

Congressman Brett Guthrie Opening Statement

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Today is our second hearing designed to examine solutions to help our seniors gain access to innovative medical drugs and technologies, help lower drug costs for seniors, as well to ensure our regulatory policies are responsive to market innovation that will help seniors live longer, healthier lives.

In July, we heard from a panel of experts about the importance of updating the Medicare program to meet the needs of a growing senior population. Now we're taking the next step to examine specific solutions, which seek to turn the principles and ideas from members, previous expert witnesses, and wide-ranging stakeholder input, into legislation to support millions of seniors across the country.

For example, according to the National Cancer Institute, cancer costs the United States about \$208 billion in 2020. Further analysis shows that late-stage cancer cost the health care system \$105,000 per patient in 2019, representing the highest costs among all cancer patients. Today, patients and their families bear a significant financial burden despite the growing availability of less invasive and more successful treatments and cutting-edge diagnostic tools that can personalize treatment plans and detect aggressive, but treatable, cancers sooner.

H.R. 2407, the Nancy Gardner Sewell Medicare Multi-Cancer Early Detection Screening Coverage Act, attempts to address this policy imbalance by increasing access to these diagnostics and potentially lowering downstream costs and helping seniors live longer lives.

Additionally, I am proud to support H.R. 1691, the strongly bipartisan Ensuring Patient Access to Critical Breakthrough Products Act, legislation would essentially codify the Trump era Medicare Coverage of Innovation Technology or "MCIT" (M-SIT) rule and provide for a predictable Medicare coverage pathway for FDA approved breakthrough therapies for at least four years while companies can collect data to make their case for more permanent coverage.

These products – many of which are FDA approved but have yet to receive CMS coverage – could transform lives and make daily activities more manageable for seniors who may currently be bedridden or one device or technology away from being able to finally manage their cardiovascular disease..

We're also looking at more effective ways to help address chronic disease management as well as other policies to provide to provide seniors access to generic drugs and biosimilars particularly by allowing for biosimilar products to be added to Medicare drug formularies throughout the plan year if a biosimilar becomes available mid-year, which would allow seniors to save more on lower cost, clinically effective drugs.

The Government Accountability Office recently finalized a report on the impact of rebates in the Medicare Part D program, specifically how rebates affect the prices seniors pay at the pharmacy counter. The report provided a detailed analysis on the impacts of rebates on seniors' cost-sharing and Medicare liabilities resulting from rebates. GAO indicated that 79 of Medicare Part D's top 100 highly-rebated drugs, seniors or others on seniors' behalf, spent \$21 billion on their drugs versus the \$5 billion the plan sponsors spent on these drugs after accounting for drug rebates. Seniors and taxpayers shouldn't be paying more for a drug than the actual value of the drug.

That's why we are considering ideas today that are designed to help address these issues. Each proposal was drafted to ultimately achieve lower costs without the Federal Government harmfully directly negotiating the prices of these medications.

Finally, we have a number of solutions to make regulatory policies work better for innovators, for providers, and most importantly, for patients. My bill, H.R. 5389, the National Coverage Determination Transparency Act, would hold CMS accountable to a more consistent process for making National Coverage Determinations, and specifically their communications with product sponsors, ensuring patients can gain access to these products as quickly as possible. We will also discuss policies that would help clarify the local coverage determination process so that medical items and services can expeditiously reach seniors. For too long, we've heard how broken the coverage process delays or, in the case of the Alzheimer's NCD which we will also discuss today, significantly restricts access to life-saving care for seniors.

In closing, it is important to note that, while these policies can help drive innovation, we also must consider the budgetary implications of each proposal. I look forward to working with my colleagues to ensuring these ideas are fully offset should as we continue our work.

I yield back.