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Guidelines Suggested for Direct-to- Consumer Gene Tests

By Michael Smith, North American Correspondent, MedPage Today
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Reviewed by Zalman S. Agus, MD; Emeritus Professor
University of Pennsylvania School of Medicine.

BETHESDA, Md., April 25 -- The American College of Medical Genetics has issued a four-point set of what it called "minimum requirements" for genetic testing aimed at consumers, a growing field.

The first, and most important, point is that a healthcare professional should be involved in ordering and interpreting a genetic test, said Michael Watson, Ph.D., the college's executive director.

"Consumers need to be cautious and always involve their healthcare provider, and in some cases a medical geneticist or genetic counselor, in their decisions about genetic testing," Dr. Watson said.

Such tests, combined with counseling and treatments, "offer tremendous possibilities for the future of healthcare," he said, "but as in any new and changing field, there is a lot of misinformation out there and more research to be done."

"Just because a genetic test exists, it does not mean it is right for everyone or even right for anyone," Dr. Watson added.

The move by the college comes amid growing debate over direct-to-consumer marketing of these tests.

Last year, the American Society for Human Genetics adopted a policy on direct-to-consumer gene testing calling for improvements in corporate transparency, education of healthcare providers, and quality control. The policy was later reprinted by the American Society of Obstetricians and Gynecologists (See: Gene-Test Marketing Raises Public Health Fears).

And the issue has been recently highlighted by reports that companies are marketing some tests direct to consumers despite a lack of evidence that they have any benefit (See: SSRI-Sensitivity Gene Tests for Consumers Called 'Misleading').

In this most recent statement, the college said gene testing is "highly technical and complex" and involving a certified medical geneticist or genetic counselor can reduce the risk of lack of informed consent, inappropriate testing, misinterpretation of results, testing that is inaccurate or not clinically valid, lack of follow-up care, and misinformation.

In addition to professional involvement, the college urged that:

- Consumers should be fully informed about what the test can and cannot tell them. Many such tests do not give definitive answers, but only provide risk or probability estimates. Interpretation of the results "is often highly nuanced" and needs to be communicated in an understandable manner.
- The scientific evidence on which a test is based should be clearly stated.
- The testing laboratory must be properly accredited under the Clinical Laboratory Improvement Amendments of the Department of Health and Human Services, and by state and other agencies. Test reports to consumers should be specific about the lab's accreditation.
- Privacy concerns must be addressed. The consumer should be told who will have access to test results, what security protects results, what happens to DNA samples after testing, and how to complain about breaches of privacy.

Dr. Watson said the new guidelines replace an earlier policy that said only that doctors should be involved.

The increasing number of companies offering "personal genomics" direct to consumers led the college to amplify its position, he said.

"We're not saying these (tests) shouldn't be done," Dr. Watson said. "We want to help the physician community deal with them so they're done right -- or as right as they can be."

The guidelines are available on the College's Web site (www.acmg.net) or in the attached PDF.

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