

Advisory Committee on Genetic Privacy and Research

Work Session Minutes — February 5, 2003

Attendees

Astrid Newell (Co-Chairperson), Ted Falk (Co-Chairperson), Barry Anderson, Emily Harris, Kara Manning, Kerry Silvey, Andrea Meyer, Michael Garland, Rory Carroll (Oregon Health Forum), Laura Zukowski

Introductions

Everyone introduced himself or herself. Partway through the meeting, news reporter Rory Carroll with the Oregon Health Forum, joined the work session as a guest.

Agenda

Today's meeting was a work session, not a full advisory committee meeting. The goals of today's session were to:

1. compile a list of issues/concepts for inclusion in the public input survey;
2. develop an outline for the committee's presentation to the Senate Judiciary Committee.

General Update

The 2001 Oregon Legislature charged the Insurance Division with writing an administrative rule regarding authorization for genetic testing when used by insurance companies as part of their application process (implementation of ORS 746.135). A hearing was held last week on the proposed rule and form for authorization. The public comment period on the proposed rule and form is open until February 7.

Several people present objected to the proposed rule and form for multiple reasons. The proposed rule and form:

- do not require insurance companies to disclose what the genetic testing will examine or tell the applicant the result(s) of the testing;
- do not address destruction of the subject's sample;
- offer no legal recourse for inappropriate disclosure;
- do not warn the subject about possible risk of discrimination to self, family members, or future relatives.

Outcome: *On behalf of the committee, Ted Falk will sign and submit a letter that discusses the above objections to the proposed rule and form by the close of the comment period on February 7. Kerry Silvey and Astrid Newell will review it, also. The letter will discuss the above objections relating to the rights of and risks to the subject, point out some errors on the form, and mention that this committee was not informed*

or consulted about the rule or form. He will mention, also, that the letter was developed within a work group, not the full committee.

Public Outreach Survey

Collins Medical Trust has accepted Geneforum's request to help fund a public opinion survey. This latest award will bring the total of grant funding for this survey up to \$30,000. The intended purpose of the survey is to provide information about the public's values, fears, misconceptions, and concerns around genetics, not necessarily to inform or educate the public. Information from ill-informed individuals has value to the group, because it will reveal associated personal values, gauge the knowledge level among the general community, and give committee members a sense of whether individuals see genetic information as inherently different from other medical information.

The group worked on broadening an earlier draft survey to include issues from its future work agenda and developing a framework for what types of information would be useful to the group. Discussion included brainstorming broad topic issues that were based on the eight statutory topics that appeared in the minutes of May 8, 2002. Potentially, a professional pollster could meet with the committee to fine tune the actual language of the questions.

Below is Kerry Silvey's summary of the concepts/ideas generated during the brainstorming session. This list includes issues that the committee will be studying over the next two years. These questions are not the actual questions that will be used in the survey. The comments in parentheses attempt to capture some of the discussion around the issues.

1. Should Oregon law address patenting of genes?
(Generally, patenting law is addressed at the federal level. Should Oregon have additional laws?)
2. Should the state regulate genetic tests?
(The FDA, which regulates medical tests, has decided not to regulate most laboratory aspects of genetic tests. Some states do regulate laboratory tests.)
3. Should protections related to life and disability insurance be strengthened?
4. What information should be provided to consumers before they are asked to give informed consent to a genetic test in a clinical setting?
5. Should Oregon have stricter protections for genetic information than federal law (HIPAA) provides for medical information in general?
6. Are research subjects adequately protected by IRBs? (Is there more we want to know about this topic?)

7. Should the definition of genetic information be expanded to include somatic mutations, or information gathered during a physical exam or from family history? (Or, Should information obtained from a clinical examination or family history, or about somatic mutations be afforded the same protections as the current definition of "genetic information"?)

8. Should "special" protections extend to a person seeking (or receiving) genetic counseling or a clinical genetics evaluation?

Legislative Presentation

As an introduction to the committee's legislative report, co-chairs Astrid Newell and Ted Falk have met with Senators Nelson, Courtney, and Minnis, and left information with Representative Shetterly. The Senate Judiciary Committee will receive the legislative report in an informational hearing, probably within the next few weeks.

Astrid and Ted introduced the concept for the legislation (recommended in the legislative report) and were instructed to draft out a bill as soon as possible. Ted Falk took the lead in drafting this concept, and a version was circulated through this committee's contact list of members and interested parties. The draft has been submitted to Legislative Counsel for review, also. It will take approximately one month to get the concept printed up into a bill. Senator John Minnis, Chairman of the Senate Judiciary Committee, has agreed to introduce the bill. A hearing by this committee should follow later in the session.

Discussion about the legislative presentation generated the following suggestions and ideas:

- give an overview of the contents of the report, educate the legislators about some of the issues, and briefly mention recommended changes to the current law;
- provide general context/brief history of current law, with an emphasis on the six years' process of balancing the needs of the research community and private individuals;
- emphasize why there is special concern around privacy of genetic information and how it is different from medical information;
- emphasize the changing nature of the field of genetics and the legal arena;
- include video excerpts in the presentation, possibly from the OPB broadcasts or the ELSI video, to highlight issues;
- emphasize the ongoing discussion and reflection that has gone into the committee's work and the report.

As far as the proposed legislation, the recommended changes to the current law are not considered to be controversial. The legislation could fail to pass if it is not perceived as important. The group discussed natural stakeholders in having this type of legislation pass. Groups and individuals to contact that might be interested in supporting the legislation include:

- Jim Gardner and other biotechnology experts and researchers
- Scott Gallant from the Oregon Medical Association

- Oregon Association of Hospitals and Health Systems
- ACLU
- Brian Boehringer from OHSU
- Barney Speight from Kaiser Permanente

Outcome: Direct feedback on the proposed legislative concept or legislative process to Ted Falk or Astrid Newell.

Future Full Committee Meetings

First Wednesdays —

- March 5
- May 7
- July 2
- September 3
- October 1
- November 5
- December 3

1:00 to 4:00 p.m.

Oregon Medical Association

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