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Implications for Existing Law/Regulations

Ellen Wright Clayton *

I just spent the last six months reviewing the pharmacogenomics and pharmacogenetics literature. When you read that literature there are an amazing number of claims made about the relevance of race and ethnicity, that people in different groups vary in the frequencies of pharmacogenetically relevant alleles—alleles that influence the way you metabolize and generally respond to drugs. These allele frequency differences will or will not translate into phenotypic differences. Many, many things influence the way people respond to drugs, and genes are not always as important as many other factors. Nor do allelic variations correlate easily with socially constructed categories of race and ethnicity.

This controversy is not a huge issue for the HapMap because the only thing that was collected about these individuals was their gender and what part of the world they came from. There was no phenotypic data at all. Moreover, at present it is not possible to identify someone from their genotype. In order to do that, it is necessary to have another genotype from them that you know is theirs—that is how DNA identification works in the forensic setting—or there has to be some existing genotype already on the web with their name on it.

One pressing issue is whether just sequence data is considered “identifying” data under HIPAA.¹ HIPAA establishes eighteen categories of identifiers.² Removing those identifiers renders the sample unidentified. However, some people argue that DNA sequences may be the ultimate unique identifier under HIPAA and, therefore, cannot be de-identified. I hope that the Department of

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1. See generally U.S. Dep’t of Health and Human Services, Office for Civil Rights, HIPAA, Medical Privacy, <http://www.hhs.gov/ocr/hipaa> (last visited Aug. 26, 2005).

2. *Id.*

Health and Human Services will address this issue and come to the right decision: that this is not personally protected health information under HIPAA. If it is, then certainly all genetics research is going to come to a screeching halt.

There also are issues of individual remuneration. Note that the word I am using is remuneration and not compensation. Lawyers know that compensation usually means that you get something because something bad happened to you. Damages are compensation. Remuneration is getting paid because you did something. And the issue that we are debating both nationally and internationally with regard to remuneration is, "what can be paid for?" and whether the amount is sufficient or coercive. At least in the United States, the rule tends to be that research participants can be paid for inconvenience, for travel expenses, for things of that nature, but may not, for example, be paid for risk. Not that there is any particular risk in this research, but one cannot be paid for that. On the other hand, in the employment context, risk can be precisely what workers get paid for.³ People who experience risk in their jobs, all other things being equal, get paid more than people who are not getting paid for risky jobs.⁴ Thus, ethical issues remain.

In the international HapMap Project, new samples were collected in Ibadan, Nigeria, the area around Tokyo, Japan, and Beijing Normal University in China. The amount of money that was contemplated was fifty U.S. dollars, which is not a very big deal in Japan, but is a really big deal in Nigeria. One of the things that people discussed was whether it was just to pay fifty U.S. dollars in Nigeria or whether it was too coercive. Would it be more appropriate to pay a smaller amount and then use the rest of the money that would otherwise be spent for creating community infrastructure? These issues are ones that apply to the HapMap

3. Peter Dorman & Paul Hagstrom, *Wage Compensation For Dangerous Work Revisited*, 52 *Indus. & Lab. Rel. Rev.* 116 (1998); Kip Viscusi, *Job Safety*, *The Concise Encyclopedia of Economics*, available at <http://www.econlib.org/library/Enc/JobSafety.html> (last visited Sept. 1, 2005); Mark Aldrich, *History of Workplace Safety in the United States, 1880–1970*, *EH.Net Encyclopedia*, <http://www.eh.net/encyclopedia/?article=aldrich.safety.workplace.us>.

4. Dorman & Hagstrom, *supra* note 3; Viscusi, *supra* note 3; Aldrich, *supra* note 3.

but, in point of fact, pervade all biomedical research throughout the world. How do you apply standards justly and fairly in different settings?

The bigger issues with regard to the HapMap have to do with community interests. One of the issues is that descriptions tend to become reified. As Professor Ossorio will address in some detail, these are socially constructed categories. These populations do not exist as distinct biological entities. More generally, it will be necessary to attend to the possibility that finding particular genetic variations to be more prevalent in one group than another may prove stigmatizing. For example, looking for a gene that predisposes to alcoholism among populations that tend to have a high rate of alcoholism is potentially stigmatizing. These are issues that we confront head-on in the HapMap, even though there is no particular desire, or even ability, to directly look and find genes of interest with this particular tool.

Claims to benefits are another big issue. Do the groups from which we collect samples have a claim to benefit? Is there something that they ought to be getting back from this? This is reminiscent of the claims of bio-piracy that were raised—whether appropriately or not—in the context of the Human Genome Diversity Project (“HGDP”). Sometimes, appearance and perception matter. That was a major issue that afflicted the HGDP.

