

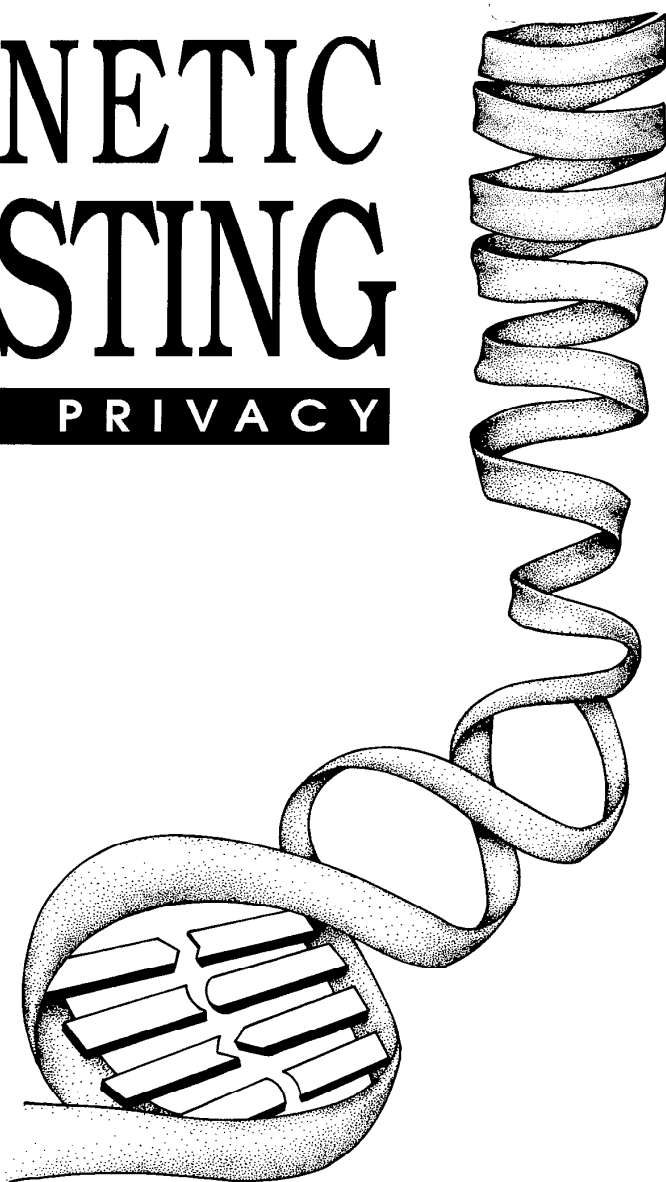


Privacy
Commissioner
of Canada

Commissaire
à la protection de
la vie privée du Canada

GENETIC TESTING

AND PRIVACY



GENETIC TESTING AND PRIVACY



The Privacy Commissioner
of Canada

Acknowledgements

The Privacy Commissioner gratefully acknowledges the work of Eugene Oscapella, LL.M, both his preparation of the initial discussion paper and his contributions to the report itself.

**The Privacy Commissioner of Canada
112 Kent Street
Ottawa, Ontario
K1A 1H3
(613)995-2410, 1-800-267-0441**

**© Minister of Supply and Services Canada 1995
Cat. No. IP34-3/1992
ISBN 0-662-58966-1**

Table of Contents

Introduction	2
Part I - The Science and Uses of Genetic Testing	5
(a) The Science -- Basic Human Genetics	5
(b) Genetics and Disease	8
(i) Monogenic (single gene) disorders	9
(ii) Multifactorial disorders	9
(iii) Chromosomal disorders	9
(iv) Non-inherited disorders caused by changes in cells	9
(c) Techniques for Genetic Testing: Gene Probes and Genetic Markers	10
(d) Screening, Monitoring and Forensic DNA Analysis	10
(e) Uses of Genetic Testing	16
Part II - Privacy Principles For Genetic Testing	29
(a) Introduction	29
(b) The Right to a Reasonable Expectation of Genetic Privacy	30
(c) Specific Testing Applications	31
(i) Employment	31
(ii) Access to services or benefits	32
(iii) Human reproduction	35
(iv) Normal medical care	41
(v) Forensic uses of genetic tests	43
(vi) Research	50

Part III - Genetic Testing and the <i>Privacy Act</i>	55
(a) The <i>Privacy Act</i>	55
(i) Personal information and genetic testing	56
(ii) Collection of personal information	57
(1) Collection without consent and volunteered information ...	57
(2) Direct collection	59
(3) Informing about the purpose of collection	60
(iii) Retention and disposal of personal genetic information	61
(iv) Accurate, complete and current information	64
(v) Uses of personal genetic information	70
(vi) Disclosure of personal genetic information	71
(vii) Access to one's own personal genetic information	74
Part IV - Regulating the Private Sector	78
Part V - Conclusion	83
Part VI - Summary of Recommendations	86
Appendix - Activities in Other Countries Relating to Genetic Testing	93

Imagine a society where the government had samples of tissue and fluid from the entire community on file and a computerized databank of each individual's DNA profile. Imagine then that not only law enforcement officials, but insurance companies, employers, schools, adoption agencies, and many other organizations could gain access to those files on a "need to know" basis or on a showing that access is "in the public interest." Imagine then that an individual could be turned down for jobs, insurance, adoption, health care, and other social services and benefits on the basis of information contained in her DNA profile, such as genetic disease, heritage, or someone else's subjective idea of a genetic "flaw."

Janet C. Hoefel, "The Dark Side of DNA Profiling: Unreliable Scientific Evidence Meets the Criminal Defendant", 42 Stanford Law Review 465 at 533-34 (1990).

Introduction

The measure of our privacy is the degree of control we exercise over what others know about us. No one, of course, has absolute control. As social animals, few would want total privacy. However, we are all entitled to expect enough control over what is known about us to live with dignity and to be free to experience our individuality. Our fundamental rights and freedoms – of thought, belief, expression and association – depend in part on a meaningful measure of individual privacy. Unless we each retain the power to decide who should know our political allegiances, our sexual preferences, our confidences, our fears and aspirations, then the very basis of a civilized, free and democratic society could be undermined.

Yet, we find that the tools are now available to deprive us of almost every vestige of privacy. Advances in computers, telecommunications, video and bio-medical technologies make it feasible for others to learn many intimate details about us, whether we want them to or not. The Supreme Court of Canada acknowledged this in its 1990 decision, *Wong v. The Queen*:

[T]he technical resources which agents of the state have at their disposal ensure that we now run the risk of having our words recorded virtually every time we speak to another human being. Professor Amsterdam . . . drives the point home with a striking image when he suggests that in view of the sophistication of modern eavesdropping technology we can only be sure of being free from surveillance today if we retire to our basements, cloak our windows, turn out the lights and remain absolutely quiet....¹

No surveillance technology is more threatening to privacy than that designed to unlock the information contained in human genes. Modern explorers have set sail on voyages into the genetic microcosm, seeking a medically powerful but potentially dangerous treasure: information about how our genes make us tick. Today, we can ask who among us is likely to have healthy babies or fall ill with a genetic disease. In the future, we may be able to use genetic testing to tell us who will be smart, be antisocial, work hard, be athletic or conform to prevailing standards of beauty.

One is struck by the parallel between unlocking the gene in the '90s and unlocking the atom in the '40s. In both cases the excitement of discovery dulled critical assessment of the implications. In both cases we allowed scientists to unleash forces which can alter life as we know it, paid for their efforts with public funds and, at least initially, set few ethical or legal controls² on the enterprises.

In a speech at Harvard University in 1986, Prince Charles reminded us:

We may have forgotten that when all is said and done, a good man, as the Greeks would say, is a nobler work than a good technologist. We should never lose sight of the fact that to avert disaster we have not only to teach men to make things, but also produce people who have complete control over the things they make.

This report examines how we might take up that challenge, how we might benefit from the potential of genetic technology without undermining our autonomy. The threat to privacy is but one of a host of possible genetic "evils" that must be countered now before we are trampled by the march of the technology.

The *Privacy Act* is the focus of this report's efforts to prevent genetics from spawning another nightmare in our surveillance society. The Act, however, is simply not up to the job. It applies only to federal government institutions. Its provincial counterparts, where they exist, also apply only to government institutions under provincial jurisdiction.

Even within the federal government, the Act is limited in what it can do to protect genetic privacy. One must torture its provisions almost to the breaking point to offer any meaningful privacy protection to Canadians. The *Canadian Charter of Rights and Freedoms*, medical ethics and laws on medical confidentiality offer some help. But let no one be fooled; existing laws will not prevent realizing our worst fears about privacy abuses through genetic testing.

Much more precise legal controls must be adopted. But law alone cannot ensure that genetic technology is used only for acceptable ends. It must be

accompanied by a concerted effort to bring the issue out of the laboratories and into public fora. Educators, labour unions, religious organizations and the media must carefully and persistently scrutinize the genetics enterprise. Our exploration of the human genome must not enable "genetic determinism"³ to become a self-fulfilling prophesy.

We must have meaningful control over the communication of genetic information in the private sector and especially in governments. Individuals must also be allowed to control when, and if, they will learn their own genetic potential. Genetic privacy therefore has two dimensions – protection from the intrusions of others and protection from one's own, hitherto unknown, secrets. Who we are and what we can become is a wonderful mystery, far too complex for even a fully "mapped" and "sequenced" genome to explain. It is far too precious to be allowed to fall victim to an unquestioning acceptance of genetic determinism.

Part I of this report offers a greatly simplified description of the scientific fundamentals of genetic testing and describes its present applications. Part II establishes broad privacy principles to guide both the public and private sectors on testing matters. Part III examines specifically how the *Privacy Act* regulates genetic testing by government institutions. Part IV addresses the growing need to consider regulating private sector genetic testing. The conclusion is contained in Part V. The appendix contains a summary of positions about genetic testing and privacy taken by other countries and by international organizations.

ENDNOTES

(1) November 12, 1990, per Mr. Justice La Forest at 7-8.

(2) To be fair, the Human Genome Project has introduced a consideration of ethical, legal and social issues into its work. Others, for example, the Boston-based Council for Responsible Genetics, have voiced concern about the genetic discrimination that may flow from testing.

(3) Genetic determinism is a concept that persons are what they are solely because of their genes. A recent study paper prepared for the Law Reform Commission of Canada defines determinism as the theory that for every human action there are causal mechanisms such that no other action is possible: B. Knoppers, *Human Dignity and Genetic Heritage: A Study Paper* prepared for the Law Reform Commission of Canada (1991) at 78.

Part I

The Science and Uses of Genetic Testing

Beware of geneticists bearing discoveries. Their findings, perhaps more than any others in science, are likely to be abused and harmfully misinterpreted in the near future. Danger usually comes from wherever you are not looking. Everybody is ready for the mutant viruses, plants and two-headed chimpanzees to crawl out of the ventilation shafts of biotechnology laboratories. That is not where the problem will come from. Everybody knows about the blue-eyed "designer babies" who will be born quoting Aristotle. But they are not the real danger either. Look instead at insurance companies, personnel departments and the health pages of next year's women's magazines. That is where the trouble is brewing.

Anthony Gottlieb, "Are your genes up to scratch?", *The World in 1991* (1990) at 18.

(a) The Science -- Basic Human Genetics

To assess the issues involved in genetic testing, one requires a basic understanding of human genetics.¹

Almost all human cells except red blood cells contain genetic information about a person's entire being. Each carries an identical set of the body's estimated 50,000 to 100,000 genes. Egg and sperm cells ("germ cells") are exceptions, carrying only the genes that the mother and father will contribute to their child when egg and sperm unite.

The genes are contained in the DNA (deoxyribonucleic acid) present in these cells. DNA is the basic bearer of genetic information in the human body. DNA looks much like a spiral ladder. The DNA contained in each cell would be about a yard long if unravelled.

