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NEWS RELEASES

[American Society of Human Genetics releases policy statement on direct-to-consumer genetic testing](#)

August 15, 2007 - A newly-released American Society of Human Genetics (ASHG) statement on direct-to-consumer (DTC) genetic testing in the United States cites “risks that consumers will choose testing without adequate context or counseling, will receive tests from laboratories of dubious quality, and will be misled by unproven claims of benefit.” After making a case that DTC genetic tests can jeopardize consumers’ health, privacy, and money, the statement recommends ways in which laboratories, professional societies, and federal agencies should work to ensure the tests’ safety and efficacy.

The statement’s authors, including Kathy Hudson and Gail Javitt of the Genetics and Public Policy Center, describe ways in which fragmentary regulation falls short in the case of DTC genetic tests – indeed, for genetic tests generally. There is little to prevent tests from entering the marketplace that may lack analytic validity (the laboratory does not reliably report the correct results), clinical validity (the results do not have a well-established tie to a health outcome), or that are marketed with misleading claims. “[Q]uality concerns are particularly acute in the DTC context because of the low barrier to market entry, the complexity of the information that consumers need to understand in order to make an informed decision, and the lack of provider scrutiny,” the authors warn.

The statement defines DTC genetic tests as those for which “consumers order tests and receive test results without an independent provider serving as an intermediary.” These tests are typically ordered through the Internet, they note, and “may be used to diagnose disease, to predict risk of future disease, to determine the risk of passing on a disease to one’s offspring, to aid in therapy selection, or to guide ‘lifestyle’ choices such as diet and skincare.”

To mitigate DTC testing’s risks, the statement makes three broad recommendations:

- **Transparency:** “To promote transparency and permit providers and consumers to make informed decisions about DTC genetic testing, companies must provide all relevant information about offered tests in a readily accessible and understandable manner.”
- **Provider Education:** “To ensure that providers are aware that genetic tests are being provided DTC and that some of these tests may lack analytic or clinical validity, professional organizations should educate their members regarding the types of genetic tests offered DTC so that providers can counsel their patients about the potential value and limitations of DTC testing.”
- **Test and Laboratory Quality:** “To ensure the analytic and clinical validity of genetic tests offered DTC and to ensure that claims made about these tests are truthful and not misleading, the relevant agencies of the federal government should take appropriate and targeted regulatory action.”

Recommended regulatory actions include creating a genetic testing specialty under the Clinical Laboratories Improvement Amendments of 1988 (CLIA). The Center has repeatedly called for the creation of such a specialty, which would establish appropriate and specific guidelines for genetic testing laboratories, bringing standards in this field into line with those governing other high-complexity laboratory tests. – *Shawna Williams*

[Full statement, including the details of each of the recommendations](#)

[Report - "Public Health at Risk: Failures in Oversight of Genetic Testing Laboratories"](#)

[Issue brief - "Direct-to-consumer genetic testing: empowering or endangering the public?"](#)

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