4. Medical underwriting is the evaluation of a person's insurability, usually assessed through a bination of answers to a written questionnaire and physical examination to identify certain condi- s determined by medical underwriters (and underwriting manuals) to reduce life expectancy or ease medical care costs beyond actuarial norms. Standards for medical underwriting vary substan- y by insurance company, and underwriting decisions are considered crucial business decisions by rers, and are thus considered "trade secrets" not subject to public disclosure.

5. The National Sickle Cell Anemia, Cooley Anemia, Tay-Sachs, and Genetic Diseases Act of 6 (Public Law 94-278) consolidated separate 1972 legislation for sickle cell anemia (Public Law 294) and Cooley anemia (Public Law 92-414) and added other genetic conditions into the provi- s of the law. It required the development of information and education materials "to persons viding health care, to teachers and students, and to the public in general in order to rapidly make lable the latest advances in the testing, diagnosis, counseling and treatment of individuals respect- genetic disease." It also required that federally assisted programs for the disorders included were e entirely voluntary. Although this legislation was repealed in 1981, with the passage of the rnal and Child Health Services Block Grant Act (Public Law 97-35), the requirement that pro- s supported with block grant funds be entirely voluntary was never repealed.

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8

Social, Legal, and Ethical Implications of Genetic Testing

Each new genetic test that is developed raises serious issues for medicine, public health, and social policy regarding the circumstances under which the test should be used, how the test is implemented, and what uses are made of its results. Should people be allowed to choose or refuse the test, or should it be mandatory, as newborn screening is in some states? Should people be able to control access to the results of their tests? If test results are released to third parties such as employers or insurers, what protections should be in place to ensure that people are not treated unfairly because of their genotype?

The answers to these questions depend in part on the significance given to four important ethical and legal principles: autonomy, confidentiality, privacy, and equity. A review of the meaning of those concepts and how they are currently protected by the law provides a starting point for the development of recommendations on the degree of control people should have in deciding whether to undergo genetic testing and what uses should be made of the results. The task is a pressing one. In a 1992 national probability survey of the public, sponsored by the March of Dimes, 38 percent of respondents said that new types of genetic testing should be stopped altogether until the privacy issues are settled.[1]

This chapter reviews some of the conflicts that will arise in the research and clinical settings, and suggests general principles that should be the starting point for policy analyses in this evolving field.

Since many of the references in this chapter are legal citations, its references appear in legal style as numbered end notes.

KEY DEFINITIONS

Autonomy

Ethical Analysis

Autonomy can be defined as self-determination, self-rule, or self-governance. Autonomous agents or actions presuppose some capacity of reasoning, deciding, and willing. Moral, social, and legal norms establish obligations to respect autonomous agents and their choices. Respect for personal autonomy implies that agents have the right or power to be self-governing and self-directing, without outside control. In the context of genetic testing and screening, respect for autonomy refers to the right of persons to make an informed, independent judgment about whether they wish to be tested and then whether they wish to know the details of the outcome of the testing. Autonomy is also the right of the individual to control his or her destiny, with or without reliance on genetic information, and to avoid interference by others with important life decisions, whether these are based on genetic information or other factors. Respect for autonomy also implies the right of persons to control the future use of genetic material submitted for analysis for a specific purpose (including when the genetic material itself and the information derived from that material may be stored for future analysis, such as in a DNA bank or registry file).

Even though respect for autonomy is centrally important in our society, it is not absolute. It can be overridden in some circumstances, for example, to prevent serious harm to others, as is the case in mandatory newborn screening for phenylketonuria (PKU) and hypothyroidism.

Legal Issues

The legal concept of autonomy serves as the basis for numerous decisions protecting a person's bodily integrity. In particular, cases have held that competent adults have the right to choose whether or not to undergo medical interventions.[2] Before people make such a choice, they have a right to be informed of facts that might be material to their decision,[3] such as the nature of their condition and its prognosis,[4] the potential risks and benefits of a proposed test or treatment,[5] and the alternatives to the proposed intervention.[6] In the genetics context, health care providers have been held liable for not providing the information that a genetic test is available.[7]

People also have a right to be informed about and to control the subsequent use of tissue that has been removed from their bodies.[8] There is some leeway under the federal regulations governing research involving human subjects for researchers to undertake subsequent research on blood samples provided for genetic tests (as in the newborn screening context) as long as the samples are anonymous and as long as the subsequent use was not anticipated at the time the sample was collected.[9] If the additional test *was* anticipated at the time the sample was collected, informed consent for that use should be obtained prior to the collection of the original sample.

Such an approach is thought appropriate to avert conflicts of interest, such as a physician/researcher suggesting that a patient undergo a particular test when the researcher actually wanted the tissue for the researcher's own additional use in a research or commercial project. In such a situation, the patient's autonomy is compromised even if the sample is used anonymously in the subsequent use. A report from the Office of Technology Assessment similarly stressed the importance of knowledge and consent:

> The consent of the patient is required to remove blood or tissue from his or her body, and also to perform tests, but it is important that the patient be informed of all the tests which are done and that a concern for the privacy of the patient extends to the control of tissues removed from his or her body.[10]

Privacy

Ethical Analysis

Among the various definitions of privacy, one broad definition captures its central element: privacy is "a state or condition of limited access to a person."[11] People have privacy if others lack or do not exercise access to them. They have privacy if they are left alone and do not suffer unauthorized intrusion by others. Once persons undergo genetic tests, privacy includes the right to make an informed, independent decision about whether—and which—others may know details of their genome (e.g., insurers, employers, educational institutions, spouses and other family members, researchers, and social agencies).

Various justifications have been offered for rules of privacy. First, some philosophers argue that privacy rights are merely shorthand expressions for a cluster of personal and property rights, each of which can be explicated without any reference to the concept of privacy. In making this argument, Judith Jarvis Thomson holds that privacy rights simply reflect personal and property rights, such as the rights not to be looked at, not to be overheard, and not to be caused distress.[12]

A second justification holds that rights to privacy are important instruments or means to other goods, including intimate relations such as trust and friendship. Being able to control access to themselves enables people to have various kinds of relationships with different people, rather than being equally accessible to all others.

A third approach finds the basis for rights to privacy in respect for personal autonomy. Decisional privacy is often very close to personal autonomy. The language of personal autonomy reflects the idea of a domain or territory of self-rule, and thus overlaps with zones of decisional privacy.

Whatever their rationale or justification, rights of privacy are the subject of ongoing debate about their scope and weight. However, their scope is not unlimited, and they do not always override all other competing interests, such as the interests of others.

Legal Issues

In the legal sphere, the principle of privacy is an umbrella concept encompassing issues of both autonomy and confidentiality. The right to make choices about one's health care is protected, in part, by the right to privacy guaranteed by the U.S. Constitution, as well as state constitutions. This includes a right to make certain reproductive choices,[13] such as whether to use genetic testing.[14] It also includes a right to refuse treatment.

An entirely different standard of privacy protects personal information. A few court decisions find protection for such information under the constitutional doctrine of privacy,[15] but more commonly, privacy protection against disclosure of personal information is found under common law tort principles.[16] In addition, there is a federal privacy act,[17] as well as state statutes protecting privacy.

Confidentiality

Ethical Analysis

Confidentiality as a principle implies that some body of information is sensitive, and hence, access to it must be controlled and limited to parties authorized to have such access. The information provided within the relationship is given in confidence, with the expectation that it will not be disclosed to others or will be disclosed to others only within limits. The state or condition of nondisclosure or limited disclosure may be protected by moral, social, or legal principles and rules, which can be expressed in terms of rights or obligations.

In health care and various other relationships, we grant others access to our bodies. They may touch, observe, listen, palpate, and even physically invade. They may examine our bodies as a whole or in parts; and parts, such as tissue, may be removed for further study, as in some forms of testing. Privacy is necessarily diminished when others have such access to us; rules of confidentiality authorize us to control and thus to limit further access to the information generated in that relationship. For example, rules of confidentiality may prohibit a physician from disclosing some information to an insurance company or an employer without the patient's authorization.

Rules of confidentiality appear in virtually every code or set of regulations for health care relationships. Their presence is not surprising, because such rules are often justified on the basis of their instrumental value: if prospective patients cannot count on health care professionals to maintain confidentiality, they will be

reluctant to allow professionals the full and complete access necessary for diagnosis and treatment. Hence, rules of confidentiality are indispensable for patient and social welfare; without those rules, people who need medical, psychiatric, or other treatment will refrain from seeking or fully participating in it. Another justification for rules of confidentiality is based on the principles of respect for autonomy and privacy, above. Respecting persons involves respecting their zone of privacy and accepting their decisions to control access to information about them. When people grant health care professionals access to them, they should retain the right to determine who else has access to the information generated in that relationship. Hence, the arguments for respect for autonomy and privacy support rules of confidentiality. Finally, duties of confidentiality often derive from explicit or implicit promises in the relationship. For instance, if the professional's public oath or the profession's code of ethics promises confidentiality of information, and the particular professional does not specifically disavow it, then the patient has a right to expect that information generated in the relationship will be treated as confidential.[18]

There are at least two distinct types of infringements of rules of confidentiality. On the one hand, rules of confidentiality are sometimes infringed through deliberate breaches. On the other hand, rules of confidentiality are often infringed through carelessness, for example, when health care professionals do not take adequate precautions to protect the confidential information. Some commentators argue that both carelessness and modern practices of health care have rendered medical confidentiality a "decrepit concept," since it is compromised routinely in the provision of health care.[19]

It is widely recognized that the rules of confidentiality are limited in at least two senses: (1) some information may not be protected, and (2) the rules may sometimes be overridden to protect other values. First, not all information is deemed confidential, and patients do not have a right to expect that such information will be protected from disclosure to others. For example, laws frequently require that health care professionals report gunshot wounds, venereal diseases, and other communicable diseases such as tuberculosis. Second, health care professionals may also have a moral or legal right (and sometimes even an obligation) to infringe rules of confidentiality, for example, to prevent a serious harm from occurring. In such cases, rules of confidentiality protect the information, but they can be overridden in order to protect some other value. Judgments about such cases depend on the probability of serious harm occurring unless confidentiality is breached. Any justified infringements of rules of confidentiality should satisfy the conditions identified earlier in the discussion of justified infringements of the principle of respect for autonomy.

Legal Issues

The legal concept of confidentiality focuses on the information that people

provide to their physicians. The protection of confidentiality is thought to serve an important public health goal in encouraging people to seek access to health care. It is thought that the patient's interest can be served only in an atmosphere of total frankness and candor.[20] Without the promise of confidentiality, people might avoid seeking medical treatment, thus potentially harming themselves as well as the community. In fact, the first doctor-patient confidentiality statute was passed in 1828 in New York during the smallpox epidemic to encourage people to seek health care. Various legal decisions have protected confidentiality of health care information,[21] as have certain state and federal statutes.

Confidentiality of health care information is also protected because disclosure of a person's medical condition can cause harm to him or her. An alternative set of legal principles—those penalizing discrimination (see below)—protects people against unfair uses of certain information.

Equity

Ethical Analysis

Issues of justice, fairness, and equity crop up in several actions, practices, and policies relating to genetic testing. It is now commonplace to distinguish formal justice from substantive justice. Formal justice requires treating similar cases in a similar way. Standards of substantive or material justice establish the identity of the relevant similarities and differences and the appropriate responses to those similarities and differences. For instance, a society has to determine whether to distribute a scarce resource such as health care according to persons' differences in need, social worth, or ability to pay.

One crucial question is whether genetic disorders or predispositions provide a basis for blocking access to certain social goods, such as employment or health insurance. Most conceptions of justice dictate that employment be based on the ability to perform particular tasks effectively and safely. For these conceptions, it is unjust to deny employment to someone who meets the relevant qualifications but also has a genetic disease. Frequently these questions of employment overlap with questions of health insurance. Practices of medical underwriting in health insurance reflect what is often called "actuarial fairness"—that is, grouping those with similar risks together so insurers can accurately predict costs, and set fair and sufficient premium rates. Although actuarial fairness may be intuitively appealing, critics argue that it does not express moral or social fairness. According to Norman Daniels, there is "a clear mismatch between standard underwriting practices and the social function of health insurance" in providing individuals with resources for access to health care[22] (see Chapter 7).

The fundamental argument for excluding genetic discrimination in health insurance amounts to an argument for establishing a right to health care. One of the central issues in debates about the distribution of health care is one's view of the

"natural lottery," in particular, a "genetic lottery."[23] The metaphor of a lottery suggests that health needs result largely from an impersonal natural lottery and are thus undeserved. But even if health needs are largely undeserved because of the role of chance, society's response to those needs may vary, as H. Tristram Engelhardt notes, depending on whether it views those needs as *unfair* or as *unfortunate*.[24] If health needs are unfortunate, but not unfair, they may be the object of individual or social compassion. Other individuals, voluntary associations, and even society may be motivated by compassion to try to meet those needs. If, however, the needs are viewed as unfair as well as unfortunate, society may have a duty of justice to try to meet those needs.