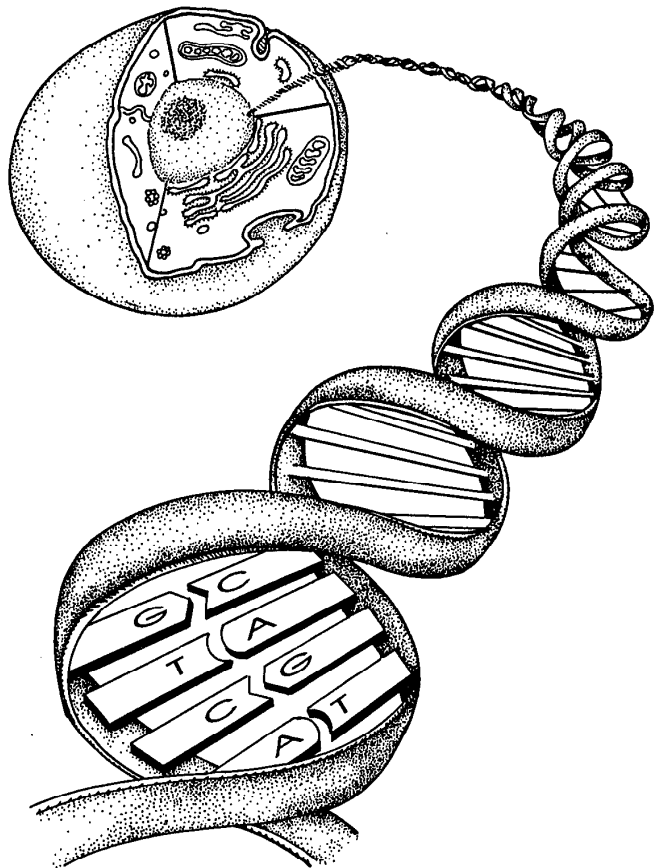
DNA is composed in part of four chemical subunits called *bases*. These bases are guanine (G), adenine (A), thymine (T) and cytosine (C). These bases normally pair with one another in predictable ways; A pairs with T, and G with C. The pairing of these bases gives DNA its "double-helix" structure; the bonds between bases can be thought of as rungs on the DNA spiral ladder. A gene is a series of "base pairs" located in a particular segment of DNA. In other words, it is a section of the spiral ladder. The segment of DNA that constitutes a gene varies.

Some genes might contain relatively few base pairs ("rungs") – for example, only a few thousand.

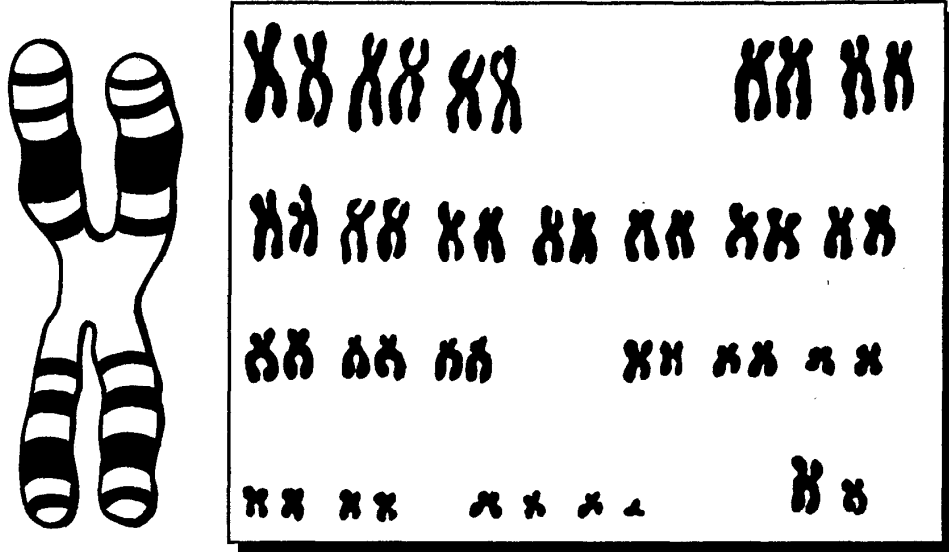
Other genes might consist of over a million.

In total, human DNA contains about 3.3 billion base pairs. The entire set of genetic material (the 3.3 billion base pairs making up 50,000 to 100,000 genes) is called the human genome. A person's genome can be thought of as a sort of genetic recipe for the person.

The body's genes are organized into larger units called chromosomes. Thus, every gene is located on a chromosome. Cells have 23 pairs of chromosomes. Each cell derives 23 chromosomes from the father and 23 from the mother.



The Structure of DNA: bases which pair to form the "double helix"



The 23 pairs of human chromosomes , the last of which is the sex chromosome

Chromosomes are of two types - *autosomal* or *sex*. Autosomal chromosomes (autosomes) are any of the 22 pairs of non-sex chromosomes. The 23rd chromosome pair - the sex chromosome - determines the sex of an individual. Women normally have two "X" chromosomes. Men normally have one "X" and one "Y" chromosome.

The human genetic structure, from smallest to largest component, can be visualized as follows:

- 3.3 billion base pairs of nucleotides (G,C,A,T)
- constituting 50,000 to 100,000 genes
- contained in 23 pairs of chromosomes
- found in the DNA contained in cells other than red blood cells.

(b) Genetics and Disease

Genes are increasingly being implicated in specific diseases. According to the Science Council of Canada, genes are probably implicated in most diseases.² The Council reports that, to date, nearly 5,000 genetic disorders and traits with classic inheritance patterns have been identified.³ Of the 5,000, about 3,600 are disorders caused by a single gene.⁴

Genetic aberrations are a major factor in failed pregnancies, particularly in the first three months after conception. Infant mortality from genetic causes is about five per 1000 live births. Up to 50 per cent of children in Canadian pediatric hospitals have disorders that are known to be strongly influenced by genetic factors.⁵

Data from the British Columbia Health Surveillance Registry show that at least 5.3 per cent of the province's population under 25 has a handicapping condition that is wholly or partly genetic. While information about genetic disease in older adults is limited, the Science Council cited estimates from the 1970s that 12.5 per cent of hospitalized adults had genetically influenced disorders. Data on severely mentally retarded individuals shows that approximately 15 per cent have disorders inherited through a single gene and 45 per cent have disorders that are in some way genetically influenced.⁶

Genetic disorders and the diseases flowing from them can occur in several ways:

- through a single mutant gene (called single gene or monogenic disorders);
- through several (polygenic) genetic disorders combined with environmental factors (called multifactorial diseases);
- through aberrations in chromosomes (chromosomal disorders); and
- through changes in cells (non-inherited genetic disorders).

These are explained below in greater detail.

(i) Monogenic (single gene) disorders

Some genetic diseases are caused by a disorder in a single gene. One of the most common, cystic fibrosis,⁷ occurs in one in every 2,500 births. Most recessive single gene disorders (disorders caused when the child receives a particular defective recessive⁸ gene from each parent) occur at a rate of one in 15,000 to 100,000 births. Even if individual single gene disorders (such as cystic fibrosis) are relatively rare, there are so many of them (about 3,600) that they have considerable impact; perhaps as many as three per cent of all persons born will develop a disease determined by a single gene.⁹

(ii) Multifactorial disorders

Multifactorial diseases stem both from environmental factors and from the effects of one or many (polygenic) abnormal genes.

Multifactorial diseases are far more common than single gene diseases. Coronary heart disease, diabetes mellitus, multiple sclerosis, schizophrenia, epilepsy, asthma, some forms of arthritis and some forms of emphysema are all multifactorial. The Medical Research Council of Canada suggests that at least one in ten persons is affected by multifactorial disorders.¹⁰

(iii) Chromosomal disorders

Chromosomal disorders arise if the number or structure of a person's chromosomes is abnormal. For example, mistakes can occur during the division of cells. This may result in too much, too little or rearranged chromosomal material in the new cells. Individuals with Down Syndrome, for example, have three copies of chromosome 21 instead of two. The Medical Research Council of Canada reports that one in 200 liveborn individuals has a chromosomal abnormality.¹¹

(iv) Non-inherited disorders caused by changes in cells

Some persons who are genetically "normal" at birth may develop disease when the DNA in a particular type of cell changes. This change may occur if genes are damaged or if environmental factors such as radiation, chemicals or viruses alter the genetic structure of cells – for example, some cancers and AIDS.¹²

(c) Techniques for Genetic Testing

(i) Gene probes

A gene probe looks for the specific gene which causes a genetic disorder. To develop gene probes, scientists must first know the sequence of base pairs of the gene that causes the disease. Gene probes can now be used to identify diseases such as cystic fibrosis and Duchenne muscular dystrophy.¹³

(ii) Genetic markers.

Genetic markers help locate genes which cause disorders if there is no known gene probe for the disorder. That is, genetic markers are useful when the specific sequence of base pairs associated with the disease is unknown.

Genetic markers are identifiable genes or stretches of DNA which may not themselves cause a genetic disorder. However, they are known to lie close to the gene that does. During human reproduction genetic markers are rarely separated from the gene causing the disorder. The presence of the genetic marker offers a high probability that the gene that causes the disorder is also present.

Many genetic markers are now known, including that for Huntington's disease.¹⁴

Genetic markers are generally less useful for indicating the presence of a given genetic trait than are gene probes. Genetic markers may appear in different forms in different persons. The person being tested for a genetic defect may therefore need to have family members who do or do not suffer from the disorder submit to genetic testing for the test to produce more accurate results. Even then, inaccuracies can remain. Among the reasons are variations in the distance of the marker from the gene and differences in family inheritance patterns.

(d) Screening, Monitoring and Forensic DNA Analysis

The general term "genetic testing" can be divided into categories: genetic screening, genetic monitoring and forensic DNA analysis (sometimes colloquially called genetic or DNA "fingerprinting"). "Genetic testing" here

will refer to these three types of tests collectively unless the context shows that a particular type of testing is intended.

(i) Genetic screening

Genetic screening presents a snapshot of one's genetic makeup at a given time. Genes, however, can mutate. Therefore a test taken long ago may not accurately identify one's genetic makeup today.

At present, screening tests available include those for the following:

- Adult polycystic kidney disease
- Fragile X syndrome¹⁵
- Sickle cell anemia¹⁶
- Duchenne muscular dystrophy
- Cystic fibrosis
- Huntington's disease
- Hemophilia
- Phenylketonuria¹⁷
- Retinoblastoma
- Thalassemia
- Tay-Sachs disease¹⁸
- Familial polyposis.¹⁹

Potential future tests may be able to detect the following:

- Hypertension
- Dyslexia
- Atherosclerosis
- Cancer

- Manic-depressive illness
- Schizophrenia
- Type 1 (insulin dependent) diabetes
- Familial Alzheimer's
- Multiple sclerosis
- Myotonic muscular dystrophy.

Future tests therefore may have the potential to identify significant genetic disorders common to millions of Canadians – the risk of developing high blood pressure and some forms of heart disease, for example. However, this list of potential future tests should be read cautiously. It grossly simplifies the complexities of genetic research and the process of developing genetic tests. For example, there are many different types of cancer – breast cancer and leukemia, among them – and many variations of those types. Each may have a complex and different genetic base. One genetic test alone will more than likely not be able to identify the genetic risk factors for all cancers.

Still, more than 800 genetically engineered "products" have been filed with the U.S. Food and Drug Administration for approval. Some will be used for therapies. Others – how many we have not been able to determine – might be used for diagnostic tests that will expand the range of future tests beyond those mentioned above.

Genetic screening has several current applications, explained more fully later. In summary, these are: during ordinary medical care; to counsel prospective parents (pre-conception), after conception (pre-implantation and pre-natal) and after birth (neonatal); before or during employment; and in research. In the future screening might be used to qualify persons for public or private sector services or benefits. And law enforcement agencies might one day consider screening to help identify the physical characteristics of an unidentified suspect at large or the psychological traits of an accused.

Screening can also identify or suggest certain genetic traits in relatives of the person tested. For example, a test that identifies a child as a carrier of the cystic fibrosis gene also tells that at least one parent carries the cystic fibrosis gene. A test that shows a child to have cystic fibrosis means that both parents carry the gene.

(ii) Genetic monitoring

Genetic monitoring is the periodic examination of individuals (such as employees or persons living near chemical dumps or nuclear facilities) to find early indications of genetic mutations. These might occur due to exposure to certain substances (toxic chemicals), effects (radiation) or viruses (for example, the human immunodeficiency virus – HIV).

