

Consumers need protection from unrealistic claims of home genetic tests, new report states

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This is James P. Evans, M.D., Ph.D., from the University of North Carolina at Chapel Hill School of Medicine. Credit: UNC Medical Center News Office

Direct to consumer (DTC) genetic tests are increasingly being marketed to the public via television, print ads, and the Internet. These home genetic tests provide access to a person's genomic information without necessarily involving a doctor or insurance company in the process.

Writing in the August 18, 2010 Online First edition of the [New England Journal of Medicine](#), medical geneticist James P. Evans, MD, PhD from the University of North Carolina at Chapel Hill School of Medicine and the UNC Lineberger Comprehensive Cancer Center, and co-authors

David C. Dale, MD from the University of Washington, and Cathy Fomous, PhD from the National Institutes of Health, state that medical professionals "must ensure that rapidly evolving and multiplying genomic technologies are responsibly harnessed and that their promise is not oversold to the public."

In their article, "Preparing for a Consumer-Driven Genomic Age," the authors argue that "a primary role of health care professionals in the future may be to interpret their patients' DTC genetic test results and advise them about appropriate follow-up."

While the authors acknowledge that individuals should continue to be permitted direct access to their genomic information, they note that "consumers must be protected from unrealistic claims and the misinterpretation of complex and dynamic genomic information."

Noting that segments of the public already embrace DTC genetic tests, the authors point out that in many cases, there is "little or no evidence of the clinical validity of tests developed from genetic technologies." The authors state that clinical validity data "are limited because they can be difficult and expensive to obtain and because there is no FDA requirement for the premarketing submission of such data for most genetic tests."

In testimony last month to the House Energy and Commerce Subcommittee on Oversight and Investigations, Evans stressed that consumers "...deserve an honest accounting of what such information means and the assurance that it is derived in a manner that ensures quality, reliability and confidentiality."

Provided by University of North Carolina School of Medicine

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