Genetic Exceptionalism: Genetic Information and Public Policy

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Summary

The Human Genome Project, from inception through completion, has generated a great deal of debate over the appropriate uses, as well as potential misuses, of genetic information. Legislation that is specific to genetics is predicated on the concept of genetic exceptionalism, or the premise that genetic information is unique and, therefore, merits both special and different, or exceptional, treatment. As applied to public policy, this translates into genetics-specific legislative approaches to various health policy issues, such as the oversight of genetic tests, privacy, and discrimination in health insurance. Amidst considerable concern over the potential for the misuse of genetic information, most states passed genetics legislation during the past decade and a half in areas such as genetic privacy, genetic discrimination in health insurance, and genetic discrimination in employment. A genetic exceptionalist approach was taken by lawmakers in the Genetic Information Nondiscrimination Act of 2008 (GINA, P.L. 110-233). Because the idea of genetic exceptionalism has had a significant influence on public policy to date, Congress may want to consider how to treat genetic information in future legislative efforts, for example, in the areas of personalized medicine or oversight of clinical laboratory testing.

This report provides an overview of the nature of genetic information and its implications for individuals, family, and society. Individuals utilize genetic information to guide health care and other decisions, when possible, and may experience anxiety as a result of genetic test results. Genetic test results for an individual may often be informative for other close family members and thus influence their care decisions. Society must grapple with the effect genetic information may have on our conception of disease, as well as its impact on issues like privacy and equity. Data are presented on public opinion regarding the nature of genetic information, the need for special protections for genetic information, and the potential effect of the passage of GINA on attitudes toward the sharing of genetic information. The report ends by summarizing issues involved when considering legislation that addresses genetic information, including (1) separating genetic information from other medical information; (2) unintended disparities between "genetic" and "nongenetic" disease; and (3) the potential effect of legislation on participation in genetic research, on uptake of genetic technology and on the delivery of high quality health care.

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Introduction

Advances in human genetics, and especially the completion of the Human Genome Project, have focused attention on the potentially numerous ways that genetic information may be used to improve and benefit health and health care. Despite excitement about the anticipated benefits that the use of such information may generate, lawmakers have raised concern about the potential for misuse of this information as well. Genetic information can be defined in many ways, but for the purposes of this report, it means information about genes, gene products, or inherited characteristics generated through either genetic testing or analysis of family history.

The term "genetic exceptionalism" refers to the concept that genetic information is inherently unique, should receive special consideration, and should be treated differently in law. This idea is based on the supposition that genetic information itself embodies several characteristics that may make it special and differentiate it from other medical or even personal information. According to the perspective of genetic exceptionalism, the characteristics of genetic information that make it different include the following: (1) it can be predictive of future disease; (2) it is a unique identifier; (3) it can reveal information about family members; (4) it is vertically transmitted (passed from parent to child); (5) it can impact communities; (6) it can be used to discriminate and stigmatize; and (7) it can cause serious psychological harm. In addition, although not specific to genetic information, the following characteristics also describe genetic information: (1) it can be obtained from small samples (possibly without consent); (2) it may be used for purposes other than those for which it was collected; (3) it is of interest to third parties (such as employers and insurers); (4) it may be important for determining susceptibility to disease and effectiveness of treatment; and (5) it can be recovered from stored specimens after many years.[1] These characteristics are not unique to genetic information; other medical information may also have some of these characteristics in common with genetic information. However, it may be argued that there is little medical or personal information that shares *all* of these characteristics with genetic information, and that therefore, genetic information is unique in that way.

Genetic information is viewed as powerful, perhaps uniquely so, by society and has been regarded with some degree of respect generally not afforded other types of health or personal information.[2] This may be due to the sense that genetic information is immutable and, therefore, that its use merits more caution than might the use of other information. This heightened caution may be warranted simply because of the perception that genetic information cannot be modified or altered, and that it is not chosen by the individual who bears it. The differential regard for genetic information may also be related to the idea of genetic determinism, or the concept that our genes exclusively predict or foretell our fate, including health, behavior, and physical characteristics. Although efforts have been made by responsible scientists to disabuse the public of this notion by stressing the role of environmental factors in disease, it is still fairly persistent, as seen in overly glowing portrayals of genetic discoveries and technologies by the media. It is difficult to specifically determine what gave rise to the concept of genetic exceptionalism; however, it does appear that, broadly, the public regards genetic information as particularly sensitive and perhaps even as unique.