Genetic monitoring can serve two purposes. First, it can identify changes in an individual's genetic makeup that require a remedy. This might include treatment or removal from the environment to prevent further mutations. Second, monitoring of a group could identify environmental hazards (in a paint shop or chemical factory, for example) that need to be reduced or eliminated.

The fundamental distinction between genetic screening and monitoring has been described as follows:

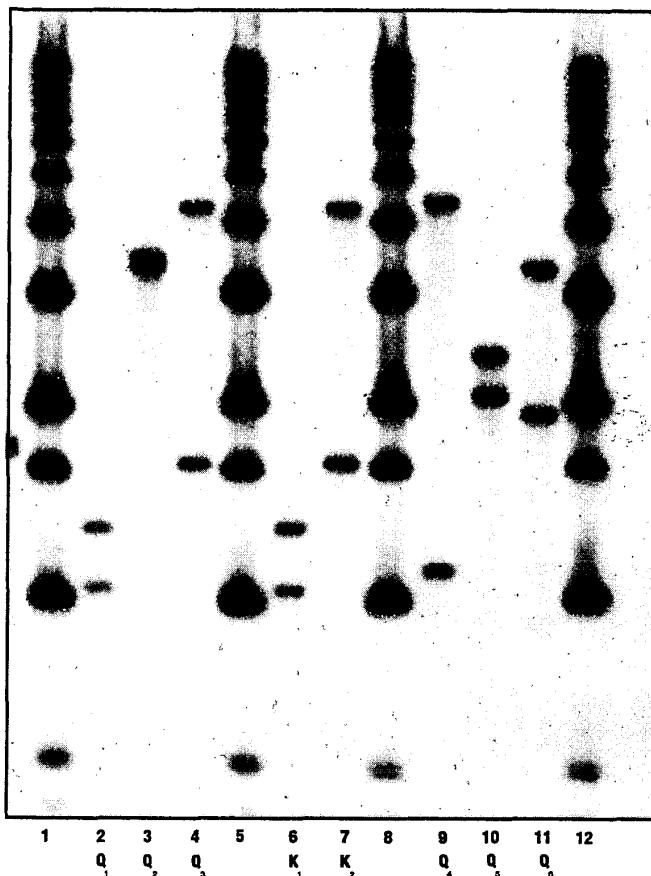
With screening, a one-time test to detect a single trait . . . is usually sufficient, while monitoring generally involves multiple tests . . . over time. Most important, genetic screening focuses on the preexisting genetic makeup [of a person]. This is distinct from genetic monitoring which focuses on hazardous . . . exposures that induce changes in the genetic material in an exposed population as a whole.²⁰

(iii) Forensic DNA analysis

Unlike monitoring or screening, forensic DNA analysis does not seek to identify genetic disorders or changes in genetic structure. In short, it is not a diagnostic tool. Instead, it looks for a match or a relationship between two

genetic samples. A specific DNA pattern can be associated with a specific individual, much like fingerprints.

This autoradiogram shows the results of an RCMP test that compares the DNA profile from two known individuals, K1 and K2, with the DNA profiles obtained from 6 blood stains of questioned origin, Q1-Q6. Lanes 2, 3, 4, 9, 10 and 11 contain DNA isolated from questioned blood stains Q1-Q6 respectively; lanes 6 and 7 contain DNA from known individuals K1 and K2, respectively. The remaining lanes contain molecular weight marker DNA.



The DNA profile obtained from K1 matches the DNA profile obtained from Q1, and

differs from that obtained from Q2, Q3, Q4, Q5, and Q6. Therefore K1 is excluded as a donor of blood stains Q2, Q3, Q4, Q5 and Q6 but may be the donor of Q1. The DNA profile obtained from K2 matches the DNA profile obtained from Q3, and is different from Q1, Q2, Q4, Q5 and Q6. Therefore K2 is excluded as a donor of blood stains Q1, Q2, Q4, Q5 and Q6, but may be the donor of Q3. Five different chromosomal regions are analyzed to determine if all DNA profiles from K1 and K2 match those obtained from Q1 and Q3, respectively. If all profiles match, an estimated frequency for a coincidental match between the profile of the questioned sample and the sample of known origin is calculated.

In criminal investigations, genetic samples found at a crime scene may be matched with a suspect's to prove or disprove the suspect's guilt. This is sometimes colloquially known as DNA "fingerprinting". Analysis may seek to establish whether persons are related by blood in paternity, estate or immigration matters. One of the most impressive applications of the technology occurred in Argentina. There, mitochondrial DNA²¹ was analyzed to match the children of "disappeared" persons in Argentina with their biological families.

The most common forensic DNA analysis technique in criminal investigations is restriction fragment length polymorphism (RFLP)²² analysis. With RFLP analysis, forensic scientists prepare an autoradiogram of RFLP patterns (the patterns look much like the product bar codes on supermarket items) from a genetic sample taken from the scene of a crime, from a victim, or from blood found on clothing. They then compare it with an autoradiogram derived from a genetic sample from the suspect. Matching patterns can link the samples more accurately than other forms of forensic identification. The comparison might show that genetic samples from the suspect matched those found at the crime scene, that samples from the suspect matched those found on the victim, or that samples from a victim matched those found on a suspect. It might also show that the samples do not match, thus exonerating the suspect.

RFLP analysis does not, however, give any diagnostic information about a person; it does not identify genetic traits. It analyses sections of "junk DNA" - DNA that at present has no diagnostic value.

As discussed above, genetic *screening*, as well as RFLP analysis, may one day have forensic applications. For example, police agencies might in the future analyze a sample from a crime scene to identify the hair and eye colour or likely race of an unknown suspect. Prosecutors or defence counsel might one day seek to place genetically-linked personality attributes before a court to support their respective cases.

(e) Current and Potential Uses of Genetic Testing

It is difficult, sometimes impossible, to determine the current extent of genetic testing in Canada. Discussions with government, labour, business and insurance organizations have yielded largely anecdotal information. Some statistics, however, are available about testing in the United States and other countries.

As the following discussion highlights, genetic testing appears rare in Canada at present. The exceptions are testing in human reproduction and, increasingly, in law enforcement. Interest in genetic technology will grow, however, as advances in the technology provide increasingly useful information.

Workplace testing

Employers (both public and private sector) may wish to identify "defective" (less productive) or potentially defective employees or applicants through genetic screening. For example, the news that an applicant may develop heart disease may make the applicant unattractive to an employer. An employer might also screen to identify applicants with above-average genetic resistance to workplace contaminants. On the other hand, prospective employees could use screening to determine if they are less or more susceptible than others to workplace contaminants, and use this information in their own decisions about accepting particular jobs.

Employers (or employees or their unions) might also wish to monitor employees for mutations due to exposure to chemicals or workplace conditions.

At present, Canadian employers appear to conduct little, if any, genetic testing. As of late 1990, the Canadian Manufacturers Association knew of no genetic testing by its members. Nor was the Canadian Labour Congress aware of any testing by employers. A 1991 report of the Science Council of Canada found no workplace programs to screen potential employees for genetic susceptibility to disease and no programs to monitor employees for mutations or diseases resulting from workplace exposures.²³

One workplace "snapshot" (although not Canadian) appears in a 1990 report of the U.S. Congress Office of Technology Assessment (OTA).²⁴ The OTA commissioned a survey in 1989 of the 500 largest U.S. industries (the "Fortune 500"), the 50 largest utilities and 33 major unions. It also covered a cross-section of large and medium-sized companies with more than 1,000 employees.²⁵ The survey examined the screening by employers of prospective employees for health status and certain behaviours, and the monitoring of workers' health. It also surveyed corporate attitudes about genetic testing. A total of 330 organizations in the Fortune 500 and 50 largest utilities categories completed and returned at least one survey questionnaire.²⁶

Genetic screening: Twelve companies reported current genetic screening of employees or job applicants for research or other unspecified reasons. Large companies were more likely than smaller companies to use genetic screening. Nine companies that screened had 10,000 or more employees, two had 5,000 to 9,999 employees and one had fewer than 5,000.²⁷

Eight additional companies reported doing genetic screening in the past 19 years. Again, these were disproportionately the larger companies surveyed.

Genetic monitoring: Only one company reported using cytogenetic monitoring (monitoring that looks for chromosome damage) in 1989. The company, in the petroleum industry, had more than 10,000 employees.²⁸ Five companies reported conducting cytogenetic monitoring in the past 19 years for research or another unspecified reason. All five had 10,000 or more employees.²⁹

Genetic Monitoring and Screening Combined: A total of 20 companies reported using cytogenetic monitoring or screening either currently or in the past 19 years. This included twelve that reported current use of genetic monitoring or screening and eight that reported monitoring or screening in the past 19 years, but not now.³⁰

The OTA report concluded that there has been little or no growth in the number of American companies doing workplace monitoring, screening or both since its previous survey in 1982. The report also examined companies'

expectations about testing. In its 1982 survey, four companies (1.1 per cent) had anticipated using monitoring or screening in the next five years, and 55 companies (15 per cent) responded that they might use the tests in the next five years.

Responses to the 1989 survey led the OTA to suggest that fewer companies anticipated future use of genetic monitoring or screening than in 1982. (This should not be taken to suggest, however, that genetic testing in employment will decline. The interest of employers in testing may well increase as genetic tests for more common genetic diseases become cheaper and more accurate.)

In October 1991 the OTA published a background paper outlining additional findings from the 1989 survey.³¹ The background paper reported that about six out of 10 corporate health officers agreed that genetic screening represented a threat to the rights of employees. Still, about six out of 10 agreed that the decision to perform genetic screening of job applicants and employees should be the employer's. The same proportion agreed that the employer should decide whether to conduct genetic monitoring.³²

The survey suggested several possible uses of genetic tests for employees or job applicants. It then asked health and personnel officers if such uses were acceptable or unacceptable. Health and personnel officers felt that it was generally acceptable to use genetic tests:³³

- to make a clinical diagnosis of a sick employee (43 per cent of health officers; 47 per cent of personnel officers);
- to establish links between genetic predisposition and workplace hazards (36 per cent of health officers; 40 per cent of personnel officers);
- to inform employees of their increased susceptibility to workplace hazards (50 per cent of health officers; 56 per cent of personnel officers);
- to exclude employees with increased susceptibility from risk situations (39 per cent of health officers; 45 per cent of personnel officers);

- to monitor chromosomal changes associated with workplace exposures (34 per cent of health officers; 39 per cent of personnel officers);
- to establish evidence of pre-employment health status for liability³⁴ purposes (41 per cent of health officers; 47 per cent of personnel officers).

Despite their general acceptance of several types of genetic testing, most personnel officers (88 per cent) said they would recommend against using genetic screening as part of pre-employment screening. Marginally more (89 per cent) would recommend against periodic genetic monitoring of employees.³⁵

Screening associated with human reproduction

This is the most common form of genetic testing. It has three elements – pre-conception, prenatal and neonatal. Couples may be screened before embarking on a pregnancy (pre-conception testing) to determine if they could produce a child with genetic disorders, such as Tay-Sachs disease or sickle-cell anemia.

Prenatal screening looks for genetic disorders in a fetus and guides decisions about possible medical treatment or abortion. Amniocentesis and chorionic villus sampling are commonly used to look for the expression of genetic defects in fetuses.

Screening of newborns (neonatal screening) identifies some treatable and untreatable genetic disorders. All provinces and territories screen newborns for phenylketonuria and hypothyroidism.³⁶ Some provinces also provide testing services for additional genetic disorders. In all cases, parents may refuse to have the tests done.³⁷

Screening as part of basic medical care

This will become increasingly common as scientific advances continue to identify and locate the genes that cause or contribute to specific diseases. Genetic screening promises to revolutionize medicine by permitting physicians to predict genetic disease (predictive testing) before the onset of symptoms.

Through early treatment and counselling, physicians may then perhaps cure or minimize the impact of the disease.

One well-known example is testing for the presence of the marker associated with the gene³⁸ that causes the fatal Huntington's disease. This can determine if a person with no symptoms will develop the disease or confirm the disease after symptoms appear.

