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House Energy and Commerce Committee
Subcommittee on Health
"FDA User Fee Reauthorization: Ensuring Safe and Effective Drugs and Biologics"
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As Prepared for Delivery

Thank you, Madam Chair.

Today, we are discussing the critical task of reauthorizing several key FDA user fee programs.

Thank you to the FDA and industry for submitting these three agreements before January's deadline...

...and for your engagement over the last year.

These programs are designed to innovate as fast as possible, while maintaining the FDA "gold-standard" of safety.

The user fees will provide FDA with the resources needed to conduct timely and efficient reviews of human medical products, invest in cutting-edge technologies, and hire and retain agency experts to carry out these tasks.

These recommendations reflect a shared commitment to America leading the world in medical innovation, spurring competition, and ensuring timely access to safe and effective drugs.

Proposed Enhancements

The Committee is in the process of reviewing the proposed agreements for the three user fee programs before us today.

These agreements include provisions that will support emerging areas of drug discovery and streamline the review and approval of treatments for rare diseases.

The PDUFA (pa-doof-ah) VII agreement also directs significant investments for the development, review, and approval of cell and gene therapy products.

The next five years could be game changing, with one-time, curative therapies for diseases such as hemophilia, sickle cell, and many rare pediatric diseases.

That innovation means hope for patients and their families, as well as lower overall health care costs required to treat those diseases today.

The new STAR pilot program, also proposed in the PDUFA agreement, will expedite the delivery of promising therapeutics for diseases with unmet clinical need.

I look forward to hearing from our witnesses on how the BsUFA (ba-soof-ah) and GDUFA (ga-doof-ah) agreements will bring competition to the market, increasing options and lowering costs for patients.

Competition, not price controls, has demonstrated the ability to lower drug prices, and these agreements are key to bringing more lower cost generics and biosimilar drugs to market.

I am pleased to see proposals in both packages that will enhance approval pathways of complex generics and interchangeable products.

COVID-19 Pandemic

Over the course of the negotiation process, we have heard from FDA, industry, and stakeholders on how the COVID-19 pandemic has impacted getting new treatments and cures to the American people.

FDA did rolling reviews to expedite the review of treatments and vaccines while not lowering the bar on safety.

Can FDA continue those process improvements for other diseases?

I also want to discuss today how the FDA is planning for an orderly transition from emergency use authorizations to full approvals, and how we can get back to normal.

We clearly have more supply of vaccines than demand, so why don’t we transition to routine distribution?

Rumor is the Biden administration may ask for more COVID-19 funding. I want to know how long the Biden administration plans to be the sole purchaser of COVID-19 vaccines in this country.

At some point, and I hope that it can be soon, the public health emergency will end.

When that happens, American patients need to continue to have access to necessary vaccines, and we need to improve access to tests and treatments.

FDA plays a large role in that transition, and I want to learn more about what that takes, and how these agreements will play a role.

FDA also works with companies designing clinical trials for approval, including a number of treatments for Alzheimer's Disease.

I was shocked to find out that the CMS proposed National Coverage Determination (NCD) severely restricts Medicare coverage for a whole class of Alzheimer's treatments, including the recently FDA-approved Aduhelm, to only cover these drugs in CMS-approved clinical trials.

It also excludes those with Down Syndrome from participating in covered trials, even though Alzheimer's may affect greater than 90 percent of those with Down Syndrome over the age of 60.

This is wrong.

We need clinical trials that more closely reflect the diversity of Americans, including those with developmental disabilities.

Further, just because they may be excluded from trials today, that should also not hurt their access to an FDA-approved drug if their doctor determines that is the best decision for their health.

Conclusion

We are committed to moving these user fee agreements through Committee on time and through regular order.

Now, more than ever, we should be working together in a bipartisan way to promote innovation, to lower costs with more competition, and deliver safe and effective drugs to Americans.

Thank you and I yield back.