

## Genetic Discrimination

### Description:

Like all information, genetic information has the potential to be misused or misinterpreted in many settings, particularly in employment and insurance. The most frequent and popular policy response to this threat has been the widespread support of strong privacy protections for genetics information. What are the existing rules that seek to protect against discrimination? Are they adequate? Does genetics information privacy provide the protection it is widely believed to? Are there circumstances where genetic based susceptibility to certain environmental threats warrant limiting exposures to them?

### Moderator:

**Aaron Katz** is a senior lecturer in the Department of Health Services and is director of the Health Policy Analysis Program for the University of Washington School of Public Health and Community Medicine. He received his B.S. degree from the University of Wisconsin, Madison, and a certificate of public health degree from the University of Toronto.

### Panelists:

**William J. Hagens** has been the Deputy Insurance Commissioner for Health Policy in Washington State since 1999. Prior to that, he served as the Senior Research Analyst for the Washington State House of Representatives Health Care Committee. He received his B.A. degree from Saginaw Valley College and his M.A. from Wayne State University.

**Jerry Sheehan** is Legislative Director for the American Civil Liberties Union of Washington. He received his Bachelor's degree from Amherst College and attended the University of Puget Sound School of Law.

**Julie Sando** is the former President of the Northwest Huntingtons Disease Society of America and a contributing editor for Suite 101.com Huntingtons Disease Web Site.

Julie is a freelance writer and speaker with interests in acting as a consumer voice for all illnesses like Huntingtons disease who need a voice but are unable or unwilling to risk being heard for fear of discrimination. She will share from a personal viewpoint the concerns and needs facing individuals who are caregivers, at risk, or carry a gene for an incurable genetic illness.

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## Research, Public Health and Privacy

### Description:

Storing human samples for future research is increasingly common. One issue that arises is whether an individual can give truly informed consent for future research on a sample. Some, but not all, genetic research can use samples whose unique identifiers have been either partially or completely removed from the sample. Is there any public interest justification for compromising absolute patient privacy of their genetic information? How can we strike a balance between respecting the privacy of the individual in a way that permits genetics research and the advancement of legitimate public health interests? How do strong privacy policies governing the exchange of genetics information affect both clinical and public health research?

### **Moderators:**

**Wylie Burke**, M.D., Ph. D. (morning) is Chair of the Department of Medical History and Ethics at the University of Washington. She currently serves on the HHS Secretary's Advisory Committee on Genetic Testing and the National Advisory Council for Human Genome Research. She received her Ph.D. and M.D. degrees from the University of Washington.

**Kenneth E. Thummel**, Ph.D. (afternoon) is on Faculty for the School of Pharmacy at the University of Washington. He has an interest in pharmacogenetics. He received his B.S. degree from Boise State University, his Ph.D. from the University of Washington and his Postdoctoral Fellow from the University of Connecticut Health Sciences Center.

### **Panelists:**

**Lee Hartwell**, Ph.D., is president and director of Fred Hutchinson Cancer Research Center. He received his B.S. degree from California Institute of Technology and his Ph.D. from Massachusetts Institute of Technology.

**Paul R. Billings**, M.D., Ph.D., is a Co-Founder, Executive Vice President and Chief Scientific and Medical Officer of GeneSage, Inc. He is also Editor-in-Chief of GeneSage's GeneLetter, the leading on-line magazine of genetic medicine, society and culture. He received his A.B. degree from the University of California, San Diego, his M.D. from Harvard Medical School, and his Ph.D. in Immunology from Harvard University Graduate School of Arts and Sciences.

Foreseeable developments in genomics, and enhancements in the current delivery of genetic information and testing, will alter how individuals relate to their DNA, genomes and genes. New uses of personal risk information, greater health related prediction and prevention, and personalized medicine may follow. Trends towards more discrimination using genetic information, a genetic meritocracy and genetic hygiene could also be fueled. Genetic information delivery should not be unnecessarily medicalized but requires up-to-date expert advisors. It ought to embody the best of the informed, consumer choice revolution—secure, empowered, "smart" individuals confronting new prospects in their lives and taking appropriate beneficial actions. Along with market development, new commitments and programs that redefine the role of communities, insure basic rights, and enhance principles of equity in the face of growing acknowledgement of biological and socio-economic differences, will be needed in the brave new post-genomic world.

**M. Elizabeth Ward**, M.N., is the CEO/President for the Foundation for Health Care Quality. She received her B.S. degree from the University of Utah, her M.N. degree from the University of Washington, and Post-master's study in Community Mental Health at the University of California, San Francisco.

