



Direct-to-Consumer Marketing for Genetic Testing

This is the fifth of six case studies, prepared for Health Progress by the staff of CHA's Theology and Ethics Department. The final study will be published in the November-December issue.

Your facility has a strong and aggressive oncology program and offers genetic testing for various types of cancer, including breast and ovarian cancer. Recently, both the medical director of the oncology program and the chair of the obstetrics-gynecology department were contacted by a company we will call "GenTest." GenTest researchers discovered BRCA1 and BRCA2, the genes that cause hereditary breast and ovarian cancer. Approximately 5 to 10 percent of breast cancer cases are caused by hereditary factors. GenTest offers clinical tests to determine predisposition to these and other cancers.*

GenTest has begun direct-to-consumer marketing of genetic testing for predisposition to breast and ovarian cancer.† The company spent

several million dollars to run commercials advertising its services on TV shows that are popular with women. It also took out ads in two popular women's magazines. In two large U.S. cities, women were targeted by an advertising campaign that asked: "Concerned about breast cancer? We offer a genetic test that shows whether you have a mutation that increases your risk."

GenTest considers its campaign successful. Its 800 line received a large number of calls from residents of the two cities. The company also saw a tenfold increase in its website hits. Its officers believe that this marketing has indeed raised awareness. In light of this success, GenTest now wants to expand its markets and diversify its marketing vehicles to include newspaper ads, billboards, and brochures for placement in doctors' offices and hospital waiting rooms.

GenTest has invited your oncology program and ob-gyn department, as well as others in the community that offer predisposition testing, to partner with it. More specifically, the firm's representatives wish to include in its new ads the names of those hospitals in the community that offer testing for BRCA1 and BRCA2. The blood samples would, of course, be sent to GenTest for analysis and the results would be sent back to the individual's physician.

Should your facility participate in this direct-to-consumer marketing campaign for predisposition genetic testing for BRCA1 and BRCA2?

QUESTIONS FOR THE BOARD

Would you advise that the hospital participate in this direct-to-consumer marketing effort?

What considerations would enter into your

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Should your facility participate in such a marketing campaign?

*BRCA1 and BRCA2 are tumor suppressor genes; that is, they prevent cells from dividing in an uncontrolled manner. A woman with an inherited mutation of either gene has an approximately 85 percent risk of developing breast cancer during her lifetime. Mutations of BRCA1 also increase the lifetime risk of developing ovarian cancer by 45 to 60 percent. Hence a positive test result indicates a predisposition to breast and/or ovarian cancer, but does not guarantee that the individual will, in fact, develop either.

On the other hand, a negative test result does not mean that the woman will not develop breast and/or ovarian cancer. A previous family history of breast and/or ovarian cancer and ethnic background (Eastern European and Ashkenazi Jews) are two indications that testing for BRCA1 and BRCA2 might be appropriate. A full genetic test costs more than \$2,700.

†A company offering services similar to those of our fictional GenTest is described in "Gene Test Ads Prompt Concern," *Boston Globe*, March 26, 2003.

decision? What would be the decisive considerations?

How, specifically, would you take into account the mission and values of the organization? How would you balance these considerations with others that have surfaced (that is, what weight would they have)?

QUESTIONS FOR EXECUTIVE MANAGEMENT

Do you believe that your organization should participate in this direct-to-consumer marketing effort?

What considerations would enter into your decision? What would be the decisive considerations? Why would they be decisive?

How, specifically, would you take into account the mission and values of the organization? How would you balance these considerations with others that have surfaced (that is, what weight would they have)?

If your organization currently does testing for BRCA1 and BRCA2, is there any policy in place that speaks to who is an appropriate candidate for testing, or do you accept anyone who wishes to be tested? If you do not screen for appropriateness, is this an adequate approach? If you do screen, why is that the case? Does such an approach fit the values of the organization and the guiding values of Catholic health care?

QUESTIONS FOR THE ETHICS COMMITTEE

What do you see as the ethical issues in this case?

What values/moral principles have a bearing on each of these issues?

How would you address each of the ethical issues involved?

What would be your recommendation to the CEO regarding the organization's participation

in this marketing effort? What would be your ethical rationale?

If your organization does BRCA1 and BRCA2 testing, does it have a policy regarding who is an appropriate candidate for testing? If there is no such policy, what do you think might be a good policy? Why? Do you think adolescents should be tested? If so, should they be told of the test results?

How does your organization decide what is and what is not appropriate marketing? Are there any guidelines or criteria for making these decisions? If there are guidelines, are they adequate? If there are none, what would you suggest?