[1] Nuffield Council on Bioethics. *Pharmacogenetics: ethical issues*. (2003), at http://www.nuffieldbioethics.org/sites/default/files/Pharmacogenetics%20Report.pdf.

[2] Roche PA and GJ Annas, "Protecting genetic privacy," *Nature Reviews Genetics*, 2:392-396, 2001.

The influence of the concept of genetic exceptionalism is reflected in genetics-specific public policy at both the state and federal level. At the federal level, Congress passed the Genetic Information Nondiscrimination Act of 2008 (GINA, P.L. 110-233), which employs an exceptionalist approach. A number of states have passed genetic nondiscrimination legislation that places various restrictions on health insurers' use, collection, or acquisition of genetic information to restrict or deny health insurance coverage. Similarly, a majority of states have passed legislation to protect the privacy of genetic information or to prohibit employers from using such information to discriminate against employees. Because the idea of genetic exceptionalism has had a significant influence on public policy to date, Congress may want to consider how to treat genetic information in future legislative efforts, for example, in the areas of personalized medicine or oversight of clinical laboratory testing.

This report provides an overview of the implications of genetic information for individuals, family, and society; examines public opinion about genetic information; and summarizes the main policy arguments for and against incorporating genetic exceptionalism into public policy.

Genetic Information vs. Other Medical Information

The differences between genetic information and other types of medical information have important implications for the individual, for families, and for society as a whole.[3] The discussion below provides a broad overview of these implications, but recognizes that there may be specific examples of nongenetic tests that have the same implications as genetic tests. However, the discussion below is meant to provide a general comparison across the two categories of tests—genetic versus nongenetic—and the information they generate.

Implications for Individuals

Genetic tests are similar to many other medical tests in that they are often used to diagnose a disease or condition. Most of these diagnostic tests, both genetic and nongenetic, provide information about treatable maladies. Unlike most other medical tests, however, genetic tests may be used to determine that a currently healthy individual is susceptible to—at increased risk of developing—a particular illness or condition (susceptibility genetic testing). Genetic tests may also be used to predict that a currently healthy person will develop an illness or condition in the future with certainty (predictive genetic testing). It is often the case that many of the illnesses and conditions tested for using predictive or susceptibility testing cannot be cured or prevented by any currently available medical intervention. For example, a genetic test is available for Huntington's disease, a disease for which no prevention or cure (or even effective treatment) currently exists.

Because of this general lack of curative measures, sometimes the only options for reducing one's risk of future disease rely on modification of personal health related behaviors; for example, undergoing frequent screening, eating healthy foods, and exercising regularly. It is unclear how knowledge of genetic risk factors will influence the modification of such behaviors. While some individuals may modify their behavior because of knowledge of their genetic risk factors, some may have the perception that because they cannot change their genetic makeup, modifying their

[3] For more information about genetic testing, see CRS Report RL33832, *Genetic Testing: Scientific Background for Policymakers*, by Amanda K. Sarata.

behavior will have little effect on decreasing their risk for disease. It is possible that these individuals may even increase unhealthy behaviors out of a sense of hopelessness. If no preventive or curative options exist, predictive genetic test results may increase a patient's anxiety level if they are positive or provide a false sense of reassurance if they are negative. Susceptibility genetic test results may also increase anxiety if they indicate an increased risk of disease while offering no options for mitigating this risk. For example, a certain allele, the APOE4 allele, has been found to increase an individual's risk of developing Alzheimer's disease. However, testing for this particular allele has been discouraged by health professionals because Alzheimer's disease cannot be prevented or cured, and, therefore, knowing one's risk status may simply increase anxiety. Furthermore, the actual increase in risk is not absolute in any sense; one may carry two copies of the APOE4 allele and still not develop Alzheimer's disease, while one may carry no copies of the APOE4 allele and still develop the disease.

