

Report on Genetic Information in the Context of Genetic Exceptionalism

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

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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.

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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 Aerial, 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

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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

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.

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OREGON GENETIC PRIVACY STATUTES
 (following enactment of 2003 legislation effective June 12, 2003)

ORS 192.531: Definitions for genetic privacy statutes. _____ 1
ORS 192.533: Legislative findings; purposes. _____ 3
ORS 192.535: Informed consent for obtaining genetic information. _____ 4
ORS 192.537: Individual's rights in genetic information; retention and destruction of information. _____ 4
ORS 192.539: Disclosure of genetic information; exceptions. _____ 6
ORS 192.541: Private right of action; remedies; affirmative defense; attorney fees. ___ 7
ORS 192.543: Criminal penalty. _____ 8
ORS 192.545: Enforcement; Attorney General or district attorney; intervention. ____ 8
ORS 192.547: Research. _____ 9
ORS 192.549: Advisory Committee on Genetic Privacy and Research. _____ 10
Chapter 588, Oregon Laws 2001, Sec. 8: Reports and Recommendations. _____ 11
ORS 659A.300: Employer prohibited from requiring genetic test. _____ 12
ORS 659A.303: Employer prohibited from obtaining, seeking or using genetic information; remedies. _____ 12
ORS 743.730: Definitions for insurance statutes. _____ 13
ORS 746.135: Insurance. _____ 13

ORS 192.531: Definitions for genetic privacy statutes.

As used in ORS 192.531 to 192.549:

- (1) "Anonymous research" means scientific or medical genetic research conducted in such a manner that 'any DNA sample or genetic information used in the research is unidentified.
- (2) "Blanket informed consent" means that the individual has consented to the use of the individual's DNA sample or health information for any future research, but has not been provided with a description of or consented to the use of the sample in genetic research or any specific genetic research project.
- (3) "Blood relative" means a person who is:
 - (a) Related by blood to an individual; and
 - (b) A parent, sibling, son, daughter, grandparent, grandchild, aunt, uncle, first cousin, niece or nephew of the individual.
- (4) "Clinical" means relating to or obtained through the actual observation, diagnosis or treatment of patients and not through research.

- (5) “Coded” means identifiable only through the use of a system of encryption that links a DNA sample or genetic information to an individual or the individual’s blood relative. A coded DNA sample or genetic information is supplied by a repository to an investigator with a system of encryption.
- (6) “Deidentified” 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. Deidentified DNA samples and genetic information must meet the standards provided in 45 C.F.R. 164.502(d) and 164.514(a) to (c).
- (7) “Disclose” means to release, publish or otherwise make known to a third party a DNA sample or genetic information.
- (8) “DNA” means deoxyribonucleic acid.
- (9) “DNA sample” 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) “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.
- (11) “Genetic information” means information about an individual or the individual’s blood relatives obtained from a genetic test.
- (12) “Genetic privacy statutes” means ORS 192.531 to 192.549, 659A.303 and 746.135 and the provisions of ORS 659A.300 relating to genetic testing.
- (13) “Genetic research” means research using DNA samples, genetic testing or genetic information.
- (14) “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.
- (15) “Identifiable” 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.
- (16) “Identified” 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.
- (17) “Identifier” means data elements that directly link a DNA sample or genetic information to the individual or a blood relative of the individual from whom the sample or information was obtained. Identifiers include, but are not limited to, names, telephone numbers, electronic mail addresses, Social Security numbers, driver license numbers and fingerprints.
- (18) “Obtain genetic information” means performing or getting the results of a genetic test.

(19) “Person” has the meaning given in ORS 433.045.

(20) “Research” means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalized knowledge.

(21) “Retain a DNA sample” means the act of storing the DNA sample.

(22) “Retain genetic information” means making a record of the genetic information.

(23) “Unidentified” means deidentified or not identifiable.

ORS 192.533: Legislative findings; purposes.

(1) The Legislative Assembly finds that:

(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.

(b) Genetic information is uniquely private and personal information that generally should not be collected, retained or disclosed without the individual’s authorization.

(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.

(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, including reproductive decisions.

(e) Current legal protections for medical information, tissue samples and DNA samples are inadequate to protect genetic privacy.

(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.

(2) The purposes of the genetic privacy statutes are as follows:

(a) To define the rights of individuals whose genetic information is collected, retained or disclosed and the rights of the individuals’ blood relatives.

(b) To define the circumstances under which an individual may be subjected to genetic testing.

(c) To define the circumstances under which an individual’s genetic information may be collected, retained or disclosed.

(d) To protect against discrimination by an insurer or employer based upon an individual’s genetic characteristics.

(e) To define the circumstances under which a DNA sample or genetic information may be used for research.

ORS 192.535: Informed consent for obtaining genetic information.

- (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:
- (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;
 - (b) For anonymous research conducted after notification or with consent pursuant to ORS 192.537 (2);
 - (c) As permitted by rules of the Department of Human Services for identification of deceased individuals;
 - (d) As permitted by rules of the Department of Human Services for newborn screening procedures;
 - (e) As authorized by statute for the purpose of establishing paternity; or
 - (f) For the purpose of furnishing genetic information relating to a decedent for medical diagnosis of blood relatives of the decedent.
- (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.
- (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.
- (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.
- (5) The Department of Human Services may not adopt rules under subsection (1)(d) of this section that would require the providing of a DNA sample for the purpose of obtaining complete genetic information used to screen all newborns.

ORS 192.537: Individual's rights in genetic information; retention and destruction of information.

- (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.

(2)(a) A person may use an individual's DNA sample or genetic information for anonymous research only if the individual:

(A) Has granted informed consent for the specific anonymous research project;

(B) Has granted consent for genetic research generally; or

(C) Was notified the sample or genetic information may be used for anonymous research and the individual did not, at the time of notification, request that the sample not be used for anonymous research.¹

(b) The Department of Human Services shall adopt rules to implement paragraph (a) of this subsection after considering similar federal regulations.

(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 representative, unless:

(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 multidisciplinary child abuse team;

(b) Retention is authorized by specific court order pursuant to rules adopted by the Chief Justice of the Supreme Court for civil actions;

(c) Retention is permitted by rules of the Department of Human Services for identification of, or testing to benefit blood relatives of, deceased individuals;

(d) Retention is permitted by rules of the Department of Human Services for newborn screening procedures; or

(e) Retention is for anonymous research conducted after notification or with consent pursuant to subsection (2) of this section.

(4) The DNA sample of an individual from which genetic information has been obtained shall be destroyed promptly upon the specific request of that individual or the individual's representative, unless:

(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 multidisciplinary child abuse team;

¹ 2003 Or Laws chapter 333 § 10 provides:

Notwithstanding ORS 192.537 (2)(a)(C), a person may use an individual's DNA sample or genetic information for anonymous research if the DNA sample or genetic information was obtained prior to June 12, 2003 and the individual was not notified the sample or genetic information may be used for anonymous research.

- (b) Retention is authorized by specific court order pursuant to rules adopted by the Chief Justice of the Supreme Court for civil actions; or
- (c) Retention is for anonymous research conducted after notification or with consent pursuant to subsection (2) of this section.
- (5) 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 informed consent.
- (6) A DNA sample from an individual for insurance or employment purposes shall be destroyed promptly after the purpose for which the sample was obtained has been accomplished unless retention is authorized by specific court order pursuant to rules adopted by the Chief Justice of the Supreme Court for civil, criminal and juvenile proceedings.
- (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's representative].
- (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.
- (9) The Department of Human Services shall coordinate the implementation of this section.
- (10) Subsections (3) to (8) of this section apply only to a DNA sample or genetic information that 'is coded, identified or identifiable.
- (11) This section does not apply to any law, contract or other arrangement that determines a person's rights to compensation relating to substances or information derived from an individual's DNA sample.

ORS 192.539: Disclosure of genetic information; exceptions.

- (1) Regardless of the manner of receipt or the source of genetic information, including information received from an individual or a blood relative of the individual, a person may not disclose or be compelled, by subpoena or any other means, to disclose the identity of an individual upon whom a genetic test has been performed or the identity of a blood relative of the individual, or to disclose genetic information about the individual or a blood relative of the individual in a manner that permits identification of the individual, unless:
 - (a) Disclosure 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 multidisciplinary child abuse team;
 - (b) Disclosure is required by specific court order entered pursuant to rules adopted by the Chief Justice of the Supreme Court for civil actions;

- (c) Disclosure is authorized by statute for the purpose of establishing paternity;
 - (d) Disclosure is specifically authorized by the tested individual or the tested individual's representative by signing a consent form prescribed by rules of the Department of Human Services;
 - (e) Disclosure is for the purpose of furnishing genetic information relating to a decedent for medical diagnosis of blood relatives of the decedent; or
 - (f) Disclosure is for the purpose of identifying bodies.
- (2) The prohibitions of this section apply to any redisclosure by any person after another person has disclosed genetic information or the identity of an individual upon whom a genetic test has been performed, or has disclosed genetic information or the identity of a blood relative of the individual.
- (3) A release or publication is not a disclosure if:
- (a) It involves a good faith belief by the person who caused the release or publication that the person was not in violation of this section;
 - (b) It is not due to willful neglect;
 - (c) It is corrected in the manner described in ORS 192.541 (4);
 - (d) The correction with respect to genetic information is completed before the information is read or heard by a third party; and
 - (e) The correction with respect to DNA samples is completed before the sample is retained or genetically tested by a third party.

ORS 192.541: Private right of action; remedies; affirmative defense; attorney fees.

- (1) An individual or an individual's blood relative, representative or estate may bring a civil action against any person who violates ORS 192.535, 192.537, 192.539 or 192.547.
- (2) For a violation of ORS 192.537 or 192.547, the court shall award the greater of actual damages or:
 - (a) \$100, for an inadvertent violation that does not arise out of the negligence of the defendant;
 - (b) \$500, for a negligent violation;
 - (c) \$10,000, for a knowing or reckless violation;
 - (d) \$15,000, for a knowing violation based on a fraudulent misrepresentation; or
 - (e) \$25,000, for a knowing violation committed with intent to sell, transfer or use for commercial advantage, personal gain or malicious harm.
- (3) For a violation of ORS 192.535 or 192.539, the court shall award the greater of actual damages or:
 - (a) \$1,000, for an inadvertent violation that does not arise out of the negligence of the defendant;

- (b) \$5,000, for a negligent violation;
 - (c) \$100,000, for a knowing or reckless violation;
 - (d) \$150,000, for a knowing violation based on a fraudulent misrepresentation; or
 - (e) \$250,000, for a knowing violation committed with intent to sell, transfer or use for commercial advantage, personal gain or malicious harm.
- (4) It is an affirmative defense to an action described in subsection (2)(a) or (b) or (3)(a) or (b) of this section that the defendant corrected the violation through destruction of illegally retained or obtained samples or information, or took other action to correct the violation, if the correction was completed within 120 days after the defendant knew or should have known that the violation occurred.
- (5) The court may provide such equitable relief as it deems necessary or proper.
- (6)(a) The court may award attorney fees to a defendant only if the court finds that the plaintiff had no objectively reasonable basis for asserting a claim or for appealing an adverse decision of the trial court.
- (b) The court shall award attorney fees to a plaintiff if the court finds that the defendant committed a violation described in subsection (2)(c), (d) or (e) or (3)(c), (d) or (e) of this section.
- (7) An action authorized by subsection (1) of this section must be commenced within three years after the date the plaintiff knew or should have known of the violation, but in no instance more than 10 years after the date of the violation.
- (8) A plaintiff may recover damages provided by subsections (2) and (3) of this section for each violation by a defendant.
- (9) ORS 18.535, 18.537, 18.540 and 18.550 do not apply to amounts awarded in actions under this section.

ORS 192.543: Criminal penalty.

- (1) A person commits the crime of unlawfully obtaining, retaining or disclosing genetic information if the person knowingly, recklessly or with criminal negligence, as those terms are defined in ORS 161.085, obtains, retains or discloses genetic information in violation of ORS 192.531 to 192.549.
- (2) Unlawfully obtaining, retaining or disclosing genetic information is a Class A misdemeanor.

ORS 192.545: Enforcement; Attorney General or district attorney; intervention.

- (1) The Attorney General or a district attorney may bring an action against a person who violates ORS 192.535, 192.537, 192.539 or 192.547. In addition to remedies otherwise provided in ORS 192.541, the court shall award to the Attorney General or district attorney the costs of the investigation.
- (2) The Attorney General may intervene in a civil action brought under ORS 192.541 if the Attorney General certifies that, in the opinion of the Attorney General, the action is of

general public importance. In the action, the Attorney General shall be entitled to the same relief as if the Attorney General instituted the action under this section.

ORS 192.547: Research.

(1)(a) The Department of Human Services shall adopt rules for conducting research using DNA samples, genetic testing and genetic information. Rules establishing minimum research standards shall conform to the Federal Policy for the Protection of Human Subjects, 45 C.F.R. 46, that is current at the time the rules are adopted. The rules may be changed from time to time as may be necessary.

(b) The rules adopted by the Department of Human Services shall address the operation and appointment of institutional review boards. The rules shall conform to the compositional and operational standards for such boards contained in the Federal Policy for the Protection of Human Subjects that is current at the time the rules are adopted. The rules must require that research conducted under paragraph (a) of this subsection be conducted with the approval of the institutional review board.

(c) Persons proposing to conduct anonymous research or genetic research that is otherwise thought to be exempt from review must obtain from an institutional review board prior to conducting such research a determination that the proposed research is exempt from review.

(2) A person proposing to conduct research under subsection (1) of this section, including anonymous research, must disclose to the institutional review board the proposed use of DNA samples, genetic testing or genetic information.

(3) The Department of Human Services shall adopt rules requiring that all institutional review boards operating under subsection (1)(b) of this section register with the department. The Advisory Committee on Genetic Privacy and Research shall use the registry to educate institutional review boards about the purposes and requirements of the genetic privacy statutes and administrative rules relating to genetic research.

(4) The Department of Human Services shall consult with the Advisory Committee on Genetic Privacy and Research before adopting the rules required under subsections (1) and (3) of this section, including rules identifying those parts of the Federal Policy for the Protection of Human Subjects that are applicable to this section.

(5) Genetic research in which the DNA sample or genetic information is coded shall satisfy the following requirements:

(a) The subject has granted informed consent for the specific research project or has consented to genetic research generally.

