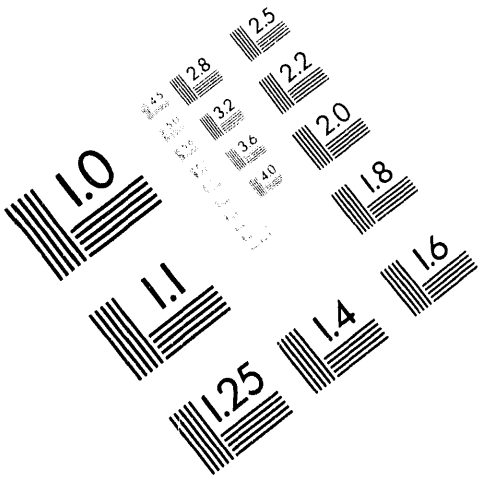
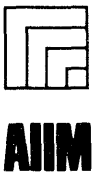


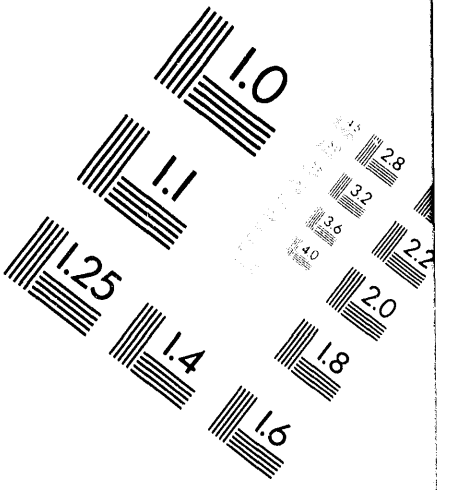


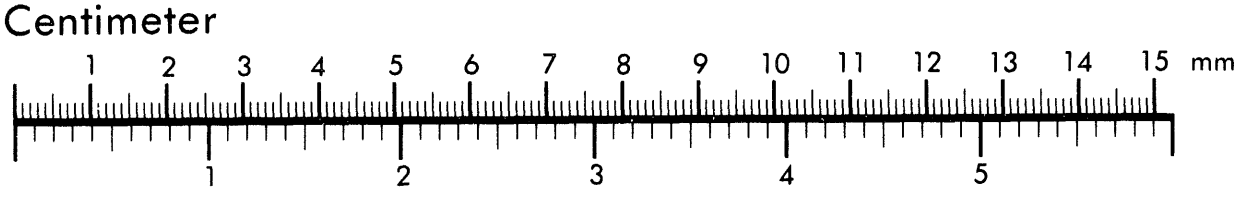
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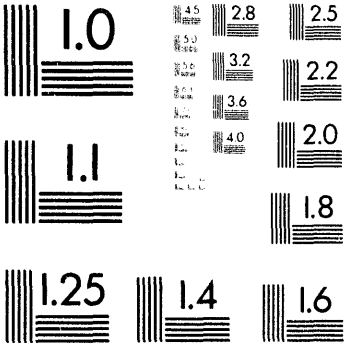
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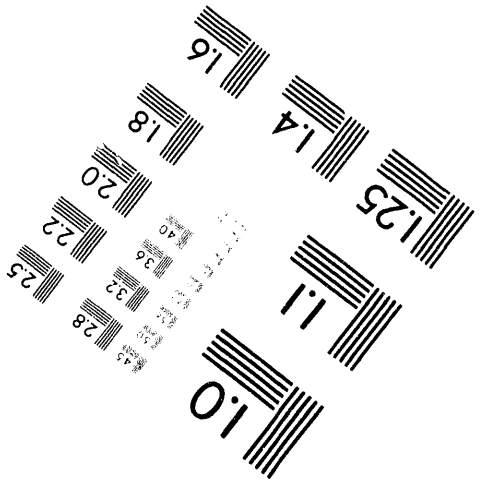
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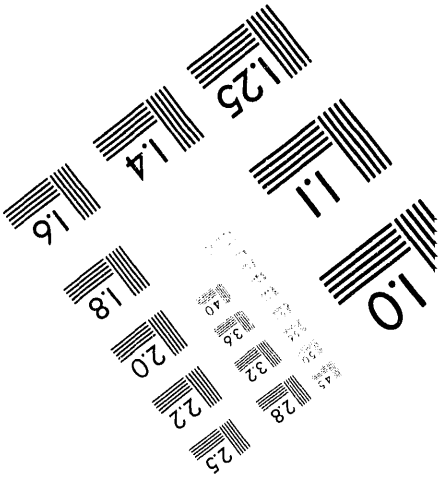
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THE LAWFUL USES OF KNOWLEDGE

FROM THE HUMAN GENOME PROJECT

FRANK P. GRAD, Principal Investigator,
J. P. Chamberlain Professor of Legislation,
Director, Legislative Drafting Research Fund

ILISE L. FEITSHANS, Associate Director,
Legislative Drafting Research Fund

LEGISLATIVE DRAFTING RESEARCH FUND
COLUMBIA UNIVERSITY LAW SCHOOL, NEW YORK

Prepared pursuant to U.S. Department of Energy
Contract No. DE-FG02-92ER61394

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The consultation of NEIL A. HOLTZMAN, M.D., M.P.H., Professor of Pediatrics, Johns Hopkins University, and Department of Epidemiology and Health Policy and Management, Johns Hopkins University School of Hygiene and Public Health; and DOROTHY WARBURTON, Ph.D., Professor of Clinical Genetics and Development, Columbia University, and Director, Genetics Diagnostics Laboratory, Columbia Presbyterian Medical Center, is gratefully acknowledged.

The Principal Investigator takes full responsibility for the policy content of this work.

TABLE OF CONTENTS

		Page
INTRODUCTION:	The Subjects Covered in the Study	1
PART I.	PROTECTION OF PRIVACY OF GENETIC INFORMATION	8
Chapter 1.	Historical Background - The Common Law Roots of Privacy Protection	8
1.	Warren & Brandeis: "The Right To Privacy"	8
2.	Common Law Invasion of Privacy Torts	12
3.	Privacy Torts Reconsidered	20
4.	Confidentiality, the Statutory or Contractual Protection of the Physician-Patient Privilege	24
	a. Disclosure by Publication	25
	b. Disclosure to Opponent in Litigation	26
	c. Disclosure to Employer	29
	d. Disclosure to Spouse	32
	e. Disclosure under New York AIDS Confidentiality Law	32
	f. Defenses	35
	g. Patient Waiver of Physician-Patient Privileges	38
	h. Physician's Testimony Ordered by Court or Otherwise Imposed by Law	38
	i. Disclosure to Spouse	39
	j. Summary of Rights of Confidentiality	40
5.	Conclusion	41
Chapter 2.	The Concept of Privacy -- What Is Protected by the Right of Privacy?	44
1.	Introduction	44
2.	Control of Information Theories of Privacy	44
3.	Privacy as Property or as Protectible Aspect of Personality	48
4.	Privacy as a Cultural Norm	51
5.	Privacy as Singular or Composite Right	59
6.	Autonomy as Included or Separate Right of Privacy	61
7.	Privacy in the Genetic Context	63
8.	Summary Analysis of Privacy Rights	67
9.	Conclusion	70

Chapter 3. Constitutional Protections of Genetic Privacy and Related Interests 73
1. Introduction: Privacy as a Constitutionally Protected Right 73
2. Informational and Associational Privacy under the First Amendment 79
3. Protection Against Interference with Physical Integrity 87
4. Protection Against Interference with Autonomous Private Decisions 91
5. Conclusion 93

Chapter 4. The Nature of Private Information 96

1. The Protection of Privacy: The Stigma of Illness 96
2. Conclusion 107

Chapter 5. Information, Databanks, Privacy and Discrimination 109

1. Introduction 109
2. The Information Society 110
3. Privacy Protection Study Commission; Views on Data Banking in Relation to Banking of Genetic Information 113
4. Security of Data Bases 119
   a. Examples of Breaches of Security 119
   b. Legal Protections 122
   c. Genetic Data Bases 123
5. The Registry of Genetic Conditions 125
   a. Privacy Protection of Patient Medical Data in Registries 130
   b. Policy Issues Relating to Genetic Disease Registries 134
6. Legal Protections 136
7. Protection of Medical Records 138
8. Employee Records 141
9. President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research - Data Emerging from Genetic Screening, Counseling and Educational Programs 142
10. Conclusion 147

Chapter 6. Information Submitted to Insurers 150

1. Introduction: Insurers and Their Use of Genetic Information; Insurance Practices in Selling Health and Life Insurance 150
2. Genetic Discrimination in Insurance 153
3. Insurance Industry Views on Genetic Testing 160
4. OTA Report on Insurance Use of Genetic Testing and History Information 163
5. State Laws Governing Genetic Discrimination in Health Insurance 169
6. State Laws Governing Genetic Discrimination in Life Insurance 173
7. State Bills on Genetic Discrimination in Insurance Introduced in 1992-1994 180
8. Conclusions 187

Chapter 7. Invasions of Privacy and Genetic Discrimination in the Workplace 189

1. Introduction: The Rationale for Workplace Testing 189
2. Employee Participation in Testing Programs under OSH Act 193
3. Workplace Testing, Collection of Information, Wellness Programs, and Prevention of Occupational Disease 195
4. Testing of Employees: Health Costs and Insurance Consequences 202
5. Genetic Testing and Occupational Disease 203
6. Current Federal Legislation Affecting Employees' Right To Privacy in the Workplace 218
7. The Occupational Safety and Health Act (OSH Act) 218
   a. Overview of the Statute 218
   b. Implications for Regulations Governing Genetic Tests 221
8. The Americans with Disabilities Act (ADA) 223
   a. Overview of the Statute 223
   b. ADA's "Insurance Exemption" 226
   c. ADA Applicability to Genetic Disabilities 228
   d. EEOC Interpretation of ADA Coverage with Respect to Non-Manifested Genetic Disease 230
   e. Summary of ADA Protections 234
9. Conclusions 236

Chapter 8. Protection of the Right Not To Know One's Own Genetic Information 239

Chapter 9. Legal Sanctions for Violations of Genetic Privacy 251

MASTER

Part II. THE USES OF GENETIC INFORMATION IN PUBLIC HEALTH PLANNING AND PROGRAMS 270

Chapter 10. Introduction - Use of Genetic Information to Advance Public Health Programs 270

1. Genetics in Public Health 270
2. Changes in the Orientation of Public Health -- from Regulation to Rendition of Services 275
3. Genetics in the Public Interest: Avoidance of Genetic Discrimination 283

Chapter 11. The History of the Federal Genetic Programs 292

Chapter 12. The History of State Genetic Programs 304

Chapter 13. Regional Programs for Genetic Services; CORN (Council of Regional Networks) 309

Chapter 14. Professional Organizations in Genetics 312

1. Professional Organizations in Medical Genetics 312
2. Professional Standards in Medical Genetics 316

Chapter 15. Access to Genetic Health Services 319

1. Access to Genetic Testing, Prenatal Diagnosis and Prenatal Care 319
2. Need for Facilities or Outpatient Opportunities 322
3. Recent History of Availability of Genetic Services. 324
4. Access to Preventive Services 325
5. Access to Essential Genetic Services 327
6. Access and Medicaid 331
7. Access to Reliable Laboratory Services; Experience among the States 334
8. Conclusions 339

Chapter 16. Genetic Testing: Autonomous Choices and Public Policy 342

1. Premarital and Preconceptual Testing 342
2. Predictive Testing for Monogenic Disorders and Multifactorial Diseases 345
3. Newborn Screening and Testing 346
4. Testing and Screening for Autosomal Recessive Disorders 350
5. Prenatal Diagnosis 352
6. Testing for Late Onset Diseases 354
7. Testing for Susceptibilities 357
8. Genetic Testing, Public Health and Autonomy 359
9. Conclusions 366

Chapter 17. Genetic Counseling and Informed Consent 371

1. Genetic Counseling 371
2. Informed Consent 377
3. Conclusion 381

Chapter 18. The Special Role and Responsibility of Women in Making Genetic Choices 383
1. Women's Issues 383
2. The Right to Refuse Prenatal Diagnosis and Treatment 385
3. Maternal Fetal Conflict and Its Resolution 387
4. Fetal Testing, Informed Consent and Counseling 394
5. Women's Autonomy and the Role of the Father and Other Members of the Family 396
6. The Special Role and Responsibility of Women in Making Genetic Choices 399

INTRODUCTION: THE SUBJECTS COVERED IN THE STUDY

The study of The Lawful Uses of Knowledge from the Human Genome Project has two parts. Part I of the project deals with the right to know or not to know personal genetic information, and examines available legal protections of the right of privacy and the adverse effect of the disclosure of genetic information both on employment and insurance interests and on self esteem and protection of personal integrity. The study examines the rationale for the legal protection of privacy as the protection of a public interest. It examines the very limited protections currently available for privacy interests, including genetic privacy interests, and concludes that there is a need for broader, more far-reaching legal protections.

The study examines the constitutional and legal background of the protection of privacy; the legal protections of privacy in medical and other protected areas; and, finally, the legal protection of privacy of genetic information. In this context, the study deals with aspects of informational privacy as well as with personal autonomy, i.e., the freedom of individual decision making based on new genetic information.

Increased genetic knowledge has implications both for private and public decision making. The second part of our study deals specifically with public decision making based on new genome knowledge, and addresses the potential contributions of new genetic knowledge to public health planning and the development of genetic services. It addresses significant legal issues that are raised by genetic screening and testing. It also addresses issues relating to the character of the decision relating to screening and testing, whether a voluntary decision by an individual, or a choice made mandatory by medical or other

authority. Other problems addressed relate to maintaining the voluntary nature of available screening and testing services, the proper targeting of at risk groups and individuals, and the organization of health services nationally and in the states to provide access to genetic testing services and to a range of counselling and followup services.

Our study examines certain Ethical, Legal and Social Issues (ELSI) as part of the impact expected from the Genome Project. It falls clearly within the range of ELSI-supported research, of legal studies of the right to privacy in the context of genetic information.

> The ELSI working group has identified four high priority issues for study: fairness, privacy, delivery of health care, and education. In the context of genetics, fairness means freedom from discrimination on the basis of genome type, privacy means an individual's control of the generation and disclosure of genetic information about himself or herself. Delivery concerns practices of the physicians, counsellors and laboratories that generate and provide genetic information. Education means helping policymakers, health care professionals, biologists and social scientists as well as the general public become aware of the new knowledge and of the problems and opportunities that it creates. In practice, many specific issues fall into more than one of those categories.[1]

The ELSI program was created as an integral part of the Human Genome Project by the National Institutes of Health (NIH) and the Department of Energy (DOE). The Human Genome[2] Initiative (HGI) is a major government sponsored research effort undertaken cooperatively by NIH and DOE to study the entire human genetic inheritance. The study is planned for a period of some 15 years, costing

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[1]Preparing for Changes, 20 LOS ALAMOS SCIENCE 304 (1992).

[2]U.S. CONGRESS OFFICE OF TECHNOLOGY ASSESSMENT, MAPPING OUR GENES: GENOME PROJECTS: HOW BIG HOW FAST (1988). "The entire complement of genetic material in the set of chromosomes of a particular organism is defined as its genome." at 21.

some $3 billion.[3] The project cooperates also with international efforts moving in the same direction, to analyze the structure of human chromosomes, to sequence the genes in that structure, to locate and map the structure, and also to find the location of defective genes that cause or contribute to human genetic disease.

Privacy protections are particularly important because in due course, it will be possible to genome "type" every individual -- i.e., to obtain the sequencing of genes in the chromosomes of specific individuals. Such genome typing will increasingly enable geneticists to make sound predictions on the genetic components of a person's future medical risks as well as the likelihood of passing certain genetic traits to the person's offspring.[4]

The Human Genome Initiative has already contributed to the development of new diagnostics, pharmaceuticals and therapies for a multitude of human genetic diseases. The biotechnical advances stemming from the Human Genome Initiative are already very impressive. The resulting changes in medicine and in the protection of public health will be as momentous as the beginning of the germ theory of

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[3]U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES AND U.S. DEPARTMENT OF ENERGY, UNDERSTANDING OUR GENETIC INHERITANCE, THE U.S. HUMAN GENOME PROJECT: THE FIRST FIVE YEARS FY 1991-1995, Washington, D.C. NIH Publication No. 90-1580 April 1990, at 1.

[4]HGI offers the following objectives for human genome projects: "to establish maintain and enhance databases containing information about DNA sequences, location of DNA markers and genes, function of identified genes, and other related information; to create maps of human chromosomes consisting of DNA markers that would permit scientists to locate genes quickly; to create repositories of research materials, including ordered sets of DNA fragments that fully represent DNA in the human chromosomes; to develop new instruments for analyzing DNA; to develop new ways to analyze DNA including biochemical and physical techniques and computational methods; to develop similar resources for other organisms that would facilitate biomedical research; and possibly to determine the DNA sequence of a large fraction of the human genome and that of other organisms." U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, MAPPING OUR GENES: GENOME PROJECTS: HOW BIG HOW FAST (1988) at 7.

disease causation in the late 19th century. The expected benefits of new knowledge of the causes and occurrence of genetic disease will help in decisionmaking on marriage, procreation, and on planning for the health of the family and of society generally.

Almost daily, media headlines hail new genetic discoveries of the Human Genome Initiative. Issues of privacy may determine the proper and improper uses of such information. In addition to beneficial social and sometimes trivial uses of the information,[5] there is other information which individuals as well as their employers and insurance companies may seek. There are some 4,000 genetic diseases, most of them with low rates of incidence, but the most frequent ones include cystic fibrosis, sickle cell anemia, Tay-Sachs, Huntington's chorea, polycystic kidney disease, Down's syndrome, multifactorial diseases like insulin dependent diabetes, Alzheimer's disease, and X-linked diseases like muscular dystrophy.[6] In the case of such relatively frequently occurring disorders, testing and screening may have very significant planning implications, but the protection of the results of genetic tests may also raise difficult issues of privacy.

The Human Genome Initiative gives us greater knowledge of our genetic inheritance to be used for knowledgeable, autonomous decision making relating to some of the most significant aspects of our lives -- marriage, family and

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[5]Certain well known and socially beneficial uses of such genetic information include DNA fingerprinting, i.e., the uses of genetic analysis for identification purposes, as well as the questionable but increasing use of prenatal testing to discover the sex of the child to be born. Anthony Pearsall, Comment: DNA Printing: The Unexamined "Witness" in Criminal Trials, 77 CALIF.L.REV. 665 (1989); Janet C. Hoeffel, Note: The Dark Side of DNA Profiling: Unreliable Scientific Evidence Meets the Criminal Defendant, 42 STANFORD L.REV. 465 (1990).

[6]Neil A. Holtzman, Examples of Genetic Disorders (arranged according to mode of inheritance), unpublished chart (1991).

planning for our health and future. But such knowledge, disseminated in an irresponsible, careless or capricious manner, may be abused for purposes of discrimination, economic and personal, for social stigmatization and for adverse manipulation.

The protection of genetic privacy is the first emphasis of our report. The protection of genetic privacy includes the protection of the making of autonomous decisions relating to matters of marriage, procreation, and family planning in the light of available genetic information. Autonomous decision making is possible only if the decision maker has access to adequate information and has the means to carry out the decision. To carry out such decisions may require the availability of medical and other facilities. Thus, private decisionmaking may involve the use of genetic information for public health planning.

The second part of our study analyzes information on available public health and therapeutic services and on program development in the genetic area. The protection of privacy in the context of public health considerations is analyzed and emphasized, as well as questions of the organization of genetic services. Significant issues covered include the voluntary nature of genetic screening and testing, the proper targeting of at risk groups and individuals, and the organization of genetic services nationally and in the states to provide for opportunities for reliable testing -- including laboratory -- services and for a full range of counselling and followup services that may be necessary or advisable.

The second part of the study is based on the assumption that as major a project as the Human Genome Project, spending billions of dollars on science which is health related, will indeed be applied for preventive and therapeutic public health purposes, as it has been in the past. Earlier public health

initiatives using genetic insights are reviewed, and an effort is made to point to future needs of public health developments based on recent genome discoveries. No broad program of mandatory public health initiatives using new genetic insights is recommended. Rather, what is advanced is the general idea that genetics has a role to play in public health and that public health has a role to play in genetics, in that public health programs of public genetic education need to be advanced, adequate facilities for screening and testing and for followup services need to be provided, and that public efforts need to be undertaken to make available facilities and personnel to enable persons to exercise autonomous choices in the area of procreation, and in other areas where facilities must be available to allow autonomous choices for screening and testing.

The second part of the study also addresses the recurring fear that public health initiatives in the genetic area must involve a new eugenic agenda. This fear is squarely addressed in a short segment that reviews the early 20th century American eugenics movement and affirms the conviction that the uses of genetics will not compel us to repeat the miserable discriminatory experiences of the past.

The plan of the first part of the study on privacy is to analyze first the late 19th and early 20th century historical background which generated early ideas and common law protections of privacy; second, to discuss privacy as a constitutional and jurisprudential concept; third, to examine what interests are protected by the right of privacy, and finally, to consider the specific protection of the right of genetic privacy, including protection of informational privacy, protection of physical privacy, and protection of the right of autonomous decision making.

We then continue with an examination of the invasion of privacy and of the use of private information in making insurance and employment decisions. We conclude Part I on privacy with a discussion of existing legislation to protect privacy and to prevent genetic discrimination. Another short analysis is devoted to a particular aspect of genetic privacy, namely the right not to know or to refuse to accept information relating to one's own genetic inheritance.

Chapter 1. Historical Background - The Common Law Roots of Privacy Protection

1. Warren & Brandeis: "The Right to Privacy"

The late 19th century brought major changes of technology and life style, and the concerns of privacy were an outgrowth of those changes.

The idea of a right to privacy under the common law begins with Warren and Brandeis' epochal 1890 article, "The Right to Privacy."[1] Drawing on precedents from 1820 onward, they described the gradual expansion of personal rights, including "the right to be let alone."[2] Political and social changes merited newer, broader definitions of rights and their protections, including the development of rights in intangible property. Modern developments, such as "Instantaneous photographs and newspaper enterprise have invaded the sacred precincts of private and domestic life."[3] Noting this trend, they sought to protect individual privacy on the theory that it was a person's property. The idea was not widely embraced by the courts at the time, but has gained currency throughout the 20th century.[4]

Warren and Brandeis outlined the common law roots for a modern regime of privacy protections. "That the individual shall have full protection in person and in property is a principle as old as the common law; but it has been found necessary from time to time to define anew the exact nature and extent of such

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[1]Samuel D. Warren and Louis D. Brandeis, The Right to Privacy, 4 HARVARD L.REV. 193 (1890).

[2]The term initially used by Judge Cooley, which Brandeis later used in his 1928 dissent in Olmstead v. United States. 277 U.S. 438, 473 (1928) (Admissibility of wiretap evidence).

[3]Warren and Brandeis at 195. They also state that "gossip . . . has become a trade." Id. at 196.

[4]See, e.g., PROSSER AND KEETON ON THE LAW OF TORTS §117, at 849 (5th ed. 1984) [hereinafter PROSSER].

protection. . . . Later there came a recognition of man's spiritual nature, of his feelings and intellect. Gradually the scope of these rights broadened; and now the right to life has come to mean the right to enjoy life -- the right to be let alone. . ."[5]

They decried several developments of "the modern age" and noted that these changes called for an expanded scope of the concept of privacy protections under the common law. In addition to photography and newspaper depictions of private matters, numerous mechanical devices threaten to make good the prediction that "what is whispered in the closet shall be proclaimed from the house-tops." Warren and Brandeis recognized the need for a legal remedy for the unauthorized use of photographs and of other devices that replicated images and speech without authorization by the individual portrayed or reproduced. In a sense, their comments were prescient for human genetic information, where modern technology can isolate and examine in detail the chromosomal nature of an individual without the individual's knowledge or consent, creating the possibility that the image may be used in ways detrimental to the person, just as unauthorized photography once had. Warren and Brandeis understood that new technologies created new risks to privacy.

Warren and Brandeis expressed concern for the harm caused by gossip and asserted that the common law provided protection of personal privacy for harms greater than mere wounded feelings.[6]

According to Warren and Brandeis, the harm to personal privacy must be

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[5]Warren and Brandeis at 196.

[6]"The matter published of him, however widely circulated and however unsuited to publicity, must, in order to be actionable, have a direct tendency to injure him in his intercourse with others, and even if in writing or in print, must subject him to the hatred, ridicule, or contempt of his fellowmen." Id. at 197.

separate and apart from damage to self-esteem, but may embrace many other harms caused by the intrusion on privacy.[7] They asserted that every person is free to control the publication of private information. [8]

The idea that private information is protectable as property needed explanation, and the authors noted that there may be injurious disclosures of private matters "yet it is difficult to perceive how, in such a case, any right of property, in the narrow sense, would be drawn in question, or why, if such a publication would be restrained when it threatened to expose the victim not merely to sarcasm, but to ruin, it should not equally be enjoined, if it threatened to embitter his life. ... But if privacy is once recognized as a right entitled to legal protection, the interposition of the courts cannot depend upon the particular nature of the injuries resulting."[9]

Warren and Brandeis theorized that there is a general right to be privacy which parallels other protected rights, such as the right not to be assaulted.[10] It was their thesis that the law took too narrow an approach to these rights. In Pollard v. Photographic Co.,[11] where in 1888 a photographer had made an unauthorized use of a photograph, the Court relied on contract and property rights to reach its decision that the plaintiff should recover for misuse of her

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[7]Id. at 197

[8]"The common law protection enables him to control absolutely the act of publication and in the exercise of his own discretion, to decide whether there shall be any publication at all." Id. at 200. This principle ought to apply today, to private genetic information.

[9] Id. at 205.

[10]"If we are correct in this conclusion, the existing law affords a principle which may be invoked to protect the privacy of the individual from invasion either by too enterprising press, the photographer, or the possessor of any modern device for recording or reproducing sounds." Id. at 206.

[11]40 Ch.Div. 345 (1888)

likeness, the absence of privacy considerations notwithstanding. According to Warren and Brandeis, the court's reasoning was wrong even though it had reached the correct result. Instead, under the Warren and Brandeis analysis, several privacy rights would enjoy protection by the state.[12] They envisioned these rights are derived not from contract or special trust, "but . . . rights against the world. . . . The principle which protects personal writings and any other productions of the intellect or of the emotions is the right of privacy, and the law has no new principle to formulate when it extends this protection to the personal appearance, sayings, acts, and to personal relation, domestic or otherwise."[13]

It follows from their analysis that invasions of privacy constitute an injury, and that redress is available. They suggested five limitations on these rights. "1. the right to privacy does not prohibit any publication of matter which is of public or general interest... 2. The right to privacy does not prohibit the communication of any matter, though in its nature private, when the publication is made under circumstances which would render it a privileged communication according to the law of slander and libel.... 3. The law would probably not grant any redress for the invasion of privacy by oral publication in the absence of special damage, 4. The right to privacy ceases upon the publication of the facts by the individual or with his consent [and] 5. The truth of the matter published does not afford a defense."[14]

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[12]Warren and Brandeis at 211 "now that modern devices afford abundant opportunities for the perpetration of such wrongs without any participation by the injured party, the protection granted by the law must be placed upon a broader foundation... the doctrines of contract and trust are inadequate to support the required protection and the law of tort must be resorted to."

[13] Id. at 213.

[14] Id. at 216-217.

A breach of the right of privacy, pursuant to Warren and Brandeis, is grounds for actions for damages and injunctive relief. Although their exception for oral publication did not anticipate dissemination by radio, television and other mass media, there is continuing relevance to their views. Though often cited, their view did not persuade many courts. Their views represented the high water mark of rights to privacy that "ought" to exist, rather than a realistic appraisal of common law rights. Their views, however, have informed all of the subsequent developments in the protection of privacy.[15]

Warren and Brandeis successfully influenced leading scholars, but had less influence in the courts. The tort of invasion of privacy was not a protected right under earlier common law, but gained increased recognition after the 1930s. It encompassed both the invasions of confidential records and the publication of private information, including the publication or disclosure of medical records. Earlier, when a hospital or a physician disclosed private information, it had been treated as a breach of contract with the patient.

2. Common Law Invasion of Privacy Torts

Prosser viewed Warren and Brandeis' formulation of the right to privacy as an admixture of defamation, invasion of a property right, and breach of contract or implied contract. Prosser found that there are four distinct actions for the tort of invasion of privacy: (1) intrusion into seclusion, (2) public disclosure of private facts, (3) publicity that places a person in false light, and (4)

[15]See, e.g., RIGHT TO PRIVACY PROPOSALS OF THE PRIVACY PROTECTION STUDY COMMISSION: HEARINGS BEFORE A HOUSE SUBCOMMITTEE ON GOVERNMENT OPERATIONS, 95th Cong., 2d Sess. (1978); REPORT OF THE PRIVACY PROTECTION STUDY COMMISSION, PERSONAL PRIVACY IN AN INFORMATION SOCIETY (1977).

appropriation of plaintiff's likeness for gain.[16] Some of these torts may become relevant to the disclosure of genetic data because new technologies may provide access to information of a person's genetic makeup, once considered to be private or intimate. For example, the tort of public disclosure of private facts could arise by placing personal genetic information into a registry without proper consent, or by abusing information that was correctly placed into such a database.

One criticism of the common law of privacy is that despite technological advances the law has become "frozen" into Prosser's well-accepted four categories. For example, the Restatement of Torts has accepted Prosser's categorization of torts for invasion of privacy.[17] Of these four torts, the one most directly relevant to genetic information is public disclosure. For the tort of public disclosure of private facts, three conditions must be met: first, disclosure, whether written or oral, must be public, not private. Second, the public disclosure must concern private facts, not public ones. For example, an obscure person in a public place may be recorded as having been there, and have her picture circulated, so long as it is true that she was there and the commentary along with the photograph is accurate.[18] Third, the matter made public must be one which would be highly offensive and objectionable to a reasonable person.[19]

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[16]PROSSER §117, at 851.

[17]Restatement (Second) of Torts, §§652a - 652I (1977).

[18]William L. Prosser, Privacy, 48 CAL.L.REV. 383 (1960). Prosser implies that there is a test of public manners, "by which there will be liability only for publicity given to those things which the customs and ordinary views of the community will not tolerate." Id. at 397.

[19]PROSSER at 857.

Warren and Brandeis were the first to recognize privacy as a protected personal right. They also recognized that technological progress would create greater opportunities for the invasion of privacy. But in 1890 their major concern was with the invasion of privacy by newspaper and the mass media publications which were growing both in size and in influence in their time. They could not anticipate the computer and data base revolution, nor the nature of the private information that would become accessible through genetic research. Disclosure of private genetic information and personal cytogenetic images touches more deeply upon personal identity than the unauthorized publication of personal photographs, and the early common law cases relating to public disclosure of private facts do not fit the contemporary problem of improper or unauthorized disclosure of genetic information, though an argument could be made that they do fit the case of the unauthorized publication of person's genetic data in a newspaper -- but there have not been any cases of that kind.[20]

Under the common law, privacy not only includes protection against intrusion into private property. It also includes invasions of seclusion and protection of private information or private decisions. One commentator has raised doubts whether cases actually exist to support the first two types of torts that were discussed by Prosser.[21] As a result of the recognition of these torts, there are cognizable interests in reputation, intangible property, and emotional tranquillity, and it is likely that these protections would extend to genetic information, such as information on chromosomal abnormalities or the sequence of individual DNA, though there are no reported decisions on the matter.

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[20]For an unsuccessful effort to complain to the Federal Communications Commission about the publication of the genetic defect afflicting a public person, see Note 37, infra.

[21]H. Gross, The Concept of Privacy, 42 N.Y.U.L.REV. 34, at 47, 48 (1967).

Prosser's views of the common law of privacy has been generally accepted,[22] but his categories have been interpreted narrowly. For instance, even though appropriation of name and image is a violation of privacy, it has never been found by a court to be a violation for a person to possess such information about another. For some privacy violations there must be an uninvited intrusion into a private realm. There is no such intrusion involved in using private information in data banking, if consent has been given. A claim for public disclosure of private facts cannot be brought against a third party who received such information lawfully or with the consent of the injured party. Thus, selling subscription lists of magazines was not actionable even though it included information relating to the subscriber's financial and personal preferences.[23] Actions taken for the purpose of harassing a debtor may meet the requirement necessary to make a claim of a breach of privacy.[24] But an investigative report that detailed plaintiff's 25 years' insurance history was not regarded as an invasion of privacy because the gathering of information for consumer reports served the "legitimate business need"[25] and there were no

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[22]Prosser's categories of privacy torts are reflected in the Restatement (Second) of Torts, §§652a-652I (1977). See also Privacy, Computers, and the Commercial Dissemination of Personal Information of Personal Information, 65 TEXAS L.REV. 1395, 1417 (1987).

[23]Shibley v. Time Inc., 45 Ohio App. 2d 69, 341 N.E. 2d 337 (1975). Individual rights not violated when a magazine publisher sells subscription lists to direct mail advertisers without the consent of the individual subscribers.

[24]Santiesteban v. Goodyear Tire, 306 F.2d 9, 10 (5th Cir. 1962). Plaintiff had purchased tires on the installment plan and was current in his payments but Goodyear removed all tires and tubes without notice, resulting in embarrassment, humiliation and wounded feelings. The Ohio court found that "the right of privacy is recognized in Florida." The tort requires publicity such as communication to the public. [at 11] The court upheld the action.

[25]Tureen v. Equifax Inc., 571 F.2d 411 (8th Cir. 1978). The plaintiff objected to his insurance company's investigation of his claim of total disability and the use of their internal records to provide reports to third

"objectionable snooping techniques."

Although there have been many lawsuits for invasion of privacy, generally based on publication of private facts, few of these cases have actually succeeded. In Time v. Hill,[26] the Supreme Court had before it a false light case involving a fictionalized newspaper account of an incident wherein escaped convicts held a family hostage. The fictionalized story used the hostages' real names, causing them substantial mental anguish. The Court denied the right of action, relying on First Amendment freedom of the press. The First Amendment ground for denying rights of action in privacy has become almost commonplace. In Florida Star v. B.J.F.,[27] the Court denied actions for the publication of a rape victim's name in violation of Florida state law. The newspaper had obtained the name from a police report placed in the department's newsroom for use by reporters. The lower court had awarded damages but the Supreme Court held that the imposition of damages on a newspaper for publishing truthful information lawfully obtained violated the First Amendment, and invalidated the state legislation which had prohibited the publication of the names of rape victims. In a similar case, Cox Broadcasting v. Cohn,[28] the action was brought for the victim's anguish by the father of the deceased rape victim. Again, the Supreme

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parties. The court found that the insurer's actions fulfilled "legitimate business needs" [at 416], distinguishing the "publicity" that gives rise to a tort from "publication" which embraces any communication by the defendant to a third person and which need not give rise to a cause of action [at 417]. The court further found, "Thus it is not an invasion of the right of privacy . . . to communicate a fact concerning the plaintiff's private life to a single person or even to a small group of persons" [at 417] as distinguished from publication in a newspaper or magazine.

[26]385 U.S. 374 (1967)

[27]491 U.S. 524 (1989)

[28]420 U.S. 469 (1975)

Court held that the public interest in having the information, protected by the First Amendment, outweighed the harm from the invasion of individual privacy.

Lower court cases, few of them involving medical privacy, generally reached similar results. The publication of nude, though not pornographic, photographs of children was held not to be an invasion of privacy though the release form clearly indicated that the photos were taken for a different purpose.[29] But damages for invasion of privacy were found in a case where the nude photograph of a woman taken by her husband and obtained by the newspaper was indeed a violation of privacy because the magazine's practice of calling the telephone number of whoever submitted the photo was inadequate to assure the model's consent to have her picture appear in Hustler magazine.[30] But no invasion of privacy was found in the newspaper disclosure of the name of a patient infected with HIV by the physician who discussed the patient's condition in the local newspaper in response to the allegations in the lawsuit. In his comment, the physician indicated that he would have diagnosed the patient's problem sooner had he been aware of the fact that the patient was HIV positive because his particular condition was common among people with HIV. The case began when the patient brought a medical malpractice action against the physician for $38 million. It is not clear whether the court would have found a violation of physician/patient confidentiality in a newspaper discussion under other circumstances.[31]

In another action, plaintiff linked her suit for sexual harassment actionable under federal law with her pendant claim of invasion of privacy under

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[29]Faloona v. Hustler, 799 F.2d 1000 (5th Cir. 1986).

[30]Wood v. Flynt, 736 F.2d 1084 (5th Cir. 1984)

[31]Lee v. Calhoun, 948 F.2d 1162 (10th Cir. 1991)

state law. The pendant claim was dismissed.[32]

Sometimes actions for the marginal violation of privacy rights were not permitted when there is an arguable element of public interest in the story. Thus, no property right and reputation was violated when the newspaper accurately reported a wifebeating by a policeman who had been named Officer of the Year.[33] So too no false light cause of action was allowed in a case where the owner of land adjacent to a toxic waste dump called the authorities to report the matter and a television newscaster then gave the incorrect impression that the toxic waste belonged to the informant.[34]

It is clear that the invasion of privacy tort has a very narrow scope and that Restatement (Second) of Torts[35] provides an indication that the publication of private facts will only be actionable if it is highly offensive to a reasonable person and not of legitimate concern to the public. Courts have rarely found these requirements to be met, because of primary First Amendment concerns. None of these cases, it should be noted, involved private facts relating to genetics. There was, however, some mention of genetic information in one case, if only in passing. In Swichlard v. Wayne County Medical Examiner,[36] the family of a chief judge of the circuit court who died by suicide sought to prevent further revelation of the facts surrounding his death by the newspapers, which had described the presence of drug paraphernalia at the death scene. The dissent in the case took a different view, asserting that there should have been at least

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[32]Walker v. Anderson Electrical Contractors, 944 F.2d 841 (11th Cir. 1991)

[33]Scheetz v. The Morning Call, 946 F.2d 202 (3d Cir. 1991)

[34]Machleder and Felexcraft v. Dias, 801 F.2d 46 (2d Cir. 1986)

[35]Restatement (Second) of Torts §§652D (1976).

[36]438 Mich. 536 (1991)

an in camera examination by a judge to redact any evidence of lawful alcoholic substances at the scene, any other embarrassing information such as evidence of AIDS, venereal disease, or genetic history, pointing out that genetic information in particular has an effect on many living people who share the same genetic history. The majority had based its decision on the grounds that protection of privacy ends with death.

In summary, recovery in privacy cases under the common law has typically been limited to unauthorized use of a name or photograph for misleading or derogatory advertising within the narrow categories described by Prosser. By contrast, individuals who face discrimination in consequence of genetic testing are not readily included in common law protections. Proof of unwarranted or unauthorized dissemination of genetic information should give rise to a cause of action for public dissemination of private facts, though First Amendment defenses might apply. The narrowness of available common law protection demonstrates the need for legislation.[37]

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[37]One instance of media dissemination of information relating to a person's genetic disability occurred in 1991 when a talk show host solicited listener comments on Los Angeles television anchorwoman Bree Walker Lampley's pregnancy. The comment was that the beautiful and very pregnant Bree Walker also has a very disfiguring disease, namely ectrodactyly, a genetic condition manifest as the absence of one or more fingers or toes. As an autosomal dominant disorder, the potential offspring would have a 50-50 chance of inheriting the disease and the talk show hostess asked the listeners' response whether it was right to conceive a child who would be at the risk of "this deformity." The opinions offered by listeners were divided, but many voiced concern over the potential for discrimination or stigmatization as knowledge of one's genetic makeup increases. Bree Walker Lampley eventually delivered a healthy baby boy who has ectrodactyly. Arguing that the biased presentation with erroneous information had been broadcast, Bree Walker Lampley and her husband with several groups filed a complaint with the Federal Communications Commission (FCC). The talk show hostess, Jane Norris, stood by her right to raise the issue and the FCC rejected Walker Lampley's complaint in February 1992 and no appeal was brought. This account, based on several contemporary newspaper sources, was recounted in a government sponsored study, in U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, CYSTIC FIBROSIS AND DNA TESTS: IMPLICATIONS OF CARRIER SCREENING, OTA-BA-532 (Washington DC: U.S. Government Printing Office, August 1992) at 191.

3. Privacy Torts Reconsidered

While Warren and Brandeis provided an early articulation of the right of privacy and foreshadowed many subsequent scientific and technological developments in communication, their article was nonetheless a product of its time. The social conditions which gave rise to the Warren and Brandeis view in 1890 changed during the following 100 years. It has been noted that the Warren and Brandeis view grew out of the tensions of the late 19th century, out of the growth of mass urban areas and industrialization which challenged the existing social standards and the older standards of a more genteel community. It has been noted that in 1890 the mass media represented a threat to settled institutions as the family and local communities. While Warren and Brandeis foresaw future developments in emphasizing the impact of technology on communication, the threats to privacy which were dominant in the 1890s are not the primary threats a hundred years later.[38]

It has been noted earlier that common law actions for breach of privacy, particularly actions for the publication of private facts, have not been very effective as a remedy, because some of its aspects are difficult to prove and because the assertion of breaches of privacy through publication regularly runs into First Amendment, freedom of expression objections. The recommendation has been made that the protection of privacy ought not to rely on the established privacy torts, most notably the tort of publication of private facts, but rather should be premised on the individual's control of information. Professor Bezanson

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[38]Randall P. Bezanson, The Right To Privacy Revisited: Privacy, News, and Social Change 1890-1990, 80 CAL.L.REV. 1133, 1134-1144. "Today the function of privacy relating to freedom of the individual as an individual is the dominant one; the function of privacy relating to social control is greatly diminished. The freedoms protected by today's more individualistic idea of privacy are of two sorts: freedom from intrusiveness and freedom to achieve identity. These are related and inseparable." Id. at 1044.

suggests that we focus privacy on confidentiality and individual control. Emphasizing the social dimension of privacy, he focuses on "the aspect of privacy that serves to foster the development of individual personality in intimate associations through excluding disclosures in other settings."[39] Thus, instead of emphasizing the earlier privacy tort as defined by Prosser, he would base protections on control of disclosure of personal information instead of seeking to control its ultimate publication. He would leave control in the hands of the individual and couple it with obligations of confidentiality on persons who possess personal information.[40] The author comments that "privacy is a communicative tort. It rests on harm arising from a communication. It therefore must reflect a realistic understanding of what communication means and how it works."[41] The author finds it difficult to accept a privacy tort based on "inward looking emotional harm,"[42] asserting that social changes have not destroyed the idea of privacy as expressed by Warren and Brandeis, but they have altered it. "The very ideas of judge-made standards of societal values, of jury determined thresholds of offensiveness and public interest, and of case by case adjudication of law as well as fact, are at odds with our shifting social environment and are incompatible with the complex institutional arrangements now emerging in the field of mass communication."[43] To replace the old privacy tort, the author would enforce obligations of confidentiality. In principle, "the ability to enforce the privacy of any item of information should depend on the

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[39]Id. at 1150.

[40]Id. at 1150-1151.

[41]Id. at 1162.

[42]Id. at 1171.

[43]Id. at 1173.

intention and conduct of the individual, and on the nexus between disclosure and the protection of constructive social relationships. Second, the legal obligation to maintain the information in confidence should be imposed through tort duties on the possessor of information, not on the publisher."[44]

The elements of the newly proposed tort for breach of confidentiality was spelled out by another writer who also rejects the publication of private facts tort as unworkable.[45] As outlined, the proposed tort would create a duty of confidentiality if the person who confided information indicated the wish to control the disclosure of information either orally or in writing and if the confidant had agreed voluntarily and explicitly to hold the information in confidence. There would have to be either written agreement of confidentiality, or the confidant would have had to respond affirmatively to the confider's question "Will you hold what I am about to tell you in confidence?"[46] The writer views the breach of confidentiality tort as based on agreement, if not contract.

> The proposed tort would therefore protect information whose transfer has been localized into a small number of confidants, who have been explicitly obligated to a duty of confidentiality. Provided the other elements of the tort are satisfied, a confidant who breaches this duty by intentionally publicizes the information (or was negligent in allowing it to be publicized) will be liable to the confider to any injuries suffered from the publicity.[47]

As a result of these requirements, members of the media would be able to publicize any information which they had not agreed to keep confidential. The scope of the proposed tort extends only to private information or information

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[44]Id. at 1174.

[45]G. Michael Harvey, Confidentiality: A Measured Response to the Failure of Privacy, 140 U.PA.L.REV. 2385 (1992).

[46]Id. at 2426.

[47]Id. at 2430.

that is inaccessible.[48] There is no indication whether data in a data bank, for instance, would be regarded as inaccessible for confidentiality protection purposes.

The appearance in 1992 of two significant articles supporting a new breach of confidentiality tort, as well as earlier comments complaining of the difficulty of enforcing the classical privacy tort of publication of private facts indicates considerable dissatisfaction with the state of the law and a strong desire for alternative resolutions of the enforcement of privacy problem.

The application of the newly proposed breach of confidentiality tort to the disclosure of a person's genetic illness or adverse genetic trait is very limited. In effect, it would apply clearly to a limited number of cases where a person who suffers a genetic condition tells another person and seeks the other person's confidentiality. This is not the problem which is normally involved in the disclosure of genetic illness, where the disclosure is not likely to be of a conversational, voluntary nature. The problem of disclosure arises in the context of the discovery of conditions through screening or testing, and through information of test results to insurers or employers or to others, such as educational establishments, in response to a request for information from institutions that want to use the information to make decisions of their own. Under such circumstances, a request for confidentiality and a promise not to disclose simply do not fit the situation, though one could assert that institutions that seek certain information relating to genetic conditions should indeed promise and agree not to publish or re-disclose the information and not to use it for other purposes than the ones specified by the questioner.

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[48]Id. at 2438.

4. Confidentiality, the Statutory or Contractual Protection of the Physician-Patient Privilege

The so-called violation of privacy torts, particularly the tort of public disclosure of private facts, was discussed earlier in dealing with the historical, common law sources of the right to privacy.[49] Because genetic information is normally part of an individual's medical records, confidentiality of medical information generally, and the physician/patient privilege with respect to medical information apply. Note, however, that no cases involving the disclosure or publication of genetic data were found. The cases that follow do, however, involve medical information of a sensitive nature, and are therefore relevant in considering the protection of genetic data of a similarly sensitive and intimate character.

The cases have been grouped in accordance with a number of distinguishing factors. They involve disclosure by general publication in the media; disclosure to an opponent in litigation; disclosure to employers; disclosure to a spouse; and disclosure under the New York AIDS Confidentiality Law. The cases are also grouped with respect to the defenses urged upon the court. These include: that disclosure was in the public interest, in the scientific interest, or in the particular personal interest of the patient; that the physician/patient privilege was waived by the patient, including instances when a patient sues a defendant other than his physician; that the physician's testimony was required by the court or otherwise required by law; that the disclosure was to a spouse. Note that in several cases, the court found both a breach of privacy and a violation of the physician/patient privilege.

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[49]See page 8 supra.

a. Disclosure by Publication

In Doe v. Roe,[50] a psychiatrist's former patient sued the physician and her husband for the publication of a book which provided verbatim part of the patient's comments during treatment, covering her thoughts, feelings, emotions, sexual fantasies and comments on other intimate personal relationships, as well as on the disintegration of her marriage. No consent had been obtained for the publication of these materials. The plaintiff's case was based on the physician/patient privilege provided for in N.Y.CPLR §4504(a) which protected confidentiality in judicial proceedings. The New York Board of Regents had also defined breach of confidentiality as unprofessional conduct, and the New York Public Health Law provides for privacy in treatment and confidentiality in the treatment of medical records. The court concluded that the prohibition of unauthorized disclosure of medical information was not limited to trials and other formal proceedings, and that there is an implied covenant on the part of the physician to keep confidential all disclosures made in the course of treatment. The court also found breaches of privacy in that the publication constituted "unreasonable intrusion" and "unreasonable publicity." It found such a breach of privacy; the publication, the court found, had no scientific value for its justification, and found the psychiatrist had been equally liable though he had not been involved in a physician/patient relationship, but because he was the co-author and was aware of the absence of consent. Finding that the disclosures had not been willful and malicious, the court denied punitive damages but awarded $20,000 in compensatory damages for injuries, including such elements as acute embarrassment, threats to livelihood, insomnia and nightmares. The further circulation of the book was enjoined.

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[50]400 N.Y.S. 2d 668 (S.Ct.N.Y.Co. 1977).

In Anderson v. Strong Memorial Hospital,[51] a patient diagnosed as HIV-positive but not diagnosed as having AIDS sued his doctor, nurse and hospital for invasion of privacy and breach of physician/patient privilege when a newspaper published the patient's photograph in an article describing the hospital's AIDS research efforts. The picture was taken by a reporter after the physician had assured the patient that his picture would not be recognizable. But it was. The publication strongly implied that the patient had AIDS, causing him and his family stress and turmoil. The court rejected a claim for breach of the common law right of privacy but found that plaintiff had a cause of action for breach of physician/patient privilege. The court relied on the earlier case of Roe v. Doe,[52] and recognized the legislative intention to prohibit the unauthorized disclosure of confidential patient information. The court also relied, in granting a recovery, on the implied covenant of confidentiality resulting from the physician/patient relationship. The court found that in this instance, it was sufficient that the defendants had disclosed that the patient had received treatment. This fact is as highly protected as is the details and nature of the treatment. The court noted that disclosure of the identity and fact of treatment would deter other persons to come for testing and treatment if they could not be assured that their presence at the clinic would remain confidential.

b. Disclosure to Opponent in Litigation

As a general rule, a patient surrenders the privilege when he/she sues the physician for malpractice. But both a doctor and his malpractice insurer were held liable when the insurer induced the doctor to divulge to it confidential

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[51]531 N.Y.S.2d 735 (S.Ct. Monroe Co. 1988).

[52]Note 50, supra.

information under the pretext that the patient was about to commence a malpractice suit. Following the disclosure, the insurer persuaded the doctor to discontinue treatment. The court held that the doctor's purposeful disclosure of the information was a willful betrayal though there had been no malice or intent to inflict injury. The case, Hammonds v. Aetna Casualty & Surety Co.,[53] refused to follow the holding in Hague v. Williams[54] in which recovery was denied, for disclosure by the physician to an insurance company in a life insurance application that the child had had heart trouble since birth. The court in the Hague case had held that once the patient had made an insurance claim involving the health of the patient, the right to nondisclosure was lost. The Hammond case in Ohio found that the Hague case, decided in New Jersey, was contrary to Ohio public policy and not applicable. While instituting a suit for compensation would necessarily lead to waiver of the privilege, this did not permit a secret conference between the doctor and the lawyer for the patient's adversary under Ohio law. It should be noted that in the Hague case where recovery was denied, the insurer had insured the patient. In the Hammond case where recovery was granted, the insurer was the defendant doctor's malpractice insurer. The court held in granting recovery that a breach of confidentiality made the doctor liable for violating the implied condition of the contract between the physician and patient. The insurer in the case was also liable because it had caused the physician to violate his fiduciary duty. The court noted that an insurance company may not persuade a doctor to interrupt the treatment of his patient and until there is a reasonable basis to believe that a claim of medical malpractice will be made against the doctor. There was no such basis in the case. However,

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[53]243 F.Supp. 793 (N.D. Ohio 1965).

[54]181 A.2d 345 (N.J. 1962).

in Rea v. Pardo,[55] the physician's disclosure and the insurance company's solicitation of disclosure were held justified when the patient authorized disclosure of the records to his lawyer for the purpose of investigating a malpractice claim, though no such claim had been filed. The patient had sought release of the records, and Dr. Pardo immediately complied but also forwarded the records to his insurer because the policy required the doctor to notify the insurer upon having reason to believe that a medical malpractice suit would be filed.

In McNerney v. Secretary of the Department of Health and Human Services,[56] an order was sought in a proceeding under the Vaccine Compensation Program directing McNerney to sign a release to give the Department access to the physicians who had treated respondent's minor daughter. The court noted that the physician/patient privilege was not recognized under the common law and had not been recognized in the federal courts. Therefore, there is no physician/patient privilege in the Vaccine Compensation Program. The question was discussed in the case whether informal ex parte contacts between the Department's counsel and a petitioner's treating physician are improper in Vaccine Program proceedings. Some cases have held such clandestine conferences improper, but some other cases have held them proper, as in Sipes v. United States[57] finding that both sides should have access to the treating physician in the Vaccine Program situation, in which state law public policy considerations relating to confidentiality were of doubtful significance.

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[55]522 N.Y.S.2d 393 (N.Y.Ap.Div. 1987).

[56]1992 W.L. 123045 (Cl.Ct. 1992).

[57]111 F.R.D. 59 (S.D.Cal. 1986).

In Cutter v. Brownbridge,[58] the plaintiff's psychiatrist disclosed details of the husband's therapy to his former wife who wanted the information for use in the pending legal action in which she sought the suspension of her former husband's visitation rights of her children. The psychiatrist submitted the information voluntarily, not under subpoena or other legal compulsion. Defendant psychiatrist had promised plaintiff not to reveal his confidences. Plaintiff sued for humiliation, shame, severe emotional injury and distress, and loss of visitation rights with his children. He also claimed violation of his constitutional right of privacy under the California state constitution. The psychiatrist claimed immunity from liability because the California code provided that disclosure in the course of a judicial proceeding is privileged and cannot form the basis for a lawsuit. The court found that the patient's right to privacy could be overridden if the need for disclosure outweighed the patient's privacy interest. In this case, though the state has an interest in shielding witnesses from collateral damage actions, the disclosures were made voluntarily without prior resort to judicial evaluation. The psychiatrist in disclosing constitutionally protected material does so at his peril, especially when he deliberately circumvented existing judicial procedures for the evaluation of constitutionally protected privileged communications prior to disclosure.

c. Disclosure to Employer

In Horne v. Patton,[59] the physician made a disclosure of his patient's medical condition to his employer, in spite of specific instructions. Plaintiff claimed that the release of the information was the cause of his dismissal. It

[58]228 Cal.Reptr. 545 (Cal.Ct.App. 1986).

[59]287 So.2d 824 (Ala. 1983).

was held that the physician had breached his fiduciary duty, created by the confidential relationship between patient and physician, that the release of information was a breach of the patient's privacy and a breach of the physician/patient contractual relationship whereby he impliedly agreed to keep the patient's information confidential. Whether a physician/patient relationship imposed a duty of confidentiality on the physician was a question of first impression in Alabama. The court relied on Hague v. Williams.[60] The Hague case found no liability, but recognized a nontestimonial privilege between physician and patient. The court also relied on Alexander v. Knight[61] where the court condemned pretrial physician disclosure, though Pennsylvania did not have a statutory physician/patient testimonial privilege at the time. The court also relied in that case on Alabama's licensing statute, which provided for license revocation in the event of a willful betrayal by the physician of a professional secret. The medical profession's Code of Ethics also supported a finding of the breach of the physician's fiduciary duty. The court found an invasion of privacy and recognized the individual's right to be free from unwarranted publicity or unwarranted appropriation or exploitation of one's personality, publicization of a person's private activities that caused mental suffering, shame or humiliation in a person of ordinary sensibilities. The court held that an employer does not have a legitimate interest in knowing each and every detail of an employee's health, and found that plaintiff's privacy had been invaded. Relying on the Hammond case, the court found that an implied contract existed and had been violated.

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[60]Supra at note 54.

[61]177 A.2d 142 (Pa.Super.Ct. 1962).

In Bratt v. International Business Machines Corp.,[62] the employer retained a physician to examine an employee with respect to her mental condition. The physician discussed the results of the examination with the employer and the employee sued for breach of confidentiality, asserting the establishment of a physician/patient relationship. Held, setting aside a summary judgment for the defendant, that a patient/physician relationship exists and the duty of confidentiality arises when the patient reasonably believes that such a relationship has been established and the physician knew that the patient had this expectation.

In Urbaniak v. Newton,[63] plaintiff had brought a workers compensation proceeding against his former employer and was then physically examined as part of a discovery proceeding in that action. At the end of the examination, the plaintiff told the nurse that he had tested HIV positive and that she should take care to sterilize the equipment used in his examination. The nurse informed the physician of the patient's HIV status and this information was included in the physician's report to the attorney for the employer's insurance company, which was then forwarded to the insurer where seven employees handled the report. The action was dismissed against the attorney and the insurer because their repetition of the employee's statement that he was HIV positive was privileged. However, compensatory and punitive damages against the physician were proper, because of the physician's covenant to keep in confidence the patient's disclosure. His failure to do so constituted a violation of the privilege.

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[62]785 F.2d 352 (1st Cir. 1986).

[63]277 Cal.Reptr. 354 (Cal.Ct.App. 1991).

d. Disclosure to Spouse

In MacDonald v. Clinger,[64] the court upheld the patient's action against the psychiatrist who disclosed personal information obtained during treatment of the patient's wife. The disclosure to the plaintiff caused his marriage to deteriorate and caused him to lose his job and to suffer financial difficulty, including the need for additional psychiatric treatment. The court relied on Doe[65] and on Hammonds[66] relying on the physician/patient contractual relation, holding that the disclosure constituted a breach of the physician's fiduciary duty of confidentiality. The breach of duty constituted a tort, not merely a breach of contract. Defendant argued that disclosures made to a patient's spouse are not actionable, relying on Curry v. Corn,[67] but the court distinguished the case because in that case the decision was based on the husband's status as head of the marital household, responsible for his wife's debts. Here the wife had sought the disclosure. Moreover, the New York General Obligations Law §3-301 provided that disclosure of confidential information by a psychiatrist or spouse will be justified whenever there is a danger to the patient, the spouse, or another person, but otherwise such information should not be disclosed without authorization.[68]

e. Disclosure under New York AIDS Confidentiality Law

In Doe v. Roe (hereinafter Doe II to distinguish it from an earlier case

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[64]446 N.Y.S.2d 801 (N.Y.App.Div. 1982).

[65]Supra at note 50.

[66]Supra at note 53.

[67]277 N.Y.S.2d 470 (Sup.Ct. Nassau Co. 1966)

[68]MacDonald supra at note 64, 446 N.Y.S.2d at 805.

of the same designation at note 50 supra), in a case of first impression, the question was whether a physician's disclosure of a patient's HIV status to the attorney representing the patient's employer in a Pennsylvania workman's compensation proceeding violated New York law. Plaintiff, who worked for the Pennsylvania company, had told the physician of his HIV positivity while consulting him for an ear and sinus problem. He asked the physician to protect confidentiality of information because he feared that disclosure would jeopardize his employment. Some months later plaintiff filed a claim for compensation benefits asserting that his ear and sinus problem was work related. Plaintiff's doctor was subpoenaed to appear at the workman's compensation hearing and was required to bring copies of the plaintiff's medical records. The employer's attorney mailed the subpoena and two medical reports to the doctor's New York office. Each of the reports included a release signed by plaintiff authorizing the release of medical information regarded the "above-reference[d] claim" to plaintiff's employer. The attorney's transmittal letter advised the physician that he would have to appear at the hearing if the requested information were submitted to the lawyer. Defendant physician forwarded plaintiff's entire chart to the attorney including the references to plaintiff's HIV positivity.

Applying New York rather than Pennsylvania law, the court held that the plaintiff had the right to maintain a private cause of action against his physician for violation of Public Health Law Article 27-F; that the disclosure violated the confidentiality provision of Art. 27-F; that plaintiff could recover punitive damages; and that plaintiff had a cause of action for breach of his oral promise to preserve confidentiality. Article 27-F, §§2780-2787 of the Public Health Law, passed in 1988, defines the confidentiality of AIDS victims. The court noted the legislature's intention that HIV related information is not

improperly disclosed in order to encourage voluntary testing. While 27-F does not provide for an express cause of action for its breach, nonetheless the right to a private cause of action could properly be implied to advance the legislature purpose of insuring confidentiality. Moreover, a private cause of action is consistent with New York's common law which allows a cause of action for a physician's breach of confidence. Public Health Law §2782 permits or compels the disclosure of HIV information, including the release of such information to insurance institutions for limited purposes if the institution secures a dated and written authorization from the protected individual so as to show that the institution or health care provider is authorized to disclose the information, the nature of the information to be disclosed and the purpose for which the disclosure may be made. Here the court held that the disclosure was not authorized because it had not been handled in accordance with the requirements of the statute and was released not to an insurance institution but to the attorney for plaintiff's employer and because the authorization did not contain the requisite information.

The court also held that the subpoena relied upon by the defendant did not authorize disclosure of plaintiff's HIV status, because under the New York Criminal Procedure Law, no disclosure of confidential HIV related information may be made pursuant to a subpoena. The defendant's disclosure also did not contain a statement prohibiting redisclosure as required under the public health law. The court allowed the imposition of punitive damages in spite of defendant's objection that the disclosure had merely responded to a subpoena. The court noted that while the subpoena directed the physician to appear at the hearing, but instead she disclosed the confidential information to the employer's attorney. Compliance with the subpoena was voluntary and could have been ignored with

impunity under the appropriate New York practice. Moreover, the authorizations to disclose were signed two years before defendant promised not to disclose plaintiff's HIV status and were therefore no longer applicable. The court treated the situation not as one of implied promise of confidentiality but as a breach of an express contract to preserve confidentiality.

In McBarnette v. Feldman,[69] the court held that the Department of Health was entitled to enforce a subpoena for the production of patient records of a dentist who had died of AIDS. The court found that the production of the records was not precluded by the physician/patient privilege because the records were needed in order to make an epidemiological study of the dentist's patients. Public Health Law §206(1)(d) and (j) authorized the Commissioner of the Department to protect the health and life of the people of the state and allowed the Commissioner to issue subpoenas during the conduct of an investigation. The physician/patient privilege has to yield when the legislature obligates the privilege to effectuate overriding public policy. Public Health Law Art. 27-F providing for confidentiality of HIV and AIDS related information was not applicable because the release of the records in this instance would not result in releasing such information of patients.

f. Defenses

The following defenses are available to physicians charged with making an unauthorized disclosure or revealing confidential information:

(1) Disclosure by physician to his malpractice insurer where a physician has reasonable belief that patient would file a claim against him. REA[70]

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[69]582 N.Y.S.2d 900 (Sup.Ct. Suffolk Co. 1992).

[70]Supra note 55.

(2) Disclosure to an insurer to whom the patient had applied for life insurance.[71]

(3) When the disclosure is in the public interest, is in the scientific interest, or in the private interest of the patient. To be actionable, the disclosure must be without legal justification or excuse.[72] When there is a need to protect the safety of the patient or others,[73] or where the patient has a sexually transmitted disease where the law so requires.[74] There are other situations where there may be justifications for disclosure which are deemed to outweigh the patient's right of confidentiality. The physician has a duty to report otherwise confidential information relating to infectious disease,[75] and incidences of cancer.[76]

In Simonson v. Swenson,[77] a case decided in 1920, the court held that when a physician is given confidential information by a patient, when the patient's disease is of a dangerous and highly contagious nature so that there is great danger of contagion, this should be disclosed to exposed persons, when no other means of protection is possible. The physician may make as much of a disclosure to such other persons as is necessary to prevent the spread of disease. The court held that when a physician believes that disclosure is necessary to prevent the

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[71]Hague, supra note 60.

[72]MacDonald, supra note 64.

[73]Tarasoff v. Regents of University of California, 17 Cal.3d 425, 131 Cal.Reptr. 14, 551 P.2d 334.

[74]Simonson v. Swenson, 104 Neb. 224 (177 N.W. 831).

[75]Pub.Health Law §§2101, 2300(5).

[76]Pub.Health Law §2401(1).

[77]177 N.W. 831 (Neb. 1920)

spread of such a disease, he cannot be held liable for damages even if his diagnosis was mistaken.

The defense of an overriding public interest was also involved in Howes v. United States.[78] An Air Force psychiatrist disclosed that his patient's husband, not the patient herself, was involved in excessive use of alcohol and marijuana. He was held not liable for damages, the court finding no physician/patient relationship between the wife and the psychiatrist, and also that even if there had been unauthorized disclosure, an applicable Air Force regulation designed to protect national security overrode the physician/patient relationship because the patient's husband held a high security clearance position of a highly sensitive nature involving cryptologic machines.

The protection of others was also involved in People v. C.S.[79] where the court upheld the constitutionality of a statute requiring a person convicted of unauthorized possession of a hypodermic to undergo HIV testing. The court also upheld the court order requiring disclosure of positive results to jail personnel and police supervisors as within the court's discretion. The purpose was to protect law enforcement personnel. However, disclosure to the state attorney general's office was disallowed.

Disclosure may also be appropriate when the purpose is to protect a patient himself. Plaintiff complained of the disclosure of protected communications by his psychiatrist to a court-appointed psychiatrist during the course of a consultation, after plaintiff's wife had petitioned the court to have the patient involuntarily hospitalized for psychiatric treatment. The court acknowledged that the patient's confidences had been violated, which, under Michigan law, was also

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[78]887 F.2d 729 (6th Cir. 1989).

[79]583 N.E. 2d 726 (Ill.App.Ct. 1991).

unprofessional conduct. The court, however, remanded the case holding that whether disclosures were reasonably necessary to protect the patient's interest and the interests of others was a question for a jury.

g. Patient Waiver of Physician-Patient Privilege

When a patient sues a defendant other than his or her physician and information acquired by the physician as a result of the physician/patient relationship would be legally discoverable by the defendant in that litigation, the patient is deemed to have waived any right to proceed against the physician for the physician's disclosure to the defendant or his or her attorney.[80] Plaintiff sued hospital for a heating pad burn, and the physician disclosed information relating to the injury to the hospital. Held, there was no infraction.[81]

h. Physician's Testimony Ordered by Court or Otherwise Imposed by Law

In Guity v. Kandilakis,[82] a psychologist testified in divorce litigation for the wife of a couple which had been in marital counseling with him. The husband sued for breach of physician/patient confidentiality. The trial judge had instructed the psychiatrist to testify only about the joint sessions, and the psychiatrist complied. Held, the presence of the wife at the sessions did not constitute a waiver of the physician/patient privilege and the psychologist was immune from suit because his testimony was pursuant to court order.

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[80]Mull v. String, 448 So.2d 952 (Ala. 1984).

[81]See also Fedel v. Wierzbieniec, 485 N.Y.S.2d 460 (Sup.Ct. Erie Co. 1985); Moses v. McWilliams, 549 A.2d 950 (Pa.Super.Ct. 1988).

[82]821 S.W.2d 595 (Tenn.Ct.App. 1991).

In Vond v. Pecaut,[83] a woman patient sued her court-appointed psychologist who had written a letter to a state court judge recommending the modification of a previous custody order granting her the custody of her son. The psychologist believed that the woman's conduct was indicative of more severe emotional difficulty than the psychologist had been previously aware. The court dismissed the claim for defamation and invasion of privacy because the information to the judge was absolutely privileged in the proceeding in which her fitness as a mother was at issue. But even if not absolutely privileged, defendant was protected by a qualified privilege because he had fulfilled the five elements of good faith, an interest or duty to uphold, the statement limited in scope to that particular purpose, a proper occasion and a publication in proper manner and to the proper parties only. The court also held with respect to the claim of invasion of privacy that the letter was at most a reasonable intrusion on plaintiff's privacy.

i. Disclosure to Spouse

Courts have frequently exercised liberality in permitting disclosure to spouses. In Mikel v. Abrams,[84] physician disclosed patient's overuse of alcohol in a letter confirming earlier telephone discussions. The disclosure was not unreasonable and it was to a person who had a legitimate interest in the subject matter.

In Curry v. Corn,[85] the court held that the prospective husband or wife

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[83]561 F.Supp. 1037 (N.D.Ill. 1983).

[84]541 F.Supp. 591 (W.D.Mo. 1982), aff'd without opinion 716 F.2d 907 (8th Cir. 1983).

[85]277 N.Y.S.2d 470 (Supr.Ct. Nassau Co. 1966).

is entitled to know before marriage whether his or her future spouse is suffering from a disease condition and during marriage each spouse has the right to know of any disease with a bearing on the marital relationship. The case has, however, been limited in its impact by the decision in Doe[86] and MacDonald.[87] In MacDonald, the court had held that more stringent standards should be applied to disclosure of psychiatric information ~~for disclosure of information in the absence of~~ an overriding concern to ~~deter the person in need from obtaining the help required~~. The court did not indicate whether this more protective ruling on privacy is applicable to medical problems other than psychiatric problems.

j. Summary of Rights of Confidentiality

A number of general conclusions are possible from the array of cases involving breach of confidentiality between physician and patient. Unauthorized publications generally present a relatively easy case, as in Anderson involving publication of a photograph implying that the plaintiff had AIDS, and in Doe, the publication of a book recounting intimate information about the patient's marriage. Disclosures to employers present a less clear case, in that disclosure to an employer is considered a breach of confidentiality or an invasion of privacy, but there may be situations in which it may be acknowledged that the employer has the right to know about certain medical conditions in his employees, as in Horne. Disclosure to a spouse, on the other hand, has often been said to involve a justifiable breach of confidentiality. In MacDonald, the disclosure of psychiatric information to a patient's spouse was permissible when there is danger to the patient, to the spouse or to another patient. In the area of

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[86]Supra note 50.

[87]Supra note 64.

genetic disease, if two carriers of a particular genetic disorder were to marry and have children, the potential for overwhelming emotional and psychological strain in rearing children with a genetic disease might, perhaps, be considered by a court to provide sufficient grounds to permit, if not to mandate, disclosure. Such a disclosure might fall under the lenient standard of the Mikel decision which allowed disclosure to a spouse when the information has a bearing on the marital relation. Under MacDonald, a psychiatrist may, to protect the spouse, disclose that the patient is psychologically or emotionally disturbed. Perhaps it could be argued that there is just as good reason to allow a geneticist to disclose to a patient's spouse that the patient carries a genetic trait which may have serious consequences if the patient's spouse also has the trait.

It is more difficult to analogize mental condition to potential genetic disorders in the case of custody battles. A mother's mental condition during an ongoing custody proceeding permitted certain disclosures relevant to her fitness as a parent. There is a question whether information relating to a person's genetic affliction which might cause physical or mental deterioration might also be a matter as to which disclosure may be permissible or required in a contest for custody. There is an additional question whether legislation permitting the disclosure of genetic information would be regarded as a statement of the state's public policy to authorized persons to bring private lawsuits for such unauthorized disclosures.

5. Conclusion

An examination of the historical background of the right to privacy establishes that the right is a recognized legal concept, though its scope is not

fully defined.It is a common law right which enjoys great respect but little enforcement. The major tort law development to protect a right to privacy was Prosser's analysis of the Warren and Brandeis ideas, particularly in the category of a right of action for public disclosure of private information. An examination of the history of the development of this tort indicates that it is not much of a shield against invasions of privacy. With current emphasis on First Amendment rights of freedom of expression and freedom of the press, the right of action for public disclosure of private information has had little success. To be sure, there is not a single reported case which involves the publication of genetic information. More recent developments in the privacy tort areas suggests that the violation be based on contractual, rather than person injury grounds, so that only the specific information which is conveyed to another under a seal of confidentiality would be protected. Though this is an imaginative development, it has not been reflected in any recent decisions in the courts.

The one area in which patients' rights have been successfully protected in some cases is the old and established field of physician-patient privilege and confidentiality. But even the confidentiality area has developed a number of exceptions to the protective scope of the privilege, in that disclosures have been allowed, not only in easily justifiable areas as in the disclosure of information for the protection of public health, or for necessary information to the patient's spouse, but also in instances where duties to inform insurers and others were relied upon. The field of physician-patient confidentiality is not an area of common law development, but rather a statutory development in the several states. It is akin to earlier common law approaches in that it relies on private law suits for its vindication and in that common law principles are frequently relied upon in the decision of the cases.

In spite of its historical utility, and in spite of its occasional availability in private litigation, the privacy torts and the actions based on physician-patient privilege and confidentiality do not provide sound protections for genetic privacy, and are not likely to provide adequate protections should efforts be made to use them for this purpose in the future. The patient-physician privilege and confidentiality cases, moreover, are limited in their scope to actions by patients against physicians, and could not be brought against anyone else who happens to breach the privacy of genetic information. The limited nature and lack of success of these remedies argue strongly for modern statutory remedies specifically addressed to the violation of genetic privacy.

Chapter 2. The Concept of Privacy -- What Is Protected by the Right of Privacy?

1. Introduction

This segment of the paper deals with the concept of privacy and the right of privacy in general, a subject that has attained a substantial literature.[1] Though some reference will be made to the applications of privacy protection to genetic information, that concern will also be separately addressed.

2. Control of Information Theories of Privacy

Alan F. Westin, in his work on Privacy and Freedom, notes that ideas of privacy are found in many cultures and suggests that privacy is a fundamental aspect of social structure.[2] Westin defines privacy as follows:

> Privacy is the claim of individuals, groups, or institutions to determine for themselves when, how, and to what extent information about them is communicated to others. Viewed in terms of the relation of the individual to social participation, privacy is the voluntary and temporary withdrawal of a person from the general society through physical or psychological means, either in a state of solitude or small-group intimacy or, when among larger groups, in

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[1]Ruth Gavison, Privacy and the Limits of Law, 89 YALE L.J. 421, 422 (1980) ("Commentators have argued that privacy rhetoric is misleading: when we study the cases in which the law (or our moral intuitions) suggest that a "right to privacy" has been violated, we always find that some other interest has been involved."). The concept of a right to privacy and its scope has been debated in the literature since Samuel D. Warren and Louis D. Brandeis, The Right to Privacy, 4 HARVARD L. REV. 193 (1890); Gerald Dickler, The Right of Privacy: A Proposed Redefinition, 70 U.S. L. REV. 435 (1936); Louis Nizer, The Right of Privacy: A Half Century's Developments, 39 MICH. L. REV. 526 (1941); William L. Prosser, Privacy, 48 CAL. L. REV. 383 (1960); Edward J. Bloustein, Privacy as an Aspect of Human Dignity: An Answer to Dean Prosser, 39 N.Y.U. L. REV. 962 (1964); Hyman Gross, The Concept of Privacy, 42 N.Y.U. L. REV. 34 (1967); Charles Fried, Privacy, 77 YALE L.J. 475 (1968); Ruth Macklin, Privacy and Control of Genetic Information, in GENE MAPPING: USING LAW AND ETHICS AS GUIDES 157 (George Annas and Sherman Elias eds., 1992).

[2]ALAN F. WESTIN, PRIVACY AND FREEDOM 7 (1967).

a condition of anonymity or reserve.[3]

Westin's definition focuses on two elements of privacy which form the basis of much subsequent writing. One element of the definition addresses the subject of control over personal information. The other part addresses aspects of both physical and psychological privacy, involving both access to the person and psychological withdrawal of the person from the immediate environment. In Privacy and Freedom Westin draws upon examples from many societies to illustrate that the desire for privacy is natural for humans and is found in many cultures. He further asserts that scientific evidence demonstrates that the desire for privacy and the need for privacy in order to flourish is so fundamental that it is even found in animals.[4] To Westin, this natural desire for privacy is balanced by an effort on the part of government and others to use surveillance as a societal mechanism for guarding against anti-social behavior. Westin writes that modern technology offers opportunities for snooping and invasion of privacy: "Technological change promises to give public and private authorities the physical power to do what a combination of physical and socio-legal restraints had denied to them as part of our basic social system." [5] While crosscultural notions of privacy do not necessarily reflect shared values, Westin notes that in Western culture each person has a series of concentric zones of privacy --

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[3] Id.

[4] Id. at 9 ("Ecological studies have demonstrated that animals also have minimum needs for private space without which the animal's survival will be jeopardized. . . . Experiments with spacing rats in cages showed that even rats need time and space to be alone [citation omitted]. When rats were deliberately crowded in cages, patterns of courting, nest building, rearing the young, social hierarchies, and territorial taboos were disrupted. Aggression and fighting increased and sexual conduct became more sadistic.").

[5] Id. at 30.

regions leading to a central core self which is protected in contemporary laws.[6]

To be effective, social systems must leave some private realm untouched. Within this analysis, which accepts privacy rights as natural and inherent in the rights protected in contemporary U.S. society, Henkin asserts that private rights are protectable as public goods.[7] The role of privacy is so basic in contemporary U.S. society that the psychological impact of disclosure, through "unmasking" or the revelation of unfavorable personal information, may include nervous breakdowns and even suicide.[8] Westin observes that "Given the delicacy of a person's relations with intimates and associates, deciding when and to what extent to disclose facts about himself-- and to put others in the position of receiving such confidences-- is a matter of enormous concern in personal interaction, almost as important as whether to disclose at all."[9]

In consequence, privacy has important implications for sensitive genetic information, because information could easily be made available through screening that remains undiscovered by the subject of the test, or by retrieving genetic information from a databank without seeking the subject's permission.

In addition to the need to protect the individual from the disadvantages of improper disclosure, Westin asserts that privacy serves the need of

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[6]Id. at 33 ("This core self is pictured as an inner circle surrounded by a series of larger concentric circles.").

[7]Louis Henkin, Privacy and Autonomy, 74 COLUM. L. REV. 1410 (1974).

[8]Westin, supra note 2, at 33-34, 41. ("Nervous breakdowns and physical collapses from overwork often have as one major ingredient the lack of that emotional relief from stimulation which is a function of privacy".). See also Sidney Jourard, Some Psychological Aspects of Privacy, LAW & CONTEMP. PROBS. 307 adding that "If he (sic) conceals his distress and discontent and impersonates a contented, conforming citizen, he may have a "breakdown" or become a socially invalidated mental patient."

[9]WESTIN, supra note 2, at 41.

individuals to process information and to plan for the future without intrusion in their thought process. In this regard, privacy functions as a condition to social thought and planning, making the lack of privacy a concern for government advisors and decisionmakers who require not just solitude, but the ability to prepare their creative ideas outside the public's limelight. He notes that the men who wrote the U.S. Constitution worked in secret and did not surrender secrecy until they revealed select parts of their deliberations, many years afterwards.[10] Citing Merton's sociological studies,[11] Westin indicates that an important function of privacy involves insulation of actions and thoughts from surveillance by others and that social values exist to facilitate calm decisionmaking.

Westin's concern for the protection of privacy is explained by the governmental and private intrusions that had become a reality by the 1960's. He describes then-recent electronic surveillance technology that was readily available at low cost. He is critical of the listening and watching devices and the sophisticated techniques available for snooping into people's private lives, decrying the collapse of legal controls against eavesdropping.[12] In the area of employment, he decries the use of personal information that has been uncovered through secret violations of privacy. Westin raises issues that have since become important in the context of genetic technologies. He questions whether employers

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[10]Id. at 46-47 ("The privacy involved in the writing of the American Constitution suggests the importance of confidentiality of organizational decisions until agreement has been reached, and confidentiality for a reasonable time thereafter of the way in which they were reached.").

[11]Id. at 58 (discussing ROBERT MERTON, SOCIAL THEORY AND SOCIAL STRUCTURE 375 (1957) ("'Privacy' is not merely a personal predilection; it is an important functional requirement for the effective operation of social structure.")).

[12]WESTIN, supra note 2, at 102 ("A final factor that has contributed to the growth of private eavesdropping is the collapse of legal controls.").

genuinely intend to fashion and administer personality tests that will sort out bad risks, and whether the true motive is proper job placement or some other use of the information they have gathered.[13] The rationale of "proper placement" on the job has also been offered for genetic testing in pre-placement examinations and for other genetic applications to occupational medicine, though the beneficial results of these programs remain unknown.[14]

3. Privacy as Property or as Protectible Aspect of Personality

Westin and other commentators believe there is a property interest in private information and that such property rights are linked to the protection of liberty.[15] In this context, Westin views "the Fourth Amendment as the Court's basic constitutional tool for defining privacy rights in the post-1945 setting of surveillance technology."[16] Edward Shils, not unlike Westin, defines the breach of privacy as involving loss of control of the dissemination of private information.[17] Shils writes of the harms that may follow intrusions and unwanted

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[13]Id. at 135-40.

[14]See chapter 7 generally regarding genetic testing in preplacement examinations.

[15]WESTIN, supra note 2, at 330; Fried, supra note 1, at 486; Warren and Brandeis, supra note 1, at 211 ("The right of property in its widest sense, including all possession, including all rights and privileges, and hence embracing the right to an inviolate personality, affords alone that broad basis upon which the protection which the individual demands can be rested.").

[16]WESTIN, supra note 2, at 343. Westin also notes that "[t]he Griswold case, as Justice Black noted to his dismay, represented the creation of a constitutional right to privacy comparable to that first advocated as a torts claim by Warren and Brandeis in 1890." Id. at 355.