Unlike most other medical testing, genetic testing may unintentionally reveal information about an individual or may reveal information with unknown significance given current scientific knowledge. For example, genetic testing may reveal unanticipated instances of non-paternity (where it is revealed that the purported father is in fact not the father). The development of microarray technology provides an increasingly cost-effective mechanism for testing hundreds or even thousands of genetic health indicators at one time.[4] Genetic testing on this scale could likely lead not only to the revelation of an enormous amount of health information about individuals, but also to a large amount of unexpected health information. This raises concerns about informed consent, as obtaining truly voluntary informed consent for each individual test might be prohibitively time consuming. Banking and storage of this vast amount of information, along with personal identifiers, provides unique challenges to existing privacy protections. Consumer advocates caution that although economic incentives favor testing for a large number of genetic characteristics at one time, testing should be limited to allow for thorough informed consent before and genetic counseling both prior to and after testing.

Genetic information can be used not only in the clinical setting, but also by forensic experts and the criminal justice system to identify individuals with a high degree of certainty. Genetic information has been used to help convict and exonerate individuals accused of committing crimes. It has been used to help identify the remains of war and accident victims. Because of these potential applications, tissue samples and certain types of genetic information collected for health care purposes may later be used in law enforcement, and vice versa. The fact that genetic information collected for health care may have forensic applications may increase lawmakers' concern with the increasingly widespread availability and use of genetic information. Concern about use of genetic information in nonhealth settings may also decrease uptake of new genetic technologies in health care and decrease participation in genetic research.

Implications for the Family

Genetic tests for *acquired* markers—genetic changes that an individual does not receive from his or her parents but rather acquires sometime post-conception—have direct medical implications

[4] Microarray technology is defined as "a developing technology used to study the expression of many genes at once. It involves placing thousands of gene sequences in known locations on a glass slide called a gene chip. A sample containing DNA or RNA is placed in contact with the gene chip. Complementary base pairing between the sample and the gene sequences on the chip produces light that is measured. Areas on the chip producing light identify genes that are expressed in the sample." See http://ghr.nlm.nih.gov/glossary=microarraytechnology.

only for the individuals taking the tests.[5] Most other medical tests also have direct medical implications only for the individual taking the test. However, unlike most other medical tests, genetic tests for *inherited* markers—markers that are transmitted from parents to their offspring—have implications for biological relatives of the individual. Parents, siblings, and children have a predictable risk of sharing certain inherited genetic markers. Furthermore, the generally unchanging nature of inherited DNA means that genetic testing for inherited markers can be performed at any stage of human development on most tissue types. This offers the possibility of testing before implantation or prenatally, and may possibly allow for fetal intervention.

Some genetic tests cannot be interpreted for an individual unless other members of her family are also tested. For example, breast cancer genetic testing on the BRCA1 and BRCA2 genes relies on sequencing the entire gene in an affected individual to pinpoint the specific familial mutation. Then other family members may be tested for that specific mutation to help accurately determine if they are at increased risk of developing breast and/or ovarian cancer and, if so, the magnitude of that risk. In those cases, all family members may or may not want to know their test results.

Implications for Society

Unlike most other medical information, genetic information challenges traditional medical conceptions of health and disease, what is normal or abnormal, and raises questions about what constitutes manifested disease. For example, lactose intolerance was long thought to be an abnormal state. Research in different populations elucidated that, in fact, it is the normal state, and the ability to digest lactose was the result of mutations that were under strong selective pressure in areas of the world where domestication of animals led to increased consumption of dairy products. These concepts are becoming increasingly blurred as genetic advances uncover the true range of "normal" and "abnormal" in many human traits.

