

Advisory Committee on Genetic Privacy and Research
Meeting Minutes – May 5, 2010
Revised and Approved September 1, 2010

Attendees:

Members: Patricia Backlar, Kara Manning Drolet, Anne Greer, Steve Nemirow, Nan Newell, Gayle Woods, Andrea Meyer

Alternate Members: Ted Falk, Stuart Kaplan

DHS staff: Bob Nystrom, Gwen Trieu, Nicoletta Voian

1. Introduction & Welcome to Nicoletta Voian
Dr. Nicoleta Voian will be working with the Genetics Program for six months to add public health experience to her current Medical Genetics residency at OHSU. She received her MD at the Victor Babes University of Medicine and Pharmacy in Timisoara, Romania. She was an Internal Medicine Resident in Romania and, after moving to the US in 1999, was a Preventive Medicine Resident at University of Buffalo. She started in medical genetics at OHSU in 2009.
2. Review of agenda; minutes for March 2010 approved
3. Nicoletta Voian presenting the analysis of the legal disclosures of four major direct-to-consumer (DTC) genetic testing companies: Do they meet Oregon's legal requirements? Do they not over promise what the results will tell the consumer?
 - 23 and Me; DeCodeMe; DNA Direct; and Navigenetics were reviewed.
 - Findings:
 - All complied with Oregon Genetic Privacy Laws, except possibly the informed consent requirement
 - All maintain confidentiality
 - DNA samples:
 - Kept for 1 year
 - Genetics information belongs to customer
 - Sample can be destroyed upon request
 - Navigenetics offers support for understanding and filling out consent form
 - Test results:

- Not FDA approved
 - Not for medical use
 - Not clinically validated
 - Difficult to interpret by most physicians
 - Purpose of these tests is for curious people who want to know about ancestry and his/her probability of hereditary illness in the family. Additionally, it was suggested that some people concerned about having the results of genetic tests in their medical records may go the DTC route for more privacy.
 - The only states that have some regulation of DTC testing are:
 - New York: All laboratories must be certified by NY when testing New York residents.
 - California: All genetic test results have to be delivered by a California licensed physician or a genetic counselor.
 - Concerns:
 - DHS has, in Rules, an informed consent form for use in genetic testing if not ordered by a physician. It is not clear if this form is relevant to DTC genetic testing with no medical or treatment results.
 - Competence of customer to give informed consent
 - Physicians not well educated about interpreting these tests.
 - This matter would become PH and ACGPR concern there are court cases with damages.
 - Reference to HFEA online group for issues
 - Conclusion: The committee will not propose any changes to Oregon law at this time and will continue to monitor the national conversation.
4. Anne's update on potential legal resources from the Health Law Section to assist in a pre-emption analysis of GINA and the Oregon Genetic Privacy Act.
- The Section declined to take on this project due to the rewrite of the Oregon Health Law Manual.
 - Rachel Arnold, a young health attorney, proposed doing this project at 2 hrs per month, but needs input from the ACGPR members due to limited knowledge on GINA and Oregon Genetic Privacy laws. A subcommittee was formed including Kara, Ted, Anne, Gwen Dayton, and Steve.

- Lisa Murphy, legal counsel from Regence, may also be interested in helping.

5. Other business

- Ron Marcum submitted his resignation from ACGPR citing time concerns. The Committee thanks him for many years of service and terrific insight into genetic privacy and HIPAA.
- DHS chose not to move forward with the Legislative Concept to license genetic counselors.
- Soon Oregon Public Health will not be carrying the DHS logo but will be under the Health Authority identity.

6. Next steps

- Anne, Ted, Kara, Steve, and Gwen D. will get together with Rachel for an initial discussion on the GINA & the Oregon Genetic Privacy Act pre-emption analysis. Anne will contact Lisa Murphy to assess her interest in joining this subcommittee.
- Nan to research HFEA, a UK committee, to look at their comments on DTC genetic testing.

No meeting in June

Next scheduled meeting – TBA