Opening Statement of the Honorable H. Morgan Griffith
Subcommittee on Health
"Maintaining America's Leadership in Biomedical Innovation: FDA's Role in Advancing U.S. Drug Development."
Wednesday, July 15, 2026, at 10:15 a.m. (EST)

Today's hearing will examine ways to maintain American leadership in biomedical innovation.

This hearing is a great opportunity to learn more about what is working, where improvements can be made, and how Congress can ensure FDA continues to serve patients, promote innovation, and maintain our nation's leadership in biomedicine.

The United States has always been the global leader in biopharmaceutical research and development, and it is important that we remain leaders in this space.

However, other countries are catching up to the United States.

It is important for Congress to reexamine our current landscape to ensure we are staying up to date with the latest biopharmaceutical advancements and examine what role Congress could play in making these processes more efficient.

This Administration has proposed efforts to do so, such as the recent launch of FDA's Operation Trialblazer, announced in June.

This is an HHS-wide effort that comes in response to the growing competitiveness of the global pharmaceutical landscape which promotes cross-agency collaboration to support research from the earliest stages of innovation.

Operation Trialblazer provides a set of initiatives and reforms to modernize and accelerate medical product development, aiming to remove the unnecessary hurdles and ambiguity that sometimes hinder patient access to innovative treatments.

Streamlining clinical trial requirements, encouraging use of modern trial designs and real-world evidence where appropriate, and reducing administrative burden can shorten development timelines and lower costs without compromising science or safety.

These improvements have the potential to bring new treatments to patients faster, increase participation in clinical

research, and make the United States even more attractive for investment in medical breakthroughs.

It is important that we begin to have these conversations as this Subcommittee looks ahead to FDA's user fee reauthorization next year—especially as initiatives like Operation Trialblazer demonstrate that an approach to maintaining America's competitive edge involves improving the efficiency of drug development.

For more than three decades, user fee programs have helped provide FDA with the resources to review innovative drugs and medical devices while maintaining the agency's rigorous standards for safety and effectiveness.

Rather than relying solely on taxpayer dollars, user fees are paid by manufacturers that submit products for review, helping ensure the FDA has the scientific expertise and capacities necessary to keep pace with rapidly advancing medical innovation.

Ultimately, user fees serve to improve health outcomes for patients.

Every day that a safe and effective therapy reaches the market is another day that patients living with cancer, rare

diseases, or other serious conditions may have access to life-changing or even life-saving treatments.

The predictability and performance goals established through the user fee agreements have helped reduce review times, improve communication between FDA and product developers, and provide greater standardization throughout the review process.

However, there is still more work that can be done, and reauthorization is not limited to just extending the status quo.

Reauthorization gives Congress the opportunity to explore and write legislation so we can continue to work to streamline regulatory processes, reduce unnecessary administrative burden, strengthen communication with product developers, and ensure the agency has the tools it needs to make the best possible use of its resources.

We can also continue to look for opportunities to modernize clinical trial networks, embedding them into routine care and expanding access to innovative treatments in rural communities.

Maintaining America's position as the global leader in biomedical innovation requires a regulatory system that is both thorough and efficient.

I am eager to look for ways that we can help ensure FDA can review drugs in a timely and predictable manner. Not only to expand patient access to innovative treatments, but to also encourage companies to invest, develop, and manufacture domestically.

Thank you to the witnesses for being here this morning. I look forward to the discussion.