One prominent argument for the societal provision of a decent minimum of health care is that, generally, health needs are randomly distributed and unpredictable, as well as overwhelming when health crises occur.[25] Because of these features of health needs, many argue that it is inappropriate to distribute health care according to merit, societal contribution, or even ability to pay. Another version of the argument from fairness holds that health needs represent departures from normal species functioning and deprive people of fair equality of opportunity. Thus, fairness requires the provision of health care to "maintain, restore, or compensate for the loss of normal functioning" in order to ensure fair equality of opportunity.[26]

Several committee members expressed concerns that these stated arguments are somewhat weakened by the fact that a number of diseases are not the result of random events, but are brought on or exacerbated by dispensable habits such as cigarette smoking and excessive alcohol ingestion. While our and other societies attempt to discourage such habits by education and taxation, there is general agreement that access to full health care must be ensured once illness develops. If a tendency to abuse alcohol, for example, were to have a genetic predisposition, an additional argument could be made for providing the same level of health care to everyone since a person does not choose his or her genetic propensities.

The argument that society should guarantee or provide a decent minimum of health care for all citizens and residents points toward a direction for health policy, but it does not determine exactly how much health care the society should provide relative to other goods it also seeks. And, within the health care budget, there will be difficult allocation questions, including how much should be used for particular illnesses and for particular treatments for those illnesses. Questions of allocation cannot be resolved in the abstract. In democratic societies, they should be resolved through political processes that express the public's will. In specifying and implementing a conception of a decent minimum, an adequate level, or a fair share of health care in the context of scarce resources, as the President's Commission noted in 1983, it is reasonable for a society to turn to fair, democratic political procedures to choose among alternative conceptions of adequate health care, and in view of "the great imprecision in the notion of adequate health care . . . it is especially important that the procedures used to define that level be—and be perceived to be—fair."[27]

Legal Issues

The concept of equity serves as the underpinning for a variety of legal doctrines and statutes. Certain needy people are provided health care, including some genetics services, under government programs such as Medicaid (see Chapter 7). In addition, some legislative efforts have been made to prohibit discrimination based on genotype. For example, some states have statutes prohibiting discrimination in employment based on one's genotype.[28] And nearly all people over age 65 are deemed to have a right to care (under Medicare).

CURRENT PRACTICE OF PROTECTION IN GENETICS

The development of genetic testing has raised numerous concerns about autonomy, confidentiality, privacy, and equity that are exacerbated by the range of contexts in which such tests are undertaken, the sheer volume of tests that could be offered, the many uses that can be made of test results, and the variety of institutions that store genetic information. To date, most genetic testing has been done in the reproductive context or with newborns, to identify serious disorders that currently or soon will affect the fetus or infant. However, the types of genetic conditions or predispositions that can potentially be tested for are much broader than those signaling serious, imminent diseases. These include characteristics (such as sex or height) that are not diseases, potential susceptibility to diseases if the person comes into contact with particular environmental stimuli, and indications that a currently asymptomatic person will suffer later in life from a debilitating disease such as Huntington disease. The genetic anomalies that can be tested for range widely in their manifestations, their severity, their treatability, and their social significance. People's ability to define themselves, to manage their destiny and self-concept, will depend in large measure on the control they have over whether they and others come to know their genetic characteristics.

Most medical testing is done within a physician-patient relationship. With genetic testing, however, the potential range of contexts in which it can be undertaken is large. Already, in the public health context, more than 4 million newborns are tested annually for metabolic disorders so that effective treatment can be started in a few hundred. Researchers are inviting people to participate in family studies and undergo genetic testing, including collection of DNA samples for present or future analyses. There are a growing number of nonmedical applications of genetic testing as well. In the law enforcement context, DNA testing is undertaken to attempt to identify criminal offenders. At least 17 states have DNA fingerprint programs for felons.[29] The armed services are collecting DNA samples from all members of the military, the primary purpose of which is to identify bodies of deceased soldiers. Employers and insurers may require people to undergo testing for genetic disorders for exclusionary purposes. One challenge for policy posed by this wide array of testing settings is that many of the existing legal

precedents about autonomy, confidentiality, and privacy apply only to the traditional doctor-patient relationship. For example, some state statutes governing confidentiality deal only with information provided to physicians and might not cover information provided to Ph.D. researchers or employers.

There seems to be great variation among institutions and among providers in the amount of attention paid to autonomy, confidentiality, and privacy. For example, some obstetricians recognize the patient's autonomy by providing them the information about maternal serum alpha-fetoprotein (MSAFP) screening but acknowledging the patient's right to decide whether or not to undergo the test. Other obstetricians run the test on blood gathered from the woman for other purposes, so the woman does not even know she has been the subject of the test unless the obstetrician delivers the bad news that she has had an abnormal result.

Geneticists differ with respect to the emphasis they place on the confidentiality of the results of genetic testing. In a survey by Dorothy Wertz and John Fletcher,[30] numerous geneticists suggested that there were at least four situations in which they would breach confidentiality and disclose genetic information without the patient's permission, even over the patient's refusal: (1) 54 percent said they would disclose to a relative the risk of Huntington disease; (2) 53 percent said they would disclose the risk of hemophilia A; (3) 24 percent said they would disclose genetic information to a patient's employer; and (4) 12 percent said they would disclose such information to the patient's insurer. Primary care physicians may be even more likely to disclose such information.[31] Health care providers should explain their policies for disclosure in advance, including for disclosure to relatives.

Institutions that store DNA samples[32] or store the results of genetic tests also differ in the amount of respect they give to autonomy, confidentiality, and privacy.[33] Some institutions do additional tests on DNA samples without the permission of the person who provided the sample. Some share samples with other institutions. Some store samples or information with identifiers attached, rather than anonymously. Indeed, storage conditions themselves differ widely. Some newborn screening programs store filter papers in a temperature-controlled, secure setting; others merely pile them in a file cabinet or storage closet. Programs also differ in the length of time the sample or the test results are maintained.

Once DNA material has been submitted, there are few safeguards concerning other present or future uses that may be made of the material. DNA from the blood spots collected for newborn screening can now be extracted for further testing.[34] No standards or safeguards currently exist to govern the appropriate use of DNA analysis and storage from newborn screening tests. These possibilities raise questions about the need to obtain consent for additional and subsequent uses (particularly since consent is almost never obtained initially in newborn screening), as well as questions about the duty to warn if disorders are detected in the blood by using the new DNA extraction testing techniques.

The issue of confidentiality of genetic information will be underscored with

the introduction of "optical memory cards," a credit card-sized device that stores medical information.[35] These cards have already been introduced for use in Houston city health clinics. There is sufficient computer memory on the cards to include genetic information about the person and, in the future, to include a person's entire genome.

Congressional legislation has been introduced that would require all patients to use optical memory cards. This bill, the Medical and Health Insurance Information Reform Act of 1992, would mandate a totally electronic system of communication between health care providers and insurers. Such a system would be based either on the optical memory card (with a microchip capable of storing data) or on a card similar to an Automated Teller Card (which simply provides access to data stored elsewhere).

APPLYING THE PRINCIPLES TO GENETIC TESTING

The principles of autonomy, privacy, confidentiality, and equity place great weight on individuals' rights to make personal decisions without interference. This is due, in part, to the importance placed on individuals in our culture and our legal system. However, individual rights are not without bound, and the area of genetics raises important questions of where individual rights end and where responsibilities to a group—such as one's family or the larger society—begin.

Medicine is generally practiced within this culture of individual rights (with provisions for patients' right to refuse treatment and right to control the dissemination of medical information about themselves), but there have been circumstances in which the medical model has been supplanted by the public health model, which encourages the *prevention* of disease—for example, by requiring that certain medical intervention (such as vaccinations) be undertaken and by warning individuals of health risks (e.g., through educational campaigns against smoking or through contact tracing with respect to venereal diseases). Some commentators have suggested that the public health model be applied to genetics,[36] with mandatory genetic screening and even mandatory abortion of seriously affected fetuses. A related measure might be warning people of their risk of genetic disorders.

There are several difficulties with applying the public health model to genetics, however. Certain infectious diseases potentially put society as a whole at immediate risk since the diseases can be transmitted to a large number of people in a short time. The potential victims are existing human beings who may be total strangers to the affected individual. In contrast to infectious disease, the transmission of genetic diseases does not present an immediate threat to society. Whereas infectious disease can cause rapid devastation to a community, the transmission of genetic disorders to offspring does not necessarily have an immediate detrimental effect, but rather creates a potential risk for a future generation in society.[37] U.S.

Supreme Court cases dealing with fundamental rights have held that harm in the future is not as compelling a state interest as immediate harm.[38]

Moreover, the very concept of "prevention" does not readily fit most genetic diseases. In the case of newborn screening for PKU, treatment can prevent mental retardation. However, with many genetic diseases today, the genetic disease itself is not being prevented, but rather the birth of a particular individual with the disease is prevented (e.g., when a couple, each of whom is heterozygous for a serious recessive disorder, chooses not to conceive or chooses to terminate the pregnancy of a fetus who is homozygous for the disorder). This sort of prevention cannot be viewed in the same way as preventing measles or syphilis, for example. There is a great variation among people in their view of disability and what constitutes a disorder to be "prevented." Many people will welcome a child with Down syndrome or cystic fibrosis into their family. In addition, some individuals have religious or other personal moral objections to abortion; even mandatory carrier status screening or prenatal screening without mandatory abortion may be objected to because people who object to abortion are concerned that the abortion rate will rise among those in the general population who learn of genetic risks to their fetus. 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.

Mandatory genetic testing might also have devastating effects on the individuals who are tested. Unlike infectious disease (which can be viewed as external to the person), genetic disease may be viewed by people as an intractable part of their nature. Persons who learn, against their will, that they carry a defective gene may view themselves as defective. This harm is compounded if they did not choose to learn the information voluntarily. This assault on personal identity is less likely with infectious diseases, although AIDS and genital herpes (for example) can also have a negative impact on self-image. Moreover, most genetic defects, unlike most infectious diseases, generally cannot now be corrected.[39] Thus, the unasked-for revelation that occurs through mandatory genetic testing can haunt the person throughout his or her life and can have widespread reverberations in the family, including others who may be at risk or related as partners. The information can serve as the basis for discrimination against the individual.

Additionally, policy concerns raised by attempts to stop the transmission of genetic diseases differ from those addressed to infectious diseases because genetic diseases may differentially affect people of different races or ethnic backgrounds. For that reason, some commentators contest the applicability of the infectious disease model to government actions regarding genetic disorders. Catherine Damme notes that "unlike infectious disease which [generally] knows no ethnic, racial, or gender boundaries, genetic disease is the result of heredity"—leaving open the possibility for discriminatory governmental actions.[40]

The government has discretion with respect to which infectious diseases it tackles. For example, it can decide to require screening for syphilis but not

chlamydia, or to require vaccinations for smallpox but not for diphtheria. Government action with respect to genetic diseases is likely to be regarded much differently, especially with respect to disorders for which an effective treatment does not exist and, consequently, the only medical procedure available is the abortion of an affected fetus. Minority groups who have been discriminated against in the past may view a screening program that targets only disorders that occur within their racial or ethnic group as an additional attack, and may view abstention from reproduction or the abortion of offspring based on genetic information as a form of genocide.[41]

Those commentators who argue that the infectious disease precedents justify mandatory genetic screening fail to recognize that even in the case of infectious disease, very few medical procedures are mandated for adults. Adults are not forced to seek medical diagnosis and treatment even if they have a treatable infectious disease. Laws that required compulsory infectious disease screening prior to marriage (e.g., for venereal disease) are being repealed. For example, New York abolished its requirements for premarital gonorrhea and syphilis testing. One of the reasons for the abolition of the requirements was that they were not the most appropriate way to reach the population at risk.[42]

Mandating diagnosis and treatment for genetic disorders is particularly problematic when the concept of disease is so flexible. Arno Motulsky has noted that "[t]he precise definition of 'disease' regardless of etiology, is difficult."[43] He notes that maladies such as high blood pressure and mental retardation are based on arbitrary cutoff levels. David Brock similarly noted that most disorders lie between the extremes of Tay-Sachs disease and alkaptonuria; what a physician advises "depends as much on the physician's ethical preconceptions as his medical experience."[44]

Despite the fact that the public health model does not fit the situation of genetics, the individual rights model should not be seen as absolute. There are certain situations in which the values of autonomy, privacy, confidentiality, and equity should give way to prevent serious harm to others. Determining the exceptions to these general principles is no easy matter, however. There may be instances in which harm can be prevented by violating one of these principles, but in which the value of upholding the principles will nonetheless outweigh the chance of averting harm. In each instance, it will be necessary to assess several factors: How serious is the harm to be averted? Is violating one of the principles the best way to avert the harm? What will be the medical, psychological, and other risks of violating the principle? What will be the financial costs of violating the principle?

The following section addresses the issues raised by the application of these principles—autonomy, privacy, confidentiality, and equity—in the contexts of clinical genetics, other medical practices, genetics research, and so forth. It also provides guidance for determining the appropriate circumstances for exceptions to these principles. The chapter concludes with the committee's recommendations on these issues.

