

# 2009 Report to the Oregon Legislature

## **Advisory Committee on Genetic Privacy and Research**

March 2009



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## EXECUTIVE SUMMARY

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The Advisory Committee on Genetic Privacy and Research (ACGPR), created in its current form by the Oregon Legislature in 2001 (Senate Bill 114), studies the effect of Oregon's regulation of the use and disclosure of genetic information. In this report, the ACGPR:

- Reviews the current national discussion of genetic privacy and a new federal law, the Genetic Information Non-discrimination Act (GINA);
- Discusses a strategy to perform a thorough review of GINA's impact on Oregon's genetic privacy statutes and resolve any potential conflict or overlap;
- Reviews input received by the committee from various stakeholders on how changes to the law in 2005 (SB 1025) have impacted their work;
- Summarizes the committee's work over the past biennium to examine the issue of genetic exceptionalism;
- Reviews items from the report to the 2007 Oregon Legislature.

In addition, this report lists ACGPR's recommended activities for the 2009-2011 biennium:

- Conduct a detailed examination of any changes needed to Oregon's genetic privacy statutes in light of the passage of GINA.
- Through collaboration with the Portland State University (PSU) Master of Business Administration program, evaluate the past and continuing financial impact of the current statutes to health care providers.
- Continue to monitor the effect of Oregon genetic privacy laws (OGPL) on medical research, access to health care, and health care providers' management of health care information.
- Continue to look for educational opportunities to fulfill the ACGPR's charge of educating the public and eliciting public input representative of the diversity of opinions on the scientific, legal and ethical development within the fields of genetic privacy and research.
- Evaluate whether the committee's charge is being adequately met through volunteer and non-funded DHS staff capacity.

**At this time, the committee does not recommend changes to Oregon's current genetic privacy statutes.**



## INTRODUCTION

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### About the ACGPR

The 2001 Oregon Legislature established the Advisory Committee on Genetic Privacy and Research (ACGPR). The committee is required to report to the Oregon Legislature biennially on the use and disclosure of genetic information as regulated by Oregon law and make recommendations for change when appropriate. Other tasks assigned to the ACGPR include advising the Oregon Department of Human Services (DHS) on the content and implementation of administrative rules, creating opportunities for public education, and eliciting public input on the issues of genetic privacy and research.

The committee is composed of 15 volunteer members and alternates appointed by the Oregon Senate president, speaker of the house, and the Oregon Department of Human Services. Members serve renewable two-year terms. Composition of the ACGPR represents the diversity of Oregon stakeholders in genetic privacy and research.

### Recent major events in national genetic privacy

Over the past biennium, genetic research and genetic privacy issues have frequented the headlines. Most importantly, on May 21, 2008, President Bush signed into law the Genetic Information Nondiscrimination Act (GINA). GINA provides individuals with federal protections against genetic discrimination in health insurance and employment. The passage of GINA was a monumental event for the nation that resulted from more than 13 years of efforts to put such a law in place. Because this law has many similarities to the existing protections in Oregon's genetic privacy laws, the ACGPR is looking carefully at the two laws to determine if there are any contradictions, redundancies or other issues that need attention. This project, which is discussed in further detail in the body of this report, will be the committee's main focus in the next biennium.

Conducting research on large banks of tissue or genetic information has also been a recent hot topic. The National Institutes of Health (NIH) is considering creating a large, national "bio-bank" involving biological samples from approximately 500,000 volunteers. The bank would also include health data from these volunteers collected over a period of years or decades. This proposal led to a public opinion study conducted by the national Genetics and Public Policy Center that included community focus groups in four cities, including Portland, Ore., which occurred in April 2008. Several ACGPR members attended.

In September 2008, a publication from the Translational Genomics Research Institute showed that the presence of one individual's genetic profile could be detected from a complete mixture of pooled genetic data. This capability led some institutions such as the NIH to remove public access to currently available genomic databases where pooled genetic data had previously been available online, where it was thought to be anonymous. The ACGPR will continue to monitor whether the Oregon genetic privacy statutes have kept pace with such modern technologies and the new privacy concerns that may surface while also evaluating the additional protections provided by GINA, the Health Information Portability and Accountability Act (HIPAA), and other applicable laws and regulations.

## Follow-up from the 2007 Report to the Oregon Legislature

In the last report, the ACGPR proposed ongoing work in five areas. A summary of progress in these areas follows:

1. *Examine the scholarly basis for special and additional privacy protections for genetic information. Determine whether significant changes in the structure and content of Oregon's genetic privacy legislation are called for given advances in genetic science and scholarly opinion about whether genetic information deserves any special consideration.* This task was completed and a summary is in Section 1.
2. *Continue to monitor the effect of Oregon's genetic privacy laws, especially SB 1025, on medical research, access to health care, and health care providers' management of medical information.* This task was begun, and the committee continues to collect information. A summary of the completed work is in Section 2.
3. *Educate the general public about the discrimination protections in the Oregon Genetic Privacy Law. Continue to monitor federal genetic anti-discrimination legislation to determine if there is a need for further state discrimination legislation.* This task is ongoing and work to date is summarized in Section 3.
4. *Monitor and collaborate with other agencies at the state and national levels working on policy issues in genetic and health care privacy.* This task is ongoing and work to date is summarized in Section 4.
5. *Participate and support community partners in efforts to continue to educate the general public and health care providers about the ethical and legal issues associated with genetics.* This task is ongoing and work to date is summarized in Section 5.

Additionally, the ACGPR indicated in the 2007 Report to the Oregon Legislature that it would create a guide for researchers and institutional review boards (IRBs) to help identify when research fits the definition of genetic research. Although the ACGPR initiated this project, the committee concluded that the broad nature of the current statute's definitions caused the guide to be less useful than anticipated. Instead, the committee plans to review the definitions of genetic information and genetic testing in GINA and discuss whether adoption of these definitions might be more helpful to researchers and health care providers in determining what is considered to be a "genetic test." The difficulty in creating such a guide illustrates that genetic technologies are very complex and constantly evolving. Because of this, developing a definition to capture which tests may detect a genetic change and what types of genetic tests should or could be covered by the law is a very challenging task.

## SECTION 1: Genetic exceptionalism

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In 2006 ACGPR commissioned a genetic exceptionalism project to provide background information to discuss whether genetic exceptionalism continues to be an acceptable logical basis for genetic privacy and research in Oregon. Ms. Summer Street created the resulting paper (Appendix 1). "Genetic exceptionalism" is the concept that genetic information is fundamentally different from other types of medical information and deserves special protection. In the 2007 report to the Oregon Legislature, the committee indicated that a major focus of the 2007-2009 biennium would be to further examine the issue of genetic exceptionalism.

As a first step, the committee determined it needed further resources to understand how genetic information is currently treated differently (or the same) in the areas of clinical care, research and discrimination. The committee produced several work products to help with this discussion, presented in Appendix 2. The committee examined the various laws that currently protect genetic information and other health information in these areas and extensively discussed various protections. A key question was whether it made sense, with the current knowledge of how individuals' genetic information contributes to their health in comparison to other types of medical information, to treat genetic information differently than other types of health information. For example, do results of a genetic test that indicate an individual may be at higher risk for heart disease mean more to the patient's medical care, insurance and employment than having high blood pressure?

After a thorough review of this issue, the committee concluded that, although there may be committee members who feel that all types of health information deserve equal protection, the passage of the GINA law showed the public does believe genetic information deserves special protection. Therefore, given the complexity of this issue and differing opinions, further examination of this issue is unwarranted.

For further reading on the concept of genetic exceptionalism, please see Appendix 3 for one committee member's review of the literature and opinion on this issue.

## SECTION 2: Summary of input on “opt-out” provision of 2005 legislation (SB 1025)

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The Oregon Legislature passed SB 1025 and revised it in 2007. The statute requires all health care providers who obtain blood, tissue, or other biologic specimens or clinical individually identifiable health information (health information) to provide a genetic notice to the patient at the first clinical visit. This notice gives patients the opportunity to opt out of allowing their specimens or health information to be used for anonymous or coded genetic research. This applies whether or not the sample or health information was originally obtained for a genetic purpose. If the patient does not opt out, it is assumed that the patient has opted in and, therefore, will allow use of his or her biologic sample or health information for anonymous or coded genetic research at sometime in the future. The opt-out provision is a one-time requirement, although the patient may change his or her mind and opt out anytime later.

After the legislation had been in place for approximately two years, ACGPR followed up on its charge to monitor the law's impact on various stakeholders. The committee agreed to question five groups:

- Genetic researchers and institutional review board (IRB) administrators;
- Hospital administrators and medical records personnel;
- Hospital and reference laboratory managers;
- Genetic counselors;
- Consumers/patients.

Representatives of the first three groups attended ACGPR meetings where they were questioned in person. All Oregon genetic counselors were surveyed online. The committee could not find an effective way to convene a group of consumers or patients without a comprehensive program requiring significant resources. A summary of the results follows. Background documents are in Appendix 4.

### Effects of SB 1025 on stakeholders

#### Genetic researchers and institutional review board (IRB) administrators

- For the most part, the law has streamlined the ability to do genetic research in Oregon.
- The definition of “genetic test” continues to be a problem for IRB administrators who must make a judgment on whether the Oregon genetic privacy laws apply.

#### Hospital administrators and medical records personnel

- Organizations approached the opt-out provision for research differently (e.g., by mail, in person); as a result, their opt-out rates and implementation costs vary widely.
- Most implementation costs were incurred up-front. These costs were burdensome to research hospitals, but on-going costs are substantially less, except in facilities where the opt-out provision is discussed with new patients in person.
- Electronic medical records make tracking the opt-out status of the patient easy, but it is difficult to track if the patient is seen outside the system.

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## **Hospital and reference laboratory managers**

- While the provision was an issue to begin with, the opt-outs have become a non-issue for most of the laboratories outside of clinical research centers. Laboratories either identified a process to track the opt-out forms or sent blanket letters stating that none of the laboratory specimens or data can be used for any type of research.
- It is unclear if the Oregon genetic privacy laws would apply to large out-of-state reference labs.
- Most commercial reference labs do not use or provide samples for research of any kind.

## **Genetic counselors.**

- Half (14) of Oregon's genetic counselors responded to the survey. General, prenatal and cancer genetic counseling were all well represented.
- None of the respondents said the opt-out provision had changed their practice.

## **Summary**

The stakeholders who were interviewed said the 2005 law has not had adverse effects on their agencies and organizations them, especially after the initial start-up costs and development of tracking systems. The committee hopes in the future to survey consumers about genetic research and whether they feel the 2005 law increased their privacy protections.

## SECTION 3: Oregon and federal law (GINA)

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Oregon's genetic privacy law was enacted in 1995 and has been amended several times since that time. Until last year there was no comparable federal law. On May 21, 2008, the Genetic Information Nondiscrimination Act of 2008 (GINA) was enacted into federal law. A good summary of GINA and its background may be found in a report of the Congressional Research Service issued on July 9, 2008 (Appendix 5).

The federal law is not preemptive, so the provisions of Oregon law remain in place and unaffected. While broadly similar, the Oregon law and GINA differ in many particulars. See the comparison in Appendix 6.

ACGPR convened a legal committee, chaired by Gwen Dayton, to consider whether to recommend that the 2009 Oregon Legislature consider amendments to Oregon law. Upon recommendation of this legal committee, ACGPR decided against proposing legislation in 2009 for the following reasons:

- The detailed comparison between GINA and Oregon law was too intricate, and the policy decisions required for legislation too numerous, to be completed for a 2009 bill.
- Federal regulations interpreting GINA are expected from several federal agencies in the coming year.
- While GINA suggests many ideas for improving Oregon law, there are no apparent conflicts large enough to require urgent action.

ACGPR expects to conduct an in-depth analysis of Oregon law by comparison with GINA and to make recommendations to the 2011 Oregon Legislature. Options include:

- Leave the Oregon law as it is.
- Conform the definitions of Oregon law to GINA.
- Conform the Oregon law generally to GINA.
- Repeal the parts of Oregon law that GINA covers.
- Repeal the Oregon law entirely and possibly draft new legislation.

During the past two years, ACGPR spent considerable time and effort discussing the question of genetic exceptionalism, i.e., whether genetic information privacy is essentially different from other sorts of health information privacy, in a way that justifies having a separate law for genetic privacy (See discussion in Section 1). While this remains an important theoretical issue, as a matter of American public policy, the enactment of GINA settles this question in the affirmative for the time being. In addition to this major federal civil rights bill, 47 states have statutes regulating use of genetic information in health insurance, and over half the states (including Oregon) have comprehensive laws governing genetic privacy. What remains to be determined is the best statutory approach for regulating this complex and evolving arena.

#### **SECTION 4: Monitor and collaborate with other agencies at the state and national levels working on policy issues in genetic and health care privacy**

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The committee worked with numerous agencies and organizations over the past two years to disseminate information on SB 1025 and GINA. These groups included the Western States Genetic Services Coalition, the Oregon Association of Hospitals and Health Systems, the Oregon Insurance Division and the Division of Medical Assistance Programs.

## **SECTION 5: Continue to look for educational opportunities to fulfill the ACGPR's charge of educating the public on the scientific, legal and ethical development within the fields of genetic privacy and research.**

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The DHS Genetics Program undertakes a variety of educational efforts. It sponsors a number of seminars and committee members also give relevant talks. The seminars in the past biennium included:

- Barbara Pettersen, M.S.  
Genetic Counseling of Central Oregon  
"Your Risk for Colon Cancer: What's Family History Have to Do with It"  
Sponsored by Oregon Public Health Division Genetics Program  
Aug. 14, 2007
- Kara Manning Drolet, Ph.D., Associate Director, Research Integrity Office  
Oregon Health & Science University  
"Oregon Genetic Privacy Act Requirements Overview & Discussion" at "Portland Privacy Summit: Confidentiality Issues Unique to Human Subjects Research." Sponsored by Legacy Health System and the Northwest Association for Biomedical Research (NWABR); Legacy Clinical Research and Technology Center, Portland  
Aug. 23, 2007
- Karen Edwards, Ph.D., Director of the Center for Genomics and Public Health  
University of Washington  
"Obesity, Nutrition, and Nutrigenomics - Oh My!"  
Sponsored by Oregon Public Health Division Genetics Program  
Sept. 7, 2007
- Kathy L. Hudson, Ph.D., Director, Genetics Public Policy Center  
Johns Hopkins University  
"Making Every Voice Count: Public Consultation on Genetics, Environment, and Health"  
Sponsored by Oregon Public Health Division Genetics Program  
April 24, 2008
- Astrid Newell, M.D., Community Health Manager  
Whatcom County Health Department, Bellingham, Wash.  
"From DNA to Disease"  
Sponsored by Oregon Public Health Division Genetics Program  
May 12, 2008

The Genetics Program posts articles of interest to a lay audience on its Web site: [www.oregongenetics.org](http://www.oregongenetics.org). The Genetics Program developed several fact sheets on family history and a number of chronic conditions, such as heart disease and diabetes. These are available on the Web site and by request and are distributed at numerous health fairs.

## Recommended focus of ACGPR activity for 2009-2011

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As we move into the next biennium, the Committee recommends five focus areas.

1. *Assess the possible conflicts and redundancies between the Oregon genetic privacy statutes and GINA, as well as other previously existing laws that protect genetic information such as HIPAA.* As part of these discussions, the ACGPR may invite public input and various stakeholders, such as the insurance industry, to advise the committee on relevant issues. Based on the committee's analyses and stakeholder input, changes to Oregon's genetic privacy statutes may be proposed for the next legislative session.
2. *Assess the cost of the implementation of the notification and opt-out requirements of SB 1025, passed by the 2005 Oregon Legislature.* While the committee collected qualitative information from stakeholders, it did not do a quantitative assessment of total implementation costs. The committee intends to work with a student group from the Portland State University Master of Business Administration program to assess implementation costs and, potentially, other areas of the bill's financial impact on health care providers or consumers.
3. *Continue to monitor the effect of the Oregon genetic privacy statutes on medical research, access to genetic services, and health care providers' management of medical information.* The committee will continue to monitor the national discussion and other issues related to genetic privacy and research that arise.
4. *Continue to look for opportunities to participate in educational efforts and elicit public input representative of the diversity of opinions through collaborations with other organizations and community partners.*
5. *Evaluate whether the charge of the committee is being adequately met through volunteer and non-funded DHS staff capacity.*



# A P P E N D I X

1. Selections from “Report on Genetic Information in the Context of Genetic Exceptionalism,” by Summer Street
2. Comparison of applicable laws & regulations pertaining to the use of genetic information
  - a. Discrimination
  - b. Clinical medicine
  - c. Research
3. “We All Have Genes,” by Patricia Backlar
4. SB 1025 – Stakeholder Impact - background documents
5. CRS Report on GINA
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## **Appendix 1**

### **Selections from “Report on Genetic Information in the Context of Genetic Exceptionalism”**

# Report on Genetic Information in the Context of Genetic Exceptionalism

for the Advisory Committee for Genetic Privacy and Research (ACGPR)

Summer Lee Street  
December 2005

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## **Executive Summary**

The purpose of this project was to provide information to the Advisory Committee for Genetic Privacy and Research (ACGPR) in order to initiate discussion of "whether genetic exceptionalism continues to be an acceptable logical basis for genetic privacy and research policy in Oregon" (ACGPR, 2005).

A large pool of literature relating to the subject of genetic exceptionalism, genetic information, genetic privacy and genetic discrimination was located through literature searches in multiple databases. After a brief review, each article either remained as candidate or was removed from the pool. This review process created a group of literature candidates that numbered less than one hundred. Each piece of literature was then read in-depth. Literature subsequently not found to be meaningful to the project was eliminated from the group. Literature found to be meaningful to the project was then reviewed once more and placed in an annotated bibliography.

The legislative findings of the Oregon Genetic Privacy Act, ORS 192.533 as written in the 2003 statute, are largely based on the concept of genetic exceptionalism. Of primary concern is: 1) the private and personal nature of genetic information, 2) the potential for genetic information to reveal the probable medical future of an individual, 3) the potential for genetic information to reveal the probable medical future of an individual's blood relatives, and 4) the potential for significant harm when genetic information is revealed. Each of these concerns was addressed individually and examples of instances where nongenetic information may pose the same concerns were provided.

Four of the main arguments against genetic exceptionalism include: 1) the lack of qualitative differences between genetic and nongenetic information, 2) the complexity of disease etiology does not fit easily within the concept of genetic exceptionalism, 3) the idea that it is unethical to treat genetic and nongenetic information differently, and 4) the fact that genetic exceptionalism may actively cause harm.

Two pieces of model health information privacy legislation, one developed by George Annas, JD, MPH, and the other by Lawrence Gostin, JD, LL.D., may provide insight into the privacy and protection needs of Oregonians. In addition, the medical testing framework created by Green and Botkin may work equally well as a tool to evaluate the protections around any type of health related information.

Though this report focused on genetic information primarily in the medical context, the use of genetic information also occurs in non-medical settings. This includes DNA data banking and profiling. It is important to remember that the potential for the creation of new genetic information is limited by the availability of usable biological samples; however, many of the concepts relating to potential genetic information will overlap with the information presented in this report. Appendix J: Abstracts on Nonmedical Uses of Genetic Information provides five abstracts on articles that relating to genetic information in non-medical settings.

## **Purpose of Project**

The purpose of this project was to provide information to the Advisory Committee for Genetic Privacy and Research (ACGPR) in order to initiate discussion of "whether genetic exceptionalism continues to be an acceptable logical basis for genetic privacy and research policy in Oregon" (ACGPR, 2005).

To this end, in-depth research into the nature of genetic information, the history of genetic exceptionalism in Oregon and nationally, and current thought on appropriate legislative treatment of genetic information was conducted; the ethical, legal and social issues of obtaining, retaining and disclosing genetic information was investigated; and the privacy protections offered in the 2003 Oregon Genetic Privacy Statutes (Appendix A: 2003 Oregon Genetic Privacy Statutes) was assessed. A Microsoft PowerPoint presentation and this report have been created to help educate the ACGPR on the current views on genetic exceptionalism and issues surrounding genetic information. These findings are hoped to help provide a foundation for the committee to begin the discussion of where to direct the path for future genetic information policies.

Please note that much of the information presented in this report may require further discussion among interested parties. It is not meant to be a complete representation of the all information that surrounds issues relating to genetic information. In addition, because this report focuses on genetic exceptionalism, the issues relating to genetic information are largely filtered through the context of medical information.

A presentation of this report was made to the ACGPR at the monthly committee meeting on December 7, 2005. The PowerPoint slides for the presentation are included in this report as Appendix B: 12/7/05 ACGPR Presentation.

All material referenced in this report is available from the Oregon Genetics Program at the Oregon Department of Human Services in PDF format.

For those who are not familiar with the Oregon Genetic Privacy Law, the "History of Oregon's Genetic Privacy Law" was included as Appendix A of the 2003 ACGPR Legislative Report and offers a very useful summary of the History of the Oregon Genetic Privacy Law. This document can be found on the Oregon Genetics Program website at: <http://www.oregon.gov/DHS/ph/genetics/docs/hxlaw.pdf>

## **Literature Search Path**

A key aspect to this project was the identification of pertinent literature. Five databases were searched to identify candidate literature: PubMed; Medline; Oregon State Library Law, Government, Policy; Oregon State Library Science and Technology; LexisNexis AlaCarte!. The search term "genetic" was used in each database, along with one or more of the following five terms: "discrimination", "ethical", "exceptionalism", "information", and "privacy", so that there were at least five and no more than nine searches conducted in each database.