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## Washington State Board of Health

### Description:

Whose genes are they anyway? What are the implications of allowing genes to be patented? How does privacy play a role in this context?

### Moderator:

**Anna C. Mastroianni**, J.D., M.P.H., teaches law and bioethics in the Health Law Program at the University of Washington School of Law, as well as in the University's Institute for Public Health Genetics. She received her B.S. degree in Economics and her B.A. degree in Spanish and Portuguese from The Wharton School and College of Arts and Sciences, her J.D. from the University of Pennsylvania School of Law, and her M.P.H. from the University of Washington School of Public Health and Community Medicine.

### Panelists:

**Clark Shores**, J.D., Ph.D., is an Assistant Attorney General with the University of Washington Division of the Washington State Office of the Attorney General. He received his B.A. degree from Reed College, and his Ph.D. and J.D. from the University of Washington.

### Human Tissue and Intellectual Property: The University Context

In the university, human tissue and intellectual property issues arise in the research and technology transfer context defined by the Bayh-Dole Act, a federal law passed in the early 1980s. This law allows universities and other recipients of federal grants or contracts to retain title to inventions developed using federal funds. It harnesses the intellectual property assets of the modern research university by providing an economic incentive to transfer those assets to the private sector. University technology transfer leads to a host of legal issues related to contracts, intellectual property ownership, and inventor rights, as well as fundamental policy questions about conflict of interest and the commercialization of the academy. Human biological materials can raise these and other, more specific issues, including appropriate research and commercial use, donor consent and ownership rights, and patent rights and the proper scope for the assertion of those rights.

**Charles E. Hart, Ph.D.**, is the Senior Director of Business Development and Strategic Planning at ZymoGenetics. Dr. Hart received his B.S. degree in Zoology from the University of California, Davis, his M.S. degree in Zoology from Oregon State University, and his Ph.D. in Pathology from the University of Washington.

The completion of sequencing of the human genome has provided an avalanche of genetic information to the worldwide research community. During the past decade, while this sequencing effort has been in progress, we have seen rapid growth in the biotechnology community. The majority of this growth has been in the establishment of new companies that are focused on the use of this genetic data. The question lying before us is how best to make use of this information for the welfare of all mankind. Is it fair for drug companies to obtain patents on "our genes" or should they be free for all to use? If patents aren't allowed, what effect will this have on the development of new pharmaceuticals? Will drug companies take on the expense and risk of bringing new drugs to market if there is no patent protection for exclusivity? This presentation will discuss the implications of obtaining patent protection on individual human genes, and the importance of this protection for the development of new therapeutics to treat unmet human diseases.

**Bradley W. Popovich, M.Sc., Ph.D.**, is Associate Professor, Molecular and Medical Genetics at the Oregon Health Sciences University. He received his B.A. degree in Biology from Oakland University, his M.S. degree in Human Genetics/Genetic Counseling from Sarah Lawrence College, his M.Sc. in Biochemical Genetics from McGill University, and his Ph.D. in Molecular Genetics from McGill University.

Genetic Patenting and Property Rights Collide in Oregon: Who Owns our DNA Anyway?

A major debate is developing in the US as consumers and professionals alike are realizing that the promised fruits of the Human Genome Project are at serious risk of being compromised by the patenting of disease genes and mutations. Virtually all characterized human genes (and their disease causing mutations) have been patented and in several cases this has directly resulted in the patent holders (or their licensee) placing restrictions on who has access to using the derived DNA sequence information to offer clinical services (e.g. BRCA1, HFE, genetic testing). The compromised access to these genetic discoveries by the clinical genetics community has led professional organizations such as the American College of Medical Genetics (ACMG) to issue statements voicing concern and opposition to the patenting of naturally occurring genetic sequence(s). This issue raises the legitimate question of who owns our DNA?

In 1995, Oregon became the first state in the US to pass a law making an individual's genetic information (defined as information derived from a genetic test) the "property" of the person from whom it was derived. The Oregon Genetic Privacy Act (OR SB 286) was further amended during the next legislative session in 1997 to make an individual's DNA (in addition to genetic information) the property of the person from whom it was derived (OR SB 1107). The Oregon Genetic Privacy Act therefore appeared to offer a simple answer to the question of ownership, but a major debate has taken place in Oregon that has brought into sharp "focus" the real question of who owns our DNA.

My talk will discuss the Oregon Genetic Privacy Act, and issues that have been debated relating to the property in our current legislation. I will also discuss suggested amendments that will be introduced during the 71st Oregon Legislative Assembly beginning January 2001.

