

Dear Distinguished members of the committee, I represent the lay advocacy group, Facing Our Risk of Cancer Empowered (FORCE), a national 501(c)3 nonprofit organization whose mission is to improve the lives of individuals and families affected by hereditary breast and ovarian cancer. I am here to follow up on the testimony presented last year to this committee by Dr. Sue Friedman, our Executive Director and present our mounting concerns about the unrestricted marketing that is being used by genetics laboratories and specifically Myriad Genetics. I would like to share with you how these actions are impacting members of the community that we serve.

As Sue Friedman testified at the last meeting, based on what we have witnessed it is our opinion and belief that Myriad's sales representatives discourage doctors and other health care providers from referring patients to genetics experts. In the past, Myriad has denied use of such a strategy, and when presented with our concerns their Vice President of Marketing dismissed them as the work of a few "rogue" sales agents. However, in a recent publication, Myriad CEO Peter Meldrum was quoted as saying that Myriad's sales force "*provides doctors [with] the tools to do counseling" in-house, and as a result, physicians can bill insurers directly for the service.*"

The same report stated that:

"Helping doctors to set up genetic counseling services in their own practices is a priority for the Myriad sales team, which is currently 300 reps strong, ahead of a direct-to-consumer effort in a particular geographic region. The company has carried out DTC ads in the Northeast and the Midwest, and is continuing marketing efforts in the South. According to Meldrum, sales representatives educate doctors and nurses about who should be tested on BRACAnalysis and how to handle patients' questions about genetic risk. Also, the company's sales reps attempt to reach doctors and show them DTC ads for BRACAnalysis ahead of its television airing in a particular locale, so they can be more prepared when patients come into their offices asking about the test."

Having reviewed Myriad's education materials for health care professionals, we are concerned that they focus **only** on the hereditary syndromes for which the lab markets a test. Unfortunately, we believe these materials are misleading and in many cases they are the only information many health care providers—particularly those being targeted by the company—receive about cancer genetics. This means that patients who might meet criteria for other hereditary syndromes (for which Myriad does not test) are not always receiving comprehensive or accurate information because their health care providers are not genetics experts and are unaware of these other syndromes.

By encouraging health care providers with limited genetics expertise to provide "in-house counseling" and order testing, it is our opinion that **Myriad is establishing a minimum competency for providing genetic information to patients which falls below published national expert guidelines.** The lab is establishing a body

of health care providers who, rather than practicing medical genetics, are trained to market BRCA testing for the company that manufactures the test. They have also begun to train a body of patients who have undergone genetic testing to act as “patient advocates” to speak out in favor of genetic testing on Myriad’s behalf. Unchecked and unregulated, Myriad has **unrestricted access to providing consumers both directly and through their health care providers with unbalanced, biased information about genetic testing for hereditary cancers.**

We have heard from health care providers, untrained in genetics, who admit that they have consulted with Myriad staff when determining the appropriateness of genetic testing rather than consulting with a genetics expert unaffiliated with the lab, and rather than referring the patient. We feel that this is a clear conflict-of-interest: consulting with a company employee is not the same as referring a patient to a specialist not affiliated with or employed by a lab with a financial incentive for selling tests. This is another way the genetic counseling process that is a national standard-of-care is being bypassed.

Following up on prior testimony, we are continuing to hear from people who have been tested without benefit of genetic counseling and receive results from doctors or nurses who have no understanding of the significance of test results. We are also learning of many incorrect or inappropriate tests ordered at significant expense to the consumer and/or their insurance company. In some cases tests are being ordered without insurance company pre-approval and individuals learn they do not meet insurance criteria only after they have already paid for testing.

Recently for example, a patient who received incorrect information from a health care provider posted her experience on the FORCE website. This woman and two of her siblings received genetic testing through a breast surgeon who received BRCA test kits from Myriad. They were not offered, and did not receive prior genetic counseling. All three were told their BRCA test was positive. Considering herself at high risk for breast and ovarian cancer, this woman had her healthy ovaries removed. However, a relative in another city went to have genetic testing for the same mutation, and was referred to a genetic counselor who reviewed our member’s test result first. The genetic counselor determined that, in fact, her result was not positive. In this case, misinformation resulted in an unnecessary and irreversible surgery. Further, between the woman and her siblings, because the result was a variant, only one of the tests was necessary. In this instance, and undoubtedly in many others, circumventing counseling before testing created additional revenue for the lab, and led to unnecessary cost for the individuals and/or their insurance company.

Since no regulatory body monitors or regulates the marketing of tests through CLIA-approved labs, and no entity documents reports of adverse events, we have no way of knowing just how many people are harmed every day by inappropriate genetic testing. Although the cases involving unnecessary surgery may be the extreme, based on the stories we are receiving, we believe individuals who are

receiving genetic testing without counseling may experience some degree of emotional or physical harm and well-meaning health care providers are being placed at risk for malpractice.

Standard medical practice calls for a referral to a specialist when specific expertise is required. Most physicians know to refer someone with a heart murmur to a cardiologist, for example, and to send a patient with a corneal laceration to an ophthalmologist. Despite published guidelines that outline genetic counseling prior to BRCA testing as standard-of-care, because much of the general population is unaware of the existence of genetics experts, and health care providers are being discouraged from referring patients, consumers have no way of knowing that they are receiving substandard care and have no venue for registering complaints.

FORCE's mission involves advocating for our community, and we are charged with speaking out when we see clear evidence that a practice is causing our community harm. On a daily basis we see the effects of Myriad's campaign to doctors and consumers. FORCE representatives have heard members of their sales force make inaccurate, dangerous claims to health care providers, and we have heard reports from the health care providers themselves that they are turning to Myriad employees to determine whether or not a genetic test (performed by Myriad) is warranted for patients.

Myriad has justified their aggressive marketing campaign by claiming there is a shortage of qualified experts in genetics and long wait times for patients who are referred to genetics experts. However, we are seeing a rise in inappropriate testing and lack of referral to experts even in areas where genetics experts are abundantly available. Genetics experts are also available nationwide by telephone.

We urge the Secretary's Advisory Committee on Genetics, Health and Society to recommend federal action to monitor, regulate, and track adverse events resulting from marketing by laboratories to both consumers and health care professionals, and to **require** doctors to know about, inform patients about, and refer patients or provide them access to standard-of-care genetic counseling prior to ordering genetic testing for a patient.

Thank you