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NEWS AND VIEWS

Harnessing the Human Genome Through Legislative Constraint

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Abstract:
The awesome predictive power of genetic medicine promises great advancements in not only the treatment of identifiable conditions but the prevention of their pathological manifestations. At the same time, the release and dissemination of this genetic or medical information poses a distinct risk of loss of privacy and stigmatization to carriers of genetic disorders. In order to safeguard the individual right of autonomy, privacy, confidentiality and informed consent—yet accommodate the legitimate interests of employers and insurers to obtain medical information relevant to their professional needs and economic responsibilities—a balance must be struck legislatively at the federal and state levels of government.

Key words:
American legislative efforts to prevent genetic discrimination.

1. Introduction

In 1973, Theodosius Dobzhansky warned that there was no better way to attack the goal and the standard of social equality than to demonstrate that since people are innately genetic they are therefore irremediably diverse and unlike. Human equality, however, should be recognized and tied not to bodily or even mental characteristics but, rather, to an appreciation and acceptance of the fact that it is more correctly to be found, achieved and honoured through protection of those fundamental rights which arise from the very sacredness of life, itself, and are realized within every human being.

While abundant fears mark the pathways for the development of the New Biology, humanity's dehumanization and depersonalization will not be fostered—in reality—as a consequence of the continuing quest for mastery of the genetic code through pursuit of the Human Genome Initiative. Indeed, if actions are undertaken and performed here with the goal of minimizing
human suffering and maximizing the social good, then the noble integrity of evolutionary and genetic progress will be preserved and the "slippery slope" of careless and irrational action will be avoided totally.

Obviously, attendant to the freedom to undertake research into the exciting frontiers of the New Biology is a co-existent responsibility to pursue the work in a reasonable and rational manner. The real—although often exaggerated—threats to genetic privacy, and the resulting forms of genetic discrimination, posed as a consequence of research in this field, can be contained by careful development and application of legal norms through legislative schemes at the state and federal levels of government. In partnership, law and science should seek to develop a contemporary agenda for social change that also seeks to fulfil socio-political goals.

When viewed as but a tool for enhancing the health of the nation's citizens, and of engineering humanity's genetic weaknesses out of the line of inheritance, biological determinism is an absolute necessity for trans-national survival in the 21st century. Simply stated, healthier and genetically sound individuals have a much better opportunity for pursuing and achieving the "good life" and making a significant contribution to society's greater well-being or, in other words, social good.

2. Insurance Discrimination

Once genetic testing is offered widely and accurately, it may become quite useful to at-risk individuals if they are enabled thereby to pursue measures designed to reduce their vulnerability to those diseases to which they have been predisposed genetically. Yet, in the crucial interim before widespread testing and successful treatment or cures occur, the acquisition and release of genetic information poses a threat especially to those employed in the work force—namely, a loss of jobs, health insurance and privacy. Prohibiting discrimination based on genetic testing information hence becomes an issue of civil rights and the preservation thereof.

The essential dilemma seen here is actually a hydra-headed one. Thus, if it is known that certain individuals have a predisposition to develop certain genetic diseases over time, they—themselves—will be motivated, most assuredly, to obtain insurance coverage at bargain premiums long before their conditions become manifest seeking thereby to transfer their anticipated financial losses to others. If insurance companies do not have access to this testing information, the very viability of the insurance industry is threatened.

Contrariwise, if genetic test information is revealed to insurance companies, it is likely that the information would be used to discriminate in
underwriting by charging not only higher premiums, but excluding coverage of genetically caused conditions or—for that matter—refusing to offer any coverage at all to the genetically unlucky individuals. To be remembered is the fact that genetic testing is rarely determinative of whether a specific individual will suffer from a disease. Even if determinative tests are achieved, they will be unable to reveal either the severity or time of onset of the actual disease. If, ultimately, loss of all insurance coverage results from disclosures of genetic information, the government will be forced to regulate directly the insurance industry and/or offer governmental insurance for genetically at-risk individuals.