All literature was limited to that which was published in 1990 or later. Further restrictions were made as follows. Literature identified by Medline as having less than 80% relevance to the search terms was excluded. Only the first 100 documents identified in each of the Oregon State Library databases and LexisNexis AlaCarte! were included as potential literature. No further limitations were used for PubMed.

Though much of the literature was identified in multiple databases, this initial search resulted in a group of nearly two hundred literature candidates. When available, the abstract of each candidate was reviewed; after abstract review the literature either remained as candidate or was removed. Articles were then located through the Portland State University Library or the Oregon State Library. After a brief review, each article either remained as candidate or was removed from the pool. This review process created a group of literature candidates that numbered less than one hundred. Each piece of literature was then read in-depth. Literature subsequently not found to be meaningful to the project was eliminated from the group. Literature found to be meaningful to the project was then added to a bibliography (Appendix C: Bibliography) and set aside to be re-read and placed in the annotated bibliography (Appendix D: Annotated Bibliography).

In addition, a few pieces of literature were identified as follows: suggested by Emily Harris, PhD, MPH, Kiley Airial, MPH, or members of the ACGPR; found through an author search in PubMed; cited in literature of interest.

### **Basis of the Oregon Genetic Privacy Act**

The legislative findings, ORS 192.533 as written in the 2003 statute, highlight the motivations for enacting the Oregon Genetic Privacy Act. The legislative findings have remained unchanged in the Oregon Genetic Privacy Act since its first enactment in 1995. The findings are largely based on the concept of genetic exceptionalism. However, they also cover information on the Human Genome Project (HGP), legal protections of medical information and the balance required between public good and private protection interests. It is important to review this information to assess any changes since 1995.

Appendix E: Timeline of Events Relating to Genetic Information shows some major events that occurred from 1981 to 2005. The second timeline shows the same events, with the addition of two quotes from Lawrence Gostin, JD, LL.D. Gostin is a leader in the field of health information, who was once a proponent for genetic exceptionalism, but after careful consideration of the subject revised his views on the matter.

**The Human Genome Project:** The Human Genome Project (HGP) is alluded to in the second sentence of subsection “a” in the legislative findings (Appendix A, ORS 192.533). The findings refer to the human genome as, “a code that is rapidly being broken”. It is important to note that the HGP was completed in 2003, though analysis of the data continues. Some of the surprising findings of the HGP include:

“The human genome, it turns out, comprises closer to 30,000, rather than the expected 100,000 genes; only one inch of the six-foot coil of DNA in each cell contains the genes that encode a person. Not only is it about twice as large as

the roundworm and fruit fly genomes, it is also more similar to those genomes than anyone expected. These findings suggest that the complexity of humans must be explained by more than just our genes, challenging the notion of genetics determinism" (Suter, 2001).

**Genetic Determinism:** Genetic determinism, in short, is the idea that your genes tell your future. The one thing universally agreed upon in the literature reviewed for this project was that genetic determinism is not only scientifically invalid, but also socially dangerous. George Annas, JD, MPH, who is a long-standing advocate of genetic exceptionalism and leader in the field of health information privacy, warns readers that genetic information can be considered predictive, but should not be considered deterministic of a person's future medical status (Annas, 2001). Lawrence Gostin, JD, LL.D., an opponent of genetic exceptionalism and leader in the field of health information privacy agrees with Annas on this matter, stating that genetic information is not deterministic and "realistically provides only a glimpse of what makes humans susceptible to disease and other conditions" (Gostin & Hodge, 1999). Ellen Clayton, MD, JD, describes the notion of genetic determinism as "an unwarranted sense of inevitability, because it reflects a fundamental failure to understand the nature of biologic systems" (Clayton, 2003). These cautions against genetic determinism are important to keep in mind throughout any discussion of the treatment and use of genetic information.

A danger relating to genetic determinism is the perceived immutability of genetic information. It is important to remember that human knowledge is incomplete and the interpretation of information will continue to change over time. In addition, genetic predispositions can often be countered with environmental changes to reduce risk of disease (Gostin and Hodge, 1999).

**Genetic Privacy Legislation:** The legislative findings also refer to "current legal protections for medical information, tissue samples and DNA samples [that] are inadequate to protect genetic privacy" (subsection f). Though this report does not offer an in-depth analysis of genetic privacy legislation, some changes have occurred since 1995.

The Americans with Disability Act (ADA), which was enacted in 1990, is a major piece of federal legislation that may currently provide "the best privacy protections for genetic information in federal law" (Everett, 2004). The ADA is usually considered legislation that protects individuals from discrimination; however, it may also indirectly offer privacy protection by prohibiting the use of information in certain situations. In 1995, the Equal Employment Opportunity Commission (EEOC) interpreted the third prong of the ADA to protect individuals with genetic predispositions from employment discrimination (Rothstein, 1998). Yet it is important to note that this interpretation has not been tested in the court system (Rothstein, 1998).

Another piece of federal legislation, referred to as the "Common Rule," 45 CFR 46, was adopted in 1991. The federal Common Rule provides general protection to research subjects. It does not provide specific protections relating to genetic information. The Oregon Genetic Privacy Act requires that all genetic research be conducted to meet the

standards set forth in the Common Rule and be reviewed by an institutional review board (IRB) (ORS 192.547).

The Health Insurance Portability and Accountability Act (HIPAA), enacted in 1996 and implemented nation-wide by 2003, also provides general privacy protection. HIPAA does not specifically address genetic information, instead treating it as one type as protected health information (Gostin, 2001). HIPAA provides a national baseline for privacy protection of health information and does not preempt stronger state laws (Gostin, 2001).

The Genetic Information Nondiscrimination Act, which has passed in the Senate (but not the House) in 2003 and 2005, “would be the first federal law to specifically address genetic privacy. Like many state laws, the senate bill treats genetic information as uniquely sensitive and as a potential source of employment and insurance discrimination” (Everett, 2004).

Oregon is not alone in its interest in protecting genetic privacy; many states have passed legislation involving genetic information. The National Conference of State Legislatures tracks genetics laws and legislative activities on a state level pertaining to: employment, genetic privacy, health insurance, life insurance, disability insurance, long-term care insurance and many other related topics. This information can be found at: <http://www.ncsl.org/programs/health/genetics/charts.htm>

**Balance of Public and Private Needs:** A key intent of the Oregon Genetic Privacy Act was to help create a balance between access to genetic information and the protection of our personal genetic information. Subsection “F” of the legislative findings states, “Laws for the collection, storage and use of identifiable DNA samples and private genetic information obtained from those samples are needed both to protect individual and family privacy and to permit and encourage legitimate scientific and medical research.” The protection of individual and family privacy is important, as the misuse of genetic data “presents actual and perceived threats to individuals through privacy breaches, discrimination, and stigmatization” (Gostin & Hodge, 1999). At the same time, the promotion of legitimate scientific and medical research must continue so that “Population-based knowledge about the contribution of gene variants and gene-environment interactions to disease ... [will help us] find more effective and targeted public health interventions” (Beskow, 2001).

### **Central Policy Issue: genetic exceptionalism**

This brings us to what might be considered the central policy issue (Calvo, 2001). How should genetic information be treated? Is genetic information special? Does it by its very nature require higher legal protections than other types of medical information? If it is simply another form of health information, should be treated the same as other forms of health information? If so, is health information currently given the appropriate amount of protection? Do different types of health information require different levels of protection? It is how you answer these questions that largely influence the policy approach (Calvo, 2001).

Genetic exceptionalism is the idea that genetic information is qualitatively different from other types of medical information and therefore requires special legal protection. (Please see Appendix F: Genetic Exceptionalism Defined in the Literature for a list of other definitions). As stated earlier, the legislative findings highlight the motivations for enacting the Oregon Genetic Privacy Act. Concepts relevant to genetic exceptionalism are identified throughout the legislative findings. These include the idea that 1) genetic information is uniquely private and personal, 2) genetic information reveals information about an individual, including their probable medical future, 3) genetic information reveals information about an individual's blood relatives, including their probable medical future, 4) knowledge of genetic information can lead to significant harm. This report will address each of these issues, so that the reader can begin to assess "whether genetic exceptionalism continues to be an acceptable logical basis for genetic privacy and research policy in Oregon" (ACGPR, 2005).

Please see Appendix G: Points and Counter Points for an alternative presentation of the following arguments regarding genetic exceptionalism.

**The Private and Personal Nature of Genetic Information:** Genetic information is accepted as being private and personal. However, opponents of genetic exceptionalism argue that genetic information is not unique in its private and personal nature. Examples of equally unique identifiers that are "sufficiently distinctive to accurately identify individuals" include one's social security number, fingerprints, hand & face geometry, voice spectrograms, and iris (Gostin & Hodge, 1999).

Much of the literature reviewed emphasized the social view of genetics, which encourages us to treat genetic information as special simply because we perceive it to be special.

"In the end, a confluence of factors and institutional forces [the media, popular culture, scientists, policy makers, etc] individually and synergistically shape and reinforce the notion that genetic information is uniquely threatening and susceptible to misuse" (Suter, 2001).

This self-fulfilling cycle, added to a limited understanding of genetics, creates a public perception of "genetics as uniquely powerful, both for good and bad" (Suter, 2001). So that "Right or wrong, genetic information is believed to reveal who we 'really' are, so information from genetic testing is often seen as more consequential than that from other sources" (Green and Botkin, 2003). This view provides a subtle but constant influence on our approach to genetic information and should be kept in mind throughout this discussion.

Furthermore, genetic information is not the only medical information that has been given special treatment status. HIV/AIDS status, mental illness and alcoholism have all been provided a further level of privacy protection through federal legislation (Lazzarini, 2001). However, some genetic exceptionalism opponents argue that information relating to the status or treatment for each of these conditions can be more easily removed from an individual's health record than genetic information can be (Gostin and Hodge, 1999). The difficulty in removing particular information from an individual's health record leads to the question of whether the intent of genetic specific legislation can be followed in practice.

**Revealing the Probable Medical Future of an Individual:** Genetic information can reveal information about the probable medical future of an individual. This is a common argument for genetic exceptionalism. An example of this is that a clinically significant *BRCA1/BRCA2* mutation would identify an increased risk of breast cancer in an individual (Green and Botkin, 2003). Presymptomatic testing for genetic predispositions to high blood pressure or high cholesterol would also identify an increased risk of developing heart disease. Yet regular screenings are conducted to check a patient's blood pressure and cholesterol levels, and both measures assess an individual's likelihood for developing heart disease, regardless of the disease's genetic or nongenetic basis. Nongenetic information, therefore, can also reveal information about the probable medical future of an individual. Other examples of this include a positive HIV test that identifies an increased risk of developing AIDS (Green and Botkin, 2003; Gostin and Hodge, 1999) or a positive tuberculin skin test that identifies an increased risk for developing active tuberculosis (Gostin and Hodge, 1999).

**Revealing the Probable Medical Future of an Individual's Family:** Another argument for genetic exceptionalism is that genetic information reveals information about the probable medical future of an individual's blood relatives. An example of this is that a woman's clinically significant *BRCA1/BRCA2* mutation would identify an increased risk of breast cancer in her relatives (Green and Botkin, 2003). Similarly, genetic testing for Huntington's disease or cystic fibrosis will reveal characteristics of future generations and potentially impact reproductive decisions. However, nongenetic information can also reveal information about the probable medical future of an individual's blood relatives. An example of this is that a positive tuberculin skin test in an individual would identify an increased risk of developing active tuberculosis for her/his entire family (Green and Botkin, 2003). In addition, a positive test for gonorrhea in an individual (which could occur through a routine pap smear) would lead us to suspect that the individual's sexual partner may also have the disease (Green and Botkin, 2003). Another example would be that a pregnant mother's positive HIV status would identify increased risk of positive HIV status in the child and the child's father (Ross, 2001).

The Oregon Genetic Privacy Act narrowly defines genetic information so that family medical history is considered to be nongenetic information. However, family history has the potential to reveal a number of disorders that may affect multiple family members, such as mental illness, alcoholism, heart disease and cancer (Gostin and Hodge, 1999).

The real difference between genetic and nongenetic information is one of transmission. Genetic based risks are transmitted vertically from parent to child and nongenetic-based risks can be transmitted in a variety of ways (Green and Botkin, 2003).

**Revealing Genetic Information Can Lead to Significant Harm:** Another argument for genetic exceptionalism is that the use of genetic information can lead to significant harm. In the history of the United States and internationally, genetic information has been used in attempts to legitimize prejudicial actions. Now, the potential harm caused by the use of genetic information is often framed in employment and insurance decisions, where there is concern that genetic information that predicts disease risk will

be used against individuals. However, instances of such abuse have been found to be rare and anecdotal (Billings, 2005). In addition, many decisions are already made with nongenetic information, which raises a question of fairness in treating genetic and nongenetic information differently. "Insurance underwriters routinely rely on such information as HIV status, serum cholesterol levels, alcohol or narcotic addiction, and even blood pressure to determine eligibility and rates for life or disability insurance" (Green and Botkin, 2003).

Other categories of harm include that of discrimination and psychological harm. Yet both of these types of harm are not restricted to the use and misuse of genetic information. "Threats of discrimination and stigmatization [will] exist as long as there are differences, and these may or may not have a genetic basis" (Ross, 2001). Discrimination issues, then, might be best addressed on a higher level through public education and broad laws protecting privacy and prohibiting discrimination, instead of focusing narrowly on protections for genetic information (Rothstein, 2005). In addition, by "enacting general laws applicable to all forms of medical information, the stigma of genetic information will be diminished rather than reinforced" (Rothstein, 2005). Similarly, "Patients who learn they may have diseases ranging from HIV infection to hypertension also experience distress" (Ross, 2001), so that it is not only the knowledge of genetic disorders that might cause psychological harm. Psychological harm, therefore, is not specific to genetic information and might be better addressed in a more encompassing manner.

### **The Arguments Against Genetic Exceptionalism**

Four of the main arguments against genetic exceptionalism include: 1) the lack of qualitative differences between genetic and nongenetic information, 2) the complexity of disease etiology does not fit easily within the concept of genetic exceptionalism, 3) the idea that it is unethical to treat genetic and nongenetic information differently, and 4) the fact that genetic exceptionalism may actively cause harm.

**Qualitative Differences Between Genetic and Nongenetic Information:** A key aspect in examining the validity of genetic exceptionalism is determining the similarities and differences between genetic and nongenetic information. In the previous section of this report, we looked at the potential qualitative differences between genetic and nongenetic information. The section focused on: 1) the private and personal nature of genetic information, 2) the idea that genetic information can reveal the probable medical future of an individual, 3) the idea that genetic information can reveal the probable medical future of an individual's family, and 4) the idea that revealing genetic information to an individual or a third party can lead to significant harm in many forms. Another way to evaluate the similarities and differences between genetic and nongenetic information is to examine information in the context of specific diseases. Appendix H: Assessing Genetic and Nongenetic Medical Information reviews four different diseases (heart disease, cystic fibrosis, Huntington's disease, and AIDS) in order to help identify any differences between genetic and nongenetic information. These tables may provide the reader some insight in the complexity and nature of genetic and nongenetic information.

**The Complexity of Disease Etiology:** It is scientifically accepted that there is a complex relationship between the genetic and nongenetic factors that underlies most diseases. Virtually all disorders have genetic and nongenetic components (Rothstein, 2005). Medical research reveals that most diseases have genetic, behavioral and environmental components, so that genetic information is only one aspect on the continuum of medical information (Gostin and Hodge, 1999). Disease penetrance (the likelihood a given genotype will result in the disease phenotype) is dependent on many factors (Vineis et al., 2001). This makes it very difficult to meaningfully define what a genetic or nongenetic condition is. Because of this difficulty, any attempt to separate genetic from nongenetic information in a given health record may become cost prohibitive (Gostin and Hodge, 1999).

**Is it Unethical to Treat Genetic and Nongenetic Information Differently?:** Another argument against genetic exceptionalism is that it is unethical to distinguish between genetic and nongenetic information. "It is difficult to make a moral argument that discriminating against people on the basis of genetic information is impermissible, but that discriminating against them on the basis of other medical information is okay" (Rothstein, 2005). In trying to avoid genetic discrimination, do we create nongenetic discrimination? "The present inconsistency concerning disclosure of results of genetic and non-genetic based tests seems unethical" (Raithatha and Smith, 2004). This inconsistency could be resolved by providing all health related information with appropriate privacy protections. "Genetic-specific statutes are often unfair because they treat people facing the same social risks differently based on the biological cause of their otherwise identical health conditions" (Gostin and Hodge, 1999). For example, an individual who develops breast cancer associated with a genetic mutation in the *BRCA1/BRCA2* genes versus one who develops breast cancer through other means (Gostin and Hodge, 1999). How do we justify the disparate treatment of two individuals who may have no meaningful differences?

**Genetic Exceptionalism Actively Causes Harm:** A final argument against genetic exceptionalism is that it actively causes harm because "it discounts the ethical and legal need for affirmative protections of other equally sensitive, personally identifiable information" (Gostin and Hodge, 1999); while at the same time reinforcing the potential stigma of genetic disorders (Rothstein, 2005).

**The Central Policy Questions:** This brings us back to the central policy questions (Calvo, 2001). How should genetic information be treated? Is genetic information special? Does it by its very nature require higher legal protections than other types of medical information? If it is simply another form of health information, should be treated the same as other forms of health information? If so, is health information currently given the appropriate amount of protection? Do different types of health information require different levels of protection? Does genetic exceptionalism continue "to be an acceptable logical basis for genetic privacy and research policy in Oregon" (ACGPR, 2005)?

### **Model Legislation**

In 1995, George Annas, JD, MPH, an advocate for genetic specific legislation, developed a model federal genetic privacy law. Though this is a federal model, recommendations from it could be applied to state law. The model can be found at: [http://www.ornl.gov/sci/techresources/Human\\_Genome/resource/privacy/privacy1.html](http://www.ornl.gov/sci/techresources/Human_Genome/resource/privacy/privacy1.html)

In addition, Lawrence Gostin, JD, LLD, as an advocate for more general privacy protection legislation, developed a Model State Public Health Privacy Act in 1999. “Between these two broad choices [of collective benefits and privacy risks] exists a carefully crafted balance that manages to respect individual privacy and provide security protections without significantly thwarting the warranted, communal uses of genetic information” (Gostin and Hodge, 1999). This model can be found at: <http://www.critpath.org/msphpa/modellaw5.htm>

### **The Green and Botkin Framework**

In their 2003 article, Green and Botkin offer us a framework to evaluate medical tests. This framework is presented in Appendix I: Green and Botkin Framework). This risk continuum approach may help conceptualize protection issues. In their framework, Green and Botkin address the risks of predictive testing in asymptomatic individuals (tests that will provide a quantitative measure of likelihood for a given individual showing no symptoms to some day develop a particular disease). They evaluate each test on four grounds: the degree in which information learned from the test can be stigmatizing, the effect of the test results on others, the availability of effective interventions to alter the natural course predicted by the test, and the complexity involved in interpreting test results. If the evaluation stays to the left of the scale, tests can be given with only the precautions of standard accepted practice. As one moves to the right on the evaluation scale, decisions about testing should be made more carefully and involve non-directive shared decision-making. This will potentially affect the consent process and documentation. Although Green and Botkin originally proposed this tool for evaluating the potential harm of a given test, it may work equally well as a tool to evaluate the protections around any type of health related information.

### **Nonmedical Uses of Genetic Information**

This report focused on genetic information primarily in the medical context. However, the use of genetic information also occurs in non-medical settings. This includes DNA data banking and profiling. It is important to remember that the potential for the creation of new genetic information is limited by the availability of usable biological samples. Please see Appendix J: Abstracts on Nonmedical Uses of Genetic Information for five abstracts on articles that may be of interest. These articles are available in PDF format from DHS.

**Acknowledgement**

I would like to thank the ACGPR for their attention, feedback and support during this project. I would especially like to thank Bob Nystrom for agreeing to sponsor me at the Oregon Genetics Program at the Department of Human Services in this endeavor. I would also like to thank Emily Harris and Kiley Ariail for their consistent guidance and encouragement and Naomi Adams for her immense logistical support. Finally, I would like to thank Patricia Backlar and Stuart Kaplan for their attention to this project in between ACGPR meetings.

