

HIGHER EDUCATION COMMITTEE
OVERSIGHT HEARING TESTIMONY
BERKELEY BRING YOUR GENES TO CAL FRESHMAN ORIENTATION PROGRAM
TUESDAY, AUGUST 10, 2010

Chairman Block and Members of the Committee,

Thank you for inviting me to testify before you today. My name is Jeremy Gruber and I am the President of the Council for Responsible Genetics, a public policy organization founded in 1983, that represents the public interest and fosters public debate about the social, ethical and environmental implications of genetic technologies. I was also a leader of the successful thirteen year effort to enact the Genetic Information Nondiscrimination Act and as such am particularly mindful of issues regarding genetic privacy and discrimination. We are very concerned by the recent announcement that the University of California, Berkeley has mailed saliva sample kits to incoming freshman and transfer students at the College of Arts and Sciences with which to send in a DNA sample. The university would have you believe this program should be judged as an educational project, but make no mistake, this program is research, however poorly designed and ill defined and should be judged by significantly higher ethical considerations.

Imagine you're an 18 year old high school graduate, you've spent four years working hard to gain admission to a top university. You've recently been admitted to one of the top institutions in the nation, the University of California at Berkeley. During the summer you begin to receive materials in the mail related to housing, meal plans, class schedules and other logistics related to the exciting journey you are embarking on.

And then you receive the following envelope (display). Looks cool, it has a large picture of a smiling student on it with an earring. You open it up, more smiling students encouraging you to send in a creative project on personalized medicine with cash prizes for the top submission. You then discover you are being asked to "Participate in the Grand Experiment" by submitting a sample of your DNA (collection kit included) in order to be tested for three gene variants as part of an introductory educational program for incoming freshman and transfer students to learn more about personalized medicine. You are told that armed with this information you will be able to make "better, more informed decisions about your own nutrition" and that "the information Berkeley students will glean from their genetic analysis can only lead to positive outcomes." You are told participation is voluntary, results anonymous and privacy breaches highly unlikely. Sounds like fun, right?

And who's to say no. Not only are you as a student being asked by faculty members and administrators to participate, but a decision to decline means not fully participating in the introduction to the next four years of your higher learning. The university minimizes half a century of evidence that "consensual human subject research can be corrupted by the power/status relationship between the subject of the research and those in charge of it" when they claim otherwise. Moreover the consent form for the project is pure marketing. The "benefits" section of the consent contains a long series of speculations about how the research might possibly benefit the student, but actually offers no documented benefits at all.

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At the same time the university touts the fact that its internal IRB approved the project. This is a weak shield in light of the recent successful lawsuit against another public university, Arizona State, by the Havasupai tribe for insufficient disclosures to the research participants. This is a project that itself had internal IRB approval.

But here's what the University is not telling their students before obtaining one of the richest sources of medical and hereditary information about an individual and their future generations that exists today, their DNA.

The university is not telling their students that the American Medical Association, the American Society for Human Genetics and the American Clinical Laboratory Association have all issued strong statements against this type of genetic testing, and recommend that a genetics expert be involved in ordering and interpreting genetic tests, that consumers be made fully aware of the capabilities of genetic tests, that the scientific evidence on which tests are based be available and stated so that the consumer can understand it, that the laboratories conducting the tests be accredited, and that consumers be made aware of privacy issues associated with genetic testing.

In fact the majority of the information being given to students about genetic testing is being offered on a voluntary basis only after the student has already decided to relinquish their genetic material. The students might not even attend these subsequent sessions despite participating in the genetic tests. Moreover the envelope mailed to students contains only a handful of pages of basic information and the corresponding website has little substantive content.

Indeed the university has provided the students with no information regarding the many opportunities for and documented instances of the misuse of genetic and other medical information, information about privacy and the potential risks involved in offering up your genetic information. They are not told about instances like the successful lawsuit against Lawrence Berkeley Laboratory by employees who had given blood samples for one purpose and discovered that their samples were subjected to undisclosed medical testing, including genetic testing. No obvious opportunities for questions and discussion are available prior to submitting a DNA sample. Nor are the students given any information about what legal protections they may or may not have available to them though the Genetic Information Nondiscrimination Act, and other state privacy and discrimination laws or additional resources for further questions in this area. Even the commercial direct-to-consumer genetic testing company 23andMe offers up such information right on its home page before a consumer makes any decision as to whether to purchase their product. Combined, these serious deficiencies fail to put the student in a position to make a fully informed decision about participating in the "Bring Your Genes to Cal" program in the first place.