2.1 Genetic Testing Groups and Genetic Information

Genetic tests, in a broad sense, provide information regarding three types of individuals: those who are presently asymptomatic and will probably acquire a range of disabilities from adult-onset conditions (e.g., Huntington’s chorea, amyotrophic lateral sclerosis, adult polycystic kidney disease); those who, while currently asymptomatic, carry a genetic predisposition, which—while not certain—may lead to the development of heart disease, diabetes, and colon cancer, for example; and—finally—those people who, while carrying the genes for conditions such as hemophilia, sickle cell anemia, or Tay-Sachs, will never themselves have the diseases but may pass them to their children. Genetic information, then, can be seen as but one type of medical information—for it is collected in much the same way and, indeed, used for the very same purposes as other such information obtain in medical examinations.

There are legitimate, nondiscriminatory reasons for employers to obtain complete medical (including genetic) information about their current and prospective work force. Many jobs require employees to have demonstrable physiologic, sensory and neurologic abilities. Just as educational prerequisites and skill requirements can be assessed and evaluated, it is by use of a medical examination that physiological limits and predispositions can be determined. When it is realized that health coverage for nearly two-thirds of all who have any kind of health insurance is provided by employers, the magnitude of the economic investment here is simply staggering. Added to this is also valid managerial concern about future risks of potential employee pay-outs in health benefits as future incapacities are factored into the demands of contemporary job profiles.
2.2 Screening Guidelines

Three working principles should be implemented by employers as they develop genetic screening programs in the workplace. First, there should be an understanding even before a screening program is operational that, all ethical issues central to its success must be explored. Second, before any screening is conducted, the individual employees in the program should give their informed consent for participation. Finally, not only should counselling be offered before and after screening occurs, but resources must be set aside for any reasonable intervention which could provide a positive benefit to the individuals who are screened before the actual screening is undertaken.

2.3 The United States Position

In the United States, under current law, employers are not compelled to limit either medical inquiries or examinations to the physical requirements of specific jobs. The implementing regulations of The Americans with Disabilities Act do require that genetic information obtained be not only kept confidential but maintained separately from all other employee personnel records.

Although permitted to collect whatever information thought necessary at the post-offer stage, physicians are supposed to limit their communications to the personnel office solely to that information bearing directly upon the applicant-employee ability to perform enumerated tasks. Yet, employers may nonetheless seek to obtain medical information relevant to an applicant-employees presymptomatic status, genetically caused sensitivity to workplace carcinogens or genetic predisposition to disease—all with the purpose of denying work to applicants or laying off or even discharging present employees whose medical problems are discovered. As more employers become self-insured, even with legislated restrictions imposed upon the release of genetic information, it becomes relatively easy for employers to still learn about the health of their workers and that of their families, by simply reviewing health insurance claims.

Forced disclosure of diagnostic studies to others, against a patient's will, would be recognized as appropriate in those situations where there is either a high probability of harm or where serious harm to identifiable individuals will occur most probably or in those cases where full precautions are followed which seek to limit the ultimate disclosure of only that genetic information considered appropriate to the needs of the particular case.
3. Seeking a Federal and State Legislative Solution

3.1 The Human Genome Privacy Act

In the area of privacy, there have been several legislative proposals which merit study. The Human Genome Privacy Act (HGPA) was introduced before the House of Representatives by Representative John Conyers on September 13, 1990. Although no action was taken on the bill following its introduction, its language responds in many aspects to the problems of confidentiality of genetic information in the workplace. It may be fully expected that similar legislation will be proposed over time. The purpose of the bill was "to safeguard individual privacy of genetic information from the misuse of records maintained by agencies or their contractors or grantees for the purpose of research, diagnosis, treatment, or identification of genetic disorders." The bill would have provided individuals access to records concerning their genome as maintained for any purpose by agencies of the federal government. The language of this proposed legislation may be studied as a potential model for future legislation both at the federal and state levels.

From a policy perspective, the HGPA would overlap with two important federal statutes. In lieu of enacting new legislation, Congress could easily amend either the Americans with Disabilities Act (ADA) or the Privacy Act in order to include relevant provisions of the HGPA. Although addressing analogous discrimination and privacy issues, the ADA and the Privacy Act fall short of extending explicit protection to asymptomatic individuals with abnormal genotypes.

