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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