

# Advisory Committee on Genetic Privacy and Research

## Meeting Minutes — March 2, 2005

### Attendees

Emily Harris (Co-Chair), Gwen Dayton (Co-Chair) via telephone, Marc Marengo, Stuart Kaplan, Robert Koler, Kiley Ariail, Nanette Newell, Michael Becker, Michael Garland, Gayle Woods, Theodore Falk, and Naomi Adams. **Also attending:** Pat Van Dyke and Muriel Ditler representing ODS.

### Introduction and Announcements

- Welcome and introductions: Everyone introduced himself or herself.
- Review of draft minutes from last meeting on February 2, 2005.
- Kiley Ariail announced that Dr. Marc Loveless of Roche Laboratories would be joining the committee beginning in April. He comes recommended by Michael Garland and Theodore Falk. He will be representing the pharmaceutical industry.
- Kiley introduced Muriel Ditler and Pat Van Dyke as representing ODS. Kiley invited them to attend to share the concerns of ODS about the proposed legislative language affecting employment and insurance practices.
- Marc Morengo announced that his grant application was funded. The Pacific Institute for Ethics and Social Policy at Pacific University will be funded by the National Human Genome Research Institute (ELSI) to do public education and research in communities of faith on genetics policy-making.

**Outcome:** Co-Chair Emily Harris directed that the minutes of February 2, 2005 were approved with the provision that they were still correctable. Contact Naomi Adams ([naomi.adams@state.or.us](mailto:naomi.adams@state.or.us) or 503-731-4021 xt: 537) if you would like to request changes to the March minutes.

### Insurance and Employment: Draft Legislative Language

Emily Harris opened the discussion of the draft legislative language for insurance and employment provisions. She emphasized that the Committee already endorsed the legislation in principle, so the decision point today is to decide which version of draft language the committee endorses.

Ted Falk described the differences between Version 1 (drafted by Gwen Dayton) and Version 2 (with additional revisions by Ted Falk). He opened with a brief review of existing statute, then described how Version 1 and Version 2 differ. In Version 1, subsection (3) of Section 1 was revised after the previous meeting to accommodate concerns expressed by Michael Becker of Regence about the legitimate use of information for underwriting. This revision makes explicit that information about actual care received and actual diagnoses are not excluded as a basis for underwriting, and uses language consistent with the Standard Health Statement. The exception for legitimate underwriting purposes was framed to apply to (A) Genetic Information, (B) Information about a request for or receipt of genetic services, and (C) medical history of

a blood relative. Parallel changes were made in the employment provisions (Section 2). Other portions of Section 1 were re-structured for clarity.

In Version 2, the lead-in language of subsection 3 was revised to read “information about an applicant **or an insured person.**” This change was made to avoid restricting the scope of the current statute to applicants only, and to ensure that protections continue to apply once a person is insured. Additionally, the scope of Mike Becker’s request for the proviso for ordinary medical underwriting was restricted to apply to information about a request for or the receipt of genetic services only. This change was made to avoid significantly altering the meaning of subsection (3)a. In Version 2, the exception for legitimate underwriting purposes applies to 3(c) only. Parallel changes were made in the employment provisions (Section 2).

Question for discussion: should the exception for legitimate underwriting purposes apply as in Version 1 (broadly) or more narrowly as in Version 2 (to request for or receipt of genetic services only)? Ted Falk argues that the more narrow application in Version 2 keeps the original strength of Section 1(a) and (b) intact.

A new concern with the wording of the legislation was noted: by using the term “about an applicant or insured person” in Section 1 (3), the meaning of “genetic information” is unintentionally restricted to the individual. By definition, “genetic information” includes information about family members, so there is a conflict in the wording and meaning. Ted said that the original statute does not say whose genetic information is being referred to, so by implication current law already implies that one can’t discriminate based on genetic information of a relative or anyone else. Emily remarked that the way this is worded, the genetic information about an applicant and whom it refers to is narrower.

Mike Becker questioned whether the wording in Version 2 would preclude claims adjudication. Ted Falk responded that this concern exists with existing statutes and that the Insurance Division, under rulemaking authority, can address this concern. To date, Ted hasn’t yet heard any concerns about this topic with respect to genetic privacy law. Mike Becker stated that he is comfortable with Version 2, but that both versions satisfy his concerns about underwriting.

Marc Marengo voiced concern about the definition of “diagnosis.” It is unclear in the context of the draft language whether diagnosis means evidence of a genetic trait or a disease diagnosis based on clinical symptoms. Kiley Ariail added, speaking from a conversation with Jon Zonana (who was not in attendance) that Jon, too, had concerns about the potential for misunderstanding the term “diagnosis.” The term “clinical” is defined in statute. Emily Harris proposed adding “clinical” to Section 1 (3)c, before the term “diagnosis” and before the term “existence of a particular illness...” No vote was taken on this idea but no opposition was voiced.