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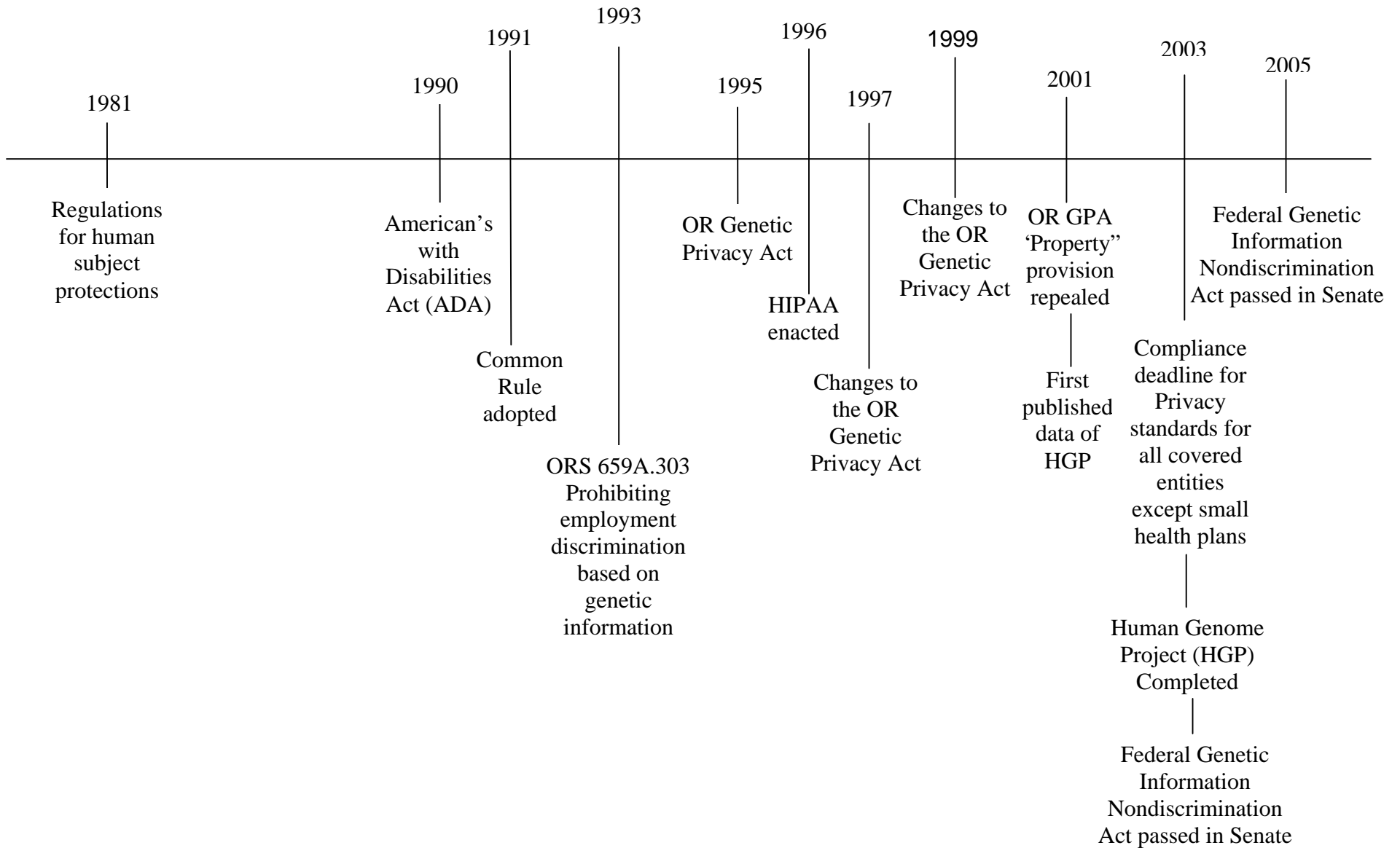
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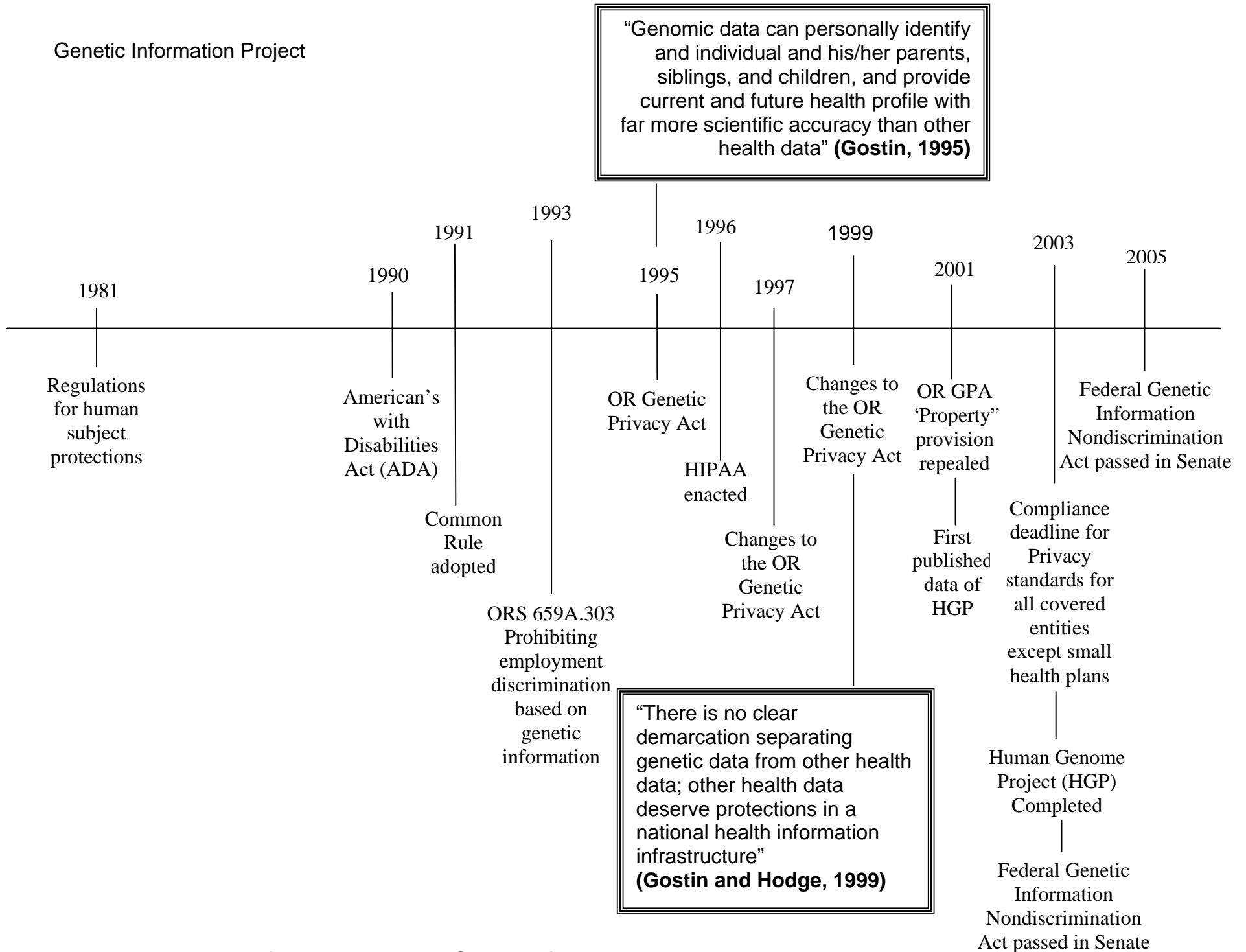
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Genetic exceptionalism is the idea that...

"genetic information is special - that personally identifiable data encrypted in the genome of every human being is so fundamentally different from other health information as to require exceptional legal protections" (Calvo, 2000).

genetic information should be protected through specific genetic privacy laws rather than generally, as a component of individual medical records (Calvo and Jones, 2000).

genetic information is "unique and especially sensitive medical information" (Everett, 2004).

"genetic information is sufficiently different from other kinds of health-related information that it deserves special [legal] protection" (Ginsburg, 1999)

genetic data should be treated "as different from other types of health data for the purposes of assessing privacy and security protections" (Gostin and Hodge, 1999).

"genetic information is unique and deserves special consideration" (Green, 2003).

special policies are needed because genetic information has unique characteristics, as compared with all other types of health information (Lazzarini, 2001).

"genetic information is morally special" (Manson, 2005).

genetic information is unique enough from other types of medical information to be deserving of laws specifically designed to protect it (Roche and Annas, 2001).

"genetic information is sufficiently different from other health-care information that it deserves exceptional treatment" (Ross, 2001).

"genetic information should be treated separately from other medical information" (Rothstein, 2005).

genetic information is unique and should be regulated and protected separately from other medical information (Rothstein, 1999).

"genetic information is unique in medicine and deserves special treatment" (Sankar, 2003).

"genetic information is qualitatively different from other medical information and therefore raises unique social issues" (Suter, 2001).

Point	Counter Point
<p>❖ Genetic information may be predictive of the future health of the individual</p> <ul style="list-style-type: none"> <li>▪ Clinically significant <i>BRCA1/BRCA2</i> mutation identifies increased risk of breast cancer (Green, 2003)</li> <li>▪ Genetically based high blood pressure or high cholesterol identifies increased risk of developing heart disease</li> <li>▪ Presymptomatic testing for Huntington's disease</li> </ul>	<p>❖ Nongenetic information may be predictive of the future health of the individual</p> <ul style="list-style-type: none"> <li>▪ Positive HIV test identifies increased risk of developing AIDS (Green, 2003; Gostin and Hodge, 1999)</li> <li>▪ Nongenetically based high blood pressure or high cholesterol identifies increased risk of developing heart disease (Green, 2003; Gostin and Hodge, 1999)</li> <li>▪ Positive tuberculin skin test identifies increased risk of developing active tuberculosis (Gostin and Hodge, 1999)</li> </ul>
<p>❖ Genetic information may be predictive of the future health of the individual's family members</p> <ul style="list-style-type: none"> <li>▪ A woman's positive <i>BRCA1/BRCA2</i> mutation identifies increased risk of breast cancer in her sisters and daughters (Green, 2003)</li> <li>▪ Genetic testing for Huntington's disease, Cystic Fibrosis, etc</li> <li>▪ Genetic information may have implications regarding reproduction and characteristics of future generations</li> </ul>	<p>❖ Nongenetic information may be predictive of the future health of the individual's family members</p> <ul style="list-style-type: none"> <li>▪ Positive tuberculin skin test in an individual identifies an increased risk of developing active tuberculosis for entire family (Green, 2003)</li> <li>▪ Positive test for gonorrhea in an individual would lead us to suspect that the individual's sexual partner(s) may also have the disease (Green, 2003)</li> <li>▪ A pregnant mother's positive HIV status would identify increased risk of positive HIV status in child and child's father (Ross, 2001)</li> <li>▪ Family medical history [considered by Oregon law to be nongenetic] potentially reveals a number of disorders that may affect multiple family members (mental illness, alcoholism, heart disease, cancer) (Gostin and Hodge, 1999)</li> </ul>

Point	Counter Point
❖ The general population regards genetic information as unique (Suter, 2001)	❖ Self-fulfilling: public perception is formed, at least in part, by legislative focus and press releases (Gostin and Hodge, 1999; Green, 2003; Suter, 2001)
❖ Genetic information carries potential to stigmatize or discriminate against the individual and their family members	❖ These issues are better addressed through public education and broad laws protecting privacy and prohibiting discrimination (Rothstein, 2005)  ❖ Rare and anecdotal evidence that genetic information would be used against individuals (Billings, 2005)  ❖ "Threats of discrimination and stigmatization exist as long as there are differences, and these may or may not have a genetic basis" (Ross, 2001)
❖ Genetic information can cause serious psychological harm (Green, 2003)	❖ Harm is not unique to genetic information, a positive HIV status or cancer diagnosis can cause serious psychological harm (Green, 2003)
❖ Other medical information has been given "special" status (HIV/AIDS and mental illness) (Lazzarini, 2005)	❖ Status and treatment of HIV/AIDS, alcoholism and mental illness can be more easily removed from an individual's health record (Gostin and Hodge, 1999)

## **Appendix 2**

### **Comparison of applicable laws & regulations pertaining to the use of genetic information**

**Discrimination**

**Clinical Medicine**

**Research**

<u>Federal Genetic Information Nondiscrimination Act</u> <u>[H.R. 493]</u>		<u>HIPAA</u>	<u>Oregon Genetic Privacy Act</u>
<b>Provides discrimination protections for people with <i>individual</i> health care plans</b>	<b>yes</b> "The first subpart 3 of part B of title XXVII of the Public Health Service Act (42 U.S.C. 300gg–51 et seq.) (relating to other requirements) is amended. SEC. 2753. PROHIBITION OF HEALTH DISCRIMINATION ON THE BASIS OF GENETIC INFORMATION“(a) Prohibition on Genetic Information as a Condition of Eligibility.—A health insurance issuer offering health insurance coverage in the individual market may not establish rules for the eligibility (including continued eligibility) of any individual to enroll in individual health insurance coverage based on genetic information. “(b) Prohibition on Genetic Information in Setting Premium Rates.—A health insurance issuer offering health insurance coverage in the individual market shall not adjust premium or contribution amounts for an individual on the basis of genetic information concerning the individual or a family member of the individual. “(c) Prohibition on genetic information as preexisting condition.—A health insurance issuer offering health insurance coverage in the individual market may not, on the basis of genetic information, impose any preexisting exclusion (as defined in section 2701(b)(1)(A)) with respect to such coverage."	<b>no</b>	<b>yes</b> ORS 746.135(3)
<b>Prevents insurance companies from requiring patients to undergo genetic testing</b>	<b>yes</b> Title I Sec 101 ""“(1) Limitation on requesting or requiring genetic testing.—A group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, shall not request or require an individual or a family member of such individual to undergo a genetic test."		<b>no...but notes conditional requirements</b> ORS 746.135 "(1) If a person asks an applicant for insurance to take a genetic test in connection with an application for insurance, the use of the test shall be revealed to the applicant and the person shall obtain the specific authorization of the applicant using a form adopted by the Director of the Department of Consumer and Business Services by rule. (2) A person may not use favorable genetic information to induce the purchase of insurance. (3) A person may not use genetic information to reject, deny, limit, cancel, refuse to renew, increase the rates of, affect the terms and conditions of or otherwise affect any policy for hospital or medical expenses..."
<b>Limitations</b>	* Does NOT apply to symptomatic individuals * Does NOT cover disability or life insurance	* Must have had health insurance for >12 months without a lapse of 63 consecutive days or longer for HIPAA to apply * Does NOT prevent insurance company from denying coverage to or increasing the rates of the entire group based on the medical records of one member of the group. * Does NOT cover individual health insurance plans Source: NSGC/FORCE genetic information pamphlet	* Does NOT apply to symptomatic individuals * Does NOT include family history in definition of genetic information * Does NOT include pursuit of genetic services * Does NOT address disability or life insurance

<b>Additional information:</b>	<p>Amends Employee Retirement Income Security Act of 1974. Amends Public Health Service Act. Amends Internal Revenue Code of 1986. Amends Title XVIII of Social Security Act relating to medigap.</p> <p>Definitions in health insurance discrimination portion of GINA</p> <p>"Genetic information":(A) In general.—The term “genetic information” means, with respect to any individual, information about—(i) such individual’s genetic tests, (ii) the genetic tests of family members of such individual, and (iii) subject to subparagraph (D), the manifestation of a disease or disorder in family members of such individual. (B) Inclusion of genetic services.—Such term includes, with respect to any individual, any request for, or receipt of, genetic services (including genetic services received pursuant to participation in clinical research) by such individual or any family member of such individual. (C) Exclusions.—The term “genetic information” shall not include information about the sex or age of any individual.</p> <p>"Genetic test"—(A) In general.—The term “genetic test” means an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, that detects genotypes, (B) Exceptions.—The term “genetic test” does not mean an analysis of proteins or metabolites that does not detect genotypes,mutations, or chromosomal changes.</p>		<p>Definitions in OR Genetic Privacy Law:</p> <p>“Genetic characteristic” includes a gene, chromosome or alteration thereof that may be tested to determine the existence or risk of a disease, disorder, trait, propensity or syndrome, or to identify an individual or a blood relative. “Genetic characteristic” does not include family history or a genetically transmitted characteristic whose existence or identity is determined other than through a genetic test.</p> <p>“Genetic information” means information about an individual or the individual’s blood relatives obtained from a genetic test.</p> <p>“Genetic test” means a test for determining the presence or absence of genetic characteristics in an individual or the individual’s blood relatives, including tests of nucleic acids such as DNA, RNA and mitochondrial DNA, chromosomes or proteins in order to diagnose or determine a genetic characteristic.</p>
	<b><u>Federal Genetic Information Nondiscrimination Act</u></b> <b><u>[H.R. 493]</u></b>	<b><u>HIPAA</u></b>	<b><u>Oregon Genetic Privacy Act</u></b>

## Summary of consumer disability and life insurance genetic discrimination protections:

### Federal laws vs Oregon Genetic Privacy Act

	<u>Federal laws</u>	<u>Oregon Genetic Privacy Act</u>
<b>Provides life insurance discrimination protections</b>	none	<p><b>Limited. Unlawful to use <i>blood relative's</i> genetic test results to deny insurance.</b></p> <p>731.162 "Health insurance." "Health insurance" means insurance of humans against bodily injury, disablement or death by accident or accidental means, or the expense thereof, or against disablement or expense resulting from sickness or childbirth, or against expense incurred in prevention of sickness, in dental care or optometrical service, and every insurance appertaining thereto, including insurance against the risk of economic loss assumed under a less than fully insured employee health benefit plan. "Health insurance" does not include workers' compensation coverages. [1967 c.359 §35; 1993 c.649 §6]</p> <p>746.135 (4) A person may not use genetic information about a blood relative to reject, deny, limit, cancel, refuse to renew, increase the rates of, affect the terms and conditions of or otherwise affect any policy of insurance.</p>
<b>Provides disability insurance discrimination protections</b>	none	<p><b>Limited. Unlawful to use <i>blood relative's</i> genetic test results to deny insurance.</b></p> <p>ORS 731.162, 746.135(4)</p>
<b>Limitations</b>		Oregon Genetic Privacy Act does NOT restrict insurance companies from underwriting disability or life insurance based on an individuals personal genetic test result, "genetic information", genetic diagnosis, or family history.

Summary of consumer employment genetic discrimination protections: Federal laws vs Oregon Genetic Privacy Act

<u>Genetic Information Nondiscrimination Act</u> <u>[H.R. 493]</u>					
		<u>Americans with Disabilities Act</u>	<u>Executive order 13145</u>	<u>Civil Rights Act - Title VII</u>	<u>Oregon Genetic Privacy Act</u>
<b>Provides protections against employment discrimination based on genetic information</b>	<b>yes</b> "(a) Discrimination based on Genetic Information.—It shall be an unlawful employment practice for an employer—(1) to fail or refuse to hire, or to discharge, any employee, or otherwise to discriminate against any employee with respect to the compensation, terms, conditions, or privileges of employment of the employee, because of genetic information with respect to the employee; or (2) to limit, segregate, or classify the employees of the employer in any way that would deprive or tend to deprive any employee of employment opportunities or otherwise adversely affect the status of the employee as an employee, because of genetic information with respect to the employee."	<b>yes</b> Part C of definition of disability "being regarded" as having a physical or mental impairment that substantially limits on or more of major life activities. EEOC interpretation: discrimination based on genetic risk="regarded as" noted above. Covers presymptomatic individual (e.g. HD predictive testing), predisposed individual (e.g. BRCA1/2 mutation carrier), does NOT cover unaffected carriers of recessive, X-linked conditions etc (e.g. cystic fibrosis carrier) EEOC interpretation UNTESTED.	<b>yes</b> Covers genetic test information, family members' genetic test information, family history, and information about request/receipt of genetic services. See definitions under "additional information".	<b>??unknown</b> Possibly some protections as there is the potential for disparate impact of genetic information based on race, color, religion, sex or national origin (e.g. Tay-Sachs disease or Sickle Cell Anemia)	<b>yes</b> 659A.303 "(1) It is an unlawful employment practice for an employer to seek to obtain, to obtain or to use genetic information of an employee or a prospective employee, or of a blood relative of the employee or prospective employee, to distinguish between or discriminate against or restrict any right or benefit otherwise due or available to an employee or a prospective employee.(2) An employee or prospective employee may bring a civil action under ORS 659A.885 for a violation of this section...." exception to no employer testing: 659A.300(5)..." (5) Subsection (1) of this section does not prohibit the administration of a genetic test to an individual if the individual or the individual’s representative grants informed consent in the manner provided by ORS 192.535, and the genetic test is administered solely to determine a bona fide occupational qualification. [Formerly 659.227]"
<b>Prohibits employer from requiring genetic testing</b>	<b>yes</b> Title II, sec 202 "(b) Acquisition of Genetic Information.—It shall be an unlawful employment practice for an employer to request, require, or purchase genetic information with respect to an employee or a family member of the employee except...."	<b>no</b>	<b>yes</b> Sec 2, 1-202(c) "The employing department or agency shall not request, require, collect, or purchase protected genetic information with respect to an employee, or information about a request for or the receipt of genetic services by such employee." Exceptions noted in sec 3, 1-301		<b>yes</b> 659A.300. Exceptions in ORS 659A.300(5)
<b>Limitations</b>	???	* Opinions vary greatly re: what types of genetic info/circumstances are covered by ADA. * Can base job decisions on medical information (if conditions met)	Only assists federal employees and federal job applicants.	Does not address genetic discrimination directly. May provide protections but is untested.	Neither family history nor pursuit of genetic services are included in employment discrimination protections noted above because of OR Genetic Privacy Act's definition of "genetic information".
<b>Additional information</b>	Also limits disclosure of genetic information and specifies how genetic information is to be handled by employers. Definitions in employment section of GINA (Title II, Section 201): "Genetic information"—(A) In general.—The term “genetic information” means, with respect to any individual, information about—(i) such individual’s genetic tests, (ii) the genetic tests of family members of such individual, and (iii) subject to subparagraph (D), the manifestation of a disease or disorder in family members of such individual. (B) Inclusion of genetic services.—Such term includes, with respect to any individual, any request for, or receipt of, genetic services (including genetic services received pursuant to participation in clinical research) by such individual or any family member of such individual. (C) Exclusions.—The term “genetic information” shall not include information about the sex or age of any individual.  "Genetic test"—(A) In general.—The term “genetic test” means an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, that detects genotypes, mutations, or chromosomal changes, mutations, or chromosomal changes.		Also limits disclosure of genetic information and specifies how genetic information is to be handled by employers. Definitions (1-201): "Genetic test" means the analysis of human DNA, RNA, chromosomes, proteins, or certain metabolites in order to detect disease-related genotypes or mutations. Tests for metabolites fall within the definition of ``genetic tests" when an excess or deficiency of the metabolites indicates the presence of a mutation or mutations. The conducting of metabolic tests by a department or agency that are not intended to reveal the presence of a mutation shall not be considered a violation of this order, regardless of the results of the tests. Test results revealing a mutation shall, however, be subject to the provisions of this order. "Protected genetic information" (1) In general, protected genetic information means: (A) information about an individual's genetic tests; (B) information about the genetic tests of an individual's family members; or (C) information about the occurrence of a disease, or medical condition or disorder in family members of the individual. (2) Information about an individual's genetic information unless it is described in subparagraph (1).		

