Committee on Energy and Commerce

Opening Statement as Prepared for Delivery
of
Ranking Member Frank Pallone, Jr.

Health Subcommittee Hearing on "Innovation Saves Lives: Evaluating Medicare Coverage Pathways for Innovative Drugs, Medical Devices, and Technology:"

July 18, 2023

Since its enactment, Medicare has played a critical role in the lives of our nation's seniors and disabled Americans. Medicare is the main source of health care for most of our nation's seniors and disabled individuals, and we must ensure it remains sustainable long term and delivers the highest quality care.

The Centers for Medicare and Medicaid Services (CMS) plays an important role in ensuring that Medicare beneficiaries can access innovative medical technologies and treatments in a timely manner. CMS does all this while maintaining appropriate safeguards that prioritize the health and well-being of our nation's seniors and the disabled.

This is particularly critical since we have seen an acceleration of scientific breakthroughs over the last few decades. We are extremely fortunate to live at a time when biomedical sciences have become so advanced and medical knowledge has progressed to allow the creation of cures and treatments to address and slow the progression of devasting diseases including Alzheimer's.

Today, nearly 6.7 million Americans are living with Alzheimer's disease, and, unfortunately, that number is expected to increase to 14 million by 2060. These numbers are sobering, and virtually no one in this country will be spared from the devastating impact of this disease.

I was pleased to see Medicare provide broad coverage of lecanemab following the FDA's decision to grant traditional approval. Medicare covers lecanemab more broadly at this point than any other payer, while facilitating the collection of real-world evidence through a patient registry. I am hopeful the drug will live up to its promise of slowing the progression of Alzheimer's disease for patients.

Because of the nature of clinical trials, the approval studies left important questions unanswered about how Medicare beneficiaries as a whole will do on this medication. Both the FDA and the neurology community have cautioned about safety in certain patient groups, and the potential deadly side effects the drug can cause. As a result, CMS is asking doctors who prescribe the drug to provide clinical data through a free registry. This registry will allow doctors and patients access to all the information they need to make the right decisions about this treatment and others like it.

I believe CMS has taken the right approach – leaving clinical decision-making between patients and doctors, while addressing current evidence gaps to better understand the benefits and side effects associated with the drug. I look forward to hearing from our witnesses today about the proposed registry, as well as opportunities for improvement to ensure that it collects the right information at the right time and does not hinder beneficiary access.

CMS has also proposed a process for covering breakthrough devices in the Medicare program while ensuring the collection of real-world evidence to fill any evidence gaps. The collection and review of this evidence will also allow CMS to adjust coverage decisions based on new developments.

We must also recognize that treatments and cures only work when patients can afford them. Lecanemab costs $26,500 per year – that's nearly the annual income of the average Medicare beneficiary. The pharmaceutical industry must stop putting profits over patients, and ensure seniors have access to effective treatments and medications that are affordable.

I thank all of our witnesses for being here today, and I yield back.