Genetic screening to determine the right of access to services or benefits

Governments may one day wish to test persons to see if they are genetically suited to have access to certain services (advanced schooling, immigration or adoption, for example) or benefits (disability payments). Private sector service providers (insurance companies, credit granting institutions) may wish to test to determine if a potential client might impose an undue financial burden because of a genetic disorder or related disease.

Although genetic screening to determine the right of access to services is not yet commonplace, non-genetic forms of testing already occur. For example, applicants for disability pensions must prove their disability, sometimes through medical testing. Applicants for immigration must show that they are suitably healthy.

Genetic testing could be used in two ways. It could be a substitute for current tests or it could look for a whole new set of traits that previously would not have affected eligibility for a service.

The Canadian insurance industry apparently does not require insurance applicants to undergo genetic testing at present. However, the industry considers it appropriate that persons aware of genetic abnormalities which may affect their insurability disclose this when applying for insurance.

The industry is following developments in genetics but generally considers genetic testing too intrusive for insurance assessments. (It might be argued, however, that insurance companies already do a crude form of genetic

"screening" by asking insurance applicants to provide a family health history. If the family has a history of heart disease, the insurance company might surmise that the applicant has inherited a genetic risk of heart disease.)

However, the 1991 OTA background paper discussed above suggests that the factor most likely to increase the use of genetic monitoring or screening in the U.S. workplace is demonstrations that it can identify health insurance risks.³⁹ Thus, at least in the United States, where health insurance is primarily a private sector concern, genetic testing to qualify for insurance might one day become widespread.

Forensic DNA analysis in criminal investigations

Forensic analysis identifies victims and connects suspects to crimes. In about one-third of the cases in which it is used in the United States, it exonerates suspects by showing that their genetic samples do not match samples taken from a crime scene.⁴⁰

Forensic DNA analysis, sometimes colloquially called "DNA fingerprinting", is starting to replace more traditional means of analyzing biological trace elements from crimes (techniques such as serology, etc.) because of its greater potential accuracy.

As of late 1990, the RCMP Forensic Laboratory in Ottawa was the only Canadian laboratory doing forensic DNA analysis. Since then a police laboratory in Montreal and the Ontario Centre for Forensic Sciences have begun testing as well. Between mid-1989 and July, 1991, the RCMP received about 80 requests for forensic DNA typing. It completed its analysis and reported on 44 cases.

To assess the value of DNA typing, analysts need to know the frequency of certain RFLPs in the general population. Accordingly, the RCMP maintains a non-nominal genetic database (a database that contains no personal identifiers). The database, based on blood samples provided by hospitals and Red Cross blood donor clinics, is grouped according to characteristics such as race.

Individuals cannot be identified through this database, although the organization providing the samples might identify the race of the persons from whom blood samples are taken. For example, the Red Cross might tell the RCMP that the samples were from a blood donor clinic attended by native Indians or Caucasians. The database contains information (which, to stress again, cannot be linked to a given person) on about 900 Caucasians, 300 native Indians and a smaller number of persons of Asian origin. Blood samples from other racial groups have also been obtained, but these have not yet been included in the database.

The RCMP is considering developing genetic databases on convicted criminals by obtaining their blood samples. This project, however, remains a concept only. The RCMP anticipates that Uniform Law Conference of Canada will eventually examine the issue.

In the United States, forensic DNA analysis is increasingly popular. The Office of Technology Assessment estimates that it had been used in over 2,000 law enforcement investigations and that it had been admitted into evidence in at least 185 cases in 38 states and in the U.S. military as of January 1, 1990. The analysis had been used for criminal investigations and proceedings in at least 45 states as of the same date.⁴¹ As of July 1991, forensic DNA analysis had been used in at least 417 hearings and trials in 49 states.⁴²

Genetic databases on convicted criminals are also becoming more common in the United States. These databases are used to store genetic information about identified individuals who have been convicted of violent crimes. In some cases, the actual genetic sample is retained; this would permit further testing as genetic technology becomes further refined.

In January, 1989, for example, the Attorney General of California announced that DNA typing was ready to be introduced in California. Blood and semen samples were being taken from persons convicted of violent sex crimes. The samples were frozen for future DNA genetic code testing. As of January, 1989, the California Penal Code expanded the requirements under which felony sex offenders must provide blood and saliva samples for forensic DNA analysis. In April 1989, the Attorney General called for legislation to make

California the first state to establish a computerized genetic database of everyone convicted of a violent crime. The information would be made available to police departments, as is done with conventional fingerprints.⁴³ As of January 1990, at least 10 other states had enacted laws to require some level of DNA typing of offenders convicted of violent crimes.⁴⁴

Other American jurisdictions and organizations (including the FBI) are contemplating the collection of DNA samples from unknown suspects and convicted felons.⁴⁵ The FBI is currently doing a pilot study for a DNA index. The index would have two working files:

- a genetic database of unknown subjects (suspects); DNA taken from a crime victim or crime scene would be analyzed; the test results would be filed in the form of a number. Neither the DNA sample nor the banding pattern formed by forensic DNA analysis would be placed on file;
- a genetic database of convicted offenders; blood samples would be collected from convicted sex offenders.

At present, however, the FBI has no DNA index. A working file may be set up by late 1992.

An Office of Technology Assessment survey of 40 countries in January, 1989 found that at least 15 had implemented or were exploring forensic applications of DNA tests. Most expected to perform DNA typing of forensic samples by late 1989 or by 1990.⁴⁶

Genetic screening (as opposed to RFLP analysis) might one day be useful in criminal investigations if it becomes possible to identify physical characteristics of an unknown suspect by testing a genetic sample left at a crime scene. Screening could arguably also prove useful if a reliable link were one day established between a given genetic trait and the propensity to commit crime.⁴⁷ Large scale screening could identify those with an undesirable genetic trait that may lead to violence. Those with the trait could then be singled out for special treatment, possibly including observation and

detention. The scenarios described in this paragraph, however, remain conjectural.

For forensic programs – both for RFLP analysis to link or exonerate criminal suspects and, in future, screening for physical or psychological traits – governments could collect genetic samples from selected groups in society or, indeed, from the whole of society. Taking samples from an entire population would be similar to fingerprinting an entire population, but would generate far more accurate information. Such an extensive use of forensic DNA analysis may seem far-fetched, but in fact a proposed program to acquire a DNA database on the entire male population of the United Kingdom was supported by a committee of the British House of Commons in 1990. The Commissioner for the Metropolitan Police has also put forward for public debate the idea of a "comprehensive index" of DNA profiles.⁴⁸

Forensic analysis in non-criminal situations may involve determining the identity of human remains after an accident, establishing paternity, assisting in settling wills and estates and identifying baby swapping.

Testing for research

Testing may identify genetic disorders in populations through screening programs. Research testing may also involve monitoring populations for genetic changes caused by radiation, chemicals or viruses. Testing will also help identify where health care funds will be required and where further research is needed. At its extreme, screening in research might become a precursor to eugenics.

Conclusion

The extent of genetic testing in human reproduction and in law enforcement in Canada is reasonably well known. How often it now occurs elsewhere in the public and private sectors and, more important, how often it may occur in the future, should be more closely examined. For example, are employers contemplating genetic testing as a future employment screening tool? How many genetic databases have been established by research organizations?⁴⁹

In short, who is collecting and using (and for what purposes) genetic information about identifiable persons, and to whom is the information being disclosed?

Recommendation 1

The Government of Canada should study the following:

- the extent to which government institutions and private sector organizations have collected, retained and disposed of personal genetic information, including genetic samples, and their anticipated activities in this area;
- the purposes of the collections;
- who had, has or will have access to the information or samples;
- the uses, past, present and future of the information or samples;
- the privacy protections provided or to be provided for the information or samples; and
- the situations in which the information has been, is being or will be disclosed to other persons or organizations.

ENDNOTES

(1) For more detailed information, see: Science Council of Canada, *Report 42: Genetics in Health Care* (1991) at 17-33, 99-105; Medical Research Council of Canada, *Guidelines for Research on Somatic Cell Gene Therapy in Humans* (1990) at 11-23; B. Knoppers, *Human Dignity and Genetic Heritage: A Study Paper* prepared for the Law Reform Commission of Canada (1991) at 5-14; U.S. Congress, Office of Technology Assessment, *Genetic Monitoring and Screening in the Workplace*, OTA-BA-455 (Washington, D.C.: U.S. Government Printing Office, October 1990) at 191 ff.. A readable primer on genetics is D. Suzuki and P. Knudtson, *Genethics: The Ethics of Engineering Life* (Stoddart, 1988).

(2) Science Council of Canada, *supra* note 1 at 19.

(3) *Ibid.*

(4) Genetic research is constantly identifying new single-gene disorders. Accordingly, estimates of the exact number will vary from source to source. A recent Law Reform Commission study paper speaks of more than 4,000 Mendelian traits, of which about 3,000 may cause disease or dysfunction: B. Knoppers, *supra* note 1 at 8.

(5) Science Council of Canada, *supra* note 1 at 21-23.

(6) *Ibid.*

(7) With cystic fibrosis, abnormally thick secretions cause obstructions in the ducts of organs.

(8) Recessive genes, such as those that cause cystic fibrosis, "express" themselves (that is, they give rise to the trait or disorder they control) only if the child inherits two recessive genes controlling the disorder or trait – one from each parent.

(9) Science Council of Canada, *supra* note 1 at 18-20; Medical Research Council of Canada, *supra* note 1 at 17-18 (the Medical Research Council refers to there being over 4,000 single gene disorders).

(10) *Supra* note 1 at 18.

(11) *Ibid.*

(12) *Ibid.*

(13) Duchenne muscular dystrophy is a progressive deterioration of muscles beginning in infancy and leading to death in a person's twenties or thirties.

(14) Huntington's disease (Huntington's chorea) results in the slow degeneration of specific brain tissues. It usually strikes between the ages of 35 and 50, and is fatal.

(15) A form of mental retardation.

(16) Sickle cell anemia has a high incidence among American blacks. It is a life-threatening autosomal recessive disease (that is, to acquire the disease, the child must inherit the recessive sickle cell gene from each parent). Carriers of the recessive gene are said to have sickle cell trait, but not the disease itself. Whether having sickle cell trait alone has adverse health consequences is still unresolved: U.S. Congress, Office of Technology Assessment, *supra* note 1 at 85.

- (17) A person with phenylketonuria lacks a necessary enzyme. Retardation and seizures commonly result. These can be avoided by placing the person on a special diet early in life.
- (18) Tay-Sachs disease results in retardation, paralysis, dementia and blindness, followed by death, usually by the end of the third year of life. The gene causing the disorder has its highest frequency among Ashkenazic Jews: B. Knoppers, *supra* note 1 at 82.
- (19) One of the most common inherited cancer susceptibilities in the United States, affecting about one in 5,000, and carrying a high risk of colon cancer.
- (20) Office of Technology Assessment, *supra* note 1 at 5.
- (21) Mitochondrial DNA is inherited only from the mother. This is unlike the inheritance pattern with chromosomes, where a person inherits half the chromosomes from the father and half from the mother. A child's version of one region of mitochondrial DNA almost never varies from that of his or her mother, brothers, sisters, grandmother, maternal aunts and uncles and other genetic relatives on the maternal side. Source: U.S. Congress, Office of Technology Assessment, *Genetic Witness: Forensic Uses of DNA Tests*, OTA-BA-438 (Washington, D.C.: U.S. Government Printing Office, July 1990) at 51.
- (22) *Ibid.* at 44-46. RFLP analysis includes the following steps:
- isolating DNA from the specimen to be examined;
 - cutting the DNA into discrete pieces with a restriction enzyme;
 - separating the different sized DNA pieces using a process called gel electrophoresis;
 - transferring the DNA from a gel to a nylon membrane; applying, or hybridizing, a DNA probe to the membrane; and
 - visualizing the location of the probe's hybridization, and hence the DNA pattern for radioactive probes, usually by exposing the membrane to x-ray film, a process called autoradiography.
- (23) Science Council of Canada, *supra* note 1 at 103.
- (24) *Supra* note 1.
- (25) *Ibid.* at 197.
- (26) *Ibid.* at 199. The response rate to the 1989 survey was 62.4 per cent.
- (27) *Ibid.* at 174.
- (28) *Ibid.* at 173-74.
- (29) *Ibid.*.
- (30) *Ibid.* at 175.
- (31) U.S. Congress, Office of Technology Assessment, *Medical Monitoring and Screening in the Workplace: Results of a Survey – Background Paper*, OTA-BP-BA-67 (Washington, DC: U.S. Government Printing Office, October 1991).
- (32) *Ibid.* at 37.
- (33) *Ibid.* at 36.
- (34) This may serve to protect an employer against claims by a worker, for example, that exposure to workplace chemicals damaged his or her health.