Many experts predict that genetics may soon provide the opportunity to test large groups of people for disease susceptibilities. However, fear caused by the possibility that a job may be lost or insurance may be cancelled—whether real or perceived—could affect individuals' decisions to seek potentially beneficial genetic testing in clinical or research settings. If people decline to participate in genetic research in large numbers, the ability to gather the data that are necessary to determine the utility or ultimately the value of genetic testing may be compromised. This may delay realization of the potential benefits of genetic advances for the larger population. However, recently enacted genetic nondiscrimination legislation at the federal level may serve to counter this concern, at least to some degree.

Genetic information may be used in order to link a person to a distinct group or heritage. This type of information may have consequences, particularly for individuals who have rights based upon heritage, such as Native Americans. Advocates of these groups are wary of the potential effect that genetic testing and information could have on their current rights and protections. Others argue that definitions of race and heredity are irrelevant or that genetic information will not supplant current nongenetic determinants of ancestry. Finally, because the prevalence of

[5] For example, the onco*type* Dx test offered by Genomic Health profiles a tumor's gene expression patterns to determine whether the tumor is likely to spread or respond to different types of treatment. Expression patterns in tumors are largely due to acquired mutations. For more information, see http://www.oncotypedx.com/en-US/Breast/PatientCaregiver/OncoOverview.aspx.

disease-causing genes often varies by ethnicity, there is potential for discrimination against groups of people that share similar genetic information.

The meaning of genetic information evolves with scientific progress, which has special implications both for privacy and for equity. In the privacy arena, a person could grant others access to genetic data that is benign by today's standards. However, with scientific advancements these same data may in time reveal more sensitive information. In the equity arena, those with health conditions for which genetic tests currently exist may suffer discrimination in the near future, while those with similarly debilitating health conditions for which there is no genetic test may escape the same discrimination simply by virtue of the current state of science. Certain initiatives in genetic research, such as large-scale banking of genetic information, could raise both privacy and equity concerns, even though they may also have widespread public health benefit.

Public Opinion About Genetic Information

Although there has been an ongoing academic debate about the concept of genetic exceptionalism, it is perhaps more relevant in terms of public policy to examine how the public views genetic information. Specifically, research has examined whether the public believes that genetic information deserves special protections or is different from other medical information, as well as with whom genetic information should be shared. After the passage of GINA, research continues to examine attitudes about the sharing of genetic information, as well as awareness of GINA's protections.

Public Opinion Regarding the Nature of Genetic Information and the Need for Special Protections

To address the question of whether genetic information merits special protections, a 2007 study examined opinions about genetic information through a series of focus groups with members of a health maintenance organization (n=46). Focus groups conducted with these members found that, broadly, participants did not feel that genetic information is special or inherently different from other medical information. In addition, the participants generally felt that all sensitive medical information, including but not limited to genetic information, should be protected. Sensitive medical information was agreed to be that information that has the potential to be used to discriminate against or stigmatize an individual.[6]

A second study compared the experiences, attitudes, and beliefs of persons with genetic conditions (cystic fibrosis and sickle cell disease) to those with other serious medical conditions (diabetes, HIV, breast cancer, and colon cancer) and to persons at risk for developing a disease (breast or colon cancer) due to strong family history. The authors found that in most instances, patients felt strongly that their health information needed to be protected regardless of whether it was genetic. In fact, respondents indicated that information about non-genetic stigmatizing conditions—such as abortion history, mental health history, drug and alcohol history, HIV status, and sexually transmitted disease—needed special protection. Based on their findings, the authors

[6] Diergaarde B. et al., "Genetic Information: Special or Not? Responses From Focus Groups With Members of a Health Maintenance Organization," *American Journal of Genetics Part A*, 143A: 564-569, 2007.

concluded that separate privacy policies for genetic and non-genetic health information would be unwarranted.[7]

Other studies and public opinion polls suggest that patients and members of the community desire and may benefit from additional protections for their genetic information. A 2003 study of 470 people with a family history of colorectal cancer showed that 39% rated their level of concern about genetic discrimination in health insurance as the most significant reason to forego testing. Those individuals with high levels of concern indicated that they would be significantly less likely to consider meeting with a health care professional to discuss genetic testing, or to undergo testing.[8] A 2007 survey by the Center for Genetics and Public Policy found that 93% of survey respondents thought employers should not have access to their genetic test results, and 93% opposed letting health insurance companies have access to results.[9] A 2006 survey conducted by Cogent Research found that 72% of survey respondents believe that laws are needed to protect the privacy of genetic information, and 85% believe that if protections are not established, employers would use genetic information discriminate.[10]