[17]Edward Shils, Privacy: Its Constitution and Vicissitudes, 31 LAW & CONTEMP. PROBS. 281, 282 (1966) ("[T]he decisive element in a breach of the boundary that defines the area of privacy . . . is the acquisition or transmission of information without the voluntary consent or initiative of those whose actions and words generate the information.").

disclosures of private information as a source of unhappiness, that may cost occupational opportunities or may cause financial injury.[18] But Shils perceives these effects as secondary in importance to the interference with "social space" (also reminiscent of Westin's concentric spaces) around an individual, affecting recollections of the past, conversation, body and image.[19]

Another definition of privacy which relies largely on control of private information is offered by Charles Fried. He views "privacy" as a construct regarding control over one's own thoughts and body which enables each person to develop trust, love, friendships and other forms of intimacy.[20] In Fried's view this aspect of privacy is part of our social structure. Fried asks why invasion of privacy offends our sense of humanity. "The necessity of privacy as a context for respect, love, friendship and trust explains why a threat to privacy threatens our integrity as persons," and thus undermines personal rights that may or may not be protected by law.[21]

Fried notes that privacy is a part of a common conception of personality and entitlement. Other commentators[22] have adopted with approval Fried's view that "[p]rivacy is not simply an absence of information about us in the minds of others; rather it is the control we have over information about ourselves."[23] Privacy seems to be related to secrecy, to limiting the knowledge of others about

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[18]Id. at 306.

[19]Id.

[20]Fried, supra note 1.

[21]Id. at 477.

[22]E.g., Ferdinand Schoeman, AIDS and Privacy, in AIDS AND ETHICS 240 (Frederic G. Reamer, ed., 1991).

[23]Fried, supra note 1, at 482.

oneself, thus ultimately controlling information that is available about us.[24]

Fried notes that "in most developed societies the only way to give a person the full measure of both the sense and the fact of control is to give him a legal title to control. A legal right to control is control which is the least open to argument; it is the kind of control we are most serious about." Fried's view suggests that legislation addressing genetic information may be needed to protect privacy while obtaining access to information to safeguard the public health; Fried also views "privacy in its dimension of control over information as an aspect of personal liberty."[25]

Privacy requires preserving a domain of information or behavior for oneself, to the exclusion of the rest of the world with whom we do not want to share that information. Under this analysis, privacy is protected by law to preserve individual freedom by safeguarding the small zone of information and personal attributes defining each person's self concept. The essence of this view is that privacy is intimate and personal, and that to be meaningful, information must be under the voluntary control of the individual. Privacy, in Fried's view, is nonetheless distinguishable from autonomy, which pertains to actions and decisionmaking.[26]

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[24]Shils, supra note 17, at 282. Shils describes "the decisive element in a breach of the boundary that defines the area of privacy... It is the acquisition or transmission of information without the voluntary consent or initiative of those whose actions and words generate the information." Id.

[25]Fried at 482.

[26]But see Mark A. Racanelli, Reversals: Privacy and the Rehnquist Court, 81 GEO. L.J. 443, 453 (1992), noting that "[t]he autonomy-based conception of privacy is the basic formula for the fully bloomed 'traditional' view of privacy."

4. Privacy as a Cultural Norm

Macklin also views privacy rights as a social construct, but as one that is possibly unique to the Western society.[27] She notes that privacy does not exist in some cultures. Under Macklin's analysis, genetic information is personal information about the individual, but it also includes the general category of medical information that is broadly available on a need to know basis, thus providing access to many people. Consequences of disclosure of genetic information range from the extremely detrimental (loss of employment, insurance or housing as experienced by AIDS patients in the recent past) to embarrassment. She notes that embarrassment too has gradations of significance. It seems that Macklin is less oriented to base privacy in the control of personal information than Westin and Fried, for instance. She notes that "[t]he claim that genetic information should be treated as private has obvious implications for the control of such information. It ought to remain in the hands of the person to whom it applies and revealed to others only with that individual's consent. Whether this ethical conclusion will be respected by policy makers in the future is something about which we can only speculate."[28]

Macklin considers justifications for breaches of confidentiality, practical as well as theoretical aspects of privacy in the medical context. Macklin notes, "A high likelihood of harm to others can justify placing limits on individual liberty,"[29] but she contends there must be sharp distinctions between the need to know and the mere desire to know. It should be noted that Macklin looks to New

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[27]Macklin, supra note 1, at 157.

[28]Id. at 160.

[29]Id.

York State AIDS legislation[30] as a model because it offers a statutory definition of the parties to whom information may legally be disclosed without consent from the "protected individual" and to the exclusion of others. These parties include health care providers, facilities, insurers, third party payors, state and local health officers and various government agencies, posing the danger that under the New York law, the exception may swallow the rule.[31] Macklin also summarizes Tarasoff v. Regents of University of California[32] and raises the question of its implications for need to know in the genetics context. She questions the requirement of a duty to disclose genetic traits to relatives in the face of rights to informational privacy. Macklin suggests that the genetic counselor should first urge the patient to disclose voluntarily, but notes that the precise role of the health care professional remains an open question. Although Macklin foresees instances where it would be proper for the health professional to disclose without the patient's consent, she does not provide examples of those situations that present an overriding need for information, weighed against the protection of individual privacy. She suggests that to justify disclosure, the need for information must be very important.[33]

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[30]AIDS Testing and Confidentiality of HIV-Related Information, N.Y. COMP. CODES R. & REGS tit. 10, §§63.1-63.10 (1993).

[31]Macklin, supra note 1, at 161.

[32]551 P.2d 334 (Cal. 1976).

[33]Macklin, supra note 1, at 170 ("To overturn existing ethical and legal presumptions in favor of protecting individuals' rights to privacy and confidentiality, a significant benefit to specific individuals or to the public must be identified."). Cf. PRESIDENT'S COMMISSION FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL AND BEHAVIORAL RESEARCH, SECRECY AND COUNSELLING FOR GENETIC CONDITIONS: THE ETHICAL, SOCIAL AND LEGAL IMPLICATIONS OF GENETIC SCREENING AND COUNSELLING AND EDUCATION PROGRAMS (U.S. Govt. Printing Office 1983), at 44.

Referring to Edgar and Sandomire,[34] Macklin notes that theories of privacy have been used by courts to restrain media disclosure, but that requirements for proof of damages are strict in those cases.[35] For secondary workers who are not directly involved in health care providing but may be involved in billing or custodial work which may inadvertently give them direct access to otherwise personal health information, she complains that the prevailing standards are unknown. It is uncertain, by ethical or legal standards, for example, what controls if any should be placed on the disclosure of information to health care personnel who do not have direct contact with the patient, while processing vital confidential information. A related issue concerns whether public health officials can credibly reassure affected populations that privacy rights will be protected to gain access to and cooperation of persons who require treatment. Macklin states that in light of the compelling personal interest in privacy, "[w]hether compulsory genetic screening programs can be ethically justified depends chiefly on the purpose for which screening is mandated and on the potential benefits to the individuals required to undergo the screening."[36] She continues, "[a]lso important, but secondary, are the safeguards employed to prevent the disclosure of sensitive genetic information to third parties."

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[34]Harold Edgar and Hazel Sandomire, Medical Privacy Issues in the Age of AIDS: Legislative Options, 16 AM. J.L. & MED. 155 (1990), discussed in Macklin, supra note 1, at 160.

[35]Id. at 162.

[36]Macklin, Mapping the Human Genome: Problems of Privacy and Free Choice, in GENETICS AND THE LAW III 107, 107-108 (Aubrey Milunsky & George J. Annas eds., 1985). Determining whether market and other considerations warrant overriding individual privacy and free choice depends on which moral principle is used as a basic premise in the argument: "The application of a utilitarian moral principle, using a cost-benefit analysis as in the examples of insurance companies and industry . . . will yield one result . . ., whereas an appeal to the primacy of individual rights of privacy and liberty will yield another." Id. at 109.

These issues of disclosure also reach beyond the health care setting, into the family context. Privacy issues involving family members who need or want access to personal genetic information raise special and difficult issues. Macklin has raised the issue of privacy for individuals in relation to their family members, noting that "[t]he identification of relatives found through genome mapping to be at risk for genetic disease may result in inflicting unwanted information on those individuals".[37]

Another view which does not emphasize control issues is that of Ruth Gavison. She views privacy as a "distinct and coherent concept" that has legal value.[38] She asks two questions: "The first relates to the status of the term: is privacy a situation, a right, a claim, a form of control, a value? The second relates to the characteristics of privacy: is it related to information, to autonomy, to personal identity, to physical access?"[39] For Gavison, control relates not only to the quantity of data but to the substantive quality of the information that is sought.[40] Gavison criticizes Fried's use of individual "control" of information as a criterion:

> People may simply be uninterested in an individual, and thus not care to acquire information about him. Such an individual will have 'privacy' even if he resents it. To say that an individual controls the flow of information about himself is thus not enough to tell us whether he is known in fact. We also must know whether there are restrictive norms, whether these are obeyed, how the individual has chosen to exercise his control, and whether others have acquired information about him in other ways or at all. The view of privacy presented by Alan Westin is not vulnerable to this difficulty.[41]

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[37]Id. at 111.

[38]Gavison, supra note 1, at 422.

[39]Id. at 424.

[40]Id. at 431.

[41]Id. at 427, n.22.

Gavison places great weight on the ability to choose privacy and have that choice respected.[42] She also points out that the mere wish for privacy may not provide an adequate justification for its protection, since criminals and other antisocial people may claim the need to invoke their right to privacy when planning anti-social deeds. Ultimately, she views privacy as a "complex of these three independent and irreducible elements: secrecy, anonymity and solitude,"[43] and she concludes that a balance between privacy and its loss is a desirable social goal to assure survival.[44] Gavison asserts that invasions of privacy in the contemporary context may be more serious and more permanent than in the past, thus rendering privacy "no different from other basic entitlements" in its value for advancing society and protecting liberty.[45]

In his chapter on "AIDS and Privacy," Schoeman discusses privacy norms in the context of the AIDS pandemic. His comments have implications for genetic information.[46] Rules that balance rights to privacy against the need for disclosure of AIDS or HIV positivity between spouses or sexual partners may have bearing on information derived from genetic testing and information on genetic conditions, generally -- allowing, of course, for the major differences between sexually transmitted and genetic disease.

Schoeman divides conceptions of privacy into the broad and narrow ranges

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[42]Id. at 427.

[43]Id. at 433.

[44]Id. at 440.

[45]Id. at 469.

[46]Schoeman, supra note 22, at 240 ("AIDS . . . is destined to have as much impact on the contours of our notion of privacy as computerization of records and the legalization of abortion did.").

of rights or norms.[47] Schoeman labels privacy norms that allow discretion in the achievement of a given objective as "narrow privacy." Schoeman refers to Fried's discussion of privacy, when describing the importance of intimacy in physician-patient relations, particularly in therapeutic situations where the essence of the treatment involves the communication of private or intimate information. According to Schoeman, narrow privacy pertains to the extent to which second parties may have information about an individual. The restriction of physical access to persons characterizes the broader concept of privacy. In a medical context, privileges of access to confidential information are afforded to the medical professional because of the need for information that promotes patient welfare in a socially responsible manner. He notes that the limits on this type of confidentiality fall clearly within the boundaries of socially acceptable behavioral norms. Notwithstanding confidentiality, information on child abuse and on dangerous violent behavior (such as gunshot wounds) are subject to mandatory reporting to the state. For Schoeman, such differences in treatment of information serve social purposes, as for instance in the therapist-client relationship where the relationship is a vehicle for achieving the goal of maintaining order in society.

To Schoeman, a broader view encompasses anonymity and restricted physical access as part of the definition of privacy. The narrow range of privacy affects the individual's ability to control personal information. Privacy is an important means of respecting or even socially constructing moral personality. At the broadest end of the spectrum, privacy is thought to be the measure of the extent an individual is afforded the social and legal space to develop the emotional,

[47]Id. at 242.

cognitive, spiritual, and moral powers of an autonomous agent, comprising qualities like independent judgment, creativity, self-knowledge, and self respect.[48] Private information about a person therefore deserves protection unless there is a "need to know" on someone's part that makes withholding the information unreasonable. In Schoeman's analysis, the role of the "need to know" -- which may be affected by cultural and social perceptions -- determines whether information is protected in a given context, and shapes the responsibility of the recipient of the information.[49]

Ronald Bayer has described the manner in which privacy concerns for victims of AIDS and HIV infection have affected the shaping of public health policy.[50] In the AIDS endemic, the traditional willingness to limit confidentiality in order to strengthen public health decisionmaking was opposed by politically strong interest groups. Consequently, there was no early decision to allow the disclosure of HIV seropositivity in order to help to protect uninfected individuals.

In contrast to other medical information which changes over time as the patient's health status changes, genetic status does not change, and its disclosure may stigmatize the person for life, with special ramifications for insurance and employment. The politicization of health policy issues surrounding AIDS privacy also may have set a pattern for genetic testing and the storage of genetic information. In genetic information, too, the protection of privacy may clash with public health concerns which may favor more testing and the selective

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[48]Id. at 242.

[49]Id. at 243.

[50]RONALD BAYER, PRIVATE ACTS, SOCIAL CONSEQUENCES: AIDS AND THE POLITICS OF PUBLIC HEALTH (1989).

disclosure of information.

Some comments on privacy have emphasized the cultural differences in privacy protection and in the definition of what is to be protected. Weisstub and Gotlieb trace privacy to the Judeo-Christian heritage society's recognition of the inherent value of privacy and the role of privacy to fulfill the religious need for inner sanctuary, similar to Westin's arguments concerning the need to "process" information in solitude. The authors also indicate that even the ancient Greek civilization made important distinctions between public and private realms; the latter were associated with the secret, mysterious and unknown. Secrecy and control regarding information brought power to those people who held the information. At the same time, secret, private realms came to be linked to the forbidden and taboo.[51]

Other aspects of cultural differences have also been applied in the context of privacy rights. Some have commented on privacy as a contract which depends on other aspects of societal values. Without assessing its cultural or natural origin, Patricia Williams questions whether the right to privacy is a function of wealth.[52] She indicates that socioeconomic status is inextricably linked to the social construct for a given individual's entitlement to privacy. This approach ultimately relies on the notion of privacy as a social construct, with

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[51]DAVID N. WEISSTUB AND C.C. GOTLIEB, THE NATURE OF PRIVACY: A STUDY FOR THE PRIVACY AND COMPUTER TASK FORCE 8-14 (1973).

[52]Patricia J. Williams, Fetal Fictions: An Exploration of Property Archetypes in Racial and Gender Contexts, 42 U. FLA. L. REV. 81, 81-94 (1990) ("I have been thinking about the degree to which it might be that public and private are economic notions, that the right to privacy might be a function of wealth. I wonder still... if the concept intimacy, (assuming privacy is related to the drive for intimacy) is premised on socio-economic status. ... 'haves' are entitled to privacy in guarded, moated castles, while 'have nots' must be out in the open--scrutinized, looked at, seen with their hands open and empty to make sure they're not pilfering.").

varied implications depending upon the social context.

5. Privacy as Singular or Composite Right

While ethicists and social scientists have no problem, apparently, in regarding privacy as a many-faceted concept that protects a variety of interests, there has been a great deal of discussion of this issue in the law. A recurring issue relating to the protection of privacy is whether privacy is a single unitary right, or whether, at most, it is a composite of a variety of separate, independent rights recognized to protect special defined or limited interests. Warren and Brandeis thought of it as a unitary, single right, though they did reflect in their article the idea that privacy consisted of specific interests which had certain common factors. Griswold v. Connecticut[53] did speak in terms of a right of privacy as discovered or assembled by the notable Douglas opinion which sought to create an integral right out of the "emanations" arising from the "penumbras" of specific separate constitutional provisions. This was the very idea which Justice Black rejected in his dissenting opinion:

> One of the most effective ways of diluting or expanding a constitutionally guaranteed right is to substitute for the crucial word or words of a constitutional guarantee another word or words more or less flexible and more or less restricted in meaning. This fact is well illustrated by the use of the term 'right of privacy' as a comprehensive substitute for the Fourth Amendment's guarantee against 'unreasonable searches and seizures.' 'Privacy' is a broad, abstract and ambiguous concept which can easily be shrunken in meaning but which can also, on the other hand, easily be interpreted as a constitutional ban against many things other than searches and seizures.[54]

In The Concept of Privacy, Hyman Gross criticizes the Griswold decision precisely for its overbroad use of the privacy concept, emphasizing what is to

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[53]381 U.S. 479 (1965).

[54]381 U.S. at 509.

him an impermissible use of language to arrive at broader, less immediately defensible concepts that do not easily fit into established modes of constitutional protection, which are directed at specific protections rather than broad, open-ended coverage. In his analysis, Gross appears to be troubled by the indiscriminate lumping in the concept of privacy of ideas of protection of mental repose, physical solitude, physical exclusiveness as well as the important idea of personal autonomy.[55] Though challenging the overbroad, indiscriminate use of the term "privacy," he does not question the inclusion of the notion of autonomy as a part of privacy.[56] In challenging the idea of a unitary right of privacy, Gross also disagrees with Bloustein's effort to construct a unitary right of privacy as a broad aspect of human dignity.[57] Bloustein, in his article, had rejected Prosser's point of view[58] which in Bloustein's view repudiated Warren and Brandeis "by suggesting that privacy is not an independent value at all but rather a composite of the interests in reputation, emotional tranquility and intangible property."[59] Gross finds that the cases do not bear out Prosser's theory of the several privacy torts and Gross also disagrees with Bloustein on the unitary aspects of the right of privacy, rejecting Bloustein's efforts to find a common core in Prosser's several privacy torts. The question whether the right of privacy is a unitary right or a composite has not been resolved except in the minds of individual scholars. It should perhaps be noted that the dispute began more than thirty years ago and seems to have troubled scholars to a far

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[55]Hyman Gross, supra note 1, at 37-38.

[56]Id. at 38.

[57]Bloustein, supra note 1.

[58]Prosser, supra note 1.

[59]Bloustein, supra note 1, at 962.

greater extent than it has the courts.

6. Autonomy as Included or Separate Right of Privacy

Some writers regard autonomy as a subset of privacy, which also includes physical seclusion, anonymity and informational privacy.[60] On the other hand, privacy has sometimes been regarded as a part of autonomy.[61] The United States Supreme Court has not resolved this conceptual difficulty, and in its opinions has often referred to "privacy" when actually referring to autonomous exercises in personal decisionmaking.[62] One such example is clearly the case of Griswold v. Connecticut,[63] one of the basic cases in the area of protection of privacy with reference to procreational decisionmaking.

Some commentators have urged the Supreme Court to separate the concepts of privacy and autonomy, while continuing their protection under the broader category of liberty.

It has even been suggested that the successful mapping of the entire genome could eliminate the concept of autonomy altogether because in the unlikely case that individual genes are found for certain traits possibly conducive to criminal

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[60]See Bruce Winick, On Autonomy: Legal and Psychological Perspectives, 37 VILL. L. Rev. 1705, 1723 (1992) ("[The] constitution protects a zone of personal privacy within which autonomous decisionmaking, at least in certain areas, is shielded from governmental intrusion absent compelling justification.").

[61]See, e.g., Ronald J. Krotoszynski, Jr., Autonomy, Community, and Traditions of Liberty: The Contrast of British and American Privacy Law, 1990 DUKE L.J. 1398 ("Although privacy is only one example of autonomy, privacy rights are a substantial subset of personal autonomy."). See also Hyman Gross, Privacy and Autonomy, in PRIVACY 169, 181 (J. Roland Pennock & John W. Chapman eds., 1971) ("[W]hile an offense to privacy is an offense to autonomy, not every curtailment of autonomy is a compromise of privacy.").

[62]See, e.g., Winick, supra note 60, at 1723.

[63]381 U.S. 479 (1965); see also Eisenstadt v. Baird, 405 U.S. 438 (1972).

conduct, this would leave less room for independent decisionmaking in certain areas.[64]

The relationship of autonomy to informational privacy has also been noted because the involuntary release of genetic information denies to individuals the autnomous right of deciding with whom to share such information.[65] Moreover, the release of genetic information to insurers and employers clearly limits practical choices for the individual involved, again diminishing the person's autonomy. Informational privacy and autonomy are also interrelated because decisionmaking must be made on the basis of knowledge to be effective.[66] At the same time, the failure to provide information may limit another person's autonomy, if that person needs the information in order to act knowledgeably. A person who carries a gene for a particular genetic condition who refuses to share that information with a sibling may prevent that person from making an informed autonomous decision.

It is clear that whether regarded as part of a major unitary right of privacy or as a special defensible interest, the notion of personal autonomy as a right has been upheld by the Supreme Court in problem situations analogous to situations in which personal decisions must be made with reference to genetic illnesses or traits. Personal autonomy as part of the right of privacy has been

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[64]See Roger Dworkin, Medical Law and Ethics in the Post-Autonomy Age, 68 IND. L.J. 727, 738 (1993).

[65]See John C. Fletcher & Dorothy C. Wertz, Ethics, Law and Medical Genetics: After the Human Genome Is Mapped, 39 EMORY L.J. 747 (1990).

[66]See Winick, supra note 60, at 1743, quoting Justice Cardozo: "We are free only if we know, and so in proportion to our knowledge. There is no freedom without choice, and there is no choice without knowledge, or none that is not illusionary. Implicit, therefore, in the very notion of liberty is the liberty of the mind to absorb and to beget. . . . At the root of all liberty is the liberty to know." (quoting The Paradox of Legal Science, in SELECTED WRITINGS OF BENJAMIN NATHAN CARDOZO 317-18 (Margaret Hall ed., 1947)).

upheld with respect to a woman's right to terminate her pregnancy,[67] with respect to a person's right to make treatment decisions for himself or herself,[68] or to make decisions relating to the continuation or termination of life support systems at the end of life,[69] and in relation to a whole range of decisions relating to family life,[70] sexual conduct, and education.[71]

7. Privacy in the Genetic Context

A lawyer who wants to advance the protection of privacy as an essential condition to the progress of genetics in medicine and public health may draw on various aspects of the different theories to support a sustainable legal program of genetic privacy. This endeavor is greatly aided by a study of privacy focused on genetic privacy by Madison Powers, Reductionist Theories of Privacy: Definition Justifications and Implications for a Theory of Rights.[72] Powers' paper views privacy as denoting a condition of limited accessibility to some aspects of a person.[73] The limited access which he would apply is one that may

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[67]Roe v. Wade, 410 U.S. 113 (1973).

[68]LAURENCE H. TRIBE, AMERICAN CONSTITUTIONAL LAW §15-11, at 1363 n.5 (2d ed. 1988).

[69]Id., §15-11, at 1364-65. See In re Quinlan, 355 A.2d 647 (N.J. 1976), cert. denied, 429 U.S. 922 (1976); see also Cruzan v. Director, Missouri Department of Health, 497 U.S. 261 (1990).

[70]See Zablocki v. Redhail, 434 U.S. 374 (1978); see also Loving v. Virginia, 388 U.S. 1 (1967).

[71]See Meyer v. Nebraska, 262 U.S. 390 (1923); see also Pierce v. Society of Sisters, 268 U.S. 510 (1925).

[72]A paper prepared for the Department of Energy under an ELSI grant pursuant to a contract with the University of California, Los Alamos 1993). Citations and quotes from the manuscript are here included with the author's permission.

[73]Id. at 1.

result in a loss or harm not reducible to other types of consequences for that individual. He refers to his conception as a purely descriptive privacy conception derived from a normative naturalistic conception of privacy.[74] He regards privacy as one of the "compound rights" which consists of a cluster of pragmatically related and mutually supporting potential interests.[75]

Powers reviews limited access definitions, accepting the notion that if cognitive access, i.e., information about a person, is obtained, the precise mode of obtaining such information does not make a significant difference.[76] He differentiates physical access from informational accessibility or inaccessibility and considers physical access as more properly subject to examination in the context of loss of bodily integrity. In his view, physical accessibility largely involves issues of autonomy.[77] Thus, if a person is compelled to undergo genetic testing, she would experience a loss of liberty as well as a loss of personal information made available to others. If she is then given that information which she does not wish to know, she has again lost privacy through the increased cognitive access to her own personal information. The compulsory character of that loss also involves a loss of individual liberty.[78]

Powers recalls the "particular domain" criterion employed in Roe v. Wade[79] and its progeny a "privacy criterion" and contrasts it with what he calls a

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[74]Id. at 2.

[75]Id. at 3.

[76]Id. at 14-19.

[77]Id. at 22.

[78]Id. at 23.

[79]410 U.S. 113 (1973).

"balancing criterion" which is the approach employed in Planned Parenthood v. Casey.[80] He regards the privacy criterion as a naturalistic one which denotes interests inherently private, relating strongly to personal matters. The balancing or undue burden approach in Casey reflects an approach that is less insistent on women's absolute right to choose abortion. The first approach asserts that there are certain contexts in which no form of interference with a woman's decisionmaking is justified. The other approach allows the weighing of efforts at interference against other competing values. Powers in general would allow the balancing approach against other rights and interests "on some occasions."[81]

In his discussion, Powers refuses to accept the superior claim of privacy in all situations, and he rejects attempts to find any singular underlying interest that explains the importance of privacy protection in all cases. While stressing the importance of privacy, he finds the reason for its importance in the fact that many interests are implicated in the loss of privacy. Relevant privacy interests, in his view, tend to cluster, though different constellations of interests may be involved in different situations.[82]

Powers regards privacy as one of the compound rights normally involving the form of increased access to personal information. Discussing his cluster theory of underlying privacy interests,[83] he refers to privacy as "contingently valuable" and analogizes some privacy rights or rights of control over access to

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[80] 112 S.Ct. 2791 (1992).

[81]Madison Powers, Reductionist Theories of Privacy: Definition, Justification, and Implications for Theory of Rights, at 41. [Unpublished paper, March 15, 1994. Copy on file with the Legislative Drafting Research Fund.]

[82]Id. at 43.

[83]Id. at 53-54.

certain kinds of information.

> Many have correctly supposed that in some instances, nothing short of some privacy rights in the form of liberty rights, or rights of control over access to certain kinds of information, will effectively secure the condition of privacy and protect the underlying interest which gives it its significance.[84]

Applying his analysis of privacy rights to genetics, he examines the questions raised by the collection, storage and dissemination of genetic information. In sound pragmatic fashion, he examines the impact the release of information has in terms of its social and economic consequences in employment and insurance. Most significantly, he notes that access to information by others who may influence decisionmaking may interfere with a person's ability to make personal choices. The exercise of autonomy may then depend upon informational privacy. He particularly notes that compelling a woman to learn of her own carrier status may unduly influence her reproductive decisions. He also refers to the impact of the release of personal information on intimate relationships and that the release of such information to others may result in the lessening of respect by others and in social stigma. He also regards as an important aspect of privacy the impact the release of information will have when persons discover their own genetic condition. This will affect their self concepts and their stability.[85] He finds a role for the protection of privacy for government in instances where persons are unable to protect their own individual privacy interests.[86]

A significant privacy interest, in Powers' view, is the right to control what information in generated, which involves questions of personal choice with

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[84]Id. at 55.

[85]Id. at 59.

[86]Id. at 60.

respect to testing and screening. The right to control the generation of information is particularly significant when there are few ways of effectively controlling its disclosure.

Powers' general approach to privacy protections is sound and persuasive in viewing privacy as a cluster of contingent interests, and in regarding privacy rights with respect to genetic interests as dependent on the specific nature of the threats to the underlying interests at stake. In terms of the pragmatics of Powers' approach, his analysis supports the legal right to privacy in areas where the violation of privacy threatens specific injuries to the person in economic and social terms, as well as in terms of self image, stability and freedom from discrimination and stigma. Powers makes a sound case for the protection of privacy in instances where disclosure would involve harm to others, but his concern for the protection of a person's self image and psychological integrity sometimes appears to outweigh his concern for the necessary information which others may need to avoid harm to their health and other significant interests.

8. Summary Analysis of Privacy Rights

The preceding excerpts from the literature on privacy provide evidence of the many approaches which lawyers, ethicists and social scientists have brought to bear on privacy issues. One of the recurring themes in the various approaches to privacy is the theme of control of information about oneself. The right to privacy is defined as a person's right to control personal information. Generally, the commentators who approach privacy as a matter of control of information also deal with the reasons for such control, emphasizing the importance of privacy as a social norm and as a condition for intimacy and other social relations. Some views of privacy emphasize autonomy as the basic concept

in the array of privacy concerns. The question in some of the works on privacy is whether autonomy is a basic liberty concept or a privacy concept, and whether the two may be fruitfully combined. The view that privacy is based on personal autonomy is related to and sometimes combined with the idea that privacy is an essential part of personality and an essential condition for the development of the person and for the person's adaptation and adjustment to society. Sometimes, too, informational privacy has been regarded as another condition for the exercise of autonomy.

Some commentators, finding the concept of privacy too broad or diffuse for adequate definition, focus rather on loss of privacy as a subject for examination. The loss of privacy may then be examined to specify what particular aspects of life, or what interests, are lost when we speak of a loss of privacy. Gavison's submission on this issue has been that loss of privacy results from the loss of secrecy, anonymity and solitude[87]. Others may refer to the original common law ideas reflected in Warren and Brandeis and in Prosser, which include in loss of privacy the loss of seclusion or solitude, the reputational loss resulting from the publication of private facts, and the dissemination of a person's name or likeness for inappropriate purposes. Some students of privacy define it in terms of other specific losses. Giving up private information in certain well-defined narrow contexts, such as the information a patient provides a physician, is regarded as narrow privacy (Schoeman[88]) and the restriction of physical access to a person as a broader concept of privacy (Schoeman[89]).

There have also been some efforts to define privacy in cultural terms. One

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[87]Supra note 1, at 433-436.

[88]Supra note 22, at 242.

[89]Id.

approach, drawing examples from many cultures and societies, seeks to demonstrate that privacy is a natural human need, while some others, generally without disputing the need for privacy, have emphasized that the need for privacy is expressed in different ways in different societies and social settings, and that the concept of privacy may have different attributes in different cultural settings.

Some descriptions of privacy, which emphasize its significance for personality development, regard privacy as a concept having a variety of aspects in different situations, rather than being a unitary concept for all purposes. In this view, every person has an inner core which he or she protects at all costs, and a number of circumferential areas or zones where different degrees of protectiveness or controls may be appropriate (Westin, "Social Space"[90]).

The concept of privacy may also have somewhat different meanings for men and women. The literature relating to women's attitudes to privacy in its aspect of physical integrity reflects greater sensitivity to such issues.[91]

One approach to privacy is to regard personal information as property, and to view the protection of privacy as akin to the protection of property generally. Personal information, or rather information about oneself, is regarded as singularly the property of the person to whom it pertains, so as to allow the person sole control over such information, except insofar as dissemination is protected by the First Amendment. If indeed such personal knowledge and information is property, then government interference with such information or knowledge would call for protection under the Fifth Amendment in that constitutionally no person may be deprived of life, liberty or property without

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[90]Supra note 2, at 33.

[91]See Chapter 18 infra.

due process of law. Some theories regard privacy as part of the social contract, arguing that we have joined in the social contract while reserving to ourselves the control of certain areas which are singularly our own.

Discussions of loss of privacy also address issues relating to situations when disclosure may be required in the interest of others or in the public interest. Reasons for disclosure generally involve the prevention of harm to persons other than the person whose privacy is being lost in the process; in the case of genetic information, the protection to be afforded by disclosure may extend to relatives or spouses.

Few of the many analysts of the right of privacy define or describe privacy as a singular concept. Indeed, viewing the different approaches to the problem, one may conclude that most of the students of privacy are eclectic in their approaches, drawing upon various theories, such as the control theory and the autonomy/liberty theory, and referring to different aspects of these approaches in different contexts.

9. Conclusion

Whether privacy is a unitary, singular concept or a composite one is an interesting academic issue. It seems to be either a composite right, having a number of separate parts, or a unitary right which can be expressed to protect different situations and different particular interests. For purposes of the protection of genetic privacy, the approach recommended by Madison Powers yields sound practical results. Whether regarded as a singular, unitary right, or as a composite right, it is clear that the right enjoys legal protection, but that like other legal rights of a constitutional nature, it is not absolute. Parental privacy, however regarded, will be constitutionally protected when there is no

sound basis for the state to interfere with it. In the genetic context, information and choices relating to procreation do not engage any state interests but are regarded as matters of sole concern of the procreative partners, but the state may impose some conditions on a woman's right to terminate the pregnancy. Genetic information relating to matters other than procreative decisions are protected by the right to privacy, except insofar as the failure to disclose information might have serious effects on the life and health of other persons, particularly on the life and health of members of the person's family. Though, as will be noted later, the matter has not as yet been authoritatively or legally resolved, there seems to be a growing body of belief that when a person has obtained information relating to his or her own genotype, such information ought to be disclosed and may not be fully protected when a sibling's life, health, or decisions relating to life and health may depend on the information.[92]

The right of privacy also protects physical privacy in that no person may be subjected to any screening, testing or other genetic procedure without his or her consent. This right is already protected by the Fourth Amendment, but it gains additional strength and relevance through the recognition of the right of privacy.

The right of privacy also includes informational privacy in that it provides a basis for the protection of genetic information against unconsented to public dissemination, unless the information is necessary in order to protect another person's life or health. Another aspect of informational privacy is

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[92]See, e.g., LORI B. ANDREWS ET AL., INSTITUTE OF MEDICINE, ASSESSING GENETIC RISKS: IMPLICATIONS FOR HEALTH & SOCIAL POLICY ch. 8, p. 18 (1990). See also PRESIDENT'S COMMISSION FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL AND BEHAVIORAL RESEARCH, SECRECY AND COUNSELLING FOR GENETIC CONDITIONS: THE ETHICAL, SOCIAL AND LEGAL IMPLICATIONS OF GENETIC SCREENING AND COUNSELLING AND EDUCATION PROGRAMS (U.S. Govt. Printing Office 1983) at 44.

reflected in a person's right not to be told information relating to his or her own genotype. In general, persons are entitled to receive information on the results of genetic screening and testing, just as there is a general right to know the result of medical tests to which one has been subjected. The literature contains no instances in which the right of a person to find out the adverse results of a biopsy for cancer has been affirmed or denied. In the case of genetic testing, however, there is a growing literature on the question of a person's right not to know the result of a test for Huntington disease or for Alzheimer disease. Again, the issue has not as yet been determined by legislation or by judicial decision, and the right not to know is clearly a matter for discussion and concern. If a right not to know is ever clearly established, it will be a part of protected informational privacy.

In this conclusion, the matter has been discussed as if a right to privacy were a clearly legally protected right. To be further discussed is the question to what extent actual, effective protections of the right to privacy exist in law or practice.

Chapter 3. Constitutional Protections of Genetic Privacy and Related Interests

1. Introduction: Privacy as a Constitutionally Protected Right

The idea of privacy as a protectable interest has developed along two parallel lines. Warren and Brandeis can be credited with originating or advancing the idea of privacy as a protectable private interest in the tort sense. The four categories of privacy torts suggested by Warren and Prandeis and articulated in the Restatement of Torts provided a charter of private protections against intrusions into the private sphere of life and, most significantly, articulated the idea that there was a remedy to protect against the public dissemination of intimate or private facts. In effect, a lawsuit to seek damages for the public dissemination of private facts is an action which deals with the issue of informational privacy, asserting that every person has a right to control information about himself or herself.

The other line of privacy protections is the protection of privacy as a constitutional matter. It probably starts with the dominant idea of the Fourth Amendment that persons should be free from unwarranted government interference in their persons, their homes, their papers, and that this protected zone should only be breached for very substantial reasons. The constitutional idea of privacy was influenced at times by parallel developments in the privacy tort area, as in Katz v. United States, a case which made the Fourth Amendment applicable to wiretaps on phone booths. While applying the Fourth Amendment, the court mentions the right of privacy, thus importing privacy tort concepts into the Fourth Amendment.[1]

In addition to the Fourth Amendment component of constitutional privacy,

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[1]389 U.S. 347, 353 (1967).

Fifth Amendment due process provides the most pervasive support for the constitutional right to privacy. The idea that government must not deprive any person of life, liberty or property without due process of law safeguards procedural protections against government interference in the life of persons, and it also defines the proper sphere of government action, excluding areas which are not areas of government concern but are matters for the private individual control of the person, unhindered and unaffected by government interference. The constitutional protection of privacy thus deals primarily with issues of personal autonomy in spheres where government interests are not involved and where private decisionmaking does not affect government or public interests. Such autonomous personal decisionmaking involves aspects of family life, intimate aspects of family life, sexual activities, and decisions whether to have children.

In the protection of aspects of privacy that involve genetics, both tort privacy and constitutional privacy are important, as is the circumstance that these areas of privacy protection have generally informed each other. At this juncture, there are few statutory protections of privacy and as more and more information becomes available from HGI and other scientific studies, the protection of personal genetic information must significantly rely on common law protections or on whatever limited protections that state legislation provides in the area of physician/patient confidentiality which protects against the disclosure of medical records. Constitutional privacy is called upon to protect autonomous decisionmaking which may be called upon when persons need to act on genetic information. Constitutional protections may also be called for in the protection of personal and physical integrity, protected by the requirement of informed consent before a person undergoes genetic screening or testing.

The current law of constitutional privacy begins with the decision of the

Supreme Court in Griswold v. Connecticut.[2] The special application of that case to privacy concerns in the genetic area is discussed at greater length infra.[3] In creating the right of privacy, Justice Douglas relied on a broad construction of specific protections in the Bill of Rights. He took the position that to make the First, Third, Fourth, Fifth, Ninth and Fourteenth Amendments meaningful, they had to be read together to result in constitutional privacy protection.

A different basis for the constitutional right to privacy was provided by the concurring views by Justices Goldberg and Harlan in the case. This view does not regard the liberty guaranteed by the due process clause as points embodied in the first eight amendments but rather a continuum provided by the Ninth Amendment which provides for liberties retained by the people not in the text of the Constitution. The protection of privacy, according to Justice Harlan's concurrence, are "implicit in the concept of ordered liberty,"[4] or "deeply rooted in the traditions and conscience" of the people so that they are to be treated as fundamental.[5] This view asserts that constitutional protections were not intended to have fixed meanings, but that their flexibility allows for the interpretation which recognizes the right of privacy.[6]

The differences between the views of Douglas, and of Goldberg and Harlan have formed the subject of numerous comments.[7] However, both analytical

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[2]381 U.S. 479 (1965).

[3]See text at page 76.

[4]Griswold at 500.

[5]Griswold at 493, Goldberg concurring.

[6]For an analysis of this view, see Mark A. Racanelli, Reversals: Privacy and the Rehnquist Court, 81 GEORGETOWN L.J. 443, 447-449 (1992).

[7]See, e.g., Lawrence H. Tribe & Michael Dorf, Levels of Generality in the Definition of Rights, 57 U.CHI.L.REV. 1057 (19990).

approaches conclude that the right of privacy is indeed fundamental. The Griswold case in its functional approach is particularly useful in protecting privacy concerns that arise out of developments in genetics.

The protection of genetic privacy safeguards a number of interests, including:

(1) The constitutional protection against governmental violation of informational privacy. This includes providing answers to questions relating to an individual's genetic makeup or requiring individuals to provide answers relating to his or her genetic makeup by way of family histories, pedigree studies, or by subjecting the individual to questions relating to the results of genetic tests or screening.

(2) Protection against governmental interference with a person's physical integrity, either by subjecting the person forcibly to genetic testing or screening, or by requiring a person to undergo genetic testing or screening without his or her informed consent.

(3) Protection against governmental interference with autonomous private decisions based on the use of genetic information by the person to whom such information pertains.

The modern law of constitutional protection of privacy, as noted, begins with Griswold v. Connecticut,[8] where the Supreme Court held unconstitutional a Connecticut law that made it a crime to use contraceptives, to supply contraceptives, and to advise on their use.[9] In his opinion, Justice Douglas

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[8]381 U.S. 479 (1965).

[9]The defendant in this test case, who had admitted "aiding and abetting" the use of contraceptives, was an officer of a Planned Parenthood Group and without his admission of the charge, the case could never have been brought, because it was clearly impossible to apprehend people in the perpetration of the crime in their bedrooms.

found that the right of privacy is derived from "emanations" of "penumbras" of certain named rights in the Bill of Rights, namely the right of marital association flowing from the First Amendment; the protections against police intrusions of the home reflected in the Third, Fourth, and Fifth Amendments; and the provision of the Ninth Amendment that recognizes the existence of non-enumerated rights. The majority of the Court took the view that the law interfered with the privacy of the marital relationship, and with the entirely private and highly protected decision whether to have children. In emphasizing the protection of the martial relationship, the Court established the basis for the recognition of the privacy of sexual relations generally.[10] The right of privacy found and pronounced in Griswold v. Connecticut has been challenged repeatedly because as has been noted again and again, no such right of privacy is stated expressly in the Bill of Rights, or in any other part of the Constitution.[11] The right of privacy as pronounced in Griswold v. Connecticut, together with the express constitutional provisions on which Justice Douglas relied in his opinion, form a coherent basis for the protection of genetic privacy. Under Griswold v. Connecticut and its clear basis for the protection of associational privacy under the First Amendment, the government is barred from asking persons about their marital or extramarital associations, their marital or sexual practices, their decisions to procreate or not to procreate, as well as from inquiries relating to any such associational matters and private conduct,

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[10]Eisenstadt v. Baird, 405 U.S. 438 (1972), where the Court invalidated a Massachusetts law which prohibited the sale of contraceptives to unmarried people.

[11]381 U.S. 479 at 508-09 (Black, J., dissenting); Id. at 530 (Stewart, J., dissenting); Moore v. City of East Cleveland, Ohio, 431 U.S. 494, 542 (1977) (White, J., dissenting); Katz v. U.S., 389 U.S. 347, 373 (1967) (Black, J., dissenting); Richmond Newspapers, Inc. v. Virginia, 448 U.S. 555, 579 (1980); Eisenstadt v. Baird, 405 U.S. 438, 472 (1972) (Burger, J., dissenting).

all of which are elements in marital decisionmaking which involves the use of information relating to a person's own genetic structure and ability to procreate, and indirectly their particular individual genetic attributes.

Under Griswold v. Connecticut, just as the government cannot stop people from using contraceptives if they want to, the government cannot compel people to avoid conception, or compel them to undergo genetic tests or to meet certain genetic conditions before marrying or procreating.[12]

The prohibition on governmental interference with individual physical integrity grows directly out of the Fourth Amendment which supplies one of the major supports for the protection of privacy under Griswold. Interference with physical integrity is a violation of the Fourth Amendment unless the invasion of a person's body or the intrusive search for evidence inside a person's body is justified by compelling reasons. Compulsory genetic testing or screening is not permissible under existing constitutional authorities, unless a compelling reason for such as invasion can be shown.[13] A compulsory genetic test violates constitutional protections against unreasonable searches unless a sufficient justification can be provided for such invasion.

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[12]Thornburgh v. American College of Obstetricians and Gynecologists, 476 U.S. 747 (1986) (there exists "freedom from unwarranted governmental intrusion into individual decisions in matters of childbearing." [Stevens, J., concurring]); Zablocki v. Redhail, 434 U.S. 374 (1978) (Wisconsin law that prevented people who have illegitimate children from marrying another partner unless they established proof that they supported the illegitimate child was unconstitutional because it burdened the right to marry). But see Matter of Kilpatrick, 375 S.E. 2d 794 (1988) which held that a West Virginia state statute requiring a serological test before license for marriage was within the state's compelling interest in that it detected communicable disease, protected the health interest of the couple and protected the interest of future children of the couple.

[13]LAURENCE H. TRIBE, AMERICAN CONSTITUTIONAL LAW §15-9, at 1331-32 (2d ed. 1988) [hereinafter TRIBE].

2. Informational and Associational Privacy under the First Amendment

Informational privacy in the context of genetics provides the right to keep one's genetic data private, at least insofar as government inquiries are concerned. So too constitutional protection of informational privacy places no restraint on insurance companies and on employers, that is, on private enterprises, who may ask for the information. The right of employers and insurers to ask for such information may be limited by legislation, as it has been by certain state laws and by the federal Americans with Disabilities Act.[14] Genetic informational privacy under the Fourth Amendment is limited, however, because privacy protections are no shield against criminal investigations. Both a person's fingerprints and the characteristics of his DNA are highly personal, but police authorities can take both fingerprints and DNA samples for purposes of criminal identification.[15] The Fourth Amendment restricts searches and seizures that infringe upon a person's reasonable expectation of privacy, generally in homes or offices, so that private papers (other than papers required to be kept by law which are generally subject to public access) stored in places where there is a reasonable expectation of privacy will also be protected.[16] Thus, medical records or other records of genetic information are protected against warrantless

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[14]Americans with Disabilities Act, 42 U.S.C. §12112(d). See, e.g., Me. Rev. Stat. Ann. tit. 39-A, §208 (West 1992); Mont. Code Ann. §50-16-502 (1987); R.I. Gen. Laws §5-37.3-4 (1987).

[15]Jones v. Murray, 962 F.2d 302 (4th Cir. 1992) (Virginia legislation which directs the Department of Corrections to take and store blood of convicted felons for subsequent DNA analysis did not violate the Fourth Amendment); U.S. v. Kelly, 55 F.2d 67, 70 (2d Cir. 1932) (fingerprinting as a means of identifying persons charged with a crime is permissible both in jurisdictions where there are statutory provisions regulating it and where it has no sanction other than common law).

[16]O'Connor et al. v. Ortega, 480 U.S. 709 (1987); U.S. v. Chadwick, 433 U.S. 1 (1977).

searches and seizures.[17] When information is accessible or displayed in a way which gives general access to the information, such as in time shared computer bases, or on electronic bulletin boards, or inn a display in a local newspaper, the privacy of such information has clearly been relinquished.[18] Under the Fourth Amendment as integrated into the protection of privacy under Griswold v. Connecticut, genetic information should be protectable against governmental inquiry, unless there are sufficient grounds to overcome the protection.

It is a recurring question how strong the public health rationale must be to justify intrusions into privacy. For instance, Tribe asks the question in a particular hypothetical context: assume the case of a child fathered by sperm obtained from a sperm bank. "If such a child develops an hereditary disease, does it violate the donor's privacy if the state requires the sperm bank to reveal his identity to the parents and physician of the child?"[19]

Since genetic information, like other personal medical information, will be collected and managed as part of a computer data base system, the question has been raised whether the placement of such data in a data base in and of itself constitutes a violation of informational privacy. The holding in Whalen,

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[17]Margaret S. v. Edwards, 488 F.Supp. 181 (E.D.La. 1980), held that a provision in a Louisiana statute regulating abortion which required that both medical records and abortion facilities be open for inspection at any time by the Department of Health and Human Resources violates the Fourth Amendment because it authorizes warrantless inspections; Hooper v. Sachs, 618 F.Supp. 963 (D.Md. 1985), held that a physician's Medicaid records, which the physician was required to keep and to make available, upon request, to state agencies, were not exempt from Fourth Amendment protection, and unreasonable inspection of those records was prohibited.

[18]TRIBE §15-16 at 1397; Freedom of Information Act, 5 U.S.C.A. §552 (1976); Cox Broadcasting Corp. v. Cohn, 420 U.S. 469 (1975) (newspaper has right to publish rape victim's identity once it has become a matter of public record).

[19]TRIBE §15-10, at 1360.

Commissioner of Health of New York v. Roe et al.[20] indicates that no such result would follow, though the issue is not entirely free from doubt. Believing that drugs were being diverted into unlawful channels, New York passed a law in 1972 classifying potentially harmful drugs and providing that prescriptions for the category embracing the most dangerous legitimate drugs, "Schedule II Drugs," be prepared on an official form. One copy of the form which required identification of the prescribing physician, the pharmacy, the drug and dosage, and the patient's name, address and age, was to be filed with the state health department where the pertinent data were recorded on tapes for computer processing. All forms were to be retained for a five year period under a system to safeguard their security and they would thereafter be destroyed. Public disclosure of the patient's identity was prohibited, and access to the files was confined to a limited number of health department and investigatory personnel. Plaintiffs were a group of patients who regularly received Schedule II drugs and prescribing doctors who challenged the constitutionality of the Schedule II patient identification requirement. The district court enjoined the enforcement of the challenged provision, holding that the doctor patient relationship is one of the zones of privacy accorded constitutional protection and that the patient identification provision was overbroad in invading the zone of privacy since the state had been unable to demonstrate the need for the requirement. The Supreme Court upheld the law in a unanimous decision, per Justice Stevens. The New York statute sought to address the misuse of dangerous drugs. It was designed to deter potential violators and to aid in the detection or investigation of instances of abuse. The state has a vital interest in controlling dangerous drugs and the legislative enactment of the patient identification requirement was a reasonable

[20]429 U.S. 589 (1977).

exercise of the state's police powers. Noting that privacy involves at least two different interests, namely the interest in avoiding disclosure of personal matters and the interest in independence in making certain kinds of important decisions, the Court found that the statute did not impair either one of these interests. The plaintiffs argued that both of these interests are impaired by the statute because the availability of the information in the department's file creates a genuine concern that the information will become publicly known and that it will adversely affects their reputations. This makes some patients reluctant to use, and some doctors reluctant to prescribe, Schedule II drugs even when their use is medically indicated. The argument is made that this affects the making of decisions vital to their health care and threatens both the interest in nondisclosure of private information and the interest in independent decisionmaking.

Referring to early privacy cases, the Court notes that in matters relating to marriage, procreation, contraception, family relationships, and child rearing and education, it has been held that there are limitations on the state's power to regulate conduct. In the Court's view, however, the statute poses no threat to the privacy concerns earlier referred to. The Court does not consider public disclosure of patient information by failures of security in the health department as a real risk; it does not provide a basis for attacking the statute as invalid on its face. Other states that have used a similar system have not had any failures of security.

An examination of the data cards and system used in the identification of genetic information in the course of the Genome Project indicates a system which matches the patient identification system involved in Whalen in every significant

respect.[21] Thus there is a reasonable basis for the conclusion that the maintenance of genetic data on tape in a computer data base is a defensible method of maintaining such data which does not violate informational privacy. However, this conclusion does not dispose of the matter, because the rationale for the maintenance of a data base to prevent widespread drug abuse[22] may provide a more compelling reason for the potential invasion of privacy than the desire to collect a detailed data base for the investigation of the human genome. Moreover, in the case of the identification of drug prescriptions, the identity of the physician and of the use of the drug was essential to the very purpose of the system -- namely the prevention of drug abuse. There may well be a question whether a similar necessity for identification of genetic data exists, and whether the use of a numerical code or the use of another system of encryption could not be used instead of the use of real names and other personally identifying data.

The Whalen Court notes that the disclosures required by the New York law are not significantly different from those that were required under the prior law,

> nor are they meaningfully distinguishable from a host of other unpleasant invasions of privacy that are associated with many facets of health care. Unquestionably, some individuals' concern for their own privacy may lead them to avoid or to postpone needed medical attention. Nevertheless, disclosure of private medicate information to doctors, to hospital personnel, to insurance companies, and to public health agencies are often an essential part of modern medical practice even when the disclosure may reflect unfavorably on the character of the patient. Requiring such disclosure to

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[21]See Figure 3, The Clone Screen in the Database Browser, in Connor, Koskela et al., Score: A Program for Computer-Assisted Scoring of Southern Blots, 20 LOS ALAMOS SCIENCE 258, 262 (1992).

[22]The district court in Whalen found that about 100,000 Schedule II prescription forms are delivered to the Department of Health in Albany each month.

> representatives of the state having responsibility for the health of the community does not automatically amount to an impermissible invasion of privacy.[23]

The Court adds the following comment:

> A final word about issues we have not decided. We are not unaware of the threat to privacy implicit in the accumulation of vast amounts of personal information in computerized data banks or other massive government files. The collection of taxes, the distribution of welfare and social security benefits, the supervision of public health, the direction of our Armed Forces, and the enforcement of the criminal laws all require the orderly preservation of great quantities of information, much of which is personal in character and potentially embarrassing or harmful if disclosed. The right to collect and use such data for public purposes is typically accompanied by a concomitant statutory or regulatory duty to avoid unwarranted disclosures. Recognizing that in some circumstances that duty arguably has its roots in the Constitution, nevertheless New York's statutory scheme and its implementing administrative procedures evidence a proper concern with, and protection of, the individual's interest in privacy. We therefore need not, and do not, decide any questions which might be presented by the unwarranted disclosure of accumulated private data -- whether intentional or unintentional -- or by a system that did not contain comparable security provisions. We simply hold that this record does not establish an invasion of any right or liberty protected by the Fourteenth Amendment.[24]

In his concurrence, Justice Brennan voices his concern about the central computer storage of data and notes that central storage and easy accessibility of such data vastly increases the potential for the abuse of information. He notes that he is not prepared to say that future developments will not demonstrate the necessity of some curb on that technology.

Another concurrence by Justice Stewart refers to Katz v. United States.[25] The Court made clear that while the Constitution affords protection against certain kinds of governmental intrusion into private matters, there is no

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[23]429 U.S. 589, 602.

[24]Id. at 605-606.

[25]389 U.S. 347 (1967).

"general Constitutional right to privacy" and that the protection of a person's general right to privacy, his right to be let alone by other people, is "like the protection of his property and of his very life, left largely to the law of the individual states."[26]

Privacy concerns under the First Amendment include not only informational privacy, but also associational privacy, as articulated in Griswold v. Connecticut, which protects the associational aspects of marriage and other intimate relations. The highly protected character of the marriage relationship and of the right to marry was articulated a few years after the Griswold decision in Zablocki v. Redhail[27] which invalidated as contrary to equal protections a Wisconsin statute which provided that any resident of that state who had "minor issue not in his custody and which he is under obligation to support by any court order or judgment" could not marry in Wisconsin or in any other state without the approval of a court, which could only be obtained upon a showing that he had meet his support obligations. The statute was attacked on the grounds that it deprived the plaintiff of equal protection and due process rights secured by the First, Fifth, Ninth, and Fourteenth Amendments. The Court invalidated the Wisconsin law relying largely on its 1967 decision in Loving v. Virginia,[28] a leading decision of the Supreme Court on the right to marry. That case involved an interracial couple who had been convicted of violating the Virginia miscegenation laws which were challenged on both equal protection and due process grounds. The Court invalidated the miscegenation laws on the basis of violation of equal protections, but went on to hold that the law had arbitrarily deprived the couple

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[26]Id. at 350-351.

[27]434 U.S. 374 (1978).

[28]388 U.S. 1 (1967).

of a fundamental liberty protected by the due process clause, the freedom to marry. Quoting its language in Loving, "The freedom to marry has long been recognized as one of the vital personal rights essential to the orderly pursuit of happiness by free men."[29] "Marriage is one of the 'basic civil rights of man,' fundamental to our very existence and survival."[30] The Court stressed that states were free to make reasonable regulations of marriage that do not significantly interfere with decisions to enter into the marital relationship. The Wisconsin law here involved clearly went beyond such reasonable constraints.

In its decision, the Court in Zablocki also relied on Griswold v. Connecticut, quoting its language: "We deal with the right of privacy older than the Bill of Rights -- older than our political parties, older than our school system. Marriage is a coming together for better or for worse, hopefully enduring, and intimate to the degree of being sacred. It is an association that promotes a way of life, not causes; a harmony in living, not political faiths; a bilateral loyalty, not commercial or social projects. Yet it is an association for as noble a purpose as any involved in our prior decisions."[31]

Whether state law could require genetic testing as a precondition to marriage has been discussed by Gostin and Curran, taking Zablocki as their point of departure.[32] Without treatment or cures for AIDS, the benefits of such a premarital screening program would be counterproductive. Screening does not lead to a change of behavior and would have a detrimental effect upon the target

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[29]434 U.S. 374, 383 (1978).

[30]Id. at 12, quoting Skinner v. Oklahoma, 316 U.S. 535, 541 (1942).

[31]381 U.S. 479, 486 (1965).

[32]L. Gostin and W.J. Curran, AIDS Screening, Confidentiality and the Duty To Warn, 77 AM.J.PUB.HEALTH 361 (1987).

population. Such broad AIDS testing of approximately 1.7 million marriages annually to prevent the spread of disease to the spouse and future offspring would be largely ineffective even for the small number of actual persons infected because people do not have to marry for intercourse or impregnation. Their conclusion that the state would have to demonstrate a compelling public health interest in order to overcome a constitutional challenge would apply not only to AIDS and venereal disease but also to testing or screening of genetic disorders. With marriage and procreation considered fundamental rights under the Constitution, a court should apply the strict scrutiny standard when examining the constitutionality of a public health regulation that limits the right to marry or procreate. To be upheld, such a public health regulation would have to serve a compelling state interest and be sufficiently narrowly drawn to protect the state interest at stake. In Zablocki,[33] both Justice Powell and Justice Stewart reasserted the constitutionality of mandatory blood tests for sexually transmitted diseases as a precondition to marriage. It is doubtful, to say the least, whether mandatory tests for genetic disease as a condition of marriage would be similarly upheld.[34]

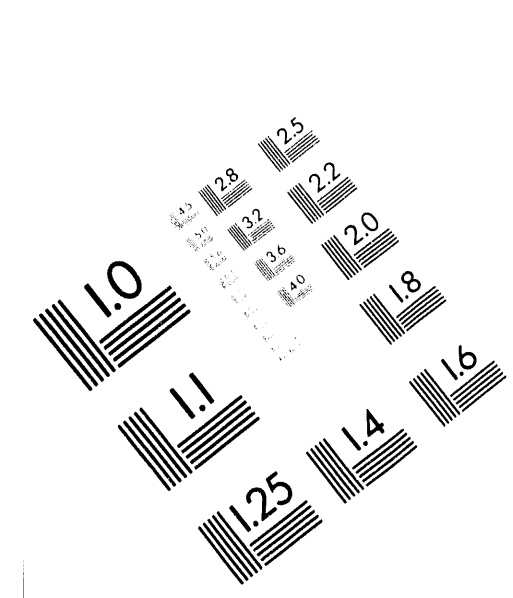
3. Protection Against Interference with Physical Integrity

The most important component of the right to privacy, as found in Griswold v. Connecticut, is the Fourth Amendment protection guaranteeing freedom from "unreasonable searches and seizures." It protects persons against arbitrary invasions of their homes and their persons by government, and particularly by law

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[33]434 U.S. 374, 387 (1978).

[34]See Cynthia S. Adelman, The Constitutionality of Mandatory Genetic Screening Statutes, 31 CASE WESTERN L.REV. 897 (1981).



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enforcement agents. The Fourth Amendment in the main protects against searches of particular physical locations, and against seizures of particular property located in the premises searched. The right of protection against unreasonable searches and seizures has been explained in terms of a person's reasonable expectation of privacy in certain locations, such as in their homes and business offices.

Privacy protection of the person under Griswold involves largely the protection against unreasonable searches and seizures of the person, involving in particular the matter of physical integrity. There is no question but that a person may be searched incidental to arrest, and that following arrest, a person may be fingerprinted. Though physical tests of a person's breath for alcohol and a blood test for alcohol content have also been upheld, there are limits to the permissible invasion of physical integrity. As Tribe has noted,

> Although compulsory vaccinations, compelled blood tests, extractions of contraband narcotics from the rectal cavity and even surgical removal of a bullet have sometimes been upheld on a showing of clear necessity, procedural regularity, and minimal pain, in each case the matter has been taken with enough seriousness to warrant a conclusion that an aspect of personality was at stake, and that government's burden was to provide more than minimal justification for its action.[35]

If indeed the right of privacy has grown out of Justice Brandeis' dissent in Olmstead v. United States,[36] which restated Judge Cooley's notion of privacy as the protection of "the right to be let alone," the right to be protected in one's physical integrity is clearly part of that right. The law of torts has long made an unlicensed or unpermitted touching the basis for a civil action in

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[35]TRIBE 1331-32.

[36]277 U.S. 438 (1928).

battery.[37] The law applies the doctrine of protection against unlicensed or unpermitted contact in the field of medical treatment, where medical contact or a medical manipulation of the body or invasion of the body by way of an operation is regarded as a battery, unless there has been informed consent by the patient to such touching or such intervention.[38]

A genetic test involves a touching of the person, and it normally involves a medical intervention, however slight. No such genetic test can therefore be undertaken, unless the subject of the test has given informed consent. There may be instances where genetic tests are administered to persons in prison, or to persons in the armed services for particular purposes authorized by law, where the legal mandate will provide the basis for the genetic test, if the state's reasons are sufficient to override privacy concerns. Whenever such a mandate has been used to authorize genetic testing, it has invariably been challenged on privacy grounds, and the adequacy of the reason for the administration of the test was litigated before an appropriate court.[39]

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[37]W. PAGE KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS §9, at 41 (5th ed. 1984) [hereafter PROSSER AND KEETON].

[38]Id. at 40.

[39]Prisoners: Jones v. Marry, 962 F.2d 302, 307 (4th Cir. 1992), supra note 15. Army: Starting on June 10, 1992, the Army announced that it would take samples of blood and saliva from every new recruit and keep them on file. If the soldier is later lost in battle or in a plane crash, the Army will retrieve these samples and try to match them with tissue from unidentified bodies found at the scene using tests on each body's unique pattern of genetic material or DNA. Eventually, the military's DNA bank will cover more than three million people, making it the largest collection of biological samples anywhere that is available for genetic testing. Critics of the Army's program, such as the Council for Responsible Genetics in Cambridge, Massachusetts, say that it will encourage widespread use of genetic testing in law enforcement, or by employers and insurance companies, violating people's rights to privacy. National Public Radio, June 10, 1992; DNA Dog Tag or Genetic ID?: The Army's New Identification Program Sends a Big-Brotherly Chill, TIME, June 22, 1992, at 35; Warren E. Leary, Genetic Record To Be Kept on Members of the Military, N.Y.TIMES, Jan. 12, 1992, at 15. See also Don Lattin, Secret Files on Americans' Genes: Scientists, Theologians

Although the collection of cells for purposes of genetic testing may involve a very minor procedure, it is nonetheless categorized as a medical procedure, if for no other reason than for its purposes. Informed consent is a fair prerequisite for medical procedures and should certainly apply to genetic tests.[40]

Mandatory genetic testing is an invasion of privacy barred under the Fourth Amendment and under Griswold v. Connecticut. As Tribe has pointed out in his discussion of privacy, there is a great deal of uncertainty and unease about any law or decision that authorizes the physical invasion of a person's body.[41] This is true even in instances where the physical invasion was considered necessary to produce evidence of a crime. Thus, taking a blood sample was viewed as a search and requiring probably cause.[42] Although a right to bodily integrity has been recognized,[43] DNA fingerprinting for criminal investigation has been upheld because it involves a compelling state interest in criminal prosecution.[44] So too the Fourth Circuit has upheld Virginia legislation that required convicted felons to submit blood samples for DNA analysis for identification purposes to be used in the creation of a data bank for unspecified future law enforcement

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Fear Databanks Could Prove Dangerous, THE SAN FRANCISCO CHRONICLE, Feb. 17. 1992, at A1; E. Donald Shapiro and Michelle L. Weinberg, DNA Data Banking: The Dangerous Erosion of Privacy, 38 CLEV.ST.L.REV. 455 (1990).

[40]PROSSER AND KEETON §18 at 114. For further discussion of Genetic Counseling and Informed Consent, see infra chapter 17 at page 371.

[41]TRIBE §15-9, at 1331-32.

[42]Skinner v. Railway Labor Executives' Ass'n, 489 U.S. 602 (1989).

[43]Minnesota State Board of Health by Lawson v. City of Brainerd, 241 N.W. 2d 624 (Minn. 1976).

[44]Jones v. Murray, 962 F.2d 302 (4th Cir. 1992).

purposes.[45]

4. Protection Against Interference with Autonomous Private Decisions

Another protected area of genetic privacy is the right to make autonomous decisions based on full genetic information. The entire purpose of the Human Genome Project, and of genetic investigations generally, is to provide more knowledge about human health and illness and about other aspects of the human condition. To be useful, such information must be acted on, because there would be little point in costly scientific investigation employing the best scientific minds in the country unless the knowledge and insights acquired are put to some use in the advancement of health. The implications of the use of new knowledge affect both public and private decisionmaking, and on the level of private decisionmaking, governmental interference amounts to an interference with autonomy, which is a necessary part of privacy.

Scientific developments in genetics present many persons with choices not earlier available. Genetic privacy protects that freedom of choice, though it is clear that the protection of freedom of choice in the genetic area may involve more than the protection of autonomous decisionmaking. It may require the affordable availability of institutions and professionals not only to help the person make a choice but also to help the person carry out the choice once an autonomous decision has been made.[46]

Clearly Griswold v. Connecticut and the cases that followed it, including

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[45]Id.

[46]See discussion of Access to Genetic Testing, Prenatal Diagnosis and Prenatal Care, infra, chapter 15 at page 319.

Roe v. Wade, have established the principle that the choice whether to carry a pregnancy to birth or to terminate it is an autonomous decision which can only be made by the pregnant woman.[47] Although subsequent cases have given recognition to the authority of state law to require certain protections for the mother, the fetus and to condition the right of women who are not of full age upon parental or judicial consent, the basic right of a pregnant woman to make an autonomous decision has not been limited.[48]

While the termination of pregnancy may arise in a number of situations in which genetic factors play a part, many other choices may arise, and decisions may have to be made. A decision to recommend that a patient be tested for one or more genetic diseases is likely to be made by the physician following the taking of a medical history or a family history in connection with the anticipated birth of a child. However, with increasing knowledge of the possibilities of genetic disease, more persons, both men and women, will ask to have a genetic test, if they consider themselves at risk by reason of family history, by reason of their ethnic or racial grouping, or sometimes even by reason of their age. A 35 year old woman having her first pregnancy will seek amniocentesis to make sure that her child will not have Down syndrome. A man of East European Jewish ancestry who is about to marry a young woman with a similar background is likely to seek a genetic test for Tay-Sachs disease. As the knowledge of the work of the Human Genome Project spreads throughout the population, and as newspaper accounts and media stories of progress in genetic science become more common, and as physician training and physician knowledge in matters of genetic illness become more

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[47]410 U.S. 113 (1973).

[48]Webster v. Reproductive Health Services, 492 U.S. 490 (1989); Planned Parenthood of Southeastern Pennsylvania v. Casey, 112 S.Ct. 2791 (1992).

thorough and more widespread, the demand for genetic tests and subsequent followup is likely to increase sharply.[49] Whether or not to be tested for genetic disease or trait is a person's autonomous decision. It is a decision which is similar to other decisions relating to health care, and like other such decisions, it depends not only on the person's autonomous decision but also on whether facilities and professionals are available to undertake the procedure. Moreover, whether or not the testing procedure will be carried out depends on whether the patient can afford it, or is covered by insurance or a medical plan which will pay for it. In many instances, whether or not the testing procedure will be carried out will depend on whether the procedure is covered by Medicaid or by some other third party payer. The exercise of constitutionally guaranteed autonomy may require public action to provide the appropriate conditions for its exercise.

5. Conclusion

The constitutional protections of privacy, particularly with respect to privacy rights involved in the protection of genetic privacy, appear to be well established on the basis of past precedent in other, though related, areas. The right to make procreational decisions, including the right to carry a pregnancy to term or to terminate it, are well established and are less likely to be challenged successfully with the passage of time. Though the right to terminate a pregnancy has been repeatedly challenged since Roe v. Wade, and though the

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[49]Daniel J. Kevels and Leroy Hood, The Genetic Labyrinth: A Global Effort To Identify Every Gene in the Human Body Could Revolutionize Medicine. It Could Also Create a Class of Genetic Outcasts, LOS ANGELES TIMES, Nov. 8, 1992, at 28; Fragile X Gene Test Sparks Hope for Mass Screening, Fear of Discrimination, BIOTECHNOLOGY NEWSWATCH, Nov. 16, 1992, at 14; Leon Jaroff, Happy Birthday, Double Helix: Forty Years After Their Discovery of DNA's Secret, Watson and Crick Celebrate Its Impact on the World, TIME, March 15, 1993, at 56.

right to terminate a pregnancy has now been encumbered with a number of conditions imposed by some state governments, the pregnant woman's autonomous choice in this matter has been upheld and is even less likely to be overturned with recent changes in the membership of the Supreme Court.

Marital rights, including the right to marry free from burdensome conditions, have been upheld repeatedly, as has the right to make procreational decisions, including the decision not to procreate.

No case has been reported involving compulsory genetic testing or compulsory prenatal testing. But on the basis of past constitutional decisions, it is fair to assume that any procedure which requires the informed consent of the pregnant woman will call for the stringent application of Fourth Amendment principles. Compulsory examination and testing of women are not likely to be tolerated, particularly in light of the past history referred to elsewhere of compulsory sterilizations growing out of the earlier misguided and wrongheaded sickle cell anemia program in the early 70s.

Earlier constitutional determinations appear to uphold the right of personal autonomy in making decisions relating to one's own body. These decisions, though not made in the context of genetic testing or other genetically related interventions, nonetheless establish the right to autonomous decisions with respect to any procedure that involves touching, or invading the body for purposes of genetic testing or for any other purpose that involves invasive procedures. Thus, though there have been no decided cases relating to genetic testing, the right to autonomous decisionmaking with respect to genetic testing or screening procedures seems secure.

It should be added that it is in the nature of constitutional protections that they are not likely to be recognized until their violation is challenged in

a judicial tribunal. To assure the proper consideration and outcome of such challenges, it would be useful to be able to refer to a body of legislation that articulates these rights, providing a panoply of procedures for their protection whose violation would then provide a basis and a framework for court challenges.

It should be noted, again, that there are few privacy protections in our law and no articulated protections for genetic privacy at all. The reality of constitutional protections will be more readily realized if Congress and the state legislatures, or both, get around to enacting sound legislation to protect privacy.

In addition to sound privacy legislation, what is necessary to make good on the promise of the free exercise of autonomous private decisions is to provide adequate facilities, including physical facilities and trained personnel to allow for genetic testing and other follow-up procedures which genetic tests may indicate to be appropriate. The exercise of autonomous choices requires governmental action to allow choices to be freely made.

Chapter 4. The Nature of Private Information

1. The Protection of Privacy: The Stigma of Illness

A major aspect of the right of privacy deals with the protection of certain kinds of information. There is personal information we do not care to share with others. This may include information about past conduct that we're ashamed of. We don't want to supply information that will make us vulnerable to manipulation by others -- this may include information about our finances and matters relating to our family life, to intimate aspects of our life, and matters relating to sexual conduct. We also do not want to provide information which shows weakness and vulnerability, including information relating to our physical condition or illness.[1]

Much of the information we want to keep to ourselves may carry a threat of social stigma and the possibility of economic, social, and other discrimination resulting from such stigma. Injuries flowing from such stigma in consequence of personal disclosures may be of a measurable, economic nature, here to be discussed in the context of insurance and employment. At least as importance as the economic consequences of discrimination resulting from stigma are the highly personal, emotional and psychic impacts which may result from breaches of privacy and stigmatization. In our society, illness is stigmatizing and the disclosure of information relating to illness will injure self esteem and the person's self perception as an effective, functioning human being.

The disclosure of private information, as noted, may have significant,

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[1]In reciting examples of private facts, the Restatement (Second) of Torts, §652D Cmt.b lists "sexual relations,...family quarrels, many unpleasant or disgraceful or humiliating illnesses, most intimate personal letters, most details of a man's life in his home, and some of his past history that he would rather forget."

far-reaching consequences. What then is "private" information? Privacy has been defined as "the right to keep legitimate secrets."[2] What is one person's secret may well be another person's proud boast. Thus, a more neutral, more general categorization is called for. Though in our society there is likely to be a fair amount of agreement as to what kind of information needs to be protected, there may still be individual differences with respect to the degree of protection sought. Consequently, allowing for such differences, the right of privacy may well be "the right to control information about oneself,"[3] Such a definition will be useful in protecting ourselves against the release of stigmatizing information.

All disclosure of illness appears to be stigmatizing because it points to disability, or at least less than full functioning. The manner in which stigma is manifested has been described:

> We use specific stigma terms, such as cripple, bastard, moron, in our daily discourse as a source of metaphor and imagery, typically without giving thought to the original meaning. We tend to impute a wide range of imperfections on the basis of the original one.[4]

This language indicates the deep social prejudice against all disabled persons. Goffman notes that persons who are not disabled look upon the disabled disapprovingly and treat them unfairly. Because many are repulsed or frightened by the disability, many people prejudge the ability or worth of the disabled person. Although the law seeks ways to protect the disabled against discrimination in employment, in public places, and in many other situations, no way has

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[2]KIM LANE SCHEPPELE, LEGAL SECRETS: EQUALITY AND EFFICIENCY IN THE COMMON LAW (1988).

[3]Rochelle C. Dreyfuss and David Leebron, Foreword: Privacy and Information Technology, 3 ANNUAL SURVEY OF AMERICAN LAW (1986).

[4]ERVING GOFFMAN, STIGMA: NOTES ON THE MANAGEMENT OF SPOILED IDENTITY 5 (1963).

yet been found to protect disabled persons against stigma and social discrimination.[5] The 1990 Americans with Disabilities Act prohibits discrimination against the disabled in employment, in public accommodations and in transportation, and its legislative history presents evidence not only of workplace discrimination but also of personal stigma suffered by disabled persons in society. There was testimony of the second class citizenship of disabled persons and comments that they had been stripped of pride and dignity, and that the stigma scarred them for life.[6]

We are mostly concerned here with privacy protection relating to information of a person's genetic condition. The comments relating to the stigmatizing impact of disabilities are particularly applicable to persons whose disabilities are caused by genetic illness.[7] Genetic information is even more sensitive than other medical information because of the intimate, detailed, and permanent nature of the conditions it describes. The information not only has a bearing on a person's current state of health, but also on the future of the

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[5]The most recent effort to protect the disabled against discrimination in the workplace, in particular, in the 1990 Americans with Disabilities Act, which took effect in workplaces with 25 or more employees in July 1992. In passing the legislation, "Congress acknowledged that society's accumulated myths and fears about disabilities and diseases are as handicapping as are the physical limitations that flow from actual impairment." H.R. Rep. No. 485(II), 101st Cong., 2d Sess. (1990), reprinted in 1990 U.S.C.C.A.N. 267, 335. The law prohibits discrimination against persons with physical or mental impairments, or persons who are "regarded as having an impairment." Americans with Disabilities Act, 42 U.S.C. §12102(2)(C) (1990). For additional discussion of ADA, see infra at ch. 7, p. 223 et seq.

[6]H.R. Rep. No. 485(II), 101st Cong., 2d Sess. (1990), reprinted in 1990 U.S.C.C.A.N. 267, 324. (testimony by Judith Heumann) Another witness testified to the unwillingness of the public to treat a disabled person as being a whole and valuable member of society. Id. at 324. (testimony of Virginia Domini).

[7]Whether the Americans with Disabilities Act (ADA) covers genetic discrimination in the workplace and to what extent is discussed infra at ch. 7 page 228.

health and life of the person to whom it pertains and on the future health and conditions of the person's children and descendants.[8] Because of the deeply personal nature of genetic information, it is also likely to be more personally stigmatizing and damaging.[9]

The stigma of genetic illness is all the more damaging and inexplicable because a person who suffers from a genetic illness or who carries a genetic trait obviously has had no role in acquiring it. At one time there was a notion that sexually transmitted diseases were more stigmatizing than others because the patient had had a part in acquiring the disease.[10] There are frequent references in the media to the innocent acquisition of a disease, in some way expressing different attitudes about hemophiliacs who acquired AIDS through a blood transfusion or infants who acquired AIDS prenatally than about other AIDS victims. We have not been able to find any evidence in the literature on stigma to determine the different stigmatizing effects of different diseases. But at least on the surface it appears that genetic disease carries as great a stigma as does AIDS. The stigmatizing effect of disease may in part reflect the common practice of blaming the victim, whether to fend off the evil eye or to distance oneself from the victim so as to avoid responsibility. It is difficult to tell

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[8]"As a species of health care information, genetic information is particularly sensitive because genetic screening and monitoring reveal much more personal information about the individual than other types of medical surveillance used by employers." Lori B. Andrews and Ami S. Jaeger, Confidentiality of Genetic Information in the Workplace, 17 AM.J.L.& MED. 75 (1991).

[9]"Prejudice, alienation and exclusion often accompany genetically related diseases even though, by definition, the condition is neither subject to the person's control nor the result of willful behavior. The fact that genetic diseases are sometimes associated with discrete ethnic or racial groups . . . compounds the potential for invidious discrimination." Larry Gostin, Genetic Discrimination: The Use of Genetically Based Diagnostic and Prognostic Tests by Employers and Insurers, 17 AM.J.L. & MED. 109, 110-111 (1991).

[10]

39% wanted every woman who is pregnant to be tested to determine if the baby has any serious genetic defects, 22% responded that a woman should have an abortion if the baby has a serious genetic defect, and nearly 10% believed that a woman should be required by law to have an abortion rather than have the government help pay for the child's care if the parents are poor.[16]

Discovery of carrier status can be severely stigmatizing and OTA cites a case in which a patient who learned that he was a carrier of the ΔF-508 mutation was severely affected by the fact that his fiancée broke off their engagement, his person life a shambles, and he full of feelings of guilt, anger and betrayal.[17]

The OTA Report notes that few empirical studies on stigmatization and carrier status have been conducted, with the most significant ones dealing with stigmatization arising out of Tay-Sachs screening in the 1970s. Other studies on the subject are currently underway.[18] The troublesome question remains whether as a matter of public policy one should oppose carrier testing in order to avoid stigmatization. Carrier testing is clearly an important aspect of genetic investigation, and is an important diagnostic tool and means for the advancement of public health. Issues of protection of privacy and protection against stigmatization clearly need to be weighed against the benefits that follow from well considered carrier testing programs for genetic diseases where there is a cure or an ameliorative program, or where there may be a choice to terminate the pregnancy. Efforts clearly are called for to offer sound programs of carrier

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[16]Id. at 190. "Twenty-two percent responded that regardless of what they would want for themselves, a woman should have an abortion if the baby has a serious genetic defect."

[17]Id. at 190-191.

[18]Id. at 191.

persons who deviate from some theoretical notion of genetic normalcy. This has given rise to certain concerns and fears:

> In his or her genome, each person harbors stretches of DNA that silently code for recessive, lethal, or debilitating genetic disorders or that predispose -- with our without certain environmental factors -- future illness. As the Human Genome Project progresses, the capacity to reveal these silent genes will increase. What will the social and psychological effect of knowing such information be to an individual? Will carriers be viewed as flawed -- by themselves or others -- or as blameworthy for having children despite identified genetic risks? Because genetic diseases sometimes cluster in ethnic or racial groups, will the potential for discrimination and stigmatization be compounded?[13]

There is fear that routine carrier screening for particular disorders might be viewed as a tacit acknowledgement that the birth of children with serious genetic illnesses should be avoided. It has been asserted that if emphasis is placed on preventing such births, less of an effort will be made to provide funding for the disabled and for the creation of conditions in which there will be greater tolerance and acceptance of persons with disabilities.[14] There is, of course, no proof of such assertions or fears.

It has been suggested that the stigmatization of carriers is related to the belief held by some ethicists that it is irresponsible and immoral for people to reproduce if they know that they will pass a serious or disabling disease to their children.[15] OTA notes that this view is not inconsistent with the views of many Americans, referring to a 1990 general population survey which found that

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[13]Id.

[14]Some studies have found evidence that women who are pregnant with a child that will suffer from genetic illness or be afflicted with an adverse genetic trait are likely to be stigmatized. Id. at 189.

[15]Id. at 190. OTA refers to J.F.Fletcher, Knowledge, Risk and the Right To Reproduce: A Limiting Principle in GENETICS AND THE LAW II (A. Milunsky and G.J.Annas, eds., 1980) and L.M.Purdy, Genetic Diseases: Can Having Children Be Immoral? in ETHICAL ISSUES IN MODERN MEDICINE (3rd ed., J.D. Arras and N.K. Rhoden, eds., 1989).

whether the stigma of disease -- or the stigma caused by particular diseases -- makes any difference in public health planning and education, or in the support of appropriations of funding for such purposes.

