



## Are Commercial DNA Tests DOA?

Want to know if your genes put you at greater risk for heart disease, cancer, or adverse drug reactions? For just \$269 you can pick up a genetic testing kit at your local pharmacy and have your DNA screened for these and other potential health issues. But hurry! You must act now because Congress and the Food and Drug Administration may soon slap regulations on the genetic testing industry that could cripple it or send it overseas.



Personal genetic tests have been available for years, but aside from some simple paternity and ancestry tests, most have only been available from Internet retailers. That changed with the announcement that San Diego's Pathway Genomics has entered into an agreement with Walgreens to sell its DNA test kits in the pharmacy giant's stores.

For \$20 to \$30 a customer can purchase a kit with a plastic test tube into which he can deposit his saliva. He can then ship the test tube off to Pathway's laboratory, where, for an additional \$79 to \$249, the company will examine his DNA to determine how his body will likely respond to certain drugs, whether he is at increased risk for certain ailments (such as heart disease or lung cancer), or what adverse genetic conditions he could pass along to his offspring. The customer, both before and after the test, can consult with Pathway to ensure that he interprets the test results correctly. After that, it is up to the customer, preferably in consultation with his physician, to determine what steps he wants to take to mitigate the risks that the test uncovered.

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In a free country, competent adults would be assumed to be capable of making decisions about having their DNA tested and taking the steps they desire after receiving the results, control over one's own body being the very essence of liberty. This being the United States of America in 2010, however, the very opposite is presumed, and so Congress and the FDA are on the case.

Typical of this nanny-state mindset is a comment made by Sharon F. Terry, head of "the Genetic Alliance, a Washington-based coalition of patient groups, researchers, private companies, government agencies and public policy organizations," as the *Washington Post* [describes](#) it. Referring to over-the-counter genetic tests, Terry told the *Post*, "It doesn't seem like a good use of resources or something people should be spending their money on yet." It never occurs to busybodies like Terry that people ought to be allowed to spend their money as they desire, even if others might consider that spending to be a waste of money.

To others, the fact that some people might misinterpret the results of these tests and therefore be given "a dangerous false sense of security" or be "needlessly alarm[ed]" (as the *Post* paraphrases the tests'



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critics) is reason enough for the federal government to put the kibosh on them. In his remarks to the *Post*, Hank Greely, director of Stanford University's Center for Law and the Biosciences, called this type of DNA testing "reckless" for this very reason.

Alberto Gutierrez, director of the FDA's office of in-vitro diagnostics, echoed these paternalistic sentiments, telling the *Post*, "We don't know whether the test works and whether patients are taking actions that could put them in jeopardy based on the test," which is why Gutierrez believes the over-the-counter tests ought to be prohibited.

All this concern for saving individuals from wasting their time and money on possibly worthless tests would be touching if not for the fact that, owing to all the regulations from Washington and the state capitals, coupled with the ridiculous malpractice awards juries routinely impose, patients are already put through countless unnecessary tests almost every time they encounter the American healthcare system. Your author, for example, had to have his blood drawn and undergo an electrocardiogram — tests that even the people administering them admitted were irrelevant to the condition being treated — in preparation for noninvasive kidney-stone removal a few months ago.

Furthermore, what currently prevents patients from discussing the results of FDA-approved tests with their doctors and then going out and taking inadvisable actions to remedy what ails them? If Joe's doctor tells him he needs to lose weight to help reduce his blood pressure, Joe is perfectly free to go on a starvation diet to accomplish that despite his doctor's advice to the contrary. With the proliferation of health information on the Internet, people who need further details on what their genetic test results mean and what they can do to mitigate the risks the tests have revealed have plenty of resources at their disposal. They do not need to be treated like helpless children by the bureaucrats in Washington.

Not to be outdone, and having no more pressing issues like a \$13 trillion debt or deteriorating wars on their hands, Congressmen have also gotten into the act. The House Committee on Energy and Commerce, chaired by Rep. Henry Waxman (D-Calif.), sent [letters](#) to the three largest genetic testing companies (23andMe, Navigenics, and Pathway) on May 19, generously giving them a whole 16 days to furnish to the committee a slew of "documents from the period from January 1, 2007, to the present."

