

Genetic Testing On Students: Going Too Far or a Necessary Learning Experience?

By Rohan Hebbar J.D., LL.M. candidate (Health Law)
rahebbbar@central.uh.edu

There has been much controversy surrounding the University of California at Berkeley's ("Berkeley") recent mass genetic testing of incoming freshmen. Are the ethical concerns well founded, or, is this a case of society and lawmakers overreacting to the increasing prevalence of genetic testing in mainstream society?

Introduction

In an effort to provide a shared learning experience for incoming freshmen, Berkeley dedicated its annual "On the Same Page" program in the summer of 2010, to the study of personalized medicine. The "Bring Your Genes to Cal" experiment gave incoming freshmen the opportunity to learn about their own genetic traits while tackling broader ethical issues associated with genetic testing.¹

Berkeley initiated the experiment by sending saliva kits, a consent form, and a link to a video version of the consent form to approximately 5,000 incoming freshmen and transfer students. Over 700 responded.² Consent materials explained that the test was completely voluntary and that confidentiality and anonymity would be ensured by a bar code number system instead of using students' names.³ Berkeley stressed privacy by assuring that the samples would be destroyed immediately after testing was completed.⁴ Consent materials also revealed that Berkeley was testing for three genes that help the body metabolize alcohol, lactose, and folates.⁵ According to the consent video, these genes were chosen because information about them could help students make decisions that would lead to healthier lives.⁶ The original plan was to disseminate the results of the test to individuals via the barcode number.⁷ When they arrived on campus, participating students would find out their results by entering their barcode number into an online program.⁸ However, due to pressures from the California State legislature, individualized results were never revealed.⁹

¹ Univ. of California, Berkley, *On The Same Page*, <http://onthesamepage.berkeley.edu/> (last visited Oct. 6, 2010).

² *Id.*

³ Mark Schlissel, *Bring Your Genes to Cal Video Version of Consent Form*, http://webcast.berkeley.edu/media/common/media/one_off/pa_20100708_ls_h264fs.mov (last visited Oct. 6, 2010).

⁴ Univ. of California, Berkley, *On The Same Page: Frequently Asked Questions: Students*, <http://onthesamepage.berkeley.edu/archive/2010-genes/student-faq.php> (last visited Oct. 6, 2010).

⁵ Schlissel, *supra* note 3.

⁶ *Id.*

⁷ *Id.*

⁸ *Id.*

⁹ Robert Sanders, Media Relations, Univ. of California, Berkley, *Berkeley Alters Genetic Testing Program*, (Aug. 12, 2010), <http://vcresearch.berkeley.edu/news/uc-berkeley-alters-dna-testing-program>.

Ethical Concerns

Critics have offered a myriad of concerns in an effort to shut down the genetic testing program. While the California State Senate Education Committee voted against proposed legislation to shut down the program,¹⁰ a few of the ethical concerns are valid and should be considered by any educational institution that plans on implementing a mass genetic testing program.

The first of these concerns is student reactions to individualized results. Berkeley argues that the genes tested for were “nutritional genes” in nature, rather than “disease causing” genetic variants.¹¹ Therefore, Berkeley posits that since students can learn to live healthier lives with the information received from the tests, only good can come from learning they may possess these genetic traits.¹² This argument, however, ignores two main issues. First, the genetic test for metabolism of alcohol illustrates whether students have a gene variant that causes them to metabolize alcohol poorly, leading to nausea and flushness when they drink.¹³ The concern here is if a student learns that he does not have this genetic variant he may feel invincible, causing him to drink alcohol more often and in greater quantities.¹⁴ In effect, the student reactions to such a test could indirectly lead to more incidences of binge drinking, which is already a significant problem on college campuses.¹⁵

Secondly, the genetic test for metabolism of folates could show that students have one of at least 24 genetic mutations of the methylenetetrahydrofolate reductase (“MTHFR”) gene.¹⁶ Some of these mutations of the MTHFR gene result in increased levels of homocysteine in the blood.¹⁷ In turn, studies have shown that elevated levels of homocysteine are associated with numerous cardiovascular diseases, neural tube defects, and possibly depression and dementia.¹⁸ If an incoming freshman knew of these studies, it may effect his/her decision to participate in the genetic testing program. Furthermore, if a participating student found out about these studies after receiving the results of the test, the student may become severely anxious and possibly depressed. Berkeley has argued that it is important for students to know about the possibility of these diseases so they can prevent them.¹⁹ However, critics argued that a supposed educationally driven genetic test, done by a university that has no experience with mass genetic testing, is not the proper forum for a student to learn about the possibility of future diseases.

¹⁰ *Id.*

¹¹ *Frequently Asked Questions, supra note 4.*

¹² Schlissel, *supra note 3.*

¹³ *Id.*

¹⁴ Tamar Lewin, *College Bound, DNA Swabs in Hand*, N.Y. TIMES, May 19, 2010, at A14.

¹⁵ *Binge Drinking On College Campuses*, Center for Science in the Public Interest (Dec. 2008), available at <http://www.cspinet.org/booze/collfact1.htm>.

¹⁶ *MTHFR*, Genetics Home Reference (Oct. 3, 2010), <http://ghr.nlm.nih.gov/gene/MTHFR>.

¹⁷ *Id.*

¹⁸ *A Biomarker for Health Problems*, 79 Consumers' Research Mag., n5 (1996).

