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June 18, 2014

The Honorable Howard McKeon  
United States House of Representatives  
2310 Rayburn House Office Building  
Washington, DC 20515

The Honorable Adam Smith  
United States House of Representatives  
2264 Rayburn House Office Building  
Washington, DC 20515

The Honorable Carl Levin  
United States Senate  
269 Russell Senate Office Building  
Washington, DC 20510

The Honorable James M. Inhofe  
United States Senate  
205 Russell Senate Office Building  
Washington, DC 20510

The Honorable Joe Wilson  
United States House of Representatives  
2229 Rayburn House Office Building  
Washington, DC 20515

The Honorable Susan A. Davis  
United States House of Representatives  
1526 Longworth House Office Building  
Washington, DC 20515

The Honorable Kirsten Gillibrand  
United States Senate  
478 Russell Senate Office Building  
Washington, DC 20510

The Honorable Lindsey Graham  
United States Senate  
290 Russell Senate Office Building  
Washington, DC 20510

Dear Chairpersons and Ranking Members of the House and Senate Armed Services Committees and their Personnel Subcommittees:

Genetic Alliance is writing to express our deep concern with what we believe are substandard healthcare services for active duty military personnel, retirees, and their families. We urge you to rectify this serious and ongoing problem as you move forward with the National Defense Authorization Act for FY2015.

Genetic Alliance is a non-profit health advocacy organization committed to engaging individuals, families and communities to transform health. The Genetic Alliance's network includes disease-specific advocacy organizations, as well as universities, private companies, government agencies, and public policy organizations.

In January of last year, TRICARE ceased coverage of more than 100 laboratory-developed tests (LDTs) when physicians in the civilian provider network ordered these tests. These tests, long covered by TRICARE, play a critical role in diagnosing and treating disease, and include tests for Fragile X syndrome, Cystic Fibrosis, Spinal Muscular Atrophy, and many common cancers. TRICARE's lack of coverage of these vital healthcare services places TRICARE out of step with other government programs and commercial health insurance. Furthermore, this two-tiered coverage policy has resulted in unequal treatment of TRICARE

beneficiaries, with those obtaining care at Military Treatment Facilities (MTFs) maintaining access to these tests and beneficiaries receiving care from the civilian provider network denied critical testing services.

TRICARE's regulations exclude from coverage "unproven" drugs, devices, medical treatments, or procedures. These regulations define an "unproven item" to include a device that "cannot be lawfully marketed without the approval or clearance of the [FDA] and approval or clearance for marketing has not been given at the time the drug or device is furnished to the patient."

FDA has a longstanding "enforcement discretion" policy with respect to LDTs, under which FDA has clearly and repeatedly said that it does not require premarket review or clearance for LDTs to be lawfully marketed. There are thousands of LDTs currently legally marketed, which neither have, nor are required to have FDA clearance or approval.

Despite acknowledging the important role of LDTs in healthcare delivery, the Defense Health Agency has denied coverage of these tests for over a year. In many cases, laboratories have continued to provide testing services to TRICARE patients, and are awaiting payment. In other cases, TRICARE beneficiaries have been forced to absorb one hundred percent of the costs for testing, or seek assistance from patient advocacy organizations. This is unacceptable.

We urge you to direct DHA to restore coverage for these laboratory developed tests. Given their incredible sacrifices for our Nation, military personnel, retirees and their families deserve the very best healthcare services, regardless of where they obtain treatment.

Sincerely,



Sharon F. Terry  
President & CEO

Signing on:

The American College of Medical  
Genetics and Genomics  
The American Military Partner Association  
American Osteopathic Association  
American Society for Clinical Pathology  
Amyloidosis Support Groups Inc.  
Appalachian Faith & Ecology Center, Inc.  
Association for Molecular Pathology  
Batten Disease Support and  
Research Association  
Baylor Scott & White Hospital  
Baylor College of Medicine

CADASIL Together We Have Hope  
Non-Profit Organization  
Capella University  
Cardio-Facio-Cutaneous International  
Carl R Darnall Army Medical Center  
Children's Hospital of Philadelphia  
Christus Schumpert Cancer Treatment Center  
The Cholangiocarcinoma Foundation  
Chromosome Disorder Outreach Inc.  
College of American Pathologists  
Counsyl, Inc.  
Cutaneous Lymphoma Foundation  
Cutis Laxa Internationale

Dana-Farber Cancer Institute  
Delta Pathology- Delta MDx  
Fabry Support & Information Group  
Family Voices Colorado  
Foundation for Prader-Willi Research  
GA DM Community & Families  
Genetic Alliance  
GENETWORx  
Greenwood Genetic Center  
Informed Medical Decisions, Inc.  
JScreen at Emory University  
The Larry & Tona Show  
Loeys Dietz Syndrome Foundation  
Lynch Mother  
Lynch Syndrome International  
M-CM Network  
Martin, Blanck & Associates, LLC  
MLD Foundation  
Moebius Syndrome Foundation  
Molecular Biology Lab in the Biology  
Department at SWOSU  
National Ataxia Foundation  
National Gaucher Foundation, Inc.  
National MPS Society  
National Organization for Rare Disorders  
National Tay-Sachs & Allied Diseases  
Association  
National Niemann-Pick Disease Foundation  
Noah's Hope

NYS Institute for Basic Research in  
Developmental Disabilities  
O&O Alpan  
Organic Acidemia Association  
OU Physicians for Women's Health  
Pathway Genomics  
PCD Foundation  
Phelan-McDermid Syndrome Foundation  
Project DOCC  
Purine Research Society  
PXE International  
RASopathies Network USA  
RetireSafe  
The School of Theoretical Modeling  
Sequrity.org  
Society for Women's Health Research  
Spina Bifida Resource  
St John Providence Health System  
Standard Medical Systems, LLC  
Statewide Parent Advocacy Network  
Sudden Arrhythmia Death Syndromes  
(SADS) Foundation  
Therapeutic Resources, Inc  
Tufts Medical Center  
University of Oklahoma Master's in Genetic  
Counseling Program  
University of Michigan Health Care System  
Wilson Disease Association  
Yale Cancer Genetic Counseling  
22q Nation