**Patricia C. Kuszler**, M.D., J.D., is an Associate Professor with the University of Washington School of Law, and an Adjunct Associate Professor with both the School of Medicine and the School of Public Health at the University of Washington. She received her B.A. degree from Mills College, her M.D. from Mayo Medical School, and her J.D. from Yale Law School.

As genome and biotechnology research has progressed from the bench science stage to that of commercial value, there is increasing question as to who should own a piece of the profit pie. This issue first began to be explored in the *Moore v. Regents of the University of California* case several years ago. In that case, California's Supreme Court held that a leukemia patient whose spleen cells had been harvested and used in the development of a potentially valuable cell line did not have an action for conversion or theft of property, as the cells were not "owned" by the patient under California law. The Court did find that the researcher/providers had failed to adequately inform Moore of their intentions and had breached their fiduciary duty to him. In the wake of the Moore case, research science, medicine and law have begun to grapple with the question of who has and should have ownership right to human tissues, cells and DNA. How long does the donor retain rights to the tissue? When do those rights abate, assuming that there has been initial informed consent? When does the researchers manipulation, processing and changing of the donor's tissue, cells or DNA result in an ownership claim on the part of the researcher? What role should the common good and societal benefit play in the analysis of ownership? This presentation will briefly consider these questions from the perspective of individual rights.

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## **Computers/Technology**

### **Description:**

The huge advances that computer technology has made in the last fifteen years have allowed us to obtain and use genetic information in many ways. Gene Chip technology may make the idea of 'genotyping' populations of people a reality. The advent of personal computers, the internet and ever more powerful computing technologies have combined with these advances, not only to quicken the pace of research and the rate of new genetics discoveries, but also potentially to place genetic information in the hands of nearly anyone. What has the synergy between computer technology and genetics produced, what may be coming, and how can the beneficial potential of these advances be secured without risking the detrimental effects that can come if privacy is not adequately protected?

**Moderator:**

**Chief Justice Richard P. Guy**, J.D., was appointed to the state Supreme Court in 1989. He did his undergraduate work at Gonzaga University before serving two years as a U.S. infantry officer. He earned his law degree from Gonzaga University.

**Panelists:**

**Thane Kreiner**, Ph.D., is Vice President of Corporate Operations and Communications for Affymetrix, Inc. He received his B.S. degree in Chemistry from the University of Texas, his Ph.D. in Neurosciences from Stanford University, and his M.B.A. from the Stanford Graduate School of Business.

As a society, we are just beginning to realize value from the Human Genome Project. The increasing availability of genetic information offers the potential to enhance the quality of our lives in many ways. We expect to understand the roles that various genes play in health and disease, to develop safer and more effective drugs that precisely target the causes of disease, and to identify lifestyle changes that may reduce the risks of some diseases. Society is also likely to benefit in many ways that are unexpected. Powerful tools to acquire and analyze genetic information will accelerate the pace of the "Genetics Revolution". GeneChip» technology is a unique marriage of microprocessor manufacturing methods and chemistry. GeneChip manufacturing utilizes photolithography – the same technique leveraged by the semiconductor industry – to build DNA on chips. These chips, GeneChip probe arrays, are used by scientists worldwide to acquire and analyze genetic information in conjunction with other elements of the complete system. Generally, scientists ask two types of questions: How much is there? And What is it? Because of the massive information power of Affymetrix' GeneChip technology, scientists in one afternoon can analyze thousands of genes simultaneously – a task considered impossible only a few short years ago. By looking at more information, scientists will better understand biology and its impact on our lives. The tremendous range of potential uses for genetic information implore us as a society to embrace these promises while offering protections against misuse of genetic or any personal information through thoughtful public policy.

**Lisa A. Vincler**, J.D., is an Assistant Attorney General in the Health Sciences Division, University of Washington, for the Washington State Attorney General's Office. She received her B.A. degree in English Literature from the University of Michigan, her J.D. from the Seattle University School of Law, and her Certificate in Health Care Ethics from the University of Washington School of Medicine.

**Cynthia L. Osborn** is directly responsible for Management Direction for Operational, Procedural, Tactical Programs in Healthcare Delivery Markets Nationally and worldwide for IBM. She received her B.S. degree from Mankato University and her M.A. from the University of Minnesota.

**Brooke P. Anderson**, Ph.D., is the Vice President for Software Development for CombiMatrix Corporation, a biotech company working on biochip (including DNA array) and software technologies for the pharmaceutical and biotech industries and for the research community. He

received his B.S. degree in Nuclear Engineering from the University of Michigan, his M.S. degree in Applied Physics and his Ph.D. in Computation and Neural Systems from California Institute of Technology.

