Opening Remarks
Chair Cathy McMorris Rodgers
Subcommittee on Health Legislative Hearing: "Check Up: Examining FDA Regulation of Drugs, Biologics, and Devices"
May 22, 2024

OPENING

Thank you, Chairman Guthrie, and thank you to Dr. Cavazzoni, Dr. Marks, and Dr. Shuren for being here today.

The FDA plays a critical role in the health and wellbeing of the American people. If it is successful in its mission, it has the potential to save—and extend—people's lives. If it fails in its mission, the costs could be astronomical and devastating.

The FDA is responsible for regulating more than 3.6 trillion dollars worth of food, tobacco, and medical products – about twenty cents of every dollar spent in the United States.

Americans must have confidence that the Agency is doing its job. They have to be able to trust that the medical products they are relying on are safe and effective….

…and it is Congress's duty to ensure that the FDA is using the resources and authorities it has been given to protect and advance public health.

INNOVATION

I am proud that America has been a leader in developing innovative treatments such as:

- non-addictive medicines for chronic pain...

- so called “n of 1” drugs, where hospitals are making drugs designed for one patient

- and implantable upper airway devices for pediatric patients with Down Syndrome and severe sleep apnea.

All these things—which will make a meaningful difference in people's lives—were recently approved by the FDA or will be seeking review in the near future.

There are also advances that could reduce the amount of time it takes for new technology to reach patients in need.

New biomarkers have been developed from advances in genetic sequencing, manufacturing techniques, and methods to generate clinical data that, if used properly, could decrease cost and time to demonstrate these new technologies meet FDA’s standards.

This committee worked in a bipartisan manner to give FDA new tools in the last user fee reauthorization, and we expect the agency to use those tools to pave the way for groundbreaking innovation.

I firmly believe that the accelerated approval pathway should be leveraged now more than ever, as more and more diseases can treated, or even cured, because of a better understanding of their mechanisms of action and genetic signatures.

FDA approval, unfortunately, is not the final hurdle for patients, as significant problems with CMS and private coverage still persist.

But it is an important first step.

CONCERNS WITH FDA

FDA cannot move backwards, and I am worried we are starting to see warning signs that may be occurring.

For example, I am disappointed to see that, according to the Fiscal Year 2023 PDUFA and MDUFA Performance Reports, all three Centers here before us today have failed to meet critical performance, process, and hiring goals, despite all-time highs in funding.

In addition, the Agency has been failing to adequately accommodate in-person meetings and respond to outreach related to major clinical and scientific development decisions in a timely manner.

This is particularly concerning as the FDA has unilaterally decided it can regulate, by its own estimate, 80,000 tests under the Laboratory Developed Tests Final Rule.

FDA leadership often says all the right things regarding speeding up innovation to patients when the benefits outweigh the risks, such as..

...not asking “nice to know” questions if the statutory standard for approval has been met

.... not moving the goal posts after a company has invested millions of dollars and years of time on a clinical trial FDA once said was the best path forward.

The challenge is making sure the sentiments expressed by the Agency’s leadership are reflected by the application reviewers.

Unfortunately, I am hearing the opposite from stakeholders who are finding FDA review staff more disconnected and difficult to work with than before.

CLOSING

Everyone on this dais wants the FDA to succeed, because if the FDA succeeds, American innovation flourishes... leading to better outcomes for patients.

I am hopeful that we can have a productive conversation about what challenges the Agency is facing and why...

...and how Congress can help the FDA streamline operations and provide clear, consistent scientific and regulatory information to innovators and drug manufacturers that are looking to improve the daily lives of Americans.

Thank you, and I yield back.