Opening Remarks
Chair Cathy McMorris Rodgers
Health Subcommittee Hearing:

Evaluating Approaches to Diagnostic Test Regulation

March 21, 2024

INTRODUCTION:

Today this committee will continue our work to ensure America remains the world leader in biomedical innovation.

We have previously heard testimony on many examples of regulatory and reimbursement challenges that are stifling innovation and delaying patient access to care.

Unfortunately, the FDA is doubling down on this troubling pattern by failing to account for the important role laboratory testing plays in this country.

Patients, doctors, and caretakers rely on diagnostic tests to detect, guide treatment decisions, and monitor a whole host of medical conditions and diseases.

Some of these tests are made in the form of kits by conventional manufacturers for use by other entities, such as laboratories, health care practitioners, or even patients.

Other tests, known as laboratory developed tests, or “L-D-Ts,” are designed, manufactured, and used within a single laboratory.

While conventional manufacturers certainly serve an important role, LDTs fill in the gaps for indications that have a smaller patient population – such as rare diseases, particularly cancers, and certain pediatric conditions – where large-scale commercial manufacturing and distribution do not make sense.

FDA PROPOSED RULE

Instead of capitalizing on advancements in precision medicine and exciting genetic technologies to help patients, the FDA has proposed dramatically increasing the regulatory burden on a subset of diagnostic tests, specifically LDTs.

These regulations extend far beyond any of the legislative proposals that Congress has considered.

Under the proposed rule, laboratories will incur significant costs to come into compliance.

New administrative and clerical burdens, along with oppressive submission fees, will be a substantial drain on a lab's limited resources.

Take, for example, a lab that offers 1,000 laboratory developed tests.

By the FDA's estimate, 50 percent of existing LDTs will require premarket submissions.

That alone translates to hundreds of millions of dollars — not even accounting for ongoing changes and maintenance.

Moreover, for a phaseout period over four years, this lab will need to submit 250 tests a year, or one per working day—something that's likely impossible for the lab to do and for FDA to review in a timely manner.

According to a recent survey of over 500 clinical laboratory respondents, only 3 percent of labs believe that they will have the financial resources to pay user fees.

For the overwhelming number of labs without the financial resources, they will have to stop performing tests...severely limiting access for some of our most vulnerable patient populations.

In its Preliminary Regulatory Impact Analysis, the FDA estimates there are 80,000 LDTs currently on the market and nearly 8,000 new LDTs per year that would be affected by the rule.

By comparison, the agency approved a little over 3,000 premarket submissions in 2022.

As currently written, the rule would take the FDA years to simply review the tests that already exist on the market.

But what does this all really mean?

Given that the FDA is already struggling to keep up with innovation in what it currently regulates, this undertaking would mean fewer diagnoses, higher costs, and delays in care for patients…who can't afford to wait for the FDA to approve a test they need to finally figure out what is wrong and the path to getting well.

Their lives depend on it.

I know Members of this committee hold a variety of positions on the need for regulating LDTs and the manner in which Congress might do so.

I would hope that we all agree this rule is the wrong path forward.

I look forward to hearing more from our witnesses about legislative alternatives to this stifling administrative action.

Thank you and I yield back.