

July 27, 2006

Opening Statement Presented to the United States Senate, Special Committee on Aging, by Carol R. Reed, MD, Senior Vice President, and Chief Medical Officer, Clinical Data, Inc.

My name is Carol Reed and I am Chief Medical Officer of Clinical Data, Inc. I would like to thank the Committee and Senator Smith for the opportunity to appear before you today. Clinical Data is a company that has been in the forefront of the development of pharmacogenetics research and testing for many years. We provide pharmacogenomic and molecular services to the research industry, including clinical trial aspects of drug development, but key to our business is our ability to discover, develop, and commercialize genetic tests to guide drug development and utilization. As the committee is well aware, drug spend is one of the largest components driving the total cost of healthcare, despite many efforts to contain it. Healthcare providers and payers face the difficult task of deciding which drugs should be prescribed to specific patients and are suitable for reimbursement. These decisions are based on medical outcome studies and economic benefit factors but with little knowledge of which individual patients are most likely to benefit from a specific drug. In fact, managed care plans employed by payers and Prescription Benefit Managers have a significant impact on providers' decisions as to which drugs should be prescribed for a specific patient. All participants in the decision to prescribe would benefit from the ability to more clearly identify drugs that are most efficacious and safest for a specific individual or patient population, resulting in optimized patient care and outcomes.

The medical community generally acknowledges that most drugs work more effectively for some patients than for others. The genomic blueprint each person inherits from his or her biological parents is contained within a person's DNA and determines not only the obvious physical characteristics that differentiate us, such as height, hair color and eye color, but also has a large impact on how we respond to medications. By understanding genetic variation and its relationship to drug response, it is possible to determine which individuals are most likely to benefit from a given drug, even before the drug is prescribed.

Clinical Data's main focus is the development and delivery of genetic tests that may be used to more confidently predict an individual's response to an intervention. As an example, our FAMILION test is used to identify mutations in ion channel genes that are associated with Familial Long QT Syndrome and other inherited arrhythmogenic disorders. This test has had a very direct and positive impact on patients' lives, helping physicians determine the right intervention for each patient, as well as assisting the family in ascertaining the status of their relatives, as these syndromes may be asymptomatic until presenting suddenly with syncope, seizures, or death. This test requires a provider's order, is performed in our CLIA-certified and compliant laboratory in New Haven, CT, and test results are reported directly to the provider for use in decision-making as clinically indicated. Despite the absence of an approved proficiency testing program for this high-complexity test, we conduct proficiency testing with the assistance of academic experts. This is the model that Clinical Data intends to follow as we develop and deliver pharmacogenetic tests to payers and providers.

Regarding nutrigenomic testing: in 2002, Genaissance Pharmaceuticals entered into an agreement with Sciona, a nutrigenomics testing company. In the good faith opinion of the company at that time, this testing did not fall under CLIA oversight. The Genaissance laboratory accepts samples from Sciona customers, extracts DNA, and performs genotyping. The genotyping results are sent to Sciona who provides interpretation and a report to their customers. Genaissance Pharmaceuticals was acquired by Clinical Data, Inc., in October 2005. Clinical Data is supportive of the interest on the part of CMS/CLIA and the federal government to consider increasing regulatory oversight of this testing.

I would again like to thank the committee for the opportunity to provide input and assistance as the Committee navigates this challenging and exciting new terrain. We support efforts to assure that all genetic testing meets standards for both process and analytical and clinical utility and stand ready to assist Congress as it explores these issues.

Sincerely,



Carol R. Reed, MD, FACP, FACC