(b) The research has been approved by an institutional review board after disclosure by the investigator to the board of risks associated with the coding.

(c) The code is:

(A) Not derived from individual identifiers;

(B) Kept securely and separately from the DNA samples and genetic information; and

(C) Not accessible to the investigator unless specifically approved by the institutional review board.

- (d) Data is stored securely in password protected electronic files or by other means with access limited to necessary personnel.
- (e) 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.
- (f) 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.²
- (6) Research conducted in accordance with this section is rebuttably presumed to comply with ORS 192.535 and 192.539.
- (7) In cases in which informed consent is required by either ORS 192.535 or the Federal Policy for the Protection of Human Subjects, samples collected before June 25, 2001, with blanket informed consent for research may be used for genetic research without specific informed consent, but samples obtained after June 25, 2001, must have specific informed consent from the individual for genetic research.
- (8) Except as otherwise allowed by rule of the Department of Human Services, if DNA samples or genetic information obtained for either clinical or research purposes is used in research, a person may not recontact the individual or the individual's physician by using research information that is identifiable or coded. The Department of Human Services shall adopt by rule criteria for recontacting an individual or an individual's physician. In adopting the criteria, the department shall consider the recommendations of national organizations such as those created by executive order by the President of the United States and the recommendations of the Advisory Committee on Genetic Privacy and Research.
- (9) The requirements for consent to, or notification of, obtaining a DNA sample or genetic information for genetic research are governed by the provisions of ORS 192.531 to 192.549 and the administrative rules that were in effect on the effective date of the institutional review board's most recent approval of the study.

ORS 192.549: Advisory Committee on Genetic Privacy and Research.

- (1) The Advisory Committee on Genetic Privacy and Research is established consisting of 15 members. The President of the Senate and the Speaker of the House of Representatives shall each appoint one member and one alternate. The Director of Human Services shall appoint one representative and one alternate from each of the following categories:
 - (a) Academic institutions involved in genetic research;
 - (b) Physicians licensed under ORS chapter 677;
 - (c) Voluntary organizations involved in the development of public policy on issues related to genetic privacy;

² 2003 Or Laws chapter 333 § 9 (2) provides:

The amendments to ORS 192.547 (5) by section 5 of 2003 Or Laws chapter 333 requiring that a subject grant informed consent for a specific research project or consent to genetic research generally for genetic research in which the DNA sample or genetic information is coded applies to DNA samples or genetic information obtained on or after June 12, 2003.

- (d) Hospitals;
 - (e) The Department of Human Services;
 - (f) The Department of Consumer and Business Services;
 - (g) Health care service contractors involved in genetic and health services research;
 - (h) The biosciences industry;
 - (i) The pharmaceutical industry;
 - (j) Health care consumers;
 - (k) Organizations advocating for privacy of medical information;]
 - (L) Public members of institutional review boards]; and
 - (m) Organizations or individuals promoting public education about genetic research and genetic privacy and public involvement in policymaking related to genetic research and genetic privacy.
- (2) Organizations and individuals representing the categories listed in subsection (1) of this section may recommend nominees for membership on the advisory committee to the President, the Speaker and the director.
- (3) Members and alternate members of the advisory committee serve two-year terms and may be reappointed.
- (4) Members and alternate members of the advisory committee serve at the pleasure of the appointing entity.
- (5) The Department of Human Services shall provide staff for the advisory committee.
- (6) The advisory committee shall report biennially to the Legislative Assembly in the manner provided by ORS 192.245. The report shall include the activities and the results of any studies conducted by the advisory committee. The advisory committee may make any recommendations for legislative changes deemed necessary by the advisory committee.
- (7) The advisory committee shall study the use and disclosure of genetic information and shall develop and refine a legal framework that defines the rights of individuals whose DNA samples and genetic information are collected, stored, analyzed and disclosed.
- (8) The advisory committee shall create opportunities for public education on the scientific, legal and ethical development within the fields of genetic privacy and research. The advisory committee shall also elicit public input on these matters. The advisory committee shall make reasonable efforts to obtain public input that is representative of the diversity of opinion on this subject. The advisory committee's recommendations to the Legislative Assembly shall take into consideration public concerns and values related to these matters.

Chapter 588, Oregon Laws 2001, Sec. 8: Reports and Recommendations.

- (1) The Advisory Committee on Genetic Privacy and Research shall report to the Seventy-second Legislative Assembly. The report shall include recommendations relating to:
- (a) Patenting of human genes;

- (b) Standards for recontacting patients who have provided samples for genetic research;
 - (c) Privacy of information about genetic conditions obtained other than through a genetic test;
 - (d) Privacy of persons who seek genetic counseling or genetic testing;
 - (e) Whether to modify or expand current statutory provisions requiring informed consent for genetic research; and
 - (f) Whether to modify the notification or consent requirement of ORS 192.537 (2) for anonymous research.
- (2) The advisory committee shall report and make recommendations to the Seventy-third Legislative Assembly on:
- (a) Patenting of human genes;
 - (b) Genetic testing;
 - (c) Use of genetic information by insurers];
 - (d) Informed consent as applied to DNA samples and genetic information;
 - (e) Whether the genetic privacy statutes can be simplified in light of federal health information privacy law;
 - (f) Procedures for protecting subjects of genetic research;
 - (g) Whether to include family history, clinical diagnosis of a genetic condition or somatic changes in the definition of genetic information; and
 - (h) Discrimination involving an individual seeking genetic counseling, genetic testing or a clinical genetics evaluation.

ORS 659A.300: Employer prohibited from requiring genetic test.

- (1) Except as provided in this section, it is an unlawful employment practice for any employer to subject, directly or indirectly, any employee or prospective employee to any ... genetic test
- (2) As used in this section:
... (b) "Genetic test" has the meaning given in ORS 192.531.
...
- (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.

ORS 659A.303: Employer prohibited from obtaining, seeking or using genetic information; remedies.

- (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.

(3) For purposes of this section, "blood relative," "genetic information" and "obtain genetic information" have the meanings given those terms in ORS 192.531.

ORS 743.730: Definitions for insurance statutes.

As used in ORS 743.730 to 743.773:

...

(27) "Preexisting conditions provision" means a health benefit plan provision applicable to an enrollee or late enrollee that excludes coverage for services, charges or expenses incurred during a specified period immediately following enrollment for a condition for which medical advice, diagnosis, care or treatment was recommended or received during a specified period immediately preceding enrollment. For purposes of ORS 743.730 to 743.773:

...

(b) Genetic information does not constitute a preexisting condition in the absence of a diagnosis of the condition related to such information.

ORS 746.135: Insurance.

(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.

(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.

(5) For purposes of this section, "blood relative," "genetic information" and "genetic test" have the meanings given those terms in ORS 192.531.

Genetic Information Project

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

Summer Lee Street
December 7, 2005

ORS 192.533 (2003)

- Legislative findings; purposes
 - Basis of the Oregon Genetic Privacy Act (1995)
 - Genetic exceptionalism
 - Other background information
 - Updates

Genetic Information

December 7, 2005

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ORS 192.533 – background update

- Human Genome Project (HGP) completed in 2003; analysis of the data continues.
- The Human Genome (Suter, 2001):
 - comprises closer to 30,000, than the expected 100,000 genes
 - has only one inch of the six-foot coil of DNA in each cell that actually contains the genes that encode a person
 - is about twice as large as the roundworm and fruit fly genomes → is more similar to those genomes than expected
- “the complexity of humans must be explained by more than just our genes, challenging the notion of genetics determinism” (Suter, 2001)

Genetic Information

December 7, 2005

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ORS 192.533 – background update

- Genetics Determinism (your genes tell your future)
 - Genetic information can be considered predictive, but should not be considered deterministic of a person's future medical status (Annas, 2001)
 - Genetic information is not deterministic and “realistically provides only a glimpse of what makes humans susceptible to disease and other conditions” (Gostin & Hodge, 1999)
 - The notion of genetic determinism “includes an unwarranted sense of inevitability, because it reflects a fundamental failure to understand the nature of biologic systems” (Clayton, 2003)

Genetic Information

December 7, 2005

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ORS 192.533 – background update

- Federal Regulations
 - Americans with Disability Act (ADA)
 - The ADA may currently provide “the best privacy protections for genetic information in federal law” (Everett, 2004)
 - “In March 1995, the Equal Employment Opportunity Commission (EEOC) issued an interpretation regarding the applicability of the ADA to genetic discrimination. According to the EEOC, covered entities (that is, employers) that discriminate against individuals on the basis of genetic predisposition are ‘regarding’ the individuals as having a disability and therefore the individuals are covered by the third prong of the definition of individual with a disability under the ADA” (Rothstein, 1998)

Genetic Information

December 7, 2005

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ORS 192.533 – background update

- Federal Regulations
 - Common Rule
 - Does not specifically cover genetics, but offers general protection of research subject information
 - Covers “federally funded studies and research conducted in anticipation of US Food and Drug Administration (FDA) approval, leaving most private research unregulated” (Gostin, 2001)

Genetic Information

December 7, 2005

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ORS 192.533 – background update

■ Federal Regulations

- Health Insurance Portability and Accountability Act
 - Does not specifically address genetic information, but treats it as one type as protected health information (Gostin, 2001)
 - Protected Health Information (PHI)
 - “includes information about past, present, or future health, the provisions of health care, and payment for care” (Everett, 2004)
 - Provides a “floor” for privacy protection and does not preempt stronger state laws (Gostin, 2001)

Genetic Information

December 7, 2005

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ORS 192.533 – background update

■ Federal Regulations

- Genetic Information Nondiscrimination Act
 - Passed in the Senate (but not 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)

Genetic Information

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ORS 192.533 – background update

■ State Regulations

- National Conference of State Legislatures
 - Genetics Laws and Legislative Activities
 - <http://www.ncsl.org/programs/health/genetics/charts.htm>
 - Tracking state genetics laws as they pertain to:
 - Employment
 - Genetic Privacy
 - Health Insurance
 - Life, Disability and Long-Term Care Insurance
 - Many other topics

Genetic Information

December 7, 2005

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ORS 192.533 – background update

■ Benefit and Harm

- Promote legitimate scientific and medical research
 - “Population-based knowledge about the contribution of gene variants and gene-environment interactions to disease requires that genetics be integrated into the public health research agenda, so that we can find more effective and targeted public health interventions” (Beskow, 2001)
- Protect individual and family privacy
 - Misuse of genetic data “presents actual and perceived threats to individuals through privacy breaches, discrimination, and stigmatization” (Gostin & Hodge, 1999)

Genetic Information

December 7, 2005

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The Central Policy Issue

- Is genetic information special?
- Does genetic information require higher legal protections?
- Or is it simply another form of health information and should be treated the same?



The answer to these questions largely influence the policy approach (Calvo, 2001)

Genetic Information

December 7, 2005

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Genetic Exceptionalism Defined

- The idea that genetic information is qualitatively different from other types of medical information and therefore requires special legal protection
 - Literature separated genetic information from biological specimens and banking issues
 - Biological specimens have the potential for revealing information at a future date, so many of the issues surrounding genetic information may be applicable
 - Oregon Genetic Privacy Act defines genetic information as “information about an individual or the individual’s blood relatives obtained through a genetic test”

Genetic Information

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Concepts Relevant to Genetic Exceptionalism

- Genetic information is uniquely private and personal
- Genetic information reveals information about an individual, including their probable medical future
- Genetic information reveals information about an individual's blood relatives, including their probable medical future
- Knowledge of genetic information can lead to significant harm

Genetic Information

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Uniquely Private and Personal

- Other Unique Identifiers
 - SSN, fingerprints, hand & face geometry, voice spectrograms, and the human iris (Gostin & Hodge, 1999)

Genetic Information

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A Matter of Perception

- Special 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 cycle, added to their limited understanding of genetics, creates a public perception of "genetics as uniquely powerful, both for good and bad" (Suter, 2001)
 - "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)

Genetic Information

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Information About the Probable Medical Future of an Individual

- Genetic
 - Positive BRCA1/BRCA2 mutation identifies increased risk of breast cancer (Green and Botkin, 2003)
- Nongenetic
 - Positive HIV test identifies increased risk of developing AIDS (Green and Botkin, 2003; Gostin and Hodge, 1999)

Genetic Information

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Information About the Probable Medical Future of an Individual's Blood Relatives

- Genetic
 - A woman's positive BRCA1/BRCA2 mutation identifies increased risk of breast cancer in her relatives (Green and Botkin, 2003)
- Nongenetic
 - Positive tuberculin skin test in an individual identifies an increased risk of developing active tuberculosis for entire family (Green and Botkin, 2003)
- A Difference of Transmission (Green and Botkin, 2003)
 - Genetic transmission is vertical (from parent to child)
 - Nongenetic transmission can occur in a variety of ways

Genetic Information

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Leading to Significant Harm

- Employment and Insurance Decisions
 - Concern that genetic information will be used against individuals
 - Rare and anecdotal evidence (Billings, 2005)
 - Decisions already made with nongenetic information
 - "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)

Genetic Information

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Leading to Significant Harm

- Psychological and Legal Harms
 - “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)
 - “Patients who learn they may have diseases ranging from HIV infection to hypertension also experience distress” (Ross, 2001)

Genetic Information

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Arguments Against Genetic Exceptionalism

- No qualitative difference between genetic and nongenetic information
- Complexity of disease etiology
- Unethical to treat genetic and nongenetic information differently
- Genetic exceptionalism causes harm

Genetic Information

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Complexity of Disease Etiology

- There is a complex relationship between 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 is dependent on many factors (Vineis et al., 2001)

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Unethical to Distinguish 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)

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Unethical to Distinguish Genetic and Nongenetic Information

- “The present inconsistency concerning disclosure of results of genetic and non-genetic based tests seems unethical” (Raithatha and Smith, 2004)
 - Insurers already use nongenetic information to make decisions
 - If the length or quality of an individual’s life will be affected by genetics, shouldn’t the insurer be informed?

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Unethical to Distinguish Genetic and Nongenetic Information

- “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)
 - An individual who develops breast cancer due to a genetic mutation in the BRCA1/BRCA2 genes versus one who develops breast cancer through other means (Gostin and Hodge, 1999)

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Genetic Exceptionalism Causes Harm

- A policy of genetic exceptionalism is actually harmful because “it discounts the ethical and legal need for affirmative protections of other equally sensitive, personally identifiable information” (Gostin and Hodge, 1999)
- Genetic specific laws reinforce the potential stigma of genetic disorders (Rothstein, 2005)

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The Central Policy Issue

- Is genetic information special?
- Does genetic information require higher legal protections?
- Or is it simply another form of health information and should be treated the same?

