Comments to the Food and Drug Administration (FDA) in response to their Draft Guidance on in vitro diagnostic multivariate index assays (IVDMIAs)

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Comments represent the opinion of Genetic Alliance and the undersigned organizations and individuals:

Alliance established the Consumer Task Force on Genetic Testing in September 2006. It is comprised of nine advocates (listed below) who have experience in genetic testing from a variety of perspectives. This Task Force has raised the participation level of consumers to a high level, allowing the various systems that desperately need consumer input to benefit from the consumer perspective. The Task Force is also instrumental in educating other consumers to be active participants in education and policymaking for genetic testing. In many cases, thus far, this has allowed competing entities or concepts to be measured by what is at stake at the core of the issue. Novel solutions, more moderate discourse and new facets of the issues have emerged as a result.

We present here the views of many concerned individuals, members of more than 600 disease-specific genetic support groups, professionals, and other stakeholders. These individuals number more than 25 million individuals affected by more than 1000 diseases. We transform the leadership of the advocacy community, build capacity in advocacy organizations, and promote consumer-informed public policies.

After reviewing the guidances, we have concerns, both about the guidances and about some of the rhetoric around ASRs and IVDMIAs from all stakeholders.

As individuals and families affected by genetic diseases, and as advocates, we are deeply concerned that we have not struck the correct balance and we are currently engaged in an inadequate dialogue to serve the end users of ASRs and IVDMIAs. We begin with overarching comments and then turn to the guidance.

Specific comments on the In Vitro Diagnostic Multivariate Index Assays (IVDMIA)

* It lacks specificity.

* A genetics specialty under CLIA would alleviate much of the perceived risk, though the problems this guidance is meant to address are not clear in the guidance.

* 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.

* 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.

* 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.

Read the full text of the comments here.