ISSUES IN GENETIC TESTING

Autonomy

One important way to ensure autonomy with respect to genetic testing is to provide adequate information upon which a person can make a decision whether or not to undergo testing. A proper informed consent in medicine generally involves the presentation of information about the risks, benefits, efficacy, and alternatives to the procedure being undertaken. In addition, recent cases and statutes have recognized the importance of disclosures of any potential conflicts of interest that the health care professional recommending the test may have, such as a financial interest in the facility to which the patient is being referred. In the genetics context, this would include disclosure about equity holdings or ownership of the laboratory, dependence on test reimbursement to cover the costs of counseling, patents, and so forth. It would also include disclosure of any planned subsequent uses of the tissue samples, even if such uses are to be anonymous.

Various kinds of information are relevant to people who are attempting to exercise their autonomy by deciding whether or not to undergo genetic testing. This includes information about the severity, potential variability, and treatability of the disorder being tested for. If, for example, carrier status testing is being proposed for a pregnant woman or prenatal testing is being proposed for her fetus, she should be told whether the disorder at issue can be prevented or treated, or whether she will be faced with a decision about whether or not to abort (see Chapters 2, 4, and 5). The proposed informed consent guidelines for research involving genetic testing suggested by the Alliance of Genetic Support Groups provide an excellent starting point for the development of informed consent policies in the genetics area (see Chapter 4).

The potential development of multiplex testing adds another wrinkle to the issue of informed consent for genetic testing. If 100 disorders are tested from the same blood sample, it may be difficult to apply the current model of informed consent in which a health care provider gives information about each disorder and the efficacy of each test to the patient in advance of the testing. The difficulty in applying the traditional mechanisms for achieving informed consent does not provide an excuse for failing to respect a patient's autonomy and need for information, however. New mechanisms may have to be developed to protect these rights. It will be possible to have results reported back to the physician and patient only about those tests (or types of tests) the patient chooses. The choices can be made by the patient, based, for example, on the patient learning through a computer program about the various disorders and the various tests. Or the choices can be made according to general categories—for example, the patient might choose to have multiplex testing but choose *not* be informed of the results of testing for untreatable or unpreventable disorders[45] (see Chapters 1, 3, and 4).

In addition to the recognition that people are entitled to information before

they make decisions, a second application of the autonomy principle comes with the recognition that the decision to participate in genetic testing and other genetics services must be voluntary. Voluntariness has been a recognized principle in past recommendations and practices involving genetics. This is in keeping with the recognized right of competent adults to refuse medical intervention, as well as the right to refuse even the presentation of medical information in the informed consent context.[46] 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 information to the woman (perhaps leading her to abort an affected fetus and saving the state money for care of that infant). Mandating such a test, however, would show insufficient respect for the woman's autonomy and would violate her right to make reproductive decisions.

Special Issues in the Screening and Testing of Children

The expansion of available tests fostered by the Human Genome Project will present complicated issues with respect to the testing of newborns and other children. Although there are clear legal precedents stating that adults are free to refuse even potentially beneficial testing and treatment, legal precedents provide that children can be treated without their consent (and over their parents' refusal) to prevent serious imminent harm. The U.S. Supreme Court has said that, while parents are free to make martyrs of themselves, they are not free to make martyrs of their children.[47] Medical intervention over parents' objection has been allowed in situations in which a child's life was in imminent danger and the treatment posed little risk of danger in itself.[48] Blood transfusions have been ordered for the children of Jehovah's Witnesses when the child's life was imminently endangered.[49]

All states have programs to screen newborns for certain inborn errors of metabolism for which early intervention with treatment provides a clear medical benefit to the child, such as phenylketonuria. Currently, the statutes of at least two jurisdictions (the District of Columbia and Maryland) clearly provide that newborn screening is voluntary.[50] In at least two states (Montana and West Virginia), screening is mandatory and there is no legal provision for parental objection or refusal based on religious grounds.[51] In the rest of the states, there are grounds for parental refusal for religious or other reasons. However, although the majority of states allow objection to screening on some grounds, very few statutes require that the parents or guardians of an infant either be sufficiently informed that they can choose whether or not their infant should submit to the screening or be told they have the right to object. Two states (Missouri and South Carolina) have criminal penalties for parents who refuse newborn screening of their children.[52]

The idea behind mandatory newborn screening is a benevolent one—to try to ensure that all children get the benefits of screening for PKU and hypothyroidism,

for which early treatment can make a dramatic difference in the child's well-being by preventing mental retardation. Yet there is little evidence that it is necessary to make a newborn screening program mandatory to ensure that children are screened under the program. Recent studies show that the few states with voluntary newborn screening programs screen a higher percentage of newborns than some states with mandatory newborn screening programs; for 1990, voluntary programs reported reaching 100 percent of newborns in their states, while some states with mandatory programs report reaching 98 percent, and some even less than 96 percent.[53] Relevant research has suggested that even when a newborn screening program is completely voluntary and parents may refuse for any reason, the actual refusal rate is quite low, about 0.05 percent (27 of 50,000 mothers). In that study, most nurses reported that it required only one to five minutes to inform a mother about newborn screening.[54]

Newborn screening for PKU—like a necessary blood transfusion for a child over the parents' refusal—has been justified on the basis of the legal doctrine of *parens patriae*, where the state steps in to order an intervention to protect a child from substantial, imminent harm. In the era of the Human Genome Project, when additional tests are being developed, some people are promoting newborn screening in part for less immediate and less clear benefits. Proposed guidelines have suggested that another benefit of newborn screening "might take the form of inscription in registries for later reproductive counseling (material PKU) or of surveillance of phenotypes (congenital adrenal hyperplasia)."[55] To achieve such an outcome, the resulting children would need to be followed until the age when reproductive counseling was appropriate—or when symptoms manifest—a daunting task in this age of mobility.

The first newborn screening programs were for disorders in which early treatment of the newborn was effective. Increasingly, however, testing is suggested for untreatable disorders. In such instances, the justification is not the benefit to the newborn but the benefit to the parents for future reproductive plans. For such reasons, several countries—and some states in the United States (e.g., Pennsylvania)—screen newborns for Duchenne muscular dystrophy. This medical intervention has no immediate medical benefit for the newborn, and carrier screening of the parents could be obtained through other methods, even when (as in the case of Duchenne muscular dystrophy and some other conditions) they may not realize they are at risk.

Moreover, screening newborns for genes for untreatable disorders or carrier status may have disadvantages. The children may be provided with information that, at the age of consent, they would rather not have. Parents might treat them differently if the results are positive. Parents may stigmatize or reject children with the abnormal genes, or may be less willing to devote financial resources to education or other benefits for such children. In addition, release of the test results might cause them to be uninsurable, unemployable, and unmarriageable.

There are additional benefits from voluntariness in newborn screening. In-

forming parents about newborn screening in advance of testing allows quality assurance: parents can check to see if the sample was actually drawn. As children are being released from the hospital increasingly early, due to insurance pressures, they might receive a false negative result because blood levels of phenylalanine have not yet risen sufficiently to be detected if elevated. Informed motivated parents may need to bring their babies to be screened after release from the hospital in order to ensure an accurate test result. The recommended informed consent process can provide the necessary education and motivation that will be required to make the return trip far better than mandatory programs.

In the postgenome era, people will be facing the possibility of undergoing many more genetic tests in their lifetimes, and will need to master a wealth of genetic information that is relevant to their health, their reproductive plans, and the choices they make about what to eat, where to live, and what jobs to take. The more settings in which they can be informed about genetics, the more able they will be to make these decisions. In addition, when newborn screening programs are voluntary, there is a greater chance that parents will be provided with material in advance about the disorder and have their questions answered, thus presenting the possibility that they will view it more seriously and will make a greater effort to ensure that the child receives proper treatment if a condition is detected. The disclosure of information to parents about newborn screening prior to newborn screening can be an important tool for public education about genetics.

Mandatory newborn screening should only be undertaken if there is strong evidence of benefit to the newborn from effective treatment at the earliest possible age (e.g., PKU and congenital hypothyroidism). Under this principle, screening for Duchenne muscular dystrophy would not be justified. In addition, mandatory newborn screening for cystic fibrosis would currently not be justified.[56] A prospective double-blind study in Wisconsin (the only controlled study on the subject) has not found benefits of early detection in newborn screening for CF; the treatment of children could be initiated with just as successful results based on the occurrence of symptoms. In addition to its lack of clear benefit, newborn screening for CF has a clear downside. Screening by its nature is overly broad; in newborn screening for cystic fibrosis, for example, "only 6.1 percent of infants with positive first tests [in the Colorado and Wyoming program] were ultimately found to have cystic fibrosis on sweat chloride testing."[57] Yet one-fifth of parents with false positives on newborn screening for cystic fibrosis "had lingering anxiety about their children's health."[58] Of the parents whose infants had initial, later disproven positive reports of CF in the Wisconsin study, 5 percent still believed a year later that their child might have CF.[59] Such a reaction may influence how parents relate to their child. A report on the Wisconsin newborn screening for CF stated that of the 104 families with false positives, 8 percent planned to change their reproductive plans and an additional 22 percent were not sure whether they would change their reproductive plans.[60] In fact, in France, the newborn screening program for cystic fibrosis was terminated at the request of parents who objected to the high number of false positives.[61] Denmark stopped screening for alpha-1-antitrypsin deficiency because of negative long-term effects on the mother-child interactions associated with identifying the infant's alpha-1-antitrypsin deficiency.[62]

Even in cases where a treatment is available for a disorder detectable through newborn screening, it may not be of unequivocal benefit if started after symptoms appear. Treatment of children identified through screening for maple syrup urine disease may have only limited effectiveness at best, and parents may face a quandary about whether or not to treat. Even if hypothetical benefits exist, newborn screening programs need close scrutiny to determine if the necessary treatments are actually provided to the children. In states that support screening but not treatment, families may be unable to afford treatment and thus children may not benefit from screening. Many children with sickle cell anemia, for example, do not get their necessary penicillin prophylaxis.[63] Although most states provide education about diet and nutrition to parents of infants with PKU, not all states provide the expensive essential diet or other food assistance.

Beyond the issue of the testing of newborns in state-sponsored programs, there are more general issues regarding the genetic testing of children in clinical settings. Some technologies designed to identify affected individuals will also provide information about carrier status. If an infant is tested for sickle cell anemia, for example, the test will reveal whether the infant is a carrier. In that case, the carrier status information is a by-product of the test for sickle cell anemia since obtaining information on carrier status is not the primary purpose of the testing. Questions arise as to whether that information should be reported to the infant's parents.

One advantage to reporting the information is that it is relevant to the parents' future reproductive plans. If the infant is a carrier, at least one of the parents is a carrier. If both are carriers, then they are at 25 percent risk of having an affected child. On the other hand, there are disadvantages to the reporting of such information to parents. Unless education and counseling are available, they may erroneously worry that the child will be affected with a disease related to the carrier status. They may stigmatize the child or otherwise treat the child as different. In addition, the disclosure of the child's carrier status may result in disruption to the family if neither of the social parents is a carrier (which most often indicates that another man fathered the child).

Since numerous tests can be added in a newborn screening program using the initial filter paper spot, the pressure to add new tests may be difficult to resist. Under the American Society of Human Genetics (ASHG) guidelines, however, before tests are added, a rigorous analysis should be made about who will benefit, who will be harmed, and who consents. In state programs for newborn screening, subsequent anonymous uses of samples for research may be undertaken.

Voluntariness of Subsequent Uses

Many state newborn screening programs, as well as research and clinical facilities, store the filter paper spots or other DNA samples for long periods after their initial use in genetic testing. Some states use newborn screening spots to experiment with new tests, and this would seem permissible as long as the samples are not identified and the uses were not anticipated prior to the initial test.[64] If the samples are identified, the person's permission would be required. However, researchers constitute just one group that might want access to the newborn screening spots. Such spots are of interest to law enforcement officials; in one case, police contacted a newborn screening laboratory when they were trying to identify a young murder victim.

The American Society of Human Genetics issued a statement on DNA banking and DNA data banking in 1990.[65] ASHG recommended the purposes for which samples are acquired for DNA analysis be defined in advance:

> Later access to DNA samples or to the profiles for *other* purposes should be permitted only when (a) a court orders the information to be released, (b) the data are to be anonymously studied, or (c) the individual from whom the sample was obtained provides written permission. In general, regardless of the purpose for which it was compiled, this information should be accorded at least the confidentiality that is accorded to medical records.[66]

Confidentiality

Confidentiality is meant to encourage the free flow of information between patient and physician so that the patient's sickness may be adequately treated. The protection of confidentiality is also justified as a public health matter, since ill people may not seek medical services in the first place if confidentiality is not protected. As a legal matter, confidentiality is generally protected in the doctor-patient relationship. However, genetic testing may not always occur within a doctor-patient relationship: a non-M.D. scientist may undertake the testing, or screening may occur in the employment setting. Moreover, it is not just the result of the test that raises concern about confidentiality. The sample itself may be stored (as in DNA banking or family linkage studies) for future use.