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Model Legislation

- Annas
 - Model “comprehensive federal genetic privacy law” (1995)
 - Recommendations could be applied to state law
 - http://www.ornl.gov/sci/techresources/Human_Genome/resource/privacy/privacy1.html
- Gostin
 - Model State Public Health Privacy Act (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)
 - <http://www.critpath.org/msphpa/modellaw5.htm>

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Conceptualizing Protections

A Risk Continuum Framework for Predictive Tests of Asymptomatic Persons

Degree in which information learned from the test can be stigmatizing

Low High

Effect of the test results on others

Low High

Availability of effective interventions to alter the natural course predicted

High Low

The complexity involved in interpreting test results

Low High

(Green and Botkin, 2003)

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ACGPR: Advisory Committee on Genetic Privacy and Research. Report to the 2005 Legislature. June 22, 2005. Not yet available on-line.

This report makes four recommendations to the 2005 Legislature. These recommendations are: 1) exempt routine disclosures of genetic information by providers and health insurers from special protections; 2) prohibit use of blood relatives' medical history for health insurance and employment decisions; 3) prohibit use of information concerning whether a person has sought genetic counseling for health insurance and employment decisions; 4) modify informed consent requirements for research under certain limited circumstances. This report also outlines three areas that the ACGPR will focus on in the 2006-2007 biennium: 1) assess whether genetic exceptionalism continues to be an acceptable logical basis for genetic privacy and research policy in Oregon; 2) monitor Oregon's genetic privacy law for unanticipated effects; 3) participate, and support community partners, in efforts to monitor the consumer/public perspective on genetic privacy and research issues.

ACGPR: Advisory Committee on Genetic Privacy and Research. Report to the 2003 Legislature. January 30, 2003. Retrieved from: <http://www.oregon.gov/DHS/ph/genetics/docs/acgprprt.pdf>; retrieved on: June 28, 2005.

This report provides an overview of the history, function and workings of the Advisory Committee on Genetic Privacy and Research (ACGPR). In the report, the committee examines issues of genetic privacy, genetic research, and public education and public input and makes recommendations for the 2003 legislature. Exhibits attached to the report include (but are not limited to): a history of Oregon's genetic privacy law; the administrative rules for genetic information and privacy; an article on the limitations of informed consent by Patricia Backlar; a summary of the HIPAA privacy rules for anonymous and coded research; a summary of Oregon's strategic plan for genetics and public health; the Geneforum public input survey report.

Annas GJ. The limits of state laws to protect genetic information. *New England Journal of Medicine*. Aug 2001;345(5):385-8.

This article examines state laws that have been created to protect genetic information. The Massachusetts genetic-testing law is examined in detail and used as an example of how genetic specific information laws may or may not provide the desired privacy and anti-discrimination effect. The Massachusetts law provides both antidiscrimination legislation and privacy rules. The author deems both of these necessary in protecting the public.

The author reviews definitions of "genetic test" and "genetic information" which could be considered to be either too broad or too narrow in scope. The author deems the Massachusetts law as an intermediate approach that "defines genetic information as not only DNA, RNA, and information derived from chromosomes

but also the results of protein tests performed 'for the purpose of identifying genes or genetic conditions.'

The author emphasizes that although genetic information can be considered predictive, it should not be considered deterministic of a person's future medical status.

The author supports the idea that federal legislation "outlaw the use of predictive genetic information by health insurance companies and employers" and address the issues of discrimination by employers, health insurers and group health plans. In addition, the author states that genetic information privacy laws would also be more effective (and uniform) coming from the federal level.

Annas GJ. Genetic privacy: there ought to be a law. *Texas Review Law & Politics*. Fall 1999;4(1):9-15.

Annas has been a consistent supporter of genetic specific legislation since the debate around genetic exceptionalism began. In this article, Annas argues that genetic information is uniquely private. He states that precedent exists for treating certain types of sensitive medical information, such as mental health, alcoholism, drug treatment, and abortion. Annas goes on to argue that genetic information is "more powerfully private" than other types of sensitive medical information because it covers information, relationships and decisions (three of what Annas claims to be four American views of privacy). Because genetic information is probabilistic in nature and can reveal information about both the individual and their family members, Annas feels that this information should by default be kept private. If and when they desire, individuals would be able to share their genetic information. Annas also worries about the potential of discrimination and stigmatization, citing historical international and national incidences of such abuses.

Annas states that genetic specific legislation must not be limited to the areas of employment discrimination and insurance discrimination, because this "assumes that the information has already been collected, analyzed, and stored somewhere." Annas believes that genetic privacy can only occur when people are protected "before the information has been collected by giving people a choice to participate or not" and calls for a legal clarification that an individual owns their DNA.

Annas suggests guidelines for the collection, storage and use of biological samples. These guidelines include that idea that no sample should be collected without informed consent for the purpose of doing DNA testing. Annas also encourages protections for the storage of genetic information, both as sensitive medical information and as potential for future sensitive medical information. Finally, Annas speaks to the disclosure of genetic information, stating that diagnostic test results "should be governed by essentially the same rules that we use now to disclose any important medical diagnostic testing."

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Annas, with Leonard Glantz and Winnie Roche “have put these concepts into statutory language for the Ethical, Legal, and Social Implications (ELSI) “Genetic Privacy Act. The core provisions of the Act are:

- No collection of DNA for analysis is permissible without an informed voluntary authorization by the individual or his or her legal representative.
- Those conducting DNA analysis are prohibited from doing so unless execution of written authorization by the individual or legal representation has been verified.
- No analysis may exceed the scope of the written authorization.
- DNA is the property of the individual from whom it is obtained.
- DNA samples must be routinely destroyed once the authorized analysis has been completed.
- Anyone who holds private genetic information in the ordinary course of business must keep such information confidential and is prohibited from disclosing it unless the disclosure has been authorized in writing by the individual or legal representative."

Beskow LM, Burke W, Merz JF, Barr PA, Terry S, Penchaszadeh VB, Gostin LO, Gwinn M, Khoury MJ. Informed Consent for Population-Based Research Involving Genetics. *Journal of the American Medical Association*. 2001;286(18):2315-2321.

In response to the lack of guidelines for population-based research involving genetics, the Centers for Disease Control and Prevention formed a multidisciplinary group (the authors) to develop recommendations for an informed consent approach. The article focuses on informed consent concepts, but the following may help with the genetic information project:

"The interaction between genes and one's chemical, physical, infectious, nutritional, social, and behavioral environment plays a role in many, if not all, diseases, including the common chronic diseases of public health interest. Fulfilling the ultimate promise of the Human Genome Project to benefit human health requires population -based data about the prevalence of gene variants, their associations with disease, and their interactions with modifiable risk factors."

The author also acknowledges that "many argue that genetic information is fundamentally similar to other kinds of health information" but reminds readers that concepts of genetics and genetic determinism currently hold great social power, which must not be ignored.

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Billings PR. Genetic nondiscrimination. *Nature Genetics*. 2005;37(6):559-558.

Billings argues that genetic discrimination exists and is actively occurring. Billings acknowledges the critique that cases are often considered anecdotal and having "incomplete methods of data collection." This is the case, he argues, because:

A "study accurately measuring the incidence or prevalence of this phenomenon would possibly require victims of discrimination to endure more adverse events as a result of their participation. It would also require the cooperation of the institutions and businesses that were the agents of this form of discrimination."

For this reason, it is hard to get quantitative evidence of genetic discrimination, but that should not belie its existence. Furthermore, genetic discrimination is not only seen in the employment and insurance fields, it has also been seen in a recent custody case, where a woman's alleged family history of Huntington's disease was given as evidence for her being ineligible for custody of her children.

Many states now have genetic nondiscrimination laws. Billing argues that the idea that the "fear of discrimination might curtail interest in new tests and associated treatments or the proper use of genetic information in medicine" should continue to be recognized and act as an impetus to pass federal nondiscrimination legislation. [Elimination "of genetic discrimination and fears associated with it may facilitate the appropriate development and deployment of genetically based human biotechnologies."

Billings ends by calling for the continued study of genetic discrimination and "more vigilance in order to truly optimize conditions for risk assessment and predictive medicine."

Calvo C. Testimony of Mr. Cheye Calvo, Senior Policy Specialist for the National Conference of State Legislatures before the Subcommittee on Employer-Employee Relations, Committee on Education and the Workforce, U.S. House of Representatives, July 24, 2001. Retrieved from: <http://edworkforce.house.gov/hearings/107th/eer/genetic72401/calvo.htm>; retrieved on: October 25, 2005.

Calvo provides a brief overview of the policy issues of genetic information in the workplace. Of interest is his statement: "The central policy issue is whether genetic information is special and requires higher legal protections or whether it is simply another form of health information and should be treated the same. The answer to this question largely influences the policy approach."

Calvo C. Genetic Privacy Protection. *NCSL: National Conference of State Legislatures Magazine*. September 2000.

Calvo presents a nice summary of the concepts that relate to the treatment of genetic information. She acknowledges that the benefit and use of genetic information must be balanced with privacy and prevention of discrimination.

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Calvo asserts that most claims of discrimination are anecdotal, with no clear evidence "of widespread workplace discrimination based on genetic information since documented cases of employers discriminating against African-Americans with the sickle cell trait in the 1970s." Michigan protects genetic information as they do all other health data. Could this be a model for Oregon?

Calvo C, Jones J. Protecting Genetic Information. NCSL: National Conference of State Legislatures LegisBrief. June/July 2000;8(28):1-2.

Calvo presents a superficial and limited summary of the issues surrounding the protection of genetic information. She highlights the need for balance between emerging genetic technologies, protecting the privacy of individuals and prohibiting discrimination. Currently, state laws differ on the subject; for group health plans (generally 50+ people) HIPAA prohibits health insurance discrimination based on health-related factors (such as genetic information). The Americans With Disabilities Act could be interpreted to include "genetic predisposition," but 1999 Supreme Court ruling suggests they interpret the ADA more narrowly.

Clayton EW. Ethical, legal, and social implications of genomic medicine. New England Journal of Medicine. 2003;349(6):562-9.

This article examines some social concerns surrounding genetic information, focusing on a few specific cases to emphasize major issues. One issue is that of privacy, specifically the "growing recognition that health information is not entirely private, despite people's expectations and desires to the contrary." Another issue is that (regardless of the truth) "people tend to see genetic information as more definitive and predictive than other types of data".

Cummings LA, Magnusson RS. Genetic privacy and academic medicine: the Oregon experience. Academic Medicine. 2001;76(11):1089-93.

This article reviews how the Oregon Genetic Privacy Act of 1995 has impacted Oregon Health & Science University (OHSU). The article provides an overview of the Act, details the impact on OHSU, and outlines OHSU's response to the issue of banking biological specimens. The authors indicate that the Act does not meet the need of all interested parties, stating: "Successful solutions must maintain a balance of meeting the needs of individuals and the needs of organizations and research in the larger context of societal needs." The authors state that there are "several issues surrounding genetic privacy to the fore: the importance of effective informed consent procedures; the question of ownership of genetic information; the necessity to balance the needs of medical research and the protection of the individual's genetic privacy; the maintenance of security of medical records; and the public's confidence in that security."

Everett M. Can You Keep a (Genetic) Secret? The Genetic Privacy Movement. *Journal of Genetic Counseling*. August 2004;13(4):273-291.

In this article Everett investigates the relationship between genetic exceptionalism (which she defines as “the idea that genetic information is different from other types of medical information”) and genetic essentialism (which she defines as “the idea that we are to a large extent shaped by our genes”).

In her introduction, Everett covers genetic privacy in current (as of 2004) state and federal law. In summary:

- 29 states have some form of genetic privacy legislation, most of which are based on the concept of genetic exceptionalism. In general, states define genetic information narrowly “as the presence or absence of a genetic characteristic through a laboratory test of DNA, RNA or mitochondrial DNA.” This definition excludes family history and information regarding genetic counseling requests or services. Colorado, Florida, Georgia, and Louisiana define genetic information as “the personal property of the individual. Oregon repealed its own property provision in 2001.”
- HIPAA treats genetic information “the same as any other “Protected Health Information” (PHI), which includes information about past, present, or future health, the provisions of health care, and payment for care.”
- The Americans with Disability Act may currently provide “the best privacy protections for genetic information in federal law”.

"The act protects those whose mental or physical impairments substantially limit an individual in one or more major life activity, as person with a record of such impairment, and a person who is 'regarded as' having such an impairment. While the ADA does not specifically mention genetic information, the EEOC issued an Interpretive Guidance in March of 1995 stating that discrimination based on genetic information should be considered unlawful under the ADA."

- Although not yet passed in the House, the Genetic Information Nondiscrimination Act of 2003 (S1053):

..."would be the first federal law to specifically address genetic privacy. Like many state laws, the senate bill treats genetic information as uniquely sensitive an as a potential source of employment and insurance discrimination."

Please note that the 2005 version of this bill has not passed in the House

Everett then introduces the arguments in favor of using genetic exceptionalism as a basis for legal statutes. Everett uses the arguments of George Annas “the leading proponent of genetic privacy protections.” Citing concerns of the

uniquely private nature of genetic information, the potential for discrimination and stigmatization, the probabilistic attributes for an individual's health and the health of their family, the potential for indefinite storage and future access to information that cannot yet be predicted, and the psychological impact of how an individual views themselves and is viewed by others.

Everett then critiques the arguments in favor of genetic exceptionalism, using the work of Rothstein, Murray, Green, Botkin and Troy to reveal its flaws. Finally, she surmises that genetic exceptionalism is a social, not scientific, phenomena and quoting Rothstein in saying "Genetic information is unique because it is regarded as unique". Everett then raises the critique that genetic exceptionalism promotes a sense of genetic determinism and enhances the "DNA mystique" to a level that is not scientifically valid. "Privacy advocates do acknowledge that the uniqueness of genetic information has as much to do with social perception as it does science."

Everett concludes with the idea that treating genetic information as "exceptional" may lead to unintended consequences. Instead, she suggests that the purpose of genetic privacy laws should be elucidated and measures should be taken to ensure that the legislation acts as a "meaningful policy interventions".

Ginsburg DH. Genetics and privacy. Texas Review Law & Politics. Fall 1999;4(1):17-23.

