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

Hearing on "Evaluating Approaches to Diagnostic Test Regulation and the Impact of the FDA's Proposed Rule"

March 21, 2024

Mr. Chairman, thank you for holding today's hearing. New technologies can improve the lives of patients. The products we are discussing today, laboratory developed tests, or LDTs, are no exception. But, for them to make a difference for patients, they must be accurate and reliable.

Congress gave the Food and Drug Administration authority over lab-developed tests under the Medical Device Amendments in 1976. In 2015, we held a hearing in this Subcommittee on regulation of diagnostic tests and laboratory operations. Even then, almost a decade ago, we saw that the use of these scientific advances also has potential to pose serious risks to patients if they are not accurate. For example, they can lead patients to undergo unnecessary treatment, or delay or forego proper treatment, resulting in harm.

In the past, FDA generally applied an enforcement discretion approach for LDTs because most were manufactured in small volumes by local laboratories to meet the needs of local patient populations, or were similar to other well-understood standard tests. However, many LDTs are now used more widely, with large laboratories accepting specimens from across the country and in larger volumes. LDTs have also gotten more complex, and they increasingly rely on more advanced technologies and software. With advancements in artificial intelligence, it is likely that this trend will continue.

FDA has expressed increasing concern that some LDTs may not produce accurate results or perform as well as tests that are reviewed by the agency or otherwise comply with FDA standards. Concerns include issues with COVID-19 diagnostic tests, genetic non-invasive prenatal screening tests, and the blood tests manufactured by the infamous biotech company Theranos. And yet, there is no required post marketing reporting for LDTs, so we don't know the full extent of harm inaccurate tests can lead to.

The Centers for Disease Control and Prevention estimates that 70 percent of medical decisions are made based on laboratory test results. With many of these results coming from LDTs, it is scary to think that these tests do not currently have oversight and are not validated by FDA. New York State's Department of Health has conducted premarket review for thousands of LDTs. The Department said that over half of the LDTs they have received for review could not be approved based on their initial submissions due to problems that called into question the reliability of the test. We have also seen that some manufacturers buy research-grade components that are not intended for clinical purposes because those parts are cheaper. It simply does not make sense that tests are treated differently based on where they are made.

I continue to believe that we have a responsibility to provide patients with greater certainty over the tools that are used to guide their medical decisions. That is why FDA's action in proposing a rule to regulate LDTs and end their enforcement discretion approach is an important step. It is my hope that this will help eliminate patient harm from unnecessary treatment or undertreatment from inaccurate LDTs—not to mention the cost to the overall health care system.

I would like to submit a letter from Dr. Dan Hayes, an expert with more than 40 years of experience as a laboratory, clinical investigator, and a medical oncologist in academic breast cancer programs. He noted that, "clinicians and patients depend on the FDA to carefully review the data and render difficult but reliable decisions about whether a drug is safe and effective." He went on to write that FDA should take the same approach towards diagnostics. He continued that, "a bad tumor biomarker test is as bad as a bad drug." I completely agree.

The information that LDTs provide clinicians and patients is of grave consequence, and that is why many major cancer advocacy groups and those in the lab community welcome greater FDA oversight.

Physicians have years of training and the best interest of their patients in mind, but by not providing oversight of LDTs, we are failing them by not ensuring they can trust the tools they have to guide their patient counseling and develop effective interventions.

The proposed rule is an important step to help ensure that health care decisions are made based on test results that providers and patients can reliably trust. I look forward to hearing from our witnesses today to understand how we can level the playing field so patients and their health care providers know they can trust the FDA process while keeping up with medical progress.

Thank you, Mr. Chairman. I yield back.