

Testimony before the Public Health Committee

March 3, 2008

Good morning, Senator Handley, Representative Sayers, and members of the Public Health Committee. My name is Ellen Matloff and I live at 34D Harbour Village in Branford. I am the Director of Cancer Genetic Counseling at Yale Cancer Center/Yale School of Medicine and am here today to testify on Bill #459, "An Act Promoting the Early Detection, Diagnosis and Treatment of Lung Cancer, Breast Cancer and Cervical Cancer."

I generally support this Bill, and am here to ask you to expand it to include legislation to protect consumers from being offered genetic testing without first being offered the option of genetic counseling by a trained professional to accurately order and interpret that test. New York and Massachusetts already have legislation in place that touch on many of these issues.

This issue arose because a private company with a forced monopoly on genetic testing for the breast and ovarian cancer genes, BRCA1 and BRCA2, has launched Direct-to-Consumer television and radio ads in Connecticut, New York and Massachusetts, which many of you have seen by now. Unfortunately, these ads are not subject to the same federal oversight as are ads for prescription drugs. We believe that these slick advertisements overstate the benefits of genetic testing, while failing to adequately address the risks, limitations and uncertainties of the test. We believe they prey on our society's fear of cancer, particularly breast cancer, to persuade consumers that they need this \$3200 test, even though few of them do. Our Attorney General's office is currently investigating whether these ads are misleading and deceptive. This company is aggressively targeting physician offices and encouraging them to order their own genetic testing, even though most physicians are not trained in genetics or genetic counseling.

We have data to show that the rate of genetic result misinterpretation is high. Accurate interpretation is critical, because women who carry a BRCA mutation are offered options to reduce their cancer risks, including preventative removal of their breasts and ovaries. Result misinterpretation could lead to a woman having her breasts and ovaries removed unnecessarily. It could also lead a woman to incorrectly believe that she is not at risk for cancer, just because her genetic testing is negative. We have already seen patients who have had unnecessary prophylactic surgery because of inaccurate counseling.

We propose legislation that will make it mandatory for health care providers to obtain written consent from patients before ordering genetic testing indicating that they have been informed that genetic counseling by a trained professional is available and recommended before testing.

The field of genetics is arguably the area of medicine with the most potential for advancement. However, if we allow corporate gain without regard to public safety to drive genetic testing, the potential for harm is staggering.

Attached to my testimony is our proposed language for this legislation and supporting documents. Thank you and I'd be happy to take any questions.

Attachments:

- Proposed language for An Act Concerning Genetic Testing
- Barriers to non-geneticist physicians providing genetic counseling and testing
- Main concerns regarding DTC marketing of genetic tests

An Act Concerning Genetic Testing

Section 1. :

- (a) No person shall perform a genetic test, not mandated by state law, on a biological sample taken from an individual without the prior written informed consent of such individual or his/her medical proxy.
- (b) As used in this section, the term genetic test means any laboratory test on human DNA, chromosomes, or gene products to diagnose the presence of a genetic variation linked to a predisposition of a disease in an individual or their offspring.
- (c) The written informed consent shall include at minimum the following:
- (1) The name of the test;
 - (2) A statement of the purpose of the test;
 - (3) A statement indicating that the consenting individual has been informed that genetic counseling by an American Board of Genetic Counseling (ABGC) or American Board of Medical Genetics (ABMG) board-certified or board-eligible genetic counselor or medical geneticist is recommended before a decision is made to undergo genetic testing and that the individual has been provided with written information identifying a genetic counselor or medical geneticist from whom the consenting person might obtain such counseling;
 - (4) A statement recommending that the result of any genetic test be read and interpreted by an ABGC or ABMG board-certified or board-eligible genetic counselor or medical geneticist;
 - (5) A statement that prior to signing the consent form, the consenting person discussed with the healthcare professional ordering the test the reliability of positive or negative test results, the level of certainty that a positive test result for that disease or condition serves as a predictor of such disease, and a description of the potential risks, benefits, and limitations of the testing;
 - (6) The name of the person or categories of persons or organizations to whom the test results may be disclosed;
 - (7) The signature of the individual subject of the test or, if that individual lacks the capacity to consent, the signature of the person authorized to consent for such individual.

Section 2.: It shall be an unfair trade practice in violation of chapter 735a for any person to perform a genetic test on a on a biological sample without having first received prior written informed consent pursuant to section 1, or to market or advertise a genetic test to any consumer or medical provider in a manner that is deceptive or misleading.

Barriers to non-geneticist physicians providing genetic counseling and testing

- Numerous regional, national, and international studies have demonstrated that non-geneticist physicians have inadequate knowledge of clinical genetics to provide genetic counseling and testing.^{1-14, 23} In fact, these studies have shown significant deficiencies in knowledge of essential concepts including inheritance patterns, prevalence of mutations, penetrance, risk factors for hereditary cancer syndromes, and availability of testing and management options.^{1,2,4,8,9,11,12,14}
- The majority of physicians have little or no formal training in genetics.^{5,12,13,15,16,17}
- The majority of physicians report having insufficient time to provide genetic counseling and testing services.^{5,15-18}
- Although most physicians obtain some family history information on their patients, most do not obtain a sufficiently detailed and extensive family history (e.g. information on second degree relatives, ages at cancer diagnosis) for accurate genetic risk assessment and result interpretation.^{10,12,13,16,19}
- Non-geneticist physicians may not fully appreciate some of the unique, complex, ethical and psychosocial issues involved in the genetic counseling and testing process (i.e. the impact of results on the entire family, the need for informed consent, the need for confidentiality, patient autonomy, and nondirective counseling).^{3,5,9,20,21}
- In one study of commercial genetic testing for hereditary colon cancer, it was shown that even physicians who directly ordered genetic testing misinterpreted test results in ~32% of cases in a way that could lead to serious clinical errors.²² They also often failed to provide adequate pretest counseling and informed consent; only ~19% of patients received pretest genetic counseling and only ~17% provided written informed consent.²²
- Some have suggested that the genetic testing practice patterns of primary care physicians may be more strongly influenced by direct-marketing, lay press, and threats of malpractice than by expert protocols and journal articles.⁵

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Main concerns regarding Direct-to-Consumer (DTC) Marketing of Genetic Tests:

- Federal oversight of genetic tests and advertisements for genetic tests is limited.^{1,2,3,7,8}
- DTC advertisements for genetic tests usually overstate the benefits and utility of genetic testing (particularly for the general population) while failing to adequately address the risks, limitations, and uncertainties inherent in genetic testing.^{1,2,3} They also often utilize themes of fear, choice, hope, and control exploiting the public's anxiety and lack of understanding of complex genetic information.^{1,2,3}
- Some DTC advertisements for genetic tests also encourage consumers to contact the commercial laboratory directly (where they are "counseled" by employees of the company); this downplays the role of health care providers, may lead to testing outside of specialized genetic counseling centers, and thus does not ensure appropriate informed consent, result interpretation, education, and support.^{1,2}
- DTC advertising of genetic tests has been shown to increase demand for genetic testing, disproportionately among "low risk" individuals, many of whom are not appropriate candidates for testing.^{3,4,5,6} If DTC marketing of genetic tests becomes more widespread, increasing demands may lead to stricter criteria for and/or denial of coverage of genetic testing by insurance companies. This may lead to restricted and/or delayed access to genetic counseling and testing, even for high risk individuals.

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