

Committee on Energy and Commerce
Opening Statement as Prepared for Delivery
of
Full Committee Ranking Member Frank Pallone, Jr.

Hearing on “Check Up: Examining FDA Regulation of Drugs, Biologics, and Devices”

May 22, 2024

Our nation faces an ongoing long-term care crisis that is impacting millions of American seniors, people with disabilities and chronic conditions. The growing need for long-term care continues to be one of the greatest threats to retirement security for American seniors, and the adult children who care for them. Today, Medicaid is the nation’s primary payer for long-term care services, but significant reform is needed to support a sustainable system. I have also long believed that we must move forward with bold solutions within both Medicaid and Medicare. This has been a priority of mine for years, and it is particularly important since demand for long-term care is expected to increase substantially as our nation’s population ages.

This Committee has long worked to expand access to long-term care for people who need it, while also improving the quality of care and promoting better pay for providers. We are continuing some of that work today by considering the Stop Unfair Medicaid Recoveries Act, bills to make the Money Follows the Person demonstration program and spousal impoverishment protections permanent, and bills to improve access to Medicaid home- and community-based services for some of the many additional Americans who need it.

While I appreciate the modest improvements these policies would make, much more significant long-term care reform is needed. Last Congress, I was proud to co-sponsor the Better Care Better Jobs Act, which would have increased funding for Medicaid home- and community-based services, ensured those funds were used to improve the quality and availability of such services, and strengthened the direct care workforce by addressing insufficient payment rates and high turnover rates.

I have also previously released a proposal to establish a long-term care benefit in the Medicare program so that millions of seniors and people with disabilities no longer have to face financial ruin before they get assistance. These are the types of sweeping reforms that we need to be thinking about in order to address the long-term care crisis.

Unfortunately, we will not be considering proposals to make those types of changes today. Instead, we will consider several Republican bills that would worsen access to quality long-term care for the millions of Americans who depend on it.

Some of the Republican bills that we will consider today go after rules the Biden Administration just finalized last week that lay the groundwork for necessary, systemic long-term care reform. The Administration’s action establishes minimum staffing standards for nursing We’re here today for an update on the hard work the Food and Drug Administration

(FDA) does every day to ensure the safety and efficacy of drugs and medical devices. Every year, FDA rigorously reviews hundreds of applications for drugs and biological products at the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER), and medical devices at the Center for Devices and Radiological Health (CDRH). Today we will hear from the center directors of each of these branches of the agency and I would like to thank you all for being here.

In recent years, FDA's work has garnered more attention from everyday Americans, especially during the pandemic. This attention has also brought increased scrutiny. I think it's important for the public to know they can trust the products available to them and that the public servants at FDA are working around the clock to protect their health and well-being. I also think it's important to discuss areas in which the agency can do more to protect public health. However, I want to note that as we ask FDA to take on additional responsibilities that it's up to Congress to provide the agency with the tools and resources it needs to fulfill these tasks.

I have repeatedly said that Congress must come together on a bipartisan basis to give FDA the additional tools and resources it needs to provide patients and health care providers with confidence that the medical products they rely on are safe, effective, and available.

We have been asking our Republican colleagues for more than a year to advance meaningful legislation that would provide additional tools and authorities to address ongoing drug shortages, prevent future drug shortages, and strengthen the medical supply chain. However, Republicans have repeatedly declined to join Democrats to pass legislation to do so, including through the Pandemic All-Hazards Preparedness Act, which they have still failed to reauthorize.

It's especially frustrating that Republicans have been unwilling to put any new requirements on drug manufacturers to help address the shortages that continue to affect Americans. For example, we should know where our drugs and their critical ingredients are being made, so that when a drug shortage or other supply interruption occurs, FDA and manufacturers can react quickly and appropriately. We should also ensure that FDA is notified when an unexpected surge in demand for a drug occurs and is likely to cause a shortage. It's also unacceptable that the agency still does not have the ability to recall unsafe, adulterated or otherwise dangerous products, and is instead forced to rely on the goodwill and voluntary compliance of manufacturers.

Committee Democrats would also like to make progress on strengthening the pipeline for pediatric drugs and ensuring that drug manufacturers are fulfilling their responsibilities to conduct studies in pediatric populations, as I mentioned at least week's markup. Unfortunately, Republicans have not been willing to work with Democrats to move forward on any of the meaningful proposals I mentioned to address these important issues.

We simply cannot expect more from the agency without providing the necessary tools and resources. It is incumbent upon Congress to provide FDA with more resources, more staff, and the appropriate authorities in order to continue to fulfill its mission. We can all agree FDA faces new and unique challenges, but they can only do what we provide them with the authority

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to do. And this task will only continue to become more complex and more demanding in the years ahead.

In closing, I hope that Congress can come together to support FDA in fulfilling its mission and addressing these challenges. Democrats stand ready to work across the aisle to support the agency's tireless work to protect Americans' health and well-being. I look forward to hearing from our witnesses and thank all of you.