Archived Policy Statement

Letter to the Centers for Medicare and Medicaid Services (CMS) requesting a genetics specialty under the Clinical Laboratory Improvement Amendments (CLIA)

June 6, 2006

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.

Acid Maltase Deficiency Association (AMDA)
Affymetrix, Inc.
Alliance for Aging Research
Alpha-1 Advocacy Alliance
American Occupational Therapy Association (AOTA)
American Pain Foundation
The Arc of Aurora
BCCNS Life Support Network
Beckwith-Wiedemann Children's Foundation
Birt Hogg Dube Family Alliance
Canadian Multiple Endocrine Neoplasia Type 1 Society, Inc.
Cancer Information & Support Network (CISN)
Cancer Research Fund / VHL Family Alliance
Cardiac Arrhythmias Research and Education (C.A.R.E.) Foundation, Inc.
Cardio-Facio-Cutaneous International
Celiac Sprue Association
Chromosome 18 Registry
Citizens for Quality Sickle Cell Care, Inc.
Cutis Marmorata Telangiectatica Congenita (CMTC)
Coalition of Heritable Disorders of Connective Tissue
Congenital Adrenal Hyperplasia Research Education & Support (CARES)
Costello Syndrome Family Network
Cystinosis Research Network
European Pharmaceutical Law Group
Family Voices
Ferre Institute, Inc.
GeneCare Medical Genetics Center
GeneDx, Inc.
Geneforum
Genetic Alliance
Genetic Alliance BioBank
Genetics and Public Policy Center
Ground Zero Pharmaceuticals, Inc.
Hadassah
Hereditary Disease Foundation
Hereditary Hemorrhagic Telangiectasia Foundation
Hermansky-Pudlak Syndrome Network
HLRCC Family Alliance
Hunter's Hope
IEEE-USA
Institute for Cultural Partnerships
International Federation of Marfan Syndrome Organizations (IFMSO)
International Myeloma Foundation
The International Society of Nurses in Genetics (ISONG)
Iona College Social Work Department
Marti Nelson Cancer Foundation

Metachromatic Leukodystrophy (MLD) Foundation
The Moebius Syndrome Foundation
Nail Patella Syndrome Networking/ Support Group
National Association of Social Workers
National Eczema Association
National Marfan Foundation
National Niemann-Pick Disease Foundation, Inc.
National Organization of Albinism and Hypopigmentation (NOAH)
National Tay-Sachs & Allied Diseases Association, Inc. (NTSAD)
National Women's Health Network
Neurofibromatosis, Inc.-Mid-Atlantic
Northern Nevada Genetic Counseling
Parent Project Muscular Dystrophy
Pediatric Adolescent Gastroesophageal Reflux Association, Inc
Pediatric Neurotransmitter Disease (PND) Association
PreventionGenetics
The Progeria Research Foundation, Inc.
Public Citizen's Health Research Group
PXE International
Shwachman Diamond Syndrome Foundation
Society for Women's Health Research
Stickler Involved People, A support group for people affected by Stickler syndrome
Sudden Arrhythmia Death Syndromes (SADS) Foundation
Trimethlaminuria Foundation
Trisomy 18 Foundation
UCLA Center for Society and Genetics
VHL Family Alliance
Wilson Disease Association
Without A Vision, LLC
Xeroderma Pigmentosum Society, Inc. Acid Maltase Deficiency Association (AMDA)
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