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Saurabh Vishnubhakat
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Mail Stop External Affairs
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Re: Comments to USPTO on Genetic Diagnostic Testing

Dear Mr. Vishnubhakat:

The Disability Rights Legal Center (DRLC) respectfully submits the following comments to the United States Patent and Trademark Office regarding genetic diagnostic testing. The DRLC is a non-profit law firm that promotes the rights of individuals with disabilities. Through our Cancer Legal Resource Center (CLRC), one of the four programs of the Disability Rights Legal Center, we have unique knowledge and experience with laws and legislation that impact the rights of individuals diagnosed with cancer, cancer survivors, and caregivers. Additionally, the CLRC has a staff attorney who is at the organization through a Skadden Fellowship to provide resources and information specifically to individuals with a genetic predisposition for cancer. Since 1997, the CLRC has assisted more than 37,500 people on the national Telephone Assistance Line and reached an additional 200,000 people across the country, through community events, outreach, and educational activities.

General Comments

These comments address the fourth area of examination in the USPTO study: "The role that cost and insurance coverage have on access to and provision of genetic diagnostic tests." Through the Telephone Assistance Line, the CLRC connects with many callers who are experiencing difficulties with insurance coverage for cancer treatments. We understand how essential insurance coverage can

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be for an individual to have access to tests, procedures, and specialists. Unfortunately, we also see that so often one of the best ways to ensure complete coverage for individuals is to mandate insurance coverage for a procedure. For this reason, the Affordable Care Act (ACA) required complete coverage for many preventive screenings and procedures and many states have mandatory insurance coverage for cancer screenings. While the ACA requires coverage for genetic counseling associated with BRCA tests, *it does not address the cost of the BRCA or any other genetic test itself*. Insurance coverage of genetic testing varies across the country and across types of insurances. We believe that there should be universal insurance coverage for genetic testing for both individuals diagnosed with a genetic condition or disease seeking treatment options and for individuals seeking information about genetic risk in order to access preventive care.

Joint CLRC/FORCE Survey

In 2011, the CLRC and Facing Our Risk of Cancer Empowered (FORCE), a national nonprofit focused on individuals and families affected by hereditary breast and ovarian cancer, created a survey to measure, in part, individuals' experiences in access to genetic testing. Between June 2011 and October 2011, 232 individuals participated in this survey, 182 of whom requested their insurance company to cover the cost of genetic testing.

The survey reflects a national audience. Individuals from 37 states and the District of Columbia answered questions. The vast majority (93.3%) of those completing the survey had a family history of breast, ovarian, or colon cancer. Additionally, 92.8% had taken a genetic test for cancer. Of those surveyed, 86.2% had a BRCA1 or BRCA2 mutation and 6.5% had other hereditary cancer mutations.

Overall, 82.7% of those who requested genetic testing had the service covered by insurance. However, it is our belief that health insurance should cover every individual for whom genetic testing has been recommended, given their family history or other identifiable risk factors.

Survey Limitations

The majority of those who filled out the survey had private, group health insurance and had incomes of \$50,000 or more; therefore, this survey is under-representative of low income populations,

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particularly those on Medicaid and other government insurance plans. Insurance coverage of genetic testing in these latter populations is particularly essential because low-income individuals are less likely to be able to get genetic testing in the absence of insurance coverage, given the high cost of testing. However, not all state Medicaid programs cover the cost of genetic testing-- therefore a significant portion of those individuals are left without access to important health information.

Insurance Type and Coverage

One of the initial results from the survey is that a person's type of insurance coverage is correlated with an individual's likelihood of denial for genetic testing. For example, 3% of those with a group or individual HMO were denied coverage of a genetic test, compared with 14% of those with POS or PPO group or individual plans and 27% of those with government plans. As mentioned above, the population size for those with government plans was small for this survey, so more information would be needed to determine if this difference is statistically significant. However, the difference in experience between those in an HMO versus those in a POS or PPO is statistically significant. Many HMOs have a robust referral system and genetic counselors within their network. Therefore, it is logical that these insurances would more readily cover the tests and procedures associated with a referral to a genetic counselor.

Cancer Diagnosis and Coverage

One of the most interesting results of the survey was that the likelihood of insurance coverage for genetic tests depended upon a cancer diagnosis. Specifically, those with a family history of cancer, but no cancer diagnosis, were statistically significantly more likely to be denied genetic testing coverage than those who had been diagnosed with cancer. For example, 67% of those who requested genetic testing coverage had no diagnosis of cancer, but this population made up 77% of the denials. This disturbing statistic shows that insurance companies are more likely to cover genetic testing when it helps determine a treatment option for somebody who has *already* been diagnosed with cancer, than for an individual trying to manage future risks. Indeed, through our callers the CLRC has seen insurance policies that specifically include coverage for diagnostic genetic testing, but not for genetic screening prior to a diagnosis. The CLRC believes that insurance companies should

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absolutely be covering tests for those already diagnosed, but that it is equally essential to cover the service as a preventive measure.

Conclusion

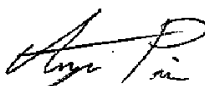
The results of the joint CLRC and FORCE survey show that many insurance companies are covering genetic tests. However, there remain important populations who are denied, or have difficulty accessing insurance coverage for genetic tests. Of particular concern to the CLRC are low-income individuals who cannot afford testing on their own. Insurance coverage should be consistent across the board, regardless of the type of insurance an individual has or whether they have been diagnosed with a genetic condition or disease. Deciding whether or not to take a genetic test is a very personal decision. Individuals should not have the additional burden of facing concerns of insurance coverage during this decision-making process.

In our survey, 23% of those individuals who were denied insurance coverage of genetic testing ultimately opted out of taking the test. There are many individuals across the country who will not be able to afford genetic testing without insurance coverage. Not knowing definitive information about genetic risk can have negative psycho-social effects and lead to negative medical outcomes. This implicates public health because individuals and their doctors will have less information about treatment options, prevention options, and implications for other family members.

Thank you for the opportunity to comment on this important topic.



Paula D. Pearlman
Executive Director
Disability Rights Legal Center



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cc: Sue Friedman, Facing Our Risk of Cancer Empowered
Shawn Kravich, CLRC

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