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House Energy and Commerce Committee
Subcommittee on Health
"The Future of Medicine: Legislation to Encourage Innovation and Improve Oversight"
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As Prepared for Delivery

INTRO

We are considering many important bills that support innovation for patients by improving rare disease research, drug discovery, clinical trial diversity, and our nation's health care supply chains.

Thank you, Chairman Pallone and my colleagues, for all the bipartisan work as we come together to reauthorize serval of FDA's user fees.

FDA's authority to collect user fees expires September 30, and without user fees, FDA's ability to keep pace with innovation for patients will be severely limited…

… so continuing this Committee's bipartisan tradition for this process is extremely important.

This reauthorization also gives us the opportunity to pursue other bipartisan policies related to the FDA that can improve the review process and ensure new cures receive consistent, timely, and thoughtful review.

I am particularly encouraged by proposals to ensure that FDA is fully equipped to review drugs manufactured using emerging technologies, conduct timely and dependable facility inspections, and support more therapies and cures for rare diseases.

These bills build on previous bipartisan efforts to address drug quality and shortage issues and give patients a voice in drug development.

We will also consider several bills for more diverse populations in clinical trials.

During the pandemic---through the use of digital health technologies--drug developers across the country were able to use modernized clinical trial protocols that allowed for greater patient involvement from more diverse populations.

We should absolutely be building on this work.

ACCELERATED APPROVAL

The agenda today also includes my bill the Accelerating Access for Patients Act.

Drugs approved through accelerated approval meet FDA's gold standard.

There is strong bipartisan support for precision medicine… and the need for more innovation and more cures, such as for ALS.

Accelerated approval is how precision medicines are approved.

If we want to have drugs approved that treat diseases before symptoms appear, it requires accelerated approval – and here is why:

Traditional approval relies on a drug sponsor showing a clinical benefit, such as longer lifespan, or reduction of clinical symptoms.

Accelerated approval relies on a "surrogate endpoint" – that is still reasonably likely to predict clinical benefit.

So – instead of a drug trial for a cancer therapy having to show you live longer, the trial can show that the drug shrinks the tumors.

Accelerated approval also can't be used for just any treatment – it has to be for a serious disease with an unmet need.

If we want to realize the promise of precision medicine, such as relying on genetics and proteins to treat diseases early, accelerated approval must be in FDA's toolkit.

I will not support anything that undermines this important pathway.

This Committee has sent a strong signal that we want America to be the world leader in medical innovation. The promise for a better life in lifesaving research is here in America.

We want patients to have options and hope …especially when it comes to serious diseases with unmet needs.

Look at 21st Century Cures Act, Right to Try, and most recently, the ACT for ALS Act.

Could there be more transparency around the pathway? Absolutely.

Could the pathway be modernized for diseases that may not have a clear surrogate, such as ALS? That is what I want to focus on today as we discuss my bill, the Accelerating Access for Patients Act.

Let's consider together how we can expand access to promising innovation with the appropriate guardrails in place.

ARPA-H

Before I close, I would like to specifically address ARPA-H and H.R. 5585.

I was disappointed the spending bill gave $1 billion to HHS to establish ARPA-H, which I fully anticipate will be transferred to NIH.

Just 6 weeks ago, this committee heard that in order for ARPA-H to be successful, it needed to be independent of NIH.

I raised many questions around duplication, accountability, and strategic priorities for ARPA-H.

The Senate just moved a different proposal than the one before Energy and Commerce.

So, with no consensus in Congress whether ARPA-H is necessary or how it should be established, it was funded with $1 billion of unauthorized taxpayer money anyway.

That’s more than we spend each year on block grants to state for mental health.

My concerns remain about accountability and the lack of a clear mission for ARPA-H.

We should all want to make sure that money for research isn’t wasted but spent wisely for our shared goal for more cures.

CONCLUSION

With that, I would still emphasize there are a number of great ideas in the bills before us today, many with strong bipartisan support.

I look forward to today’s discussion and moving the FDA user fee reauthorization package through committee.

Thank you and I yield back.