

Opening Statement of Chairman Brett Guthrie
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.

Good morning, and thank you, Chairman Griffith, for holding a hearing on this important topic. Additionally, thank you to our witnesses for joining us today. We appreciate your expertise as we examine how Congress and the FDA can strengthen America's leadership in biomedical innovation by supporting early-stage drug development, clinical research, and domestic manufacturing.

For decades, the United States has set the global standard—a gold standard—for developing safe and effective medical products, which benefit patients around the world along with Americans who gain earlier access to groundbreaking therapies. This is possible because innovators have chosen to develop them here first. But our leadership cannot be taken for granted.

Other countries – particularly China – are making significant investments to attract biotechnology companies, clinical trials, and domestic manufacturing. Our ability to develop and manufacture lifesaving medicines, vaccines, and

other medical products here in the U.S. depends on a strong domestic biotechnology sector and a regulatory environment that supports innovation, while preserving FDA's standards for safety and effectiveness.

Bringing new therapies to patients requires clinical trials that are efficient and modern, leveraging new digital technologies and novel evidence, supported by sound science.

This Committee has a strong record of advancing these goals. Through the FDA User Fee reauthorizations, this Committee has worked in a bipartisan way to modernize FDA's authorities, improve regulatory predictability, and help Americans access new cures without compromising FDA's gold standard of review.

Today's hearing is an opportunity to continue that work, learning from our witnesses where barriers to innovation remain, how FDA can further improve the efficiency and predictability of early-stage drug development, and what legislative changes Congress should consider as we prepare for the next FDA user fee reauthorization cycle.

Thank you, Mr. Chairman, and I yield back.