Regarding disabilities under the ADA, the current policy is "can't ask, don't tell." The major uncertainty with this policy is "whether a genetic trait that has not manifested itself counts as a disability within the meaning of the statute."

It would appear that the most fruitful path in the legislative arena would be by amendment to these legislative schemes. As amended, these statutes should recognize the fundamental importance of privacy and equality rights while explicitly extending the protection of these principles to problems of discrimination based on disclosure and dissemination of genomic information. Such amendments to an established statutory framework would simplify the process of effectuating newly enacted protections, rather than establishing a new area of law subject, in turn, to the promulgation of complex regulations and interpretative judicial clarification.
The Genetic Privacy Act was drafted, initially, in 1995 by Professors George J. Annas and Leonard H. Glantz, together with Patricia Roche, of the Health Law Department of the Boston University School of Public Health. A grant from the United States Department of Energy supported this project. A version of this Act entitled, "The Genetic Privacy and Nondiscrimination Act of 1995" was submitted subsequently to the Congress by the then Senator Mark O. Hatfield of Oregon whereupon it was referred to the Senate Law and Human Resources Committee. Representative Clifford B. Sterns of Florida introduced the same bill in the House of Representatives where, in turn, it was referred to the House Committees on Commerce, Economic and Educational Opportunities and Government Oversight. Both of these legislative proposals died in committee.

When legislative proposals "die" in committee, they do so because the chairman of the particular committee to which a bill is assigned, for whatever reasons, chooses not to place the proposed legislation on the committee agenda for a hearing on its merits. When such an action occurs, a bill is stopped effectively for that particular session of the Congress. Alternatively, a recommendation may come from a committee to the full house (or senate), that proposed legislation be "killed" formally or postponed indefinitely and thus not considered. A house vote confirming a committee report or recommendation of this nature has the effect of also officially killing a bill.

The central tenet of the original Genetic Privacy Act is to forbid the acquisition of DNA samples or genetic information about another individual unless, "that individual specifically authorizes the collection of DNA samples for the purpose of genetic analysis, authorizes the creation of that private information, and has access to and control over the dissemination of that information."
Senate Bill 422 entitled, "The Genetic Confidentiality and Nondiscrimination Act of 1997," whereupon it was referred to the Labor and Human Resources Committee. Representative Sterns re-introduced his version of the Genetic Privacy Act, entitled "The Genetic Privacy and Nondiscrimination Act of 1997." Both these bills follow the broad mandates of the original Genetic Privacy Act developed by Professor Annas and his associates.

Under the Domenici draft, Section 201 mandates "a person may disclose genetic information characterized from the DNA sample of an individual only with the written authorization of the individual..." Individuals are, furthermore, given the opportunity to make clear choices regarding the uses to which the tissue they donate for research are put.

When used as part of a research project, a DNA sample may be analyzed only, when for example, an Institutional Review Board has determined such samples are an essential part of a research project, the potential benefit to society of the project outweighs the risks to the research subjects, the research protocol contains adequate safeguards to project against disclosure of genetic information as well as requires an informed consent by the subjects who participate in the project.

This bill also has provisions disallowing any requests or requirements for personal genetic information as a condition of employment or insurance coverage, except for what may be necessary to protect employees from hazards in the workplace. A level of legal liability for employment discrimination based on the unauthorized disclosure of genetic information is set at $50,000.00—with treble damages being assessed in cases where the discrimination has resulted in profit or gain to the employer.

3.4 Limiting the Disclosure of Genetic Information and Safeguarding Women's Health

On March 27, 1996, H.R. 3178 was introduced by Representative Louise M. Slaughter of New York in the United States House of Representatives entitled the "Women's Health Equity Act of 1996." Under Title II of the proposed legislation, Subtitle B, is found the Genetic Information Nondiscrimination in Health Insurance Act of 1996. On April 23, 1996, the duplicate Senate version of the proposed legislation was introduced by Senator Olympia J. Snow of Vermont under the same title as found in Title II of the Health Equality Act.

