

Title	Privacy of Genetic Information
Author(s)	Setoyama, Koichi
Citation	Osaka University Law Review. 2005, 52, p. 75-105
Version Type	VoR
URL	https://hdl.handle.net/11094/8602
rights	
Note	

Osaka University Knowledge Archive : OUKA

<https://ir.library.osaka-u.ac.jp/>

Osaka University

Privacy of Genetic Information

*Koichi SETOYAMA**

Content

- I. Introduction: Human Genome Project**
- II. Legal Issues Over the Availability of Genetic Information**
- III. Genetic Privacy**
 - A. Four Meanings of Genetic Privacy**
 - B. Model Genetic Privacy Act of 1995**
 - C. Interests at Stake in Legal Policy over Genetic Privacy Protection**
- IV. Nature of Genetic Information**
 - A. Genetic Exceptionalism**
 - B. Critical Review of Genetic Exceptionalism**
- V. Conclusion**

I. Introduction: Human Genome Project

Now we are in the beginning of the twenty-first century. What is one of the most controversial issues in law and society in countries all over the world in this new century? It may not be an exaggeration to say that the issues over genetic

* Koichi SETOYAMA, Lecturer and Foreign Student Advisor at the Graduate School of Law and Faculty of Law, Osaka University. M.L.I., LL.M., S.J.D. Dissertator at the University of Wisconsin Law School, U.S.A.

This paper is a part of my LL.M. thesis submitted to the University of Wisconsin Law School U.S.A. in summer 2002, in partial fulfillment of the requirement for the degree of Master of Laws. Although the original thesis has been modified to some extent, in general the content is not revised nor updated at this time.

technology and the human genome are definitely one of them. In the USA, it is often stated that “[d]iscoveries of genetic information could be the civil rights battle of the next [21st] century.”¹⁾

The scientific implantation of genetic issues dates back to about a half century ago. In 1953, James Watson and Francis Crick discovered the double helix structure of DNA (Deoxyribonucleic Acid), the basic building block of life.²⁾ Now, it is widely known that the genome is the pattern of DNA that codes for proteins and physical processes.³⁾ Our hereditary information is transmitted from generation to generation by molecules of DNA⁴⁾. According to a report, genetic disease is responsible for 20% of infant death and is the leading cause of death in the 1-to-4 year old age group and genetic disorders account for 25-30% of acute care hospital admissions of persons under 18 and about 13% of adult admission.⁵⁾ Scientists are increasingly learning what people seldom think of as genetic—conditions as diverse as cancer, heart disease, schizophrenia, and alcoholism.⁶⁾ And the rapid development of biotechnology and the human genome, and strong social awareness about the implications of elucidating the human genome have been initiated since the Human Genome Project (HGP) was launched in October 1990. It is an international collaboration research effort in which nearly 20 countries are involved in order to map the genes on the twenty-three human chromosomes that are made

-
- 1) This is a phrase which is quoted as an introductory epigraph in his Note by Burk Burnett. Burk Burnett, Note, *Genetic Discrimination: Legislation Required to Keep Genetic Secrets*, 21 SETON HALL LEGIS. J. 502 (1997); the original statement made by Rep. Cliff Stearns, 142 Cong. Rec. H2845 (daily ed. Mar.26, 1996).
 - 2) James Watson and Francis Crick, *Molecular Structure of Nucleic Acids: A Structure for Deoxyribose Nucleic Acid*, 171 NATURE 737 (1953); James Watson, *DOUBLE HELIX: A PERSONAL ACCOUNT OF THE DISCOVERY OF DNA* (1968).
 - 3) See Sonia M. Suter, Note: *Whose Genes Are These Anyway? : Familial Conflicts over Access to Genetic Information*, 91 MICH. L. REV. 1854 n3 (1993).
 - 4) The structure of DNA consists of two long strands coiled around one another to form a double helix. Variability within the molecule is provided by four different bases: adenine (A), guanine (G), thymine (T), and cytosine (C). See REPRODUCTIVE GENETICS AND THE LAW I (George J. Annas & Sherman Elias eds., Year Book Medical Publishers, Inc. 1987).
 - 5) CASES AND MATERIALS ON LAW AND MEDICINE 803-04 (Walter Wadlington et al., 1980) (relying on U.S. DEPARTMENT OF HEW, PUBLIC HEALTH SERVICE, NATIONAL INSTITUTES OF HEALTH DRAFT, CONSENSUS DEVELOPMENT CONFERENCE ON ANTENATAL DIAGNOSIS, TASK FORCE REPORT: PREDICTORS OF HEREDITARY DISEASE OR CONGENITAL DEFECTS (1979)).
 - 6) Lori A. Whittaker, *The Implications of the Human Genome Project for Family Practice*, 35 J. FAM. PRAC. 294 (1992).

up of our DNA and determine the location of all human genes.⁷⁾ The U.S. Congress funded the Human Genome Project \$3,000,000,000, to map and sequence the entire human genome.⁸⁾ The main goal of the project was to identify all the approximately 30,000-35,000 genes in the human DNA and identify the genetic disorders which cause diseases and eventually prevent or cure such genetic diseases.⁹⁾ The project was originally planned to complete its task in 2005. However, rapid technological advances have accelerated its speed in mapping the genetic sequences. It is not far from our memory that in June 2000, former President Clinton announced that the International Human Genome Project and Celera Genomics Corporation have completed an initial sequencing of the human genome (the genetic blueprint for human beings).¹⁰⁾ And on February 12, 2001, the international HGP public consortium announced the publication of a draft sequence which covers more than 90 percent of the human genome—the genetic blueprint for a human being and the result of initial analysis, the content of which appeared in the February 15 issue of the journal *NATURE*.¹¹⁾ And on April 14th, 2003, exactly in the 50th year anniversary of the discovery of the DNA double helix, the sequencing of the human genome was completed¹²⁾. It was two years earlier than the originally planned schedule.

II. Legal Issues Over the Availability of Genetic Information

With the beginning of the twenty-first century, the frontier of biotechnology and our world has literally entered into the new genetic era. While findings of the

7) For details of the Human Genome Project, see < <http://www.ornl.gov/hgmis/>>; <http://www.nhgri.nih.gov/About_NHGRI/>; Oak Ridge National Laboratories, Human Genome Project Information, Frequently Asked Questions, available at <http://www.ornl.gov/hgmis/faq/faqsl.html> (last modified Feb. 15, 2002).

8) Funding for the Project began in 1990 and it was completed in 2003. See James D. Watson, *The Human Genome Project: Past, Present, and Future*, 248 *SCIENCE* 44 (1990).

9) Sonia M. Suter, Note: *Whose Genes Are These Anyway? : Familial Conflicts over Access to Genetic Information*, 91 *MICH. L. REV.* 1854 (1993).

10) The White House Office of the Press Secretary, *President Clinton Announces the Completion of the First Survey of the Entire Human Genome*, June 25, 2000. Available at <<http://www.ornl.gov/hgmis/project/clinton1/htm>> (last visited July 1, 2002).

11) <http://www.ornl.gov/hgmis/project/feb_pr/summary_of_sequence.html> (last visited July 1, 2002); <http://www.ornl.gov/hgmis/project/feb_pr/initial_sequencePR.html> (last visited July 1, 2002); <http://www.ornl.gov/hgmis/project/feb_pr/physical_map.html> (last visited July 1, 2002).

12) <http://www.ornl.gov/sci/techresources/Human_Genome/project/timeline.shtml> (last visited December 21, 2004).

