This Program Brought to You By …

The American consumer seems to be growing weary of TV ads for erectile dysfunction drugs, and even the jokes on late night TV seem stale. Yet the advertisements haven't gone away. Not a surprise; they sell product, and not infrequently to individuals who really don't need the medications. Get ready for a new round of discussions regarding advertisements with your patients: DTC marketing has entered the genomic age.

Most of us are equipped to deal with patient questions regarding the latest "purple pill" they heard about during the advertisement on the big game last Saturday. Are we, though, ready to answer questions about nutrigenetics, DNA-based chronic disease susceptibility testing, or whole genome scans? Unlike medications, patients can access most of these tests without a physician's order. Direct to consumer marketing of genetic testing is not only legal, but is essentially unregulated in the sense that there is no requirement that a test be shown to have any clinical utility (Does the test do any good for the patient - and/or society?) before it is marketed. Further, many tests are offered without even the benefit of oversight by Medicare's Clinical Laboratory Improvement Amendments (CLIA) program, which brings even the tests' analytic validity (Does the test reproducibly measure what it claims to measure?) into question. Where FDA or Medicare rules exist, enforcement has been inconsistent. Recently the FDA has ventured into the arena of genetic testing with draft guidance for complicated genetic tests that include internal interpretation mechanisms – so-called 'In Vitro Diagnostic Multivariate Index Assays (IVDMIAs).' However, much controversy remains over which tests are covered, and in what setting (especially regarding 'home-brew' tests developed by a hospital laboratory, for example). The bottom line for the consumer and health care provider: *caveat emptor*.

How bad can this be? In 2006 the Government Accountability Office (GAO) a federal watchdog for fraud and abuse examined the field of nutrigenetic testing – basically the idea that genetic testing can be used to select a diet that will allow you to live to be 1,000 without need for Botox. What did the GAO find?

> "The results from all the tests GAO purchased mislead consumers by making predictions that are medically unproven and so ambiguous that they do not provide meaningful information to consumers."

Clearly not a ringing endorsement of the field of nutrigentic testing. Most of us, even without being savvy to genetics, would have recognized this stuff as snake oil. Someday such nutrigenetic testing may actually be scientifically valid and clinically useful, but someday is not today.

The distinctions are not always that clear. Many of us are familiar with recent consumer-directed campaigns directed at testing for hereditary breast and ovarian cancer syndrome. Good or bad? It's hard to tell. Certainly heightened awareness of this serious disorder is of value, but is it driving demand for unneeded (and expensive) testing?

2007 has seen a bounty of new genomic discoveries regarding the genetics of common disease. For reputable testing companies these discoveries make for extremely tempting product development opportunities; tests that might just sell themselves to lots (and lots) of people. One can imagine the internal debate at a testing company: "Who wouldn't want to know their risk of developing diabetes based on their genes? How many people are out there who might benefit from the test? What, you say just about everyone?" It will come as no great shock that genetic testing for diabetes predisposition has arrived on the market – as have genetic tests for the predisposition to several other common complex diseases. Do we know how these tests perform prospectively? Do we know if they are appropriate in all populations? Do we know if the knowledge from testing makes people healthier or saves healthcare dollars? Not yet. To paraphrase someone far wiser than I: "We need to be able to distinguish what we know from what makes sense." Certainly this is true for all of medicine, but poorly thought out use of genetic testing will be expensive and may have serious consequences for individuals and society.

Soon, marketing individual gene tests for susceptibility to chronic disease will be old news. Large and well-funded companies are releasing plans to market "whole genome scans," complete with an interpretation of what the scan means. This amounts to direct to consumer marketing of the genetic equivalent of a full body CT scan. Even the genetics community is having difficulty coming to grips with what this will mean. Undoubtedly, some of our patients will undergo this type of testing, and we will likely be asked to help them make sense of the results. I encourage you do to some research on these topics (you can start at www.genome.gov) before being confronted by a patient, as the answers won't be easy. This is a new frontier for everyone.