

GENETIC ALLIANCE

March 14 , 2006

Dr. Mark McClellan
Commissioner
U.S. Food and Drug Administration
Rockville MD 20857

Dear Dr. McClellan:

As organizations and individuals dedicated to improving patient outcomes in health care, we are writing to urge you to issue proposed regulations for a genetic testing specialty under the Clinical Laboratory Improvement Amendments (CLIA) of 1988.

While we recognize the perspectives of all of the stakeholders, our focus is set squarely on improving outcomes for patients. That means high quality testing services that are accessible. As knowledge of genetics continues to grow and the number of genetic tests made available to consumers increases, the U.S. government has a responsibility to initiate and maintain a regulatory framework under CLIA that ensures the safety and utility of the tests being conducted without limiting the accessibility of those tests.

In 2000 the Centers for Disease Control and Prevention (CDC) issued a Notice of Intent indicating that the Centers for Medicare and Medicaid Services (CMS) would be issuing a proposed rule based on stakeholders' comments received and elucidated by the CDC. More than five years later, no such rule has been issued, and the genetic testing specialty that was recommended has not been established.

We believe that the establishment of a genetic testing specialty under CLIA is a necessary first step toward a regulatory system that encourages new technology and ensures safety and accuracy when those technologies are implemented. Since the CDC issued its Notice of Intent more than five years ago, the number of genetic tests available has increased substantially. Today, there are more than 900 diseases for which genetic tests are clinically available, several hundred used in research, and even more in various stages of development. Without a genetic testing specialty, CLIA cannot adequately ensure that consumers receive genetic testing services that are safe, accurate, and clinically useful.

We urge CMS to act quickly by issuing proposed regulations for a genetic testing specialty under CLIA. We welcome the opportunity to meet with you and discuss these issues in further detail.

Organizations Signed-on (as of March 29, 2006)

Alpha-1 Advocacy Alliance
American Occupational Therapy Association (AOTA)
The Arc of Aurora
Birt Hogg Dube Family Alliance
Cancer Research Fund / VHL Family Alliance
Chromosome 18 Registry
Coalition of Heritable Disorders of Connective Tissue
GeneDx, Inc.
Geneforum
Genetic Alliance
Genetic Alliance BioBank
IEEE-USA
International Myeloma Foundation
National Niemann-Pick Disease Foundation, Inc.
National Women's Health Network
Neurofibromatosis, Inc.-Mid-Atlantic
Northern Nevada Genetic Counseling
Parent Project Muscular Dystrophy
Pediatric Adolescent Gastroesophageal Reflux Association, Inc
PXE International
Society for Women's Health Research
Stickler Involved People, A support group for people affected by Stickler syndrome
Sudden Arrhythmia Death Syndromes (SADS) Foundation
Wilson Disease Association
Without A Vision, LLC