Because of the severe impact of breaches of informational privacy in cases involving genetic information, informational privacy assumes particular importance in this context. Because genetic information importantly forms a basis for action, the informational aspect of privacy may be difficult to separate in this field from privacy involving the making of significant decisions, or the aspect of privacy covered under the concept of autonomy. The protection of autonomy as part of the protection of privacy allows persons to make independent decisions and to act on such decisions free from government interference in any area in which there are no countervailing government interests. Such private autonomous decisions, as will be discussed at length, involve interests in intimate matters of family, sex and procreation. These are areas which are clearly covered by informational privacy as well.

As noted earlier, stigmatization of persons who are ill or disabled is not unique to genetic conditions. Certain infectious diseases, such as leprosy, tuberculosis or AIDS, have caused the ostracism of persons afflicted. So, too, ostracism has been the lot of persons who have cancer or schizophrenia, diseases for which we now know some genetic components.[11] Stigmatization has been defined as the branding, marking, or discrediting of persons because of a particular characteristic.[12] The fear and concern has been expressed that increased knowledge of the human genome will in some way lead to the stigmatization of

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[11]CONGRESS OF THE U.S., OFFICE OF TECHNOLOGY ASSESSMENT, CYSTIC FIBROSIS AND DNA TESTS: IMPLICATIONS OF CARRIER SCREENING 189 (1992).

[12]Id.

screening without stigmatizing a screened population as being disabled. In the context of cystic fibrosis, the OTA concludes as follows:

> Achieving this requires a commitment by health professionals and government that only those wanting to be screened will be screened; that all who want screening can have access to it; that results will remain confidential; and that individuals will not be coerced -- overtly or covertly -- into making any particular reproductive decision following screening.
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> Reducing perceived biases -- so individuals can autonomously access the data needed to make informed choices about bearing children with CF -- is of paramount concern if widespread CF carrier screening is to be viewed acceptable to those concerned about disability rights and the potential for stigmatization.[19]

In addition, to screen without increasing stigma requires a considerable effort at public education, and such public education efforts should address not only the screened population, but the entire population so as not to exacerbate stigmatization.[20]

Congress has considered the issue of stigmatization in discussions of the Human Genome Project. In one of the House Reports,[21] the Committee noted that the information revealed by a map of the human genome may extend medical conditions or predictions of disease, since there have been reports suggesting the existence of an identifiable genetic basis for retardation, alcoholism, homosexuality, and criminal or other antisocial behavior.[22] Characterizing the impact of stigmatization, the committee referred to a number of examples of resulting insurance and employment discrimination, and indicated the committee's

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[19]Id. at 192. Citation of authorities omitted.

[20]Id. at 192.

[21]COMMITTEE ON GOVERNMENT OPERATIONS, DESIGNING GENETIC INFORMATION POLICY: THE NEED FOR INDEPENDENT POLICY REVIEW OF THE ETHICAL, LEGAL, AND SOCIAL IMPLICATIONS OF THE HUMAN GENOME PROJECT, H.R. REP. NO. 102-478, 102d Cong., 2d Sess. at 2 (1992).

[22]Id. at 13.

fear that the information may be used to identify persons with assertedly weak or inferior genes, contributing to racial and other forms of discrimination. Dr. Bernardine Healy, the former Director of NIH, commented about the use of genetic information to categorize people unfairly and to stigmatize them, exposing them to discrimination and the loss of access to social and economic opportunities. She also referred to the impact of state-based screening programs for sickle cell disease during the 1970s:

> This is particularly important in light of the current efforts to unravel . . . conditions that already bear the burden of stigmatization in our society. . . . You may add to this the burden placed on people by the shame and disgrace of this badge of inferiority. It is possible that this badge of disgrace or poor self image will not only justify their being tracked into various categories and jobs, but they may track themselves and come to believe they are an underclass.[23]

Another witness expressed concern that genetic information might be used in schools to track children, possibly preventing them from achieving their full potential.[24] One of the problems with the results of genetic testing is that they are so frequently misunderstood. In instances where tests reveal a predisposition to disease or condition, their likelihood of suffering from a particular disease may be greater than that of the average person, but it may still be very small. Often people who are found to have a greater risk of cancer may be treated as if they already have cancer or will inevitably develop cancer in the future. This may result in persons' actually changing their behavior as a result of a change in their self image.

Similar testimony and considerations were involved in the legislative

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[23]Id. at 21-22.

[24]Testimony of Jeremy Rifkin, President of the Foundation on Economic Trends, quoted at H.R. Rep. 104-478 (1992) at 23.

history of the Alcohol, Drug Abuse and Mental Health Administration Act of 1991.[25] In discussing the impact of mental illness and substance abuse, the Report from the Senate Committee on Labor and Human Resources also referred to the impact of stigma on affected persons, noting that these conditions have not been fully recognized as illnesses, and many persons react unsympathetically when confronted with a mentally ill individual or a substance abuser.[26]

Concerns for stigmatization were also reflected in the legislative history of the Americans with Disabilities Act.[27] The Report of the House Committee on Education and Labor refers to testimony on the experience of a young person who had to use a wheelchair because of disablement by poliomyelitis. Starting with nursery school and elementary school, she was refused admission because her wheelchair was regarded as a fire hazard. This segregation and discrimination continued through high school and college, where she was refused admission into a dorm because she was in a wheelchair and needed assistance. She was also denied elementary school teaching credentials because of the paralysis of her legs. At age 25, she was told to leave a plane on a return trip to Washington where she works for the Senate because she was flying without an attendant. She and another friend in a wheelchair were almost forcibly removed from an auction house because they were "disgusting to look at." Numerous other incidents are also recounted in the testimony and she testified that this kind of stigma scarred her for life.[28] The House Committee Report on ADA discusses the connection between

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[25]Pub.L. 102-321, 106 Stat. 323 (1991).

[26]S.Rep. 102-131 at 1-4 (1991).

[27]42 U.S.C. §12101.

[28]Testimony before the House Committee on Education and Labor and Senate Committee on Labor and Human Resources, Sept. 27, 1988, pp. 74-75, H.R. Rep. 101-485 (II) (1990). The testimony referred to helplessness and loss of dignity and

stigmatization and discrimination. The report notes that discrimination often results from false presumptions, generalizations, and misperceptions, patronizing attitudes, ignorance, irrational fears, and pernicious mythologies. It also notes that discrimination includes the effects a person's disability may have on others.[29]

Similar testimony relating to stigma and discrimination appears in testimony before House Subcommittees on Select Education and Employment Opportunities.[30] The report indicates that there is a secondary stigmatizing effect on disabled persons growing out of the reaction that the non-disabled manifest towards them.

Stigma as such is rarely a subject for judicial decision or consideration, though courts do, of course, address the discrimination which commonly arises from stigma. One of the few cases on the subject of stigma is Wisconsin v. Constantineau.[31] The case involved the constitutionality of a Wisconsin statute pursuant to which the plaintiff's name was posted in retail liquor stores as a person to whom intoxicating beverages should not be sold. The court required a full hearing before the determination to post a person's name in this fashion could be undertaken, because "the label or characterization given an individual by posting, though a mark of serious illness to some, is to others such a stigma

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self respect, and that the disability is a source of shame, causing loss of pride and dignity.

[29]One example cited in the Congressional Record for this included a story reported in the Washington Post in March 1988 referring to a New Jersey zookeeper who refused to admit children with Down syndrome because he feared they would upset the chimpanzees. Other instances involved persons who lived in a household with others afflicted with AIDS. 117 CONG.REC. 45974 (1971).

[30]H.R. REP. No. 458(II), 101st Cong., 2d Sess. 31 (1990), reprinted in 1990 U.S.C.C.A.N. 303, 312-13.

[31]91 S.Ct. 507, 400 U.S. 433 (1971).

or badge of disgrace that procedural due process requires notice and an opportunity to be heard."[32] In this instance the stigmatizing publication was government action.

2. Conclusion

All illness stigmatizes, and genetic illness appears to have particularly heavy stigmatizing effects. Because the consequences of stigma in our society are usually discrimination, a person may be very reluctant to have himself/herself tested for genetic illness if the likely result of such a test is stigma resulting in discrimination on the job, in insurance, and in personal relationships. In light of the importance of genetic screening and testing for decisionmaking, particularly procreative decisionmaking, efforts should be made to assure persons that genetic testing will not have any stigmatizing impact. It appears that even the fact that a person has undergone a genetic test may be stigmatizing. There is a need, therefore, to provide appropriate legal protections so as not to allow information flowing from genetic tests to be used as a basis for stigma and discrimination in the workplace and in the provision of health insurance. This will be addressed in somewhat greater detail in the context of a discussion of work and insurance discrimination, infra.

Since information relating to genetic testing is also seriously stigmatizing in a personal and emotional sense, in addition to legislation prohibiting employment and insurance discrimination, broad scale efforts must be made to provide adequate public health education to explain the nature of genetic illness and to explain the carrier state for certain genetic illnesses, and to clarify that genetic illnesses and traits are widely shared, that carrier states

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[32]Id. at 436.

generally have no adverse impacts, and that in any event so many of us have one or more defective genes that they ought not to provide a basis for any personal discrimination.[33]

With relation to the stigmatizing impact of information relating to genetic disease, it ought to be noted also that in this instance stigmatizing will not even serve to blame the victim. In the case of certain kinds of diseases, such as in sexually transmitted diseases, there may be an assessment of blame on the part of the person who discriminates based on the element of volition in acquiring the disease. Newspaper obituaries, in their obituaries noting that someone has died of AIDS, will often mention that the disease was acquired as a result of blood transfusion, as in the reports of the death of the tennis star, Arthur Ashe. Clearly, no "blame" attaches to persons who have a genetic disease because they certainly played no part in acquiring it. With increasing reports of genetic illnesses in the media, the need for adequate education on the subject gains increasing urgency.

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[33]TROY DUSTER, BACK DOOR TO EUGENICS, Appendix C, The Ethnic Distribution of Disease, 160-162 (1990). The Table shows that many groups carry particular genetic defects, so that there is no grounds for discriminatory attitudes based on defects more prevalent in one group than in another, because every group has some prevalent defects of a nature not too dissimilar from the prevalent defects of another group. Duster makes the point that not all genetic disorders are tied to any ethnic, racial or religious grouping. Those that are make it easier to mobilize programs. Id. at 75-76.

Chapter 5. Information, Databanks, Privacy and Discrimination

1. Introduction

Integral to the protection of privacy and the prevention of discrimination is the growing reliance on databanks which collect, classify and distribute information. The availability of databanks -- of information in organized and readily accessible, computer retrievable form -- has become the most significant resource of our age. The use of databanks has significant implications for genetic information and privacy. It is certain that genetic information will find its way into databanks through insurance information, through information gathered in the workplace, and through restricted but highly personal medical records. Databanks also have great significance for genetic information because genetic information may become the subject matter of special registries.

The availability and usefulness of databanks raises the question of their security. Questions of databank security were raised some sixteen years ago, long before the ubiquity of the computer, when -- for the first, and until now, the last time -- the federal government studied the issue as part of the work of the Privacy Protection Commission. Though 16 years old, the work of the Commission still provides the benchmark for privacy protection in the nation, and the fact that the Commission found issues of data security troubling should trouble us as well, because computer storage of data is not necessarily more secure than the storage of paper records in file cabinets.

This chapter, therefore, will address issues of data collection and security with special application to genetic data and their protection against improper dissemination. Consideration will also be given to the need for effective legal sanctions against breaches of privacy, and against the invasion

of data bases for unauthorized, improper or criminal purposes.

2. The Information Society

Our society has been described as an information society.[1] Numerous transactions which used to be conducted on an interpersonal, face to face level are now being conducted by way of submission or exchange of information. In most instances, information is submitted to a particular governmental or private organization for a particular purpose. We submit information to the government to obtain a social security card, to claim social security and other benefits, to obtain a Medicare or a Medicaid card, to obtain a professional or occupational license, and to meet our various federal, state and city income tax and other tax obligations.

We submit very detailed personal information to banks to open a bank account, to brokers to open a brokerage account, to credit card companies to obtain a credit card, and even to the supermarket in order to get check cashing privileges.

We submit very detailed personal data to universities and other schools to be admitted for a course of study, or to have our children admitted for a course of study.

We give very detailed personal information relating to our health, our personal habits, and our family situation to our physicians, to other health care providers, such as hospitals, nursing homes and other health care institutions, and to insurance companies that are responsible for meeting the cost of care.

In most of these instances, we provide the information without objection,

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[1]PRIVACY PROTECTION STUDY COMMISSION, PERSONAL PRIVACY IN AN INFORMATION SOCIETY (1977) [hereinafter PRIVACY COMMISSION].

either because we know that we are legally obligated to do so, particularly in submitting information to governmental agencies, or because there is a quid pro quo -- we cannot get certain benefits unless we provide the information. We cannot open the bank account or obtain the credit card or attain admission to a school or, on the governmental side, obtain the professional or occupational license unless we submit the required information. Very often, there is a quid pro quo for the information in that the submission of the information serves a number of our own purposes. There may indeed be questions, occasionally, whether all of the requested information is necessary to advance the purpose of the transaction. We would resent it, for instance, and might object if a credit card questionnaire were to call for aspects of our medical history. On the other hand, when filling out a request for medical history data, we normally respond without objection whether we are covered by a health insurance plan or Medicare. The provision of information for a particular purpose is generally submitted on the tacit assumption that it is to be used for that purpose only and for no other. We do not expect our bank to submit private financial information to our health care provider, and we do not expect our health care provider to share our personal medical histories with our bank or broker.

Because the information we submit becomes part of a vast system, the greatest risk to private information is its use for purposes for which it was not intended. Since access to data banks is far easier than it ought to be, one of the major privacy issues of our time is not the occasional, random leak, but rather the possibility of access to the data for unintended purposes. Before it extends a substantial loan or mortgage to a person, a bank may indeed be interested in the condition of his or her health. Before opening a margin account for someone, a brokerage firm might well be interested in that person's fiscal,

as well as physical, well being.[2]

Data banking and the linkage of unrelated data bases threatens to disseminate information in a manner that may have harmful effects on an individual. Data relating to persons are regularly exchanged by airlines, car rentals, insurance companies, real estate agents and credit bureaus, and a person may be refused credit because of some information which appeared through data base linkages.[3] There is no legislation which prohibits such linkages (except for linkages with federal databases under the Federal Computer Matching Act[4]) and the matter may not be of any particular relevance to genetic privacy unless health records containing genetic information were to be linked with commercial data bases of the nature referred to. Such combined information may be used for decisionmaking by third parties, such as credit ratings, and it may be used by commercial enterprises to predict future spending behavior whether or not this kind of use was originally intended in the collection of data. Courts have been unwilling to impose liability in this area of the law; there are no precedents which appear to limit the flow of information, and there seems to be no limit on the kind of data that may be gathered. There also appears to be no practical limit on how information once collected can be used. As a practical matter, once information finds its way into a data base -- and this would include genetic data -- there appear to be few practical ways in which its subsequent release and use

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[2]See generally, PRIVACY COMMISSION, supra note 1.

[3]See Jonathan P. Graham, Note, Privacy, Computers and the Commercial Dissemination of Personal Information, 65 TEX. L. REV. 1395, 1398-99 (1987) [hereinafter Graham].

[4]Computer Matching and Privacy Protection Act of 1988, 5 U.S.C. §552a(a)(8) to (13) (Supp. 1994).

can be controlled.[5]

3. Privacy Protection Study Commission: Views on Data Banking in Relation to Banking of Genetic Information

How to protect the privacy of persons whose personal information has been incorporated in a data bank has been a longstanding concern. In 1978, the Privacy Protection Study Commission, a federally established commission, published significant proposals for the federal protection of the right of privacy. These early proposals were presented during hearings before a subcommittee of the Committee on Government Operations of the House of Representatives in the 95th Congress.[6] Although the Privacy Commission prepared a significant report on "Personal Privacy in an Information Society," the recommendations of the Commission, reflected in H.R. 10076[7], did not become law, though they set a standard for the future protections of privacy, establishing a benchmark for future proposals for privacy protection. Much recent work on privacy still relies heavily on the 1978 proposals.[8]

The Commission's report in 1978 did not address, or even mention, issues relating to the confidential nature or the protection of privacy relating to information on a person's genotype. The Commission's report and proposals are

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[5]See Graham, supra note 3.

[6]Right to Privacy Proposals of the Privacy Protection Study Commission: Hearing Before a Subcommittee of the House Committee on Government Operations, 95th Cong., 2d Sess. (1978) [hereinafter Hearings].

[7]H.R. 10076, 95th Cong., 1st Sess. (1977).

[8]For example, the work by Professor George J. Annas at the Boston University School of Medicine and Public Health relies on the Commission proposal in developing rules of privacy for genetic data banks. George J. Annas, Privacy Rules for DNA Databanks: Protecting Coded "Future Diaries", 270 J.A.M.A. 2346, 2349 (1993) [hereinafter Annas, Privacy Rules].

nonetheless relevant to the consideration of the protection of genetic information, because genetic information is indeed collected in data banks.[9] The inclusion of such materials in data banks and the possibility of matching information from several data banks may become significant unless such matching is prohibited. Employers and insurance companies relying on other data-banked information would clearly be interested in collecting data on genotype, as part of the data they are currently collecting on life and health insurance applicants generally.[10]

H.R. 10076, entitled "A bill to protect the privacy of individuals from governmental and nongovernmental intrusion, and for other purposes" (1977 Privacy Bill) was introduced on November 11, 1977 by Congressmen Preyer, Koch and Goldwater. This bill would have established a Federal Information Practices Board which would have functioned to conduct oversight of the effect of governmental and non-governmental data collection, storage, retrieval, and transfer policies, operations, systems on the rights and privileges of individuals including compliance with federal laws such as the Freedom of Information Act (FOIA)[11], the Privacy Act of 1974;[12] the Government in the

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[9]NEIL A. HOLTZMAN, PROCEED WITH CAUTION: PREDICTING GENETIC RISKS IN THE RECOMBINANT DNA ERA 49 (1989) [hereinafter HOLTZMAN, PROCEED WITH CAUTION]. See also Ricardo Fontag, DNA Fingerprinting: A Guide to Admissibility and Use, 57 MO. L. REV. 501, 508-09 (1992); E. Donald Shapiro & Michelle L. Weinberg, DNA Data Banking: The Dangerous Erosion of Privacy, 38 CLEV. ST. L. REV. 455 (1990) [hereinafter Shapiro & Weinberg].

[10]For the use of genetic information by insurers and employers, see infra n. 29.

[11]Freedom of Information Act, 5 U.S.C. § 552 (1977 & Supp. 1994).

[12]Privacy Act of 1974, 5 U.S.C. § 552a (1977 & Supp. 1994).

Sunshine Act;[13] the Fair Credit Reporting Act;[14] the Fair Credit Billing Act;[15] and the Family Educational Rights Act.[16] The bill limited the requirement for disclosure by providing an exemption in situations that involved national security; classified documents; law enforcement purposes; to prevent an unfair adjudication, or if disclosure would "constitute an unwarranted invasion of personal privacy."[17]

As the first of its findings, the 1977 Privacy Bill stated, "(1) the right to privacy is a personal and fundamental right protected by the Constitution of the United States."[18] The bill further stated that the free flow of information needed to be balanced "by protection of the right of privacy."[19] Noting that the increasingly detailed collection of information that affects individuals must be counterbalanced by increased direct control over personal information, the bill sought to make personal information readily available to the individuals about whom the information had been collected.[20]

Today, some sixteen years after the Commission's report, personal information collected which needs protection might well include data relating to genotype as well as other health data.

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[13]Government in the Sunshine Act, 5 U.S.C. §§ 551, 552, 552b, 556, 557 (1977 & Supp. 1994).

[14]Fair Credit Reporting Act, 15 U.S.C. § 1681 (1982).

[15]Fair Credit Billing Act, 15 U.S.C. §§ 1601, 1610, 1531, 1632, 1637, 1666 (1982 & Supp. 1994).

[16]Family Educational Rights Act, 20 U.S.C. § 1232g (1990 & Supp. 1994).

[17]Hearings, supra note 6 at 21.

[18]H.R. 10076, 95th Cong., 1st Sess. § 2(a)(1) (1977).

[19]Id. at § 2(a)(2).

[20]Id. at § 2(b).

The requirement that an individual about whom information has been collected be informed of the contents of that information, and also that a person about whom information has been collected be informed of the uses made or to be made of that information, has been considered in the context of information relating to genotype which is included in data banks. Both of these requirements were articulated in Human Genome Privacy Act, proposed but not enacted in 1990.[21]

The 1977 Privacy Bill would have authorized the Board to investigate compliance by the relevant agencies. It would have granted the Board the authority to require that agencies make accessible records or copies of records in a form that is comprehensible and that reflects accurately the context and manner in which the agency uses the information. This would give individuals an accounting of the use of information and disclosure to third parties. The bill would have covered financial assistance records, medical records (today, including genetic information), fair credit reporting act amendments, tax records, and educational privacy rights.

The Commission Report began on a note that was consistent with the writings of Warren and Brandeis, "in American Society today records mediate relationships between individuals and organizations and thus affect an individual more easily, more broadly, and often more unfairly than was possible in the past. ... It will remain true unless steps are taken soon to strike a proper balance between the individual's personal privacy interests and society's information needs."[22]

The Commission noted that information recorded one hundred years ago was

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[21]H.R. 2045, 102nd Congress, 1st Sess. (1990). See discussion, infra at page 90.

[22]PRIVACY COMMISSION, supra note 1 at 3; see Samuel D. Warren & Louis D. Brandeis, The Right to Privacy, 4 HARV. L. REV. 193 (1890).

typically limited to the average person's birth, baptism, marriage, death and land ownership.[23] By contrast, the modern age has generated documentation of the characteristics and health care history of most individuals; many of those records are not available to the persons to whom they pertain, but are accessible to third parties.[24] "A significant consequence of this marked change in the variety and concentration of institutional relationships with individuals is that record keeping about individuals now covers almost everyone and influences everyone's life. . . ."[25]

The Commission continued:

> The substitution of records for face-to-face contact in these relationships is what makes the situation today dramatically different. . . . It is now commonplace for an individual to be asked to divulge information about himself for use by unseen strangers who make decisions about him that directly affect his everyday life. Furthermore, because so many of the services offered by organizations are, or have come to be considered, necessities, an individual has little choice but to submit to whatever demands for information about him an organization may make. Organizations must have some substitute for personal evaluation in order to distinguish between one individual and the next in endless stream of otherwise anonymous individuals they deal with, and most organizations have come to rely on records as that substitute.[26]

In essence this situation creates the potential for harm based on the misuse of information making more urgent the effective protections of privacy. For the Commission, the need to protect privacy meant that people should be

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[23]PRIVACY COMMISSION, supra note 1 at 3.

[24]Id. at 10-11.

[25]Id. at 4.

[26]Id. at 4-5. "Each individual plays a dual role in this connection--as an object of information gathering and as a consumer of the benefits and services that depend on it." Id. at 5. "Often one also hears people assert that nobody minds organizational record-keeping practices, 'if you have nothing to hide,' and many apparently think of themselves as having nothing to hide, not realizing whether an individual does or not can be a matter of opinion." Id. at 5.

concerned about the balance of power between the government and the rest of society. "Accumulations of information about individuals tend to enhance authority by making it easier for authority to reach individuals directly.... By opening more avenues for collecting information and more decision-making forums in which it can employ that information, government has enormously broadened its opportunities both to help and to embarrass, harass, and injure the individual." [27]

The Commission cited two leading cases that illustrated individuals' diminishing ability to exercise control over personal information.[28]

The Commission noted that most record-keeping organizations consult the records of other organizations to verify the information that they have obtained from an individual and then pay as much or more attention to what other organizations report about an individual than they pay to the individual's own reports. Thus, there is great, perhaps undue weight granted to the information contained in such files.[29]

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[27]Id. at 5-6.

[28]PRIVACY COMMISSION, supra note at 471, citing State ex. rel. Tarver v Smith 470 P.2d 172 (Wash. 1971), cert. denied 402 U.S. 1000 (1971) in which a mother unsuccessfully sought to have damaging, untrue information about her parenting removed from her welfare files; and United States v. Miller 425 U.S. 435 (1976), where a businessman was found to have no legitimate "expectation of privacy" in his personal bank records (it should be noted that the holding in United States v. Miller has been limited by the Right to Financial Privacy Act of 1978, 12 U.S.C. §§ 3401-3421 (1989 & Supp. 1994).

[29]This has been the experience in the case of the use (or abuse) of genetic information by insurance companies. See ADVANCES IN GENETIC INFORMATION: A GUIDE FOR STATE POLICY MAKERS, THE COUNCIL OF STATE GOVERNMENTS (R. Steven Brown & Karen Marshall, eds., 1992); Joseph M. Miller, Genetic Testing and Insurance Classification: National Action Can Prevent Discrimination Based on the "Luck of the Genetic Draw", 93 DICK. L. REV. 729, 742-43 (1989); Susan O'Hara, The Use of Genetic Testing in the Health Insurance Industry: The Creation of a "Biological Underclass", 22 SW. U. L. REV. 1211 (1993).

4. Security of Data Bases

a. Examples of Breaches of Security

Because of the sensitivity of personal information contained in databases, there has been increasing concern with their security. This concern has grown, because in recent years breaches of security in data kept as part of electronic storage have been widespread. Though no major breaches involving the security of health or genetic data have been reported, past breaches in other sensitive areas indicate the vulnerability of such data.

Some of the breaches involved hackers who either obtained information from data bases for illegal uses or simply inserted "viruses"[30] or "worms"[31] into supposedly secure computer systems. The most notable case involved a PhD student at Cornell University, Robert Tappan Morris, United States v. Morris.[32] Morris released into INTERNET, a national computer network, a computer program known as a "worm" that spread and multiplied, eventually causing computers at various educational institutions, medical research facilities and military sites to "crash" or cease functioning.[33] The costs of repairing the damage at each installation affected ranged from $200 to $53,000.[34] Morris was convicted of unlawful use of computers and theft of services under the Computer Fraud & Abuse

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[30]A "virus" is a migrating program that attaches itself to the operating system of any computer it enters and can infect any other computer that uses files from the infected computer. U.S. v. Morris, 928 F.2d 504, 505 n.1 (2d Cir. 1991).

[31]A "worm" is a program that travels from one computer to another but does not attach itself to the operating system of any computer it "infects." Id.

[32]928 F.2d 504 (2d Cir. 1991), cert. denied, 112 S.Ct. 72 (1991) [hereinafter Morris].

[33]Id. at 505.

[34]Id. at 506.

Act of 1986.[35] The Second Circuit upheld the conviction.[36]

Morris is not the only "hacker" who has broken into national computer data bases. The New York Times recently reported that computer insecurity is on the rise.[37] Computer intruders recently have broken into hundreds of university and government commercial computers by obtaining the passwords for hundreds or thousands of the computers attached to INTERNET. Government and private security specialists are quite concerned about the use of passwords as a method of protecting network security in the future.[38]

There are several state cases that show how simple it is for anyone with a modem and ill intentions to access a basic data base. For example, a hacker can use a personal computer and a modem to call the general access number of a long distance company. The computer then randomly selects a six-digit number and a long distance number. When the modem successfully dials a password, it records that number giving the hacker a credit or calling card number that will charge long distance phone calls to the unsuspecting owner of that card. Hackers then sell these lists or trade them with other hackers for more numbers. See State of Washington v. Riley.[39]

Commonwealth of Pennsylvania v. Gerulis involved a group of hackers who cracked the secret passwords of voicemail users to access voicemail systems and

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[35]Computer Fraud and Abuse Act of 1986, 18 U.S.C. § 1030 (a) (5) (A) (Supp. 1994).

[36]Morris, supra note 32 at 511.

[37]John Markoff, Computer Insecurity on the Rise: Intruders Set Snares On Data Highway, NEW YORK TIMES, Monday, Nov. 1, 1993, at D1 [hereinafter Markoff].

[38]Id. at D1; See also Cindy Skrzycki, Dark Side of the Data Age: Privacy Is Prey in Cyberspace, WASH. POST, May 3, 1993, at F19.

[39]846 P.2d 1365 (Wash. 1993).

leave messages for other "phone phreakers" (people who illegally market telephone systems).[40] The phone phreakers would oust the intended voicemail user and use the free message space to leave lists of illegally obtained credit and calling card numbers.

In addition to hackers breaking in from the outside, data bases are also vulnerable to illegal uses by those who have access to them for legitimate purposes. In 1990, vandalism and embezzlement in office computers cost the business community more than $3 billion.[41] In one case, a person with access to a credit reporting agency charged others $1,500 per file to alter entries in credit histories, racking up a sizable profit.[42] A recent IRS audit revealed that over a 28-month period 369 IRS employees in nine states used their computer access codes to "browse" through taxpayer refund records.[43] Finally, in early 1992 the FBI announced indictments of a network of people who were buying and selling information contained in sensitive government databases.[44] A private detective in Tampa, Florida advertised that, for a price, he could obtain information about any person's employment and earnings history. This information is protected by law and contained only in the massive Social Security Administration data base in Baltimore. The breaches of security occurred both at

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[40]616 A.2d 686, 688 (Pa. Super. 1992).

[41]William F. Jung, Detecting and Preventing Computer Crime in the Office Setting, 65 FLA. B. J. 50 (1991) [hereinafter Jung], citing NATIONAL RESEARCH COUNCIL, COMPUTERS AT RISK (1990), quoted in TAMPA TRIBUNE, May 12, 1991 at 11; see also People v. Lett, 589 N.Y.S.2d 528 (1992) (defendants entered undocumented overtime into company's computer system and were convicted of computer trespass.)

[42]Jung, citing C. SWANSON, N. CHAMELIN & L. TERRITO, CRIMINAL INVESTIGATION 445 (4th ed. 1988).

[43]IRS Computers vs. Privacy, THE PLAIN DEALER, Aug. 23, 1993, at 8A.

[44]Edmund Mahoney, Increasing Use of Databases Raises Privacy Concerns, THE HARTFORD COURANT COMPANY, Nov. 25, 1992, at A2 [hereinafter Mahoney].

the Social Security system computer and the FBI's National Crime Information Center computer in Washington. The culprits bribed police officers and Social Security Administration employees to provide them with confidential data on people's incomes and criminal history information that local police departments can obtain through the FBI computer.[45]

b. Legal Protections

There are some legal protections against vandalism and hacking in computer data bases. Specific federal legislation includes the 1984 Computer Abuse Act and the 1986 Computer Fraud & Abuse Act.[46] The 1984 Act resulted in only one prosecution.[47] The 1986 Computer Fraud and Abuse Act has had more success.[48] Other statutes used to control computer crime include the National Stolen Property Act, mail and wire fraud statutes, and the Electronic Communication Privacy Act.[49] In 1991, the Department of Justice created the Computer Crime Unit within the Criminal Division.[50]

In addition to federal laws, states also provide various limits on access

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[45]Id. at A2.

[46]Counterfeit Access Device and Computer Fraud and Abuse Act of 1984, as amended by Computer Fraud and Abuse Act of 1986, 18 U.S.C.A. § 1030 (1986).

[47]Barry J. Hurewitz and Allen M. Lo, Computer Related Crimes, 30 AM. CRIM. L. REV. 495 (1993) [hereinafter Hurewitz] citing U.S. v. Fadriquela, No. 85-CR-40 (D. Colo. 1985).

[48]United States v. Morris, 928 F.2d 504 (2d Cir. 1991); United States v. Wittman, No. 91-CR-327 (D. Colo. 1991) (Defendant plead guilty to accessing and damaging data in a NASA computer without authorization, violating 18 U.S.C. § 1030(a)(5)); United States v. Lauffenberger, No. 91-0594-T (S.D. Cal. 1990) (Employee plead guilty to attempted computer tampering with employer's federal interest computer, in violation of 18 U.S.C. § 1030(a)(5)(A) and 1031(b)).

[49]Hurewitz, supra note 47 at 500-01.

[50]Id. at 503.

to computer information. However, the fact that regulations vary from state to state causes enforcement problems.

> Every time a person applies for a license, checks into a public hospital, pays (or fails to pay) taxes, registers to vote, is arrested (regardless of outcome), or even applies for a telephone number, computers record reams of data to which the state has access. In addition, most (if not all) states share information. As such, even if one state designates a portion (or all) of the information in a record as confidential, perhaps imposing particular penalties for improper dissemination, other states might be able to disseminate the same records legally under their own laws. Indeed, states seeking extra revenue may structure their laws to permit the collection and sale of data.[51]

Businesses capitalize on the differences among states' laws by collecting public information from each state and selling it to subscribers.[52]

c. Genetic Data Bases

Differences between genetic data bases and other data bases lie in the type of information they provide. While other health records look primarily to the past, genetic data also provide indications of the future -- not only for the subject of the data but also for the subject's family.

Law enforcement agencies and the military are anxious to begin compiling files of DNA identification patterns with the intention of storing the files in computerized data bases.[53] In 1992, the United States Military began a five-year project to collect DNA samples as a means of identifying wartime (or other

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[51]Bruce D. Goldstein, Comment, Confidentiality and Dissemination of Personal Information: An Examination of State Laws Governing Data Protection, 41 EMORY L. J. 1185, 1194-95 (1992).

[52]See Goldstein at 1197.

[53]Dan L. Burk, DNA Identification Testing: Assessing the Threat to Privacy, 24 U. TOLEDO L. REV. 87, 95 (1992) [hereinafter Burk].

disaster) casualties, a "DNA dog tag."[54] DNA identification patterns haven proven to be powerful tools for investigating crimes and for determining relatedness. These patterns could be equally useful in other areas, such as identifying missing children or identifying anonymous human remains.

The form these databanks will take is unclear. DNA identification testing involves the analysis of Restriction Fragment Length Polymorphisms (RFLPs). RFLPs generate a banding pattern, much like a bar code on grocery items, which reveals specific and limited information about a particular physical feature of the DNA molecule. These banded patterns may be digitized and stored in a computer database much like FBI fingerprints are now stored. However, digitized patterns cannot be retested to confirm their accuracy or to employ new forensic techniques that may become available. "Southern blots" from the actual RFLP testing procedure may therefore be stored, or the original DNA sample may be preserved.[55]

There is concern that highly sensitive personal information might be derived from DNA testing.[56] In some cases, a careful researcher may in fact be able to glean from a computerized DNA databank information about an individual that could not be had from an individual's identification pattern alone.[57] There is also a danger that information obtained through DNA identification tests, once gathered, could be misused in some fashion. For example, the information could be either purposely or inadvertently distributed to employers, insurers, or other

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[54]Jody W. Zylike, Examining Life's (genomic) Code Means Reexamining Society's Long-held Codes, 267 J.A.M.A. 1715(2) (1992), citing 267 J.A.M.A. 909 (1992).

[55]Id. at 95.

[56]Id. at 88.

[57]Id. at 98.

private parties.[58] The presence of a particular RFLP banding allele might signal the presence or absence of a particular stigmatizing genetic trait.[59]

Several state statutes providing for DNA testing require that the actual sample rather than simply a digital banding pattern be preserved. Also, some commentators have suggested that law enforcement agencies must preserve forensic samples in order to allow defendants to independently test the samples used against them. When the actual sample is preserved, the opportunity for genetic testing beyond that needed for identification becomes a legitimate concern.

5. The Registry of Genetic Conditions

A registry of genetic conditions consists of a list of individuals who at a specified point in time develop the disease or condition for which the registry was established.[60] One of the characteristics of disease registries is that they do not only identify diseases but also the individuals who suffer from them. To function properly as a register requires that a permanent record for each entry be established, and that cases be followed, that basic statistical tabulations be prepared both on frequency and survival.[61]

Disease registries can serve a number of functions. In the communicable disease area, they may provide preventive information and in general, they may provide projections of future needs for hospital and support services and may

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[58]Id. at 88.

[59]Id. at 94.

[60]EILEEN M. BROOKE, WORLD HEALTH ORGANIZATION, THE CURRENT AND FUTURE USE OF REGISTERS IN HEALTH INFORMATION SYSTEMS 31 (1974) [hereinafter BROOKE].

[61]Id. at 2, citing EXPERT COMMITTEE ON HEALTH STATISTICS, WORLD HEALTH ORGANIZATION, EPIDEMIOLOGICAL METHODS IN THE STUDY OF CHRONIC DISEASES no. 365 (1967).

supply information for research and statistical purposes.[62]

The usefulness of genetic registries has been noted:

> A full count of the frequency of genetic disorders in a cohort of live births requires the reporting of all genetic abnormalities in the cohort as it grows older. This has been accomplished successfully by the Health Surveyance Registry of the Canadian Province of British Columbia. The rate of genetic disorders appearing before the age of 25 years in more than one million consecutive live births was found to be greater than 5.3 percent. The vast majority were multifactorial disorders.[63]

In the U.S. another genetic registry is provided by the Birth Defects Monitoring Program of the March of Dimes (BDMP) which has provided the mechanism for tracking the incidence rate for more than 160 genetic disorders.[64] 1991 statistics tracking 178,331,123 congenital malformation cases from 1970-1992, most recurrent malformations include: congenital anomalies affecting the nervous system (34,043); other heart anomalies (42,525); birth weight (277,611 cases) and congenital limb anomalies (148,751). Birth weight problems may be rectified by early intervention during prenatal care. The twenty-year trend for this genetic disorder peaked in 1987-89, but is slow to decline, (1992 estimates approximately 6,000 of 95,549 total births will generate birth weight problems).

Of the 95,549 births recorded by BDMP in 1992, 459 babies with genetic disabilities died in the hospital. There were 265 stillbirths. This indicates a need for greater specialization in the field of medical genetics, but also represents a significant improvement in prenatal care compared to 1979-82, when 9,222 cases died in the hospital and 28,389 were stillborn. As recorded, the

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[62]BROOKE, supra note 60 at 5.

[63]HOLTZMAN, PROCEED WITH CAUTION, supra note 9 at 49.

[64]Larry D. Edmonds & Levy M. James, Temporal Trends in the Prevalence of Congenital Malformations at Birth Based on the Birth Defects Monitoring Program, United States, 1979-1987, M.M.W.R., Dec. 1990, at 19(5) [hereinafter Edmonds & James].

twenty-year trend indicates greater attention to prenatal testing, diagnosis and treatment.

The usefulness of a genetic registry is likely to depend on the frequency of particular diseases. The less frequent a particular genetic condition, the less useful the registry.[65] The accuracy and reliability of genetic registries will also depend on the full cooperation of the target population. Though a number of disease-specific organizations such as the Cystic Fibrosis Foundation have attempted to compile accurate data, nationwide coverage for major genetic diseases is still sparse, because there is limited funding for it, and because in many instances the collection of such data is regarded as controversial.[66] Another problem in the establishment of genetic registries arises from the inability of neonatal testing to show genetic diseases that will manifest later, though some significant diseases such as muscular dystrophy, cystic fibrosis and sickle cell all manifest early.

Cancer registries and communicable disease registries appear to have made considerable contributions to the treatment and cure of the diseases involved. But there has been considerable recent opposition to the development of genetic registries. The basic issue is that of privacy and confidentiality. When a physician submits data to a genetic registry, the data which form part of the knowledge acquired by the physician in the course of treatment retain their confidential and protected character. From early on, beginning with writings on the development of registers in health information systems, the secrecy or privacy issue has been of considerable concern. In dealing with the issue in 1974, Brooke, while stressing the necessity of secrecy and protection of data,

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[65] Id.

[66] Id. at 117, 165.

nonetheless seemed to indicate that participation in the registry should be made compulsory, with little appreciation some 20 years ago of the extent to which privacy issues would become controlling issues in the field.[67]

One of the major problems with genetic registries appears to be that the better they are, the more risks they appear to create for the person whose information is included in the registry. For Brooke, for instance, an adequate registry should contain a minimum operating protocol which includes reference to the severity of the disease, socio-demographic information, previous medical history, time frame for follow-up, instructions for obtaining complete information and instructions for checking notification and registration. Such a registry would not only add new cases but it would also update information about old cases to maintain an accurate registry.[68]

Questions have also been raised relating to the uses of health care data from individual patients' medical records, from public health and vital statistics data, from research data collections and data banks and from biomedical bibliographic data. Often, the passage of time between the initial collection of data and their analysis and use may render them considerably less persuasive or useful.[69] In reviewing the possible improvement of the completeness and validity of a hospital-based cancer registry, it was found that there was poor agreement between information gleaned from interviews with patients when compared to information in the registry. While there was no direct

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[67]BROOKE, supra note 60 at 17-19.

[68]BROOKE, supra note 60 at 32.

[69]Walter J. Hierholzer, Jr. Health Care Data, The Epidemiologist's Sand: Comments on the Quantity and Quality of Data, 91 AM.J.MED. 3B-21S (1991).

disagreement, much of the information simply did not get into the registry.[70]

In 1985, during the Council of Regional Networks for Genetic Services' (CORN) first year of operation, a standing committee comprised of members from each of 10 regional networks was established to develop a plan of action to assemble a national database.[71] The program which emerged, the Birth Defects Monitoring Program/Commission on Professional and Hospital Activities (BDMP/CPHA) is a national program for monitoring congenital malformations which has some of the attributes of a national registry for genetic conditions. The program relies on hospital discharge data about newborns to identify changes in patterns of occurrence for 161 birth defect categories.[72] BDMP/CPHA is one of the few programs that can evaluate long-term trends in birth defect prevalence, because it currently holds data on 16 million births between 1970 and 1993, occurring in 1200 community hospitals.

CORN issued its Final Report in 1992 for the Newborn Screening Report: 1990. CORN functions "to ensure open communication among the ten regional networks and to encourage the development of minimum guidelines for services, laboratories, educational programs, collection of data, etc. In addition, CORN promotes the collection of data regarding genetic services in order to document the utilization of such services." [73] CORN committees include "Birth Defects

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[70]M. McDiaramid, R. Bonanni and M. Finocchiaro, Poor Agreement of Occupational Data between a Hospital-Based Cancer Registry and Interview, 35 J. OCCUPATIONAL MED. 726, 728 (1991).

[71]THE COUNCIL OF REGIONAL NETWORKS FOR GENETIC SERVICES (CORN), NEWBORN SCREENING REPORT: 1990 3 (1992) [hereinafter CORN Report].

[72] Edmonds & Levy, supra note 64 at 19.

[73] CORN Report, supra note 71 at 3.

Surveillance" and "Newborn Screening."[74] Newborn Screening data is a major component of CORN's responsibility for reporting "the current level and scope of clinical genetic services provided by each state."[75] The report is designed to be useful for evaluation of existing state screening programs and identifying needed policy changes. The data collected in its survey, "provides no formal analysis of the newborn screening data collected, but concentrates instead on the compilation and presentation of the most current and comprehensive information available."[76] The data collected in the survey reflects the initial screening, follow-up second screening, confirmed diagnosis and initiation of treatment for ten (10) genetic or metabolic disorders,[77] as well as the numbers and types of laboratories performing these tests in each state.

a. Privacy Protection of Patient Medical Data in Registries

In 1972, the World Health Organization (WHO) recommended the use of registries to enhance the delivery of genetic services:

> It is recommended that medical genetics centres should set up registries of genetically determined disorders, so that genetic counselling can be offered to all who would benefit by it. Physicians in medical genetics centres should be ready to exchange information with the usual safeguards of confidentiality, whenever they obtain information about a person at risk near another clinic.

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[74] Id. at 3.

[75] Id. at 6.

[76] Id. at 6. The report notes that "[a]lthough we have attempted to make this report as reliable as possible, we cannot guarantee the accuracy of the data provided by the individual states. . . . If you have questions regarding these data you may contact the state directly." Id. at 6. The report also cautions that these data represent information at a point in time and that people should contact the state of interest for further information. Id.

[77] Phenylketonuria; Hypothyroidism; Galactosemia; Maple Syrup Urine Disease; Homocystinuria; Biotinidase Deficiency; Cystic Fibrosis; Adrenal Hyperplasia; Hemoglobinopathies; Tyrosinemia; and Toxoplasmosis. Id. at 8.

> The data held in these registries should be linked with a computerized health record linkage system where available, using a uniform system of nosology.[78]

In 1972, when WHO made this recommendation, "the usual safeguards of confidentiality" were not nearly as thoroughly developed and as exacting as they are now, because the attenuated emphasis on privacy controls was developed during the AIDS crisis, which had not as yet come upon us in 1972. A hopeful and somewhat overly optimistic note on confidentiality was sounded in the lead article in the British Medical Journal in 1979 which endorsed the WHO recommendation of genetic registries.[79] The article suggested that genetic registers be used to reduce the inheritance of genetic disease, and noted that the alarm associated with genetic registers is based on the fact that they "identify people who are healthy but who risk transmitting inherited disorders to their children," thus making them the target for discrimination and stigma against which they would have been protected had their genetic status remained unknown.[80] The article added that despite the "totalitarian excesses of the twentieth century," the development and use of registries is adequately supported.[81] "The gain from the existence of a register [for Duchenne muscular dystrophy] would be the avoidance of the agony for all concerned in watching affected boys slowly die of untreatable disease--and it would almost certainly save money, too."[82] The editorial suggested that other diseases to be included

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[78]GENETIC DISORDERS: PREVENTION, TREATMENT AND REHABILITATION, WORLD HEALTH ORGANIZATION 37 (Tech. Rep. Ser. No. 497, 1972).

[79]Editorial, Registered for the Prevention of Genetic Disease, 27 BRIT. MED. J. 215 (January 1979).

[80]Id. at 215.

[81]Id. at 215.

[82]Id. at 215.

in the registry include recessive disorders. Benefits of registers include carrier detection or prenatal diagnosis and increased opportunities to provide support such as genetic counselling and support services.[83] The editorial further noted that if registers are seen to be a part of diagnosis and support they are likely to be accepted.[84]

Reflecting a more current point of view, apparently widely shared by geneticists and ethicists is that "the price for using the new genetics in medicine may be privacy and autonomy itself."[85] Annas has the view that the control of and access to the information contained in an individual's genome gives others power over that person's life and allows them to discriminate on the basis of this information. Since much genetic information will also provide information about the person's parents, siblings and children, personal liberty can be protected only by stringent safeguards on access to and use of genetic information. Using DNA databanks for criminal identification as a basis for some of his comments, he expresses the concern that such a databank provides a "future

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[83]Id. at 215.

[84]Id. at 215. For a contrary contemporary view, see T. Van Den Berg, Preventive Genetic Registers, 3 BRITISH MEDICAL JOURNAL 618 (March 1979). Van Den Berg viewed genetic registers as creating more stigma for parents of handicapped children and as a contribution to unnecessary abortions and abortions for sex selection purposes. In another contemporary article, Chiu, Teltscher and Davies noted that their Huntington's Disease Register was an invaluable clinical tool in the diagnosis and management of this disorder. In their view, a properly maintained register assists in the diagnosis of the disease by clinicians, provides valuable data in the planning of management now and in the future and it provides us with a view of the "family network system" to begin to make full use of family resources by support for the ill members of the family. Chiu, Edmond, Teltscher, and Davies, Registers for the Prevention of Genetic Disease, 94 BRITISH MEDICAL JOURNAL 823 (March 1979). It should be noted that these comments in the British Medical Journal were made in March 1979, when genetic knowledge, particularly with respect to Huntington's disease had not as yet reached the current level of information.

[85]Annas, Privacy Rules, supra note 8 at 2346.

diary" which will disclose unintended information regarding an individual's entire family. It is likely that physicians, insurance companies, employers and others will base decisions affecting the individual on such information. Relying largely on the findings of the 1975-77 Privacy Commission[86] which have also been more recently reflected in the Uniform Health Care Information Act,[87] Annas recommends that no DNA databank should be created or begin to store samples until there is a public notice, a privacy impact statement and until the bank has met the burden of proof to establish the necessity of storage.[88] Moreover, no collection of DNA samples destined for storage is permissible without prior written formal consent of the individual. Such consent would require information regarding the purpose of storage, the uses of the materials including any commercial uses, guarantees relating to long-term access to the sample, the individual's right to correct information, and the right to have the sample destroyed. Also there is to be a return of the sample and a destruction of samples if the bank is under new ownership or ceases operations. Proper federal oversight with a new agency with authority to implement protective guidelines is also recommended.[89]

The very far-reaching protection for materials in genetic databanks envisaged by George Annas are applicable to databanks consisting of actual genetic materials, such as blood samples or DNA which could be used for further genetic investigation. It is not quite clear whether a databank consisting of

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[86]See discussion supra chapter 5, p. 113.

[87]UNIF. HEALTH CARE INFO. ACT §§ 1-101 to 9-106, 9 U.L.A. 479-520 (1988 & Supp. 1993).

[88]Annas, Privacy Rules, supra note 8 at 2349.

[89]Id. at 2349.

repositories of information only would require the same degree of protection, because such a databank would create less of an opportunity to use the materials in the databank to provide the future diary that Annas is concerned about.

Annas' approach, shared by many, raises the question whether such a restricted and limited databank is worth having at all. It also raises some significant issues about the science of genetics generally. Most other fields of medical science encourage access by others to existing data of researchers. Free access to a repository of existing data is normally a tenet of scientific investigation, and particularly of medical investigation. If such data can be used without identifying information, or can be used in aggregate rather than disaggregated form, there may be less of a problem. It is not entirely clear what scientific access Annas anticipates, though he does mention scientific uses. The protection of such data clearly requires the limitation of the use of such data to the purposes for which they were created. Such purposes may include not only diagnosis and treatment of the person to whom they pertain, but also scientific uses relating to studies of the origin of the particular condition, treatment for the condition, and other aspects of knowledge in which the particular information is used as part of the data and information to be applied in the investigation, diagnosis and treatment of the condition which provided the basis for securing the particular information relating to a specific individual in the first place.

b. Policy Issues Relating to Genetic Disease Registries

Genetic disease registries are a significant tool for the development of genetic knowledge, and for knowledge on which future programs to provide necessary genetic services can be based. There seems to be little question that

genetic registers are useful, if not essential for the future development of the field. Claims of privacy and confidentiality must clearly be reflected in the development of any successful genetic registry. Legislation is necessary to provide that information supplied to the registry can only be used for the benefit of the patient and for scientific purposes, but for no others. There are a number of legislative prototypes which may provide the beginning of a successful draft of legislation in this area. The Genetic Privacy Act of a few years ago provides a sound start, as does George Annas' more recent work.[90] In addition to relying on legal prohibitions on the abuse of such information, it should also be possible to protect the information by available methods of encoding or encryption in order to provide initial barriers against its dissemination. As noted elsewhere in this report, there ought to be an effort to have less of an inducement to use such materials for improper purposes. The major abuses today are insurance and employment discrimination. When a system of universal coverage in health insurance becomes a reality, there will be little inducement to abuse private information for such insurance discrimination purposes. When the Americans with Disabilities Act is amended to protect persons in the workplace fully against genetic discrimination, another inducement to the improper use of such information will also disappear.

Although the collection of genetic information in computerized data bases is extremely new, several federal cases and other examples of concern over the security of the information have already appeared. In Vanderlinden v. Kansas,[91] prisoners in Kansas state correctional facilities challenged the

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[90]Genetic Privacy Act, H.R. 2045, 102d Cong., 1st Sess. (1991); Annas, Privacy Rules, supra note 8.

[91]1992 WL 42912 (D.Kan. 1992)

constitutionality of K.S.A. 21-2511 (1991 Supp.) which directs state officials to collect blood and saliva specimens in a medically approved manner from certain convicted felons. These specimens are forwarded to the Kansas Bureau of Investigation for analysis, categorization and placement in a central repository data base of genetic marker information. The District Court of Kansas held that this collection did not represented a serious or intrusive invasion of privacy of anyone.[92]

A similar challenge was made to the Virginia Code which requires convicted felons to submit blood samples for DNA analysis "to determine identification characteristics specific to the person" and provides for the creation of a data bank of the information for future law enforcement purposes.[93] In Jones v. Murray,[94] the Court of Appeals held that the benefits of such a data bank in improving law enforcement vastly outweighed any "minor intrusion" caused by the taking of blood samples.[95]

6. Legal Protections

In the fledgling field of DNA data banking, little regulation currently exists. In 1990, Representative Conyers introduced the "Human Genome Privacy Act" to Congress.[96] Both the bill and its abbreviated version, introduced in

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[92]Id.

[93]VA. CODE ANN. § 19.2-310.2 TO -310.5 (Michie 1993).

[94]962 F.2d 302 (4th Cir. 1992), cert. denied 113 SCt 472 (1992).

[95]Id. at 306.

[96]H.R. 5612, 101st Cong., 2d Sess. (1990).

1991, gained little support in the House of Representatives.[97] The bill was aimed at "safeguarding the individual privacy of genetic information from the misuse of records maintained by [federal] agencies."[98]

The FBI claims that analysis of (RFLPs) involves the data banking of information which bears no genetic significance.[99] However, at this time scientists do not know which information may prove to be genetically significant in the future. Moreover, some state statutes require that the entire DNA sample be kept on file by authorities in the DNA data bank.[100] Given the lack of security in data bases generally, it may be difficult to present that information stored in DNA data banks will eventually circulate.[101]

Current commercial groups are also involved in genetic data banking. For example, Life Codes Corporation plans to start data banking of newborn infants for parents who wish to trace and positively identify kidnapped, runaway or otherwise estranged children. The immigration authorities, other government agencies and private doctors also are considering ways to keep genetic tabs on the people they serve.[102]

Many states including Arizona, California, Colorado, Florida, Georgia,

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[97]Burk, supra note 53 at 101, citing H.R. 5612, 101st Cong., 2d Sess. (1990); Burk at 101, citing H.R. 2045, 102d Cong., 1st Sess. (1991).

[98]Burk, supra note 53 at 101.

[99]HOLTZMAN, PROCEED WITH CAUTION, supra note 9 at 60.

[100]Shapiro & Weinberg, supra note 9.

[101]For example, George Steinbrennar, drawing on a twenty year working relationship with the FBI, often enlisted past and present agents of the bureau's Tampa office to conduct unofficial background checks on business associates as well as his own employees according to former Tampa FBI agents, Id. at 484 n. 147.

[102]Id. at 472, quoting Unger, Court Challenge Casts Pall Over DNA Testing Industry, NEWSDAY, July 30, 1989, at 45.

Indiana, Iowa, Kentucky, Minnesota, Nevada, South Dakota, Virginia, Washington and West Virginia have legislation authorizing the storing of DNA data in DNA "data bases" or "libraries."[103]

7. Protection of Medical Records

The Privacy Protection Commission[104] in 1978 gave special attention to medical records and the comments appear sound today. These Commission comments are clearly applicable to genetic data which are commonly part of patient records. The Commission expressed its concern that medical information will be inappropriately used in making non-medical decisions and that offhand comments written by physicians into the record will be used in this fashion.[105] These comments are still appropriate sixteen years later. Neither law nor technology has provided individuals with the ability to protect legitimate interests in these records.[106] Medical records are frequently available to a wide variety of hospital staff and third parties, beyond the medical personnel who are

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[103]ARIZ. REV. STAT. ANN. § 31-281 (Supp. 1993); CAL. GOV'T CODE § 76104.5 (1993); COLO. REV. STAT. § 17-2-201(1)(g)(I) (Supp. 1993); FLA. STAT. ANN. § 943.325 (West Supp. 1994); O.C.G.A. § 24-4-60 (Supp. 1993); IND. CODE ANN. § 20-12-34.5-1 to -34.5-6 (Burns 1991); IOWA CODE § 13.10 (1989); KY. REV. STAT. ANN. § 17.175 (Baldwin 1992); MINN. STAT. § 609.3461 (Supp. 1994), § 299C.155 (1991); NEV. REV. STAT. ANN. § 179A.075 (Michie 1992); S.D. CODIFIED LAWS ANN. §§ 23-5-14 to -18 (Supp. 1993); VA. CODE ANN. §§ 19.2-270.5 to 19.2-310.2 (1990 & Supp. 1993); WASH. REV. CODE § 43.43.754 (Supp. 1994); W. VA. CODE § 15-2-24a (Supp. 1993).

[104]PRIVACY COMMISSION, supra note 1.

[105]Id. at 284.

[106]Id. at 10. "The sharing of information among record-keeping organizations also transmits the stigma that goes with some kinds of information... Questions are seldom asked about the social or bureaucratic processes by which the information came to be in the other organization's records, so that unwarranted assumptions can easily be made about its value. For the individual, of course, such an unwarranted assumption can start a progression of fortuitous events that may permanently deprive opportunities he deserves. . . ." Id. at 10.

directly involved in the treatment and care of an individual. Each contact with a medical care provider generates a new record, and each record is retained for 10 to 25 years.[107] Generating medical records creates the dual problems of ensuring patient access to the records, while limiting the record's exposure to third parties who may misuse the information to make judgements that are inappropriate given the information in the records, or who may use the information for unintended, inappropriate purposes. Unlike the Warren and Brandeis approach, which views personal information as a type of intangible property, medical records containing personal information are frequently viewed as the property of the hospital, insurer or health professional.[108]

The Commission pointed out that this development is contrary to traditional medical practice from the last century up to World War II. At that time, physicians practicing alone delivered 85% of the medical care and they generated minimal records, keeping most patient information locked in their memory. By contrast, the Commission found in 1978, attending physicians generate a third of a patient's hospital record and private insurance coverage has caused the creation of many more medical records.[109] According to the Commission, hospitals and clinics produce hundreds of thousands of copies of these records each year for use not only by insurers, but by third parties who are not directly involved in the medical relationship.[110] These records have many unintended uses, as described in detail by the Commission, such as a role in hiring and promotion decisions. Such records are also used by investigative firms to assist

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[107] Id. at 277.

[108] Id. at 280-81.

[109] Id. at 278.

[110] Id. at 280-81.

lawyers and insurance companies to estimate the value of particular claims for damages.[111] The Commission also noted the lack of redress for breach of confidentiality by health professionals who generate records because the allied health professions are not included in the laws that govern disclosures made by physicians. This situation caused the Commission to suggest that privacy in medical records has been eroded.[112] The Commission's comments, though not expressly addressed to genetic information, seem particularly appropriate in that situation, especially using such information in making employment and insurance determinations.[113]

The Commission made several recommendations in response to this situation. The recommendations included amendment of the Social Security Act to ensure protections; enactment by the states of statutes for individual rights of access to medical records and confidentiality for medical records; the amendment of state penal codes to make it a criminal offense to knowingly request or obtain medical records under false pretenses; and legislation to ensure that medical care providers make medical records available only on a "need-to-know" basis.[114]

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[111]Id. at 281.

[112]Id. at 281-82. "New balances must be struck, recognizing not only that existing law and public policy on the subject are inadequate but also that many of the gatekeeping and credentialling functions that depend on information derived from medical records are essential." Id. "The physician patient relationship is an inherently intrusive one in that the patient who wants and needs medical care must grant the doctor virtually unconstrained discretion to delve into the details of his life and his person." Id.

[113]See 169, 173 infra and chapter 7 generally.

[114]Id. at 292-308. "Recommendation (10): That each medical care provider be considered to owe a duty of confidentiality to any individual who is the subject of a medical record it maintains and that, therefore, no medical care provider should disclose, or be required to disclose, in individually identifiable form, any information about any such individual without the individual's explicit

8. Employee Records

The issue of privacy in the workplace has been treated elsewhere in this report. Here we address only the issue of employment records, as viewed in particular by the Privacy Commission. The Commission was especially concerned about the creation, use and disclosure of employer-generated records concerning employees.[115] Records containing personal information pertaining to finances and health status play a significant role when comparing individuals for selection, placement, transfer, promotion, demotion or training, etc. In order to minimize intrusiveness and create the basis for achievable confidentiality, the Commission made the following recommendations: (1) that employers periodically and systematically examine employment and personnel record-keeping practices to facilitate informing employees about the information contained in their records; (2) that employers articulate and implement fair information practice policies, including limiting the collection of information that is relevant to specific decisions and informing applicants, employees and former employees of the uses for information and (3) a prohibition of the use of polygraphs by employers.[116] When the Commission prepared its report, the connection between employment and health insurance had not yet attained the importance in the decisionmaking process that it has since then. The Commission's comments have thus achieved even greater urgency.

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authorization. . . ." (with nine exceptions). Id. at 306.

[115]Id. at 223. For further discussion of this issue, see comments on the Americans with Disabilities Act (ADA), 42 U.S.C. §12101-12213 (Supp. 1994), infra at 223-36.

[116]Id. at 231-240.

9. President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research - Data Emerging from Genetic Screening, Counseling and Educational Programs

The President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research in 1983 published its report on Secrecy in Counseling for Genetic Conditions: The Ethical, Social and Legal Implications of Genetic Screening, Counseling and Education Programs.[117] In its discussion of the need for genetic screening, counseling and education programs, the Commission provided the major outlines for a public health program of genetic services. In so doing, the Commission stresses important aspects of privacy which emerge in the context of genetic screening and counseling.[118] The Commission identified the ethical and legal issues presented by genetic screening and counseling in medical care and public programs.

> The main ethical principles are autonomy, beneficence (including the prevention of harm), justice (including equity and fairness), and privacy (including confidentiality).[119]

With respect to confidentiality, which the Commission identifies so as to include privacy, the Commission mentions three areas of concern. These include the disclosure of information to unrelated third parties, such as employers or

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[117]PRESIDENT'S COMMISSION FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL AND BEHAVIORAL RESEARCH, SCREENING AND COUNSELING FOR GENETIC CONDITIONS: A REPORT ON THE ETHICAL, SOCIAL, AND LEGAL IMPLICATIONS OF GENETIC SCREENING, COUNSELING, AND EDUCATION PROGRAMS (1983) [hereinafter SCREENING AND COUNSELING].

[118]"By providing this important information [on genetic diseases], well-designed and carefully implemented genetic screening and counseling programs give individuals greater opportunities to make informed, autonomous decisions about their own health and about reproduction. Screening and counseling programs can also make major contributions to public health and personal well-being by reducing the incidence of genetic disease and by facilitating more effective management and treatment." Id. at 41.

[119]Id. at 41.

insurers; access to materials stored in data banks; and disclosure of information to relatives, either to advise them that they are at risk for genetic disease or to gain information from them for more accurate diagnosis of the person screened. The Commission concludes that because of the potential for misuse, as well as for unintended social or economic injury, information from genetic testing should be given to insurers or employers only with the explicit consent of the person screened.[120] To secure control by the person screened, consent forms for disclosure are to include specific rather than blanket consent. Moreover, the person screened should be told what information was disclosed, to whom and for what purpose.

With respect to data banks, the Commission notes that the confidentiality of materials is not peculiar to genetics. However, concerns of privacy are particularly acute because genetic information involves such sensitive matters as personal identity and reproductive fitness, and "banks" with actual cell samples will probably include materials that are placed in the system which will contain information that may be revealed by new tests, though the information may have been impossible to determine at the time the material was placed in the bank.[121] The Commission recommended that private and government agencies that use data banks for genetics-related information should require that stored information be coded, both to preserve anonymity and to minimize the risk of unauthorized computer access. Such coding should be required whenever coding is compatible with the reason for the storage of the information.[122]

The Commission also discussed the issue of the release of information to

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[120] Id. at 42.

[121] Id. at 43.

[122] Id. at 43.

relatives of the persons screened. The only person normally entitled to the result of genetic screening is the person who is screened. However, when serious harm to relatives could be prevented by providing them information not otherwise available in a timely fashion, then there is a question whether such information ought to be disclosed even without the consent of the persons screened. In particular, when a genetic condition is discovered in one family member, the question is whether the physician, knowing that the disease is genetic, should try to advise others in the family to be screened. The Commission recommends that prospective screenees be advised prior to testing of the value of informing relatives who are at risk in order to obtain their voluntary consent to disclosure. It is also suggested that making access to the test conditional on prior agreement to disclose information "may be justifiable."[123] The same policy may also be justified in the case of publicly funded programs, in the Commission's view, because even if citizens have a right to participate in a testing program, the right is not absolute and is limited by the state's interest in protecting others from harm. Since such a policy might deter some people from participating, the Commission notes that a decision to require consent to disclosure must take into account that balance of the harm that might be done with the benefits that might be foregone if some individuals chose not to participate.[124]

When no advance agreement has been reached as in the case when genetic testing produces unexpected information that could benefit a person's relatives, persons may oppose disclosure of their test results because they fear that positive findings or even their participation in the screening could lead to

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[123]Id. at 43.

[124]Id. at 43-44.

stigmatization by relatives. Persons screened may also want to withhold information because they believe that their relatives would not want it.[125]

While a genetic counsellor should not disclose information against the wishes of a client because his professional duty is primarily to the client, it may still occur that a professional's primary obligation may be subordinated by the need to prevent harm to others. The Commission analogizes the case of information relating to communicable disease and while noting that transmission is "horizontal" in one case and "vertical" in the other, nonetheless in both cases the duty to prevent harm to others may place limits in some instances on the professional's duty of confidentiality.[126] The Commission concludes:

> A professional's ethical duty of confidentiality to an immediate patient or client can be overridden only if several conditions are satisfied: (1) reasonable efforts to elicit voluntary consent to disclosure have failed; (2) there is a high probability both that harm will occur if the information is withheld and that the disclosed information will actually be used to avert harm; (3) the harm that identifiable individuals would suffer would be serious; and (4) appropriate precautions are taken to ensure that only the genetic information needed for diagnosis and/or treatment of the disease in question is disclosed.[127]

The screened individual's family history should be analyzed carefully to identify relatives at risk accurately so as to present information only to the proper individuals, preserving anonymity whenever possible. The Commission suggests that in light of the weighty nature of the decision to breach professional confidentiality, review by an appropriate third party may also be advisable.[128] Note that none of these recommendations of the Commission have

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[125]Id. at 44.

[126]Id. at 44.

[127]Id. at 44.

[128]Id. at 44-45.

as yet found their way as legal requirements or as legal authorizations.[129]

The Commission notes that with increased education and information about genetic disease the stigmatizing effect of information is likely to be lessened and persons' willingness to share information with others and particularly with members of their family is likely to increase.[130] The Commission gave somewhat similar advice with respect to the provision of genetic information in instances of adoption.[131]

The Commission also discusses the subject of autonomy, which is generally regarded as an important part of privacy, and in some views as perhaps the most significant aspect of privacy. The Commission notes that the principle of autonomy is important in the relationship of individual patients and health care professionals through the requirement of informed consent, but that it is also important in personal choices in the use of genetic services. The Commission notes that one of the "central ethical issues in screening and counseling is that of voluntariness."[132] It discusses the issue of whether participation in screening and counseling programs should always be voluntary and whether treatment of genetic disease should always be voluntary. The issues form a significant part of the discussion in the second part of this paper which deals with public health aspects of the use of genetic information.[133]

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[129]Compare legal requirements in AIDS confidentiality. In New York, for instance, a court may order that a physician may advise the spouse or companion of an HIV-positive patient of his or her positive diagnosis if the patient fails to do so. N.Y. PUB. HEALTH § 2785 (1)(b) (Supp. 1993); N.Y. CIV. PRAC. L. & R. C4504:1 (Supp. 1994).

[130]SCREENING AND COUNSELING, supra note 117 at 45.

[131]Id. at 45-47.

[132]Id. at 47.

[133]See discussion infra chapter 10 at page 270 et seq.

Genetic information is a particularly sensitive part of medical information because of its special significance and because of the broad area of sensitive personal information it conveys. The polymorphic marker that determines the location of the allele that leads to Huntington's disease provides information that a person may suffer this severe neurological disease in midlife. The information that a person is a heterozygote for cystic fibrosis or for Tay-Sachs disease should inform the recipient of the information that the person will never suffer from the disease but is likely to have a child with the disease if he or she has a child with another person of similar genotype. As the Human Genome Project succeeds in locating more and more alleles for particular diseases or conditions, more and more of a person's future medical risks are likely to become predictable from their medical records.

Two special though closely related instances of transmission of information have not as yet been referred to. They are the submission of information to a prospective employer, and the submission of information to an insurance company in order to obtain health or life insurance coverage. These are addressed in separate chapters.

10. Conclusion

In our information society, the free flow of information must be balanced by protection of the right of privacy. Genetic data, as a particularly sensitive part of health data, are in need of special protection. The rule that applies to other data applies to genetic data as well. A person about whom data have been collected is entitled to both the knowledge of what the data contain and the uses to be made of them. The abuse of data for unintended purposes is facilitated by the circumstance that data in databanks today take the place of personal

encounters in the past.

There is significant evidence that information in databanks is not entirely secure, and that data have become accessible to unauthorized persons by technologically adept hackers, and by questionable or corrupt acts of government employees. More significant, however, than improper or criminal access to data is the ready exchange of data between government agencies, and the accessibility of data through computer matching. This is likely to create particular dangers for medical records, including genetic records. The problem is exacerbated in the absence of effective legal remedies for the pilfering and misapplication of data, even though there have been a number of convictions under the Computer Fraud and Abuse Act of 1986. An earlier 1984 Computer Abuse Act resulted in only one prosecution. Other laws used to control computer crime include the National Stolen Property Act as well as the Mail and Wire Fraud statutes and the Electronic Communication Privacy Act. There is little evidence, however, that there has been much prosecutorial activity under these laws. Prosecutions occur in major cases, and there appears to be little concern for the more casual and impermissible transfers of information that are apparently hard to police.

An area of special interest in the development of genetics and of special risk in the protection of privacy are genetic registries or genetic or DNA databanks. There is little doubt of the enormous scientific benefits that would flow from the establishment of sound genetic registries. The Health Surveillance Registry of the Canadian province of British Columbia registers genetic abnormalities of all live births and tracks the cohort as it grows older. It has been suggested that an adequate registry should contain a minimum operating protocol including reference to the severity of the disease, socio-demographic information, previous medical history, and the time frame for followup. The Birth

Defects Monitoring Program/Commission on Professional and Hospital Activities (BDMP/CPHA) relies on hospital discharge data about newborns to identify changes in patterns of occurrence for 161 birth defects. CORN promotes data collection relating to birth defects surveillance and newborn screening. WHO has recommended the use of registries to enhance the delivery of genetic services. There appears to be a general consensus that genetic registries with adequate followup would be enormously useful to the field, just as there appears to be agreement that such registries may present major hazards to personal privacy.

The very substantial benefits of genetic registries for the development of genetic science and for the benefit of public health planning for institutions and facilities to perform genetic services seems to argue in favor of the establishment of such registries, subject to stringent privacy controls. Such controls will involve limiting access to the use of the materials in patient treatment and to scientific exploration. In addition, possibilities of encryption of the data and of the use of special access codes should be considered to make registries serve the purpose for which they are designed while providing the greatest measure of privacy protection technically possible. Legal remedies need to be strengthened for unpermitted access to medical data generally, and ought to be observed with special stringency in the case of the protection of genetic data.

Special data protection should apply also in connection with genetic data produced in the workplace. Genetic data in the workplace represent a significant at risk category, because employers maintain substantial personnel files with detailed and sometimes highly personal information about employees which will create special risks when combined with health data, and particularly when combined with genetic data.

Chapter 6. Information Submitted to Insurers

1. Introduction: Insurers and Their Use of Genetic Information: Insurance Practices in Selling Health and Life Insurance

The analysis of insurance practices which follows shows that there is genetic discrimination in the sale of health or life insurance contracts and in the sale of contracts for the costs of health maintenance or the reimbursement of the costs of hospitals for health service providers. Although the analyses undertaken by insurers, both by health and life insurance associations, cavil at the term "discrimination," it is clear that they do discriminate simply because it is the business of insurance to differentiate, or discriminate, between acceptable risks, which they will insure, and unacceptable risks, which they will decline. The entire business of insurance, as the following account will show, is based on actuarial determinations, and decisions relating to the kind of risks that ought to be included in a risk pool so as to allow the company to meet its obligations under the contract when the insured event occurs, without suffering undue business losses. In this sense, genetic risks are not distinguishable in insurance practice from other health risks, except for the fact that they may be more substantial or costly. Insurance companies may well discriminate against deep sea divers and tightrope walkers, but this would normally be regarded as good business judgment rather than discrimination.

From the insurers' point of view, it makes very good sense to refuse to grant a health insurance policy to the family of a person who is a carrier of the cystic fibrosis trait. Whether the insurance company is knowledgeable enough to know that the particular person will never contract the disease, good underwriting judgment will tell the company that a member of the person's family is more

likely to have the disease than a member of the family of a person who does not bear such a trait.

Prohibiting genetic discrimination in insurance involves a substantial policy judgment that health insurance is necessary, and that insurers ought to be under an obligation to provide it regardless of adverse business consequences. Indeed, the prohibition of genetic discrimination in insurance also makes the judgment that other persons who buy insurance should pay more for their insurance in order to carry the additional risk created by the inclusion in the risk pool of a person with a genetic disease or trait. This, it appears, is what actually happens in the sale of major group health insurance policies.

Under current conditions, prevention of genetic discrimination in insurance is clearly desirable because of our need to meet the cost of health services. In a sense, genetic discrimination grows out of the competitive sale of insurance policies. The easiest way to do away with genetic discrimination in the provision of health care through health insurance is to provide for a national health plan that covers everyone. Once a national entitlement to health care has been enacted, i.e., once everyone is entitled to health care regardless of their genetic status, there will no longer be a reason for genetic discrimination, and the issue will disappear as the cost of care for genetically disadvantaged persons is absorbed as part of the general cost of health care for all under a national health plan.[1] Whether or not this will happen in 1994 or soon thereafter will soon become apparent. If future plans for national health care

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[1]However, genetic status may still be important even under a national health care system for such purposes as the allocation of scarce resources: a person at great risk genetically may not be eligible for certain risky or expensive procedures. Mark Rothstein, Genetics and Employment Discrimination, in ADVANCES IN GENETIC INFORMATION: A GUIDE FOR STATE POLICY MAKERS 65, 72 (The Council of State Governments eds., 1992).

involve both private and government insurance, then there is a good likelihood that higher risks -- such as the risks of persons with genetic conditions and persons with HIV -- will be treated differently and will be managed through a different risk pool than more ordinary risks. In that event, persons with genetic conditions will also be in a somewhat better position, because rather than being stigmatized as high risk because of genetic defects, they will simply fall into a more general pool of persons with high risk health problems. In anticipation of developments in genetic technology and changes in the health care system, the NIH/DOE Working Group on Ethical, Legal and Social Implications of Human Genome Research established a Task Force on Genetic Information and Insurance to examine the effects of genetic information on insurance and health care coverage.[2]

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[2]The Task Force made the following recommendations concerning health care coverage stating that these recommendations "should not be applied uncritically to other forms of insurance, such as life or disability income insurance":

1. Information about past, present or future health status, including genetic information, should not be used to deny health care coverage or services to anyone.
2. The US health care system should ensure universal access to and participation by all in a program of basic health services that encompasses a continuum of services appropriate for the healthy to the seriously ill.
3. The program of basic health services should treat genetic services comparably to non-genetic services, and should encompass appropriate genetic counseling, testing and treatment within a program of primary, preventive and specialty health care services for individuals and families with genetic disorders and those at risk of genetic disease.
4. The cost of health care coverage borne by individuals and families for the program of basic health services should not be affected by information, including genetic information, about an individual's past, present or future health status.
5. Participation in and access to the program of basic health services should not depend on employment.
6. Participation in and access to the program of basic health services should not be conditioned on disclosure by individuals and families of information, including genetic information, about past, present or future health status.
7. Until participation in a program of basic health services is universal, alternative means of reducing the risk of genetic discrimination should be developed. As one step, health insurers

Until the anticipated changes in our health care system occur, it is clear that all genetic information is likely to be used in a "discriminatory" manner in the insurance context. It is also clear, as will appear from what follows, that any person who undergoes a genetic test may have the results of that test used in his/her disfavor when insurance determinations are made, and such discriminatory judgments will continue to be made until an entitlement to health care becomes part of the law, at which point genetic discrimination may become irrelevant for insurance coverage.

Currently, the disclosure of personal medical information, including genetic information, has both economic consequences and consequences of psychic injury to personality. The failure to obtain or retain employment and the failure to secure insurance coverage carry heavy economic consequences and burdens, and these and other disclosures of private information carry with them also severe injuries to self esteem and personal integrity. The release of personal health information in particular may give rise to embarrassment, shame, and fear of rejection by family, friends or colleagues who may attach a stigma to disease and ostracize the individual, whether actually ill or the carrier of an adverse genetic condition.

2. Genetic Discrimination in Insurance

Both companies that sell life insurance and companies that sell health

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should consider a moratorium on the uses of genetic tests in underwriting. In addition, insurers could undertake vigorous educational efforts within the industry to improve the understanding of genetic information.

TASK FORCE ON GENETIC INFORMATION AND INSURANCE, NIH/DOE WORKING GROUP ON ETHICAL, LEGAL, AND SOCIAL IMPLICATIONS OF HUMAN GENOME RESEARCH, GENETIC INFORMATION AND HEALTH INSURANCE 2 (pre-publication copy May 10, 1993).

insurance are interested in the health and life expectancy of their insureds. Their interest in genetic information is not different in nature from their interest in their insureds' other health conditions. Insurance companies are clearly more interested in health conditions that are likely to lead to long and protracted treatment and that is likely to be very expensive and, in the case of life insurance, in diseases that are likely to reduce life span significantly. But insurance companies have asserted that their interest in genetic information is no different from their interest in the health and medical history of their insureds generally.[3]

In examining health insurance practices, and considering insurance companies' interest in genetic information of insurance applicants, the basic nature of insurance must be kept in mind. Insurance companies sell insurance, and insureds buy insurance to protect against financial losses from unexpected events. Insurance companies operate to spread or pool risks, and they are able to pay for losses because only some of the people they insure sustain such losses. Thus, persons who pay for insurance and do not have losses pay premiums so that others who do have losses may recover. Another aspect of insurance is that there is no certainty that a loss will occur. One cannot insure against a loss that is certain to occur. Sophisticated actuarial calculations are used to establish the amount of the insurance premium in light of the expected losses the company expects to pay for. Moreover, the cost of insurance normally reflects the

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[3]AMERICAN COUNCIL OF LIFE INSURANCE AND THE HEALTH INSURANCE ASSOCIATION OF AMERICA, ACLI SUBCOMMITTEE ON PRIVACY LEGISLATION, TASK FORCE ON GENETIC TESTING, GENETIC TEST INFORMATION AND INSURANCE: CONFIDENTIALITY CONCERNS AND RECOMMENDATIONS 4 (1990) [hereinafter 1990 ACLI REPORT]; AMERICAN COUNCIL OF LIFE INSURANCE AND THE HEALTH INSURANCE ASSOCIATION OF AMERICA, REPORT OF THE ACLI-HIAA TASK FORCE ON GENETIC TESTING 6 (1991) [hereinafter 1991 ACLI REPORT].

dimension of the risk involved.[4]

In the case of health insurance, there is a significant difference between individual and group insurance contracts. The greatest difference between individual and group insurance underwriting practices lies in the matter of risk selection. Group insurance is generally issued without medical examination or other evidence of insurability. The group, with whom the contract is made, is often an employer or a labor or fraternal organization, and when a large group of employed persons and their families are covered, the insurer will assume that it is accepting an average overall risk, and that there are few individuals in the group who have such severe health needs as to affect the needs of the group as a whole. Where the group is reasonably large, such individual differences will wash out. This is the case because if the group as a whole is of working age and actively employed, the likelihood of excessive numbers of severely ill persons in the group is minimized. The insurance company may adopt different approaches if the group is relatively small and represents a membership which is atypical in some respect.

Quite different criteria are used by insurers in the case of individual health insurance contracts. Individual applicants for health insurance are not part of a well defined group that is likely to be generally healthy. In the case of individual health insurance contracts, insurers apply "medical underwriting" to determine whether to approve the coverage, and under what terms. The primary concern in the case of individual contracts is "adverse selection," namely that persons most likely to apply for individual coverage are persons who are most likely to incur a loss. In the health insurance situation, a person who has a

[4]In the case of genetic disorders, insurers may have difficulties in setting rates because there may not as yet be an adequate number of cases or data on cost of treatment or outcome to provide an adequate base for projections.

medical condition that has not as yet fully manifested itself is likely to seek insurance. The adverse selection problem is particularly strong in individual coverage, though adverse selection may also play some part in group insurance. Insurers commonly will not insure a group that has been formed for the specific purpose of obtaining insurance, because such a group is more likely to have members who seek insurance that may reflect their adverse selection.