Human Genome Project brings about tremendous medical benefits such as the possibility of genetic therapy and prevention of human diseases caused by the defects of DNA, on the other hand, it also raises serious social problems such as genetic discrimination in employment and insurance, etc. The new advancement of genetic technology removes the "veil of ignorance" concerning the individual's future illness and life span. The Human Genome Project has already opened the door of Pandora's Box of the genetic secret. Inside the unlocked box, there is a "Book of Life," the most fundamental biological information of the human being and we can neither lock the door any longer nor go back to the past. It poses new privacy concerns and discriminations in a variety of social settings. Science-fiction motion picture thriller "Gattaca"¹³⁾ directed by Andrew Niccol describes the possible future world where people are judged by their genes, and the main character Vincent is classified as a genetic underclass citizen on birth and he "struggle[s] to achieve his life's goal of space travel in the face of legal and social barriers."¹⁴⁾ In the real world, our science already has a technology known as Polymerase Chain Reaction (PCR) which can amplify enough DNA from even the back of a stamp.¹⁵⁾ If we got a hair or saliva of a person and asked an institution

-
- 13) Columbia Tri-Star 1997. For descriptions and discussion of the issues explored in the film, see Bob Kurson, *Dabbling in DNA: "Gattaca" Director Exploring Ethics*, CHI. SUN-TIMES, Nov. 16, 1997, at 7-NC, available in 1997 WL 6379554; Kathi Wolfe, *Genetic Engineering: Two Sides of the Coin*, LAS VEGAS REV.-J., Nov. 28, 1997, at 15B, available in 1997 WL 4558846; Roger Ebert, *Future Tense: "Gattaca" Sees Flaws in a Perfect World*, CHI. SUN-TIMES, Oct. 24, 1997, at 35, available in 1997 WL 6375250; Rene Downing, *'Gattaca' Premise: Future's Not in Stars, but in Our Genes*, ARIZ. DAILY STAR, Nov. 20, 1997, at 1C, available in 1997 WL 7934923. "Gattaca, whose title is comprised of the letters G, T, C, and A, which represents the four nitrogenous bases making up deoxyribonucleic acid (DNA), is a 'vision of a possible high-tech-militarized-corporate future' with elements of Aldous Huxley's 'social-control dystopia,' Brave New World." See, *id.*
- 14) Peter H. W. van der Goes, Jr., *Comment, Opportunity Lost: Why and How to Improve the HHS-Proposed Legislation Governing Law Enforcement Access to Medical Records*, 147 U. PA. L. REV. 1009, 1010 n5 (1999).
- 15) Thomas H. Murray, *Genetic Exceptionalism and "Future Diary": Is Genetic Information Different from Other Medical Information?*, in GENETIC SECRETS: PROTECTING PRIVACY AND CONFIDENTIALITY IN THE GENETIC ERA 60, 60 (Mark A. Rothstein ed., Yale Univ. Press 1997) (giving an episode that the FBI investigation laboratories had conducted analysis of samples connected to the bombing in 1993 of the former World Trade Center in Manhattan and they had an envelope in which an incriminating document had been sent. By using the polymerase chain reaction technique, they amplified enough DNA from the back of the stamp to link it with one of the chief suspects through a genetic fingerprint and found that someone else had licked the envelope itself.)

which has the technique to decode genetic information to test genetic diseases, we could find out the genetic fingerprint of that person. The possibility of misusing genetic information for non-medical purposes tremendously increases. Therefore, it seems urgent to ban genetic tests without informed consent by law and protect the genetic privacy of individuals in order to guarantee that genetic information will be used to maximize the medical benefits such as diagnosis, prevention and treatment of diseases, etc., and not used to discriminate or stigmatize against genetically unlucky persons or groups. This genetic technology raises many new unexpected social, ethical and legal issues. Responding to these concerns, the U.S. Department of Energy (DOE) and the National Institutes of Health (NIH) have “devoted 3% to 5% of their annual Human Genome budgets toward studying the ethical, legal, and social issues (ELSI) surrounding the availability of genetic information.”¹⁶⁾

All that we can possibly do after having unlocked the door of Pandora’s Box is to minimize the unintended adverse consequences of the HGP. Legal professionals are facing many new legal issues posed by new genetic technology and the completion of the HGP, for example, reproductive genetics such as preconception genetic testing, prenatal diagnosis and selective abortion; patent issues over the new findings of DNA products and diseases, and the like. Genetic information and technology may also be used by a variety of entities in the many legal settings for nonmedical purposes: in insurance (in the underwriting process, setting premiums, coverage, etc.); in employment (in the decisions of hiring, promotion, fringe benefits, etc.); in commercial transactions (loans, mortgage, credit cards, etc.); in forensics or criminal justice (identification of dead bodies of the victims in criminal settings or in the war, investigating criminal suspects, using defendant’s genotype as a defense or in parole hearings, etc.); in litigation (determination in parentage or heirship, medical malpractice, and other causes of action based on genetic medicine, proof of causation in personal injury cases, in assessing compensatory damages, child custody disputes, adoption proceedings, etc.); in education or school (especially professional schools such as medical or law schools, etc.).¹⁷⁾

16) Human Genome Project Info., Ethical, Legal, and Social Issues (ELSI) of the Human Genome Project, at <http://www.ornl.gov/hgmis/elsi/elsi.html> (last visited July 2, 2002).

17) For an overview of these legal issues regarding the nonmedical uses of genetic information, see, e.g., Mark A. Rothstein, *The Use of Genetic Information for Nonmedical Purposes*, 9 J.L. & HEALTH 109 (1994-1995) (classifying nonmedical uses of genetic information into eight categories: (1) identification, (2) employment, (3) insurance, (4) commercial transactions, (5) domestic relations, (6) education, (7) criminal justice, and (8) tort litigation.); also see Mark A. Rothstein, *Recommendations: Genetic Secrets: A Policy Framework*, in GENETIC SECRETS: PROTECTING PRIVACY AND CONFIDENTIALITY IN THE GENETIC ERA 451 (Mark A. Rothstein ed., Yale Univ. Press 1997) and their accompanying texts.

Genetic discrimination has occurred and will occur in the variety of fields in the above-enumerated list. However, discussing each of the genetic discrimination issues is beyond the scope of this thesis. As a preliminary examination to discuss the genetic discrimination issues, in this paper I will clarify the meaning of genetic privacy which is the central concept for protection in the issues of genetic discrimination. I will identify the meaning and scope of genetic privacy by referring to the observations made by scholars and the model Genetic Privacy Act of 1995. Also I will identify the competing interests that need to be balanced in formulating a comprehensive genetic privacy protection policy; on one hand, the individuals' interests such as protection of individuals' social and economic well-being, the individuals' psychological interests, relational (family) interests, and autonomy, while on the other hand, social interests such as the promotion of scientific research, public health or safety, and economic efficiency. The main purpose of this paper is to demonstrate what kind of genetic privacy is put in danger by genetic discrimination and to delineate the compelling reasons why genetic discrimination should be legally banned. I will explain how genetic discrimination undermines not only genetic privacy but also the goal of the Human Genome Project, and public benefits and social interests. In order to explore an appropriate legal policy for genetic discrimination issues, it seems indispensable to identify the nature and the unique characteristics of genetic information. Before discussing this issue, the meaning of genetic privacy will be examined in the following sections.

III. Genetic Privacy

When we explore genetic discrimination issues, genetic privacy is the key concept because the interests at stake to be protected from genetic discrimination are derived from this concept. I will clarify the meaning and scope of genetic privacy and also refer to the model Genetic Privacy Act of 1995. The concept of "privacy" is a huge concept and has many meanings. There has been a great number of scholarly works and explanations about "privacy" in American legal theory and the jurisprudence of the courts but I will not review them in this paper, since it is beyond the scope of this thesis. Rather, for the purpose of this paper, it is beneficial to identify the meaning of "genetic privacy" in the light of genetic discrimination.

A. Four Dimensions of Genetic Privacy

Anita L. Allen identifies the meanings of genetic privacy. Allen observes that “[w]hen used to label issues that arise in contemporary bioethics and public policy, ‘privacy’ generally refers to one of four categories of concern.”¹⁸⁾ Allen describes current patterns of linguistic usage of genetic privacy by categorizing them into (1) informational privacy; (2) physical privacy; (3) decisional privacy; and (4) proprietary privacy.¹⁹⁾

(1) Informational privacy includes the concept of confidentiality, secrecy, anonymity and fair information practice and mainly “concerns about access to personal information.”²⁰⁾ She states that “[s]ubstantial limits on third-party access to confidential, anonymous, or secret genetic information are requirements of respect for informational privacy.”²¹⁾ Mark A. Rothstein also notes that “[t]he essence of informational privacy is controlling access to personal information.”²²⁾ When we discuss about genetic discrimination, the typical third party is insurance companies or employers.

(2) Physical privacy is the dimension of “concerns about access to persons and personal spaces.”²³⁾ It is “at issue in relation to population [genetic] screening or the [genetic] testing of adults without informed consent.”²⁴⁾ It “underlies concerns about genetic testing, screening, or treatment without voluntary and informed consent.”²⁵⁾ In other words, it is related to “issues of bodily integrity surrounding genetic testing.”²⁶⁾

(3) Decisional privacy is the category that refers to “concerns about governmental and other third-party interference with personal choices.”²⁷⁾ It is the dimension which is related to “issues of the right to make autonomous health

18) Anita L. Allen, *Genetic Privacy: Emerging Concepts and Values*, in *GENETIC SECRETS: PROTECTING PRIVACY AND CONFIDENTIALITY IN THE GENETIC ERA* 33 (Mark A. Rothstein ed., Yale Univ. Press 1997).