Dr. Anderson's presentation will cover three questions. What genetic information can we typically gather and make use of today and what will we be able to do in the future? What are the advantages and disadvantages of our society having that capability? What might we be able to do to guard against the disadvantages?

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## **Genetics and Medicine: Privacy and the Duty to Disclose**

### **Description:**

Genetic information is an important part of the medical record. It can be critical in the diagnosis and management of complex diseases. Because of the potential for discrimination, individuals may opt for completely anonymous genetic testing. However, difficulty in obtaining genetic information may compromise care by limiting the amount of information the health care provider can use in planning the course of treatment. In addition, a patient's genetic information can be valuable to the family of the individual. What duty does the health care provider have to disclose genetic information to promote coordinated health care and disease management and to provide important information to the patient's family about the patient's or the family's health risks? What duty does the patient have to contact his or her family?

### **Moderator:**

**Debra Lochner Doyle, M.S., C.G.C.**, is the State Coordinator for Genetic Services for the Washington State Department of Health. She received her B.S. degree in Genetics from the University of Washington, and her M.S. degree in Human Genetics/Genetic Counseling from Sarah Lawrence College.

### **Panelists:**

**Susie Ball, M.S., C.G.C.**, is a Genetic Counselor with the Central Washington Hospital Genetics Program in Yakima, WA. She received her B.A. degree from the University of Colorado and her M.S. degree from the University of Colorado Health Sciences Center.

While patients expect and deserve privacy and confidentiality of their medical records, genetic services often deal with families, rather than an individual patient. Thus, providing appropriate services to an individual patient may at times require sharing information from another person's medical records. In addition, because medical records can be disclosed to employers and insurers, some patients at times don't want their genetic medical information (especially genetic testing that indicates a future risk, not current health) included in their records, hampering the

ability to provide information to other family members. Finally, do providers have an obligation to re-contact families if new information about the condition in their family becomes available due to research or the Human Genome Project? These points will be illustrated with case examples and we will review the Code of Ethics of the National Society of Genetic Counselors for guidance in addressing these issues.

**Sharon Davis, Ph.D.**, is Director of Professional and Family Services for The ARC, a national organization on mental retardation. Dr. Davis received her Ph.D. in Education from Cornell University.

Dr. Davis will address family perspectives on testing and privacy of genetic information and the duty to disclose to others. She will discuss concerns about the proliferation of tests, problems with tests themselves, and the lack of specialists to properly interpret results. These issues affect who should be provided with information based on probabilities that may or may not be accurate. She will present data from The ARC's survey of families participating in a Human Genome Education Program. Family members provided views concerning whether or not someone with a genetic condition in the family should be tested before having children, whether or not spouses should be informed and whether or not blood relatives should be told about a genetic condition in the family. She will also address issues of family participation in genetic research and who should be informed if a genetic condition is identified in the family. Finally, she will address concerns about disclosure to third parties who may discriminate against affected individuals.

**Geoffrey MacPherson, M.D.**, is the Medical Director for Quality Assurance at PacifiCare. Dr. MacPherson received his B.A. degree in Zoology from the University of Washington, and his M.D. from the University of Washington

Health care management has long ago moved beyond the traditional closed physician-patient relationship. Third party payor relationships and managed care have created stakeholders concerned with the processes and outcomes of care. These stakeholders include government and private health care insurers.

Genetic information will be a new and valuable set of indicators for diagnosing, preventing, managing and curing disease. Genetic information created as a result of the human genome project should be treated with the same respect and guidelines that exist for all medical information.

Protections of privacy and confidentiality, plus protection from discrimination already exist for medical information and they can easily accommodate genetic information if it is viewed within the current medical model.

**Richard R. Sharp, Ph.D.**, is a Biomedical Ethicist at the National Institute of Environmental Health Sciences, one of the National Institutes of Health. He also holds appointments at the Woodrow Wilson International Center for Scholars and the Duke University Center for the Study of Medical Ethics and Humanities. He received his B.A. degree in Philosophy/Sociology from Western Michigan University, his M.A. in Philosophy from Michigan State University, and his Ph.D. in Philosophy from Michigan State University.

