforts participating in this initiative. In the interest of time, let's begin our discussion. And I'd like to begin, Sabrena, with you. Could you talk a little bit about your aspirations for this initiative?

Sabrena McCarley: Thank you so much. It's such an honor to be part of this initiative, and also to be representing occupational therapy practitioners. This project really highlights the need for disease prevention in the home versus solely focusing on disease management. This focus is really needed, as the home is important for an individual's quality of life. And it's really where health and wellness are established. My aspirations for this project are that it will bring a more global awareness to the fact that individuals are able to safely live and age in place with a multitude of medical diagnosis when their home is modified to meet their needs, and that they have access to healthcare providers that are able to work collaboratively with each other. It is important that an individual's home be modified to meet their needs so that they can safely manage their daily routines, their activities of daily living as well as their medication management. One of the things that does excite me about this project is that it really focuses on going beyond that medical diagnosis of the individual, or, as we sometimes call - the reason for referral - and really focuses on the home for everything, from prevention to maintenance and living a healthy lifestyle in healthcare. It's very easy for healthcare providers to really focus on that primary diagnosis. But when we bring the focus to the home, such as the home as a healthcare hub, we must be comprehensive in our assessments. We cannot just make recommendations for an individual without understanding truly that comprehensive medical history and that includes items that we've already discussed, things such as visual impairments, peripheral neuropathy, their behavioral health, their cognitive impairment, and their muscle strength. Just to name a few. We also must understand their cognitive level, their health literacy and their economic stability, as well as that overall social support from a occupational therapy perspective, we utilize what is called our occupational profile as that foundation when we're working with individuals and within their home. What we do is, we assess, a multitude

of health devices, and are able to bring technology not only into the conversation about their daily routines and their needs of the individual, but also into the treatment interventions, as it relates to activities of daily living, in order for them to manage their daily routines within their home. And one of the things of this initiative that I really do love is that it brings awareness for the need to ask questions about an individual's daily routine. So what is working for them? What's not working for them? What would they like to be able to do that they can't do right now, and what do they need to be able to do in order to manage their diabetes in their home. So, therefore, by focusing on the home as the individuals healthcare hub, it really does allow us to gain a better insight and be able to tailor the interventions around those social determinants of health items that we know can either have a positive or a negative impact on health equity such as their income, their social support, the setup of their home environment, as well as access to their basic amenities as well as affordable healthcare, providers, access and quality. These are all very important factors when we talk about determining home modifications as well as technology recommendations. Thank you.

Matthew Diamond: Thanks very much, Sabrena. As a rehabilitation physician myself, I'm really so pleased to have the occupational therapy perspective. And what you described about, really understanding what the home is, and how a person goes about their activities and their living, is so important. So, thank you.
Julianne, thanks for your remarks earlier. I was wondering if you could talk a little bit about your aspirations for this program, and also, if you have any concerns about bringing care into the home.

Julianne Lally: Sure, happy to do so. Thank you, Dr. Diamond. Thank you, Dr. Nanda, for that presentation, and the great overview of what at least our steering committee has been working for, and also thanks all the speakers so far, who's really helped us set the stage. Lastly, and firstly, thanks for having me to represent the voice of the people with T1 diabetes. I'm happy to be here today regarding aspirations for this program. I think they are quite broad and simple, and likely shared by most, which would be to be advancing technologies in the home that improve outcomes, improve daily life and are accessible to all, not for just patients with diabetes specifically T1, but with any type of health condition across the spectrum. For this home as a healthcare hub initiative, I aspire that medical device developers will be able to better understand the needs and challenges at home that may act as barriers to the anticipated utilization of their products by listening to both the patient voice and the opinions of the healthcare providers who will inevitably play a part as Sabrena referenced. And also for device companies to work together to ensure their devices, work together, to really meet and exceed clinical needs while being accessible to all, to help achieve health equity. To me personally, this sounds like a very challenging balancing act, but I'm hopeful that this initiative will help to remove barriers to uncover solutions regarding concerns about moving care into the home. A primary concern that I just want to mention, that is, with any type of change and moving care into the home comes resistance due to fear of the unknown. Not only will it take time for medical device companies to develop novel technologies for the home, for

these devices to be approved for use and time for these devices to be widely available. It will, of course, then, take time for both the patient and the healthcare providers to overcome that natural and inherent barrier, to change which might further delay some desired rates of adoption for new at-home devices. I am allowed to speak to the challenges of change as a healthcare provider. As I am one myself, so I've lived it. Even if an item is made to be available and its benefits are widely known and shared. This doesn't mean it's going to be utilized and utilized as hoped or expected. To take a look at a quick example, continuous glucose monitors, which you might all be familiar with, have been around for decades. Their benefits are widely known, and there is use for recommended use by the ADA for people with diabetes once they start initiation of insulin treatment. Right? That's in the ADA standards of care. Despite all we know about the clinical benefits of CGMs, this wonderful technology studies estimate that less than half of people living with T1 diabetes use a CGM. And there's significant socio-demographic disparities within that that brings me to one of my final concerns, which is cost from my previous walk of life before BreakthroughT1D. I know that transitioning hospital level care into the home has shown significant cost-saving benefits that's due to many factors, fewer diagnostics, fewer consultations, reducing readmissions and really not just having to pay to keep the lights on. Now, the concept of developing novel technologies to transition health and wellness care into the home is different, and it may very well be accompanied by higher costs, especially at the start, before there's time for our wonderful advocacy. Groups to work their magic for time, for production cost to be reduced, time for competition to increase driving down cost. So for this initiative to impact public health in the way it's intended cost definitely needs to be considered right from the start to wrap up. I know I've mentioned probably more concerns than aspirations about moving care into the home. There is a common trend that all of the concerns I've listed in include, which is all that all change takes time right? It takes time to learn, and it takes time to accept something new. Time to drive down production costs time to increase accessibility. Overall moving more healthcare into the home will be the norm. Thanks to technological advances helped by this initiative, but it will take time. Thank you.

Matthew Diamond: Thanks, Julianne, and really appreciate you helping to bring the perspective of patients with diabetes into everything that we're doing with this initiative.
René, I want to go to you next. Based on your experience with consumer technology, what concerns do you have about moving care into the home?

René Quashie: Yeah, just to pull on a thread that Julianne raised. Thank you very much to you, Dr. Diamond, Dr. Shuren, and Dr. Tarver for this incredible project and this opportunity to talk to the audience today. So for me, I think Julianne brought up something about cost. But I want to sort of look at it from a different angle, a different perspective. I, my major concern, is that many tools that are using the home may not be properly covered and reimbursed by payers, insurers, either public or private. Right? So, I think one of the things we need to think very thoughtfully about is, how do we ensure payers are made aware of the

development of these tools. and that they are presented with the clinical substantiation for medical necessity. Right? Even tools that have been cleared by FDA doesn't necessarily mean that payers are going to cover and reimburse for those tools. And so one of the reasons I think we need to be thoughtful about this is because we may end up in a situation where a lot of these incredible tools, especially as they get more sophisticated are going to end up in the hands only of those who can afford the out-of-pocket costs and something we've seen other sectors, I mean healthcare for example, when it comes to wearables, which is an example that I see that sometimes the wearables are only available to certain populations. I think part of this concern, by the way, could be alleviated by preemptively discussing all these issues with insurers at the outset to understand their concerns, their pain points, what issues need to be addressed. And then I think designers and developers could take all that information and build home and health tools with better prospects for coverage because what we don't want is a development of effective home and health tools that can only realistically be used by certain populations because of cost issues. So that's my first one. Second one I'll mention is around patient support. I think when you think about home and health tools. One of the things we got to think about is who is going to help consumers with device malfunctions; connectivity issues, software bugs, troubleshooting when training is necessary to operate some of these devices and tools? Who will be providing that training? Who will pay for that support and training? How do we ensure patients are compliant and engaged? We have to be thoughtful by answering all those questions. Look, the fact matter is that we have different levels of digital literacy and competency. And I fear that once these tools are in patients, homes or consumers, I should say, to address Dr. Shuren's concerns. But consumers are going to lack the infrastructural support. To deal with these technological issues as they arise, and they will arise. So in addition to that view, the sophisticated use of the technology, we have to be mindful of building an infrastructure that supports consumers with the use of that technology. And I think I don't hear enough of that sort of address that in some of our conversations. And the last one I'll leave you with is, we always talk about privacy and trust issues. And I think you know, poll after poll shows the data privacy issues are one of the primary reasons for the lack of trust. In many aspects of the healthcare system. Patients are concerned. A lot of their data is going to be sent to 3rd parties without consent. Now HIPAA addresses some of those concerns, but increasingly, as technology becomes more adopted in healthcare, care delivery circles, many stakeholders and care fall outside of HIPAA's jurisdiction. That's why CTA has long held the position that we need comprehensive privacy legislation that pre-empts varying State laws to build one standard that will engender trust. But I think we are ready to address these issues as a country, and I'm very hopeful about it, but those are some of the concerns that CTA has been thinking about.

Matthew Diamond, FDA: Rene. Thanks very much. And you raise a lot of important issues and look forward to partnering with you and the broader set of stakeholders to address them. So thanks. Joe, I want to go to you next to talk about something that we heard a little while ago from Mark Leahy, when he was giving his opening remarks he mentioned about some of

your work during Covid to monitor patients at home. Could you talk a little bit about that? We don't have too much time but particularly interested in how that experience informs your thinking, in general and about this initiative.

Joe Kiani: Thank you. Happy to be here on behalf of MDMA, as you know, I'm also founder and CEO of Massimo. We were working with the FDA to bring about something called opioid halo, which was a way to monitor people that are taking opioids at home and alarm them, alarm their caregivers, and eventually ambulances near them, if they were having an opioid induced respiratory depression when Covid occurred. And we were shocked how Covid impacted so many hospitals, and there were patients in the hallways and we reached out to the FDA, saying, Hey, can we use this technology to help hospitals, send patients home and monitor them remotely, and only bring them in if they need ICU. These are people with Covid. The FDA under Emergency Act within a week, maybe 2 Max, clear the product. We work with University of Ohio's Dr. Peter Ponost and team to iron out the wrinkles in the product, and within a month we deployed it. Hundreds of hospitals deployed it, and as a way to send patients with Covid home that didn't need ICU care remotely, monitor them, only bring in when they needed it. It really worked. University of Ohio published a study that showed they not only reduced mortality by 70%, but they reduced the cost of care by $11,000 a patient by doing this type of remote monitoring. So yeah, I think that was the experience that Mark was referring to.

Matthew Diamond, FDA: Great Joe. Thank you so much. Next, I want to move to Deborah and ask if you could talk a little bit about how you think this initiative could positively impact health equity.

Deborah Wingler: I'd be more than happy to, and thank you so much, Dr. Diamond for having me here. I know that what I'm about to say is not the 1st thing that will come to people's minds. But as we start to really reimagine what the optimal connected home could really look like right, this future forward place that we all want to get to to support the monitoring and managing of diabetes, as well as a healthy and active lifestyle for those living with diabetes in low-income housing. I believe the greatest impact is in advancing health equity is in considering how the home itself can become a nexus for addressing digital and health literacy. You know, we have data. It has been shown that those living in rural areas of an older age and colored individuals are most impacted by the digital divide in this country, specifically, those in low-income areas. And we also know that digital literacy is highly correlated with health literacy, both of which can greatly impact an individual's health outcomes. So I believe one of the greatest opportunities for this effort is to help advance health equity, and considering how policy as well as housing regulations could or should transform to ensure that all individuals, regardless of income bracket, age, ethnicity, can have access to a home that has a minimum, a base level of health readiness for integrating technology into the home that can help individuals with diabetes live healthier longer. And as Dr. Nanda so well-articulated, we

are a long way off from having a base level of health readiness for everyone's homes. So I believe that's the biggest opportunity here in terms of advancing health equity.

Matthew Diamond, FDA: Thanks very much, Deborah. Susan, I want to ask you, what would you like to add about how this initiative could help advance health equity.

Susan Alpert: Oh, 1st of all, thank you. And thank everybody who's spoken. Who's talked today and put this together. I wanna talk about three quick things, one or needs. The second is time, and the 3rd is cost. I grew up in a rural environment without access to emergent or easily accessible healthcare. So I understand from a personal experience how it is to not have the healthcare around you that you need, whether that's because you're living in a in an area of a city that doesn't have access, or you're living in a rural area. So patients needing that care. The second thing is that I'm a clinician spent some time as the regulator as the FDA, and spent some time as the industry, and then looking at at all of those aspects there's needs and what this initiative does is it brings the patient, the provider. the support team, the industry, and the regulator all to one table to talk about. What? What can we do to make this happen faster? So we identify the real needs, the not just, the diagnostic needs or the therapeutic needs, but the home and all the tools that are needed. The second thing is to decrease the barriers between the innovator, the regulator, the clinician cause if you're developing something sometimes, you're developing something. The clinicians have no idea what to do with it, but by bringing the patient, the clinicians and the developers and the regulators to the table we can, we can work in a more efficient way to cut the time and the cost of developing new technologies that will be accessible, useful in the home address. The patient needs all of those, all of those things. So to me, the beauty of doing all of this is that we can cut costs, we can cut need. We can cut time. We can make the communications happen in a more, in a much more efficient way and get what's needed to have the impact on the healthcare system. We're just really lucky. We're living at a time when there's technology and access and communication and all these things that didn't exist, they exist. We're trying to find a way. And I think what FDA is doing is to try to find a way to integrate all of that and make it all happen, as I said, faster, more efficiently, more cost effectively, and more appropriately for the patient, the caregiver. the clinician, and the healthcare system. So that's where I come from working in this. And I think this is a great idea, and we need with this example, I hope we will learn how to do this for all diseases.