The Genetic Information Nondiscrimination in Health Insurance Act of 1996 is designed simply to prevent an insurance provider from either requesting or requiring "an individual to whom the provider provides health insurance coverage, or an individual who desires the provider to provide health insurance coverage, to disclose to the provider genetic information
about the individual or family members of the individual. Similarly, no
denial or cancellation of health insurance coverage or a variance in premiums,
terms or conditions for health insurance coverage for an individual or a family
member of an individual is allowed under the Act.

Proceeding to define “genetic information” as information about genes,
gene products, or inherited characteristics, the Act empowers the Secretary
of Health and Human Services to promulgate necessary regulations to effect
the purpose of the proposed legislation and authorizes civil actions and/or
legal relief in monetary damages to enforce it.

Before an insurance company ever seeks to disclose any genetic
information about an individual policy holder, it must have first received prior
written authorization from that individual or from his legal representative.
Each disclosure of information must be accompanied with a specific
authorization and must “include an identification of the person to whom the
disclosure would be made.”

Having died subsequently in committee, the undaunted Representative
Slaughter introduced a similar bill on January 7, 1997, to the 105th Congress
entitled, “The Genetic Information Nondiscrimination in Health Insurance
Act of 1997.” In her introduction of this Bill, she expressed her hope that this
proposal would enable women to take newly developed genetic tests in order
to determine their susceptibility to breast cancer and thereby,
“ensure that no American woman will have to worry that if she takes a
genetic test for BRCA or BRCA 2 breast cancer gene, she will lose her
insurance coverage; or, that if she develops breast cancer, she will be
denied coverage for treatment because her genetic pre-disposition will be
considered a 'pre-existing condition.'

Section Two of this 1997 proposed legislation seeks to amend the Employee
Retirement Income Security Act of 1974 to prevent group health insurance
coverage from being denied, cancelled or refused renewal or from varying the
premiums, terms or conditions on the basis of information or because a
participant or beneficiary has either requested or received genetic services. A
group health plan is forbidden from requesting or requiring either a
participant or a beneficiary to disclose genetic information about a
participant, beneficiary or applicant.

Section Three of the legislation seeks to amend the Public Health Service
Act by requiring that a group health plan or a health insurance issuer offering
health insurance coverage not disclose genetic information about a participant
or beneficiary (or applicant for coverage) without first obtaining the
authorization of anyone seeking to participate in the health plan.

Defining “genetic information” consistent with the previous definition of
it as used in Representative Slaughter's 1996 proposed legislation on genetic nondiscrimination, this new 1997 Bill authorizes individual civil actions for violations of the proposed law and allows for the assessment of compensatory, consequential and punitive damages. On January 21, 1997, Senator Olympia Snow co-sponsored Representative Slaughter's 1997 proposal as Senate Bill 89.

3.5 State Responses

Over the last several years, a number of states have also shown their legislative interests in limiting not only the accessibility to genetic information, but its uses as well. Wisconsin, for example, in 1991 prohibited health insurance from not only requiring or requesting an individual or a member of an individual's family to obtain a genetic test and, furthermore, requiring or requesting directly or indirectly into the results of a genetic test but also forbade conditioning the provision of insurance coverage or benefits on genetic testing as well as considering genetic testing results in determining rates. This approach is considered an exceptionally balanced model—for not only does it seek to integrate protection against discrimination, for example, insurance practices and coverage, but also grants a level of privacy protection for the insured and his family.

Similar approaches to the Wisconsin model have been seen in legislation passed successfully in thirteen states. Rather than focusing on structuring prohibitions against discrimination based on genetic information taken from medical records and physical examinations, these state statutes emphasize controlling the genetic test, itself. Interestingly, task forces or commissions to study the social and legal ramifications of the acquisition and disclosures of genetic information have been organized in Nebraska, Ohio and Virginia.