Findings from this selected research suggest that people view genetic information as sensitive, but not necessarily more so than other sensitive medical information such as HIV status. These studies found, although not uniformly, that the public believes that genetic information needs to be kept private from employers or insurers, and that special protections may be required to achieve this goal.

Attitudes Toward Sharing Genetic Information

Since GINA was enacted relatively recently, data assessing the public's attitudes after enactment are limited. However, some surveys have been carried out that evaluate both public attitudes about the sharing of genetic information, as well as attitudes toward GINA itself.

A 2008 survey on personalized medicine found that very few consumers were readily willing to share the results of genetic tests with current employers (2%), health insurers (3%), or a prospective employer (1%).[11] This survey was conducted very shortly after the passage of GINA, but prior to its effective dates. There was a significant amount of media coverage leading up to GINA's passage; however, this survey's results suggest that the increased media attention to this issue, and to the actual passage of the law, did not immediately result in a high degree of receptivity to the idea of sharing genetic information with either health insurers or employers.

This finding is supported by another survey conducted by Cogent Research at almost the same time (late May through early June of 2008). This survey found that compared to in 2006,

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[7] Plantinga L. et al., "Disclosure, Confidentiality, and Families: Experiences and Attitudes of Those with Genetic Versus Nongenetic Medical Conditions," *American Journal of Medicine*, General Part C, vol. 119C (2003), pp. 51-59.

[8] Hadley D.W. et al., "Genetic counseling and testing in families with hereditary nonpolyposis colorectal cancer," *Arch Intern Med*, 163(5): 573-82, 2003.

[9] Williams S., "The Impact of Genetic Discrimination," *Genetics and Public Policy Center Issue Brief*, Updated April 2007.

[10] Presentation by Ms. Christy White at the Ninth Meeting of the Secretary's Advisory Committee on Genetics, Health, and Society. March 28, 2006. Accessed at http://oba.od.nih.gov/oba/SACGHS/meetings/March2006/white.pdf.

[11] Burrill & Company/Change Wave Research. Personalized Medicine and Wellness Survey (2008). Accessed at http://www.burrillandco.com/content/CWSurvey_61708.pdf on July 1, 2010.

Americans are less interested in sharing the results of their genetic tests with their health insurer (decrease of 3%); the lab that conducted the genetic test (decrease of 9%); and even with their doctor (decrease of 9%).[12] Cogent carried out a survey again in 2010, and found that Americans are still concerned about who can access their genetic information; specifically, the 2010 Cogent survey found that 71% of Americans are concerned about storage of and access to their information, with the same percentage concerned specifically about access by health insurers.[13] In addition, the survey found that Americans worry about life insurance companies and the government accessing their genetic information, and are increasingly concerned that their information will be used without their authorization (56% up from 49% in 2008).[14]

Taken together, these findings indicate that since the 2008 survey just after the enactment of GINA, consumer concern about access to genetic information, and specifically by health insurers, may in fact be growing. However, data suggest that public awareness of GINA is low. Specifically, in its 2008 survey, Cogent found that "only 16 percent of respondents to the survey knew that there were laws that protect the privacy of genetic information, and only one-quarter of those felt that protections were sufficient."[15] The 2010 Cogent survey found that awareness of laws protecting privacy held steady at 16%, with 77% of Americans unsure whether they are protected by law. Level of education and age both demonstrated a very modest correlation with awareness of legal protections; specifically, those with a graduate or professional education and those ages 18-34 were more likely than those with less education or ages 55 or greater to be aware of GINA.[16] It is possible that as public awareness of GINA increases over time, attitudes toward the sharing of genetic information will change.