Matthew Diamond, FDA: Thank you very much, Susan.
We're actually out of time. I want to thank all the panelists for a great discussion. And I'm going to pass this back to you. Ankurita. Thank you very much.

Ankurita Datta: Thank you to our audience, to our participating organizations, and to Dr. Diamonds before you all step away for your short 10 min break. Please take a moment to respond to our poll. That should be coming up shortly, and we will see you all back here at 1 45. Welcome back everyone. We'll now hear from some members of the public who shared videos on the barriers and opportunities they see with bringing health technology to the home. 2 weeks ago.

Julie Heverly: Good afternoon. I'm Julie Heverley, a senior director with the Diatribe Foundation, an organization dedicated to ensuring that people with diabetes have the information needed to thrive. I live with type one diabetes and have submitted additional scientific evidence to support my comments today. Thank you for the opportunity to provide comments on FDA's home as a healthcare hub initiative. The home is the healthcare setting where the vast majority of health outcomes and improvements in quality of life for individuals occurs. It's critical that this initiative's focus reflects this reality of daily diabetes management and incorporates the latest technologies without increasing the burden on patients. Two weeks ago I had the privilege of hearing Commissioner Califf speak at the American Diabetes Association's scientific sessions. He raised several important issues about the value of technology for addressing the diabetes epidemic that are relevant to our discussion. Dr. Califf highlighted the shortage of endocrinologists to care for the 38 million Americans with diabetes. We agree with his assessment that addressing this care gap will require both integration of other types of healthcare providers and developing and deploying evidence-based digital tools to everyone who needs them. Fortunately for people with diabetes, there is high quality evidence proving the benefits of continuous glucose monitors or CGMs. Both patients and clinicians use CGM metrics like time and range to guide healthcare decision making. CGM data is actionable and empowering and current devices are so accurate that insulin can be dosed using them. There is clinical consensus on the value of CGM metrics for diabetes management. We hope that the steps FDA is taking to incorporate CGM metrics into drug labels will further encourage the use of this essential digital tool. But as Dr. Califf questioned, are these technologies reaching the majority of people who need them? For CGM, while progress has been made the answer is still no. We urge the agency to include payers and healthcare system level changes to expand access, such as device metric integration into electronic health records and adequate reimbursement for remote care. Extended coverage improves outcomes, Medicare expansion for CGMs in ‘23 has improved uptake and reduced a1c in populations where CGM adoption was previously lower. A key barrier to the home becoming a healthcare hub is the lack of coverage and burdensome cost sharing that puts essential digital health technologies out of reach. We urge FDA to work closely with CMS to ensure that approved technologies are accessible and affordable for all beneficiaries, particularly those from minoritized and rural communities. Thank you for the opportunity to share our views.

Mati Choppu: Hi, everyone. I'm Mati Choppu, the VP of design at Delve a medical device design and development consultancy. Designing for home environment requires medical device manufacturers to shift their mindset. I'd like to highlight four specific shifts that align with the FDA home

as healthcare hub initiative. The first shift we must make is to go beyond focusing on safety and effectiveness. We must also focus on desirability. Home healthcare consumers expect engaging intuitive experiences, they expect something as intuitive as the devices that they use every day. This means our medical devices must not only work well, but also deliver frictionless and delightful user experiences. For example, the Dexcom G6 and G7, significantly improved appearance and usability compared to earlier generation, and the result was a product that users loved and adopted widely. The second shift involved designing for the home environment rather than the hospital. Traditional healthcare settings are controlled and predictable, but homes are not. To address this we need to challenge old assumptions and rethink product requirements to account for the variability and complexity of the home environment. Investing in contextual research and testing products in real home settings can reveal insights that are crucial in designing effective medical devices meant to be used at home. The 3rd shift is to move focus from trained healthcare professional to lay users. Lay users have a wide range of abilities, and our design must reflect this. Simplifying device interaction and applying principles of universal design can make devices more accessible. Don't make the mistake of thinking that your device is simple, and therefore is inherently simple to use. In-home setting with safety syringes, for example, revealed use of limitation, like arthritis and long fingernails, and other varying cognitive and physical abilities. The 4th shift, we must integrate digital solution and physical products. The medical device industry has lagged in this area, but digital experiences are becoming essential. Consumers expect digital solutions to guide them through their healthcare journey. This can start small with video instructions or companion apps and evolve into more complex digital solutions. Building digital design capabilities within R&D teams and ensuring collaboration between digital and physical product designers can drive innovation and meet consumer expectation. In conclusion, by following these best practice, we can create healthcare products that are not only safe and effective, but also desirable, intuitive and user-friendly. This approach is essential for meeting the needs of modern healthcare consumers and supporting the FDA initiative to make the home a central hub for healthcare. Thank you for watching, and I hope that these insights will help you designing better home healthcare products.

Paul Conway: Thank you very much to the FDA for allowing the American Association of Kidney patients to provide a perspective on home as a health care. Hub. My name is Paul Conway. I serve as chair of policy and Global Affairs for the American association of kidney patients. This is an issue that is of great interest to kidney patients in particular, because when you consider the arc of technology over the past decade, more and more devices are being designed and enabled to be home-based, so patients can share more information with their practitioners in real time, and get the benefits of having more flexible schedules and greater information flowing back and forth with their healthcare professionals. We think this is particularly important for patients that may be in historically underserved areas or living in rural areas, so they can be better connected, not only to new technologies, but more importantly, to more timely care. There are a few issues that we are concerned about, and I'll be very direct about that. Number one, on devices that are used in

the home or home being a health care hub we are particularly concerned about anything that would be on the IT safety side in terms of hackability of devices or devices and home-based use of devices that would create a privacy issue for patients, meaning more data is collected than the patient may be aware of. That would have to be something that's disclosed. Any potential risk for that is very important. The other thing is any type of regulatory apparatus that would come around the definition of home as a healthcare hub in particular. Sometimes we see mission creep with government, where, because a home-based activity, whether it's daycare or other things, bring in a number of different questions about the income in a household, what the household is constituted by in terms of number of kids, number of adults that are living there, or other lifestyle issues or interests. We would want to make certain that the focus stays on healthcare delivery and the safety of people with different types of devices and not go beyond that. We would be very interested in any type of regulatory language that goes around the precautions and the transparency of what it would look like. But in general we would be very supportive of more work in this area, because we think it captures where the archaeology is going, and where the patient interest lies. We appreciate the collaboration with FDA. We're always available to give more particular advice. But thank you very much to the career staff for leaning forward, not just for patients, but for your service to an agency that's charged with many different things, including safety and greater access to devices that can help improve and save lives across the nation. More than 300 hospitals in 37 States are providing home hospital care to patients which was made possible through the Federal public health emergency, acute hospital care home waiver in 2016, and continues to demonstrate strong outcomes nationally today at Mass General Brigham. Understanding the value of novel approaches to care delivery we initiated the home hospital service even before the pandemic as a very early adopter, and we now have one of the largest home hospitals in the country. Since 2022 alone, our home hospital care model has served over 3,000 patients, a diverse, patient population that spans age, gender, ethnicity, income, and insurance status. At Mass General Brigham, we are committed to improving health outcomes for all, and promoting equitable access to services in the home, including food security interpreters and digital connectivity. The benefit of home hospital is enormous. Researchers have found through numerous studies that patients and family caregivers prefer home hospital, which delivers excellent clinical outcomes and substantial reductions in adverse events, including reduced patient mortality as well as an enhanced patient and family experience, lower caregiver stress, improved patient mobility, and desirable shorter lengths of stay, which means a quicker return to health. Home hospital is also a desirable new career option for clinical staff, who report high job satisfaction when delivering hospital-level care in the patient's home setting, where they're often most comfortable. Importantly, home hospital also helps address the capacity challenges many hospitals face freeing up inpatient beds for individuals who require sophisticated interventions most efficiently available in a traditional hospital. Having the privilege of delivering care inside the patient's home yields unexpected benefits. It gives our medical team an opportunity to identify other factors that could be impacting a patient's health, including critical safety and basic life needs that we would not uncover if the patient was in the traditional hospital setting. For example, our

teams are trained to routinely check the refrigerator to understand food availability. They also assess if there's hot water and determine if the heat or air conditioning works. All of these elements and more can create risks to the well-being of the patient. If our team identifies these types of issues, they connect the patient to additional services that will address them. However, failure to extend the acute hospital care home waiver before it expires at the end of this year will only further exacerbate inequities in care, an outcome no one wants. A five-year extension will prove crucial to providing reliable and high quality care for all, and will advance the progress we have made locally at Mass General Brigham, while expanding access to care in underserved areas across the country.

Kimberly Dowdell: Greetings. My name is Kimberly Dowdell, and I'm the 2024 AIA President. the American Institute of Architects fully supports the home as a healthcare hub initiative, and we thank the US Food and Drug Administration for bringing it to fruition. AIA is delighted that the FDA's center for devices and radiological health is collaborating with an architecture firm to help develop these much-needed health solutions. It's a fitting choice, because architects have historically played a pivotal role in developing a healthier built environment for all by working directly with manufacturers to develop healthier building materials like bio-based materials, non-toxic insulation, low-emitting materials, sustainable flooring, and much more. Architects have campaigned tirelessly to build a healthier way of life for everyone to pursue that goal. A growing number of architects and firms have committed to AIA's architecture and design materials pledge, an initiative that focuses on holistically evaluating building products based on sustainability, health impacts, and social considerations, encouraging an industry-wide shift in material selection practices. Of course, architects understand that health disparities have no one-size-fits-all solution. Dozens of factors affect health from food deserts, to access to pharmacies, to walkability, to differences in healthcare infrastructure, to the availability of prenatal care, just to name a few. And now, through the FDA's latest initiative, architects will carefully evaluate the myriad ways in which home healthcare is delivered, and help develop inclusive solutions. Architects are again a fitting choice, because inclusiveness is at the core of what we deliver. AIA's framework for design excellence promotes inclusiveness through several key principles and strategies designed to ensure that architectural projects are equitable, accessible, and beneficial to all. As a leader in the push for greater equity, diversity, inclusion, and belonging AIA is eager to assist the FDA and its partners as they develop a home health solution that advances health equity. AIA and our nearly 100,000 members believe that good health is a basic human right that must be accessible for all. Thanks once again to the FDA for this much needed and forward-looking initiative, and for inviting architects to play a crucial role in designing for progress.

Julie Heisenberg: Hello, everyone. I'm Julie Heisenberg, Global Lead for connected care at Amazon web services, and I'm joined by my colleague, Ian Sutcliffe, principal solution architect here at AWS. Thank you for this opportunity to share our experience on such an important topic. In our company we have a dedicated team focused on connected care with the ambition to support the transition from hospital to home, simplify the

patient and clinician experience through technologies such as data platforms and generative AI, we also have a specific program on health equity at the global scale to reduce disparities in healthcare. This focus allows us to speak to several stakeholders and work backwards from their needs when building a care at home delivery model. For instance, for medical companies, priority goes to device innovation security and build a strategy where devices data will support continuously diagnosis and prevention. On provider side our customers are focused on security of the devices at hospitals, asset management to reduce administrative burden on nurses, and trials for care at home with IOT solutions for chronic conditions, such as diabetes with these new possibilities. What we're seeing on the patient side is that they prioritize easy access to primary care and interactive communication with the provider and devices that are simple to use. In our experience so far, what works well are these three things: One, have specific clinical objectives of need. Some of our customers and partners were able to reduce minus 80% readmission for chronic conditions. To have a clear data strategy in place we helped a medical device company to reach 90 million patients through their devices and understand more on sleep apnea and free leverage technology for engaging more with patients. For instance, as part of our health equity program, we use machine learning, AI, and text message communication to increment by 27 the checkups on pregnant women in sub-Saharan Africa which help reduce maternal deaths. I'll do that. And thanks, Julie. As Julie mentioned, we work backwards from customers' needs when helping them develop their solutions. We also try and take on a lot of that heavy lifting by building services that provide commodity capabilities so customers can then focus on building their innovative solutions. This has resulted in a plethora of capabilities that support the entire connected care ecosystem from devices at the edge in the home, through to big data analytics and the AI machine learning in the cloud we see and are helping solve many challenges along the entire technology chain from in-home configuration, internet connectivity, especially in rural areas or for mobile clinics to device communications and IOT standards. Then there's the logistics of getting devices to the home. And then the device management. Of course, the value is in the growing data sets which require cheap and highly available storage. And then we need everything from near real-time, alerting for that patient, monitoring use case to population level and analytics. So connectivity to EHR systems, multiomics repositories is becoming essential. And finally, the growing need for AI and generative AI to draw value from those vast datasets. So we're seeing many of the technology challenges, we are helping address them. But more consistency is required to reach scale. We strongly believe that working as an ecosystem and with government leadership we can build the foundations for sustainable and equitable healthcare.