4. Future Concerns and Potential Resolutions

Until health care is made available in the United States to all citizens regardless of their present or future health status under national health reform, it has been urged that a moratorium on the use of genetic information in insurance underwriting be observed. Alternatively, it is suggested that only single-gene disorders which cause a definite disease (as opposed to genetic predisposition) should not be insured against. Yet another proposal would utilize state created "high risk pools." Thus, while permitting the use of genetic information by insurers in medical underwriting of individuals who are uninsurable medically, these pools would be financed as such by a
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combination of, for example, individual premiums, payments by commercial insurers and state revenues.\textsuperscript{57}

If employers continue to hold a financial stake in the American health care system of the future, the central question to be posited is: "whether changes in health care will simply shift the incentive to discriminate from the insurer to the employer."\textsuperscript{58} To be remembered is the fact that presently "bad insurance risks" are discriminated by life insurance companies with coverage being either denied or provided at much higher premiums for those who either engage in hazardous activities or whose life styles include unhealthy habits such as smoking.\textsuperscript{59} Car insurance coverage premiums are also determined based upon the age, experience, occupation and previous accident convictions of the applicant-insured.\textsuperscript{60} It would require very little for insurance adjusters to consider either long or short term genetic risks in writing a health or life insurance policy.

5. Conclusion

Man's dehumanization and depersonalization will not be fostered as a consequence of the continued quest for mastery of the genetic code. Attendant to the freedom to undertake research into the exciting and fertile frontiers of the "New Biology" is a coexistent responsibility to pursue the work in a reasonable and rational manner. Pursuing the "New Biology" in such a manner requires adequate attention to the safety factor in all aspects of the experimentation.\textsuperscript{61} The undesirable events of a Brave New World can be tempered only when knowledge is pursued with the purpose of establishing the truth and integrity of the question, issue, or process. The vast potential for advancing society and ridding it of a verisimilitude of its present ills is an obvious good which must be pursued steadily. Little sustaining harm can result from a reasonable pursuit of truth and knowledge; for, indeed, truth and knowledge are the basic interstices in any balancing test.\textsuperscript{62} If actions are undertaken and performed with the goal of minimizing human suffering and maximizing the social good, then the noble integrity of evolution and genetic progress will be preserved.

Man must endeavour to execute his investigatory and manipulative or creative powers within the scientific laboratory with a rational purpose and in a spirit of humanism. Man should seek to minimize human suffering, thereby contributing to the social goal of allowing each member of society an equal opportunity to achieve their maximum output within the economic market place, and to maintain personal integrity and seek spiritual tranquillity. Genetic engineering which contributes to the social good should be utilized
fully. There can be no real doubt that genetic manipulation provides a perilous opportunity that may either threaten freedom or enhance it depending upon the balance struck between its use for individual need satisfaction and societal good. The role of the government at both the federal and state level, must be to ensure that this balance be struck and maintained through realistic legislative safeguards. Some government control is needed obviously. The level of governmental oversight must be always tempered with the reality that, as Ralph Waldo Emerson, stated, "The less government we have, the better." 63

Notes
* Professor of Law, The Catholic University of America, Washington, DC, USA. Professor Smith served as a consultant to the International Bioethics Committee of UNESCO as it works toward the completion of a Universal Declaration on the Human Genome and Human Rights. The views expressed in this essay are his own.
2. Idem.
7. Ibid, at p. 162.
8. Ibid, at p. 166.
10. Supra note 6 at p. 162.
11. Idem.
13. Supra note 6 at p. 166.
18. Idem, supra note 16.


34. Ibid., Sec. 501.

35. Ibid., Sec. 401.

36. Ibid., Sec. 402.

37. Ibid., Sec. 701(f).

38. S.1694.

39. Ibid., Sec. 2(B)(1).

40. Ibid., Sec. 2(A)(3).

41. Ibid., Sec. 2(E)(3).

42. Ibid., Sec. 2(C)(3).

43. Ibid.

44. Ibid., Sec. 2(B)(2).


47. Idem, *supra* note 42. See Sec. 3(1)(c) of the 1997 Bill.

48. Sec. 3(b)(2)(c) of the 1997 Bill.


52. Ibid., at pp. 314—15.

53. Ibid., at p. 313.

54. Ibid., at p. 317.


56. Idem.
59. Rogers & le Bousinger, supra note 57 at p. 141.
60. Idem.