Because of the difference in underwriting practices between individual and group insurance, and because of the general averaging process in group insurance, group insurance is far less expensive than individual insurance. In effect, older and younger members in a group, and healthier and less healthy members cross subsidize each other, thus providing a major advantage in terms of the cost of the premiums. In writing insurance for groups, the insurer bases the premiums on a number of risk classification factors, which include the size of the group, the industry it is employed in, the composition of the group, its location, the particular plan of insurance, the manner in which costs are shared, the applicable administrative arrangements, and the previous claims experience of the group. Experience rating in group policies is based on the amount of claims payments made for the group in a prior period, which is usually the preceding year. The smaller the group, the more the losses resemble that of an individual policy, because with a smaller group, the possibility of risk spreading diminishes.

In underwriting individual health insurance contracts, the premium is based on likely benefit costs. This in turn is based on the morbidity of the policy holder which reflects the estimated frequency and severity of loss, of illnesses and accidents in a well defined class of persons to whom the individual policy holder belongs. Probability of loss and severity are affected by such factors as

age, sex, health status and history, amount of benefits, the policy holder's financial status, occupation and other relevant factors. The insurer then makes the determination whether the person insured can be offered standard rates or substandard rates, or whether the policy should contain certain limitations or whether insurance should be declined. It is clear for instance that under these standards a person who is HIV positive will not be able to obtain either health or life insurance.

Applicants for individual coverage are reviewed with respect to their health history. Past illnesses or accidents will be given weight considering the severity of the original illness and the degree of permanent impairment, the possibility of recurrence, and the possibility of complications. Certain kinds of impairments may recur more frequently than others. An ailment that is recurring such as peptic ulcers has bearing on future risk claims whereas other impairments, such as a broken leg or appendicitis, do not. Chronic conditions that involve large claims may result in the declination of the insurance. Family health information relating to the health of parents, children and spouses may also be requested. Insurers would have an interest, for instance, in a family history of diabetes. The applicant's current physical condition is also evaluated and based on available data and observation, the insurance company may request certain tests or studies, such as blood chemistry, urine analysis, or an electrocardiogram, depending on the age of the applicant and the coverage sought.[5]

Insurance companies generally use inspection reports to determine eligibility for coverage, based on pooled information from several key

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[5]The preceding account of insurance practices is based on U.S. Congress, Office of Technology Assessment, Medical Testing and Health Insurance, OTA-H-384 (Washington, DC: U.S. Government Printing Office, August 1988) 41-47.

information gathering services. The investigators seek detailed information regarding character traits, sobriety, drug usage, life style, types of persons and organizations with whom the subject of the investigation is affiliated, in addition to medical history and other intimate details. Such personal information will then enter the record of an individual's insurability. Much of the information may not have any direct bearing on insurability at all, though it is likely to be used.[6]

The practice of inquiring about certain tests or to require tests for persons who sought individual coverage was accepted by the insurance industry, and major concerns were raised not about testing itself but about the need for confidentiality of the test results. Applicants for insurance who were at high risk were concerned about privacy issues and discrimination in such areas as employment and housing. The National Association of Insurance Commissioners (NAIC) developed a Model Information and Privacy Protection Act which has been adopted by a number of states. It deals with the disclosure of personal and privileged information including unauthorized disclosures to employers.[7] In addition, a number of states have adopted legislation that prohibits discrimination in issuing, continuing or canceling insurance policies, or charging higher premiums because the applicant has certain physical handicaps, including blindness, deafness, or mental disabilities. So, too, a number of states prohibit rating or rejecting persons who have certain genetic characteristics, such as

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[6]Ruth Macklin, Mapping the Human Genome, Problems of Privacy and Free Choice, in GENETICS AND THE LAW III, 107, 109 (Aubrey Milunsky and George J. Annas eds., 1985). "There are socially unacceptable traits that may have no bearing at all on risk in a particular line of insurance.... An inspection report, however, does not make these fine distinctions, nor can it take account of the prejudices or other idiosyncracies of the people who are asked to make such subjective judgments including, in many cases, the investigator himself."

[7]OTA supra n. 5 at 47; see also id. at Appendix C.

sickle cell anemia.[8] Legislative prohibitions on testing by insurers appear to have had their origin with respect to predictive testing for AIDS. Insurance companies then devised a variety of procedures on the handling of suspected seropositive results, including long approbation periods for applicants and certain limitations on benefits. These procedures do not appear to be practicable in the case of genetic disorders.[9]

Health insurance is a highly regulated business, and states require that individual health insurance policy forms as well as group insurance contracts be filed with the health insurance agency. These documents are generally reviewed by the insurance department, and certain contracts or forms may be disapproved if premiums are excessive or if the policies are discriminatory in charging higher premiums for persons with certain handicaps unless the discrimination can be justified by sound actuarial practice.[10]

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[8]Id. at 48. See also discussion infra at 169-179.

[9]Id. at 47-49.For another account of how insurers make risk determinations and underwriting decisions, see R. Steven Brown, The Impact of Advances in Genetics on Insurance Policy, in ADVANCES IN GENETIC INFORMATION, A GUIDE FOR STATE POLICYMAKERS, 43 (The Council of State Governments eds., 1992). The article also addresses the question as to why genetic information should be treated differently from other medical information. One argument is that genetic makeup is beyond a person's control and the person should not be punished for such involuntary conditions through denial of health insurance, relying on D.S. Karjala, A Legal Research Agenda for the Human Genome Initiative, 32 JURIMETRICS J. 121 (1992). (One might add that a heart attack is also beyond a person's control and is involuntary in nature, though life style may have a bearing on the matter.) Another argument is that genetic information has implications for persons other than the person to whom it directly pertains. Such other persons may not have consented to publication or use of the information. A third reason for difference in treatment is the fact that samples taken for one reason may be used for a different purpose later and sometimes many years later than the one for which they were originally intended.

[10]OTA supra n. 5 at 49-51.

3. Insurance Industry Views on Genetic Testing

The insurance industry itself has devoted some attention to issues of privacy relating to genetic testing. In 1990, the ACLI (American Council of Life Insurance) Subcommittee on Privacy Legislation to the Task Force on Genetic Testing supplied its report, which to some extent applied earlier experience in the area of AIDS confidentiality to analogous problems arising out of genetic condition.[11] The report primarily addresses confidentiality principles for individually underwritten coverage for life and health insurers. The report notes that information will be obtained during the underwriting process as well as in the claims context.[12] In general, the report states that it supports voluntary confidentiality initiatives on the part of the industry, with clear indications that voluntary initiatives should be undertaken to forestall legislative requirements in this area.

The ACLI report sets forth a number of principles for the industry to follow, including the principle that redisclosure of genetic test information will not be made to third parties without the written authorization of the individual to whom they pertain. However, authorization for redisclosure to other insurers and to the Medical Information Bureau (MIB), which serves some 700 insurance companies, and which is in the business of redistributing the information, would be sought whenever a person makes an application for insurance.[13] While paying lip service to privacy concerns, the principles set forth end up allowing wide redisclosures and provide little protection to the

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[11]1990 ACLI REPORT, supra note 3.

[12]Id. at 4.

[13]Id. at 4.

insurance applicant.[14] The report notes that the image of the insurance business is under attack and that at the CEO level, programs should be undertaken by the insurance industry to stave off legislation and the regulatory process in this area.[15] The report also advises companies to adhere voluntarily to the principles of the model NAIC Privacy Act which, in its view, contains a program of special confidentiality principles.[16] The 1990 report notes that recent experience with AIDS testing and confidentiality regulation has cost the industry expensive administrative burdens. Strong reservation with respect to federal legislation on the subject is voiced and the report expresses deep concern that any Congressional involvement in protecting genetic confidentiality in the insurance area might lead to extremely close scrutiny of the underwriting process as a whole, a prospect which the industry clearly fears.[17]

Based on the recommendations of the Subcommittee of the American Council of Life Insurance (ACLI), the ACLI-HIAA (Health Insurance Association of America) in 1991 issued a Task Force Report on Genetic Testing.[18] The task force report expressly refers to ELSI group projects that involve consideration of discrimination by insurers.[19] The task force report considers two questions to be the most significant. (1) How genetic information might be used in risk classification to determine insurability, and (2) how the confidentiality of such information will be protected. To allay public fears, the task force notes that

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[14]Id. at 13-15.

[15]Id. at 6.

[16]Id. at 6.

[17]Id. at 8.

[18]1991 ACLI REPORT, supra note 3.

[19]Id. at 3.

97% of all applicants are accepted for life insurance, 92% at standard rates and 5% at substandard rates. With respect to health insurance, 85-90% is currently purchased through group plans which accept all full-time employees and dependents without evidence of insurability. The report sees no real problem with insurability exclusions, and concludes that genetic testing is unlikely to affect the typical American health insurance consumer who gets coverage through existing employer-based group health plans.[20]

In its 1991 report, the task force notes that genetic tests are not required by life or health insurers because they are too expensive. This will change only if insurers can afford genetic testing.[21] The report also notes that no genetic tests are necessary because genetic conditions are detectable through family histories or through other diagnoses -- i.e., a predisposition to heart disease is detectable through high cholesterol and high blood pressure levels. The report generally downplays the predictive value of genetic testing for the insurance industry, because it will not foretell when an illness will strike. Because of the many variables, "it cannot be assumed insurers would deny coverage based merely on the genetic test result."[22] The report asserts that genetic tests are not of immediate concern for the industry, "because health care providers are using them infrequently."[23] In general, the report seeks to reassure the public and sets forth a number of principles similar to the principles relating to privacy protection proposed by ACLI.[24] The assertion is

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[20]Id. at 5.

[21]Id. at 5.

[22]Id. at 6.

[23]Id. at 6.

[24]See supra text accompanying notes 11-13.

made that the industry must be more fearful of genetic testing than consumers because genetic testing could be used to assist consumers in making adverse selection decisions exploiting the insurance system.[25] It is interesting that the insurance industry resists efforts to pass legislation to prohibit insurers from obtaining genetic testing information, while asserting at the same time that the industry does not use such information. The task force assumes that it will have a difficult time to defeat legislation to limit insurer access to genetic test results.[26]

4. OTA Report on Insurance Use of Genetic Testing and History Information

In spite of industry disclaimers, there is some evidence that genetic test results do indeed affect individuals' health care coverage. The Office of Technology Assessment (OTA) in its 1992 report on Cystic Fibrosis and DNA Tests: Implications of Carrier Screening notes that existing information is largely anecdotal but that quantifying such information has proved difficult and verifying it impossible because some of it fails to distinguish between health, life or disability insurance and between genetic and other bases for rejection.[27]

OTA undertook a survey of insurers' attitudes towards genetic risk factors and notes in its report that over the last decade, i.e., in the 1980's, health

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[25]See 1991 ACLI REPORT at 6.

[26]Id. at 6.

[27]U.S. Congress, Office of Technology Assessment, Cystic Fibrosis and DNA Tests: Implications of Carrier Screening, OTA-BA-532 (Washington, DC: U.S. Government Printing Office, August 1992) 199 [hereinafter OTA Report, Cystic Fibrosis and DNA Tests].

insurers have exhibited a tendency to avoid risks, rather than to find ways to spread risks more widely. It seems that genetic analyses will mean that fewer people will have access to health insurance because genetic tests identify risks. On the other hand, genetic tests may also rule out an individual's risk, and hence increase access to coverage. OTA undertook its survey in order to discover how third party payers viewed genetic information and genetic testing in decision making. While the majority of insurers seemed to view genetic information as no different from other medical information, a significant minority did regard it differently. There was also considerable majority agreement that genetic conditions such as CF or Huntington's disease are preexisting conditions, but carrier status such as for CF or Tay-Sachs is not. Thus, in general, the majority of insurers agreed that genetic conditions are preexisting conditions but that carrier status is not. However, the responses to the survey were not wholly consistent with factors insurers' view as important to insurability. Personal and family medical histories were regarded as very important to insurability. In contrast, medical directors and underwriters felt less strongly about genetic predisposition to significant conditions than they did about medical history.[28] "Carrier risk for genetic disease" was found to be less important where the individual has no symptoms of the disease, with only a small minority of respondents regarding it as significant.[29]

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[28]Id. at 195.

[29]"On the other hand, when specifically asked how an individual's application would be treated if the applicant were asymptomatic but had a family history of CF, 27 medical directors (93 percent) from commercial insurers would accept the person with standard rates; 1 respondent would accept the applicant at standard rates, but with an exclusion waiver; and one would decline coverage. All 11 HMOs (100 percent) offering individual coverage would accept CF carriers at standard rates. But for the BC/BS [Blue Cross/Blue Shield] plans, 16 chief underwriters (55 percent) would accept at standard rates, while six (21 percent) would accept at the standard rate with a waiting period, and 2 (7 percent) would

OTA concluded on the basis of its survey that genetic history is indeed used in assessing risks for individual policies and medically underwritten groups. In decision-making on insurability based on genetic history, the particular condition seems important and its health care costs. What is important is that CF, diabetes, and sickle cell anemia involve substantial costs and this is the disabling factor and not that the condition is genetically based.[30]

The OTA study sought reactions of commercial insurers, HMOs and Blue Cross/Blue Shield plans to the following hypothetical situation, based on a real case:

> Prenatal diagnosis indicates the fetus is infected with cystic fibrosis; the couple decides to continue the pregnancy. The health insurance carrier, which paid for the test, informs the couple they will have no financial responsibility for the CF-related costs for the child.[31]

A substantial majority of the responders disagreed with the decision in the hypothetical and about two-thirds of the responders disagreed strongly. A substantial minority, however, agreed with the decision, and a smaller number agreed strongly.[32]

OTA concludes that third party payers do rely on genetic information, much of it derived from responses to personal histories which form part of the

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decline the cover the carrier. Thus, the mere fact that a medical director or underwriter considers carrier status important to insurability does not appear to translate into difficulties in obtaining health care coverage (rating). For those who responded they would accept with a waiting period or decline to cover, reluctance to offer standard insurance might stem from not wanting to pay for possible children or from a misunderstanding of the meaning of carrier status." Id. at 196-197 (citation omitted).

[30]Id. at 197.

[31]Id. at 197.

[32]Id. at 197. There were some differences in the strength of opinion between commercial vendors, medical directors of HMOs, and underwriters for Blue Cross/Blue Shield.

insurance application. OTA also relies on the 1991 Health Insurance Association of America Survey indicating that no health insurer requires genetic tests, and that at this time the ordering of tests in connection with an insurance application appears remote. Looking into the question whether insurers will require genetic tests of applicants who have a family history of serious genetic conditions ten years from now, OTA reports that only a minority of insurers believes that such a course of events is very likely or even somewhat likely but about a third of the responders indicated that they will in ten years require genetic testing of insurance applicants with a family history of serious conditions.[33] Few of the companies responding anticipate that their companies will require genetic tests within the next five or ten years and they do not believe either that optional testing or screening will be part of company policy in that time frame. However, a small majority of HMO-based medical directors considered it very likely that their HMO would ten years from now offer optional genetic testing and carrier testing. OTA surmises that the difference in response between HMOs and other insurers reflects the HMO emphasis on preventive care. OTA notes that insurers do not need genetic tests to determine genetic status. It is less expensive for them to ask questions and to obtain medical records.[34]

To determine whether individuals who underwent genetic tests had problems in obtaining or keeping health insurance, OTA asked genetic counsellors and nurses in genetics, trying to count actual occurrences. Seven hundred ninety-four members of the National Society of Genetic Counsellors and the International Society of Nurses in Genetics were asked whether any of their patients experienced difficulties in obtaining or retaining health insurance as a result

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[33]Id. at 197-198.

[34]Id. at 199.

of genetic testing. Four hundred thirty-one persons responded and 50 respondents, or 14%, reported that some of their clients had such experiences. Some respondents described more than one case and the examination of responses resulted in the conclusion that difficulties had been encountered in 68 individual cases. Difficulties were reported where positive results had been involved for Huntington disease, for polycystic kidney disease and Marfan Syndrome. In addition there were reports of patients who feared that their coverage would be dropped if they requested payments for tests from insurers. In many instances patients apparently self pay in order to avoid this perceived difficulty. Some of the responders apparently advise patients not to request reimbursement for a test if they don't want the insurer to know that the test had been given. Such fears persist in spite of the fact that most health insurance contracts preclude blanket nonrenewal and limit increases in rates for individuals who have been continuously covered and who develop a new condition. An insurer, however, may legally refuse to renew a group contract based on the results of one individual's genetic or other medical test, because group policies generally are not guaranteed renewable. The insurer thus has the option of demanding a steep premium increase at renewal time.[35]

OTA notes that its figures on consumer difficulties in obtaining or retaining coverage after genetic tests permit neither extrapolation of the number of cases nationwide nor any speculation on trends.[36]

The OTA report did not ascertain whether patients had challenged insurer determinations and what the final outcome of these challenges, if any, had been. OTA notes that in all 50 states and the District of Columbia the insurer must

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[35]Id. at 201.

[36]Id. at 201.

cover a newborn child if there is a valid insurance contract covering parents. It is not clear, however, whether the insurance company may deny benefits for the newborn under the preexisting condition clause of the insurance contract.[37] There is also a question of whether some cases of exclusion or increased rates result because a diagnostic test revealed an adverse medical condition, and the test happened to be genetic. The line between genetic tests and other diagnostic tests is becoming increasingly blurred, and genetic based predictive tests will increase in use, thereby enlarging the dimension of the problem. Access to medical care is determined by private health insurers in the U.S., and the increased availability of genetic tests is likely to increase reliance on them.

Thus, whatever the current dimensions of the problem, there is a likelihood that problems of genetic discrimination will increase.[38] OTA also comments that most of the cases revealed in its surveys would not involve recessive disorders and carrier screening for conditions like cystic fibrosis. While health care for

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[37]Id. at 201.

[38]Id. at 201. On increased availability of, and reliance on, genetic tests, see also NEIL A. HOLTZMAN, PROCEED WITH CAUTION: PREDICTING GENETIC RISKS IN THE RECOMBINANT DNA ERA 152-4 (1989). For additional, though largely anecdotal evidence of genetic discrimination in insurance, see Paul R. Billings, Genetics and Insurance Discrimination, in ADVANCES IN GENETIC INFORMATION, A GUIDE FOR STATE POLICY-MAKERS 43, 51-52 (Council of State Governments eds., 1992). Dr. Billings notes a number of specific instances in which the mere fact that the person undergoes a genetic test or inquires of a professional about genetic information on a particular disease may render the person uninsurable. Expressing an interest in undergoing a test turned out, in some instances, to be enough to prevent a person from obtaining insurance or from obtaining insurance without major difficulties. Certain diagnoses will disable a person from obtaining health insurance, including a diagnosis of Huntington disease, sickle cell anemia and muscular dystrophy. Dr. Billings notes that genetic data are not a good predictor of risk categories or for the cost of clinical illness. There are instances of people with a gene which can cause a debilitating and costly illness who may never experience health problems. There are also persons who inherit a gene which causes severe illness but who are treated by diet or other inexpensive interventions and never get sick. Nevertheless, such information is often used to deny insurance.

CF would not be an issue because these individuals are asymptomatic, and few insurers require a waiting period or deny coverage in such instances.[39]

5. State Laws Governing Genetic Discrimination in Health Insurance

An insurer that sells health or life insurance may ask any question that is relevant to an applicant's state of health. Such information will be used to make the decision whether to underwrite the risk, i.e., to issue the policy, to issue the policy at a higher premium rate, or to deny coverage. When an adverse decision is based on genetic grounds, persons who are denied insurance will regard this as genetic discrimination, even though it may not be illegal under state or federal law. It has been noted that, "One of the ironies in the current crisis in health care coverage is that developing more accurate biomedical data could make things worse rather than better for those most in need. Knowledge useful in predicting the individual's likelihood of developing a particular disease opens the door to both the welcome preventive strategies and the unwelcome possibility of genetic discrimination."[40]

There are at least nine "genetic or gene-influenced conditions for which insurance companies have unconditionally denied medical insurance."[41] These conditions are sickle cell anemia, aplastic anemia, angina pectoris, arterial sclerosis, Huntington's chorea, insulin dependent diabetes, Downs Syndrome,

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[39]OTA Report, Cystic Fibrosis and DNA Tests, supra note 27 at 201-202.

[40]TASK FORCE ON GENETIC INFORMATION AND INSURANCE, NIH/DOE WORKING GROUP ON ETHICAL, LEGAL, AND SOCIAL IMPLICATIONS OF HUMAN GENOME RESEARCH, GENETIC INFORMATION AND HEALTH INSURANCE 1 (pre-publication copy May 10, 1993).

[41]NEIL A. HOLTZMAN, PROCEED WITH CAUTION: PREDICTING GENETIC RISKS IN THE RECOMBINANT DNA ERA 195 (1989).

polycystic kidney disease, and muscular dystrophy.[42] With respect to health insurance, a few states have laws prohibiting health insurers from testing for and excluding people with genetic traits or, in a few instances, people with genetic diseases. Alabama[43], for instance, prohibits discrimination in the denial of coverage to applicants diagnosed with sickle cell anemia. However, no restriction is placed on the rates such insurers may charge for coverage.[44]

California does not accept this approach as a valid exception to the prohibition on genetic discrimination.[45] The law governs self-insured employee welfare benefit plans. It makes unlawful the refusal to insure a person "solely by reason of the fact that the person carries a gene which may, under some

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[42]Id. at 195.

[43]ALA. CODE § 27-5-13 (1988).

[44]ALA. CODE § 27-12-11 (1988).

[45]CAL. INS. CODE §10123.3 (West 1993):

> (a) No self-insured employee welfare benefit plan shall refuse to enroll any person or accept any person as a subscriber after appropriate application solely by reason of the fact that the person carries a gene which may, under some circumstances, be associated with disability in that person's offspring, but which causes no adverse effects on the carrier. Such genes shall include, but not be limited to, Tay-Sachs trait, sickle cell trait, thalassemia trait, and X-linked hemophilia A. No plan shall require a higher rate or charge by reason of the fact that the person carries such traits than is at the time required of any other individual in an otherwise identical classification, nor shall any plan make or require any rebate, discrimination, or discount upon the amount to be paid or the service to be rendered under the plan because the person carries such traits.
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> (b) No discrimination shall be made in the fees or commissions of a solicitor or solicitor firm for an enrollment or a subscription or the renewal of an enrollment or subscription of any person solely by reason of the fact that the person carries a gene which may, under some circumstances be associated with disability in that person's offspring, but which causes no adverse effects on the carrier. Such genes shall include, but not be limited to, Tay-Sachs trait, sickle cell trait, thalassemia trait, and X-linked hemophilia A.

circumstances, be associated with disability in that person's offspring, but which causes no adverse effects on the carrier."[46] The law applies to Tay-Sachs trait, sickle cell trait, thalassemia trait, and X-linked hemophilia A. Covered plans must also charge the same rate for coverage, despite the presence of a trait for genetic disease. In addition, the insurance code requires that non-profit hospital insurance plans comply with similar requirements and not discriminate on the basis of genetic traits for the same group of diseases.[47]

Maryland[48] forbids any differential in the ratings, premiums or dividends based solely on the grounds that the applicant carries a genetic trait which is harmless within itself, unless there is actuarial justification for such discrimination. Thus, carrying a genetic trait for a late onset genetic disease, such as Huntington's chorea, could provide a basis for the denial of health insurance. The Maryland law would allow denial of health insurance to a family where the applicant carries a trait but is not personally threatened with genetic disease, but where the children may suffer such a disease because actuarially such a family would create a problem for the insurer.

A similar escape hatch based on an actuarial basis is provided under Michigan[49] law, which prohibits Health Maintenance Organizations from discriminating on the basis of age, sex or health status, but allows it in situations where applicants for health insurance are likely to utilize its services more often than an actuarially determined average. Unfair discrimination against various genetic disease traits may be barred under Michigan law, but the

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[46]Id.

[47]CAL. INS. CODE §11512.95 (West 1988).

[48]MD. INS. CODE ANN. § 223(a)(3) (1993).

[49]MICH. COMP. LAWS ANN. §333.21071 (West 1992).

nature of the unfair discrimination remains undefined. While discrimination on the basis of health status is banned, the term "health status" too remains undefined.

Nebraska has passed a Genetically Handicapped Person Act which is designed to establish "a program for the medical care of [indigent] persons of all ages with genetically handicapping conditions."[50] The Act specifically includes cystic fibrosis, hemophilia and sickle cell disease but does not limit coverage to those conditions. However, the statute limits eligibility for coverage to those who are fully insured under any other private, state, or federal programs and are not otherwise insured.[51]

In North Carolina,[52] discrimination in premium rates and in insurance eligibility is prohibited if it is based solely on the fact that the applicant had a sickle cell trait or the trait for hemoglobin C. Though limited in the diseases it covers, the law is complete in its prohibition of discrimination against persons afflicted with specific traits referred to and may have a broad scope.

Texas[53] does not specifically address the exclusion of carriers of genetic traits from health insurance coverage but plans that provide coverage for the

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[50]NEB. REV. STAT. §§ 68-1401 to 68-1406 (1990).

[51]The services and treatment provided by the act include initial intake and diagnostic evaluation; rehabilitation services, including reconstructive surgery; the cost of blood transfusion and use of blood derivatives, or both; expert diagnosis; medical treatment; surgical treatment; hospital care; physical therapy; occupational therapy; materials and prescription drugs; appliances and their upkeep, maintenance and care; maintenance, transportation, or care incidental to any form of services; and appropriate and sufficient staff to carry out the provisions of the Act. NEB. REV. STAT. §§ 68-1403, 1404 (1990).

[52]N.C. GEN. STAT. §58-51-45 (1991).

[53]TEX. INS. CODE § 3.51-6-3E(B) (West 1994).

immediate family may not exclude a policyholder's grandchildren from coverage if such children are listed as dependents for income tax purposes. This would clearly include instances in which such grandchildren are likely to have a genetic disease because of a trait carried in the family.

In Vermont,[54] providers of small group health benefit plans must guarantee acceptance of all members of the small group and of each of their dependents. On its face, the prohibition would bar the exclusion of persons who carry a trait of genetic disease or who are afflicted with a genetic disease itself.

West Virginia,[55] in its Health Maintenance Organization Act, prohibits HMOs from discriminating in enrollment policies or in quality of services on the basis of race, sex, age, religion or health status. The act does, however, allow differences in rates based on valid actuarial distinctions.

In addition to such specific legislation, almost all states prohibit unfair discrimination by health insurers. They also explicitly prohibit discrimination based on "physical handicap" but these are usually limited to blindness or deafness. Since the violation of genetic privacy most often results in discrimination, the narrow scope of legislation against genetic discrimination in health insurance does little to discourage privacy violations.

6. State Laws Governing Genetic Discrimination in Life Insurance

A few states have enacted legislation against genetic discrimination in the sale of life insurance. No state has fully banned the use of genetic testing in rate-setting or coverage determination for life insurance. Nor has any state prohibited the denial of insurance or restricted the rates charged to carriers

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[54]VT. STAT. ANN. tit. 8, §4080a(d)(1) (1993).

[55]W. VA. CODE §33-25A-14(6) (1992)

of genetic disease; the laws in the ten states that have legislation covering these issues have a narrow scope but can be analogized to meet the needs of broader issues of genetic discrimination in some cases. It has been argued that insurance companies seldom discriminate unless there is an actuarial basis for discrimination, and some laws, such as Maryland, take into account this need on the part of insurance companies thereby legalizing certain discriminatory inquiries.

In 1989, Arizona prohibited insurers from refusing consideration of life insurance applicants on the basis of "genetic condition."[56] In addition, determination of rates, terms or dividends of a life insurance contract based on "genetic condition . . . constitutes unfair discrimination" unless substantial differences in claims are foreseen as a result of the "applicant's medical condition and history, claims experience or actuarial projections." Under the Arizona law, however, no insurance companies may "refuse to consider" any application for insurance even from a person who has a "genetic condition," although there is no ban on discrimination against genetically challenged applicants. Arizona's law does little to assure that carriers of an adverse genetic trait will be able to buy life insurance. Denial of life insurance is legal in Arizona so long as insurance companies can demonstrate actuarially that a carrier of a particular genetic trait will have a higher claim rate than the average member of the population.[57]

In California, insurers are prohibited from refusing to sell or renew life insurance solely on the grounds that the applicant carries a gene, which causes

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[56]ARIZ. REV. STAT. ANN. § 20-448(d) (West 1990). In the statute "genetic condition" is defined as "a specific chromosomal or single-gene genetic condition." Id. at § 20-448(F)(3).

[57]ARIZ. REV. STAT. ANN § 20-448(E) (West 1990).

"no adverse effect on the carrier" but may cause disability in the carrier's offspring.[58] Furthermore, no insurer can charge increased rates or insert into a policy "any condition or stipulation" whereby a carrier of genetic diseases receives a sum or service "less than the full value or amount of the policy." Despite the seemingly comprehensive nature of the California law, the statute does not require insurers to provide insurance to genetic carriers who are adversely affected by their genetic traits.[59] Like the Arizona law, California's statute does not restrain insurers from discriminating against people with genetic disabilities who may be most affected by their condition and have the greatest need for insurance. Unlike California, Arizona's law allows discrimination against carriers, not "adversely affected" if there is an actuarial basis for the discrimination. The California statute, in contrast, is unconcerned about actuarial and statistical justification for discrimination. Discrimination is only allowed if there are adverse affects on the carrier. Its plain language rejects adverse financial effects on the life insurance company as a justification for discrimination in California. Practically, however, there is no difference: if the genetic trait will have no effect on its carrier, there should never be an actuarial justification for discrimination. In addition, the California law includes a unique provision prohibiting an insurance company licensed to do business in California from offering reduced commissions to agents or brokers selling policies to carriers of genetic disease.[60]

Florida prohibits life insurers from considering the presence of the

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[58]CAL. INS. CODE §10143(b) (West 1993).

[59]The statute only requires sale of life insurance to those whose genetic disabilities have "no adverse effects on the carrier." CAL. INS. CODE §10143(a) (West 1993).

[60]CAL. INS. CODE § 10143(c) (West 1993).

sickle-cell trait in determining coverage or rates.[61] The Florida law explicitly refers only to the sickle-cell trait and does not include discrimination based on other genetic traits; however like the North Carolina law, the Florida statute might be interpreted to be broader. The Florida statute does not allow any discrimination even where it may be actuarially justifiable.[62]

Louisiana also prohibits discrimination in the selling of life insurance. These protections are limited to people with sickle-cell trait. The laws are limited to: charging premiums, providing of policies and payment of benefits.[63] Unlike statutes in other states, Louisiana's statute includes a vague provision which allows insurance policies to include clauses that require waiting periods; exclude pre-existing conditions, or "dreaded disease" rider exclusions "if they do not unfairly discriminate."[64] Unfair discrimination is not defined in the statute.

In Maine,[65] there are requirements that insurance rates not be excessive, inadequate or unfairly discriminatory, and insurers must provide supporting evidence to that effect. Such filings are public records.

In Maryland, an insurer may not refuse to insure, charge higher rates or award lower dividends to a carrier of "any genetic trait which is harmless within itself."[66] This provision appears to extend to all carriers who, by definition, are not affected by the genetic traits that they may pass on to their children.

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[61]FLA. STAT. ANN. § 626.9706 (West 1991).

[62]See supra text accompanying note 52.

[63]LA. REV. STAT. ANN. §22:652.1(D) (West Supp. 1994).

[64]LA. REV. STAT. ANN. § 22.652.1 (A), (B) (West Supp. 1994).

[65]ME. REV. STAT. ANN. tit. 24, § 2321(2) (West Supp. 1993).

[66]MD. INS. CODE ANN. §223(a)(3) (1991).

Like Arizona, Maryland allows discrimination when "there is an actuarial justification for it." Under this construct, even if a genetic condition is harmless, an "actuarial justification" will allow for a permissible discriminatory result. This renders the Maryland law ambiguous and vague. In California, by contrast, an "actuarial justification" does not provide legally sufficient reason for discrimination. California's life insurers can only discriminate if the trait that is carried is expected to develop into a genetic disease that will "adversely affect" the carrier. Thus, Maryland's statute does not guarantee that people with genetic disabilities will be provided life insurance by the private sector.

Since 1991, Montana's insurance law[67] has prohibited insurers from "refus[ing] to consider", a life insurance applicant based on "genetic condition."[68] Under the statute, distinctions based on genetic conditions constitute "unfair discrimination," but nothing prohibits an insurer from charging increased rates if the "applicant's medical condition and history and either claims experience or actuarial projections establish that substantial differences in claims are likely to result from the genetic condition."[69] The Montana law, like the law in Arizona, requires insurance companies at least to "consider" any application for insurance even from those who have a genetic condition. After consideration, however, an application can be rejected for a legitimate actuarial reason.

In New Mexico, so-called "unfair discrimination" is prohibited on the basis

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[67]MONT. CODE ANN. § 33-18-206 (1993).

[68]"Genetic condition," in the statute, refers to one with a "specific chromosomal or single-gene genetic condition." MONT. CODE ANN. §33-18-206(5)(c) (1993).

[69]MONT. CODE ANN. § 33-18-306(4).

of the race, color, religion or national origin of any individual or group of persons,[70] although subpart (b) of the law excludes fraternal benefit societies from the provisions of the law. As mentioned elsewhere in this report,[71] the North Carolina code provides clear and specific prohibitions against discrimination against persons with sickle cell anemia or who are carriers of sickle cell trait.[72]

North Carolina law prohibits any insurer licensed in the state to refuse to issue a life insurance policy or charge a higher premium solely because an applicant possesses sickle cell trait or hemoglobin C.[73] While limited only to the sickle cell condition and hemoglobin C, the North Carolina law, unlike the laws of most other states,[74] does not allow a life insurer to deny coverage to or increase the premiums of people with genetic diseases or disabilities even in cases where there may be an actuarial justification for doing so. An argument could be made that the North Carolina statute's explicit reference to the sickle cell trait and Hemoglobin C does not attempt to exclude carriers of other genetic traits; rather, the reference merely serves as an example of two especially prevalent genetic traits. It also proves that special protections can be

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[70]N.M. STAT. ANN. § 59A-16-12 (Michie 1993).

[71]See supra page 172.

[72]N.C. GEN. STAT. § 58-51-45 (1991). The term "hemoglobin C trait" is defined as the condition wherein the major natural hemoglobin components present in the blood of the individual are hemoglobin A (normal) and hemoglobin C as defined by standard chemical and physical analytic techniques, including electrophoresis, and the proportion of hemoglobin A is greater than the proportion of hemoglobin C or one natural parent of the individual is shown to have only normal hemoglobin components (hemoglobin A, hemoglobin A2, hemoglobin F) in the normal proportions by standard chemical and physical analytic tests.

[73]N.C. GEN. STAT. §58-58-25 (1991).

[74]Including Arizona, California, Maryland and Montana.

instituted once a legislature has been persuaded that such protections are appropriate.

Similar provisions regarding sickle cell trait and hemoglobin C exist under Tennessee law,[75] providing protections for a specifically stated class of persons.

Concluding Comments on State Laws

A review of state legislation relating to genetic discrimination in life and health insurance leads to the conclusion that the major purpose of the laws enacted was to create the appearance of protection of privacy, without unduly limiting insurers' risk selection practices. The only possible exceptions are the very few states that prohibit discrimination against persons with a sickle cell trait. But even there the protections appear to be limited, and the main purpose appears to be the avoidance of the appearance of racial discrimination. As has been noted earlier, in the case of health group insurance plans, there appears to be little advantage for the insurer in trying to exclude persons with genetic disabilities from coverage, and by the same token, laws to prevent genetic discrimination in the case of major group insurance plans also seem to make very little difference. A very few states seek to prohibit genetic discrimination in insurance, and the prohibitions make little difference in outcome in any event. To be effective, such prohibitions would have to be more specifically and accurately targeted on the specific situations in which such genetic discrimination does make a difference, namely in the situation of small group health plans, and in the case of individual contracts for health insurance.

Preventing genetic discrimination in the case of life insurance raises a

[75]TENN. CODE ANN. § 56-7-207 (1989).

number of policy issues. The primary issue is whether the public interest in protecting the availability of life insurance is as significant as the interest in providing for health insurance. In the case of life insurance, moreover, aspects of adverse selection and inherent moral risks raise policy issues of a considerably different nature than in health insurance. In the case of health insurance, we may more readily accept the idea that broader coverage including more persons with costly ailments should be provided at greater cost to society generally than in the case of life insurance, typically sold by individual contract, following the consideration of the individual risks.

7. State Bills on Genetic Discrimination in Insurance Introduced in 1992-94

There is clear evidence of a growing interest in the prevention of genetic discrimination in insurance. Many state legislatures meeting in early 1993, and some in 1994, addressed this important subject.

Alaska House Bill 40, introduced January 11, 1993, prohibits health care insurers from requiring or requesting an individual or a member of an individual's family to obtain a genetic test, or requiring or requesting an individual to reveal whether he or she or a member of his or her family has obtained a genetic test and what the results of such tests were. In California, Senate Bill 1146, introduced March 5, 1993, prohibits refusal to insure or discrimination in insurance by health care service plans, self insured employee welfare benefit plans, and by disability insurers and nonprofit hospital service plans on the grounds that the person carries a gene which may under some circumstances be associated with a disability in that person or that person's

to insure or making or permitting any differential in ratings, premium payments or dividends in connection with a life insurance, life annuity, or health insurance contract solely because of a genetic trait or condition of the applicant or policy holder. Another Maryland bill, House Bill 517, introduced January 28, 1993, prohibits a health care provider or any other person from disclosing the medical records, findings, or results of a genetic test to any person, including an insurer, employer or potential employer of an individual who is the subject of the test. It allows an exception if written consent is given and allows the person who has the authority to consent to medical care for the subject to provide written consent for disclosure in specified circumstances. Maryland House Bill 1016 introduced February 5, 1993 prohibits employers and labor organizations from soliciting, requiring, or administering genetic tests to employees, members or applicants as a condition of employment or membership. Limited use of genetic testing is allowed but the use of the results is restricted as specified. The Commission of Labor and Industry is authorized to seek to resolve any violation and the Attorney General is authorized to bring an action on behalf of any employee, member or applicant for relief or damages.

Michigan House Bill 4398, introduced March 2, 1993, prohibits genetics tests or the results of genetic testing as a basis for insurability. The bill's definition of "genetic testing" includes a test of "a person's genes, gene products, or chromosomes for abnormalities or deficiencies, including carrier status."

Nevada Assembly Bill 243, introduced February 22, 1993, makes it an unlawful employment practice for an employer, labor organization, or employment agency to take actions relating to genetic testing and prohibits such persons from requiring or administering a genetic test or from disclosing certain

offspring.[76]

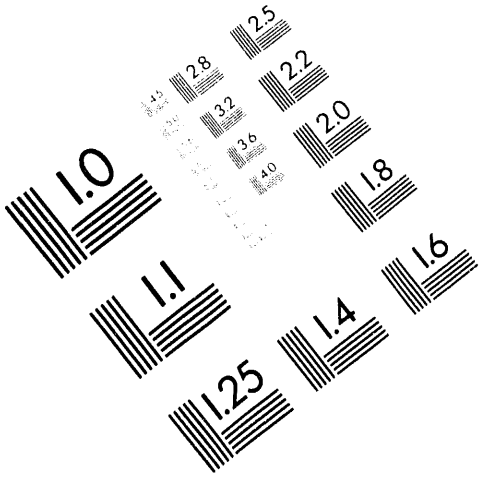
Hawaii House Bill 83, introduced January 21, 1993, prohibits any organization, employment agency or licensing authority to require or solicit directly or indirectly, or to administer a genetic test to any person as a condition of employment, labor or organization membership, or licensure. A similar Senate Bill 1320 was introduced on January 27, 1993. Another Hawaiian introduction was Senate Bill 894 which provides restrictions on the use of genetic test results in insurance. In Illinois, House Bill 2381, introduced March 10, 1993, amends the insurance code to provide that accident and health insurance coverage may not be denied based on a DNA test, other genetic test, or family history except when proof of a pre-existing condition exists.

Indiana Senate Bill 409, introduced on January 10, 1994, prohibits an insurer (except an insurer issuing or deciding whether to issue life insurance or income continuation insurance) from requiring or requesting that an individual have a genetic test, reveal whether the individual has had a genetic test, or disclose genetic test results.

Several bills have been introduced in Maryland, including House Bill 310, introduced on January 20, 1993 which prohibits an employer, employment agency, labor organization or licensing agency from soliciting, requiring, administering, or using genetic tests as a condition of employment, membership, or licensure, or privileges or benefits thereof. It also allows limited use of genetic testing but restricts the use of the results in employment and vests the enforcement authority in the Commission of Labor and Industry and the Attorney General. House Bill 317, also introduced on January 20, 1993, prohibits insurers from refusing

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[76]California Senate Bill No. 1146 was passed by the California Senate on May 28, 1993 and is pending before the Assembly.

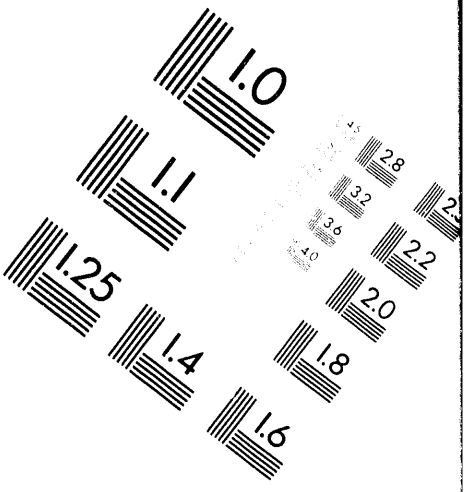


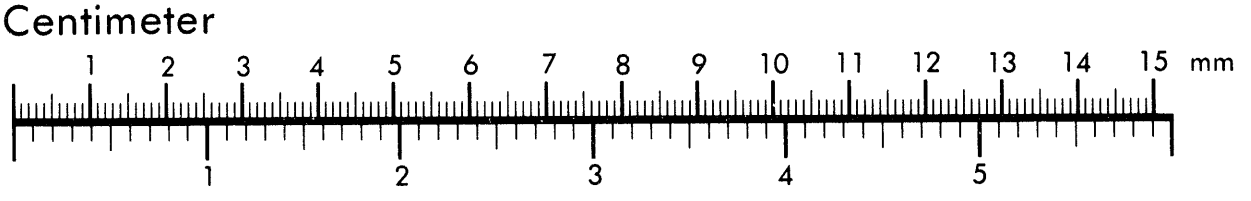


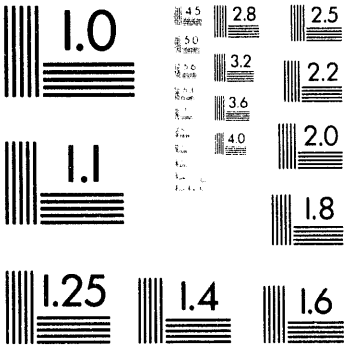
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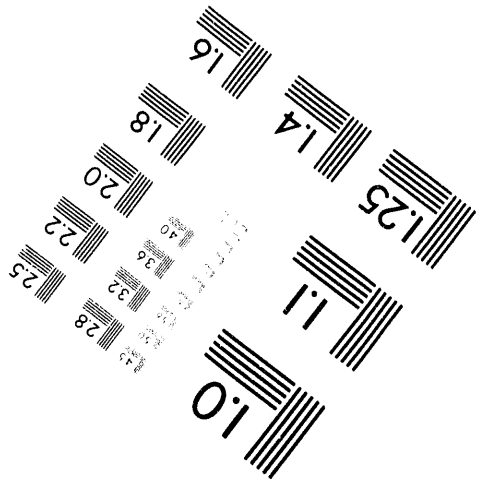
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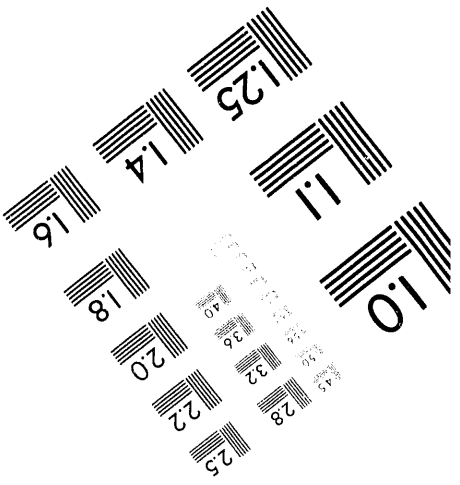
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information concerning a genetic test. The bill provides for exceptions and prohibits certain insurers from taking designated actions concerning genetic testing. Penalties and other remedies are provided. On January 4, 1994 New Hampshire introduced House Bill 1423 that prohibits genetic testing solely for employment or insurance purposes. The bill also requires written consent in other cases of genetic testing.

New York has also had introduced several relevant bills. Assembly Bill 2117, introduced on January 27, 1993, provides that all records, findings and results of genetic testing shall be confidential and shall be the exclusive property of the person upon whom the tests were performed, but authorizes disclosure for law enforcement purposes. A similar bill, Senate Bill 1191, was introduced in the Senate on January 27, 1993. It provides that all records, findings and results of genetic testing shall be confidential and shall be the exclusive property of the person upon whom the tests were performed, unless disclosure is for law enforcement purposes. Another bill, Assembly Bill 5771, was introduced on March 2, 1993. It simply prohibits discrimination based on genetic predisposition. On June 18, 1993, Assembly Bill 8584 was introduced. It restricts the use of genetic test results by insurance companies with respect to insurance coverage.

In Ohio House Bill 71 was introduced on January 21, 1993. It prohibits in specified circumstances the use of genetic screening or other information regarding genetic predisposition in connection with subscriber contracts of health maintenance organizations, policies of life, disability, or sickness and accident insurance, or plans of self insurance.[77] In Pennsylvania Senate

[77]The Ohio Bill was signed into law on November 10, 1993 (to be codified at OHIO CODE ANN. §§ 1742.42, 1742.43, 3901.49, 3901.491, 3901.50, and 3901.501).

Resolution 30 introduced on March 23, 1993 encourages the placing of a two year moratorium on the practice of insurance companies which deny individuals insurance coverage because of genetic abnormalities, while the Department of Health conducts a study relating to genetic predisposition. In Vermont, House Bill 330 was introduced on February 18, 1993. It prohibits the use of genetic testing in determining eligibility and rates for insurance.

On February 2, 1994, Wisconsin Assembly Bill 1080 was introduced. Current Wisconsin insurance law prohibits an insurer from requiring that an individual or family member undergo or reveal the results of a genetic test for the basis of insurance coverage. Assembly Bill 1080 broadens the definition of "genetic test" by deleting the criterion that such test use DNA. Instead, the bill focuses on the purpose of the test, i.e., whether an individual has or is predisposed to a genetic disease or disorder. Despite this broadening of the definition of "genetic test", the bill also narrows the scope of prohibition of discrimination by deleting provisions that prohibit insurers from requiring or requesting genetic tests. The bill would retain the requirement that coverage may not be considered in the determination of rates or other aspects of coverage but limits this requirement to insurers offering health care coverage and state and local governmental agencies providing health care services.

Also noteworthy is a proposed amendment to the previously enacted California insurance code, Section 10143.[78] Under the law as passed, agents who

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[78]CAL. INS. CODE §10143 (1993). Prohibited discrimination against persons carrying gene associated with disability in offspring; Adverse effects on carrier.

> (a) No insurance company licensed in this state shall refuse to issue or sell or renew any policy of life or disability insurance after appropriate application solely by reason of the fact that the person to be insured carries a gene which may, under some circumstances, be associated with disability in that person's offspring,

write such policies shall be given the same renumeration and cannot discriminate in rate setting or willingness to accept enrollment.[79] A broader bill amending the same code section, Assembly Bill 1888, did not pass. Assembly Bill 1888 would have prohibited discrimination in employment as well as in insurance and housing, based on a person's genetic characteristics. The bill also offered a broader

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but which causes no adverse effects on the carrier. Such genes shall include, but not be limited to, Tay-Sachs trait, sickle cell trait, thalassemia trait, and X-linked hemophilia A. No such policy issued and delivered in this state to any association, corporation, firm, fund, individual, group, order, organization, society, or trust subject to the supervision of the commissioner shall demand or require a higher premium rate or charge by reason of the fact that the person to be insured carries such traits than is at that time required of any other association, corporation, firm, fund, individual, group, order, organization, society, or trust in an otherwise identical classification, nor shall any association, corporation, firm, fund, group, individual, order, organization, society, or trust make or require any rebate, discrimination, or discount upon the amount to be paid or the service to be rendered on such policy because the person to be insured carries such traits.

(b) No insurance company licensed in this state shall insert in a policy of life or disability insurance any condition, nor make any stipulation, whereby the person insured who carries a gene which may, under some circumstances, be associated with disability in that person's offspring, but which causes no adverse effects on the carrier, including, but not limited to, Tay-Sachs trait, sickle cell trait, thalassemia trait, and X-linked hemophilia A, shall bind himself, his heirs, executors, administrators, or assignees to accept any sum or service less than the full value or amount of the policy in case of a claim accruing thereon other than such as are imposed upon other persons in similar cases and any such stipulation or condition so made or inserted shall be void.

[79]CAL. INS. CODE § 10143(c) (1993):

(c) No insurance company licensed in this state shall fix any lower rate in the fees or commissions of agents or brokers for writing or renewing a policy of life or disability insurance solely because the applicant carries a gene which may, under some circumstances, be associated with disability in that person's offspring, but which causes no adverse effects on the carrier. Such genes shall include, but are not limited to, Tay-Sachs trait, sickle cell trait, or X-linked hemophilia A.

definition of genetic characteristics.[80]

In addition, California had introduced a new version on March 5, 1993 of the earlier bill, Senate Bill 1146, on insurance discrimination based on genetic characteristics.[81] The new version appears to be a somewhat more detailed bill covering the subjects earlier referred to. The significant portion of the bill provides that no insurance company licensed in California may refuse to issue or renew a policy of disability insurance "solely by reason of the fact that the person to be insured carries a gene which may, under some circumstances, be associated with disability in that person or that person's offspring..." The bill prohibits higher premium rates or charges by reason of the fact that the person to be insured carries those traits.[82] According to a memo supporting the draft legislation, authored by the Legislative Counsel's Digest, "Violation of these provisions with regard to a health care service plan is punishable as a crime."[83]

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[80]Rather than listing a few diseases, A.B. 1888 would define, "(b) 'Genetic characteristics,' as used in this part, means any scientifically or medically identifiable gene or chromosome, or alteration thereof, which is known to be a cause of a disease or disorder, or determined to be associated with a statistically increased risk of development of a disease or disorder, and which is asymptomatic of any disease or disorder." A. B. 1888 also prohibited discrimination in the fees to be paid for soliciting such policies for enrollment or renewal of an insurance subscription. The bill also would embrace nonprofit hospital service plans, requiring that persons who carry genetic traits that may be associated with a disability have a right to be enrolled in such plans at the same rate as other enrollees.

[81]The California Senate Bill 1146 was passed by the Senate on May 28, 1993 and is currently pending before the Assembly.

[82]CAL. INS. CODE §10143(a) (1993).

[83]1993 Ca.S.B. 1146 Legislative Digest, as introduced, Johnston, Insurance Discrimination: Genetic Characteristics.

8. Conclusions

A review of insurance company practices persuasively demonstrates that insurance companies do practice genetic discrimination. They practice genetic discrimination because persons with genetic illnesses and even persons with genetic traits who have families present not only a greater risk, but also present a risk of longer and more expensive treatment needs than others. It is the business of insurance to differentiate or discriminate between acceptable risks and unacceptable risks, i.e., risks that will cost too much from the insurance company's point of view. Although there have been a number of efforts made in several states to prohibit insurance discrimination on genetic grounds, such efforts have all been rather limited and unlikely to be broadly effective.

Insurance companies are concerned over the possibility of federal legislation in this field, clearly because of the enormous power insurance company lobbies wield in the state legislatures. Consequently, any full remedial legislation in this area will have to be federal.

The most effective federal legislation would clearly be legislation which would relieve the insurance companies of their need to discriminate. If universal health coverage were provided, nationwide, and if such coverage would also include persons with genetic traits and illnesses as fully insurable, so as to cover the significant health expenses that may be incurred by persons with genetic illnesses and by children of persons with genetic traits, the concern for insurance discrimination on genetic grounds would quickly disappear.

What is here recommended is the adoption of the recommendations of the NIH/DOE Working Group on Ethical, Legal and Social Implications of Human Genome Research, Task Force on Genetic Information and Insurance.[84] In addition to

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[84]Reproduced supra at note 2.

recommending the adoption of universal access to health care, the recommendation also includes the following:

> 3. The program of basic health services should treat genetic services comparably to non-genetic services, and should encompass appropriate genetic counseling, testing and treatment within a program of primary, preventive and specialty health care services for individuals and families with genetic disorders and those at risk of genetic disease.

Chapter 7. Invasions of Privacy and Genetic Discrimination in the Workplace

1. Introduction: The Rationale for Workplace Testing

Privacy protection in the workplace, including protection against unlimited preemployment testing and testing on the job, are of relatively recent origin. In the 50s and 60s, preemployment testing was frequently used by employers to determine whether the job applicant used illegal drugs or whether the applicant was in physical condition to perform the intended work without danger to himself or herself or to others. In the case of drug use, the question was whether the prospective employee could be trusted in running vehicles, or in managing dangerous machinery. Testing for HIV in the case of pilots involved similar concerns -- whether the pilot's neurological condition made it appropriate for him/her to fly an airliner.[1]

In the absence of specific legal protection, either by federal or state law, employees had no significant privacy protections (or protection against discrimination based on disability) until the passage of the Americans with Disabilities Act (ADA) in 1991.[2] Objections to employee testing, based on constitutional grounds, particularly Fourth Amendment grounds, were limited generally to required testing of government employees and of employees of government contractors.[3] In addition to claimed protections against searches and seizures under the Fourth Amendment, such employees could also rely on Fifth Amendment prohibitions against self incrimination (particularly in instances of

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[1]U.S. Congress, Office of Technology Assessment, Medical Testing and Health Insurance, OTA-H-384 (Washington, DC: U.S. Government Printing Office, August 1988) [hereinafter OTA 1988].

[2]Americans with Disabilities Act, 42 U.S.C. §§ 12101 - 12213. (Supp. 1993).

[3]OTA 1988, supra note 1, at 95-96.

drug testing), on the requirement for a rational basis for testing under the Equal Protection provision of the Fourteenth Amendment, and possibly on privacy rights included in the Fifth Amendment.[4] Such objections were frequently urged in the context of urine drug screening. There were also a number of states, namely California, Illinois, Louisiana and Florida, which in their state constitutions provided for a right to privacy which could be asserted against AIDS antibody testing or drug related urine testing.[5] Prior to the 1991 Americans with Disabilities Act, the only remedy available to persons objecting to employment based testing was the Vocational Rehabilitation Act of 1973 which applied only to federal employees and to employees of federal contractors.[6] There are provisions in the Vocational Rehabilitation Act relating to the testing of handicapped persons, persons with tuberculosis, alcoholics, and drug abusers, but these provisions were limited to federal employees or federal contractors' employees.[7]

Protection of privacy in the workplace faced a particular problem in light of the employment relationship in the large number of instances when employment was at will. Employment at will, the original common law employment relationship, gave the employee very few rights. The employee at will had no assurances of employment and no employment contract with relation to the term of employment. The employment was at the will of the employer, who, having hired the employee, can terminate the worker's employment at any time, for any reason, or for no

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[4]OTA 1988, supra note 1, at 96.

[5]Id.

[6]Vocational Rehabilitation Ace of 1973, 29 U.S.C. §§ 701-797 (1985 & Supp. 1994).

[7]Id. at § 706 (15), (22) (Supp. 1994).

reason. The consequence of the employment at will relationship is that unless the employee is protected under federal or state legislation, such as for instance the Americans with Disabilities Act, the employer may, as a condition of employment, require the employee to answer any questions about health, habits, or life style, and may as a condition of employment require the employee to undergo a preemployment test or examination. If the employee or job applicant refuses to answer questions or refuses to undergo tests, examinations or screening procedures, he or she will not be hired.

Once hired, the at will employee faced similar risks. Since the employer could discharge the employee for any reason or for no reason, the employer could subject the employee to interrogation and examination into his or her health condition, habits, style of life, and if the employee failed to respond or failed to permit testing or screening, the employer could terminate the employment and the employee had no recourse.

A number of efforts, mostly unsuccessful, were made in the recent past to challenge the employer's powers under at will employment in light of allegedly intrusive invasions of privacy. On occasion, a court has imposed an obligation of good faith and fair dealing on employers in employment at will situations. In Luedtke v. Nabors Alaska Drilling Inc.[8], an employee was tested for drug use without prior notice when no other employee was so tested. When he tested positive, the employee was immediately suspended. The court held that there is a public policy supporting the protection of employee privacy. Violation of that policy here had risen to the level of a breach of the implied covenant of good faith and fair dealing.[9] But the Alaska decision stood alone and was not

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[8]Luedtke v. Nabors Alaska Drilling, Inc., 834 P.2d 1220 (Alaska 1992).

[9]Id. at 1226.

followed in any other jurisdiction.

A number of cases were decided just prior to the effective date of the Americans with Disabilities Act. All of them involved privacy invasions through detailed questionnaires;[10] unauthorized drug screening;[11] unauthorized examinations for private prescription drug use;[12] purported insubordination by failure to carry out improper research orders as a physician;[13] and failure to respond to intrusive questionnaire when unanswered questions did not relate to job qualifications.[14] In all of these cases, the court upheld the discharge of at will employees, and rejected employees' reliance on public policy protections for employees' privacy.

The situation for at will employees changed considerably with the enactment of ADA and OSH Act. At will employees can get protection for certain privacy rights in the workplace under ADA and they can also get protection under OSH Act for blowing the whistle with respect to health and working conditions in the workplace.[15]

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[10]Mares v. Conagra Poultry Co., Inc., 971 F.2d 492 (10th Cir. 1992)

[11]Borse v. Piece Goods Shop, Inc., 963 F.2d 611 (3rd Cir. 1991).

[12]Hennesy v. Coastal Eagle Point Oil Co., 609 A.2d 11 (N.J. 1992).

[13]Pierce Ortho Pharmaceutical Corp., 417 A.2d 505 (N.J. 1980).

[14]Cort v. Bristol-Myers Company, 431 N.E.2d 908 (Mass. 1982).

[15]For early cases under ADA, see, e.g., Grinstead v. Pool Company of Texas, 1994 US Dist Lexis 793 Eastern District of Louisiana (1994); EEOC and Wessel v. AIC Security Investigations, Ltd., 823 F.Supp. 571; 1993 U.S. Dist. LEXIS 11307 (1983); 440 Mich. 496; 486 N.W. 2d 657; 1992 Mich. LEXIS 2005; 59 Empl. Prac. Dec. (CCH) P41,705 (1991); Sanchez v. Lagoudakis, 440 Mich. at 501.

For early OSH Act cases involving wrongful discharge of whistle blowers, see Schweiss v. Chrysler Motors Corp., 922 F.2d 473; 1990 U.S. App. LEXIS 22413; 117 Lab. Cas. (CCH) P10,469; 1991 OSHD (CCH) P29,199; 6 BNA IER CAS 110; 14 (BNA) 2039; Kilpatrick v. Delaware County Society for the Prevention of Cruelty to Animals (S.P.C.A), 632 F.Supp. 542; 12 OSHC (BNA) 1756 (1986); Tyrna v. Adamo,

Prospective employees and employees who disclose their disabilities or who are treated in a discriminatory manner as if they were disabled are protected by the ADA, even if they are employees-at-will. At will employees who are discharged because they have "blown the whistle," i.e., have disclosed violations of the OSH Act, are also protected.

2. Employee Participation in Testing Programs under OSH Act

There is a question whether employer participation in testing programs can be compelled under existing laws.[16] No express language in relevant OSHA standards, for example, requires that employees give their informed consent to testing, but the language also does not condone mandatory testing. There is an important question to be resolved by legislatures and the courts whether and to what extent testing in the workplace context can or should be voluntary. OSHA standards, for example, are silent regarding whether employees may refuse to participate in such programs but requires that employer "shall make available" a variety of medical programs. For example, under 29 C.F.R. § 1910.1025, employers have an obligation to provide monitoring of lead; workers are not required to participate but are "strongly encouraged to participate in a meaningful fashion", (See Appendix B of the lead standard).[17]

Inc., 159 Mich. App. 592; 407 N.W.2d 47; 1987 OSHD (CCH) P27,969; 2 BNA IER CAS 407 (1987); Western States Minerals Corp. v. Jones, 1991 Nev. LEXIS 17; 6 BNA IER CAS 556; 199 Lab. Cas (CCH) P56,629; Carracchio v. Leeds, 223 N.J. Super. 435; 538 A.2d 1292; 1988 N.J. Super. LEXIS 76; 1988 OSHD (CCH) P28,193; 75 A.L.R.4th 1; 3 BNA IER CAS 726; 13 OSHC (BNA) 1723 (1988).

[16] Informed consent would also require counseling, raising the issue whether effective counseling could be conducted in-house or would require the presence of neutral third parties. See S. ELIAS & G. ANNAS, REPRODUCTIVE GENETICS AND THE LAW 54 (1987).

[17] 29 C.F.R. § 1910.1025 (1993).

But nothing in OSH Act or the implementing regulations specifically precludes an employer from making participation a condition of employment: in fact, where respirators are in use, physical exams are required. Rothstein commented, "[e]ven where medical surveillance is not required by OSHA or a collective bargaining agreement, employee participation in the surveillance program can be made a valid condition of employment. Consequently, employees who refuse to have a periodic medical examination may be discharged. In addition, employees found to be unfit for continued employment on the basis of periodic medical examination may be discharged, with their only protection being the right to workers' compensation if they can demonstrate that their medical condition is work-related."[18] There is no clear language to prevent testing as an invasion of privacy, either to require informed consent, or to prevent such consent from becoming a condition of employment.

Our laws provide relatively weak protections of personal privacy generally.[19] Thus, the scarcity, not to say absence, of privacy protection in the workplace is not surprising. There was no concern for genetic privacy because genetic screening and monitoring in the workplace was not an issue until the development of nuclear power, when concerns grew out of exposure to radiation in nuclear powerplants, with possible mutations affecting the next generation.[20] Studies also showed that chemical exposures could cause genetic damage. From early on, the difficulties raised by testing for such genetic damage became

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[18] MARK ROTHSTEIN, MEDICAL SCREENING OF WORKERS 11 (1984) (citation omitted) [hereinafter ROTHSTEIN, MEDICAL SCREENING OF WORKERS].

[19] See generally supra at chapter 1.

[20] U.S. Congress, Office of Technology Assessment, Genetic Monitoring and Screening in the Workplace, OTA-BA-455 (Washington, DC: U.S. Government Printing Office, October 1990) at 57 [hereinafter OTA 1990].

apparent.

3. Workplace Testing, Collection of Information, Wellness Programs, and Prevention of Occupational Disease

While it may be technologically and economically impossible to achieve a zero level of exposure to hazardous agents in the workplace, if testing could identify individuals or groups who were predisposed to specific types of occupational illness, preventive measures, if available, could be specifically directed at that population. There is immediate concern, however, that the use of genetic testing might result in excluding certain workers unfairly from jobs and that emphasis on identification of at-risk groups would deemphasize efforts to reduce workplace hazards.[21]

It is likely that employment testing will become more frequent as tests become available. Employment testing is driven by the employers' interest in reducing health insurance and retirement benefit costs.[22] Efforts at genetic testing are on the increase, as are other methods of medical testing by employers, particularly in larger companies with more than 500 employees, in companies with industrial hygiene and safety programs, as well as in companies that are unionized.[23] There is likely to be more genetic testing in the workplace in the future, even though "it is doubtful whether current tests can detect predispositions to harm from workplace exposures with sufficient accuracy

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[21]U.S. Congress, Office of Technology Assessment, The Role of Genetic Testing in the Prevention of Occupational Disease, OTA-BA-194 (Washington, DC: U.S. Government Printing Office, April 1983) at 5 [hereinafter OTA 1983].

[22]NEIL A. HOLTZMAN, PROCEED WITH CAUTION: PREDICTING GENETIC RISKS IN THE RECOMBINANT DNA ERA 201-5 (1989) [hereinafter HOLTZMAN, PROCEED WITH CAUTION].

[23]OTA 1988, supra note 1, at 101

to justify the testing or removal of susceptible workers."[24]

Predisposition to occupational disease is not controlled by genetic factors alone. Other factors may also interact with the workplace environment, such as age, sex, preexisting illness, nutritional status, lifestyle, smoking history, and prior exposure to environmental stresses.[25]

Employers want to obtain information relating to their employees' genotype through genetic screening, namely the administration of a onetime genetic test, or through monitoring, which is the periodic examination of an employee to determine whether he or she has suffered chromosomal or genetic damage through exposure to hazardous chemicals. Such monitoring will be useful to determine the impact of workplace exposure to asbestos, chromium, nickel, vinyl chloride, and to any number of other substances.[26] Certain immutable genetic characteristics invariably play a role in selecting persons for employment, "from basketball to neurosurgery,"[27] and such a selection, based on certain genetic factors, is reasonable from an employer's prospective. To the employee it may involve a significant threat of invasion of privacy and discrimination. Screening and monitoring in the workplace may be "a marvelous tool to protect the health of workers or . . . a terrible vehicle for invidious discrimination."[28]

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[24]HOLTZMAN, PROCEED WITH CAUTION, supra note 22, at 202.

[25]OTA 1983, supra note 21, at 12.

[26]Lori B. Andrews and Ami S. Jaeger, Confidentiality of Genetic Information in the Workplace, 17 AM. J. L. & MED. 75, 76 (1991) [hereinafter Andrews & Jaeger].

[27]OTA 1983, supra note 21, at 16.

[28]Genetic Screening of Workers: Hearings Before the Subcommittee on Investigations and Oversight, House Committee on Science and Technology, 97th Cong,. 2d Sess. 2 (1982) (testimony of Congressman Albert Gore). See also, ROTHSTEIN, MEDICAL SCREENING OF WORKERS, supra note 18.

Though the law may limit an employer from asking certain personal questions, employers believe that they need answers to two kinds of questions: (1) Questions relating to the employee's health status relating to occupational health, because in this area the employer has clear responsibilities; (2) Questions that relate to matters of personal health off the job concerning lifestyle, personal habits, exposures to toxic and hazardous substances not under the employer's control, as well as aspects of personal behavior that may create risks in the workplace. The employee's obligation to supply health information of a private nature relevant to occupational health may be a matter of contractual arrangement and collective bargaining. It may be viewed by the employee either as an invasion of privacy or as a matter which will help him/her to stay healthy in the workplace.

Information on occupational health may be obtained from screening and monitoring and through information supplied by the employee. Occupational health information, derived from testing or monitoring, reveals the presence of carcinogens or toxic or hazardous materials from the workplace in the worker's body and may provide evidence of the damage of occupational exposures. Similar information may also be obtained through a comprehensive medical history of the employee, including a complete work history, information on personal health habits such as eating or smoking, and detailed information on the person's past health status. For example, information of a history of chemical sensitivity preceding certain employment, or repeated testing of blood lead levels may be relevant for certain jobs.[29]

The two categories, occupational health information and nonoccupational

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[29]But see Mark A. Rothstein, Genetic Discrimination in Employment and the Americans with Disabilities Act, 29 HOUS.L.REV. 23, 62 (1992). (hereinafter Rothstein, Genetic Discrimination).

information pertaining to health status, may overlap, but although there are few legal protections, there should be (but there often is not) privacy for information regarding personal lifestyle, such as eating habits, use of leisure time, sexual activities and sexual orientation, the environment surrounding one's residence, alcohol consumption and smoking habits, even though these factors may affect an employee's health. The information needed by employers for occupational health purposes is limited. Even though employers may want information concerning an employee's personal lifestyle, medical history, and off-the-job activities, there is a question whether such information must be produced by employees unless it is relevant to job performance or occupational safety and health. However, there is not much law to protect the employee against improper questions, except insofar as the Americans with Disabilities Act may be applicable.

Since the level and duration of exposure to occupational hazards is within the employer's exclusive control, employers may want information pertaining to the employee's health status after exposure to the dangers of the work environment in order to prevent future liability and to further in-house research to prevent workplace illnesses and their consequences.

An additional source of employer information on employees' health status is provided through the development of workplace "wellness programs." For some time major and medium sized employer corporations have instituted and have invited employees to join plantwide wellness programs. At this point, there are literally tens of thousands of such programs in operation.[30] There is no special

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[30]Jonathan E. Fielding and Philip V. Piserchia, Frequency of Work Site Health Promotion Activities, 79 AM. J. PUB. HEALTH 16 (1989) [hereinafter Fielding & Piserchia]. In 1989 at least one type of health promotion activity was reported by 65.5% of all worksites surveyed by Fielding and Piserchia. Of all worksites, 29.5% had some type of health risk assessment activity. These included health risk appraisal, health examinations, physicals, or screenings. Periodic health or physical examination was available at 77.4% of these worksites

legal authorization of such programs, they are simply "voluntary" arrangements whereby employers invite employees to advance and improve the condition of their own health. An early review, in 1989, of such wellness programs emphasized the natural role of the work site as a target for health activities. The authors of the survey of such wellness programs cited deficient delivery of health promotion, economic and other incentives for employers to invest in health promotion, and peer pressure toward ameliorative changes in health-related behaviors as advantages of work site wellness programs. The wellness programs included in their survey included such health activities as "hypertension control, smoking cessation, weight control, nutrition, exercise/fitness, stress management, . . . accident prevention, cancer risk reduction, mental health counseling, drug abuse education/referral, and cardiopulmonary resuscitation (CPR)."[31] In addition to such "wellness" interests, the writers of the survey noted that 29.5% of the wellness programs they surveyed had some type of health risk assessment, including screenings for cancer, cholesterol and other risks.[32] In the light of such risk assessment activities, one may assume that it would be easy for a wellness program to undertake to provide tests for genetic conditions, including Huntington disease, cystic fibrosis, or tests for genetic propensities that may be aggravated by occupational exposure to certain environmental

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and included blood pressure screening, 55.4%; tests of physical fitness, 15.0%; cancer screening, 19.5%; and blood tests for cholesterol, 28.3% or sugar, 39.0%. Id. at 17. The Department of Health and Human Services estimates that two-thirds of the nation's worksites with 50 or more workers have at least one health promotion activity. ROTHSTEIN, MEDICAL SCREENING AND EMPLOYEE HEALTH COST CRISIS 210 (1989).

[31]Fielding and Piserchia, supra note 30, at 16.

[32]Id. at 17.

conditions in the workplace.[33]

Wellness programs are worthwhile investments for employers. In 1989, it was noted that for every dollar spent by the employer in a certain group of wellness programs, the employer saved $3.44 in employees' health costs for illness and down time.[34]

While such wellness programs seem beneficent and beneficial in their impact on employees, they also allow employers to acquire a great deal of information relating to employees' life style and "off the job" problems that the employer otherwise would find difficult to obtain information on or to inquire about. The question has also been asked whether resources are being diverted from the prevention of occupational hazards to work site health promotion. Employees may be lulled into a false sense of security when occupational hazards are not mentioned or dealt with by health educators working within the wellness program framework.[35] It is clear that confidentiality requirements which apply to information obtained by employers within the framework of ADA do not extend to "voluntary disclosures" by employees made in the context of totally unregulated "voluntary" wellness programs. The question may be extended to other aspects of such programs. If there is any testing in an employer-sponsored wellness program, who controls the information? Such information may well invade the employee's

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[33]However, Rothstein makes the following observation: "Focus Technologies of Washington, D.C., received $1 million from the Equitable Life Assurance Society to develop a program of risk assessment involving 'high tech' biochemical tests, including genetic testing. It is not clear that the science supports these risk analyses. Moreover, detailed 'lifestyle' questions, a part of some risk assessments, raise concerns about confidentiality." ROTHSTEIN, MEDICAL SCREENING AND THE EMPLOYEE HEALTH COST CRISIS, supra note 30, at 211-12.

[34]MARK ROTHSTEIN, MEDICAL SCREENING AND EMPLOYEE HEALTH COST CRISIS, supra note 30, at 210-11.

[35]Charles Levinstein, Work Site Health Promotion, 79 AM. J. PUB. HEALTH 11 (1989).

privacy rights and confidentiality.[36] Thus, wellness programs may indeed advance workers' health and save employers insurance and downtime costs, but they are also likely to provide the employer with an additional source of information about his employees, sometimes to the employees' detriment.

Employee monitoring in the workplace, and detailed inquiries into employees' health, presents the employees with a difficult question. Such information may be used to develop preventive strategies which will not only avoid future liability on the employer's part, but which may also protect the employee's health. But such information may also be used to the employees' detriment, in making them less eligible for insurance coverage, as well as in providing a basis for discrimination in the workplace with respect to job assignments, and selection for higher paying, though potentially more risky tasks.

Under applicable federal legislation, employers must disclose to employees long-term toxic or otherwise hazardous health effects of exposure to mutagens.[37] Health information discovered or derived from the workplace is subject to disclosure to government agencies, such as OSHA and the National Institute of Occupational Safety and Health (NIOSH). When a physician has knowledge of an employee's medical condition, such information may affect third parties, such as coworkers who share similar exposure to workplace mutagens and may suffer injuries similar to those disclosed by the result of a fellow employee's monitoring results. There is an unresolved question whether a corporate physician has a duty to maintain confidentiality under such circumstances. Weighing the

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[36]If test results are obtained in consequence of legally authorized occupational testing, the employer probably is under an obligation to keep such information confidential. OTA 1990, supra note 20, at 116.

[37]OSHA Hazard Communication Standard, 29 C.F.R. § 1910.1200 (1993).

benefits of confidentiality against the protection that might be afforded to a fellow employee's health, controlled and limited disclosure is probably called for.[38]

4. Testing of Employees: Health Costs and Insurance Consequences

Focusing on the use of diagnostic and predictive tests to screen for medical and health related conditions among prospective employees in order to hold down health care costs, the Congressional Office of Technology Assessment in 1988 published its report on Medical Testing and Health Insurance.[39] In its report, the Office of Technology Assessment (OTA) also considered the use of tests to determine whether the job applicant can physically perform the work, and after hiring, to determine whether the employee has any health conditions that require special precautions because of known workplace exposures. Such tests might also be used for monitoring workers exposed to known or suspected environmental hazards and to establish a baseline for future work site monitoring.[40]

Noting that large numbers of employees are exposed to federally regulated hazardous substances in the workplace, in 1988 OTA considered biological screening and monitoring, but largely dismissed such testing as a possibility because of its potential discriminatory aspects.[41] OTA also reviewed the use of

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[38]See Andrews & Jaeger, supra note 26, at 90-98.

[39]OTA 1988, supra note 1, at 95.

[40]Id. at 95.

[41] "Genetic testing to screen individuals for hypersusceptibility to hazardous materials has been controversial in the past, because genetic traits frequently are associated with particular racial or ethnic backgrounds. The Dupont Corporation's routine screening of all black job applicants for sickle cell anemia trait, initiated in 1972, drew so much criticism as a discriminatory

genetic testing by some large industrial and union organizations. It found that the use of such tests was very rare, and noted that although newly developing genetic tests might come into greater use, it clearly did not believe that such tests would come into broad general use.[42]

There was some indication, however, that industrial developments in the production of genetic testing materials was likely to lead to its increased use.[43] In general, in 1988 OTA concluded that individuals may not find such tests useful other than for reproductive planning, but that in the case of debilitating, late onset conditions, having risk information early may help in making employment and other decisions. If genetic tests become readily available, and easy to use, OTA surmised that insurers may find them attractive to determine an applicant's risk.[44] It is clear that in 1988, OTA saw no immediate prospect of expanded application of genetic testing in the workplace.

5. Genetic Testing and Occupational Disease

The Human Genome Project had not as yet begun when OTA prepared its 1983 report on The Role of Genetic Testing in the Prevention of Occupational Disease, or its 1988 Report on Medical Testing and Health Insurance. The situation and the state of knowledge had changed significantly by 1990 when OTA published its

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practice when it was reported in 1980 that it was discontinued. Florida, Louisiana and North Carolina specifically prohibit sickle cell testing and New Jersey prohibits testing for sickle cell and other genetic traits, (e.g., Louisiana Rev.Stat. §23:1002(A)(1) (West Sup. 1984-85))." Id. at 102, citing G. Aumann and T. Murray, Striking a Moral Balance in Screening, 3(10) BUS. & HEALTH 10-12 (1986); M.P. Lavine, Industrial Screening Programs for Workers, 24 ENV'T June 1982, at 26-38.

[42]OTA 1988, supra note 1, at 103.

[43]Id. at 132.

[44]Id. at 140-141.

report on Genetic Monitoring and Screening in the Workplace.[45] The report noted that genetic monitoring and screening transcends workplace issues in that it has a significant impact on the worker as a person and as a member of a family.[46] The report discussed new data about one-time genetic screening for placement and periodic genetic monitoring of workplace exposures that interact with environmental exposures, lifestyle habits and inherited propensities for illness.[47]

OTA considered some of the scientific insights resulting from the findings of the genome project relating to individual predisposition to certain genetic diseases, such as cancers that have familial links in their occurrence, but which may also be activated by environmental triggers such as exposure to workplace carcinogens. According to OTA, "[t]he influence of environment remains the wild card in most cases, because possession of the genetic predisposition alone may not be sufficient to cause disease."[48]

OTA indicated, as it had in earlier reports, that major emerging scientific issues are reliability, validity and quality control, as the number of tests grows:[49]

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[45]OTA 1990, supra note 20, at 8.

[46]Id. at 19.

[47]"Genetic screening differs significantly from genetic monitoring. With screening a one-time test to detect a single trait in a worker or job applicant is usually sufficient, while monitoring generally involves tests of a worker over time. Most importantly, genetic screening focuses on the preexisting genetic makeup that workers or job applicants bring to the job. This is distinct from genetic monitoring which focuses on hazardous workplace exposures that induce changes in the genetic material in an exposed population as a whole." Id. at 5.

[48]Id. at 88.

[49]"Limits of Molecular Based Tests: No matter what the mode of screening, two questions must be asked before administration of the test: 1) does the test reliably identify either the genetic trait or specific damage? and 2) does this

> While technologies associated with genetic monitoring and screening in the workplace have continued to advance, OTA found no significant change in the use of these technologies since 1983. Thus, several of the policy issues and options for congressional action offered in the 1983 OTA report are still valid and remain unchanged.[50]

In 1983, OTA found that none of the genetic tests evaluated were appropriate for routine use in an occupational setting. Though there were criteria for validity and reliability, the methodology and application of genetic monitoring and screening merited further research.[51] Although the OTA in 1990 reiterated that in its view genetic testing in the occupational setting was not as yet sufficiently well developed, nevertheless the 1990 OTA report reflected the advances in the state of the art that had occurred in less than a decade. In the interim years, new methods had been developed and new genetic susceptibilities had been identified,[52] but reliability and validity remained to be proven. OTA forecast even further advances, commenting, "[m]uch of the research done for the genome project will be important to the scientific advancement of genetic monitoring and screening techniques"[53] because of HGI's ability to expand understanding of human molecular genetics.

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particular trait or damage cause the individual to be at increased risk for disease?" Id. at 83.

[50]Id. at 24.

[51]Id. at 8.

[52]"New methods may provide better estimates of the health effects of low doses for some mutagens, as well as providing qualitative data on the nature of mutation. ... If the tests are valid and reliable, establishing procedural safeguards and designing well-conceptualized test protocols can avert erroneous and misleading conclusions. ...Since the 1983 OTA report there have been several technical advances in genetic screening tests. In addition, several new susceptibilities to occupational disease have been identified, and progress in detecting some nonoccupational disorders has been made." Id. at 10.

[53]Id. at 36.

According to OTA, "genetic screening in the workplace can be used in two distinct ways. First, genetic screening can detect traits that may indicate an increased susceptibility to occupational illness after exposure to specific agents. Second, screening tests can be used to identify genetic disorders not associated with specific job exposures."[54]

On balance, it appears that the 1990 report of the Office of Technology Assessment, Genetic Monitoring and Screening in the Workplace, marks a departure from OTA's earlier views on genetic screening and monitoring, and their implications for detection and treatment of occupational disease.[55] It noted advances in technology comparing them to the traditional approach of testing for exposure to mutagens which had been relied on earlier.[56] It noted new tools for detection in uncovering DNA "adducts."[57] OTA further noted,

> The obstacles to understanding associations between predisposition and disease are slowly eroding as the use of synthetic probes, PCR, and automated DNA sequencing machines increase the efficiency and lower the cost of mass screening.[58]

Thus, while OTA retained its cautionary approach expressed in the 1983

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[54]Id. at 77.