19) *Id.* at 41-47.

20) *Id.* at 33.

21) *Id.*

22) Mark A. Rothstein, *Genetic Secret: A Policy Framework*, in *GENETIC SECRETS: PROTECTING PRIVACY AND CONFIDENTIALITY IN THE GENETIC ERA* 453 (Mark A. Rothstein ed., Yale Univ. Press 1997).

23) Allen, *supra* note 18, at 33.

24) *Id.* at 46.

25) *Id.* at 34.

26) Rothstein, *Recommendations: Genetic Secret: A Policy Framework*, at 453.

27) Allen, *supra* note 18, at 33.

choices based on genetic information.”²⁸⁾ Allen states that “[a] degree of choice with regards to genetic counseling, testing, and abortion are requirements of respect for decisional privacy.”²⁹⁾

(4) Proprietary privacy is the class of “concerns about the appropriation and ownership of interests in human personality.”³⁰⁾ It “encompasses issues relating to the appropriation of individuals’ possessory and economic interests in their genes and other putative bodily repositories of personality.”³¹⁾

Informational privacy is the main privacy interest which is infringed by genetic discrimination because insurers’ and employers’ access to genetic information is the very issue at stake in genetic discrimination. However, the scope of genetic privacy is not limited to this category. When insurance companies require genetic testing as a condition to obtain insurance policy or employers request genetic tests as a condition for final job offer and screening employees, physical privacy is also threatened.

Decisional privacy is also a very important genetic privacy interest which is exposed to danger by genetic discrimination. The crucial personal decision of whether to undergo genetic tests or not itself is a very important aspect of decisional privacy. The right not to know one’s own genetic information should be protected. For example, if there is no medical technique to cure a specific genetic disease, such as Huntington’s disease, some people may not want to know their future fate and short life span.³²⁾ However, if insurance companies and employers are allowed to request genetic tests as a condition of insurability or employment, decisional privacy is likely to be threatened because it infringes and denies the right not to know one’s ultimate personal information and undermines one’s decision not to take genetic tests. Furthermore, as will be discussed later, because of the nature of genetic information, taking genetic tests sometimes reveals that other blood family members also have a high possibility of being affected by the same genetic disorder as the person who took the genetic tests. Therefore, forcing genetic tests as a requirement of insurability or employment may not only infringe the right not

28) *Id.*

29) *Id.* at 34.

30) *Id.* at 33.

31) *Id.*

32) The suicide rate is four times greater among patients diagnosed with Huntington’s disease than among the corresponding American Caucasian population. See Lindsay A. Farrer, *Suicide and Attempted Suicide in Huntington Disease: Implications for Preclinical Testing of Persons at Risk*, 24 AM. J. MED. GENETICS 305, 305-11 (1986).

to know the genetic misfortune of the person who took genetic tests but also some of his or her family members' right not to know.

Moreover, if there is no legal protection to prevent genetic discrimination, for fear of losing health insurance or being unable to obtain insurance or employment, the people are hesitant and reluctant to undergo genetic tests which are extremely beneficial to early detection of their genetic disorders, if any, which may cause serious genetic diseases, such as breast and ovarian cancers caused by the BRCA1 gene. As a consequence, the people with genetic disorders lose an important opportunity to make their lifestyle change and to take regular medical examinations which detect cancer at an early stage and receive necessary medical treatment to save their lives. In this context, strong fears of genetic discrimination affect peoples' decisions to take genetic tests and therefore restrict peoples' right to know their own genetic information.

Indeed, to prevent the chilling effect of undergoing genetic tests is one of the main arguments to support legal prohibition on the insurers' use of genetic information in the insurance underwriting process.

B. Model Genetic Privacy Act of 1995

In the USA, one of the initial models in drafting current genetic privacy and genetic anti-discrimination legislations is the model Genetic Privacy Act of 1995 (Hereinafter MGPA).³³⁾ MGPA was a proposal for federal legislation. Originally, it was drafted as a federal statute to provide uniformity across state lines. However, the Act also has been used as guidelines by individual states.³⁴⁾

MGPA was designed to protect individual genetic privacy while permitting medical uses of genetic analysis, legitimate research in genetics, and genetic analysis for identification purposes.³⁵⁾ Therefore, the main goal of MGPA is to balance these important interests at stake. MGPA is thoughtfully and comprehensively drafted and defines many terms, followed by a detailed

33) George J. Annas, Leonard H. Glantz & Patricia A. Roche, *Genetic Privacy Act and Commentary*. The model Genetic Privacy Act of 1995 is the final report of a project entitled "Guidelines for Protecting Privacy of Information Stored in Genetic Data Banks" which was funded by the Ethical, Legal & Social Implications of the Human Genome Project, Office of Energy Research, U.S. Department of Energy, No. DE-FG02-93ER61626. This act and commentary is available at http://www.ornl.gov/TechResources/Human_Genome/resource/privacy/privacy1.html (last visited July 12, 2001).

34) *Id.* at 5.

35) *Id.* at 5-6.

commentary.

George J. Annas, one of the drafters of MGPA, summarizes the core provisions of the Act:

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."³⁶⁾

Here, it is useful to observe the objectives of the bill for the purpose of this paper. Mark A. Rothstein suggests eight key policy goals "underlying any effort to protect privacy and confidentiality of genetic information."

- (1) preventing at-risk individuals who want to undergo genetic testing from being dissuaded from doing so because of a fear that the information generated by the tests may be used to their detriment;
- (2) preventing individuals from being coerced into genetic testing;
- (3) preventing individuals untrained in genetics, both laypeople and health professionals, from making decisions based on genetic information, which they may misinterpret;
- (4) conserving medical resources by preventing genetics professionals and medical technologies from being used for inappropriate nonmedical purposes;
- (5) preserving the quality of genetic testing and counseling by limiting their use in nonclinical settings, where testing may not be of the best quality and counseling may not be provided;

36) George J. Annas, *Genetic Privacy: There Ought to be a Law*, 4 TEX. REV. L. & POL. 9, 14-15 (1999).

- (6) conserving human resources by not disqualifying individuals from current activities (such as employment) because of a fear of future illness;
- (7) preventing discrimination based on genetic information;
- (8) preventing genetic reductionism and determinism, in which genetic explanations for health and behavior are predominant factors in evaluating various aspects of human affairs.³⁷⁾

C. Interests at Stake in Legal Policy over Genetic Privacy Protection

When we explore into an adequate legal policy for protecting genetic privacy and preventing genetic discrimination, what kind of competing interests are at stake? In this section, I will consider interests which would be the basic factors to seek an adequate legal policy over privacy protection by referring to the argument delivered by leading scholars in this field.

Lawrence O. Gostin and James G. Hodge, Jr. address the interests at issue over genetic privacy. They argue that the key issue lies in how to reconcile genetic information privacy and collective benefits. They point out several public collective benefits of genetic information: (1) Enhanced Patient Choice; informed individual choices by giving individuals predictive information about their health status; (2) Clinical Benefits: identification of the etiology and physiology of disease; (3) Improved Research: clinical advances to treat genetic diseases; (4) Protection of Public Health: improved public health protection through the use of genetic information to track the incidence, patterns, and trends of genetic carrier states or diseases across populations, thus leading to more effective, targeted prevention.³⁸⁾

Gostin and Hodge present a series of recommendations which reconcile collective benefits of genetic information and privacy risks such as discrimination or stigmatization, etc. According to them, by following these recommendations, legislation can achieve a "carefully crafted balance that manages to respect individual privacy and provide security protections without significantly thwarting the warranted, communal uses of genetic information."³⁹⁾ Their recommendation is what they call "fair information practices or principles" which consist of (a)

37) Mark A. Rothstein, *Recommendations: Genetic Secrets: A Policy Framework*, at 451-52.

38) Lawrence O. Gostin & James G. Hodge, Jr., *Genetic Privacy and the Law: An End To Genetics Exceptionalism*, 40 JURIMETRICS J. 21, 22, 37-39 (1999).

39) *Id.* at 53.

