

Genetic Testing

Gail H. Javitt, J.D., MPH
Director of Law and Policy at the Genetics and Public Policy Center and a Research Scientist in the Berman Bioethics Institute at Johns Hopkins University
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Javitt has served as an adjunct professor of law at the University of Maryland School of Law, where she has taught Food and Drug Law and Genetics and Law, and at the Johns Hopkins School of Public Health, where she co-taught Health Law and Regulation. She was a Greenwall Fellow in Bioethics and Health Policy at Johns Hopkins and Georgetown Universities. She was an Associate at Covington and Burling in Washington, D.C., where she specialized in FDA regulatory issues. She served as law clerk to the Honorable Gary L. Taylor, U.S. District Court, Central District of California. She has written on a variety of science regulatory and legal issues on topics including direct-to-consumer advertising of genetic testing and FDA regulation of biotechnology. She holds the Juris Doctor (J.D.), cum laude, from Harvard Law School, a Masters of Public Health (M.P.H.) from the Johns Hopkins University and a B.A., magna cum laude, Phi Beta Kappa, from Columbia College.

From The Post:

[Too Much Information](#) (June 13)

The transcript follows.

Gail H. Javitt, J.D., MPH: Hello, this is Gail Javitt, and I am here with my colleague at the Genetics and Public Policy Center, Juli Murphy, who is a genetic counselor. We are looking forward to answering your questions. You can also to the Center's Web site, dnapolicy.org to find out more about policies related to human genetics.

Washington, D.C.: The article claims genetic testing and advertising for genetic testing services is "largely unregulated". Is it not true that genetic testing and all commercial marketing & advertising practices are currently and fully regulated under US Law as well as State and Federal Statute? So why then do you personally and your center continue to make public statements that testing services, advertising, and marketing activities are unregulated by governmental oversight bodies? Is it not a disservice to the legitimate public debate over the appropriate utilization of genetic tests and services to be dishonest with the lay public about the facts?

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Gail H. Javitt, J.D., MPH: There are several issues embedded in your question, so let me address them separately.

With regard to genetic testing laboratories, they - like all clinical laboratories - are subject to the federal law called the Clinical Laboratory Improvement Amendments of 1988 or "CLIA." CLIA covers basic and generic lab practice issues. Genetic tests are considered "high complexity" under CLIA meaning they are more difficult to perform and interpret. Unlike other high complexity tests that have special standards, genetic tests do not. So they are LESS WELL regulated laboratories than others.

With regard to genetic tests, of the close to 1000 diseases for which tests are available, almost none have been reviewed by any government agency to ensure they do what they say they do.

With respect to advertising, there are laws that prohibit false advertising, but they have not been enforced yet with respect to genetic test advertising.

New England: I am about to get tested for the BRCA gene. I'm worried about who can access my medical information. If I have the gene, will I lose my life insurance policy? Will employers be able to see this info? I have been delaying getting tested because I'm worried about who will have access to this information.

Gail H. Javitt, J.D., MPH: This is a difficult question and it would be best to speak to a genetic counselor in your area. There is no comprehensive federal protection but some states do have laws that address these concerns.

Boston, Mass.: Do you think pregnant women will ever be able to test for autism while the baby is still in utero, like they can now test for Down's, etc.?

Gail H. Javitt, J.D., MPH: While I am not a medical expert, the causes of autism are likely multifactorial and poorly understood. While we certainly hope one day to have a better understanding of the cause or causes as well as tests, it is difficult to predict when such a test might be available.

Harrisburg, Pa.: It is possible to purchase a DNA test, but how reliable are these laboratories? Pennsylvania will soon be debating legislation that would have the Health Department certify DNA laboratories? Is this a good idea?

Gail H. Javitt, J.D., MPH: Any laboratory that is offering genetic testing to the public is required, at a minimum, to be certified under the Clinical Laboratory Improvement Amendments. But, there is no easy way for a consumer to know if a lab is CLIA certified, since the government does not make this information easily available. We are aware of genetic tests offered directly to consumers by non-CLIA certified laboratories.

Even if a laboratory is CLIA certified, CLIA does not address the clinical validity of tests, meaning whether they provide information that is relevant to disease or future disease or condition.

Norfolk, Va.: In your opinion, would it be fair to say that the recommendations of the Task Force on Genetic Testing and those of the Secretary's Advisory Committee on Genetic Testing have been largely ignored by the federal government? If so, would you agree that a significant push to improve the public's understanding of the state of genetics and genetic testing is the best hedge against problems raised by either DTC genetic testing or the use of genetic tests by non-specialists in genetics?

Gail H. Javitt, J.D., MPH: Government advisory committee recommendations over the past ten years have for the most part not led to concrete legislative or regulatory change. Raising consumer awareness is very important, particularly given the current regulatory environment.

Maryland: Are there any tests in the pipeline for behavioral health type illnesses?

Gail H. Javitt, J.D., MPH: The best place to find information about what tests are available for what diseases, either clinically or at the research stage, is GeneTests - www.genetests.org - this is an NIH-funded Web site.

Bethesda, MD: Do any of these services include enough information that those of us with appropriate training can use to draw our own conclusions?

E.g.:

(a) a common identifier for the SNP (single-nucleotide-polymorphism) being measured

(b) the position of that SNP on human chromosomes

(c) the primers used to extract that SNP

(d) some sort of probability score (e.g., a log-odds score) that the vendor has correctly identified the correct nucleotide base in the SNP

(e) the technology being used (e.g, Affymetrix or Illumina)

?

