Direct-to-Consumer (DTC) Marketing of Genetic Testing: A New Frontier for Cancer Genetics

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Myriad Genetic Laboratories, Inc. (MGL), the sole laboratory performing hereditary breast and ovarian cancer testing (BRCA1 and BRCA2), launched its first major DTC marketing campaign in 2007, targeting Boston, Hartford, Providence and New York City*. The campaign primarily utilized television commercials and magazine advertisements. It targets women between the ages of 25 to 55 with any family history of breast and/or ovarian cancer, advising them to talk to their physician about genetic testing. The DTC campaign presents an opportunity to expand awareness about hereditary breast/ovarian cancer, and yet it can also be problematic. As MGL prepares to focus its DTC marketing efforts on Texas and Florida in September 2008, I examine the main concerns that cancer genetics professionals and others have documented.

DTC advertising of genetic tests has been documented to increase demand for testing, particularly among individuals who are not appropriate candidates for the test. To review, only ~10% of breast and ovarian cancers can be attributed to a hereditary cancer syndrome. Ideal candidates for BRCA testing include:

- Personal history of young breast cancer (<50 years) or ovarian cancer at any age, bilateral breast cancer, breast and ovarian cancer in the same individual AND/OR
- Maternal/paternal family history of 2 or more close relatives with breast/ovarian cancer, 1 or more close male relatives with breast cancer, early-onset breast/ovarian cancer in a close relative, or relative with confirmed BRCA mutation.

The main concern for many cancer genetics professionals is the possible elevated anxiety for the general population after seeing these advertisements, as it may lead to increased testing of low-risk individuals. In a recent article, Matloff and Caplan postulate that a significant increase in inappropriate referrals could incite insurers to tighten genetic testing criteria. If criteria become more exclusionary, it would be even more difficult for appropriate individuals to qualify for testing.

Another important issue regards the message conveyed to the general population within the advertisements. Since federal oversight of genetic tests and advertisements for genetic testing are limited, DTC advertisements can overemphasize the benefits of genetic testing while not adequately acknowledging the risks and limitations. Certain themes, like control, choice, fear and hope, are often utilized in purveying the message. This could intensify the lay-public’s anxiety and exploit the lack of understanding in regards to complex genetic information.

Some DTC advertisements of genetic testing encourage people to contact the commercial laboratory directly to learn more about testing, which can minimize the role of genetics professionals, oncology nurses and other clinicians. A significant concern is a private company providing the medical education in which they would profit if more testing is done. This could lead to lack of appropriate informed consent, result interpretation, education and support. Pre- and post-test genetic counseling has been recommended by several professional organizations (ASCO, ONS, SGO, NSGC, etc.), and it is a requirement of many insurance companies (Aetna, Blue Cross Blue Shield) in order to have testing covered for their clients. This counseling is integral in enabling a patient to understand the benefits, limitations, and cancer risk-reduction options associated with hereditary

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* Author's note: The campaign was initially targeting specific cities, but later expanded to other areas.
cancer and genetic testing. It is critical that oncology nurses are familiar with cancer genetic testing, as well as its benefits and limitations, in order to reduce confusion and anxiety for their patients and family members.

Although DTC offers the opportunity to raise awareness about cancer genetic testing, it is important that patients receive unbiased and balanced medical education from the nursing community. For example, when offering BRCA genetic testing, it is important to test a family member affected with breast or ovarian cancer first (if possible), since an affected individual has a higher empiric likelihood of carrying a mutation. If the affected patient has a genetic mutation, then presymptomatic testing for that single mutation can be done for other at-risk family members at considerably lower cost (comprehensive BRCA costs $3,120 vs. single-site cost of $385). This can determine which family members are at increased risk for cancer, as well as clarifying risk for those who are not at increased risk for cancer (which would be the case for those who do not carry the mutation). This information is not clearly conveyed in the DTC marketing campaign to the patients.

Many people are concerned about the possibility of genetic discrimination. Several states already had legislation in place to prohibit the use of genetic test results to deny insurance coverage or to prohibit employment. In May 2008, President Bush signed the Genetic Information Non-Discrimination Act (GINA). It provides patients with federal protection against genetic discrimination in regards to health insurance and employment; however, no state or federal laws exist regarding genetic discrimination and life or disability insurance at this time. This is important information that should be disclosed in pre-test genetic counseling.

DTC marketing of genetic testing is only one piece in the larger scope of DTC genetic testing. In the last several years, DTC genetic testing has become a lucrative business enterprise, enabling any person to send in a sample (typically saliva or buccal swab) for different types of genetic screening. Several of these companies have been discussed in the lay-press, including 23andMe Inc. and Navigenics Inc. These companies offer genomic scans, using polymorphisms (genetic markers) to help quantify risk for many health concerns, from back pain to breast cancer. They have also come under fire recently in the state of California. The California Department of Public Health sent cease-and-desist letters to 13 DTC genetic testing companies, demanding that they stop sales to California residents until it is demonstrated that their laboratories meet state and federal regulations. Per report, these investigations were initiated after several consumer complaints were received regarding these tests’ accuracy and cost.

As more genetic tests are developed, the controversy of direct access to genetic testing and DTC marketing of genetic testing will only increase in stature on the (inter)national stage. This has led many professional societies to issue opinion statements on DTC advertising for genetic testing and DTC genetic testing, including the American College of Obstetricians and Gynecologists (ACOG), American Society of Human Genetics (ASHG) and others. These opinions generally address the significant concerns raised by DTC marketing of genetic testing.

DTC advertising for genetic testing is both an opportunity and a challenge for the oncology community. It is important for oncology nurses to be current with the status of cancer genetic testing and to have the resources available for both their education and their patients. Genetic counselors are available to assist the oncology community with concerns and questions about cancer genetic testing. To find a genetic counselor or other genetic professional in your area, the National Society of Genetic Counselors (www.nsgc.org) has a database that can be searched by location and/or specialty. The National Cancer Institute has an information service (www.cancer.gov or 1-800-4-CANCER) to help
answer questions and locate genetics resources in your area. Additional resources for more information on \textit{BRCA1/BRCA2} and genetic testing include:

- National Cancer Institute (NCI)
  - \url{http://www.cancer.gov/cancertopics/pdq/genetics/breast-and-ovarian/healthprofessional}
  - \url{http://www.cancer.gov/cancertopics/Genetic-Testing-for-Breast-and-Ovarian-Cancer-Risk}
  - \url{http://www.cancer.gov/cancertopics/pdq/genetics/risk-assessment-and-counseling/healthprofessional}

- Centers for Disease Control and Prevention
  - \url{http://www.cdc.gov/genomics/training/perspectives/factshts/breastcancer.htm}

- National Comprehensive Cancer Network (NCCN)
  - \url{http://www.nccn.org/professionals/physician_gls/PDF/genetics_screening.pdf}

** Please see the following link for a New York Times article that documents the Northeast campaign: \url{http://www.nytimes.com/2007/09/11/business/media/11genetics.html?_r=1&oref=slogin}

References:

11. American College of Medical Genetics (ACMG) statement on direct-to-consumer genetic testing: http://www.acmg.net/AM/Template.cfm?Section=Policy_Statements&Template=/CM/ContentDisplay.cfm&ContentID=2975

12. See Sections 1241, 1287, 1288 and 1288.5 of the Business and Professions (B&P) Code of California.