

**Comments on the Guidances:
In Vitro Diagnostic Multivariate Index Assays (IVDMIA) Guidance**

Prepared by the Consumer Task Force on Genetic Testing

Convener: Sharon F. Terry, President & CEO, Genetic Alliance

Genetic 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.

Consumer Task Force on Genetic Testing

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Camron King	VHL Family Alliance
Andrea Williams	Children's Sickle Cell Foundation
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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 IVDMIA's 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 IVDMIA's. We begin with overarching comments and then turn to each of the guidances.

Overall

We believe that what is at stake and what truly matters to us as a community: availability, access, affordability, innovation and transparency are not served in this approach. This guidance fails to

adequately deal with this dynamic reality: In our community, a great deal is at stake and we need to get this right – right now.

Process

We first question process. FDA should regulate by rule-making, not by guidance. It is important that formal process be followed allowing for sufficient notice and comment periods. The comment period for the guidances, though extended, created an unrealistic timeline for highly complex and controversial areas of regulation. Advocacy groups could not adequately respond. We are certain that the aims of the FDA should be advances, and question unenforceable and nonbinding draft guidances as a mechanism to advance the FDA's aims. We are concerned that the FDA process could lead to litigation and artificial procedural delays. In addition, the recommendations in the guidances create a disjointed regulatory strategy between the FDA and CMS and others. There appears to be unintended consequences and/or potentially harmful effects from the enforcement of the draft guidances.

Who and What is Covered by the Guidance

The guidance is not specific enough – it needs to clearly define what is covered. In addition, it is not clear to what entities are under these guidances, and in fact it suggests that labs doing rare and esoteric testing are in fact manufacturers.

Services vs. Devices

It is not clear if the guidance reclassifies services as devices, and if so, if such a reclassification would work in practical terms. We also question if this is an overextension of the medical device safety act and its amendments into an arena that was never contemplated in the original intent of the regulations. At present, CLIA oversees process, and FDA product – are these guidances a departure from this?

Is this technology-based rather than risk-based in its approach?

The guidances appear to be technology based, rather than risk-based in its approach. Consumers are far more concerned about risk, than method of delivery (technology) and look forward to the coming innovation in this field. We wonder if there are any findings, violations or other apparent wrong-doing in the clinical marketplace motivating this technology approach, and if so, what is the nature of these findings that lead to this approach.

Getting up to speed and keeping pace with discovery and commercialization

We are always interested in keeping pace with both discovery and commercialization. We are concerned with the FDA's ability to share that interest. We have concerns about the FDA's focus, resources, staffing and training, experience in clinical laboratory operations, knowledge base in genetics/genomics/proteomics, and technological aptitudes.

Patient access to tests

Of primary concern to us is a patient's access to tests. We are concerned that the effect of these guidances may impeded a patient's access, prove costly to the patient, cause delays for commercial adaptation of tests, and be difficult to access in a timely manner.

We ask if the FDA is balancing access to powerful innovation with regulation that would improve clinical outcomes for patients? We also ask if the FDA is creating new processes that will facilitate the integration of new technologies into traditional markets?

Innovation in the information and technological renaissance in healthcare

We look forward to innovation in the information and technological renaissance in healthcare. The existing industrialized manufacturing regulatory model from the 19th century will not overlay well in a new era of information-based medicine. We want federal authorities to be looking forward in this new age. We stand at the tipping point for dramatic and powerful advances in our understanding and potential management of disease pathways. The regulatory paradigm can either promote or stymie innovation, access, affordability and transparency.

Potential Next Steps

We recommend FDA withdraw the draft guidances, and initiate a formal rule-making process. In addition, we request a formal public engagement initiative to be established by Secretary Leavitt. This initiative should apply to all Federal agencies involved in the establishment of a process that will deliver a regulatory pathway to enable 21st century healthcare.

Our Challenge to Every Entity Involved:

- Consider the issue not from your own perspective, but from the whole system's need - forget turf.
- Create methods for supporting innovation and access, transparency and accountability, that all support novel solutions for the men, women and children who depend on you to get it right, so that they may live in health and strength and comfort.
- Plan and execute action from "WHAT MATTERS FOR PATIENTS", and not only from the limited perspective of advocacy, research, regulation, laboratory, or industry.

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.