

SENATE COMMITTEE ON JUDICIARY

January 31, 2001 Hearing Room 343
1:00 PM Tapes 18 - 19

MEMBERS PRESENT: **Sen. Minnis, Chair**
 Sen. Courtney, Vice-Chair
 Sen. R. Beyer
 Sen. Burdick
 Sen. Duncan
 Sen. Harper
 Sen. Metsger

STAFF PRESENT: **Marilyn Odell, Counsel**
 Jane Bodenweiser, Committee Assistant

MEASURE/ISSUES HEARD: **SB 114 PUBLIC HEARING**

These minutes are in compliance with Senate and House Rules. Only text enclosed in quotation marks reports a speaker's exact words. For complete contents, please refer to the tapes.

TAPE/#	Speaker	Comments
TAPE 18, A		
004	Chair Minnis	Calls the meeting to order at 1:10 p.m. and opens a public hearing on SB 114.
		<u>SB 114 PUBLIC HEARING</u>
006	Vice Chair Courtney	Introduces SB 114 referring to genetic privacy and discusses the legislation enacted in 1995 regarding protection of individuals' rights in the area of genetic research and testing. Explains that legal protection was determined to be inadequate, thus the Genetic Research Advisory Committee (GRAC) was formed, and new civil and criminal sanctions were employed as safeguards in SB 114. Explains that this is an extremely complicated piece of legislation.
102	Barney Speight	Co-Chair, Genetic Research Advisory Committee Represents Kaiser Permanente. Submits testimony and testifies in support of SB 114 (EXHIBIT A). Gives a broad overview of what's happened in the past year with GRAC, acknowledges its members, and highlights the policy changes suggested.
269	Dr. Brad Popovich	Chair, Genetic Research Advisory Committee Testifies in support of SB 114. Discusses his role as a faculty member at OHSU in the Department of Molecular and Medical Genetics. Gives clinical examples of when an individual would want to know of a pre-disposition to an illness as well as when a person would absolutely not want to know. Explains that anonymity in the world of genetic medicine, with the technology available, is becoming increasingly more difficult. Expresses his desire to make it clear that genetic testing is going to become a very common commodity in health care.
TAPE 19, A		

034	Ted Falk	Member, Genetic Research Advisory Committee Testifies in support of SB 114. Describes what the 1995 law has done, and what this legislation will do to change the law. Reviews the executive summary found on page 3 in Exhibit A regarding remedy, family issues, informed consent, property, continued study and oversight. Recommends the continuation of a standing committee.
178	Chair Minnis	Asks if there have been any cases filed relevant to establishment of a property right with respect to genetic material.
180	Falk	Replies that he is not aware of any cases in Oregon, and that the single best known case he knows of is “Moore vs Board of Regents, U of C”, filed in California. Describes case.
218	Chair Minnis	Asks about the issue of property rights and who owns the developed artifacts from genetic materials.
222	Falk	Replies that in the California case the State Supreme Court rejected the property rights theory, but Moore won on the grounds that his informed consent had been violated.
245	Speight	Discusses further the issue of property rights and suggests that the GRAC wanted to focus on the privacy/confidentiality issues rather than how federal patent law interdigitate with the State.
269	Sen. Harper	Asks if a researcher can patent a human gene sequence today in the State of Oregon.
271	Dr. Popovich	Replies, yes; but explains that while Oregon has helped to center the debate around patenting genetic sequences, the question of patents is presently covered under federal patent law.
302	Sen. Harper	Asks if these kinds of follow-up discussions might generate further amendments next session.
306	Speight	Replies, yes. The issue of patents as well as the issue of genetic information that is not necessarily derived from DNA testing, but is in the medical records, will be at the top of the work list.
317	Chair Minnis	Asks about collection of evidence at a crime scene and wonders if the genetic privacy law would apply.
321	Falk	Explains that there is a list of crimes for which there are exceptions relating to informed consent.
362	Margaret Everett	Health care consumer representative on GRAC Submits testimony and testifies in support of SB 114 (EXHIBIT B). Discusses her son’s rare genetic disorder, and how important it was to be able to make informed decisions about how his samples were used. Advocates the implementation of minimum damages, criminal penalties, and continued study and oversight, and public involvement.