# HIPAA and OGL comparisons in the Clinical setting

10/01/2007

Definitions	HIPAA Requirements 45 CFR 160, 162, 164	Oregon Genetic Privacy Act Requirements ORS 192.531-549, OAR 333-025-	Assessment
<b>Treatment (Clinical)</b>  <b>Health Care</b>	<p><b>§ 164.501 Definitions.</b>  <i>Treatment</i> means the provision, coordination, or management of health care and related services by one or more health care providers, including the coordination or management of health care by a health care provider with a third party; consultation between health care providers relating to a patient; or the referral of a patient for health care from one health care provider to another.</p> <p><i>Health care</i> includes, but is not limited to, the following:            (1) Preventive, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care, and counseling, service, assessment, or procedure with respect to the physical or mental condition, or functional status, of an individual or that affects the structure or function of the body; and            (2) Sale or dispensing of a drug, device, equipment, or other item in accordance with a prescription.</p>	<p><b>192.531 Definitions for ORS 192.531 to 192.549.</b>            (4) <b>“Clinical”</b> means relating to or obtained through the actual observation, diagnosis or treatment of patients and not through research.</p>	<p>HIPAA: broad with extensive parameters            Includes PHI obtained in clinical research relevant to care of patient</p> <p>Oregon: excludes research information</p>
<b>Disclose</b>	<p><b>§ 160.103 Definitions.</b>  <i>Disclosure</i> means the release, transfer, provision of, access to, or divulging in any other manner of information outside the entity holding the information.</p>	<p><b>192.531 Definitions for ORS 192.531 to 192.549.</b>            (7) <b>“Disclose”</b> means to release, publish or otherwise make known to a third party a DNA sample or genetic information.</p>	HIPAA = Oregon
<b>Health Information;</b>  <b>Individually Identifiable Health Information; and,</b>  <b>Protected Health Information</b>	<p><b>§ 160.103 Definitions.</b>  <i>Health information</i> means any information, whether oral or recorded in any form or medium, that:            (1) Is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and            (2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.</p>	<p><b>192.531 Definitions for ORS 192.531 to 192.549.</b>            (8) <b>“DNA”</b> means deoxyribonucleic acid.            (9) <b>“DNA sample”</b> means any human biological specimen that is obtained or retained for the purpose of extracting and analyzing DNA to perform a genetic test. “DNA sample” includes DNA extracted from the specimen.            (10) <b>“Genetic characteristic”</b> includes a gene, chromosome or alteration thereof that may be tested to determine the existence or risk of a disease, disorder, trait, propensity or syndrome, or to identify an individual or a blood relative. “Genetic characteristic” does not include family history or a genetically transmitted characteristic whose existence or identity is determined other than</p>	<p>HIPAA: does not distinguish genetic information and considers it Health Information, IIHI and PHI</p> <p>Oregon: specifically calls out genetic information with a number of sub-definitions</p>

	<p><b><i>Individually identifiable health information</i></b> is information that is a subset of health information, including demographic information collected from an individual, and:</p> <p>(1) Is created or received by a health care provider, health plan, employer, or health care clearinghouse; and</p> <p>(2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and</p> <p>(i) That identifies the individual; or</p> <p>(ii) With respect to which there is a reasonable basis to believe the information can be used to identify the individual.</p> <p><b><i>Protected Health</i></b> information means individually identifiable health information:</p> <p>(1) Except as provided in paragraph (2) of this definition, that is:</p> <p>(i) Transmitted by electronic media;</p> <p>(ii) Maintained in electronic media; or</p> <p>(iii) Transmitted or maintained in any other form or medium.</p> <p>(2) Protected health information excludes individually identifiable health information in:</p> <p>(i) Education records covered by the Family Educational Rights and Privacy Act, as amended, 20 U.S.C. 1232g;</p> <p>(ii) Records described at 20 U.S.C. 1232g(a)(4)(B)(iv); and</p> <p>(iii) Employment records held by a covered entity in its role as employer.</p>	<p>through a genetic test.</p> <p>(11) <b>“Genetic information”</b> means information about an individual or the individual’s blood relatives obtained from a genetic test.</p> <p>(16) <b>“Identifiable”</b> means capable of being linked to the individual or a blood relative of the individual from whom the DNA sample or genetic information was obtained.</p> <p>(17) <b>“Identified”</b> means having an identifier that links, or that could readily allow the recipient to link, a DNA sample or genetic information directly to the individual or a blood relative of the individual from whom the sample or information was obtained.</p> <p>(20) <b>“Obtain genetic information”</b> means performing or getting the results of a genetic test.</p> <p>(24) <b>“Retain genetic information”</b> means making a record of the genetic information.</p>	
<b>De-identified</b>	<p><b>§ 164.514 Other requirements relating to uses and disclosures of protected health information.</b></p> <p>(a) <b><i>Standard: de-identification of protected health information.</i></b> Health information that does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual is not individually identifiable</p>	<p><b>192.531 Definitions for ORS 192.531 to 192.549.</b></p> <p>(6) <b>“De-identified”</b> means lacking, or having had removed, the identifiers or system of encryption that would make it possible for a person to link a DNA sample or genetic information to an individual or the individual’s blood relative, and neither the investigator nor the repository can reconstruct the identity of the individual from whom the sample or information was obtained. De-identified DNA</p>	<p>HIPAA: specific and proscriptive</p> <p>Oregon: uses HIPAA parameters</p>

	<p>health information.</p> <p>(b) <b>Implementation specifications: requirements for de-identification of protected health information.</b> A covered entity may determine that health information is not individually identifiable health information only if:</p> <p>(1) A person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable:</p> <p>(i) Applying such principles and methods, determines that the risk is very small that the information could be used, alone or in combination with other reasonably available information, by an anticipated recipient to identify an individual who is a subject of the information; and</p> <p>(ii) Documents the methods and results of the analysis that justify such determination; or</p> <p>(2)(i) The following identifiers of the individual or of relatives, employers, or household members of the individual, are removed:</p> <p>(A) Names;</p> <p>(B) All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geo codes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census:</p> <p>(1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and</p> <p>(2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.</p> <p>(C) All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;</p> <p>(D) Telephone numbers;</p> <p>(E) Fax numbers;</p> <p>(F) Electronic mail addresses;</p> <p>(G) Social security numbers;</p>	<p>samples and genetic information must meet the standards provided in 45 C.F.R. 164.502(d) and 164.514(a) to (c).</p>	
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	<p>(H) Medical record numbers;</p> <p>(I) Health plan beneficiary numbers;</p> <p>(J) Account numbers;</p> <p>(K) Certificate/license numbers;</p> <p>(L) Vehicle identifiers and serial numbers, including license plate numbers;</p> <p>(M) Device identifiers and serial numbers;</p> <p>(N) Web Universal Resource Locators (URLs);</p> <p>(O) Internet Protocol (IP) address numbers;</p> <p>(P) Biometric identifiers, including finger and voice prints;</p> <p>(Q) Full face photographic images and any comparable images; and</p> <p>(R) Any other unique identifying number, characteristic, or code, except as permitted by paragraph (c) of this section; and</p> <p>(ii) The covered entity does not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is a subject of the information.</p>		
<b>Informed Consent</b>	<p><b>§ 164.506 Uses and disclosures to carry out treatment, payment, or health care operations.</b></p> <p><b>(b) <i>Standard: Consent for uses and disclosures permitted.</i></b></p> <p>(1) A covered entity may obtain consent of the individual to use or disclose protected health information to carry out treatment, payment, or health care operations.</p> <p>(2) Consent, under paragraph (b) of this section, shall not be effective to permit a use or disclosure of protected health information when an authorization, under § 164.508, is required or when another condition must be met for such use or disclosure to be permissible under this subpart.</p>	<p><b>192.535 Informed consent for obtaining genetic information.</b> (1) A person may not obtain genetic information from an individual, or from an individual's DNA sample, without first obtaining informed consent of the individual or the individual's representative, except:</p> <p>(a) As authorized by ORS 181.085 or comparable provisions of federal criminal law relating to the identification of persons, or for the purpose of establishing the identity of a person in the course of an investigation conducted by a law enforcement agency, a district attorney, a medical examiner or the Criminal Justice Division of the Department of Justice;</p> <p>(b) For anonymous research or coded research conducted under conditions described in ORS 192.537 (2), after notification pursuant to ORS 192.538 or pursuant to ORS 192.547 (7)(b);</p> <p>(c) As permitted by rules of the Department of Human Services for identification of deceased individuals;</p> <p>(d) As permitted by rules of the Department of Human Services for newborn screening procedures;</p> <p>(e) As authorized by statute for the purpose of establishing paternity; or</p> <p>(f) For the purpose of furnishing genetic information</p>	<p>HIPAA: optional for using or disclosing PHI for TPO</p> <p>Oregon: required before obtaining genetic information from the individual</p>

		<p>relating to a decedent for medical diagnosis of blood relatives of the decedent.</p> <p>(2) Except as provided in subsection (3) of this section, a physician licensed under ORS chapter 677 shall seek the informed consent of the individual or the individual's representative for the purposes of subsection (1) of this section in the manner provided by ORS 677.097. Except as provided in subsection (3) of this section, any other licensed health care provider or facility must seek the informed consent of the individual or the individual's representative for the purposes of subsection (1) of this section in a manner substantially similar to that provided by ORS 677.097 for physicians.</p> <p>(3) A person conducting research shall seek the informed consent of the individual or the individual's representative for the purposes of subsection (1) of this section in the manner provided by ORS 192.547.</p> <p>(4) Except as provided in ORS 746.135 (1), any person not described in subsection (2) or (3) of this section must seek the informed consent of the individual or the individual's representative for the purposes of subsection (1) of this section in the manner provided by rules adopted by the Department of Human Services.</p>	
<b>Protection of genetic information</b>	<p><b>§ 164.502 Uses and disclosures of protected health information: general rules.</b></p> <p>(a) <i>Standard.</i> A covered entity may not use or disclose protected health information, except as permitted or required by this subpart or by subpart C of part 160 of this subchapter.</p>	<p><b>192.537 Individual's rights in genetic information; retention of information; destruction of information.</b></p> <p>(1) Subject to the provisions of ORS 192.531 to 192.549, 659A.303 and 746.135, an individual's genetic information and DNA sample are private and must be protected, and an individual has a right to the protection of that privacy. Any person authorized by law or by an individual or an individual's representative to obtain, retain or use an individual's genetic information or any DNA sample must maintain the confidentiality of the information or sample and protect the information or sample from unauthorized disclosure or misuse.</p>	<p>HIPAA: applies protections to all PHI with extensive parameters</p> <p>Oregon: general</p>
<b>Retention of genetic information and uses of genetic information</b>	<p><b>§ 164.502 Uses and disclosures of protected health information: general rules.</b></p> <p>(1) <i>Permitted uses and disclosures.</i> A covered entity is permitted to use or disclose protected health information as follows:</p> <p>(i) To the individual;</p>	<p><b>192.537 Individual's rights in genetic information; retention of information; destruction of information.</b></p> <p>(3) A person may not retain another individual's genetic information or DNA sample without first obtaining authorization from the individual or the individual's</p>	<p>HIPAA: Applies standard Use and Disclosure rules, no authorization required for TPO</p>

	<p>(ii) For treatment, payment, or health care operations, as permitted by and in compliance with § 164.506;</p> <p>(iii) Incident to a use or disclosure otherwise permitted or required by this subpart, provided that the covered entity has complied with the applicable requirements of § 164.502(b), § 164.514(d), and § 164.530(c) with respect to such otherwise permitted or required use or disclosure;</p> <p>(iv) Pursuant to and in compliance with an authorization that complies with § 164.508;</p> <p>(v) Pursuant to an agreement under, or as otherwise permitted by, § 164.510; and</p> <p>(vi) As permitted by and in compliance with this section, § 164.512, or § 164.514(e),(f), or (g).</p> <p><b>§ 164.508 Uses and disclosures for which an authorization is required.</b></p> <p>(a) <i>Standard: authorizations for uses and disclosures.</i></p> <p>(1) <i>Authorization required: general rule.</i> Except as otherwise permitted or required by this subchapter, a covered entity may not use or disclose protected health information without an authorization that is valid under this section. When a covered entity obtains or receives a valid authorization for its use or disclosure of protected health information, such use or disclosure must be consistent with such authorization.</p>	<p>representative, unless:</p> <p>(a) Retention is authorized by ORS 181.085 or comparable provisions of federal criminal law relating to identification of persons, or is necessary for the purpose of a criminal or death investigation, a criminal or juvenile proceeding, an inquest or a child fatality review by a county multidisciplinary child abuse team;</p> <p>(b) Retention is authorized by specific court order pursuant to rules adopted by the Chief Justice of the Supreme Court for civil actions;</p> <p>(c) Retention is permitted by rules of the Department of Human Services for identification of, or testing to benefit blood relatives of, deceased individuals;</p> <p>(d) Retention is permitted by rules of the Department of Human Services for newborn screening procedures; or</p> <p>(e) Retention is for anonymous research or coded research conducted after notification or with consent pursuant to subsection (2) of this section or ORS 192.538.</p>	<p>Oregon: Requires authorization, but may be oral (written authorization is not required) . As of 2007 legislative session, OGL now mirrors HIPAA as it relates to use of genetic information for TPO.</p>
<p><b>Inspection, amendment, access</b></p>	<p><b>§ 164.524 Access of individuals to protected health information.</b></p> <p>(a) <i>Standard: access to protected health information.</i></p> <p>(1) <i>Right of access.</i> Except as otherwise provided in paragraph (a)(2) or (a)(3) of this section, an individual has a right of access to inspect and obtain a copy of protected health information about the individual in a designated record set, for as long as the protected health information is maintained in the designated record set, except for:</p> <p>(i) Psychotherapy notes;</p> <p>(ii) Information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding; and</p> <p>(iii) Protected health information maintained by a covered entity that is:</p> <p>(A) Subject to the Clinical Laboratory Improvements Amendments of 1988, 42 U.S.C. 263a, to the extent the provision of access to the individual would</p>	<p><b>192.537 Individual's rights in genetic information; retention of information; destruction of information.</b></p> <p>(7) An individual or an individual's representative, promptly upon request, may inspect, request correction of and obtain genetic information from the records of the individual.</p>	<p>HIPAA: specific parameters for amendment and access</p> <p>Oregon: very general with no guidance for implementation</p>

	<p>be prohibited by law; or</p> <p>(B) Exempt from the Clinical Laboratory Improvements Amendments of 1988, pursuant to 42 CFR 493.3(a)(2).</p> <p>(2) <i>Unreviewable grounds for denial.</i> A covered entity may deny an individual access without providing the individual an opportunity for review, in the following circumstances.</p> <p>(v) An individual's access may be denied if the protected health information was obtained from someone other than a health care provider under a promise of confidentiality and the access requested would be reasonably likely to reveal the source of the information.</p> <p><b>§ 164.526 Amendment of protected health information.</b></p> <p>(a) <i>Standard: right to amend.</i></p> <p>(1) <i>Right to amend.</i> An individual has the right to have a covered entity amend protected health information or a record about the individual in a designated record set for as long as the protected health information is maintained in the designated record set.</p>		
<p><b>Use of genetic information by others of deceased individual; or, on request of individual</b></p>	<p><b>§ 164.502 Uses and disclosures of protected health information: general rules.</b></p> <p>(f) <i>Standard: deceased individuals.</i> A covered entity must comply with the requirements of this subpart with respect to the protected health information of a deceased individual.</p> <p>(g)(1) <i>Standard: personal representatives.</i></p> <p>(4) <i>Implementation specification: deceased individuals.</i> If under applicable law an executor, administrator, or other person has authority to act on behalf of a deceased individual or of the individual's estate, a covered entity must treat such person as a personal representative under this subchapter, with respect to protected health information relevant to such personal representation.</p>	<p><b>192.537 Individual's rights in genetic information; retention of information; destruction of information.</b></p> <p>(8) Subject to the provisions of ORS 192.531 to 192.549, and to policies adopted by the person in possession of a DNA sample, an individual or the individual's representative may request that the individual's DNA sample be made available for additional genetic testing for medical diagnostic purposes. If the individual is deceased and has not designated a representative to act on behalf of the individual after death, a request under this subsection may be made by the closest surviving blood relative of the decedent or, if there is more than one surviving blood relative of the same degree of relationship to the decedent, by the majority of the surviving closest blood relatives of the decedent.</p>	<p>HIPAA = Oregon</p>

<b>Notice</b>	<b>§ 164.520 Notice of privacy practices for protected health information.</b>	<b>192.538 Notice by health care provider regarding anonymous or coded research.</b>	HIPAA requires notice at first provision of care  Oregon: requires similar notice regarding genetic information
<b>Restriction of use and disclosure</b>	<b>§ 164.522 Rights to request privacy protection for protected health information.</b> (a)(1) <i>Standard: right of an individual to request restriction of uses and disclosures.</i>	<b>192.538 Notice by health care provider regarding anonymous or coded research.</b>  (3) A health care provider described in subsection (1) of this section shall provide a notice to the individual describing how the biological specimen or clinical individually identifiable health information may be used and allowing the individual to request that the specimen or information not be disclosed or retained for anonymous research or coded research. <b>The notice must contain a place where the individual may mark the individual's request that the specimen or information not be disclosed or retained for anonymous research or coded research before returning the notice to the health care provider.</b>	HIPAA: individual may request restriction but covered entity not required to agree to request  Oregon: requires acceptance of restriction as it relates to anonymous or coded genetic research
<b>Penalties</b>	Failure to comply with HIPAA can result in civil and criminal penalties (42 USC § 1320d-5). No private cause of action in federal law.	192.541 Private Right of Action 192.543 Criminal Penalty 192.545 Enforcement; Attorney General or district attorney; intervention	

## HIPAA vs. Common Rule vs. OGPL – Research Issues

Updated 6/5/07	Common Rule Requirements 45 CFR 46	HIPAA Requirements 45 CFR 160, 162, 164	Oregon Genetic Privacy Act Requirements ORS 192.531-549, OAR 333-025-
<b>Anonymous/ Deidentified Genetic Research</b> <i>OGPA is most restrictive</i>	-Research using completely anonymous (unable to link back to identify individual) samples or information is not considered human subjects research and does not require review.	-Deidentified information (as defined in HIPAA) can be obtained from hospitals/covered entities for research without authorization. An application to the IRB or Privacy Board for a waiver of authorization is not required.	-An individual must be notified of the potential for future anonymous/coded genetic research and given the opportunity to opt-out [192.538] -An IRB must perform an initial review of the anonymous genetic research project [192.547(1)(c)]
<b>Waiver of consent or Authorization</b> <i>Requirements for allowing a waiver are most restrictive with OGPA (consent or opt out is required for new samples), however, HIPAA also has many restrictions</i>	<p><b>-Consent may be waived or altered [45 CFR 46.116(d)] under the following criteria:</b></p> <ol style="list-style-type: none"> <li>1) The research involves no more than minimal risk* to the subject.</li> <li>2) The waiver or alteration will not adversely affect the rights and welfare of the subjects.</li> <li>3) The research could not practicably be carried out without the waiver or alteration.</li> <li>4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.</li> </ol> <p><b>*MINIMAL RISK</b> A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests [Federal Policy §____.102(i)].</p> <p>For example, the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of routine physical examination.</p>	<p><b>-For a researcher to obtain Protected Health Information (PHI) without authorization by the research participant, one of the following documents need to be provided to the hospital or covered entity [164.512(i)]:</b></p> <ol style="list-style-type: none"> <li>1) Documented Institutional Review Board (IRB) Waiver of Disclosure Authorization</li> <li>2) Representation that PHI is Sought Preparatory to Research <ol style="list-style-type: none"> <li>a) The researcher will not remove any PHI from the hospital or other covered entity</li> <li>b) This provision might be used, for example, to design a research study or to assess the feasibility of conducting a study.</li> </ol> </li> <li>3) Representation that PHI is Sought for Research on Protected Health Information of Decedents</li> <li>4) Data Use Agreement for the Use of Limited Data Sets [164.514(e)]</li> </ol> <p><b>-Waiver of Authorization</b> Authorization may be waived by the IRB or Privacy Board if the following criteria are met:</p> <ol style="list-style-type: none"> <li>1) The use or disclosure of PHI involves no more than a minimal risk to the privacy of individuals, based on, <i>at least</i>, the presence of the following elements: <ol style="list-style-type: none"> <li>a) An adequate plan to protect the identifiers from improper use and disclosure;</li> <li>b) An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and</li> <li>c) Adequate written assurances that the PHI <u>will not be reused or disclosed to any other person or entity</u>, except as required by law, for</li> </ol> </li> </ol>	<p><b>-Waiver of consent is possible for anonymous or coded research under the following conditions: [192.547 (7)(b) and 192.537(2)]</b></p> <ol style="list-style-type: none"> <li>1) Subject was notified in accordance with ORS 192.538 and did not opt out; or</li> <li>2) Subject has granted consent for genetic research generally</li> <li>3) Subject is deceased (or died before receiving opt out notice); or</li> <li>4) Sample/genetic information was obtained prior to July 29, 2005</li> </ol> <p><b>-Additional requirements for coded research: [192.547(5)]</b></p> <ol style="list-style-type: none"> <li>1) The code is: <ol style="list-style-type: none"> <li>a) Not derived from individual identifiers;</li> <li>b) Kept securely and separately from the DNA samples and genetic information; and</li> <li>c) Not accessible to the investigator unless specifically approved by the institutional review board.</li> </ol> </li> <li>2) Data is stored securely in password protected electronic files or by other means with access limited to necessary personnel.</li> <li>3) The data is limited to elements required for analysis and meets the criteria in 45 C.F.R 164.514(e) for a limited data set.</li> <li>4) The investigator is a party to the data use agreement as provided by 45 C.F.R. 164.514(e) for limited data set recipients.</li> </ol>