[55]"There are over 3,000 diseases known to be caused by a single-gene defect and chromosomal anomalies are found in 1 in 700 live births.... Recognition of genetic factors in disease presents new opportunities for detection, prevention, and treatment". At 56 OTA noted health effects attributed to mutations caused by toxic agents fall in 2 classes of genotoxic agents: chemicals and radiation. At 58, OTA defined "a mutagen is a substance capable of inducing heritable change in the genetic material of cells". At 59 OTA commented "the purpose of monitoring tests is to detect biologically significant exposures early, even though the results are currently unsuitable as a basis of quantitative risk assessment." Id. at 55.

[56]Id. at 60.

[57]DNA adducts are a type of alteration that can force replication of repair errors. Id. at 67.

[58]Id. at 11, noting also that validity of these tests is unclear.

report, it also emphasized the new technological and scientific developments which confirm the connections between genetic disease or propensities and occupational illness. In its 1990 report, OTA noted new developments in setting limits for low-level radiation and noted that genetic research has uncovered several genetic markers for key diseases, has been the automation of certain DNA diagnostic procedures,[59] and OTA referred to the discovery of the location of genes for some major diseases.

In its 1990 report, OTA provides a significant overview of the state of art of genetic monitoring.

> Genetic screening is a process that considers attributes or indices of altered DNA that may put an employee at high risk for developing disease, whether work related or not....Monitoring, on the other hand, involves the periodic evaluation of employees for either the effects of a toxic substance or its byproducts. Genetic monitoring evaluates the genetic damage caused by such substances. In short, genetic monitoring ascertains whether an individual's genetic material has altered over time.[60]

In its report, OTA briefly reviews the health effects of mutation, noting the effort to quantify the correlation of mutagenesis with carcinogenesis. The report also compares mutagenic effects of radiation with those of chemicals.[61]

In discussing technologies for genetic monitoring, OTA notes that in simple terms, a mutagen is a substance capable of inducing a heritable change in genetic material of cells. The purpose of monitoring tests, then, is to detect biologically significant exposures early "even though the results are currently unsuitable as a basis of quantitative risk assessment."[62] In reviewing improved

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[59]Id. at 80.

[60]Id. at 55.

[61]Id. at 56-57.

[62]Id. at 59.

tests of mutagenicity, the report notes the enormous progress made in consequence of the development of the Ames tests.[63] Among other studies, OTA refers to cytogenetic indicators, chromosomal aberrations, sister chromatid exchange, and micronuclei assay. The report discusses the expectations and limitations of the various new technologies and comments on the application of cytogenetic tests to occupational exposure and report:

> Over 100 cytogenetic studies have been reported from various occupational exposure groups. Among the occupational chemicals with best documented positive cytogenetic tests are ethylene oxide, styrene, benzene, and alkylating anticancer agents. Occupational cytogenetic studies of arsenic, benzine, epichlorohydrin, ethylene oxide, lead, cadmium, zinc, and vinyl chloride were described in the 1983 OTA report.[64]

The report does not discuss these findings anew, but they are included in the 1990 report at Table 4-3 which lists the most common occupational exposures that induce cytogenetic abnormalities. The report notes that since 1983, increased chromosomal abnormalities (CAs) have been reported in individuals exposed to phosphine, a grain fumigant, and a range of pesticides, including organo-phosphorous, organo-chlorinated, and carbonate groups. The report notes that chemical agents are more likely to induce sister chromatid exchange (SCEs) than CAs which are more likely to be induced by ionizing radiation. However, the conclusions of the OTA report pertaining to the appropriate use of cytogenetic assays for occupational testing still hold true. The conclusions of the 1983 report to which OTA's 1990 report adheres include:

- the appropriateness of cytogenetic tests for occupational monitoring needs to be considered on a case-by-case basis for each chemical;
- a monitoring program should be instituted when in vitro and animal tests have proved that the chemical in question is

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[63] Id. at 60-61.

[64] Id. at 65.

mutagenic or carcinogenic;
- no occupational studies, to date, directly relate cytogenetic abnormalities to increased individual risk for disease; and
- at the present time, cytogenetic monitoring is insufficient to predict health risks for an individual although it may have predictive value for a group.[65]

However, OTA draws some significant conclusions relating to appropriate industrial practice.

> For industrial practice this implies that when workers are in the vicinity of an established genotoxin, exposures should be reduced to a level that does not affect their chromosome morphology or DNA. In a sequence of cytogenetic studies on vinyl chloride exposed workers, a reduction of CAs was detected when the exposure level to the agent was decreased. To date, data on CAs are routinely used by regulatory agencies as contributing information for setting safe exposure standards. In view of the lack of threshold level where there is zero risk, there is no safe level of exposure. Thus, this should apply to all workers, not just to those determined by some test to be susceptible.[66]

OTA notes that until recently, tests for mutagenicity were mere indicators of exposure.

> This limitation is being removed as more techniques at the molecular level are being developed, refining the ability to document exposure and, in some cases, providing qualitative information about the nature of the mutation. As the nature of mutation becomes more clearly defined, the connection between mutation and disease will also become better understood.[67]

The report then refers a variety of new analytical techniques to provide a means for identifying workers who are at increased risk in occupational groups exposed to certain carcinogens.[68]

The 1990 report, in discussing methodological considerations, relies on the same analysis of validity, reliability and predictive value as did the 1983

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[65]Id. at 66.

[66]Id. (citations omitted).

[67]Id.

[68]Id. at 68.

report. The validity of genetic testing should be evaluated before any test is placed into routine use, meaning that there is a probability that a test will correctly classify true susceptible and true nonsusceptible individuals. Reliability must also be demonstrated under conditions of routine use. The report emphasizes that the predictive value of a test is determined by its sensitivity and specificity as well as by the prevalent of the trait or genetic damage in the population. When a prevalence of a particular trait is low in the population, there will be large number of false positives.[69]

Emphasizing procedural safeguards and difficulties, the need for good sampling and data collection are stressed. Individual factors that can affect test results "include such confounding variables as sex, age, race, ethnic group, work history, diet, genotype, medication, alcohol and drug consumption, and smoking."[70] All of these factors must be controlled in any population study. OTA suggests:

> The most sensible approach to genetic monitoring, if validated, would be to employ a battery of relevant and sensitive tests, rather than rely on any one test for valid and reliable information.[71]

In OTA's view, both intermediate and longterm effects must be measured particularly since ntermediate effects will always be higher than longterm adverse health outcomes.

In its summary and conclusions on genetic monitoring, OTA stresses a basic go slow approach, noting that not all mutations cause disease, and that occupational exposures are likely to cause nonheritable damage to somatic cells, rather than germline or heritable damage, and that cancer, a disease of somatic

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[69]Id. at 70.

[70]Id.

[71]Id.

cells, is the most common class of genetic disease correlated with genotoxic substances. Until health effects of exposures are better understood, it is noted that monitoring can only provide a gross indication that genetic changes have occurred and that adverse health effects would follow. However, newer methods will provide greater specificity and will augment tests already in use. Lest there be overconfidence, OTA notes that the greatest difficulties may lie in such procedural matters as eliminating biases, obtaining controls, and keeping good records, rather than in the technical difficulties themselves.

In its chapter on the State-of-the-Art in Genetic Screening,[72] OTA notes that genetic screening the workplace can be used to detect genetic traits that may indicate an increased susceptibility to occupational disease after exposure to specific agents. The screening test can also be used to identify genetic disorders not associated with specific job exposures.[73] OTA focuses on the interaction of occupational exposures and genetic influences evaluated in its 1983 report. In addition, a number of newly recognized susceptibilities to occupational disease are discussed. In discussing progress in the detection of nonoccupational disorders, OTA notes that they may be of interest to employers because they are likely to affect large populations, screening tests for them are under investigation or are being developed, and they might be of interest to an employer if available for preemployment screening.[74]

OTA discusses biochemical techniques for detecting genetic disease. These are particularly useful in detecting errors of metabolism such as PKU and sickle cell anemia. Also discussed are molecular techniques for genetic screening, more

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[72]Id. at 75-99.

[73]Id. at 77.

[74]Id.

recently developed. Such techniques include restriction fragment length polymorphisms (RFLPs), which require at least one living affected family member, and the knowledge of paternity. OTA stresses the importance of RFLPs in population studies, noting that certain rare alleles are often concentrated within certain ethnic groups. Other techniques are also noted.[75]

In its discussion of the newly available techniques, OTA raises two questions: whether the test can reliably identify either the genetic trait or specific damage, and whether the particular trait or damage causes the individual to be at increased risk for disease. Answering these questions, the criteria of validity, reliability, predictive value and relative risk will again be most significant. In its 1990 report, OTA noted the possible occupational effects of disease on workers who have glucose-6-phosphate dehydrogenase deficiency;[76] sickle cell anemia and sickle cell trait;[77] the thalassemias;[78] acetylation phenotype;[79] serum alpha-1-antitrypsin deficiency;[80] aryl hydrocarbon

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[75]The other techniques noted in the report include: HLA typing and genetic disease, direct analysis of mutant genes, polymerase chain reaction, and automation of DNA diagnostic procedures. Id. at 80-83.

[76]Such individuals are at enhanced risk for destruction of red blood cells if exposed to oxidant drugs or certain industrial compounds. Id. at 85.

[77]"Individuals with sickle cell anemia have reduced lifespans with many health problems directly attributable to being homozygous for the sickle cell gene. But . . . whether sickle cell trait carriers are at increased risk from the challenges of rigorous training at high altitudes (where oxygen is low) remains unresolved." Id. at 85.

[78]"Thalassemia is a deficiency in the production of hemoglobin that results in smaller red blood cells. . . . It has been suggested that beta thalassemic individuals are at increased risk after exposure to several chemicals, including benzene and lead." Id. at 85.

[79]"[A] growing body of epidemiologic studies further suggests that slow acetylation is a predisposition factor for the recurrence of arylamine-induced bladder cancer." Id. at 85 (citation omitted).

hydroxylase and cytochrome p-450;[81] ataxia telangiectasia heterozygonisity;[82] paraoxonase variants;[83] and HLA associations.[84]

OTA also was keenly aware of employers' economic incentives for genetic testing, which present the opportunity to screen-out persons who have potential genetic disabilities from nonoccupational causes, such as Huntington disease and predispositions to certain cancers, such as colon cancer, and bladder cancer. Also referred to was predisposition to mental and addictive disorders, predisposition to atherosclerosis; and to diabetes.[85] The consideration of both occupational and non-occupationally related disease was seen as reducing the employer's overall burden for health insurance and related health costs.[86] OTA considered the potential costs of occupational illness to employees; to employers; to insurance industry; and to society.[87]

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[80]Serum alpha-1-antitrypsin (SAT) deficiency is believed to be "a contributing factor in the development of emphysema in heterozygotes" even though emphysema has a multifactorial etiology. Id. at 85.

[81]Cytochrome P-450 plays a central role in metabolizing many molecules. This may play an important role in understanding genetic cancer. Id. at 86.

[82]"Such individuals are predisposed to both immune deficiencies and certain cancers. The cancer risk is over 100 times greater than for control groups." Id. at 86 (citation omitted).

[83]"Individuals with variations in esterase activity are expected to be at increased risk to organophosphate toxicity from any given exposure and would require longer recovery before resuming pesticide spray work." Id. at 87.

[84]"HLA typing has been used for several years in matching tissue and organ donors with recipients and for paternity determinations. Increasingly, various HLAs are being associated with specific human diseases." Id. at 87.

[85]Id. at 92-94.

[86]"Although the concept of screening out unhealthy workers has been around since the early part of this century, most screening technologies have only recently become available." Id. at 44.

[87]Id. at 46.

OTA comments on the growth of commercial developments of genetic tests, anticipating very substantial growth in that industry. OTA cites industry and insurance sources, pointing to the expectation that genetic testing in the workplace would increase, including a prediction that by the year 2000, most people will have genetic profiles, probably obtained through testing in the workplace.[88] OTA notes that identification of individuals predisposed to either occupational disease or to non-occupationally related disease remains problematic because people who carry predisposing genes do not all develop the disease. A variety of factors, including reduced penetrance, affect the certainty of diagnosis.[89]

In its conclusions, OTA notes that obstacles to certainty are being slowly removed with improved technology which increases efficiency and lowers the cost of mass screening. These advances provide insights into genetic predispositions to adverse health effects from a variety of causes. The conclusion notes that 50 human genetic traits have been identified which potentially enhance individual susceptibility to toxic or carcinogenic agents. Nonetheless OTA notes that "the environmental agents that trigger the predisposition often remain the wild card."[90]

As understanding of the medical and social costs associated with genetic disorders that are not related to workplace exposures increases, employers may want to use "wellness" programs as a tool for gathering employee health status

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[88]Id. at 94-95.

[89]Id. at 95. See also Eric T. Juengst, Priorities in Professional Ethics and Social Policy for Human Genetics, 266 J.A.M.A. 1835 (1991) [hereinafter Juengst].

[90]OTA 1990, supra note 20, at 95.

information.[91] If testing occurs in an employer-sponsored wellness program, does the employer have proprietary rights in the information that is uncovered, which it may use to make insurance decisions? As medicine attaches greater meaning to such personal health factors as age, and family history, as well as nutritional status (typically examined in wellness programs), information gathered in this manner will gain increased importance in shaping health profiles and determining employment.[92] Such interests should not outweigh the employees' privacy and confidentiality rights[93] and the release or redisclosure of such information to third parties should be prevented by appropriate privacy legislation. Disclosure to employees who are the subjects of such tests should be guaranteed.[94]

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[91]"There are two categories of genetic characteristics that are relevant in the occupational setting: those that predispose the individual to adverse health effects because of environmental exposure and those that predispose the individual to adverse health effects, regardless of job, thereby having an impact on employee 'wellness' and possible job performance." Id. at 95.

[92]"[G]enetic factors do not exist in isolation. Nutritional status, age, preexisting disease, and the interactions of various medications may affect an individual's susceptibility to toxic substances in ways that may be relatively long lasting or only temporary. The overall state of the art for genetic screening has not been developed broadly enough to distinguish genetic factors from these other variables. . . . A substantial amount of evidence exists to support the proposition that some individuals have a genetic predisposition to industrially related disease . . . The principal problem however is that the levels of exposure required to cause the response are not usually documented. Therefore, it is difficult to estimate the risk or to determine the adequacy of established workplace exposure standards in protecting worker health." NICHOLAS A. ASHFORD ET AL., MONITORING THE WORKER FOR EXPOSURE AND DISEASE: SCIENTIFIC, LEGAL AND ETHICAL CONSIDERATIONS IN THE USE OF BIOMARKERS 75-76 (1990) [hereinafter ASHFORD].

[93]Regarding the employer's duty to keep test results confidential, OTA states: "It can be argued that employers who learn of their employees' genetic defects and susceptibilities through genetic screening in the workplace could have a duty to keep this information confidential and not disclose it to anyone absent express consent of the employee. Failure to do so could result in a charge of invasion of privacy brought by an employee against an employer." OTA 1990, supra note 20, at 116.

[94]Juengst, supra note 89, at 1836.

There continues to be a great question on the usefulness of genetic testing in the workplace to promote occupational health. In their work, Monitoring the Worker for Exposure and Disease: Scientific, Legal and Ethical Considerations in the Use of Biomarkers, Nicholas A. Ashford et al. comment (in apparent agreement width the OTA view) that it is difficult to establish whether exposure to any particular substance causes observed changes in the biological parameter or biological marker.[95] Another emerging scientific issue is analysis of the combined effects of multiple exposures or of single exposures to multiple substances, such as the relationship between slow acetylator phenotype in relation to exposure to certain workplace carcinogens.[96] Ashford has recommended certain standards, similar to the standards recommended by OTA, to be used in determining the appropriateness of periodic testing.[97] Goals to be accomplished have been set forth as follows:

> 1. Detect evidence of absorption of industrial toxins; 2. Detect the early signs or symptoms of disease; 3. Provide data indicating evaluation of the plant's control measures; 4. Detect any changes in the health of the employee since the time of the preemployment examination or of the last periodic examination that might indicate the need for change in the work process or in job placement; 5. Detect any patterns of disease in the workforce that might indicate any underlying workerrelated problems; and 6. Provide the option to

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[95]ASHFORD, supra note 92, at 53.

[96]Slow acetylator phenotype aromatic amines used in dyes are associated with bladder cancer. Theoretically, people who are fast acetylators might be less likely to develop aromatic-amione-induced cancer. This conclusion was based on their study concerning workers with occupational exposure to benzidine. "Qualitatively, therefore, evidence of some increased susceptibility in this case is relatively strong. It is not possible from these limited data to calculate how much greater the risk of similar aromatic amine exposure might be for average people with the 'slow' phenotype. However, the indicated difference seems likely to be at least severalfold. Whether this is enough to justify screening programs is a social policy judgment that needs to be made in light of the absolute magnitude of the risk indicated for a specific exposed population, and other opportunities to reduce risk." Id. at 74.

[97]Id. at 88-89.

conduct tests of personal health maintenance.

. . .

> These examinations should give special attention to target organs or bodily organ systems that are most likely to be affected by substances to which the workers are exposed. The testing intervals should be designated on a substance-by-substance basis so as to detect any adverse health effects early enough to permit remedial action and preclude lasting consequences."[98]

Genetic testing in the workplace provides an opportunity to institute secondary prevention programs for employees potentially affected by workplace exposures to hazardous or toxic substances, using individual programs shaped by the worker's interest in wellness or programs developed at the employer's discretion.[99] An undesirable aspect of such programs, however, is the shift of the burden of protecting occupational safety and health from the employer to the employee. By screening out conditions which may affect workers with certain genetic propensities, employers can avoid health care costs. This may help employers evade statutory obligations to clean up the work site, while creating a category of persons who are unemployable by reason of a genetic predisposition to disease.

Any program of employee testing in the workplace will give rise to significant privacy issues. An employee may always refuse to be the subject of human monitoring unless it is required by a regulatory agency.[100] One situation that raises this problem is the Occupational Safety and Health Administration (OSHA) requirement that medical approval is necessary before work that requires

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[98]Id. at 88-89 (citation omitted).

[99]Rothstein, Genetic Discrimination, supra note 29, at 62.

[100]"In general, employers are entitled to information that bears upon the employee's ability to perform his or her job, and to information that indicates the levels of toxic substance exposure in the workplace. Although not all information gathered through health and exposure monitoring meets these criteria, much of it does. In the absence of protective statutes, employers will have a right of access to such data." ASHFORD, supra note 92, at 144.

the use of a respirator is undertaken, in order to insure proper fit of the respirator and to insure that the employee is physically able to perform the assigned task. If such respiratory equipment is required, there would then be no effective right to refuse such medical testing because such a refusal would be tantamount to refusing the assignment.[101]

6. Current Federal Legislation Affecting Employees' Right To Privacy in the Workplace

A number of laws currently affect employees' privacy rights in the workplace. These include the Occupational Safety and Health Act (OSH Act), Title VII of the Civil Rights Act, the Toxic Substances Control Act, the Vocational Rehabilitation Act, now largely displaced by the Americans with Disabilities Act (ADA), in addition to laws governing workers compensation, which are generally state laws, as well as certain common law privacy rights which may be arguably applicable. Though violations of the Toxic Substances Control Act, or violations of occupational safety and health provisions may give rise to claims in workers compensation, the most significant legislation to be discussed here are the Occupational Safety and Health Act and the Americans with Disabilities Act (ADA).

7. The Occupational Safety and Health Act (OSH Act)

a. Overview of the Statute

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[101]But see Occupational Safety and Health Act of 1970 §20(a)(5), 29 U.S.C. § 669(a)(5) (1985), which exempts workers from screening and testing who object on religious grounds. Ashford notes that this important exception may be consistent with the privacy rights articulated in Griswold, allowing workers to withhold information and preserve physical integrity by refusing tests in the workplace. However, it has not as yet been decided whether such a refusal would lead to the loss of the job because the employee gave up his right to the job by his objection. ASHFORD, supra note 92, at 125.

The Occupational Safety and Health Act (OSH Act)[102] assures covered employees the right to "safe and healthful working conditions"[103] and requires employers to provide "employment and a place of employment which are free from recognized hazards."[104]

The OSH Act does not directly address genetic screening and monitoring. However, OSH Act imposes upon employers a dual obligation: to prevent harm to workers and to prevent exposing workers to other persons who present a threat of harm, using the best available technology to prevent "recognized hazards."[105]

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[102]29 U.S.C. §§ 651-678 (1985).

[103]29 U.S.C. §651(b) (1985).

[104]The clause in full reads: "(a) Each employer--(1) shall furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees." 29 U.S.C. §654(a)(1) (1985).

[105]29 U.S.C. §654(a) (1985). The "General Duties" clause of OSH Act has been consistently interpreted to require that employers incorporate state of the art methods into their work processes in order to prevent "recognized hazards." Occupational Safety and Health Act of 1970 § 5(a)(1), 29 U.S.C. 654 (a) (1985). See, e.g., ASARCO v. OSHRC, 501 F.2d 504 (8th Cir. 1974); Teal v. Dupont, 728 F.2d 799 (6th Cir. 1984); McLaughlin v. Union Oil Co., 869 F.2d 1039 (7th Cir. 1989). For a detailed explanation of the "free from recognized hazards" requirement, see OCCUPATIONAL SAFETY AND HEALTH LAW 115 (Stephen A. Bokat & Horace A. Thompson eds., 1988). This duty includes prevent harm from people, such as contractors and coworkers, as well as chemicals or physical hazards. There is OSHA case law supporting the broad scope of this duty, limited only if the employee misconduct leading to harm is unforseen and "idiosyncratic." See, e.g., Pennsylvania Power & Light Co. v. OSHRC, 737 F.2d 350 (3d Cir. 1984).

Thus, the employer must protect against foreseeable employee misconduct and any other threats to employees safety and health caused by persons on those premises within the employer's control. This raises the issue whether employers have a duty to prevent persons who may cause harm from entering the workplace because of the threat of harm that they present to other employees. The potential overlap between OSH Act of 1970 and Americans with Disabilities Act (ADA) has been discussed among safety professionals, who must supervise the placement of disabled persons in places of employment where it is feared that their slower reflexes or physical problems might present a hazard to their fellow employees. Employers must provide special protections but not bar their presence from the workplace in order to prevent conflicts between OSH Act and the ADA, which requires reasonable accommodations unless the threat of harm is so great that reasonable accommodation cannot be made. The presence of persons who may pose a

This might provide a rationale for excluding workers with "dangerous" predispositions, however defined. On the other hand, employers who attempt to exclude workers based on risk must provide employment and places of employment that are equally safe and equally healthful for all employees, following an interpretation under Title VII of the Civil Rights Act of 1964.[106]

The U.S. Supreme Court's decision in International Union of Automobile Workers v. Johnson Controls held that occupational safety and health policies must be gender neutral and nondiscriminatory.[107] The case involved a defendant corporation that announced a policy barring all fertile women from jobs involving actual or potential lead exposure exceeding the levels specified by OSH Act as critical for a worker planning to have a family. The plaintiffs, a group of employees affected by the fetal-protection policy, filed a class action suit asserting that the policy was discriminatory.[108] The decision has important implications for genetic discoveries regarding polymorphic diseases with relevance to workplace exposures because of the Court's view that the protection of occupational health cannot be used to justify exclusionary policies. Since equal levels of safety must be extended to high-risk and low-risk employees, this precedent may ultimately protect persons confronted with exclusionary policies based on genetic conditions.

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threat to other employees also raises the question whether an employer could be liable under the General Duties clause in the event that an infected co-worker harmed other employees by spreading an infectious or communicable disease, such as tuberculosis. These questions remain unresolved.

[106]International Union, United Automobile, Aerospace and Agricultural Implement Workers of America, UAW v. Johnson Controls, Inc., 499 US 187 (1991).

[107]Id. at 198.

[108]Id. at 191-92.

b. Implications for Regulations Governing Genetic Tests

It might be argued that OSHA has authority to promote or otherwise regulate genetic screening and testing in the workplace, in order to detect and prevent mutagenic harms. To date, OSHA has not undertaken such regulations, though the matter was considered originally in 1980, and was not proceeded with.[109]

OSHA, however, encourages programs that require employees to disclose their genetic history, because such information-gathering is considered part of the practice of good occupational medicine. For this reason, OSHA does not prohibit genetic testing and may increase its involvement in fostering such tests in the future.

While genetic information may be useful in protecting workers, such information may also be detrimental to employee privacy and may result in discriminatory personnel actions.[110] Genetic testing creates other problems when the information gathered from genetic screening or monitoring leaves the premises

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[109]"Standards in the Occupational Safety and Health Act of 1970 regarding health examinations of certain workers state: 'The examination shall include the personal history of the employee, family and occupational background, including genetic and environmental factors.' In a memo dated 22 August 1980, the Occupational Safety and Health Administration (OSHA) indicated that the standards do not require genetic testing of any employee, nor do they require the exclusion of otherwise qualified employees on the basis of genetic testing. Nothing in the memo however, prohibits genetic testing. Although only a few companies include genetic tests in their examinations, the picture could change as tests become more widely available." HOLTZMAN, PROCEED WITH CAUTION, supra note 22, at 200-201 (citations omitted).

[110]Rothstein notes the "use, misuse, and abuse of diagnostic procedures and predictive medical screening procedures." The following example of misuse of medical screening was offered in the text: "Workers on offshore drilling rigs in the Gulf of Mexico traditionally have been hardy, young males. Recently, an attractive, athletic 22 year old woman applied for a job with a drilling company. During her preemployment physical examination she was given a low-back x-ray . . . [which] indicated a slight, clinically insignificant curvature of the spine, or scoliosis. Based simply on this x-ray, the woman was told she was physically unfit for the job. Off the record, however, she was informed that a young woman with her good looks might be disruptive and cause a morale problem at sea." ROTHSTEIN, MEDICAL SCREENING OF WORKERS, supra note 18, at xix.

of the occupational health services, to affect decisionmaking in the personnel office, and affecting other aspects of the employment relationship. The application of tests to asymptomatic or well persons may stigmatize a "healthy" but genetically high-risk part of the workforce and be used to deny constitutional and other established rights of employees. Thus, the use of genetic information in situations that are not directly related to occupational health destroys the potential benefits of genetic testing and monitoring in the workplace.

The result of employee medical tests, including genetic tests, may be made available to employees. This is required by OSHA regulations, but test results need not be shared with job applicants.[111] Moreover, the Access to Medical Records Standard, in the OSHA Regulations, requires that "all employee and medical records" generated by the employer shall be disclosed to employees upon the employees' request.[112] Reasonable interpretation of this broad standard should require disclosure of any records pertaining to genetic screening or monitoring at the request of the employee or the employee's representative.

Many states amplify the OSHA regulations with broader disclosure requirements of their own. Some states require that the employers disclose medical findings to rejected applicants who are not covered by the OSH Act. These laws require disclosure of information that is in the possession of the employer which may not be known to the employee, and which the employee would not have access to under the common law, even though the information directly concerns the

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[111]Andrews and Jaeger, supra note 26, at 76-77.

[112]29 C.F.R. § 1910.20 (1993). "This section applies to all employee exposure and medical records and analyses thereof, of such employees, whether or not the records are mandated by specific occupational safety and health standards." 29 C.F.R. § 1910.20 (a)(2). "Access means the right and opportunity to examine and copy." 29 C.F.R. § 1910.20 (c)(1) (1993).

employee.[113] OSHA regulations also require disclosure of such information to OSHA, to the National Institute for Occupational Safety and Health (NIOSH), or to "health professionals"; the latter with consent from the employee.

8. The Americans With Disabilities Act (ADA)

a. Overview of the Statute

Finding that 43 million Americans have one or more physical or mental disabilities, the U.S. Congress passed the "Americans with Disabilities Act" of 1990 (ADA) to prohibit discrimination against disabled individuals in employment, transportation and public accommodations.[114] In passing this legislation, "Congress acknowledged that society's accumulated myths and fears about disability and diseases are as handicapping as are the physical limitations that flow from actual impairment."[115] Under the law, the term "disability" means, with respect to an individual:

> (A) a physical or mental impairment that substantially limits one or more of the major life activities of such individual; (B) a record of such an impairment; or (C) being regarded as having such an impairment.[116]

Persons whose physical or mental impairments substantially limit activities such as walking, talking, seeing, hearing or caring for oneself are protected by the statute, as are persons who have a history of such impairment or persons who

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[113]E.g., NEV. REV. STAT. § 613.075 (1992), R.I. GEN. LAWS § 5-37.3-5 (1987); Andrews and Jaeger, supra note 26, at 92.

[114]Americans with Disabilities Act, 42 U.S.C. §§ 12101-12213 (Supp. 1993).

[115]H. REP. NO. 101-485 (II), 101st Cong., 2d Sess. 53 (1990), reprinted in 1990 U.S.C.C.A.N. 303, 335, citing School Board of Nassau County v. Arline, 480 U.S. 273, 284 (1987) [hereinafter 1990 U.S.C.C.A.N.].

[116]Americans With Disabilities Act (ADA), 42 U.S.C. § 12102 (2) (Supp. 1993).

are the victims of prejudice against the disabled because they are regarded as having an impairment. It is unclear, however, whether the terms of the statute extend to persons who suffer genetic discrimination because of their carrier status or the possibility of their future impairment by a disease with long latency such as Huntington. They are not covered, though this point has been debated in the literature and has been the subject of advisory opinions by the staff of the Equal Employment Opportunity Commission (EEOC), which administers ADA enforcement.[117]

People in the category of "regarded as impaired" may be in perfect health even though they have suffered from discrimination.[118] The ADA prohibits discrimination in pre-employment, hiring, advancement, discharge, compensation or training of qualified disabled individuals.[119]

Under ADA, employers must "accommodate" the needs of disabled employees and qualified disabled applicants for employment. Employers must take all reasonable steps towards accommodation, but need not initiate measures that cause them "undue hardship." Relying on examples from the legislative history concerning discrimination against individuals with physical or mental impairments,[120]

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[117]Infra.

[118]"For example, many people are rejected from jobs because a back x-ray reveals some anomaly, even though the person has no symptoms of back impairment. The reasons for the rejection are often the fear of injury, as well as increased insurance or workers' compensation costs. These reasons for rejection rely on common barriers to employment for persons with disabilities and therefore, the person is perceived to be disabled under the third test." 1990 U.S.C.C.A.N., supra note 115, at 453.

[119]"No covered entity shall discriminate against a qualified individual with a disability because of the disability of such individual in regard to job application procedures, the hiring, advancement, or discharge of employees, employee compensation, job training, and other terms, conditions and privileges of employment." 42 U.S.C. § 12112 (Supp. 1993).

[120]1990 U.S.C.C.A.N., supra note 115, 310-332.

Congress described the term "discrimination" as including "not making reasonable accommodations to the known limitations of a qualified individual with a disability unless such entity can demonstrate that the accommodation would impose an undue hardship on the operation of business."[121]

Prior to ADA, the principal statutory remedy available to persons objecting to employment based screening was the Vocational Rehabilitation Act of 1973.[122] That law applied only to federal employees and to government contractors. The area relating to the testing of handicapped persons, persons with tuberculosis, and alcoholics and drug abusers under the Vocational Rehabilitation Act are now covered under ADA.[123] Congress expressly stated in the legislative history, "[t]he ADA incorporates many of the standards of discrimination set out in regulations implementing Section 504 of the Rehabilitation Act of 1975."[124]

Under ADA, an employer is prohibited from inquiring about the severity or the nature of a qualified individual's disability. 42 U.S.C. Section 12117 provides for enforcement applying the procedures and remedies set forth in the Civil Rights Act of 1964, 42 U.S.C. Title VII, Sections 2000e-4, 2000e-5, 2000e-6, 2000e-8 and 2000e-9.

Employers who refuse to hire, promote or accommodate the special needs of persons covered may assert three defenses under the ADA: (1) failure to accommodate is job related consistent with business necessity; (2) the disabled person is a direct threat to other workers; or (3) the employer has an undue

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[121]1990 U.S.C.C.A.N., supra note 115, at 432.

[122]29 U.S.C. §§701-796 (1973). For a detailed discussion of the Vocational Rehabilitation Act of 1973 see GARY PHELAN AND JANET BOND ARTERTON, DISABILITY DISCRIMINATION IN THE WORKPLACE §§ 3.01-3.04 (1992 & Supp. 1993).

[123]OTA 1988, supra note 1, at 96.

[124]1990 U.S.C.C.A.N., supra note 115, at 304.

hardship defense for failure to make reasonable accommodation.[125] The business necessity defense concerns the criteria used in job selection criteria. The direct threat defense applies to conditions where the disabled person is considered to be a "significant risk to the health or safety of others that cannot be eliminated by reasonable accommodation."[126]

b. ADA's "Insurance Exemption"

Insurance issues are covered in 42 U.S.C. Section 12201(c), commonly referred to as the "insurance exemption." This section of the law states that ADA "shall not be construed to prohibit or restrict an insurer, hospital or medical service company, health maintenance organization, or any agent, or entity that administers benefit plans . . . from classifying risks, or administering such risks. . . . [But these provisions] shall not be used as a subterfuge to evade the purposes of subchapters I and III of this chapter."[127]

The purpose of the provision is to leave insurance practices unchanged.

> The Committee does not intend that any provisions of this legislation should affect the way the insurance industry does business in accordance with the State laws and regulations under which it is

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[125]42 U.S.C. § 12113 (Supp. 1993). The term "undue hardship" means "an action requiring significant difficulty or expense" in light of specific factors enumerated in the statute. It is likely that the meaning of this term will be shaped by future litigation. 42 U.S.C. § 12111 (10) (Supp. 1993); See also Steven D. Gravely, The Americans With Disabilities Act: New Rights For the Disabled, New Complexity for Businesses, VA. LAW., March 1992, at 27, 29-30.

[126]The term "reasonable accommodation" may include "(A) making existing facilities used by employees readily accessible to and usable by individuals with disabilities; and (B) job restructuring, part-time or modified work schedules, reassignment to a vacant position, acquisition or modification of equipment or devices, appropriate adjustment or modifications of examinations, training materials or policies, the provision of qualified readers or interpreters, and other similar accommodations for individuals with disabilities." 42 U.S.C. § 12111 (9) (Supp. 1993).

[127]42 U.S.C. § 12201 (c) (Supp. 1993).

regulated.

. . .

> [T]he plan may not refuse to insure or refuse to continue to insure . . . except where the refusal, limitation, or rate differential is based on sound actuarial principles or is related to actual or reasonably anticipated experience.[128]

By leaving the existing practices in place, the law seems to suggest that present insurance plans do not discriminate. It is not clear whether an insurance classification by risk can be approved by the states or the ADA despite its discriminatory effect on persons with an impairment or genetically caused impairment. It also does not provide for any remedies if insurance practices are found to be illegally discriminatory.

Congressional comments in the course of the Act's legislative history further confuses this situation by stating:

> However, employers may not deny health insurance coverage completely to an individual based on the person's diagnosis or disability. For example, it is permissible for an employer to offer insurance policies that limit coverage for certain procedures or treatments (e.g., a limit on the extent of kidney dialysis or whether dialysis will be covered at all, or a limit on the amount of blood transfusions or whether transfusions will be covered). It would not be permissible, however, to deny coverage to individuals, such as persons with kidney disease or hemophilia, who are affected by these limits on coverage for procedures or treatments for other procedures and treatments connected with their disability. [FN] It would also not be permissible to deny coverage to such individuals for other conditions not connected with these limitations on coverage, such as treatment for a broken leg or surgery. . . . Persons with disabilities must have equal access to the health insurance coverage that is provided by the employer to all employees."[129]

The insurance exemption provision also allows pre-existing conditions to

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[128]1990 U.S.C.C.A.N., supra note 115, at 419-20.

[129]Id. at 460-61. The footnote indicated in the text reads: "Of course, if the insurance plan had a pre-existing condition clause which limited coverage for a specified time, that clause would govern to limit coverage."

be excluded from insurance coverage.[130] Thus, a person who is protected by ADA may nonetheless not be entitled to insurance coverage. This has direct implications for disabilities caused wholly or partially by genetic factors. Since workplace illnesses may be the result of interactions between genetic propensities and environmental factors, the insurability of such illnesses remains unclear.

c. ADA Applicability to Genetic Disabilities

The legislative history of ADA is silent regarding genetic diseases and genetic traits. Although there are a few references to hemophilia and the manifestation of other genetic diseases, the ADA and its legislative history look to the manifestation of the disability itself and remain silent regarding the origins of the disabilities that are covered.

Disabilities covered by the ADA have a variety of origins, including communicable or infectious diseases, accidental harms or genetic diseases. Hemophilia is one genetically caused disease that is mentioned in the legislative history, although widely-discussed genetic diseases such as sickle cell anemia and cystic fibrosis are absent from the Congressional discussion of ADA coverage. It should be noted, however, that including genetically caused disabilities is a matter of interpretation. To include them would be a sound interpretation if the disabling manifestations of genetic diseases are not different from other, differently caused disabilities.

The case against ADA coverage of genetic illnesses is based on the view that the disabling manifestations of genetic diseases were not expressly contemplated in the legislative history. If such diseases have unusual effects

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[130]42 U.S.C. § 12201 (c) (Supp. 1993).

that make accommodation difficult or expensive because of their rarity or the extreme severity of impairment, then ADA might not have been intended to apply to disabilities caused by genetic disease. ADA coverage might also be denied if latent genetic disease or genetic traits result in no immediately visible manifestations of physical or mental impairment leading to reduced ability in major life functions. Thus, ADA could be interpreted -- though not very readily -- to allow an employer to refuse to hire an outwardly healthy person who has the gene for Huntington disease and who might manifest the disease in twenty years, even though the basis for the refusal was a discriminatory decision rooted in the presence of a late-onset genetic disease.

But there is a strong argument to be made favoring coverage of disabling manifestations of genetic diseases. The legislative history is replete with examples of the need to accommodate disabled persons who use wheelchairs, hearing aids or suffer visual impairment. If an individual has a genetic disease which manifests in disability consisting of impairment of one or more of these life functions, that individual's disability is covered. For example, department stores or restaurants must make room for wheelchairs and have wheelchair accessible restrooms regardless of the reason why the disabled individual uses the wheelchair. In addition, genetic traits may be granted protection under the ADA, given the legislation's broad mandate to combat prejudice against people who suffered discrimination as if they were disabled, even though they were not impaired. If someone suffers discrimination because of a genetic trait that is treated as an impairment, that individual should be covered under the "regarded as having an impairment" criterion for ADA coverage.[131]

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[131]"Whether a genetic marker or a trait constitutes an 'impairment' under ADA is unclear. Preemployment medical examinations or inquiries are to be used only as a tool for determining the applicant's ability to do the job. Thus,

d. EEOC Interpretation of ADA Coverage with Respect to Non-Manifested Genetic Disease

As noted earlier, ADA covers genetic diseases that have become manifest, but does not directly address discrimination against persons who have genetic diseases that are not readily apparent, or who carry the trait for a genetic disease. It remains an open question whether there is ADA coverage for carriers of genetic diseases or for individuals who might manifest Huntington disease in the future but are currently healthy. Some employers may be reluctant to hire them because of the potential expense associated with providing insurance coverage for individuals with late-onset disease. Similarly, employers may be unwilling to hire persons who are carriers of genetic disease because they would like to avoid paying high insurance rates for their dependent family members who may develop the disease if the carrier marries another carrier. Thus, under one view such persons are covered because they are "regarded as impaired" although healthy, entitling them to the benefits of protection under the law. Under another interpretation of the law, this class of employees and applicants may have no protection under the law at all, because the law does not specifically address these issues.

In 1991 the Equal Employment Opportunity Commission (EEOC) promulgated regulations to implement the requirements of ADA. EEOC regulations do not resolve genetic discrimination issues. 29 C.F.R. §1630.13 prohibits pre-employment

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genetic screening for non-occupationally related conditions would seem to be prohibited. ADA language, however, does not specifically address genetic monitoring or screening." OTA 1990, supra note 20, at 16. See also Id. at 115: "When applied to genetic monitoring and screening, the definition of disability does not expressly address the question of increased risk of disease based on genetic factors. . . . On the other hand, if an employer 'regards' any individual with a marker or trait for a genetic condition as impaired, then perhaps the individuals would come under the protection of the Act."

medical examinations and inquiries;[132] it allows for employment entrance examinations after an offer of employment has been made but before placement, pursuant to 29 C.F.R. §1630.14.[133] Although the medical examination need not be job-related or consistent with business necessity, according to the regulations, "if certain criteria are used to screen out an employee or employees with disabilities as a result of such an examination or inquiry, the exclusionary criteria must be job-related and consistent with business necessity, and performance of the essential job functions cannot be accomplished with reasonable accommodation as required in this part."[134] The regulations leave unanswered the question whether information about latent genetic diseases or carrier status has to be excluded from medical examinations or interviews, unless the information was job related. These issues will have to be resolved either by legislative action or through litigation.

Testimony during hearings before the House Committee on Operations, Subcommittee on Government, Information, Justice and Agriculture on April 10 and October 17, 1991 indicated that at the April 29 workshop in Los Alamos, New Mexico, the ELSI Working Group discussed the EEOC proposal for regulations to

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[132]Concerning prohibited Medical Examinations and Inquiries the Code states, "[e]xcept as permitted by §1630.14, it is unlawful for a covered entity to conduct a medical examination of an applicant or to make inquiries as to whether an applicant is an individual with a disability or as to the nature or severity of such disability." 29 C.F.R. § 1630.14 (b) (1993).

[133]"Employment entrance examination. A covered entity may require a medical examination (and/or inquiry) after making an offer of employment to a job applicant and before the applicant begins his or her employment duties, and may condition an offer of employment on the results of such examination (and/or inquiry), if all entering employees in the same job category are subjected to such an examination (and/or inquiry) regardless of disability." 29 C.F.R. 1630.14(b) (1993). Note that 29 C.F.R. § 1630.14(b)(1) preserves the confidentiality of these medical records.

[134]29 C.F.R. § 1630.14(b)(3) (1993). See generally, 56 Fed.Reg. 35,726-55 (1991), describing the Agency's rationale for these regulations.

implement ADA. The Working Group of ELSI identified three areas in which ADA is unclear in its reference to genetics.[135]

The Working Group sought EEOC's interpretation of regulatory language pertaining to genetic discrimination. It noted, "Although individuals who already manifest symptoms of a severe genetic disease and individuals at increased risk of a severe genetic disease are covered by Section 3(2) and Section 1630.2 [of the regulations], the proposed regulations do not expressly state that unaffected heterozygote carriers of recessive disorders and x-linked disorders are covered when the basis for their exclusion is the fear that the individual is at risk of parenting a child who will have the condition."[136]

The Working Group also expressed the concern that "EEOC should amend Section 1630.12 (b)(3) [of the regulations] to provide that post-offer, employment entrance medical examinations must be limited to assessing job-related physical and mental conditions."[137] This position was endorsed by Paul Berg and Sheldon Wolff, Co-Chairs of the NIH-DOE Joint Subcommittee on the Human Genome in a letter to the Chairman of the EEOC, Evan J. Kemp, dated July 10, 1991.[138]

When EEOC promulgated regulations, in defining physical and mental

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[135]The 3 areas identified by the ELSI working group were: 1) Coverage of Genetic Conditions (by statutes); 2) Job-related Employment Entrance Examinations; 3) Access to Genetic Information in Medical Records and Health Insurance Claims. Domestic and International Data Protection Issues: Hearings before the Government Information, Justice and Agriculture Subcommittee of the Committee on Government Operations, 102d Cong., 1st Sess. 488-89 (1991) [hereinafter Data Protection Hearings].

[136]Id. at 489.

[137]Id. at 489.

[138]Id. at 492-93 (letter from Paul Berg and Sheldon Wolff, Co-Chairs, NIH-DOE Joint Subcommittee on the Human Genome).

impairment and in dealing with post-offer medical examinations, no mention was made of genetic conditions or diseases.[139]

On August 2, 1991, Elizabeth M. Thornton, Deputy Legal counsel of EEOC replied to the July 10 letter from Paul Berg and Sheldon Wolff. Her letter stated, "the ADA does not protect individuals who are not otherwise impaired, from discrimination based on genotype alone."[140] She further indicated that, "Nothing in either the statute or the legislative history, however, indicates that Congress intended such examinations to be limited in the way [that ELSI suggested]. Rather, entrance examinations, like other selection criteria, need only be job-related and consistent with business necessity if they screen out, or tend to screen out, an individual with a disability or a class of individuals with disabilities."[141]

In November 1991, Ronnie Blumenthal, writing on behalf of the agency took

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[139]In discussing 29 C.F.R. § 1630.2(h) regarding the definition of "physical or mental impairment" the EEOC states that, "[i]t is important to distinguish between conditions that are impairments and physical, psychological environmental cultural and economic characteristics that are not impairments. The definition of the term "impairment" does not include physical characteristics such as eye color, hair color, left-handedness, or height, weight or muscle tone that are within the "normal range" and are not the result of physiological disorder. The definition likewise, does not include characteristic predisposition to illness or disease. Other conditions, such as pregnancy, that are not the result of a physiological disorder are also not impairments. Similarly, the definition does not include common personality traits such as poor judgement or quick temper where these are not symptoms of a mental or psychological disorder. Environmental, cultural, or economic disadvantages such as poverty, lack of education or a prison record are not impairments. Advanced age, in and of itself, is also not an impairment. However, various medical conditions commonly associated with age, such as hearing loss, osteoporosis, or arthritis would constitute impairments within the meaning of this part. See Senate Report at 22-23; House Labor Report at 52; House Judiciary Report at 28-29." 56 Fed. Reg. 35, 741 (1991).

[140]Data Protection Hearings, supra note 135, at 494 (letter from Elizabeth Thornton, Deputy Legal Counsel, EEOC).

[141]Id. at 495.

the position that, "there is no indication in the ADA legislative history that Congress intended for the ADA to cover discrimination based on genotype."[142] The letter further states that the Commission is unable to answer questions whether individuals with late-onset genetic disorders (such as Huntington disease), heterozygous carriers of recessive (e.g., cystic fibrosis) or x-linked disorders (e.g., hemophilia) or atypical genotypes that limit procreation are covered by ADA. In addition the letter took the position that there is no right to refuse a genetic test or HIV test because, "whether or not a particular test or test result is job-related does not affect an employer's right to require an applicant to submit to the test."[143]

Linda McDermott, member of the staff of the Legal Counsel for the Equal Employment Opportunity Commission (EEOC), stated in a conversation with the office of the Principal Investigator on May 14, 1992 that whether the act covers genetic diseases or genetic traits that have been the subject of discrimination is an open question. It was not expected that EEOC would have an official position on the matter soon.[144] It is clear that EEOC does not intend to protect persons with genetic conditions under ADA, when they do not suffer from manifest disabilities.

e. Summary of ADA Protections

As has been noted, the ADA "is a monumental piece of civil rights legislation . . . [but] the ADA's coverage of a wide range of genetic conditions

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[142]Id. at 436 (letter from Ronnie Blumenthal, Acting Director, Communications and Legislative Affairs).

[143]Id.

[144]Telephone Interview with Linda McDermott, Staff of Legal Counsel, Equal Employment Opportunity Commission (May 14, 1992).

is not resolved. The employment entrance examinations contemplated by the ADA have been construed to permit the use of mandatory, non-job-related medical examinations and inquiries -- even though the results may not be used in deciding employability."[145]

Without question, persons who have manifest disabilities associated with a genetic illness enjoy ADA's statutory protections. Their disability cannot be used as a basis for employment discrimination. But persons who have unexpressed but potentially disabling genetic illnesses are not but should be granted protection under ADA's "regarded as impaired" standard which accords statutory protection to currently healthy people who are regarded as disabled for a variety of reasons.[146]

The EEOC's failure to acknowledge the importance of disabilities based on genetic diseases is surprising, given the progress of the statute reflected in the legislative history to protect not only persons with manifest disabilities, but also persons perceived to be disabled. Although ADA coverage could reasonably extend to persons with genetically caused disabilities and also to persons with genetic traits that are (rightly or wrongly) perceived as disabling, EEOC has rejected this interpretation, though there is no specific support for EEOC's view in the legislation or legislative history; nothing in ADA limits its scope to exclude redress for genetic discrimination. Based on the current position taken

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[145]Rothstein, Genetic Discrimination, supra note 29, at 83-84.

[146]"Discrimination against people with disabilities also includes adverse actions taken against individuals with histories of a disability, and adverse actions taken against those regarded by others as having a disability. It also includes discrimination against persons associated with individuals with disabilities. Such discrimination often results from false presumptions, generalizations, misperceptions, patronizing attitudes, ignorance, irrational fears, and pernicious mythologies." H. REP. NO. 101-485 (II), 101st Cong., 2d Sess. 30 (1990), reprinted in 1990 U.S.C.C.A.N. 303, 311. See also discussion of ADA supra, text accompanying notes 114-129.

by EEOC and its staff, it is not likely that there will be a change in interpretation.

In view of the permissibility of more preemployment testing under ADA, it is possible that the law leaves persons with genetic conditions in a worse position than before, because an employer can obtain information on unmanifested genetic conditions more easily than before, possibly allowing more opportunity for discrimination.

It has been noted that "the Human Genome Project also carries the possibility of stigmatization and discrimination against individuals with current and possible future genetic disorders.... The ADA as it currently reads, however, is inadequate to protect all of the vital interests raised by the prospect of genetic-based discrimination. New legislative initiatives are essential and inevitable."[147] Clarification of these issues and protection of workers rights may require new legislation.

9. Conclusions

The privacy of workers is regularly invaded in the workplace, through intrusive preemployment tests or questionnaires, detailed preemployment medical examinations and the taking of wide-ranging and detailed medical histories, including medical histories of the employee's family. In addition, employers obtain a great deal of personal information relating to an employee's health and life style through employees' purportedly voluntary participation in employment connected wellness programs. Much of this purports to be for the employee's benefit and protection, though generally it is for the protection of the employer in avoiding excessive costs of health care and health insurance and in avoiding

[147]Rothstein, Genetic Discrimination, supra note 29, at 84.

employee absenteeism and other failures of performance on the job.

It is clear that many intrusive questionnaires and employee examinations are directed not at the examination of the worker's susceptibilities to workplace risks, but look to the employee's general physical condition, including genetic data, to obtain information which may help the employer to avoid excessive health insurance costs.

While ADA is a major piece of civil rights legislation, it is defective in not protecting persons with genetic illnesses that have not as yet manifested, and it is not effective in protecting individuals who are heterozygotes for disabling diseases. It seems that in some respects ADA leaves persons with genetic conditions in a worse position than before. Such persons may have to disclose their genetic situation in prehiring examinations, providing the employer with information, though ADA's insurance exemption allows them to be discriminated against.

What is urgently necessary is an amendment of ADA to protect persons with genetic conditions who are currently excluded from ADA coverage. An amendment of the legislation seems called for because past interpretations by EEOC and its legal department offer little hope that appropriate changes will be made by regulation, even though the text of ADA would clearly allow corrective regulatory changes to carry out the legislative purposes of ADA as originally articulated. In the absence of such a revision of ADA, employers should be barred from inquiring into a job applicant's genetic traits or illnesses, or into the genetic traits or illnesses of the employee's or job applicant's family.

Although there is considerable agreement among geneticists and persons in industrial hygiene that it is too early for any broad program of testing in the workplace to protect workers with certain genetic propensities against particular

industrial exposures, it is nonetheless clear that great progress is being made in that direction, and that it is a question of time until such workplace testing will be possible to protect susceptible members of the work force against particular pollutants. Assuming that such tests will provide information capable of protecting workers' health, such a development will create massive regulatory problems which will need to be addressed before such large-scale testing and workplace monitoring can be realized. With rapid scientific progress in this area, this particular ethical, legal and social impact of scientific development ought to be considered and worked on in advance of the scientific developments to be anticipated.

OTA has offered eight recommendations concerning genetic monitoring and screening in the workplace, not covered by current laws.[148] The eight recommendations made by OTA would seem to be appropriate for any broad screening and monitoring program in the future. The recommendations require that the employer demonstrate the need for a genetic monitoring or screening program; that the purpose for conducting such a program be attainable and clearly articulated before it is implemented; that the participation of individual workers and of the work force in general be voluntary; that the program of genetic monitoring or screening in the workplace apply equally to all workers and that any worker undergoing genetic monitoring be given an opportunity of informed consent, which may also require counseling; that any worker who participates in the program must have access to the results; that professional interpretations of genetic monitoring and screening results be provided for both workers and employers so that genetic monitoring and screening are used in accordance with their intended ends; and that genetic monitoring and screening results be confidential.

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[148]OTA 1990, supra note 20, at 149-150.

Chapter 8. Protection of the Right *Not* To Know One's Own Genetic Information

Every person is entitled to know details of his or her genetic makeup. Persons who voluntarily have themselves tested are entitled to the test results.[1] Even when a person consents to be tested at the instance of a third party, such as an employer or an insurance company, the organization that arranges for the test is obligated to inform the subject of the test results.[2]

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[1]PRESIDENT'S COMMISSION FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL AND BEHAVIORAL RESEARCH, SCREENING AND COUNSELING FOR GENETIC CONDITIONS (1983) at 59:

> Genetic screening and counseling have the same central purpose: to make people into informed decision makers about their genetic constitution, to the extent it is relevant to choices about their own well-being or that of their family. . . .
>
> But note:
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> A genetic screening test undertaken to detect a particular genetic condition sometimes uncovers other information that could be very traumatic to the screenee. Genetic counselors and providers must decide whether such incidental information should be revealed to the individuals screened and, if so, how to reveal it. Id. at 59.

[2]PRESIDENT'S COMMISSION FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL AND BEHAVIORAL RESEARCH, SCREENING AND COUNSELING FOR GENETIC CONDITIONS (1983) at 42:

> Because of the potential for misuse as well as unintended social or economic injury, information from genetic testing should be given to people such as insurers or employers only with the explicit consent of the person screened.

Mark A. Rothstein, Genetic Discrimination in Employment and the Americans with Disabilities Act, 29 HOUS. L. REV. 23, 52-62 (1992). See also Americans with Disabilities Act; 42 U.S.C.A. § 12112 (d)(3) (1990):

> A covered entity may require a medical examination after an offer of employment has been made to a job applicant and prior to the commencement of the employment duties of such applicant, and may condition an offer of employment on the results of such examination, if--. . .
>
> (B) information obtained regarding the medical condition or history of the applicant is collected and maintained on separate forms and

A person may intentionally avoid his/her genetic information. A person could do so simply by not requesting such a test, or by avoiding situations in which he or she may be required to be tested in the course of medical examination, or as part of an employment or an insurance medical test.

Knowledge of one's own condition may be desirable because it may provide the subject with a number of choices. On the other hand, a person's unintentional discovery of an adverse genetic trait or condition may be an undesirable or even devastating experience. When a person who is the member of an ethnic or other risk group discovers that his or her brother or cousin has the trait for Tay-Sach's disease or sickle cell anemia, this may come as a shock. Such information is likely to be gained by the subject in the course of taking a family medical history, in the course of a pedigree study, or accidentally as part of verbally transmitted family information. Though a person might rather not have disturbing knowledge, there seems to be no way to avoid getting the information. Although the unexpected and untoward disclosure of the information may cause shock and pain, there appears to be no reported case which finds liability for such an unwanted disclosure. If the information were conveyed to a person with the intention of causing emotional harm, then possibly a damage action for personal

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in separate medical files and is treated as a confidential medical record.

Unless one can infer from the fact that the ADA requires information obtained from a medical examination to be treated "as a confidential medical record" to mean employees have access to that information, employees do not always have legal rights to see their medical records. However, some states give employees these rights. See e.g. Conn.Gen.Stat.Ann. § 31-128c; Wis.Stat.Ann. § 103.13. Also, OSHA's Access to Employee Exposure and Medical Records Standard, 29 CFR § 1910.20 (1992), requires that the employer provide access to both exposure records and medical records. However, the standard only covers employees who are exposed to toxic substances. See MARK A. ROTHSTEIN, ANDREA S. KNAPP AND LANCE LIEBMAN, CASE AND MATERIALS ON EMPLOYMENT LAW at 169, note 7 (2d ed. 1991).

injuries would lie based on the intentional infliction of emotional harm.[3]

The right not to know may also find an application in the case of prenatal diagnosis. A pregnant woman may decide not to have a prenatal test, because she wants to carry the child to term regardless of genetic disabilities, and because she does not want the stigma of genetic disability to be raised, regardless of the possible outcome of the test.[4]

The primary importance of a person's right not to know emerges in situations where he/she is at risk of a disease that manifests itself later in life, as most notably in the case in Huntington's chorea.[5] When only the subject

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[3]W. PAGE KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS §12, at 55 (5th ed. 1984). B.N. v. K.K., 538 A.2d 1175 (Md. 1988). A nurse who alleged that a physician, with whom she had had a romantic relationship, know he had genital herpes, but nonetheless engaged in sexual intercourse with the nurse without divulging that information, which resulted in giving her the disease had an action for intentional infliction of emotional distress if she could demonstrate the severity of her emotional distress. "Even if Dr. K. did not actually intend to inflict severe emotional distress, it is enough if 'he [knew] that such distress [was] certain, or substantially certain, to result from his conduct; or where [he acted] recklessly in deliberate disregard of a high degree of probability that the emotional distress [would] follow.'" B.N. v. K.K. at 1180 citing Harris v. Jones, 380 A.2d 611 at 614 (1977).

[4]"[Persons] should not be forced through mandatory genetic testing to learn about traits or disorders, even if this may alert them to the need for treatment." THE PRIVACY COMMISSIONER OF CANADA, GENETIC TESTING AND PRIVACY, 30 (1992). Also see Adrienne Asch, Reproductive Technology and Disability, in REPRODUCTIVE LAWS FOR THE 1990s 69, 81-95 (Sherrill Cohen & Nadine Taub, eds., 1989); NEIL A. HOLTZMAN, PROCEED WITH CAUTION: PREDICTING GENETIC RISKS IN THE RECOMBINANT DNA ERA 227-28 (1989) [hereinafter HOLTZMAN, PROCEED WITH CAUTION].

[5]Marion Steinman, In the Shadow of Huntington's Disease, Nancy Wexler's Quest for a Cure, COLUMBIA, Nov. 1987, at 14. The article describes Dr. Wexler's work on finding the source and identification of Huntington's disease and her own reluctance to be tested for the disease, though she was at risk. Like many other persons at risk, she decided that not knowing made it easier to continue life in a productive fashion, rather than reducing life to awaiting the inevitable outcome once one learns that one has the disease. There is evidence that relatively few persons who are known to be at risk for Huntington's disease actually take the test. In one survey 23% of those at high risk for Huntington's disease said they would prefer not to be tested. R. Wachbroit, Making the Grade, 16 HOF.L.REV. 583, 584 (1988).

is involved, the right not to know may well be observed, because no one is likely to provide the unwanted information. Such a right is difficult to protect, other than by imposing penalties on unwanted disclosures, but most penalties may not be adequate and will be difficult to enforce.

The autonomous right of a person to refuse information on a potentially disabling and deadly condition, which is certain to occur in the future, and which is both untreatable and irremediable, must, of course, be maintained. The International Huntington Association (IHA) and the World Federation of Neurology (WFN) have proposed Recommendations to provide guidelines for the use of the Huntington's Disease Molecular Genetics Predictive Test.[6] The first recommendation and comments indicates that individuals should have updated information "in order to make an informed voluntary decision".[7] Taking the test must be the "sole choice" of each individual, free of coercion from families, physicians insurance companies, employers or other third parties.[8] "The patient should be encouraged to select a partner to accompany him/her throughout the different stages" of testing. The test shall be offered without regard to financial status but only to people who have reached majority. There must be no

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Cheryl L. Becker, Note, Legal Implications of the G-8 Huntington's Disease Genetic Marker, 39 CASE WESTERN RES. 273, 297 (1989): "Every child has a right to know if his parent has tested positive for the Huntington's marker." Such a rule would leave the child free to determine whether or not to be tested.

[6]Concept: Ethical Issues Policy Statement on Huntington's Disease Molecular Genetics Predictive Test, IHA and WFN Research Group on Huntington's chorea, Committee on Genetic Testing. "The establishment of a committee with the specific task of preparing such guidelines was decided at the WFN and IHA conferences in Lille, September, 1985. The recommendations were adopted by both organizations at their respective meetings in Vancouver, Canada, June 30 to July 3, 1989 and published in J.Neurol. Sciences 1989; 94; 327-32 and J. Med. Genetics 1990; 27; 34-8" Concept paper at 1.

[7]WFN-IHA guidelines, Number 1.

[8] WFN-IHA recommendation 2.

testing for the purpose of adoption. Laboratories which examine the test must meet rigorous standards. The recommendation prohibits the disclosure of test results to third parties without the written consent of the patient. Information that should be given to the patient should include such matters as the potential consequences of taking the test, including the effect of test results on the individual patient, patient's spouse, parents, other family members, and consequences pertaining to employment, insurance, social security and data security.[9] It is also recommended that patients have access to "alternatives" to taking the test, including but not limited to not taking the test or storing their DNA.[10] The Recommendations also offer guidance for prenatal and antenatal testing, designed to ensure the integrity of the patient's medical decisions. The delivery of test results to patients must be through counseling, in person, rather than over the telephone or by mail. The patient always has the right to refuse having the results.[11] Followup counseling within one week of the results, and also one month after the delivery of test results is recommended.[12]

Just as the autonomous choice not to have such devastating information must be respected, so must the choice of an afflicted person to know the full truth. There are many instances when patients want to know about terminal conditions such as cancer or other deadly diseases. Individuals differ greatly in their ability to withstand devastating information. Persons should have the choice to

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[9] WFN-IHA Recommendation 5.3.5

[10] WFN-IHA Recommendation 5.4

[11] WFN-IHA Recommendation 8.3 "The results of the test should be given in person by the counselor to the individual and his/her partner. No result should ever be given by telephone or by mail. The counselor must have sufficient time to discuss with the individual any questions".

[12] WFN-IHA Recommendations at 9.1 and 9.3

make decisions, to change their agenda, and to make arrangements which otherwise they might not have made. Individuals also differ enormously in the amount of control they think they can exercise over their lives, and a person ought to make the autonomous choice of how much control in relationship to his/her affairs the person wants to exercise. Thus, the determination to hear or not to hear the information also requires a knowledgeable, autonomous decision, which, at the person's choice, might involve the appropriate assistance of physicians, genetic counselors or other suitable specialists.

The right not to know stands in a different posture when other persons' right to the information is involved. The communicable disease area offers easy examples in the well-established cases involving claims by one sexual partner against the other for failing to disclose a venereal disease.[13] The courts have generally held that consent to have intercourse does not include consent to be infected.[14] More recently, the doctrine has been applied in cases of sexual partners infected with AIDS.[15] The question has been raised whether a person's ignorance of his or her disease is a defense to an action for physical injury

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[13]Crowell v. Crowell, 105 S.E. 206, 208 (N.C. 1920); Mussivand v. David, 544 N.E.2d 265 (Ohio 1989). Current application of traditional methods of case tracing and partner notification as a part of an AIDS control program in Denver, Colorado, can be found in 78 AM.J.PUB.HEALTH 387 (1988).

[14]PROSSER ON TORTS, § 18, at 120 (5th ed. 1984): "[A] woman who consents to intercourse may still recover when she is infected with venereal disease, although nothing was said about it." See also G.L. v. M.L., 550 A.2d 525 (N.J.Super.Ch. 1988); Crowell v. Crowell, 105 S.E. 206 (N.C. 1920); Kathleen K. v. Robert B., 198 Cal.Rptr 273 (1984).

[15]The only case law found applying the doctrine that consent to intercourse does not include consent to be infected to the AIDS virus are military cases: 28 M.J. 775; 27 M.J. 798; 27 M.J. 749.

resulting from intercourse with a diseased person.[16] As a general matter of law, knowledge involves obligations. If I know that I am drunk, I have no business driving off in my car. If I know that there is a hidden defect in the home I'm selling, I must tell the purchaser of that defect or bear the consequences of his/her getting hurt. Ordinarily, a person has no right to claim ignorance as a defense when he or she could easily have discovered the facts. Thus, a person who could easily have discovered his or her diseased condition usually cannot claim ignorance of the condition in defense of the claim of having infected another. There may, of course, be a question of whether or not the person had any reason to find out, or could have found out without too great a difficulty. Sometimes liability depends on whether the person knew certain facts which should have put him/her on notice, or whether he or she should have known.[17] In situations where knowledge of the dangers of unprotected sex, for instance, is widespread and well known, and where opportunities for diagnostic tests are readily at hand, the defensive claim of ignorance is not likely to succeed,[18] as it has not succeeded in other situations, where for instance the driver who causes an accident claims

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[16]See, MARGARET L. DAVIS, LOVERS, DOCTORS, AND THE LAW: YOUR LEGAL RIGHTS AND RESPONSIBILITIES IN TODAY'S SEX-HEALTH CRISIS 72-80 (1988). (Legal standard varies from state to state.)

[17]Berner v. Caldwell, 543 So.2d 686 (Ala. 1989): One who knows or should know, that he or she is infected with genital herpes is under a duty to either abstain from sexual conduct with others or, at least, to warn others of the infection prior to having contact with them, and breach of that duty gives rise to cause of action for tortious transmittal of the disease.

[18]R.A.P. v. B.J.P., 428 N.W.2d 103, 108 (Minn.App. 1988): "A reasonable person should know that if he/she has a contagious, sexually transmissible disease . . ., the disease is likely to be communicated through sexual contact."

See also, Mussivand v. David, 544 N.E.2d 265, 269 (Ohio 1989).

that he did not know that his brakes were defective.[19]

No cases of this kind have been found, but it is clear that the transmission of disease in the area of sexually transmitted diseases might well form a sound precedent for actions for the adverse consequences of failure to inform a partner of a genetic trait or disease. When a heterozygote fails to inform his or her partner and the partner also has the trait for sickle cell anemia or cystic fibrosis, and an ill child is born, could an action for damages be brought for the consequences of the failure to inform? The situation is not wholly analogous to the situation of sexually transmitted disease, because in that situation only the other partner is harmed in consequence of the failure to inform. In the case of a genetic trait, the other partner also suffers significant adverse consequences, but a third person, the child who is born ill, suffers the major consequences. But the illness of the child may give rise to a claim of wrongful life or wrongful birth.[20] Although wrongful life actions have been discussed in the literature with some frequency, none of the cases discussed have thus far raised the question as to whether the partner in the marriage who

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[19]See e.g., Maloney v. Rath, 445 P.2d 513, 516-17 (1968). The accident was caused by a failure of defendants's brakes that resulted from her independent contractor's negligence. Since her duty to maintain her brakes in compliance with the provisions of the Vehicle Code is nondelegable, the fact that the brake's failure was the result of her contractor's negligence is no defense.

[20]See M.V. Kelly, The Rightful Position in 'Wrongful Life' Actions, 42 HASTINGS L.J. 505 (1991). The author discusses wrongful life actions as genetic counselling torts, and notes that few successful wrongful life actions have been brought. He concludes, however, that the action for wrongful life has sound foundations in tort law, though some courts have been reluctant to consider whether no life might be worse than life. Only three states have allowed a claim for wrongful life, namely California, New Jersey and Washington. See, e.g., Turpin v. Sortini, 31 Cal. 3d 220, 643 P.2d 954, 182 Cal. Rept. 337 (1982); Procanik v. Cillo, 97 N.J. 339, 478 A.2d 755 (1984); Harbeson v. Parke-Davis, Inc., 98 Wash.2d 460, 656 P.2d 483 (1983); cf. Cowle v. Forum Group, Inc., 541 N.E.2d 962 (Ind.Ct.App. 1989)(wrongful life action by a healthy child of severely retarded parents in a state institution).

did not disclose his or her genetic defect or trait is liable to the other partner. But in one case[21] the court found that a physician owed a duty to the unconceived child when testing the child's sibling for a hearing defect because the effect of a genetic hearing defect on the parents and subsequent children was foreseeable.[22]

The difference between actions for wrongful birth and wrongful life have also been discussed.[23] New York, for instance, rejected the action for wrongful life, asserting that there was no legal right to be born without deformity, and that the monetary value for the damage of being born was not calculable.[24] The wrongful life action was, however, upheld in California. The case involved a laboratory's failure to diagnose Tay-Sachs in a genetic test. The parents' suit against the laboratory on behalf of the child was upheld.[25] The wrongful life and wrongful birth causes of action are not determinative on the question of the duty owed by one of the partners to a marriage to inform the other of his or her genetic defect. Since the consequences of such failure to inform may give a right of action to the child, there would seem to be justification for allowing one parent to claim against the other.

The right not to know has never been declared though writers have taken positions on the issue. Robertson believes that court "mandating that persons

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[21]Turpin v. Sortini, 31 Cal.3d 220, 643 P.2d 954 (1982).

[22]See Thomas D. Rogers III, Wrongful Life and Wrongful Birth: Medical Malpractice in Genetic Counselling and Prenatal Testing, 33 S.C.L.REV. 713 (1982); Melinda A. Roberts, Distinguishing Wrongful from 'Rightful' Life, 6 J.CONTEMP. HEALTH L. & POL'Y 59 (1990).

[23]Berman v. Allen, 404 A.2d 8 (N.J. 1979) where the court upheld a wrongful birth action but denied a suit for wrongful life.

[24]Becker v. Schwartz, 386 N.E.2d 807 (N.Y. 1978).

[25]Curlender v. Bio-Science Laboratories, 165 Cal.Reptr 477 (1980).

learn their carrier status or fetal status cannot be justified."[26] Holtzman makes a similar point, noting that just as not allowing people to have their genetic information would be a violation of reproductive autonomy, so would forcing them to have the information,[27] though there is no logical inconsistency between the two positions.

The protection of the right not to know may run into other difficulties. If a genetic disease is treatable, it may be the duty of the parent to provide medical care for their children. To do so, they must first become aware of the disease. The law does impose legal duties to take affirmative action to safeguard the welfare of other individuals when a special relationship exists between the parties to create such a duty. The case of Tarasoff v. Regents of University of California[28] is frequently cited for this proposition, and the medical profession appears to have been mesmerized by a decision which imposes new affirmative duties on physicians. The case involved a psychiatrist who was sued because he failed to warn a person that one of his patients had expressed an intention to go out and kill his former wife. When he did, the physician was held liable for failure to warn. It is difficult to analogize the situation presented in Tarasoff with the case of a physician who fails to warn a pregnant patient of adverse genetic outcomes. Nonetheless, the case is frequently referred to in the literature on a physician's duty to advise parents of possible adverse outcomes. One need not rely on Tarasoff, however, to conclude that in the ordinary course of good medical practice, a physician has a duty to give information to a patient

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[26]J.A. Robertson, Procreative Liberty and Human Genetics, 39 EMORY L.J. 697, 716 (1990).

[27]HOLTZMAN, PROCEED WITH CAUTION, at 246, supra note 4.

[28]17 Cal.3d 425, 551 P.2d 334 (1976)

on potential adverse outcomes when the physician has reasons to know of such a possibility. Holtzman notes that as a matter of professional ethics, physicians should refuse to perform genetic testing if the results cannot be released to the spouse. He believes that since most testing is conducted for reproductive planning purposes, both partners are entitled to the information. If it is good professional ethics to provide the information, there seems to be little reason not to require it as a matter of law.

Conclusions

Although the legal right not to know has never been established by statute or case law, there is general consensus that persons have a right to protect themselves against information they do not want. With respect to such untreatable and deadly diseases as Huntington disease, the International Huntington Disease Association (IHA) and World Federation of Neurology (WFN) research group on Huntington's chorea has prepared guidelines for the protection of such interests which have been widely accepted. The same approach is followed in the 1992 report on Genetic Testing and Privacy by the Privacy Commissioner of Canada and the 1993 report of the Institute of Medicine on Assessing Genetic Risks.

The need to protect persons who are in the latent stage of Huntington disease against knowledge of their condition ought not to affect our judgment with respect to the true nature of autonomous decisionmaking, which leaves it to the patient in every instance to decide whether he or she wants the information, regardless of its nature. Persons should be free to know or not to know, as they see fit, and excessive protectiveness may also work to deny autonomous decisionmaking. Persons differ with respect to their capacity to accept bad news, and persons also have different life styles and plans in dealing with such news,

which ought to be respected.

In instances where the news is not devastating, and where knowledge may well impose responsibilities, the right not to know should not become a shield to prevent individuals from recognizing and meeting legal obligations. Where a patient is under an obligation to inform another of his or her condition so that the other person may take steps to protect him/herself, the right not to know is inappropriate. Although there is currently no legal obligation for any person to inform his or her marriage partner of genetic traits or conditions, the law may in due course impose such an obligation, and when it does, as is here recommended, the right not to know -- when it is easy enough to find out -- ought not to be available as a defense when there is a duty to inform.

The right not to know has clear implications for physicians' ethical and legal obligations. Apparently none of these obligations are covered by law, and physicians generally feel bound to protect their patients against information they do not want. In instances where there is no current duty of a marriage partner to inform his or her spouse, a physician might well be considered in breach of obligations of confidentiality if information is conveyed to the spouse. In light of the desirability of spousal information, it is recommended that the law be changed to permit a physician to provide the information to a spouse without fear of a lawsuit for breach of confidentiality. Note that the proposal here is not to impose an obligation on the physician to tell, but simply to free him or her of liability if he/she regards it as a professional obligation to inform the spouse.

Chapter 9. Legal Sanctions for Violations of Genetic Privacy

Although the right to privacy has been the subject of hundreds of articles and dozens of books, the legal protection of privacy is very thin. This is true of the protection of privacy generally, and particularly of the protection of genetic privacy. Although violations of privacy very frequently lead to discriminatory practices in employment and insurance, violations of the right to privacy and discrimination have generally been treated separately in law and legislation.

Early protections of privacy involved common law protection against the unauthorized commercial use of a person's name or image,[1] but there were no effective general protections of privacy under common law. The generally statutory patient-physician privilege does not establish a right of privacy generally, but protects the patient against disclosures by the physician of information obtained in the process of diagnosis and treatment. The patient-physician privilege is clearly applicable to genetic information obtained by the physician in the course of diagnosis and treatment.[2] The patient-physician privilege grows out of the physician-patient relationship, and does not apply to third persons who discover such information outside that relationship.[3]

Constitutional protections of privacy are not only limited in scope but also difficult to vindicate. There is no express constitutional right of privacy in the U.S. Constitution nor in any state constitution. However, the Constitution

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[1]Supra at Chapter 1, page 8.

[2]PROSSER AND KEETON ON THE LAW OF TORTS §117, at 851-52 (5th ed. 1984). See discussion supra at ch. 1, page 8.

[3]REPORT OF THE PRIVACY PROTECTION STUDY COMMISSION, PERSONAL PRIVACY IN AN INFORMATION SOCIETY at 285 (1977).

contains an express prohibition of unlawful searches and seizures, which covers a person's right not to be subjected to genetic testing against his or her will. The constitutional right of privacy applicable to procreation and to the marital relation in general, first articulated in Griswold v. Connecticut,[4] is a construct created from other express constitutional rights, including the protection against searches and seizures, the protection of due process, and the violation of the right to the equal protection of the law.[5] To the extent that privacy related to genetic information ties into procreational decisions, it is protected by the constitutional protections relating to such information and decisions.[6] Since it is not an express constitutional right, it is clear that its protection must be articulated in appropriate judicial decision or by legislation, but no case directly involving genetic privacy has thus far come to the United States Supreme Court, and there has been little by way of effective legislation to provide for its vindication.

Elements of privacy protection are found in the Freedom of Information Act which became law in 1974. Section 552a applies to government records maintained relating to individuals and defines "record" as:

> any item, collection, or grouping of information about an individual that is maintained by an agency including, but not limited to, his education, financial transactions, medical history, and criminal or employment history and that contains his name, or the identifying number, symbol, or other identifying particular assigned to the individual, such as a finger or voice print or photograph.[7]

The disclosure of a personal record without the consent of the individual to whom

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[4]381 U.S. 479 (1965).

[5]See Chapter 3, Constitutional Protection of Genetic Privacy and Related Interests, supra at 73.

[6]LAURENCE H. TRIBE, AMERICAN CONSTITUTIONAL LAW §15-10, at 1337 (1988).

[7]5 U.S.C. §552a(a)(4) (1974).

the record pertains is limited to certain conditions specified in the statute. The conditions are very broadly defined and include disclosure for law enforcement purposes, disclosure to Congressional committees with appropriate jurisdiction, disclosure to a court with competent jurisdiction, or to a person pursuant to a showing of compelling circumstances affecting the health or safety of an individual if upon such disclosure notification is transmitted to the last known address of the individual to whom the record pertains.[8]

The Freedom of Information Act also excludes from disclosure "personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy."[9] However, in order to be protected the information must first get into the official files.

The provisions of the Freedom of Information Act of 1974 which pertain to the exception of personal information and which set forth Congressional findings and statements of purpose were initially referred to as the Privacy Act of 1974. The reference in the note is to 5 U.S.C. §552(a) referring to records maintained on individuals. An important amendment took effect in 1988, entitled "Computer Matching and Privacy Protection Act of 1988,"[10] which deals with matching programs involving any computerized comparison of two or more automated systems of government records or of a system of records with state or local records undertaken for the establishment of eligibility for benefits under designated federal programs or for the recouping of payments or delinquent debts under federal programs or the comparison of federal personnel or payroll systems with

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[8]5 U.S.C. §552a(b) (1974).

[9]5 U.S.C. §552(b)(6) (1974).

[10]Pub.L. 100-503, codified as amended at 5 U.S.C. §§552a(a)(8) to 552a(a)(13), 552a(e)(12), 552a(f), 552a(o) to 552a(q) (1988).

non-federal records of a similar nature. Such computerized matching programs and the results of matches are limited to certain designated purposes including ferreting out ineligible beneficiaries of aid programs. The computer compares the records of two separate data bases, looking for individuals or organizations that appear in both files. This produces a list of "raw hits," which become the subject of additional investigation. The information provided by program applicants also may be compared with data in other government files.[11] Under the act, there must be a matching agreement between the two agencies whose data will be matched. The agreement must specify the purpose and legal authority for the matching program and describe the nature of the match and the expected results. It must also include procedures for notifying individuals affected by the match, for verifying information, and describing how the records will be protected. Before any adverse action is taken based on the computer match, independent verification of information resulting from the match is required unless independent verification is unnecessary, which imparts a measure of discretion into the determination. Affected individuals must be given notice and an opportunity to contest findings resulting from a computer match.[12]

Whether genetic information may be included in a matching program is not entirely clear. The statute states that "matches performed to support any research or statistical project, the specific data of which may not be used to make decisions concerning the rights, benefits, or privileges of specific individuals are not included under the term 'matching program.'"[13] Genetic

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[11]H.R.Rep. No. 802, 1100th Cong., 2d Sess., reprinted in 1988, U.S.C.C.A.N. 3107, 3110.

[12]H.R.Rep. No. 802, 100th Cong., 2d Sess., reprinted in 1988 U.S.C.C.A.N. 3107 (summarizing 5 U.S.C. §552a(o)).

[13]5 U.S.C. §552a(a)(8)(B)(ii)

information could be used under certain circumstances to make decisions concerning the rights, benefits or privileges of specific individuals, thus making this section of the statute appear applicable. The Computer Matching and Privacy Protection Act clearly allows the disclosure of information to the officers of both the receiving and sending agency of computer matches.

Information may be disclosed under the Computer Matching and Privacy Act only if such disclosure would be permitted under the Privacy Act of 1974. Exceptions for disclosure include disclosure for a routine use as defined in subsections (a)(7) of 5 U.S.C. §552(a)(b). Thus far all computer matches between federal agencies have come under the routine use exception which is referred to in the Privacy Act of 1974 as the use with respect to the disclosure of a record for a purpose which is compatible with the purpose for which it was collected.[14] This routine use exception appears to provide a significant element of discretion to the agency relating to the use to be made of recovered information.

Records covered by the act would include laboratories operated by government agencies, and may well deal with genome information. However, the provision would not include the records of private research laboratories that are supported by government grants.[15] The law provides for the establishment at each affected agency of a "data integrity board" to oversee and coordinate the implementation of provisions relating to data sharing and dissemination.

