



## **USPTO Roundtable Written Commentary**

In response to this committee's request for quantitative data, FORCE has gathered information from sources including healthcare providers, the hereditary breast and ovarian cancer (HBOC) patient community, and respected institutions such as the Cancer Legal Resource Center and the Michigan Department of Community Health.

Of the four key questions presented in Section 27 of the America Invents Act, we are best-qualified to address the issues surrounding the role that cost and insurance play in access to genetic testing; and the desire for confirmatory or second opinion testing in the patient and healthcare provider communities.

### **1) The role that cost and insurance coverage have on access to and provision of genetic diagnostic tests.**

In 2005, the United States Preventive Services Task Force (USPSTF) released a Grade B Recommendation Statement entitled "Genetic Risk Assessment and *BRCA* Mutation Testing for Breast and Ovarian Cancer Susceptibility: Recommendation Statement indicating that at least fair evidence was found that the service improves health outcomes and that the benefits outweigh the harms. That statement specifically states:



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“Women whose family history is associated with an increased risk for deleterious mutations in *BRCA1* or *BRCA2* genes [should] be referred for genetic counseling and evaluation for *BRCA* testing.”

The National Comprehensive Cancer Network (NCCN) has published guidelines for *BRCA* counseling and testing for women and men with a personal history of breast cancer; women with a personal history of ovarian cancer; and, individuals with a relative with a known genetic mutation. It should also be noted that NCCN has guidelines for cancer risk management services for women who test positive for a *BRCA* mutation.

Unfortunately, based on data from the Michigan Department of Community Health, nearly half of health insurers don't follow the testing guidelines, and two-thirds have not adopted NCCN guidelines for risk management services. Our testimony to this committee in February 2012 noted that Tricare discontinued coverage of *BRCA* testing last January. Approximately 9 million people insured by Tricare didn't have access to this critical genetic test. Tricare reinstated coverage of *BRCA* genetic tests in August.

The Michigan Department of Community Health is a leader in the utilization of genetic information to provide statewide public health benefits. Its Cancer Genomics Program has done extensive work to increase the availability of cancer-related genetic information in order to decrease barriers to “risk-appropriate” services. After significant efforts to get insurers’



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written policies in alignment with national guidelines, only 14 out of 25 (an increase from 4 in 2009) major Michigan health plans have written policies aligned with USPSTF—which also require or strongly recommend genetic counseling prior to testing. Seven health plans aligned with NCCN recommendations for cancer risk management services for BRCA positive women.<sup>1</sup>

Medicare only covers BRCA genetic testing for women who have had a cancer diagnosis. It doesn't cover any BRCA testing for men. Tens of thousands of high-risk people over age 65 cannot access BRCA testing through Medicare, and many can't afford to pay out-of-pocket for genetic testing. This has a significant impact on these individuals and their families in determining if there is a genetic mutation or which side of the family a mutation comes from.

Cost and health insurance coverage—or lack thereof—place a significant financial and health burden on the patient population. In a MDCH study conducted 2007-2011, of the 1,722 patients who had genetic counseling and did not have BRCA testing, nearly 15% cited inadequate insurance coverage as their reason for not receiving genetic testing. This data demonstrates the importance of inadequate insurance coverage as a barrier for many patients who would benefit from such testing.

In response to the request from the USPTO for more data, FORCE developed an online survey which we promoted to consumers and healthcare professionals. Over 500 people completed the survey. Of the 38 individuals who responded that they did not undergo genetic testing,



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26% indicated that health insurance denied coverage of genetic testing and they could not pay out of pocket; 5% stated that they were uninsured and unable to pay out-of-pocket as the reason they did not undergo testing.

Of those who did have genetic testing, 7% indicated that insurance initially denied coverage and they had to appeal to get the testing covered. Another 7% of respondents said that their health plan denied coverage of their testing completely, and 1.5% didn't have health insurance but were able to pay for genetic testing out-of-pocket. Given the cost of some genetic tests, this is a significant burden on the patient community.

We queried the healthcare community about their experiences with the impact of cost and health insurance on patients who meet nationally published guidelines for BRCA genetic testing. A summary of this information and more is provided for your review.

Of 116 healthcare providers who answered this question, 22% indicated that their patients often experience difficulty in getting health insurance to pay for genetic testing and 64% said occasionally. Over half of the healthcare providers indicated that at least 80% of their uninsured and underinsured patients are unable to access genetic testing through other means such as participation in research or via financial aid.



**2) The impact that the current lack of independent second opinion testing has had on the ability to provide the highest level of medical care to patients and recipients of genetic diagnostic testing, and on inhibiting innovation to existing testing and diagnoses.**

At least eleven states and Medicare currently mandate private insurance coverage for some form of second medical opinions<sup>ii</sup>. The majority of these laws allow for patients to visit a second physician. While they don't explicitly mention genetic test results, it is important to acknowledge that there is a trend to value second opinions as a cost-saving measure for insurance companies, and a right for patients before making life-changing medical decisions.

On the question of demand for second opinion testing, the FORCE survey indicated that 60% of healthcare professionals and 35% of patients who underwent testing for a gene mutation indicated that they would like the option of a 2nd opinion / verification genetic test.

Comprehensive information on the impact of insurance and cost on access to genetic counseling and testing, as well as information about desire for 2<sup>nd</sup> opinion testing is detailed in the attached summaries of our survey. Additionally, we have provided some personal accounts of the impact these issues have on the already over-burdened high-risk community and the healthcare providers who serve them.



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In closing, I would like to emphasize again that cost and health insurance coverage are key factors in patient access to genetic counseling, testing and preventive services. I also want to bring attention to the fact that Myriad's "comprehensive panel" is less than comprehensive. The BART rearrangement panel, offered at an additional cost of \$700, finds mutations missed by Myriad's comprehensive BRACAnalysis. Cost of this additional panel on top of the cost of full sequencing places a financial burden on populations that already face disparity. People of Hispanic ethnicity, for instance, are more likely to carry a BART rearrangement.

Thank you for the opportunity to submit commentary on this important topic.

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<sup>i</sup> Michigan Department of Community Health, Genomics and Genetic Disorders Section

<sup>ii</sup> Cancer Legal Resource Center. California, Florida, Illinois, Indiana, Kentucky, Maryland, Missouri, New York (only in the case of cancer), Oregon, Washington, West Virginia, and Wisconsin require coverage of a second medical opinion.