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KENNEDY WORKS TO PROTECT PATIENTS BY IMPROVING THE QUALITY OF MEDICAL TESTS

Washington, D.C.: Today as the National Genetics Policy Summit in takes place Washington, DC., Senator Edward M. Kennedy continues his work on legislation that will better protect patients by ensuring that tests developed in laboratories are of proven validity. Senator Kennedy is committed to preserving innovation in this rapidly evolving area of medical technology. He plans to introduce his bill in the coming months so that it will move through Congress next year.

"Doctors and patients are making important medical decisions based on the results of clinical laboratory tests in the field of genetics. We need to ensure that they understand the clinical significance of the results, and are confident that the tests are accurately performed. My bill will focus the Congress and others on the need for an important role for FDA in this area."

Kennedy's legislation will:

· Clarify that the Food and Drug Administration has the authority to regulate these tests, which some have questioned, and to provide direction to FDA about how to exercise this authority.

· Clarify that when FDA has cleared or approved a diagnostic, similar lab tests must also be cleared or approved by FDA.

The use of such genetic tests in medical practice is expected to increase in the coming years. Already, some of these tests influence major medical decisions, such as whether a woman should have a prophylactic mastectomy, or whether a particular drug is appropriate for a patient. This century of the life sciences offers the promise of ever more such tests.

Senator Kennedy commended the Genetics and Public Policy Center for having the summit, which brings together national experts to focus on policy issues related to genetics. He looks forward to the ongoing discussion of important public health issues related to this area of medical technology.

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