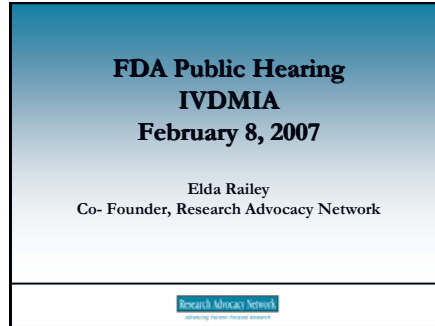


**Docket: 2006D-0347 - In Vitro Diagnostic Multivariate Index Assays;  
Public Meetings**

Elda Railey, Research Advocacy Network

1



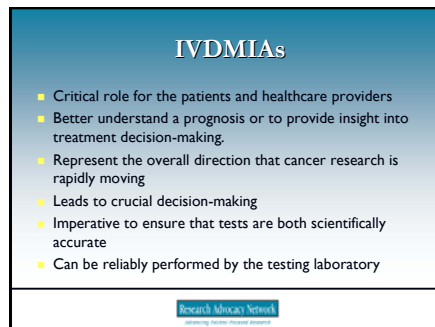
My name is Elda Railey. I am co-founder of the Research Advocacy Network.

2



At the Research Advocacy Network we are focused on de-mystifying the science behind cancer research and providing advocates with the tools they need to participate effectively in the research process, in an effort to ensure the inclusion of the patient perspective as clinical trials are designed and conducted, and as new diagnostics and therapeutics are developed.

3

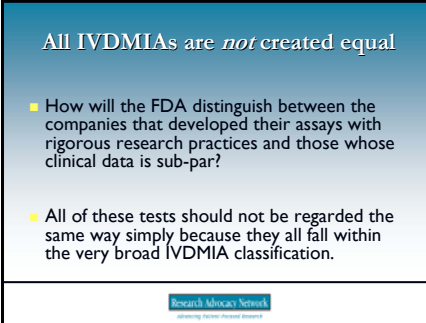


As advocates, we believe that IVDMIA's play a critical role for the patients and

healthcare providers who use them to better understand a prognosis or to provide insight into treatment decision-making. In addition, these tests and this field of genetic and genomic research also represent the overall direction that cancer research is rapidly moving, holding the promise of earlier diagnoses, more effective treatments, and better patient outcomes.

However, we also acknowledge that because the information provided by these assays leads to crucial decision-making on the part of the patient and the physician, it is imperative to ensure that genetic and genomic tests are both scientifically accurate and can be reliably performed by the testing laboratory. We recognize that there is a very fine balance to be achieved, protecting patient safety while still enabling patient access and promoting scientific innovation.

4



All IVDMIA's are *not* created equal

- How will the FDA distinguish between the companies that developed their assays with rigorous research practices and those whose clinical data is sub-par?
- All of these tests should not be regarded the same way simply because they all fall within the very broad IVDMIA classification.

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It is from this perspective, then, that we ask the Agency to address the following issues and questions as it considers how to effectively provide oversight of IVDMIA's. Because all IVDMIA's are *not* created equal, it does not make sense for all of these tests to be regarded the same way simply because they all fall within the very broad IVDMIA classification. There could be a significant difference in the quality of the science being conducted by the individual companies who develop and manufacture these tests.

How will the FDA distinguish between the companies that developed their assays with rigorous research practices and those whose clinical data is sub-par?

5

### Scientific Evidence

- What standard will FDA use to determine the sufficiency of a company's scientific evidence?
- When has a company fulfilled its research obligations with regard to demonstrating the clinical accuracy and validity of its test?
- Will companies that have validated tests be required to re-do clinical studies under new regulations?

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- What standard will FDA use to determine the sufficiency of a company's scientific evidence? When has a company fulfilled its research obligations with regard to demonstrating the clinical accuracy and validity of its test?

We feel that some of the IVDMA developers have already provided a breadth of clinical data attesting to the scientific utility of their assays, despite the lack of FDA regulation in the past. Will these companies be forced to go back and re-do their clinical studies under this new regulation?

6

### All IVDMIAs are *not* created equal

- Could be a significant difference in the quality of the science by the individual companies who develop and manufacture these tests.
- Will the FDA allow patients to continue to have access to those tests that are already scientifically validated and readily available to patients throughout these changes to the regulatory process?

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Since some of these assays are already scientifically validated and are readily available to patients, does the FDA plan to allow patients to continue to have access to those tests throughout these changes to the regulatory process?

We believe that it is important for these tests to be "grandfathered in" to any new regulatory policy, providing that adequate clinical data exists to demonstrate a test's scientific validity. Otherwise patients and healthcare providers who have come to rely on these tests will lose out on the important information that they provide.

**Complex Issues**

- Much at stake
- Proceed carefully
- Remain mindful of the community's perspective

*Thank You!*

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These are just a few of the complex issues our organization would like addressed through the draft guidance issued by the FDA. As the science of genetics and genomics advances rapidly, we anticipate that the Agency may be challenged to develop regulatory policies and procedures that keep pace with the research in this field. And as new policies and procedures are developed, we urge the FDA to create a clear, fair-balanced, and scientifically-informed process, so that new regulations are rational and truly support the best interest of patients.

Additionally, it is important that the FDA and the community come together to work out the details of new regulation in this arena. We all want the new science to move forward as long as it is safe and effective and results in better patient care. Increased costs and lengthened regulatory timelines should not stand in the way of potentially life-saving ideas and scientific concepts.

With so much at stake, we ask the Agency to proceed carefully and remain mindful of the community's perspective. Thank you for your consideration and this opportunity.