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		<p>authorized oversight of the research project, or for other research for which the use or disclosure of PHI would be permitted by this waiver;</p> <ol style="list-style-type: none"> <li>2) The research could not practicably be conducted without the waiver or alteration; and</li> <li>3) The research could not practicably be conducted without access to and use of the PHI.</li> </ol> <p><b>-Limited Data Set</b>  A limited data set can be disclosed without authorization under a data use agreement. A limited data set excludes specified direct identifiers of the individual or of relatives, employers, or household members of the individual. The data use agreement must:</p> <ol style="list-style-type: none"> <li>1) Establish the permitted uses and disclosures of the limited data set by the recipient, consistent with the purposes of the research.</li> <li>2) Limit who can use or receive the data; and</li> <li>3) Require the researcher to agree to the following: <ol style="list-style-type: none"> <li>a) Not to use or disclose the information other than as permitted by the data use agreement or as otherwise required by law;</li> <li>b) Use appropriate safeguards to prevent the use or disclosure of the information other than as provided for in the data use agreement;</li> <li>c) Report to the covered entity any use or disclosure of the information not provided for by the data use agreement of which the researcher becomes aware;</li> <li>d) Ensure that any agents, including a subcontractor, to whom the researcher provides the limited data set agrees to the same restrictions and conditions that apply to the recipient researcher with respect to the limited data set; and</li> <li>e) Not to identify the information or contact the individual.</li> </ol> </li> </ol> <p><b>-Minimum necessary standard [164.514(d)]:</b> When using or disclosing PHI for research without an Authorization, a covered entity must make reasonable efforts to limit the PHI used or disclosed to the minimum necessary amount to accomplish the research purpose</p>	
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<p><b>Consent &amp; Authorization</b>  <i>The common rule provides the most comprehensive requirements on the process and information to be contained in the consent form, however, both HIPAA and the OGPA add some additional details to what must be included in the consent/ authorization document and discussed in the consent process.</i></p>	<p><b>Federal regulations require that certain information must be provided to each subject</b> [Federal Policy §____.116(a)]:</p> <ol style="list-style-type: none"> <li>1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;</li> <li>2) A description of any reasonably foreseeable risks or discomforts to the subject;</li> <li>3) A description of any benefits to the subject or to others which may reasonably be expected from the research;</li> <li>4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;</li> <li>5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;</li> <li>6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;</li> <li>7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and</li> <li>8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.</li> </ol> <p>The regulations further provide that the following additional information be provided to subjects, where appropriate [Federal Policy §____.116(b)]:</p> <ol style="list-style-type: none"> <li>1) A statement that the particular treatment or procedure may involve risks to the subject</li> </ol>	<p><b>A valid authorization must contain at least the following core elements [164.508(c)]:</b></p> <ol style="list-style-type: none"> <li>1) A description of the PHI* to be used or disclosed that identifies the information in a specific and meaningful fashion.</li> <li>2) The name or other specific identification of the person(s), or class of persons, authorized to make the requested use or disclosure.</li> <li>3) The name or other specific identification of the person(s), or class of persons, to whom the covered entity may make the requested use or disclosure.</li> <li>4) A description of each purpose of the requested use or disclosure.</li> <li>5) Signature of the individual and date. (If a legal representative signs, then the person's authority to act for the individual must be included.)</li> <li>6) The participant's right to revoke the authorization in writing,</li> <li>7) The potential for PHI to be redisclosed by the researcher to agencies (e.g. for health oversight activities to Federal or State authorities), or to others who may not be subject to the Privacy Rule (e.g. to Sponsors)</li> <li>8) Expiration date or event for the authorization (for research can be "none" or "at end of study")</li> <li>9) Statement concerning the ability or inability to condition treatment, payment, enrollment or eligibility of benefits based on the signing or not signing of the authorization (i.e., the signing of the authorization is voluntary, refusal to sign the authorization will not affect your health care relationship, etc.)</li> </ol> <p><b>*Definition of PHI:</b> Health information which includes <u>any of the following identifiers</u> of the individual or of relatives, employers, or household members, <u>is considered PHI</u>, and so subject to the regulations contained in the privacy rule:</p> <ol style="list-style-type: none"> <li>1) Names;</li> <li>2) All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census:</li> </ol>	<p><b>333-025-0140 (3)</b>  <b>The consent document for a genetic research study must include*:</b></p> <ol style="list-style-type: none"> <li>1) The name of the individual whose DNA sample is to be tested;</li> <li>2) The name of the individual, company, or organization requesting the genetic test for the purpose of obtaining genetic information;</li> <li>3) A statement signed by the individual whose DNA sample is to be tested indicating that he/she authorizes the genetic test; and</li> <li>4) A statement that specifies the purpose of the test and the genetic characteristic for which the DNA sample will be tested.</li> </ol> <p>Process for obtaining informed consent using the form contained in Appendix 1 or a form that is substantively similar:</p> <ol style="list-style-type: none"> <li>1) Explain that the genetic test is voluntary;</li> <li>2) Inform the individual that he/she may choose not to have his/her DNA sample tested;</li> <li>3) Inform the individual that he/she has the option of withdrawing consent at any time;</li> <li>4) Explain the risks and benefits of having the genetic test, including: <ol style="list-style-type: none"> <li>a) A description of the provisions of Oregon law pertaining to individual rights with regard to genetic information and the confidential nature of the genetic information;</li> <li>b) A statement of potential consequences with regard to insurability, employability, and social discrimination if the genetic test results or genetic information become known to others;</li> <li>c) The implications of both positive and negative test results; and</li> <li>d) The availability of support services, including genetic counseling.</li> </ol> </li> <li>5) Inform the individual that it may be in his/her best interest to retain his/her DNA sample for future diagnostic testing, but that he/she has the right to have his/her DNA sample promptly destroyed after completion of the specific genetic test which was authorized;</li> <li>6) Inform the individual about the implications, including potential insurability, of authorizing</li> </ol>
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	<p>(or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;</p> <p>2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;</p> <p>3) Any additional costs to the subject that may result from participation in the research;</p> <p>4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;</p> <p>5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and</p> <p>6) the approximate number of subjects involved in the study.</p> <p><b>-OHRP Guidance on Informed Consent:</b> Informed consent is a process, not just a form. Information must be presented to enable persons to voluntarily decide whether or not to participate as a research subject. It is a fundamental mechanism to ensure respect for persons through provision of thoughtful consent for a voluntary act. The procedures used in obtaining informed consent should be designed to educate the subject population in terms that they can understand. Therefore, informed consent language and its documentation (especially explanation of the study's purpose, duration, experimental procedures, alternatives, risks, and benefits) must be written in "lay language", (i.e. understandable to the people being asked to participate).</p>	<p>a) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and</p> <p>b) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.</p> <p>3) All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;</p> <p>4) Telephone numbers;</p> <p>5) Fax numbers;</p> <p>6) Electronic mail addresses;</p> <p>7) Social security numbers;</p> <p>8) Medical record numbers;</p> <p>9) Health plan beneficiary numbers;</p> <p>10) Account numbers;</p> <p>11) Certificate/license numbers;</p> <p>12) Vehicle identifiers and serial numbers, including license plate numbers;</p> <p>13) Device identifiers and serial numbers;</p> <p>14) Web Universal Resource Locators (URLs);</p> <p>15) Internet Protocol (IP) address numbers;</p> <p>16) Biometric identifiers, including finger and voice prints;</p> <p>17) Full face photographic images and any comparable images; and</p> <p>18) Any other unique identifying number, characteristic, or code</p>	<p>disclosure to a third party payer that the genetic test was performed, and that he/she has the option of paying the cost of the genetic test out of pocket rather than filing an insurance claim;</p> <p>7) Ask the individual whether he/she has any further questions, and if so, provide the individual with the opportunity to ask questions and receive answers from either a genetic counselor or another person who is sufficiently knowledgeable to give accurate, understandable and complete answers to his/her questions;</p> <p>8) Request that the individual read, complete, sign and date the consent form; and</p> <p>9) Provide the individual with a copy of the completed form for his/her personal records.</p> <p><i>*Note blanket informed consent (not specifying genetic research) is allowed for sample or information obtained prior to June 25, 2001</i></p>
<p><b>Additional Requirements &amp; Notes</b> <i>The OGPA affords specific rights on the right to have</i></p>	<p><b>-Definition of a human subject [46.102 (f)]</b> Note that the definition of a human subject is a living individual, therefore the Common Rule does not apply to research involving deceased individuals</p>	<p><b>-Right to revoke authorization [164.508(b)]</b> A research participant has the right to revoke his or her authorization to have PHI used or disclosed, except to the extent that the covered entity (or researcher) has acted in reliance of the authorization. Thus, the continued use and disclosure of PHI already obtained with a valid authorization is permitted, but only to the extent necessary to preserve the integrity of the</p>	<p><b>-Right to have DNA Sample destroyed [192.537(5)]:</b> A DNA sample from an individual that is the subject of a research project, other than an anonymous research project, shall be destroyed promptly upon completion of the project or withdrawal of the individual from the project, whichever occurs first, unless the individual or the individual's representative directs otherwise by</p>

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<p><i>your DNA sample destroyed and also has specific requirements for “recontact”. However, the clinical laboratory improvement amendments (CLIA- 42 CFR 493) also apply if results of any lab test are to be released to the patient/subject</i></p> <p><i>Accounting for disclosures is unique to HIPAA.</i></p>		<p>research study.</p> <p>For example, the reliance exception would permit the continued use and disclosure of PHI</p> <ol style="list-style-type: none"> <li>1) to account for a subject’s withdrawal from the research study</li> <li>2) as necessary to incorporate the information as part of a marketing application submitted to the Food and Drug Administration</li> <li>3) to conduct investigations of scientific misconduct,</li> <li>4) to report adverse events.</li> </ol> <p>However, the reliance exception would not permit a covered entity (or researcher) to continue disclosing additional PHI to a researcher or to use for its own research purposes information not already gathered at the time an individual withdraws his or her authorization.</p> <p><b>-Accounting for Research Disclosures [164.528]</b></p> <p>The Privacy Rule gives individuals the right to receive an accounting of certain disclosures of PHI made by a covered entity.</p> <ol style="list-style-type: none"> <li>1) This accounting must include disclosures of PHI that occurred during the six years prior to the individual’s request for an accounting, starting from the compliance date (April 14, 2003), and must include specified information regarding each disclosure</li> <li>2) A more general accounting is permitted for subsequent multiple disclosures to the same person or entity for a single purpose.</li> <li>3) A more general accounting is permitted for disclosures of PHI for research purposes where 50 or more individuals’ PHI is disclosed</li> </ol> <p>Among the types of disclosures that are exempt from this accounting requirement are:</p> <ol style="list-style-type: none"> <li>1) Research disclosures made pursuant to an individual’s authorization; and</li> <li>2) Disclosures of the limited data set to researchers with a data use agreement.</li> </ol>	<p>informed consent.</p> <p><b>-Recontact (disclosure of genetic research findings to a subject) 333-025-0130</b></p> <ol style="list-style-type: none"> <li>1) Recontact of a research subject should not occur unless the subject was informed during the initial consent process that recontact may occur under specified circumstances and with this understanding, the research subject consented to participate in the study.</li> <li>2) If recontact of subjects is contemplated, the researcher must provide research protocols to the IRB describing the circumstances that might lead to recontact, as well as a plan for managing the process. If a subject declines the possibility of recontact, the researcher may not recontact the subject.</li> <li>3) Notwithstanding (1) above, in order to consider recontact in a situation where recontact was not contemplated and therefore not addressed in research protocols a researcher must seek approval from the IRB for re-contact and must assure the following conditions exist: <ol style="list-style-type: none"> <li>a) The findings are scientifically valid and confirmed;</li> <li>b) The findings have significant implications for the subject's or the public's health; and</li> <li>c) A course of action to ameliorate or treat the subject's or the public's health concerns is readily available.</li> </ol> </li> <li>4) Under conditions described in (3), the researcher shall determine and adhere to the expressed wishes and desires of the research subject in relation to disclosure of genetic information to that individual.</li> <li>5) When research results are disclosed to a subject, appropriate medical advice and referral must be provided.</li> <li>6) In all cases, a decision to recontact research subjects must have prior approval of the IRB.</li> </ol>
<p><b>Penalties</b></p>	<p>-[46.103] Federal Office of Human Research Protections may terminate or suspend an institution’s Federal-Wide Assurance (no federally funded human subjects research can be conducted)</p>	<p>Failure to comply with HIPAA can result in civil and criminal penalties (42 USC § 1320d-5). No private cause of action in federal law.</p>	<p>192.541 Private Right of Action 192.543 Criminal Penalty 192.545 Enforcement; Attorney General or district attorney; intervention</p>

## **Appendix 3**

### **“We All Have Genes”**

**Submitted opinion piece by ACGPR member**

**Professor Patricia Backlar**

ACGPR member Steven Nemirow concurs with Professor Backlar's statement

## **We All Have Genes: *Genetic Exceptionalism*?**

### **Prepared for the Committee by Professor Patricia Backlar**

(Patricia Backlar is Research Associate Professor of Biomedical Ethics, Department of Philosophy, Portland State University; and an Adjunct Associate Professor of Bioethics, Department of Psychiatry; a Senior Scholar, Center for Ethics in Health Care, Oregon Health & Science University. She was a commissioner on the National Bioethics Advisory Commission).

An octopus is nothing like a mouse, and both are quite different from an oak tree. Yet in their fundamental chemistry they are rather uniform, and, in particular, the replicators which they bear, the genes, are basically the same kind of molecule in all of us – from bacteria to elephants.

– Richard Dawkins (1976, p.22).

The modern story of human biology has been linked and shaped by two bookends: the work of Andreas Vesalius, *De humani corporis fabrica* (*The structure of the human body*) published in 1543 (Porter, R. 1997); and the recent work of James Watson and Francis Crick, “Molecular structure of nucleic acids: A structure for Deoxyribose Nucleic Acid,” published in 1953 (*Nature*, Vol. 171, No. 4356, pp. 737-738). This modern story of human biology is the purview of the Oregon Advisory Committee on Genetic Privacy and Research (ACGPR).

From its inception the ACGPR has grappled with the concept of *genetic exceptionalism*. The idea that genetic information should be treated differently has been an irritant to our committee. In our attempts to unpack the concerns embedded in this concept we have exposed an underlying tension in the work of the committee: The ACGPR has conflicting obligations: on the one hand the ACGPR was constituted to provide a privacy protection for a person’s genomic information, while on the other hand, ACGPR also has an obligation to enhance the public good.

As is exemplified in the words of Elliot Sober (2001) we all have genes: “Genes do two things. They provide a mechanism of inheritance, and they influence how organisms develop. When genes do the former, they effect a connection between generations – parents pass genes along to their children. When genes do the latter, they participate in processes that occur within a generation; they affect how a fertilized egg – a single cell—divides and differentiates, and eventually becomes an adult, who has numerous traits that were not present at conception.”

### **If we all have genes is *genetic exceptionalism* a fallacy?**

The concept of *exceptionalism as relevant to a medical diagnosis* was developed in the early 1990s; we borrowed this concept of ‘exceptionalism’ as it was used in conjunction with the HIV diagnosis:<sup>1</sup> “‘HIV exceptionalism’ is the notion that being diagnosed with HIV is so different from any other diagnosis that it must be handled very differently” (Wynia, 2006, p. 5). However, the characterization of ‘exceptional’ – *vis a vis* a particular

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<sup>1</sup> “The idea that genetic information should be treated differently is known as ‘genetic exceptionalism’ .... The term was first used during deliberations of the Task Force on Genetic Information and Insurance, formed in 1991 by the Joint NIH-DOE Working group on the Ethical, Legal, and social Implications (ELSIE) of Human Genome Research” (Department of Health and Human Services’ Secretary Advisory Committee on Genetics, Health, and Society, Draft Report 11-5-2007).

and distinct HIV diagnosis – is different from characterizing as exceptional a molecule *common to all* “animals, plants, bacteria, and viruses.”

In 1995, when I was a commissioner on the National Bioethics Advisory Commission (NBAC) we asked the more specific question: “Is genetic information different from other medical information?” We concluded that “genetic information is not inherently distinct from other types of medical information... Other types of medical information may be strongly correlated with particular diseases. Moreover, infection with a virus has implications for people other than the person actually infected. Likewise, the health status of a person living in a toxic environment, such as near the Chernobyl nuclear accident site, has implications for others living in the same environment. Clearly, many of the concerns that pertain to the misuse of personal genetic information apply equally to other types of personal medical information” (NBAC, 1999, pp. 3-4).

Professor Lawrence Gostin (1995) defines “*genetic information infrastructure* as the basic, underlying framework of collection, storage, use and transmission of genomic information (including human tissue and extracted DNA) to support all essential functions in genetic research diagnosis, treatment and reproductive counseling” (pp.320, 321). In his paper on “Genetic Privacy,” Professor Gostin examines whether “genetic information is sufficiently different from other health information to justify special treatment”:

*It must also be observed that genetic-specific privacy statutes could create inconsistencies in the rules governing dissemination of health information [emphasis mine]. Under genetic-specific privacy statutes, different standards would apply to data held by the same entity, depending on whether genetic analysis had been used. The creation of strict genetic-specific standards may significantly restrain the dissemination of genomic data (even to the point of undermining legitimate health goals), while nongenomic data receive insufficient protection. Arguments that genomic data deserve special protection must reckon with the fact that other health conditions raise similar sensitivity issues (for examples, HIV infection, tuberculosis, STDs, and mental illnesses. Indeed, carving out special legal protection for sensitive data may be regarded as inherently faulty, because the desired scope of privacy encompassing a health condition varies from individuals to individual. Some patients may be just as sensitive about prevalent nongenetic or multifactorial diseases like cancer and heart disease as they are about diseases with a unique genetic component [as is the case with Huntington’s Disease]. Even if it could be argued that most diseases will one day be found to be, at least in part, genetically caused, this will still raise questions about why purely viral or bacterial diseases should receive less, or different, protection” (p.326).*

In 1999, law professors Gostin and Hodge revisited genetic exceptionalism in their paper “Genetic Privacy and the Law: An End to Genetics Exceptionalism.” The authors argue: ...that genetic exceptionalism is flawed for two reasons—the first argument relates to the balance between public and private goods in understanding privacy, and the second relates to the understanding of ‘genetics’ itself. First, much of the scholarship, and resulting legislation, often wrongly assumes that protecting the privacy of genetic information (e.g., through regulation of testing, information

management, and harmful uses) must be an inherent good. However, it is not at all clear that this kind of regulation provides unmitigated benefits. In fact, *fierce protection of autonomy, privacy, and equal treatment of persons with genetic conditions entails a cost in terms of the public goods that could have been achieved if government permitted more liberal uses of genetic data* [emphasis mine]. Genetic regulation entails complex tradeoffs, and the resulting choices are difficult: should the systematic collection and uses of genetic information be sharply limited to achieve reasonable levels of privacy? Alternatively, is the value of collecting genetic information so important to the achievement of communal goods that the law ought not to promise absolute or even significant levels of privacy? Perhaps the law should simply require that genetic data be acquired, used, disclosed in orderly and just ways, consistent with the values of individuals and communities.

Second, genetic exceptionalism creates significant legal protection for some information but denies it for other health information. It ranks genetic information above other information as deserving a special legal status. Why is it wrong to afford certain kinds of data, because of their sensitivity or other special value, a higher status? *A fundamental reason is that there is no clear demarcation that separates genetic data from other health data* [emphasis mine]. Clinicians cannot always differentiate genetic information from other medical information in a medical record. Even if we could clearly distinguish genetic data, there are good reasons for not affording genetics a higher status. Genetic exceptionalism discounts the ethical and legal need for affirmative protections of other, equally sensitive, personally identifiable health information (e.g., mental health, HIV, STD, or other stigmatizing conditions in a national health information infrastructure. Genetic exceptionalism, moreover, is unfair to persons with non-genetic conditions by excluding them from the protection of private interests which they would otherwise be entitled if their condition had a genetic origin. Consider two women with breast cancer, the first with a positive BRCA1 test and the other without a discrete genetic etiology. It would hardly be fair to treat these two women differently for legal purposes, but that is exactly what genetic-specific legislation does.

Patrick Taylor (2008) in his paper, “When consent gets in the way” (*Nature*, pp. 32,33) concurs with the Gostin and Hodge analyses (and fears) should an unwarranted adherence to the concept of ‘genetic exceptionalism’ bring about a too narrow legislative protection<sup>2</sup>:

The recent US Genetic Information Nondiscrimination Act prohibits intentional discrimination in employment and insurance, but not other spheres of life. And it doesn’t directly address commercial reidentification, or constrain government

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<sup>2</sup> See also the 2003 ACGPR Report to the Oregon Legislature, Exhibit D: Backlar, P., “‘Informed consent’: A limited protection,” p. 51 “...in order to respect autonomy and privacy, the problem is neither that of status or consent, nor of confidentiality and security of samples and information but rather the locus of that respect and the tool(s) to achieve it within society, human rights being both individual, collective and above all procedural in their realization” (Knoppers, p.56).

from expanding DNA databases through coercively linking sample extraction to public health, misdemeanours, violations or immigration. It should.

