Thank you Chairman Buchanan and Ranking Member Doggett for the opportunity to testify today.

My name is Josh Makower and I have dedicated the past 34 years of my life to developing therapies and technologies to improve patient care. Over this time I've founded 10 independent medical device companies which collectively have improved the lives of millions and created thousands of jobs in the United States. In addition to being a physician-inventor and entrepreneur, at Stanford University where I am a Professor of Medicine and Bioengineering, I am also the co-founder and Director of the Stanford Byers Center for Biodesign. Our organization is focused on improving health outcomes and health equity through innovation education, translation and innovation policy. For 22 years we've been teaching students, fellows and faculty the process of medical innovation and the innovations our students have created have touched the lives of over eight million patients to date. I am also on the board of nine medical device companies and an advisor to New Enterprise Associates. The opinions in my testimony today are my own and do not represent the opinions of any of the organizations I am affiliated with.

Throughout my time working in the medical technology innovation ecosystem, I, along with my fellow innovators, have encountered many hurdles. We work with all of the stakeholders involved in delivering patient care to overcome them, because our shared and common goal is to save and improve the quality of life for patients. I am here today because of a growing concern that threatens our ability to continue to deliver the improvements to health outcomes innovators like myself have worked so hard to achieve over the years. Increasingly, medical technology innovators are confronting a "valley of death" where their technologies have received FDA authorization, but often no CMS or insurance coverage is in place to allow patients to gain access to them. Simply put, America's seniors and patients across the country are all too often not getting timely access to critical medical technologies for many years, if ever.

Being science and data driven, my colleagues and I at Stanford Biodesign Policy Program have taken some time to study just how difficult the environment has become. In work which we published last January, we surveyed 336 healthcare innovators and investors to ask how long, based on their own experience, it took for breakthrough new technologies to achieve Medicare coverage, coding and payment. The survey also asked questions to determine whether a clear path to reimbursement would affect innovation and investment in clinical areas of particular importance to Medicare patients. I have included the full survey as a part of my submitted testimony, but I did want to highlight some of the deeply concerning results that we found.

Our research found that Medicare patients often wait many years to get access to FDA-authorized technologies. Survey respondents reported that nationwide Medicare coverage for breakthrough medical products takes an average of 4.7 years following FDA authorization. While a survey of innovator opinions was a place to start, our group followed up on this further and using publicly available data – assessing a cohort of novel technologies approved or cleared by the FDA between 2016 and 2019, we discovered the results were much worse than initially presented. In this second study, we discovered only 44% of that cohort achieved nominal Medicare coverage by December 2022, and the median time to achieve this nominal coverage was actually 5.7 years. One whole year longer than our initial survey indicated. We are working towards publishing the results of this second study in the near future.

A swift, predictable pathway for coverage of breakthrough medical technologies would encourage innovators and investors to take on high-impact projects in fields that are important to Medicare beneficiaries, such as cardiovascular disease, stroke, and cancers. Achieving appropriate reimbursement is one of the greatest risks that innovators, and the investors who fund them, must consider in deciding whether to undertake new projects to improve patient care.

In our original survey, 84% of innovators said they would likely take on a novel or breakthrough product as their next project if there was an accelerated reimbursement pathway in place, while 53% said that they were unlikely to do so without such a pathway. While it is increasingly difficult for small start-ups with novel technologies to attract investment, it is all the more notable that investors agreed with our findings. The reimbursement pathways are so challenging right now that 69% of respondents who made investments in companies developing breakthrough medical devices said they would be less likely to do so again without an expedited reimbursement pathway.

While we have not yet studied the impact of these delays on actual patient morbidity and mortality, given that these technologies address diseases such as diabetes, stroke, cancer, heart disease, spine and orthopedic disorders, we are confident that when we do this further analysis we are likely to find the impact on patients will be significant.

Based upon our extensive research and findings, we do believe that a well-designed program that enables coverage while continuing to collect evidence could benefit patients by accelerating access to important health advances and encouraging invention, innovation and investment in critically important areas of unmet clinical needs.

For the past three presidential administrations, CMS has examined creating a new dedicated accelerated coverage pathway for novel medical technologies that addresses unmet needs for America's seniors. We are eagerly awaiting the release of a proposed rule and hope that it is a meaningful and impactful proposal that will accelerate patient access to critical medical technologies. The tragic truth is while this "valley of death" remains, patients throughout the United States – in each of your Congressional districts – are being impacted, unable to access breakthrough medical technologies that have been proven to be safe and effective by the FDA. In addition to CMS's rulemaking, Congress has introduced legislation to address these serious concerns for the past three sessions with strong, bipartisan support, including in the last session: "CURES 2.0". At root, the concept that would be ideal is to obtain coverage very shortly after FDA authorization, allowing any continued evidence collection needed to be obtained as the process of adoption begins. As a physician and innovator, and honestly as a potential Medicare patient someday sooner than I'd like to admit, I encourage all of you to continue the strong bipartisan work towards addressing this growing concern.

The work that we have invested in inventing and developing cures, therapies and diagnostics are only beneficial when patients and providers can access them. Our work in this area has clearly identified a serious challenge that is confronting innovation and patient care, and I remain hopeful that a policy solution can be provided which would help bridge this gap, and put an end to the "valley of death" for many innovations created to help Americas seniors.

Thank you again Chairman Buchanan and Ranking Member Doggett for the opportunity to testify today. I also want to thank the entire committee for their support of the science that has led to these important breakthroughs and I look forward to working with you and all the members of this body to achieve our common goal of improving patient care. I look forward to answering any of your questions.