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Experts say direct-to-consumer genetic tests need innovative oversight

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Direct-to-consumer (DTC) genetic tests available from retailers and the Internet let people learn about their genomes without going to a doctor, but they raise the question of who is responsible for oversight and regulation of these tests. Critics worry about safety risks if consumers base important lifestyle or medical decisions on inaccurate or misunderstood test results.

A group of four leading bioethical, legal and medical researchers believes the solution will require an innovative approach that combines premarket studies done before tests enter the market with ongoing postmarket evaluations to confirm how well tests perform once they are in use. Because DTC tests move in a global Internet marketplace, close international cooperation also will be required.

The team, led by Amy L. McGuire of the Center for Medical Ethics and Health Policy at Baylor College of Medicine in Houston, also includes Barbara Evans of the University of Houston (UH) Law Center, Canadian legal expert Timothy Caulfield and Wylie Burke, M.D., of the University of Washington School of Medicine. The group's policy recommendations for DTC genetic tests appear in the Oct. 8 issue of *Science* magazine, the world's leading journal of original scientific research, global news and commentary.

In their Science article, the authors note that more than 90 percent of the genetic tests now available in the United States have never been through a regulatory review to prove the tests are safe and actually improve

human health. A broad consensus exists for some form of regulatory review before new tests enter the market, but potential solutions have been mired in controversy. There are practical barriers to forcing all new genetic tests to go through the same sort of data-intensive premarket review the Food & Drug Administration requires for other medical products, such as drugs.

"Many genetic tests make long-term predictions, and there may be decades of uncertainty before their risks and benefits are fully known," McGuire said. "If we wait until robust premarket data are available, that could delay development of new tests and essentially regulate many DTC companies out of existence."

"We favor a risk-stratified approach that tailors the regulatory requirements to the level of risk a DTC test actually presents," said Evans, who is also co-director of UH's Health Law & Policy Institute. "Genetic testing is not risky in itself, but a test can have significant risks if inaccurate results may lead to serious, irreversible medical decisions or if the test reveals troubling facts that cause psychosocial harm. A recreational test that tells you fascinating facts about who your ancestors were is fundamentally different from a cancer susceptibility test that may panic you to go get preventive surgery."

The article's authors suggest that regulators should pursue a hybrid approach that would continue to let most DTC tests reach the market quickly, with relatively light premarket review requirements. However, they believe that regulators should have the power to keep a higher-risk test off the market until studies confirm it has an acceptable risk-benefit ratio. For all tests, there is a need for enhanced postmarket follow up to confirm that the test is safe and effective, with prompt steps taken to protect the public if any problems emerge.

"The public needs frank disclosure of what is not known about these

tests," Evans said.

The group concludes that collaboration among regulatory agencies and informal groups, such as the proposed National Institutes of Health Genetic Testing Registry, could yield the best possible result – a market where consumers have ready access to most DTC tests and where innovation is encouraged, yet where sellers of high-risk tests would be required to meet more stringent pre-release standards.

Provided by University of Houston

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