...If we protect privacy effectively, we will not reduce ethics to autonomy, and autonomy to data ownership. Reducing ethics to ownership comes at a high price: ethics that care only about ownership and consented transfers are, by exclusion, indifferent to distributional justice and optimizing social outcomes.

### **Remembering the goals of medicine**

“Writing 97 years ago, Sir William Osler described the goals of medicine this way: ‘To wrest from nature the secrets that have perplexed philosophers in all ages, to track the causes of disease, to correlate the vast stores of knowledge, that they may be quickly available for the prevention and cure of disease – these are our ambitions.’ The Human Genome Project, with its audacious goal of providing the tools to uncover the hereditary factors in virtually every disease, has become a major component of Osler’s vision” (Collins, 1999, p. 36).

### **References**

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## **Appendix 4**

### **SB 1025 – Stakeholder Impact - Background documents**

**Researchers and IRB Members**

**Clinical Laboratories**

**Genetic Counselors**

Stakeholder Meeting<sup>1</sup> – Genetic Researchers and IRB Administrators –  
Accessing Anonymous and Coded Research Samples  
February 6, 2008

Participants:

Susan Hayflick, OHSU

Casey Bush & Cate Morris, Legacy Health Systems

Pierre-Andre LaChance, Kaiser Permanente

Summary:

- For the most part, the law has clarified and enhanced the ability to do genetic research in Oregon.
- When the definition of a “genetic test” under the law was unclear (e.g., genetic testing of tumors to determine therapy), the organizations got legal opinion from their counsel.
  - This issue is particularly a problem to IRBs, who must make a judgment on each research protocol in determining whether or not the law applies. Further guidance from DHS, perhaps with the ability to revise the definitions in administrative rule, would be helpful to address this problem.
- The organizations approached the “opt-out” provision for research differently, which possibly affected their opt-out rates:
  - OHSU and Kaiser sent opt-out forms to all their patients by mail. In order to opt-out, the recipient had to sign it and send it back. Their opt-out rates are 10-12%.
  - Legacy had personal discussions with every patient, and the patients had to either opt-out or opt-in, i.e., everyone had to make a decision and sign a document. Their opt-out rates are 30-35%.
  - Because of the differences in approach, Legacy also estimated their annual cost of implementation of the opt-out to be higher, whereas OHSU and Kaiser thought that most of the cost was spent up front.

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<sup>1</sup> These meetings were held with various stakeholders to determine if the genetic privacy legislation passed in 2007 is having its intended effects.

Stakeholder Meeting<sup>1</sup> – Hospital and Reference Lab Managers – Clinical  
Testing and Handling of Samples  
December 5, 2007

Participants:

Ken Devereaux, Interpath Lab, Pendleton  
Rich Eastburn, Corvallis Clinic  
Steve Joyce, Rogue Valley Medical Center, Medford  
Harlan Acres, Good Samaritan Hospital, Corvallis  
Vivian Benfield, Oregon Medical Laboratories, Eugene  
Ted Tosterude and colleagues, Quest Diagnostics, Tigard  
Kelly, Labcorp, Seattle  
Rebecca, Salem Regional Hospital  
Jim MacLowry, OHSU

Summary:

- The new legislation did have an impact on clinical labs.  
The laboratories were critical of the way the law was "rolled out".  
They felt that the information to the individual providers was lacking;  
therefore, the laboratorians were handed the task of implementation.
- The tracking of the opt-out forms was a huge undertaking for the mid size labs.
- Some of the reference and hospital labs consider all samples opted-out. It is too hard to track opt-outs otherwise.
- There was a sense that the laboratory and medical records / compliance professionals should have been more involved in the initial writing of the law.
- Samples are used for the ordered test and nothing else.
- No samples from reference labs are used in research.
- The opt-out responsibility falls on the physician, not the lab, but the lab must track if the sample comes with an opt-out form.
- At OHSU, if there is a high interest in doing research on particular samples, the patient's records are reviewed for an opt-out.

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<sup>1</sup> These meetings were held with various stakeholders to determine if the genetic privacy legislation passed in 2007 is having its intended effects.

Updated summary (3/27/2008) from the labs:

- The "opt-outs" have become a "non-issue" for most of the laboratories.
- When talking about 20-50 bed hospital labs and 2-40 doctor clinics labs, these facilities don't have the systems and resources to add another tracking task and do not get requests for samples for research anyway.
- In the practical application of the law, laboratories have either identified a process to track the opt-out forms or sent blanket letters to their reference labs stating that none of the laboratory specimens or data can be used for any type of research.
- With a number of out-of-state large reference labs, I'm not sure that the Oregon Law would even apply, if they were ever approached for research samples or data.
- The laboratories' managers talked to their directors and legal counsel to determine their read on the intent of the original law and acted accordingly.
- The labs have moved on, and they do not have any burning questions or input for the Committee.

## Results of ACGPR survey of Oregon genetic counselors

Total responses = 14

	Yes	No	Don't Know
1. In 2005 the Oregon Legislature passed an amendment to the Genetic Privacy Law allowing all patients the ability to "opt-out" of anonymous genetic research on any biological sample (e.g., tissue, blood) taken for any reason. Did you know that the law changed in 2005?	13	1	0
2. Are you familiar with the basic requirements of the 2005 changes to the law?	10	3	1
3. Does your clinic or institution provide information to patients about the "opt-out" provision in the 2005 law?	13	0	1
4. Has the 2005 change to the law affected your genetic counseling practice?	0	14	0

5. If the law has affected your practice, has it:

Made your genetic counseling practice more difficult?	11.10%	1
Made your genetic counseling practice easier?	0.00%	0
Had a financial impact on your genetic counseling practice?	0.00%	0
Not changed your genetic counseling practice.	88.90%	8

Please explain:
We do not perform genetic research on information was sent by institution to patients, i.e., more of an administrative task.
There is just an extra line on the amniocentesis form that pts can ck yes or no.
The law causes confusion. Most of my patients' blood samples are sent to out of state labs. My understanding is that the out of state labs are not obligated to honor the Oregon law.

**6. Please include any other comments about the 2005 "opt-out" provision of the Oregon Genetic Privacy Law.**

Honestly, I think it does a disservice by creating an atmosphere of uncertainty about the impact of research testing on the individual.

The law is impossible to enforce.

Most of the questions patients have regarding the law are addressed to and answered by the front desk staff.

**7. What institution or clinic do you work for?**

OHSU perinatology clinic

OHSU research position

Kaiser

Kaiser

Kaiser West Interstate

Center for genetic and maternal fetal medicine

OHSU

OHSU

OHSU

Hemophilia Clinic, CDRC, OHSU

**8. In which area of genetics do you work? (Please check as many as apply.)**

General	42.90%	6
Prenatal	50.00%	7
Cancer	35.70%	5
Research	7.10%	1
Other (please specify)	7.10%	1

Bleeding and Clotting

## **Appendix 5**

### **Congressional Research Service Review of GINA**

# CRS Report for Congress

## The Genetic Information Nondiscrimination Act of 2008 (GINA)

**July 9, 2008**

Nancy Lee Jones  
Legislative Attorney  
American Law Division

Amanda K. Sarata  
Analyst in Genetics Policy  
Domestic and Social Policy



**Prepared for Members and  
Committees of Congress**

# The Genetic Information Nondiscrimination Act of 2008 (GINA)

## Summary

On May 21, 2008, the Genetic Information Nondiscrimination Act of 2008 (GINA), referred to by its sponsors as the first civil rights act of the 21<sup>st</sup> century, was enacted. GINA, P.L. 110-233, prohibits discrimination based on genetic information by health insurers and employers. The sequencing of the human genome and subsequent advances raise hope for genetic therapies to cure disease, but this scientific accomplishment is not without potential problems. An employer or health insurer could decide to take adverse action based on a genetic predisposition to disease, and situations have arisen where discriminatory action based on genetic information did occur. In addition, there is evidence that the fear of genetic discrimination has an adverse effect on those seeking genetic testing, as well as on participation in genetic research. GINA was enacted to remedy this situation.

GINA is divided into two main parts: Title I, which prohibits discrimination based on genetic information by health insurers; and Title II, which prohibits discrimination in employment based on genetic information. Title I of GINA amends the Employee Retirement Income Security Act of 1974 (ERISA), the Public Health Services Act (PHSA), and the Internal Revenue Code (IRC), through the Health Insurance Portability and Accountability Act of 1996 (HIPAA), as well as the Social Security Act, to prohibit health insurers from engaging in genetic discrimination. Title II of GINA prohibits discrimination in employment because of genetic information and, with certain exceptions, prohibits an employer from requesting, requiring, or purchasing genetic information. The law prohibits the use of genetic information in employment decisions — including hiring, firing, job assignments, and promotions — by employers, unions, employment agencies, and labor-management training programs.

This report provides background on genetic information, legal implications regarding the use of this information, and relevant laws. It also discusses the statutory provisions of GINA.

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# The Genetic Information Nondiscrimination Act of 2007(GINA)

## Introduction

On May 21, 2008, the Genetic Information Nondiscrimination Act of 2008 (GINA), referred to by its sponsors as the first civil rights act of the 21<sup>st</sup> century, was enacted. GINA, P.L. 110-233, prohibits discrimination based on genetic information by health insurers and employers.

In April 2003, the sequence of the human genome was deposited into public databases. Scientists involved in the Human Genome Project (HGP)<sup>1</sup> reported that the finished sequence consists of overlapping fragments covering 99% of the coding regions of the human genome, with an accuracy of 99.999%.<sup>2</sup> These rapid advances provide powerful tools for determining the causes of, and potentially the cures for, many common, complex diseases such as diabetes, heart disease, Parkinson's disease, bipolar disorder, and asthma.

Although the sequence information should facilitate the identification of genes underlying disease and create a foundation for the development of genetic therapies, this scientific accomplishment is not without potential problems. For instance, the presence of a specific genetic variation may indicate a predisposition to disease but does not guarantee that the disease will manifest. An employer or health insurer could decide to take adverse action based on a genetic predisposition, and situations have arisen where discriminatory action based on genetic information did occur. GINA was enacted to remedy this potential situation. This report provides background on genetic information, legal implications regarding the use of this information, and relevant laws. It also discusses the statutory provisions of GINA.

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<sup>1</sup> The Human Genome Project, begun in 1990, was a 13-year effort coordinated and funded by the U.S. Department of Energy and the National Institutes of Health to identify all of the protein-coding genes in human DNA; determine the sequence of the 3 billion chemical bases that make up human DNA; store this information in databases; develop tools for data analysis; and address the ethical, legal, and social issues (ELSI) that may arise from the project. For more detailed information see "The National Human Genome Research Institute," [<http://www.genome.gov/>], and "Human Genome Project Information," [[http://www.ornl.gov/sci/techresources/Human\\_Genome/home.shtml](http://www.ornl.gov/sci/techresources/Human_Genome/home.shtml)].

<sup>2</sup> "International Human Genome Sequencing Consortium Describes Finished Human Genome Sequence," Oct., 20, 2004, at [<http://www.genome.gov/12513430>].

## Background

### Human Genome Research

In congressional testimony, Dr. Francis Collins, the Director of the National Human Genome Research Institute, described the potential that the information generated by the HGP holds for medicine and public health.<sup>3</sup> He stated that

the human genome sequence provides foundational information that now will allow development of a comprehensive catalog of all of the genome's components, determination of the function of all human genes, and deciphering of how genes and proteins work together in pathways and networks. Completion of the human genome sequence offers a unique opportunity to understand the role of genetic factors in health and disease, and to apply that understanding rapidly to prevention, diagnosis, and treatment. This opportunity will be realized through such genomics-based approaches as identification of genes and pathways and determining how they interact with environmental factors in health and disease, more precise prediction of disease susceptibility and drug response, early detection of illness, and development of entirely new therapeutic approaches.<sup>4</sup>

As Dr. Collins stated, with completion of the human genome sequence, scientists will now focus on understanding the clinical and public health implications of the sequence information. All disease has a genetic component and, therefore, genomic research has the potential to substantially reduce the collective burden of disease in the general population. Clinical genetic tests are becoming available at a rapid rate, with 1,271 clinical genetic tests currently available.<sup>5</sup> In addition, private insurers are beginning to include some clinical genetic tests in their health insurance benefits packages as evidence of the tests' clinical validity accumulates.<sup>6</sup>

### Concerns About the Use of Genetic Information

These scientific advances in genetics, while promising, are not without potential problems. The ethical, social, and legal implications of genetic research have been the subject of significant scrutiny and a portion of the funds for the Human Genome

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<sup>3</sup> Dr. Collins is expected to be stepping down as director of the National Human Genome Research Institute in August 2008. For more information on NHGRI, please see [<http://www.genome.gov/>].

<sup>4</sup> Testimony of Francis S. Collins, director, National Human Genome Research Institute, National Institutes of Health, Before the Subcommittee on Health of the House Committee on Energy and Commerce (May 22, 2003).

<sup>5</sup> Gene Tests, available at [<http://www.genetests.org/>]. Accessed May 29, 2008.

<sup>6</sup> For more information on the status of genetic tests and further discussion of what constitutes "genetic information," see CRS Report RL33832, *Genetic Testing: Scientific Background for Policymakers*, by Amanda K. Sarata.

Project were set aside to support the analysis and research of these issues.<sup>7</sup> As scientific knowledge about genetics becomes increasingly widespread, numerous researchers and commentators, including Dr. Francis Collins, have expressed concerns about how this information will be used.<sup>8</sup> In congressional testimony, Dr. Collins stated,

while genetic information and genetic technology hold great promise for improving human health, they can also be used in ways that are fundamentally unjust. Genetic information can be used as the basis for insidious discrimination....The misuse of genetic information has the potential to be a very serious problem, both in terms of people's access to employment and health insurance and the continued ability to undertake important genetic research.<sup>9</sup>

Legal cases of genetic discrimination have been few.<sup>10</sup> However, studies have shown that public fear of discrimination is substantial and negatively influences the uptake of genetic testing and the use of genetic information by consumers and health professionals. The Secretary's Advisory Committee on Genetics, Health and Society (SACGHS) learned that 68% of Americans are concerned about who would have access to their personal genetic information; 31% state this concern would prevent them from having a genetic test; and 68% agree that insurers would do everything possible to use genetic information to deny health coverage.<sup>11</sup> A 2004 survey

<sup>7</sup> The group working on these issues is referred to as the Ethical, Legal and Social Implications (ELSI) program. See [<http://www.genome.gov/page.cfm?pageID=10001618>].

<sup>8</sup> Testimony by Dr. Francis Collins, director, National Center for Human Genome Research, before the Senate Committee on Labor and Human Resources (Mar. 6, 1996). See also, Hudson, Rothenberg, Andrews, Kahn, and Collins, "Genetic Discrimination and Health Insurance: An Urgent Need for Reform," 270 *Science* 391 (Oct. 20, 1995); Annas, Glantz, and Roche, "Drafting the Genetic Privacy Act: Science, Policy and Practical Considerations," 23 *J. of Law, Medicine and Ethics* 360 (1995); Gostin, "Genetic Discrimination: The Use of Genetically Based Diagnostic and Prognostic Tests by Employers and Insurers," 17 *Am. J. of Law & Med.* 109 (1991); Rothstein, Mark, *Genetic Secrets: Protecting Privacy and Confidentiality in the Genetic Era* (1997).

<sup>9</sup> Testimony of Francis S. Collins, director, National Human Genome Research Institute, National Institutes of Health, before the Senate Health, Education, Labor and Pensions Committee (July 20, 2000).

<sup>10</sup> But see *Norman-Bloodsaw v. Lawrence Berkeley Laboratory*, 135 F.3d 1260 (9<sup>th</sup> Cir. 1998), where blood tests for sickle cell trait were found to give rise to a Title VII claim. See also the discussion of the Americans with Disabilities Act, *supra*, and Geller, Alper, Billings, Barash, Beckwith, and Natowicz, "Individual, Family, and Societal Dimensions of Genetic Discrimination: A Case Study Analysis," 2 *Science and Engineering Ethics* 71 (1996), which found that a number of institutions, including health and life insurance companies, health care providers, blood banks, adoption agencies, the military, and schools, were reported to have engaged in genetic discrimination against asymptomatic individuals. This study has been criticized by the insurance industry as relying on anecdotal information. See American Council of Life Insurance, "Statement Regarding the Council for Responsible Genetics 'Study' on Genetic Discrimination" (Apr. 11, 1996).

<sup>11</sup> Meeting of the Secretary's Advisory Committee on Genetics, Health, and Society, October 2005. Accessed at [<http://www4.od.nih.gov/oba/SACGHS/meetings/>]  
(continued...)

conducted by the Genetics and Public Policy Center found that 92% of Americans oppose employer access to personal genetic information and 80% oppose access to this information by health insurers.<sup>12</sup>

In addition, SACGHS as well as its predecessor committee, the Secretary's Advisory Committee on Genetic Testing (SACGT), sponsored two public forums in 2000 and 2004 to gather perspectives on genetic discrimination. Many comments were received from patients, consumers, health professionals, scientists, genetic test developers, educators, industry representatives, policymakers, lawyers, students, and others representing a wide range of diverse ethnic and racial groups.<sup>13</sup> The comments and testimony revealed several anecdotal cases of discrimination. SACGT sent the first of two letters to the Secretary of HHS urging support for nondiscrimination protections after the 2000 forum:

During consultations with the public SACGT heard from many Americans who are concerned about the misuse of genetic information by third parties, such as health insurers and employers, and the potential for discrimination based on that information. Many stated that fear of genetic discrimination would dissuade them from undergoing a genetic test or participating in genetic research studies. Others stated that they would pay out of pocket for a genetic test to prevent the results from being placed in their medical record. Such concerns are a deterrent to advances in the field of genetic testing and may limit the realization of the benefits of genetic testing.<sup>14</sup>

A joint report by the Department of Labor, the Department of Health and Human Services, the Equal Employment Opportunity Commission (EEOC), and the Department of Justice summarized the various studies on discrimination based on genetic information and argued for the enactment of federal legislation. The report stated that “genetic predisposition or conditions can lead to workplace discrimination, even in cases where workers are healthy and unlikely to develop disease or where the genetic condition has no effect on the ability to perform work” and that “because an individual’s genetic information has implications for his or her family members and future generations, misuse of genetic information could have intergenerational effects that are far broader than any individual incident of

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<sup>11</sup> (...continued)

October2005/10-20%20Public%20Attitudes%20toward%20Advances%20in%20Genetics-White.pdf].

<sup>12</sup> Testimony of Kathy Hudson, director, Genetics and Public Policy Center, before the Secretary's Advisory Committee on Genetics, Health, and Society. Accessed at [http://82.165.149.27/news.eneews.article.php?action=detail&newsletter\_id=16&article\_id=55&newsletter\_title=Issue+5].

<sup>13</sup> Highlights and transcripts of Jan. 27, 2000, testimony can be found on the SACGT website at [http://www4.od.nih.gov/oba/sacgt/sacgtmtg.htm]. Transcripts of the Oct. 18, 2004, testimony can be found on the SACGHS website at [http://www4.od.nih.gov/oba/SACGHS/meetings/October2004/SACGHSOct2004postmeeting.htm].

<sup>14</sup> From a letter from SACGT to Secretary Tommy Thompson, May 3, 2001, at [http://www4.od.nih.gov/oba/sacgt/ltr\_to\_secDHHS5-3-01.pdf].

misuse.”<sup>15</sup> Concluding that existing protections are minimal, the report went on to call for the enactment of legislation.

The National Council on Disability (NCD), an independent federal agency that advises the President and Congress on issues affecting individuals with disabilities, published a position paper on March 4, 2002, arguing for the enactment of federal legislation prohibiting genetic discrimination. The NCD argued that recent advances in genetic research have brought an increasing potential for genetic discrimination, that genetic discrimination is a historical and current reality, that genetic discrimination undermines the purposes of genetic research and testing, that genetic test information has little value for purposes of making employment decisions and insurance decisions, and that existing laws are insufficient to protect individuals from genetic discrimination.<sup>16</sup>

## **Federal Law Relating to Genetic Discrimination Prior to GINA**

### **Health Insurance Portability and Accountability Act of 1996 (HIPAA).**

Title I of GINA extends the current HIPAA protections against discrimination by group health plans and issuers of health insurance in both the group and individual markets. HIPAA prohibits a group health plan or issuer of a group health plan from using genetic information to establish rules for eligibility or continued eligibility and provides that genetic information shall not be treated as a preexisting condition in the absence of the diagnosis of the condition related to such information. It also prohibits a group health plan or issuer of a group health plan from using genetic information in setting a premium contribution. These protections apply to individuals within the group plans; however, they do not apply to the acceptance of the whole group or to the premiums set for the group. Thus, HIPAA prohibits group health plans or issuers of group health plans from charging an individual a higher premium than a similarly situated individual; however, the law does not prevent an entire group from being charged more. The HIPAA nondiscrimination provisions do not apply to individual health insurance policies, and genetic information may be used to set premiums for individual policies (although HIPAA establishes both guaranteed issue for individuals who lose group coverage and guaranteed renewal for those with existing individual coverage).

HIPAA would not prohibit group health plans or issuers of plans (i.e., insurers) from requiring or requesting genetic information or testing and does not prevent them from excluding coverage for a particular condition or imposing lifetime caps on all benefits, or on specific benefits. Finally, HIPAA does not address the use of genetic information in contexts other than health insurance, such as employment.

