The recent marketing of “at home” genomic tests for disease risk may be premature, according to Dr. Kenneth Offit, MD, MPH, Chief of the Clinical Genetics Service at Memorial Sloan Kettering Cancer Center (MSKCC). “Health professionals are now faced with the prospect of their patients coming to the office, a DNA profile in hand, asking for preventative management tailored to their specific disease risks,” Dr. Offit writes in the March 19 special genomics issue of the *Journal of the American Medical Association (JAMA)*. [PubMed Abstract]

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Kenneth Offit, MD, MPH, Chief, Clinical Genetics Service

In recent years, more than two dozen companies have been marketing a range of genetic tests directly to consumers concerned about genetic conditions. These conditions include those related to risks for disease, other genetic traits, and ancestry. Some of these companies have marketed "whole genome scans," which provide assessments of risk for various health conditions ranging from the type of earwax an individual forms to his or her risks for diseases including cancer, diabetes, and blindness.

In his *JAMA* commentary, Dr Offit offers several caveats and recommendations to help doctors and counselors as they consider offering these research-based tests in clinical practice. Dr Offit voices concerns about the scientific accuracy of some of these tests, because "they have not yet been validated in forward looking (prospective) clinical studies." In addition, he writes, the laboratory accuracy of these tests may vary.

A second concern voiced in the commentary is the "direct to consumer" aspect of the marketing of these tests, which excludes guidance from healthcare professionals. According to Dr. Offit, this limits the sources of information available to consumers about these tests and their accuracy from those marketing the tests. "This critical lack of information," he says, "raises concerns that patients/individuals may not have the resources to make unbiased decisions regarding whether to proceed with genetic testing."

Dr. Offit also expresses apprehension that once these self ordered test results are relayed, individuals receiving the results may not also receive counseling regarding appropriate medical interventions for prevention and early detection of genetic disorders. The article reminds readers that certain state health departments, New York's for instance, have indicated that genetic testing for disease risk must be requested by a licensed healthcare professional and must be performed in an approved clinical laboratory.

Dr. Offit points to recent academic and governmental reports that suggest that greater regulation is required to oversee the accuracy and quality of "direct to consumer" genetic testing. As one of the leaders of the clinical introduction of genetic testing for breast and colon cancer over the past decade, Dr. Offit argues for the cautious introduction of new "whole genome" testing, preferably in the setting of ongoing clinical trials. "Those of us in the field of genetic testing for cancer risk proceeded cautiously…The same approach should be followed for genomic testing for other disease risks" he says. "Not doing so runs the risk of dangerously reassuring some and needlessly worrying the already worried well."