In this article, Ginsburg presents a broad overview of the flaws to genetic exceptionalism. Ginsburg uses Thomas H. Murray's definition of genetic exceptionalism, "the claim that genetic information is sufficiently different from other kinds of health-related information that it deserves special [legal] protection." Ginsburg argues that genetic exceptionalism can easily be turned into "genetic essentialism or determinism--the notion that we are nothing but our genes, which determine who we are in every important respect." The author proposes that the issues surrounding the modern genetics debate, including genetic testing, discovery, and insurance and employment discrimination, "are simply the latest iterations of issues that the legal system has faced previously."

Ginsburg argues, "the difference between a state-of-the-art DNA test and a simple medical history form is merely one of degree." In addition, "HIV-testing provides a recent example of non-genetic medical information that raises the same concerns that are at the heart of calls for special legislation to protect the results of genetic testing." In terms of discovery in tort suits, "genetic information differs from other medical information only as a matter of degree" as well. In his final area of focus, Ginsburg examines discrimination in insurance and employment. Ginsburg first questions "whether the government should be involved in spreading the cost of genetically based illnesses across society." Ginsburg then follows with the idea that a third party can as easily use genetic test information as family history to discriminate, and "it is hard to understand why the two should be treated any differently--why it might be permissible to

discriminate upon the basis of a family medical history but not upon the basis of a genetic profile”.

Ginsburg also argues that George Annas' use of the term “future diary” in reference to DNA is inappropriate, and concludes:

“The sober, unexciting realization that genetic information is but the latest iteration of our evolving medical knowledge yields one final suggestion: areas in which changes in degree are endemic are not well suited to statutory solutions. Courts, following in the common law tradition, can address the issues that genetic information raises as the extension of an existing phenomenon. Recognizing that genetic information is not qualitatively different from other types of medical information allows courts to draw upon past experience and to adapt that experience to meet new challenges. Engrafting a unique statutory solution for genetic information onto this common law landscape will simply create two divergent legal regimes for what is essentially a single problem.”

Gostin LO. National health information privacy: regulations under the Health Insurance Portability and Accountability Act. *Journal of the American Medical Association*. June 2001;285(23):3015-3021.

This article is not specific to genetic information, but instead reviews HIPAA in the context of medical information privacy, highlighting the possible successes and shortcomings of the law.

Gostin points out that the computerization of medical and financial transactions “makes it efficient to acquire, manipulate, and disseminate vast amounts of information.” While this information is used for health-related purposes, “The data are also used for many nonhealth-related purposes such as commercial marketing, litigation, and law enforcement.”

HIPAA does not specifically address genetic information and treats it as one type as protected health information (PHI). HIPAA provides a “floor” for privacy protection and does not preempt stronger state laws. HIPAA does not cover human subjects research. The Common Rule covers “federally funded studies and research conducted in anticipation of US Food and Drug Administration (FDA) approval, leaving most private research unregulated.”

Gostin LO, Hodge JG. Genetic Privacy and the Law: An End to Genetics Exceptionalism. *JURIMETRICS: The Journal of Law, Science, and Technology*. Fall 1999;40:21-58.

In this article, the authors present that the concept of genetic exceptionalism is unsound on two grounds: “(1) strict protections of autonomy, privacy, and equal treatment of persons with genetic conditions threaten the accomplishment of public goods: and (2) there is no clear demarcation separating genetic data from other health data; other health data deserve protections in a national health information infrastructure.”

The authors present genetic information as an integral part of health data. They present the idea that genetic specific legislation emphasizes the differences between genetic information and other medical information, when these differences do not actually exist or are not meaningful. Genetic specific legislation causes harm by 1) devaluing the public good that can occur through the use of genetic information and 2) furthering misconceptions of what genetic information is.

The authors affirm, "there is no clear demarcation that separates genetic data from other health data." And go further to state: "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. They continue: "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."

"Our analysis of the differences and similarities of genetic information concludes with our finding that genetics information is not so different as to legally and ethically justify its distinction among health data."

"The collection of genetic data may benefit individuals and society by enhancing patient choices about their lifestyle, diet, treatment, and reproduction, introducing numerous clinical advancements, furthering medical research to improve the detection, prevention, and treatment of disease, and protecting public health."

The authors define genetic exceptionalism as "the societal practice of treating genetic data as different from other types of health data for the purposes of assessing privacy and security protections." They evaluate the hypothesis underlying this practice (that genetic information is unique when compared to other health information) and ultimately find it invalid. Highlights of their evaluation follow:

- Genetic information is not deterministic and "realistically provides only a glimpse of what makes humans susceptible to disease and other conditions." Perceptions "of genetic permanency are misguided. Genetic flaws, environmental diseases, can increasingly be altered or corrected through clinical interventions."
- Genetic and nongenetic information exist on a continuum of medical information "and that most diseases have genetic as well as behavioral and environmental components." Because of this, "it is not feasible to separate genetic from non-genetic information in a medical record." In addition, "...many diseases already are known to have a genetic component, and more, if not most diseases, are likely to have genetic links. Many routine observations entered in a medical record are genetic such as sex, eye color, blood type, and nationality." Furthermore, "many

traditionally diagnosed medical indicators, which are not genetic per se, may predict with some degree of certainty whether an individual will develop a certain malady. High blood pressure, elevated cholesterol, obesity, ingestion of caffeine, use of illegal drugs or tobacco, or HIV infection are well-known examples.”

- “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.”
- “The potential impact of genetic information on the relatives of an individual may justify privacy protections for such information, but this impact is certainly not unique to genetic information. Family medical histories have long been an important component of clinical practice. Physicians routinely query patients as to their family history for a multitude of medical conditions, including mental disorders, alcoholism, heart disease, and cancer, because prior familial disorders are a predictor of current maladies in an individual.”

Further in the article, the authors state that “National, genetic-specific privacy legislation would be afflicted with problems of statutory construction (due to the difficulty of clearly defining genetic information), practicality (due to the difficulty of distinguishing genetic from non-genetic information, and ethics (because of the unfairness of protecting the privacy of some patients but not others).” The authors apply a previously created “model public health information privacy statute” model to health information, including genetic information. With this application, the authors believe they can create a balance between the public and private good of genetic information. In their conclusion, the authors “propose abandoning a legislative strategy that exceptionalizes genetic information. Genetic information is not truly unique compared to other health information. It is thus not deserving of special protections to the exclusion of other health data that are equally sensitive. Rather, we support comprehensive health information privacy legislation that includes genetic information. Though such legislation will not provide complete privacy, the public should be assured that genetic information will be treated in an orderly and respectful manner and that individual claims of control over those data will be adjudicated fairly.”

Gostin LO. Genetic Privacy. *Journal of Law, Medicine & Ethics*. 1995;23(4):320-330.

In this article, Gostin examines issues surrounding genetic privacy. Gostin focuses on four main areas: 1) the collection and use of genetic data, 2) privacy implications, 3) current (1995) law, and 4) the balance between societal needs and those of individuals and families.

At the time Gostin wrote this article, he supported the idea of genetic exceptionalism and believed that "Genomic data can personally identify an individual and his/her parents, siblings, and children, and provide a current and future health profile with far more scientific accuracy than other health data."

Gostin also states: "The features of a person revealed by genetic information are fixed--unchanging and unchangeable."

Gostin LO. Genetic Discrimination: The Use of Genetically Based Diagnostic and Prognostic Tests by Employers and Insurers. *American Journal of Law & Medicine*. 1991. XVII(1&2):109-144.

Please note that this article was published in 1991 and may not correctly represent current law. This article approaches the concept of genetic discrimination from an ethical and legal perspective (emphasis on legal). The Human Genome Project provides a unique opportunity to learn more about the genetic basis of disease, yet "As our ability to detect genetic defects or propensities toward illness increases, so too does the threat that such detection will be used to discriminate."

The article focuses on the employment and insurance sectors within the US. Gostin covers a number of ideas that should be addressed in the pursuit of quality public policy. First, the reliability and predictive value of genetic tests is highly variable. Second, perception is as important to the issue of discrimination as is reality (i.e. a carrier of a disease may be perceived to have the disease, or a pre-symptomatic individual may be perceived to be ill). Third, (as of 1991) only anecdotal reports of genetic discrimination have been reported (i.e. no systematic study). Fourth, cost savings is thought to be the primary goal of any genetic discrimination occurrence. Public policy may need to address the social and other non-financial costs/benefits for protecting against genetic discrimination.

This article also calls for a reassessment of the role that insurance should play in our society. Should health and life insurers be viewed solely as a business or should they be expected to fulfill a societal benefit? If the sick--who have the greatest need for insurance--are excluded, how will society bare the burden of their care?

Gostin concludes that current (1991) municipal, state and federal laws may not sufficiently protect employees and insured individuals from genetic discrimination. Calling for genetic-specific legislation, Gostin recommends that future policy clarify the protection of disability to include "future" disabilities that may be known or expected due to genetic information.

Green MJ, Botkin JR. "Genetic Exceptionalism" in medicine: Clarifying the differences between genetic and nongenetic tests. *Annals of Internal Medicine*. 2003;138(7): 571-575.

Calling for an end to genetic exceptionalism: Green argues that the four main arguments in favor of treating genetic information with special precautions are equally true for genetic and non-genetic information. The arguments are: 1) genetic information can predict a person's medical future, 2) genetic test results divulge information about family members, 3) genetic information can be used to discriminate against and stigmatize individuals, and 4) genetic testing can cause

serious psychological harm. For each one, Green provides examples where there is little difference in the outcome of having each type of information.

A framework to use before seeking information: Green then proposes that both genetic and non-genetic information should be applied to a framework that addresses four areas: 1) the degree to which information learned from the test can be stigmatizing, 2) the effect of the test results on others, 3) the availability of effective interventions to alter the natural course predicted by the information, and 4) the complexity involved in interpreting test results. Each medical procedure that will provide health (genetic and non-genetic) information could be put to this "test" to see what level of precaution should be taken with the information.

Thoughts: Issues of 1) discrimination/stigmatization, 2) the health impact of one individual on other individuals, 3) the ability for an individual to change their health outcome, and 4) the ease in understanding medical information should all be taken into account during health information policy making.

Hall MA, Rich SS. Patients' fear of genetic discrimination by health insurers: the impact of legal protections. *Genetics in Medicine*. 2000;2(4):214-221.

The purpose of this study was to "evaluate the perceptions [of genetic discrimination] and the resulting behavior by patients and clinicians." Hall and Rich conducted "a comparative case study analysis of seven states (Colorado, Florida, Iowa, Minnesota, New Mexico, North Carolina, and Ohio). States were grouped "according to whether they had mature laws (CO, NM, OH, all enacted in 1995 or earlier), recent laws (NM, FL, NC), or no law (Iowa)." The authors found that "Patients' and clinicians' fear of genetic discrimination greatly exceeds reality". They concluded, "Existing laws have not greatly reduced the fear of [genetic] discrimination."

Hall and Rich noted a significant difference in discrimination concerns between prenatal/pediatric settings and adult settings:

- "For pediatric and prenatal patients, almost all counselors said that insurance discrimination concerns play no role in decisions about testing, for the obvious reason that, for people who are carrying a baby or have a child with a problem, the urgency of their immediate situations is so great and they are so anxious that they will undergo just about any test they can to find out more specifically what is going on with their child."
- "For adult patients, a number of counselors (8 of 21) said that discrimination concerns are a major barrier to testing, and that large numbers of their clients decline testing, primarily for this reason. All counselors said that when discrimination is a concern, health insurance, rather than life or disability, is the primary concern, and the majority (13 of 22) said that only health insurance is a concern. Four counselors

mentioned lesser concerns over life insurance, one mentioned disability insurance, and four mentioned employment discrimination."

- "Several counselors observed that discrimination concerns vary by insurance and socioeconomic status."

Hall and Rich provide two hypotheses for the fact that "health insurance is the focus of discrimination concerns, even though the documented record of an potential for discrimination is stronger for life and disability insurance. One explanation is that health insurance is more important to people, but another is that health insurance is what patients and geneticists depend on to pay for testing."

Juengst ET. FACE facts: why human genetics will always provoke bioethics. *Journal of Law, Medicine & Ethics*. 2004;32(2):267-275.

In this article, Juengst evaluates discrimination issues in terms of genetic information and how it compares to an individual's familial role, ancestral origins, community membership and ethnic affiliation (FACE).

Juengst argues that "there are other forms of biomedical information [than genetics] that can threaten people's understanding of their personal identity, and 'cause people to lose their internal moorings' in even more direct ways." Furthermore, "genomics itself is undermining the fear that genetic information will betray essential secrets about individual's personal potential" and "as genetic information becomes more like other forms of health risk data, even the patient groups most at risk of genetic discrimination are increasingly less interested in trying to hide their genotypes as shameful secrets."

Juengst concludes, "that the basic social challenges of genetic information are not the clues it can give us about future health risks. As long as people use familial role, ancestry, community membership or ethnic identity as indicators of social standing, genetic information will continue to be socially potent." It "is the risk that genetic information will [be] used to hammer scientific wedges into the social cracks that we have always used to make "others" out of each other."

Kaebnick GE. Making Policy. *Hastings Center Report*. 2005;35(4):2.

Kaebnick briefly summarized Rothstein's "Genetic Exceptionalism & Legislative Pragmatism" article. He then mentions other thinkers on the balance of policy and politics. Kaebnick ends with the idea that there is room for setting policy in the systematically logical / conceptual analysis way that Rothstein suggests (passing imperfect legislation when unable to pass perfect legislation). Yet Kaebnick also suggests there is still a need to approach policy setting with empirical reasoning that would allow for experience and observation to help resolve the issue.

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Lanie AD, Jayaratne TE, Sheldon JP, Kardia SLR, Anderson ES, Feldbaum M, Petty EM. Exploring the public understanding of basic genetic concepts. *Journal of Genetic Counseling*. 2004 Aug;13(4):305-20.

The data analyzed in this study "are from Phase I of a multiphasic 3-year NIH-ELSI study to examine how Americans use and interpret genetics as related to their underlying beliefs about individual and group differences for human traits." Phase I involved a qualitative phone interview with 44 individuals. The study identified among the participants confusion about where genes are located in the body and the meaning of "genetic". This "confusion among individuals may impact their understanding of more complex genetic concepts and phrases commonly used including gene therapy, genetic discrimination, and genetic testing, among many others."