This issue also necessitates questioning whether research should be conducted in resource-poor countries. One of the complaints that has been raised about the effort to do this research, to collect samples among the Yoruba in particular, is “How are they going to benefit from this in the near term?” One answer is that, in fact, nobody benefits from this in the near term. The hope is that the HapMap will facilitate gene discovery. That is a hypothesis, not an assumption. If the hypothesis turns out to be true, that will be great. If the hypothesis turns out to be bad, then that will be unfortunate. To return to the question, “Can we do this sort of basic science research in resource poor countries?” it is important to do this research in poor countries. Doing the HapMap with only people of Northern European ancestry would be even more profoundly unjust than trying to look throughout the world as we try to figure out how to do gene discovery for health problems that afflict all populations, not just those from Northern Europe.

In doing this research, it is important to be attentive to cultural and language differences. The idea of asking permission in a way that we think is completely normative in the U.S. in 2004 is not normative in many other parts of the world. Negotiating permission turns out to be a profoundly difficult ethical issue. The ability to talk about genetics can be incredibly difficult, especially when the potential subject does not have a word for “genetics” in his or her language. However, many investigators have found that all cultures have an idea about things running in families, so that is a possible starting point.

If one is going to do research throughout the world, another issue is capacity building. One has to make sure that study populations not only benefit from the research, but also have the capacity to undertake research that is relevant to their own populations. The HapMap contributed to capacity building at the outset in an administrative sense by putting mechanisms in place to make sure that there is appropriate review by independent bodies of the government and independent bodies of investigators who actually look at the soundness of the research design, the quality of the investigators, the appropriateness of procedural and security provisions, and the adequacy of informed consent.

A foundational question for the HapMap project is, “Who has access to the samples and under what conditions?” The decision was made early on to store these in the Coriell-NIGMS Repository in New Jersey. These samples will be made available to any investigator throughout the world who has an Institutional Review Board (“IRB”)-approved protocol and who is approved by the Coriell IRB. Moreover, the use of these samples is going to be overseen by community advisory groups in all of these various populations who will be apprised of the kind of research that is being done, and who, if they choose, has the ability to remove samples from the repository if they do not like the kind of research that is being undertaken.

Now for a few words about intellectual property. One of the things about the HapMap is that because it is a basic research tool, because it has no clinically associated information, there is going to be almost nothing to patent there. But one of the major ongoing debates in genetics has been, “What do we do about protection of intellectual property in genetics, and how is this really going to be

made available?" We have heard some discussion, although I think not nearly enough, about the issues with intellectual property in this area.

We all know about companies like Myriad which have aggressively acted to protect their patents and to make sure nobody else can do the testing.⁵ We have also seen many other instances of defensive patenting, where the goal is to make sure that things are available on a reasonable basis. No clear model for that exists yet. From the donors' perspective, the perspective of the people who provide the DNA samples in the HapMap setting, there is no possibility of sharing any intellectual property interest with these donors because we do not know who they are. But, certainly, other groups like PXE International which, I believe, Professor Malinowski talked about before I arrived here yesterday, have explored other kinds of models that allow some benefit sharing.

The main concern that many of these entities have is that they want to make sure any resulting genetic tests associated with disease are available on a reasonable basis. The consideration that they may not fully take into account is that, unless there is some commercial benefit to somebody somewhere, these products are not going to be brought to market. In the context of the HapMap, a click-wrap agreement basically said that people who use this data promise not to seek intellectual property protection on it until they defined its utility.⁶

In closing, this was a rather rapid romp through issues associated with the HapMap, which have not been primarily legal thus far. The issues have been political, social, and ethical. I hope that, in the process, we have managed to learn some things about how better to proceed in a way that creates trust with people who are going to be involved in genetic epidemiology research as research participants. It would be hubris to say that we have either gotten this right or that the HapMap is going to be the be-all and end-all of tools. HapMap is a step. It is a hypothesis. Let us hope it fulfills the vision.

5. *Chemicon Enters Into Agreement with Myriad Genetics for Patented Research Tools*, Pharma Agreement News, Jan. 19, 2004, available at 2004 WLNR 293572; Nola M. Ries and Stacey E. Grubb, *Patents and Your Health*, Law Now, Jan. 1, 2004, available at 2004 WLNR 61763.

6. *Mapping of Human Genetic Variation Will Speed Search for Disease Genes Haplotyping*, Health & Medicine Week, Jan. 3, 2005, 2005 WLNR 10268; *Life Science Weekly*, Jan. 4, 2005, 2005 WLNR 11657; *Medical Letter on the CDC & FDA*, Jan. 9, 2005, 2005 WLNR 13117; *Genomics & Genetics Weekly*, Jan. 7, 2005, 2005 WLNR 9685.

