ABSTRACT: Marketing of genetic testing, although similar to direct-to-consumer advertising of prescription drugs, raises additional concerns and considerations. These include issues of limited knowledge among patients and health care providers of available genetic tests, difficulty in interpretation of genetic testing results, lack of federal oversight of companies offering genetic testing, and issues of privacy and confidentiality. Until all of these considerations are addressed, direct or home genetic testing should be discouraged because of the potential harm of a misinterpreted or inaccurate result.

With the increase in the number of clinical genetic tests requested by health care providers, there has been an increase in direct-to-consumer advertising and offering of genetic tests, including at-home tests and those provided by private companies. Although similar to direct-to-consumer advertising of prescription drugs, marketing of genetic testing raises additional concerns and considerations. These include issues of limited knowledge among patients and health care providers of available genetic tests, difficulty in interpretation of genetic testing results, lack of federal oversight of companies offering genetic testing, and issues of privacy and confidentiality.

All genetic testing, including at-home tests, should be considered medical testing because results might have an impact on future medical care and clinical decision making. Although some tests have been marketed as nonmedical, such as paternity testing and early fetal sex prediction from maternal blood, these also should be considered medical tests. Decisions based on these results regarding a pregnancy may cause a patient to seek further medical treatment or intervention.

Despite the clear limitations of direct-to-consumer genetic testing, women still use the service. Physicians should acknowledge that one factor that might contribute to this trend is the belief among some patients that adequate privacy safeguards do not exist when genetic testing is performed in the office. Physicians should use mechanisms in their practice environment that would provide the reassurance that women seek when being tested for gene mutations associated with disease.

Some companies offering direct-to-consumer testing promote the increased privacy of a direct test in their marketing efforts. However, patients are not made aware that failure to indicate results of genetic testing in life insurance or disability applications could be considered fraud. In addition, many laboratories have not indicated their policies on what is done with the DNA sample after analysis. To ensure privacy, DNA samples should be destroyed after the requested test is performed. Those overseeing procedures for testing should continue to work to address patient privacy concerns.

The U.S. Federal Trade Commission, U.S. Food and Drug Administration, and the Centers for Disease Control and Prevention have issued a public message about at-home genetic tests. They advise consumers to be skeptical of the claims of the tests that are offered. Many tests may be of questionable value. The agencies also advise talking to a health care practitioner or genetic counselor before and after testing to help ensure understanding of what the test offers and what the results of testing reveal. In addition, they point out that unlike other home-use medical tests, the U.S. Food and Drug Administration has not reviewed any of the at-home genetic tests. Because of this, the validity and accuracy of many of these tests are unknown.
All genetic testing should be provided only after consultation with a qualified health care professional. For complex testing, this may involve referral to a genetic counselor or a medical geneticist. Appropriate pretest and posttest counseling should be provided, including a discussion of the risks, benefits, and limitations of the testing. It must be recognized that direct-to-consumer genetic testing will create downstream needs for counseling, support, and care for those identified as carriers of genes associated with undesired medical conditions. In many locales, the current health care system is not sufficient to meet those needs. Although some companies offer genetic counseling, concerns have been raised regarding a potential conflict of interest when the company providing the testing employs the genetic counselor because a company advertising directly to consumers may receive no compensation for counseling alone and is compensated only if the test is ordered by the consumer.

Until all of these considerations are addressed, direct and home genetic testing should be discouraged because of the potential harm of a misinterpreted or inaccurate result.

Resources