Substantive Review; (b) Procedural Review; (c) Control of Personal Health Data; (d) Right to Review and Correct Personal Data; and (e) Use of Data for Intended Purpose. According to Gostin and Hodge, Fair Information Practices mean “fundamental legal and ethical principles concerning individual privacy and information collection that underlie the acquisition, use, and disclosure of identifiable health information.”⁴⁰⁾ Here, let us take a look at each concept in detail respectively.

(a) Substantive Review: One of the fair information principles is substantive review which imposes a burden on the collector of health data “to assert a substantial public interest” and “to demonstrate that it would be achieved.” Gostin and Hodge state as follows.

Information should only be collected when the need for the information is *substantial*, the collection of the data would actually achieve the *objective*, the purpose could not be achieved without the collection of identifiable information, and the data would be held only for a period necessary to meet the valid objectives.⁴¹⁾

(b) Procedural Review: Gostin and Hodge state that procedural review also should be required in collecting health information: “[D]ecisions to create health databases . . . ought to require *procedural review*. Some mechanism for independent review by a dispassionate, expert body would provide a forum for careful examination of the justification for the collection of data, the existence of thoughtful consent procedures, and the maintenance of adequate privacy and security.”⁴²⁾

(c) Control of Personal Health Data: Moreover, fair information principles require that “individuals about whom data are collected must be afforded the right to know about and, to a meaningful extent, control the uses of those data.”⁴³⁾ In other words, it should be guaranteed that “individuals have a legitimate claim to information about: (1) how privacy and security will be maintained; (2) how to access and review records; (3) the length of time that the information will be stored and the circumstances under which it would be expunged; (4) third parties who are authorized access to the data; and (5) future secondary uses.”⁴⁴⁾

(d) Right to Review and Correct Personal Data: Fair information principles also

40) *Id.* at 54.

41) *Id.* (emphases added).

42) *Id.* at 54-55 (emphasis added).

43) *Id.* at 55.

44) *Id.*

require that “individuals have the right to see data about themselves and to amend inaccurate or incomplete record. This right respects a person’s autonomy and better assures the accuracy of data.”⁴⁵⁾ And an individual “must be fully informed about the content and meaning of any genetic analysis—past, current, or future.”⁴⁶⁾ Therefore, “[i]f the tissue [collected and stored] were used in the future to predict an unrelated condition in the donor, she would have to consent and would have to access to any new information derived from that particular genetic analysis.”⁴⁷⁾

(e) Use of Data for Intended Purpose: Finally fair information principles require that possessors of genetic information of somebody else “have an obligation to (1) use health information only for limited purposes, (2) disclose information only for purposes compatible with the purpose for which the data were obtained, (3) curtail disclosure to the minimum necessity to accomplish the purpose, and (4) account for any disclosures.”⁴⁸⁾

Madison Powers also examined competing interests that need to be taken into account in formulating a comprehensive genetic privacy protection policy.⁴⁹⁾

According to Powers, in the traditional picture, “individual interests widely cited on behalf of privacy protection policies are contrasted with various social interests in making more information readily accessible to other individuals or institutions for the sake of public good.”⁵⁰⁾ Powers identifies four general headings that classify interests that individuals have in genetic privacy protection: (1) the protection of individuals’ social and economic well-being; (2) psychological interests; (3) relational interests; and (4) autonomy.⁵¹⁾

The first heading that Powers suggests is the protection of individuals’ “social and economic well-being.” If there is no restriction on gaining access to genetic information of the individual by a third party, it may create “social stigma and discrimination” against that person and cause “adverse social and economic consequence such as the loss of employment opportunity and insurability.”⁵²⁾

45) *Id.*

46) *Id.*

47) *Id.*

48) *Id.* at 56.

49) Madison Powers, *Justice and Genetics: Privacy Protection and the Moral Basis of Public Policy*, in *GENETIC SECRETS: PROTECTING PRIVACY AND CONFIDENTIALITY IN THE GENETIC ERA* 355 (Mark A. Rothstein ed., Yale Univ. Press 1997).

50) *Id.* at 356.

51) *Id.* at 357-59.

52) *Id.* at 357.

The second interest individuals may have in any genetic privacy policy choice that Powers observes is the “individual’s psychological interests.” The dissemination of genetic information to others “may result in severe emotional distress due, for example, to the perception of social stigma or loss of respect by others.”⁵³⁾ The disclosure of genetic information may create “significant adverse consequences for social standing and sense of self-worth”⁵⁴⁾ and “profoundly affect an individual’s very self-concept and capacity for functioning in society.”⁵⁵⁾

The third interest at stake is what he calls “relational interests.” He notes that “[w]hen genetic information obtained from one patient or subject is revealed to other family members”⁵⁶⁾ without his/her informed consent, “the ability of persons to shape their most intimate relationship is compromised, and the trust and patterns of usual communication within families can be compromised.”⁵⁷⁾

The fourth interest at stake is “autonomy.” Powers states that “[a] crosscutting set of genetic privacy interests comprises the interests individuals have in the protection of their autonomy.”⁵⁸⁾ He asserts that “the ability to make a variety of medical and other personal choices without substantial interference by others often depends on the protection of informational privacy.”⁵⁹⁾ This is because if “learning one’s own genetic status creates legal duties or economic pressure to make such information available to employers or insurers, then an individual’s autonomy within both medical and nonmedical spheres of life may be undermined.”⁶⁰⁾

Another example that Powers gives as undermining interests of autonomy is the adverse affect on one’s reproductive freedom. Powers maintains that “a decision to have children who may develop heritable medical conditions may cause their employer to impose limits on the insurance coverage available to their families.”⁶¹⁾ Therefore, Powers asserts that “[t]he lack of assurances that privacy will be protected also may deter persons from seeking beneficial medical testing and treatment for themselves.”⁶²⁾ This chilling effect that makes people hesitate or refrain from taking beneficial medical testing and treatment is not likely to be

53) *Id.* at 358.

54) *Id.*

55) *Id.*

56) *Id.*

57) *Id.*

58) *Id.*

59) *Id.* at 359.

60) *Id.*

61) *Id.*

62) *Id.*

apparent compared to adverse economic consequence but is a very important factor that should be taken into consideration when examining the genetic privacy and discrimination issues in the insurance and employment settings.

The next question is to identify competing social interests that conflict with these individual interests at stake in privacy protection. Powers observes (1) the promotion of scientific research; (2) public health or safety; and (3) economic efficiency.

Powers states that if “the genetic screening to track the incidence of genetic conditions . . . or carrier status is used to provide individuals with information that they can use to enhance patient choice or improve patient outcomes for themselves or their children,” the benefit society gets as a whole “can be considerable.”⁶³⁾ He maintains that “[s]ome researchers worry that stringent privacy protection policies can have the undesirable effect of reducing the available data crucial for research.”⁶⁴⁾

However, Powers also observes that there is a situation in which, between individual interest and social interest, “potentially conflicting interests can be harmonized” because not only society as a whole, but also “individual patients ultimately stand to benefit from public policies that ensure that genetic information is made available for research purpose.”⁶⁵⁾ He notes:

Research conducted as a result of access to data obtained from both population screening and individualized genetic testing may provide the knowledge basis needed for enhanced patient decision making. Knowledge of genetic susceptibilities may allow patients to make more informed decisions about examinations, diet, behavior, and exposures to environmental hazards. Individuals may benefit from the knowledge gained from genetic research in making such reproductive decisions as preconception planning, preimplantation diagnosis, or deciding whether to terminate a pregnancy.⁶⁶⁾

Hence, making genetic data more readily available to medical researchers will develop new findings and knowledge about genetics, and enhance the possibility of medical treatment to cure or prevent genetic diseases.

I call this argument a “paternalistic argument” for restricting genetic privacy because the core logic of this argument is that permitting access to an individual’s

63) *Id.* at 360.

64) *Id.*

65) *Id.*

66) *Id.* at 360.

genetic information by a researcher ultimately results in benefiting that person in the long run. However, it is sometimes dubious whether the person whose genetic information was accessed would be the person who would receive the benefit because normally there is a time lag in getting the benefit from the research. Also the benefit from the advancement of genetic research will be shared by all members of the society. Therefore, it may have a similar structure as in the situation of taking property by the government which requires just compensation, if genetic information can be regarded as a property right.