The limitations of the Freedom of Information Act with respect to medical records and with respect to matching programs may well have implications for genetic privacy. Genetic information may find its way into medical records of a

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[14]5 U.S.C. §552a(a)(7).

[15]Forsham v. Califano, 587 F.2d 1128, 1135 (D.C.Cir. 1978), aff'd sonom. Forsham v. Harris, 445 U.S. 169 (1980).

public nature, including, for example, records relating to Medicare and other reimbursement programs, when programs begin matching federal personnel and employment records with private personnel and employment records which may contain references to genetic information. While these are clear possibilities, no annotations or case law reports documenting specific instances in which this legislation was applied to genetic information have been found. Neither have there been any instances of the application of sanctions for the violation of the federal legislation.

The Privacy Protection Act of 1980[16] was designed to address the related harms of invasion of privacy and warrantless searches. This Act was passed in order to reverse the decision in Zurcher v. Stanford Daily.[17] Zurcher was a Fourth Amendment search and seizure case that involved a warrantless search of the offices of a student newspaper, in search of photographic evidence to identify participants in a student protest that involved an assault on police officers. The newspaper and its staff did not participate in any crime and were not suspects, but the U.S. Supreme Court in a split opinion upheld the search. The Court's opinion addresses the question of the need for a warrant, particularly in light of First Amendment concerns. The Privacy Act was written to prevent such searches and to protect third parties, especially newspapers, as sources for criminal investigation.

Under the Privacy Protection Act, it is unlawful for a government employee who is collecting evidence in the prosecution of a criminal offense to search for or seize work products reasonably believed to be intended for dissemination to the public in a book, newspaper, broadcast, or in other media in or affecting

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[16]42 U.S.C. §2000(aa) et seq.

[17]436 U.S. 537 (1978).

interstate commerce unless there is reason to believe that the person possessing the materials has committed the criminal offense to which the materials relate. Law enforcement officials may not search for or seize materials if the offense to which the materials relate consists of the receipt, possession, or withholding of such materials or information unless the information relates to the national defense, classified information, restricted data, or if immediate seizure is necessary to prevent death or serious bodily injury to a human being. This exception is designed to protect national security and protect the integrity of restricted data. A similar rule applies to searches for other documents aside from work product materials.

Section 2000aa-6 of the PPA provides for a right of civil action for persons aggrieved by a search or seizure that violates this law. The law grants a cause of action against the United States or against a state or any governmental unit acting within the scope or color of their authority. It also grants a cause of action against an officer or employee acting within the scope or color of authority if the state has not waived sovereign immunity. Good faith belief in the lawfulness of the action is a complete defense for the employee, but not for the governmental authority. Actual damages of not less than $1,000 and attorneys fees and other costs of litigation are provided for.

These remedies are exclusive of any other civil action or proceeding for conduct constituting a violation of this chapter. The Attorney General may settle a claim for damages brought under this law and shall promulgate regulations to provide for the commencement and administrative inquiry following a determination of violation of this law. Jurisdiction lies with the district courts.[18]

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[18]42 U.S.C. §2000aa-7 defines: (a) documentary materials; (b) work product materials; (c) "any other government unit". Section 2000aa-11 provides guidelines for federal officers and employees. Section 2000aa-12 provides that guidelines

The application of this provision to genetic privacy is remote and unlikely unless particular genetic information is part of the information involved in a criminal case. This situation may occur when genetic data are applied in "DNA fingerprinting," in which case genetic privacy could hardly be urged as a defense.

Other federal legislation relating to rights of privacy include the Fair Credit Reporting Act,[19] Fair Credit Billing Act,[20] and the Family Educational Rights Act,[21] and the protection against "Wrongful Disclosure of Video Tape Rental or File Records,"[22] an outgrowth of the Robert Bork Supreme Court confirmation hearing, none of which have genetic implications.

The most recent effort to protect genetic information is the Human Genome Privacy Act.[23] The bill was created/intended to safeguard individual privacy of genetic information against the misuse of records maintained by agencies or their contractors or grantees for the purpose of research, diagnosis, treatment, or identification of genetic disorders, and to provide to individuals access to records concerning their genome which are maintained by agencies for any purpose.

In an exemplary statement of the right of genetic privacy, Congress finds that the right to privacy is a personal and basic right protected by the Constitution of the United States, that collection, maintenance, use and dissemination can threaten an individual's right to privacy; that the increasing

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issued under the subchapter have the full force and effect of regulations.

[19]15 U.S.C. §1681 et seq.

[20]15 U.S.C. §1666 et seq.

[21]20 U.S.C. §1221

[22]18 U.S.C. §2710

[23]H.R. 2045, 102nd Cong., 1st Sess. (1990).

use of biotechnology and sophisticated genetic screening techniques in the advancement of the Human Genome Project and the expanded understanding of the genetic links to a variety of physical and psychological diseases and disorders have greatly magnified the potential harm to individual privacy that can occur from any collection, maintenance, use, or dissemination of personal genetic information; and that the opportunities for an individual to secure education, employment, health care, insurance, and credit, and that his or her right to due process and other legal protections are endangered by the misuse of genetic information systems. To protect the genetic privacy of individuals in informational systems maintained by agencies, Congress must regulate the collection, maintenance, use and dissemination of such information by such agencies.

The bill recites the substantial appropriations Congress has made toward the Human Genome Project and then states the purpose of the act to protect individuals with certain safeguards against the invasion of personal genetic privacy by requiring agencies -- except as otherwise provided by law -- to permit an individual to determine what records pertaining to him or her are collected, maintained and disseminated by such agencies; to permit an individual to prevent such records obtained by an agency for a particular purpose from being used or made available for another purpose without his or her consent; to permit an individual to gain access to records and to have a copy made or to correct or amend such records; to collect, maintain, use or disseminate any record of identifiable personal genetic information so as to assure that the information is current and accurate for its intended use and to provide adequate safeguards to prevent any misuse of such information; the individual to whom such records pertain may permit exceptions from the requirements with respect to personal

genetic records maintained anonymously for research purposes only. Agencies shall be subject to civil suit and criminal penalties for any damages which occur as a result of negligent, wilful, or intentional action which violate any individual's rights under the act.[24]

The term "agency" is defined as in the title of the act and "genetic information" is defined to mean any information that describes, analyzes, or identifies all or any part of a genome identifiable to a specific individual. "Individual" is defined to mean a living individual.[25]

Any individual has the right to inspect genetic information that the agency maintains about him or her and must allow the individual to have a copy of the information. The right to inspect and to obtain copies may be delegated and the agency must offer to explain or interpret the information. Agencies may require written requests for inspection and copying but must comply or deny a request for inspection within a period of ten days. No fee is to be charged for access or copying.

An agency is not required to permit inspection or copying by an individual if the information consists of psychiatric, psychological, or mental health treatment notes and the agency does not permit disclosure of such notes to any person not engaged in treatment of the individual except with the individual's authorization or under compulsion of law. There is no right to inspect information that relates to individuals other than the subject individual or if the disclosure of the information would constitute a danger for the physical safety of any individual, or if the information duplicates information available for inspection under earlier provisions. In the case of information consisting

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[24]Human Genome Privacy Act §2.

[25]Id. at §101.

of psychiatric, psychological or mental health treatment notes, the agency must permit information to be inspected and copied by a person selected by the individual who is a licensed or certified health professional, an attorney, a family member, or any other person permitted to be designated under state law. The agency is not under an obligation to permit inspection and copying by a family member selected by the individual if this would cause harm to the individual or to a family member so as to outweigh the desirability of permitting access. In that situation, the agency must permit the individual to select another person in accordance with earlier provisions. If the agency denies a request for copying or inspection under the section, it must provide the individual or his or her designated representative the written statement of the reasons for denial.[26]

An agency that maintains genetic information about an individual must take certain action within 45 days if the individual requests in writing that the agency correct or supplement the genetic information. The agency may make the amendment requested and inform the individual or his representative that the amendment has been made or inform the individual of the reasons for its refusal to make the amendment, indicating any procedures for further review and the individual's right to file with the agency his reasons for disagreeing with the agency's refusal, and thereafter in any subsequent disclosure of the disputed portion of the genetic information, the agency must include a copy of the individual's statement.[27] The agency must prepare a written notice of its genetic information practices, describing the procedures under the law as well

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[26]Id at §111.

[27]Id. at §112.

as procedures adopted by the agency.[28]

An agency may not disclose genetic information about an individual except to the individual or to his or her designated representative unless the individual has authorized disclosure under §115 of the act, or unless the disclosure is permitted under Part C of the act without such an authorization. The person to whom disclosure is made must be properly identified and the disclosure must be limited to the information authorized to be disclosed and only for the purpose specified within the authorization.[29]

Authorization for disclosure of genetic information must be made by the individual in writing, dated, and signed. The agency must be specifically named or generically described in the authorization as authorized to disclose the information. The person to whom the information is to be disclosed must be specifically or generically described in the authorization as a person to whom such information may be disclosed. The information to be disclosed must be described in the authorization, and the purpose of the disclosure must be specified. A disclosure must occur before the date or event specified in the authorization, which is the date or event upon which the authorization expires. The individual may revoke or amend an authorization in writing in whole or in part at any time except when action has already been taken in a reliance on the authorization. Agencies must maintain copies of authorizations.[30]

Similar rules relating to authorizations apply to government contractors and grantees who are to be considered employees of the agency, subject to the same obligations as the agency.

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[28]Id. at §113.

[29]Id. at §114.

[30]Id. at §115.

The bill sets forth the rights of incompetents. It allows the individual's next of kin to exercise the rights of the individual if the individual suffers from a medical condition that prevents him or her from acting knowingly or effectively on his or her own behalf.[31] Special provision is made for the rights of minors. A person who is 18 years of age or older has full rights under the act, or any individual who acting alone has the legal capacity to apply for and obtain genetic information and who sought such information, may exercise the rights of an individual under this title. The reference here is to young persons acting as emancipated minors.

Individuals under 14 years of age can only exercise their rights through parents or legal guardians. Fourteen to 17 year olds may exercise the right of inspection, amendment, and the right to authorize the disclosure of genetic information either by themselves or by their parents or legal guardians.[32]

Provision is also made for the disclosure of genetic information without authorization. The act provides that the law shall not be construed to require an agency to disclose genetic information without the authorization of the individual to whom it pertains. The agency may impose additional requirements for disclosures that are made without such authorization.

Information may be disclosed without authorization to a person who has a need for the genetic information in the performance of his duties. Such genetic information may not be further disclosed except as provided in the law.[33]

Genetic information may also be disclosed by the agency about an individual without authorization if the disclosure is to a medical professional who will use

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[31]Id. at §117.

[32]Id. at §118.

[33]Id. at §122.

the information in connection with the care or treatment of a specific individual. Note that the section does not provide that it is the treatment of the individual to whom the information pertains. But if genetic information about an individual is disclosed under this section and is used in connection with the care or treatment of another individual, it must not be further disclosed except where required by law or necessary to fulfill the purpose for which the information was obtained.[34]

Genetic information about an individual may also be disclosed without authorization if the disclosure is based on the reasonable grounds to believe that the information is necessary to assist in the identification of a dead individual or as an aid to that dead individual's relatives; to alleviate emergency circumstances affecting the health or safety of any individual; or in clinical care or adoption situations where reasonable efforts to locate an individual or individuals to secure voluntary consent to disclosure have failed and where the disclosure of genetic information to identifiable third parties is likely to prevent serious harm to such third parties as long as there is no objection by such third parties.[35]

No authorization disclosure is necessary if the disclosure of genetic information is directed by a court in connection with a court-ordered examination of an individual.[36]

The Human Genome Privacy Act reflects a first effort to balance the requirements of genetic privacy and the protection of the right of access by any individual to his or her own genetic information with certain designated public

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[34]Id. at §123.

[35]Id. at §124.

[36]Id. at §125.

needs for the information. In a sense, the bill provides a skeleton for further amplification and for detailed statements relating to the specific purposes for which access to genetic information of an individual will be allowed without his or her authorization. As proposed, the bill is overbroad with respect to the need of an employee of the agency for the information "in the performance of his duties." The bill is also inadequately specific with respect to disclosures to medical professionals for purposes of care and treatment without specifying the precise circumstances under which such disclosure is authorized and specifically referring to the kind of care and treatment for which the information will appropriately be needed. Some attention should be paid, too, to protecting against further disclosures by persons who have obtained the information without specific authorization. The disclosure for the alleviation of emergency circumstances also needs to be more specifically described and there needs to be some limitation as to who is to be the recipient of such information in emergency circumstances. Similar specificity is probably necessary also with respect to the exception to the authorization requirement in order to "prevent serious harm."

The provision relating to disclosures directed by a court are open ended and provide no guidance as to the circumstances in which a court may order the disclosure of genetic information and in connection with the particular nature of examination of an individual that is sought.

The Human Genome Privacy Act was introduced by Congressman Converse, Chairman of the Committee on Government Operations. The bill was referred to that committee, which provides some indication that it was considered a significant measure, and that the purposes of the bill and its coverage are deserving of full attention, because they reflect the thinking of significant interests in Congress.

The protection against genetic discrimination has not as yet been expressly incorporated in any federal legislation. The Americans with Disabilities Act (ADA)[37] enacted in 1992 is not a law to protect against genetic discrimination but a law to shield Americans with disabilities of whatever kind against discrimination in the workplace. While the law clearly covers persons who are manifestly disabled by genetic ailments, the law has not been interpreted to cover non-manifest genetic disorders.[38]

The Human Genome Privacy Act should be reintroduced and supported. It is the only sound piece of legislation on the subject that has attained public attention and it needs support at this time.

The discussion of remedies and sanctions for violations of privacy, or breaches of privacy, ought to consider the reasons for such breaches in order to develop more effective policy responses. In general, much privacy is breached by stupid or idle gossip. There seems to be little that can be done about that, unless the gossip is picked up and becomes an item in the media, in which case some of the privacy torts, referred to earlier in the discussion of common law remedies for violations of privacy, would become applicable.[39]

Major breaches of privacy occur because there is an incentive to breach it. As in Warren and Brandeis' day, the media have an insatiable taste for personal information of a highly invasive nature because the public will buy more papers or listen to more television programs -- the incentive for publication and invasion of privacy -- which would clearly include genetic data -- is the desire for economic gain through greater increase in circulation and more profitable

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[37]42 U.S.C. §12101 et seq. (1992).

[38]See chapter 7 Discrimination in the Workplace at 223.

[39]See discussion <u>supra</u> at page 20.

dissemination of the story.

Other breaches of privacy earlier discussed in this report include invasions of privacy by insurance companies. The incentive in that instance is clearly the insurance company's desire to maximize profits in the sale of health insurance and life insurance by reducing or avoiding liabilities.[40]

A similar incentive for the invasion of privacy on the part of employers is the avoidance of employees' health insurance costs, as well as the avoidance of expensive organizational problems, such as the replacement of key executives because of illness, or the replacement of key personnel of a highly trained technical nature.[41]

The law seeks to prevent breaches of privacy, as indicated in the earlier discussion of legislation, either by imposing civil liabilities as in the case of lawsuits for the commission of privacy torts, or by imposing criminal liability with fines or jail terms. The use of criminal liability for privacy violations is reflected in recent privacy protection legislation for persons who suffer from AIDS. There are very few cases in which criminal liability for privacy breaches has been imposed, and there are not very many cases in which civil liabilities for violations of privacy have been imposed either. Because such sanctions and remedies have apparently had little impact on the violation of privacy in the past, another additional avenue should be explored to limit or control the invasion of privacy by reducing, or by doing away with the inducement to privacy violations, by taking the gain or profit out of breaches of privacy. In the case of violation of genetic privacy by insurance companies, the enactment of a universal national health plan which would cover everyone, including persons

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[40]See chapter 6 supra at 150.

[41]See chapter 7 supra at 203.

suffering from a genetic disease or trait. When legislation provides for general insurability of all, there would no longer be any point in discriminating against persons with genetic problems. This assumes that such a national health insurance scheme would include coverage of persons with particular longlasting and expensive to treat illnesses.

A national health plan would also reduce employment discrimination because it would reduce the employer's risk in hiring persons with genetic illnesses or traits, particularly with respect to insurance costs. It would also reduce the risk of employers in having to replace highly trained key personnel, because it would significantly broaden the pool of available employees.

Unfortunately, there is no practical remedy for media dissemination of highly personal news, because any limitation on the dissemination of highly personal material is likely to run into the protections of free expression under the First Amendment. Considering the freedoms to be protected, this is not too high a price to pay.

Conclusion

The protection of privacy, and particularly the protection of genetic privacy, has been minimal. Remedies and sanctions are few and weak, and enforcement is lacking. Aside from some common law remedies and some state statutory remedies for breaches of confidentiality, there are virtually no remedies. The federal Privacy Act and other federal privacy legislation protects against breaches of privacy by the government itself, but currently has little scope in the area of genetic privacy. Other federal privacy legislation does not address issues of medical or genetic privacy.

The Human Genome Privacy Act, proposed in 1990, reflects some thorough

Congressional work on the subject, and though some parts of it should be strengthened, on the whole it is the best effort ready for legislative action, and it ought to be supported.

In addition to sound legislative protection for genetic privacy, breaches of genetic privacy should be discouraged by reducing the incentive to violate privacy, either by insurers or employers, by the enactment of a universal health insurance measure, to provide for general insurability as well as for insurability of hard to treat and expensive disorders, including genetic illnesses.

PART II. THE USES OF GENETIC INFORMATION IN PUBLIC HEALTH PLANNING AND PROGRAMS

Chapter 10. Introduction - Use of Genetic Information to Advance Public Health Programs

1. Genetics in Public Health

This entire study was undertaken to address legal issues arising from the use of new genetic information from the Human Genome Project. The first part of the study addressed issues of privacy and autonomy in the use of such information for private decisionmaking, primarily in procreational decision-making. The second part of the study as proposed in our grant application to the Department of Energy projected the study of legal and related issues arising out of the use new knowledge from the Human Genome Project in public decisionmaking.

The two parts of our study are closely related, because the ability to make informed and effective autonomous decisions on the basis of genetic knowledge is dependent on the availability of public services and facilities. The very acquisition of new knowledge needed by individuals for decisionmaking purposes may depend on the availability of screening or testing facilities, the availability of laboratories to examine the results, the availability of geneticists to interpret them, the availability of genetic counselors to explain their meaning to the patient, and the availability of hospitals -- and third-party reimbursement arrangements -- for whatever follow-up may be necessary.

The second reason for the inclusion of an analysis of public initiatives in medical genetics is a matter of continuity of current concerns with past public efforts in the field. The U.S. has had a public health program in medical genetics since 1972. Issues of public initiatives in the field are not recent,

though new developments and the acquisition of new knowledge call for reconsideration of the legal problems raised by such public initiatives.

The third reason for the consideration of legal issues of public health arising from recent genetic knowledge is the public pressure which such new knowledge will inevitably create to apply this knowledge in public programs. New knowledge recently publicized relating to the multifactorial genetic basis for colon cancer and breast cancer are likely to provide pressures to establish public programs to deal with these illnesses. Even if public initiatives in these areas will not be forthcoming, issues of regulatory control will demand attention. With the development by the pharmaceutical industry of new drugs and of many new diagnostic kits and devices, issues of economic control and concerns of quality control will demand public attention.

The fourth reason for attention to legal issues of public health arising from new genetic knowledge is the Human Genome Project itself. The Human Genome Project which is expected to spend some three billion dollars on its research agenda during the next several years has already been challenged by a number of critics who view it as spendthrift big science. Though one may be convinced, as we are, that the Human Genome Project must be big science by the nature of the task it has set itself, a significant response to the big science charge are the big benefits which will result from the undertaking. These results will ultimately be translated into public programs to make genetic diagnostic services as well as follow-up services available, or to provide for appropriate quality controls for laboratory services, for new pharmaceuticals, and for other appropriate controls on the dissemination of diagnostic and other materials growing out of recent developments in genetics.

A very detailed and searching study by a committee of the Institute of

Medicine came to the conclusion, in an otherwise admirable and impressive study, that medical genetics was not appropriate for the development of public health programs, because in the view of the committee, medical genetics did not meet the paradigm of public health.[1] Whether medical genetics meets the paradigm of public health is a separate issue. But it is clear that the provision of opportunities for diagnostic testing and for appropriate follow-up, as well as the regulation of clinical laboratories and the supervision of the quality and dispensing of medical appliances and pharmaceutical substances to be used in self-administered tests are common public health activities, i.e., they call for government controls for the protection of public health in the usual course of the work of public health agencies.

Our report recounts the early development of genetic programs through federal and state legislation. It also recounts the parallel development of medical societies and the development of mechanisms for the accreditation of professionals in the field of medical genetics, so that such groups may be entrusted with tasks of standard-setting and accreditation. Such activities, as the setting of standards for professionals in the field and for the accreditation of such professionals are commonly attributes of public health programs.

Our report then continues with an account of the roles geneticists perform in testing, screening and diagnosis of patients and in undertaking appropriate preventive and therapeutic measures. The effort here will be to comment on and discuss the policy issues surrounding a public health program in genetics. The idea of a genetic public health program makes some knowledgeable people recoil, in the fear of launching some novel eugenic enterprise. This is clearly not

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[1]Committee on Assessing Genetic Risks, Division of Health Sciences Policy, Institute of Medicine, ASSESSING GENETIC RISKS: IMPLICATIONS FOR HEALTH AND SOCIAL POLICY at ch. 5, 9 & Ch. 8, p.10 (1993) [hereinafter IOM Report].

proposed here. Indeed, there has been a public health program in genetics ever since the passage of the National Sickle Cell Anemia Control Act of 1972, discussed in greater detail infra. What is here discussed -- and supported -- is the public involvement and support for the establishment of facilities and for the support of public health undertakings to assist persons with genetic conditions and traits to obtain appropriate testing and screening and to obtain the help necessary for them to make well-informed choices regarding their own health and regarding the health of their families and children. What is here discussed is a program of a public nature which will do for persons with genetic illnesses and traits what public health has long done for persons with infectious disease, or for persons who were at risk of contracting infectious disease. Similar to the communicable disease area, where preventive measures include the immunization of groups within the population who are at risk of contracting an infectious disease, such as children at risk of contracting a variety of childhood diseases, a program which addresses genetic conditions, illnesses and traits is primarily preventive in nature and meets the primary purpose of public health, which is the prevention of disease and the improvement of health generally.

As noted, the recent report published by the Institute of Medicine[2] has taken the position that genetic disease falls outside of the general paradigm of the commonly accepted range of the usual communicable disease control of public health. This report takes the position that the Institute of Medicine is in error. In the view here adopted, the paradigm of public health to prevent disease and advance the public health is broad enough to accommodate the area of genetic illness as readily as that of communicable disease, and that mandatory controls

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[2]IOM Report, supra note 1.

are not the defining element of public health programs.

To ease the concern that any public health oriented activity in the area of genetics will have eugenic implications, the materials here submitted provide support for the idea that public health efforts related to genetics can, must, and will remain free of any eugenic taint.

The emphasis here will be on the normal tasks of public health as applied to genetic illness. To make good on the promise of personal autonomy in making genetic choices, the matter of access to facilities and services will be stressed. What is to be emphasized is access to facilities to offer premarital, preconceptual, prenatal and newborn genetic testing as part of a genetic diagnostic program. In addition to access to facilities, there must also be assured access, physical and economic, to available genetic services. This should include the availability of necessary personnel support, including qualified physicians and geneticists, qualified laboratory personnel, and properly trained genetic counselors. There should also be properly equipped facilities for prenatal and postnatal treatment to the extent such treatments are available. What is here recommended is not a mandatory program of screening and testing. The only mandatory program recommended is a mandate to government to provide access to genetic services. The mandate is not to individuals to be tested, but to government to make it possible for individuals to be tested if they need or want such tests.

To provide proper access, the knowledge of the availability of facilities and personnel must be conveyed to the public. As part of the provision of access, public information and public health education programs relating to genetic illness should be established, supported and maintained. In a broader sense, access requires outreach by facilities and programs, so as to inform persons with

genetic illnesses or traits of the availability of help. This will involve in some situations the identification of at risk groups who are the appropriate population for outreach programs.

Important developments in the area of public health protection are taking place with respect to occupational health and safety. Screening and testing for genetic diseases that may involve both genetic propensities and environmental exposures in the workplace may not as yet be appropriate, but it is clear that recent developments in the diagnosis of multifactorial genetic illness may make it possible in the foreseeable future to undertake occupational health programs relying on genetic testing and screening.[3]

2. Changes in the Orientation of Public Health -- from Regulation to Rendition of Services

The traditional public health process is to focus on a disease which creates a problem to public health, to identify risk factors, including vectors and manner of communication, to develop and test possible interventions, to implement these interventions, to evaluate their effectiveness, and to develop a national program or a more narrowly focused regulatory program depending on the nature of the issue. For many years, and until the appearance of AIDS, public health relied on the state exercise of regulatory elements of the police power, the power to protect and advance public health, safety and welfare, reaching its goals primarily by regulatory means. Thus many diseases were successfully overcome by mandatory immunization, such as vaccination, and by measures which were challenged and upheld against the assertion that they violated due process,

[3]See discussion of genetic testing and screening in the workplace, at chapter 7, supra.

i.e., in that they deprived persons of life or liberty without due process of law.[4] Similarly upheld were such restrictive measures as quarantine, contact tracing in the case of sexually transmitted diseases, and commitment to communicable disease hospitals when, but for such commitment, there was a real danger of communication of serious or deadly communicable disease to others, as in the case of tuberculosis. While many of these measures have gradually become used less and less frequently, because of a general improvement in sanitation and reduction in the prevalence of communicable diseases, and while public health had long insisted on the least restrictive method of treatment, nonetheless the field had long kept mandatory measures in reserve, in the event of the occurrence of major public health problems which arguably required their application.[5] The advent of AIDS at a time when there was greater consciousness of protection of civil liberties, protections against discrimination, and protection of privacy, began a process which drastically changed the balance of public protection vs. protection of individual privacy rights to come down more heavily on the side of protection of privacy concerns.

The first group to be affected by the AIDS endemic were white homosexuals, generally middle class and sufficiently secure economically to pick up the legal challenge. The political activism surrounding the "exceptionalist"[6] policies regarding AIDS have been documented.[7] In spite of the "special stigma"[8] AIDS was

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[4]Jacobsen v. Massachusetts, 197 U.S. 11 (1905).

[5]FRANK P. GRAD, PUBLIC HEALTH LAW MANUAL 74 (Am. Pub. Health Assn., 2d ed. 1992).

[6]NATIONAL RESEARCH COUNCIL, NATIONAL ACADEMY OF SCIENCE, THE SOCIAL IMPACT OF AIDS IN THE U.S. 10, 26 (1993) [hereinafter NRC].

[7]See RONALD BAYER & DAVID KIRP, AIDS IN THE INDUSTRIALIZED DEMOCRACIES: PASSIONS, POLITICS AND POLICIES (1993) [hereinafter Bayer & Kirp]; for a more detailed discussion of "exceptionalist" policies regarding AIDS, see RONALD

supposed to bring with it, public education and information programs were successful in bringing about the passage of legislation to prohibit AIDS discrimination in insurance and employment.[9] In addition, in fighting AIDS, unlike other communicable diseases,[10] reliance on mandatory testing was outlawed, placing emphasis on voluntary testing and full confidentiality of test results. To be sure, information on sexually transmitted diseases has always been subject to the highest level of confidentiality within departments of health,[11] and there is no evidence that this confidentiality has ever been breached. Nonetheless, neither HIV nor ARC are reportable in all jurisdictions,[12] with only AIDS falling into the reportable category.[13] In most systems of public health control, the category of reportable diseases makes a significant

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BAYER, PRIVATE ACTS, SOCIAL CONSEQUENCES (1989).

[8]Larry Gostin, Hospitals, Health Care Professionals, and AIDS: The "Right to Know" the Health Status of Professionals and Patients, 48 MD. L. REV. 12,46 (1989), quoted in Snyder v. Mekhjian, 593 A.2d 318 (N.J. 1991).

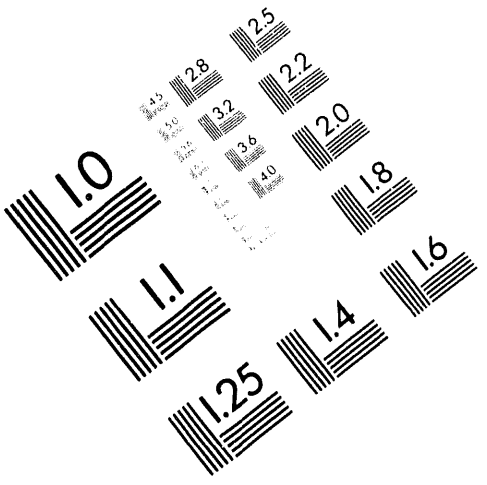
[9]See, e.g., N.Y. PUB. HEALTH §2785(1)(b) (Supp. 1993) entitled, "AIDS Testing and Confidentiality of HIV Related Information."

[10]Modes of transmission for AIDS for public health concern include transmission sexually by homosexual or heterosexual intercourse; by sharing infected hypodermic needles; by blood transfusion of infected blood; through open lesions or wounds; or transplacental transmission from mother to child, and transmission in breast milk.

[11]No cases have been reported involving disclosure or breach of confidentiality by public health officials.

[12]"Moves to extend such reporting requirements to HIV infection have been fiercely resisted by gay groups, civil liberties organizations, and others because of concerns about privacy and confidentiality. Public Health officials in areas with a large number of AIDS cases also tended to oppose reporting because of the potential negative impact on the willingness of individuals to seek voluntary HIV testing and counseling. Such concerns also informed the recommendations of the Institute of Medicine (1988a) in its report, Confronting AIDS." NRC, supra note 6, at 30.

[13]"A diagnosis of full-blown AIDS has been a reportable condition in every state since 1983." Id. at 30.

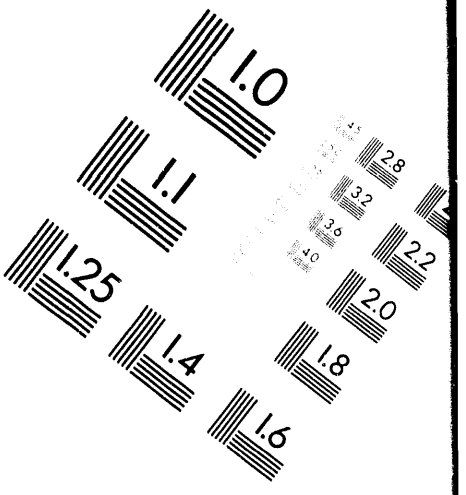


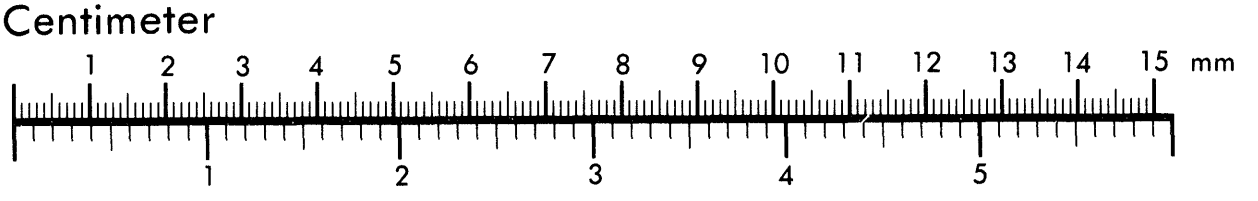


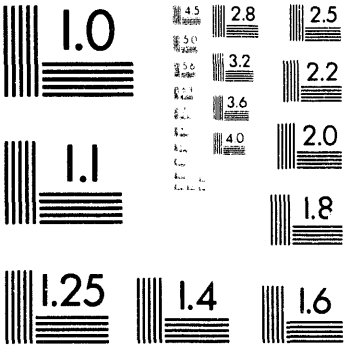
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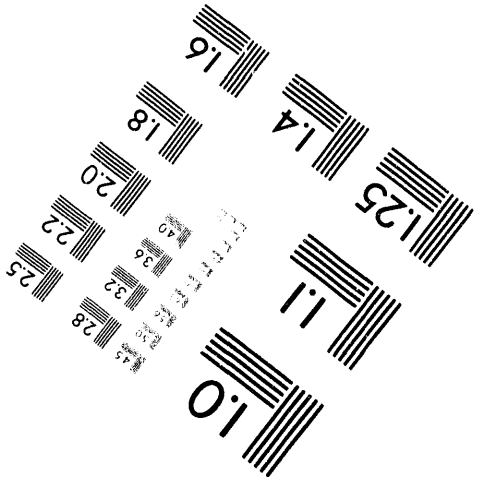
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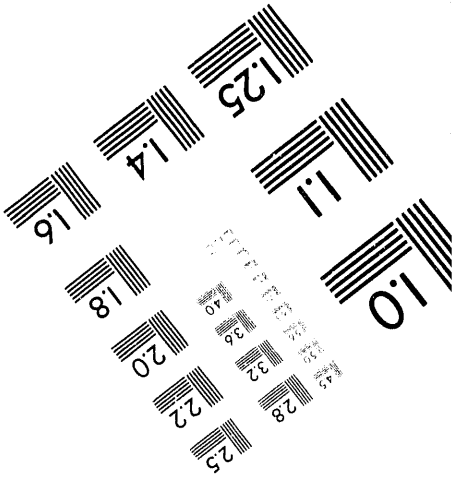
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difference, because normally it is the reportable diseases that provide the basis for other public health interventions. In some states, such as in New York, where HIV is not a reportable disease, the usual requirements for contact tracing, as in the case of other sexually transmitted diseases, thus were not applicable. Special privacy protections in the case of AIDS also mean that a physician who diagnoses his/her patient as afflicted with AIDS is not required to provide this information to the patient's spouse or companion. So highly valued is the protection of the confidentiality of test results that when a newborn infant is tested for AIDS, as most of them are, the test result may not be conveyed to the mother because it would provide her with information which she did not seek and may not desire, even though such information may affect her future conduct, particularly with respect to the possibility of further pregnancies.[14]

Though AIDS and genetic conditions have little in common, privacy issues arising in the area of genetics often encounter legal decisions arrived at in the context of AIDS. Though such specific precedents may not be particularly helpful because of the different contexts in which they arose, it is clear that AIDS has brought about a general change in public health approaches, and it is likely that a number of these approaches will have lasting effects outside the area of AIDS. The National Academy of Sciences, in its report on The Social Impact of AIDS in the United States,[15] described this dichotomy between the older "coercive" model

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[14]Ronald Bayer, AIDS and the Future of Reproductive Freedom, 68 MILLBANK Q., Suppl. 2179 (1990). See also: SOCIAL IMPACT OF AIDS IN THE UNITED STATES 215 (Albert R. Jansen & Jeff Stryker eds., 1993) [hereinafter SOCIAL IMPACT].

[15]SOCIAL IMPACT supra note 14, at 25; Bayer & Kirp posit two "polar ideal types" of a "contain and control strategy" and a "cooperation and inclusion" strategy which are blended in public health practice. Bayer & Kirp, supra note 7, at 5.

of public health policy and the newer persuasive approach.[16] Bayer and Kirp differentiate between a "contain and control strategy" and a "cooperation and inclusion strategy," differentiating between the two approaches in that the contain and control strategy would seek by compulsory means to identify those with HIV infection and then to isolate them as a way of preventing the further spread of disease, and a cooperation and inclusion strategy which would attempt to engage those most vulnerable to AIDS through education, voluntary testing, and counseling, and by protecting their privacy and social interests as members of the commonwealth.[17] Though the older, "coercive" model is still widely relied on in such contexts as compulsory immunization, it is clear that the "cooperation and inclusion strategy" is more widely advocated today, despite the threat of the newer, drug resistant strains of tuberculosis.[18] Bayer and Kirp suggest that the public health practice in AIDS will blend both of these approaches, and it is likely that this will be the case as well in other areas of public health management. The "cooperation and inclusion" strategy is also in line with the

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[16]NRC, supra note 6, at 25. See also David J. Rothman, The Single Disease Hospital: Why Tuberculosis Justifies a Departure That AIDS Does Not, 21 J. L. MED. & ETHICS: THE DUAL EPIDEMICS OF TUBERCULOSIS & AIDS [Ron Bayer, Nancy Nebeloff Dubler, and Laurence O. Gostin, eds.] 296 (1993), "Although HIV disease has set a new model for resolving the tensions between civil liberties and public health interests, with an unprecedented commitment to privacy and autonomy, the resurgence of tuberculosis has sparked new and troublesome concerns."

[17]Bayer & Kirp, supra note 7, at 5.

[18]See David A. Hansell, Comment, The TB and HIV Epidemics: History Learned and Unlearned, 21 THE JOURNAL OF LAW MEDICINE & ETHICS, 376, 377-8. "In response to the widespread recognition of a second TB epidemic in recent years, the public health approach to infectious disease epidemics is, in a symbolic sense, approaching one full revolution. . . . What emerged instead was a 'voluntarist' strategy which recognized that for a number of reasons, HIV was likely to be more amenable to an approach that focused on public education behavioral change, and incentives to seek care or treatment . . . the opposition between traditionalist TB coercive strategies and voluntarist HIV strategies does epitomize the underlying conceptual frameworks."

changes in public health in relying on the rendition of services more than on bare regulatory controls.

What this means in the area of genetics is an emphasis on autonomous decisionmaking, and a deemphasis on mandatory screening and testing programs. It should be remembered, however, that the approach which has been adopted for AIDS does not necessarily carry over into genetic privacy issues, and while there have been many cases that deal with issues of privacy in AIDS, it is difficult to point even to a single case that has made similar protections applicable to genetic privacy. But there is little doubt that privacy issues in the future will pay due regard to the protection of autonomy, privacy and confidentiality, as well as to the related idea of informed consent. Does this mean that mandatory approaches to genetic screening and testing should necessarily be barred from public health initiatives in the prevention of genetic illness? Perhaps such mandatory approaches should be limited to the narrow areas where, for a variety of reasons, they may be necessary. To the fullest extent possible, reliance in testing and screening should be on voluntary participation and informed consent. There may be situations, such as, for instance, in the case of newborn testing for PKU, when such informed consent may be spurious or impossible to achieve. In the case of newborn testing, the decision will not be made by the person affected in any event, but will be the consent of another person, i.e., surrogate consent by the mother. There may be other instances when the value of personal autonomy and personal decisionmaking may have to yield to significant long-term interests of another persons which might be disregarded if formal consent is insisted upon. The application of the preference for autonomous decisionmaking and informed consent will be further analyzed, in the context of particular testing and screening decisions in genetic decisionmaking.

To demonstrate the extent to which earlier ethical and legal determinations in the AIDS area have parallels in the field of genetics, we may cite the following fairly limited examples:

(1) Both in the AIDS area and in the field of genetics, test results relating to the newborn infant will provide information which the mother may not have requested, may not want and would prefer not to have. Most recently, this has raised special problems in that physicians or counselors are reluctant to inform the mother that her child has AIDS or a harmful genetic trait, even though such information may and possibly should affect the mother's future procreative behavior -- whether or not to have another child.

(2) Both HIV positivity and evidence of certain genetic traits may provide evidence that the person or his or her family may cast substantial burdens on health insurance costs, most likely giving rise, in both instances, to insurance discrimination.[19]

(3) Full informed consent and counseling are necessary both in AIDS testing and in testing for genetic conditions. In both instances, both pretesting and

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[19]There are a number of reported cases of such discrimination based on AIDS or HIV positivity. Bayer & Kirp cite a survey by the American Civil Liberties Union that found more than 13,000 complaints of HIV-related discrimination between 1983 and 1988, with a substantial increase in later years. Bayer & Kirp, supra note 7, at 19. Regulations promulgated by the Insurance Commissioner of Mass. in order to prohibit discrimination in insurance based on HIV infection or HIV risk were successfully challenged in Life Insurance Company of Mass. v. Commissioner of Insurance, 530 N.E.2d 168 (Mass. 1988). The concept that discrimination on the basis of AIDS constitutes valid grounds for a cause of action was articulated in Mule v. First Colony Life Insurance, 127 Bankr. 82, 1991 U.S. Dist. Lexis 4006 (1991). Note that Mule is a bankruptcy case where the trustee was charged with failure to include AIDS discrimination claims as an asset. The history of discrimination against persons with AIDS in the insurance and employment context has also been documented, and it has been held under ERISA that employers are allowed to change the health insurance coverage provided for employees so as to avoid substantial liabilities for the care of AIDS victims. McGann v. H&H Music Company, 742 F.Supp. 392 (S.D.Tex. 1990). Compare chapter 6 on genetic insurance discrimination.

posttesting counseling should be provided for, because in both instances, in consenting to the diagnostic test, the person should have full information on the implications of positive findings. Informing a person that he or she is HIV positive should not be done unless appropriate counseling services and other support services are immediately available. The same is true of the disclosure that a genetic test has shown that the person has Huntington's chorea and is likely to suffer the full expression of the disease at some future time.

Perhaps another, more useful analogy is the following: Both genetic disease and AIDS, particularly AIDS in the early days, shortly after its emergence, call for public health initiatives in terms of efforts at public information and public education. The story of AIDS in this respect is most impressive in that it shows what a thorough public education program can achieve. The AIDS education campaign, for instance, included the mailing of a simple, straightforward booklet to every family in the country under a cover letter and signature of the Surgeon General, Dr. Charles Koop. The substantial success of this educational campaign can be surmised from the change in the character of new AIDS cases, resulting in the reduction of cases from the early at-risk groups, at whom early educational efforts were first directed, and the later awareness of the number of cases from groups that had not been affected earlier to the same extent. While it is probably easier to explain the mechanics of AIDS transmission than to explain even some of the simpler aspects of the transmission of genetic disease, the AIDS experience with public education is encouraging, in that though easier to comprehend than genetic concepts, AIDS education had to overcome the early barrier of preventing the spread of a disease to and from such disfavored groups in the population as homosexual men and drug addicts, and had to address the general population to make special efforts on behalf of such disfavored groups

more acceptable.[20]

3. Genetics in the Public Interest: Avoidance of Genetic Discrimination

Any proposal of the uses of genetic information in a public health program raises the specter of old eugenics programs, and even of the racist policies, persecutions, and the crimes of the Holocaust. Both the murderous Nazi policies and the American nativist eugenics movement were based on abysmally bad science. Unfortunately, even the results of good science can be abused for racist and discriminatory purposes, though modern genetics has nothing in common with earlier efforts to create a specially favored race of men.

The aims of contemporary genetics are not to advance racial purity or to improve any particular part of the human breed. As long as genetic insights and knowledge help to make individual procreative decisions or to prevent or cure genetic illnesses, the purpose is the usual purpose of medicine: to cure the ill and to prevent human disease. This is true even in situations where public health practice requires the identification of particularly susceptible groups in the population in order to provide testing or monitoring services for purposes of prevention or treatment, as in making available to designated Eastern European Jewish groups for testing for Tay-Sachs or African Americans or Mediterranean groups to test for sickle cell anemia. As recently as twenty years ago, during the ill conceived first federal sickle cell anemia program, such group designations raised the possibility of the identification of members of the group, likely to be followed by discriminatory measures.

With increasing concern for the prevention of discrimination and for the

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[20]"Education, it was broadly agreed, had to be the centerpiece of the effort." NRC, supra note 6, at 26.

advancement of equality of treatment generally, measures to identify population groups for special health protection should not give rise to such fears when there is no discriminatory purpose and when emphasis on public health education and on greater genetic literacy will seek to resolve difficulties, and prevent efforts of abuse. Our knowledge of past abuses, the fact that groups concerned are politically aware, politically articulate, and not likely to tolerate such abuses provides some assurances that abuses of genetic information for eugenic or racial, religious or ethnic discriminatory purposes are not likely to recur in the future. It is true that the past history is discouraging, but must that mean that we must forever view "the Past as Prologue."[21]

The past history of the American eugenics movement has been relied on to make the argument that much genetic investigation and even the Human Genome Project itself will inevitably lead to genetic discrimination. Much of the argument is based on evidence of past racial discrimination in the rendition of health services generally and in the way in which public health programs have been administered. To be sure, the history of the 1920s is most discouraging. The Nativist American Eugenics Movement, largely based on the "Eugenics Record Office," of Cold Spring Harbor, Long Island, collaborated with other groups who objected to the huge rise of immigration from Central and Eastern Europe to the United States between 1880 and 1924.

The movement led to the enactment in 1924 of the Immigrant Restriction (or Johnson-Reed) Act of 1924. The act restricted immigration to the United States of Russian and Polish Jews, Italians, and other Central Europeans who were said to have had a greater number of inborn socially inadequate qualities including

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[21]Patricia King, The Past as Prologue: Race, Class and Gene Discrimination in GENE MAPPING: USING LAW AND ETHICS AS GUIDES 94 (George Annas and Sherman Elias, eds. 1992) [hereinafter King].

insanity, feeblemindedness, dependency, criminal behavior, deformities, and tuberculosis than the older Nordic and Anglo-Saxon stock. The act imposed severe quotas for the purpose of maintaining the racial and ethnic status quo in the United States. During the Progressive Era, from 1900 to 1920, there was a general desire to apply so-called scientific approaches to managing the ills of society. A form of Social Darwinism was adopted leading to extolling the Anglo-Saxon heritage and encouraging virulent prejudice against such allegedly inferior races as Russian Jews and Southern Italians, as well as persons of color. There was a fear that unlimited immigration of such "inferior" groups would dilute and weaken the native stock with undesirable inheritable traits, including degenerative illness, feeblemindedness, poverty, insanity, and certain infectious diseases such as typhus and cholera. The prevailing trend of the time has been described as a "quarantine mentality" advancing the separation of healthy society from others labelled ill or abnormal.[22] The work of Charles B. Davenport and the Eugenics Record Office was well supported financially by a number of prominent members of American society and was also accepted by a number of members of Congress who relied on pseudo-scientific charts, tables and graphs illustrating the genetic inferiority of Central European immigrants.[23]

The nativist American Eugenics Movement also led to the enactment in a number of states of laws providing for the sterilization of certain categories of persons of degenerate or inferior quality, frequently as part of the

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[22]Howard Markel, The Stigma of Disease: Implications of Genetic Screening, 93 AM.J.MED. 209-211 (1992). The impact of the Johnson-Reed Act during the Nazi period in Germany was to allow the Principal Investigator's family to enter the U.S. because they were born in Vienna, Austria, but to exclude his grandmother, who was born in Poland and came to Vienna at the age of three months. (She and other members of the family died at Auschwitz.)

[23]Id.

sentencing process, or as part of a process of institutional treatment. Charles B. Davenport and others associated with the Eugenic Records Office at Cold Spring Harbor favored the sterilization of hereditary paupers, criminals, feebleminded, tuberculars, shiftless and ne'er-do-wells.[24] At the turn of the century, states began enacting involuntary sterilization laws to deal with idiots and imbecile children, and hereditary criminals and otherwise genetically defective persons. By 1931, about 30 states had enacted compulsory sterilization laws including mostly the "insane" and "feebleminded" in their coverage. These categories as such laws were interpreted included recent immigrants and others who were functionally illiterate and who did poorly on I.Q. tests. The law also often extended to sexual perverts, drug fiends, drunkards, epileptics, and others considered ill or degenerate. While most of these laws were not enforced in all of the states, by January 1935 some 20,000 people in the U.S. had been involuntarily sterilized, mostly in California. The California law was not repealed until 1979.[25] Some 19 states had laws that permitted the sterilization of mentally retarded persons.[26]

It is against this background that Justice Oliver Wendel Holmes in 1927 wrote the opinion in Buck v. Bell[27] which has haunted the field of genetics for

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[24]ALLAN CHASE, THE LEGACY OF MALTHUS: THE SOCIAL COST OF THE NEW SCIENTIFIC RACISM 124 (1977).

[25]RUTH HUBBARD & ELIJAH WALD, EXPLODING THE GENE MYTH: HOW GENETIC INFORMATION IS PRODUCED AND MANIPULATED BY SCIENTISTS, PHYSICIANS, EMPLOYERS, INSURANCE COMPANIES, EDUCATORS, AND LAW ENFORCERS, 19-21 (1993) [hereinafter HUBBARD & WALD].

[26]Arkansas, Colorado, Connecticut, Delaware, Georgia, Idaho, Kentucky, Maine, Minnesota, Mississippi, Montana, North Carolina, Oklahoma, Oregon, South Carolina, Utah, Vermont, Virginia and West Virginia. PHILIP R. REILLY, THE SURGICAL SOLUTION: A HISTORY OF INVOLUNTARY STERILIZATION IN THE UNITED STATES, 148 (1992).

[27]274 U.S. 200 (1927).

many years. The oft-cited opinion concluded with the assertion that "Three generations of imbeciles are enough."[28] The case involved the enforcement of an involuntary sterilization law in the state of Massachusetts that called for the sterilization of feebleminded persons in state institutions. Carrie Buck was ordered sterilized on the basis of "proof" that she was the feebleminded daughter of a feebleminded mother and had herself given birth in the institution to a feebleminded daughter. The sentence was carried out shortly after the decision in 1927. Subsequent investigation seemed to show that none of the three generations of women involved in the case were really feebleminded.[29] Although the case has never been formally overruled, it has been thoroughly undermined and sidelined by the decision in Skinner v. Oklahoma.[30]

We need not rehearse the outrages of the Nazi holocaust which was based in its entirety on racist notions and which used racist theories as a basis for the murder of six million people because they were viewed as subhuman.[31] In addition to Buck v. Bell, opponents of the Human Genome Project on eugenic grounds are also likely to cite other instances of involuntary sterilization, in particular,

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[28]274 U.S. at 207.

[29]C.L. Gaylord, The Sterilization of Carrie Buck, 83 CASE & COM. 5, 18 (1978). The author's investigation showed both that Carrie was not feebleminded and that her daughter was a bright child. The comment also reviews sterilization legislation developed in the course of the eugenics movement in the earlier part of this century.

[30]316 U.S. 535 (1942).

[31]See generally WHEN MEDICINE WENT MAD: BIOETHICS AND THE HOLOCAUST (Arthur L. Caplan, ed., 1992). See especially Gisela Konopka, The Meaning of the Holocaust for Bioethics; Benno Muller-Hill, Eugenics: The Science and Religion of the Nazis 43-52; Arthur 1. Caplan, How Did Medicine Go So Wrong? 53; George J. Annas, The Human Genome Project in Perspective 301-319.

the cases that arose out of the early sickle cell anemia program.[32]

Another example of the racist nature of American medicine and of American medical research is the so-called Tuskegee Institute Study which involved the intentional failure to treat African Americans in Macon County, Alabama, who were suffering from syphilis.[33]

Scholarly writings about the Human Genome Project and government programs relating to genetics do not generally oppose such investigations on the grounds that the project is designed to create a master race, or to advance the kind of eugenic principles supported by the nativist American eugenic movement. The objection is generally that in a racist society such as ours, the result of genetic investigation is not going to benefit disadvantaged groups, but rather that it will exacerbate existing racial discrimination.[34] The point is also made that even if the Genome Project yields medically useful results, these will be used as are other medical services in our society, to benefit the dominant group in society rather than groups that have been traditionally discriminated against.[35] In addition, it is likely that in the course of mapping and

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[32]Such cases grew out of the botched sickle cell anemia program in the 1970s. Such mismanagement and racial discrimination occurred in treating people who carried the sickle cell trait as though they were ill and disabled. Women who were believed to carry the sickle cell trait were urged to be sterilized as in the well known case of Avery v. County of Burke, 660 F.2d 111 (4th Cir. 1981) in which a young woman was wrongly advised as to her condition and was pressured into consenting to sterilization. Following sterilization, testing showed that she did not have the sickle cell trait. For more detailed discussion, see History of State Genetic Programs, chapter 12 infra at note 55.

[33]TROY DUSTER, BACK DOOR TO EUGENICS 83-86 (1990) [hereinafter DUSTER]. See generally King, supra note 21 at 96-98; Hubbard & Wald, supra note 25 at 16.

[34]King, supra note 21 at 96-98; DUSTER supra note 33, at 83-86; HUBBARD & WALD, supra note 25 at 16.

[35]See generally DUSTER, supra note 33 at 86-87; HUBBARD & WALD, supra note 25 at 159.

sequencing the human genome, correlations will emerge between genetic characteristics and race or ethnicity.[36] In the view of some opponents, the rather substantial amounts to be spent on the Human Genome Project would be better spent on other social projects to improve the lot of the poor, and racial and other minorities. Hubbard and Wald believe that the trend is to overstate the significance of genetic factors and downplay the importance of environmental carcinogens.[37] Duster would like to see more money spent on primary care to pregnant women and on efforts to reduce their smoking and alcohol intake.[38] Instead of spending tremendous amounts on genetic research, he recommends that we spend more on cervical cancer studies and other non-genetic programs.[39]

Other objections to the Human Genome Project are based on the circumstance that it is "big science" which in some authors' view is likely to be less productive of results than less momentous initiatives which will produce more, better, and more usable results by disadvantaged groups in the population. The emphasis in the view of Hubbard and Wald should not be on the significance of the genetic factors, but should rather be on destructive carcinogens in the environment.[40] In general, opponents stress that human problems today are not based on inheritance and genetics but rather on environmental factors and factors that involve social structure. In some views, the emphasis on inheritance and genetics undermines efforts to clean up the environment and take steps to improve our society.

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[36]See King, supra note 34; DUSTER, supra note 33, app. at 160-62.

[37]HUBBARD & WALD, supra note 25 at 83.

[38]DUSTER, supra note 33 at 117.

[39]Id. at 121.

[40]HUBBARD & WALD, supra note 25 at 83.

There is much in these views that deserves attention and respect. But the Human Genome Project, and any public health efforts that may emerge from it, ought not to operate under the shadow of the old eugenics. Modern public health efforts utilizing new genetic discoveries and scientific insights do not rely on mandatory testing. The proposal made here is not for mandatory testing except insofar as mandatory newborn testing for PKU and some other diseases is currently part of the law of several states.

The proposal here made does not fall under the strictures of the critics of any purported new genetics. The only mandatory features proposed are requirements imposed on government to make facilities for genetic testing and facilities to carry out other autonomous choices available to the fullest extent possible to the population that requires them regardless of ability to pay and on a basis which does not discriminate against anyone, except on the basis of a need for services.

The fear of the abuse of genetics for eugenic purposes, or for discriminatory purposes, is based on a historical slippery slope argument. Because government has made rotten choices before and has done cruel and indefensible things, the argument goes, government cannot be trusted to do any better in the future, but on the contrary, having done so badly in the past, it is likely to do worse in the future because the greater knowledge obtained through the Human Genome Project will put it in a position to do even worse.

There is no logical response to such arguments. Ultimately, such arguments are based on belief or disbelief, trust or distrust. Perhaps there is no overwhelming reason why we should trust our government with respect to the Human Genome Project. On the other hand, at this juncture we have no particular reasons stemming from the Genome Project itself why we should not accept the assurances

of its basic scientific direction. The public health program here proposed seeks to avoid both the taint of eugenics and of genetic discrimination. Clearly, any kind of regulatory program has political aspects, and any program that provides opportunities for genetic discrimination ought to be opposed politically and ought not to be authorized or funded. If special watchdog committees to accomplish such a purpose are necessary, then thought should be devoted to the creation of appropriate safeguards so as to prevent any threat of genetic discrimination from arising. The Human Genome Project is indeed a grand undertaking and some of us like grand undertakings more than others. But a major scientific initiative ought to be allowed to proceed, no longer in the shadow of long-dead eugenic ideas. A public health program which is primarily a service program, and which consciously avoids discriminatory elements should not be tarred with the eugenics brush.

Chapter 11. The History of the Federal Genetic Programs

The first major federal legislation concerning genetic screening was the National Sickle Cell Anemia[1] Control Act of 1972[2] which was repealed and supplanted by the current laws for block grant legislation. Four Congressional Committees held hearings on the bill in October and November of 1971, which resulted in changing the bill's name and increased funding.[3] The Act was passed as the difficulties in the growing number of state screening programs (described became evident. It authorized $85 million in grants-in-aid[4] over a three year

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[1]National Sickle Cell Anemia Control Act of 1972, Pub. L. 92-294, 86 Stat. 136 (Originally Codified in Scattered Sections of 42, 33 U.S. C. Supp. II, 1972) [hereinafter National Sickle Cell Anemia Control Act].

[2]President Nixon highlighted Sickle Cell anemia in his health message, February 18, 1971. The President proposed up to $5 million in federal spending, but the U.S. Congress responded with a much more ambitious proposal, proposing $100 million for over three years. Senator John Tunney of California introduced S. 2676, a bill originally entitled the National Sickle Cell Anemia Prevention Act. Tunney's bill proposed spending for three purposes: (1) voluntary sickle cell anemia screening and counseling, (2) public education and (3) research on the disease, its prevention, and its treatment. PHILIP REILLY, GENETICS AND THE LAW 65 & 78 [hereinafter REILLY].

[3]The Department of Health Education and Welfare (DHEW) approved the proposal on the following grounds: (1) genetic testing legislation should not be disease specific; (2) more research was needed before effective service programs could be designed and (3) the proposed access of the general public to Public Health Service facilities. Id. at 78-79.

[4]FRANK P. GRAD, PUBLIC HEALTH LAW MANUAL 13 (American Public Health Association, 2nd ed. 1990) [hereinafter GRAD] defines grant-in-aid programs as follows: "Grant-in-aid programs involve a grant of funds by the federal government to a state or to a municipal government for a particular legislatively defined purpose. The state or local government may obtain the grant funds and spend them for the designated purpose if it accepts the conditions of the grant. These conditions usually require the [entity] to provide some matching funds, but, more important from the point of view of the exercise of federal authority, the conditions generally require the state to comply with certain federal requirements or to carry out the purpose of the grant in certain prescribed ways. An early grant-in-aid program, the Hill-Burton Hospital Construction program, now replaced by Subchapter IV, on Construction and Modernization of Hospitals and other Medical Facilities, provides for the federal funding of state hospital

period for establishment and implementation of voluntary testing and counseling.[5] Grant-in-aid programs provide funding to state governments and municipalities so long as those government entities meet certain conditions expressly set forth in the federal legislation.[6] They have authorized research and educational programs.[7] A key aspect of the law, found in Section 1103, was that participation in any program under the law was voluntary, and participation in sickle cell programs could not be made a prerequisite to participation in any other programs.[8] Thus, voluntary participation is an early requirement of genetic programs. Consistent with the protection of the autonomy of individual participants, Section 1104 required all grant or contract applicants to state in

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construction programs and of nonprofit community hospitals."

[5]$85 million was appropriated with an additional $30 million for research into diagnosis treatment and control of the disease; public education programs and development of treatment and counseling. REILLY, supra note 2 at 79. However, no funds were appropriated using this authorization, according to SHERMAN ELIAS AND GEORGE ANNAS, REPRODUCTIVE GENETICS AND THE LAW 77 (1987). According to Legislative Testimony from Senator John Tunney, (California), "The problem is that the administration and HEW have decided not to use the law, as is passed, as you and I and the cosponsors have hoped for. Unfortunately, they have decided they are going to ignore the authority of the act, apparently because they do not want a line appropriation for sickle cell anemia. They prefer to fund the program under general authority through the National Heart and Lung Institute budget and through the HEW general budget." U.S. SENATE COMMITTEE ON LABOR AND PUBLIC WELFARE, SUBCOMMITTEE ON HEALTH, AMENDMENTS TO REVISE PROGRAMS FOR SICKLE CELL ANEMIA AND OTHER GENETIC DISORDERS, July 15, 1975. U.S. Government Printing Office, Washington, D.C. 1975 at 81.

[6]GRAD supra note 4 at 14, "Through these categorical grant-in-aid programs, the federal government influences the manner in which public health is administered and the methods of service delivery".

[7]See National Sickle Cell Anemia Control Act, supra note 1 at §1101 and 1101(a)(3).

[8]Id. at §1103: "The participation by any individual in any program or portion thereof under this title shall be wholly voluntary and shall not be a prerequisite to eligibility for or receipt of any other service of assistance from, or to participation in, any other program."

their applications the methods to be employed to assure privacy protections for the information that obtained in the course of their work.[9]

The Act also provided for community outreach with especial concern for outreach to persons "entering their child producing years and . . . to children under the age of 7".[10] The latter provision created great confusion because it did not differentiate between carriers and people with disease, and it inadequately addressed the purpose of testing, since children under the age of seven were the least likely group to make good use of the information. Such children, however, did provide a good link to their parents who could use test results in deciding whether to have another child, assuming that the parents had been properly informed about the disease and that they planned to have more children in the near future. The law also required that genetic counseling be available to all "persons found to have sickle cell anemia or the sickle cell trait" at facilities that were made available under the auspices of the U.S. Public Health Service.[11]

The National Sickle Cell Anemia Control Act of 1972 was followed by the National Cooley's Anemia Control Act.[12] It followed the language of the earlier

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[9]Id. at §1104(a)(2): "Each applicant shall-- (2) provide for strict confidentiality of al test results, medical records, and other information regarding screening, counseling or treatment of any person treated except for (A) such information as the patient (or his guardian) consents to be released; or (B) statistical data compiled without reference to the identity of any such patient;."

[10]Id. at §1104(a)(4)(A): "The screening and counseling services to be provided under the program for which the application is made will be directed first to those persons who are entering their child producing years and secondly to children under the age of 7."

[11]Id. at §1105.

[12]National Cooley's Anemia Control Act of 1972, Pub.L. No. 92-414, 86 Stat. 650 (1972) [Repealed 1976]. See also Legislative History, National Cooley's Anemia Control Act P.L. 92-414 at 3112, H.R. Rep. No. 1184, 92d Cong., 2d Sess.,

act, but the new law emphasized research rather than outreach, because a reliable test for Cooley's Anemia had not yet been discovered at the time of the bill's passage. Again, the act emphasized voluntary participation. The two acts also required similar protection for confidentiality by grant or contract applicants as well as similar community outreach and access to U.S. Public Health Service facilities. This gradual policy approach, handling each disease similarly but separately, was consistent with the tradition of contemporary public health legislation. Soon thereafter, the National Tay Sachs Control Bill was introduced, but by that time, its sponsors were persuaded that disease-specific legislation was an inefficient way to approach genetic disease programs.[13] Consequently, it was an important development when these two acts, one disease-specific bill, and increased Congressional interest regarding other genetic diseases were consolidated into one major act of legislation.[14]

In 1976 the National Sickle Cell Anemia, Cooley's Anemia, Tay Sachs and Genetic Diseases Act, ("National Genetic Diseases Act")[15] was enacted. The Act

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reprinted in 1972 U.S. Code Cong. & Ad. News 3111, 3112.

[13]The sponsors of that legislation, Senators Jacob Javits (R-NY) and Harrison Williams (D-NJ) came to support a broader approach to providing genetic testing. In the Senate hearings in 1975, Javits noted that "more than 50 genetic disorders could be detected before birth," and that "[w]hen a person is seen in a single-disease program, such as Tay-Sachs or Sickle Cell Anemia, we neglect other potential health problems which might have a genetic component." U.S. SENATE COMMITTEE ON LABOR AND PUBLIC WELFARE, SUBCOMMITTEE ON HEALTH, AMENDMENTS TO REVISE PROGRAMS FOR SICKLE CELL ANEMIA AND OTHER GENETIC DISORDERS, July 15, 1975. U.S. Government Printing Office, Washington, D.C. 1975 at 60.

[14]The alternative was to reauthorize the existing disease-specific acts, a course advocated by leading figures in sickle cell treatment, who feared that a broader approach to genetic disease would mean that the "focus on sickle cell anemia would be lost." Testimony of Dr. Charles Whitten of the Sickle Cell Detection and Information Program, Inc. Id. at 144.

[15]National Sickle Cell Anemia, Cooley's Anemia, Tay Sachs and Genetic Diseases Act henceforth "National Genetic Diseases Act" Pub. L. No. 94-278 90 Stat 407 (1976) 42 U.S.C. Sec. 300b.

was modelled on the federal sickle cell anemia and Cooley's anemia legislation but moved away from disease-specific legislation towards a uniform approach to genetic diseases. Like its predecessors, the National Genetic Diseases Act authorized the provision of voluntary testing, counselling services and for education, but unlike previous laws, it embraced many diseases within the purview of the statute. Subsection 285b-3 (I) provides for:" establishment of programs for study and research into heart, blood vessel, lung, and blood diseases of children (including cystic fibrosis, hyaline membrane, hemolytic diseases such as sickle cell anemia and Cooley's anemia and hemophilic diseases) and for the development and demonstration of diagnostic, treatment and preventive approaches to such diseases".

The extension of federal funding, and thus of uniform policies, to a wide range of genetic testing programs was partly a result of dissatisfaction with certain state sickle cell screening programs. A 1975 study by the National Academy of Sciences had criticized many sickle cell programs for unclear objectives, poor selection of target populations, little or no confidentiality, and poor counseling and public education.[16] The National Genetic Diseases Act, retained the requirements of voluntary participation and confidentiality found

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[16]See National Research Council, GENETIC SCREENING: PROGRAMS, PRINCIPLES, AND RESEARCH Washington, D.C.: National Academy of Sciences, 1975. See also PRESIDENT'S COMMISSION FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL AND BEHAVIORAL RESEARCH, SCREENING AND COUNSELING FOR GENETIC CONDITIONS: A REPORT ON THE ETHICAL, SOCIAL, AND LEGAL IMPLICATIONS OF GENETIC SCREENING, COUNSELING, AND EDUCATION PROGRAMS Washington: U.S. Govt. Printing Off., 1983 at 21; U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, CYSTIC FIBROSIS AND DNA TESTS: IMPLICATIONS OF CARRIER SCREENING Washington, D.C.: U.S. Govt. Printing Off., August 1992 at 54 [hereinafter OTA, CYSTIC FIBROSIS AND DNA TESTS].

in earlier federal legislation.[17]

The National Genetic Diseases Act authorized greater funding for genetic testing through fiscal year 1987. The act was extended and reauthorized in 1978 under the "Health Services Extension Act of 1978"[18] This law remained in effect until genetic services and seven other federal health care programs were consolidated into the Maternal and Child Health (MCH) block grant by the Omnibus Budget Reconciliation Act of 1981, (OBRA), discussed below.

The Health Services Extension Act of 1978 authorized a total of $65 million over three years for genetic services.[19] It also made three changes to the original enactment. It made a change in terminology; the act's scope was rewritten to show awareness of the distinction between genetic diseases and genetic condition.[20] Second, the legislation mandated development of a mechanism to allow public and scientific comment.[21] This recalled the National Sickle Cell Anemia Control Act's view of appropriate community representation as a means of

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[17]See the National Genetic Diseases Act Pub.L. 94-278, Title IV, §403(a). Section 403(a) created a new section 1103 in the Public Health Services Act requiring "Voluntary participation by individuals" in programs under the authority of this part, codified as 42 U.S.C. §300-b2. Section 403(a) also contained a confidentiality requirement which replaced §3(c) of the National Sickle Cell Anemia Control Act as amended, now codified at 42 U.S.C. §300b-3(a)(2).

[18]Health Services Extension Act of 1978, Pub. L. 95-626, Title II, Sec. 205; 92 Stat 3583, 3584 (1978) [Partially repealed 1981] [hereinafter Health Services Extension Act].

[19]See id. at §205(e)(1), which authorized $17.5 million, $21.5 million, and $26 million respectively for the three following fiscal years.

[20]See id. at §205(a), partially amending Section 402 of the National Genetic Diseases Act, Pub.L. 94-278.

[21]See id. at §205(c)(2), amending §1104 of the Public Health Services Act, as codified at 42 U.S.C. §300b-3, to require the Secretary to "have developed a procedure" for such outside scrutiny when making any grant or concluding any contract.

encouraging public acceptance and awareness of genetic services. Third, it allowed the Secretary to "conduct epidemiological assessments and surveillance of genetic diseases," and to provide direct "technical assistance to States," including grants for demonstration projects.[22]

After reauthorization, the National Genetic Diseases Act was used to provide federal funding for a large number of state genetic service programs. Twenty-one state programs were partially supported by such federal funds in fiscal year 1979; an additional thirteen state programs were funded in 1980.[23] These genetic service programs administered a total of over three million genetic tests and counseled over 130,000 at-risk individuals.[24] Federal legislative developments throughout the 1970s, improved tests, and a wider awareness of certain genetic disorders all contributed to a significant expansion of public access to genetic services.[25] In 1983, the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research found that the federal funding provided by the National Genetic Diseases Act, as well as better coordination of genetic services, had "played an important role" in the development of effective statewide genetic programs.[26]

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[22]See id. at §205(d)(1), adding a complete new section 1107, entitled "Applied Technology," to the Public Health Services Act, codified at 42 U.S.C. §300b-6.

[23]See Stephen J. Sepe et al., Genetic Services in the United States 1979-1980, 248 J.A.M.A. 1733.

[24]Id. Individuals were considered at-risk, and were provided counseling, only after physician referral, either because of advanced maternal age (35 years or older) or due to family histories of genetic illness.

[25]See OTA, CYSTIC FIBROSIS AND DNA TESTS, supra note 16 at 52.

[26]See PRESIDENT'S COMMISSION FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL AND BEHAVIORAL RESEARCH, SCREENING AND COUNSELING FOR GENETIC CONDITIONS: THE ETHICAL, SOCIAL, AND LEGAL IMPLICATIONS OF GENETIC SCREENING, COUNSELING, AND EDUCATION PROGRAMS 34 (1983).

The Reagan Administration undertook a sweeping 25% reduction in discretionary spending for most federal health care programs.[27] Health care cost-cutting was a part of the Administration's economic goals to reduce government expenditures, lower taxes, and achieve a balanced budget.[28] Federal spending was similarly reduced for other domestic social welfare programs such as education, employment, and energy assistance.[29] The original Reagan budget proposal was for $60 billion less for health and health-related programs than had been allocated in the Carter Administration budget it replaced.[30]

The Reagan Administration also advocated the consolidation of numerous health care programs, and the delegation of authority for those programs to state and local governments, as part of the "new federalism" championed by the President,[31] in order to promote administrative efficiency, cost containment, and program flexibility.[32] Consequently the budget allocated federal funds for genetic services and for many maternal and child health programs, through block grants to the states.

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[27]See, e.g., Health Program Spending Cut by 25 Percent, 39 CONG. Q. 1501 (1981) [hereinafter Health Program Spending Cut by 25 Percent].

[28]See, e.g., Karen Davis, Reagan Administration health Policy, 2 JOURNAL OF PUBLIC HEALTH POLICY 312, 313 [hereinafter Davis].

[29]See Kenneth R. Wing, The Impact of Reagan-Era Politics on the Federal Medicaid Program, 33 CATH. U. L. REV. 1, 36-37 (1983) [hereinafter Wing].

[30]Id. The actual decline in spending was even larger, because this figure does not include the net reduction in health care services already planned by the outgoing administration.

[31]See Ross N. Rubin, The New Federalism for Health: Shifting Responsibilities and Reducing Costs in the 1980s, JAMA 2911 (1982). See generally, e.g., B. Drummond Ayres, Jr., Reagan Again Pledges to Increase the Power of States, N.Y. Times, May 13, 1981, at A28.

[32]See Wing, supra note 29, at 37, n. 131. But cf. Andrew H. Mott, Block Grants, N.Y. Times, March 20, 1981, at A27 (critiquing the record of earlier federal block grants).

Under block grants, recipients choose whether or not to continue specific federal programs, subject to the requirement that funds must be utilized for the general purposes authorized by Congress.[33] Block grants have certain distinguishing characteristics: federal aid is authorized for a wide range of activities, recipients have a great deal of managerial discretion, federal administrative oversight is minimized, aid is distributed based upon a statutory formula, and there are eligibility guidelines which favor devolution of authority.[34] Block grants are often justified on the ground that they produce lower administrative costs and allow a flexible response to local conditions. Leading criticisms of block grants are that states cannot adequately monitor the programs, that reductions in the costs of administering programs are small in relative terms, and the approach generally leads to an uneven distribution of public services.[35]

Prior to 1981 there had been only five major federal block grants, and these efforts were focused upon localities at least as much as state governments.[36] The great majority of federal aid had always been in the form of

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[33]See Joan Schleef, Comment, Federal Funds and Separation of Powers: Who Controls the Purse?, 53 U. CIN. L. REV. 611, 611 n.1, describing the division of federal funding into unconditional grants-in-aid, block grants which can be used for broad purposes, and categorical grants-in-aid which fund specific programs. See also Health Program Spending Cut by 25 Percent, supra note 27, at 1501.

[34]See ADVISORY COMMITTEE ON INTERGOVERNMENTAL RELATIONS (ACIR), 6 BLOCK GRANTS: A COMPARATIVE ANALYSIS (1977)

[35]See Robert A. Weyer, Block Grants at the Local Level: New Jersey and the New Federalism, 5 NEW ENGLAND JOURNAL OF HUMAN SERVICES 12 (1985) [hereinafter Weyer]. See also, Davis, supra note 28 (citing a skeptical Congressional Budget Office analysis of the Reagan budget).

[36]Thomas R. Ascik, Block Grants and Federalism: Decentralizing Decisions, 144 HERITAGE FOUNDATION REPORTS 1 (1981) (for example, only local governments were included in the community development block grant). See also Weyer, supra note 35.

program-specific funding; the Reagan proposals represented a major shift from categorical funding to block grants.

Congressional opposition to the original grouping of block grants in the budget led to a legislative compromise which left some categorical health programs intact and consolidated the rest into four, rather than two, block grants.[37] These addressed preventive health services, alcohol and drug abuse, mental health, primary care, and maternal and child health.

Enactment of the Omnibus Budget Reconciliation Act (OBRA) of 1981[38] consolidated genetic services and seven other programs into a Maternal and Child Health (MCH) Block Grant.[39] The grant appears in Subtitle D of the OBRA,[40] amending Title V of the Social Security Act (SSA).[41] OBRA made some significant changes in prior law. It repealed the authorization[42] and reporting[43] sections

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[37]Reconciliation's Health Block Grants Ease Federal Control of 19 programs, 39 CONG. Q. 1502-1503 (1981) (this article provides a good summary of the block grants which emerged during reconciliation).

[38]Omnibus Budget Reconciliation Act of 1981, Pub.L. 97-35, tit. XXI, 95 Stat. 357 (1981).

[39]See OTA, CYSTIC FIBROSIS AND DNA TESTS, supra note 16, at 53.

[40]Subtitle D of the OBRA may be cited as the "Maternal and Child Health Services Block Grant Act."

[41]Social Security Act of 1935, codified at 42 U.S.C. subsection 301-1397e (West 1983 & Supp. 1991).

[42]Section 2193(b)(1) of the OBRA repealed section 1101 of the Public Health Services Act of 1944, Title XI, Section 1101, as added Apr. 22, 1976 by the National Genetic Diseases Act, P.L. 94-278, Title IV, Section 403(a), 90 Stat. 407, and amended Nov. 10, 1978 by the Health Services Extension Act of 1978, P.L. 95-626, Title II, Section 205(b), (d)(20,(e), 92 Stat. 3583, 3584, and as codified at 42 U.S.C. Section 300b.

[43]Section 2193(b)(4) of the OBRA repealed section 1106 of the Public Health Services Act of 1944, Title XI, Section 1106, as added Apr. 22, 1976 by the National Genetic Diseases Act, P.L. 94-278, Title IV, Section 403(a), 90 Stat. 407, and as codified at 42 U.S.C. Section 300b-5.

of the National Genetic Diseases Act, P.L. 94-278, among other changes in the underlying Public Health Services Act.[44] As a result, all funding for genetic screening and testing is now tied to the Social Security Act.[45] A series of conforming amendments modified federal contracting provisions for genetic services to reflect this shift between statutory authorities.[46] Transitional monies were also authorized for the next fiscal year to allow current grantees time to seek new funding sources.[47]

OBRA reflected a fragmented way of health care funding, with major impact on genetic screening programs. But it left intact certain portions of the prior statute which still remain in force. These include most of the provisions which authorize the Secretary of HHS to encumber Title V funds for research and for applied technology projects, as discussed above.[48]

The most important surviving provision of the National Genetic Diseases Act was the requirement that individual participation in federally funded testing

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[44]Public Health Services Act of July 1, 1944, codified as amended at 42 U.S.C. Subsection 201-300z-6 (1982 and Supp. III 1985).

[45]Social Security Act of 1935, Chapter 7, Title V, presently codified at subsection 701-731 (West 1983 & Supp. 1991).

[46]Section 2193 of OBRA. See Section 2193(b)(2) and Section 2192(b)(3), amending section 1104 of the Public Health Services Act of 1944, Title XI, Section 1104, as amended Apr. 22, 1976 by the National Genetic Diseases Act, P.L. 94-278, Title IV, Section 403(c), 90 Stat. 407, and as added to on Nov. 10, 1978 by the Health Services Extension Act of 1978, P.L. 95-626, Title II, Section 205(c)(1), and as codified at 42 U.S.C. Section 300(b)(-3 (which shifts authority for research contracts). See also Section 2193(b)(5), amending section 1107 of the Public Health Services Act of 1944, Title XI, Section 1107, as added on Nov. 10, 1978 by the Health Services Extension Act of 1978, P.L. 95-626, Title II, Section 205(d)(1), 92 Stat. 3584, and as codified at 42 U.S.C. Section 300b-6 (shifting authority for applied technology funding).

[47]See Section 2193(a)(1)(B) allocating $9,680,000 out of MCH for the transition period.

[48]See note 48, supra.

must be completely voluntary.[49]

Holtzman has noted the impact of these changes for health policy and public health planning, "Cutbacks in federal support for genetic services, together with a growing recognition of the market for genetic and chromosome tests, led commercial laboratories to expand their testing. A few biotechnology companies perceive a market in DNA-based genetic testing and have invested in test development. Commercial involvement will accelerate the development of genetic tests and their dissemination to the public, but it is not clear that the tests will be applied appropriately" or permit wide access.[50] It is therefore likely that these effects of the reduction of funding under OBRA will continue to have a significant impact on genetic programs for some time.

The Council of Regional Networks for Genetic Services (CORN) recently conducted a survey of state genetics services. Of the 41 state programs that responded to the CORN survey, 84% were initially established with federal funding under the Genetic Diseases Act of 1976; 77% still received some support for genetic services from the state through federal Maternal and Child Health (MCH) block grant funds. However, MCH block grants generally represented less than 25% of total state funding.[51]

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[49]Public Health Services Act of 1944, Title XI, Section 1103, as added Apr. 22, 1976 by the National Genetic Diseases Act, P.L. 94-278, Title IV, Section 403(a), 90 Stat. 407, and as codified at 42 U.S.C. Section 300b-2. This section states: "The participation by any individual in any program or portion thereof under this part shall be wholly voluntary and shall not be a prerequisite to eligibility for or receipt of any other service or assistance from, or to participation in, any other program."

[50]HOLTZMAN, PROCEED WITH CAUTION: PREDICTING GENETIC RISKS IN THE RECOMBINANT DNA ERA, 66 (1989).

[51]INSTITUTE OF MEDICINE, ASSESSING GENETIC RISKS: IMPLICATIONS FOR HEALTH AND SOCIAL POLICY, ch. 7, p. 9 (1993).

Chapter 12. The History of State Genetic Programs

Federal law had a significant impact on the enactment and administration of state law provisions, and many state laws were stimulated by federal grant-in-aid programs. Many early state and federal programs in the 60s and 70s targeted genetic screening, especially for newborns. This early state legislation provided for compulsory screening of neonates for PKU and for testing for sickle cell anemia. These early laws were often modified in the 1970s and 1980s to correct some earlier errors and misjudgments.

Mandatory testing provisions for PKU were first introduced in S. 110 A of the Massachusetts Public Health Code in 1963, following a voluntary program in 1962. With the assistance of the federal Children's Bureau and the various state associations for retarded children, PKU testing laws were passed by 43 states in the following five years. These early laws imposed a mandatory obligation to test, reporting requirements to the state Department of Health. Exceptions to the testing requirement were limited to objections on religious grounds, although meaningful opportunities to object to testing were not readily available and were controversial[52]. Under these programs, children who tested positive for PKU were placed on a special diet. Some subsequent amendments to these laws provided for voluntary testing, confidentiality, or counseling.

A second wave of state legislation began in the 1970's and provided for screening for sickle cell anemia.[53] Fear of false negatives or "missed" cases of sickle cell anemia encouraged a desire for greater numbers of tests. For

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[52]In practice, parents were not generally given an opportunity to object. See REILLY, GENETICS, LAW AND SOCIAL POLICY (1977).

