Modernizing Regulation of Diagnostic Tests is Essential to Improve Patient Care and Support Innovation

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ISSUE: Diagnostic tests for clinical use, including both Laboratory Developed Tests (LDTs) and *In Vitro* Diagnostics (IVDs), examine specimens (e.g., blood, tissue, etc.) taken from the human body, as well as data derived from specimens, in order to screen or diagnose patients for diseases or other conditions, monitor, cure, treat, and prevent disease. These tests are used to inform 70 percent of all health care decision making.

Current oversight of the development and quality of these tests is outdated and fragmented. Lagging behind scientific advances and the increasing complexity of testing, present regulation is based *not* on the tests themselves, but rather on where the test is developed, leading to inconsistencies in the accuracy and reliability of tests for clinical decision making.

NEEDED ACTION: Modernization of the regulation of all LDTs and IVDs under a single, diagnostic-specific regulatory framework under the Food and Drug Administration (FDA) is needed to foster innovation, embrace scientific advances, ensure consistency in development, accuracy and reliability of all tests, for the advancement of patient care and public health. **Under a modernized new framework, LDTs and IVDs would be known collectively as *in vitro* clinical tests (IVCTs).**

ADVAMEDDX POSITION: AdvaMedDx supports the establishment, through legislation, of a modernized and predictable, risk-based diagnostics regulatory framework under FDA to which all developers of IVCTs would be subject. The framework should recognize the unique characteristics of diagnostic tests, allowing developers to leverage smart, modernized review pathways, speeding high-quality, reliable and innovative tests to providers and patients, while providing FDA with the tools to administer effective oversight of these tests.

In the last Congress the introduction of the Verifying Accurate, Leading-edge IVCT Development (VALID) Act by Sens. Richard Burr (R-NC) and Michael Bennet (D-CO) in the Senate, and Reps. Diana DeGette (D-CO) and Larry Bucshon, MD (R-IN) in the House, is a major milestone toward modernizing IVCT oversight, making diagnostics regulatory reform a reality. The VALID Act, poised to be reintroduced in the 117th Congress, would seek to establish a single, diagnostics-specific, risk-based regulatory framework under the FDA for all IVCTs.

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AdvaMedDx member companies produce advanced, *in vitro* diagnostic tests that facilitate evidence-based medicine, including through the early detection of disease and guiding of appropriate treatment, improving quality of patient care and public health, serving as a foundation of personalized medicine, and often reducing overall health care costs. Functioning as a division of the Advanced Medical Technology Association (AdvaMed), AdvaMedDx is the only advocacy organization exclusively addressing policy issues facing diagnostics manufacturers both domestically in the United States and abroad.

Current Outdated Regulation

Oversight of tests is currently based on where tests are developed, *not* on the tests themselves.

Laboratory Developed Tests (LDTs)

Developed in hospital labs or free-standing laboratories where patient specimens are brought for analysis.

The Centers for Medicare & Medicaid Services (CMS) oversees laboratories that perform testing on patient specimens under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). Laboratory operations may be monitored by states and some CMS-approved accrediting organizations. Analytical validity of tests is also assessed under CLIA and voluntarily through other accrediting bodies.

In Vitro Diagnostic Tests (IVDs)

Developed by manufacturers for the commercial market for laboratories, providers and other users. Manufacturers develop stand-alone tests and platforms/instruments on which tests are performed, and the collection devices used to collect the specimens tested. Many also develop test components. Often tests are sold as kits.

The Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Medical Device Amendments of 1976, regulates the validation, manufacturing and distribution of IVDs as medical devices, while also regulating the manufacturing processes of IVDs, quality management systems, and the analytical and clinical validity of IVDs, along with certain requirements after tests are on the market.

The Benefits of Modernized, Diagnostics-Specific Regulation of *In Vitro* Clinical Tests

AdvaMedDx seeks a modernized, diagnostics-specific regulatory framework for all IVCTs that would:

ADVANCE PATIENT CARE AND PUBLIC HEALTH by establishing a single, predictable, and risk-based regulatory framework for all IVCTs, regardless of where they are developed, providing patients and clinicians with necessary confidence in the accuracy and reliability of IVCTs for clinical decision-making—including reasonable assurance of analytical and clinical validity for all IVCTs.

ENHANCE TRANSPARENCY OF ALL IVCTS by requiring all IVCT developers to provide information about IVCTs for clinical use in a comprehensive public database, including intended use of the IVCTs. This would provide important clarity for patients, clinicians, researchers, and other stakeholders about available IVCTs.

FOSTER INNOVATION through modernization of regulatory pathways, allowing IVCT developers with robust quality systems to bring cutting-edge IVCTs to patients more quickly and make patient care-driven modifications to existing diagnostics more rapidly, while ensuring high standards for accuracy and reliability.

FURTHER PRECISION MEDICINE by recognizing the advancing science of IVCTs, essential in an era of personalized medicine. IVCTs are increasingly leveraged to develop patient-specific diagnosis and therapeutic care plans.

PROVIDE BALANCED REGULATION OF IVCTS through a right-sized approach. While all IVCTs would be subject to clear FDA authority, under a risk-based regulatory framework FDA oversight should be focused most heavily on IVCTs where an inaccurate result could have the highest-potential risk to negatively impact clinical decision making.

What is the Analytical and Clinical Validity of a Test?

Analytical validity is focused on ensuring the test performs as intended—that is, that it measures what it claims to measure. **Clinical validity** focuses on how the test result relates to the presence, absence, and/or risk of a disease or condition.