Genetic information is unlike other medical information. It reveals not only potential disease or other risks to the patient, but also information about potential risks to the person's children and blood relatives. The fact that geneticists may wish to protect third parties from harm by breaching confidentiality and disclosing risks to relatives is evidenced in the study by Wertz and Fletcher, cited earlier, in which half of the geneticists surveyed would disclose information to relatives over a patient's refusal. The geneticist's desire to disclose is based on the idea that the information will help the relative avoid harm. Yet this study indicated that about the same number of geneticists would disclose to the relative when the

disorder was untreatable as when the disorder was treatable (53 percent would contact a relative about the risk of Huntington disease; 54 percent about the risk of hemophilia A). Since most people at risk for Huntington disease have not chosen testing to see if they have the genetic marker for the disorder,[67] geneticists may be overestimating the relative's desire for genetic information and infringing upon the relative's right not to know. They may be causing psychological harm if they provide surprising or unwanted information for which there is no beneficial action the relative can take.

In the legal realm, there is an exception to confidentiality: A physician may in certain instances breach confidentiality in order to protect third parties from harm, for example, when the patient might transmit a contagious disease[68] or commit violence against an identifiable individual.[69] In a landmark California case, for example, a psychiatrist was found to have a duty to warn the potential victim that his patient planned to kill her.[70]

The principle of protecting third parties from serious harm might also be used to allow disclosure to an employer when an employee's medical condition could create a risk to the public. In one case, the results of an employee's blood test for alcohol were given to his employer.[71] The court held the disclosure was not actionable because the state did not have a statute protecting confidentiality, but the court also noted that public policy would favor disclosure in this instance since the plaintiff was an engineer who controlled a railroad passenger train.

An argument could be made that health care professionals working in the medical genetics field have disclosure obligations similar to those of the physician whose patient suffers from an infectious disease or a psychotherapist with a potentially violent patient. Because of the heritable nature of genetic diseases, a health professional who—through research, counseling, examination, testing, or treatment—gains knowledge about an individual's genetic status often has information that would be of value not only to the patient, but to his or her spouse or relatives, as well as to insurers, employers, and others. A counterargument could be made, however, that since the health professional is not in a professional relationship with the relative and the patient will not be harming the relative (unlike in the case of violence or infectious diseases), there should be no duty to warn.

The claims of the third parties to information, in breach of the fundamental principle of confidentiality, need to be analyzed, as indicated earlier, by assessing how serious the potential harm is, whether disclosure is the best way to avert the harm, and what the risk of disclosure might be.

Disclosing Genetic Information to Spouses

The genetic testing of a spouse can give rise to information that is of interest to the other spouse. In the vast majority of situations, the tested individual will share that information with the other spouse. In rare instances, the information will not be disclosed and the health care provider will be faced with the issue of

whether to breach confidentiality. When a married individual is diagnosed as having the allele for a serious recessive disorder, the spouse might claim that the health care provider has a duty to share that information with him or her to facilitate reproductive decision making.[72] A few court cases have allowed physicians to disclose medical information about an individual in order to protect a spouse or potential spouse.[73] The foundation for this approach is laid by cases allowing disclosure of communicable diseases.[74] In situations such as disclosure of information about venereal disease or AIDS, the argument is made that sacrificing confidentiality, by notifying spouses and lovers, is necessary for public health and welfare, and is essential as a warning to seriously endangered third parties where the risk of transmission is high.

Since genetic disorders are not communicable to the spouse, a counter argument could be made that there is no legitimate reason for disclosing them. However, the spouse might have a great interest in the genetic information because he or she would like to protect any potential children from risk. Consider the case of a doctor who learns that a young man will later suffer from Huntington disease. The wife would appear to have at least some claim to that information since, if she and her husband have children, there will be a 50 percent chance that each child would inherit the disease. Similarly, each spouse would seem to have a claim to the information that the other was a carrier of a single gene for a recessive defect. Because of the importance of reproductive decisions, such information is crucial to the spouse.

Another instance in which genetic risk information arises in the marriage context is through prenatal screening. A fetus may be found to have an autosomal recessive disorder, which occurs only if both parents transmit the particular gene. If, in the course of prenatal diagnosis, it is learned that the mother is a carrier of the gene but her husband is not, the health care professional has knowledge that the husband is almost certainly not the father of the child. A claim could be made that the health care professional has a duty, or at least a right, to advise the husband of his misattributed paternity, so that he will know that any future children he has will not be at risk for that particular disorder.

On the other hand, an argument could be made that spouses should not be entitled to genetic risk information about a patient, even if it is arguably relevant to their future reproductive plans.[75] The right of reproductive decision making is viewed as the right of the individual.[76] The U.S. Supreme Court has held that a woman can abort without her husband's consent even if this will interfere with her husband's reproductive plans.[77] More recently, the U.S. Supreme Court held that a husband was not even entitled to notice that his wife intends to abort.[78] The court expressed concerns that the husband might react to the disclosure with violence, with threats to withhold economic support, or with psychological coercion.[79] Similar reactions could occur with information about misattributed paternity, particularly because the primary purpose of the testing was not to get paternity information.

Disclosing Genetic Information to Relatives

Blood relatives of the patient may have a more convincing claim than spouses for requiring that health care providers breach confidentiality. They could argue that the information about genetic risks or the availability of genetic testing may be relevant to their own future health care.[80] The strongest case for a warning would exist when there is a high likelihood that the relative has the genetic defect, the defect presents a serious risk to the relative, and there is reason to believe that the disclosure is necessary to prevent serious harm (e.g., by allowing for treatment or by warning the person to avoid harmful environmental stimuli). Malignant hyperthermia is an autosomal dominant genetic condition causing a fatal reaction to common anesthesia. Prompt warning of families can literally save lives, especially from death due to minor surgeries such as setting broken bones in children.

If the patient does not want to inform relatives, however, questions arise as to whether the health care provider or counselor should contact the relative over the patient's refusal. The President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (1983) recommended that disclosure be made only if (1) reasonable attempts to elicit voluntary disclosure are unsuccessful; (2) there is a high probability of serious (e.g., irreversible or fatal) harm to an identifiable relative; (3) there is reason to believe that disclosure of the information will prevent harm to the relative; and (4) the disclosure is limited to the information necessary for diagnosis or treatment of the relative.[81]

Even in the more compelling situation of disclosure to relatives, the health care provider is not in a professional relationship with the relative, and previous legal cases regarding a duty to provide genetic information have all involved a health care provider in a professional relationship with the person to be informed. Although infectious disease cases provide a precedent for warning strangers about potential risks,[82] genetic diseases are simply different from infectious diseases. The only potential argument that the health care professional could make for contacting the relative is that through diagnosis of the patient, the health care professional has reason to believe that the relative is at higher risk than the general population of being affected by a genetic disorder. If disorders are highly likely and are treatable or preventable, many medical geneticists would overrule a patient's refusal to disclose, and would inform a relative. Although there may be no legal obligation to single out relatives as creating a special duty for physicians, the knowledge that a defined, unknowing relative is at high risk for a serious or life-threatening, treatable disease may allow rare exceptions to the principle of confidentiality.

Confidentiality and Discrimination When Third Parties Seek Genetic Information

Many entities may have an interest in learning about people's genetic information. Insurers, employers, bankers, mortgage companies, educational loan of-

ficers, providers of medical services, and others have an interest in knowing about a person's future health status. Already, people have been denied insurance, employment, and loans based on their genotype. Such discrimination has occurred both when the information has been obtained through genetic testing and when the information has been obtained in other ways (e.g., inadvertent release of a relative's medical record or disclosure from payment for medical service for a child).[83]

In the future, third parties may want access to genetic information or may wish to mandate genetic testing. In child custody cases, one spouse may claim that the other spouse should not get custody because of his or her genetic profile, for example, when the latter person has the gene for a serious, untreatable late-onset disorder. Professional schools (such as medical schools or law schools) may wish to deny admission to someone with such a disorder on the theory that such a person will have a shortened practice span.

Insurers underwriting individual health insurance currently use medical information to determine whether coverage should be granted and to determine how to price a particular policy. According to the Office of Technology Assessment, each year about 164,000 applicants are denied individual health insurance.[84] Far more Americans are covered by group plans—85 to 90 percent—with about 68 percent[85] covered by employment-based group plans rather than by individual plans. Although medical underwriting is not generally done as part of large employers' group policies, medical information is sometimes used against people in other ways in that context. People with medical problems or whose family members have medical problems have been refused jobs because employers do not want their insurance premiums increased due to payments for the care of the employee or the employee's family members.

In addition, employers that self-insure may choose to restrict coverage under their insurance plans so as not to pay for care for existing employees. One major airline already permanently excludes coverage for preexisting conditions for new employees.[86] Other employers have curtailed plan benefits once an employee has been diagnosed as having a particular disorder. In *McGann v. H. & H. Music Co.*, for example, a man was covered by employer-provided commercial insurance that had a million dollar medical benefit maximum.[87] Once the employee was diagnosed as having AIDS, however, the employer switched to self-insurance and established a $5,000 limitation for AIDS, while keeping the million dollar cap for other disorders. The court held that an employer who is self-insured could modify its plan in this way—an ominous decision when one considers that at least 65 percent of all companies and 82 percent of companies with more than 5,000 employees are self-insured.[88] The U.S. Supreme Court decided not to hear the case and let stand the lower court's decision. Employees who are covered by their employers' self-insurance are thus in a precarious position, akin to having no insurance at all:

> When one considers that many employees contribute substantial amounts of money to purchase this "coverage," that many of them forego purchasing other insurance products in reliance on this coverage, and that few of them understand the precise nature of the self-insurance system, the entire system verges on fraud.[89]

This is particularly true, given that many people choose jobs because of the health benefits.[90] The Equal Employment Opportunity Commission is reportedly endeavoring to use the Americans with Disabilities Act to challenge companies' practices of setting caps on health insurance payouts for employees with AIDS.[91]

The advent of genetic testing, as well as the increasing identification of genetic diseases, makes genetic information, like other medical information, available for use as a basis for medical underwriting in health insurance. The danger, according to one study, is that "genetic testing made possible as we continue to map the human genome may result in many more individuals being denied private insurance coverage than ever before."[92] Genetic tests are not necessary to find out genetic information on applicants. Insurers already obtain genetic information from medically underwritten applicants through family histories and laboratory tests (e.g., cholesterol levels). This was of as much concern to the committee as the use of genetic information from other sources. Although insurers generally do not perform or require genetic tests when doing medical underwriting, they may seek to learn the results of any genetic tests from which an applicant may have information. This could deter people from seeking these tests.

The existence of medical underwriting can lead people to avoid needed medical services:

> If people worry that their use of health services may disqualify them from future insurance coverage, they may limit their use of needed services, fail to submit claims for covered expenses, or pressure physicians to record diagnoses that are less likely to attract an underwriter's attention. The last two actions add error to data bases used for health care research and monitoring.[93]

A survey of insurers undertaken by the Office of Technology Assessment (OTA) of the U.S. Congress found that insurers see a role for genetic information in medical underwriting. OTA surveyed commercial insurers, Blue Cross and Blue Shield companies, and large health maintenance organizations, which offered individual and medically underwritten small-group health insurance coverage. Data were gathered on underwriting practices, including requirements for diagnostic tests or physical examinations before an insurance policy can be issued. Data on reimbursement practices, as well as general attitudes toward genetic testing, were also obtained.

Insurers generally believed that it was fair for them to use genetic tests to identify those at increased risk of disease; slightly more than one-fourth of medical directors indicated that they disagreed somewhat that such use was fair.

Three-quarters of the responding companies said they thought "an insurer should have the option of determining how to use genetic information in determining risk."[94]

OTA's survey of insurers found that genetic information is not viewed as a special type of information.[95] What seems important to insurers when making insurability and rating decisions is the particular condition, not that the condition is genetically based. OTA found that the majority of insurers did not anticipate using specific genetic tests in the future. However, a majority of medical directors from commercial insurers agreed with the statement that "it's fair for insurers to use genetic tests to identify individuals with increased risk of disease." In a comparison survey, OTA found that 14 percent of responding genetic counselors reported that they had clients who had experienced difficulties obtaining or retaining health care coverage as a result of genetic testing.

Surveys by Paul Billings and colleagues,[96] as well as by the Office of Technology Assessment,[97] uncovered specific examples of people being denied health insurance coverage based on their genotype. These incidents include cases in which a person with a positive test for a genetic disorder had his or her insurance canceled or "rated up" as a result;[98] where genetic disorders such as alpha$_1$-antitrypsin were defined as preexisting conditions, thus excluding payment for therapy; where a particular genetic condition resulted in exclusion from maternity coverage;[99] and where the birth of a child affected with a serious recessive disorder led to the inability of the parents and unaffected siblings to obtain insurance.[100]

Genetic information provides serious challenges to the traditional operation of insurance. Health insurance in this country is premised on the notion that risks can be predicted on a population-wide basis, but not well on an individual basis; thus insurance becomes a mechanism for spreading risks. If, through genetic testing or the use of genetic information acquired by other means, insurers can learn of people's actual future health risks (e.g., the risk of a serious late-onset disorder), the benefit of risk spreading will be lost; the individual will be charged an amount equal to future medical costs, which may in some cases make insurance prohibitively expensive.