Scott Lucas: Hello! I'm Scott Lucas, Vice President of Device Safety at ECRI. We support the FDA for exploring innovative ways to improve healthcare at home, particularly for higher acuity health care needs. This initiative has the potential to improve care outcomes and expand accessibility and equity, but it could also further widen the health equity gap. The average American home is a uniquely challenging care. environment. We must carefully evaluate all of the variables that impact home-based care to reduce preventable harm. While many considerations

must be addressed. today I want to focus on just four topics that could improve advancing equitable care at home under the rubric of total system. safety. Number one, most medical devices are designed for use by healthcare professionals in a clinical environment. Many medical devices are too complex for laypeople to use safely and effectively. ECRI researchers have encountered many examples of patient harm for home use devices. In fact, we named it our number one healthcare technology hazard of 2024. For example, harm can occur if a home ventilator alarm fails to activate or goes unheard. If a venous needle becomes dislodged during use of dialysis, the results can be deadly. Problems like these will worsen as more patients adopt home healthcare unless device manufacturers embrace human factors engineering principles, which I'll share in a moment. Number 2, it is critical we take a human factors approach to home health considering the intended users, the environment, and the device user interface. Home health puts the onus of care on the patients or their caregivers, who may have little to no clinical supervision, no training and low technology and or health literacy. Implementing healthcare at home requires providing comprehensive education and training and ensuring a robust infrastructure's support to facilitate equitable care. Designers must consider the environmental factors, such as the reliability of power supply and internet access, air, quality space restrictions and the home layout itself. Plus consider how equipment and care instructions will be received by patients and caregivers with varying levels of literacy, language barriers, socioeconomic backgrounds, insurance coverage and comorbidities and disabilities. Number 3, the device recall process is not sufficient with major implications for home health care. Device manufacturers seldom have direct communication with patients, and alerts and recalls do not make it to end user patients or caregivers. Healthcare providers don't always proactively contact patients about recalls so patients who use medical devices in the home may learn about a recall and what to do next long after the recall has been issued. Number 4, at ECRI, we've identified trends and recommendations about home health based on decades of experience, conducting research, accident investigations, consultations and hands-on device testing. We have a few recommendations summarized here. Thank you for this opportunity from the FDA for ECRI to share our insights into home health. Together we can really reimagine the home environment for healthcare. Thank you for your time.

Hello! My name is Dan Ding, and I represent an interdisciplinary team of clinicians and engineering researchers from the University of Pittsburgh. We specialize in implementing smart technologies for accessible, home-based solutions that support health, independence, and participation of individuals with disabilities and older adults. Our ongoing research has highlighted 2 primary considerations for transforming a home into a healthcare hub technology, readiness and user readiness in terms of technology readiness. We've identified a lack of comprehensive accessibility testing in medical and consumer health technologies and interfaces. For example, many commercial available skills do not consider the safety needs of older dogs who use walkers and have balance issues. and there are no viable weighing solutions for wheelchair users at home. Furthermore, the mobile apps, linked with many health devices, often fail to meet accessibility standards limiting their utility for users with

diverse abilities. Usability testing is also essential to ensure that devices and apps are straightforward, intuitive, and capable of detecting and clearly communicating errors. This testing must also actively involve users with diverse abilities. These gaps in accessibility and usability pose significant barriers when selecting appropriate technologies and currently restricting many individuals from fully utilizing health tech solutions within their homes. User readiness is also vital for successfully integrating technology into home-based healthcare. The ease and confidence user feels when interacting with technology influences, how readily individuals will adopt new technologies into their daily routines and long-term management. Digital literacy is often overlooked, but foundational for effectively navigating digital tools, and without it many participants in our studies face challenges even with basic password management. Further, financial and social supports, such as family government programs and non-profit assistance are all indispensable in promoting successful technology, availability and use to address these issues. Our research has shown that tailored training and robust support are critical. Our findings indicate that customized training programs focusing on problem solving can help bridge the gap between user capabilities and technology demands. Continuous support is essential to maintain engagement and ensure effective ongoing use of technology. We are committed to creating an inclusive environment where health technologies and services are universally accessible and effectively support everyone in their own homes. We look forward to assisting this new initiative. Thank you. We are a global nonprofit dedicated to advancing the safe, effective, and equitable use of digital technologies to redefine healthcare and improve lives in the digital era of healthcare. I strongly believe that home must be a health care Hub, in order to meet the needs of all of the patients our industry exists to care for. and in particular, people whose health and health care is most negatively affected by the limitations of our current system. Why. since 2020, 36 rural hospitals have closed. gone, there are no alternate sites of local hospital care for patients in those areas. 1 3rd of patients in skilled nursing facilities aren't there because they need skilled nursing care. They are there because they have nowhere else to go to age safely and independently with basic medical support. Today, patients cannot access the care they need, and society cannot afford to pay for care in the usual way. We cannot keep sitting in the clinic waiting for patients to present, already sick at our doorstep before we care for them. In fifteen-minute increments we need to build care around the patient and their home, not the clinic. We need to move beyond a sick care system to a healthcare system, and we need to be absolutely certain that this new system works for everyone. because the people who will benefit most are the people we most routinely fail. Today. I'm confident that digital innovation can reimagine what it means to care for people. Many people agree with me. Hundreds of billions of dollars have been poured into digital innovation in our industry. But the digitization of healthcare won't work, and this investment will be wasted if we don't redefine where we provide care. A fit for purpose-built environment is the foundation of healthcare in the digital era. We must not only redesign the traditional clinic and hospital environments to account for new workflows powered by digital innovation, including AI. We must also reimagine the home as an essential site of care. Delivery home is where we can reach every patient where they are. Home is where patients and their care partners, the

people they trust the most may need us. The most technology can help us overcome the malistribution of specialist clinicians and the patients who need them flows of data, analytics, capabilities and communications. Technologies can reduce the burden of seeking and receiving care can help ensure access to culturally appropriate care can help ensure that we can reach every person our healthcare system exists to care for. But technology must be combined with clinical expertise and a supportive environment, including a built environment to transform healthcare. In the digital era. At dime we host a thriving, virtual 1st care coalition, and we are planning a variety of projects, including hospital at home and aging in place as part of a multi-stakeholder connected health initiative. We see the work of the home as a healthcare hub, as essential to driving affordable, accessible and equitable care. and on behalf of the clinical payer and technology innovator stakeholders in our community as well as our patient partners. We look forward to building on the success of the home as a healthcare hub, continuing to champion home-based care that advances health equity.

I'm David Moss, CEO. And co-founder of care daily. Today I want to address the FDA's home as a healthcare Hub initiative. personalized care must place families, not just patients at the center. By shifting the care model into homes and including multi-generational families. we can triage scarce resources to those with the most urgent needs. Even between check-ins. however, many providers trying to utilize the home as a virtual clinical setting, have overlooked unifying infrastructure. Many devices designed for homes function as independent point solutions. And just like Ehr platforms, unify and manage patients. We need AI platforms that unify and manage information from the physical world. And it's not just the devices that need to be integrated. Often patients' entire families are disconnected. Care daily is uniting a consortium of innovators with the Care Daily alliance. a healthcare hub that unifies health tech products with a software intelligence that we call an AI caregiver. AI caregivers never sleep. They predict problems using ambient lifestyle patterns enabling remote families and care providers to intervene before a major health problem occurs. Surprisingly. Ambient sensors to be used by AI. Caregivers may already be in millions of Americans' homes in the form of security systems, Wi-fi routers, TVS wearables, and connected appliances. Let me introduce you to Kelly Franklin to describe her experience, caring for her dad at home with care. Daily they would actually create these alerts. And so I was able to know if he was moving around in a way that was outside of his normal pattern. It was really great at learning our patterns in the household, so that if he were for some reason up at 4 in the morning it would trigger me to go and check on him, and so I wasn't running every hour, because I heard a noise downstairs. When a problem happens. we need the intelligence to open communications to the right people at the right time, protecting privacy and dignity. It actually increased our communication among family members, who you may not always get to see or talk to and help them to get involved in a way that was comfortable and not overvaring for them the transformation of homes into healthcare hubs is not about the AI or the devices. This is about bringing people together and adding a virtual assistant to their team by enabling collaboration and promoting innovation. we can ensure homes become central to the new healthcare models of the coming century.

Paul Christie: Thank you for inviting me to contribute this pre-recorded message to the FDA's public hearing into its health as a home Hub initiative. I'm Paul Christie. I'm the CEO of Tachmed. And I'm here to tell you about our vision for democratized health, starting with platform technologies that we've developed for diagnostic hubs in every home that we think can be an incredible force for good. We want to make a very positive impact on everybody's health by putting health data information in the hands of patients, informing them exactly what their health is at any one time, and enabling them to share that information, at their discretion, immediately with health professionals, and other people that they trust, that can help them make the right decisions. It's very important for health service technology companies like ours to be inventive, accessible, reliable, easy to use and intuitive. We have to be inclusive, bold, embracing new technologies, looking for them, finding them wherever they might be, in the benchtops of universities or other areas of technological research and development and bringing them to market, putting them in the hands of everyone, not just the select few.

Tachmed is at an intersection of medical devices and demand for consumer technologies, empowering patients everywhere to take this responsibility for their health. Such a technology is by design systematic in its use, reducing costs, risks, improving patient outcomes through better knowledge, more secure environments, and changing everybody's relationship to managing and knowing the state of their health. We had a very simple goal when we started Tachmed, and that was to give everybody the best information about what their health is at any one time, enabling them to measure frequently and share that information with whoever they wish. What we want to end up with is providing enough data to patients about their health, so that everybody can determine a pathway to what state of health, how healthy they actually want to be, and know what to do to get there. Take those necessary steps with the support of professionals and friends available through a whole new digital ecosystem that is developing around them.

I hope that we can continue to contribute to the discussion surrounding the development of that ecosystem, and I hope that we can contribute to a discussion and deliver on all the promises that we're making to support that in the most secure, trustworthy way, so that patients build better relationships with technology companies and professionals alike. I look forward to hearing all the exciting feedback from this initiative, from governments, peers, and professionals, and I wish you every success. Thank you.

Ankurita Datta: Thank you very much to all of our contributors. Next we'll hear the perspectives of patients, providers, industry, and regulators, on delivering care to the home. We'll start off with Arianna Gehan.

Arianna Gehan: So before begin, I would just like to thank the FDA and everyone involved in this initiative for their work and also for including Breakthrough T1D and really taking into account the voices of the patients. So Hello! My name is Arianna Gehan. I do not have any financial conflicts of interest, as I am speaking here today as a patient.

I was diagnosed with type one diabetes 11 years ago, at the age of 11. I'm an active volunteer and advocate with Breakthrough T1D, formerly JDRF, and I currently work as a software engineer at Daia Diabetes. So in my discussion today, I will be talking about my access to providers, clinical trials, technology, and the community. And I'll begin with a day in the life of living with diabetes. However, I always like to throw on my disclaimer that there is no typical day with diabetes. Each day brings its own new set of challenges.

So, starting off in the morning I either wake up from my alarm clock or alerts from my diabetes technology. I wear a continuous glucose monitor, which is a small sensor that reads my blood sugar every 5 min and sends these values to my phone and to my insulin pump. My insulin pump is a device that delivers insulin to my body continuously throughout the day. And every time I input that I am eating carbohydrates. So this means that I have to count and track all of the carbs I'm eating throughout the day. So there are 2 main factors that impact my blood. Sugar food will cause my blood sugar to rise. Physical activity will bring my blood sugar down. However, it's more complicated than this. Some types of physical activity will actually cause my blood sugar to increase or spike, and there are a whole host of other factors that I can't even begin to get into that cause my blood sugar to react in unpredictable ways.

So with so many variables in this equation, it's no surprise that I make mistakes, and I make mistakes often. Here is a snapshot of a few days ago, where I received over 60 notifications on my phone from my insulin pump and continuous glucose monitor. So it's important to understand that alarm. Fatigue is real and diabetes burnout is a serious issue that is faced by many diabetics in just trying to manage this disease in their day to day, and this actually extends beyond just the diabetic, as I will sometimes share my blood sugar with a family member or caregiver. And so they are also facing these alarms and alerts.