- (35) *Supra* note 31 at 42-43.
- (36) Hypothyroidism is caused by inadequate production of the thyroid hormone. Persons who are not identified and treated promptly may suffer mental retardation and growth failure, deafness and neurologic abnormalities, among other consequences.
- (37) Science Council of Canada, *supra* note 1 at 104.
- (38) Huntington's disease is caused by an autosomal dominant gene. Autosomal dominant genes are dominant genes located on any of the 22 pairs of non-sex chromosomes. Each somatic (body) cell has two copies (alleles) of the gene at any specific locus. Dominant alleles (sometimes called dominant traits) express themselves regardless of the companion allele. That is, a dominant allele will express itself whether its companion is dominant or recessive.
- (39) U.S. Congress, Office of Technology Assessment, *supra* note 31 at 45.
- (40) Conversation with an official from the U.S. Federal Bureau of Investigation, September 1991.
- (41) U.S. Congress, Office of Technology Assessment, *supra* note 21 at 14.
- (42) J.T. Sylvester and J.H. Stafford, "Judicial Acceptance of DNA Profiling", *FBI Law Enforcement Bulletin*, July 1991 at 27.
- (43) A. Adema, "DNA Fingerprinting Evidence: The Road to Admissibility in California", 26 *San Diego Law Review* (1989) 377 at 393.
- (44) U.S. Congress, Office of Technology Assessment, *supra* note 21 at 122-23. For example: in Arizona, a 1989 law requires DNA testing of convicted sex offenders; in Colorado, all sexual assault offenders released on parole will be subject to genetic testing; a 1989 Florida law calls for a computer bank for genetic information on convicted sexual offenders; a 1989 Iowa law permits DNA testing in the criminal law context. The attorney general's office will issue rules about which crimes are covered and who will be required to provide DNA samples.
- (45) Janet C. Hoeffel, "*The Dark Side of DNA Profiling: Unreliable Scientific Evidence Meets the Criminal Defendant*", 42 *Stanford Law Review* 465 at 535, n. 404.
- (46) U.S. Congress, Office of Technology Assessment, *supra* note 21 at 24.
- (47) See the discussion of the controversial theory that an XYY chromosomal structure may predispose males to violent or antisocial behaviour in D. Suzuki and P. Knudson, *Genethics: The Ethics of Engineering Life*, *supra* note 1 at 141-59.
- (48) House of Commons, Home Affairs Committee, *First Report: Annual Report of the Data Protection Registrar* (12 December 1990, London: HMSO) at xi; see also *Seventh Report of the Data Protection Registrar* June 1991 (London: HMSO) at 5-6.
- (49) For example, in the United States, several genetic databases have been established, primarily for medical or scientific research: Office of Technology Assessment, *supra* note 21 at 120-24. We are not certain about the extent to which these databases contain personal genetic information, although we have been advised informally that none do.

Part II

Privacy Principles For Genetic Testing

A socially conscientious system would be a national registry; blood and skin tests done routinely at birth and fed into a computer-gene scanner would pick up all [genetic] anomalies, and they would be printed out on data cards and filed; then when marriage licenses are applied for, the cards would be read in comparison machines to find incompatibilities and homozygous conditions.

The objection is, predictably, that it would "violate" a "right" - the right to privacy. It is even said, in a brazen attack on reason itself, that we have a "right to not know." Which is more important, the alleged "privacy" or the good of the couple as well as of their progeny and society? (The couple could unite anyway, of course, but on the condition . . . that sterilization is done for one or both of them. And they could even have children by medical and donor assistance, bypassing their own faulty fertility.)

Joseph Fletcher, *The Ethics of Genetic Control: Ending Reproductive Roulette* (1974) at 182-83.

(a) Introduction

Part I identified the specific uses of genetic testing: testing in employment, testing to determine access to services or benefits, testing in reproduction, testing as part of normal medical care, forensic testing and testing in research. This part discusses the broad privacy considerations arising from these applications.

The arguments set out in this part apply equally to the government and private sectors. Both are capable of violating the genetic privacy of Canadians.

(b) The Right to a Reasonable Expectation of Genetic Privacy

One issue that runs across every testing application is the extent of a person's right to a reasonable expectation of genetic privacy. This issue has two elements – the right not to have others know one's possible genetic "destiny", and the right "not to know" about oneself.

The ethical principle of autonomy suggests that one should have meaningful physical and psychological control over oneself.¹ Any form of mandatory genetic testing and the reporting of results to oneself or to others – even for purposes that may initially seem quite justifiable – violates that principle and threatens the right to privacy. The loss of autonomy and privacy can be the genesis of a life-long psychological prison – the prison of one's perceived genetic "programming".

The right not to have others know: One's reasonable expectation of privacy can be violated by having others learn about one's genetic makeup. This loss of privacy can be debilitating. How others perceive us has a significant impact on our lives.

Whether to yield to testing that will disclose genetic traits should be a decision for the person alone – a fully informed decision taken freely. The state, an employer, a provider of services or a medical professional should have no right to inspect the genetic information in the individual human genome without consent (the one exception – because it yields no "diagnostic" information – being strictly controlled DNA analysis in criminal investigations²). This is so even if there is a perceived good for society or for the person flowing from the testing.

The right not to know about oneself: Persons should have a right of privacy that protects them from the information that their own bodies can yield. They should not be forced through mandatory genetic testing to learn about traits or disorders, even if this may alert them to the need for treatment. They should not be forced to learn about conditions that may one day cause them discrimination, suffering or premature death, or even that may cause harm to their offspring. Society does not force knowledge on persons in similar

circumstances. There is no obligation to be tested for cancer, heart disease or high blood pressure. Why, then, should there be any obligation to learn one's possible genetic destiny?

Recommendation 2

Persons should have a reasonable expectation of genetic privacy. There should be no mandatory genetic testing at the behest of the state (except in strictly limited circumstances in criminal investigations) or the private sector.

Governments and the private sector should not oblige persons to learn their genetic traits or disorders.

(c) Specific Testing Applications

(i) Employment

Genetic testing in employment may take either of two forms – screening or monitoring. Both can reveal intimate details about a person's genetic makeup to an employer or prospective employer. Even if a person consents to the testing, we recognize the limitations of such consents in the employment setting. Persons looking for employment, continued employment or promotion have little real power to resist an employer's request to take a "voluntary" test.

Workplace genetic screening: Since the collection of genetic information by employers could result in discrimination against employees or applicants, there is a heavy burden on employers to justify the collection. During this study we have found no employment situation that warrants the compulsory or voluntary collection of personal genetic information for the benefit of employers. Without compelling arguments to the contrary, genetic screening for the benefit of the employer is inappropriate. Screening might, of course, benefit employees or applicants. However, they and not the employer should have the absolute right to control the genetic sample and the uses and disclosures of any personal information derived from it.

Recommendation 3

Employers should in general be prohibited from collecting personal genetic information about job applicants or employees through mandatory or voluntary genetic screening. However, employers should be permitted to screen employees or applicants who volunteer for the screening if the employees or applicants retain absolute control over the genetic samples and any related personal information.

Workplace genetic monitoring: Mandatory genetic monitoring is as objectionable as mandatory screening. Like screening, it can provide reams of highly sensitive personal genetic information. We therefore recommend against it. We would not, however, object to voluntary participation in genetic monitoring programs. Genetic monitoring can help to identify workplace hazards and ultimately prevent serious harm to persons and their future offspring. However, the genetic samples and personal information generated by the monitoring should be collected, used and disclosed only as the employee permits.

Recommendation 4

Employers should in general be prohibited from collecting personal genetic information about employees through mandatory or voluntary genetic monitoring. However, employers should be permitted to genetically monitor employees who volunteer for monitoring if the employees retain absolute control over the genetic samples and any related personal information.

(ii) Access to services or benefits

What role, if any, should genetic testing play in determining eligibility for government or private sector services or benefits?

The federal government provides direct services or benefits to millions of Canadians. Some (police and military protection, for example) are granted automatically. To obtain others, however, persons may need to meet certain

conditions, such as being unemployed or having a disability. Private sector bodies sometimes provide services only to those who meet certain conditions: Disability insurers prefer to insure persons in good health; credit granting institutions will give credit to persons who are able to meet their financial obligations.

Similarly, persons can be denied access to services or benefits because of a disability or medical condition – applicants for immigration, for example.

Genetic testing may provide more extensive information about persons applying for services or benefits than their providers have been able to obtain to date. Should the providers use the deep-probing abilities of genetic testing to impose more stringent conditions on access to services?

For example, should government add genetic disorders that it could not identify through traditional medical screening to the list of medical conditions that would prevent applicants from immigrating to Canada? Should it require genetic evidence of a superior intellectual potential (as genetics may one day be able to identify) as a condition of giving a grant for advanced education or as a condition of immigration? Should insurers be permitted to genetically screen applicants for pre-symptomatic genetic disorders?

The temptation will surely grow, particularly among cost- and profit-conscious service providers, to use genetic technology to introduce additional hurdles before giving services or benefits. As test costs fall, their accuracy increases, and the amount of information they can reveal grows, the temptation to test will grow still further. Insurance companies in the United States are already exploring the use of genetic screening to determine eligibility for services.³ One day, credit-granting institutions (banks, for example) may want to do the same. Government institutions might be similarly tempted.

This office has consistently urged restraint in collecting personal medical information. Where, however, a case for collection can be made, genetic testing (but *only* with the consent of the subject) may be an appropriate means of acquiring the information. After all, if it is now a condition of being permitted to immigrate that a person not have a given health condition, it

should not matter if the test for the condition is genetic or non-genetic.⁴ Isolating this information by a genetic test need be no more intrusive than isolating the information by a non-genetic form of medical examination, particularly if strict controls are applied to prevent non-essential genetic information from being revealed.

Our acceptance of this type of testing, however, is subject to strict conditions. First, a person should have the option to be tested by any means that will provide reliable information, including genetic testing. There should be no obligation to be genetically tested. The person might choose not to be tested at all, although this could result in loss of the benefit or service.

Second, the type of information obtained from the genetic testing should be strictly controlled. We strongly caution public and private sector institutions against acquiring more personal information through genetic tests than they would have acquired using other methods. For example, the government should not start eliminating potential immigrants because of a susceptibility to genetically-linked cancers which are not now grounds for exclusion. Even if the law permits the collection of additional personal information through genetic screening, we recommend that no further collection occur without a thorough review of the ethical and human rights implications.⁵

Third, only the information needed to tell whether the person meets the required standard should be collected.

Recommendation 5

- 1. As a general principle, there should be no denial of services or benefits to a person who refuses to undergo genetic testing to obtain a service or benefit. The person should be permitted to provide justifiably required information through testing other than genetic testing if he or she wishes. The person should also have the option of refusing to be tested at all, although this may result in the loss of the service or benefit.**
- 2. The type of information gathered by service or benefit providers through genetic testing should be strictly controlled. Even if the provider can legally**

collect this information, no new types of information should be collected through genetic testing without a thorough review of the ethics and human rights implications of the additional collection.

3. Service or benefit providers should collect and use only the genetic information needed to tell whether the person meets the required standard.

(iii) Human reproduction

Genetic testing in the reproductive sphere can take any of several forms:

- pre-conception and pre-implantation: potential parents, ova, or a fertilized ovum, are screened to determine if a genetically "defective" child may result;
- pre-natal: the fetus or mother is tested to determine if the fetus has any genetic disorders;
- neonatal: newborns are screened for genetic disorders.

