

## Patient Considerations Regarding the FDA's Draft Guidance on the Regulation and Oversight of Genetic and Genomic Tests

**Background:** The U.S. Food & Drug Administration (FDA) has recently developed draft guidance on the potential regulation and oversight of complex genetic and genomic tests, in an effort to ensure consistency and quality in the development of these diagnostic assays.

Currently, different genetic and genomic tests are available, and these tests have been designed to give healthcare providers a better understanding of the patient's condition by using complex genetic information to analyze the specific characteristics of that patient's cancer. For example, these tests might be used to diagnose cancer, or predict which treatments the cancer is most likely to respond to, or provide insight into the patient's prognosis. With this information, the patient and physician can then work together to come up with the most appropriate treatment plan based on the genetic and genomic make-up of the individual's cancer. The tests being scrutinized by the FDA are important because in addition to the critical role that they play for the patients who use them, they also represent the direction that cancer research is moving.

However, since the information provided by these tests 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. This is not a new concept to the cancer community, since questions about the accuracy of HER2 testing have swirled around the two assays commonly used to test for HER2 overexpression, leading patients and advocates to question the reliability of these two tests and to wonder whether one is clinically superior to the other.

Because this is a multifaceted issue relating to complicated regulatory policy, it is especially essential for the patient community to understand the implications of this draft guidance. Additionally, it is important for patients and advocates to consider participating in the public comment period, so that the patient perspective is reflected in any changes to the regulation of these tests.

To help de-mystify the issue, here are some key points and concerns that the patient community can take into consideration to better understand the potential impact of the FDA's draft guidance:

- Currently, the complex genetic and genomic assays that the FDA may decide to regulate are classified as laboratory services – not medical devices or therapeutics – which are typically performed by a single company. However, the draft guidance re-classifies these laboratory services as medical devices, and the agency is asserting its right to regulate the tests based on that re-classification.
- Historically, the FDA has only been charged with the regulation of *products* such as devices and therapies, and not with the regulation of *processes*, such as laboratory testing. The five page draft guidance does not currently provide any insight or specific details into how the agency plans to regulate laboratories and these tests, now that they have been re-classified as medical devices.
- Since this draft guidance took many in the community by surprise, it would be helpful to know what prompted the FDA to issue it. Has the agency discovered problems with any specific tests? Is the FDA concerned about its ability to replicate these tests without having access to the proprietary algorithms that the companies have used to develop these assays?

- While it is imperative for the FDA to protect patient safety by ensuring that these tests are backed up by rigorous clinical data and high-quality science, there is a fine balance between patient protection and impeding the development of these assays, which could ultimately limit patient access to them and undermine the promise of genetic and genomic research.
- As new policies and procedures are developed, it is crucial that the FDA follow a clear, fair-balanced, and scientifically-informed process, so that new regulations are rational and in the best interest of patients.
- 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?
- Because 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 those with rigorous research practices and those with sub-par clinical data?
- Because the science of genetics and genomics is advancing so rapidly, how will the FDA develop regulatory policies and procedures that keep pace with the research in this field?
- How does the agency plan to address the negative impact that new regulatory procedures could have on the patient community, as fewer diagnostic tests are developed due to increased costs and lengthened regulatory timelines? If innovation is hindered, it is impossible to estimate the number of potentially life-saving ideas and scientific concepts that will be abandoned by companies who can no longer afford to invest in that research.
- After the public comment period closes, it will important for the community to continue to monitor the issue to ensure that the FDA incorporates the comments of patients and advocates in the development and implementation of its new policies and procedures. The agency should be held accountable to demonstrate to the community how it has integrated feedback from patients and advocates into the new regulations.

Advocates can read the five page draft guidance online at <http://www.fda.gov/cdrh/oivd/guidance/1610.html> . Comments can be submitted by mail to the Division of Dockets Management (HFA-305), Food & Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. Alternatively, electronic comments can be submitted to [http://www.accessdata.fda.gov/scripts/oc/dockets/comments/commentsmain.cfm?EC\\_DOCUMENT\\_ID=1215&SUBTYP=NEXT&CID=&AGENCY=FDA](http://www.accessdata.fda.gov/scripts/oc/dockets/comments/commentsmain.cfm?EC_DOCUMENT_ID=1215&SUBTYP=NEXT&CID=&AGENCY=FDA). **Public comments must be submitted by December 6, 2006 and should include the docket reference number 2006D-0347.**



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