Under the HIPAA Privacy Rule, health plans and insurers may use or disclose health information for payment and other health care operations, including

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<sup>15</sup> Department of Labor, Department of Health and Human Services, Equal Employment Opportunity Commission, Department of Justice, “Genetic Information and the Workplace,” Jan. 20, 1998, [<http://www.dol.gov/oasam/programs/history/herman/reports/genetics.html>].

<sup>16</sup> National Council on Disability, “Position Paper on Genetic Discrimination Legislation” [[http://www.ncd.gov/newsroom/publications/2002/geneticdiscrimination\\_principles.html](http://www.ncd.gov/newsroom/publications/2002/geneticdiscrimination_principles.html)].

underwriting, premium rating, and other activities related to the creation, renewal, or replacement of an insurance contract.

**Americans with Disabilities Act.** The Americans with Disabilities Act (ADA)<sup>17</sup> prohibits discrimination against an individual with a disability in employment, public services, public accommodations, and communications. The threshold issue in any ADA case is whether the individual alleging discrimination is an individual with a disability. The act defines the term disability with respect to an individual as having “(A) a physical or mental impairment that substantially limits one or more of the major life activities of such individual; (B) a record of such an impairment; or (C) being regarded as having such an impairment.”<sup>18</sup> Although the statutory language of the ADA does not reference genetic traits, there was a discussion of the issue during congressional debate.<sup>19</sup> So far there have been no judicial decisions specifically dealing with genetic predisposition to disease and the ADA, but one case was brought by the EEOC and settled.<sup>20</sup> In addition, Terri Seargent filed with the EEOC alleging genetic discrimination and received a determination on November 21, 2000, that the EEOC’s investigation supported her allegation of discrimination under the ADA.<sup>21</sup>

The ADA has been interpreted by the EEOC as including genetic information relating to illness, disease, or other disorders.<sup>22</sup> The legislative history was cited by

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<sup>17</sup> 42 U.S.C. § 12101 et seq. For a detailed discussion of the ADA see CRS Report 98-921, *The Americans with Disabilities Act (ADA): Statutory Language and Recent Issues*, by Nancy Lee Jones.

<sup>18</sup> 42 U.S.C. § 12102. Legislation, H.R. 3195, 110<sup>th</sup> Cong., and S. 1881, 110<sup>th</sup> Cong., is currently pending that would amend the ADA to change the definition of disability. For a discussion of this legislation see CRS Report RS22901, *The Americans with Disabilities Amendments Act*, by Nancy Lee Jones.

<sup>19</sup> Rep. Owens stated that “[t]hese protections of the ADA will also benefit individuals who are identified through genetic tests as being carriers of a disease-associated gene. There is a record of genetic discrimination against such individuals, most recently during sickle cell screening programs in the 1970s. With the advent of new forms of genetic testing, it is even more critical that the protections of the ADA be in place.” 136 Cong. Rec. H 4623 (daily ed. July 12, 1990) (remarks of Rep. Owens). Similarly, Rep. Edwards and Rep. Waxman also stated that individuals who are carriers of a disease-associated gene may not be discriminated against under the ADA. 136 Cong. Rec. H 4625 (daily ed. July 12, 1990) (Statement of Rep. Edwards); *Id.* at H 4627 (Statement of Rep. Waxman).

<sup>20</sup> The EEOC alleged that Burlington Northern Sante Fe (BNSF) Railroad tested its employees for a genetic marker linked to carpal tunnel syndrome in an attempt to address a high number of repetitive stress injuries leading to employee compensation. The EEOC and BNSF reached a settlement agreement rejecting the testing of employees for the genetic marker. See Paul Miller, EEOC commissioner, “Analyzing Genetic Discrimination in the Workplace,” 12 Human Genome News (Feb. 2002) at [[http://www.ornl.gov/sci/techresources/Human\\_Genome/publicat/hgn/v12n1/09workplace.shtml](http://www.ornl.gov/sci/techresources/Human_Genome/publicat/hgn/v12n1/09workplace.shtml)].

<sup>21</sup> Testimony of Janiori Goldman before the House Committee on Energy and Commerce, Subcommittee on Health, 107<sup>th</sup> Cong., 1<sup>st</sup> sess. (Mar. 22, 2001).

<sup>22</sup> Equal Employment Opportunity Commission, Compliance Manual, vol. 2, section 902, (continued...)

the EEOC in its guidance to the definition of disability for its compliance manual. In this guidance, the EEOC examined the definition of disability under the ADA, noting that the definition was composed of three prongs: disability means (1) a physical or mental impairment that substantially limits one or more of the major life activities of an individual, (2) a record of such an impairment, or (3) being regarded as having such an impairment.<sup>23</sup> It was under the third prong that the EEOC determined that discrimination based on genetic information relating to illness, disease, or other disorders was prohibited.

Although this EEOC interpretation was widely heralded as a significant step for the protection of rights for individuals whose genes indicate an increased susceptibility to illness, disease, or other disorders, it is limited in its application and may be even more limited after the recent Supreme Court decisions on the definition of disability.<sup>24</sup> However, the EEOC has not withdrawn this guidance, and at Senate hearings EEOC Commissioner Paul Miller stated that the ADA “can be interpreted to prohibit employment discrimination based on genetic information. However, the ADA does not explicitly address the issue and its protections are limited and uncertain.” In addition, Commissioner Miller observed that even if the ADA were found to cover genetic discrimination, the requirements of the ADA may not protect workers from all types of genetic discrimination. He stated, “for example, the ADA does not protect workers from requirements or requests to provide genetic information to their employers.... In addition, once the applicant is hired, the employer may request that the employee take a medical exam, such as a genetic test, if the employer can demonstrate that the information from that test is job related and consistent with business necessity.”<sup>25</sup>

Although the combination of the ADA’s legislative history and the EEOC’s guidance has led some commentators to argue that the ADA would cover genetic discrimination, the merit of these arguments has been uncertain since there have been no reported cases holding that the ADA prohibits genetic discrimination. This uncertainty has increased in light of Supreme Court decisions on the definition of

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<sup>22</sup> (...continued)

order 915.002,902-45 (1995). It is also possible that Title VII of the Civil Rights Act of 1964, 42 U.S.C. § 2000e et seq., may provide some protection against certain kinds of genetic discrimination since an argument could be made that discrimination based on genetic disorders that are more common in certain racial or ethnic groups, such as sickle cell disease, is prohibited under Title VII. There are relatively few genetic conditions that have a strong connection with a racial or ethnic group, thus limiting the scope of potential coverage. However, in *Norman-Bloodsaw v. Lawrence Berkeley Laboratory*, 135 F.3d 1260 (9<sup>th</sup> Cir. 1998), blood tests for sickle cell trait were found to give rise to a Title VII claim.

<sup>23</sup> 42 U.S.C. § 12102(2).

<sup>24</sup> See *Sutton v. United Airlines*, 527 U.S. 471 (1999); *Murphy v. United Parcel Service, Inc.*, 527 U.S. 516 (1999).

<sup>25</sup> Statement of Commissioner Paul Steven Miller, U.S. Equal Employment Opportunity Commission, before the Senate Committee on Health, Education, Labor and Pensions, July 20, 2000.

disability under the ADA.<sup>26</sup> The Supreme Court's decisions do not directly address ADA coverage of genetic discrimination. They emphasize an individualized approach to the determination of whether an individual has a disability under the ADA. Although an argument could be made that the ADA would cover individuals with genetic defects in certain cases, the Court's decisions, particularly *Sutton* and *Murphy*, use reasoning that would make it unlikely that most ADA claims based on genetic discrimination would be successful.<sup>27</sup>

In addition, even assuming the ADA was found to apply, it may not protect employees from having their employers have access to their genetic information. Although the ADA prohibits an employer from making medical inquiries prior to a job offer, the employer may obtain medical information in certain cases after the offer of employment has been made. Assuming that the prohibitions against discrimination in the ADA would apply, it is difficult to prove that genetic information was the reason for discrimination.

**Executive Order.** On February 8, 2000, President Clinton issued an executive order prohibiting discrimination against federal employees based on protected genetic information. The executive order defines "protected genetic information" as "(A) information about an individual's genetic tests; (B) information about the genetic tests of an individual's family members; or (C) information about the occurrence of a disease; or medical condition or disorder in family members of the individual." Current health status information would not be protected under this executive order unless it was derived from the information described above. The EEOC has issued guidance on the executive order.<sup>28</sup>

## State Statutes Relating to Genetic Nondiscrimination

Many states have enacted statutes dealing with various aspects of genetic discrimination. Early state statutes focused on particular genetic conditions. The first statute to prohibit discrimination based on a genetic trait was enacted in North Carolina and prohibited employment discrimination based on the sickle cell trait. In 1991 Wisconsin became the first state to enact a comprehensive law to prohibit

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<sup>26</sup> For a discussion of the Supreme Court's ADA decisions see CRS Report RL31401, *The Americans with Disabilities Act: Supreme Court Decisions*, by Nancy Lee Jones.

<sup>27</sup> In testimony before the Senate Committee on Health, Education, Labor and Pensions, Andrew J. Imparato, the President and CEO of the American Association of People with Disabilities, testified that "the ADA as drafted does provide some protections against genetic discrimination in employment, but the law has been interpreted by the Supreme Court and lower federal courts in a manner which weakens its protections. Whereas the ADA can be and has been used to stop genetic discrimination in some instances, the protections it affords offer little security to people with genetic markers and health conditions that have not yet developed into full-blown debilitating conditions." Testimony of Andrew J. Imparato, "Protecting Against Genetic Discrimination: The Limits of Existing Laws," before the Senate Committee on Health, Education, Labor and Pensions, 107<sup>th</sup> Cong., 2<sup>nd</sup> sess. (Feb. 13, 2002), reprinted at [[http://help.senate.gov/Hearings/2002\\_02\\_13/Imparato.pdf](http://help.senate.gov/Hearings/2002_02_13/Imparato.pdf)].

<sup>28</sup> [<http://www.eeoc.gov/policy/docs/guidance-genetic.html>]

discrimination based on genetic test results. Currently, the states vary in their provisions with some prohibiting discrimination in employment while others deal solely with discrimination in insurance. A recent survey of state law found that 34 states and the District of Columbia have enacted genetic nondiscrimination in employment laws.<sup>29</sup> These laws vary and the National Conference of State Legislatures noted the following:

All laws prohibit discrimination based on the results of genetic tests; many extend the protections to inherited characteristics, and some include test results of family members, family history and information about genetic testing, such as the receipt of genetic services. Most states also restrict employer access to genetic information, with some prohibiting employers from requesting, requiring and obtaining genetic information or genetic test results, or directly or indirectly performing or administering genetic tests. Some states may also make exceptions to statutory requirements if, for example, genetic information may identify individuals who may be a safety risk in the workplace.<sup>30</sup>

A related survey found that 47 states and the District of Columbia have passed laws pertaining to the use of genetic information in health insurance.<sup>31</sup> Many state genetic laws also include specific provisions relating to genetic privacy.<sup>32</sup> In a recent survey, 27 states were found to require consent to disclose genetic information while 17 states require informed consent for a third party to perform or require a genetic test or obtain genetic information. Nineteen states were found that establish specific penalties for violating genetic privacy laws.<sup>33</sup>

Although these state statutes do provide some measure of protection against discrimination, they do not cover employer self-funded plans providing private health insurance for employees and their dependents. These plans are exempt from state insurance laws due to the preemption provision in the federal Employee Retirement Income Security Act (ERISA).<sup>34</sup> Since 55% of covered workers obtain their coverage through self-funded plans, the ERISA exemption limits the application of state laws significantly.<sup>35</sup>

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<sup>29</sup> National Conference of State Legislatures, Genetics Tables, State Genetics Employment Laws, [<http://www.ncsl.org/programs/health/genetics/ndiscrim.htm>].

<sup>30</sup> *Id.*

<sup>31</sup> National Conference of State Legislatures Genetics Tables, State Genetic Nondiscrimination in Health Insurance, [<http://www.ncsl.org/programs/health/genetics/ndishlth.htm>].

<sup>32</sup> National Conference of State Legislatures Genetics Tables, State Genetic Privacy Laws, [<http://www.ncsl.org/programs/health/genetics/prt.htm>].

<sup>33</sup> *Id.*

<sup>34</sup> 29 U.S.C. §§ 1001-1145.

<sup>35</sup> Kaiser Family Foundation, “Employer Health Benefits, Annual Survey 2007,” accessed at [<http://www.kff.org/insurance/7672/upload/76723.pdf>].

## **Genetic Information Nondiscrimination Act of 2007 (GINA)**

### **Background**

On May 21, 2008, GINA was signed into law. The path to enactment of P.L. 110-233 was lengthy and tortuous. H.R. 493, the Genetic Information Nondiscrimination Act of 2007, was introduced by Representative Slaughter with 143 cosponsors on January 16, 2007. After being reported out of the House Education and Labor Committee, the House Energy and Commerce Committee, and the House Ways and Means Committee, the bill passed the House on April 25, 2007, by a vote of 420 to 3. On April 24, 2008, the Senate took up H.R. 493, replaced the existing language with an amendment in the nature of a substitute, added new language strengthening the “firewall” between Title I (discrimination by health insurers) and Title II (discrimination in employment), and passed the measure, as amended, by a vote of 95-0. The House passed H.R. 493 (as amended) on May 1, 2008. On May 2, 2008, both the House and Senate passed H.Con.Res. 340 to make corrections in the enrollment of H.R. 493. These changes would

- revise deadlines for implementation of requirements related to Medicare supplemental policies;
- exempt an employer that conducts DNA analysis for purposes of human remains identification from the prohibition against an employer, labor organization, or joint labor-management committee requesting, requiring, or purchasing an employee’s genetic information; and
- remove the requirement that DNA analysis conducted by an employer for law enforcement purposes as a forensics laboratory be included in the Combined DNA Index System.

The first legislation relating to genetic discrimination was introduced in 1995 by Representative Slaughter (H.R. 2748, 104<sup>th</sup> Cong.) and Representative Stearns (H.R. 2690, 104<sup>th</sup> Cong.). In each subsequent Congress legislation was introduced, and twice legislation passed the Senate. In the 108<sup>th</sup> Congress, the Senate passed the Genetic Information Nondiscrimination Act of 2003 (S. 1053).<sup>36</sup> This bill would have prohibited health insurance plans from denying enrollment or charging higher premiums to individuals based on the individual’s or family members’ genetic information. In addition, the bill banned the collection, use, and disclosure of genetic information for insurance underwriting purposes. In the employment context, this bill would have prohibited the use of genetic information in employment decisions, such as hiring, firing, job assignments, and promotions. The bill also would have prevented the acquisition and disclosure of genetic information as well as applied the procedures and remedies authorized under the Civil Rights Act of 1964 to cases of genetic discrimination. Although President Bush supported genetic discrimination

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<sup>36</sup> 149 Cong. Rec S12394-12508 (daily ed. Oct. 4, 2003).

legislation and the House held a hearing in July 2004,<sup>37</sup> the House did not pass a bill in the 108<sup>th</sup> Congress.

In the 109<sup>th</sup> Congress, S. 306, the Genetic Information Nondiscrimination Act of 2005, was introduced by Senator Snowe on February 7, 2005. The Senate Health, Education, Labor and Pensions Committee reported S. 306 out with an amendment in the nature of a substitute by a voice vote. The bill was passed, with an amendment, on February 17, 2005, by a vote of 98-0. The amendment would have deleted former Section 103 which would have added a prohibition of discrimination based on genetic information or services in church health insurance plans to the Internal Revenue Code because this provision had to originate in the House. A companion bill, H.R. 1227, was introduced in the House on March 10, 2005, by Representative Biggert but did not pass.

## Overview of Statutory Provisions

GINA contains a statement of findings which discusses the significance of the sequencing of the human genome, the history of discrimination based on genetics, and the inadequacy of current federal and state laws. The statute is then divided into three titles: Title I, which prohibits genetic discrimination in health insurance, Title II, which prohibits genetic discrimination in employment, and Title III, which contains miscellaneous provisions on severability and child labor protections.

## Definition of Genetic Information

One of the most discussed provisions of GINA was the definition of genetic information. Both Title I and Title II contain a definition of genetic information which states the following:

GENETIC INFORMATION-(A) IN GENERAL- The term ‘genetic information’ means, with respect to any individual, information about — (i) such individual’s genetic tests,(ii) the genetic tests of family members of such individual, and (iii) the manifestation of a disease or disorder in family members of such individual.(B) INCLUSION OF GENETIC SERVICES AND PARTICIPATION IN GENETIC RESEARCH- Such term includes, with respect to any individual, any request for, or receipt of, genetic services, or participation in clinical research which includes genetic services, by such individual or any family member of such individual. (C) EXCLUSIONS- The term ‘genetic information’ shall not include information about the sex or age of any individual.

## Definition of Genetic Test

The definition of genetic test is of pivotal importance to defining the scope, and ultimately determining the impact, of the law. Importantly, this definition is different in Title I and Title II of the act. The Title I definition exempts genetic tests that are “an analysis of proteins or metabolites that [are] *directly related to a manifested*

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<sup>37</sup> “Genetic Non-Discrimination: Examining the Implications for Workers and Employers” Subcommittee on Employer-Employee Relations, House Committee on Education and Workforce (July 22, 2004).

*disease, disorder, or pathological condition* that could reasonably be detected by a health care professional with appropriate training and expertise in the field of medicine involved.” While Title II does not include this exception, it does contain Section 210, which states,

An employer, employment agency, labor organization, or joint labor-management committee shall not be considered to be in violation of this title based on the use, acquisition, or disclosure of medical information that is not genetic information about a manifested disease, disorder, or pathological condition of an employee or member, including a manifested disease, disorder, or pathological condition that has or may have a genetic basis.

This difference in the definition of genetic test implies that employers who use genetic information about a manifested disease to discriminate may be in violation of this act, while health insurers who use genetic information about a manifested disease to discriminate will not be in violation of this act.

## **Genetic Nondiscrimination and Health Insurance**

**Overview of Health Insurance Provisions.** Title I of GINA strengthens and clarifies existing HIPAA nondiscrimination and portability provisions through amendments to the Employee Retirement Income Security Act of 1974 (ERISA), the Public Health Services Act (PHSA), and the Internal Revenue Code (IRC), as well as to the Social Security Act (SSA). In this way, group plans under ERISA, group and individual plans under the PHSA, Church Plans under the IRC, and Medigap plans under the SSA are all brought under the jurisdiction of the law. The complexity of the health care financing system required this multi-faceted approach in order to ensure protection for all individuals, regardless of their insurance situation.

**Prohibited Health Insurer Practices.** Broadly, GINA prohibits health insurers from engaging in three practices: (1) using genetic information about an individual to adjust a group plan’s premiums, or, in the case of individual plans, to deny coverage, adjust premiums, or impose a preexisting condition exclusion; (2) requiring or requesting genetic testing; and (3) requesting, requiring, or purchasing genetic information for underwriting purposes. Each of these provisions is discussed below in more detail.

***Discrimination in Premium Setting and Eligibility Prohibited.*** GINA prohibits health plans, group and individual health insurers and issuers, and issuers of Medicare supplemental policies from adjusting a group or individual’s premium based on genetic information about an individual in the group, an individual seeking individual coverage, or an individual’s family members. It also prohibits individual insurers from conditioning eligibility or continuing eligibility on genetic information, and prohibits individual insurers from treating genetic information as a preexisting condition. Issuers of supplemental Medicare policies may not deny or condition the issuance of a policy based on genetic information (and may not impose a preexisting condition exclusion based on genetic information).

**Genetic Testing Requirements Prohibited.** GINA prohibits health plans, group and individual health insurers and issuers, and issuers of Medicare supplemental policies from requesting or requiring that individuals or their family members undergo a genetic test. This prohibition does not limit the authority of a health care professional to request that an individual undergo genetic testing as part of his or her course of health care. The act provides for a research exception to this provision, by allowing a group or individual insurance issuer to request, but not require, an individual to undergo genetic testing if specific conditions are met.

**Collection and Use of Genetic Information Restricted.** GINA prohibits health plans, group and individual health insurers and issuers, and issuers of Medicare supplemental policies from requesting, requiring, or purchasing genetic information for the purposes of underwriting prior to an individual's enrollment or in connection with enrollment. "Incidental collection" of genetic information would not be considered a violation.

**Application to Genetic Information of a Fetus or Embryo.** Title I of the act clarifies that genetic discrimination based on the genetic information of either the fetus of a pregnant woman or an embryo legally held by an individual or family member is prohibited.

**Rule of Construction.** GINA provides clearly that nothing in the act should be construed to preclude the use of information about a manifested disease or disorder in an individual (or an individual's family member) by health plans, group and individual health insurers and issuers, and issuers of Medicare supplemental policies to establish premiums or conditions of eligibility. In addition, nothing in the act should be construed to prohibit health plans, group and individual health insurers and issuers, and issuers of Medicare supplemental policies from obtaining or using the results of genetic tests to determine payment. However, only the minimum amount of information required to achieve this purpose may be requested.

**Privacy and Confidentiality.** GINA directs the Secretary of Health and Human Services to revise the HIPAA Privacy Rule<sup>38</sup> to reflect that genetic information shall be treated as health information and the use or disclosure by a covered entity of protected health information (i.e., genetic information) for the purposes of underwriting shall not be a permitted use or disclosure. The Secretary, in consultation with the Secretaries of Labor and the Treasury, has 12 months after enactment of the act to issue final regulations to carry out these revisions.

