

**Energy & Commerce
Health Subcommittee Hearing
July 18, 2023**

OPENING STATEMENT
As Prepared for Delivery

INTRO

America is the global leader in medical innovation.

Today, there are more than 160,000 clinical trials taking place around the country. That's more than the European Union, Australia, and South America combined.

And that means hope for patients with diseases like Spinal Muscular Atrophy, Alzheimer's, ALS, and many others...

It means hope that a treatment or cure is likely to be studied and approved in the US first.

But, it does not necessarily mean that patients in the U.S. will have access to those breakthroughs first.

Today, we will discuss how to remedy government policies standing in the way of or slowing down patient access to treatments and cures...

I think about how America was home to one of the first successful treatments for sickle cell disease and multiple sclerosis.

In 2010, a woman named Jennifer Century underwent a then-experimental procedure that changed the course of her life.

For ten years following her stem cell transplant, her quality of life improved in ways she never imagined possible. She worked, walked miles a day, and had hope for the future.

Tragically, Jennifer passed away from COVID-19 in 2022 but she left a legacy of advocating for other sickle cell patients in hope for a cure.

Imagine having sickle cell disease or other diseases, knowing there's a possible cure, and not being able to access it.

Unfortunately, in 2016, CMS issued a National Coverage Determination or "NCD" that might prevent others from accessing the same treatment.

And these decisions to limit coverage--- like the one for new Alzheimer's treatments--- discourage innovation that could help patients and improve people's lives

As our competitors like China continue to invest more money into biotechnology, it is crucial that we maintain our competitive edge so that people continue to look to America for lifesaving medical products and treatments.

MEDICAL INNOVATION SHOULD BE BIPARTISAN

As such, I remain extremely concerned about the impact of the so-called "Inflation Reduction Act" price controls on innovation. I hope that Democrats heed the warnings of outside experts – who see lost innovation happening in real-time – and work with us to mitigate the damage before it is too late.

Bipartisan concerns over CMS's heavy-handed coverage policies present us an opportunity to work together to ensure seniors can access new and innovative treatments.

CMS “TCET” PROPOSAL

For example, I look forward to hearing from our witnesses about how we can strengthen the CMS “TCET” [tee-set] proposal.

There appears to be some good in the notice, but I remain concerned by the uncertainty for patients and doctors created by CMS’s lack of transparency, accountable timelines, and a predictable coverage pathway for FDA-approved technologies.

That said, I remain encouraged by the strong bipartisan support for key policies in the previous administration’s Medicare Coverage of Innovative Technology (“MCIT”) rule. I believe it will help us come together to strengthen the TCET proposal for patients.

ALZHEIMER’S PATIENTS COVERAGE

Predictability in these coverage pathways is also important for America’s leadership in cures and treatments.

Predictability is compromised when a health care bureaucracy is tasked with determining whether a treatment is “reasonable and necessary” for Medicare patients.

Take the example of how Alzheimer’s afflicts the Medicare population: namely millions of Americans over 65 and people with disabilities, like Downs Syndrome.

First-of-their kind medicines were brought to market, and CMS decided that these medicines – and any future ones like them – did not meet the “reasonable and necessary” standard for those that depend on Medicare for coverage.

This is unacceptable.

Not only did CMS cut off access for the very population these medicines were intended to treat...

... but it also stopped innovation in its tracks by passing judgement on products that do not yet exist or whose clinical outcomes were under review.

It is a self-fulfilling prophecy: By saying future products won't be covered, CMS is ensuring investors will never take the risks necessary to bring them to market.

CONCLUSION

We want to provide hope to all patients, like those with sickle cell disease, MS, or Alzheimer's, that a cure or treatment is on the way.

We want an innovation ecosystem that constantly seeks new cures, new treatments, and new ways to help people.

That is the Promise of America--- where hope turns into real lifesaving breakthroughs.

I want to thank the witnesses and look forward to hearing their ideas for how we can make these processes work better for patients.