The western world has had an unhappy history of abuses associated with the quest for eugenically "healthy" or "pure" societies. These range from the sterilization of the "mentally deficient" by the thousands in many countries to the sterilization (or, often, murder) of other socially unpopular groups by the Nazis.

Canada was an active participant in the eugenics movement. In 1928, Alberta passed a *Sexual Sterilization Act*. The original Act required the consent of institutionalized mentally ill persons to be sterilized. In 1937, the consent requirement was removed. Between 1928 and 1971, 2,822 cases were approved for sterilization in Alberta.⁶

In 1933, British Columbia passed its *Sexual Sterilization Act*, which permitted sterilizing persons "likely to beget or bear" children "who would have a tendency to serious mental disease or mental deficiency". The consent of the person was required if he or she was capable of consenting. If not, spouses, guardians or the Provincial Secretary could consent. No records remain on

how many persons were sterilized under the Act. The Science Council of Canada estimates that the number was in the order of a few hundred.⁷

The B.C. and Alberta legislation remained in force until 1972.

Ontario never passed sterilization legislation, although a bill was introduced in 1912, and two Ontario royal commissions – in 1929 and 1938 – recommended a sterilization policy. Despite the lack of legislation, sterilizations of the mentally retarded were performed in Ontario.⁸

A 1991 Science Council of Canada report states that sterilizations in Canada were clearly performed more frequently on specific groups. For example, during the last few years of the Alberta legislation's existence, over 25 per cent of sterilizations were carried out on Indians and Métis. These groups comprised only 2.5 per cent of the Alberta population. Furthermore, the Science Council concluded, "There is no evidence that sterilization had an effect on the overall frequency of mental 'deficiency.'"⁹

Eugenics movements in the United States have been equally troubling. At one time, 24 states had sterilization laws.¹⁰ Between 1905 and 1973, almost 100,000 "feeble-minded" women were involuntarily sterilized to prevent further defective children.¹¹ A 1937 poll in *Fortune* magazine found 63% of Americans in favour of sterilizing habitual criminals.

Even in the 1980's and 1990's, governmental pressures for eugenic improvement are evident in the United States. A recent *Los Angeles Times* poll asked Californians if they thought female drug users of child-bearing age should be forced to have devices implanted in their bodies to stop them having children. Sixty-one per cent approved.¹² *The Economist* reports that this debate over compulsory sterilization of "offenders and misfits" arose because of the development of a long-lasting contraceptive capsule. The capsule can be embedded in a woman's arm and slowly releases a contraceptive substance for up to five years.¹³

The then-candidate for governor of Louisiana, David Duke, only narrowly failed to persuade the state to offer cash to welfare women to take this

contraceptive capsule. Critics argued that this was a form of racial eugenics, since most welfare women were black.¹⁴

Singapore offers another example of a modern nation tinkering with eugenics. There, like elsewhere, educated women of higher socio-economic classes tend to marry less often and have fewer children than other women. The government of Singapore has used various devices to encourage these educated women to have children.¹⁵

On a more subtle level, governments can practice eugenics by funding certain health services. For example, a government that, through its health insurance, funds pre-conception or pre-natal screening for certain genetic disorders and not others, may be seen as indirectly supporting eugenics by promoting discriminatory decisions by pregnant women and prospective parents.¹⁶

Any discussion of possible government acquisition of personal genetic information related to reproductive technology is deeply tinged with memories of past eugenic abuses and the prospect for continuing abuses. After all, significant economic costs are associated with a society caring for genetically "defective" persons. The pressure to reduce health care costs is growing. What better way than to reduce the number of economically burdensome persons through careful eugenics? And does it not make sense to encourage or force social "misfits" – as the government of the day perceives them – not to bear or beget others of a similar ilk?

On the surface, these arguments have a simple logic. But it chills one to think that the same reasoning – efficiency, purity, economy – has been behind many eugenics movements in history.

There is little doubt that prospective parents now practice "private" eugenics through prenatal and, less commonly, pre-conception and pre-implantation screening.¹⁷ A fetus may be screened for genetic disorders (prenatal screening) through amniocentesis or chorionic villus sampling; if a serious disorder is found, the parents may decide to abort the fetus.¹⁸ In some cultures, even discovering a basic genetic characteristic like the sex of the child may lead to abortion.

Prospective parents sometimes have themselves tested before they conceive, usually for a specific disease prevalent in their family or ethnic group, to see if they risk producing seriously defective children. Pre-conception carrier screening for Tay-Sachs disease, cystic fibrosis and (in the United States and Mediterranean regions) sickle-cell anemia and thalassemia are better known examples. Another technique is to screen unfertilized ova to see if they carry desirable or undesirable genetic characteristics. Once a suitable ovum is found, it can be fertilized and implanted in the mother.¹⁹

Benefits can flow to prospective parents who use genetic testing. Serious ethical and moral concerns also arise. But government is largely out of the way. It does not become directly involved in pressing for screening with eugenic implications.²⁰ Should it?

First, should governments one day oblige prospective parents to be tested to see if the union of their genes might produce a child with a serious genetic disorder? Should prenatal testing be mandatory?

What could governments do with personal genetic information relating to the reproductive process? One can foresee several possibilities, few of them attractive to a democratic society:

- relatively neutral advice to parents about the risk of giving birth to a genetically defective child, given their possible genetic makeup or the genetic disorders identified in a fetus, (this is the current practice in pre-natal diagnostic clinics);
- advice to parents not to have children, or advice to abort a fetus with a serious (as defined, perhaps arbitrarily, by the authorities of the day) genetic disorder;
- positive financial incentives to abort or not to conceive;
- imposition of financial responsibility for the additional health care and other costs arising from giving birth to a genetically defective child; or
- compulsion not to have children, or compulsion to abort.

Governments may have a legitimate role to play in supporting research that will help resolve the mysteries of genetic disorders and perhaps lead to therapies. But they should generally not become involved in acquiring personal genetic information about the reproductive process.²¹ This rule should apply to personal genetic information about parents, embryos, fetuses and newborns.

There may be limited exceptions to the rule. The federal government, through Health and Welfare Canada, gives medical care to some Canadians and their families. Genetic test results may be part of a person's health record held in Health and Welfare files. But this information should be used only to inform a person's own decisions about reproduction. It should not become part of a broad government-sponsored assembly of personal genetic information for regulating reproduction or for any other purpose.

Recommendation 6

Government institutions should generally not collect, use or disclose personal genetic information relating to the reproductive process, whether through mandatory or voluntary genetic screening.

Recommendation 7

Personal genetic information relating to reproduction that is collected by government institutions providing medical care should be used only to inform a person's own decisions about reproduction. This information should not be used for any other purpose.

Testing for treatable genetic disorders in fetuses or screening newborns:

Some argue that it is appropriate to identify treatable genetic disorders through mandatory screening of fetuses or newborns. Others suggest that parents will almost always act in the interests of their offspring, and that, with proper education, mothers will volunteer themselves for prenatal testing or parents will volunteer their newborns for screening. While this issue requires further consideration, we suggest the following principles:

- that there be no mandatory pre-natal screening, as this would involve coercing the mother through mandatory physical inspection of, or intrusion into, the mother's body;
- that the extent of coverage (that is, the percentage of newborns tested) of mandatory versus voluntary screening programs for treatable genetic disorders in newborns should be assessed; if voluntary programs achieve sufficiently broad coverage to achieve the objectives of the program, they should always be preferred to mandatory programs;
- that if mandatory screening of newborns is to be introduced, it be done only for serious genetic disorders that can and must be treated early in life (for example, PKU); the child, on reaching the age of responsible thought, should decide whether to be screened for late onset genetic diseases;²²
- that the information derived from mandatory screening should be available only to the parents (if they desire), the child (when the child reaches the age of responsible thought, but only if the child wants to know) and, if the parents agree, an appropriate health care worker. Government should not retain any personal information related to the screening; and
- that the screening should be limited to acquiring information necessary to identify serious genetic disorder(s); it should not be used to identify other genetic traits.

Fetal sex selection: An issue of growing concern is the use of genetic testing to identify the sex of the fetus and the decisions that may flow from that knowledge. This is not an issue of government involvement in acquiring personal genetic information. Instead, it involves ethics, public policy and the future privacy rights, if any, of the fetus. To what extent should genetics be employed to generate information for decisions that are repugnant to some, like abortion, as a means of sex selection?

Fetal sex is being used in some cultural or ethnic groups to decide whether to abort a fetus. The propriety of this has come under question in several fora.

One working group of the Council of International Organizations of the Medical Sciences (CIOMS) had this to say:

The working group considers it a misuse of new genetic technologies to use chorionic villus sampling to make a diagnosis of sex in the eighth or tenth week of pregnancy. Since sex is no disease, the use of fetal diagnosis only for knowledge of fetal sex is to be discouraged, at least in European and American cultures.²³

The issue of genetic testing for fetal sex selection requires further analysis. We understand that the Royal Commission on New Reproductive Technologies is examining issues surrounding sex selection.

(iv) Normal medical care

Genetic testing can play two important roles in ordinary medical care, apart from its uses in reproduction:

1. improving accuracy in diagnosing diseases caused by genetic disorders, where disease symptoms are already present; and
2. improving the prediction of diseases that have a later onset, such as Huntington's disease.

Some federal institutions (Health and Welfare Canada, for example) provide ongoing medical care for certain government employees and dependants. Medical information about these people will be stored in government files. Personal genetic information could be among that information.

Mandatory collection by government institutions of personal genetic information as part of ongoing medical care would violate the *Privacy Act*.²⁴ Mandatory collection by government physicians and private sector physicians would also likely violate medical ethics and the common law on consent to treatment. Accordingly, neither government physicians nor private sector physicians should collect personal genetic information through mandatory

genetic screening (the one possible exception being the screening of newborns for treatable disorders, discussed above).

The collection of personal genetic information through voluntary screening is another matter. It is appropriate for a government institution involved in ongoing medical care to collect information obtained through voluntary testing. Similarly, private sector physicians can collect personal genetic information with the consent of their patients. In both situations, however, the information should not be used or disclosed for purposes other than the medical care of the person involved (but see the discussion of the possible exception for information that could help genetic relatives, immediately below).

Recommendation 8

Personal genetic information collected by government institutions or private sector physicians providing ordinary medical care should be used only to inform a person's own decisions about medical care. This information must not be used for any other purpose.

Disclosure to genetic relatives: Genetic information about one person may identify or suggest a genetic disorder or trait in a relative. If the relative were at risk of passing this disorder on to a child or if the knowledge would permit the relative to seek treatment, the information could be particularly helpful.

This poses a dilemma in the physician-patient relationship. Patient confidences are not to be disclosed by physicians without the patient's consent. What can a physician do if the patient does not want the information disclosed to a relative?

This issue has given rise to considerable debate. One author states:

[In the past], [o]nly with the person's consent was the doctor allowed to act on [information about the person]. Genetic medicine, however, is greatly expanding . . . views [of privacy and bodily integrity] into a wider concept of corporate ownership of

familial and ethnic autonomy. It now seems that the totality of a person's physical existence exceeds the limits of a single person's body. Some already say that genetic information is the common property of the family as a 'corporate personality'. Are we then entering a new era of medicine . . . an era where information is governed not only by rules of individual confidentiality but also by the duties of common solidarity?

In developing new rules it will be necessary to fully weigh the dangers and pitfalls of structural breaches of confidentiality. Four such pitfalls are: (1) the mere biological link with relatives may be an insufficient basis for the intrusion into the psychosocial components of privacy; (2) it remains difficult to draw the line between medical information which is relevant to genetic counselling and information which is not relevant; (3) as ever more diseases will appear to contain hereditary components the breach of confidentiality is in principle unlimited; (4) perhaps a policy of taking away all data control from the screened will prove to be counterproductive and scare them away from participation in family programmes. What these points clearly prove is the immediate need to further elaborate the fundamental principle of "who owns genetic information", as well as practical rights of individuals and groups to process the information.²⁵

This situation has implications for government physicians. Professional ethics and legal obligations will be involved in a decision to release a person's personal information to genetic relatives.²⁶ The *Privacy Act* may apply to allow disclosure by government institutions.²⁷ The ethical problems outlined immediately above, however, remain.

