

National Tay-Sachs & Allied Diseases Association, Inc. (NTSAD)
2001 Beacon Street, Suite 204
Boston, MA 02135
RE: FDA docket number 2006D-0347 comments

National Tay-Sachs & Allied Diseases Association, Inc. (NTSAD) is dedicated to the treatment and prevention of Tay-Sachs, Canavan and all the lysosomal storage diseases and leukodystrophies, and to provide information and support services to individuals and families affected by these diseases, as well as the public at-large. The strategies for achieving these goals include public and professional education, research, genetic screening, family services and advocacy.

NTSAD is very concerned by the FDA's Draft Guidance for Industry, Clinical Laboratories, and FDA Staff: In Vitro Diagnostic Multivariate Index Assays (IVDMIA) for the following reasons:

- It lacks specificity. The FDA established requirements for IVDMIA are broad definitions that fail to clearly identify which tests are subject to this regulation.
- The guidelines do not specifically name the problems it intends to address.
- A much simpler solution is a genetics specialty under CLIA that would alleviate much of the perceived risk.
- It appears to interfere with the practice of medicine, since a laboratory physician reports to an ordering physician at this time. If the guidance were enacted, this would change which would likely lead to delays receiving lab results that could ultimately lead to disease exacerbation and extensive emotional turmoil for expectant carrier couples.
 - Certain anti-psychotic medications are known to worsen neurological symptoms of Late Onset Tay-Sachs.
 - Carrier couple parents already often must wait weeks into the 2nd trimester for results; any delay could lead to the abortion of a wanted pregnancy well into the 2nd trimester.
- If this guidance is enforced, important medical tests may become unavailable, be frozen in their current state, become more expensive, or potentially lose insurance coverage.
 - There is no treatment or cure for Tay-Sachs and other lysosomal storage diseases and related leukodystrophies affecting the central nervous system. The only 'cure' is prevention which is only possible through carrier testing of high risk ethnic groups and prenatal testing. Without these vital tests the number of newly diagnosed Tay-Sachs children would significantly increase.
- The current guidance does not provide a transition "grace" period or grandfather clause for currently marketed tests to provide companies with time to adapt to a new regulatory environment. A two to four year grace period would allow industry to transition current services through the new regulatory environment.