## **Peeing in the Gene Pool**

## By Reg P. Wydeven January 12, 2014

One of my kids was recently studying ancestry at school. This unit led to an interesting discussion at our dinner table about our family's heritage. My wife indicated that she comes from 100% Dutch stock. I explained that despite my Dutch surname, I am predominantly German, followed by equal parts Dutch and French.

So my kids determined that they are mostly Dutch. We pointed out to them that because of our Dutch heritage, we will occasionally not pronounce the 'h' in words containing a 'th' sound and that we tend to be frugal, or t'rifty, as it were.

But seriously, the kids were excited to learn about their history and their ancestors emigrating to the U.S. from Uden, Holland. And to be honest, my wife and I were very proud to share it with them.

A person's ancestry can tell a lot about who they are and what they might become. Some people, however, want to learn more than ethnic tendencies – they want precise genetic tarot cards.

23andMe Inc. is a genetic testing company that provides ancestry-related information to its customers. About five years ago, the company also started selling DNA test kits online for \$99, claiming the company could use them to inform customers of their risk for contracting over 250 diseases and health conditions.

People who purchased the kit would receive a small tube in the mail containing a cotton swab. The customer would rub the inside of their cheek and return the swab to 23andMe for testing. The company saw a surge in sales after actress Angelina Jolie underwent a preventative double-mastectomy after learning from her doctors that her genetic markers indicated she was predisposed to breast cancer.

Late last year, though, the U.S. Food and Drug Administration sent a letter to 23andMe warning the company that it is marketing its kits without the agency's approval and that its product raises concerns. The FDA went on to say that 23andMe failed to satisfactorily answer questions it raised about the kits and did not provide sufficient information to support its marketing claims.

According to the FDA, only medical tests that have been cleared by the government are permitted to make such claims about links between a person's genetic markers and predisposition to disease. The agency fears that customers will rely too heavily on the tests, resulting in unnecessary medical care for customers having possibly false positive results, or failure to seek treatment for customers having possibly false negative results.

Accordingly, the FDA has ordered 23andMe to stop selling its genetic testing kits. The company will continue to provide ancestry-related information and raw genetic data without interpretation to customers. Customers who bought kits since the FDA issued its order will be eligible for refunds. If the FDA does approve the test in the future, existing customers could receive the results of their genetic tests.

I just hope that my kids didn't inherit my hairline gene.

This article originally appeared in the Appleton Post-Crescent newspaper and is reprinted with the permission of Gannett Co., Inc. © 2014 McCarty Law LLP. All rights reserved.