¹⁹ Schissel, *supra note 3.*

Another concern is coercion. While it is true that Berkeley emphasized that participation was completely voluntary,²⁰ incoming freshmen can be very impressionable at such an early stage of their collegiate experience. They may feel pressured to participate in a genetic testing program promulgated by faculty in order to impress and get to know a professor.²¹ Additionally, the genetic testing offered by Berkeley was free. The opportunity to have a test that normally involves significant costs may add to the level of coercion. Lastly, there may be peer pressure to participate because incoming freshmen may not want to be left out of the first and possibly only collective experience they will have as a class.²²

The last ethical concern that must be addressed is informed consent. As a threshold issue, some critics argue that informed consent could never have been given in this situation because incoming freshmen, due to their lack of experience and education in the field of genetics, could never fully appreciate the gravity of their decision to provide a DNA sample even if they had thoroughly read the consent form. Moreover, the lecture designed to teach the students about issues associated with genetic testing was scheduled for months after the students consented to the test.²³

Altering of the Program

In early August, the California Department of Public Health (“CDPH”) instructed Berkeley not to reveal the results of the tests to individual students. The reason for the instruction was that the CDPH categorized the experiment as medical in nature, therefore requiring Berkeley to comply with the federal Clinical Laboratory Improvement Amendments (“CLIA”) and the California Business and Professions Code (“CBPC”). The CLIA and the CBPC mandate that laboratories that provide genetic tests for medical experiments must be certified for accuracy and reliability and Berkeley’s labs were not. Berkeley argues that the CLIA and CBPC do not apply in this situation because students are not patients, the tested genetic variants are not disease related, and this was an educational rather than medical experiment.²⁴ This argument is severely discredited by the fact that results from the folate metabolism test express gene mutations that are directly attributable to cardiovascular and mental diseases.²⁵ As such, the CDPH was correct in categorizing Berkeley’s experiment as medical rather than experimental in nature. Berkeley complied with the CDPH’s instructions and presented aggregated findings rather than providing individualized results to students.²⁶

²⁰ *Id.*

²¹ Troy Duster, *Welcome Freshmen, DNA Swabs Please*, THE CHRON. OF HIGHER EDUC., May 28, 2010, <http://chronicle.com/article/Welcome-Freshmen-DNA-Swabs/65729/>

²² Ferris Jabr, *Exposing the Student Body: Stanford Joins U.C. Berkeley in Controversial Genetic Testing of Students*, SCIENTIFIC AM., July 6, 2010, <http://www.scientificamerican.com/article.cfm?id=exposing-the-student-body>

²³ Robert Sanders, *Tempest in a Spit Cup*, UC BERKELEY NEWS, Sept. 10, 2010, http://berkeley.edu/news/media/releases/2010/09/10_tempest_over_DNA_testing.shtml

²⁴ Sanders, *supra* note 9.

²⁵ *A Biomarker for Health Problems*, *supra* note 18.

²⁶ Sanders, *supra* note 9.

Future Scholastic Mass Genetic Testing Programs

It may be true that students in college will most likely have to deal with difficult genetic decisions in their lifetimes. Teaching students about genetic issues so they can make informed decisions later in life should be very important to universities. Providing individualized results may also be beneficial in order to keep students interested in important genetic issues that may affect their lives. However, while most mass genetic testing performed on college students will draw some scrutiny, universities attempting to teach students about genetic issues through an experiment such as Berkeley's must learn from Berkeley's mistakes.

First, universities must clearly establish that the experiment is being done for education rather than medical purposes. In order to establish this, universities should emphasize the benefits of learning how to make informed genetic decisions by analyzing risks, benefits and error rates. Furthermore, universities should choose purely innocuous genes that students likely already have information about, such as genes for colorblindness, lactose metabolism, and blood type. By choosing innocuous genes, universities eliminate the chance that their experiments will be shut down for having a medical purpose and mitigate the possibility of adverse student reactions to adverse results. To curb this risk, universities may want to have mandatory, confidential counseling sessions with trained geneticists to ensure participants fully understand their results.

Secondly, universities should limit coercion as best they can. Coercion may inherently be present in a situation where a faculty member is promoting something to a student due to the dynamics of the professor-student relationship, however universities should guard against coercion by testing upperclassmen who are not subject to the same vulnerabilities as incoming freshmen. Additionally, the tests should not be free or discounted for students. Any price-based promotion results in direct coercion on behalf of the university due to the expensive nature of genetic tests.

Lastly, universities must meet a heightened standard of informed consent in order to test college-aged individuals. To meet this standard, universities should only offer students who have taken, or are currently enrolled in, genetics classes to participate. This will provide students with the context and background necessary to make an informed decision whether to participate. Furthermore, in addition to the written consent form, universities should verbally present the consent form in a mandatory lecture with a question and answer forum following the presentation.

Conclusion

It is not clear whether universities that learn from Berkeley's mistakes and follow the guidelines discussed above will be allowed to perform genetic tests on students, and present the results of such genetic tests to individuals. However, state legislatures would likely be much less appalled by the idea of genetic testing on students if universities took simple steps to ensure the privacy and well-being of participating students.

Health Law Perspectives (November 2010)

Health Law & Policy Institute

University of Houston Law Center

<http://www.law.uh.edu/healthlaw/perspectives/homepage.asp>

The opinions, beliefs and viewpoints expressed by the various Health Law Perspectives authors on this web site do not necessarily reflect the opinions, beliefs, viewpoints, or official policies of the Health Law & Policy Institute and do not constitute legal advice. The Health Law & Policy Institute is part of the University of Houston Law Center. It is guided by an advisory board consisting of leading academicians, health law practitioners, representatives of area institutions, and public officials. A primary mission of the Institute is to provide policy analysis for members of the Texas Legislature and health and human service agencies in state government.