

Sure Genomics whole-genome direct-to-consumer test pushes regulatory limits

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[Sure Genomics](#), a startup based in Utah, [launched](#) a genetic testing service today that costs a whopping \$2,500 upfront, with an additional \$150 subscription fee that guarantees DNA analysis updates every six months. The price is unusually high for a direct-to-consumer genetics company, since [23andMe](#) and [Ancestry](#) offer genetics reports for \$199 and \$99, respectively. But Sure Genomics says it's worth it; customers who pay the fee will get their entire genome sequenced, and unlike others, the startup says it won't sell anonymized genetic information to third parties to turn a profit.

But from a regulatory standpoint, Sure Genomics is treading on thin ice. The FDA has warned [similar companies](#) about telling people their disease risk or how their bodies might respond to a drug. Sure Genomics plans to deliver exactly those kinds of results — without getting clearance from the FDA first.

It's been three years since the now-famous genetics company 23andMe first received a warning letter from the FDA telling them to stop marketing its Personal Genome Service. At the time, the FDA said that some of the intended uses for the service — uses like determining a person's drug response or their genetic risk for breast cancer — were "concerning." The FDA feared patients could be put at risk if they received incorrect test results, or if they didn't understand the results they got.

Read full, original post: [Sure Genomics wants to sell private genetic profiles for \\$2,500, but it's really testing the FDA](#)