Controversy surrounding **consumer genetic testing** has come to the foreground recently with the **FDA**'s order that **23andMe** discontinue marketing its popular "personal genome service."

The genome testing service, which provided analysis of genetic markers for various conditions via a saliva-based test, has suspended sales during the regulatory review process. Most observers see little chance of the company being given a second chance any time soon.

BakerHostetler partner **David Rivkin** argues in the December 9 *USA Today* opinion piece below that the FDA's move is a violation of the company's First Amendment rights. Blocking 23andMe from continuing its services, he argues, keeps valuable genetic information out of patients' hands and prevents them from making informed choices about treatment.

"The FDA does not claim that 23andMe is a scam or could cause direct injury," Mr. Rivkin writes. "Instead, its concern is that people using the genome service 'may begin to self-manage their treatments.' Essentially, the agency wants to 'protect' patients from knowing about their own health."

He adds: "The FDA, of course, does not want Americans to make bad health choices, but it does seem determined to keep them in the dark about how to make good ones."

Mr. Rivkin, who heads the national appellate practice for BakerHostetler, is well known for his work in regulatory, legislative and policy matters, as well as constitutional law. He served in two presidential administrations, including a stint as associate general counsel with the Department of Energy.

USA Today:
Your DNA and your First Amendment

By David Rivkin Jr. and Andrew Grossman

December 9, 2013

The FDA is blocking 23andMe's genome service. But the real target is free speech.

Did you know that you cannot be trusted with knowledge of your own genetic background? That's what the Food and Drug Administration decreed late last month when it ordered

23andMe to stop marketing its "
Personal Genome Service
."

23andMe is at the cutting edge of mass-market genomics. For $99 , the company tests a saliva sample to identify genetic markers that correspond to various conditions and predispositions, as well as ancestry. Based on these markers, the company produces a report describing genetic health risks and inherited traits, along with citations to the research that backs up its analysis and the current scientific "confidence" for each point.

The FDA does not claim that 23andMe is a scam or could cause direct injury. Instead, its concern is that people using the genome service " may begin to self-manage their treatments ." Essentially, the agency wants to "protect" patients from knowing about their own health.

Proactive prevention

The service is not marketed as a diagnostic tool but as a way for individuals to take a proactive approach to their health through prevention and management, while providing themselves and their physicians with more information to make better choices.

The agency worries that individuals, with information about their genetics, could make the wrong choices. As an example, the agency suggests a customer informed of a heightened risk for breast or ovarian cancer might undergo unnecessary prophylactic surgery or chemotherapy. But this could not happen without first consulting a doctor and undergoing diagnostic tests.

The FDA also claims that individuals shouldn't be able to receive health information based on their genes, unless and until the underlying correlations have been subjected to rigorous " clini cal validation
," the same as an approved drug or medical device. Last week, a
$5 million class action suit
was filed against 23andMe by one dissatisfied customer claiming its test results are not supported by scientific evidence.

Anne Wojcicki, co-founder of 23andMe , responded that her company and the regulators are entering uncharted territory. She said the FDA is set up to approve individual tests, not the millions of tests her company does on a person's DNA.

To be sure, the FDA does have a legitimate interest in ensuring that consumers are not misled by false claims and bad products. But that's not at issue here.

The interpretation of genetic markers is grounded in recent discoveries and could be tentative. 23andMe, like others in the field, acknowledges this and is constantly revising its interpretation of genetic data. But that fact does not mean these services aren't useful to consumers, particularly when combined with traditional diagnostics.

Suppressing speech

Yet the FDA maintains that 23andMe has to keep that knowledge away from its customers. Forget about the FDA's medical " device " claims, its stance puts the agency in direct conflict with our free speech rights. Shuttering a service such as 23andMe is no different from censoring home medical references or any of myriad websites that link symptoms with medical conditions.

In fact, the Supreme Court has long rejected the premise that government may " substitute its judgment as to how best to speak for that of speakers and listeners.
" While the FDA may prefer that scientific research be limited to professionals and then filtered through a physician or FDA-approved service for the rest of us, the
First Amendment
prevents it from suppressing speech.

What's troubling is that the FDA knows this. Two years ago, the Supreme Court struck down on First Amendment grounds a state law that blocked pharmacists from disclosing information about doctors and their prescribing habits to pharmaceutical manufacturers, who would use it for research and marketing. As the court observed, the free flow of information has "great relevance in the fields of medicine and public health, where information can save lives."

That connection is far more direct here. The knowledge that a person is at heightened risk for a particular disorder could prompt lifestyle changes to reduce the risk or encourage early detection and treatment.

For now, 23andMe has voluntarily taken its service off the market. The FDA, of course, does not want Americans to make bad health choices, but it does seem determined to keep them in the dark about how to make good ones.

Rather than regulate by assuming that consumers are incapable of understanding their personal genetics, the FDA should be thinking about the enormous opportunities to improve health offered by widespread, affordable genetic testing.

David Rivkin and Andrew Grossman practice law in the Washington, D.C., office of BakerHostetler. Rivkin served in the Justice Department and the White House Counsel's Office in the Reagan and George H.W. Bush administrations.