Assertions of genetic responsibility and irresponsibility have a long and unfortunate history. Eugenic programs and mandatory-sterilization campaigns, for example, maintained that government interest in preventing genetically irresponsible choices could trump the reproductive autonomy of individuals. This history demonstrates the social influence of appeals to genetic responsibility and the corresponding need to examine such moral judgments carefully. As a result, philosophers and ethicists have focused much attention on the moral assumptions implicit in appeals to genetic responsibility and irresponsibility, at least in relation to reproductive decision-making. In other areas of personal decision-making, however, it is remarkable how little analysis has taken place regarding genetic responsibility and irresponsibility. Issues that have not been carefully examined include: whether patients have a "right not to know" about their genetic predispositions to disease, whether employers have a moral obligation to determine which workers are genetically vulnerable to workplace hazards, whether partners are acting irresponsibly in failing to reveal genetic traits to their companions, and whether individuals with genetic hypersensitivities to environmental agents are morally blameworthy if their choices place them in close proximity to those environments. As a first step toward clarifying concepts of genetic responsibility and irresponsibility in nonreproductive decision-making, this paper examines how genetic information may influence individual choices to avoid environmental hazards to which an individual is genetically sensitive. I argue that choices which place an individual at increased risk of disease can be said to be genetically irresponsible if an individual knows (or should have known) about their genetic vulnerabilities to a particular environmental hazard and failed to take these risks into consideration before acting. Like other moral judgments, however, there may be excusing conditions or justifying considerations that affect allegations of genetic irresponsibility. Consequently, we should avoid making assertions of genetic irresponsibility unless we possess a rich set of supporting information about the moral deliberation that preceded an individual's action. Nonetheless, in practice, it is likely that allegations of genetically irresponsible decision-making will become more common as we learn more about genetic sensitivities to environmental hazards. These moral judgments about a broader range of health-related choices could significantly affect social attitudes toward individual autonomy, impacting such things as health-insurance coverage, life-insurance premiums, and the provision of health care to those who are viewed as having acted irresponsibly. Thus, there are important practical reasons for examining when assertions of genetic irresponsibility are appropriate and when they are misplaced.

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## **Primary Prevention or Eugenics?**

### **Description:**

Mankind has long sought to improve the quality of its next generation. As of today, scientists have developed many genetic tests that, with varying levels of certainty, can predict human health and developmental futures for children that have yet to be conceived or borne. Should these tests and related technologies be used to improve the genetic make up of future generations? If so, how will we decide what constitutes improvement? Should we use any sort of

genetic information for the purposes of reproductive decision-making? If so, what limits should be observed on the use of the information? Who should determine these limits and how should they be communicated and enforced? What role does privacy play in promoting the best use of genetics information in this context?

**Moderator:**

**Asha Singh, M.D., M.S.**, is the Superintendent of Fircrest Residential Center for the Department of Social and Health Services. She received her M.D. from MLN Medical College, and her M.S. in Administrative Medicine from the University of Wisconsin.

**Panelists:**

**Nuhad D. Dinno, M.D.**, is a Developmental Pediatrician at the University of Washington Center on Human Development and Disability. She received her medical degree from the University of Baghdad.

**Robert G. Resta, M.S., C.G.C.**, is the Director of Genetic Counseling Services at Swedish Medical Center and is the Editor-in-Chief of Journal of Genetic Counseling. He received his B.A. degree in Anthropology from Brooklyn College, his M.A. in Anthropology from Washington University, and his M.S. in Genetic Counseling from the University of California, Irvine.

Genetic counseling and testing has been viewed by many critics as simply a modern day form of eugenics. While such criticism contains an element of truth, it is also unfair to characterize genetic counseling strictly in these terms. Genetic counseling involves a range of services, decisions and activities, most of which have little to do with eugenic goals and ideologies. To reduce genetic counseling to a euphemism for eugenics is to ignore a richly human and humanistic aspect of medical genetics, and ignores valuable medical and psychosocial benefits offered by genetic counseling and testing. On the other hand, some aspects of genetic counseling do hang precariously over the slippery slope to eugenics, and society must take care to ensure that genetic information does not serve nefarious or special interest purposes, either private or public. In particular, the voice of the disability community must not be ignored.

**Edith Yee Tak Cheng, M.D.**, specializes in genetics and prenatal diagnosis and coordinates these services for the Department of Obstetrics and Gynecology, University Hospital, University of Washington. She received her medical degree from the University of Washington and is board-certified in medical genetics, obstetrics and gynecology, and maternal-fetal medicine.

**James Levy, M.A., J.D.**, is a Research Associate for the Center for Technology and Disability Studies and a Law Fellow for the Center on Human Development and Disability at the University of Washington. He received his M.A. degree from the University of Washington and his J.D. from the Seattle University School of Law.