**Remedies and Enforcement.** GINA permits the Secretary to impose a penalty of \$100 per day per beneficiary or participant to whom the failure relates during a period of noncompliance with the provisions in Title I. Where willful neglect was found, there is established a minimum penalty of \$2,500, or \$15,000 for more severe or prolonged violations. There are three limitations to the penalties that may be imposed by the Secretary. First, the penalty does not apply if the person otherwise liable for the penalty did not know that the noncompliance occurred. Second, the penalty does not apply to failures corrected within 30 days (in cases not

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<sup>38</sup> 45 C.F.R., Part 46.

due to willful neglect). Finally, a limit to the total penalty for unintentional failures is set at \$500,000 or 10% of the aggregate amount paid or incurred by the plan sponsor during the preceding year for group health plans.

## Genetic Nondiscrimination and Employment

**Overview of Employment Provisions.** GINA prohibits discrimination in employment because of genetic information and, with certain exceptions, prohibits an employer from requesting, requiring, or purchasing genetic information. The law prohibits the use of genetic information in employment decisions, including hiring; firing; job assignments; and promotions by employers, unions, employment agencies, and labor-management training programs.

**Definition of Employee and Employer.** GINA defines employees and employers as those defined in Section 701(b) and (f) of Title VII of the Civil Rights Act of 1964,<sup>39</sup> a state employee or employer as defined in Section 304(a) of the Government Employee Rights Act of 1991,<sup>40</sup> and a covered employee or employing office as defined in Section 101 of the Congressional Accountability Act.<sup>41</sup> Generally, this includes employees and applicants working in the private sector for an employer who employs 15 or more employees, federal and state governments, as well as congressional employees. The corresponding employers of these individuals, as well as employment agencies, labor organizations, and training programs, also are covered by the law.

**Prohibited Employment Practices.** As noted previously, GINA prohibits the use of genetic information in employment decisions, including hiring; firing; job assignments; and promotions by employers, unions, employment agencies, and labor-management training programs. In addition, an employer, employment agency, labor union, or training program may not “request, require or purchase genetic information” with respect to the employee, individual, union member, or family member.

There are exceptions to this prohibition on employers, employment agencies, labor unions, and training programs. The first exception applies when one of these entities inadvertently requests or requires family medical history of the employee, individual, union member, or a family member. The House Education and Labor Report noted that this exception “addresses the so-called ‘water cooler’ problem, in which an employer unwittingly receives otherwise protected genetic information in the form of family medical history through casual conversations with a worker.”<sup>42</sup> The second exception is for health or genetic services offered by the entity as part of a wellness program. To qualify for the exemption

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<sup>39</sup> 42 U.S.C. §§ 2000e(f)(employees), 2000e(b)(employers).

<sup>40</sup> 42 U.S.C. § 2000e-16c(a).

<sup>41</sup> 2 U.S.C. § 1301.

<sup>42</sup> H.Rept. 110-28, Part 1 at 37 (March 5, 2007).

- the employee, individual or union member must provide prior, knowing, voluntary, and written authorization;
- only the employee, individual, union member, or family member and the licensed health care profession or board certified genetic counselor involved in providing such services can receive individually identifiable information concerning the results of the services; and
- any individually identifiable genetic information is only available for such services and shall not be disclosed to the employer except in aggregate terms that do not identify individuals.

The third exception is for information necessary for certification procedures under federal and state family and medical leave laws. This exception was described as “eliminat[ing] the potential for conflict with existing laws.”<sup>43</sup> The fourth exception, like the first, concerns the inadvertent acquisition of genetic information by the purchase of documents, such as newspapers, that are commercially and publicly available and that include family medical history. This exception was intended to address the concern that GINA could be violated by such actions as the purchase of a newspaper “containing the obituary of an employee’s parent who died of breast cancer.”<sup>44</sup>

The fifth exception applies when the information involved is to be used for genetic monitoring of the biological effects of toxic substances in the workplace. However, in order for this exception to apply,

- the employer, employment agency, labor union, or training program must provide written notice of the genetic monitoring to the employee;
- the employee, individual, or union member must provide prior, knowing, voluntary, and written authorization; or the genetic monitoring is required by federal or state law;
- the employee, individual, or union member must be informed of individual monitoring results;
- the monitoring must be in compliance with federal genetic monitoring regulations, or state genetic monitoring regulations; and
- the employer, employment agency, labor union, or training program, excluding any licensed health care professional or board certified genetic counselor, must receive the results only in aggregate terms that do not disclose the identity of specific employees.

There is a sixth exception for employers and training programs but not for employment agencies or labor unions. This exception, which was changed by H.Con.Res. 340, would allow employers and training programs that conduct DNA analysis for law enforcement purposes as a forensic laboratory or for purposes of human remains identification to request or require genetic information from their

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<sup>43</sup> *Id.* at 38.

<sup>44</sup> *Id.*

employees, but only when it is used for analysis of DNA identification markers for quality control to detect sample contamination.

GINA also provides that, even if an exception applies, genetic information may not be used in a manner that violates nondiscrimination or confidentiality requirements.

**Confidentiality of Genetic Information.** Generally, GINA requires that genetic information shall be maintained on separate forms and in separate medical files and be treated as a confidential medical record, and prohibits employers, employment agencies, labor unions, and joint labor-management committees from disclosing genetic information. These entities are considered to be in compliance with the maintenance of information requirements if the genetic information is treated as a confidential record under § 102(d)(3)(B) of the Americans with Disabilities Act.<sup>45</sup> However, the general prohibition on disclosure is subject to six exceptions. Genetic information may be disclosed

- to the employee or member of a labor union (or family member receiving genetic services) at the written request of the employee or member;
- to an occupational or other health researcher if the research is conducted in compliance with 45 C.F.R. Part 46, which provides for protection of human research subjects;
- in response to a court order except that only the genetic information expressly authorized by the order shall be disclosed; if the court order was obtained without the knowledge of the employee or member to whom the information refers, the employee or member shall be informed of the court order and the information may be disclosed;
- to government officials who are investigating compliance with Title II of GINA, if the information is relevant;
- where such disclosure is made in connection with the certification provisions of the Family and Medical Leave Act or state family and medical leave laws; or
- to a federal, state, or local public health agency regarding a contagious disease that presents an imminent hazard of death or life-threatening illness, and there is notification.

GINA also contains a provision concerning the relationship of the confidentiality provisions with the HIPAA Privacy Rule. GINA does not prohibit an entity covered under HIPAA “from any use or disclosure of health information that is authorized for the covered entity under such regulations.”

**Remedies and Enforcement.** Generally, GINA uses the remedies and enforcement mechanisms available in Title VII of the Civil Rights Act of 1964,<sup>46</sup> although for employees covered by the Government Employee Rights Act of 1991,

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<sup>45</sup> 42 U.S.C. § 12112(d)(3)(B).

<sup>46</sup> 42 U.S.C. § 2000e-4 et seq.

the Congressional Accountability Act of 1995, chapter 5 of Title 3 of the U.S. Code, or Section 717 of the Civil Rights Act of 1964, the remedies and procedures track those acts and statutory provisions. Under Title VII, complaints of discrimination are filed with the Equal Employment Opportunity Commission (EEOC) and may result in the award of back pay, hiring, promotion, reinstatement, front pay, or other equitable relief that will make an individual “whole.” Remedies also may include payment of attorneys’ fees, expert witness fees, and court costs.

**Disparate Impact.** Section 703(k) of Title VII of the Civil Rights Act of 1964 provides for a cause of action based on the disparate impact of a particular employment practice on employment based on race, color, religion, sex, or national origin.<sup>47</sup> GINA specifically provides that such disparate impact does not create a cause of action under its provisions. However, GINA requires that a commission be established six years after the date of enactment to review the science of genetics and make recommendations to Congress regarding whether to provide a disparate impact cause of action under GINA.

**Construction.** Section 209 of GINA contains several rules of construction, including a provision concerning the relationship between Title I and Title II of the act. GINA provides that nothing in Title II is to be construed to limit the rights or protections of an individual under any federal or state statute that provides equal or greater protection. In addition, nothing in Title II is to limit the rights or protections of an individual to bring an action, or provide for enforcement of, or penalties for, any violation under Title I of GINA, certain sections of ERISA, the Public Health Services Act, and the Internal Revenue Code. This provision has been referred to as a “firewall” between Titles I and II, and has been described as clarifying “that employers are not liable for health insurance violations under civil rights laws unless the employer has separately violated a provision of Title II governing employers.”<sup>48</sup>

GINA also states that it does not

- apply to the Armed Forces repository of specimen samples for the identification of remains;
- limit or expand the protections, rights, or obligations of employees or employers under applicable workers’ compensation laws;
- limit the authority of a federal department or agency to conduct or sponsor health research conducted in compliance with rules for research on human subjects;
- limit the statutory or regulatory authority of the Occupational Safety and Health Administration or the Mine Safety and Health Administration regarding workplace safety and health laws and regulations; or
- require any specific benefit for an employee or member or a family member under any group health plan.

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<sup>47</sup> 42 U.S.C. §2000e-2(k).

<sup>48</sup> 154 Cong. Rec. H2972 (daily ed. May 1, 2008)(statement of Rep. Dingell).

Section 209 also specifies that any reference in Title II to genetic information concerning an individual or family member also includes the genetic information of any fetus carried by a pregnant woman. In addition, genetic information on any embryo legally held by the individual or family member would also be included in the reference to genetic information.

Finally, Section 209 provides that Title II does not prohibit the activity of a group health plan or health insurance issuer offering group health insurance coverage that is authorized by Title I, and certain sections of ERISA, the Public Health Services Act, and the Internal Revenue Code.

**Manifested Diseases.** Section 210 of GINA clarifies that the act does not cover medical information that is not genetic information about a manifested disease, disorder, or pathological condition, including a manifested disease, disorder, or pathological condition that has or may have a genetic basis.

**Regulations.** Regulations are to be issued by the EEOC within a year of enactment.

**Authorization of Appropriations and Effective Date.** Such sums as may be necessary are authorized to be appropriated. The effective date of GINA is eighteen months after the date of enactment.

## Title III — Miscellaneous Provisions

GINA includes a severability provision. If any provision of the act is declared unconstitutional, the remainder of the act is not to be affected.

Section 16(e) of the Fair Labor Standards Act<sup>49</sup> regarding child labor protections is amended.

## Issues for Consideration

The enactment of GINA raises some issues for consideration. Educating the public and health care providers about the scope and application of GINA will be an important part of the implementation phase. This is particularly the case because there are very relevant limitations to the law of which the public and practitioners should be made aware in order to avoid confusion or misunderstanding. First, the scope of the law is limited to the settings of health insurance and employment. It does not cover the following: long term care insurance; life insurance; short-term disability insurance; or long-term disability insurance. Moving forward, this distinction may need to be presented clearly to the public, so they do not expect blanket protection from any genetic discrimination in all settings where genetic information may be disclosed, requested, required or used.

Second, the scope of Title I excludes genetic information about manifested disease. The distinction between manifested (i.e., diagnostic) genetic information,

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<sup>49</sup> 29 U.S.C. §216(e).

as opposed to predictive or predispositional genetic information, may need to be highlighted to the public as well as awareness that GINA does not extend protections to genetic information about existing disease in health insurance.

**Appendix 6**  
**Comparison of OGPL and GINA**

## Oregon Genetic Privacy Law Compared with Genetic Information Nondiscrimination Act of 2008

Oregon Law	Genetic Information Nondiscrimination Act of 2008 (GINA)
DEFINITIONS AND SCOPE	
<p>“Genetic test” means an analysis of human DNA, RNA, chromosomes, proteins, or metabolites that detects genotypes, mutations, or chromosomal changes.</p> <ul style="list-style-type: none"> <li>• Informed consent to genetic testing generally required.</li> <li>• Research use and biological sample banks regulated.</li> </ul> <p>“Genetic information” means information about an individual or the individual’s family members obtained from a genetic test:</p> <ul style="list-style-type: none"> <li>• Family members are blood relatives up to the second degree.</li> <li>• Family history of manifestation of disease excluded.</li> <li>• Unclear whether family members include fetuses.</li> <li>• Family members exclude embryos held for assisted reproduction unless related by blood.</li> <li>• Newborn screening tests excluded.</li> <li>• Paternity tests excluded.</li> <li>• Request for, or receipt of, genetic counseling, or education</li> </ul>	<p>“Genetic test” means an analysis of human DNA, RNA, chromosomes, proteins, or metabolites that detects genotypes, mutations, or chromosomal changes.</p> <ul style="list-style-type: none"> <li>• Applies to genetic testing only for insurance or employment.</li> <li>• Research use and biological sample banks not regulated, unless samples are from health insurance or employment.</li> </ul> <p>“Genetic information” means information about an individual or the individual’s family members obtained from a genetic test:</p> <ul style="list-style-type: none"> <li>• Family members are dependents, and blood relatives up to the fourth degree.</li> <li>• Family history of manifestation of disease included.</li> <li>• Family members include fetuses.</li> <li>• Family members include embryos held for assisted reproduction.</li> <li>• Newborn screening tests included.</li> <li>• Paternity tests included.</li> <li>• Request for, or receipt of, genetic counseling, or</li> </ul>

Oregon Law	Genetic Information Nondiscrimination Act of 2008 (GINA)
<p>services is not genetic information.</p> <ul style="list-style-type: none"> <li>• Request for genetic test is not genetic information.</li> <li>• Includes participation in genetic research.</li> <li>• Tests for a manifested disease or disorder included for all purposes.</li> <li>• Tests for identification of persons for law enforcement are exempt.</li> </ul>	<p>education services is genetic information.</p> <ul style="list-style-type: none"> <li>• Request for genetic test is genetic information.</li> <li>• Includes participation in genetic research that arises from health insurance or employment.</li> <li>• Tests for a manifested disease or disorder excluded for purposes of health insurance and included for purposes of employment.</li> <li>• Tests for identification of persons for law enforcement are exempt from employment provisions.</li> </ul>
FINDINGS	
<p>(a) The DNA molecule contains information about the probable medical future of an individual and the individual's blood relatives. This information is written in a code that is rapidly being broken.</p> <p>(b) Genetic information is uniquely private and personal information that generally should not be collected, retained or disclosed without the individual's authorization.</p> <p>(c) The improper collection, retention or disclosure of genetic information can lead to significant harm to an individual and the individual's blood relatives, including stigmatization and discrimination in areas such as employment, education, health care and insurance.</p> <p>(d) An analysis of an individual's DNA provides information not only about the individual, but also about blood relatives of the individual, with the potential for impacting family privacy,</p>	<p>(1) Deciphering the sequence of the human genome and other advances in genetics open major new opportunities for medical progress. New knowledge about the genetic basis of illness will allow for earlier detection of illnesses, often before symptoms have begun. Genetic testing can allow individuals to take steps to reduce the likelihood that they will contract a particular disorder. New knowledge about genetics may allow for the development of better therapies that are more effective against disease or have fewer side effects than current treatments. These advances give rise to the potential misuse of genetic information to discriminate in health insurance and employment.</p> <p>(2) The early science of genetics became the basis of State laws that provided for the sterilization of persons having presumed genetic 'defects' such as mental retardation, mental disease,</p>

Oregon Law	Genetic Information Nondiscrimination Act of 2008 (GINA)
<p>including reproductive decisions.</p> <p>(e) Current legal protections for medical information, tissue samples and DNA samples are inadequate to protect genetic privacy.</p> <p>(f) Laws for the collection, storage and use of identifiable DNA samples and private genetic information obtained from those samples are needed both to protect individual and family privacy and to permit and encourage legitimate scientific and medical research.</p> <p>(2) The purposes of the genetic privacy statutes are as follows:</p> <p>(a) To define the rights of individuals whose genetic information is collected, retained or disclosed and the rights of the individuals' blood relatives.</p> <p>(b) To define the circumstances under which an individual may be subjected to genetic testing.</p> <p>(c) To define the circumstances under which an individual's genetic information may be collected, retained or disclosed.</p> <p>(d) To protect against discrimination by an insurer or employer based upon an individual's genetic characteristics.</p> <p>(e) To define the circumstances under which a DNA sample or genetic information may be used for research. [Formerly 659.705; 2003 c.333 §2]</p>	<p>epilepsy, blindness, and hearing loss, among other conditions. The first sterilization law was enacted in the State of Indiana in 1907. By 1981, a majority of States adopted sterilization laws to 'correct' apparent genetic traits or tendencies. Many of these State laws have since been repealed, and many have been modified to include essential constitutional requirements of due process and equal protection. However, the current explosion in the science of genetics, and the history of sterilization laws by the States based on early genetic science, compels Congressional action in this area.</p> <p>(3) Although genes are facially neutral markers, many genetic conditions and disorders are associated with particular racial and ethnic groups and gender. Because some genetic traits are most prevalent in particular groups, members of a particular group may be stigmatized or discriminated against as a result of that genetic information. This form of discrimination was evident in the 1970s, which saw the advent of programs to screen and identify carriers of sickle cell anemia, a disease which afflicts African-Americans. Once again, State legislatures began to enact discriminatory laws in the area, and in the early 1970s began mandating genetic screening of all African Americans for sickle cell anemia, leading to discrimination and unnecessary fear. To alleviate some of this stigma, Congress in 1972 passed the National Sickle Cell Anemia Control Act, which withholds Federal funding from States unless sickle cell testing is voluntary.</p> <p>(4) Congress has been informed of examples of genetic discrimination in the workplace. These include the use of pre-employment genetic screening at Lawrence Berkeley</p>

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	<p>Laboratory, which led to a court decision in favor of the employees in that case <i>Norman-Bloodsaw v. Lawrence Berkeley Laboratory</i> (135 F.3d 1260, 1269 (9th Cir. 1998)). Congress clearly has a compelling public interest in relieving the fear of discrimination and in prohibiting its actual practice in employment and health insurance.</p> <p>(5) Federal law addressing genetic discrimination in health insurance and employment is incomplete in both the scope and depth of its protections. Moreover, while many States have enacted some type of genetic non-discrimination law, these laws vary widely with respect to their approach, application, and level of protection. Congress has collected substantial evidence that the American public and the medical community find the existing patchwork of State and Federal laws to be confusing and inadequate to protect them from discrimination. Therefore Federal legislation establishing a national and uniform basic standard is necessary to fully protect the public from discrimination and allay their concerns about the potential for discrimination, thereby allowing individuals to take advantage of genetic testing, technologies, research, and new therapies.</p>
CONFIDENTIALITY	
Prohibits disclosure of genetic information in all settings. HIPAA covered entities may use genetic information for treatment, payment or health care operations, except health insurance underwriting.	Prohibits disclosure of genetic information in relation to health insurance underwriting and employment. HIPAA covered entities may use genetic information for all purposes permitted by HIPAA regulations, except health insurance underwriting.

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EMPLOYMENT	
<p>Prohibits discrimination in employment because of genetic information:</p> <ul style="list-style-type: none"> <li>• Applies to all employers.</li> <li>• Does not apply to employment agencies, labor organizations, or labor-management training programs.</li> <li>• Prohibits seeking, obtaining, or using genetic information.</li> <li>• No exception for inadvertent receipt.</li> <li>• No exceptions for wellness programs or to comply with family and medical leave laws.</li> <li>• Exception to determine a bona fide occupational qualification.</li> <li>• General confidentiality restrictions apply.</li> <li>• Silent on disparate impact.</li> <li>• Same civil remedies as under other state employment laws.</li> </ul>	<p>Prohibits discrimination in employment because of genetic information:</p> <ul style="list-style-type: none"> <li>• Applies to an employer of 15 or more employees.</li> <li>• Applies to employment agencies, labor organizations, and labor-management training programs.</li> <li>• Prohibits requesting, requiring, or purchasing genetic information.</li> <li>• Exception for inadvertent receipt,</li> <li>• Exceptions for wellness programs and to comply with family and medical leave laws.</li> <li>• Exception to monitor biological effects of toxic substances in the workplace.</li> <li>• Specific confidentiality provisions for employment disclosures.</li> <li>• Disparate impact on the basis of genetic information does not establish a cause of action.</li> <li>• Same civil remedies as under other federal civil rights laws.</li> </ul>

Oregon Law	Genetic Information Nondiscrimination Act of 2008 (GINA)
INSURANCE	
<p>Prohibits discrimination in insurance because of genetic information:</p> <ul style="list-style-type: none"> <li>• Genetic information about a family member may not be used to underwrite any policy of insurance (all lines).</li> <li>• Prohibits use to adjust a group's or individual's health insurance premium.</li> <li>• May not be a preexisting condition in individual or group health insurance policies.</li> <li>• Prohibits use to deny coverage or condition eligibility for any policy of individual or small group health insurance.</li> <li>• Applicant for insurance may be required to take a genetic test after specific informed consent.</li> <li>• Allows use or disclosure for treatment, payment or health care operations, except for underwriting.</li> <li>• Applies to insured health plans.</li> <li>• Remedies for violations under ORS chapter 746.</li> </ul>	<p>Prohibits discrimination in health insurance because of genetic information:</p> <ul style="list-style-type: none"> <li>• Genetic information about a family member may not be used to underwrite any policy of health insurance.</li> <li>• Prohibits use to adjust a group's or individual's health insurance premium.</li> <li>• May not be a preexisting condition in individual (or Medicare supplement) health insurance policies.</li> <li>• Prohibits use to deny coverage or condition eligibility for any policy of individual (or Medicare supplement) health insurance.</li> <li>• Applicant for health insurance may not be required to take a genetic test.</li> <li>• Allows use or disclosure for any purpose permitted by HIPAA regulations, except for underwriting.</li> <li>• Applies to insured or self-insured health plans.</li> <li>• Federal enforcement where state fails to enforce.</li> </ul>





