AdvaMedDx Media TALKING POINTS on VALID Act Reintroduction

June 2021

1.) What's the take-away here?

- We are pleased with the recent reintroduction of the bipartisan VALID Act in the House and Senate. We thank Senators Bennet and Burr and Representatives Bucshon and DeGette for reintroducing this important legislation.

- Bipartisan, bicameral bill refinement and reintroduction represents a major step forward in our efforts to secure diagnostics regulatory reform, and we look forward to a thoughtful legislative process to advance and secure comprehensive reform.

- Diagnostics regulatory reform would be good for industry – including manufacturers of *in vitro* diagnostics ("IVDs") and creators of laboratory-developed tests ("LDTs") – and it would be good for patients. It would help incentivize and speed innovation, and development of quality, accurate, clinical diagnostic tests. It would also help drive continued improvements in patient care and public health.

- It would do this by creating a single, modernized, predictable, risk-based, regulatory framework for all diagnostic tests, regardless of where developed – whether by a laboratory or by an IVD manufacturer. We are eager to work with the VALID sponsors and committees throughout the legislative process to achieve these aims.

2.) Why now? Why is diagnostics regulatory reform legislation so important?

- Diagnostic technologies are advancing more quickly than ever, leading to more rapid identification of disease and direction to appropriate treatment. But the current regulatory framework for clinical diagnostics is outdated. It has not kept pace with scientific and technological changes. It is not even tailored specifically to diagnostics.

- In fact, IVDs and LDTs are currently regulated by a patchwork of laws developed decades ago. The COVID-19 pandemic highlighted the uncertainty laboratories and IVD manufacturers face in regulation and the need for a new oversight system.

- IVDs are regulated by the FDA, which oversees the analytical and clinical validity of tests, and quality manufacturing. Labs that develop LDTs largely receive oversight of their operations – and of the analytical validity of tests – by the Centers for Medicare & Medicaid Services (CMS). However, current FDA regulation of clinical diagnostics as medical devices does not work as well as it could to incentivize innovation in testing, and CMS regulation is not intended to assess clinical validity. Patients and providers are united in that timely access to innovative clinical diagnostic tests that are analytically and clinically valid is paramount.

3.) What does the solution look like?

- The solution is modernizing the regulatory framework for all *in vitro* clinical tests. TheVALID Act is an important step to reform as it would seek to create a single, diagnostics-specific, risk-based regulatory framework for both IVDs and LDTs, separate from medical devices, and overseen byFDA.

- It would aim to provide patients and health care providers confidence that all tests have been subject to robust oversight and assessment, meeting the same evidentiary standards for analytical and clinical validity.

- At the same time, it would look to help unlock the potential for diagnostics innovators to do more to bring new tests to market and keep existing tests up to date. They would be able to further empower patients and providers to make informed clinical decisions, advance personalized medicine, and continue to improve health care for the benefit of patients and their families.

4.) What do you mean when you say the new regulatory framework will be "risk-based"?

- The VALID Act would seek to create a new, smart regulatory framework specific to diagnostics, one that is modernized and risk-based.

- Risk-based means regulatory rigor would be appropriately commensurate with potential risks. Itwould be most heavily focused on tests where an inaccurate result could have the highestpotential risk to negatively impact clinical decision-making on patient care. It would align FDA's review resources with protection of patients.

- We look forward to working with the VALID sponsors in a thoughtful legislation process to ensure the legislation would create a truly risk-based framework.

5.) What are some of the other provisions of the VALID Act?

- We are continuing to review the details of the legislation. The bill contains a range of provisions we are looking at closely.

- These include a provision for a voluntary pathway for test developers with robust quality systems, which would allow for smart reviews and more efficient consideration of tests that all use the same technologies. We think this pathway, called Technology Certification, holds great promise, and we are eager to analyze the details.

- We are also looking for policies in the various regulatory pathways set forward by VALID that would facilitate certain modifications to already-marketed tests in a timely fashion. These would help keep pace with science and ensure high-quality products. Under these policies, the agency and test developers would agree, during review of a test

or a suite of tests, on the kinds of modifications that could be made to that test, once on the market, without having to come back for review.

6.) How will diagnostics regulatory reform make a difference to patients and providers?

- Diagnostics regulatory reform would provide a uniform regulatory framework for both IVDs and LDTs specific to diagnostics.

- It would help expand the reach of cutting-edge diagnostics, allowing patients tobenefit more broadly, rapidly, and confidently from the latest diagnostic technologies.

- It would allow patients and their clinicians to have the confidence they need that innovative diagnostics of the highest standards would be available to them across the health care delivery system.

- It would support expanding scientific knowledge, and development of new complex genomic and molecular technologies, and other high-quality diagnostics.

7.) How do diagnostics in general fit in to the overall health care delivery system?

- Today, it is often reported that over 70% of clinical decisions are informed by *in vitro* clinical diagnostic tests that use specimens from the human body to help make sure that the right patient gets theright treatment – or health care decision – at the right time.

- For example, advanced gene-based tests can facilitate targeted cancer treatments – or personalized medicine – based on specific genetic makeup. These tests can improve survival rates and lower health care costs. Cancer deaths have declined 27 percent over the past 25 years in part due to advances in early detection and treatment. Advanced diagnostic testing, which in many ways is the foundation of personalized medicine, has helped facilitate these advances. The future promises more.

8.) Who introduced this legislation and how did it come about?

- The VALID Act was introduced in the Senate by Sens. Michael Bennet (D-Colo.), and Richard Burr (R-N.C.), and in the House by Reps. Diana DeGette (D-Colo.) and Larry Bucshon (R-Ind.).

- We are grateful for the wide range of stakeholders with whom we share the goal of comprehensive diagnostics regulatory reform, including the laboratory community and – particularly important – the patient community.

- The diagnostics industry is privileged to work with various patient organizations committed to the goal of comprehensive diagnostics regulatory reform.

9) What has the COVID-19 pandemic taught us about the need for diagnostics regulatory reform legislation?

- The COVID-19 pandemic has underscored the need for ensuring transparency for patients and clinicians, so they know which diagnostic tests are available and how well those tests perform. The VALID Act would provide that transparency by creating a comprehensive database containing information about available diagnostic tests regardless of the developer. The pandemic also reinforces the need to ensure risk-based oversight and review of all diagnostic tests by FDA.

- Further, during the pandemic laboratories have faced a lack of clarity on regulatory requirements under Emergency Use Authorization (EUA), further reinforcing the need for clarity and transparency in oversight.

10) When do you expect diagnostics regulatory reform legislation to be enacted?

- We look forward to working with VALID Act co-sponsors, other leaders in the House and Senate, the FDA, as well as with our partners in the patient, provider, and laboratory communities, to secure diagnostics regulatory reform as part of the medical device user fee reauthorization (MDUFA) legislation.

11) How does the VALID Act differ from Sen. Rand Paul's VITAL Act?

- Where the VALID Act aims to provide a comprehensive regulatory framework for all developers of clinical diagnostics – LDTs and IVDs – under the FDA, the only agency with the expertise to assess diagnostic tests and technologies for both analytical and clinical validity, the VITAL Act would seek to modify Centers for Medicare and Medicaid Services (CMS) existing oversight of laboratory operations. CMS does not assess the clinical validity of diagnostic tests and does not employ the experts that could make that assessment. The VALID Act appropriately identified the FDA as the regulatory body that can assess diagnostic tests for analytical and clinical validity.