In addition to requesting rather sensitive information, potentially including trade secrets, the committee also asked for "policy documents and protocols regarding collection, storage, and processing of individual DNA samples; policy documents and protocols relating to protection of consumer privacy; and documents regarding collected DNA sample uses other than to provide individual genetic counseling to a consumer, including documents relating to third-party use of collected DNA samples." Again, the concern for American's privacy regarding their voluntarily given DNA samples would make one's heart flutter had not this very same House of Representatives [voted](#) to pay state governments to forcibly collect DNA samples from anyone arrested for a crime and then to store those genetic profiles indefinitely in an FBI database regardless of whether the arrestee is later found guilty or not — a bill for which three of the four signatories to the committee's letters [voted](#) (Rep. Joe Barton, R-Texas, being the exception).

In an article entitled "[Would Regulation Kill Consumer Genetic Testing?](#)" *Newsweek* points out that direct-to-consumer genetic tests have been on the market for three years. Despite no evidence that any harm has come to consumers from these tests in all that time, *Newsweek* says that "most experts agree that some federal oversight is needed." (Don't they always?) The rules, avers *Newsweek*, must simply be "done right," and all will be well.



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Among the potential regulations that *Newsweek* mentions are FDA guidelines that could require clearance from the FDA before the tests could be sold to consumers; a “genetic-test registry that the National Institutes of Health is already planning to build so that consumers will have a way to compare different testing services side by side” (voluntary for now but perhaps mandatory later); requirements that the testing companies be certified by the government; and a bill before Congress to create “a new office focused on personalized medicine” and to implement some of the aforementioned regulations. All of these can be expected to increase the cost of genetic tests, reduce their speed in getting to market, and compromise the industry’s trade secrets and its customers’ privacy.

Of course, it’s quite possible that the big three genetic testing companies, which for now are resisting regulation, will ultimately get on board with it. That is, after all, how most regulations happen. As even *Newsweek* recognizes, regulations such as these “would raise the barriers to entry, possibly discouraging startups or driving them overseas.” This would, naturally, be good for those already in the business but bad for potential competitors and customers. As so many government policies have already done for other industries, it could also end up sending much of the genetic testing business to China, where, *Newsweek* reports, “institutes ... have lately been buying genetic sequencing machines in droves.”

Are these genetic tests really worthwhile? Sharon Begley, in a *Newsweek* [blog](#), suggests they may not be:

23andme, for instance, offers a test for a gene variant that makes people susceptible to serious side effects from warfarin (a.k.a. Coumadin), a blood thinner. Yet published studies have thrown so much doubt on this that Medicare last year ruled that it will not cover the genetic test, since the test does not improve patient outcomes.... Research has also cast doubt on whether the presence of other “disease genes” produces a more accurate assessment than traditional factors such as family medical history. Navigenics has a prominent page on its Web site arguing specifically that family history isn’t enough. In fact, for some diseases — Alzheimer’s being the most recent — the use of disease genes (with the exception of one rare one, called apoE4, in Alzheimer’s) does not make predictions of whether someone will develop a disease any more accurate.

At worst, then, genetic tests are of no more value than traditional diagnostic techniques. At best, they may make consumers aware of potential health issues, enabling them to take steps to avert those problems before they occur. In any event, the tests themselves are harmless; it is up to the consumer to make an informed decision as to what to do with the results. Unless a testing company gives a customer inaccurate test results or specific medical advice that, when followed, brings harm to the customer, the company should not be held responsible for the actions the customer takes in response to its test.

In the meantime, all those people in Washington who seek to control Americans’ access to information about their own DNA while permitting the government to vacuum it up at will have far more for which to answer. The FDA alone [causes](#) the deaths of hundreds or even thousands of Americans annually owing to its delays in approving life-saving drugs and other treatments. Congresses and Presidents are responsible for the deaths of thousands of American military personnel, not to mention innocent foreigners, in various wars and so-called police actions around the world — none of them, since World War II, constitutional. Spitting into a test tube isn’t going to kill anyone.

Perhaps the one worthwhile regulation the federal government could institute would be mandatory genetic testing on everyone in government, with the results made public. It would be a genuine public



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service to find out what genes turn people into control freaks; and it would strongly encourage such people to go into other lines of work.

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