The authors emphasized the importance of communicating to the general public the concept of genetics as being "an important contributor, not as fate". In conclusion the authors stated that: "this study provides further evidence to support previous research demonstrating that misconceptions about genetic science are not infrequent in the general public, and suggests the need for improved genetic literacy and understanding."

Lazzarini Z. What lessons can we learn from the exceptionalism debate (finally)? *Journal of Law, Medicine & Ethics*. 2001;29(2):149-151.

Lazzarini builds from Lainie Friedman Ross's article "Genetic Exceptionalism vs. Paradigm Shift: Lessons from HIV." Lazzarini briefly reviews Ross's arguments against exceptionalism, and agrees with her assessment that there is ultimately little difference between genetic and nongenetic information. Lazzarini then suggests that it is time we move beyond the debate of "the precise nature and scope of the similarities and differences between genetic information and all other health-related information." Instead, Lazzarini proposes that we now address "How should we treat the coming onslaught of genetic information, and what arguments--scientific, ethical, or legal--should we use to justify our chosen model?" Pertinent debate would then cover whether or not a particular public policy serves the needs of the community and reaches the appropriate balance between protection of and access to health related information.

Manson NC. How Not to Think about Genetic Information. *Hastings Center Report*. 2005;35(4):3.

This article is a brief commentary of Rothstein's "Genetic Exceptionalism & Legislative Pragmatism" article. Manson agrees with Rothstein that current legislative decision making which upholds the idea of genetic exceptionalism is shortsighted and problematic, where "no good arguments exist in favor of them". Manson argues that the language that we use to discuss genetic information, giving it a "causal" role, makes the concept of genetic exceptionalism more rational than it actually warrants.

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Melo-Martin I. Firing up the nature/nurture controversy: bioethics and genetic determinism. *Journal of Medical Ethics*. 2005;31:526-530.

Melo-Martin calls for bioethicists to be more careful in their discussion of genetic issues, so as not to inadvertently promote the ideals of genetic determinism.

Melzer D, Zimmern R. Genetics and medicalisation. *BMJ*. April 2002;324(7342):863-4.

Melzer and Zimmern call for an evaluation of the use of genetic testing in the clinical setting. They argue, "With the exception of the relatively rare high penetrance, single gene disorders, genetic tests differ little from most other medical tests, providing evidence of statistical risk only." The authors are concerned that an over estimate of their value will lead to an over use of genetic tests in the clinical setting. In support of their concerns, the authors remind readers, "The genes that play a part in the pathogenesis of most common disorders are for the most part as yet unidentified and their role ill understood." Furthermore, "Genetic tests for markers that may not result in symptoms for half a century or more could be new examples of a process of premature medicalisation--of attaching the 'disease' label before it has been established that prevention or treatment is clearly beneficial." In conclusion, the authors state, "The antidote to genetics as a driver of medicalisation lies in remaining skeptical and level headed" and advise, "Genetic technologies have the potential to be of major benefit to society, but their introduction must be measured, attentive to the social and ethical considerations of the day, and, most importantly, based on best evidence."

Miller T. Congressional Testimony: Genetic Information Collection and Privacy Concerns. September 2002.

Executive Summary (in entirety): "There is little, if any, evidence that health insurers are using or likely to use presymptomatic genetic information in their medical underwriting. Evidence that employers try to obtain, let alone use, such information generally is limited to isolated anecdotes. In any event, erecting legal barriers against discrimination based on genetic information would strain the limits of genetic exceptionalism, defy precise definition, pose serious threats to the functioning of private insurance and labor markets, and overlook more effective alternative remedies."

Miller discounts the demarcation of genetic information from other types of medical information, citing the article by Gostin and Hodge (1999).

Miller then summarizes the Health Insurance Portability and Accountability Act of 1996 (HIPAA) as it relates to genetic information. Including:

- [HIPAA] prohibits discrimination against individual workers who are members of an employer group plan - either on the basis of their current health status or on the basis of their predisposition to a particular disease based on genetic information.

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- Genetic information also is treated as protected personal health information under HIPAA's health privacy regulations.
- HIPAA does not govern the use of genetic information in the individual health insurance market.

NBAC: National Bioethics Advisory Commission. Research Involving Human Biological Materials: ethical issues and policy guidance. Volume 1. Rockville, MD. August 1999.

"Genetic information is one form of biological or medical information. Like certain other types of medical information, genetic analyses can reveal sensitive information about an individual" (pg 3).

Many "of the concerns that pertain to the misuse of personal genetic information apply equally to certain types of personal medical information" (pg 4).

Discrimination is largely concerned with health insurance and employment. Restricting third party access to genetic information would not be as much of an issue if we did not have private insurance and individual medical underwriting. (pg 44-45)

ORS 192.533. Legislative findings; purposes. Retrieved from: <http://www.oregon.gov/DHS/ph/genetics/docs/03law.pdf>; retrieved on: November 2, 2005.

The Oregon Genetic Privacy Act is largely based on the following findings:

ORS 192.533: Legislative findings; purposes.

(1) The Legislative Assembly finds that:

(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.

(b) Genetic information is uniquely private and personal information that generally should not be collected, retained or disclosed without the individual's authorization.

(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.

(d) An analysis of an individual's DNA provides information not only about the individuals, but also about blood relatives of the individual, with the potential for impacting family privacy, including reproductive decisions.

(e) Current legal protections for medical information, tissue samples and DNA samples are inadequate to protect genetic privacy.

(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.

Raithatha N, Smith RD. Disclosure of genetic tests for health insurance: is it ethical not to? *The Lancet*. January 2004;363: 395-396.

In this article, Raithatha and Smith take a logical, business perspective to argue that it is unethical to deny insurers access to known genetic information that is relevant to an individual's health or life insurance policy. Three ideas support this belief: 1) Insurers regularly use genetic information (such as gender and family history) to establish coverage or premium level; 2) Individuals may have control over their health outcome regardless of genetic predispositions; 3) The results of many conventional tests (such as cholesterol screening) are influenced by genetics. Their argument assumes that there is no social value in spreading risk broadly across all insurance groups.

The authors make a few recommendations for the handling of information gained through genetic tests in the UK. They propose that concerns over the predictive power of genetic tests be addressed through limitations on the use of genetic information when gained through a method with undesirable predictive power. They also suggest that rules against compulsory genetic tests be established.

Roche PA, Annas GJ. Protecting genetic privacy. *Nature Genetic Reviews*. May 2001;2(5):392-396.

In this article Roche and Annas "explain why genetic information is different to other sensitive medical information. The authors disagree with the sentiment that "specific laws that are designed to protect genetic information...would perpetuate the misconception that genetic information is uniquely private and sensitive."

The authors "emphasize the distinguishing features of DNA-sequence information." This includes the idea that "The DNA molecule itself is a source of medical information and, like a personal medical record, it can be stored and accessed without the need to return to the person from whom the DNA was collected for permission." Furthermore, the authors have a number of concerns, including: (1) "DNA also contains information about an individual's future health risks, and in this sense is analogous to a coded 'future diary';(2) "An individual's DNA can also reveal information about risks and traits that are shared with genetic relatives"; and (3) "DNA has also been culturally endowed with a power and significance exceeding that of other medical information." Each of these concerns illustrates the need for consideration in endowing genetic information with special treatment.

The authors are very concerned with the use of biological specimens, and argue:

"Even if one believes that the DNA-sequence information extracted from an individual's DNA is no more sensitive than other medical information,

this says nothing about the need to protect the DNA molecule itself. In this regard, we think it is useful to view the DNA molecule as a medical record in its own right. Having a DNA sample from an individual is like having medical information about the individual stored on a computer disk, except that in this case the information is stored as blood or as other tissue samples. Like the computer disk, the DNA sequence can be 'read' by the application of technology. So, regardless of the rules developed to control the use of genetic information when it is recorded in traditional paper and electronic medical records, separate rules are also needed to regulate the collection, analysis, storage and release of DNA samples themselves."

Ross LF. Genetic exceptionalism vs. paradigm shift: lessons from HIV. *Journal of Law, Medicine & Ethics*. 2001;29(2):141-8.

Ross explores the similarities and differences between HIV and genetics, to see if genetics should remain "exceptional" while HIV moves into mainstream practice. Ultimately Ross argues that genetic information is not qualitatively different than HIV information and should therefore not remain in an "exceptional" context. Furthermore, Ross argues that the increasing opportunity for genetic information should be used "as a catalyst for a paradigm shift in clinical medicine from disease intervention and treatment to preventive medicine and risk reduction."

Ross describes the history of HIV exceptionalism and then begins comparing genetics and HIV. Ross presents four instances where genetics might be considered to reveal fundamentally unique information: 1) can be used for eugenic purposes; 2) reveals something about one's whole family or community; 3) is immutable; or 4) is probabilistic. Ross indicates the fallacy of each argument and shows how genetic information does not fundamentally differ from HIV.

Ross then goes on to argue that neither does genetic information fundamentally differ from other non-genetic information. Her defense of this reasoning was largely based on the findings of "The Task Force on Genetic Information and Insurance, a joint working group of the National Institutes of Health and the U.S. Department of Energy on the ethical, legal, and social implications of the human genome project" and the Gostin & Hodge article "Genetic Privacy and the Law: An End to Genetics Exceptionalism".

Ross highlights the need for genetics training and education among healthcare professionals, advocating that that current lack of knowledge not justify genetic exceptionalism. Ross calls for a "paradigm shift" where genetic exceptionalism policies, laws, and regulations are eliminated and replaced with those that can transform "our conceptions of health and disease." Ross argues that emerging genetic information provides us the opportunity to create a healthcare system focused on prevention of disease. Ross concludes that though genetic information brings about important policy issues including those of privacy and

confidentiality, these issues are not unique to genetics. Policy, therefore, should be designed to address the broader field of medical information.

Rothstein MA. Genetic Exceptionalism and Legislative Pragmatism. *Hastings Center Report*. 2005;35(4):27-33.

Rothstein argues, "that genetic exceptionalism represents poor public policy." Rothstein devotes much of the article in describing the three conditions that he feels must be met in order for genetic-specific laws to be successful: "(1) the term 'genetic' must be defined clearly, logically, and with scientific precision; (2) there must be an efficient, low-cost way to separate genetic information from nongenetic information in health records; and (3) it must not only be possible to treat genetic information differently from other health information, but there must be a compelling reason to do so." As part of the third condition (treating genetic information differently), Rothstein presents reasons why seven of the main arguments in favor of genetic exceptionalism should not be supported.

Rothstein then presents the idea of using "generic" privacy and protection laws instead of genetic-specific laws to prevent or redress "harms caused by the uses and disclosures of genetic information." Rothstein argues that genetic-specific laws establish an environment of genetic discrimination, because they separate genetic disorders from nongenetic disorders. Furthermore, genetic-specific laws do not address the underlying social issues (access to health care, health and life insurance, rights of employee/employer in healthcare decision making, etc) that cause the need for genetic privacy and protection laws.

In the final part of this article, Rothstein evaluates current policy and discusses circumstances where genetic-specific laws may be acceptable or why they might be chosen. Rothstein suggests that the passing of genetic-specific laws can be viewed as a 'half-loaf' situation, where limited or flawed protection is better than a complete absence of protection. He presents four conditions that would make genetic-specific laws acceptable: 1) the law meets a need within the community it protects; 2) unintended consequences are avoided; 3) the law does not hinder the enactment of better laws; and 4) the law is accepted by both legislature and the general public as "not ideal but merely the best that can be achieved at the moment." Even in situations meeting all four of the above conditions, Rothstein views genetic exceptionalism as a dangerous lure away from good public policy.

Rothstein MA. Why Treating Genetic Information Separately is a Bad Idea. *Texas Review of Law & Politics*. Fall 1999;4(1):33-7.

In this article, Rothstein briefly outlines two practical arguments against the concept of genetic exceptionalism.

- "First, it is impossible to develop a working definition for what genetic information is." Either the definition is too narrow and excludes information such as family history, or too broad and including information on any condition with a genetic component.

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- Second, "it would be economically infeasible, if not totally impossible, to separate genetic information from other information in medical records."

Rothstein views the genetic-specific legislation that has been passed by a number of states as "illogical" and "ineffective" for a number of reasons, including:

- Such legislation protects individuals with the same disease (or risk of disease) differently depending on whether or not the disease has a genetic basis.
- The legislation covers "unauthorized disclosure of genetic information", but not "the *authorized* disclosure of genetic information." Rothstein is very concerned with the idea that "after an employer makes a conditional offer of employment, it is lawful for the employer to require as a condition of employment that the individual sign a blanket release authorizing the disclosure to the employer of all the individual's personal medical records" including their genetic information. "So the employer is now able to obtain genetic information that, theoretically, it is not supposed to use."

Rothstein then suggests that our attention should move towards the treatment of genetic information in long-term care insurance. He asks the reader to consider whether long-term care insurance is more analogous to health insurance "to which more people say that there is some sort of societal right" or to life insurance, which people are more willing to view as a commercial transaction. Rothstein concludes, "What we lose sight of in the debate about whether genetic information is special relative to other medical information is what the implications are for every one of these areas: mortgages, employment, insurance, commercial transactions, and so forth."

Rothstein MA. Genetic Privacy and Confidentiality: Why They Are So Hard to Protect. *Journal of Law, Medicine & Ethics*. 1998;26:198-204.

In this article, Rothstein examines genetic privacy and confidentiality issues in health insurance, life insurance, long-term care insurance and employment settings. Rothstein emphasizes his belief "that measures to protect against the unauthorized disclosure of genetic information are necessary but not sufficient to protect genetic privacy and confidentiality. Furthermore, this approach is fundamentally flawed if it is to be used as the primary method to protect against the involuntary disclosure of genetic information." Rothstein states, "less emphasis should be placed on regulating the procedures for disclosure of information by physicians and other holders of medical records and more detailed focus placed on the circumstances surrounding the acquisition of the information by third parties."

Health insurance setting: Rothstein leads the reader through a 'thought experiment' that ends in the conclusion (whether or not it is true) that our current health insurance system is "unfair and illogical". Rothstein then poses the question: "is it possible to prevent genetic-based discrimination in health

insurance within a system that is unfair and illogical?" Rothstein the questions "whether it is efficacious, tactically sound, or ethical for genetic advocacy groups to promote legislation prohibiting genetic discrimination in health insurance (or other areas) when the laws have so little value to those at risk of genetic disorders and no value to those who have illnesses from other causes."

