AdvaMedDx
Vital Insights | Transforming Care

AdvaMedDx Responses
House Energy & Commerce Committee, Subcommittee on Health
Questions for the Record
Hearing on "Evaluating Approaches to Diagnostic Test Regulation and the Impact of FDA's Proposed Rule"

The Honorable Gus Bilirakis

1. As we consider possible legislative approaches, such as the VALID Act, to address the issues raised in this hearing, what are the key objectives we should pursue, and what should we avoid?

When considering legislative approaches like the VALID Act, the primary objectives should include fostering an environment that promotes rapid innovation and flexible adaptation of technological advances in diagnostics. At the same time, it is imperative that revised frameworks include standards that ensure accuracy and reliability of tests to protect patients. Importantly, we should avoid imposing restrictive regulations that unnecessarily complicate the development and deployment of new diagnostics, as this could stifle innovation and delay the availability of crucial tests, particularly for managing rare diseases where timely and accurate diagnostics are vital. An important component of any legislation should be that in vitro diagnostics should be regulated based on their level of risk, not on the source of the test. A streamlined regulatory framework that supports innovation will also help FDA, by providing modernized regulatory oversight tools that help the agency manage workload in a least burdensome manner.

2. I have raised concerns about the impact of the FDA's rule or any new regulatory framework on patients with rare diseases, given their challenging diagnostic odyssey. Do these same concerns about access to accurate diagnostic tests for rare diseases exist under the VALID Act's framework? How does the legislation seek to address those concerns?

The VALID Act is designed to mitigate concerns about access to diagnostics for rare diseases by implementing a risk-based regulatory approach. This framework seeks to balance patient protection with the need for rapid access to diagnostic tests. It allows for expedited pathways and reduced regulatory burdens for diagnostics that serve unmet needs, including those used in rare disease populations. This approach aims to ensure that patients facing rare and complex health challenges continue to have access to essential diagnostic tools without undue regulatory delay. However, it is AdvaMed's view that the VALID Act that was under consideration by Congress in 2022 could be further revised to support and encourage the development of safe and effective in vitro diagnostics for rare diseases and other unmet needs. We would be happy to work with Congress on further refinements to address these issues.

3. How can we ensure that any legislative proposal would ensure safety while maintaining a strong innovative pipeline for LDTs?

AdvaMedDx members are among the world's most innovative companies, and they have successfully brought to market, nationwide and accessible to patients of all backgrounds, exceptionally sophisticated, groundbreaking, and technologically advanced diagnostic products, all while operating within the existing FDA medical device framework. Ensuring test safety, and accuracy, while supporting innovation requires

a balanced legislative approach that incorporates both rigorous accuracy standards and flexibility for innovation. Legislation should focus on creating clear, transparent regulatory pathways that are predictable and facilitate faster development cycles, such as the Technology Certification program included in the VALID Act. Moreover, by adopting a tiered risk-based classification system for diagnostic tests, legislation can prioritize resources and scrutiny where it is most needed, thus reducing unnecessary burdens on lower-risk tests and focusing on those with higher potential risks to patients. This approach would not only uphold high accuracy and reliability standards but also promote a robust pipeline of innovative diagnostics essential for advancing public health.

The Honorable Dan Crenshaw

1. Mr. Rothstein, given the current program, is it realistic for FDA to estimate that at least 50 percent of LDTs would seek review by a third-party organization?

We are unable to speak to how FDA derived its estimate regarding the use of third party review. Currently, the third party review program accounts for a small portion of overall 510(k) submissions. It is important to note that the LDT Final Rule includes provisions that could potentially support greater use of the third party review program by laboratories by utilizing existing third-party review frameworks such as the New York State Clinical Laboratory Evaluation Program (CLEP).

2. Mr. Rothstein, would you say the third-party review program needs reform generally? Just as good FDA policy?

In 2023, the FDA third-party review program handled 18 510(k) submissions. *See*, 2023 Third Party Review Organization Performance Report, p. 14, *available at* https://www.fda.gov/media/165143/download. CDRH, in contrast, received over 3,200 510(k) submissions. *See*, 2023 MDUFA Performance Report to Congress, p. 13, *available at* https://www.fda.gov/media/177975/download?attachment. We agree the program requires reform to be more broadly useful.

However, as we have previously stated, we support the provisions within the VALID Act that are designed to improve the third-party review program as specifically applied to diagnostic tests, including provisions that would expand the pool of third-party review organizations and promote global harmonization.

The Honorable Troy Balderson

1. Can you assure the American people that the FDA LDT proposal will not interrupt access to LDTs already proven effective in diagnosing rare genetic disorders, immune dysregulation, immunodeficiencies and other complex disorders affecting more than one organ system?