Currently it is permissible in most states to do medical underwriting based on genetic information. However, the expansion of genetic testing presents a serious challenge to medical underwriting and could lead to an alternative policy approach in which medical underwriting is eliminated altogether. Originally, health insurance was based on health risks for entire communities, known as community rating, rather than on individual rating of health risks or conditions. Insurers gradually began to offer lower rates to employers based on the generally better health and lower risks of employed persons, and competition ensued among insurers to insure the "best" (i.e., lowest) risks. This has led to many of the problems in our current health insurance system in which some people have become permanently uninsurable.[101] In a system of community rating,

> . . . there would be no place for [the use of the results of] genetic testing, since applicants would not be rated according to their individual health risks and conditions.[102]

Rochester, New York has had a successful system of community rating; a key factor in its success has been the belief of large employers who would normally self-insure that their participation in a system that emphasizes risk sharing and collective strategies to contain costs, results in a system that will keep costs lower over the long term than they would be in a segmented, risk-rated competitive health insurance market.[103] The states of Maine and New York have recently passed legislation requiring health insurers offering policies in their states to return to community rating by 1993.[104] Several other states have introduced legislation to protect people from discrimination based on their genotype. In addition, more general antidiscrimination laws may provide some remedy for people who are discriminated against because of their genotype.

Much of this legislation has been a direct response to the debacle in the early 1970s with respect to sickle cell screening. When mandatory sickle cell screening laws were adopted, some insurers and employers began making decisions about insurance coverage and employment opportunities based on the results of the testing. In particular, carriers of sickle cell trait were denied jobs and charged higher insurance rates without evidence that possession of the *trait* placed a person at a higher risk of illness or death.[105] As a result, some states have adopted laws protecting people with sickle cell trait. At least two states prohibit denying an individual life insurance[106] or disability insurance,[107] or charging a higher premium,[108] solely because the individual has sickle cell trait. A few states have similarly adopted statutes to prohibit mandatory sickle cell screening as a condition of employment,[109] to prohibit discrimination in employment against people with sickle cell trait,[110] and to prohibit discrimination by unions against people with sickle trait.[111]

More recently, some states have adopted laws with a broader scope. A California statute prohibits discrimination by insurance companies against people who carry a gene that has no adverse effects on the carrier, but may affect his or her offspring.[112] Under a Wisconsin law,[113] insurers are prohibited from requiring that applicants undergo DNA testing to determine the presence of a genetic disease or disorder, or the individual's predisposition for a particular disease or disorder. Nor may insurers ask whether the individual has had a DNA test or what the results of the test were. Insurers are also prohibited from using DNA test results to determine rates or other aspects of coverage. However, insurance discrimination based on genetic information not obtained through DNA testing is not forbidden by the law.

There is also much concern about the use of genetic information in the employment context. The Council of Ethical and Judicial Affairs of the American Medical Association has taken the position that it is inappropriate for employers to perform genetic tests to exclude workers from jobs.[114] The opinion acknowl-

edges that the protection of public safety is an important rationale for medical tests of employees. However, the opinion states:

> Genetic tests are not only generally inaccurate when used for public safety purposes, but also unnecessary. A more effective approach to protecting the public's safety would be routine testing of a worker's actual capacity to function in a job that is safety-sensitive.[115]

The opinion points out that capacity testing is more appropriate because it would not cause discrimination against someone who has the gene for a disorder but who is totally asymptomatic, yet it would "detect those whose incapacity would not be detected by genetic tests, either because of a false-negative test result or because the incapacity is caused by something other than the disease being tested for."[116]

In the employment context, a New Jersey law prohibits employment discrimination based on an "atypical hereditary cellular or blood trait."[117] In New York, a statute prohibits genetic discrimination based on sickle cell trait, Tay-Sachs trait, or Cooley anemia (beta-thalassemia) trait.[118] In Oregon, Wisconsin, and Iowa, even more comprehensive laws prohibit genetic screening as a condition of employment.[119]

At the federal level, it is still an open question whether the Americans with Disabilities Act (ADA)[120] will provide adequate protection against genetic discrimination. There are three definitions of persons considered to have a disability and, therefore, protected under the statute. Individuals currently with a disability comprise the first group, persons with a history of a disability comprise the second group, and persons who have the appearance of being disabled constitute the third. This latter category should protect carriers of genetic disease who are themselves healthy but could be refused employment because they have a high risk of giving birth to a child with a genetic disorder that might be expensive in insurance or health care costs to the employer. This third category for those with the appearance of disability should also protect persons with an increased risk of disease due to genetic susceptibility to breast cancer, or who have a gene for a late-onset disorder such as Huntington disease.

The NIH-DOE Joint Working Group on Ethical, Legal, and Social Implications (ELSI) of the Human Genome Project petitioned the Equal Employment Opportunity Commission (EEOC), which is responsible for implementing the law. ELSI requested that the EEOC broaden its proposed rulemaking to include these protections related to genetic testing and genetic disorders, or susceptibility to a genetic disorder.

However, according to an interpretation by the EEOC, the act does not protect carriers of genetic diseases who are themselves healthy but could be refused employment because they have a 25 percent risk of giving birth to a child with a genetic disorder. Also, the EEOC does not view a person with an increased risk of disease due to genetic factors, or who has the gene for a late-onset disorder such as Huntington disease, as having a disability and thus being protected by the law.

Legislation has been introduced to extend the definition of disability to a "genetic or medically identified potential of, or predisposition toward, a physical or mental impairment that substantially limits a major life activity."[121]

Another limitation of the ADA is that it allows employers to request any type of medical testing on an employee after a conditional offer of employment is made. In contrast, statutes in 11 states limit such testing to that which is job related.[122]

There may in fact be a narrow set of circumstances in which genetic testing may be appropriate to determine a person's ability to undertake a particular job. For example, a person with an active seizure disorder might be excluded from a job in which he or she could cause serious harm. Such a possibility would seem to be appropriate only if the potential harm were serious and screening were the most appropriate way to avert the harm. The committee was concerned, however, that employers might confuse having the gene for, or a genetic predisposition to, a particular disorder with currently being symptomatic. The possibility that someone, later in life, might become incapable of doing a job does not provide a sufficient rationale for not letting him or her undertake the job at the current time. Consequently, in most situations, periodic medical screening for symptoms rather than genetic screening will be a more appropriate means of determining whether an employee presents a serious risk of harm to third parties.[123]

FINDINGS AND RECOMMENDATIONS

Overall Principles

The committee recommends that vigorous protection be given to autonomy, privacy, confidentiality, and equity. These principles should be breached only in rare instances and only when the following conditions are met: (1) the action must be aimed at an important goal—such as the protection of others from serious harm—that outweighs the value of autonomy, privacy, confidentiality, or equity in the particular instance; (2) it must have a high probability of realizing that goal; (3) there must be no acceptable alternatives that can also realize the goal without breach of these principles; and (4) the degree of infringement of the principle must be the minimum necessary to realize the goal.

The committee recommends that regardless of the institutional structure of the entity offering genetic testing or other genetics services, there be a mechanism for advance review of the new genetic testing or other genetics services not only to assess scientific merit and efficacy, but also to ensure that adequate protections are in place for autonomy, privacy, confidentiality, and equity. The usual standards for review of research should be applied no matter what the setting. In particular, an institutional review board (IRB) should review the scientific and ethical issues related to new tests and services in academic research centers, state public health departments, and commercial enterprises.

These reviews should include any proposed investigational use of genetic tests, as well as more extensive pilot studies. In all instances the review body should include people from inside and outside the institution, including community representatives, preferably consumers of genetic services. In the clinical practice setting, professional societies should be encouraged to review studies and issue guidelines, thereby supplementing the guidance provided by IRBs (see Chapter 3).

The committee also recommends that the National Institutes of Health (NIH) Office of Protection from Research Risks provide guidance and training on how review bodies should scrutinize the risks to human subjects of genetic testing. IRBs may also need technical advice from a local advisory group on genetics (see Chapter 1). To the extent that a National Advisory Committee on Genetic Testing and its Working Group on Genetic Testing are established (see Chapter 9), these bodies should be consulted by IRBs and the NIH Office of Protection from Research Risks.

All laboratories offering genetic testing are included under the Clinical Laboratory Improvement Amendments of 1988 (CLIA88), and the committee recommends that the Health Care Financing Administration expand its existing lists of covered laboratory tests to include the full range of genetic tests now in use (see Chapter 3).

New tests, not validated elsewhere, that are added to the battery of tests should be considered investigational if they are used to make a clinical decision. The committee recommends that IRB approval be obtained in universities, commercial concerns, and other settings where new tests for additional disorders are being undertaken, even if the tests rely on existing technologies. IRB approval should be obtained before new tests are added to newborn screening.

Autonomy

Informed Consent

The committee recommends that for a proper informed consent to be obtained from a person who is considering whether to undergo genetic testing, the person should be given information about the risks, benefits, efficacy, and alternatives to the testing; information about the severity, potential variability, and treatability of the disorder being tested for; and information about the subsequent decisions that will be likely if the test is positive (e.g., whether the person will have to make a decision about abortion). Information should also be disclosed about any potential conflicts of interest of the person or institution offering the test (e.g., equity holdings or ownership of the laboratory performing the test, dependence on test reimbursement to cover the costs of counseling, patents). The difficulty in applying the traditional mechanisms for achieving informed consent should not be considered an excuse for failing to respect a patient's autonomy and need for information.

The committee recommends that research be undertaken to determine what patients want to know in order to make a decision about whether or not to undergo a genetic test. People may have less interest in information about the label for the disorder and its mechanisms of action than they have in information about how certainly the test predicts the disorder, what effects the disorder has on physical and mental functioning, and how intrusive, difficult, or effective any existing treatment protocol would be. Research is also necessary to determine the advantages and disadvantages of various means of conveying that information (e.g., through specialized genetic counselors, primary care providers, single-disorder counselors, brochures, videos, audiotapes, and computer programs). People also need to know about potential losses of insurability or employability or social consequences that may result from knowledge about the disorder for which testing is being discussed.

Multiplex Testing

Performing multiple genetic tests on a single sample of genetic material—often using techniques of automation—has been called *multiplex testing*. **The committee recommends that informed consent be gained in advance of such multiplex testing.** New means (such as interactive or other types of computer programs, videotapes, and brochures) should be developed to provide people—in advance of testing—with the information described in the previous recommendations, such as descriptions of the nature of tests that are included in multiplex testing and the nature of the disorders being tested for (discussed in Chapter 4). A health care provider or counselor should also provide information about each of the tests, or if that is not possible because of the number of tests being grouped together, the provider or counselor should supply information about the categories of disorders so that the person will be able to make an informed decision about whether to undergo the testing.

The committee identified the area of multiplex testing as one in which more research is needed to develop ways to ensure that patient autonomy is recognized. The more general research the committee has advocated on determining what information should be conveyed and how it should be conveyed should be supplemented with additional research dealing with the unique case of multiplex testing where many disorders could be tested for at once, and those disorders may have differing characteristics. **In multiplexing, tests should be grouped so that tests requiring similar demands for informed consent and education and counseling may be offered together.** Only certain types of tests should be multiplexed; some tests should only be offered individually, especially tests for untreatable fatal disorders (e.g., Huntington disease).

The committee also recommends that research be undertaken to make

decisions about which tests to group together in multiplex testing, based on the type of information the tests provide. The committee believes strongly that tests for untreatable disorders should not be multiplexed with tests for disorders that can be cured or prevented by treatment or by avoidance of particular environmental stimuli.

Voluntariness

The committee reaffirms that voluntariness should be the cornerstone of any genetic testing program. The committee found no justification for a state-sponsored mandatory public health program involving genetic testing of adults, or for unconsented-to genetic testing of patients in the clinical setting.

Screening and Testing of Children

The committee recommends that newborn screening programs be voluntary. The decision to make screening mandatory should require evidence that—without mandatory screening—newborns will not be screened for treatable illnesses in time to institute effective treatment (e.g., in PKU or congenital hypothyroidism). The committee bases its recommendation and preference for voluntariness on evidence from studies of existing mandated and voluntary programs that demonstrate that the best interests of the child can be served without abrogating the principle of voluntariness. Voluntary programs have delivered services as well or better than mandated programs. There is no evidence that a serious harm will result if autonomy is recognized, just as there is no evidence that mandating newborn screening is necessary to ensure that the vast majority of newborns are screened.

The committee recommends that newborn screening should not be undertaken in state programs unless there is a clear, immediate benefit to the particular infant being screened. In particular, screening should not be undertaken if presymptomatic identification of the infant and early intervention make no difference, if necessary and effective treatment is not available, or if the disorder is untreatable and screening is being done to provide information merely to aid the parents' (or the infant's) future reproductive plans. **The committee recommends that states that screen newborns have an obligation to ensure treatment of those detected with the disorder under state programs, without regard to ability to pay for treatment.**

The committee recommends that in the clinical setting, children generally be tested only for disorders for which a curative or preventive treatment exists and should be instituted at that early stage. Childhood screening is not appropriate for carrier status, untreatable childhood diseases, and late-onset diseases that cannot be prevented or forestalled by early treatment. Because only certain types of genetic testing are appropriate for children, tests specifically directed to obtaining information about carrier status, untreatable childhood diseases, or late-onset diseases, should not be included in the multiplex tests offered to children. Research should be undertaken to determine the appropriate age for testing and screening for genetic disorders in order to maximize the benefits of therapeutic intervention and to avoid the possibility that genetic information will be generated about a child when there is no likely benefit to the child in the immediate future.