And my impact on my family extends beyond just phone alerts as diabetes has taken over our dining room. It's become our control center where I am taking calls with insurance companies filling my insulin pump. And it's also great to have all of my care centralized in one location, because in case if emergency services have to come for some sort of treatment, it's easier to point them to one direction, so I can get the care that I need. We have faced some issues in the dining room as the alcohol wipes used for the sterilization process has actually damaged the wooden table we have in there. But it's still the ideal room in my house, because this is a space that isn't used very often. So it's easy to keep my supplies out and ready to use. There additionally is no carpeting, because it's a lot

easier to wipe up some blood from a hardwood floor than it is on carpeting. And there is also lots of storage. Here's a snapshot of our china cabinet, not the most organized, but it's important to have all this storage, because I don't need just enough supplies to get through the day, or even the week. I'm often getting 3 months worth of supplies on top of the supplies I need in case of emergencies.

And this is actually extended beyond my dining room. Here is a photo of my refrigerator, where we keep the insulin in the butter cabinet. We purchased a refrigerator specifically with a special section for the butter, because we were told that was the ideal temperature to store the insulin at. What's also important to note is that after my diagnosis we purchased a backup generator for my house because we need the electricity for my refrigerator to store this insulin. If the insulin is not kept at the ideal temperature, it will go bad, which can be a life-threatening situation.

Additionally, my purse is always filled and ready to go with juice, portable chargers, and anything else I'll need to manage my diabetes one away from home. And then at night I do my pump set changes. This involves using a needle to put a tube in my body as animated here so that my pump can actually deliver the insulin. I do this at night, because when I was younger I thought if it hurt I'd be going to bed, and I wouldn't feel the pain.

So I mentioned I do this in my dining room, which means this is my view when I'm doing my set changes. But this is my neighbor's view. And it goes to show that diabetes isn't always pretty. Healthcare isn't always pretty. I'm doing these set changes on my butt. So there really is a need for privacy when you are bringing healthcare into your home.

And then at the end of the day, I am going to sleep. But diabetes doesn't sleep. So I'm grateful to have technology that's working in the background and trying to regulate my blood sugar even while I'm sleeping. But it's not perfect. My nightstand is stocked with snacks that don't leave crumbs because I'm eating in my bed and apple juice, which is room temperature, because I don't like to have a refrigerator in my bedroom. And some other people use innovations that will they'll use alarm clocks that are extremely loud to wake up from notifications or have modifications to physically shake their bed if they're having trouble waking up during a low blood sugar emergency.

So shifting now to my access to providers. During the pandemic I had a lot of virtual Dr. visits which were a very appropriate setting for more my general care and interacting with my healthcare provider and getting the care that I needed to manage my diabetes. Of course, this means that I needed to have Wi-fi Internet connection and privacy. I found that post pandemic there's been limited access into having a virtual Dr. visit, even though it felt that it was an appropriate way to get my care, and my home was a suitable setting for these Dr. visits.

Another note is that durable medical goods, like my insulin pump, are not covered by homeowners insurance. And so it's really important that you

have a secure and safe place to keep your supplies within your home, because, replacing my insulin pump would cost over $4,000.

And slightly less relevant but still important to note is that I've had issues in the past where my insurance company has changed what type of insulin I am being covered for. So there has been an issue where insurance companies are controlling your prescription or your medical devices, whereas that should be something that is determined between the provider and the patient.

So now, looking at clinical trials, I have participated in research studies before, but I've never participated in a clinical trial. I've signed up, but just have never been connected or matched for one. But I would be interested in taking part in this if it could ideally be done at my home, or even if it was at a local or nearby healthcare provider.

And then looking into technical support, my insulin pump has failed at 2 Am. And it's failed at 2 pm. So it's important to have access to be able to call customer service at all hours of the day and have short wait times. I've additionally performed software updates for these devices at home. So it's again crucial where the few times I've had hiccups, I've been able to just call and get the support I needed pretty quickly. But it is important to have that when you are performing these technically demanding updates at home. When I was also choosing what insulin pump I wanted, and which brand I wanted, my family invited the sales representatives into my house so that I could get a feel for the technology in the setting that I would be using them the most. And for all these devices I have a lot of wires to charge them. I do not have the best cable management. So it's also important to make sure that there is access to outlets and easy ways for people to charge and keep these devices ready to use when they need them. I'd also like to say that these devices that I'm using are like my insulin pump and my continuous glucose monitor have been designed for home use, which I greatly appreciate and has really helped in my care and management. It's important that these devices stay simple, but also give the control to the diabetic, so that they can really manage their care and also give the data to the diabetic. The patient should be able to access and work with their own data and choose which devices they want, and make sure that they're interoperable and able to work with each other so that the diabetic can really take control and manage their own care.

I'd also like to make a quick note about the community. When bringing healthcare into my home, having the strong support of the diabetic community, and always feeling like I had people I could turn to and help me out when I was dealing with this at home has been extremely crucial, and I'm so grateful for the network that exist within the type one diabetic community.

So just to wrap up. I'd like to conclude by saying that diabetes technology really has been built for home use, and that has made such a difference in my care, and it's important that we keep making sure these devices are simple to use and give the control and the data to the patients. With that being said, there will always be a need for lots of storage, electricity and Internet connection. I think there's also a

great opportunity to increase access to providers virtually, as the home is a very suitable setting, once you have all of these necessary items in place. And of course it is very important to consider privacy. This is privacy from neighbors as doing healthcare is a very intimate act. But it's also privacy from your household. I don't want my diabetes care to get in the way of my family and living in their home. And also from the patient perspective: I'm dealing with my diabetes 24/7. This is my home, my place of rest, and it's important that it doesn't feel like a hospital at the end of the day. It feels like my home, where it just happens to be I'm managing my care as diabetic. Thank you for your time. I really appreciate it, and thank you for all the work you're doing on this initiative.

Ankurita Datta: Thanks so much, Arianna. Next we'll hear from Dr. Courtney Lias, and Dr. Martin Mendoza.

Courtney Lias Hello! My name is Courtney Lias, and I am the acting Director of the Office In Vitro Diagnostics here in CDRH. At FDA. Our office regulates the medical devices that people living with diabetes rely on every day, including blood glucose meters, CGMs, insulin pumps, insulin dosing calculators, and hemoglobin A1c tests. Today, I'm here to describe how important the voice of the diabetes community has been over the past 15 years in influencing the evolution of diabetes technology in the United States, and as an extension, around the world.

This incredible evolution in device design and innovation facilitates the use of technology in people's homes at their workplaces and on the go to improve their quality of life, and in many cases their health outcomes. We just heard an awesome summary from Arianna about the things she deals with daily. I will now speak from a regulatory perspective on how these types of experiences can be integrated into medical device design.

I remember sitting in a diabetes conference back in 2012, hearing about a day in the life of people with diabetes. They described that in order to go about their daily lives they had to carry around a blood glucose meter, test strips, lancets, glucose tablets, CGM Receiver unit, insulin, glucagon rescue syringes, and well, you get the picture. Simply to go to work or school, one had to bring several devices and a multitude of supplies. Teenagers rarely tested their blood sugar because they were embarrassed about the conspicuous nature of testing with a meter and the resulting unwanted attention from their friends. In addition, we learned that when going to the Dr., one had to wrestle with a nest of tangled cords to manually download their glucose data for the Dr. to review, because each meter brand had a unique plug interface in a unique software program. It seemed at times not even worth it for a fifteen-minute visit.

Learning these things made us realize that there were simple things we could do in the device regulatory arena through working with patients, Dr.s and device developers to improve the lives of these patients by easy technology fixes. So we contacted the manufacturers to encourage them to develop wireless data transmission that would eliminate the need for that tangle of ports. We encouraged the device developers to integrate device displays into mobile apps so that people could carry only their phone and not a bulky meter and CGM receiver. If we were doing all of our banking

and buying things with our phone every day, why couldn't we view our data and interact with our diabetes devices with our phones as well?

This new understanding led us to learn more about the experiences of people living with diabetes, and to look for other ways that we at FDA could influence better integration of treatment technology into their daily routines. Some things may seem like small issues when you look at them in isolation, but they are meaningful to the people who are dealing with them. For example, I learned that it was difficult to read the screen on some insulin pumps in direct sunlight. We began asking pump developers to consider screen technology that would allow better visibility outside akin to what is used in some E-reader devices. We learned that when people traveled across time zones, how the pump or mobile app handle time updates was critical, especially when calculating insulin on board estimations. We learned that having different options in the design of devices is meaningful to people. For example, one teenager who loved to wear dresses, chose a tubeless pump so she could more easily navigate using the restroom. Learning about these daily struggles enabled us to request during our interactions with device developers that these issues be addressed in device design, to make these diabetes technology more usable in a home setting.

People living with diabetes also deserve to feel safe when dealing with the 24-7 condition like diabetes. As you all know, parents of young children who have type one diabetes routinely need to monitor their child's blood sugar at night, to avoid nighttime complications of dysglycemia. They would set alarms and get very little uninterrupted sleep, or they would sleep in the room with their child to be near enough to wake up and respond to the CGM alarms. When we learned this, it was a no brainer for us to contact CGM companies and ask for them to work on remote monitoring technologies that would allow an alarm in a remote location, like the parent’s bedroom, so they could get better sleep if all was well. Once this was in place, we heard stories of the tremendous impact where a parent could remotely monitor their child's blood glucose from work when the child was in daycare and call that daycare facility to make sure the correct intervention was taking place. Family members were able to call emergency services when they were alerted to severe hypoglycemia in an elderly patient who lived alone in a different state, and it saved their life.

One of the hard truths I learned from the diabetes community is that many people feel they never get a vacation from diabetes. That they have to think about it as soon as they wake up, every time they eat, if they want to drive or exercise or travel. That it ironically even gets worse when they're sick. The promise of what used to be called artificial pancreatic systems, that we now call automated insulin dosing, or AID systems, loomed large as a way to help take the edge off the constant decision making that people with diabetes who need insulin must live with. Some feared that a computer algorithm guiding dosing of insulin--a drug that, when used incorrectly, can be one of the most dangerous drugs we use--would need an extremely high bar for approval. That every risk should be highly mitigated, so there was no remaining risk to users. But the diabetes community taught us that they felt differently. They felt that their baseline lives at home were already full of dangers that those of

us without diabetes didn't face. They were already at risk of accidentally giving themselves the wrong dose of insulin or miscalculating how much they needed of forgetting to take a dose or of getting dangerous nocturnal hypoglycemia. So, they were willing to accept that there may be some risks associated with novel AID technology as long as there were benefits that they cared about. The potential benefits of having a sensor detect that nocturnal dip in blood glucose and then automatically shut off their insulin pump was worth the risk that it might not work perfectly at first. Perhaps they would get better sleep. Perhaps this device could take some of the decision burden off their plate and allow them to take a break from having to constantly think about diabetes.

For these reasons we worked closely with AID developers to push the faster development of home use fully closed loop AID systems. We designed a focused clinical study that could efficiently address the safety of the device. In this way, we were able to approve the 1st AID system a full 3 years earlier than the company had projected.

But remember what we had already learned about the importance of choices to fit the individual lives of people that are living with diabetes. We had learned that devices fit differently into each person's environment and lifestyle. So, we developed a vision of an ecosystem of diabetes technology components that could work interoperably, in a mix and match kind of way. Perhaps one person liked this sensor and that pump, while another person like this pump and that sensor, perhaps all of them wanted them to be connected in their home environment. We soon realized that our traditional way of regulating these devices as systems that work as a package deal here at FDA would prevent that from becoming a reality. So we designed a new and creative regulatory paradigm for interoperable AID system components, and we were able to implement it in under 2 years from inception to execution.

So what does all this look like today? Today, I'm proud to say that we have authorized several types of AID systems and multiple CGMs, giving people choices of the technologies that fit into their lifestyles. Teenagers can monitor their blood sugar more discreetly at school using phones without standing out. We have recently authorized 2 CGMs as over the counter devices that will be available to anyone, regardless of the type of diabetes or their insurance policy. Now we now have flexible regulatory pathways for diabetes devices, and many of the diabetes technologies are interoperable with our cell phones, because that's how people live their lives in 2024. I wish I could say we currently live in a Shangri-La of unlimited choices, and with the infrastructure to implement more healthcare at home for diabetes. But we're not there yet. However, we've come so far from where we were 15 years ago, and with the Home as a Healthcare Hub initiative, I know we will continue this amazing progress. So thank you. And I look forward to the discussion.

Martin Mendoza: So Hello, everyone. I'm so happy to be here with you today during this exciting virtual forum. I'm Dr. Martin Mendoza, CMS Chief Health Equity Officer and the Director of the CMS Office of Minority Health. I'm a Hispanic male wearing a blue jacket. So I'm

honored to join your conversation in this forum focused on home as a health care hub.

