Committee on Energy and Commerce
Opening Statement as Prepared for Delivery
of
Subcommittee on Health Ranking Member Anna Eshoo

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

March 21, 2024

Thank you, Mr. Chairman and good morning, colleagues. Good morning to the witnesses and thank you for being here. Today we will discuss how diagnostic tests are regulated by the FDA and hear how Congress can improve processes in place to ensure tests that patients rely on are safe and effective.

Congress passed the Medical Device Amendments to the Federal Food, Drug, and Cosmetics Act in 1976 to give the FDA additional authority over medical devices. The FDA has generally not required diagnostic tests to complete pre-marketing approval and instead, allows tests to be used in medical settings if they can meet certain requirements.

Today, we're in a golden era of medical innovation. Diagnostic tests available are increasingly complex and identify an array of medical conditions for large patient populations. Diagnostic tests are firmly enmeshed in our health care system and their results influence more than 70 percent of all medical decisions.

Tests we may think of as simple can be a big deal and there should be better processes in place to validate whether tests patients rely on are reliable and effective for detecting Covid, cancer or other medical conditions.

Certainty is sorely needed. FDA's Center for Devices and Radiological Health reviewed 125 requests to grant Covid tests emergency use authorization (EUA) and found two-thirds of tests had major issues such as inadequate or missing data. 41 percent of tests with major issues were ultimately denied or declined EUA status or withdrawn from consideration.

Another study completed in 2022 of sophisticated technology for analyzing cancer-causing genes produced substantially different results despite assessing samples of the same DNA. We should ensure test results are accurate and don't contribute to worsening health outcomes or higher costs for patients.

Simply put, tests Americans rely on should be safe and effective and I think that's something we all agree on which is why I support the FDA's intent to bring certainty to diagnostic tests by requiring lab developed tests (LDTs) to go through more rigorous review processes. However, I don't believe the FDA's proposed rule is the only way to achieve our shared goal, and the device 510k review process is not perfectly tailored for LDTs.

Our Subcommittee previously considered the *VALID Act*, introduced by Reps. Bucshon and DeGette, which establishes a specific framework for regulating diagnostic tests, similar to how drugs are approved and monitored for safety or quality issues. The legislation also directs a report on the unique challenges academic medical centers and hospital-based labs face. I

believe the FDA's proposed rule should reinvigorate discussions on the legislation and call all stakeholders back to the table to earnestly negotiate the framework.

I genuinely look forward to the testimony today on this rather complex issue. Thank you Mr. Chairman and I yield back.