The majority of the committee recommends that carrier status of newborns and other children be reported to parents only after the parents have been informed of the potential benefits and harms of knowing the carrier status of their children. Because of the risk of stigma for the newborn, such pretest information should be provided to parents when they are informed about newborn screening. Provision should be made for answering any questions the parents may have; these questions are best answered in the context of genetic counseling. The decisions of the parents about whether to receive such information should always be respected (see Chapter 4). **Where such information is not disclosed after parents are given the option to get such information and then knowingly refuse the information, the courts should take this policy analysis and the recommendation of this committee into consideration and not find liability if parents sue because the carrier status of their child was not disclosed and they subsequently give birth to an affected child.** Research is needed on the consequences of revealing carrier status in newborns to identify both harms and benefits from disclosing such information in the future.

Subsequent Uses

The committee recommends that before genetic information is obtained from individuals (or before a sample is obtained for genetic testing), they (or, in the case of minors, their parents) be told what specific uses will be made of the information or sample; how—and for how long—the information or sample will be stored; whether personal identifiers will be stored; and who will have access to the information or sample, and under what conditions. They should also be informed of future anticipated uses for the sample, asked permission for those uses, and told what procedures will be followed if the possibility for currently unanticipated uses develops. The individuals should have a right to consent or to object to particular uses of the sample or information.

Subsequent anonymous use of samples for research is permissible, including in state newborn screening programs. Except for such anonymous use, the newborn specimen should not be used for additional tests without informed consent of the parents or guardian.

If genetic test samples are collected for family linkage studies or clinical purposes, they should not be used for law enforcement purposes (except for body identification). If samples are collected for law enforcement purposes, they

should not be accessible for other nonclinical uses such as testing for health insurance purposes.

Confidentiality

Disclosure to Spouses and Relatives

As a matter of general principle, the committee believes that patients should be encouraged and aided in sharing appropriate genetic information with spouses. Mechanisms should be developed to aid a tested individual in informing his or her spouse and relatives about the individual's genetic status and informing relatives about genetic risks. These mechanisms would include the use of written materials, referrals for counseling, and so forth.

On balance, the committee recommends that health care providers not reveal genetic information about a patient's carrier status to the patient's spouse without the patient's permission. Furthermore, information about misattributed paternity should be revealed to the mother but should not be volunteered to the woman's partner.

Although confidentiality may be breached to prevent harm to third parties, the harm envisioned by the cases generally has been substantial and imminent.[124] The spouse's claim of future harm due to the possibility of later conceiving a child with a genetic disorder would not be a sufficient reason to breach confidentiality. The committee found no evidence of a trend on the part of people to mislead their spouses about their carrier status. Moreover, since most people *do* tell their spouses about genetic risks, breaching of confidentiality would be needed only rarely.

The committee believes that patients should share genetic information with their relatives so that the relatives may avert risks or seek treatment. Health care providers should discuss with patients the benefits of sharing information with relatives about genetic conditions that are treatable or preventable or that involve important reproductive decision making. **The committee believes that the disadvantages of informing relatives over the patient's refusal generally outweigh the advantages, except in the rare instances described above.**

The committee recommends that confidentiality be breached and relatives informed about genetic risks only when attempts to elicit voluntary disclosure fail, there is a high probability of irreversible or fatal harm to the relative, the disclosure of the information will prevent harm, the disclosure is limited to the information necessary for diagnosis or treatment of the relative, and there is no other reasonable way to avert the harm. When disclosure is to be attempted over the patient's refusal, the burden should be on the person who wishes to disclose to justify to the patient, to an ethics committee, and perhaps in court that the disclosure was necessary and met the committee's test.

If there are any circumstances in which the geneticist or other health care professional could breach confidentiality and disclose information to a spouse,

relative, or other third party—for example, to an employer—those circumstances should be explained in advance of testing; and, if the patient wishes, the patient should be given the opportunity to be referred to a health care provider who will protect confidentiality.

On a broader scale, the committee recommends that:

- **all forms of genetic information be considered confidential and not be disclosed without the individual's consent** (except as required by law), including genetic information that is obtained through specific genetic testing of a person as well as genetic information about a person that is obtained in other ways (e.g., physical examination, knowledge of past treatment, or knowledge of a relative's genetic status);
- **confidentiality of genetic information should be protected no matter who obtains or maintains that information**, including genetic information collected or maintained by health care professionals, health care institutions, researchers, employers, insurance companies, laboratory personnel, and law enforcement officials; and
- **to the extent that current statutes do not ensure such confidentiality, they should be amended so that disclosure of genetic information is not required.**

The committee recommends that codes of ethics of those professionals providing genetics services (such as those of the National Society of Genetic Counselors (NSGC), or of geneticists, physicians, and nurses) contain specific provisions to protect autonomy, privacy, and confidentiality. The committee endorses the NSGC statement of a guiding principle on confidentiality of test results:

> The NSGC support individual confidentiality regarding results of genetic testing. It is the right and responsibility of the individual to determine who shall have access to medical information, particularly results of testing for genetic conditions.[125]

The committee also endorses the principles on DNA banking and DNA data banking contained in the 1990 ASHG statement.

To further protect confidentiality, the committee recommends that

- **patients' consent be obtained before the patient's name is provided to a genetic disease registry and that consent be obtained before information is redisclosed;**
- **each entity that receives or maintains genetic information or samples have procedures in place to protect confidentiality**, including procedures limiting access on a need-to-know basis, identifying an individual who has responsibility for overseeing security procedures and safeguards, providing written information to each employee or agent regarding the need to maintain confidentiality,

and taking no punitive action against employees for bringing evidence of confidentiality breaches to light;

- **any entity that releases genetic information about an individual to someone other than that individual ensure that the recipient of the genetic information has procedures in place to protect the confidentiality of the information;**
- **any entity that collects or maintains genetic information or samples separate them from personal identifiers** and instead link the information or sample to the individual's name through some form of anonymous surrogate identifiers;
- **the person have control over what parts of his or her medical record are available to which people**; if an optical memory card is used, this could be accomplished through a partitioning-off of data on the card; and
- **any individual be allowed access to his or her genetic information in the context of appropriate education and counseling**, except in the early research phases during the development of genetic testing when an overall decision has been made that results based on the experimental procedure will not be released and the subjects of the research have been informed of that restriction prior to participation.

Discrimination in Insurance and Employment

In general, the committee recommends that principles of autonomy, privacy, confidentiality, and equity be maintained, and the disclosure of genetic information and the taking of genetic tests should not be mandated. Such a position, however, is in conflict with some current practices in insurance and employment.

Although more than half the U.S. population (approximately 156 million people) is covered by some kind of life insurance,[126] the use of genetic information in medical underwriting[127] decisions about life insurance appears to raise different and somewhat lesser concerns than the use of genetic information in health insurance underwriting. More of life insurance has historically been medically underwritten. Complaints of genetic discrimination in life insurance have been made.[128] Apparently, fewer Americans believe that life insurance is a basic right. In contrast, the Canadian Privacy Commission believes that life insurance is a basic right, and recommends that Canadians be permitted to purchase up to $100,000 in basic life insurance without genetic or other restrictions; underwriting for larger amounts of life insurance could be subject to a variety of life-style and health restrictions, including the use of genetic information.[129] **Most of the committee agrees with the spirit of the Canadian Commission's recommendation that a *limited* amount of life insurance be available to everyone without regard to health or genetic status. However, health insurance was considered a much more pressing ethical, legal, and social issue.**

The committee recommends that legislation be adopted so that medical risks, including genetic risks, not be taken into account in decisions on whether to issue or how to price health care insurance. Because health insurance differs significantly from other types of insurance in that it regulates access to health care, an important social good, risk-based health insurance should be eliminated. A means of access to health care should be available to every American without regard to the individual's present health status or condition, including genetic makeup. Any health insurance reform proposals need to be evaluated to determine their effect on genetic testing and the use of genetic information in health insurance (see Chapter 7).

The committee recommends that the unfair practices highlighted by the *McGann* case be prevented. Such situations could be eliminated by Congress in three ways. First, the antidiscrimination provision of the Employee Retirement Income Security Act (ERISA, see Chapter 7), section 510, could be amended to prohibit various types of employer conduct. For example, the legislation could prohibit: (1) the alteration of benefits or the alteration of benefits without a certain notice period; (2) the reduction of coverage for only a single medical condition; (3) the reduction of benefits after a claim for benefits already had been submitted, and so forth. At the very least, the committee recommends that an amendment be adopted making those practices illegal.

A second way of legislatively preventing *McGann*-type situations would be to amend the ERISA preemption provision, section 514. By amending this section to limit the preemptive effect of ERISA (e.g., that permits ERISA provisions to override state insurance regulations) or to eliminate ERISA preemption entirely, the result would be to allow the states to regulate self-insured employer benefits in the same way that state insurance commissions regulate commercial health insurance benefits. Although state regulation may be preferable to no regulation, it could lead to the burdensome multiplicity of state regulations that ERISA was intended to eliminate. For this reason, the committee believes that federal prohibition of the type of conduct in the *McGann* case would be preferable.

A third way to eliminate discrimination in employee health benefits by self-insured employers would be to amend section 501 of the ADA. The ADA is essentially neutral on the issue of health benefits; clauses on preexisting conditions, medical underwriting, and other actuarially based practices, to the extent permitted by state law, do not violate the ADA. Thus, the ADA could be amended to prohibit differences in health benefits that result in discrimination against individuals with disabilities. Amending the ADA in this manner would, in effect, mandate uniform coverage (although it is not clear what conditions would be covered) at community rates for employees. If Congress wanted to mandate that all employers offer a package of health benefits, a good argument could be made that it ought to do so separately and not via amendments to the ADA.

The committee recommends that legislation be adopted so that genetic information cannot be collected on prospective or current employees unless it

is clearly job related. Sometimes employers will have employees submit to medical exams to see if they are capable of performing particular job tasks. The committee recommends that if an individual consents to the release of genetic information to an employer or potential employer, the releasing entity should not release specific information, but instead answer only yes or no regarding whether the individual was fit to perform the job at issue.

The committee recommends that the EEOC recognize that the language of the Americans with Disabilities Act provides protection for presymptomatic people with a genetic profile for late-onset disorders, unaffected carriers of disorders that might affect their children, and people with genetic profiles indicating the possibility of increased risk of a multifactorial disorder. The committee also recommends that state legislatures adopt laws to protect people from genetic discrimination in employment. In addition, the committee recommends an amendment to the ADA (and adoption of similar state statutes) limiting the type of medical testing employers can request or the medical information they can collect to that which is job related.

Ultimately, new laws on a variety of other topics may also be necessary to protect autonomy, privacy, and confidentiality in the genetics field, and to protect people from inappropriate decisions based on their genotypes.[130] The ability of genetics to predict health risks for asymptomatic individuals and their potential offspring presents challenges in the ethical and social spheres. **The committee recommends that careful consideration be given to the development of policies for the implementation of genetic testing and the handling of genetic test results.**

NOTES

1. March of Dimes Birth Defects Foundation, *Genetic Testing and Gene Therapy: National Survey Findings* 18 (September 1992). New York.

2. See, e.g., *Satz v. Perlmutter*, 362 So.2d 160 (Fla. App. 1978) aff'd 379 So.2d 359 (Fla. 1980).

3. See, e.g., *Salgo v. Leland Stanford Jr. Univ. Bd. of Trustees*, 154 Cal. App. 2d 560, 317 P.2d 170 (1957); *Canterbury v. Spence*, 464 F.2d 772 (D.C. Cir.), cert. denied, 409 U.S. 1064 (1972).

4. *Gates v. Jensen*, 92 Wash. 2d 246, 595 P.2d 919 (1979).

5. *Salgo v. Leland Stanford Jr. Univ. Bd. of Trustees*, 154 Cal. App. 2d 560, 317 P. d 170 (1957).

6. *Kogan v. Holy Family Hospital*, 95 Wash.2d 306, 622 P.2d 1246 (1980).

7. See, e.g., *Becker v. Schwartz*, 46 N.Y.2d 401, 386 N.E.2d 807, 413 N.Y.S.2d 895 (1978). For a review of relevant cases, see Lori B. Andrews, "Torts and the Double Helix: Liability for Failure to Disclose Genetic Risks," 29 *U. Houston L. Rev.* 143 (1992).

8. L. Andrews, "My Body, My Property," 16(5) *Hastings Center Report* 28 (1986). See also *Moore v. Regents of the University of California.*

9. The federal regulations governing informed consent in the context of human experimentation provide that informed consent is not necessary for research on pathological or diagnostic specimens "if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects." 45 C.F.R. § 46.101(b)(5) (1991).