Other social interests that Powers observes are “public health or safety” and “economic efficiency.” He gives an example in the workplace and states that “[e]mployers may be able to decrease workplace hazard abatement cost and reduce their financial liability from tort litigation or workers’ compensation for work-related illnesses through selective hiring and placement practices, or reduce the costs of health insurance benefits for their employees by eliminating medically costly employees and reducing available employee health insurance coverage for certain conditions.”⁶⁷⁾ However, Powers asserts that “it is an open question whether important societal interests, such as the promotion of public health or economic efficiency, are arrayed on the side of increasing, rather than restricting, access to genetic information.”⁶⁸⁾

Powers suggests a pragmatic approach to privacy policy. Here it seems to be useful in balancing these various competing interests by referring to his pragmatic approach argument. He asserts that “a pragmatic approach to privacy protection will be required to accommodate the diverse set of interests at stake in a variety of research, clinical, and administrative context.”⁶⁹⁾ According to him, essential to the pragmatic approach is the following recognition.

[A] recognition that the kinds of information that ought to be protected from access, the degree and nature of the protection needed, and the institutional arrangements that determine the contingent importance of privacy will vary, depending upon the kinds of harms threatened by a loss of privacy and the vulnerabilities of persons under any given set of economic and social arrangements.⁷⁰⁾

According to Powers, there are at least two types of policy options which are available for the policy maker:

67) *Id.* at 361.

68) *Id.*

69) *Id.* at 362.

70) *Id.*

Either access to genetic information may be prohibited or restricted through the creation and enforcement of a system of legal rights and duties, or the institutional arrangements themselves may be changed, such that incentives for some to gain access to genetic information to the detriment of others are reduced or eliminated.⁷¹⁾

The first policy option, what he calls “the traditional privacy policy approach,” is “the creation and enforcement of legal right” and “[t]he most stringent types of privacy rights are rights of informational self-determination.”⁷²⁾ Under this approach, “the only feasible way of protecting the interests that give rise to privacy concerns is to create a right to control what information is generated or a right to control subsequent disclosure of, or uses for, information once it is generated and revealed to designated persons for specific purposes.”⁷³⁾

Another option that the policy maker has for protecting genetic privacy is “reconfiguring” or making “substantial modifications of existing institutional arrangement.”⁷⁴⁾ He asserts that “[r]ather than achieving the goal of reducing access to genetic information through a system of legally enforceable rights, the same desired effect may be achieved by making access to such information economically worthless.”⁷⁵⁾ One example of the measures of the genetic privacy protection policy by institutional reform that Powers mentions is a “health care financing policy that eliminates the market incentives for gaining access to genetic information.”⁷⁶⁾

According to him, the choice between these two different alternatives (creating new legally enforceable rights of privacy or adopting institutional reform) is dependent on the following considerations.

[I]f laws restricting employer access to genetic information reasonably require exceptions that allow employer access for purposes other than the determination of insurance eligibility or coverage decisions, then restrictions may be difficult to enforce or easily circumvented. If the financial viability of insurance plans offered by employers or other insurers depends on access to information about medical risks generally, prohibition of one type of risk-related information may not produce an

71) *Id.* at 363.

72) *Id.*

73) *Id.*

74) *Id.* at 363-35.

75) *Id.* at 365.

76) *Id.*

economically stable environment adequate to guarantee solvency and continuity of health insurance. In light of such considerations, policy makers must take seriously the possibility that the most feasible alternative for protecting the interests at stake may be the elimination of a risk-based insurance scheme.⁷⁷⁾

However, Powers did not address any specific answer to the question in regards to what extent legal protection policy over genetic privacy should be required or to what degree the access to genetic information by employer or insurance company or researcher or family members should be limited. This is because he observes that “[t]he variety of interests at stake and complexity of the patterns in which those interests intersect make uniformly applicable solutions impossible.”⁷⁸⁾ Therefore, there is “no single answer to the protection of the interests put at risk by the increased access some persons and institutions have to genetic information.”⁷⁹⁾ However, he goes on to state that “the pragmatic approach does provide useful guidelines for policy makers.”⁸⁰⁾ Then, what is this guideline? He asserts:

When other alternatives for privacy protection are unreliable, the underlying interests of the individual are substantial, and the interests at stake include important aspects of individual autonomy, individual rights of control, both the generation and subsequent disclosure of genetic information, may be the only feasible policy alternative. In other cases, the best vehicle for protecting the interests underlying our concerns about genetic privacy may require changes in the economic and social institutions themselves.⁸¹⁾

His pragmatic approach to privacy policy does not suggest any specific prescription for the policy maker although it suggests a rough guideline in regards to the interests at stake when the policy maker considers an adequate balancing of interests and solves the privacy protection issue. However, his argument shows how difficult it is to reach an appropriate policy over the genetic privacy issue, and he appropriately points out that “[f]undamental issues of justice lie at the core of any policy meant to ensure the protection of genetic privacy.”⁸²⁾ When he mentions “fundamental issues of justice,” he stresses especially “distributive justice and the

77) *Id.* at 364-65.

78) *Id.* at 366.

79) *Id.*

80) *Id.*

81) *Id.* at 366-67.

82) *Id.* at 367.

role of the state in affecting patterns of distribution within society.”⁸³⁾ As Powers points out, there is the fundamental question of political philosophy. Behind the arguments and debates over the legal policies of the genetic discrimination issues in insurance and employment, there is a fundamental theoretical conflict over distributive justice and fairness. To identify the theoretical conflict is beyond the scope of this paper, although this issue has been discussed in my original thesis. Here, it is important to confirm that it is indispensable to consider the underlying legal and political philosophy in examining an appropriate legal policy for genetic privacy and genetic discrimination.

In sum, it is important to confirm the following insights that I have demonstrated. As the main goal of the model Genetic Privacy Act and also as the arguments presented by commentators have demonstrated, the key issue is how to balance and reconcile the interests of individual genetic privacy and the interests of promotion of scientific research and public health or safety. And as has been pointed out, genetic discrimination undermines not only the genetic privacy of the people who are discriminated against but also hinders further development of genetic research and public health. Accordingly, preventing genetic discrimination is one of the prime social agenda of most importance in the twenty-first century. Therefore, legal protections against genetic discrimination are indispensable in order to prevent creating a “genetic underclass,” to preserve the “right to know” and “right not to know” of our own genetic information, to eliminate fear which discourages people undergoing genetic tests or participating in genetic research, and as its result, to develop medicine and biology, and ultimately enhance public health by curing and preventing genetic diseases which will lead to cutting overall health care costs.

As we have seen, the above examination explains the compelling individual and public need to prevent genetic discrimination and to protect genetic privacy legally. However, in order to explore an appropriate legal policy for the genetic discrimination issues, it is also necessary to ask what the nature of genetic information is. In the next section I will examine the so called “Genetic Exceptionalism.”

III. Nature of Genetic Information

The main purpose of this section is to identify the nature and character of

83) *Id.* at 366.

genetic information by reviewing the arguments of “genetic exceptionalism.”⁸⁴⁾

In the Introduction of the model Genetic Privacy Act of 1995, it is stated that “[t]he Act is based on the premise that genetic information is different from other types of personal information in ways that require special protection.”⁸⁵⁾ Virtually all the genetic privacy laws or genetic anti-discrimination statutes and their proponent arguments which assert that genetic privacy requires special protection by law presuppose that genetic information is unique and different from other kinds of personal information. Therefore, one important angle to evaluate legal policy protecting genetic privacy such as the genetic-specific anti-discrimination laws lies in exploring the question of “what is genetic information?”

A. Genetic Exceptionalism

What makes genetic information different from other medical information? George J. Annas, Leonard H. Glantz, and Patricia A. Roche, drafters of the model Genetic Privacy Act of 1995, assert in the Introduction of the Act that “[g]enetic information is powerful and personal. As the genetic code is deciphered, genetic analysis of DNA will tell us more and more about a person’s likely future, particularly in terms of physical and mental well-being.”⁸⁶⁾ They go on to state:

Genetic information is uniquely sensitive . . . [because] [f]irst . . . the

84) See, e.g., Thomas H. Murray, *Genetic Exceptionalism and “Future Diary”: Is Genetic Information Different from Other Medical Information?*, in *GENETIC SECRETS: PROTECTING PRIVACY AND CONFIDENTIALITY IN THE GENETIC ERA* 60 (Mark A. Rothstein ed., Yale Univ. Press 1997); Lawrence O. Gostin & James G. Hodge Jr., *Genetic Privacy and the Law: An End to Genetics Exceptionalism*, 40 *JURIMETRICS J.* 21 (1999); Zita Lazzarini, *What Lessons Can We Learn From the Exceptionalism Debate (Finally)?*, 29 *J.L. MED. & ETHICS* 149 (2001); Glenn McGee, *Foreward: Genetic Exceptionalism*, 11 *HARV. J.L. & TECH.* 565 (1998); Lainie Friedman Ross, *Genetic Exceptionalism vs. Paradigm Shift: Lessons From HIV*, 29 *J.L. Med. & Ethics* 141 (2001); Natalie E. Zindorf, *Comment, Discrimination in the 21st Century: Protecting the Privacy of Genetic Information in Employment and Insurance*, 36 *TULSA L.J.* 703, (2001); Jennifer S. Geetter, *Coding for Change: The Power of the Human Genome to Transform the American Health Insurance System*, 28 *AM. J.L. & MED.* 1 (2002).