Aging in place in the community and home can be beneficial for so many people as it enables family and community members to support their loved ones as they age, avoiding feelings of social isolation, and providing a stable, safe, and familiar environment. And as all of you here are so acutely aware of, aging in place is increasingly important in order to give individuals and families an alternative to clinical or institutional residential care settings, especially as care settings, like hospitals and long-term facilities, face staffing and bed shortages. It's an especially critical option to have available for individuals in rural and geographically isolated communities where the nearest long-term residential setting may be hours away, as those types of situations effectively sever aging individuals from their community, family, and friends. But a home environment may need modification or accommodations for chronic or age-related health conditions, or to account for social drivers of health. This is why your work here is so vital. So today I'll spend our time together hopefully adding some health equity considerations to your discussion. And I'll share how we are working to operationalize health equity across CMS and a few updates on recent and proposed policies.

So for my talk today, I'll start with an overview of our office and how CMS is strategically working to advance health equity. I'll discuss our 2 companion frameworks and then I'll close with some recent policy updates on CMS focused on coverage, access, quality, safety, and payment.

So this slide will help to level-set our discussion as explains how we think about health equity here at CMS. So on the left is text that is also on the CMS health equity landing page. And so to ground us today, this is CMS's definition of health equity. So to CMS, health equity means the attainment of the highest level of health for all people where everyone has a fair and just opportunity to attain their optimal health. At CMS, we strive to embed health equity in all we do, designing, implementing and operationalizing policies and programs that eliminate avoidable health differences and help healthcare professionals provide the care and support our enrollees need to thrive.

So with that as our foundation, I want to dive a little into the background on the office I lead. So the CMS Office of Minority Health is one of 8 Offices of Minority Health, or OMHs across the Department of Health and Human Services. We are all sister offices, and each of us focuses on our own agency and programs. So within CMS, our Office of Minority Health's mission and vision are to embed health equity into CMS programs, policies, and partnerships, so that every person served by our agency can achieve their highest level of health and well-being, and the disparities in healthcare access, quality, and outcomes are eliminated.

So more broadly than CMS, however, is CMS's overall approach to health equity. So across the agency, as you can see from this slide we have a strategic plan. And so this slide and the next slide describe a little bit how we are operationalizing that strategic plan, and specifically that we have 2 frameworks that work in tandem to help us identify areas

to prioritize and focus our efforts. So on the left of the slide are the 6 pillars of CMS's strategic plan. And as you can see, health equity is that 1st pillar. So we also focus on expanding access, engaging partners, driving innovation, protecting programs and fostering excellence. And on the right-hand side of the slide are 2 screenshots from our equity focus frameworks: The CMS health equity framework and the CMS framework for advancing healthcare in rural, tribal and geographically isolated communities. So these frameworks each have specific priorities and they aren't meant to be considered in isolation as in they both work together and reflect our holistic approach to health equity. So you may be wondering, why do we have 2 frameworks. Well, that is because we consider health equity priorities and needs broadly, and also recognize that rural, tribal and geographically isolated communities experience healthcare differently. From the way providers are paid, to the distance people travel for care, and lack of broadband, there are really unique considerations for geographically isolated areas like the U.S. Territories, frontier communities and tribal nations that must be incorporated into policy decisions intentionally. And so, as you think about the infrastructure of rural and geographically isolated communities, what they might need, adaptations for people with disabilities, aspects of the workforce, and how it can support care delivery, and inform in the home most effectively. And really, those cultural considerations that specific communities, for example, tribal communities may have about their home care settings. So this is especially important to consider as we think about healthcare technology coming home, and what that home environment may look like. Whether someone has broadband connectivity in our community, or their home may be really an important determinant of success. So, whether someone is experiencing housing insecurity or instability from poor housing quality to utility insecurity to homelessness or living in a temporary residence like a hotel or being doubled up. These social drivers of health are ones CMS encourages screening for because in clinical care and in care of the home they are critically important to consider for how a person might experience care at a home, and what adaptations are needed to realize the intended benefit and positive outcomes of the home as a healthcare hub initiative.

So, with that part overview, I'll briefly share just a few specific policy updates that you might consider as you drive your work on 'home as a healthcare hub' forward. First, is the recently finalized section in 1557 rule, which is a set of regulations and guidelines for all federally funded health entities and programs, including federal, state and local health programs, including those administered by CMS. So, it applies to all healthcare organizations, including providers, practices, facilities and home healthcare agencies, insurers, health plans and healthcare insurance marketplaces. It covers both telehealth in-person care and decision support tools. So, changes to 1557 were finalized just last month with several important updates, including a protection against discrimination and requirements for recipients of federal funds to take reasonable steps to provide access to people with limited English proficiency and those with disabilities. So next, HHS has recently updated their language access plan, and all agencies, such as CMS, are following suit with updates to their own language access plans, and those are due to be released soon. So please stay tuned. And finally, CMS has

finalized a number of policies aimed at increasing access to affordable prescription drug coverage for individuals with Medicare part D, including the yearly cap on out-of-pocket costs, annual adult vaccines provided with no cost sharing, making insulin available at $35 per month, and expanding eligibility to low-income subsidy program to people who are up to 150% of the federal poverty level. So, these changes help make prescriptions more affordable for over 300,000 low-income people on Medicare, and we are working to ensure people know about their covered benefits and can use them to get better care.

The next set of updates has a few items that are recently proposed. So, some of these are still in open comment periods, and we encourage you to take a look at these rules linked in the CMS fact sheets below and provide comments if you have them. First, the annual physician fee schedule for the coming years recently proposed several policy proposals relating to advancing health equity, strengthening primary care, expanding access to behavioral health, oral health and caregiver training services, maintaining telehealth flexibilities and expanding access to screening for colorectal cancer and vaccinations for Hepatitis B. Next, moving on, moving into the safety space, CMS recently finalized a regulation related to minimum staffing standards for nursing homes. On April 22nd, CMS affirmed our commitment to holding nursing homes accountable for providing safe and high-quality care for the nearly 1.2 million residents living in Medicare and Medicaid certified long-term care facilities by issuing this final rule, which revolves around a total nursing staffing standard of 3.4 hours per resident per day. Finally, on the right, I've highlighted a proposed bill that CMS recently released related to outpatient hospital payment, with several additional health equity provisions and protections for maternal health care.

And so now I know I've just shared a huge amount of information in a very short time, and there's so much more we could talk about. So, on the slide is our website and some contact information so you can find our office, our team and the frameworks I mentioned as you dig into your work on this exciting home as a healthcare Hub initiative. I want to thank FDA and Dr. Tarver and the Center for Devices and Radiological Health so much for having me today, and I look forward to seeing this initiative grow. Thank you very much.

Ankurita Datta: Thank you, Dr. Lies and Dr. Mendoza. Next, we'll hear from Andrew Cleland.

Andrew Cleeland: Right. Hi, folks, I'm Andrew Cleeland. It’s a pleasure to meet you all. I'm sorry. I'm just trying to set this up. Alright, I just wanna first of all, thank Dr. Tarver for the opportunity to participate in today's discussion. I'm on it to provide an innovator's perspective on the concept of home as a healthcare hub. I'm Andrew Cleeland, CEO of Fogarty Innovation, a nonprofit MedTech incubator whose goal is to accelerate the invention development and deployment of new technologies into clinical care.

MedTech innovation is time consuming, costly, and complex as we balance the needs of an interdependent community of people. This ecosystem consists of patients and importantly, their families, physicians and

providers, regulatory agencies, insurance and payers, investors and acquirers, and entrepreneurs and their startups.

The essence of innovation is truly understanding the problem from the perspective of all stakeholders, and assessing whether it needs or is worth solving. And quite frankly, this is where most med tech innovation fails, and this is on the shoulders of the innovator entrepreneur, not government, not industry, not the providers nor the insurers. It's on the top shoulders of the innovator. MedTech Innovation is the product of need, opportunity, and motive. I'm going to spend just a minute describing what I mean here.

I think Commissioner Califf very eloquently highlighted the issues our society faces and the issues that the MedTech community is here to help solve. We have an increasingly aging population. 70% of the U.S. Population is over the age of 65, and over the coming decades that's going to grow by 25%. Why is that a concern? The concern is the increased burden of care that that's going to cause, along with a simultaneous reduced workforce and a reduced tax and revenue base. We're also seeing, despite all the efforts, an increasing prevalence of chronic disease. Cardiovascular disease, cancer, lung disease and diabetes are all on the rise. Over the coming decades, we're going to see a 42.8% increase in the prevalence of ischemic heart disease. Clearly, we're also facing an unsustainable cost here with spending more than 4.3 trillion dollars or 70% of our GDP on healthcare. And despite that spend our life expectancy is, as highlighted by Commissioner Califf, at birth is the lowest of the developed world. The number of avoidable deaths is the highest. And I think, most impactful to me, the rate of infant and maternal deaths is the worst in the developed world. And last, but not least, we're all aware, and some of it is reflected in those numbers I just quoted, that we have a significant issue regarding access, affordability, and outcomes.

So today, I think it's fair to describe that we have an imperfect system primarily focused on treating late-stage chronic conditions in a hospital setting. The decentralization of healthcare, including healthcare at home, is possibly the only way we can solve these problems. Moving from a basis of high-cost care to a lower cost setting may improve the economics for providers, while providing better, more appropriate, and more acceptable care for patients. Of note, McKinsey has identified up to 265 billion dollars' worth of care or care services that could shift to the home in the immediate future.

Dr. Alpert also noticed earlier in the discussion today that we're fortunate to live where we live today. We're seeing the convergence of advances in digital technology and infrastructure, telecommunications, micro processing power, sensors, nanotechnology, material science, amongst others, which is enabling the discussion that we're having today. It's also important to point out that the pandemic accelerated the acceptance of new remote telecommunication technologies and home-based diagnostic testing, amongst others. I think this is also reflected in a remarkable number that I just noted. Telehealth visits increased from 840,000 in 2019 to over 50,000,000, 1 year later. The pandemic also underscored the fragility of our hospital-based healthcare system,

requiring us to truly reimagine healthcare for the future. One of those other things, and then we've probably noticed it in a few things today, that not only are we seeing these advances in technology and the acceptance of these technologies, but we're also seeing innovative, regulatory strategies from folks like the people on this call, from the FDA.

Getting to motive. And I think a simple truth is that innovation is driven by investment and more importantly, return on investment. It's not good enough to have a great idea. It's not good enough to show that your idea works. It must be a good investment for someone. Someone needs to be able to make some money so that we innovators can do our job. Home healthcare is not a new idea. Yeah, we've been working in this for decades. Orthotic and mobility aids, cpap machines, blood pressure monitoring have been around for decades. As you've heard today, we've been making advances in home dialysis, diabetes, management telemedicine and wearables with varied, complex diagnostic capabilities are both current and emerging. And we're also seeing innovation in the delivery of care with outpatient clinics and potential retail health. That said, less than 5% of medical devices are developed for home use, or specifically for home use in our portfolio of cutting-edge companies. Only 2 of the 24 are dedicated for home use. What is new? I think it's the holistic vision communicated by FDA today. Home as a healthcare hub, I think, is a tremendous opportunity. We're also seeing the emergence of smart MedTech. And so, the implantables that have other functions than their initial intended use. But it is the convergence of these technological and societal conditions that are providing the opportunity for us to accelerate along the spectrum of care moving from simple monitoring to diagnosis to treatment, and ultimately, I hope to prevention. The MedTech industry faces significant challenges. We are. We've grown up treating patients rather than consumers. So, it's a lesson for us to understand who were actually treating. Home-based care is going to identify new risks around who's responsible for action? Is it? Is it the consumer, the patient? Is it a hospital provider? And these are going to generate significant workflow issues within the provider community. As mentioned earlier today, who owns the data is going to be an issue? Is it the patient who owns the data? Is it the patient who owns their own individual data? But the companies that own the combination or the aggregation of that data, the key question is, who pays? Again, yeah given, the equity issues that we've been discussing, this is not going to be a self-pay sort of situation and identifying very clearly who pays for this is important. We also got to overcome nascent, regulatory and reimbursement pathways. There's a lot of work in this area, but it's still new and ultimately for digital health, and particularly for home-based digital health. There are too few acquirers, and that gets back to my point before on return on investment. And I think what's made the key point, the key worry that I have has been made numerous times today, which is, we need to see the integration. Many of these individual devices, applications, and data feeds into one cohesive platform. I think Dr. Shuren noted that we need to move from siloed care to integrated care. It's no better highlighted than here. And I think, truly understanding the needs of each player in this ecosystem, as I said earlier, is key to delivering a sustainable, impactful innovation. So, from my humble position here, what are the conditions for success? I

think we need to see strong collaboration here between tech and MedTech, between government and industry, between small and large within our industry and other industries, like the real estate industry. I think we need very rapid development of standards and guidance very similar to what happened with the communications industries, and an semiconductor industry years ago. Love to see some funding to boost initial research and development into this space. Something I love, the Chips Act. We need a clear, consistent, and rapid, regulatory pathway. And most importantly, I think we need an attractive reimbursement landscape. And what I mean by that is a reimbursement landscape that actually incentivizes providers, innovators to develop into this field, not simply to cover cost. What I'd love to see ultimately is a genuine coordinated national effort. What I'd like to quickly finish on is to personally to thank Dr. Shuren on what he has accomplished for patients, what he has accomplished for our industry over the time he served within FDA and wish him the very best on his next endeavors. Thank you very much.