Life insurance setting: Rothstein reminds readers: "the number of individuals with late-onset, single-gene disorders is quite small. The real challenge of genetics and life insurance involves more common multifactorial disorders, such as breast cancer, ovarian cancer, and colon cancer." Rothstein then questions the role of life insurance in society. "Is life insurance a purely commercial relationship, an estate-building investment vehicle, and an income-replacement arrangement? If so, it is reasonable to permit life insurers to have access to any information they want in underwriting, so long as the decisions are actuarially justified and medical information is kept confidential. On the other hand, if life insurance has some other social value, such as preventing social disruption caused by the death of the primary wage-earner in a family, then it is reasonable to regulate the information on which underwriting is based and thereby the availability of the insurance product." Rothstein end this section of his article with the statement: "As with health insurance, it is simplistic to say that restrictions on a life insurance company's access to genetic information will protect the privacy and confidentiality of genetic information. It is necessary to prove the underlying assumptions about the role of life insurance in contemporary American society."

Long-term care insurance setting: Rothstein suggests that long-term care insurance will become increasingly important to Americans. He asserts: "The development of public policy on long-term care insurance depends to a large extent on whether long-term care is viewed more like health insurance or life (and disability) insurance."

Employment setting: Rothstein evaluates the ability of the Americans with Disabilities Act (ADA) to prohibit genetic discrimination. Most worrisome to Rothstein is the second part of the act, which "permits employers to make offers conditioned on a satisfactory report following a post-offer ("employment entrance" or "pre-placement") medical examination. The medical examiner may be a company-paid, full-time employee or, more often the case, an independent consultant. The ADA places no limitation on the scope of this examination. Except in the states where prohibited by a specific law, an employer may even require genetic testing." Also troubling, is that "under the ADA, the employer may require, as a condition of employment, that a conditional offeree sign a blanket release, authorizing the disclosure of all of the individual's personal medical records to the company for review." "In March 1995, the Equal Employment Opportunity Commission (EEOC) issued an interpretation regarding the applicability of the ADA to genetic discrimination. According to the EEOC, covered entities (that is, employers) that discriminate against individuals on the basis of genetic predisposition are "regarding" the individuals as having a disability and therefore the individuals are covered by the third prong of the

definition of individual with a disability under the ADA." Rothstein evaluates the EEOC interpretation to be limited on the grounds that the interpretation: (1) is "not binding on the courts, and the issue has not yet been addressed by any court"; (2) "does not apply to the unaffected carriers of recessive and X-linked disorders, who might be subject to discrimination by employers concerned about the health care costs of future dependents"; and (3) "does not prohibit employers from requiring as a condition of employment that an individual sign a broad medical release, thereby giving the employer access to clinical records that could contain genetic information."

In conclusion, Rothstein states: "The problem of genetic privacy and confidentiality cannot be solved by a single procedural law; resolution of the issues raises fundamental matters of equality of opportunity and allocation of resources. Only if we begin to understand the complexity and the difficulty of the challenge will we be able to develop comprehensive and thoughtful proposals to address genetic privacy and confidentiality."

Sankar P. Genetic Privacy. *Annual Review of Medicine*. 2003;54:393-407.

Sankar is concerned with the rapidly increasing number of genetic tests given in the clinical setting. Even in states with genetic privacy laws, information from such tests is not always protected. "Genetic privacy laws in the United States, designed to demarcate sensitive genetic information, often define genetic information as the results of DNA-based tests. However, as more precisely written laws illustrate, this definition excludes other potentially sensitive information, such as the results of tests on gene by-products, e.g., the sweat test for cystic fibrosis."

An increasing number of states have some form of genetic privacy protection. "Between 1993 and 2001, two thirds of the states passed laws to protect the privacy of genetic tests results, and in 2000 an executive order by President Clinton barred the federal government from discriminatory use of genetic information in hiring and employment practices." "Current Legislation includes laws that address genetic privacy generally, as well as more narrow laws that amend existing statutes on insurance discrimination." "One commonality among these laws is that they require a patient's permission to release genetic information." However, these laws are based on the concept of genetic exceptionalism and are of little value in protecting other types of sensitive medical information that might warrant similar protection. "Infections disease test results are relevant to persons beyond the patient taking the test and, if conducted early enough in the disease course, predict ill health for presymptomatic individuals."

"The debate [over whether genetic information is unique in medicine] has shown that although genetic information is sometimes particularly potent or sensitive, it has no subset of features that consistently distinguish it (except perhaps for the belief that it differs). The failure to distinguish genetic information should come as no surprise; separating medical and genetic information into distinct categories

would require delineating the divide between environmental and genetic features, or nature and nurture, a task at which no theoretician from any field, medical or philosophical, has succeeded."

"Genetic determinism is the belief that genetic contributions to disease, appearance, behavior, and personality are more important than other factors--such as culture and the natural and social environments. Genetic determinism privileges genetic information, increases its perceived values, and creates, or seems likely to create, a demand for it. Genetic determinism implies that knowing a person's genetic make-up is tantamount to knowing his or her future."

"Genetic determinism provides the foundation of arguments supporting genetic exceptionalism. Genetic exceptionalism is seen as having fostered genetic privacy legislation and public concerns, despite the scarcity of evidence for overt or common discrimination. One approach for effective use of genetic tests, which addresses genetic privacy concerns, recommends a balanced understanding of their risks and benefits. Attention to the limitations of testing, such as the 'therapeutic gap,' should curtail unnecessary testing and result minimally in less genetic information in circulation to trigger privacy concerns. Furthermore, a cautious attitude toward ordering genetic tests may also foster a more realistic assessment of the meaning and importance of genetic information generally."

Suter SM. The Allure and Peril of Genetics Exceptionalism: do we need special genetics legislation? Public Law and Legal Theory Working Paper No. 19. Washington University Law Quarterly. 2001;79(3).

In this article, Suter examines the concept of genetic exceptionalism from a legal perspective. Her article "challenges this approach [of genetic exceptionalism], arguing that concerns about genetics raise long-standing problems concerning privacy and discrimination. Policy makers, however, wrongly view these concerns as exceptional merely because the issues are cloaked in new technological guises. This article asserts that genetic information is not unique and that concerns about abuses of information should not be limited to genetic information, but should extend to other medical information."

Suter reminds readers that the Human Genome Project (HGP) was completed in 2003 and analysis of the data continues. "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 recommends, "Rather than focus on genetics per se, policy makers should turn their attentions to the *features* of genetic information that make it seem uniquely threatening. As they do so, they will discover that these features apply to most other medical information. It is my hope, that this recognition will inspire

efforts to address the problem of insurance/employment discrimination and privacy more broadly by focusing on medical information, rather than just genetic information.”

Suter applauds HIPAA, as “the regulations protect the most sensitive medical information - identifiable medical information - and they include, but are not limited, to genetic information. The HIPAA privacy regulations, in short, avoid the trap of genetics exceptionalism.”

Excerpts of her main arguments follow:

The cycle of genetic exceptionalism

Suter argues that “Not only is genetic information like other medical information, but treating the two differently under the law leads to unintended inequities between individuals and classes, raising serious questions about the propriety of public policy based on genetics exceptionalism.” She believes that the media, popular culture, scientists, and policy makers all “contribute to and reinforce the mystical view of the gene as powerful and uniquely threatening.” This creates a cycle, where “Public perceptions are shaped by media messages and scientific statements; the media use images of genetics that appeal to the public; and scientists are attentive to public perceptions in trying to ensure funding for their work. Likewise, legislators respond to public concerns, media stories, and scientists’ messages, even as their legislation provides news material and shapes public views. In the end, a confluence of factors and institutional forces individually and synergistically shape and reinforce the notion that genetic information is uniquely threatening and susceptible to misuse.” Yet “Much of the public does not understand how far we still are from using our knowledge of genetics to cure diseases.” So that “the public perceives genetics as uniquely powerful, both for good and bad. Its strongly deterministic view of genes intensifies the sense that genetic information is uniquely threatening and susceptible to misuse.”

Discrimination / Privacy

“Although numerous rationales motivate genetics legislation, they can be divided into two categories: concerns related to genetic discrimination and concerns related to privacy interests. The most frequent justification for this legislation is to prevent genetic discrimination. At heart, this is a fairness argument. We cannot *control* the genes we inherit.” “Genetic discrimination is also a concern because certain characteristics of genetic information make it particularly vulnerable to insurance or employment discrimination.” “Others worry that genetic information is prone to discrimination because it can be misunderstood” “Another justification for genetics legislation is to allay public concerns. Some have argued that public fears of genetic discrimination may prevent people from undergoing valuable genetic testing or participating in genetic research. Thus, whether or not genetic information is in fact unique, the public perceives it as uniquely threatening. Genetics legislation therefore addresses the public health consequences potentially raised by public concerns.”

“The second line of arguments describes why genetic information should be accorded privacy protections. Perhaps the most common argument, captured in part by the ‘future Diary’ metaphor, is that genetic information, like a diary, is personal information. Some describe genetic information as highly sensitive and stigmatizing, calling it a ‘figurative scarlet letter’. In addition, genetic privacy is important because, as some preambles suggest, genetic information is unique—we each have a different genome sequence. Indeed, because of its uniqueness, genetic analysis can be used for identification purposes. It can also be used to probe into the personal lives of historical figures, as was done to prove that Thomas Jefferson probably fathered children with Sally Heming.”

“We may also have privacy interests in genetic information for a variety of more complex reasons. First, genetic information can reveal information about, and it is therefore important to, family members. Thus what we or others learn about ourselves implicates knowledge about our family, making privacy interests more complex. In addition, one may want control over one’s genetic information both because it’s hidden from and potentially unknown to us and others and because it can identify health risks long before the condition manifests itself or treatment is available.”

In terms of genetic discrimination, Suter argues that even if it “is not currently a significant problem, the future remains uncertain. As our understanding about the clinical significance of various disease genes increases, genetic test will improve and become more prevalent and cost-effective. Potentially vastly increasing numbers of individuals will undergo genetic testing. Insurers and employers may be far more interested in using this information as it becomes more meaningful.” She continues, “Whether genetic discrimination will become problematic in the future is less important for this discussion than the fact that the media overstate both the promise and current risks of genetic discrimination, reinforcing genetics exceptionalism.”

“Legislators use two approaches to address the threat prevent of genetic discrimination: 1) direct prohibitions of discrimination or 2) the creation of privacy protections for genetic information. The first approach – nondiscrimination legislation – is the most common. Forty-four states prohibit health insurers from discrimination based on genetic information, and twenty-two prohibit employers. The approaches vary considerably. Some statutes prohibit insurers or employers from *obtaining* genetic information in connection with insurance or employment decisions.” “Some statutes prohibit *particular uses* of genetic information in insurance or employment decisions.” “Genetic nondiscrimination laws in employment also vary in their scope. All laws prohibit discrimination based on the results of genetic tests. Some prohibit employers from both obtaining and using genetic information for employment decisions.” “The second and often overlapping approach to prevent genetic discrimination is through the enactment of genetic privacy statutes, some version of which exists in twenty-one states.”

Legislation

Suter highlights the over and under-inclusiveness of genetic legislation. “Not all genetic information requires protective legislation, making genetics legislation over-inclusive. More important, a great deal of other medical information shares many of the features of genetic information that have inspired this legislation, making it dramatically under-inclusive.”

“Most of this enacted or proposed state and federal genetics legislation embodies the notion of genetics exceptionalism, either directly or indirectly. Some statutes explicitly declare the uniqueness of genetic information.”

“Genetics legislation, intentionally or not, reinforces the idea that genetics raises unique concerns deserving of special protections. Genetic concerns regarding discrimination and privacy, however, are not exceptional. The presumption that genetic information is unique is severely tested by the fact that no sharp line divides genetic from non-genetic information.” “Virtually all of the arguments for protecting genetic information apply equally to a great deal of nongenetic information. This under-inclusiveness is much more serious than the over-inclusiveness because it results in grave inequities between individuals and among classes.”

“The first chink in the armour of genetics exceptionalism appears when one tries to define the genetic information that should receive special legislative protections. This task has proven more challenging than those who presume genetic information is unique might expect. Indeed it is virtually impossible fully to distinguish genetic information from other medical information.”

“Some legislation uses very tight and narrow definitions, such as, ‘the results of a genetic test’ or ‘DNA analysis’. But not all genetic information comes from genetic tests or DNA analysis. Indeed, of the over 10,000 catalogued genetic diseases, genetic tests exist for only a few hundred. Most genetic information, at this point at least, comes from clinical evaluations, non-genetic tests, and family and medical history. As a result, those narrow definitions are under-inclusive, leaving unprotected a great deal of relevant and significant genetic information. For example, a family history of Huntington’s Disease (‘HD’), which indicates a 50% risk of the condition and is precisely the kind of predictive information that people want to protect, would not fall within the legislatively protected class of information.”

Yet using “broader definitions, such as ‘information about genes, gene products, or inherited traits that may derive from an individual or family member’” does not solve the problem. “These definitions would include a family history of HD, but they are over-inclusive, protecting more information than was intended, such as information about height, eye color, and sex, all of which are primarily genetic traits.” So how do we treat that fact that “Genes play some role in all disease, but environment plays a role as well, even with genetic diseases”? “The difference is merely the degree to which each plays a role. AIDS and phenylketonuria (PKU) illustrate this point nicely. AIDS is a classic non-genetic condition caused by infection with HIV. Yet genetic is crucial with respect to

whether the infection will cause illness, how soon one becomes ill, and how quickly the disease progresses. Conversely, PKU, a classic genetic condition, caused by two recessive non-functional genes, is highly influenced by environmental factors. If you eliminate phenylalanine from the diet, PKU will not develop. These points demonstrate how difficult it is to divide up the world into what is genetics and what is not.”

“Although no sharp line divides genetic from non-genetic information, one might argue that we can nevertheless identify distinctions at the extremes. In other words a spectrum of medical information exists: at one end lie conditions in which genetics plays a major role (Huntington’s disease, for example) and at the other end, conditions in which genetics plays a minor role (AIDS and other infectious diseases, for example).” Yet “most medical conditions about which we are concerned do not fall at either end of the spectrum. Instead, most conditions lie awkwardly in the middle. Huntington’s disease is the rarity, whereas cancer, heart disease, and numerous other conditions that affect vast numbers of individuals lie within the fuzzy margins where both genes and environment play a large, complicated and interrelated role.”