85) George J. Annas, Leonard H. Glantz, & Patricia A. Roche, *Genetic Privacy Act and Commentary (1995)* available at <http://www.ornl.gov/TechResources/Human_Genome/resource/privacy/privacy1.html> (last visited Nov. 17, 2000); also available at <<http://www.ornl.gov/hgmis/resource/privacy/privacy1.html>> (last visited June 17, 2002). Also see George J. Annas, Leonard H. Glantz & Patricia A. Roche, *Drafting the Genetic Privacy Act: Science, Policy, and Practical Considerations*, 23 *n4 J. L. MED & ETHICS* 360 (1995); Patricia Roche et al., *The Genetic Privacy Act: A Proposal for National Legislation*, 37 *JURIMETRICS J.* 1 (1996).

86) Patricia Roche et al., *The Genetic Privacy Act: A Proposal for National Legislation*, 1.

information in the genetic code is largely unknown to the person in whose genetic material it is found. Therefore, if this information is obtained by someone else without the individual's permission, another person would learn intimate details of the individual's likely future life. A stranger could, in effect, read the future diary of an individual without even knowing that the diary exists. . . . Second, deciphering an individual's genetic code also provides the reader of that code with probabilistic health information about that individual's family, especially parents, siblings and children. Third, since the DNA molecule is stable, once removed from a person's body and stored, it can become the source of an increasing amount of information as more is learned about how to read the genetic code. Finally, genetic information (and misinformation) has been used by governments to viciously discriminate against those perceived as genetically unfit.⁸⁷⁾

Annas strongly asserts that "genetic information is uniquely private and should be protected by law."⁸⁸⁾ Therefore, it is required to treat genetic information differently and give special legal protection to genetic information.

Thomas H. Murray labeled these arguments "Genetic Exceptionalism."⁸⁹⁾ According to Murray, Genetic Exceptionalism means "the claim that genetic information is sufficiently different from other kinds of health-related information that it deserves special protection or other exceptional measures."⁹⁰⁾ Murray observes three bases of genetic exceptionalism: (1) concern about genetic prophecy; (2) concern for kin; and (3) concern about genetic discrimination.

(1) Genetic prophecy: The reason why it is named "prophecy" is that genetic information is regarded as a "future diary."⁹¹⁾

87) *Id.*

88) George J. Annas, *Genetic Privacy: There Ought to be a Law*, 4 *Tex. Rev. L. & Pol.* 9, 13 (1999) (Technological Innovation & Legal Tradition: Enduring Principles For Changing Times, The Federalist Society 1998 National Lawyers Convention).

89) Thomas H. Murray, *Genetic Exceptionalism and "Future Diary": Is Genetic Information Different from Other Medical Information?* in *GENETIC SECRETS: PROTECTING PRIVACY AND CONFIDENTIALITY IN THE GENETIC ERA*, 60, 61 (Mark A. Rothstein ed., Yale Univ. Press 1997). Murray was the chair of the Task Force on Genetic Information and Insurance of the NIH-DOE Joint Working Group on Ethical, Legal, and Social Implications of the Human Genome Project. And this Task Force used the term "Genetic Exceptionalism" in the above meaning.

90) *Id.*

91) *Id.* at 62. Murray borrows this phrase from Nancy Wexler.

Genetic information “can predict an individual’s likely medical future for a variety of conditions.” . . . DNA [is] a “coded probabilistic future diary because it describes an important part of a person’s unique future and, as such, can affect and undermine an individual’s view of his/her life possibilities. Unlike ordinary diaries that are created by the writer, the information contained in one’s DNA, which is stable and can be stored for long periods of time, is in code and is largely unknown to the person. Most of the code cannot now be broken, but parts are being deciphered almost daily.”⁹²⁾

(2) Concern for Kin: Genetic information “divulges personal information about one’s parents, siblings, and children.”⁹³⁾ “Genetic information about each of us, then, is also to some extent information about our ancestors, descendants, and other such biological relations as sisters and brothers.”⁹⁴⁾

(3) Concern about Genetic Discrimination: This was derived from “a fear of discrimination” by looking back at the history of eugenics which stigmatized and victimized people.⁹⁵⁾

Roger B. Dworkin also points out the differences between gene information and other medical information.⁹⁶⁾

Genetic information is different from other kinds of medical information because although most medical information about a person’s health tells us nothing about anybody else’s health, learning about one person’s genetic makeup often requires learning about someone else, and gaining genetic information about one person inevitably reveals information about others. . . . Genetic information is family information. People seek genetic advice because of concerns about conditions that exist in their family; once learned, the information is relevant to many members and potential members of the family . . . [for example] the diagnosis of a child with a genetic disease reveals information about the child’s parents

92) *Id.* at 62 (quoting George J. Annas, Leonard H. Glantz & Patricia A. Roche, *Drafting the Genetic Privacy Act: Science, Policy, and Practical Considerations*, 23 *n4* J. L. MED & ETHICS 360, 360 (1995)).

93) *Id.* (quoting Annas, Glantz & Roche, *Drafting the Genetic Privacy Act: Science, Policy, and Practical Considerations*, at 365).

94) *Id.* at 62, 65.

95) *Id.*

96) ROGER B. DWORIN, *LIMITS: THE ROLE OF THE LAW IN BIOETHICAL DECISION MAKING* (Indiana Univ. Press 1996).

and the parents' relatives that may be relevant to those persons' reproductive decision making; the diagnosis of a person with a genetic disease reveals information about that person's relatives that may be relevant to their own health; genetic testing to diagnose or confirm the diagnosis of a condition may reveal that a women's husband is not the parent of her child.⁹⁷⁾

Ronald M. Green and Mathew Thomas observe five distinguishing features which make DNA-derived information different from ordinary confidential medical information: (1) informational risk; (2) the longevity of DNA; (3) DNA as an identifier; (4) familial risks; (5) and community impacts.⁹⁸⁾

B. Critical Review of Genetic Exceptionalism

Murray gives an objection against genetic exceptionalism. According to him, the reasons which support genetic exceptionalism are also true of other medical information. He notes that "[g]enetic information is neither unique nor distinct in its ability to offer probabilistic peeks into our future health. Many other things afford equally interesting predictions."⁹⁹⁾ For example, "asymptomatic hepatitis B infection, early HIV infection, and even one's cholesterol level" also "have implications for future health that are every bit as cogent and sensitive as genetic predispositions."¹⁰⁰⁾ Consequently, "genetic prophecy" argument is not compelling.

He also doubts the argument appealing to "concern about kin." He notes: "That one member of a family has tuberculosis is certainly relevant to the rest of the household, all of whom are in danger of infection Likewise, if one partner in a marriage has a sexually transmitted disease, that information is important for the other partner."¹⁰¹⁾ Accordingly, he asserts that "it is difficult to claim uniqueness, or even special importance and sensitivity, for genetic information."¹⁰²⁾

Based on the same reason, Murray criticizes the argument appealing to "concern about genetic discrimination" as a basis for genetic exceptionalism. He argues that

97) *Id.* at 94

98) Ronald M. Green & Mathew Thomas, *DNA: Five Distinguishing Features for Policy Analysis*, 11 HARV. J. LAW & TECH. 571 (1998).

99) Murray, *supra* note 414, at 64.

100) *Id.* at 64.

101) *Id.* at 65.

