Committee on Energy and Commerce

Opening Statement as Prepared for Delivery
Of
Chairman Frank Pallone, Jr.

Hearing on "The Future of Medicine: Legislation to Encourage Innovation and Improve Oversight"

March 17, 2022

Today, we will discuss 22 pieces of legislation to boost biomedical research and innovation, diversify clinical trials, and improve program integrity at the Food and Drug Administration.

While I do not have time to discuss every bill before us today, I did want to mention a few. First, we have a bill from Chairwoman Eshoo authorizing the creation of the Advanced Research Projects Agency for Health, or ARPA-H. This proposal has the potential to be transformative and bring about medical breakthroughs that have the power to change our society for the better. I was pleased to see that the final omnibus funding bill that Congress passed on a bipartisan basis last week and President Biden signed into law on Tuesday included $1 billion for ARPA-H. Now, this Committee must pass comprehensive legislation to properly establish the agency. I hope my Republican colleagues will work together with us on the authorizing language to make ARPA-H as effective as possible.

Next, I'd like to highlight a number of bipartisan bills introduced by members of our Committee, including another bill from Chairwoman Eshoo, as well as legislation from Representatives Ruiz and Blunt Rochester, to improve diversity within clinical trials, both among clinical trial participants and investigators. FDA, researchers, and drug manufacturers all have a role to play in improving clinical trial diversity, and I look forward to hearing from our witnesses about how more diverse clinical trials can not only improve health equity, but also improve scientific discovery and the practice of medicine.

The Committee is also continuing its work to improve competition and reduce drug prices. A bill from Representative Kuster would make it easier for generic drug manufacturers to ensure their drugs are biomedically equivalent to their brand counterparts. It does this by improving FDA's communication about the correct proportion of ingredients during the application process. This bill would simplify the process for generic manufacturers and reduce needless delays, bringing generic competition to market more quickly.

We will also discuss the Accelerated Approval Integrity Act, which I introduced last week. I want to thank Representative Maloney for her joining me on this legislative effort. FDA's accelerated approval program has led to patients getting faster access to medical breakthrough treatments, including treatments of HIV and several forms of cancer. In order to be approved under the accelerated approval program, an investigational drug must have a positive effect on a so-called "surrogate endpoint." These endpoints can include a lab measurement,

ultrasound image, or a physical sign, that is reasonably likely to predict a clinical benefit, but is not itself a clinical benefit.

After being approved under this pathway, the sponsor is responsible under FDA regulations for conducting a well-controlled clinical trial to confirm that an actual clinical benefit exists for patients. Unfortunately, however, under the current system, some sponsors have failed to conduct trials in a timely manner.

For example, take Aduhelm, the Alzheimer's drug that was approved by FDA last June. Here we are nine months later, and the sponsor has not screened a single patient for its required confirmatory trial. Other drugs have stayed on the market for eight or nine years without proving a clinical benefit, and as Dr. Cavazzoni testified last month, the process for removing these drugs from the market is cumbersome and can take months or even years.

Patients deserve to know that the drugs they are taking are safe and effective. My bill protects patients by providing FDA with the authority it needs to ensure approved drugs provide a clinical benefit. The bill requires that FDA and the sponsor set out a clinical trial protocol before a drug is approved. It also allows FDA to require that the trials are underway prior to approving the drug.

The bill would also improve transparency and streamline the process for withdrawing approval when clinical trials are not conducted with due diligence or no clinical benefit is shown. These reforms will strengthen the accelerated approval program and help facilitate additional medical discoveries and product development.

As we look to strengthen program integrity at FDA and improve research and development, it is critical that we ensure we are not doing anything that could weaken FDA's gold standard for safety and efficacy. We must be mindful of FDA's resources and must always put public health and patients first. I commend all the members for introducing the bills before us today and look forward to the discussion.