FDA, as the regulatory authority, would provide the most definitive response to this question. Under the current system, it is not entirely clear how well LDTs perform given that most of them have not undergone review for efficacy. However, in the Final Rule, FDA has included provisions specifically designed to prevent disruption in access to critical LDTs, such as those used in diagnosing complex

genetic and immune disorders. The final rule outlines measures to "grandfather" existing LDTs that have demonstrated effectiveness, allowing them to continue being used without interruption. Similarly, FDA's Final Rule has provided ongoing enforcement discretion for tests used within health care systems specifically to address unmet needs. AdvaMed supports the goal of avoiding any interruption in access to needed in vitro diagnostics.

The Honorable Frank Pallone, Jr.

1. In the case of New York State, do you agree that the consequences for patients could have been severe if these tests were not evaluated and their problems addressed first? 1(a) Doesn't this evidence from New York State tell us that it is important for FDA to make sure these tests are actually working, regardless of who makes them?

The situation in New York State illustrates the crucial need for rigorous premarket evaluation of diagnostic tests. The discovery of design flaws, inadequate validation data, and process issues through such evaluations reflects the importance of ensuring the reliability and safety of tests. FDA noted in the preamble to the Final Rule that the findings mentioned in the New York comments similarly reflected FDA's own experiences and findings. Addressing these issues before the tests are used is vital to preventing potential misdiagnoses or other adverse consequences that could severely impact patient health. This underscores the importance of a robust regulatory framework, like the one implemented by FDA, which aims to safeguard patient health by ensuring that all tests meet high standards for safety and effectiveness before they reach the market.

1(b). Do you agree that FDA has the authority to regulate these tests, or do you believe these are services as some have argued?

AdvaMedDx believes that FDA has the statutory authority to regulate LDTs as medical devices. Section 201(h)(1) of the Federal Food, Drug, and Cosmetic Act (FDCA), provides that whether a test is a medical device is based on its intended use to diagnose disease or other conditions, or to cure, mitigate, treat, or prevent disease. This definition hinges on the intended use of the test, not on who manufactures it or where it is made.

The Honorable Nanette Barragán

1. Can FDA regulation of these tests be carried out in a way that will encourage innovation and promote access to effective tests?

AdvaMedDx members have demonstrated the ability to bring innovative tests to market, through FDA's regulatory system, which have greatly benefited patients. However, we also recognize that the existing framework can and should be improved to reflect the technological advances in diagnostics and the differences between in vitro diagnostics and other devices. The VALID Act emphasizes the need for a balanced approach that protects patients and fosters innovation, and provides reforms that would support innovation and provide FDA with updated regulatory tools to provide appropriate oversight to these innovative tests. Comprehensive legislative reform would not only support public health by ensuring test reliability but also encourage ongoing innovation in the diagnostics field.

2. Can you share how FDA regulation of laboratory developed tests will improve the reliability of these tests, which can save time and money for both patients and the health care system?

FDA oversight should be based on the risk of the test, not on what entity develops the test. In the Final Rule preamble, FDA identified the benefits of regulatory oversight in ensuring the safety and effectiveness of LDTs, as is the case with other in vitro diagnostic devices. These oversight tools include registration and listing, reporting of adverse events and malfunctions (MDRs), reporting of corrections and removals (recalls), disclosure of labeling, development of a quality system, and, ultimately, premarket review for those tests that are not exempt from premarket review.

The Honorable Angie Craig

1. There are approximately 330,000 CLIA laboratories in the United States, all likely having some laboratory developed tests (LDTs) and many with tens or hundreds of unique LDTs subject to proposed FDA oversight. Can you explain how FDA will ensure that requests are processed in a timely fashion to not negatively impact immediate patient care?

FDA is better positioned to detail their specific strategies and projections, and to comment on the estimates of the numbers of LDTs. However, the Final Rule includes a phased implementation period, provisions for grandfathering of all LDTs already marketed, and specific exemptions which are designed to alleviate the immediate regulatory burden. AdvaMed supports FDA's efforts in the Final Rule to take steps to avoid any disruptions to patient access to safe and effective tests.

2. What are the specific current test development gaps by clinical laboratories that the Administration's proposal aims to resolve to make health care safer?

FDA is in a better position to address this question. In the Proposed Rule and Final Rule, FDA has primarily identified the concerns about the quality of certain LDTs, the lack of transparency as to what LDTs exist and their performance, and that the lack of clarity as to the regulatory status of LDTs may potentially inhibit innovation in certain areas of testing.