102) *Id.*

insurers use evidence of current disease or future disease risk—whether it is genetic or nongenetic doesn't matter—to decide who gets a policy, what that policy covers, and how much it costs. Whether this discrimination should be regarded as fair or unfair is debated. But it is difficult to make the argument that it is fair to discriminate on nongenetic factors but unfair to discriminate on genetic ones.”¹⁰³⁾

However, in my view, some of the counter-arguments would seem to have misinterpreted the point of the unique character of genetic information which Murray calls concern about kin. Genetic information can be unique and sensitive not in the sense that it may harm one's family who have not yet undergone genetic tests, both physically and economically by incurring financial damage associated with unemployment or losing insurance or even death of the breadwinner who underwent genetic tests and was found to have genetic defects, or by infecting family members with a contagious disease. But rather it can be unique in the sense that genetic information of a family member may also disclose the rest of the family members' genetic profiles or increase the possibility of their having the same genetic defects, and therefore social stigmatization and discrimination for the rest of the family members would more likely happen than in the case of other non-genetic medical information.

One reason Murray tries to reject genetic exceptionalism is to avoid genetic reductionalism or genetic determinism.¹⁰⁴⁾ He is afraid that genetic exceptionalism would lead to such reductionalism or determinism. Genetic determinism will not be discussed in this paper but I would like to confirm the following matter. Either identifying the uniqueness or sensitiveness of genetic information or giving special protection to genetic information does not necessarily commit to genetic reductionalism or genetic determinism. It means at most, genetic exceptionalism. In my view, one difference between genetic exceptionalism and genetic reductionalism or genetic determinism is that the former implies that genetic information is unique and has its own special nature but the latter rejects environmental factors which cause genetic diseases and regards human beings as the sum of our genes. Undoubtedly, genetic exceptionalism does not go as far as to assert to that extent. As we have seen, Murray does not support genetic exceptionalism. He concludes that genetic information does “not differ substantially from other kinds of health-related information.”¹⁰⁵⁾

103) *Id.*

104) *Id.* at 69-72.

105) *Id.* at 61.

When we consider the nature and features of genetic information, it is important to take the different types of genetic diseases into account. In regards to this, it is useful to understand different types of genetic anomalies which can cause many diseases. Eric Mills Holmes classifies them into four different types.

(1) Monogenic or single gene disorders. Some diseases may be caused by one improperly functioning gene... This type of disorder is characterized by a pattern of transmission in a family. If an abnormality is evident when only one of the chromosomal pair contains the variant gene, the disorder is termed a dominant single gene order. . . . If the disease manifests itself only when both of the chromosomal pair possess the variant gene, it is termed a recessive single gene disorder. The recessive disorder occurs when an affected person inherits a mutant gene from each parent, often even though neither parent has the disease. . . . Common examples are sickle-cell anemia . . . and cystic fibrosis . . . [and] there are about 3600 different identified disorders.¹⁰⁶⁾

(2) Chromosomal disorders. Other diseases result from visible aberrations in chromosome structure or number[] . . . These disorders account for a significant percentage of birth defects, mental retardation, and miscarriages. . . . Disease results because there is either a missing or an extra chromosome which results in physical or mental maldevelopment." These disorders account for a significant percentage of birth defects, mental retardation, and miscarriage. [e.g. Down's syndrome] ¹⁰⁷⁾

(3) Multifactorial disorders. . . . these disorders result from the interaction of environmental factors and many abnormal genes presumably on different chromosomes. Examples include asthma, epilepsy, coronary heart disease, diabetes mellitus, multiple sclerosis, schizophrenia, some sort of arthritis and emphysema.¹⁰⁸⁾

(4) Non-Inherited disorders: [These are diseases] resulting from genetic changes occurring during one's life that are not inherited disorders. . . . This change can happen when genes are damaged or if external factors

106) Eric Mills Holmes, *Solving the Insurance/Genetic Fair/Unfair Discrimination Dilemma in Light of the Human Genome Project*, 85 Ky. L.J. 503, 527-28 (1996-97). His description of the four classifications of genetically-caused disease is based on *the Ohio Task Force on Genetic Testing, Final Report* (Dec. 31, 1995) at 3-4.

107) *Id.* at 528.

108) *Id.*

(such as chemicals, radiation, viruses, or cigarette smoking) alter the genetic structure of cells. Most cancers are examples.¹⁰⁹⁾

As these classifications indicate, when we mention “genetic disorder” or “genetic disease,” its implication differs widely depending on what kind of “genetic disorder” or “genetic disease” we have in mind. For example, if we talk about monogenic or single gene disorders such as Huntington’s disease, sickle-cell anemia, and cystic fibrosis, etc., it is certain that they are very different from other diseases which have been traditionally seen as non-genetic diseases because the environmental or lifestyle factors play little role to develop or manifest these monogenic diseases. However, the difference between these types of genetic diseases and HIV are smaller than the difference between HIV and other medical information in that both carriers of HIV and genetic diseases caused by a single disorder will surely develop diseases at an unknown future time and after their manifestations, it is difficult to cure these diseases by using present medical techniques. On the other hand, genetic diseases caused by multi-factorial genetic disorders have very similar characters with diseases such as heart disease, diabetes, etc., that we have traditionally regarded as non-genetic diseases. These kinds of genetic diseases are different from HIV or other infectious diseases such as Hepatitis C virus, etc. Accordingly, we can say that the features of some types of genetic diseases overlap with other traditionally seen non-genetic diseases and some do not. And it is also important to note that most of the diseases are caused by complicated interaction between genetic factors and non-genetic factors such as environmental exposure or lifestyle but the degree of each factor’s contribution varies widely disease by disease. Confusion which stems from this complicated nature of the disease onset causation seem to be one reason that genetic information is difficult to define.

Although, there are controversial debates over the issue of whether or not genetic information is different from other medical information, all observe a certain uniqueness of genetic information. However, when discussing genetic information as a social issue, not as a biological one, the issue we have to discuss is not the question of whether or not genetic information and other medical information *are* substantially different from each other but the question of whether a line can be drawn between them in drafting and enforcing law and whether the law *ought to* treat them differently or not. However, unfortunately, there is no space to address the details of these issues here, although they have been discussed

109) *Id.* at 528-29.

in my original thesis.

VI. Conclusion

More and more people will have an awareness that the Human Genome Project has already opened the door of Pandora's box and inside this box there is a book entitled "Genetic Secret of Our Lives" containing biological genetic information. In the twenty-first century, the advancement of genetic technology would seem to pose one of the most serious civil rights issues. In the twentieth century, race and gender have been the center of the class of discrimination. There is no doubt that in this century genetic discrimination will be the most serious and widespread class of discrimination in legal discourse. Under this understanding, this paper starts by clarifying the meaning and scope of "genetic privacy" which is the central concept for protection in the issues of genetic discrimination and I have noted that access to genetic information by insurance companies and employers put "informational privacy" in danger and the requesting of genetic tests as a condition to obtain insurance policy or final job offer infringes the "physical privacy" and "decisional privacy" of the people. Especially "decisional privacy" is exposed to being threatened by genetic discrimination. Requiring genetic tests undermines the right not to know one's own genetic information. Even though the law prohibits insurers and employers from performing mandatory genetic testing, if using genetic information in discriminatory decisions in the workplace and insurance underwriting is not banned by law, the people hesitate to undergo genetic tests due to fear of genetic discrimination. Hence, strong fears of genetic discrimination affect people's decisions not to take genetic tests and therefore restrict people's right to know their own genetic information. And then, I briefly described the model Genetic Privacy Act of 1995 and observed that reconciling the two competing interests; securing genetic privacy and social benefits such as the promotion of scientific research, public health or safety is the main goal of the Act.

Furthermore, I delineated the detail of the competing interests that need to be balanced in formulating a genetic privacy protection policy and introduced fair information practices or principles presented by Gostin and Hodge as an analytical tool which reconciles the competing benefits at stake. However, I pointed out that the pragmatic approach which balances these competing interests cannot give a perfect guideline in exploring adequate legal protection to genetic privacy because there is the fundamental issue of justice or fairness that still needs to be answered.

The primary purpose of this part was to highlight the compelling reasons why

genetic discrimination should be legally banned. And the insight which has been reached was that genetic discrimination undermines not only the genetic privacy of the people who are discriminated against but also hinders further development of genetic research and public health. I concluded by asserting that legal protections against genetic discrimination are indispensable in order to prevent creating a “genetic underclass,” to preserve the “right to know” and “right not to know” of our own genetic information, to eliminate fear which discourages people from undergoing genetic tests or participating in genetic research, and as a result, to develop medicine and biology, and ultimately enhance public health by curing and preventing genetic diseases which will lead to cutting overall health care costs.

