Energy & Commerce
Health Subcommittee Hearing
July 18, 2023

CONGRESSMAN BRETT GUTHRIE OPENING STATEMENT
As Prepared for Delivery

Our goal today is to identify possible solutions to help address the financial sustainability of the Medicare program that also can help promote a greater quality of life and give way to a longer life-expectancy for today's seniors and for future seniors.

Over the past 50 years, we have developed therapies to help treat and manage chronic conditions, such as diabetes and other conditions associated with diabetes, like diabetic retinopathy. We have also developed transformative diagnostic imaging technology, such as MRI, CT scans, and ultrasound technology to help diagnose other complex conditions that were once death sentences because of the inability to detect the diseases entirely.

Now, researchers are racing against the clock to help diagnose and treat other diseases that reduce patient's overall quality of life and serve as a cost burden on our health care system. Perhaps, the most high-profile recent example of this is the FDA's accelerated approval of the Alzheimer's Disease drug Aduhelm two years ago and the agency's subsequent traditional approval of Leqembi only two weeks ago.

With an aging population and with the greater availability of diagnostic tools, our regulatory policies must be able to keep up the market without penalizing innovators for their discoveries. Despite the unprecedented advancements in treatments for Alzheimer's Disease, the Biden Administration has decided to limit access to these therapies through onerous coverage with evidence development standards and only cover therapies for Medicare patients if they are enrolled in a registry.

I remain extremely frustrated by the Biden Administration's restrictive approach to addressing this vicious disease. I understand that the total lifetime costs of treating someone living with Alzheimer's Disease patient is roughly $420,000. The costs associated with treating patients earlier in the disease may not only potentially save Medicare money, but, more importantly, it will also give these patients more time with their families until more effective treatments are developed.

The Biden Administration is also undermining our innovative ecosystem through actions taken to limit Medicare access to FDA approved breakthrough medical devices and technologies. By definition, these products more effectively treat or diagnose debilitating or life-threatening conditions than other approved competitor products. Instead of rewarding this innovation by providing a streamlined path to Medicare coverage, which is what bipartisan members of this committee publicly supported the Trump Administration for doing in its Medicare Coverage of Innovative Technologies rule, the Biden Administration is removing the predictable coverage pathway and significantly narrowing the number and type of products for inclusion through the proposed Transitional Coverage of Emerging Technologies notice.

While I am pleased to see action on this important issue from CMS, I don't believe this proposal provides enough incentives for product sponsors to develop truly innovative medical technologies This

also undermines the bipartisan work this committee did by creating the Breakthrough Devices program in the 21st Century Cures Act. I look forward to working with my colleagues on the subcommittee to address many of the proposal's shortcomings and to provide greater clarity for patients, their doctors, and innovators by by passing H.R. 1691, the Ensuring Patient Access to Critical Breakthrough Products Act, which would more provide patients more predictable access to FDA approved breakthrough devices if certain conditions are met.

Congress could also act to ensure patients are able to access these therapies by identifying reimbursement models that drive value. For example, the Medicare Advantage program could lead in the adoption of value-based contracting for certain drugs or therapies. We can also use these models to help pay for other forms of care, like proven preventative care. MA plans could demonstrate the value of certain preventative services, such as multicancer screening diagnostic tools, that can help detect cancer earlier in patients to save money and lives.

Above all, we have a unique chance to work across the aisle to answer some of the most important questions facing patients and providers because of the health care renaissance we're currently experiencing. It is absolutely imperative for policy makers to ensure we are appropriately striking the balance of rewarding innovation while providing access to quality care in a way that doesn't bankrupt the system. I look forward to working with my colleagues on the subcommittee to achieving this objective, and I yield back.