Archived Policy Statement

FDA Transparency Task Force Meeting

Written Public Testimony
Kristi Zonno, MS, CGC, Director of Genetics and Health Policy, Genetic Alliance
For release on delivery, expected:
June 24, 2009

Good morning. Thanks for the opportunity to comment publicly on how the FDA can increase transparency in information, activities, and decisions.

I am providing comments today on behalf of Genetic Alliance. We are a network of thousands of health-related organizations, including 1,000 groups dedicated to specific diseases. We bring together parent and family groups, community organizations, professional societies, corporations, and government agencies to create novel partnerships in advocacy; integrate individual, family, and community perspectives to improve health systems; and revolutionize access to information to enable translation of research into services and individualized decision-making. We have four specific recommendations for you today.

Genetics transforms how we understand human health. Dramatic advances in understanding the causes of diseases have occurred, spurred on by the powerful datasets, open data access, and new technologies arising from the Human Genome Project. Both bold and focused, the Human Genome Project gave us much more than the sequence of our genome; it established a robust foundation to learn about the genetic basis of disease and gave us the promise of developing life-saving tests and treatments. Further, it modeled the power of transparency of data and the paradigm changes that it causes. Integrating genetic information into health management requires proactive and informed decision-making, and access to reliable information is instrumental to this process.

Creation of a public registry for genetic tests will enable transparency and promote informed decision-making for consumers and providers. I know this firsthand because prior to my work with Genetic Alliance, I worked in the clinical setting as a genetic counselor and in public health, and I have navigated the complexities of the genetic testing system with patients and providers. A registry of genetic tests would greatly serve consumers, patients and families, and their healthcare providers as they seek understanding through genetic testing to answer questions such as:

- What is the diagnosis or prognosis?
- What is the risk of developing a condition?
- What is the risk of having a child with a specific condition?
- What is the optimal treatment?
- What is the predicted benefit of a specific intervention?

These are big questions. The answers to many of these questions can be life-altering, and important decisions flow from their answers. So, how can one seek truly informed answers to these questions without having access to accurate, reliable, and key information about tests and laboratories performing tests and understanding what their options are?

But it is not just about patients and providers; a registry will benefit all stakeholders, including researchers, industry, payors, and especially the federal agencies who are tasked to oversee some piece of the genetic testing system. Otherwise, how can we assure patients of oversight when we don't even know what tests are out there, where they are being done, and the performance characteristics of those tests?

A public laboratory test registry could and should include the myriad genetic, genomic, and pharmacogenomic testing available to the U.S. market. At a minimum, the publicly-accessible registry should include the name of the laboratory performing a specific test, the name of the laboratory or company that developed the test, and information to support claims about how useful the test is in obtaining correct results and improving clinical care. This will in turn strengthen oversight of clinical laboratory quality, currently tasked to the Centers for Medicare and Medicaid Services (CMS), to make sure that the information provided by genetic and other advanced diagnostic tests is accurate, reliable, and timely.

In developing the registry, we have a huge potential and grand opportunity in front of us. If this is done as a collaborative process across all health-related agencies that have a tie to genetics and includes input from all stakeholders in the genetic testing system, we can make this a forward-looking, forward-thinking, comprehensive product that has roles related to oversight, ensuring quality, providing education, and serving as a gateway to information in services for those considering testing and in follow-up to testing when results are delivered to patients and providers to answer those important questions I previously mentioned. The registry should be overseen by the FDA and be housed at the National Center for Biotechnology Information to allow integration with all of the other genetic resources in the nation.

In addition to the registry, and moving from genetics and genomics, we urge you to define and apply transparency consistently across the various divisions of the FDA. A key to transparency is providing information via your website, which is the major interface with the public, including consumers. As part of transparency, appropriate resources should be allocated to information management and improvement of the FDA website. Information must be disclosed and available to the public in a timely manner. Therefore, in addition to transparency through a mandatory registry of genetic tests, we suggest additional mechanisms to promote transparency:

Immediate release of any and all FDA warning letters, including all untitled letters, are issued to industry but not consistently (or always) available to the public. Patients and physicians should know who is getting letters from the FDA and why, and this information should be available in real time.

As public meetings are a mechanism for stakeholder engagement, information from public meetings should be archived and maintained so that it is easily accessible to the public.

Finally, when citizen's petitions are filed, we ask that they are made public and posted on the FDA website, in a manner that is easily accessible to the public. Any responses or actions should be clearly evident.

In closing, Genetic Alliance, working together with the Coalition for 21st Century Medicine, Genetics and Public Policy Center, and various professional societies, has concerns about the transparency of the FDA and is grateful for your work. We are committed to better health for all Americans, and we welcome the opportunity to work with the FDA and other health-related agencies to make this happen.