In the final section the nature and character of genetic information has been examined by reviewing the arguments of “genetic exceptionalism.” However, I noted that the important matter in the light of establishing legal protection for genetic privacy is not in the question of whether genetic information has a unique character compared to other medical information. The question of whether we can distinguish genetic information from other kinds of medical information should be examined. This is because even though a certain unique character of genetic information can be identified, many commentators have pointed out that it is impossible to treat genetic information differently from other medical information based on practical reasons. The more genetic technology advances, the more practically impossible it will become to distinguish between the two and find where the line is to be drawn. Therefore, in order to protect genetic privacy appropriately, the law should also protect the privacy of all predictive medical information as well as the so-called genetic information.

More importantly, when enacting genetic-specific antidiscrimination law or genetic privacy law, it should be discussed as a fundamental question of whether it is fair and equal to protect only genetic privacy and prohibit only genetic discrimination while leaving the people with non-genetic diseases unprotected.

Although there is no space left to address these issues in detail in this paper at this time, I plan to publish it on another occasion in the near future¹¹⁰⁾.

110) Much space has been devoted to discuss these issues in my original thesis. The following is the Title and the Table of Content of my LL.M. thesis submitted in 2002.

GENETIC DISCRIMINATION AND GENETIC EXCEPTIONALISM

— **UNDERLYING ISSUES AND PROBLEMS OF GENETIC ANTI-DISCRIMINATION LAWS
IN INSURANCE AND EMPLOYMENT: WHAT IS FAIR IN THE GENETIC ERA?** —

I. INTRODUCTION 1

II. GENETIC PRIVACY	12
A. FOUR MEANINGS OF GENETIC PRIVACY	12
B. MODEL GENETIC PRIVACY ACT OF 1995	16
C. INTERESTS AT STAKE IN LEGAL POLICY OVER GENETIC PRIVACY PROTECTION	18
III. LEGAL PROTECTIONS AGAINST GENETIC DISCRIMINATION AND THEIR LIMITATIONS	31
A. CURRENT FEDERAL LAWS AND LIMITATIONS	31
1. Federal Legal Protections in Health Insurance	32
a. Health Insurance Portability and Accountability Act of 1996	32
i. Protections	32
ii. Limitations	34
b. Americans with Disabilities Act of 1990 (ADA)	36
2. Federal Legal Protections in Employment	41
a. Title VII of the Civil Rights Act of 1964	41
b. Executive Order	44
c. Americans with Disabilities Act of 1990 (ADA)	48
i. Applicability (Establishing an ADA Claim): Qualified Individual with a Disability	49
(1) Scholarly Interpretation: Three Prongs of the Definition of Disability	49
(1-a) First Prong of the Definition of “Disability”— Impairment Substantially Limiting a Major Life Activity	51
(1-b) Second Prong of the Definition of “Disability”—Record of Impairment	53
(1-c) Third Prong of the Definition of “Disability”—Regarded as Having Impairment	54
(2) EEOC Compliance Manual (policy guideline)	57
(3) Judicial Responses: <i>Bragdon v. Abbott</i> (1998)	59
ii. Obtaining Genetic Information Under the ADA: Genetic Tests	63
(1) Genetic Tests: Genetic Screening and Genetic Monitoring	63
(2) Pre-employment Testing (Medical Examination) of Job Applicants	66
(3) Pre-placement Testing (Entrance Examination) after Conditional Job Offer	68
(4) Periodic Testing of Current Employees (During Employment)	72
(5) Judicial Response: <i>Norman-Bloodsaw v. Lawrence Berkeley Laboratory</i> (1998)	77
iii. Employers’ Defense Under the ADA: Undue Hardship and Direct Threat	79
(1) Undue Hardship Defense	79
(2) Direct Threat Defense	82
(3) EEOC’s Regulations: Direct Threat to Self-Risk (Paternalistic Interpretation) ..	83
(4) Judicial Responses: <i>Chevron U.S.A. Inc. v. Echazabal</i> (2002)	85
iv. Inadequateness and Limitations of the ADA	89
v. Proposed Amendments to the Text of the ADA	91
B. STATE LEGISLATIONS BANNING GENETIC DISCRIMINATION	94
1. State Legal Protections in Insurance	94
a. Existing State Anti-Discrimination Laws	94
b. Shortcomings and Limitations	96
2. State Legal Protections in Employment	97

a. Existing State Anti-Discrimination Laws	97
b. Shortcomings and Limitations	100
C. PROPOSED FEDERAL BILLS IN THE U.S. CONGRESS	101
IV. PROBLEMS OF GENETIC ANTI-DISCRIMINATION LAWS: GENETIC EXCEPTIONALISM	105
A. KEY ISSUES OF GENETIC ANTI-DISCRIMINATION LAWS	107
1. Scope of Genetic Information	107
a. Problems in Narrow Definition	107
b. Problems in Broad Definition	109
2. Affirmative Use of Favorable Genetic Information	111
3. Authorized Disclosure and Regulatory Strategy: Front- / End-loading Approach	118
B. PRACTICAL FLAWS OF LEGISLATION: PRACTICAL PROBLEMS OF GENETIC EXCEPTIONALIS	123
1. Nature of Genetic Information: Genetic Exceptionalism	124
2. Definitional Dilemma: Two-Bucket Quandary	133
3. Over-Inclusiveness	138
4. Under-Inclusiveness	141
C. THEORETICAL FLAWS OF LEGISLATION: NORMATIVE PROBLEMS OF GENETIC EXCEPTIONALISM ..	145
1. Inequality between People with Genetic and Non-genetic Health Problems	146
2. Inequality between the Classes	149
3. Incrementalism: Plausible Defense for Genetic-Specific Legislation	151
4. Alternative Ways Out of the Dilemma	155
a. DHHS Privacy Regulations of 2000	156
b. Universal Single-Payer /Community-Rating Health Care System	158
V. ARGUMENTS FOR AND AGAINST GENETIC PRIVACY PROTECTION LAWS	163
A. MARNE E. BROM	165
1. Insurers' Justifications for Using Genetic Tests to Classify Risks	165
2. Arguments Opposing Use of Genetic Testing	167
B. T. H. CUSHING	172
1. Insurers' Arguments in Favor of Using Genetic Testing	172
a. Fair Discrimination Perspective	172
b. Genetic Testing Not Revolutionary	173
c. Consequence of Legislative Prohibitions	174
2. Arguments Against Insurers' Use of Genetic Testing	175
a. Uninsurability as Denial of Health Care	176
b. Confidentiality	177
c. Infliction of Emotional Harm	178
C. ERIC MILLS HOLMES	179
1. Supporting Arguments for Use of Genetic Information by Insurers	179
a. Fair Discrimination Is Efficient in Insurance Underwriting	179
i. Equitable, Not Equal, Justification	179
ii. History of Insurance Risk Classification	181
iii. Use of Genetic Tests Is Efficient and Equitably Fair	183

b. Equal Access to Genetic Information Fairly Rectifies the Unfairness of Imperfect Information in Underwriting	187
i. Applicant's Good Faith Duty to Disclose Genetic Information	187
ii. Adverse Selection	188
iii. Incontestability Clauses	190
c. State's Unfair Trade Practices Statute	192
d. Insurers Will Fairly Use Genetic Information in Risk Rating	193
e. Genetic Testing Conforms to Current Underwriting Practices and Will Not Affect an Applicant's Ability to Obtain Insurance	194
f. Analogous Employment Discrimination Based on Genotype Is Fair	195
2. Opposing Arguments for Use of Genetic Information by Insurers	196
a. Use and Availability of Genetic Information Is Subject to Abuse	196
b. Unfair Discrimination in Insurance Pricing and Availability	198
i. Insurance Requires Fair Redistribution, Not Fair Discrimination	198
ii. Misunderstanding and Misuse of Genetic Information	199
iii. Availability of Insurance	200
c. Prohibiting the Use of Genetic Information Protects Individual Right to Privacy	201
i. Genetic Information Can Cause Stigmatization and Psychological Trauma	202
ii. Confidentiality Must Be Protected	203
iii. Preferred Social Ignorance	204
D. RICHARD A. EPSTEIN (Libertarian Argument): Open Access to Genetic Information	205
E. COLIN S. DIVER AND JANE MASLOW COHEN	212
F. ANALYSES: ADVERSE SELECTION	220
1. Practical Problems of Adverse Selection	221
2. Normative Problems of Adverse Selection	231
VI. CONCLUSION: RECONSTRUCTING THE REAL ISSUES FOR FURTHER DISCUSSIONS	234
APPENDIX: SELECTED BIBLIOGRAPHY	245