

Regulation of genetic tests

[30 April 2008](#) | By Dr Sowmiya Moorthie and Dr Caroline Wright | **News story**

In recent weeks, the [health department](#) of New York State has issued letters warning companies which offer direct-to-consumer tests that they require a permit in order to carry out gene scans ([see news source](#)). Public health law in New York State prohibits clinical laboratories from providing direct-to-consumer tests without the intervention of a medical professional, unless the tests have been approved by the [FDA](#) for direct, over-the-counter sale to consumers (see [guidance on Direct Access Testing](#)). In California, health regulators are investigating companies that offer genetic tests without the presence of a physician ([see news source](#)). The need for an adequate framework to regulate genetic tests and companies that offer them direct-to-consumer is becoming an increasingly important issue.

A number of US organisations have called for policies to regulate genetic tests, especially those that are available direct-to-consumer. The [American College of Medical Genetics](#) has released a [policy statement](#) outlining five minimum requirements for genetic testing protocols. This follows a [statement on direct-to-consumer genetic testing](#) released by the [American Society for Human Genetics](#) containing similar recommendations, and a report from the [UK Human Genetics Commission](#) on the availability, marketing and regulation of genetic tests supplied directly to the public ([see previous news story](#)), both published in December 2007. The US [Genetics and Public Policy Center](#) has also recently called for tighter regulation of genetic tests in an [article](#) published in [Science](#) (see [press release](#)).

These organisations call for greater transparency in the evidence in support of genetic tests so that physicians and the public can make an informed choice. They also recommend health professionals to be involved in ordering and interpreting tests and a greater oversight of laboratories and companies that provide them.

Keywords: [Genetic Tests](#), [Testing & Screening](#), [Legal Issues](#), [Regulatory Framework](#)

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Company Number: 5823194, Charity Number: 1118664

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