(v) Forensic uses of genetic tests

Genetic analysis is increasingly being used in law enforcement. Comparing genetic samples from a crime scene with that of a suspect may exonerate the suspect or lead to a conviction. Compiling a database of genetic information or a bank of genetic samples from convicted criminals (or others perceived by

those in power as socially deviant) might make it easier to link persons with later crimes or other anti-social behaviour.

In general, there is no specific statutory authority in Canada to collect blood or body samples in a criminal investigation. Testing for driving while impaired is one exception. The Law Reform Commission of Canada notes in a 1991 report that very few investigative procedures that use a suspect as a source of evidence are clearly regulated by statute.²⁸ It continues:

[T]here is no common law (or statutory) basis in Canada for issuing a search warrant to extract evidence from a human body by means of surgery; the taking of blood samples from a suspect without consent or statutory authority has been held to constitute an unreasonable search or seizure; and the cases are conflicting as to whether hair samples may be seized from a person in the course of a search incident to arrest. [references to footnotes omitted]²⁹

The Law Reform Commission has recommended a statutory scheme to permit the taking of hair and saliva samples, among other body samples. A peace officer would be obliged to apply for a warrant to take the samples. Of course, the suspect could consent to the taking of the sample; if it was a true consent, no warrant would be needed. It would not be possible under the Law Reform Commission's scheme to take blood samples without consent.³⁰

The application for a warrant would need to disclose the applicant's grounds for believing that the procedure would provide probative evidence of the person's involvement in the crime. Thus, genetic samples would not be taken as a matter of course. It would also need to state the grounds for believing that there is no less practicable and less intrusive means for obtaining the evidence.³¹

Note that the recommendations of the Law Reform Commission contemplate using these procedures only for specific crimes under investigation. Section 59 of the Commission's draft code of procedure, for example, requires the application for a warrant to identify the crime under investigation. Thus, it is

clear that the Commission is not recommending allowing the collection of genetic samples for "general" crime control (see the discussion of collection for general crime control below at p. 46).

Recommendation 9

In criminal investigations, suspects should be compelled to provide genetic samples only if specific statutory authority, such as proposed by the Law Reform Commission of Canada, authorizes the mandatory collection.

Collection would therefore be restricted to persons suspected of a specific crime, likely a crime involving serious violence. The Law Reform Commission would allow collection only to obtain evidence or information relating to the person's responsibility for the commission of a crime.³² It is not clear whether the Law Reform Commission would allow genetic samples to be used for purposes other than identification.

Forensic DNA analysis (RFLP analysis) is relatively new. Some argue that it is not sufficiently tested to be relied on to identify someone who committed a crime. Still, forensic DNA analysis has been used in over 400 hearings in 49 U.S. states as of July, 1991.³³ There seems little prospect that its use will decline, unless a future forensic identification technique proves superior.

DNA screening could also be used one day to supplement RFLP analysis. Screening in the future might suggest genetic traits that could be useful to investigators – the likely race or eye colour of an unknown suspect, for example. Prosecutors might one day focus on genetically linked personality traits that might predispose a person to crime or other anti-social behaviour.

It may be appropriate to use DNA screening to identify the likely physical characteristics of an unknown suspect. However, to use screening to identify likely psychological characteristics or criminal propensities would be a potentially dangerous use of genetic technology due to the possible inaccuracies of the analysis.

The use of genetic technology in criminal investigations should be restricted to suggesting or confirming the identity of the suspect or exonerating the suspect through identification evidence.³⁴ It should not be appropriate, for example, for a prosecutor to place certain genetic characteristics of a suspect before a judge or jury to suggest that the accused was somehow genetically predisposed to criminal activity.³⁵

Recommendation 10

Mandatory analysis (whether RFLP analysis or genetic screening) of a suspect's genetic sample should be limited to suggesting or confirming the identity of a suspect, or exonerating the suspect. Genetic screening should not be used to suggest psychological characteristics of the suspect.

Genetic Databases and Banks of Genetic Samples for General Crime

Control: With the growing use of forensic DNA analysis in criminal matters comes the issue of assembling DNA databases or banks of genetic samples for crime control. Genetic *databases*, containing the results of RFLP analysis, can be used today only for identification. A genetic database of an entire population would be the equivalent of fingerprinting and photographing every member of the population to make it easier to solve future (and some past) crimes.

At one extreme, forensic DNA analysis of a single criminal suspect could be used to secure a conviction or exonerate an accused. The analysis could be discarded after being kept for an appropriate time. No further record would be kept of the genetic analysis. At the other extreme, governments could create a genetic database or bank of genetic samples of an entire, largely non-criminal, population. Genetic samples found at the scene of a crime could then be matched with samples from this all-encompassing database or bank.

The position taken by the Home Affairs Committee of the British House of Commons and by the Metropolitan Police Commissioner show how real the

prospect of a national database may be. The Committee reported as follows in December, 1990:

The development of a database of DNA profiles which would supplement existing criminal records is a policy we have advocated before. We asked the [U.K. Data Protection] Registrar to comment on any particular data protection concerns he might have. His major worry was over the technical feasibility of such a database and he pointed to recent comments by statisticians that "the percentages of certainty are not quite as high as are being stated". He also opposed the establishment of a DNA database on the whole male population, a move that has been mooted by the Metropolitan Police Commissioner: "I would feel it a step too far in data protection terms simply to collect information on the whole male population on the basis that you might not prevent a crime but you might prevent a second one." *Although the creation of a DNA database on the whole male population would undoubtedly be expensive, we consider it a development that would provide considerable benefits for the police.* [Committee's emphasis]³⁶

The June 1991 report of the United Kingdom Data Protection Registrar notes that the Home Office will consider the Committee's support for the creation of a database on the whole male population. The Data Protection Registrar continues:

Establishing a database of DNA profiles calls for careful consideration of data protection requirements. Issues such as obtaining, disclosure, relevance, accuracy, retention and security of such sensitive data will all be important. These issues will arise in connection with DNA profiles held to supplement criminal records. They arise starkly if the database is one of the population at large, regardless of any specific supporting justification.³⁷

One actual example of mass screening in criminal investigations merits mention. To solve two murders, English police asked men in three towns to volunteer DNA samples. Over 97% of the men and boys requested gave samples; over 3,600 samples were taken. The suspect was caught, however, not directly by a test result, but through an act of deception which he had hoped would foil the test. He had persuaded a friend to give a sample for him for DNA analysis. The friend admitted this to co-workers, who later called police. The suspect was arrested, and confessed to both murders.³⁸ An earlier suspect who had confessed to one of the murders was exonerated by forensic DNA analysis.

However, the samples were not used for this investigation alone. Police officers later matched a DNA print from one of the volunteers to a semen sample from a previous unsolved rape. For the police, this was merely clever sleuthing. For civil libertarians, it raised the spectre of future population databases of genetic characteristics, not merely identification features, being used as yet another instrument of control in society.

We acknowledge the value of RFLP analysis in solving crimes of violence. We accept its potential utility when authorized by statute and when sufficient care is taken to ensure the accuracy of the information generated by the analysis. But we strongly oppose a government cataloguing the identifying genetic characteristics of the overwhelmingly non-criminal male population. We therefore reject a broad genetic database similar to that being considered in the United Kingdom.

In Canada, such a database would likely violate the *Charter of Rights*. The mandatory collection of genetic samples would almost certainly be considered unreasonable search or seizure under section 8 or violate the section 7 right to life, liberty and security of the person. The collection might also violate the anti-discrimination provisions of section 15 by singling out males.

And should it be the object of government privacy policies to make life easier for the police, as the U.K. Home Affairs Committee seems to imply? Democracies accept that police efficiency must yield to respect for

fundamental human rights – in this case, the right to privacy. The availability of DNA technology should not be allowed to undermine this principle.

A genetic *databank* – a collection of the actual genetic samples, not just the results of an RFLP analysis – offers even greater, and hence more objectionable, possibilities for privacy intrusions. Besides performing RFLP analysis on samples for identification, governments might genetically screen samples to single out persons with genetic traits thought to contribute to criminal or other anti-social behaviour. In the extreme, "deficient" individuals could be singled out for surveillance, treatment (including sterilization) or isolation, to avoid perpetuating socially deviant tendencies.

The story of the "XYY" male suggests the dangers of screening banks of genetic samples to identify anti-social or other undesirable characteristics. Some males have an extra Y ("male") chromosome. Instead of the typical "XY" sex chromosome configuration, they have an XYY configuration.³⁹ In the 1960s and 70s, some scientists thought that males with an extra Y chromosome were predisposed to criminal or anti-social behaviour. Acceptance of this theory led to mass screening for the trait and the labelling of many males as social deviants before the theory was eventually challenged.⁴⁰

The temptation for governments to rely on contentious genetic findings coupled with the ready availability of a large bank of genetic samples is a recipe for privacy and other human rights disasters.

Conclusion: There may be proper uses for personal genetic *databases* where crimes of serious violence are involved. Databases, however, should continue to be used only for identification.⁴¹ RFLP analysis should continue to be structured to avoid disclosing genetic characteristics beyond those needed for identification. Future techniques for identification through genetic analysis should similarly avoid collecting information other than that needed for identification. Furthermore, not every form of criminal activity would warrant including a criminal's DNA profile in a genetic database. Databases should be considered only for persons who have been convicted of crimes involving serious violence. We acknowledge that further study is needed, but offer this as our initial position.

We reject the idea of governments acquiring a genetic database of large sectors of the population. We also oppose governments establishing genetic databanks – banks of genetic samples.

Recommendation 11

Governments should not establish banks of genetic samples of convicted persons or the general population for criminal justice purposes.

Governments should not establish genetic databases of the general population for criminal justice purposes.

Genetic databases containing identification information about persons convicted of crimes involving serious violence should not be assembled for criminal investigations or prosecutions without

- (a) further study of the privacy and other human rights implications and**
- (b) specific authorizing legislation, if the study finds the database to be acceptable.**

If genetic databases are to be found acceptable, they should be used only for identification. The information contained in a genetic database and any genetic samples related to the crime should not be used to try to identify other characteristics that may have a genetic link, such as personality.

(vi) Research

At present, a massive international effort is under way to "map" and "sequence" the human genome. This is hardly the first program to examine human genetics. However, it is certain to be the most revealing.

Research is fundamental to progress in the science of genetics. The issue is the extent to which personal genetic information should be permitted to be used in research.

The principal concern of this office remains the protection of privacy. Curiosity may be the mark of a good researcher or scientist, but that curiosity must not be allowed to trample privacy. Institutions conducting research must not ignore the very human desire to be free from the intrusions of others.

Research involving genetics should, wherever possible, use anonymous, unlinked data or genetic samples. The use of nominal data or samples should, except in compelling circumstances and with the authority of a governmental or governing body, occur only with consent.

The appendix to this report contains guidelines on epidemiological research prepared for the Council of International Organizations of the Medical Sciences. This office may differ with the guidelines on points concerning the protection of privacy in epidemiological research. In general, however, the office is pleased to see the international attention being devoted to privacy in research.

Recommendation 12

Wherever possible, genetic research should use anonymous, unlinked genetic samples or information to preserve anonymity.

ENDNOTES

- (1) B. Knoppers, *Human Dignity and Genetic Heritage: A Study Paper* prepared for the Law Reform Commission of Canada (1991) at 60-63.
- (2) Forensic DNA analysis using the RFLP technique does not yield diagnostic information. It merely indicates whether two samples of genetic material may belong to the same person. Accordingly, disclosing the results from a forensic RFLP analysis would not violate one's right not to know or to have others know one's genetic traits or disorders.
- (3) Delegates at a recent conference were told about one U.S. insurance company that paid for prenatal screening of a fetus for cystic fibrosis; on finding that the fetus would develop the disorder, the company refused to provide insurance. The company ultimately backed down from this position; comments by Eric Lander, II Workshop and International Cooperation for the Human Genome Project: Ethics, Valencia, Spain, November 11 - 14, 1990. Pressure will inevitably grow to use genetic screening to qualify people for (or deny) access to services,

particularly in activities like insurance. See L. Gostin, "Genetic Discrimination: The Use of Genetically Based Diagnostic and Prognostic Tests by Employers and Insurers", *17 American Journal of Law & Medicine* (1991) at 109, and A. Lippman, "Prenatal Genetic Testing and Screening: Constructing Needs and Reinforcing Inequities", *17 American Journal of Law & Medicine* (1991) 15 at 35. On the impact of genetic technology on insurance, see a paper presented by Professor G.W. de Wit of Erasmus University, Rotterdam, "Genetechnology, Insurance and the Future" at the Valencia Workshop mentioned above. On ratemaking in insurance generally, see G.W. de Wit, "The Politics of Rate Discrimination: An International Perspective", *53 The Journal of Risk and Insurance* (1986) 644-661.

