THE VALUE OF DIAGNOSTICS

Diagnosis tests are at the forefront of medical innovation, providing vital insights into patient health and care.

THE UNITED STATES AND ABROAD.

Functioning as a division of AdvaMed, the medical device trade association, AdvaMedDx is the only advocacy organization exclusively addressing policy issues facing diagnostic manufacturers both domestically in the United States and abroad.

ReForM is neeDeD to imProve Patient care

The vaLue oF Diagnostics

Diagnostics: A Vital American Industry

DIAGNOSTICS CAN LOWER HEALTH CARE COSTS

DIAGNOSTICS CAN DECREASE HEALTHCARE-ASSOCIATED STAPH INFECTION RATES BY 70%. IF NOT PREVENTED, STAPH INFECTION TREATMENT CAN COST AS MUCH AS $19,000

REFORM IS NEEDED TO IMPROVE PATIENT CARE

MODERNIZE THE DIAGNOSTICS PAYMENT SYSTEM

• The current Medicare framework for payment of diagnostic tests is flawed and outdated. It fails to reflect the real value of modern diagnostic tests, devalues incentives for innovation, and slows access to new tests.

• Private health insurers largely base their payment models for tests on the Medicare schedule.

• More than a decade ago, the Institute of Medicine reported that the outdated Medicare payment system could threaten patients’ access to care and the use of enhanced testing methodologies in the future. [Institute of Medicine, 2000]

• Patients deserve a system that encourages the development of innovative and life-changing diagnostic technologies.

ENSURE EFFECTIVE, RISK BASED REGULATION

• All diagnostic should be overseen by the Food and Drug Administration (FDA) under a risk-based approach that ensures timely patient access to safe and effective diagnostic tests.

• Focus FDA resources on tests that pose the highest risk to patients – regardless of whether made by manufacturers or clinical laboratories (FDA is currently not assessing its oversight authority over laboratory developed tests, or LDTs).

• Expedite patient access to lower risk tests by more efficient use of the pre-market review process, including exemptions for well-established tests.

• FDA has regulatory authority over all diagnostic tests. To support public health and assure the safety and effectiveness of diagnostics, FDA has announced plans to implement its enforcement authority over LDTs through implementation of a risk-based regulatory framework.

Sources:
1. Institute of Medicine, “Laboratory Medicine: A National Status Report,” p. 3
5. Gene, For Value of Diagnostic Innovation, Retraction and Reloading,” July 2010
6. “IM AGED PATHOLOGISTS’节日 如 lh”“(63)““ A Diagnostic Pathway,” July 2011

AdvamedDx 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 a division of AdvaMed, the medical device trade association, AdvaMedDx is the only advocacy organization exclusively addressing policy issues facing diagnostic manufacturers both domestically in the United States and abroad.