Policy Issues

When considering public policy that involves genetic information, policymakers may chose to treat genetic information differently from other medical information. For example, GINA takes this approach. Conversely, policymakers may treat genetic information the same way as they treat other medical information. For example, the HIPAA Privacy Rule treats genetic information in a non-exceptional way.

When considering whether to take an exceptionalist approach to any policy involving genetic information (e.g., oversight of direct-to-consumer genetic testing or oversight of genetic clinical laboratory tests), policymakers may consider several issues. These include, for example (1) whether the policy requires the separation of genetic information from other medical information;

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[12] Cogent Research. Cogent Genomics Attitudes and Trends: 2008. Accessed at http://oba.od.nih.gov/oba/SACGHS/meetings/March2009/White_slides.pdf on July 1, 2010.

[13] Cogent Research. "Americans' Concern about the Privacy of Their Genetic Information Reaches New High." Accessed at http://www.cogentresearch.com/news/Press%20Releases/CGAT%202010_press%20release%20-%20Privacy%20Concerns%20-%2001-10-11.pdf on May 26, 2011.

[14] GenomeWeb. "Survey Shows Declining Public Interest in PGx, Poor Grasp of Genomics Issues." Accessed at http://www.genomeweb.com/dxpgx/survey-shows-declining-public-interest-pgx-poor-grasp-genomics-issues on May 26, 2011.

[15] SACGHS. "Genetics Education and Training of Health Care Professionals, Public Health Providers, and Consumers." (May 2010) Accessed at http://oba.od.nih.gov/oba/SACGHS/SACGHS%20Draft%20Genetics%20Education%20and%20Training%20Report.pdf#page=56 on July 1, 2010.

[16] Council for Responsible Genetics. "Genetic Privacy Worries on the Rise." Accessed at http://www.councilforresponsiblegenetics.org/genewatch/GeneWatchPage.aspx?pageId=324 on May 26, 2011.

(2) the potential for unintended disparities between "genetic" and "nongenetic" disease; and (3) the potential effect on participation in genetic research, on uptake of genetic technology, and on the delivery of high quality health care.

Separation of Genetic Information from Nongenetic Information

Separating genetic from non-genetic information in medical records may pose a practical challenge. However, adoption of electronic medical records may facilitate such a separation (both for purposes of maintaining the information and releasing the information).[17] The Personalized Health Care Work Group of the American Health Information Community (AHIC) released a statement in July of 2008 recommending that, if federal policy were developed that would provide for limited access to sensitive medical information in EHRs (i.e., through data masking), genetic/genomic information should be subject to these limitations.[18] The authors argue that genetic information is characterized by a series of attributes that, while not all unique to genetic information, make genetic information unique because they in aggregate characterize such information. They further maintain that in order to realize the promise of personalized medicine, both access to and use of genetic/genomic information must be controlled to a greater extent than it is for other, less sensitive, medical information. Conversely, other commentators argue that genetic exceptionalism is an outdated concept. These experts claim that the rest of the information contained in the medical record is highly identifying; that penetrance of the genotype (i.e., how predictive it is and how strongly it correlates therefore to a certain clinical endpoint) may be more important to policy discussions than the fact that the information was generated by genetic technologies; and that in fact, the more clinically relevant the information, the less desirable is a genetic exceptionalist approach.[19] These experts express concern that a genetic excpetionalist approach might interfere with health care providers' ability to provide the best care to patients.

Disparity Between Genetic and Nongenetic Disease

Several experts have voiced concern that genetic exceptionalist laws may result in unintended disparities.[20] For example, they argue that such laws may create a situation where individuals affected by a disease or condition with a *known* genetic basis (i.e., breast cancer in the presence of a BRCA1 mutation) would be protected from discrimination while those with breast cancer with no *known* genetic basis would not be protected. After the passage of GINA, it remains unclear whether these disparities have manifested.

Congress has, in recent years, considered legislation to address direct-to-consumer (DTC) genetic testing. Some commentators have noted that the genetic exceptionalist approach should be avoided,[21] while others noted that it is merited, given that "never before have we had a situation

[17] Ibid.