And the privacy concerns are serious. As stated in the consent forms, the student's DNA sample will "become the property of the University of California" until it is destroyed and the university will "save the data for future teaching purposes and for possible publication of the aggregated data and its analysis." Indeed samples sent to the university will necessarily have personally identifiable information attached to them so that it can be determined whether consent forms were properly completed. This process is to be handled as far as we know by untrained administrative personnel with no experience or credentials working in research laboratory settings. What protocols, if any, have been adopted to ensure that the DNA samples are destroyed after testing has never been disclosed. It is also unclear who will keep the data, how it will be specifically used in the future, and to whom it might be distributed. Moreover the university's faith in anonymization is misplaced, as current science clearly establishes there is no way to make an individual's DNA profile or his genetic information anonymous, even when de-identified. Perhaps a student would be more wary of participating in the project were they aware that two years ago, the National Institutes of Health pulled de-identified aggregated data from its website and began encouraging other institutions to follow suit because a team of scientists had figured out how to re-identify DNA samples. Thus, claims to privacy and confidentiality cannot be guaranteed despite the university's assurances. This is troubling to many individuals and organizations familiar with information security issues, including the potential for both intentional and accidental data breaches. Examples abound of

such data being lost, stolen or otherwise publicly released. For example in 2005 the California Department of Managed Health care fined Kaiser Permanente \$200,00 for accidentally exposing records.

Moreover the University fails to inform the students that the US General Accounting Office recently released a report heavily critical of the analytical validity and clinical utility of companies that Berkeley is endorsing through its program. The FDA and Congress are currently investigating this type of testing, described as “snake oil” by a member of the House Energy and Commerce Committee at a recent hearing, also described as “not ready for prime time” by the Centers for Disease Control. In fact, the California Department of Health actually stepped in to caution commercial companies engaged in similar testing from making improper analytical claims. This information should have been provided to students along with the university’s endorsement of these companies. Indeed, beyond the conjecture offered to students in the “benefits” section of the consent form, no statements are made to indicate just how far away we are from knowing whether information on one's lactose metabolism or alcohol dehydrogenase alleles is actually beneficial. The entire project appears to be a strong marketing ploy for direct-to-consumer genetic testing industry despite the university’s claims to the contrary, especially given that the commercial genetic testing company 23andMe was originally participating as part of a program contest and that the actual consent form given to students directs them to 23andMe, Navigenics and other such commercial companies should they want to obtain “similar information” (consent form).

It is perhaps not surprising that the University would fail to offer students such information since the creator and principal investigator of the “Bring Your Genes to Cal” program, Professor Jasper Rine, founded his own genetic testing company less than a year ago and is completing a four-year \$ 1 million grant by the Howard Hughes Medical Institute to revamp undergraduate biology curriculum. This program includes a proposed module where students analyze their own DNA. These are conflicts of interest that become particularly alarming in light of the fact that the university has made alternating public and private statements to the fact that they have secured private funding for the “Bring Your Genes To Cal” program but refused to identify the source as anything but anonymous. Indeed a public records inquiry by the Council for Responsible Genetics for information related to funding for the program resulted in written statements to CRG from the university that indeed private funding had not been secured. Less than a week after making these statements in writing, the university was quoted again in multiple publications that indeed private outside funding had been obtained with no specific details forthcoming. In fact, the process of responding to our inquiries was so fraught with missteps, that we have filed a formal complaint with the California Fair Political Practices Commission. It is absolutely outrageous that a public university should act in this manner, stonewalling the public out of one side of their mouth and speaking in double talk with the other.

Finally, by conducting the actual testing at the School of Public Health, a decision announced prior to sending out the consent forms to students but not reflected on the consent forms, Berkeley may be in violation of the California Business and Professions Code. Genetic tests of this sort are considered clinical laboratory tests by the California Department of Public Health, as indicated by letters the Department sent to direct-to-consumer testing firms. Therefore any lab conducting these tests must obtain a license from the Department of Public Health. As far as we know, no laboratory at Berkeley's School of Public Health has obtained such a license. Furthermore, it is unclear whether a licensed clinical laboratory director or even clinical laboratory technicians are involved. Therefore, Berkeley's genetic testing program may violate California law.

Also, the consent form implies that they are practicing medicine on the students. And personalized medicine to boot. Personalized medicine would take into account much more than a person's genes, so in this respect they are not doing personalized medicine, they are promoting the very suspect ideology that personalized medicine means nothing more than knowing about your genes. Nevertheless, the principal investigator Jasper Rine, is not a medical doctor and the university has not indicated that a medical doctor will be involved in the project.

I urge this committee to request a full accounting of the “On the Same Page: Bring Your Genes to Cal” program. Today’s hearing cannot just be an opportunity to scold the university, it must be the beginning of a full inquiry into this program. I support innovative teaching and exploration of science and I support the

academic freedom of teachers, students and researchers to express their ideas and conduct research with intellectual honesty and without fear of reprisal. However, academic freedom should not be considered a blank check to shield teaching methods and research from all outside scrutiny, otherwise it becomes the generic excuse for any number of irresponsible acts. The fundamental rights of students to informed consent and confidentiality must be protected as well.

This Committee has the power to demand a full accounting of the ‘Bring Your Genes to Cal’ program” in a transparent and open process. I urge you request that the University delay the implementation of the program until these concerns can be satisfactorily addressed. I welcome the opportunity to work with you to ensure that the best interests of the students of the University of California system are protected. Thank you.