Current Perspective

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Direct-to-Consumer Advertising in the Molecular Era

In late August, I received an email from 23andMe announcing "exciting news." It read, "The Food and Drug Administration allows marketing of first direct-to-consumer tests that provide genetic risk information for certain conditions." The email went on with lengthy and carefully written disclaimers. One of these stated, "23andMe does not provide medical advice." It encourages consumers to talk with a physician or genetic counselor about the results.

Remember Super Bowl XXXVIII? It is famous not only for the Janet Jackson wardrobe malfunction but also for the first direct-to-consumer (DTC) marketing of an erectile dysfunction drug. Considering that the average Super Bowl ad that year was about $2.3 million, going DTC was not an inconsequential decision!

DTC marketing took another leap on Nov. 22, 2007, when viewers of the Dallas Cowboys–New York Jets game witnessed a commercial for a drug-eluting stent to be used with coronary angioplasty. As I watched, I thought, "Really? In the midst of a heart attack someone's going to say, 'Excuse me. I want the stent advertised during the Jets game.' Come on!"

DTC advertising of medical devices, sophisticated niche pharmaceuticals, and diagnostic testing services seem to be everywhere—but only in a few countries. In the United States, growth in DTC marketing has far outstripped growth in pharmaceutical research and development. In 2015, U.S. pharmaceutical companies are estimated to have spent nearly $5 billion on DTC television advertising. A study showed returns up to $2.50 for every $1.00 invested in DTC advertising.

No doubt there is a positive side to DTC drug and device marketing—disease awareness, public education, and increased medication adherence. On the negative side, we have stimulated unnecessary demand, consumer confusion, and economic costs. Notably, drugs and devices generally require physician prescription for use.

Consumer-initiated genetic testing heralds a new era: Physician involvement is not at the front end of the care process, deciding based on patient phenotype (family history, symptoms, signs, and diagnostic data) whether genotyping is indicated. It is at the back end. The patient has ordered the test and now is trying to make sense of the results.

How would you respond if you walk in your exam room and hear, "Doctor, I sent my spit to company X to see if I was at risk for disease Y, and the results show I may get glaucoma (or age-related macular degeneration or some other ophthalmic disease). What do you think? I'm worried."

How many of us would know if the right gene is tested, if the testing is clinically meaningful, if the laboratory is high quality, etc.? (Just last month, one laboratory had to retest 50,000 samples for incorrect reporting about a serious inherited disease.) It's a consumer purchase, and we are being asked to validate and explain its significance—perhaps a 1-hour process for a certified genetic counselor.

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You might say that this is an argument for enhanced training in ophthalmic genetics, one of the most fascinating, complex, and increasingly clinically relevant disciplines in our field. Is testing rendering ophthalmologists diagnostically less relevant? Absolutely not. Ed Stone and colleagues recently commented: "As genetic tests have become larger in scope and sensitivity, the need for exceptionally detailed and accurate clinical information also has increased."[1] Anthony Moore, in an accompanying editorial, stated explicitly, "…testing should be directed by clinical findings, and equally important, molecular genetic findings need to be carefully evaluated in the context of the clinical phenotype to avoid errors in molecular diagnosis."

The genie is out of the bottle. Consumers are becoming more engaged in their own disease management. Mailing bottled spit is easy and not dangerous. But accurately and appropriately dealing with the results will be difficult and may have dangerous consequences. As physicians, we must realize that no matter how many detailed educational resources the testing companies put on their websites, patients will ask, "Doctor, am I going to get this disease?"

1 Stone EM et al. *Ophthalmology*. 2017;124(9):1314-1331.