Similarly, some state human experimentation laws do not seem to extend their coverage to research on removed parts. In Virginia, for example, the law does not cover "the conduct of biological studies exclusively utilizing tissue or fluids after their removal or withdrawal from a human subject in the course of standard medical practice." Va. Code Ann. § 37.1-234(1) (1984). Under the New York law, human research is defined to exclude "studies exclusively utilizing tissue or fluids after their removal or withdrawal from a human subject in the course of standard medical practice." N.Y. Public Health Law § 2441(2) (McKinney 1977).

10. Office of Technology Assessment (OTA), U.S. Congress, *Human Gene Therapy* 72 (Washington, D.C.: U.S. Government Printing Office, 1984).

11. Ferdinand D. Schoeman, "Privacy: Philosophical Dimensions of the Literature," in *Philosophical Dimensions of Privacy: An Anthology*, ed., Ferdinand D. Schoeman (New York: Cambridge University Press, 1984).

12. See Judith Jarvis Thomson, "The Right to Privacy," *Philosophy and Public Affairs* 4(summer):315-333, (1975).

13. See, e.g., *Griswold v. Connecticut*, 381 U.S. 479 (1965); *Roe v. Wade*, 410 U.S. 113 (1973); *Planned Parenthood v. Casey*, ___ U.S. ___, 112 S.Ct. 2791 (1992).

14. *Lifchez v. Hartigan*, 735 F. Supp. 1361 (N.D. Ill. 1991), aff'd without opinion sub. nom.; *Scholber v. Lifchez*, 914 F.2d 260 (7th Cir. 1990), cert. denied, 111 S.Ct. 787 (1991).

15. *Carter v. Broadlawn Medical Center*, 667 F. Supp. 1269, 1282 (S.D. Iowa 1987). In that case, the court held that the privacy of patient records in a county hospital is protected by the Fourteenth Amendment's concept of personal liberty. See also *Whalen v. Roe*, 429 U.S. 589, 599 n. 23 (1977).

16. *Horne v. Patton*, 291 Ala. 701, 287 So.2d 824 (1973); *MacDonald v. Clinger*, 84 A.D.2d 482, 444 N.Y.S.2d 801 (1982).

17. Privacy Act of 1974, 5 U.S.C. § 552a (1991).

18. For further discussion of these arguments (and others in this section), see Tom L. Beauchamp and James F. Childress, *Principles of Biomedical Ethics*, 3rd ed. (New York: Oxford University Press, 1989, chap. 7).

19. Mark Siegler, "Confidentiality in Medicine—A Decrepit Concept," *N. Engl. J. Med.* 307: 1518-1521 (1982).

20. Research has found that people who are told that their answers would not be confidential provide less intimate information. Woods and McNamara, "Confidentiality: Its Effect on Interviewee Behavior," 11 *Prof. Psychology* 714, 719 (1980).

21. See, e.g., *Horne v. Patton*, 291 Ala. 701, 287 So.2d 824 (1973); *MacDonald v. Clinger*, 84 A.D.2d 482, 444 N.Y.S.2d 801 (1982). See W. Prosser and W.P. Keeton, *Prosser and Keeton on Torts* 856-863 (1984). See also S. Newman, "Privacy in Personal Medical Information: A Diagnosis," 33 *U. Fla. L. Rev.* 394-424 (1981). According to the latter article, the tort of invasion of privacy has been rejected only in Rhode Island, Nebraska and Wisconsin. *Id.* at 403. However, two of these states now recognize it by statute. R.I. Gen. Laws § 9-1-28 (1984); Wisc. Stat. § 895.50 (1985-86).

22. Norman Daniels, "Insurability and the HIV Epidemic: Ethical Issues in Underwriting," 68 *The Milbank Quarterly* 497-515 (1990). See also Mark A. Rothstein, "The Use of Genetic Information in Health and Life Insurance." In Friedman, T. (ed.) *Molecular Genetic Medicine* (New York: Academic Press, 1993).

23. On the natural lottery, see H. Tristram Engelhardt, Jr., *Foundations of Bioethics* (New York: Oxford University Press, 1986).

24. *Id.*

25. See Gene Outka, "Social Justice and Equal Access to Health Care," *Journal of Religious Ethics* 2 (1974). See also President's Commission for the Study of Ethical Problems in Biomedical and Behavioral Research, *Securing Access to Health Care*, Vol. 1: Report (Washington, D.C.: U.S. Government Printing Office, 1983).

26. Normal Daniels, "Equity of Access to Health Care: Some Conceptual and Ethical Issues," *Milbank Memorial Fund Quarterly/Health and Society* 60 (1982). See also Norman Daniels, *Just Health Care* (New York: Cambridge University Press, 1985).

27. President's Commission for the Study of Ethical Problems in Biomedical and Behavioral Research, *Securing Access to Health Care*, Vol. 1: Report (Washington, D.C.: U.S. Government Printing Office, 1983), p. 42.

28. Rothstein, "Genetic Discrimination in Employment and the American with Disabilities Act," 29 *Houston L. Rev.* 23, 31 (1992). See also the discussion *infra* in this chapter, "Discrimination."

29. Office of Technology Assessment (OTA), U.S. Congress, *Genetic Witness: Forensic Uses of DNA Tests* (Washington, D.C.: U.S. Government Printing Office, 1990).

30. D. C. Wertz and J.C. Fletcher, *Ethics and Human Genetics: A Cross-Cultural Perspective* (New York: Springer-Verlag, 1989); and D.C. Wertz and J.C. Fletcher, "An International Survey of Attitudes of Medical Geneticists Toward Mass Screening and Access to Results," 104 *Public Health Reports* 35-44 (1989).

31. G. Geller, E. Tambor, G. Chase, K. Hofman, R. Faden, N. Holtzman. "How Will Primary Care Physicians Incorporate Genetic Testing: Directiveness in Communication," 31 *Medical Care* 625-631 (1993).

32. There are several reasons why institutions store DNA samples, rather than just information from samples. The first is for future potential clinical benefit, such as when a new test may be developed that could provide a more accurate diagnosis. The second is for litigation purposes, so that the sample can be retested if the results are challenged. The third is for research purposes, to use the DNA for the development of additional tests.

33. Philip Reilly, Presentation to Ethical, Legal, and Social Implications Program Committee, January 1991.

34. Yoichi Matsubara, Kuniaki Narisawa, Keiya Tada, Hiroyuki Ikeda, Yao Ye-Qi, David M. Danks, Anne Green, Edward R.B. McCabe, "Prevalence of K329E Mutation in Medium-Chain Acyl-CoA Dehydrogenase Gene Determined from Guthrie Cards," 338 *Lancet* 552-553 (1991).

35. Joe Abernathy, "City Health Clinics Unveil Controversial 'Smart Card'," *Houston Chronicle*, October 11, 1992, sec. A, p. 1.

36. See, e.g., M. Shaw, "Conditional Prospective Rights of the Fetus," 5 *J. Legal Med.* 63 (1989).

37. Moreover, it should be noted that this risk (transmission of genetic disease to offspring) is one that society has always lived with, and seems to have flourished despite that risk.

38. For example, in *The New York Times v. United States*, 403 U.S. 713 (1971), the U.S. Supreme Court, in a per curiam opinion held that the government had not met its "heavy burden" of proving that national security required that the Pentagon Papers be suppressed. The logic of the case was explained further in the concurrences; the right of free speech is to be infringed by a prior restraint only when disclosure "will surely result in direct, immediate, and irreparable damage to our Nation or its people." *Id.* at 730 (Stewart, J., concurring). Or when there is "governmental allegation and proof that publication must inevitably, directly, and immediately cause the occurrence of an event kindred to imperiling the safety of a transport already at sea . . ." during wartime. *Id.* at 726-727 (Brennan, J., concurring).

The standard of irreparability for granting an injunction against protected speech is an absolute, not a comparative standard. Even if the speech could cause great harm, that would not be sufficient. As Justice White pointed out in his concurrence in *New York Times*, it is not sufficient that there may be "substantial damage to public interests." *Id.* at 731 (White, J., concurring). Similarly, Justice Stewart said "I am convinced that the Executive is correct with respect to some of the documents involved [i.e., they should not, in the national interest, be published]. But I cannot say that disclosure of any of them will surely result in direct, immediate, and irreparable harm to our Nation or its people. That being so, there can under the First Amendment be but one judicial resolution of the issue before us." *Id.* at 730 (White, J., concurring).

Even if irreparable harm were a possibility, *New York Times* indicates that an injunction should not be issued against the press unless such harm would come about directly and immediately. The term "immediately" is easy enough to understand; it requires a present, not future, harm. The term "directly" relates to the lack of intervening influences during that time period. The irreparable harm would not occur directly if another important influence would or could intervene. Another way of

expressing the immediacy and directness that is necessary is by saying the harm is "inevitable"—it will occur within a short period of time during which nothing will or could change it or stop it.

Even when a prior restraint is not at issue, high standards are required for showing a compelling state interest when a fundamental right is at issue. Also in the First Amendment area, speech that is not false should not be the basis for subsequent punishment unless it provided an immediate threat of serious harm. (See, e.g., *Bridges v. California*, 314 U.S. 252, 263 (1941) ("the substantial evil must, be extremely serious and the degree of imminence extremely high before utterances can be punished").)

39. AIDS, of course, is an infectious disease that cannot be cured and that is strongly identified with certain minority groups (e.g., homosexuals). It is interesting to note that for many of the same reasons that are applicable to mandatory genetic screening, mandatory AIDS screening has not been adopted. Instead, anonymous voluntary screening has been the model.

40. C. Damme, "Controlling Genetic Disease Through Law," 15 *U. Cal. Davis L. Rev.* 801, 807 (1982).

41. Such charges were leveled by blacks when mandatory sickle cell carrier screening was put into place.

42. L. Andrews, *Medical Genetics: A Legal Frontier* 233 (1987).

43. A. G. Motulsky, "The Significance of Genetic Disease," 59, 61 in B. Hilton, D. Callahan, M. Harris, P. Condliffe, B. Berkley, eds., *Ethical Issues in Human Genetics: Genetic Counseling and the Use of Genetic Knowledge* (Fogarty International Proceedings No. 13, 1973).

44. Statement of D. Brock in B. Hilton et al., eds., *id.* at 90.

45. The idea of choosing by category was discussed by Alta Charo, J.D., at the committee's June 1992 workshop.

46. e.g., *Cobbs v. Grant*, 8 Cal.3d 829, 104 Cal. Rptr. 505, 502 P.2d 1, 12 (1972). Some states' informed consent statutes explicitly recognize a right to refuse information. Alaska Stat. § 09.55.556(b)(2) (1983); Del. Code Ann. tit. 18, § 6852(b)(2) (Supp. 1984); N.H. Rev. Stat. Ann. § 507-C:2(II)(b)(3) (1983); N.Y. Public Health Law § 2805-d(4)(b) (McKinney 1985); Or. Rev. Stat. § 677.097(2) (1985); Utah Code Ann. § 78-14-5(2)(c) (1977); Vt. Stat. Ann. tit. 12, § 1909(c)(2) (Supp. 1991); Wash. Rev. Code Ann. § 7.70.060(2) (Supp. 1991).

47. *Prince v. Massachusetts*, 321 U.S. 158, 170 (1944).

48. *In re Green*, 448 Pa. 338, 292 A.2d 387, 392 (1972). See also Brown and Truit, "The Right of Minors to Medical Treatment," 28 *DePaul L. Rev.* 289, 299 (1979).

49. *Jehovah's Witnesses v. King County Hospital* 278 F. Supp. 488 (W.D. Wash. 1967), 390 U.S. 598 (1968), denied, 391 U.S. 961 (1968).

50. D.C. Code Ann. § 6-314(3) (1989); Md. Health-Gen. Code Ann. §§ 13-102(10) and 109(e)-(f) (1982).

51. Iowa Admin. Code § 641-4.1 (136A) (1992); Mich. Comp. Laws Ann. § 333.5431(1) (West 1992); Mont. Code Ann. § 50-19-203(1) (1991); W. Va. Code Ann. § 16-22-3 (Supp. 1992).

52. Mo. Ann. Stat. § 191.331(5) (Vernon 1990); S.C. Code § 44-37-30(B) (1991).

53. Council of Regional Networks for Genetic Services (CORN), *Newborn Screening: 1990*, Final Report (February 1992). New York.

54. R. R. Faden, A. J. Chwalow, N. A. Holtzman, and S. Horn, "A Survey to Evaluate Parental Consent As Public Policy for Neonatal Screening," 72 *Am. J. Pub. Health* 1347 (1982).

55. "Consensus Statement Proposed for Routine Newborn Genetic Screening." Based on October 1989 conference in Quebec, Canada. Reported in Bartha Maria Knoppers and Claude M. LaBerge (eds.), "Genetic Screening: From Newborns to Data Typing," *Excerpta Medica* 382 (1990).