Ankurita Datta: Thanks so much, Andrew. Next, We'll hear from Casper de Clerk.

Casper L de Clercq: Good morning, everybody. It's afternoon already there. Look, I'm delighted to be here. Thank you for CMS, Dr. Tarver, and Dr. Matthew Diamond who invited me. So, thank you for that. I represent and I'm speaking for myself. But I work at Norwest venture partners. We're a 15-billion-dollar fund. We've been around 65 years. Our first investments, funny enough, were Dairy Queen and Cray supercomputing, both considered high tech at the time, and we invested. I've got a team of about 12 people working on the healthcare venture side and we invest all the way across therapeutic devices, medical devices, biotechnology services including services to the home like two companies called Omada Health and Monogram Health, that I'll talk about a little bit. And then actually also an insurance plan. So, a Medicare advantage plan. And so, we have a sense, too, of with this team - the whole ecosystem as we just heard about. So, thank you, Andrew. So I think that the role of the FDA is very important. Now I've seen 15 years of digital health quote unquote innovation. And I think, I think 15 billion or so has gone into the industry, and very little has come out. And I think it's primarily because studies weren't done properly. They weren't. People were not looking at efficacy and outcomes when they should have from early days. So, I do appreciate the need for CMS, sorry, FDA and CMS getting engaged in terms of what? Really, what? What difference are we truly making with a placebo controlled or randomized control? When appropriate? Without CMS, obviously we wouldn't be here really encouraging of the breakthrough designation and some of the CPT codes which facilitate payment from day one that's made a huge difference on the device side for some of our companies. So, I've got three main things to talk about. Number one, what I call the 4 P's. Number two, where do we focus with respect to home healthcare? And number three, how does one get paid? And just some suggestions there? What I call the 4 P's are patience, Physicians, providers, as I think of those would be hospitals or delivery networks, and finally, payers, which obviously are private insurers as well as the government and patients. I would also add, as we just heard with respect to health equity, the social determinants of health. And I think that as well as age, really thinking about how to segment or serve, all those

different patients. But I think the reason I use that rubric is that we need to make sure that all the incentives are aligned for every one of those groups. If one of them is not incentivized. We don't get proper innovation. We don't get payment, and we don't actually get a change in outcomes. And so, it's both the interest aligned, and the incentives aligned. It's better for the patient, but a physician doesn't get paid to provide the service. It's not gonna happen. If it's too big of an out of pocket for a patient. It's not gonna happen if a payer doesn't think it's cost effective. Well, it's not gonna happen. So really, just to encourage all of us to think about what again, I call the 4 P's where to focus. I've probably spent most of my time on this one, I guess. Let me just take two different ends of the spectrum. If we have this company called Omada Health, which is involved in that we've invested in which is focused on diabetes and diabetes prevention, even though we know diabetes is this inexorable progress towards unfortunately dialysis and amputation and really an awful outcome if it isn't treated early in the beginning. It's hard to justify that expense because the payback for any insurer is years away. And contrast that with somebody whose end stage renal disease is on dialysis and is constantly going into the hospital or somebody with congestive heart failure. 60% of congestive heart failure patients are re-hospitalized within 90 days. They keep coming back. Too much sodium diet, whatever you know, whatever issues. If we could provide care for those patients and just reduce one hospitalization which typically costs $10,000. You could invest a huge amount of coordination and home health care to keep those folks out of the hospital. So, I do think this focus is really important to think about the spectrum of care. Where do we intervene? Where does it make sense to intervene. And where do we most improve clinical outcomes and cost effectiveness? So, I'm gonna go back to, you know I think Arianna and Courtney gave some good examples of diabetes. So, using again the same thought, I've been absolutely passionate about diabetes now for 20 years. And I called it in the early days, interstitial care, so the care between visits. That's a little bit how I think about home health care. You get to a physician once a year, maybe twice a year, if you've got insulin dependent diabetes. But the excursions in terms of how much insulin one needs are all over the place. It could be 20 units in one month, it could be 70, 80 units. The progression is there. The diversion, if you will, or dispersion of results, is tremendous. So there was a real need, for example, to not only have patients primarily be agents, you know, have agency for their own control, but what about oversight and coaching for a type one or an insulin dependent person with diabetes incredibly useful. The same thing with congestive heart failure, same thing with chronic, abstractive pulmonary disease. So back to diabetes. If you've got a hypoglycemic or hyperglycemic event that is very, you know, dangerous, it's costly. It's terrible for the patient's health that is absolutely worth investing in. There were some companies that started 10 years ago with, you know, monitoring and so forth, to type 2 patients, but honestly, if you're on Metformin and your blood glucose is relatively under control, it's a lot more like coaching than needing all kinds of fancy monitoring in the home. Because it really makes no difference, and I don't think we should pay a lot for that. And then, you know, we, as I talked about in the end, looking at diabetes prevention. Omada Health is a company there. And there is payback, but it is harder to demonstrate. In the near term we see it at a year. We see it at 2 years, and it definitely isn't the case

at 3, 4 years. So, the incentives there. What we've had to do is i, the company has gone to employers who have employees for 4 or 5 years. Same thing might make sense for CMS where somebody's part of Medicare advantage plan for multiple years. That, unfortunately, has not been approved yet for telemedicine, if you will, the remote monitoring, remote coaching, yet. So that would be terrific to see at some stage. But there is a big ecosystem of private insurers. I'm sorry, private companies and insurers, who will pay now for this home coaching, home monitoring, and the way Omada does it is they have a scale. They get daily readings. There's texting and there's food advice. I'll get to this a little later. They have tremendously sophisticated algorithms to see what the weight trends are, what the intervention should be, what works, what doesn't work in literally millions of patients. So, I do think systems like that, ecosystems like that are effective. But we have to think very carefully about how much money do we put into prevention from a sort of prevention versus addressing acute care and hospitalizations? They're very different. So again, just that was my issue on focus. The last one is really; how does one get paid as an investor? That's what keeps me in business, and honestly, the only way we stay in business, if is, if we're having a true effect, cost effective or patient improvement, so our interest are as aligned as anybody else in the healthcare system to do the right thing and make sure that we have placebo-controlled outcomes that show their efficacy. CMS so there! There are a couple of ways to get paid. So the three areas would be the appropriate codes. CMS came out with some terrific codes called the RPM, remote patient monitoring codes 99453 and 99454, that pay 46 to $47 per month for monitoring just purely for the data flow. It could be a scale, it could be a blood pressure cuff, or it could be a glucose monitor. So, there's a technical component. And then there's a labor component 99457, which, based on spending 20 min with a patient once a month, will reimburse $48 that has opened up a whole ecosystem of providers that are able to do that to provide those services. It's probably the adoption has been a bit slower than one would have hoped, or one expected, simply because there are some disincentives or not appropriate incentives for physicians to be engaged in this, so it's quite difficult to actually get patients to enroll. But I do think it's a great example of what we're starting to talk about with home healthcare is that this you know the hub so that might be an interesting way to go about it. I think, as it relates to the CPT codes, for example. as you can imagine, we are currently paid for professional time. That's what a CPT code is. But this world is moving. Pardon the cliche, much more towards AI. And algorithms and companies need the incentive to build those algorithms which are quite expensive. And so, I think it would be very helpful at some stage to see combined CPT codes, which would be technology enabled labor, for example. So not just the pure 20 minutes. If you have a good algorithm that saves you from 20 minutes and takes you down to 10 minutes, maybe it isn't half the reimbursement, but there would be some element there where it's paid where the technology's paid for. I say, those are primarily the areas that I would focus on with respect to the payment side and then finally, on value-based care. That's the 3rd area where payment potentially makes sense. So, what value-based care does with Medicare advantage, for example, is rather than focusing on specific fee for service codes, an insurer or payer is incentivized to provide the best care, and probably the best example we have of that. My last comment is on Monogram Health,

which is another company, very instructive, primarily dealing with rural care. Patients who are not well taken care of, who have either have no primary doctor , or they have 4 or 5 doctors that don't speak to each other. And these are these are patients who have very advanced end-stage, renal disease, or late-stage kidney disease. They're about to go on dialysis. When a patient gets hospitalized, they can quickly run up a $203,000 bill and so I joke, it is literally worth it to the company to send a nurse to somebody's home. Pick them up. Do a full physical exam, and if so bring them to the physician or primary care doctor,. or a nephrologist if needed, to prevent that unnecessary hospitalization. And the company does exactly what we've been talking about which is, they have both home health aides that come and visit, but then remote patient monitoring with a scale, a height, a pressure cuff, and so forth. Which is really, I believe, the right intervention. Is this integration of not just digital technology, but also coaching motivation, appropriate clinical care nurses, and nurse assistance? And again, I think, as Andrew mentioned, we have a really complicated ecosystem where we need to coordinate care across multiple stakeholders. So, I'll leave with those two words, just coordination.

Ankurita Datta: Thanks so much, Casper. Next we'll hear from Dr. Ricky Choi.

Ricky Choi: Well, thank you so much for inviting me to speak today, and thanks to the FDA for your leadership on this exciting and timely topic. My name is Ricky Choi, and I'm the head of Digital Health at Samsung Electronics, America, and a practicing physician as faculty at Stanford. As many of the previous speakers have noted we are at a critical time as health needs are rapidly growing, but the means to address them in a comprehensive and equitable way are shrinking. We're all aware of the growing, aging population and ongoing high costs of healthcare. And yet the workforce to address these needs is shrinking and projected to shrink further. And at the same time digital technologies are rapidly becoming a viable option to close some of these gaps as witnessed during the global pandemic, consumers are more open than ever to using these technologies. And significantly, you know, we physicians were famously slow to adopt new standards of practice or seeing digital technologies as acceptable ways to deliver care. Now trends show that care is moved from the home and we are seeing a growing preference of care at home today. Today, technology digital technologies are empowering users to prevent, detect or manage diseases from home and when needed, have a telehealth visit with their doctor. Funding streams, such as reimbursement for remote patient monitoring, as previously mentioned, and remote therapies, is increasingly enabling business models at an industry level. We're witnessing this change and are rising to meet it. I have the privilege of being the incoming Vice Chair for the Health Division Board at the Consumer Technology Association. This board works to advance the use of consumer-based technology-enabled health solutions to deliver better health outcomes and reduce overall healthcare cost. We have groups focused on data and policy as well as heck, health equity! And in many ways, we've been building towards care in the home for many years. So, in contrast to a sterile clinical environment. There's tremendous value to addressing health needs in the home context where social determinants of health are truly at work. As a pediatrician at a Federally Qualified

Community Health Center(FQHC),for many years I had patients from immigrant and other vulnerable populations who were low income and had very few resources, but they all had a smartphone. It was required to work, to play, to go to school, to access care, and to stay connected with loved ones, both local and abroad. In the United States more than 85% of people own a smartphone with almost no difference in rates of ownership across race or ethnic lines. And in fact, 86% of Americans on Medicaid also own a smartphone for 20% of Americans. A mobile device is the only way of connecting to the Internet while at home. And you can imagine these digital technologies unlock a whole universe of connectivity to one's hospital medical devices, health services and information. According to a report co-developed by our CTA Health Division board, digital health technologies can promote health equity in many ways for convenience and improved access for patients like reducing the need to take time off work, to secure child and elder care, and find transportation. To improved patient engagement through patient portal, use of new models of low acuity care and chronic disease management, improved reporting capabilities, and using standardized systematic data collection for health surveillance and interventions. At Samsung, our vision is to build a healthier future for everyone, and we aim to do this by connecting devices, connecting services, and connecting people. We feel there is no more important place for one's health than in the home where one's health journey begins each day. Home is where you manage your daily health through decisions about what you eat, your activities and sleep. It's where you first discover you're sick and where you may have to have a telehealth visit with your Dr., when you return after a visit to the hospital. It's where you manage your chronic illnesses. It's where you care for your children as well as your aging parents. So we see care at home as critical. We're proud of the fact that households across the United States have already made Samsung part of their home. In fact, 70% of American homes have Samsung technology in it, and that includes home appliances like refrigerators and stoves, as well as our SmartThings IT platform. So, imagine now, tying that in with our biosensing wearables, smartphones, TVs, and tablets. And so, as a leader of the health team, I'm trying to figure out, how do we use these touch points to better understand the health goals of our users. What their health needs are, their gaps in care and how do we nudge them to help make the healthy choice, the easier choice, for all populations. Central is the idea of empowering users with data, information, and capabilities to improve their health and the health of their loved ones. Our strategies include developing technologies to detect disease early by developing next generation biosensing capabilities, including FDA cleared Software's medical devices for sleep, apnea, atrial fibrillation, and more technologies to care for health needs, for aging parents, and children to manage their daily routines. For example, when permitted, caregivers can help aging parents safely use appliances like turning off stovetops by via smartphone if their family member accidentally leaves it on or receive a notification when their children return home from school. As well as a suite of software development kits(SDKS) to harness the broader and frankly fragmented ecosystem, in order to deliver better insights and a more cohesive experience. Samsung Health is building the future of consumer empowered health through an end-to-end platform for home-based health journeys to help our users and their families achieve their health goals. We also know and firmly believe, that health and healthcare is a

team sport. There are amazing technologies being developed every day, many of which discussed during this seminar. Through partnerships, we aim to reduce fragmentation and harness the ecosystem through user-centric platform that can deliver solutions at scale. I think we can all agree that the need is clear. But there are a lot of unknowns, and it will take creativity and collaboration to make a meaningful difference in millions of people's supplies. Samsung is eager to be a partner to help make this a reality. Thank you.