[18] McGuire AL et. al. (2008) "Confidentiality, privacy and security of genetic and genomic test information in electronic health records: points to consider." *Genetics in Medicine* 10(7): 495-499.

[19] Burke, W and JP Evans. (2008) "Genetic exceptionalism. Too much of a good thing?" *Genetics in Medicine* 10(7): 500-501.

[20] Diergaarde B. et al., "Genetic Information: Special or Not? Responses From Focus Groups With Members of a Health Maintenance Organization," *Am J Genet Part A*, 143A: 564-569, 2007.

[21] PHG Foundation: Consultation Response- Medical Profiling and Online Medicine: The Ethics of 'Personalized' (continued...)

where new biomarkers move from discovery to DTC provision with no intervening period of gradual adoption by the medical profession."[22] In this case, an exceptionalist approach could lead to a different level of protection for consumers seeking DTC genetic testing as opposed to those seeking non-genetic DTC testing results.

Considerations Regarding Uptake/Utilization of Genetic Technologies and Participation in Genetic Research

Prior to the passage of GINA, experts often asserted that without genetic-specific legislation in place, individuals would not utilize and, therefore, may lose out on, the clinical and other benefits of new genetic technologies out of concern about misuse of their genetic information. In addition, these experts maintained that without protections in place, genetic research would be stifled.[23] It is possible, however, that genetic exceptionalist laws, GINA included, might reinforce perceptions among the public that genetic information is special, unique, or deterministic and that this might affect the utilization of genetic technologies or participation in genetic research. Although many argued that protections were needed to encourage participation in genetic research and the uptake of genetic technologies and tests, it is possible that reinforcing the notion that genetic information is uniquely powerful (i.e., has such high potential for misuse that it requires its own special protections) might have the unintended consequence of decreasing participation in genetic research or decreasing utilization of genetic tests that could guide treatment. This is especially potentially a concern if GINA is perceived by the public to be weak or lacking thoroughness in the protection it offers.

The passage of GINA may provide an opportunity to assess what effect, if any, taking an exceptionalist approach has had on public opinion regarding uptake/utilization of genetic technologies and participation in genetics research. Limited data are available addressing the potential impact of GINA on consumers' decisions to undergo genetic testing. A 2008 survey on personalized medicine found that while 28% of respondents said the passage of GINA made it either more, or somewhat more, likely that they would undergo genetic testing, 68% stated that the passage of GINA would have no effect on their decision to have genetic testing performed.[24] A 2010 survey carried out by Cogent Research indicated that general concern about access to genetic information is more likely now than it was in 2008 to deter utilization of a genetic test (37% in 2010 vs. 30% in 2008).[25]

A series of town hall meetings conducted across the country by the Genetics and Public Policy Center (GPPC) evaluated Americans' attitudes toward research on genes, environment, and health. Three of the five meetings were conducted before the passage of GINA; two were conducted after its passage. GPPC reported that concern about the potential for the misuse of genetic information was significant, and that no difference in the level of concern about potential

(...continued)

Healthcare in a Consumer Age. See http://www.phgfoundation.org/file/4720.

[22] Hogarth, S. "Myths, Misconceptions and Myopia: Searching for Clarity in the Debate about the Regulation of Consumer Genetics." *Public Health Genomics* 13: 322-326, 2010.

[23] Slaughter L.M., "Your Genes and Privacy," *Science*, 316(5826): 797, 2007.

[24] Burrill & Company/Change Wave Research. Personalized Medicine and Wellness Survey (2008). Accessed at http://www.burrillandco.com/content/CWSurvey_61708.pdf on July 1, 2010.

[25] Ibid.

misuse was noted between meetings held prior to, and those held after, the passage of GINA. Specifically, participants were concerned that health insurers might be able to access information used to conduct this research.[26]

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[26] Center for Genetics and Public Policy. "The Genetic Town Hall. Public Opinion about Research on Genes, Environment, and Health." Accessed at http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Reports/Genetics_and_Public_Policy/2009PCPTownHalls.pdf on July 1, 2010.