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May 24, 2010

Mr. Jeremy Gruber
Council for Responsible Genetics
5 Upland Road, Suite 3
Cambridge, MA 02140

Dear Mr. Gruber,

I am writing in response to your recent letter asking us to abandon a teaching program we have organized at Berkeley for next Fall as part of our On The Same Page program. I'd like to explain where the idea for this project came from and address each of the potential problems you outlined in your letter.

We decided to focus our activities around the theme of personalized medicine—the set of emerging and rapidly improving technologies that will allow physicians to use a person's own genetic information to more effectively help prevent, diagnose, or treat disease. We share CRG's interest in fostering "public debate about the social, ethical and environmental implications of genetic technologies" as per the mission statement on your web site. We considered sending out a book or set of magazine articles to provide the "study object" in advance of our discussion of this topic. However, we decided that involving students directly and personally in a genetic experiment of personal relevance would capture their imaginations and lead to a deeper learning experience. You question whether the genetic information we obtain in this study might be used for unintended purposes to the detriment of our students and analogized our project to the products sold by direct-to-consumer genetic testing companies. In addition, you expressed concern that students might feel compelled to participate in this study by providing a DNA sample, whether students would be asked to give valid informed consent, and whether this study had been considered by our human subjects research institutional review board.

This project has been considered and approved by Berkeley's Committee for Protection of Human Subjects Institutional Review Board (IRB). Instructions provided to students will make absolutely clear that participation is completely voluntary. Regardless of whether they return a DNA sample, all students will be invited to attend various lectures and panel discussions organized around this program. Since we will have no record of which students submitted samples and which did not, no pressure could be brought to bear on students to participate and we will make this fact clear to them. Each student will be asked to read and sign a detailed informed consent form describing exactly what we plan to do with their DNA sample, how the information will be used and safeguarded, how this information might benefit them, and what the alternatives are to submitting a sample. If the student has not yet turned 18, a parent must also sign the form in order for the sample to be analyzed.

In order to assure confidentiality and privacy, each student will receive two bar code stickers in the packet we are mailing: they affix one to the sample and keep the other. When we receive the envelopes an employee (not a scientist) will open the envelopes and check the consent forms. If the forms are signed, those bar-coded swabs will be passed on to the scientists to analyze. If the form is not signed, that swab will be destroyed. No identifying information beyond the bar code will accompany the swabs

to the lab and no record of names associated with bar codes will ever exist. After the analysis is complete, the results will be posted, by barcode number, on a website, where each student can if they wish check his or her results. Thus, the only person who will have access to a specific individual's test results is that individual. Tests for common polymorphisms in each of three well-studied genes involved in metabolism will be performed. Only these three common gene variants will be tested for and all remaining DNA will be incinerated immediately. The data will be used only in its aggregated form. As noted above, the University will not at any point have information linking specific sample results to individual students.

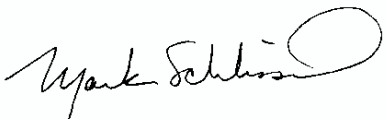
As you know, commercial direct-to-consumer DNA tests examine a large number of genetic markers many of which are associated with serious disease including cancer, diabetes, heart disease and kidney failure. There is active debate in the public and within the medical profession about the appropriateness of providing personal genetic information about disease predisposition in a non-medical setting. In the case of our program, we are testing for three common genetic variants that are not indicators of disease but rather represent variation between individuals in how they metabolize various nutrients. We will thoroughly explain the significance of these gene variants in writing to students before they send in their samples and again to those students who download their individual test results. Finally, we will go over these facts again in a public lecture delivered by Professor Rine, an expert in this area. In addition, Professor Rine and I will make ourselves available to discuss test results with students individually if they so wish. There are obvious differences between examining three well-studied common genetic polymorphisms unrelated to disease as part of an educational program and commercial direct-to-consumer analyses of large numbers of disease associated markers.

We had initially intended to use product donated by a commercial DNA testing company as a prize in a contest related to this program. We have reconsidered this aspect of our project, and decided not to offer this as a prize so as to avoid the appearance of endorsing a particular company or being perceived as taking a position on the issue of direct-to-consumer DNA testing.

I hope that we have adequately addressed your concerns and that you agree with us that provoking a free and open discussion about issues surrounding genetic testing is an important aspect of educating our students to be informed citizens. Berkeley is the perfect place for such a program since we have among our faculty great expertise in the science, ethics, politics, sociology and law relevant to the set of emerging technologies underlying personalized medicine.

Finally, thank you for your public advocacy on this topic.

Sincerely,



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