TAPE 18, B

020	Dr. Susan Hayflick	Associate Professor and Vice-Chair, Department of Molecular and Medical Genetics Submits testimony and testifies in support of SB 114 (EXHIBIT C). Explains that this bill will protect the genetic privacy of her patients, and feels that the inclusion of civil and criminal penalties is a strong and needed assertion that genetic discrimination will not be tolerated in Oregon.
056	Chair Minnis	Asks what happens to materials used in research after the research is completed.
064	Dr. Hayflick	Replies that it really depends on the kind of research planned and if ongoing studies are considered.
073	Chair Minnis	Asks if there is any law governing how genetic materials are disposed of.
078	Dr. Hayflick	Replies that she knows of no law, but explains that it is understood that the way samples are handled is very important.
082	Scott Gallant	Director of Government Affairs, Oregon Medical Association (OMA). Replies that there are regulatory and statutory standards for the disposal of medical materials that would have to be followed.
101	Chair Minnis	Asks if the research papers produced are kept under lock and key.
105	Dr. Hayflick	Explains that her materials are kept locked up and that she is the only one with access to the code relating the information to the individuals participating.
112	Sen. Duncan	Asks who would have responsibility if the person doing the research is incapacitated.
116	Dr. Hayflick	Replies that her expectation is that the University would take responsibility for managing the information and overseeing the continuing research.
122	Gallant	Points out that page 10, lines 34-43, addresses the disposal of DNA samples.
133	Vice Chair Courtney	Asks how samples are destroyed.
143	Dr. Hayflick	Explains that samples are disposed of in such a way that they cannot be recovered. They are either mixed with chemicals or multiple samples that would be in a form that would not be identifiable.
167	Gallant	Submits testimony and testifies in support of SB 114 (EXHIBIT D). States that the OMA believes strongly in this bill and feels it is very important to continue the work of GRAC in looking at future issues.
217	Sen. Burdick	Asks how this bill addresses informed consent and the protection of that consent.
235	Gallant	Replies that the legislation provides for internal review boards to be applied so that patients are assured that their genetic information will be confidential, retained as such, and used for the purposes of the research explained to them through informed consent.
258	Sen. Burdick	Expresses her concern about an individual's patent that might prohibit the research from being used in the way it was intended.
265	Everett	Talks about a case in Florida where a group of people with the same genetic disorder knowingly consented to research, and later said they did not understand that the gene would be patented and

		that the availability for testing for other families at risk would be limited, and a royalty would be charged. Acknowledges that this is a concern.
289	Sen Burdick	Wonders if this bill has protections against such cases.
293	Gallant	Explains that one of the objectives for continuing GRAC is to look at the issue of patents.
308	Sen. Beyer	Asks why there is an emergency clause in this bill.
321	Gallant	Replies that the current statute has a sunset clause and it was feared it might go into effect before the new legislation could be heard.
355	Jim Gardner	Representing the Pharmaceutical Research and Manufacturers of America Testifies in support of SB 114. Commends this bill for its comprehensive applicability to privately funded genetic research in the state of Oregon, and its specified and stiff penalty structure self-contained within the bill. Discusses the patent issue and explains that it is under very active study at the federal level.
429	Steve Chase	Testifies in opposition to SB 114. Expresses his concerns with regard to genetic privacy and genetic property rights. Asks why the property clause should be removed. Expresses his desire to see more private citizens on the advisory committee.
TAPE 19, B		
082	Rep. Cherryl Walker	Testifies that she will be submitting an amendment to SB 114 which is not back from LC yet, and explains that it would add additional protections to persons born as a result of genetic alterations prior to their birth.
122	Chair Minnis	Asks why there is no mention of violations via negligence, and asks for clarification of lines 13-15, page 1, regarding fines.
140	Falk	Suggests review of Exhibit A, page 5 that clearly illustrates penalties for violation of Oregon's genetic privacy statutes.
176	Chair Minnis	Asks for an explanation of "willful neglect".
184	Speight	Discusses a hypothetical instance discussed by the committee to clarify willful neglect.
228	Chair Minnis	Asks who enforces fines.
231	Falk	Replies that it is a civil action, but one could also have an action brought by a public prosecutor for the same remedy. Speaks to the Health Information Portability Act (HIPA), a law aimed at protecting privacy.
276	Chair Minnis	Asks for clarification of the "Federal Policy for the Protection of Human Subjects," referenced on page 3, line 26, 27 of SB 114.
278	Falk	Responds that this refers to a federal "common rule" which governs and regulates all research on human subjects.
302	Chair Minnis	Asks who is referenced in line 31, page 3, "credible national and state organizations."
308	Falk	Gives example of credible organizations that might include the National Bio-ethics Advisory Commission and the National Association of Insurance Commissioners to name just two, but explains that there is no exclusive list.
316	Chair Minnis	Asks why mention of these organizations is necessary.
318	Speight	Explains that these organizations help to develop a framework from which regulation can be developed.
335	Sen. Metsger	Asks if it is intended that a research firm would be protected from having to be held responsible if there was a theft of genetic

372	Dr. Popovich	material.
402	Speight	Responds that this is not the intent of the bill. Discusses the intentions of the defined offenses and states that the minimum fines are only suggested guidelines.
428	Sen. Metsger	Asks about economic damages as defined in ORS 18.450 and referred to on page 2, line 8 and 9.
442	Falk	Responds that this will have to be referred to counsel.
453	Chair Minnis	Asks if there is a value to genetic material.
460	Dr. Popovich	Replies that there is potential for tremendous value.
488	Chair Minnis	Closes the public hearing on SB 114 and adjourns the meeting at 3:05 p.m.

Submitted By,

Reviewed By,

Jane Bodenweiser,
Committee Assistant

Marilyn Odell,
Counsel

EXHIBIT SUMMARY

- A – Written testimony submitted by Barney Speight, dated 1/31/01, 7 pp**
- B – Written testimony submitted by Margaret Everett, dated 1/31/01, 2 pp**
- C – Written testimony submitted by Dr. Susan Hayflick, dated 1/31/01, 1 p**
- D – Written testimony submitted by Scott Gallant, dated 1/31/01, 7 pp**