Ankurita Datta: Thank you. Dr. Troy. Next Dr. Joel Brill.

Joel Brill: Good afternoon. Give me just a moment, and I'll pull up my slides. Technology work. Thank you, folks. Good afternoon. Thank you, Dr. Califf, Dr. Shuren and Dr. Tarver for inviting me to participate in this very important panel. My name is Jewel Brill. I'm a physician. I'm an internist and a gastroenterologist. I've had a varied career, including private practice, being a health plan medical director, having bought a risk bearing medical group, having been a CPT advisor for 26 years and having participated in the AMA's work process for 25 plus years. My comments will reflect only mine, and do not represent any organization or any other entity. With regards to reimbursement, there are several elements of reimbursement, and several of these speakers who have just spoken have addressed certain components of this. We have to look at this as a puzzle. Within reimbursement we have to think about coding coverage payment site of service and the pay permits, each one of those plays a very important role in how things get adopted. How things get paid for. How things get utilized by patients. One of the greatest challenges is that when we have a technology that can help people to live fulfilling lives in their homes, but when their technologies cannot get paid for, it cannot get reimbursed, or the reimbursement remains inadequate. What can we do? What should we do? As has been alluded to by several, there are building blocks of reimbursement coding. Whether code is granted by the AMA, the CPT code, or whether CMS establishes a Healthcare Common Procedure Coding System (**HCPCS**) **Code**. Coding links coverage and payment, but it does not guarantee coverage, nor does it guarantee favorable reimbursement sadly. Coverage is not guaranteed when one receives FDA approval for clearance. And aside from the short time when we had a policy in place during the past administration, there is currently no mechanism for breakthrough devices to automatically attain coverage, coding, and reimbursement upon FDA approval and clearance. Coverage does not guarantee a new or favorable billing code, nor does it guarantee favorable reimbursement payment. Thus, is a function of coding and coverage. It may be subject to limits. It may be standalone. It may be bundled, and it may be driven by existing breakthrough technologies as I've mentioned within healthcare common procedural coding system HCPCS codes. There are two principal subsystems. Level one HCPCS codes or CPT codes and those are maintained by the AMA. Those are codes that for the most part begin with a number level. Two codes are used primarily to identify products, supplies, and services not included in those CPT codes and for the most part they are maintained and distributed by Medicare in conjunction with private peer organizations. Why is this important? Because, as I'm going to show you, there's some barriers that exist within the current system. Some of which we hopefully working collaboratively. can overcome. This is the current schedule for applying

for a CPT code and, as you can see here, it can take over 2 years' time in order to get a category. One code, for example, a CPT application that was due in November of 2023 would not receive a category one CPT Code until January 1st of 2026 - to go over 2 years without having a code, without having reimbursement, without having coverage. And some of the current speakers, you know, speakers have already mentioned, this can be devastating to a company. How do you help patients with the technology? If there is no mechanism in place for them to code for the procedure, for them to get coverage by commercial carriers or whether to get paid. Category CPT 1 codes usually have relative value units or work values that have been assigned by Medicare and have an associated physician payment amount. Category 3 CPT codes are temporary codes for emerging technologies, services or procedures, and they allow for specific data collection associated with those services and procedures. But there are no RVUs relative value units or established payment positions assigned for category 3 codes. We see that many commercial insurers treat category 3 codes as experimental and investigational, not otherwise covered. So we now have a quandary. We have codes that are getting created, but there is no mechanism for coverage. There is no mechanism for payment because reimbursement is really at the discretion of the payer. When thinking about the road to coverage. One thus, has to provide adequate evidence that the treatment strategy using the new therapeutic technology, or the incremental information obtained by the new technology, changes recommendations by healthcare professionals, results in changes in management, and it leads to improved, clinically meaningful health outcomes. This means that data collection needs to start early. When does it need to start? Probably the day before company decided to go down the pathway of speaking with the FDA. Yes. data collection and demonstrating robust data needs to start very, very early. The data collection publication and doing robust studies unfortunately costs money. So you have to ask questions. Does your service improve outcomes? Does it lead to longer life and improve function, and participation. Does it lead to significant symptom improvement. allowing better function and participation, especially in an at-home setting? Does it reduce the need for burdensome tests and treatments? And have we accounted for the person's desires to receive high quality healthcare without hospitalization? The latter of evidential strength is costly. The gold standard from CPT's perspective, from payer's perspective. from CMS's perspective is a meta-analysis of individual patient data or large random double-blind studies. How can emerging technologies fund, operate and collect the data needed to show this. As data becomes lower on the ladder of evidential strength. We start seeing things, such as single site, random trials, small trials, or cohort studies. Payers are less likely to accept that as evidence. and thus technologies that could be very, very helpful and vital in helping people to have healthcare at home, to have a healthcare connected Hub may not get access to these technologies. or they may be forced to pay for these technologies out of pocket. and when an average Medicare beneficiary is living on an income of less than $3,000 a month, they may not have the disposable income. They may not even have 40 or $50 a month to help them to live fully functional lives in a non-hospital setting. So I leave you with this. We have a variety of payment mechanisms. We do not have a healthcare system. We have payment mechanisms that differ, whether it is Medicaid, whether it is Medicare or whether it is a private payer. Clearly, we need to give credit where

credit is due. We need to give credit, for example, to CMS for taking the lead for paying for technologies. for taking the lead many times and paying for technologies when there is no national or even a local coverage determination for those technologies. But we need to do a better job, and we need to bring the payers into the mix as early as possible to give these companies the guidance that they need when the data that should be collected. and the robustness and the depth of the studies that are conducted so that as these technologies get approval from the FDA, they can lead to coverage and payment early and helping the people that we are dedicated to serve, thank you.

Ankurita Datta: Thank you, Dr. Brill. Now we'll hear from Dr. Jesse Ehrenfeld. Thank you, Dr. Brill. Now we'll hear from Dr. Jesse Ehrenfeld.

Jesse Ehrenfeld: Well, great! Thank you so much for having me today and for pulling this session together. It's been a really great conversation. I want to just talk a little bit about the ama's perspective on why health at home, health in the home is so important. How we conceptualize it. What our framework for envisioning the transition for these care models can be and then how we think about the infrastructure needs which obviously ties back to the FDAs initiatives, and I'll touch on some of the factors that we think are really important to consider, and then I'll try to end with 2 quick examples of what a patient journey could kind of look like. I I don't have slides, but I will show one graphic at some point in my 7 or so minutes of remarks. So as you know, obviously, today, the majority of healthcare services are happening in physician offices, clinics, facilities. But because of our aging population, disease, burden, clinic capacity constraints, care teams who are overextended burnout and the fact that the per patient healthcare expenditures are higher in healthcare settings than anywhere else in the world. We've got to deliver care in alternative settings and including the home. If we're going to improve access, provide higher quality of care, improve clinical outcomes, drive down cost, and so importantly improve the patient experience. The patient journey. So, delivering healthcare at home with appropriate technology and infrastructure around it, is clearly an important solution to some of those points of friction as we transform. How do we think about delivering care to patients, like I do think it's important to recognize, though, there is historical context. And you know, in the thirties 40 percent of healthcare was delivered in the home. Right and the model of care delivery shifted because what we had in the thirties was obsolete because of constraints with scalability, logistics efficiency. And we have this medical system built up that predominantly organized around clinical facilities, physician offices, hospitals, emergency departments. But we're at a point where obviously with the advances in digital health emerging technologies. Clearly, we can start to return back to the home and and we saw what happened with COVID-19. The pandemic, the tremendous shift the important flexibility the care. How cost, what home individual waiver that opened the door to start to deliver high acuity care in the home. And certainly, progress and technology innovation policy are key drivers that are allowing us to expand the types of care that can occur. Why is this important? We obviously know the demographics. Two-thirds of individuals between 60 and 79 say that they want to stay in their home as they age. And so these

programs are incredibly attractive, not just from a delivery mechanism standpoint, but also because of patient preferences. And I expect that that trend is only going to in increase. We know that shifting care delivery into the home has tremendous implications for the cost curve potentially for how we deliver care to Medicare beneficiaries. So there's a lot of opportunity here. Let me share one slide. If I can get this up. I believe that is working perfect. Which is the ama's conceptualization of a health at home framework. And in this figure, really sort of delineates how you know, as we think about the different settings of care, the different types of care. You know the different used cases. There clearly are places where we can conceptualize how care can be delivered across ambulatory on demand or urgent care, transitional or post-acute care. acute care, inpatient care, and then end of life, care and I don't have time to go into the types of examples associated with those levels of care that are happening in home. And nontraditional settings. But they're examples in in all those settings. It's really important, though, that the flow of information between the patient environment at home, and the care teams occurs. And so the framework that we conceptualize outlines What are those key infrastructure needs to operationalize this framework and provide effective high quality digitally enabled care. And so the 4 components that we have outlined that we think are so critical are the logistics and operations management components. The clinical monitoring component, and that could be a center or It could be organized in other kinds of ways, Having a mobile clinical workforce and then having the technology stack and digital platforms. And I'll just, talk about each of those for a minute, and then I'll end with the 2 examples that I wanted to give. Logistics and operation so broad category. How does information get processed, made actionable? How do we deploy resources? Processing of information is going to be application of clinical context to the patient data and sharing of that information through some integrated system. Thinking about resources that could be deployed, physical items, supplies, people, members of the care team sent out to a home. Effective management of the logistics and operations is the crux of a well operating, financially viable approach to delivering healthcare in the home. The second aspect is having that clinical monitoring right somewhere where information is monitored, processed use to drive and make decisions. Now that can be a physical location, it can be a building, a command center. It can be a digital center software, a tech hub, it's important to understand and have clarity around how information is being monitored. Who's responsible for monitoring the data and escalating up information as needed? The 3rd element is a mobile clinical workforce. This is such a core component of driving healthcare into the home, because when you're delivering care outside of the traditional 4 walls of an institution, you've got to have a workforce that is trained and capable and this could be from partner organizations or companies to go out and deliver certain aspects of care under the leadership of the healthcare team. And then, finally, there's the there's the tech stack and the digital platforms, right? That represent all of the solutions. We've heard a lot a lot about these products today that can enable the delivery. And these can be physical solutions. It can be a a remote monitoring device. It can be a digital solution like an online patient portal. Some form of technology is going to be used in all of these opportunities to capture the data monitor, the data. And of course, the type of technology, the degree use is going to vary, depending on the

conceptualization of the institutions. There are a lot of factors that are unique to consider. The landscape continues to evolve. We're trying, obviously, as an association, to help our members understand how they can pivot into these programs. And we really appreciate the FDA taking on this topic. The 2 examples, I want to give patient examples, because again, this all comes back to the patients. Are our 2 scenarios. So imagine you've got a patient. They've got chronic obstructive pulmonary disease. COPD, and they have some minor, restricted breathing. y They're having difficulty breathing. They think they have to go to the emergency department. They call their primary care. Dr.'s office. Based on triage, symptom, burden, the history of the patient, the primary care office can activate an on-demand care provider. A mobile unit can go to their home. That mobile unit has licensed team members under supervision of the care team at the office. They can do moderate complexity labs, diagnostics procedures. They can deliver a nebulization therapy to the patient in their home, prevent the emergency need. Right? You think about logistics, operations, documentation triage supplies clinical monitoring who's doing the triaging the tech stack to enable it. The second example, you know, is really one That I think I'll just skip given time, and maybe we can cover some more in the QA. Thank you.

Ankurita Datta: Thanks so much, Dr. Ehrenfeld. We'll move to our last panel discussion for today, which will be moderated by Dr. Michelle Tarver, our deputy Center director for transformation. As before, to contribute to the discussion, please enter your thoughts in the Zoom. QA. Box, and as time allows, they will be shared with Dr. Tarver.

Michelle Tarver, FDA: Well, thank you very much, Ankurita, and I want to thank all the speakers for your incredible talks. I'm gonna take the liberty of using your 1st names in the interest of time. And we're gonna have a really speedy round of discussion. So let's jump right in with pithy responses. I ask you all to turn your cameras on, and we're gonna have the 1st question. Start with you, Arianna. As you think about some of the top challenges you have with managing diabetes that you wish or hope could be alleviated. By what kinds of innovations that you think could help support wellness and health at home.