[53] Other conditions included galactosemia, hypothyroidism and other rare disorders.

example, in some states mandatory testing was required for entry into high school, application for a marriage license, or during pregnancy.[54] There is evidence that in some states the sickle-cell anemia program was grossly mismanaged in the seventies, justifiably giving rise to charges of racism and abuses stimulated by eugenic notions. It is clear that women who were diagnosed (or believed) to carry the sickle-cell trait were urged to be sterilized, as in the highly publicized case of Avery v. County of Burke.[55] The appellant, Avery, brought a suit under the Civil Rights Act, 42 U.S.C. §1983, alleging that the County of Burke, its Board of Health, and several individuals wrongfully caused her sterilization after informing her that she had the sickle-cell trait. Plaintiff became pregnant at the age of 15 and sought pre-natal care at the clinic operated by the Burke County Health Department. Following a blood test she was told that she had the sickle-cell trait and was urged to consider sterilization. The appellant and her mother were told quite wrongly that a woman with sickle-cell trait is unable to take birth control pills, that childbirth would endanger her life or take two or three years off her life, and that pregnant women with sickle-cell trait are more susceptible to many diseases. The information was conveyed by nurses and physicians at the clinic. She was accompanied to state court by a Burke County social worker and based on N.C. Gen.Stat. §90-272, the sterilization was authorized. After the appellant was sterilized, subsequent testing showed that she did not have the sickle-cell trait. The Court of Appeals vacation the summary judgment of the district court

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[54]Illinois, Kentucky, Alaska and New York provided for mandatory testing for sickle cell anemia for entry into school or application for a marriage license as described in LORI ANDREWS, MEDICAL GENETICS: A LEGAL FRONTIER 233 (1987) [hereinafter ANDREWS].

[55]660 F.2d 111 (4th Circ. 1981).

and remanded the case on the grounds that genuine issues of material fact remained. One commentator noted that experiences of this nature gave rise to 257 charges that the state sickle-cell programs were racist in nature, casting a shadow on any subsequent developments in genetic programs.[56] In the 1980s, sickle-cell screening programs mandated by state legislatures were gradually replaced by voluntary programs following federal legislation. The earlier state programs with their inadequate provisions for confidentiality led to stigmatization and discrimination in employment and insurance with disastrous consequences for the African American community affected.[57]

The state sickle-cell anemia laws were grossly defective in failing to distinguish between carriers of the sickle-cell trait and persons actually ill with sickle-cell anemia. Inadequate counseling and public education meant that many people were unable to distinguish sickle-cell anemia from sickle-cell trait.[58] As a result, carriers of the trait were stigmatized and suffered employment discrimination as if they had the disease (a discrimination which was unlawful in any event).[59] The adverse effects resulting from the mishandling of state sickle-cell anemia legislation, including employment and insurance discrimination has been documented.[60]

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[56]Patricia A. King, The Past as Prologue: Race, Class and Gene Discrimination in ANNAS, GEORGE AND ELIAS, SHERMAN, GENE MAPPING: USING LAW AND ETHICS AS GUIDES, Oxford University Press, New York (1992).

[57]Id.

[58]Mark A. Rothstein, Genetic Discrimination in Employment and the Americans with Disabilities Act, 29 HOUS.L.REV. 23, 31 (1992).

[59]Cynthia S. Adelman, The Constitutionality of Mandatory Genetic Screening Statutes, 31 CASE W. RES. L. REV. 897, 912 (1981).

[60]LORI B. ANDREWS, STATE LAWS AND REGULATIONS GOVERNING NEWBORN SCREENING 2 (1985), "The public criticism of these laws focussed on the problem of stigmatization of and discrimination against carriers of sickle cell trait....The

The adverse impact of the 1970s sickle-cell anemia legislation was also noted by the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research: "For many people the overall impact of sickle-cell screening was negative: rather than providing information that enhanced choices, screening seemed to merely burden the people screened.[61] Understandably, strong resistance to sickle-cell programs resulted.[62]

In the late 1970s, Alaska, Connecticut, Maryland, Massachusetts, Montana, New York, Ohio Oregon and Rhode Island introduced screening programs for genetic disorders such as Tay-Sachs disease, adenosine deaminase deficiency, galactosemia, homocystinuria, Maple Syrup urine disease, tyrosinemia and histidinemia. Many of the issues surrounding sickle cell anemia quieted as other types of genetic testing became commonplace and as laws provided for confidentiality and voluntary participation.

In the 1980's state legislation addressed confidentiality and voluntariness

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fear that state-authorized sickle cell screening might provide a source of discrimination was not unfounded. In a paper delivered in 1972 at the National Conference on the Mental Health Aspects of Sickle Cell Anemia, Dr. James Bowman detailed some of the actual incidents of what he called 'genetic discrimination' which he maintained were engendered by screening legislation. These included to grounding of black airline employees who were carriers because of concern that they might go into a sickling crisis if the plane depressurized. In addition, insurance companies charged higher rates for carriers of sickle cell trait without substantial evidence that possession of sickle cell trait placed a person at a significantly higher risk of death or illness. And the armed forces considered deferment of sickle cell trait carriers, thereby potentially foreclosing on substantial employment opportunities for some blacks. These types of discrimination were fostered by a general misunderstanding of the nature of sickle cell anemia-- a misunderstanding embodied in the language as well as in the provisions of early laws."

[61]PRESIDENT'S COMMISSION FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL AND BEHAVIORAL RESEARCH, A REPORT ON THE ETHICAL, SOCIAL AND LEGAL IMPLICATIONS OF GENETIC SCREENING, COUNSELING AND EDUCATION PROGRAMS, Washington, D.C., U.S. Government Printing Office (1983).

[62]ANDREWS supra note 54, at 238.

of treatment programs. Several states initiated programs for parents of newborns who tested positive for various diseases, with legislative provisions that attempted to protect the confidentiality of results except for research purposes. But many programs that were initiated in the 1970's ended during the budgetary changes that came with the Reagan administration. Grant in aid programs to states were replaced with block grants, but these appropriations did not specifically designate the allocation of federal funds to genetics programs in a given state.

Chapter 13. Regional Programs for Genetic Services: C.O.R.N. (Council of Regional Networks)

The Council of Regional Networks for Genetic Services (CORN) was created in 1985 to coordinate activities among federally funded genetics research and screening networks and to implement nationally significant regional initiatives for the development of coherent genetic programming throughout the United States. Another purpose of CORN was the development of state-based regional networks for genetic planning and testing in key locations throughout the nation. CORN's mission as a federally funded project is to improve the quality, quantity and availability of cost effective genetic services nationwide.[63] CORN's goals include the development of a national system of data collection and analysis of genetic services; the establishment of national standards for quality assurance and proficiency testing of laboratories providing genetic services; the promotion of national efforts to improve professional and public awareness of human genetics and its impact on health and disease; and the advocacy of a comprehensive integrated approach in the provision of genetic services.[64] A Data and Evaluation Committee consisting of one representative from each of ten regional networks was established by CORN to provide current and comprehensive information regarding several aspects of genetic services; including newborn screening, education, finance, quality assurance and other disciplines.

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[63]COUNCIL OF REGIONAL NETWORKS FOR GENETIC SERVICES (CORN), NEWBORN SCREENING REPORT: 1990, 3 (1992).

[64]James W. Hanson, Implications of the New Genetic Technology in Health and Other State Policy Areas 31 in STEVEN R. BROWN & KAREN MARSHALL [eds], The Council of State Governments ADVANCES IN GENETIC INFORMATION Lexington Ky. (1992)

Member organizations in CORN include the ten regional networks[65], national sickle cell disease programs, the Alliance of Genetic Support Groups, genetic service providers, public health officials, consumers and other health care professionals. Like other regional networks, the Genetics Network of the Empire State (GENES), which includes New York state, Puerto Rico and the Virgin Islands, is responsible for rating the clinical genetic services provided by a the states and territories within its region. There are benefits to regional service delivery and evaluation, yet, for regional or national level planning to operate effectively, coordination of state and federal programs with activity on the local level is necessary. GENES and other regional organizations undertake this coordinating process.

Another important facet of regional planning is the potential for monitoring and promoting the funding and insurance coverage for genetic services. In 1987, the New York State Department of Health conducted a study of genetic reimbursement programs under the auspices of its Bureau of Health Planning and Policy Development. The study analyzed genetic service providers statewide to

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[65] These regional networks are:
Genetics Network of the Empire State [GENES] - New York, Puerto Rico and Virgin Islands
Great Lakes Regional Genetics Group [GLaRGG] - Illinois, Indiana, Michigan, Minnesota, Ohio and Wisconsin
Great Plains Genetic Services Network [GPGSN] - Arkansas, Iowa, Kansas, Missouri, Nebraska, North Dakota, Oklahoma and South Dakota
Mid Atlantic Regional Human Genetics Network [MARHGN] - Delaware, District of Columbia, Maryland, New Jersey, Pennsylvania, Virginia and West Virginia
Mountain States Regional Genetics Services Network [MSRGSN] - Arizona, Colorado, Montana, New Mexico, Utah and Wyoming
New England Regional Genetics Group [NERGG] - Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island and Vermont
Pacific Northwest Regional Genetics Group [PacNoRGG] - Alaska, Idaho, Oregon and Washington
Pacific Southwest Regional Genetics Group [PSRGN] - California, Hawaii and Nevada
Southeast Regional Genetics Group [SERGG] - Alabama, Georgia, Florida, Kentucky, Louisiana, Mississippi, North Carolina, South Carolina and Tennessee
Texas Genetics Network [TEXGENE] - Texas

locate gaps in incentive for third-party payer programs. As of June 1988, the Laboratory of Human Genetics administered the Department of Health's Genetic Service Program, funding 23 genetic service programs with a $2.2 million budget allocation from federal and state sources. This funding is used to pay for genetic service programs, private physicians offering services such as genetic testing and prenatal care and specialized clinics. The reimbursement study concluded that there is inadequate insurance coverage, both public and private, for genetic services, and that this lack of insurance coverage limits the utilization of genetic services.[66] Individuals requiring genetic services are divided into two categories: non-prenatal care and exclusively prenatal care.[67] In general, physician referrals are required for non-prenatal treatment insurance coverage. A family history of genetically-related disorders or high maternal age is adequate to obtain coverage for prenatal treatment. In New York, insurance coverage is more widely available for genetic lab services than for counseling, which underscores the need for clear definition of the guidelines and expectations concerning genetic counseling services.

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[66]NEW YORK STATE GENETIC REIMBURSEMENT STUDY, June 1988. (Albany: New York State Department of Health, David Axelrod, M.D., Commissioner), at 7. The study used data from more than 80% of New York's insured population.

[67]Non-prenatal care refers to treatment (counseling, laboratory testing or physician examinations) of people with genetic disabilities. Prenatal testing would refer to amniocentesis, chorionic villus sampling and other fetal tests, and to counseling for expectant parents of a child with genetic disabilities.

Chapter 14. Professional Organizations in Genetics

1. Professional Organizations in Medical Genetics

An editorial in the American Journal of Human Genetics 1992 called attention to the organizational arrangements and needs in the field of medical genetics. In the view of the writer, each medical field should have a society to provide for professional exchange of information and interaction, a board to certify practitioners and accredit training programs, and a college to establish standards for clinical practice.[68] The professional organizations currently functioning in medical genetics apparently meet these various needs to a considerable extent. The following are the major organizations in the field: The American Society of Human Genetics (ASHG), the American Board of Medical Genetics (ABMG), and the American College of Medical Genetics (ACMG).

The American Society of Human Genetics (ASHG), the oldest professional organization for medical genetics, was organized in 1948 to bring together North American researchers in human genetics. The Society has grown into an international organization for physicians, researchers, genetic counselors, and other health care professionals specializing in human genetics numbering five thousand members.[69] The ASHG sponsors an annual meeting featuring symposia, workshops, and research presentations;[70] publishes a monthly periodical;[71]

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[68]Charles J. Epstein, Editorial: Organized Medical Genetics at a Crossroad, 51 AM. J. HUM. GENET. 231, 231-232 (1992) [hereinafter Epstein].

[69]American Society of Human Genetics, 42nd Annual Human Genetics Conference Meets in San Francisco, PR Newswire, Nov. 9. 1992 (available on LEXIS).

[70]Id.

[71]The ASHG publishes the respected American Journal of Human Genetics.

expressing the opinions of the medical genetics community on medical[72] and legal[73] issues. Although its primary focus remains genetic research, over time the ASHG has developed a series of regular and ad hoc committees to address wider concerns such as the Human Genome Initiative (HGI), genetic testing, and the provision of genetic services. The ASHG plays a prominent role in clinical matters in the absence of other professional organizations with a clinical emphasis in genetics. ASHG has responded to the demands created by the profession's growth by fostering the recognition of genetics as a medical specialty.

In 1980, the American Board of Medical Genetics (ABMG) was organized under the sponsorship of the ASHG. The ABMG provides accreditation of training programs in medical genetics, and certifies qualified practitioners in this specialty and in a number of subspecialties.[74] In the latter role, as a

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[72]The ASHG and its committees issue statements on areas of concern to the Society. See, e.g., C. Thomas Caskey, M.M. Kaback, and A.L. Beaudet, American Society of Human Genetics statement on cystic fibrosis screening, 46 AM. J. HUM. GENET. 393 (1990). With regard to cystic fibrosis, the ASHG was "first to make the point that population-wide screening would be premature, given the need for education of the public and of physicians and the failure to detect a high percentage (30%) of mutations." C. Thomas Caskey and Victor A. McKusick, Medical Genetics, 263 J.A.M.A. 2654, 2654 (May 16, 1990).

[73]For example, the ASHG signed the AMA brief asking the Supreme Court to overturn a Missouri law restricting abortion in Webster v. Reproductive Health Services. See Martin Tolchin, Medical Groups Ask High Court to Reject Restrictions on Abortion, N.Y. TIMES, April 5, 1989, at A23, c. 1.

[74]There are six subspecialties as of 1992: (1) Clinical Genetics, (2) PhD Medical Genetics, (3) Clinical Cytogenetics, (4) Clinical Biochemical Genetics, (5) Clinical Molecular Genetics, and (6) Genetic Counseling. The educational credentials required for certification in each subspecialty are different. Each applicant for overall certification must sit for at least one subspecialty exam in addition to the general examination. See generally, American Board of Medical Genetics, Application for 1993 Examinations. Note however that for the first time genetic counseling will be certified through a different board after 1993. This division was established because the genetic counseling requires a masters but all other subspecialties require a doctoral degree.

specialty board, and associated with the American Board of Medical Specialties, the ABMG fulfills two functions: it assures the public that specialists in medical genetics are competent, and it creates educational and testing standards which will allow the adoption of ever-higher standards of care as the profession develops.[75] There is, of course, an important difference between state-mandated licensure to practice and voluntary certification as a specialist.[76] However, in a relatively new area such as genetic services, the certification process is important in defining the quality of the profession.[77]

The ABMG has an unusual role because it certifies both genetic counselors with masters degrees and medical doctors and other holders of doctoral credentials in genetics. There are currently no doctoral programs in genetic counseling.[78] This shared certification referred to in a 1975 ASHG committee

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[75]See AMA Council on Medical Education, Future Directions for Medical Education, 248 J.A.M.A. 3225 (Dec. 24/ Dec. 31 1982).

[76]FRANK P. GRAD AND NOELIA MARTI, PHYSICIANS' LICENSURE AND DISCIPLINE (1979). Grad and Marti explain, at 81: "Specialty board certification is not required for a physician to practice medicine or even to practice a particular specialty. Regulation of specialists' competence by specialty boards is limited, therefore, to those physicians who voluntarily seek such certification. Many seek the certification because it is an important asset. Although HEW regulations disavow any intention of having certification control staff privileges ... the very disavowal in the regulations indicates that certification still exerts substantial influence." (footnote omitted)

[77]Cf. Kathleen W. Rao, in Chromosome Analysis in the Clinical Setting, 111 ARCH. PATHOL. LAB. MED. 698, 699 (1987) who discusses the ABMG's subspecialty examination in clinical cytogenetics. Rao states that "[t]his effort to define qualified laboratory directors appears to have been fairly successful as most of the position advertisements for directors of cytogenetics laboratories list as a necessary qualification either board certification or eligibility (ABMG)" at 699.

[78]Joy Shaleban Lewis, High Technology: Genetic Counselors Multiply," N.Y. Times, March 23, 1986, at sec. 12, p. 22, c. 1. At the time there were over one thousand genetic counselors with an M.S. and 19 universities offered two year masters programs in the field. "Sensitivity as well as science serve genetic counselors," N.Y. Times News Service, Oct. 14, 1990 (available on LEXIS). There is strong support amongst graduates of these programs for the possible creation

report on genetic counseling which supported a multidisciplinary approach to providing certain genetic services and spoke of the need for "appropriately trained nurses, social workers, and/or genetic associates."[79] Joint certification was originally seen as implicit in the concept of a medical genetics center: minimizing jurisdictional issues, possible concerns about third-party reimbursement of service providers, and similar problems associated with differential treatment of genetic counselors.[80]

However, despite the current ASHG position supporting joint certification, a separate certification for genetic counselors has been proposed. The change would result in the creation of an American Board of Genetic Counseling (ABGC) to certify genetic counselors, as well as a Council of Medical Genetics Societies (COMGENS) to coordinate the various constituencies within the medical genetics community.[81] The issue arose when the American Board of Medical Specialties (ABMS)[82] agreed to admit the ABMG as a primary specialty board on an equal

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of Ph.D. programs in the field. See, for example, the survey reported in Katherine M. Gaupman, et al., The Doctoral Degree in Genetic Counseling: Attitudes of Genetic Counselors, 49 AM. J. HUM. GENET. 488 (1991).

[79]ASHG Ad Hoc Committee on Genetic Counseling, Genetic Counseling, 27 AM. J. HUM. GENET. 240, 242 (1975).

[80]Victor A. McKusick, The Growth and Development of Human Genetics as a Clinical Discipline," 27 AM. J. HUM. GENET. 261, 268-271. McCusick pointed out several factors which distinguish the field of medical genetics from more traditional specialties, including its direct growth out of a vibrant scientific discipline, and the fact that the field does not lend itself to independent practices.

[81]Epstein, supra note 68. See also Audrey Heimler, et al., American Board of Medical Genetics Restructuring: Make an Informed Decision, 51 AM. J. HUM. GENET. v-vii (1992).

[82]The ABMS was founded in 1933. It now recognizes 57 areas of general or special certification recognized by the ABMS. "Specialty boards that are constituent members of the ABMS have a unique role in American medicine." Council on Medical Education, supra note 75.

footing with all other recognized medical specialties, subject to the condition that it only certify geneticists with doctoral credentials.[83] The achievement of recognition by ABMS has met with different response in different parts of the profession.[84] Changes are contingent upon two-thirds approval by the membership of the ABMG, necessary to change its old certification standards, and upon the successful negotiation of an agreement between the proposed ABGC and the National Board of Medical Examiners to conduct new certification testing.

The newest of the three major organizations, the American College of Medical Geneticists (ACMG), is a recent spinoff of the ASHG. The College is still in its formative stages.[85] However, its creation is intended to allow the ASHG to relinquish its role in solely clinical issues and allow it to concentrate on scientific investigation and information exchange. The ACMG thus provides a way for geneticists to begin to formulate professional codes and standards, and a comprehensive system of professional self-regulation similar to that of other medical specialties.

2. Professional Standards in Medical Genetics

Despite the many ethical issues raised by genetic testing, diagnosis, and treatment, there is currently no formal code of ethics governing the field of medical genetics. This does not mean that there are no professional standards, as surveys have found a significant degree of consensus on certain key ethical

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[83]Epstein, supra note 68. Epstein notes that even the certification of Ph.D.s by a ABMS-recognized board is unusual; only one such arrangement now exists.

[84]Compare id. (a "tremendous victory for medical genetics") with Audrey Heimler, et al., op.cit. (citing the risk that genetic counselors might be relegated to a second class status in the profession).

[85]Id.

issues which face medical practitioners in this field.[86] This professional consensus finds expression through journals, meetings, and other informal mechanisms. The extensive ASHG activities have clearly facilitated the development of certain traditions in medical genetics, but as with other research-oriented medical societies, the ASHG has normally stopped short of codifying these areas of agreement.

Fletcher and Wertz have strongly criticized the prevailing informal approach on several normative grounds: (1) geneticists should be more accountable, (2) geneticists will inevitably be involved in shaping future public policy, (3) medical practitioners have an affirmative duty to make moral judgments, and (4) a profession needs a code of governing ethics.[87] A formal code of professional ethics would also have several strong practical advantages for those in the practice of medical genetics; it would provide guidance to practitioners facing ethical dilemmas, and it would help to protect geneticists who comply with this codified standard of accepted professional practice from malpractice liability.[88] The newly founded ACMG provides medical genetics with an appropriate institutional mechanism to promulgate a code of ethics regulating

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[86]John C. Fletcher and Dorothy C. Wertz, Ethics, Law, and Medical Genetics: After the Human Genome is Mapped," 39 EMORY L.J. 747. Fletcher and Wertz's twelve nation survey found "that strong agreements are present worldwide on some crucial approaches to several of the major ethical problems in the old and new genetics," at 785. The exceptions, ethical issues upon which there was no strong international consensus, were: (1) prenatal diagnosis for purposes of sex selection, (2) protection of patient confidentiality when relatives are at high genetic risk, and (3) the appropriate form of guidance in counseling impaired or incapacitated patients.

[87]Id. at 760.

[88]Ilise L. Feitshans, Potential Liability of Industrial Hygienists under USA Law Part II: Prescription for Reducing Potential Liability, 6 APPLIED OCCUPATIONAL & ENVIRONMENTAL HYGIENE 205 (1991), discusses the AAIH Code of Ethics and its implications for malpractice liability.

clinical practice (and to establish a formal system of peer review) in the future.[89]

[89]Peer review plays an important role in building public confidence in a profession, the evolution of new professional standards, and in policing otherwise unenforceable professional codes.

Chapter 15. Access to Genetic Health Services

1. Access to Genetic Testing, Prenatal Diagnosis and Prenatal Care

Access to facilities that provide genetic services is necessary to exercise autonomous choices for treatment or other courses of action. In addition, more knowledge of human genetic conditions gained from the Human Genome Project creates increasing demands for genetic services. Access requires the availability of suitable facilities and personnel, as well as equitable distribution of medical and health care services among racial, ethnic, social and economic groups.[1] There is a concern that groups currently underserved by the health care system, namely the poor, African Americans, and other underserved ethnic and social groups, will have even less access to genetic services.[2] It has been emphasized that genetic services should be provided to population groups according to the needs of each group, not according to financial status or

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[1]See, e.g., George J. Annas and Sherman Elias, The Major Social Policy Issues Raised by the Human Genome Project 3 and Social Policy Research Priorities for the Human Genome Project 269, in GEORGE J. ANNAS & SHERMAN ELIAS, GENE MAPPING: USING LAW AND ETHICS AS GUIDES (1992) [hereinafter ANNAS & ELIAS].

[2]See: TROY DUSTER, BACKDOOR TO EUGENICS (1990); Patricia King, The Past as Prologue: Race, Class and Gene Discrimination, in ANNAS & ELIAS supra note 1, at 100 [hereinafter King]. King notes that "the 'biologic underclass' may turn out to be composed of minority group members and the poor."(footnotes omitted) Abby Lippman, Prenatal Genetic Testing and Screening: Constructing Needs and Reinforcing Inequities, 17 AMER.J.LAW & MED. 15 No. 1 and 2 (1991) [hereinafter Lippman, Reinforcing Inequities] See also: Ruth Hubbard and Elijah Wald, EXPLODING THE GENE MYTH: HOW GENETIC INFORMATION IS PRODUCED AND MANIPULATED BY SCIENTISTS, PHYSICIANS, EMPLOYERS, INSURANCE COMPANIES, EDUCATORS AND LAW ENFORCERS. (1993). Lu Ann Aday, Ronald Andersen and Gretchen Fleming, HEALTH CARE IN THE U.S. EQUITABLE FOR WHOM? (1980) [hereinafter EQUITABLE FOR WHOM?] See also Stephen J. Sepe, James S. Marks, Godfrey P. Oakley, & Audrey F. Manley, Genetic Services in the United States 1979-1980, 248 J.A.M.A. 1733 (1982) [hereinafater Sepe et al.] noting that although during 1972-82 genetic services became more available, less than 50% of pregnant women who needed counselling received it. Most women who received counselling or amniocentesis obtained it by reason of advanced maternal age.

ethnicity. Unless this is done, an underserved genetic underclass will be created to whose usual discrimination will be added discrimination in the availability of genetic services.

The need for access to facilities and services is documented here as well as in other descriptions of need here cited. In the absence of any available literature on costs, no reference to such costs and to necessary approaches has been undertaken, in the belief that this should be the subject of a separate study if data are developed or become available.

In order to exercise autonomous choices, facilities must be available for genetic counselling, testing, diagnosis and treatment. Access to services not only requires the availability of such services, but the dissemination of knowledge among affected groups and persons that such services are indeed available. This may require public information, education and outreach to enable persons to make full use of available facilities.

Prenatal diagnosis, the most widespread application of genetic technology today, is as yet "a ritual of pregnancy, at least for white, middle class women in North America."[3] Its availability should not be limited in this fashion. Prenatal testing and other genetic services related to birth and services to newborns are more likely to be made available and used whenever women have received regular prenatal care in the hospital.

There is evidence that genetic services should be made more widely available. Not only is there a need for more services, but there is also a need for a greater availability and geographic distribution to make services available

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[3]Lippman, Reinforcing Inequities, at 19 citing Rayna Rapp, The Power of Positive Diagnosis: Medical and Maternal Discources on Amniocentesis in CHILDBIRTH IN AMERICA: ANTHROPOLOGICAL PERSPECTIVES 103, 105 (K. Michaelson ed. 1988) [hereinafter Lippman, Reinforcing Inequities]; See generally EQUITABLE FOR WHOM? supra note 2 at Chapter 7.

wherever necessary.[4]

As noted earlier, in the 1960s and early 1970s, limited access to genetic services was available and after the passage of the National Genetic Diseases Act, the federal government sought to expand the range of available genetic services in the United States. In fiscal years 1979 and 1980, the Genetic Diseases Service Branch of the Health Services Administration funded 34 state genetic service programs in the United States under the 1976 act. This expansion ceased after the passage of the Omnibus Budget Reconciliation Act of 1981. Services were substantially reduced when genetic services were consolidated with other federal health care programs under one block grant.[5] The Committee on Health Objectives for the Year 2000 of the Institute of Medicine noted that access to medical services generally divided along racial and ethnic lines as well as along economic class distinctions. For instance, twelve percent of Hispanics, 8.8% of blacks and 4.3% of whites did not seek and did not receive prenatal care until the third trimester of pregnancy which would clearly exclude them from any efforts at preventive care and prenatal diagnosis of genetic conditions.[6] Some of the differences in the utilization of health services are due to uneven insurance coverage and to the fact that persons who are unemployed also have no health benefits. Other differences in utilization are explained by

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[4]Lori Andrews et al, Institute of Medicine, National Academy of Sciences, ASSESSING GENETIC RISKS: IMPLICATIONS FOR HEALTH AND SOCIAL POLICY (Washington, D.C. 1993) (hereinafter IOM, ASSESSING GENETIC RISKS).

[5]Neil A. Holtzman, The Impact of Federal Cutback on Genetic Services, 15 AMER.J.MED.GENETICS 353 (1983) [hereinafter Holtzman Impact]. See also: David C. Sokal, J Rogers Byrd, Jr. Andrew T.L. Chen, Marshall F. Goldberg, Godfrey P. Oakley, Jr. Prenatal Chromosomal Diagnosis: Racial and Geographic Variation for Older Women in Georgia, 244 J.A.M.A. 1355 (1980) [henceforth Prenatal Chromosomal Diagnosis].

[6]Michael A. Stoto, Ruth Behrens, & Connie Rosemont, eds.,HEALTHY PEOPLE 2000: CITIZENS CHART THE COURSE (1990) [hereinafter HEALTHY PEOPLE] at 54.

cultural and geographic factors.[7] What is true of particular groups and areas with respect to health services generally applies to genetic testing and counseling services as well. A report found that in Georgia utilization of genetic services was substantially lower among rural white and black women than among white urban women.[8] It was noted that low utilization probably reflected lack of access to services and lack of knowledge that services were available rather than unwillingness by expectant mothers to use the services.[9]

2. Need for Facilities or Outpatient Opportunities

Access to health services has been defined as "those dimensions which describe the potential and actual entry of a given population group into the health care delivery system."[10] Under this definition, "equitable distribution" of health care services means "one in which illness (as defined by the patient and his family or by health care professionals) is the major determinant of the allocation of resources."[11] Under this approach, genetic services should be determined by health status; not financial status or ethnicity. But there is concern that persons who have limited access to genetic services as a result of financial or other disadvantages may become special targets of discrimination, as a group that will be doubly disadvantaged.[12]

The National Academy of Science Institute of Medicine in its 1993 report,

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[7]Id. at 55.

[8]Prenatal Chromosomal Diagnosis supra note 5.

[9]Id.

[10]EQUITABLE FOR WHOM? supra note 2 at 26.

[11]Id. at 41.

[12]See supra note 2.

Assessing Genetic Risks: Implications for Health and Social Policy,[13] notes that access to genetic counselling, prenatal diagnosis and treatment requires the resolution of difficult issues of ethics and funding. Designing programs to ensure equitable access to genetic services and follow-up care for everyone, in the view of the Institute of Medicine, requires not only facilities and personnel. It also requires educating the public -- which is quite ignorant of such scientific matters -- so that they understand genetic disorders and the available methods of prevention and treatment.[14] In addition, there must be information on available services, and programs to improve outreach to underserved populations.[15] There also is a need to include genetics in the training of physicians and other health care professionals. Adequate resources must be allocated for public education and outreach to targeted populations.

Facilities and personnel are also needed to offer screening (preconceptual and prenatal) as well as treatment for fetal health and services for terminating pregnancies in cases involving "therapeutic" abortions. Such programs should reach women across all classes and ethnic divisions, ensuring that they have access to prenatal care without financial, geographic or linguistic barriers.

Facilitating access also involves a needs assessment for the newborns by neonatal service providers. Key services include the capacity to test newborns in the hospital, particularly for PKU, and within the first 24 hours of life. The

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[13]See generally IOM ASSESSING GENETIC RISKS, supra note 4.

[14]Id. ch. 5 at 10, Public Education in Genetics. "Genetic testing is not an end in itself....[A] genetically literate public that understands basic biological research, understands elements of the personal and health implications of genetics, and participates effectively in public policy issues involving genetic information."

[15]Id. ch. 5 at 12: "Particular effort will be needed to include the perspectives of women, minorities, and persons with disabilities, who may feel especially affected by developing genetics technologies."

need for these services can be expected to expand after more discoveries from the human genome project are publicized.

3. Recent History of Availability of Genetic Services

In the 1960s and early 1970s access to basic genetic services (counseling, prenatal diagnosis, carrier testing, etc.)[16] was limited not only by the scope of the available science, but to those individuals who knew the services were available, had access through geographic proximity to medical centers and had financial resources to afford testing. The National Genetic Diseases Act,[17] of 1976 expanded the range of available genetic services in the United States. The new law intended to increase knowledge about genetic diseases generally, to promote wide access to services and to encourage genetics programs. In fiscal years 1979 and 1980 the Genetic Diseases Service Branch of the Health Services Administration funded 34 state genetic service programs in the United States through monies from the National Genetic Diseases Act of 1976. This legislation held great promise for expanding access, but was supplanted by the Maternal and Child Health (MCH) block grant by the Omnibus Budget Reconciliation Act of 1981 (OBRA).[18] Services were substantially reduced when genetic services were consolidated with seven other federal health care programs under one block grant, thereby decreasing funding for genetic services.

Data from annual progress reports of each program funded through the

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[16]See supra pp. 319ff.

[17]Supra Chapter 11 at note 16.

[18]Holtzman Impact supra note 5 states that the total budget for the MCH Services Block Grant was reduced so that it was less than the sum of its component parts.

National Genetic Diseases Act have been analyzed.[19] The authors note that in 1979, 21 state programs were supported in part by money from the National Genetic Diseases Act; 13 more programs were funded in 1980. Writing in 1982, the writers note that in states reporting utilization of screening in the newborn population the rate was approximately 96% ranging from a low of 86% to a high of 100%. The authors note that "although during the past decade genetic services have become more available, less than 50% of pregnant women needing counseling seem to be receiving it. The most common indication noted for women receiving counseling and/or amniocentesis was advanced maternal age." [20]

4. Access to Preventive Services

Whether or not preventive services are used, depends in major part on economic distinctions as well as on racial and ethnic lines.[21] It has been noted that for certain groups in the population, the emergency room is likely to be the point of entry into the health care system.[22] In general, minority groups receive few preventive services.[23] It is likely that this pattern will apply also in the case of diagnosis of genetic conditions and in preventive care,

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[19]Sepe et al. supra note 2 at 1733 and 1735. The authors attempted to assess the effect of genetic services in the United States on the reduction of mortality and morbidity from genetic disease and based on this data they concluded that even though the availabilty of genetic services increased, less than 50% of pregnant women who needed counseling obtained it. They therefore predicted an increase in the need for genetic services in the years ahead.

[20] Id.

[21]HEALTHY PEOPLE supra note 6. See Comments by Milton Roemer at 68 and comments of Harold Shoults at 69.

[22]Id. at 69.

[23]Id. "As discussed in Chapter 6, the poor, the homeless, and many racial and ethnic minorities have severe problems gaining access to preventive services and even basic health care."

unless special efforts are made to reach out to such groups.

While some of the racial and ethnic differences in the utilization of health services may be explained by cultural and geographic factors,[24] much of it is due to the fact that certain areas such as inner city and rural areas, particularly in the south, are underserved by health providers and have high concentrations of racial and ethnic minority groups.[25] Other reasons aside, members of such groups are more likely to be impoverished, unemployed, or employed with inadequate health benefits, and thus unable to afford genetic health services.

IOM has written about the shortage of genetic counselors and genetically-trained health professionals, with particular reference to the need for genetics training in medical schools. An older IOM report, Healthy People 2000: Citizens Chart the Course recorded the needs of underserved communities for improved health services,[26] a concern that was echoed by Annas and Elias when predicting future access to genetic services in the wake of the human genome project.[27]

The subjects of somatic gene therapy and germline therapy are not currently considered as an essential part of genetic services. While indubitably remedial in nature, the cost and as yet exceptional and unusual character of such interventions argue against their inclusion among the genetic services for which a strong argument for access can be made.

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[24]Id. for discussion of disproportionately high infant mortality among minorities at 55.

[25]King supra note 2, at 95.

[26]HEALTHY PEOPLE supra note 6 at 78.

[27]GENE MAPPING supra note 1 at 15.

5. Access to Essential Genetic Services

The following services are likely to be included as part of a medical genetics program: (1) Premarital and preconceptual tests and screening for high risk persons who are thinking of becoming parents. This would include persons with known genetic illnesses or traits in their family, including persons from certain ethnic or religious groups with relatively high prevalence of certain genetic illnesses.[28] (2) Tests and screening for high risk pregnant women -- of unusually young or unusually advanced maternal age, or an earlier history of pregnancies resulting in miscarriage, low birth weight or prematurity.[29] (3) Tests and screening for high risk newborns, particularly where genetic concerns are based on the family history of at least one parent, or where infant testing or screening is required by law, as for instance for PKU.[30] (4) Testing of

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[28]NEIL A. HOLTZMAN, PROCEED WITH CAUTION: PREDICTING GENETIC RISKS IN THE RECOMBINANT DNA ERA 105-6 (1989) [hereinafter, HOLTZMAN, PROCEED WITH CAUTION] states "For many disorders, neither drugs nor diets nor lifestyle changes have been found that markedly improve the outcome of those born with the condition. ... Some diseases may prove intracable despite considerable gains in knowledge. Even in the early stages, however, predictive genetic testing will be possible. Some people... will use the tests as their rationale for avoiding conception or birth of affected offspring. Predicitng diseases for whioch management remains costly because effective interventions have not yet been developed will also be important to third parties such as insurers and employers". See also discussion of DOR YESHORIM, infra chapter 16 at note 6. Dor Yeshorim had religious origins, providing the service of genetic testing and providing confidential results to members of the same religious community. Outreach to groups with sickle cell amenia had similar goals.

[29]See discussion of the California law pertaining to screening for high risk women based on maternal alpha-fetoprotein levels, infra note 37 of this chapter.

[30]HOLTZMAN, PROCEED WITH CAUTION, supra note 28 at 101-2 states, "The success of newborn screening in preventing or greatly reducing mental retardation due to phenylketonuria (PKU) indicates that early treatment can be effective in single-gene disorders. Treatment after symptoms appear accomplishes little. Newborns throughout the United States are screened for PKU (and for congenital hypothyroidism) and in some states are screened for sickle cell anemia and cystic fibrosis, as wellas for a few rare single-gene disorders (galactosemia, maple syrup urine disease, homocystinuria, biotinase deficiency, and congential adrenal hyperplasia)" Many states have legislation newborn testing for these conditions

adults for such late manifesting diseases as Huntington's chorea or polycystic kidney disease.[31] (5) Occupational testing and screening. Currently the testing of persons for genetic propensities for occupational disease where exposed to particular environmental conditions is not as yet fully supported.[32] It is likely that with increasing knowledge and improved technology, such testing will be regarded as an essential medical service. (6) Multi- factorial disease testing. It is likely that the recent progress by the Human Genome Project in finding the genetic basis for certain kinds of colon and rectal cancer and for breast cancer will increasingly be used to find persons of high risk[33] and this may increasingly call for testing in this area as an appropriate genetic service. The recurring evidence of the linkage between cancer and certain genetic predispositions[34] will probably bring about an increasing demand for the availability of services to provide the relevant tests.

The provision of essential services will clearly include genetic services and other newborn services required by state law. In California, for instance, physicians are required by law to offer testing for Down syndrome and for alpha-

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as discussed in chapter 16 of this report.

[31]See e.g. Concept: Ethical Issues Policy Statement onf Huntington's Disease Molecular Genetics Predictive Test, IHA and WFN Research Group on Huntington's Chorea, Committee on Genetic Testing. See discussion of these guidelines supra chapter 8 at note 6 et seq.

[32]See chapter 7 supra concerning Testing and Screening in the Workplace.

[33]Nicolas A. Ashford MONITORING THE WORKER FOR EXPOSURE AND DISEASE: SCIENTIFIC, LEGAL AND ETHICAL CONSIDERATIONS IN THE USE OF BIOMARKERS, (1990); U.S. Congress Office of Technology Assessment GENETIC MONITORING AND SCREENING IN THE WORKPLACE, (1990).

[34]James W. Hanson, Implications of the New Genetic Technology in Health and Other State Policy Areas in THE COUNCIL OF STATE GOVERNMENTS, ADVANCES IN GENETIC INFORMATION (1992) at 24.

fetoprotein (AFP) deficiency to their pregnant patients.[35] AFP is not a disease but a risk factor for Down syndrome with the test clearly designed to avoid Down syndrome babies. It has been recommended that all pregnant women who desire AFP screening should be offered access to screening and to followup services regardless of ability to pay.[36] A number of states require the provision of screening and testing services for a variety of genetic conditions, clearly with a view to affording these services to persons who would not otherwise be able to obtain them.[37]

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[35]Janet Weiner and Barbara A Bernhardt conducted a survey of coverage reported in their article, A Survey of State Medicaid Policies for Coverage of Abortion and Prenatal Diagnosis Procedures in 80 AM.J.PUB.H. 717 (1990) [hereinafter Weiner & Bernhardt].

[36]Leroy Walters Ethical Perspectives on Maternal Serum AFP Screening and Diagnosis of Neural Tube Defects in Barbara Gastel et al. (eds), PROCEEDINGS OF A CONFERENCE OF THE NATIONAL CENTER FOR HEALTH CARE TECHNOLOGY AND THE FOOD AND DRUG ADMINISTRATION, 1980 [hereinafter Walters] at 68 discusses the problems regarding equitable access to maternal alpha-fetoprotein screening for women who cannot afford to pay for the testing.

[37]The following states have adopted legislation aimed at increasing prenatal testing programs and making them more accessible to the general public:

Alabama (ALA. Code Sec. 22-10A-2 (1991)); CHAPTER 10A. Sec. 22-10A-2. (b)(2) is designed to "assure that genetic counseling is available to those Alabama families who need it." Subsection (3) requires "a graduated fee schedule, based on the ability of the patient to pay".

California (CAL. Health and Safety Code §116.5 (1993)) Subsection (q) provides for testing for many diseases, including sickel cell, Tay-Sachs, Huntington disease. California Health and Safety Code §156 (1993) creates a statewide program for prenatal testing.

Iowa (IOWA Code §136A.3 (1993) Creates a birth defects institute to: "1. Conduct scientific investigations and surveys of the causes, mortality, methods of treatment, prevention and cure of birth defects; 2. Publish ... investigations and surveys"; "3. Develop and administer genetic and metabolic screening programs to detect and prevent or treat birth defects ...; 4.Develop specifications for and designate a central laboratory" and provide counseling;

Maine (22 ME. REV. STAT. ANN. TIT. 22 §1533 (1991)); creates a "voluntary statewide genetics program ... which offers testing, counseling and education to parents and prospective parents."

Michigan (MICH. COMP. LAWS §333.5411 (1991)) establishes a chronic disease prevention and control program which includes genetic disease, in co-operation with the department of mental health to create a statewide program for genetic screening and counseling for mental disabilities.

The area of prenatal testing requires both economic and medical access. Prenatal testing must occur early to provide choices. The initial cost of testing may often prevent participation and since public health clinics have long waiting lists for appointments, it is important that the first prenatal appointment not occur after screening is no longer useful. Thus, delays resulting from inability to pay for services, and delays in establishing Medicaid entitlement, may have substantial medical consequences.[38]

Although there is no legal requirement for counseling before or after

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Tennessee (TENN. CODE ANN. §68-5-504 (a) (1) (1992)). Genetic and other testing services are provided to persons and "Unborn children whose testing would result in treatment". By law, "Induced abortion shall not be regarded as treatment. Therefore, procedures or services designed to search out disorders in unborn children which are not treatable shall not be provided ... the use of this program to abort unborn children is against the public policy of the state of Tennessee." The statute provides screening to prevent, detect and assure follow-up for birth defects and genetic disorders. [There is a question whether the earlier limitation does not negate the entire program]. The law states, "(c) It is the specific intent of the general assembly that neither abortion nor abortion research should be funded."

Washington (WASH. REV. CODE SEC. 48.21.244 (1991) requires all group disability contracts to offer prenatal diagnosis of congenital disorders through screening and diagnostic procedures during pregnancy "to such enrollees when those services are determined to be medically necessary" (WASH. REV. CODE SEC. 48.42.090 1992) Requires carriers or providers of any group disability contract, health care services contract or health maintenance agreement to continue coverage provided despite the outcome of any prenatal test; (WASH. REV. CODE SEC. 70.54.220 (1992) requires practitioners in Washington to "provide information regarding the use and availability of prenatal tests to all pregnant women in their care"; (WASH. REV. CODE SEC. 70.83B.010) Legislative findings emphasize that "the availability and competent utilization of certain prenatal tests for congenital and heritable disorders is crucial to protect the health of both mothers and infants." (WASH. REV. CODE SEC. 70.83B.020) Defines (3) "Prenatal tests"; (WASH. REV. CODE SEC. 70.83B.040) creates a prenatal test advisory committee within the Department of Health to develop prenatal test reporting and obtain data concerning: (a) availability of prenatal tests to all pregnant women; and under subsection (d) standardization of prenatal tests and follow-up of abnormal results; (e) "coordination with existing prenatal testing programs of the department"; and (f) educational materials for pregnant women. Subsection (2) provides that the committee shall have a broad representation from the medical community.

[38]Walters, supra note 36, at 68 discussing equitable access to prenatal diagnosis.

genetic screening or testing, there appears to be general agreement on the part of geneticists and other knowledgeable persons in the field that counseling is an essential part of the process to inform women of the availability of certain tests, to alert them to what the test may show, to prepare them for the need to make decisions following the result of the test, and for information on choices relating to treatment or other courses of action when the test results become available.[39] Though the desirability of genetic counseling is generally supported, the relative shortage of counselors has given rise to questions about genetic counsellors' capacity to deal with cultural differences and the lack of access to information by poor and minority women.[40] For purposes of access to prenatal testing, a number of commenters have stressed the urgent need for the provision of prenatal care as a point of entry for attention to genetic screening and testing.[41]

6. Access and Medicaid

Access to genetic services by poor persons who do not carry health

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[39]See IOM ASSESSING GENETIC RISKS, supra note 4, at Chapter 4: Issues in Genetic Counseling; HOLTZMAN, supra note 5 at 174-180, "Communicating information on genetic tests and test results". See also President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, SCREENING AND COUNSELING FOR GENETIC CONDITIONS: A REPORT ON THE ETHICAL SOCIAL AND LEGAL IMPLICATIONS OF GENETIC SCREENING, COUNSELING AND EDUCATION PROGRAMS, U.S. Government Printing Office, Washington, D.C. 1983, especially Chapter 2, Ethical and Legal Implications: Autonomy, at 47-56.

[40]King Supra note 2 at 104 notes that "social service counseling is based on the values and interests of the dominant group or profession: white, middle-class, and English-speaking."

[41]Id. at 103; Lippman Reinforcing Inequities, supra note 3 at 26; See also HASTINGS CENTER, REPORT ON GUIDELINES FOR THE ETHICAL, SOCIAL AND LEGAL ISSUES IN PRENATAL DIAGNOSIS (1979). In general, RUTH HUBBARD & ELIJAH WALD, EXPLODING THE GENE MYTH: HOW GENETIC INFORMATION IS PRODUCED AND MANIPULATED BY SCIENTISTS, PHYSICIANS, EDUCATORS, AND LAW ENFORCERS (1993) have pointed to the need for increased access to prenatal care for minority and poor women.

insurance or whose health insurance will not cover genetic tests or therapeutic abortions depends on Medicaid, the federally subsidized program operated by the states for the payment of medical services for so-called "medically indigent" persons. Following the decision in Roe v. Wade, which created the right of women to choose abortion, three-fourths of the states by 1974 covered most abortions under their Medicaid programs. In 1977, Congress passed by Hyde Amendment,[42] which currently limits federal reimbursement for abortions to situations that threatened the life or health of the mother, and to victims of rape or incest. Each state may decide by state law to cover the cost of abortions, and about half of the abortions in the nation are covered by state funding.[43]

Payment for abortions covers only one part of access to services. A survey conducted in 1990 found that the majority of states covered the cost of amniocentesis, fetal ultrasound, CVS, MSAFP, DNA analysis, karyotypin and genetic counseling.[44] All of the states and the District of Columbia cover amniocentesis, and all but one cover MSAFP. Two-thirds of the states cover CVS and three-fourths cover DNA analysis. Seven states, including the District of

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[42]Walters, supra note 36, at 68, provided early recognition of a problem that persists in the contemporary situation, stating, "Under the terms of the Hyde Amendment... no federal funds may be provided to the states for abortion following a positive prenatal diagnosis."The Hyde Amendment has been a long-standing source of restrictions for the use of federal funds to reimburse states for abortions. According to the Amendment to the Medicaid program under the Social Security Act, (42 USC Section 1396 et seq. Title XIX) federal reimbursement for abortions was previously limited to cases where pregnancy jeopardized the life of the mother. A recent narrowing of these limitations under PL 103-112 (1993) currently allows for federal funding for abortions that involve rape or incest.

[43]Telephone Interview with Eve Paul, Planned Parenthood (April 4, 1994).

[44]Weiner & Bernhardt, supra note 35. "A combination of Medicaid regulations has led to the incongrous policy in many states of covering prenatal diagnostic services but not the selective aboriton in cases of diagnosed fetal abnormality. We believe that these policies discriminate against poor women and interfere with ethical medical practice."

Columbia, pay for abortion on demand; all states cover abortions that save the life of the mother. In 29 states, saving the life of the mother is the only situation in which Medicaid will cover an abortion. Eleven states cover an abortion when there is an indication or there is a known or suspected fetal anomaly and two states evaluate coverage for abortion on a case by case basis when fetal anomaly is suspected. One-fourth of the states will pay for abortions, for victims of rape or incest.

Though states are increasingly covering the cost of abortions through Medicaid, in a number of states it has become increasingly difficult to obtain an abortion. Under earlier law, state legislation limiting a woman's choice had to serve "a compelling state interest." Under the most recent abortion decision by the Supreme Court in 1992, in Casey v. Planned Parenthood of Pennsylvania,[45] states may impose conditions on the woman's right to choose abortion as long as the states requirements do not place an "undue burden" on the woman's choice. While it has been determined that the husband's consent places an undue burden on the decision, there are a variety of situations in which state conditions may be regarded by the Supreme Court as permissible because they do not impose an undue burden. While Casey upholds the woman's autonomous right to an abortion, the permissible conditioning of that right by an individual state may indeed work a serious limitation on a woman's free exercise of autonomy.[46]

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[45]-- U.S. --; 112 S.Ct. 2791 (1992).

[46]Wendy Mariner, The Supreme Court, Abortion, and the Jurisprudence of Class, 82 AMER.J.PUB.H. 1556 (Nov. 1992) at 1561 notes, "For many poor women, the question is not whether they have a right to choose abortion but whether they can get one."

7. Access to Reliable Laboratory Services

Personal decisions depend on test results and the reliability of the results of genetic testing, including personal diagnoses, depend on accuracy of the work of clinical laboratories, which are entirely controlled and licensed by state governments. At this time, very few states are involved in the regulation of genetic testing. In too few states, cytogenetic proficiency testing is used to resolve issues of the sensitivity and specificity of testing and the reliability of test results, which are otherwise unregulated.[47] The Institute of Medicine has expressed great concern over misinterpretation of laboratory results.[48] Citing several important testing errors, the IOM noted that errors are likely to continue because labs are unfamiliar with recombinant DNA techniques; small changes can affect the sample results; there is a high likelihood that results will be normal, thereby reducing vigilance of those performing the test; the test may not be sensitive to all disease causing mutations; and test results may not predict severity of a disease. Overall, the report of the Institute of Medicine paints a bleak picture of the reliability of testing and relevant standards. However, there are significant regulations in key states such as New York, New Jersey and California, and there have been significant developments under the federal Clinical Laboratory Improvement Act, (CLIA) of 1988 ("CLIA88").

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[47] HOLTZMAN, PROCEED WITH CAUTION, supra note 28 at 150 notes that voluntary testing following procedures have been set forth by the College of American Pathology, (CAP) but there are no sanctions for inaccurate testing; See also: IOM ASSESSING GENETIC RISKS, supra note 4 at ch. 3 p. 2,

[48] IOM ASSESSING GENETIC RISKS, supra note 4 at ch. 3, p. 10.

Experience Among the States

According to IOM, proficiency testing for genetic testing is an important area in need of regulation. IOM stated: "Since 1990 New York has been the only state that has specific mandatory standards and permits for DNA genetics laboratories performing tests on its citizens".[49] Tests that are included on this list must meet identified criteria following accepted methodologies. As was noted by geneticists at the GENES (Genetic Network for the Empire State) meeting in July, 1993, IOM has also recognized that "The reach of the New York State program extends beyond the geographic borders of the state, since any laboratory wishing to perform a genetic test on a citizen of New York must be certified just as if it were located in New York; thus most large commercial genetic testing laboratories who accept specimens from around the United States are licensed to meet New York DNA laboratory standards" IOM further states that New York's approach is the most rigorous. [50]

New York law has for a long time regulated the credentials of laboratory personnel; the process for review of credentials; proficiency testing; and standards for quality control in genetics laboratories. [DICTATION March 24, 1994:] New York provides for certifications of qualification which require that any person who accepts specimens for analysis, unless the director of the laboratory or a person in the laboratory has a valid certificate of qualification for the particular necessary procedure. The law provides minimum standards for the issuance of certificates, requiring that the competence in necessary

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[49]Id. ch. 3, p. 4.

[50]Id. ch. 3, p. 4. See generally: N. Y. ADV. LEGIS. SERV. 1993 REGULAR SESSION CH. 436 SEN. BILL NO. 5596-C 1993 N.Y. ALS 436; 1993 N.Y. LAWS 436; 1993 N.Y. S.N. 5596

methodology has been demonstrated before a certificate is issued.[51] The New York State Department of Health may inquire into the operation of laboratory facilities and their methods, procedures, materials, staff and equipment pursuant to regulations consistent with CLIA 88. A laboratory which fails to meet the Department's standards of proficiency will lose its permit until the inadequacy of the laboratory has been corrected.[52] The law also provides for the inspection of facilities and for civil penalties for violations. A person who owns or operates a clinical laboratory without a valid permit is guilty of a misdemeanor, punishable by a fine of not more than $2000, imprisonment for not more than one year, or both such fine and imprisonment.[53] New York has promulgated a very substantial and detailed set of regulations to implement the law. Both law and regulations emphasize the requirement that only laboratories and persons whose capacity to undertake certain tests has been certified may do such tests. New York State publishes a Proficiency Testing Handbook pursuant to its Clinical Laboratory Evaluation Program. The Clinical Laboratory Evaluation Program is a CLIA 88 approved proficiency test center which currently reviews overall quality of testing conducted by all clinical laboratories and blood banks throughout the state and by out of state clinical facilities which accept specimens obtained in New York State.[54] Genetic testing requires a specific Certificate of Qualification approved for each director or assistant director of a clinical

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[51]N. Y. Pub. Health Law Title 10 Section 572. (Laboratory Standards)

[52]N. Y. Pub. Health Law Title 10 Section 576.

[53]N. Y. Pub. Health Law Title 10 Section 578.1.

[54]CLINICAL LABORATORY EVALUATION PROGRAM, PROFICIENCY TESTING HANDBOOK (Wadsworth Center, Albany, New York 10/93) at Introduction I-1.

laboratory.[55] The law and regulations pertaining to the testing of genetic specimens have no special provisions relating to the confidentiality of information and the protection of test results.[56] New York clearly has the most highly developed and advanced system of standards and laboratory controls.[57] While a handful of states have made an effort to regulate laboratories in this area, none of them have reached the detail and sophistication of the New York system. In Maryland, there is only one state laboratory approved for newborn screening.[58] New Jersey recognizes the New York proficiency requirement,[59] and Florida licenses cytogenetics laboratories using the College of American Pathology (CAP) guidelines.[60] California limits newborn screening to eight state

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[55]Clinical Laboratory Evaluation Program, Wadsworth Center for Laboratories and Research, 10 N.Y.C.R.R. Part 19, Clinical Laboratory Evaluation Program, Regulation No. HLT-100-91-407-P filed February 24, 1992.

[56]Compare: "AIDS Testing and Confidentiality of HIV Information", N. Y. Pub. Health Law Tit. 10 Part 63, which provides for very far-reaching protections of HIV related information, providing that the very fact that a person has undergone a test is a matter of high confidentiality. With respect to HIV test results, special authorization by the patient for the release of such information is legally required. The law is particularly clear in its restriction of the release of such information to insurance companies. The AIDS law and the regulations all provide detailed requirements for pre-test counseling. Special provisions are also made with respect to informed consent. The right to refuse testing is emphasized and the subjects of tests are furnished with the telephone number of the New York State Human Rights Commission to be used by any patient who believes he or she is the victim of HIV-based discrimination. Whether such requirements should also be provided for to protect persons with genetic conditions ought to be considered.

[57]IOM ASSESSING GENETIC RISKS, supra note 4 at ch. 3 p. 4.

[58]Id. ch. 3 at 4.

[59]Id. See also: N. J. Rev. Stat. Sec. 26: 5B-4 (1993)

[60]N.J. Rev. Stat. Sec 26:5B-4 (1993) refers to the fact that "Florida licenses cytogenetics laboratories using College of American Pathology (CAP) proficiency testing but its legislation is now expiring" (no citation included). In the 1993 regular Session, House Bill No. 1633, (1993 FL.ALS 204) would address juvenile DNA fingerprinting for violent crime which includes genetic testing, but does not offer standards for test requirements.

monitored laboratories which have quality controls.[61] California has enacted a Heredity Disorders Act.[62] The law focuses primarily on the development of programs for the detection and management of hereditary disorders, but also contains reference to clinical testing procedures established for use in such programs, facilities or projects. California also has regulations governing the "testing for heritable disorders."[63] No specific standards for testing are however set forth in the California regulations. It is perhaps noteworthy that many states that mandate a variety of prenatal tests do not, however, provide standards for the clinical laboratories that must examine the specimens resulting from such tests. It has also been reported that many states are moving towards a system of voluntary regulation, applying standards set through professional societies.[64]

The law in New York is implemented through extensive regulations; it is a misdemeanor under Article 5, Title V, Section 578.1 of the Public Health Law to operate a laboratory without a permit, punishable by fine, imprisonment or both. In order for a laboratory to be approved, the director and assistant director(s) must hold certificates of qualification for the specific tests and procedures the laboratory undertakes.

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[61]CAL. HEALTH & SAFETY CODE Sec. 309 (1993) "(a) It is the policy of the State of California to make every effort to detect, as early as possible, phenylketonuria and other preventable heritable or congential disorders leading to mental retardation or physical defects".

[62]"Hereditary Disorders Act" CAL HEALTH & SAFETY CODE Section 151 (1993).

[63]"Testing for Preventable Heritable Disorders" CAL. CODE REGS. tit. 17. Sec. 6507.2 (1993).

[64]IOM ASSESSING GENETIC RISKS, supra note 4, ch. 3 in general at 5-8 especially Box 3-2 "Voluntary Quality Assurance and Proficiency Testing Programs: at 6-7. HOLTZMAN, PROCEED WITH CAUTION, supra note 4, recommends, "a centralized proficiency-testing program for DNA based tests should be established."

8. Conclusions

An essential and least controversial aspect of a public health program applied to genetics is the provision of facilities adequate to meet the requirements of genetic testing, prenatal diagnosis and prenatal care. Access requires not only that suitable facilities and personnel are available, but also that such facilities and services are equitably distributed among all parts of the population, making sure that previously underserved groups will be given a full opportunity to share in and benefit from genetic services. Only if efforts are made to inform underserved groups of the availability of facilities and services, and only if the necessary outreach is undertaken, can it be said that such services will be made fully available to underserved groups. In particular, emphasis must be placed on prenatal medical services to assure access to genetic services by groups that have not made full use of prenatal services in the past.

It is clear that some groups within the population do not use genetic services because of lacking geographic access, and because of lack of knowledge that such services are available. Equitable distribution of health care services, including genetic services, means distribution in which illness is the major determinant of the allocation of resources. The availability of genetic services should be determined by health needs, not by financial status or ethnicity. Outreach requires educating the public and it requires facilities and personnel for screening and testing programs to reach women across all classes and ethnic divisions so as to assure their access to prenatal care without financial, geographic or linguistic barriers. The past history of federal funding of genetic programs has been uncertain and intermittent. A continuing federal commitment to fund such services at an adequate level is essential to meet the requirements of access without discrimination on financial grounds.

Essential genetic services for which access should be assured include premarital and preconceptual tests and screening, tests and screening for high risk pregnant women, and tests and screening for high risk newborns or for newborns whose testing and screening is required by law, as for PKU. Also, testing for adults with late manifesting diseases such as Huntington disease or polycystic kidney disease. Included also should be occupational testing and screening of persons for genetic propensities for occupational disease when such testing can be fully supported as an essential medical service. Included also would be access to multifactorial disease testing, as progress by the Human Genome Project in finding the genetic basis for such diseases as colon and rectal cancer and for breast cancer will increasingly make it possible to find persons at high risk.

The list of essential services must clearly include genetic services and other newborn services required by state law. In different states, testing for Down syndrome and for alpha-fetoprotein deficiency must be offered. In some of the states, such services must be afforded to pregnant women regardless of ability to pay. There must be assurances that the initial cost of testing does not prevent participation and that the cost of testing not postpone the first prenatal appointment until after screening is no longer useful.

Since many poor persons do not carry health insurance or do not carry insurance that will cover genetic tests or therapeutic abortions, dependence on Medicaid requires that necessary genetic services be covered by Medicaid. Many such services are currently covered by the majority of the states, and full coverage in all of the states should be accomplished.

The Hyde Amendment allows states to deny Medicaid funding for therapeutic abortions. This represents a significant interference with a woman's free

exercise of autonomy. A change in the law in such states is clearly called for, in spite of political difficulties that should be overcome.

Another significant need is access to reliable laboratory services. Genetic screening and testing depends on accurate and reliable laboratory services. It is evident that reliable laboratory services are not available in many states. Proficiency testing for genetic tests is an important field in need of regulation, and states which have not achieved adequate standards must emulate the performance of New York state in this regard. Though the developments under the federal Clinical Laboratory Improvement Act of 1988 have led to significant improvements, further progress in this area is essential and ought to be funded appropriately.

Chapter 16. Genetic Testing: Autonomous Choices and Public Policy

Genetic testing is the primary diagnostic procedure for determining the existence of genetic illness and genetic conditions. Genetic testing must be viewed as part of a preventive effort.[1] It is the starting point for the process of medical decisionmaking regarding appropriate courses of action following the result of the test.

1. Premarital and Preconceptual Testing

Different policy considerations apply to different stages of life and different occasions for genetic testing. In the case of premarital or preconceptual testing, testing will determine whether one or both prospective partners are heterozygotes or carriers for an autosomal recessive disorder such as cystic fibrosis, sickle cell anemia, Tay-Sachs disease, PKU or thalassemia. If both parties are heterozygotes, and if they have a child, there is a one in four risk of their producing a homozygous child, i.e., a child affected with a disease and a one in two chance of having a child who like themselves would be

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[1]NEIL HOLTZMAN, PROCEED WITH CAUTION: PREDICTING GENETIC RISKS IN THE RECOMBINANT DNA ERA 32-33 (1989) [hereinafter HOLTZMAN, PROCEED WITH CAUTION]:

> three strategies for reducing the burden of disease are possible: (1) preventing the disease or its manifestations from occurring in the first place; (2) effectively treating the disease after its manifestation appears; or (3) avoiding the conceptual birth of infants at risk for developing it. Strategies for avoiding the conception of infants at risk include adoption and the use of sperm or ovum donated by someone who is not at risk for having affected offspring. The principle strategy for avoiding the birth of an affected child is abortion.

a carrier.[2] Similar rationales for testing would underlie the effort to avoid recessive diseases caused by alterations on the X-chromosome which have consequences such as hemophilia, Duchenne muscular dystrophy or fragile X syndrome. Thus, any person looking forward to marriage and having a child may opt for a genetic test if they (or their physician) consider them to be at-risk, that is, if a particular genetic disease has appeared in their family history.

Information relating to a person's genetic traits for an illness such as sickle cell anemia or cystic fibrosis would enable people to avoid certain genetic diseases in their offspring by seeking alternative means of having a child, or by prenatal testing of the fetus to determine whether the fetus will have the disease, and to make an appropriate choice. In a recent report on cystic fibrosis, the Office of Technology Assessment suggested that if carrier screening becomes routine, it may be incorporated in programs for family planning and reproductive health.[3] Alternative forms of conception will include in vitro fertilization, artificial insemination, and in the alternative, adoption.

Other issues relating to premarital testing involve the question of privacy and the impact that information relating to genetic illness or genetic traits may have on the relationship of the parties. The parties may wish to keep such information from each other, and there appears to be no provision in federal or state law to compel one prospective partner in a marriage to tell the other of his/her genotype.

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[2] U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT (OTA), CYSTIC FIBROSIS AND CARRIER TESTS: IMPLICATIONS OF CARRIER SCREENING 90 (1992), [hereinafter OTA CF REPORT]

[3] OTA CF REPORT at 151 "While most respondents [to the OTA survey] state that the ideal population to target for carrier screening is the preconceptual adult, in reality, the first target population is likely to be the prenatal population because it has been the traditional entry point into genetic services for many people." (emphasis in original).

But ignorance of each other's genotype may also have serious impact on the relationship. It may lead to the unexpected birth of a very sick child, or to a decision whether to terminate or continue the pregnancy. These possible consequences of ignorance argue for a need for openness between the partners, and for a right to know.[4] While it would be easy to draft a law imposing a legal obligation of disclosure of genotype on the parties, some opposition to such legislation can be expected on privacy grounds, as an improper burden on the right to marry,[5] and some on the basis of problems of enforceability. Given the problems failure to inform may create, such a legal obligation should be considered seriously. While genetic disease is quite a different matter from sexually transmitted communicable disease, in the communicable disease situation where the other marriage partner would be infected, there is a legal duty to tell. Failure to tell of adverse genetic traits or of genetic illness is clearly not as devastating in its result as failure to tell of HIV positivity or AIDS. But in our judgment the impact of failure to tell of a genetic disease or trait is sufficiently serious in its potential consequences so that it might well argue for a change in law and practice to require disclosure.[6]

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[4]See discussion of the Right Not To Know Genetic Information, ch. 8 at page 239 et seq. supra.

[5] Zablocki v. Redhail 434 U.S. 374 (1978) upheld the fundamental right to marry; Griswold v. Connecticut 381 U.S. 479, (1965) upheld the right to procreative freedom in marriage and procreative privacy. See discussion of these cases in chapter 3, Privacy Issues, this report.

[6]For an unusual system of disclosure already begun in practice, see the voluntary premarital testing in Dor Yeshorim, developed by a close-knit Chasidic community to utilize the Tay-Sachs screening test for premarital testing to avoid infants afflicted with the Tay-Sachs disease in a community in which the disease has some prevalence.

> [P]arents wishing to have their [marriage-aged] children tested could contact Dor Yeshorim to arrange an appointment at Mount Sinai. In order to protect the anonymity of the families, every person at

2. Predictive Testing for Monogenic Disorders and Multifactorial Diseases

In addition to premarital, preconceptual testing, there may also be an interest in predictive testing by at-risk persons into mono-genic disorders that do not manifest themselves until middle age. Such diseases, including Huntington disease, adult polycystic kidney disease and hemochromatosis, are diseases which it may not be possible to avoid, after birth, though at the very least, affected persons may be able to plan for the disability which will befall them on the onset of the disease, though there is a question whether a person is better off knowing or not knowing. The International Huntington Disease Association, (IHA) and the World Federation of Neurology, (WFN) have prepared detailed guidelines for the application of the Huntington's Disease Molecular Genetics Predictive Test which protects persons against such information except at their own choice and with appropriate protections.[7]

With new discoveries of the genetic causation of many diseases, there may be an increasing demand for testing for susceptibility genes. In this area of

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> the time of the test received a card with an assigned coded number, and Dor Yeshorim only recorded the number, the birthdate and the telephone number. Names were never taken. ... When a prospective couple became serious about each other, they would contact Dor Yeshorim with both numbers and be informed whether the match was "compatible" or "incompatible." If the match is compatible, the parties are not told if one of the prospective mates is a carrier. Unless at match is found to be incompatible (which means that both parties are carriers) no one will ever know whether an individual is in fact a carrier.

The results of the test are revealed only to carriers engaged to be married. Otherwise the information is stored in such a manner that individuals involved never learn about their carrier status where there is a pattern of arranged marriages. It is clear that the system will work only in a small closely-knit community. See Schmuel Lefko[illegible], Dor Yeshorim: A Grassroots Success Story in GENESIS: THE NEWSLETTER OF THE GENETIC NETWORK OF THE EMPIRE STATE Vol. IV No. 2 at 1 (1992).

[7]See supra Chapter 8, Protection of the Right Not To Know, at note 6.

multifactorial diseases, genetic susceptibilities may adversely interact with environmental factors, such as occupational toxins, environmental pollutants, smoking, or diet. Such factors may play a role in such diseases as hypertension, diabetes and allergies, as well as in colon and rectal cancer and in breast cancer. In addition, it is increasingly possible to test for a variety of other rarer genetic disorders.[8]

3. Newborn Screening and Testing

Newborn screening, a very common procedure, currently uses blood samples from each newborn to test for the presence of key genetic diseases. These tests are performed on four million babies born annually in the United States. The blood spots are used for a variety of tests, though test results from the analysis of blood spots must generally be confirmed by a specific test for the disease in question. The first newborn screening program to be required by law was for PKU, an enzyme deficiency that if not corrected early may lead to progressive mental retardation. The disease occurs in 1/10,000 Caucasian births. Mental retardation in cases of diagnosed PKU can be avoided by a special diet started soon after birth and continuing through early infancy. Pursuant to state law, in almost every state in the US, infants are routinely screened for genetic errors of metabolism, such as PKU and congenital hypothyroidism, both of which are treatable, as well as for a variety of other diseases. "Some states screen for as many as 11 conditions, including 42 states that screen routinely for sickle cell anemia (Table 2-1). Colorado and Wyoming added CF to their mandatory newborn testing program in 1989. Newborn screening for genetic disease is one

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[8]See U.S. CONGRESS OFFICE OF TECHNOLOGY ASSESSMENT (OTA) GENETIC MONITORING AND SCREENING IN THE WORKPLACE at 90-93 (1990). See also Chapter 7, Invasions of Privacy and Genetic Discrimination in the Workplace, supra.

area of genetic services that, because of its public health history and justification, has remained almost exclusively within the province of state control."[9]

Newborn testing is the only area in which the principle of autonomy and voluntarism historically has been neglected. In neonatal testing, most states that have such requirements have simply imposed the requirement legislatively, and have disregarded the more recent reliance in such matters on individual autonomy.[10]

There has been a general preference in the field of genetics for autonomous decisionmaking even in the case of newborn testing.[11] Though there is considerable support for relying on parental consent in instances of newborn testing,[12] the position is less well supported legally and ethically than is the preference for autonomous decisionmaking in other testing situations. There is hardly an issue of autonomous decisionmaking by the person affected, because the

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[9]Lori Andrews et al. COMMITTEE ON ASSESSING GENETIC RISKS, DIVISION OF HEALTH SCIENCES POLICY, INSTITUTE OF MEDICINE, ASSESSING GENETIC RISKS: IMPLICATIONS FOR HEALTH AND SOCIAL POLICY, ch. 2 at 6-7 (1993) [hereinafter IOM, ASSESSING GENETIC RISKS]

[10]Id. ch. 8 at 12.

[11]The Major Social Policy Issues Raised by the Human Genome Project, In: SHERMAN ELIAS & GEORGE ANNAS [Eds.] GENE MAPPING: USING LAW AND ETHICS AS GUIDES. [hereinafter GENE MAPPING] at 9 (1992).

[12]HOLTZMAN, PROCEED WITH CAUTION, supra note 1, at 186 "about half of a representative sample of Maryland women who had just had babies favored informed consent for PKU screening, and 80 percent wanted to be informed prior to testing, even when the test was required and they did not have the right to refuse testing. Given this finding, it is hard to argue that reasonable people would not want the opportunity to consent to, or refuse, any form of genetic testing. [footnotes omitted]. See also: IOM ASSESSING GENETIC RISKS, supra note 9, favors parental consent for newborn testing, noting ch. 8 at 13, "additional benefits from voluntariness in newborn screening [include] [i]nforming parents about newborn screening in advance of testing allows quality assurance: parents can check to see if the sample was actually drawn."

infant is clearly not in any position to exercise its autonomy. Moreover, there is little ethical or legal support for surrogate decisionmaking, because the Supreme Court has often found that the interests of the parent and of the child are not necessary identical.[13] Mandatory testing for newborns has never been challenged and is most likely to withstand a challenge, in view of the long established parens patriae power of the state, which can assume decisionmaking powers for a child or other legally incompetent person who does not have enough judgment to know his or her own best interest and who is incapable of exercising that judgment in any event.[14]

In testing for PKU in particular, there is another persuasive argument against the possible delay that reliance on parental consent may bring about. In order for the special diet required for PKU to be effective, it must be instituted as soon after birth as possible.[15] In balancing the right of the protection of the infant against the parents' autonomy, a court may find this a close call at best. There is evidence, however, that some states that have sought voluntary compliance by parents and have been testing as many newborns as would have been tested had the mandatory rule been applied.[16] The issue is not likely

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[13]IOM ASSESSING GENETIC RISKS, supra note 9, ch. 8 at 13 suggests that newborn screening for PKU has been justified on ground analogus to the use of the parens patriae doctrine to provide necessary blood transfusions over the parental religious objections to the treatment. Some of the oldest applications of parens patriae included compulsory medical treatment of children for any serious illness or injury in Prince v. Massachusetts, 321 U.S. 158 (1944); and most recently, the use of parens patriae in relation to minor's independent decisionmaking about abortions, H.L. v. Matheson, 450 U.S. 398 (1981).

[14]"Some of the oldest applications of parens patriae protected children against their 'objectionable' parents. E.g. Wellesley v. Wellesley 2 Bl. n.S. 124, 133-4, 4 Eng. Rep. 1078, 1082 (H.L. 1828) as cited in H.L. v. Matheson, 450 U.S. 398 (1981).

[15]HOLTZMAN, PROCEED WITH CAUTION, supra note 1, at 109.

[16] Maryland and Vermont have voluntary testing of newborns.

to be litigated, because of the significant difficulties which would stand in the way of making a sound case for parental decisionmaking.

As a practical matter, providing adequate information for informed consent to literally millions of women recovering from childbirth is an enormously burdensome and expensive undertaking, and one cannot help but suspect that in reality consent has been reduced in these situations to a mere signature on a form. It seems preferable to inform the smaller number of parents whose infants have tested positive of the need to provide a special diet for the infant. Not only is it easier to explain the special diet rather than the genetic condition, it is also far more readily understood by the mother.

In PKU testing, one of the arguments made against mandatory testing is the recurrence of false negatives and false positives resulting from the test.[17] False positives raise the problem in that infants are subjected to the special diet who don't really need it which may have adverse consequences, which are not so serious apparently as to militate against PKU testing. False negatives and false positives are not a sound argument against mandatory testing, because the occurrence of false negatives or false positives in mass testing situations has really no relation to the mandatory or voluntary nature of the test though it may be argued that a high frequency of false positives and false negatives challenges the justification for mass mandatory testing.[18]

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[17]HOLTZMAN, PROCEED WITH CAUTION, supra note 1, at 5 -6 "In the case of PKU, some infants were falsely labeled as having the disease and suffered irreparable damage".

[18] Id. at 142 "In those already born, [a false positive] could result in unecessary and perhaps unsafe treatment--- perhaps for a lifetime-- or living with needless dread that a disease will eventually appear".

4. Testing and Screening for Autosomal Recessive Disorders

Testing and screening for autosomal recessive disorders, such as sickle cell anemia, cystic fibrosis or Tay-Sachs disease, are essentially preventive measures to help the parent (or more particularly, the mother) to make informed reproductive decisions. Carrier detection for these disorders presents the parents with a choice to continue the pregnancy to term, gambling on the possibility that they will have a healthy child, because there is only a 25% possibility that the child will be affected. A likely choice is to undergo prenatal diagnosis to determine whether the fetus is or is not affected, and then to choose to terminate the pregnancy through abortion if it is.[19] They could also choose, as an alternative prior to conception, to go by way of in vitro insemination, using a sperm or ovum donor. Note the distinction between carrier testing of persons considered to be at risk, and carrier screening, which involves persons of no previous family history.[20] Such carrier screening is

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[19] The high likelihood that a fetus who is believed to be affected with CF will be aborted has lead the CF Foundation and advocates of CF-affected families to oppose CF prenatal testing. People who have CF can live until age 40 or 50 with a good quality of life, although they may never have a "normal" life, (whatever that is). But raising a child with CF and providing daily therapies; specially needed medical care and paying for care is an emotional, psychological and financial burden that some families might not want to bear. The situation is further complicated because there are several variations of the CF gene, but severity of the future illness cannot be determined by prenatal diagnosis. see generally: IOM ASSESSING GENETIC RISKS, supra note 9, ch. 8 at 9, "Furthermore, some people with a particular disability or genetic risk may view mandatory genetic testing for that risk or disability as an attempt to eradicate their kind, as a disavowal of their worth". This sentiment is consistent with the view expressed by CF advocacy groups.

[20] OTA CF REPORT, supra note 2, at 50, "the difference between testing and screening is illuminated by considering a person contemplating procreation. He or she could inquire about the probability that he or she could have a child affected with CF. If there are no relatives with the disorder, the individual could be informed that a test would provide information about his or her genetic status. for CF. The person could then elect to be screened to determine whether or not he or she is a carrier for CF. If, however there is a family history of the disease, a practicioner would ideally inform the individual and his or her

likely to be used in order to determine whether or not they are at risk.[21] Note that for many autosomal recessive disorders, it is unlikely at this time that any program of screening of a significant part of the population would be undertaken. Cystic fibrosis, for instance, is the most frequent potentially deadly autosomal recessive disorder in the United States. One in 2,500 newborns nationwide is affected by CF; according to OTA, "Thus while approximately 30,000 people in the United States have CF, as many as 8 million people could be carriers of one CF mutation". [22] There is no cure for CF currently available, though daily treatments have extended the life expectancy of victims of CF to age forty or fifty. The large number of CF mutations recently discovered, however, has complicated carrier detection though examination of different mutations of the disease has disclosed that different forms of cystic fibrosis are associated with a particular severity of the disease and that some mutations give rise to milder forms. While testing of persons with a history of cystic fibrosis in the family is being supported, opposition to routine screening for CF has been expressed by the American Society of Human Genetics (ASHG), supporting testing only when such tests are accurate, sensitive, and specific. In 1989, the CF test identified only 70% of carriers so that only 49% of the couples at risk would be detected. A consensus emerged that routine screening should be offered only when the test is at least 90%-95% sensitive, and when experience with appropriate education,

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partner about CF carrier assays and they might choose to be tested to determine if they are both carriers." [emphasis in original].

[21] SHERMAN ELIAS, GEORGE ANNAS & JOE LEIGH SIMPSON, Carrier Screening For Cystic Fibrosis: A Case Study in Setting Standards of Medical Practice in: GENE MAPPING at 200, (1992), "Good science and solid education strategies must be in place before CF screening is routinely offered to those with a negative family history".

[22] OTA CF REPORT, supra note 2, at 49.

counseling, and the setting for such screening has been evaluated.[23]

5. Prenatal Diagnosis

Prenatal diagnosis is generally recommended for women 35 years or older, considered to be of advanced maternal age. Since the incidence of chromosomal abnormalities increases with maternal age, the American College of Obstetrics and Gynecology has determined that offering prenatal diagnosis should be part of the medical standard of care for such older women. Such women are offered maternal serum alpha-fetoprotein (MSAFP) screening, a blood test to determine the presence of a neurotube defect (NTD), Down syndrome, and other fetal malformations. As many as 2.1 million pregnant women are screened annually in the United States using MSAFP.[24] Potential problems with such prenatal testing include the invasive nature of some prenatal tests, putting the fetus at some small risk. Other problems include the possibility of false positives, giving rise to great anxiety as well as possibly the abortion of a healthy fetus.[25]

Geneticists seem to agree that prenatal diagnosis does not ensure future parents that they will have a perfectly healthy baby. Most genetic disorders cannot be diagnosed prenatally, and the prospect of gene therapy and genetic engineering is not as yet a realistic possibility. DNA technology will make it

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[23]IOM ASSESSING GENETIC RISKS, supra note 9, ch. 2 at 12-3. OTA CF REPORT, supra note 2, at 58-9, "The current test however leaves ambiguity when results are negative."

[24]OTA CF REPORT, supra note 2, ch. 6 at 144, Box 6-A "Maternal Serum Alpha-fetoprotein Screening" describes the test and the various effects of testing, including recognition of cases of fetal spina bifida and Down syndrome. See also: IOM, ASSESSING GENETIC RISKS, supra note 9, ch. 2 at 13.

[25]IOM, ASSESSING GENETIC RISKS, supra note 9, ch.2 at 14. For an excellent analysis of current prenatal diagnostic technology, see id. ch. 2 at 15-16, Box 2-2 Current Prenatal Diagnostic Technologies.

possible, however, to increase the number of genetic disorders for which prenatal diagnosis is possible.

