Chairman Rick Scott's Opening Remarks
February 26, 2026 Hearing

"*The U.S. Senate Special Committee on Aging will now come to order.*

Today, we are here to ask a simple but important question: Is the FDA doing everything Congress intended it to do to quickly get safe, effective treatments to patients with rare diseases who cannot afford to wait?

For more than 30 million Americans living with a rare disease, making sacrifices every day is just part of life. But something they cannot afford to give up is time.

Time means the ability to walk. Time means independence. Time means being able to speak, eat, or even recognize a loved one.

And too often, time is exactly what patients lose while therapies sit in regulatory limbo.

Growing up, I saw firsthand how a rare disease can affect a family. My family didn't have health insurance, and my brother had a rare hip condition. My mom drove him 200 miles round-trip, just so he could get the care he needed.

She made that sacrifice because care couldn't wait. My brother couldn't afford to sacrifice time.

Congress has been clear. On an overwhelmingly bipartisan basis, we have given the FDA flexibility to move faster for patients with serious and life-threatening conditions.

In 2016, Congress passed the 21st Century Cures Act.

In that bill, and other bills that followed, Congress gave direction to the FDA and encouraged the use of real-world evidence, highlighting that rare disease drug development requires adaptability and urgency.

These laws were meant to help cut through bureaucratic delays and give patients access to the care and cures they so desperately need.

Yet here we are, almost 10 years later, hearing from patients, physicians, and drug developers that the system is not working as Congress intended.

I've heard from Commissioner Makary that he is working hard to fix longstanding problems at the FDA, and I want to thank him for the work he's doing to try and make a strained system work better for patients.

However, advocates here today will describe inconsistent review practices, shifting standards, and redundant, often-late-appearing data requests that, in many cases, may not be driven by safety concerns but by an overly cautious and rigid approach that puts bureaucratic processes ahead of patients.

As we will hear, the human cost of this regulatory slow walking is real.

Many of the patients affected by these delays have NO OTHER treatment options.

Patients from every state come and talk to our offices, sharing the irreversible declines in health that happen while they or someone they care about waits for a treatment that may never come.

It's heartbreaking to hear from families who are left watching their loved ones deteriorate while promising therapies remain stuck in review.

Meanwhile, small biotech companies struggle to survive years of uncertainty, even when their science is sound.

Beyond individual patients, there are serious national security consequences that come with the FDA's inaction and delays.

Our adversaries have been accelerating their drug development and approval, attracting investment, talent, and clinical trials.

FDA inaction here at home creates an economic and national competitive issue.

Let me be clear: this hearing is not about weakening safety standards. Safety must ALWAYS come first.

But safety and speed are not mutually exclusive. A system CAN protect patients while still acting with urgency, transparency, and common sense.

Some of you may be asking why the Senate Aging Committee is tackling this issue when so many of those impacted by issues with rare disease treatments are young.

Here's why: Part of caring for America's aging population is making sure that more Americans are given the opportunity to grow old.

It may sound cliché, but we are all aging. And if something is standing in the way of a younger American making it to their senior years, that is absolutely the business of this committee and something we need to try and fix.

It is my hope that today's hearing will serve as a useful tool to help us understand what we can do to bring accountability, transparency, and efficiency to the process.

We are joined by an incredible panel of witnesses here today representing a wide range of perspectives, but all working toward a better future for people living with rare diseases."

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