“Various persuasive arguments can be made for protecting genetic information. But this fact alone does not offer a principled account for protecting *only* genetic information (or indeed for protecting *all* genetic information). The real issue is whether these arguments apply *only* to genetic information. After examining the different rationales that motivate genetics legislation, this section argues that they do not apply to all genetic information, but more important, they apply equally to other types of medical information. In short, there is a grossly imperfect fit between the justifications for carving out special protections for genetic information and the category of genetic information; genetic information is both over and under-inclusive with respect to its legislative purposes. This imprecise fit, particularly the under-inclusiveness, suggests that the line between genetic and non-genetic information is questionable.”

“Five states – Colorado, Florida, Georgia, Louisiana, and Oregon – protect genetic privacy by declaring that genetic information is the “unique’ or “exclusive” property of the individual to whom the information pertains. Oregon is the only state to proclaim that one also has a property right in one’s genetic *samples*.” (this part of the OR Genetic Privacy law repealed in 2001).

Taylor B. Genetic Privacy. Background Brief. Legislative Committee Services, State of Oregon. May 2004;2(1).

This article provides a brief review of genetic privacy in Oregon, federally and in other states. This article highlights that fact that Oregon law is based on the idea that "genetic information is uniquely private and personal and should not be collected, retained or disclosed without the individual's authorization."

Of interest is the approach to genetic privacy taken by other states:

"Twenty-nine states have laws that pertain directly to genetic privacy. Of these states, sixteen require informed consent for a third party to either perform or require a genetic test or to obtain genetic information. Twenty-three states require informed consent to disclose genetic information. Rhode Island and Washington require written authorization to disclose genetic information. Four states explicitly define genetic information as the personal property of the individual. One state, Oregon, repealed its property right to genetic information and replaced it with a privacy right."

Vineis P, Schulte P, McMichael AJ. Misconceptions about the use of genetic tests in populations. *Lancet*. 2001;357(9257):709-712.

Please note: (1) "Penetrance" is defined by Merriam-Webster as: " the proportion of individuals of a particular genotype that express its phenotypic effect in a given environment". (2) Unless the penetrance of a disease is 100%, not everyone with a given genetic predisposition for a disease will develop said disease. DNA, therefore, should not be considered "the book of life" or deterministic.

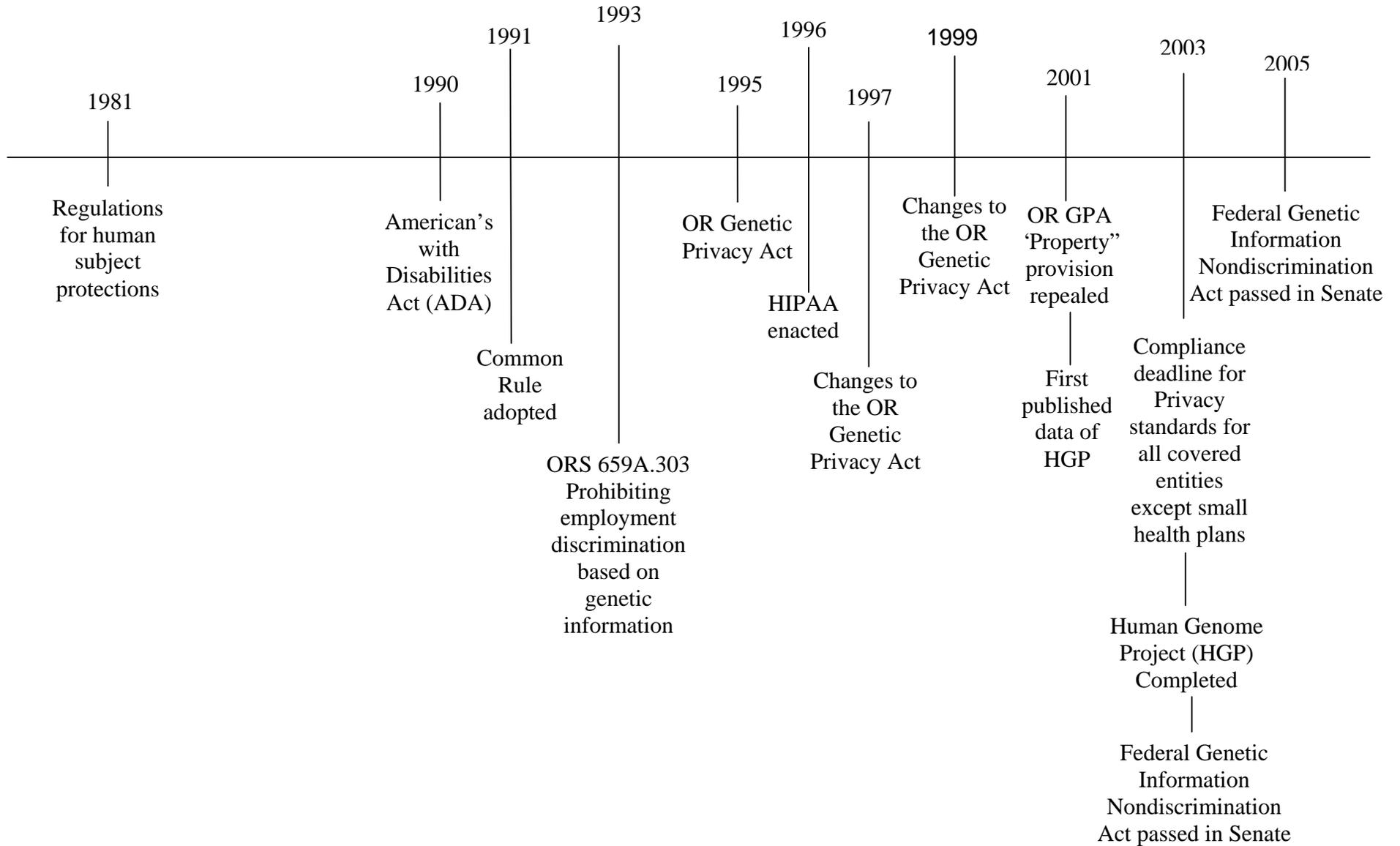
This article reviews what is currently known about disease penetrance. "Penetrance depends on at least six factors: (a) importance of the function of the protein encoded by the gene (eg, in crucial metabolic pathways as in phenylketonuria, or in key regulatory aspects of the cell cycle--mutations in these types of gene are highly penetrant); (b) functional importance of the mutations (eg, a deletion vs a mild loss of function due to a point mutation); (c) interaction with other genes; (d) onset of somatic mutation; (e) interaction with the environment; (f) existence of alternative pathways that can substitute for the loss of function. The last three factors can vary between individuals."

Wolf SM. Beyond genetic discrimination, towards the broader harm of geneticism. *Journal of Law, Medicine & Ethics*. 1995;23(4):345-352.

In this article, the author calls for a reframing of the "genetic problem" that does not depend on the antidiscrimination approach. Wolf claims that this approach establishes "a norm that does not exist in genetics and merely entrenches genetic bias."

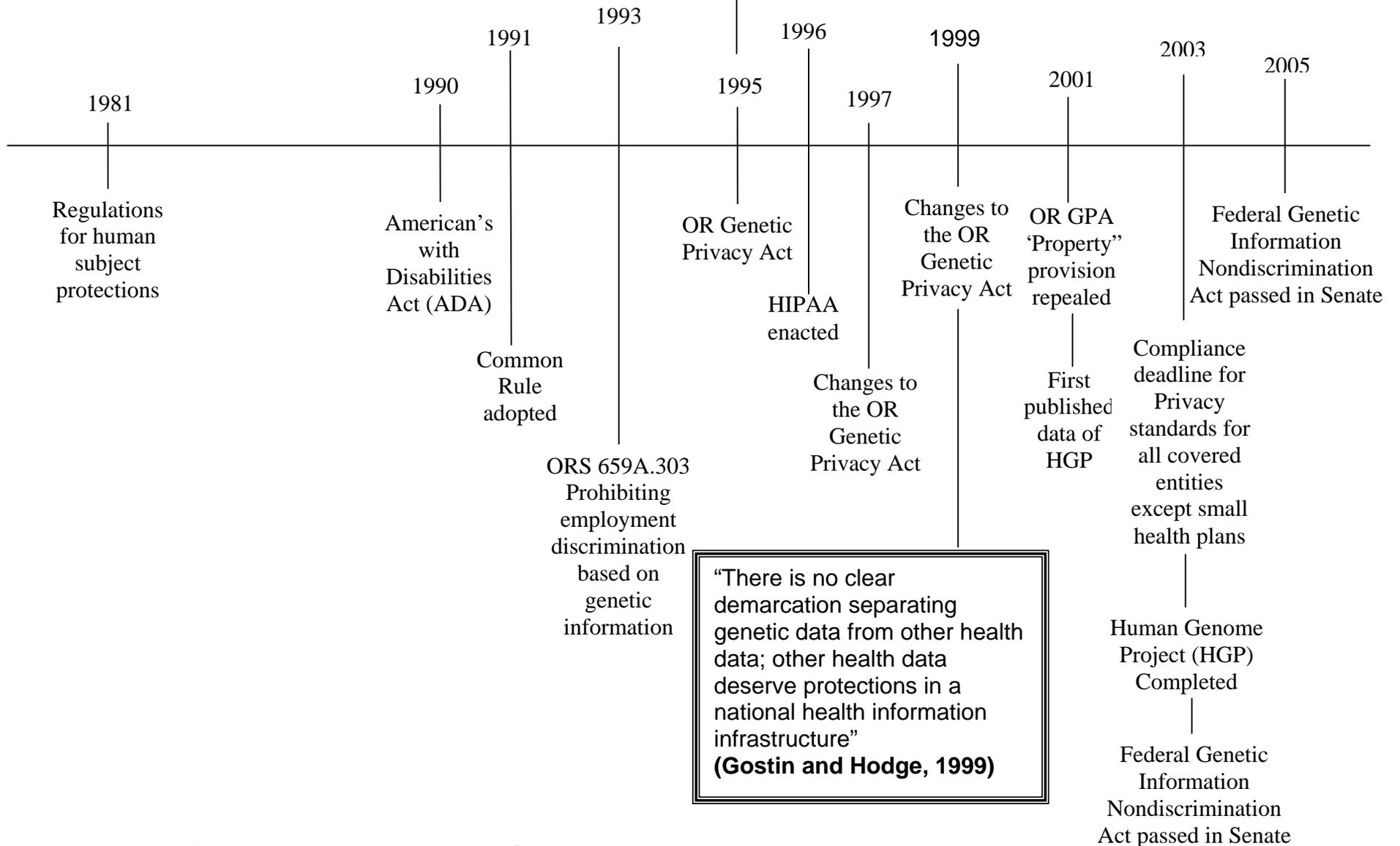
Of interest, the author stated: "The Task Force on Genetic Information and Insurance has expressed skepticism that genetic information can be segregated effectively from the rest of a person's medical record, especially as we come to appreciate the complex interaction between genetic and nongenetic factors underlying many diseases."

Genetic Information Project



Genetic Information Project

“Genomic data can personally identify and individual and his/her parents, siblings, and children, and provide current and future health profile with far more scientific accuracy than other health data” **(Gostin, 1995)**



Genetic Information Project

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

❖ Genetic information may be predictive of the future health of the individual

- Clinically significant *BRCA1/BRCA2* mutation identifies increased risk of breast cancer (Green, 2003)
- Genetically based high blood pressure or high cholesterol identifies increased risk of developing heart disease
- Presymptomatic testing for Huntington's disease

❖ Nongenetic information may be predictive of the future health of the individual

- Positive HIV test identifies increased risk of developing AIDS (Green, 2003; Gostin and Hodge, 1999)
- Nongenetically based high blood pressure or high cholesterol identifies increased risk of developing heart disease (Green, 2003; Gostin and Hodge, 1999)
- Positive tuberculin skin test identifies increased risk of developing active tuberculosis (Gostin and Hodge, 1999)

❖ Genetic information may be predictive of the future health of the individual's family members

- A woman's positive *BRCA1/BRCA2* mutation identifies increased risk of breast cancer in her sisters and daughters (Green, 2003)
- Genetic testing for Huntington's disease, Cystic Fibrosis, etc
- Genetic information may have implications regarding reproduction and characteristics of future generations

❖ Nongenetic information may be predictive of the future health of the individual's family members

- Positive tuberculin skin test in an individual identifies an increased risk of developing active tuberculosis for entire family (Green, 2003)
- 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)
- A pregnant mother's positive HIV status would identify increased risk of positive HIV status in child and child's father (Ross, 2001)
- 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)

Genetic Information Project

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)

Heart Disease - measures of impact

	<u>Genetic Information</u>		<u>Nongenetic Medical Information</u>	
	Asymptomatic Testing	Symptomatic Testing	Asymptomatic Testing	Symptomatic Testing
Example of test	mutation analysis of LDL receptor gene	-	evaluation of risk factors (cholesterol, blood pressure, etc)	cardiac catheterization
Is this test 'gold standard' or definitive?	no	-	no	yes
What does the <u>act of being tested</u> tell us about the individual?	family history of heart disease, hypercholesterolemia or other serious heart disease risk factor	-	nothing--standard screening questions	suspected disease state
What does the <u>test result</u> predict / tell about individual's risk of developing the disease?	likelihood of developing familial hypercholesterolemia	-	likelihood of developing heart disease	not a disease risk assessment; tells presence or absence or disease state and severity
Under the current OR genetic privacy law, can the test result affect decisions about health insurance in the individual market?	no	-	yes	yes
Without the current OR genetic privacy law, could the test result affect decisions about the health insurance in the individual market?	yes	-	yes	yes
How is the information protected?	OR genetic privacy / HIPAA	-	HIPAA	HIPAA
Does OR law make reporting this information mandatory?	no	-	no	no
Level of risk (probability of developing the disease)	genetics is only one of many risk factors for heart disease	-	increases with number and severity of risk factors	na
Can the probability of developing the disease be controlled or changed for this measure of risk?	no	-	yes	na
Given a high probability of developing the disease, can expected outcome be controlled or changed?	yes, through lifestyle and medication	-	yes	na