The benefits of prenatal diagnosis are clearly to give the prospective parents (especially the mother) the information she needs to make autonomous procreative choices. The NIH Workshop on Reproductive Genetic Testing (1991) noted that the availability of prenatal testing and screening services may have a number of adverse consequences as well. They have "the potential to increase anxiety; place excessive responsibility, blame, and guilt on a woman for her pregnancy outcome; interfere with maternal-infant bonding; and disrupt the relationships between a woman, family members and her community."[26] To avoid such adverse consequences, proper counseling and other supportive services may be needed. There is also a question whether these adverse consequences are sufficiently weighty to avoid prenatal testing.

One of the recurring problems is the question of supplying information on options which are not going to be utilized for religious, moral or other reasons. An important aspect of the situation is to ensure that each woman can make choices entirely free from any coercion, however slight. It is improper, as a criterion for selecting candidates for amniocentesis or other prenatal tests, to require parents to commit themselves to choose abortion if the fetus is found to have a genetic disorder.[27]

There appears to be general agreement that prenatal testing for the early

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[26]HOLTZMAN, PROCEED WITH CAUTION, supra note 1, at 107; IOM, ASSESSING GENETIC RISKS, supra note 9, ch. 2 at 17.

[27]NICHD, 1979, as quoted in IOM, ASSESSING GENETIC RISKS, supra note 9, Chapter 2 at 18.

determination of the gender of the fetus is an improper use of such procedures.[28] Since under the law, women have an absolute right to terminate a pregnancy, this effort to limit the use of prenatal tests is really inconsequential, because there is clearly nc obligation on the part of a woman to inform anyone why she has decided to terminate the pregnancy. The general policy reflected in the condemnation of this abuse of genetic tests is clearly supportable on ethical grounds, though it is of no legal consequence.[29]

6. Testing for Late Onset Diseases

Different problems are presented by testing for disorders with late onset, disorders such as Huntington disease, polycystic kidney disease or Alzheimer disease, which will not manifest until adulthood or later. Presymptomatic testing may provide information regarding susceptibility for a disease and not clear predictions. [30]

Where there has been a family history of persons with the disease, testing

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[28]IOM, ASSESSING GENETIC RISKS, supra note 9, Chapter 2 at 18, citing inter alia a policy statement from the European Council of International Organizations of Medical Sciences, 1988. See also: TROY DUSTER, BACKDOOR TO EUGENICS at 32-3 With prenatal determination of the sex of the fetus and the attendant matter of sex selection, there is a new arena for this old conflict. ... the issue is clear: the right of individuals to choose the genetic destiny of their offspring is counterpsed against the interests of the collectivity (the state, the ethnic group, the kinship linkage) in maintaining the balance of the sex ratio."

[29] See also: PRIVACY COMMISSION OF CANADA, GENETIC TESTING AND PRIVACY at 40-1 (1992). Citing the council of International Organizations of the Medical Sciences, 'The Working Group considers it a misuse of new genetic technologies... to make a diagnosis of sex in the eighth or tenth week of pregnancy. Since sex is no disease, the use of fetal diagnosis only for knowledge of fetal sex is to be discouraged, at least in European and American cultures'.

[30]The Institute of Medicine in its report, ASSESSING GENETIC RISKS, has taken a strong stance in opposition to testing of minors for genetic diseases. The International Huntingon Disease Association has also expressed opposition to testing of minors.

will provide information whether the mutant gene for the disease is present. In addition to monogenic diseases of late onset, such as Huntington disease and Alzheimer disease, some late onset diseases are multifactorial, which involve both genetic predisposition and the effects of certain environmental exposures. Included are coronary artery disease, certain cancers, diabetes, high blood pressure, rheumatoid arthritis and some psychiatric diseases.[31] In instances involving multifactorial diseases, definite predictions cannot be made, and it will be difficult to determine whether the person is at low risk or high risk. Since there is an environmental element in multifactorial diseases, a diagnosis of a propensity for such a disease will enable the patient to obtain guidance from the physician relating to diet and other environmental exposures in order to reduce the risk.

With late onset monogenic diseases, such as Huntington disease and Alzheimer disease, for which there is no known treatment, testing raises many ethical issues and problems. There are no legal prohibitions on testing an infant or a child for Huntington disease or Alzheimer disease, though it is questionable professional practice.[32] With the recent development of direct DNA testing for

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[31]IOM, ASSESSING GENETIC RISKS, supra note 9 at Chapter 2 at 20, 21. See also: HOLTZMAN, PROCEED WITH CAUTION, supra note 1, at 25 for a discussion of multifactorial diseases.

[32]The International Huntington Association (IHA) and the World Federation of Neurology (WFN) have proposed Recommendations to provide guidelines for the use of the Huntington's Disease Molecular Genetics Predictive Test, IHA and WFN Research Group on Huntingon's Chorea, Committee on Genetic Testing. Test, CONCEPT: ETHICAL ISSUES POLICY STATEMENT ON HUNTINGTON'S DISEASE MOLECULAR GENETICS PREDICTIVE TEST [hereinafter WFN-IHA Guidelines] "The establishment of a committee with the specific task of preparing such guidelines was decided at the WFN and IHA conferences in Lille, September, 1985. The recommendations were adopted by both organizations at their respective meetings in Vancouver, Canada, June 30 to July 3, 1989 and published in J.Neurol. Sciences 1989; 94; 327-32 and J. Med. Genetics 1990; 27; 34-8.; IOM, ASSESSING GENETIC RISKS, supra note 9, ch. 2 at 21, ch 9 at 7, "In general the committee does not recommend predispositional genetic testing for minors unless delays would result in significant harm to the

Huntington disease, fewer than 300 individuals have been tested in the United States with a variety of effects, with some of the persons tested being devastatingly traumatized by the test result and others coping in a variety of ways -- including the reaction that the test was probably wrong or the hope that there was an answer in the future through God or science. The decision to be tested for Huntington disease is clearly voluntary, to be adequately prepared for by counseling and other support systems. Much of the literature on the subject strongly suggests that this is a situation where not knowing may be preferable to having the certain knowledge of the disease.[33] While the decision to be tested or not must clearly be a voluntary, autonomous decision, in the clear view of geneticists and others in the field, account should be taken of the likelihood that some persons who consider themselves at risk for the disease by reason of familial experiences may want to have full information for purposes of making sound preparations for themselves and their families, and also for purposes of decisionmaking relating to planning for children. Very substantial differences in the reactions to the bad news have been reported. Interestingly, there have been some adverse reactions to good news as well, with persons experiencing guilt that they were free of the disease while their siblings might not be so fortunate.[34]

A number of late onset monogenic disorders are treatable, including hemochromatosis and familial hypercholesterolemia. Though these are treatable diseases, the question arises whether siblings should be informed of the

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child."

[33]See supra chapter 8, Protection of the Right Not To Know; WFN-IHA Guidelines, supra note 32.

[34]IOM, ASSESSING GENETIC RISKS, supra note 9, ch 2 at 22.

diagnosis since they are at a 25% risk of developing this disease as well. The question whether or not to tell siblings has been widely discussed.[35] Though informing relatives clearly breaches confidentiality, the impact of breach of confidentiality must be balanced against the potential gain of health when the information is shared with a sibling who may otherwise go untreated.

Autosomal dominant polycystic kidney disease, which is fairly frequent, another late onset disease for which there is no definite treatment, will lead to renal failure in middle age, though treatment of hypertension and urinary infections may defer the onset of renal failures.[36]

7. Testing for Susceptibilities

Studies have increasingly documented that susceptibility to some cancers is genetic. The number of persons in the population with inherited cancers is large. "Screening for inherited susceptibility to cancers raises many issues, including appropriate therapy, access, intense anxiety, and discrimination."[37] Substantial research in the area includes studies of the rare Li-Fraumeni syndrome, "in which mutations of a common tumor suppressor gene (p53) are transmitted by autosomal dominant inheritance and may cause tumors in multiple

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[35]HOLTZMAN, PROCEED WITH CAUTION, supra note 1, at 187-8; IOM ASSESSING GENETIC RISKS ch 8 at 18, citing the PRESIDENT'S COMMISSION FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMENDICAL AND BEHAVIORIAL RESEARCH, SCREENING AND COUNSELING FOR GENETIC CONDITIONS 6 (1983). Under the criteria set forth by the President's Commission, disclosure may be made to relatives for the limited purpose of diagnosis and treatment if disclosure has not been made voluntarily and if failure to disclose would cause irreversible or fatal harm.

[36]IOM, ASSESSING GENETIC RISKS, supra note 9 at ch 2 at 24-25.

[37]Id. at ch 2 at 25.

organs, including breast cancers and sarcomas, sometimes beginning in childhood."[38] Predictive testing for p53 in clinically healthy individuals from cancer-prone families has become the subject of NIH consensus conferences which have come up with a variety of recommendations, including further genetic research as well as lifestyle changes for affected individuals. One of the recommendations was the establishment of registries to collect data on Li-Fraumeni families, and to collate findings from p53 testing programs worldwide. It is clear that all of these developments are likely to increase the demand for access to genetic testing facilities.

Other recent studies that are likely to increase pressures on access include diseases in which certain genetic factors appear to play a part. These include coronary heart disease, hypertension, certain cancers of complex origin, diabetes and rheumatoid arthritis. So, too, certain genetic factors affect the susceptibility to certain infectious diseases, and genetic factors also play a role in psychiatric diseases such as schizophrenia and manic depressive disorders. Many of these areas not only present substantial challenges to research, but also create new and substantial ethical issues.[39] This area may riase problems relating to personal responsiblity and such philosophical considerations as determinism versus free will. The potential harm from leaving such diseases untreated may also hold implications for the right not to know and the duty of professionals to warn of harm.[40] This area also holds the potential to redefine the societal notions of disease, as the knowledge that individuals

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[38]Id. at Chapter 2 at 25. See discussion of databanks and registries in chapter 5 of this report.

[39]IOM, ASSESSING GENETIC RISKS, supra note 9 at ch 2 at 26-30.

[40]See ch. 8, Protection of the Right Not to Know One's Own Genetic Information, at page 239 et seq.

possess certain potentially dangerous genetic traits becomes more commonplace.

8. Genetic Testing, Public Health and Autonomy

The decision to undergo a genetic test should be the autonomous independent decision of the patient. As a medical decision, probably made in the context of other diagnostic procedures, or in the context of reproductive decisionmaking, the decision will be made in a physician's office, in the case of reproductive decisions, most likely in the office of a gynecologist/obstetrician. Thus, while the decision whether to be tested or not is ultimately the patient's, it is not likely to be a decision free of physician advice and physician guidance. Genetics is a very complex field, and the general public illiteracy with reference to scientific matters generally and genetic information in particular has been frequently commented on and documented.[41] The ideal of patient autonomy in the context of genetic testing is therefore somewhat circumscribed, and to preserve patient autonomy, considerable emphasis must be placed on the informational function of physicians and genetic counselors who will need to impart the necessary information to the patient without exercising any influence on the patient as to what choice to make. Autonomy in this context requires protection against whatever subtle influences there may flow from the information the physician or counselor imparts to the patient.

The literature of autonomy is silent on the issue of whether a decision based on a knowledgeable person's advice is any the less an autonomous decision, and in light of the complexity of genetic choices, patients may indeed seek a

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[41]OTA CF REPORT, supra note 2, at 24 "The need for better scientific literacy has been a topic of wide discussion in recent years ...Public education programs targeted to genetic diseases have been nonexistent since those established under the National Genetic Diseases Act were phased out in 1981." See also: HOLTZMAN, PROCEED WITH CAUTION, supra note 1, at 176-7.

specialist's advice, particularly when issues of degrees of disability or incapacity are involved in procreative counseling, and where outcomes can only be stated in probabilistic terms. Nonetheless, choices involving genetic testing are highly personal and Neil Holtzman is probably right in asserting that no one is wise enough to make such choices on the patient's or anybody else's behalf.[42] The autonomous choice should therefore be the norm whenever there is an adult patient of full competence to make such a choice. In light of the general scientific and genetic illiteracy of the population, and the real possibility that, in spite of serious efforts of education and explanation, the information may not be understood or its significance appreciated, perhaps there ought to be some tolerance for choices made with the advice of a trusted adviser, including the physician.[43] The following criteria are intended to resolve the most difficult counseling issues in a manner which is both realistic and humane:

> 1. The person who needs to make a decision has received all relevant information necessary to provide informed consent, or otherwise necessary to make a knowledgeable decision.
>
> 2. The person has had a fully opportunity to ask questions about the information presented as well as about the consequences of making a decision, the range of consequences of not making a decision, the range, if any, of alternative decisions that can be made.
>
> 3. The person has expressed a sense of uncertainty or confusion on the information covered, or on the different available choices and the possible consequences, and has expressly asked for help in making the decision -- then the counselor may provide advice in making the decision in the advisee's best interest.

Such private autonomous choices can only be made meaningfully wherever, as

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[42]HOLTZMAN, PROCEED WITH CAUTION, supra note 1.

[43]IOM, ASSESSING GENETIC RISKS, supra note 9, at ch 5 at 1, "the public should know that DN is the information molecule; they should value the variation and diversity that is expressed from that molecule; and they should be able to participate in the public debate about the use of genetic information".

a matter of protection of the public health, the state has provided the facilities, personnel and conditions to allow such choices to be made conscientiously.[44] In the context of autonomous choices relating to genetic issues, it is necessary that there is public access to genetic testing services of a wide range, leaving open for the moment whether access to such services should not be subject to the same constraints relating to the need for the service as are other health services. However, necessary genetic testing services, services which are regarded as necessary in sound medical practice, ought to be available without economic barriers to access and without barriers of a geographic nature or barriers that implicitly discriminate between different groups in the population.[45]

There should be a preference in favor of early preconceptual screening, in advance of pregnancy, based on the determination that one or both of the prospective parents are at risk or of carrier status. In preconceptual carrier testing, as well as in other testing situations, the procedure, i.e., the taking of a blood sample, is normally sufficiently routine so as not to require formal informed consent, formally witnessed by a consent form. Though the physical procedure is not regarded as invasive, the consequences of carrier testing may involve the subject in a process of decisionmaking which is very difficult and emotionally trying. Under the circumstances, subjects who are about to undergo preconceptual testing should consent not only to the simple physical procedure, but also to the likely consequences which the test results may bring about. They should be fully aware of the purpose of the test, of the likely nature and range

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[44]See Chapter 15 supra on Access to Genetic Health Services.

[45]E.g., for a discussion of data on barriers to abortion, see supra Chapter 15, Access to Genetic Health Services, at note 42 et seq.

of test results, and of the nature of the decisions they will have to make on the basis of the test results when available. Such preconceptual carrier testing and screening should therefore be based on full information and counseling.

Prenatal diagnosis may raise even more difficult questions; based on the information obtained from prenatal diagnosis, it may become the woman's decision whether to continue the pregnancy or whether to terminate the pregnancy to avoid bearing a child with a given genetic disorder.[46] Before consenting to prenatal diagnosis, counseling is necessary, as is full information on the nature of the result of the prenatal test, and of the risks and benefits of such a test.[47] Again, the determination whether to carry the fetus to term or to abort is the choice of the mother, and, under law, it is her choice alone. Counseling in this instance requires not only sound information on the character of the possible birth defect or genetic disorder, but also objective information on the burdens of raising a child with a serious disability and the social stigma of raising such a child.

On the other hand, it is also the counselor's obligation not to be directive in dealing with such information,[48] and to allow the mother to exercise her autonomous, independent judgment in light of her religious beliefs and ethical values. Few of the sources that deal with this problem comment on the

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[46]See Chapter 18, infra, on Women's Issues.

[47]IOM, ASSESSING GENETIC RISKS, supra note 9 at ch.8 at 12, "If, for example, it becomes possible to accurately screen fetal cells isolated from a pregnant woman's blood in order to determine the genetic status of the fetus, state public health departments might be interested in requiring the test on the grounds that it is a minimally invasive procedure that can provide informastion to the woman... Mandating such a test, however, would show insufficient respect for the woman's autonomy and would violate her right to make reproductive decisions."

[48] PETER S. HARPER, PRACTICAL GENETIC COUNSELLING, at 13 (1993). See also: discussion of genetic counseling, chapter 17 infra.

economic costs to the family or the impact on other children and any plans for more children or the costs to society of raising a seriously disabled child. In no event is it permissible to allow eugenic considerations to enter into the decisionmaking process. The issue is the choice of the mother, and it must be her own autonomous choice without regard to the impact of her decision on future generations or future population goals.[49]

With respect to newborn screening, most states currently provide for a range of newborn screenings without specific parental consent.[50] The point has been made earlier that autonomous decisionmaking in the case of newborn screening is a fiction in any event. The consent of the parent is a surrogate consent on behalf of the infant, who clearly is in no position to exercise autonomous judgment. Mandating newborn screening seems an appropriate exercise of the state's parens patriae power, to make necessary decisions on behalf of persons who are incapable of making such decisions on their own. Though parental consent is possible, and the change of the system to provide for parental consent has been recommended in the past, the system of prompt newborn testing for PKU and hypothyroidism is in place, has been effective, and allows the prompt and timely treatment of newborn infants to prevent the consequences of the genetic disease.[51] There is no convincing reason to change a working system for the sake

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[49]See chapter 18, Section 5, infra on Women's Autonomy. Note that under Roe v. Wade 410 US 113 (1973) it legally remains the woman's decision to continue or abort a pregnancy, even though this decisionmaking process may be tempered by the views of the father or other family members, with concommitant implications for decisional autonomy.

[50]Maryland and Vermont provide for voluntary screening of newborns. See: discussion of newborn screening, supra at section 3 of this chapter.

[51]IOM, ASSESSING GENETIC RISKS, Exec. Summary, supra note 9, at 5, "however it is appropriate to mandate the offering of established tests (e.g. PKU and hypothyroidism) where early diagnosis leads to improved treatable outcomes."

of conformity with the theoretical standard of autonomy in this instance.

A special issue arising from the testing of newborns is the protection of newborn blood spots that result from newborn testing. Such blood spots should only be made available for research purposes if the privacy of the newborn is protected. This will require the removal of all identifying information from the blood spot and compliance with the requirements applicable -- or that should be made applicable -- to data banks which store genetic materials.[52]

Postnatal testing and testing of minors generally should only include necessary tests, normally tests for conditions and diseases for which a treatment is immediately available. In general, professionals in the field take the position that there is no reason to test children for late onset diseases since no treatment is available, and since knowledge of the likelihood of a child's succumbing to a late onset disease will have an adverse impact on the way the child is treated, even by its parents, and may give rise to stigma and discriminatory treatment.[53] While this is a generally accepted view, the question should be raised whether the inclusion of such information, properly coded, in an appropriate genetic data bank may not provide opportunities for regular followup which may have considerable value in providing information on the symptomatology and progression of late onset diseases, in order to provide sound information for public health planning purposes in the management of such diseases.

With respect to late onset disorders generally, issues of informed consent by the subject and protection of test results is of the utmost importance to

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[52]See supra Chapter 5; George J. Annas, Privacy Rules for DNA Databanks: Protecting Code "Future Diaries," 270 J.A.M.A. 2346 (1993).

[53]IOM, ASSESSING GENETIC RISKS, supra note 9, at ch 8 at 13.

avoid the discriminatory uses of such information by insurers and employers. Since the Americans with Disabilities Act[54] does not provide any protection for late onset genetic disorders,[55] it is particularly important that information relating to late onset diseases be kept highly confidential and protected.

Late onset diseases and such monogenic disorders as Huntington disease and Alzheimer disease may provide information of significance to the subject's siblings. While generally the point is made that the protection of the privacy of the subject is of great importance, and that the sibling may not be anxious to have the information,[56] it seems that the information ought to be made available to siblings if there is any possibility that such information may be useful for planning purposes, or in the case of hemochromatosis and familial hypercholesterolemia, that the information may actually be used for treatment purposes.[57] Thus, there is a need to reconcile the competing interests of personal genetic privacy and the familial right to know.

While the protection of privacy and protection against stigma and insurance discrimination as well as discrimination in the workplace is of the utmost importance, and should be more thoroughly protected by law than it is currently, privacy considerations must always be weighed against treatment considerations when the information is of a nature which would advance the treatment of a sibling or other family member. If the subject whose test disclosed the information may be of great significance not only to the subject but to others

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[54]Americans with Disabilities Act of 1992, 42 U.S.C. Section 12101.

[55]See supra Chapter 7, pp. 223-236.

[56]THE PRIVACY COMMISIONER OF CANADA, GENETIC TESTING AND PRIVACY at 30 (1992) addresses the right not to have others know.

[57]See discussion of the recommendations by the President's Commission, supra note 18 as cited by IOM, ASSESSING GENETIC RISKS.

as well, then providing such information to others is also in the interest of public health, in providing the basis for public health planning and for preventive services.

9. Conclusions

Genetic testing is the primary diagnostic procedure for determining the existence of genetic illness and genetic conditions. Genetic testing provides both the focus for autonomous choices on the part of the subject and for the policy choices in determining the direction of publicly supported genetic programs.

Genetic testing is primarily used at this time in the making of procreational decisions. It is the beginning of a preventive effort, to avoid the birth of children with a serious genetic illness, as in the case of premarital or preconceptual testing to determine whether one or both prospective parents to carry the trait for an autosomal recessive disorder such as cystic fibrosis, sickle cell anemia, Tay-Sachs disease, PKU or thalassemia. If carrier screening becomes routine, the Office of Technology Assessment has suggested that it be incorporated in programs for family planning and reproductive health. Such genetic testing may have adverse impact on the relationship of the parties who may keep genetic information from each other. It is here suggested that though no legal obligation of mutual information currently exists, ignorance may also have a serious impact on the relationship in the birth of a very sick child or in the need to determine whether to terminate or continue the pregnancy. Such possible consequences of failure of information argue for a need for openness between the partners. The creation of a legal obligation to inform the other partner should be considered seriously, even though opposition to such a

requirement can be expected on privacy grounds and on the grounds that it constitutes an improper burden on the right to marry. Though there may be significant problems of enforceability, a requirement of disclosure would avoid serious health consequences. There is a current obligation of mutual information when sexually transmitted disease is involved. While failure to inform of a genetic trait is not as devastating in its result as a failure to tell of HIV positivity, failure to tell of a genetic disease or trait is sufficiently serious in its consequences to argue for a change in law and practice to require disclosure.

Another area of genetic testing for procreational decisionmaking is that of prenatal testing. For women 35 years or older, the offering of prenatal diagnosis has become part of the medical standard of care. More than two million pregnant women undergo maternal serum alpha-fetoprotein screening to determine the presence of a neurotube defect, Down syndrome and other fetal malformations. Though prenatal testing does not assure a perfectly healthy baby, and though prenatal tests put the fetus at some small risk and include the possibility of false positives -- giving rise to anxiety as well as the possible abortion of a healthy fetus -- these possibly adverse consequences ought not to discourage this medically approved practice. Other adverse consequences of prenatal screening that have been mentioned is their tendency to increase anxiety and to place excessive responsibility on a woman for her pregnancy outcome. Such screening may also interfere with maternal-infant bonding and affect a woman's relationship with her family. To avoid such consequences, proper counseling and other supportive services are needed. Since prenatal testing raises the possibility of the termination of the pregnancy, there is a recurring whether the outcome will raise options which are not going to be utilized for religious, moral or other

reasons. Thus, choices in this area must be entirely autonomous and free of coercion. Candidates for amniocentesis or other prenatal tests must not be required to commit themselves to choose abortion if the fetus is found to have a genetic disorder. Here, as in other genetic testing situations, we must rely on voluntariness and autonomous decisions.

The only area in which autonomy and voluntarism has not been relied on in the past is in newborn testing. Most states have imposed newborn testing requirements legislatively and have not called for parental consent in newborn testing. The system of newborn testing appears to have worked well in PKU and has prevented a number of adverse outcomes. The neonatal testing situation does not truly involve autonomous decisionmaking, because the neonate is in no position to make an autonomous decision. The decision is that of a surrogate, namely the parent. The law has recognized that the interests of the surrogate and the infant are not necessarily identical. There are issues of timeliness involved in neonatal testing, because in PKU the special diet ought to be instituted as early as possible. While parental consent to newborn testing has had good results in some states, there appears to be little reason to change current practices which seem to work well. Another reason to stay with current practice is the early release time of mothers and babies from hospitals following delivery, which provides little opportunity for securing parental consent prior to release.

Testing decisions relating to procreation and the birth of children should be made with proper and full information and no genetic testing ought to be undertaken without informed consent and without adequate genetic counseling. These should provide the detailed information and the detailed awareness of the possible range of consequences so as to enable the prospective mother to make sound and autonomous decisions.

There is widespread recognition of the fact that there is great public ignorance and illiteracy with respect to scientific subjects in general, and genetic information in particular. There may be instances when a person who has received all relevant information and has received information on the consequences of making particular decisions expresses a sense of uncertainty or confusion on the information covered and on the different choices available. When such a person expressly asks for help in making a decision, then it ought to be permissible for the counselor to provide advice in the advisee's best interest. If these criteria are met, then a decision made with the advice of a counselor ought to be properly regarded as an autonomous decision.

Autonomous decisions made by the mother will involve her religious and ethical beliefs. They are private decisions which ought not to be influenced by any notions of which choices are better for the public, or the public health.

Another area that calls for difficult and burdensome decisions is testing for late onset diseases such as Huntington disease, polycystic kidney disease or Alzheimer disease. With special reference to Huntington disease, where there is no known treatment, the recurring issue is whether a person is better off knowing or not knowing that he or she will manifest the disease at some time in the future. There is no point in testing an infant or a child for Huntington disease, and much of the literature on the subject suggests that not knowing may be preferable to having the certain knowledge of the dread disease. Nonetheless, here too the ultimate decision is that of the person at risk. While knowledge of the disease is likely to have an utterly devastating effect, persons do differ with respect to their tolerance for disastrous news, and some may prefer to have the disastrous news in order to make preparations for themselves and their families, as well as to make decisions in planning for children. This is an area

where genetic counseling and special care in dealing with the information are absolutely necessary, and the generally accepted WFN-IHA guidelines, covered in chapter 17, ought to be followed.

As knowledge grows with respect to inherited susceptibilities to cancers such as colon cancer and breast cancer, it is likely that demands for such tests will increase in order to provide access to appropriate therapies. Predictive testing for certain diseases such as coronary heart disease, hypertension, diabetes and rheumatoid arthritis, as well as diseases in which genetic factors play a role as in schizophrenia and manic-depressive disorders are likely to create new issues of genetic discrimination -- as well as great possibilities that an early discovery of disease may lead to preventive interventions. These clearly ought to become the subjects for further studies of ethical, legal and social implications.

It is evident that autonomous decisionmaking with respect to genetic testing depends on the availability of facilities and personnel to provide genetic tests, the availability of accurate clinical laboratories and the availability of hospitals and other facilities to implement the choices made. As pointed out in the earlier discussion of access to genetic services, such access is a current task of governmental programs in public health.

Chapter 17. Genetic Counseling and Informed Consent

1. Genetic Counseling

In earlier discussions, frequent reference has been made to genetic counseling[1] in the context of genetic testing or screening of newborns, in prenatal diagnosis and in screening for other genetic conditions or diseases. Thus, genetic counseling plays a most significant role in educating and informing the subject of the nature and possible results of the test, and also in helping the subject to make decisions based on test results, or in helping the subject cope with adverse results.

Although genetic counseling is generally regarded by geneticists as essential to the decisionmaking and informed consent process involved in the management of genetic tests and genetic screening, there is no legal requirement that genetic counseling be provided. While in general it is assumed that knowledge imparted in the counseling process will be part of the information used in the process of obtaining the informed consent of the subject, again, there is no legal requirement that counseling be part of the process of obtaining informed consent, even though informed consent is indeed required in many instances of genetic testing and screening. In general, the subject of counseling and the subject of informed consent are viewed as related, but may be treated quite

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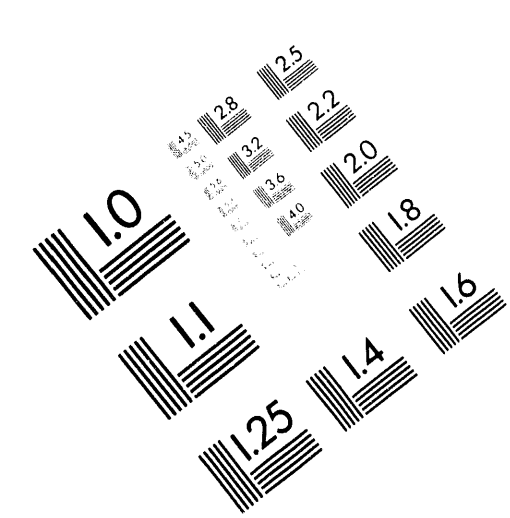
[1]Peter S. Harper, PRACTICAL GENETIC COUNSELLING, 3 (4th Ed. 1993) "Genetic counselling is the process by which patients or relatives at risk of a disorder that may be hereditary are advised of the consequences of the disorder, the probability of developing or transmitting it and of the ways in which this may be prevented, avoided or ameliorated.". Harper also cites Kelly, CLINICAL GENETICS AND GENETIC COUNSELLING who defines genetic counseling as: '[a]n educational process that seeks to assist affected and/or at risk individuals to understand the nature of the genetic disorder, its transmission and the options open to them in management and family planning." Id. at 3.

separately in the literature. The legal requirement of informed consent is essential to protect the patient, but it is also essential to protect the physician against claims of medical malpractice.

Genetic counseling, conducted by genetic counselors who have specialized training and who are capable of dealing both with the informational and emotional aspects of the task, are involved in a sophisticated process of communication relating to the decisions persons must make who are faced with problems involving genetic diseases or traits. The participation of genetic counselors is particularly important in prenatal diagnosis or genetic screening, and in counseling of parents with difficult reproductive choices. It is up to the counselor to make the person who is counselled fully aware of the nature of the disorder, to indicate to the person what choices or alternatives there are in dealing with the problem, to help the person to make appropriate choices in a non-directive[2] fashion, taking account of the nature of the risk and considering also the person's own standards, including both ethical and religious standards, and to help the subject make appropriate adjustments in her future life and in her future relations with her family. In the prenatal situation, this may involve consideration of available treatments, if any, or termination of a pregnancy. The counselor in some situations may be faced also with the question of whether or

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[2]Dorothy C. Wertz and John C. Fletcher, Attitudes of Genetic Counselors: A Multinational Survey, 42 AM. J. HUM. GENET. 592 at 592 (1988) state as the goals of modern genetic counseling, as helping clients 'to understand their options and to choose the course of action which seems most appropriate to them in view of their risk and their family goals and act in accordance with that decision', citing F.C. Fraser, Genetic Counseling 26 AM. J. HUM. GENET. 636,(1974). They further comment that, "Counselors act as 'decision facilitators' providing information without being directive". In their research there "was almost 100% consensus that the seven listed goals of counseling were important or essential... [including] ' helping individuals/couples understand their options and the present state of medical knowledge so they can make informed decisions." Id. at 595.

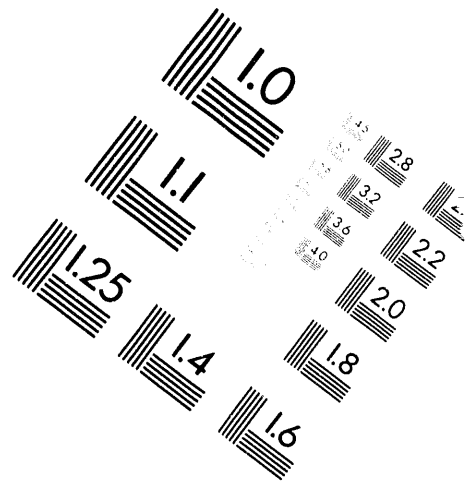


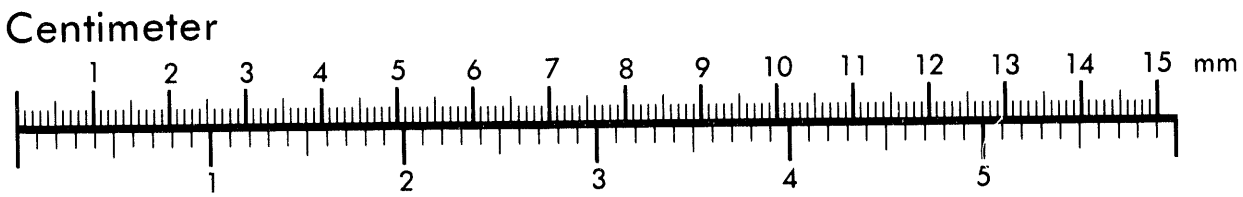


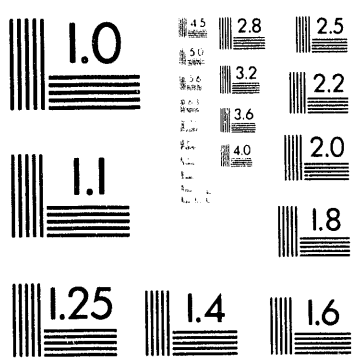
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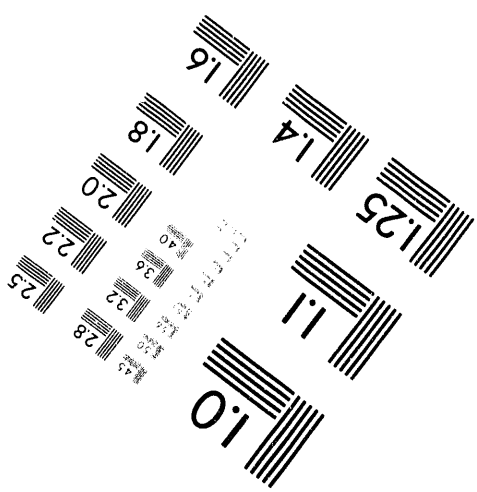
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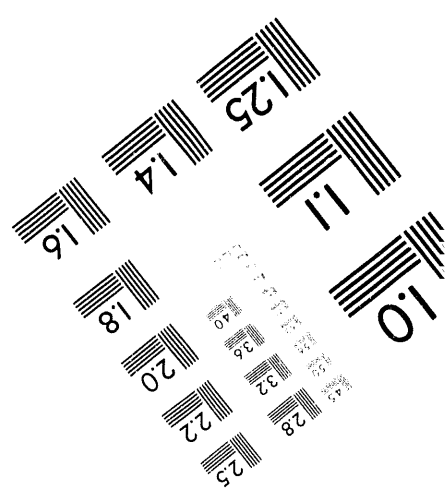
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not members of the family should be informed of a particular test result, when such results may indicate that members of the family may also be at risk.

If autonomous decisionmaking on the part of the patient or subject is accepted as the guiding principle, then it follows that the genetic counselor's role in providing information and possible choices of action must be wholly nondirective.[3] It is clear that the emphasis on nondirectiveness is a reaction against earlier experience with counseling during the early 20th century eugenic movement.[4] In view of the general scientific and genetic illiteracy of the population, sound explanations and factual information to the person being counselled is of the utmost importance. The principle of nondirectiveness should be protected, of course, against efforts to use genetic counseling as a platform for eugenic notions. It should be clear, however, when a genetic counselor is asked for advice, and offers advice, the mere fact that the patient takes the advice ought not to be considered as evidence of counselor directiveness.

Whether or not to be counselled is also the patient's autonomous decision. While there appears to be general agreement that counseling is necessary, no

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[3]INSTITUTE OF MEDICINE, ASSESSING GENETIC RISKS: IMPLICATIONS FOR HEALTH AND SOCIAL POLICY (1993) [hereinafter IOM, ASSESSING GENETIC RISKS] ch.4 at 6, "Concern about early abuses in the eugenics movement helped to make the principle of nondirectiveness, and the corollary of respect for client autonomy, key concepts of genetic counseling today", citing the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, 1983. SCREENING AND COUNSELING FOR GENETIC COUNDITIONS: THE ETHICAL, SOCIAL AND LEGAL IMPLICATIONS OF GENETIC SCREENING, COUNSELING AND EDUCATION PROGRAMS. (1983); D. KEVELES, IN THE NAME OF EUGENICS,(1985), and TROY DUSTER, BACKDOOR TO EUGENICS (1990).

[4]The concept of genetic counseling has its unfortunate beginnings in the unscientific eugenics movement of the early 20th century, discussed earlier in this chapter. At that time, "counseling" was the term used to describe eugenic efforts to improve the human race and especially its American component. Pataricia King, Thinking Ahead: Planning Politics and the Genome Initiative, STANFORD CENTENNIAL SYMPOSIUM, THE HUMAN GENOME PROJECT: BIOLOGICAL NATURE AND SOCIAL OPPORTUNITIES (1990) [hereinafter King, Thinking Ahead].

legal requirement for counseling ought to be imposed upon patients. However, any public health program that provides access to genetic services ought to provide an opportunity for counseling.

Some ten percent of the U.S. population may obtain genetic counseling at some time,[5] but utilization is likely to increase when new tests become available. So, for instance, with recent discoveries, related to HGI, that breast cancer and ovarian cancer are often genetic in origin, and that colon or rectal cancer may also be attributed to a genetic defect, the demand for tests and the need for genetic counseling is likely to increase substantially.

Genetic counseling, at a minimum, involves advising persons with genetic traits or illnesses or their immediate families of the nature of the condition, the risks and prognosis for their condition or the health of an expected child. The following definition of genetic counseling was provided by the Ad Hoc Committee on Genetic Counseling of the Americna Society of Human Genetics:

> Genetic counseling is a communication process which deals with the human problems associated with the occurrence, or risk of occurrence, of a genetic disorder in a family. This process involves an attempt by one or more appropriately trained persons to help the individual or family to (1) comprehend the medical facts, including the diagnosis, probable course of the disorder, and the available management; (2) appreciate the way heredity contributes to the disorder, and the risk of recurrence in specified relatives; (3) understand the alternatives for dealing with the risk of recurrence; (4) choose the course of action which seems to them appropriate in view of their risk, their family goals, and their ethical and religious standards, and to act in accordance with that decision; and (5) to make the best possible adjustment to the disorder in an affected family member and/or to the risk of recurrence of that disorder.[6]

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[5] Id.

[6]As quoted by IOM ASSESSING GENETIC RISKS ch 4 at 3; Alexander Morgan Capron in Tort Liability in Genetic Counseling 79 COLUMBIA L. REV. 618 (1979) [hereinafter Capron] at 621. For a different and probably unacceptable view of counseling, see C. Adelman, The Constitutionality of Mandatory Genetic Screening Statutes, 31 CASE WESTERN L.REV. 897. At 908: "Some physicians, counselors and

It has been noted that in some instances the disclosure of test results for such incurable and devastating disorders as Huntington disease may call for additional psychosocial therapy, which is not part of normal counseling but which may well be a necessary service in some situations.[7]

In any particular testing or screening situation, it is unclear, and it has not been the subject of judicial determinations, whether the physician or the genetic counselor, or both, are responsible for informing individuals on the details of their prognosis, their risks, or the risks to their children. Liability for failure to inform has generally been placed on physicians,[8] but

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scientists think that the only valid purpose associated with genetic counseling is personal counseling of the family. These professionals believe that a counselor's role should not extend beyond the family counselled. A contrary view proposed that genetic counseling should go beyond the best interests of the individual family under counsel and instead drive to reduce the genetic load, thus benefitting the entire population....Although many of these counselors strive for objectivity, their personal views may nevertheless be influential. As the severity of the genetic disease increases, the goal of objectivity becomes more difficult to maintain. In counseling a client, for example, who is pregnant with a fetus with Tay-Sachs disease, a genetic counselor's opinion about the severity and hopelessness of the disease might lead him or her to counsel aborting the fetus."

[7]Disclosure of adverse genetic information that affects self-image also suggests the need for therapy as an essential service. For individuals born with a genetic disorder, adjustment to the disorder may occur as the person matures. For disorders with an onset occurring later in life, like Huntington disease, knowing can harm the patient's self-esteem, raising fears of intellectual deterioration, abandonment, loneliness and dependency. (Nancy Wexler, In the Shadow of Huntington's Disease, COLUMBIA November 1987 at 16.) Late onset genetically challenged adults may believe that they have lost all that they previously were capable of doing. In cases where the onset of disease occurs later in life, individuals may feel that their whole life has been devoted to education, career, family and other forms of self-development only to have it nullified by the surfacing of a "bad gene." These effects spill over onto family functioning, often causing marital discord, divorce, sexual dysfunctions (impotence, extramarital affairs), and increased consumption of alcohol. Such effects also commonly follow the birth of a genetically challenged child due to the stress the disorder places on the family unit.

[8]Aubrey Milunsky, Prenatal Diagnosis: New Tools, New Problems in GENETICS AND THE LAW III at 335-346 (George Annas, ed.) (1984). Milunsky has reviewed cases involving physician or laboratory failure in cases of genetic disorder and

there is at least a potential liability which genetic counselors have for their failure to provide adequate information or warnings.[9] The possibility has also been raised that a counselor's failure to provide needed information may result in a lawsuit for wrongful life.[10]

The lack of available genetic counselors is a current problem in genetic counseling . Currently there are some 1,000 master's level genetic counselors practicing in the U.S. and at present 68% of genetic counselors have been certified by ABMG.[11] There also are a number of non-master's level counselors and a number of single disorder counselors (i.e., counselors specialized in providing counseling in particular areas of genetic disorders).[12] It is agreed that there is a substantial need for more genetic counselors and particularly a need for counselors who speak languages other than English. In a recent survey of genetic counselors and nurses in genetics revealed that only 14% are fluent in a language other than English.[13] As noted earlier, minority groups at this juncture are far less likely to use genetic services than white middle class groups. Caution has been advised to avoid linking race, ethnicity, class or

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concluded, "Actions in the courts are replete with examples of physician failure to provide or to refer for genetic counseling on the basis of advanced maternal age, parental ethnic group, previous family history, erroneous or missed diagnosis, and laboratory errors." at 335. Under these cases, courts have allowed recoveries for such failures.

[9]See generally Capron, supra note 6.

[10]Milunsky, supra note 8 at 335.

[11]IOM, ASSESSING GENETIC RISKS, supra note 3 at chapter 6, p. 7.

[12]This situation is likely because of the shortage of genetic counselors, as documented by the Insitute of Medicine in ASSESSING GENETIC RISKS supra note 3 at ch. 6. See also Randi Zinberg and Karen Greendale, Do We Have A Shortage of Genetic Counselors in New York State? 3 GENESIS, THE NEWSLETTER OF THE GENETICS NETWORK OF THE EMPIRE STATE No 3 at 1 Summer, 1991.

[13]IOM, ASSESSING GENETIC RISKS, supra note 3, at ch. 4 p. 13.

gender considerations to genetics.[14] It is therefore considered to be of great significance and importance that the counselor understand social and cultural differences, particularly in light of growing numbers of persons in the United States who are African Americans, Asian and Pacific islanders, Native Americans or Hispanics who have their own traditions and family values which are of considerable significance in making decisions based on the results of genetic testing or screening.[15]

2. Informed Consent

The connection between counseling and informed consent was earlier referred to, and it is clear that in light of the consequences of genetic screening and testing, the patient's informed consent should be obtained.

The question of the exact procedure for conveying the necessary information preparatory to obtaining informed consent has been a subject of some comment. It has been said that the disclosure of information should not be mechanical but interactive, responding to the patient's need. In any event, signing an informed consent form is not in and of itself meaningful, because it is mere evidence of informed consent, which can be rendered nugatory by other evidence.[16] The concerns for proper informed consent procedures are dealt with in the Uniform Law

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[14]King, Thinking Ahead, supra note 4.

[15]See, e.g., IOM, ASSESSING GENETIC RISKS, supra note 3 at ch. 4 pp. 11-13 (1993).

[16]See, e.g., T.M. Grunder, How To Make Consent Forms More Readable, IRB: A REVIEW OF HUMAN SUBJECTS 3, No. 4 (1981) at 9-10; The American Hospital Association's, A Patient's Bill of Rights (1972) as cited in James E. Ludlam, Contemporary Overview, INFORMED CONSENT (1978) [hereinafter Ludlam].

Commissioners' Model Health-Care Consent Act[17] approved by the National Conference of Commissioners on Uniform State Laws in 1982 and adopted by Indiana in 1987.[18] The law states a number of general concepts and restates the common law rule that requires the patient to be competent to consent to health care. It also makes some provisions for surrogate decisionmaking by the person's family members in the event the person is unconscious or incompetent. The proposed uniform law has not been adopted outside Indiana and does not seem to advance informed consent issues significantly. The useful emphasis, however, is on the provision of significant and complete information by the physician in a manner calculated to be fully understood by the patient. This rule has clear applicability in informed consent matters affecting genetic screening and testing.

Though prenatal testing may involve some invasive procedures, genetic testing in general requires nothing more than taking intravenous blood, for which normally no informed consent has previously been required, because it was viewed as a routine procedure.[19] The spread of the HIV/AIDS pandemic has changed the rules, by instituting new requirements for pre-test and post-test counseling, in

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[17] Uniform Law Commissioners' Model Health-Care Consent Act, Uniform Laws Ann. Vol 9, Part 1 at 453 et seq.

[18] Indiana P.L.C. 205 (1987) West's A.I.C. 16-8-12-1 to 16-8-12-12.

[19] Ludlam, supra note 16, at 9 (1978); Cathy J. Jones, Autonomy and Informed Consent in Medical Decisionmaking: Toward a New Self-Fulfilling Prophecy, 47 WASH. & LEE L.REV. 379. At 298-405, she describes her personal observations of physician-patient interactions across six months. Regarding the behavior of physicians, she notes, "The informed consent procedures most of them used, while sometimes meeting the letter of the informed consent doctrine, rarely met what should be its spirit, i.e., providing adequate information and attempting to ensure that patients understand the information so that they can make knowing and voluntary decisions about medical care." (Id. 405)

connection with HIV testing.[20] Mindful of this potential, the IOM report, Assessing Genetic Risks, urged genetic counseling before and after genetic testing and expressed profound concern for the rights of people who are tested. Genetic tests, however, raise special problems in terms of patient understanding and the likely consequences arising from the results of such a test. Informed consent for genetic testing should normally involve full information relating to the nature of the possible results of the test and relating to the questions and decisions which the patient may need to make once the results are available.

In general, informed consent addresses the medical or health consequences of the procedures consented to. In the genetic testing situation, the physical consequences are less significant than the social and psychological consequences, a matter which has not been noted particularly in the literature. Again, the decision to have a genetic test should be the autonomous decision of the patient and not that of the patient's physician. Thus, informed consent properly obtained

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[20]See Ilise L. Feitshans, Foreshadowing Future Changes: Implications of the AIDS Pandemic for International Law and Policy of Public Health [Book Review of AIDS In The Industrialized Democracies by Bayer and Kirp and The Social Impact of AIDS in the United States by the National Research Council, National Academy of Science), MICH. J. INT'L L. (1994) (forthcoming, April, 1994)]. "Nowhere has the influence of advocacy groups for people with AIDS been more distinctive than in the area of mandatory testing and confidentiality of test results. ... [As a result of political activism], voluntary testing with informed consent after counseling became the centerpiece of several public health initiatives in the first decade of the AIDS pandemic. ... AIDS has therefore set a precedent for informed consent and counseling prior to testing, (with a right to refuse testing), which was not previously indicated for tests such as a 'routine' blood test." See also RON BAYER AND DAVID L. KIRP, AIDS IN THE INDUSTRIALIZED DEMOCRACIES (1993) at 27. "To assure that [HIV] testing would in fact be voluntary, some states enacted statutes requiring that written specific consent be obtained before testing occured. The insistence on such rigor stood in marked contrast to the standard American practice in medicine, where consent to diagnostic blood tests is assumed once an individual has come for treatment."

after full information protects both the patient and the physician.[21] It is evident that persons with full information will be ready to provide voluntary consent to testing procedures.[22] It has also been noted that informed consent and autonomous choices are reached more easily when the counselor or health professional communicates with the patient in a culturally familiar way; the information given to the patient should employ shared values in order for the patient to understand it fully prior to making a decision.[23]

The legal basis for informed consent was articulated by Justice Cardozo in 1914: "Every human being of adult years and sound mind has a right to determine what shall be done with his own body, and a surgeon who performs an operation without his patient's consent commits an assault for which he is liable in damages."[24] In the context of genetic screening and testing, in most situations the need for informed consent is based not on the unusual or invasive nature of the test, but rather on the importance of the patient's awareness of what the test results may bring about. A patient who undergoes a genetic test should be made aware not only of the decisions the test results may require, but also

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[21]Ludlam, supra note 16, at 9.

[22]HOLTZMAN, PROCEED WITH CAUTION: PREDICTING GENETIC RISKS IN THE RECOMBINANT DNA ERA 186 (1989).

[23]King, Thinking Ahead, supra note 4 at 104.

[24]Schloendorff v. Society of New York Hospital, 211 N.Y. 125; 105 N.E. 92 (1914), quoted in HOLTZMAN, PROCEED WITH CAUTION, supra note 22 at 186. The reasonable patient standard was established in Canterbury v. Spence, 464 F.2d 772, 150 U.S.App. D.C. 263 (1972) at 780: "True consent to what happens to one's self is the informed exercise of a choice, and that entails an opportunity to evaluate knowledgeably the options...The average patient has little or no understanding of the medical arts, and ordinarily has only his physician to whom he can look for enlightenment with which to reach an intelligent decision. From these almost axiomatic considerations springs the need, and in turn the requirement, of a reasonable divulgence by physician to patient to make such a decision possible." [footnotes omitted]

should be informed of the fact that test results that show the presence of a genetic illness or a genetic trait or predisposition may well be used by employers and insurance companies to the patient's significant disadvantage, if these test results get into the insurer's or employer's hands in spite of privacy protections. Such results are likely to come to the insurer's attention when the patient seeks insurance reimbursement for the cost of the test.[25]

3. Conclusion

Though there is no legal requirement for genetic counseling, it is generally regarded as an essential component of genetic screening and in making decisions that rely on screening and testing results, and particularly in making reproductive choices. The role of the genetic counselor in conveying genetic information and in explaining alternatives and choices presented by the results of genetic tests, and the need for nondirectedness in counseling have been generally accepted. The need for a true effort at communication which will take into account the subject's background and religious and ethical commitments has also been recognized, paying the utmost respect to the patient's autonomy.

In view of the widespread popular ignorance of scientific and genetic information, it is here recommendedd that it is permissible for a patient to ask for a genetic counselor's advice, and the patient's decision, though based on such advice, need not necessarily be considered a violation of the patient's autonomy, if indeed all necessary steps have been taken to provide information and to allow the patient to ask questions in order to inform the patient fully. The proposal sets forth the criteria to be met to make the subject's request for

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[25]See supra chapter 6, pp. 153-160.

help acceptable as an autonomous choice.[26]

In addition to the role of genetic counselors in procreative decision-making, such counselors also have a special role in counseling persons with respect to testing for such incurable, late manifesting diseases as Huntington disease. The responsibility in such instances is a very heavy one, and a decision whether to be tested for such a disease must be left to the patient following appropriate genetic counseling. The process of advising persons in that situation has become the subject of guidelines by the International Huntington Disease Association (IHA) and the World Federation of Neurology (WFN). In every instance of genetic counseling, the primary obligation is to help the patient to obtain full information and to make the best personal decisions autonomously.

Though genetic counseling is not formally a part of the informed consent process, no genetic testing can be undertaken until the subject's informed consent has been obtained. The requirement of informed consent and the need for counseling are in this sense parallel aspects of the process.

Current problems in genetic counseling are the inadequate numbers of available genetic counselors and the lack of genetic counselors who speak languages other than English, or who belong to groups who share the ethnic, religious or social background of their subject. Major efforts must be undertaken to bridge this gap in order to make access to genetic counseling and genetic services more generally available.

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[26]See supra chapter 16 pp. 360.

Chapter 18. The Special Role and Responsibility of Women in Making Genetic Choices

1. Women's Issues

By law, procedures relating to childbirth and procedures affecting the fetus require the mother's informed consent. Thus, all medical decisionmaking relating to the application of new technologies in the testing of the fetus and in in utero treatment of the fetus for possible therapeutic interventions to improve the fetus' genetic condition require the woman's consent. Hence, all new genetic discoveries, new diagnostic developments and new possibilities of fetal treatment raise new questions for the woman who is carrying the fetus because without her consent, none of the new procedures -- which affect her body -- can be undertaken. In some instances, this may raise new questions as to the specific interest of the fetus and of the mother with respect to new treatments. Assuming that successful genetic interventions in utero become readily available, and assuming that such interventions are in the best interest of the health of the fetus, is there an obligation on the part of the woman to permit such an intervention, with whatever risks, discomforts, and dangers such an intervention may raise for her. In light of the possible clear interest in preserving and advancing the health of the fetus, what about the maternal right to prevent unwanted procedures that affect her body, such as in utero surgery. As long as interventions of this nature are regarded as unusual and not routine, and as long as such interventions will remain prohibitively expensive, gene therapy and fetal surgery are not likely to present major social issues. If such procedures become more routine and more readily available, emerging issues will not only involve questions of informed consent but also of an equal availability of certain new

technologies depending on ability to pay, recurringly raising the question of which group in the population is likely to be benefitted by some of these developments.

The difficulty of decisionmaking will remain that of the mother. Decisionmaking, however, may become more difficult when the decision may put the interests of the mother in conflict with the interests of the fetus she is carrying. Among some theorists, this has been characterized as an emerging "maternal-fetal conflict." But this is not a useful analytical approach because it assumes that mother and fetus have equal decisional capabilities, opposing legal interests and that they face equal risk. In reality they are not equals because one is a person and the other a developing mass of cells. State power has sometimes been used to equalize these interests by treating the fetus as a person in order to resolve such conflicts. But this approach opens the door to state intervention into every maternal decision. It also understates a pregnant woman's assertion of the natural maternal role, which may actually guide her towards the best decisions for her baby, and it infantilizes her by subjecting her medical decisionmaking to outside review and control.

Application of new technologies for embryonic and fetal therapies, whether germ line or somatic, raise the question of what is a "healthy" or "normal" baby, and may change societal notions of an acceptable pregnancy outcome. Testing programs raise the issue of rational and irrational choices implicit in the reproductive freedoms guaranteed to women under constitutional law. In light of new knowledge and new genetic technologies, what is a preventable condition, what is a genetic defect, what are medically necessary interventions, and what are acceptable outcomes in the case of a pregnancy, or in the case of surgical or other interventions will become increasingly more difficult questions in the

context of preconceptual genetic testing and prenatal diagnosis. Some of these questions affect how the society will regard prenatal testing programs and may also affect women's choices whether or not to bear a child with a particular genetic disease.

2. The Right to Refuse Prenatal Diagnosis and Treatment

Prenatal testing, diagnosis and treatment of the fetus all involve the mother's body. Hence, a pregnant woman has the clear constitutional right to refuse any such interventions. Since pregnant women have the sole decisionmaking power in the law relating to the fetus, and because there are no limits on maternal autonomy in this respect, prenatal testing and diagnosis have been viewed as both empowering maternal decisionmaking and expanding the scope of their responsibility for the choices that they make.[1] While prenatal diagnosis and testing may expand the mother's choices, it may also increase and enlarge her responsibilities. While there are no limits on maternal autonomy, it has been suggested that testing for sex selection and other trivial reasons should be discouraged.[2] And some commentators fear that failure to subject herself to a preconceptual or prenatal genetic test might be viewed as irresponsible, placing an undue burden on prospective mothers. The difficulty which such choice imposes has been noted by a number of feminist commentators. The decision may be viewed as a Hobson's choice,[3] or on the other hand, the difficulty may prove to be

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[1]Abby Lippman, Prenatal Genetic Testing and Screening: Constructing Needs and Reinforcing Inequities, 17 AM.J.LAW & MED. 22-23.

[2]It has been suggested that prenatal diagnosis "approaches children as consumer objects subject to quality control." Id. at 23.

[3]Helen Holmes, Genetic Testing: A Feminist Bioethics Analysis [Testimony at the Meeting of the National Academy of Sciences, Washington, D.C. Institute of Medicine Committee on Assessing Genetic Risks Issues and Implications for Health

almost overwhelming, causing the comment that prenatal diagnosis creates "a situation where women make a big mistake whichever path we take."[4] The fear has been expressed that a woman who refuses testing or treatment for the fetus may be viewed as inadequate or uncaring.[5]

In addition to these personal difficulties in decisionmaking, other questions may arise once the results of the test are known. While a father's opposition to abortion has no current legal significance, it may clearly create pressures for the woman as a decisionmaker, because the interests and concerns of the father or of other members of the family may affect decisionmaking in a variety of ways, including the economic costs of the decision.

The decision to terminate a pregnancy has often been emotionally devastating. One woman's account relates events after chorionic villus sampling revealed a defect, and termination of pregnancy was decided on. Despite the presence of a supportive husband, she clearly viewed the decision to terminate the pregnancy as her own. She stated that counselling had perhaps erroneously, concentrated on the testing process itself and how likely it was that the baby would be normal, rendering her ill-prepared to cope with abnormal results; obtaining the news on a Friday without access to help over the weekend. She wrote:

> A choice. A choice sounded better than not having a choice. Yet, the idea of choosing was overwhelming and confusing. We were devastated at the thought of either course of action. It wasn't until later that I realized the real tragedy was the loss of a healthy child, and that I had not had a choice about...Did the knowledge of a specific chromosome pattern

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Public: Genetic Testing and Screening Availability, Accessibility, Financing, Appropriateness and Ethical Issues, Thursday, September 17, 1992] [hereinafter Holmes].

[4]Id. at 2.

[5]Lippman supra note 1 at 26, 28.

actually help us, as prospective parents, make the best decision for our family? Many, I think, would say yes; knowledge is good. But I am not so sure. We had only one isolated piece of information, not a whole crystal ball. How were we to know what would be best?

One week later we went to the hospital to end the pregnancy. My husband was very supportive, but I was the one to walk into the operating room alone. It took several weeks to recovery physically; emotional scars are still raw 2 years later.

...the semblance of control and the heart-wrenching options magnified the pain many times over. I had chosen my pain.[6]

Another special problem which complicates a woman's decisionmaking is the problem of false positives after prenatal testing. Following a positive result which then leads to retesting and a decision not to terminate the pregnancy may also have difficult consequences. Surveys of parents whose children were diagnosed as having a genetic disease but were then informed that the tests were wrong showed that despite the revised diagnosis, parents were afraid that something was wrong with their children and treated them accordingly.[7]

3. Maternal Fetal Conflict and Its Resolution

Since women make the decision whether or not to have preconceptual or prenatal testing, and then make the decision following such test on prenatal treatment if any, or on the termination of the pregnancy, the unfortunate result may be to make women accountable for pregnancy outcomes. While there is clearly no such legal responsibility at this point, there appears to be some concern on the part of feminists and others that there are many social pressures in that direction.

There have been earlier instances and even legal decisions -- clearly not

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[6]J. Brown, The Choice, 262 J.A.M.A. 2735 (1989).

[7]Holmes supra note 3 at 3.

arising in the genetic context -- which have imposed obligations on women to protect a "safe passage" for the fetus, even at considerable cost to their own wellbeing. The earliest cases in this area of the law involved cases in which the highest court of the state of New Jersey granted a hospital the authority to administer blood transfusions to a pregnant patient against her religious objections, in order to save her life and the life of her unborn child. The blood transfusions had been refused by the patient because they were contrary to her beliefs as a Jehovah's Witness.[8]

These older blood transfusion cases provided some of the rationale for the decision in Jefferson v. Griffin Spalding County Hospital Authority.[9] At the request of the hospital, the court examined the constitutional question involved, and authorized the Caesarean section and any necessary blood transfusions upon an out patient if she presented herself to the hospital for the delivery of her unborn child. The case involved a situation of a woman who had a "complete placenta previa" which indicated that normal vaginal delivery would kill the fetus/child which at that point had reached the full level of viability. The court granted the request for Caesarean delivery, granted the Department of Human Service in Georgia temporary custody of the unborn child as "a deprived child without proper parental care necessary for his or her physical health" under Georgia law. The court found that the intrusion into the life of the mother and her husband was justified and outweighed by the duty of the state to protect a

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[8]Raleigh Fitkin-Paul Morgan Memorial Hospital v. Anderson, 201 A.2d 537 (N.J.), cert. denied 377 U.S. 985, relying on State v. Perricone, 37 N.J. 463 (1962) and Smith v. Brennan, 31 N.J. 353 (1960).

[9]274 S.E.2d 457 (Ga. 1981).

living, unborn human being against likely death.[10] It is perhaps worth noting that the court's order took effect only if the defendant mother voluntarily seeks admission to the hospital for the emergency delivery of the child.

The issue of coerced or judicially ordered Caesareans was clearly presented in the case of In Re A.C.[11] In an en banc decision, the Court of Appeals for the District of Columbia reversed the findings of the lower court which had ordered a Caesarean section for a terminally ill, 27-year-old woman who was 26 weeks pregnant. The Caesarean was authorized at the time when the woman was competent

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[10]274 S.E. 2d at 458-9. The court stated: "Defendant is in the thirty-ninth week of pregnancy. In the past few weeks she has presented herself to Griffin Spalding County Hospital for pre-natal care. The examining physician has found and defendant has been advised that she has a complete placenta previa; that the afterbirth is between the baby and the birth canal; that it is virtually impossible that this condition will correct itself prior to delivery; and that it is a 99% certainty that the child cannot survive natural childbirth (vaginal delivery). The chances of defendant surviving vaginal delivery are no better than 50%. The examining physician is of the opinion that a delivery by caesarean section prior to labor beginning would have an almost 100% chance of preserving the life of the child, along with that of defendant. On the basis of religious beliefs, defendant has advised the Hospital that she does not need surgical removal of the child and will not submit to it. Further, she refuses to take any transfusion of blood. The Hospital is required by its own policies to treat any patient seeking emergency treatment. It seeks authority of the Court to administer medical treatment to defendant to save the life of herself and her unborn child. [*87] "The child is, as a matter of fact, viable and fully capable of sustaining life independent of the mother (defendant). The issue is whether this unborn child has any legal right to the protection of the Court.

"To abort this child would be a criminal offense in Georgia. Ga. Code Ann., §§ 26-1201; 26-1202. A viable unborn child has the right under the U.S. Constitution to the protection of the State through such statutes prohibiting the arbitrary termination of the life of an unborn fetus. Roe v. Wade, 410 U.S. 113 (93 S.C. 705, 732, 35 L.E.2d 147) (1973). Because the life of defendant and of the unborn child are, at the moment, inseparable, the Court deems it appropriate to infringe upon the wishes of the mother to the extent it is necessary to give the child an opportunity to live.

"Accordingly, the plaintiff hospitals are hereby authorized to administer to defendant all medical procedures deemed necessary by the attending physician to preserve the life of defendant's unborn child. This authority shall be effective only if defendant voluntarily seeks admission to either of plaintiff's hospitals for the emergency delivery of the child."

[11]573 A.2d 1235 (D.C. 1990).

and had clearly indicated that she did not want it done.[12] The Caesarean, having been ordered by the trial court, was carried out long before the appeal was heard. The baby died three hours after Caesarean delivery and the mother died two days later. On appeal, the order that mandated the surgery was reversed and the appellate decision apparently put a stop to other efforts at court ordered Caesareans.[13] The issue of court ordered Caesareans has caused a great deal of unease because of its interference with what were regarded as clearly unchallengeable autonomous rights of the prospective mother. The case of In Re A.C. appears to be the only published case on the subject, but other, unpublished cases have been referred to, though not clearly documented.[14] A New England

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[12]In Re A.C. 573 A.2d 1235, at 1241 (D.C. 1990) en banc, the court reversed the findings of the lower court, which had ordered a caesarean section for a terminally ill twenty seven year old woman who was twenty six weeks pregnant. Evidence in the record indicated that the woman's husband, her family and the woman herself opposed the procedure, although she indicated that she would have consented to the procedure if she had been able to carry the fetus until twenty eight weeks of gestation. In testimony before the court, Dr. Weinhold stated, " She does not make sound because of the tube in her windpipe. She nods and she mouths words. One can see what she's saying rather readily. She asked whether she would survive the operation. She asked [Dr.] Hamner if he would perform the operation. He told her he would only perform it if she authorized it but it would be done in any case. She understood that. She then seemed to pause for a few moments and then very clearly mouthed words several times, I don't want it done. I don't want it done. Quite clear to me. I would obviously state the obvious and that is this is an environment in which, from my perspective as a physician, this would not be an informed consent one way or the other. She's under tremendous stress with the family on both sides, but I'm satisfied that I heard clearly what she said."

[13]Barbara Ann Leavine, Court Ordered Caesareans: Can a Pregnant Woman Refuse?, 29 HOUS.L.REV. 185-188 (1992): "The court's holding halted, at least for now, the erosion of the rights of pregnant women. Additionally, the court may have implicitly protected the medical community from the eventual imposition of a new legal duty to override the seemingly unreasonable choices of pregnant women."

[14]Id. at 190. See also: Nancy K. Rhoden, The Judge In the Delivery Room: The Emergence of Court-Ordered Caesareans, 74 CALIF.L.REV. 1951 (1986) "many more cases are completely unpublished, depriving this issue of the public concern and scrutiny that it deserves" and see: Elizabeth Eggleston Drigotas, Comment: Forced Caesarean Sections: Do the Ends Justify the Means? 70 N.C.L. REV. 297 (1991)

Journal of Medicine study reported on 15 instances of court orders to perform a Caesarean section, an intrauterine transfusion, or a forced detention. The Caesarean was indicated because of fetal distress in seven of the fifteen cases; previous Caesarean in three; and placenta previa in two. Most women consent to the surgery their physicians recommend and the reasons for refusal to consent are either religious beliefs or concern for their own health. Some hospitals will not accept the woman's refusal and will seek a court order out of fear of future liability or a belief that the woman has made a wrong or even immoral decision.[15]

There is concern that these cases may provide a basis for future interferences with women's autonomous decisions based on the outcome of genetic tests. This concern that the judicial protection of the fetus is likely to interfere with women's autonomous decisionmaking is furthered to some extent by

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citing Veronica E. B. Kolder et al., Court-Ordered Obstetrical Interventions, 316 NEW ENG. J. MED. 1192 (1987) stating that there have been 15 court orders sought by 1986, and since that time, several more. She described the study as follows: "The researchers sent a questionnaire to 90 directors of maternal-fetal fellowship programs and directors of maternal-fetal medicine in obstetrics-gynecology residencies; the physicians represented 45 states and the District of Columbia (Alaska, Idaho, Montana, North Dakota, and Wyoming were not represented). The study asked the physician to report incidents they knew of in which doctors had sought a court order to perform a cesarean section, an intrauterine transfusion, or a forced detention. Id. at 1192-93." She also noted that "the risk of maternal morbidity is four times greater with cesarean sections than it is with vaginal deliveries. There are a number of reasons why a physician might [*298] decide a cesarean is necessary. The cases reported in the New England Journal of Medicine study provide a sample: the cesarean was indicated because of fetal distress in seven of the fifteen; previous cesarean in three; and placenta previa in two. While most women consent to the surgery their physician recommends, some women refuse. Two reasons often given for the woman's refusal to consent are religious beliefs and concern for her own health. Out of fear of future liability or a belief that the woman has made a wrong, or even immoral, decision, some hospitals will not accept the refusal and instead take the case to court."

[15]Veronica E.B. Kolder et al., Court Ordered Obstetrical Interventions, 316 N.ENG. J. MED. 1192 (1987), as cited by Drigotas, supra at 298.

the aggressive efforts of right to life groups, who have managed to involve themselves in a number of judicial proceedings in direct opposition to the interest of the woman involved and her family.[16] Efforts have been made to protect the fetus from maternal drug use during pregnancy.[17] This approach places a double burden on pregnant drug users different from the approach taken towards other drug addicts.[18]

Though only a few cases nationwide have raised these issues, there is considerable concern that the assertion of fetal rights may be used to the detriment of pregnant women. Since the fetus is completely dependent on its mother, virtually everything the pregnant woman may have some effect on the fetus. Thus, her failing to eat properly, using prescription, non-prescription and illegal drugs, smoking or drinking, engaging in immoderate exercise or sexual intercourse may have some effect on the fetus which might be considered unacceptable and become the basis for criminal prosecution or a civil suit by a husband or other relative.[19] Noting that maternal-fetal conflicts arising during pregnancy do not involve a woman's right to procreate, but rather her right to

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[16]See Susan Goldberg, Of Gametes and Guardians: The Inappropriateness of Appointing Guardian Ad Litems for Fetuses and Embryos, 66 WASH.L.REV. 503 (1991).

[17]"Stopping the Stones" The Courier Journal, Oct. 3, 1993 at 2D. See also Janet Gallagher, Prenatal Invasions & Interventions: What's Wrong with Fetal Rights," 10 HARV. WOMEN'S L. J. (1987); Dawn Johnson, Substance Use During Pregnancy: Legal and Social Responses: Promoting Health Births Without Sacrificing Women's Liberty, 43 HASTINGS L.J. 569 (1992). Advocating such legislation, see Louise Marlane Chan, SOS from the Womb: A Call for New York Legislation Criminalizing Drug Use During Pregnancy 21 FORDHAM URB.L.J. 199 (1993).

[18]Note: Rethinking Motherhood: Feminist Theory and State Regulation of Pregnancy, 103 HARV.L.REV. 1325, 1341-2 (1990).

[19]See generally Dawn E. Johnsen, The Creation of Fetal Rights: Conflicts with Women's Constitutional Rights to Liberty, Privacy, and Equal Protection, 95 YALE L.J. 599 (1986).

bodily integrity. "Once she decides to forgo abortion and the state chooses to protect the fetus, the woman loses the liberty to act in ways that would adversely affect the fetus."[20] It follows from this point of view that compelled Caesareans may be appropriate and that civil and criminal liability may properly be imposed for harmful conduct during pregnancy. Note that the Robertson point of view antedates by more than ten years the recent emphasis on legal and ethical concerns for women's autonomy.

A recent response to the purported maternal-fetal conflict has emphasized the interrelation or "connectedness" between maternal health and the fetus, taking maternal concerns fully into account. Rejecting the idea that maternal rights and fetal interests are in irreconcilable conflict, that view is also rejected on the grounds that this purported conflict of power may easily be manipulated to reinforce gender hierarchy.[21] The idea of conflicting rights, it is said, was inappropriate to describe pregnancy which is a condition of continuous connection and dependence.[22] It is asserted that through mothering "women develop a sense of connection that entails a distinct concept of value and the way of moral reasoning . . . characterized by a standard of responsibility rather than a standard of rights and autonomy."[23] The connectedness approach places greater reliance on the mother, who must obtain access to health care and make decisions about medical treatment during pregnancy without judicial opinions

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[20]John Robertson, Procreative Liberty and the Control of Pregnancy, Conception and Childbirth, 69 VA.L.REV. 405, at 437 (1983), citing Note: Constitutional Limitations on State Intervention in Prenatal Care, 67 VA.L.REV. 1051 (1981).

[21]Rethinking Motherhood supra note 18 at 1335-37.

[22]Id. at 1337.

[23]Id. at 1337.

to support her rationale. Since fact finding in these cases is impossible, "a presumption should operate in favor of the woman's choice about medical procedures and birthing conditions. Absent clear evidence that the decisionmaking process has failed, courts should not substitute their own judgment or that of a doctor for the woman's." Emphasis must therefore be placed on education through genetic counseling and on universal access to good prenatal care. Women must have access to the relevant information and weigh for themselves the risks and benefits of various tests or treatments in order to make procreational decisions. The idea of connectedness recognizes the intimate attachment of the prospective mother to the fetus she is carrying, a connectedness which is to taken into account in making genetic testing determinations.

4. Fetal Testing, Informed Consent and Counseling

About half of the 4.2 million pregnancies in the United States each year are screened prenatally for major fetal disorders using one of several tests or biochemical measurements during the second trimester.[24] As technology improves, the number of women screened, i.e., the number of fetuses tested, is likely to increase substantially. This is likely to occur when a process is perfected for providing a diagnosis using fetal cells isolated from maternal blood. Once perfected, this will probably mean that nothing more invasive than an ordinary blood test will be required for prenatal testing and diagnosis. In the past, any kind of invasive procedure that required informed consent would emphasize the full explanation of the invasive procedure and of its physical consequences. In the case of prenatal genetic testing, informed consent will require considerably

[24]James Haddow, FDA's Action To Ban Importation of Kodak Products Used for Prenatal Screening, GENESIS (Newsletter of the Genetics Network of the Empire State), Vol. V No. 2 (June 1993) at 3.

more information than simply information relating to the testing procedure. It will require information as to the likely outcomes of the testing procedure and as to the nature of the choices and decisions which the testing results will then present to the mother.[25]

The decision whether or not to have a prenatal test is likely to depend less on the nature and risk of the testing procedure, but rather on the readiness of the prospective mother to assume and face up to a very difficult and possibly emotionally highly trying decision process. Informed consent to prenatal testing must fully inform the prospective mother what issues and problems she is likely to face once the test results are available. The need for genetic counseling at the time test results become available has also been emphasized and forms an important part of the process. Access to prenatal testing thus means more than access to the clinical facilities that provide such testing, but also full institutional capacities to meet the requirements of informed consent and to provide genetic counseling both before and immediately after the test, particularly immediately after test results become available.

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[25]INSTITUTE OF MEDICINE, ASSESSING GENETIC RISKS: IMPLICATIONS FOR HEALTH AND SOCIAL POLICY, Chapter 2, at 19, Box 2-3 (1993), "New Techniques in Prenatal Diagnosis" describes this process as follows: "Diagnosis using fetal cells isolated from maternal blood hold the promise of noninvasive prenatal diagnosis by genetic analysis of fetal cells isolated from a sample of the mother's blood (Bianchi et al 1991). Techniques have been developed to isolate or concentrate genetic material from the very few fetal cells circulating in maternal blood. These techniques include fluorescence-activated cell sorting using monoclonal antibodies, polymerase chain reaction and in situ hybridization of fetal cells. Once concentrated, selected genetic components need to be multiplied so they can be analyzed correctly. Fetal cells have been detected in maternal blood as early as nine weeks of gestation. First trimester prenatal diagnosis of Down Syndrome has now been reported in fetal cells from maternal blood (Elias et al. 1992). PCR has been used to amplify a sample for prenatal testing from a single fetal cells. One limitation of this technique is that some fetal cells may be left from previous pregnancies (Bianchi et al. 1991). The slightest contamination can result in incorrect diagnosis (both false positives and false negatives). This technique is still being evaluated."

The information that the fetus has a genetic disease of a serious nature is viewed as creating pressures on the woman to decide to terminate the pregnancy. Though the situation can be differentiated, because AIDS is a deadly communicable disease, the pressure on women who have given birth to an HIV-infected infant has been recognized.[26] Just as governmental restrictions might limit autonomy, there is a distinct possibility that such autonomy can also be limited by directive professional advice. Though AIDS and genetic disorders are not comparable, the impact on the autonomous choice of the mother may be similar. ? The infantile AIDS situation and the serious genetic defect situation are analogous in that professional advice in both instances is likely to be benign in intent and designed to protect both the mother and a future child she may have. There is little question that only a few years ago under then prevailing notions of the protection of public health the mother would have been advised in both instances to avoid future pregnancies. It probably requires a very highly developed sense of the protectability of autonomy as a value to be wholly critical of the earlier decisional outcomes.

5. Women's Autonomy and the Role of the Father and Other Members of the Family

In Planned Parenthood of Pennsylvania v. Casey,[27] the Supreme Court's

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[26]"How will the threat of maternally transmitted lethal infection affect the tolerance for an ethos that has proclaimed the utter primacy of each woman's reproductive decision? Will the grim reality of pediatric AIDS generate pressure for social interventions that would shape, direct, constrain, limit, or control those decisions in a way that might contradict the pronatalist demands of the movement that seeks to restrict severely or eliminate the right to abortion?" Ronald Bayer, AIDS and the Future of Reproductive Freedom, 68 MILBANK QUARTERLY Supp. 2, 179 (1990) at 180.

[27]112 S.Ct. 2791 (1992).

latest comment on abortion rights, the Court upheld the urgent claims of the woman to retain the ultimate control over her destiny and her body, claims implicit in the meaning of liberty.[28] In that decision, the Court upheld the right of the woman to terminate her pregnancy and her right to be protected against interference with that decision, even by her husband. While family members and fathers may have traditionally recognized interests, these interests, the Court held, did not subordinate the rights of the pregnant woman. The Court commented: "In well-functioning marriages, spouses discuss important intimate decisions such as whether to bear a child. But there are millions of women in this country who are the victims of regular physical and psychological abuse at the hands of their husbands. Should these women become pregnant, they may have very good reasons for not wishing to inform their husbands of their decision to obtain an abortion."[29] The Court therefore found unconstitutional statutory provisions in the state of Pennsylvania that would have compelled married women to notify their husbands of their decision to terminate the pregnancy. While certain interferences -- such as court-ordered Caesarean sections -- have limited women's autonomy in a relatively small and unusual number of cases, it is clear that women will be protected against interferences in their autonomy by their husbands and, by implication, by other members of the family.

There are no cases where reports that involve family pressure or interference with a woman's autonomous choice to terminate the pregnancy or to proceed to carry a genetically ill fetus to term. Women may be subject to pressures either way from their families, and resistance to family pressures is probably a matter on which appropriate counselling should be available. There may

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[28]Id.

[29]Id. at 2828.

be some special problems with relation to the propriety of informing family members of a positive test result that may provide family members with information that they too are at risk. This would be the case in instances of autonomous single gene defects such as sickle cell anemia, Tay-Sachs, cystic fibrosis, or in the case of such autonomous dominant diseases such as Huntington disease. In such instances, there appears to be no obligation either on the woman who underwent the test or on the physician to inform relatives and to give them adverse news which they did not ask for and which they may not wish to receive. Whether an ethical obligation exists to convey such information to relatives is a significant issue in instances where the relatives may benefit from such information because it may enable them to protect themselves against similar adverse outcomes in the future. In addition to information relating to the presence or absence of genetic illness, there sometimes arise situations where a prenatal test demonstrates that the husband or other putative father is not the actual father of the prospective child. There seems to be no obligation on the part of the mother to convey this information to the putative father, or for that matter, to the real father, if she knows his identity. There is a question as to the possible ethical obligation to inform the putative father that he is not the source of the genetic trait or disease, so as to relieve him of future anxiety and free him to make future procreative choices. It is clear in every one of these instances that currently the woman's physician is under no obligation to inform the husband or family members, but rather that he is bound by the physician/patient privilege not to disclose such information unless the patient has provided appropriate authorization for such disclosures. While clearly a supportive role for fathers and relatives in the decisionmaking process has not been ruled out, and while one hopes that in the situation of well-working, loving

marriages decisions relating to procreation and the birth of a defective child will be made jointly by the parents, there is no such legal obligation and the burden to decide is clearly that of the woman alone.

6. The Special Role and Responsibility of Women in Making Genetic Choices

In the making of genetic choices, and in issues relating to genetic screening and in prenatal testing, as well as in any in utero treatment of the fetus, the prospective mother is directly and intimately involved. In any of these procedures it is essentially her body that is being tested or examined. By law, the making of procreational choices is ultimately that of the woman, who, after all genetic counseling and all supportive services are completed, is the one who must make the decision and suffer the emotional upheaval of determining whether to terminate or continue pregnancy, with all of the risks either course entails.

While the fetus may be viewed as part of the mother's body, it is still a separate entity and, in a number of situations, the law has regarded the interest of the mother as separate and distinct from that of the fetus. There have been a number of instances of involuntary Caesarean sections to preserve the life of the fetus, and concern has been expressed that these earlier cases provide the basis for future interferences with a woman's autonomous decisions based on the outcome of genetic tests. Although the matter of maternal-fetal conflict has been discussed in the literature, the notion appears to have been rejected in favor of an approach that stresses the interrelation, the close connectedness between maternal health and the fetus, rejecting the idea of an irreconcilable conflict between the two. The idea of the separateness of the fetus and the mother has been stressed in situations where the mother has been prosecuted for drug and

alcohol abuse because of its adverse impact on the fetus. The emphasis on such criminal prosecution has not had any impact, however, on the woman's ultimate right to decide whether to carry the child to term or to terminate the pregnancy.

While clearly the role of the father and of other members of the family may be significant in making personal decisions relating to the birth of children, and while fathers in particular may have a role in the counseling process and often should be included in counseling sessions, the father's participation has no impact on the legal power of decision which is that of the woman alone, for better or for worse making her responsible for the decision, though not for genetic outcomes. It is this aspect of the decisional burden which ought to be eased through genetic counseling.

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