GUIDING ETHICAL PRINCIPLES

The following principles are intended to provide some moral guidance to discussions of the questions above. They are not exhaustive of the principles that might be relevant to the case and to the various questions raised. They should, however, be of some help. These principles are drawn and adapted from the *Ethical and Religious Directives for Catholic Health Care Services*, the Catholic moral tradition, the social teaching of the church, and secular bioethics.

A statement of the mission and values of the organization should play a central role in these discussions as well.

- *Veracity* Communication between and among individuals and organizations should be truthful and should avoid being misleading or manipulative. In this light, health care advertising should be truthful, fair, accurate, and complete. It should address genuine health care needs, foster the appropriate use of therapeutic modalities, promote realistic expectations, avoid manipulat-

Continued on page 50

RESOURCES

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COMMUNICATION STRATEGIES

Continued from page 11

while exercising at a gym. Returning to his home, he complained about the pains to his daughter. She called the EMS. When the paramedics arrived, they immediately taped ECG leads to the man's chest.

The ECG data went straight via cellular transmission to Paul Campbell, MD, a cardiologist on call at NorthEast. Dr. Campbell read the ECG tracings transmitted from the patient's home and quickly determined that he needed an immediate cardiac catheterization because of blockage of a coronary artery. Dr. Campbell knew that if proper blood flow were not quickly restored to the patient's heart muscle, he could sustain severe heart damage and perhaps even die.

Dr. Campbell told the paramedic team, "Take the patient directly to the catheterization lab." He also notified the catheterization team that it must hurry to the lab and prepare it for the patient's arrival. When the ambulance

pulled into the ED 19 minutes later, the lab was ready for the patient, who was taken straight to the catheterization lab, where Dr. Campbell and the team awaited him.

The door-to-dilation clock started the moment the patient was wheeled through the lab door, and, 33 minutes later, Dr. Campbell successfully established good blood flow through the affected coronary artery to the heart muscle. "Under normal circumstances, it takes 30 minutes just to get the team assembled, but this experience proved that new technology and training can really pay off," Dr. Campbell says.

GOOD NEWS FOR INFARCTION VICTIMS

In NorthEast's case, the new technology and training was funded by the Duke Endowment and William T. Morris Foundation, which together gave more than \$175,000 to provide EMS personnel and cardiologists in

Cabarrus County with field-transmission ECG devices and receiving equipment. In addition, the grant provides English and Spanish language materials to help people become more aware of warning signs and symptoms.

As part of the project, NorthEast and Cabarrus County EMS is conducting clinical research in collaboration with Duke University. "A team of doctors at Duke will review analysis and reporting of data collected during the year-long study," says Dianne Snyder, RN, executive director of NorthEast's department of Health, Wellness, and Community Outreach. Bringing the project to fruition required more than two years of research, grant application work, and training.

The hospital's public relations department is also part of the team, according to Lee Brower, director of public relations and marketing at NorthEast. □

CASES IN GENETICS

Continued from page 36

ing desires, and contribute to the well-being of patients.

• **Professionalism** The provider-patient relationship is professional in nature and therefore implies a fiduciary responsibility to those being served; that is, the well-being of those being served takes precedence over the interests of health professionals and health organizations. The professional responsibility of clinicians and health care organizations also requires that patients are provided only care that is needed and beneficial.

• **Respect Human Dignity** Because we believe that each person is made in the image and likeness of God, we ought to treat others with profound respect and utmost regard.

• **Benevolence** Our decisions and actions ought to contribute to the

well-being of others.

• **Nonmaleficence** Our decisions and actions should not harm others.

• **Informed Consent** When making decisions about possible diagnostic or therapeutic modalities, individuals should have adequate and accurate information and understanding of the nature of the modality, its risks, benefits, and burdens (as well as information about and understanding of the alternatives to that modality) and should make the decision about its use freely—that is, without force, coercion, or manipulation.

• **Stewardship** Health care resources should be delivered and used prudently, efficiently, effectively, equitably, and in a manner that reflects professional standards of quality. Providing unnecessary services is a violation of good stewardship.

• **Solidarity** Because we are made in the image of a triune God, we are social by nature. This fundamental relatedness with others implies responsibilities to them. At minimum, we should not harm them. Optimally, we ought to seek their good.

• **Distributive Justice** Societal goods and resources should be distributed equitably.

• **Common Good** Because of our social nature, we ought to contribute to the creation of "conditions of social life by which individuals, families, and groups can achieve their own fulfillment in a relatively thorough and ready way" (*The Church in the Modern World*, section 74). In this light, health care organizations ought to contribute to the public good, in part by seeking to improve the health status of the community. □

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