Arianna Gehan: Yes, so the 1st thing I'd like to touch upon is just access to virtual care. During the pandemic I was able to have my visits with my endocrinologist virtually, and my home was a very suitable setting where I had Internet connection. I had Wi-fi and I had privacy, and it was a very adequate way of receiving my care as a diabetic. But now that we have shifted to more post pandemic times, my access to virtual care has decreased, especially because I was going to a provider across state lines. So I think there is a great opportunity for improving access to providers in a virtual setting and kind of bring the provider into your home through virtual care. The other thing I'll touch upon quickly is just the importance of making sure that as we are designing these devices, we are keeping in mind kind of the mental health toll that they're taking. Alerts and alarms are fatiguing. And it's really important that we're creating technology that gives the control to the patient and allows them to have devices that are interoperable and allow them to control their data. But it's important that we create this

empowering technology that reduces the burden as opposed to adding on to it. Thank you.

Michelle Tarver, FDA: That's very helpful. I'm going to turn to you, Ricky. Actually, from that point. So what interesting lessons have been learned by the consumer tech industry when they have been developing devices that are going to be used in managing healthcare or managing a healthcare condition.

Ricky Choi: Please, I. Michelle Tarver, FDA: I am.

Ricky Choi: Go ahead. I'm sorry, I interrupted. You.

Michelle Tarver, FDA: I was gonna just say, and in particular, when it's being used in the home environment.

Ricky Choi: Absolutely. So, you know, as a physician, you know, I think one of the biggest challenges in managing and delivering care is around what we call adherence, right, patient adherence. And in technology, we call it engagement. So I see, the consumer technology secret sauce is in usability and being enjoyable to use. And, as I mentioned before, a lot of these technologies already in the homes and the risks in the hands of people. You know, they love to use it. They use it to stay connected with people they care about to get news, get more information, but also to manage our health. There's a kind of this pride of ownership. And so the way we think about it is, we hope to leverage this towards driving behavior, change and health improvement. And so through avenues like, you know, software as a medical device through FDA designation and ongoing convergence between the medical device and consumer technology. We see, continue to continue. So we're really eager to partner close with medical device companies to help drive health outcomes.

Michelle Tarver, FDA: Totally helpful, Catherine, I'm gonna ask you for the next question, what are the interesting approaches and technologies that that are garnering the investors' eyes, that kind of covers, that gray area you talked about the 2 extremes right? The early stage is in the later stage. But what's that? What about that in between stage and what kind of technologies are sparking you all's interest.

Casper L de Clercq: Yeah, I would. Well, I think Ricky just mentioned it.. If we go to less acuity, then it needs to be really engaging and keeping people. Yeah, and I think that's often going to have to be mediated by people. So not just technology. But you know, coach on the other end. I think the most interesting area for this group is, you know, if we want to see, early success would be to really focus on the chronic diseases that are very expensive because you can pay for a lot by preventing a hospitalization. And so you know, and I think it's always it's going to take a long time before we have truly commoditized technology at home. It's going to take people and some expense. And as we learn more and more, we can start doing algorithms and automating things more.

Michelle Tarver, FDA: I'm sorry to interrupt. That's very helpful. I think, Joel, I have a question for you. So we're talking about making it make financial sense. Can you allude to some precedence of coverage or reimbursement in the health and wellness arena that may kind of lay breadcrumbs for how the industry might want to develop over time.

Joel Brill: Sure. So I'll start with a non wellness example. but one that I think will be very familiar to the clinicians, and that's heart failure when a patient comes to the hospital and they get admitted and they get discharged from heart failure. What do we want to do? We want to help them to stay out of the hospital again. So we've used remote technologies, even things as simple as scales, to check. to see if the person is gaining weight or not and combine that with coaching from a nurse or another clinician to help them to manage their condition so that they can keep their heart failure under control so that they don't have their lungs fill up with fluid so that they don't need to come to the emergency room. And if we look at it from that aspect, then we have the examples, for example, of what was described in the 1st session today about the advances in diabetes, monitoring and like how far we have come over the past 2 decades in helping people with type one or type, 2 diabetes. and able to manage their condition and help them to live productive lives at home. We have an example now where we're seeing, for example, technologies used to help people who have respiratory difficulties to people who have, for example, chronic, obstructive, pulmonary disease, to be able to use remote technologies to help them to identify when they need medications in order to again keep them from having exacerbation and going to the hospital. So those are the. I will say the no so wellness examples. but I think those are the breadcrumbs of demonstrating that the technology led to a change in management. It was quantifiable. And I think that's what we should be looking at in terms of looking wellness, examples that are quantifiable as well.

Michelle Tarver, FDA: I think evidence it sounds like is critical in order to justify payment and coverage as well as integration and adoption into clinical care. I'm going to ask Jesse if you could speak a little bit about the opportunities that you see with these technologies that are being used in the home to help support that in the evidentiary pathway towards not only regulatory decisions, but payment and care decisions.

Jesse Ehrenfeld: Well, I think there's a lot of opportunity. And Joel Brill raised some interesting issues. Obviously, the time that it takes for us to generate the evidence, to generate the code set, to have things valued, to ultimately get it in the hands of the people who need it. Our patients takes a long time. And so are there alternate approaches that can allow us to collect that data, develop that evidence in a framework that doesn't cost millions and millions of dollars, and require, you know, research nurses to go out and do all the things through a traditional clinical trial, I think, is, is going to be important. But I think it. It links to the larger question about how do we know that emerging digital technologies, whether they're AI enabled or not work? And I think we all agree that the existing paradigm that the FDA has

loved and embraced for decades for traditional approval of medicines, devices, supplies. Does not work in this era. Right? It it's challenging. And Michelle, you could never hire enough colleagues to have product reviewers to look at Algorithm software changes for all the stuff Ricky and his company right? Potentially could throw at you. There's just no way, it doesn't scale. So there have to be new paradigms to allow us. And I think, certainly, there's an opportunity to potentially generate robust new types of knowledge. By the data acquisition that could potentially occur through the pathways that happen in the home.

Michelle Tarver, FDA: Yeah, I'm gonna turn to Andrew. You know, we've heard a lot about some of the challenges. In terms of moving technologies that are gonna be used primarily in the home. What are some levers you think that could help encourage these early startups, these companies that may be more naive to the regulatory and commercialization challenges and healthcare sector. What are some levers you think that we could exercise that would encourage them to explore developing technologies for them?

Andrew Cleeland: Yeah, I think a couple of them have already been identified just in this conversation here, and it's one of the key things and entrepreneurs want to invent, They want to solve problems. And this is a very attractive and very meaningful problem that we're talking about here today. But we need to have money and funding to do so. So we've got to, you know, the clear one, and I'm sorry to repeat it, but we've got to make it economically attractive. I think we also from our side of the world. I think you just said it, that entrepreneurs need to truly understand. and not only customers four Ps, you know I'd expand that to add in the regulatory pathway what the investors need, what the acquirers need. So I think that that is, is, is crucial here. but a clear, consistent, regulatory path. I agree with what was just said. You have a difficult job in the coming years, because we have to really rethink this attractive early reimbursement and some real practical considerations. Our whole industry is being geared at supplying our technology to hospitals and to clinics, not to home. And so the distribution channels. How we actually leverage those distribution channels to get to the clinic is probably gonna limit us in the in the intermediate term to digital answers. Not technically, not hardware answers. It's okay. Mine's 2 bit.

Michelle Tarver, FDA: I think you know it's very interesting to hear the medical device ecosystem and the healthcare ecosystem speak about care. I want to flip this a little bit, Upali, could you talk a little bit about how you envision all these different stakeholders from your vantage point as an architect, as a builder. Integrating these perspectives into what future homes could potentially look like that leverage care and home.

Upali Nanda: Thank you, Michelle. 1st of all, thank you for making the space for this conversation. I don't think we have had such diversity of perspectives around this conversation before. That's where it starts. I think it starts with making a space for these conversations with people who haven't spoken to each other before, I think where we start is also,

you know, ironically, when you think about it, the home was the site of care 200 years ago. It is not a completely novel concept. We've just taken care away from the home, and now we are struggling to bring it back to the home. food, water, shelter. Those were the basics of our life. But shelter has gone out of the equation in this conversation, so I think to have a place where all of us can play together and think together and create together is vital. If each of us goes back and does our daily work in the same silo that we started with, we've failed in what we are trying to do. I think the concept or the promise of an idea lab is that anything that you are developing, you do it in the context of the human experience. You do it in the context of the environment that it is rooted in and in the regulatory ecosystem that it is defined by. So I think it's really taking that approach that fundamentally meta-disciplinary approach to whatever each of us does. Who else are we inviting to the table? And the promise of the project is an experiment of creating a lab where whatever new idea we have, we can test in the context of the human experience rooted to the environment. And then the larger ecosystem that surrounds it. That's how we start.

Michelle Tarver, FDA: Alright. Well, thank you. We're gonna enter into our lightning round. I think it's a question that we've all seen multiple times. But I'm gonna ask you, in one word, what is the most important thing we should keep in mind when we're moving some health care to the home and keeping health equity in mind. I'm going to start 1st with Courtney.

Courtney Lias - FDA: I'm gonna cheat and use 3 words. Ask, don't assume getting a diverse perspective. You'll always be surprised what people really need.

Michelle Tarver, FDA: Arianna.

Arianna Gehan: Privacy.

Michelle Tarver, FDA: Arianna followed the rules. Thank you alright. And then, Jesse, how about you?

Jesse Ehrenfeld: Seamless. We've got to have a seamless experience for our patients, seamless integration into the existing healthcare infrastructure so that I can actually benefit from what's happening at home. Got seamless pathways for payment, reimbursement.

Michelle Tarver, FDA: All right. What about you, Joel?

Joel Brill: Respect for the individual, respect for the needs of the user and the patient meeting them on their territory, not telling them what they should be doing.

Michelle Tarver, FDA: Andrew.

Andrew Cleeland: Holistic. I'm just gonna leave it at that one word.

Michelle Tarver, FDA: Okay. Casper.

Casper L de Clercq: Similarly collaboration. And my, my one addition would be. this is a fantastic group. I would see if we could get private payers commercial payers involved, too. That's the one part, you know. Could CMS or the FDA somehow bring them to the table because they have very valid points, but they're also full of resistance. So let's figure out what works for them too.

Michelle Tarver, FDA: Ricky.

Ricky Choi: Probably my word would be connection, I think, connection between someone understanding their body and the changes their bodies are going through connection with their healthcare provider, as well as connection between an individual and the people within their home and their broader community. We know how important that is in terms of supporting health, as well.

Michelle Tarver, FDA: Last Upali

Upali Nanda: He took my word. So mine was going to be connected. But I'm going to now say “phigital” convergence of the digital and physical, and what that looks like.

Michelle Tarver, FDA: Phigital. All right, we’ve got a new word today. And Courtney, you earned your 3 words because you said it very concisely alright. So I’m gonna thank everyone for the panel discussion. That ends our panel discussion and conclude starting to conclude our meeting. I want to thank all of our speakers, our moderators and members of the public who shared their perspectives and questions with us today, I also want to extend a heartfelt appreciation to Ankurita Datta for guiding us through the day, and all those folks behind the scenes like Marcus Washington, Nooshin Kiarachi, Liz McNamara and Aja Hardy, who've been monitoring and managing the tech as well as the questions. And I want to give a very big thank you to Lindsay Lloyd, who's been our fearless organizer extraordinaire, helping to make sure that the day went smoothly. Thank you so much. I do want to remind you that we have a docket where you can share written comments following the meeting today and don't worry-- We are collecting your questions and comments, and we'll consider them as we continue to build the initiative. We're keeping track of them. We've heard from our speakers and our following panel that it's critical that we design at the outset with health equity in mind. We understand there are many different types of homes in the US. Which is why we are designing prototypes of the home focused on those who may have limited financial resources with the idea that that can potentially scale in the future to other homes. Intentional development that includes members from different geographies, different resources, different cultures, different generations, different genders and different lived experiences helps us to assure that the solutions developed can meet the needs of all. Collaboration amongst all stakeholders in this arena,

including other Federal agencies, other sectors will be critical, and no one agency or organization can tackle this opportunity of bringing healthcare home alone. Today we appreciate all the ideas that were planted, and as we think of home, that cherished place where you and your family go to recharge, I hope you all are beginning to collectively dream with me. Consider this, being surrounded by the latest technology, intuitive to operate and privacy protected. That puts you and your loved ones at the center of the latest care. Thanks to technology, you and your family can be a hundred percent confident now, and in the future. To this vision we hope the prototypes we develop which we're calling Lily Pad will help support health as we move forward, serving as a launching pad for great ideas that we can translate into tangible health benefits to the US public. Thank you all for attending, and we hope you have a wonderful day.