56. Currently, Colorado and Wyoming include cystic fibrosis testing as a part of their mandatory newborn screening program; Wisconsin includes cystic fibrosis in newborn screening as part of an experimental research protocol.

57. Neil A. Holtzman, "What Drives Neonatal Screening Programs," 325 *New Engl. J. Med.* 802-809 (Sept. 12, 1991), referring to K.B. Hammond, S.H. Abman, R.J. Sokol, F.J. Accurso, "Efficacy of

Statewide Newborn Screening for Cystic Fibrosis by Assay of Trypsinogen Concentration, 325 *New Engl. J. Med.* 769-74 (1991).

58. *Id.*

59. *Id.*, citing P. Farrell, personal communication.

60. Norm Fost presentation, June 1992 committee workshop.

61. Statement of Claude LaBerge at June 1992 committee meeting.

62. See T. McNeil, B. Harty, T. Thelin, E. Aspergren-Jansson, T. Sveger, "Identifying Children at High Somatic Risk: Long-Term Effects on Mother-Child Interactions," *Acta-Psychiatrica Scandinavica* 74(6):555-562 (December 1986).

63. Ellen Wright Clayton, "Screening and Treatment of Newborns," 29 *Houston L. Rev.* 85 (1992).

64. The federal regulations governing informed consent in the context of human experimentation provide that informed consent is not necessary for research on pathological or diagnostic specimens "if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects." 45 C.F.R. § 46.101(b)(4)(1991).

Similarly, some state human experimentation laws do not seem to extend their coverage to research on removed parts. In Virginia, for example, the law does not cover "the conduct of biological studies exclusively utilizing tissue or fluids after their removal or withdrawal from a human subject in the course of standard medical practice." Va. Code Ann. § 37.1-234(1) (1990). Under the New York law, human research is defined to exclude "studies exclusively utilizing tissue or fluids after removal or withdrawal from a human subject in the course of medical practice."

Some researchers argue that blood and urine left over after a patient's tests are done should be available without requiring the patient's informed consent. However, the issue is not as straightforward as it might seem. Research surreptitiously done on a patient's blood might generate information that could be damaging to the patient. If a cystic fibrosis test were being developed with excess blood from a PKU test, and the blood tested positive for cystic fibrosis, it could be argued that, depending on how reliable the test seemed, the infant's parents should be informed. But if the result ultimately turned out to be a false positive, the family may have been harmed by unnecessary worry. With respect to research on leftover blood from adults, if testing is being developed for a potentially stigmatizing disorder (such as AIDS) or a disorder that might influence employment or other opportunities for the person (such as Huntington disease) the risks to the patient if confidentiality were compromised might be so high that it would seem unethical not to solicit the individual's consent before the research is undertaken.

65. ASHG Ad Hoc Committee on Individual Identification by DNA Analysis, "Individual Identification by DNA Analysis: Points to Consider," *Am. J. Hum. Genet.* 46:631-634 (1990).

66. *Id.* at 632.

67. Nancy Wexler, "The Tiresias Complex: Huntington's Disease as a Paradigm of Testing for Late-Onset Disorders," *FASEB Journal* 6:2820-2825 (1990).

68. See, e.g., *Skillings v. Allen*, 143 Minn. 323, 173 N.W. 663 (1919); *Davis v. Rodman*, 147 Ark. 385, 227 S.W. 612 (1921). For a more recent case, regarding a duty to warn third parties of communicable diseases, see *Gammill v. U.S.*, 727 F.2d 950 (10th Cir. 1984).

69. *Tarasoff v. Regents of the University of California*, 131 Cal. Rptr. 14, 17 Cal. App. 3d 425, 551 P.2d 334 (1976).

70. *Id.*

71. *Collins v. Howard*, 156 F. Supp. 322, 325 (S.D. Ga. 1957) (dicta).

72. The individual generally asks that his or her spouse be informed as well. Statement of J. Lejeune in B. Hilton, D. Callahan, M. Harris, P. Condliffe, B. Berkeley, eds., *Ethical Issues in Human Genetics: Genetic Counseling and the Use of Genetic Knowledge*, 70 (Fogarty International Proceedings No. 13, 1973).

In a March of Dimes-sponsored national public opinion survey, 71 percent of respondents said that if a doctor of a woman who plans to have children finds through testing that her children might

inherit a serious or fatal genetic disease, the doctor has an obligation to tell her husband. March of Dimes Birth Defects Foundation, *Genetic Testing and Gene Therapy: National Survey Findings* 7 (New York, September 1992). However, in some instances, an individual may or may not want personal genetic information disclosed to his or her spouse.

73. *Berry v. Moensch*, 8 Utah 2d 191, 331 P.2d 814 (1958); *Curry v. Corn*, 52 Misc.2d 1035, 277 N.Y.S.2d 470 (1966) (during marriage, each has the right to know the existence of any disease that may have bearing on the marital relation).

74. See, e.g., *Simonsen v. Swenson* 104 Neb. 224, 177 N.W. 831 (1920).

75. The man whose nonpaternity is shown through prenatal screening might argue that, in addition to its relevance to his future childbearing plans, the information that he is not the father of his wife's child has an immediate financial implication since he might not wish to support the child. However, state paternity statutes preserve that a child born during a marriage is the husband's child and require him to support the child, even if it could conceivably be shown through genetic testing that he was not the biological father of the child. The logic behind such cases is that there is a societal interest in the integrity of the family.

76. *Eisenstadt v. Baird*, 405 U.S. 438 (1972).

77. *Planned Parenthood v. Danforth*, 428 U.S. 52 (1976).

78. *Planned Parenthood v. Casey*, ___ U.S. ___, 112 S.Ct. 2791 (1992).

79. *Id.*

80. If a patient is the carrier of the gene for a serious autosomal recessive disorder, his or her relatives might also argue that they would be harmed by not knowing that they, too, are at risk of having children with that disorder. However, the risk to future offspring may be too remote to warrant breaching confidentiality, as it is in the case of a spouse.

81. The President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *Screening and Counseling for Genetic Conditions* 6 (1983).

82. See, e.g. *Simonsen v. Swenson*, 104 Neb. 224, 177 N.W. 831 (1920).

83. In one instance, for example, a woman was denied disability insurance when her father's medical records were released to the insurer.

84. Office of Technology Assessment, U.S. Congress, *Medical Testing and Health Insurance* 73 (1988).

85. S. Rep. 100-360, 100th Cong., 1st Sess. 20 (1988).

86. Report of Committee on Employer-Based Health Benefits, citing Seeman (1993).

87. *McGann v. H. & H. Music Co.*, 946 F.2d 401 (5th Cir. 1991), *cert. denied sub nom.*; *Greenberg v. H. & H. Music Company*, ___ U.S. ___, 112 S.Ct. 1556 (1992).

88. Eric Zicklin, "More Employers Self-Insure Their Medical Plans, Survey Finds," *Business and Health* 74 (April 1992).

89. Mark Rothstein, "The Use of Genetic Information in Health and Life Insurance," in *Molecular Genetic Medicine*, ed., Ted Friedman (New York: Academic Press, 1993).

90. According to *American Healthline*, Briefing on Health Insurance, November 17, 1992, more than half of Americans would not accept a job that did not provide health insurance.

91. "EEOC Said Ready to 'Fast Track' Complaints of Insurance Caps under Title 1 of the ADA," 7 No. 18 *AIDS Policy & Law* 1-2 (October 2, 1992).

92. N. Kass, "Insurance for the Insurors," *Hastings Center Report*, 6-11 (November-December 1992).

93. Institute of Medicine (IOM), National Academy of Sciences, M. Field and D. H. Shapiro (eds.) Employment and Health Benefits: A Connection at Risk. Committee on Employer-Based Health Insurance (Washington, D.C.: National Academy Press, 1993).

94. OTA, 1992a, p. 180.

95. OTA, 1992b.

96. See, e.g., P.R. Billings, M.A. Kohn, M. de Cuevas, J. Beckwith, J.S. Alper, M.R. Natowicz, "Discrimination as a Consequence of Genetic Testing," 50 *Am. J. Hum. Genet.* 476-482 (1992).

97. U.S. Congress, Office of Technology Assessment, *Cystic Fibrosis and DNA Tests: Implications of Carrier Screening* (Washington, D.C.: U.S. Government Printing Office, 1992a).

98. The disorders included adult polycystic kidney disease, Huntington disease, neurofibromatosis, Marfan syndrome, Down syndrome, Fabray disease.

99. The conditions included a balanced translocation.

100. The disorder was cystic fibrosis.

101. Kass, 1992.

102. *Id.* at 10.

103. Report of Institute of Medicine Committee on Employer-Based Health Benefits.

104. See Kass, 1992 for descriptions of these plans.

105. P. Reilly, *Genetics, Law and Social Policy* 62-86 (Cambridge, Mass.: Harvard University Press, 1977).

106. Fla. Stat. Ann. § 626.9706(1) (West 1984); La. Rev. Stat. Ann. § 22:652.1(D) (West Supp. 1992).

107. 22 Fla. Stat. Ann. § 626.9707(1) (West 1984); La. Rev. Stat. Ann. § 22:652.1(D) (West Supp. 1992).

108. Fla. Stat. Ann. § 626.9706(2) (West 1984) (life insurance), § 626.9707(2) (West 1984) (disability insurance); La. Rev. Stat. Ann. § 22:652.1(D) (West Supp. 1992).

109. This same law appears in three places in the Florida statutes: Fla. Stat. Ann. § 448.076 (West 1981); § 228.201 (West Supp. 1989); and § 63.043 (West 1985).

110. Fla. Stat. Ann. § 448.075 (West 1981); N.C. Gen. Stat. § 95-28.1 (1989); La. Rev. Stat. Ann. § 23:1002(A)(1) (West 1985).

111. La. Rev. Stat. Ann. § 23:1002(C)(1) (West 1985).

112. Cal. Ins. Code § 10143 (West Supp. 1992).

113. 1991 Wisc. Act 269, codified as Wisc. Stat. Ann. § 631.89.

114. Council on Ethical and Judicial Affairs, "Use of Genetic Testing by Employers," 266 *JAMA* 1827 (1991).

115. *Id.* at 1828.

116. *Id.* at 1828.

117. N.J. Stat. Ann. § 10:5-12(a) (West Supp. 1992).

118. N.Y. Civ. Rights Law § 48 (McKinney 1992).

119. 1992 Iowa Legis. Serv. 93 (West); Or. Rev. Stat. § 659.227 (1991); 1991 Wis. Laws 117.

120. 104 Stat. 327 (1991). For sections of the Americans With Disabilities Act relating to employment, see 42 U.S.C.A. §§ 12101-12117 (Supp. 1992).

121. L. Gostin and W. Roper. "Update: The Americans with Disabilities Act," *Health Affairs* 11(3):248-258.

122. Alaska Stat. § 18.80.220(a)(1) (1991); Cal. Gov't Code § 12940(d) (West Supp. 1991); Colo. Rev. Stat. § 24-34-402(1)(d) (1988); Kan. Stat. Ann. § 44-1009(a)(3) (Supp. 1991); Mich. Comp. Laws Ann. § 37.1206(2) (West 1985); Minn. Stat. Ann. § 363.02(1)(8)(i) (West Supp. 1991); Mo. Ann. Stat. § 213.055.1(1)(3) (Vernon Supp. 1992); Ohio Rev. Code Ann. § 4112.02(E)(1) (Anderson 1991); 43 Pa. Cons. Stat. Ann. § 955(b)(1) (1991); R.I. Gen. Laws § 28-5-7(4)(A) (Supp. 1991); Utah Code Ann. § 34-35-6(1)(d) (Supp. 1991).

123. Office of Technology Assessment (OTA), U.S. Congress, *Genetic Screening in the Workplace*, OTA-BA-456 (Washington, D.C.: U.S. Government Printing Office, 1990).

124. See, e.g., *Simonsen v. Swenson*, 104 Neb. 224, 177 N.W. 831 (1920); *Tarasoff v. Regents of the University of California*, 131 Cal. Rptr. 14, 17 Cal. App. 3d 425, 551 P.2d 334 (1976).

125. National Society of Genetic Counselors (NSGC), "Guiding Principles," *Perspectives on Genetic Counseling* (October 1991).

126. American Council on Life Insurance, *1992 Life Insurance Fact Book* 19 (1992).

127. Medical underwriting is the evaluation of a person's insurability, usually assessed through a combination of answers to a written questionnaire and physical examination to identify certain conditions determined by medical underwriters (and underwriting manuals) to reduce life expectancy below actuarial norms. Standards for medical underwriting vary substantially by insurance company, and underwriting decisions are considered crucial business decisions by insurers and are thus considered "trade secrets."

128. Paul Billings, "Testimony Before Human Resources and Intergovernmental Relations Subcommittee of the Committee on Government Operations," U.S. House of Representatives, 102nd Congress, July 23, 1992.

129. Canadian Privacy Commission, *Genetic Testing and Privacy* (Ottawa, 1992).

130. Neil A. Holtzman and Mark A. Rothstein, "Invited Editorial: Eugenics and Genetic Discrimination," 50 *Am. J. Hum. Genet.* 457-459 (1992).