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## **Do Consumers Want Expanded Access to Direct-to-Consumer Genetic Testing?**

New York, New York, June 7, 2017—In mid-April, the direct-to-consumer genetic testing firm 23andMe received US Food and Drug Administration (FDA) authorization to sell tests for 10 genetic health risk reports directly to consumers. As the *New York Times* reported on May 12, the tests pose potential programs for long-term care insurers who may not have access to results. While policymakers have been debating the appropriateness of these tests for more than a decade, little is known about past consumers' views regarding the regulation of these products or whether personal experience with testing is related to these views. A new [study](#) in the June issue of *The Milbank Quarterly* by Sarah E. Gollust of the University of Minnesota School of Public Health and colleagues has found that a majority of consumers support expanded access to direct-to-consumer personal genomic testing (DTC-PGT) services and oppose additional government regulation, while those who have had a negative experience with the tests were less supportive of expanded availability without a medical professional.

### **Background**

Scholars have examined the potential benefits of and limitations to making genetic test results directly available to consumers for many years, arguing, for instance, that the potential impact of genetic risk information on consumers' privacy, health, health care utilization, behavior changes, and well-being warrant heightened attention and regulation. Data from previous PGT consumers is important to inform the policy process, to provide evidence on consumers' perspectives and the impact of PGT testing on consumers' attitudes, behaviors, and health care utilization.

### **Findings**

The researchers used data from a sample of 941 participants in a longitudinal study of consumers of two PGT companies—23andMe and Pathway. These consumers enrolled in the study in 2012, prior to FDA action that halted 23andMe providing test results to consumers (and well before the April 2017 announcement that opened up access to health-related testing). The study was funded by a grant from the National Human Genome Research Institute (Scott Roberts and Robert C. Green, Principal Investigators).

At the six-month follow-up after receiving their genetic test results, they found:

- Most participants believed that people have a right to access genetic information directly (90%), that parents should be able to get DTC-PGT testing for their children (82%), and that genetic information should be kept private (83%).
- Participants supported health insurance coverage of PGT (60%)
- Participants were less supportive of government regulation (28%)

- Participants' computed genetic risk for common disease that they received from the companies showed no relationship with attitudes. However, those who perceived that they had received elevated risk results expressed lower support for expanded availability and incorporation of PGT into health care. Those who reported being upset by their genetic test results were less likely to endorse access to DTC products without a medical professional.

“Our findings—showing that consumers enthusiastically support access to genome testing—suggest the recent FDA decision is in line with the sentiment of interested consumers,” said Dr. Gollust. “However, we also found that those who felt upset by their test results were more likely to support more medical professional involvement, suggesting an ongoing need to monitor and evaluate these services.”

### **About *The Milbank Quarterly***

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