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News

For Immediate Release

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AdvaMed Dx Statement on FDA Public Meeting on the Oversight of Laboratory Developed Tests

WASHINGTON, D.C. – Janet Trunzo, executive vice president, technology and regulatory affairs at the Advanced Medical Technology Association (AdvaMed), released the following statement on behalf of AdvaMed Dx regarding the Food and Drug Administration (FDA) public meeting on the oversight of laboratory developed tests:

“AdvaMed Dx supports timely access to safe and effective diagnostics, and wholeheartedly agrees that a risk-based approach to regulation should be applied to all diagnostic tests, whether developed by manufacturers or clinical labs.

“We have proposed a risk-based approach to regulation that recognizes FDA authority to regulate all diagnostic tests. Our approach builds on the strengths of the current system and infrastructure and adds objective criteria for stratifying pre-market regulatory data requirements. We also believe that well standardized, low-risk tests should be exempt from pre-market notification.

“Regulation should be based on the risk of the test—not on who happens to develop or make a test—and should be focused on the probability of harm associated with how the test is used in patient care. A risk-based approach will concentrate scarce FDA resources where they are needed—on tests that are unproven or that pose a high risk to patients if results are incorrect.”

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AdvaMed Dx member companies produce advanced, in vitro diagnostic tests that facilitate evidence-based medicine, improve quality of patient care, enable early detection of disease and reduce overall health care costs. Functioning as an association within AdvaMed, AdvaMed Dx is the only multi-faceted, policy organization that deals exclusively with issues facing in vitro diagnostic companies both domestically in the United States and abroad. For more information, visit www.advamed.org.