Huntington's Disease - measures of impact

	<u>Genetic Information</u>		<u>Nongenetic Medical Information</u>	
	Asymptomatic Testing	Symptomatic Testing	Asymptomatic Testing	Symptomatic Testing
Example of test	mutation analysis of IT15 gene	mutation analysis of IT15 gene	family history	clinical evaluation, CT scan, MRI, PET
Is this test 'gold standard' or definitive?	No	Yes, with symptoms	No	No
What does the <u>act of being tested</u> tell us about the individual?	1st or 2nd degree relative has HD	HD is suspect	family history	symptoms
What does the <u>test result</u> predict / tell about individual's risk of developing the disease?	likelihood of developing HD	likelihood of developing HD	likelihood of risk	possible neurological disorder
Under the current OR genetic privacy law, can the test result affect decisions about health insurance in the individual market?	no	no (but the diagnosis can)	yes	yes
Without the current OR genetic privacy law, could the test result affect decisions about the health insurance in the individual market?	yes	yes	Yes	yes
How is the information protected?	OR genetic privacy / HIPAA	OR genetic privacy / HIPAA	HIPAA	HIPAA
Does OR law make reporting this information mandatory?	no	no	no	no
Level of risk (probability of developing the disease)	100% if have HD gene	na	50% if one parent has HD	na
Can the probability of developing the disease be controlled or changed for this measure of risk?	no	na	No	na
Given a high probability of developing the disease, can expected outcome be controlled or changed?	no	na	No	na

Cystic Fibrosis - measures of impact		The information below is for a POST-NATAL individual.		
	<u>Genetic Information</u>		<u>Nongenetic Medical Information</u>	
	Asymptomatic Testing	Symptomatic Testing	Asymptomatic Testing	Symptomatic Testing
Example of test	new born screening	CF mutation analysis	family history	sweat test
Is this test 'gold standard' or definitive?	yes, if in combination with one of the following: symptoms or family history	yes, if in combination with one of the following: symptoms, family history, or positive new born screen	no, can only indicate likelihood of carrier or disease status	yes, if in combination with one of the following: symptoms, family history, or positive new born screen
What does the <u>act of being tested</u> tell us about the individual?	family history of CF unless routine screening conducted	symptomatic	family history	affected family member or symptomatic
What does the <u>test result</u> predict / tell about individual's risk of developing the disease?	carrier status or presence of CF mutation(s)	disease state or carrier status	likelihood of risk	disease state or not
Under the current OR genetic privacy law, can the test result affect decisions about health insurance in the individual market?	no	No (but the diagnosis can)	yes	yes
Without the current OR genetic privacy law, could the test result affect decisions about the health insurance in the individual market?	yes	yes	yes	yes
How is the information protected?	OR genetic privacy / HIPAA	OR genetic privacy / HIPAA	HIPAA	HIPAA
Does OR law make reporting this information mandatory?	no	no	no	no
Level of risk (probability of developing the disease)	significantly elevated risk if have two mutations	na	up to 25% if both parents are CF carriers	na
Can the probability of developing the disease be controlled or changed for this measure of risk?	no	na	no	na
Given a high probability of developing the disease, can expected outcome be controlled or changed?	yes, through treatment	yes, through treatment	no, not without further testing to make a diagnosis	yes, through treatment

AIDS - measures of impact				
	<u>Genetic Information</u>		<u>Nongenetic Medical Information</u>	
	Asymptomatic Testing	Symptomatic Testing	Asymptomatic Testing	Symptomatic Testing
Example of test	na	na	HIV test	diagnostic work-up
Is this test 'gold standard' or definitive?	na	na	yes	yes
What does the <u>act of being tested</u> tell us about the individual?	na	na	perceived risk (self or otherwise)	symptoms or positive HIV status
What does the <u>test result</u> predict / tell about individual's risk of developing the disease?	na	na	HIV Status	disease state or not
Under the current OR genetic privacy law, can the test result affect decisions about health insurance in the individual market?	na	na	yes	yes
Without the current OR genetic privacy law, could the test result affect decisions about the health insurance in the individual market?	na	na	yes	yes
How is the information protected?	na	na	HIPAA	HIPAA
Does OR law make reporting this information mandatory?	na	na	yes	yes
Level of risk (probability of developing the disease)	na	na	if positive HIV status, then high risk to develop AIDS	na
Can the probability of developing the disease be controlled or changed for this measure of risk?	na	na	if positive HIV status, possibly based on treatment	na
Given a high probability of developing the disease, can expected outcome be controlled or changed?	na	na	if positive HIV status, possibly based on treatment	yes, through treatment

Genetic Information Project

I. Genetic and Nongenetic Tests

A. Similar purpose

1. "Identify those at increased risk for developing a health-related disorder later in life" (Green and Botkin, 2003)
 - a. *BRCA1/BRCA2* testing to identify increased risk of breast cancer
 - b. Cholesterol testing to identify increased risk of heart disease

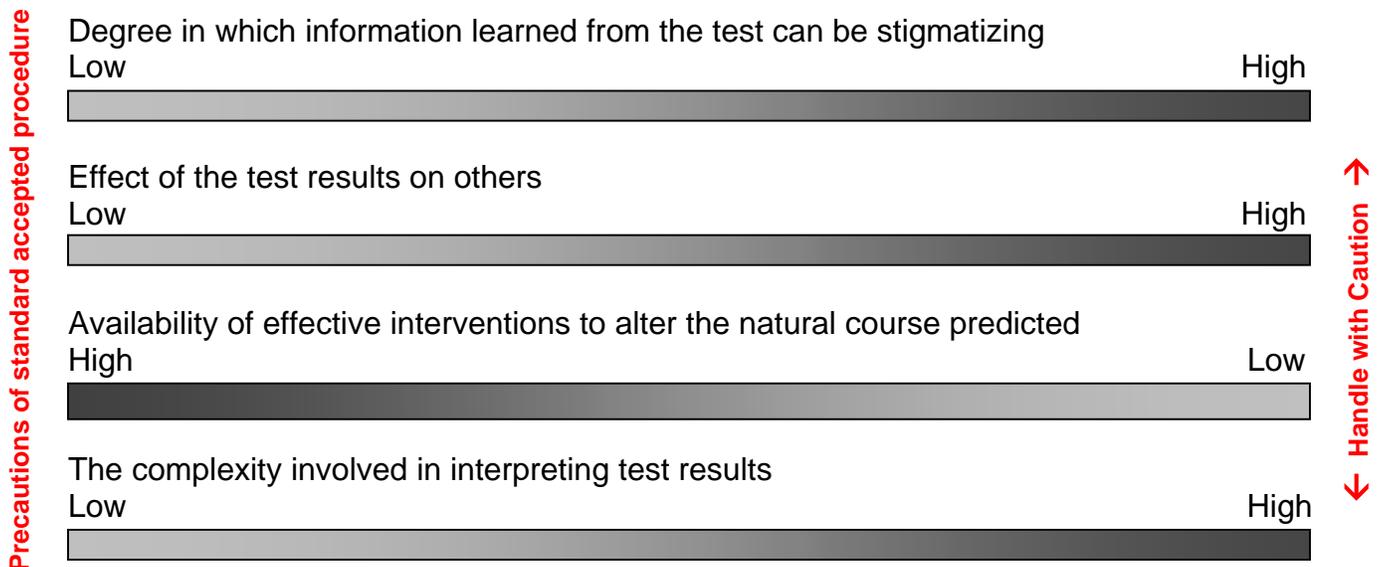
B. Similar clinical process

1. Visit doctor, evaluation, discussion, test, test results, discussion, etc

C. Similar storage and retrieval of test information

1. "All of the advantages and disadvantages of medical record keeping, including lapses of privacy, apply equally to genetic and nongenetic information" (Green and Botkin, 2003)

A Risk Continuum Framework for Predictive Tests of Asymptomatic Persons



"Tests that should be handled with caution include those that identify stigmatizing diseases, substantially affect family members, lack acceptable and effective treatments, and have results that are difficult to interpret. Tests for Huntington disease, HIV, and inherited breast cancer, for example, raise all of these concerns" (Green and Botkin, 2003)

"...tests for conditions that are less stigmatizing, have few serious implications for others, can be effectively treated, and yield results clinicians are trained to interpret require no additional consent and privacy precautions beyond standard, accepted procedures. Examples include glucose or cholesterol testing, tests of thyroid-stimulating hormone for hypothyroidism, and perhaps testing for suspected hereditary hemochromatosis" (Green and Botkin, 2003)

Reference:

Green MJ, Botkin JR. "Genetic Exceptionalism" in medicine: Clarifying the differences between genetic and nongenetic tests. *Annals of Internal Medicine*. 2003;138(7): 571-575.

Articles Regarding the Nonmedical Use of Genetic Information

Cho MK, Sankar P. Forensic genetics and ethical, legal and social implications beyond the clinic. *Nature Genetics*. Nov 2004; Supplement(36):S8-S12.

Data on human genetic variation help scientists to understand human origins, susceptibility to illness and genetic causes of disease. Destructive episodes in the history of genetic research make it crucial to consider the ethical and social implications of research in genomics, especially human genetic variation. The analysis of ethical, legal and social implications should be integrated into genetic research, with the participation of scientists who can anticipate and monitor the full range of possible applications of the research from the earliest stages. The design and implementation of research directs the ways in which its results can be used, and data and technology, rather than ethical considerations or social needs, drive the use of science in unintended ways. Here we examine forensic genetics and argue that all geneticists should anticipate the ethical and social issues associated with nonmedical applications of genetic variation research.

Giarelli E, Jacobs LA. Issues related to the use of genetic material and information. *Oncology Nurses Forum*. April 2000;27(3):459-67.

PURPOSE/OBJECTIVES: To review issues regarding the use of genetic materials and information. **DATA SOURCES:** Professional literature, regional and federal legislation. **DATA SYNTHESIS:** An analysis is provided of the relationship among advances in genetic technology, use of genetic material and information, and the development of laws that protect the interests of donors, researchers, and insurers. Rapid technological achievements have generated complex questions that are difficult to answer. The Human Genome Project began and the scientific discoveries were put to use before adequate professional and public debate on the ethical, legal, social, and clinical issues. The term "proper use" of genetic material and information is not defined consistently. An incomplete patchwork of protective state and federal legislation exists. **CONCLUSIONS:** Many complicated issues surround the use and potential misuse of genetic material and information. Rapidly advancing technology in genetics makes it difficult for regulations that protect individuals and families to keep pace. **IMPLICATIONS FOR NURSING PRACTICE:** Oncology nurses need to recognize their role as change agents, understand genetic technology, and advocate for patients by participating in the debate on the proper use and prevention of misuse of genetic material and information.

Kimmelman J. Risking Ethical Insolvency: A Survey of Trends in Criminal DNA Databanking. *Journal of Law, Medicine & Ethics*. Fall 2000;28(3):209-221.

Over ten years have elapsed since Virginia passed the nation's first criminal DNA banking law, which authorized law enforcement authorities to collect DNA samples from certain categories of offenders for the purposes of performing profile analysis. Within nine years, Rhode Island became the fiftieth state to enact a similar statute. The passage of a decade since the first enactment

provides a convenient opportunity to assess the strengths and weaknesses of ethical safeguards under present law as well as predict the likely direction of future developments.

DNA forensics are merely the latest in a long line of biologically based identifying law enforcement technologies that include fingerprints and serotyping. Nevertheless, DNA has properties that make it significantly different than its predecessors with respect to the ethical and social concerns it raises. First, DNA is predictive for sensitive information such as an individual's hereditary diseases, phenotypic propensities, and familial relations. Secondly, it can be amplified from minute quantities, and because it is shed in detectable quantities in the form of sloughed skin, hand smudges, hair follicles, and saliva residues, it is more abundant as a source of evidence than fingerprints and serotypes. Third, DNA profiles are partially shared with biological relatives, which means an offender's profile cannot be collected without consequentially obtaining incomplete information about non-offending relatives' profiles. Moreover, certain alleles and allele frequencies are predictive for biologically defined racial and ethnic categories. Finally, DNA is a relatively durable material, and therefore retains its "informational content" much longer than would other sources of biological evidence. Together, these properties qualitatively distinguish DNA samples and profiles from fingerprints and militate against convenient analogies to fingerprints.

Earlier reviews of DNA databanking statutes concentrated on incipient trends in databanking laws. Many new laws have since been enacted, while others have been amended. A second wave of databank expansion appears to be underway, as several states consider significant qualitative and quantitative expansions in their DNA databanking policies.

In this paper, I review and catalog the various US statutes and compare them with databanking policies in England and Canada. In addition, I've identified several areas where criminal offender DNA databanking statutes may inadequately protect persons' rights to privacy, bodily integrity, and presumptive innocence. I further attempt to contextualize developments in offender DNA databanking by discussing other social trends that may effect their social benefits and risks. Finally, I make several recommendations that would substantially repair these weaknesses and diminish the social risks of deploying these powerful technologies.

Reilly PR. Efforts to regulate the collection and use of genetic information. Archives of Pathology Laboratory Medicine. Nov 1999;123(11):1066-70.

Public fascination with and support for genetic medicine is complicated by a deeply held fear that genetic information will be used by third parties (eg, insurers, employers, school systems) in ways that will harm the individuals from whom it was derived. Since the mid-1990s there has been much state and some federal legislative activity to address 2 closely related issues: the maintenance of genetic privacy and the prevention of genetic discrimination. These laws have had to confront several challenging questions such as what constitutes a genetic

test, is genetic information qualitatively different from other medical information, and is there a means to distinguish between the two. In general the state laws are not well crafted. I will argue that a far more preferable policy is to draft a global, comprehensive medical records privacy law and to develop a model statute that defines the role of predictive genetic information in insurance underwriting. Concerns over misuse of genetic information also pose major issues for the conduct of genomic research. Among those I discuss are ownership of the DNA sample, significant changes in the scope of consent that must precede the decision to volunteer as a subject in genomic research, the reuse of long-archived samples, the challenges to intellectual property rights that flow from research, and the rise of the doctrine of community consent.

Williams R, Johnson P. Inclusiveness, Effectiveness and Intrusiveness: Issues in the Developing Uses of DNA Profiling in Support of Criminal Investigations. *Journal of Law Medicine and Ethics*. 2005 Fall;33(3):545-58.

Reports on the development and application of forensic DNA profiling in support of criminal investigations in the U.S. Implementation of Polymerase Chain Reaction based on extraction and amplification methods; Effectiveness of DNA-aided investigations with assertions of potentially problematic ethical and social consequences of their uses; Intrusion and denigration of privacy rights caused by the storage and use of tissue samples.