Gail H. Javitt, J.D., MPH: There are no requirements regarding what a company must disclose when offering a genetic test, and there is much variation regarding what information is provided. I don't know whether a company would provide the answers to the questions you posed if asked.

Richmond, Va.: Is there legislation pending?

Gail H. Javitt, J.D., MPH: At the federal level, genetic discrimination legislation is pending.

Washington, D.C.: It seems like one of the great problems lies in the quote from the genetic counselor from DNA Direct: "Everybody uses the Web differently."

Do these companies make any efforts to see that all of the necessary information is delivered along with results? Do they refer customers to doctors, or interact with their current providers?

Gail H. Javitt, J.D., MPH: There are no standards governing how much information and what type of information must be provided to consumers, so each company makes these decisions for itself.

Portland, Ore.: Could you please explain for "listeners" what the difference is between testing for genes related to diseases and paternity testing? Where does genealogy testing fit into all this?

Gail H. Javitt, J.D., MPH: Paternity and genealogy testing look at genetic markers that indicate relatedness between individual people or populations. They are not regulated under CLIA because they do not relate to health. In the health context, a genetic test can be used to diagnose current disease, predict risk of future disease, and screen for carriers of

genetic mutations that may cause disease if passed on to offspring. Different genetic tests look at different genes, depending on the disease or condition at issue.

Washington, D.C.: I'm adopted and have absolutely no health history. Although at 65, I've always been healthy, I'm haunted by not having a health history to judge possible future complications. I never had children because I didn't know what disease(s) I might pass on. Would DNA testing give me answers?

Gail H. Javitt, J.D., MPH: This is an important question and would be best answered by a genetic counselor who can guide you in whether there are tests that are appropriate for you in order to help answer your questions.

Richmond, Va.: Is that genetic NONdiscrimination legislation?

Gail H. Javitt, J.D., MPH: Yes, there is genetic nondiscrimination legislation that is pending in Congress.

Germantown, Md.: What can I do to help make sure that my genetic test information cannot be used against me?

Gail H. Javitt, J.D., MPH: There is no comprehensive federal legislation to protect against discrimination. Some states have passed non-discrimination legislation. The National Conference of State Legislatures tracks state legislation on this issue.

Indianapolis, Ind.: Don't direct to consumer AIDS tests have to be approved by the FDA? Why, then, shouldn't genetic tests be regulated the same way?

Gail H. Javitt, J.D., MPH: Very perceptive question. Yes, HIV tests are regulated by FDA. There is a "two path" system at play with respect to genetic tests. If a laboratory uses a "test kit" to make its test, that kit must go through FDA review. Most laboratories don't use test kits to perform genetic tests but instead use in-house developed methods that are not currently reviewed by FDA.

West Hartford, Conn.: How do I find a genetic counselor?

Gail H. Javitt, J.D., MPH: The National Society of Genetic Counselors has a Web site, www.nsgc.org, and directions for how to find a genetic counselor in your area. Good luck!

Norfolk, Va.: Are you optimistic that adequate regulation of the genetic testing industry will be forthcoming? What do you think have been the most significant obstacles to the implementation of adequate regulations to date?

Gail H. Javitt, J.D., MPH: Because of the increasing public attention that is being focused on this issue, we are more hopeful than we have been, but mindful of the many years of inaction. It is hard to say what the cause or causes of delay have been, but the more citizen awareness and engagement in the process, the more likely the government will be to realize this is an important issue for consumers.

Washington, D.C.: Hello,

Will the fact that direct tests and their providers aren't regulated make these companies harder to file lawsuits against when things go wrong? Or will these companies be even more exposed, since there are no standards they can say they have met?

Gail H. Javitt, J.D., MPH: It would depend on what the lawsuit was claiming. A claim of injury from a test would be most likely governed by tort law, which differs by state. In such a case, lack of regulation would not prevent someone from claiming they were harmed by a test.

On the other hand, as you note, in the absence of mandated legal standards, it would be hard for someone injured to claim that specific standards were violated by the company.

So, it really depends on the case.

Washington, D.C.: Are there rules on requiring counseling with AIDS tests?

Gail H. Javitt, J.D., MPH: To our knowledge there is one home-use HIV test kit that has been approved by FDA, and the manufacturer offers both pre- and post-test counseling in conjunction with the test.

Washington, D.C.: What is the Coalition on Genetic Fairness?

Gail H. Javitt, J.D., MPH: The Coalition for Genetic Fairness was founded by a group of advocates to press for federal legislation to protect against genetic discrimination in employment and insurance. You can visit its Web site at www.geneticfairness.org

Washington, D.C.: What is the pending legislation?

Gail H. Javitt, J.D., MPH: There are several federal bills that touch on this issue. You can track legislation through the Library of Congress using <http://thomas.loc.gov>

Norfolk, Va.: I assume that most people believe that genetic testing services are regulated by the federal government, though that is clearly not the case. Given the widespread ignorance regarding genetics in general and the state of the genetic testing industry, what strategies would you recommend for increasing awareness or educating consumers?

Gail H. Javitt, J.D., MPH: A step in the right direction is awareness and attention from key media like the Washington Post. The Center has been very active in public engagement on these issues and expects to continue this work. To sign up for our e-newsletters visit us at DNApolicy.org.

Gail H. Javitt, J.D., MPH: Thanks so much to everyone for your great questions! This is an important issue and we will continue to follow it. Hope this has been helpful.

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