



Archived Policy Statement

Comments to the Food and Drug Administration (FDA)

Comments to the Food and Drug Administration (FDA) On *Direct-to-Consumer Marketing of Genetic Tests*

November 2, 2005

On behalf of Genetic Alliance—an international coalition comprised of more than 600 advocacy, research, and healthcare organizations that represent more than 14 million individuals with genetic conditions and their interests—I want to thank you for the opportunity to address this panel.

As you examine the issues surrounding direct-to-consumer promotion of regulated medical products, it is vital that you consider the perspectives of all of the different stakeholders. Because our members represent individuals with genetic conditions, many of them rare genetic conditions, our concerns related to direct-to-consumer marketing focus primarily on genetic tests.

Specifically, two related, but distinctly different, areas of concern are:

- The current state of regulatory oversight of genetic tests. Are the tests safe and accurate, and are there gaps in the regulatory process?
- The potential for irresponsible or misleading promotion of genetic tests. Do the tests do what the advertisements say they do? Do consumers have enough information to make informed decisions about tests?

As a representative of a community of people concerned about safety, accuracy, and accessibility of genetic tests, I can say that the current state of regulation of genetic tests poses a significant problem. **At present, the oversight mechanisms associated with genetic tests have gaps, a fact that makes direct-to-consumer marketing of these tests a serious concern.** That is, the marketing of a test presents two discrete areas of concern: the claims made in an advertisement and the validity and utility of the test itself.

Currently, more than 1,000 genetic tests are available; but, only a handful—packaged as test kits—are regulated by the Food and Drug Administration. As a result, the vast majority of genetic tests available are only regulated by the oversight of the laboratory under the Clinical Laboratory Improvement Amendments (CLIA) of 1988. Under CLIA, laboratories are held to certain standards, based on the complexity of the test performed. In this, the Genomic Age,

more rigorous regulation, performed by either the FDA or via CLIA, or some complement of both, is necessary. However, to ensure that nothing falls through the cracks, a coordinated effort across agencies would be ideal.

That said, an onerous system of regulation for genetic tests, one that discourages testing, is also unacceptable. Just as important to our organization and its members as safety and accuracy is the accessibility of genetic tests. Overregulation—and the implications that follow—would likely make genetic tests, specifically those for rare genetic conditions, inaccessible to most individuals and their families. This is an equally problematic outcome, one that must not be ignored or underestimated. The safety and accuracy of testing is essentially irrelevant if the tests are not accessible to the individuals who need them.

Once genetic tests have received the regulatory attention they require, direct-to-consumer marketing of those tests, with appropriate information and support, could be acceptable for some tests. As science continues to move forward and as more and more genetic tests become available, access to these tests may be the key to improved health outcomes. However, it is irresponsible simply to offer genetic tests to the public with no validation and without context or explanation. Genetic tests often offer predictive information and information about the health of both individuals and their families. Like many other medical tests and procedures, this information can be confusing and intimidating if not appropriately translated by a healthcare professional. As such, genetic tests offered directly to consumers should include opportunities for genetic counseling, opportunities that provide an individual with all the information needed to make the most appropriate decisions about his/her own healthcare and the healthcare of his/her family.

On behalf of Genetic Alliance, I urge this panel to address both concerns: concerns about the adequacy of oversight and concerns regarding the potential for irresponsible direct-to-consumer marketing and sale of those tests. Genetic tests should be accessible to consumers in a form that is safe, reliable, and accurate. But, above all else, they must be accessible. We must find a balance between regulation that accomplishes the desired goals—quality genetic tests that improve public health—and excessive regulation that places too onerous a burden on laboratories and limits the availability of tests.

Genetic Alliance has made the quality of genetic testing a priority for the upcoming year. We will be working with patient groups, industry members, policy organizations, and government officials to craft sensible solutions to ensure quality tests that are accessible. We look forward to working with you.

Thank you.

Sharon F. Terry, President & CEO, Genetic Alliance