At this point, the discussion moved to solicit the concerns of the representatives of ODS Health Plans. Previously, Kiley Ariail received a communication from a lobbyist representing ODS that voiced concern about the proposed legislative language. This message requested the insertion of the term “genetic” into the proposed legislation before the term diagnosis in Section 1(3). Emily Harris explained to the ODS representatives that the term “genetic” was omitted deliberately based on ongoing

conversations and agreement among Committee members. The primary points of argument are that the potential to differentiate between a “genetic disease” and a non-genetic disease is diminishing, and that in the near future, most common diseases will be discovered to have a genetic component. The ODS representatives seemed satisfied by this explanation.

At this point, Gwen Dayton joined by telephone.

Ted Falk: motion to accept Version 2 with the following changes: strike phrase “about an applicant or insured person in Section 1(3),” add the term “clinical” before “diagnosis” and before “existence of a particular...” in Section 1(3)(c). Michael Garland seconded. Michael Becker expressed that he is comfortable with the proposed revisions.

Emily Harris called for a vote: Seven members or alternates voted yes, with one (Gayle Woods) abstaining. Gayle does not oppose the proposed legislation, but feels she is not authorized to speak on this issue on behalf of her agency.

**Outcome: Version 2 of the proposed legislative language relating to employment and insurance provisions is accepted with the changes noted above.**

**Outcome: Gwen Dayton will seek a legislative sponsor.**

### **Research Proposal Status Report**

Gwen has been working with the OHSU lobbyist to identify a legislative sponsor for the research proposal. No hearing date has been set.

Stuart Kaplan said that he, Andrea Meyer, and David Fidanque had discussed the ACLU position on the research proposal. The ACLU is opposed to the proposal, particularly the section on coded research, because the opt-out provision is lost. They maintain that as a general principle, people should have complete control over personal information. The proposal primarily allows for disclosure of results of genetic tests subject to conditions of Federal regulations. The ACLU is not confident that the Federal provisions will allow for the amount of protection they are seeking. The ACLU may question some provisions of this bill as it moves through the legislature.

Ted Falk doesn't agree with the ACLU concerns. The rationale behind the original opt-out provision was to provide consumer protection when not otherwise protected. Coded research is heavily regulated, and highly protected, so the opt-out provision should not extend to coded research. It is true that situations will arise in which a person cannot opt-out, but current statute imposes the HIPAA standard on coded research, which is stricter than the IRB standard. Individual choice is lessened in these instances, but privacy protection is still strong. Michael Garland voiced that the harm may lie in not being asked permission and Stuart Kaplan agreed, and said that ACLU does not feel the language is strong enough.

## **SB99**

Scott Gallant, on behalf of the OMA, sent Kiley Ariail an email in which he expressed concern about the ACGPR recommendations. It appears that Mr. Gallant is responding to the report, not necessarily SB99 or any other legislative proposal itself. Mr. Gallant expressed that the OMA might be forced to oppose any legislative proposals based on these recommendations.

Relating to the provider/insurer portions of the SB99 discussion, Mr. Gallant is concerned that the committee recommendations may roll back protections for genetic information.

Gwen volunteered to talk with Scott Gallant and explain to him the reasoning behind the recommendations.

**Outcome:** Gwen will contact Scott Gallant about this issue and try and clarify the recommendations.

## **Legislative Report:**

The due date for the legislative report is still not set. In the meantime, work on the report continues. The most recent version of the report was distributed prior to the meeting. Any and all comments are welcome and can be directed either to Emily, Gwen or Kiley in particular.

Emily requested that in the time remaining, the group consider the topics listed in the "Moving Forward/Next Steps" section of the report and ask whether they reflect the highest priority items that the committee should assign for the upcoming biennium. Ted Falk proposed striking item #3, relating to informed consent for special populations and minors. Ted offered the opinion that the concept is too complex both legally and conceptually for it to be a productive and worthwhile topic of deliberation.

**Outcome:** Committee members should send their comments and/or edits of the draft report to Kiley Ariail, Emily Harris, or Gwen Dayton.

## **Adjournment**

### **Meeting Schedule**

April 6	August 3
May 4	September 7
June 1	October 5
July 6	November 2
	December 7

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First Wednesday of each month  
1:00 to 3:00 p.m.  
Oregon Medical Association  
5210 S.W. Corbett Avenue in Portland