(4) We are not judging the validity of the particular exclusion criteria that immigration authorities now apply. We are simply addressing whether genetic testing should be one potential means of determining whether the criteria have been met.

(5) For a discussion of the legal and ethical implications of genetic technology, see B. Knoppers, *supra* note 1.

(6) Science Council of Canada, *Report 42: Genetics In Canadian Health Care* (1991) at 76.

(7) *Ibid.*

(8) *Ibid.* at 76-78.

(9) *Ibid.* at 78.

(10) *The Economist*, June 1, 1991 at 21. However, in D. Suzuki and P. Knutson, *Genethics: The Ethics of Engineering Life* (1988), the authors state (at 40) that some 30 states (not 24) passed sterilization laws aimed at barring loosely defined "hereditary defectives" from reproducing. Compulsory sterilization laws applied to a variety of persons categorized as feeble-minded, alcoholic, epileptic, sexually deviant and mentally ill.

(11) B. Wilford, N. Forst, "The Cystic Fibrosis Gene: Medical and Social Implications for Heterozygote Detection", *Journal of the American Medical Association* (May 23/30, 1990) Vol. 23, no. 20.

(12) *The Economist*, *supra* note 10.

(13) *Ibid.* In January 1991, a California county superior court judge offered a one year sentence and a probation condition that a 27 year-old woman have a contraceptive device implanted in her. The alternative was a state prison sentence. The device would prevent the woman from becoming pregnant for three years. The woman, a mother of four, had been convicted of abusing two of her children. She was expecting a fifth. The judge is quoted as saying: "Clearly, I could just have locked her up for four years, but I thought it would be better to try to keep the family together, to see if she could get her act together. I thought that not having more children for the next three years would help in her potential rehabilitation." The defendant apparently initially accepted the arrangements, but later had second thoughts. The case has been appealed to the California Court of Appeals: *Parade Magazine*, September 1, 1991 at 8-9.

(14) *The Economist*, *supra* note 10.

(15) One means to achieve this – the "love boat" cruise – hardly seemed diabolical. But underlying this encouragement of the "elite" to procreate was a clear desire to engineer a better society through a crude form of eugenics.

(16) See A. Lippman, *supra* note 3 at 35.

- (17) Perhaps even the choice of a mate is a basic form of eugenics.
- (18) Perhaps surprisingly, some parents will decide not to abort even if they have paid for genetic testing and learned that the fetus may have a serious defect.
- (19) This procedure might be of use, for example, to parents who are both carriers of a genetic disorder, like cystic fibrosis. Only some of the mother's ova and father's sperm will carry the defective gene. An ovum without the defective gene could be identified, then fertilized with non-carrier sperm and implanted. This would ensure that the child would not develop the disease or even be a carrier.
- (20) But see A. Lippman, *supra* note 3 at 35 and the related discussion in the text of this report.
- (21) Information about a person's sex or eye colour is, of course, genetic information. We would not restrict the collection of such information by a government institution where that collection was directly related to one of its operating programs or activities. Accordingly, it is not reasonable to recommend categorically prohibiting collection, use or disclosure of some genetic information.
- (22) For example, Huntington's disease.
- (23) M.F. Niermeijer, "Screening and Counselling: Report of Discussion Group" [on genetic screening, counselling and intervention], in Z. Bankowski and J. Bryant, ed., *Health Policy, Ethics and Human Values: European and North American Perspectives: Conference Highlights, Papers and Conclusions from the XXIst CIOMS Conference (CIOMS, Geneva, 1988)* 91 at 93.
- (24) See the discussion of section 4 of the *Privacy Act* in part III.
- (25) M.A.M. de Wachter, "Screening and Counselling - Ethical and Policy Aspects", in Z. Bankowski and J. Bryant, ed., *supra* note 23, at 72.
- (26) One might suggest that some of these problems can be avoided by having patients sign a contract before testing allowing the dissemination of genetic information to relatives. The problem remains, however, if the patient refuses to sign such a contract. Would it be appropriate for a physician to refuse to have a patient tested if the patient would not allow potentially useful information to be given to genetic relatives?
- (27) Section 8 of the *Privacy Act* allows the disclosure of personal information for any purpose where the head of the institution thinks that disclosure would clearly benefit the individual to whom the information relates. The Act may therefore solve this dilemma for government physicians where their patients do not consent to the disclosure of genetic information to relatives; it might sometimes be argued that the genetic information does relate to the relative and that it would clearly benefit the relative.
- (28) Report 33, *Recodifying Criminal Procedure, Part I* (1991) at 58.
- (29) *Ibid.*
- (30) The Law Reform Commission apparently considered the forced taking of blood to be too serious an intrusion, except in cases involving impaired driving. Source: Personal conversation with Law Reform Commission consultant, March 18, 1991. See also *supra* note 28 at 60-63. DNA analysis could in any event be done on hair or saliva samples, which the Commission would allow to be taken.

- (31) *Supra* note 28 at 63 (section 59).
- (32) *Ibid.* at section 55.
- (33) See Part I, note 42 and related text.
- (34) It might also, for example, be used to genetically match blood stains found on a suspect's clothes with a genetic sample from the victim.
- (35) J.C. Hoeffel, "The Dark Side of DNA Profiling: Unreliable Scientific Evidence Meets the Criminal Defendant", 42 *Stanford Law Review* 465 at 532-33.
- (36) House of Commons, Home Affairs Committee, *First Report: Annual Report of the Data Protection Registrar* (12 December 1990, London: HMSO) at xi (references to footnotes omitted).
- (37) *Seventh Report of the Data Protection Registrar*, June 1991 (16 July 1991, London: HMSO) at 6.
- (38) U.S. Congress, Office of Technology Assessment, *Genetic Witness: Forensic Uses of DNA Tests*, OTA-BA-438 (Washington, D.C.: U.S. Government Printing Office, July 1990) at 8.
- (39) Females normally have an XX chromosomal configuration.
- (40) See D. Suzuki and P. Knutdson, *Genethics: The Ethics of Engineering Life* (1988) at 151-52.
- (41) It would also be appropriate to maintain an "open case" datafile containing genetic information derived from samples left at the scene of a crime. This could allow investigators to determine if a crime or series of crimes were committed by the same unknown person.

Part III

Genetic Testing and the *Privacy Act*

(a) The *Privacy Act*

Parliament enacted the *Privacy Act* in 1983. The Act embodies international standards designed to regulate the collection, use and disclosure of personal information by governments. The Act sets out principles of "fair information practices". It requires some 150 federal government institutions to:

- collect only the personal information they need to operate programs;
- collect the information directly from the person concerned, if possible;
- tell the person how it will be used;
- use personal information only for the purpose for which it was collected or for a "consistent" purpose;
- disclose the information only as the Act permits;
- take all reasonable steps to ensure the accuracy and completeness of the information;
- allow the person access to his or her personal information; and
- allow the person to make objections to the correctness of personal information kept by government, have the objections stated on file, request changes to the file, and notify users of the information of the objections.

Under the *Privacy Act*, personal information cannot be collected simply out of curiosity. It must not be collected in a manner that risks inaccuracy. It must not be collected secretly, except in tightly controlled circumstances. The Act thus attempts to counter the thirst for information that typifies modern organizations.

The *Charter of Rights* adds another dimension to *Privacy Act* protection against governmental intrusions. Federal legislation that permits collecting, using or disclosing personal information could override the *Privacy Act*. However, it might still violate *Charter* rights protections. For example, a law might seek to permit government to collect, use or disclose personal information in a way that violates the *Charter* protection against "unreasonable search or seizure"¹ or that violates the right to "life, liberty and security of the person".² If the law violating the *Charter* is challenged, a court will likely hold the law void.

(i) Personal information and genetic testing

Privacy Act rules governing collection, use and disclosure apply only to "personal information" as the Act defines it. "Personal information" under the Act means information about an identifiable individual.³ It includes information relating to race, ethnic origin, colour and medical history. The definition is clearly broad enough to cover the personal information generated by genetic testing. For example, information that an identifiable person carries the gene that causes cystic fibrosis is personal information. Personal information also includes the following:

- the fact that a person has asked to be tested, undergone genetic testing, or has been asked or ordered to be tested;
- any discussions that the person may have had about his or her genetic testing; and
- any information about blood relationships between people (e.g., information that X is the natural child of Y and Z).

This last category warrants further explanation. A genetic test performed on one person may identify genetic characteristics of a relative. For example, if one parent is a carrier of the cystic fibrosis gene or has cystic fibrosis, a natural child theoretically could be an asymptomatic carrier of the cystic fibrosis gene or a non-carrier. If both parents were carriers, the child could be a carrier, a non-carrier, or could have cystic fibrosis.

This can work in reverse as well. A child may have cystic fibrosis. This means that each natural parent will either be a carrier of the cystic fibrosis gene or

will have cystic fibrosis. Thus, genetic information about one person may give rise to definite or speculative personal information about predecessors and successors. For this reason, personal information identifying genetic ("blood") relationships assumes considerable importance in discussions about genetic privacy.

(ii) Collection of personal information

(1) Collection without consent and volunteered information

Government institutions may want to collect personal genetic information through mandatory genetic screening – that is, without first obtaining the consent of the person to whom the information relates. They might want to do so by taking genetic samples from the person, or by using genetic samples taken earlier for another purpose.

Restricting the collection of personal information is the most obvious, but often understated, line of defence against violations of privacy by government. In short, government institutions are less likely to violate a person's privacy if they do not collect information about that person.⁴

Section 4 of the *Privacy Act* embodies the philosophy that government institutions should collect only the information they truly need:

No personal information shall be collected by a government institution unless it relates directly to an operating program or activity of the institution.

The key issue in every case of collection is whether the information collected relates directly to an "operating program or activity". In earlier reports, this office argued that legislative authority should be sought for any mandatory collection (through testing) of information about HIV antibody status or drug use.⁵ Such legislation would satisfy section 4 by making it clear that the collection was directly related to the operating program or activity of the institution.⁶

In other circumstances, this office is less adamant that there be explicit statutory authority for the collection of personal information. Whether specific statutory authority beyond general authorizing legislation is needed to collect personal information will depend largely on its potential sensitivity. One's date of birth is personal information. However, it is generally not as sensitive as information about a genetic disorder that will lead to premature death. At some point along the continuum ranging from relatively benign to extremely sensitive personal information, statutory authority to collect will be necessary.

This office interprets section 4 of the *Privacy Act* to require specific statutory authority for the collection of most information derived from genetic testing. Some personal genetic information (sex, for example) may be relatively benign. Other information, however, could be much more sensitive. For more sensitive information, specific legislative authority should be sought to ensure that the collection complies with section 4.

Some readers may suggest that this interpretation stretches section 4 to give it a meaning that its words cannot support. Perhaps they are right. The *Privacy Act* was simply not designed to take account of the privacy threats posed by new biotechnologies. Nevertheless, we must apply our existing legislative tools in the face of new circumstances. However, elected officials, not faceless bureaucrats, should have the burden of responsibility for authorizing its use: thus, the need for Parliament to examine genetic privacy.

The greatest practical impact of section 4 lies in regulating the mandatory collection (collection without the consent of the person) of personal information. However, section 4 also limits the collection of volunteered information. For example, a government employee might during a casual conversation with a superior volunteer that he or she has a genetic trait that increases the risk of developing heart disease. In most cases,⁷ the superior should not collect (record) this information.⁸ It will not likely be directly related to an operating program or activity of the government institution, nor will there likely be statutory authority to collect it. Volunteered information must pass the same "relevance" test as personal information collected without consent, such as through a mandatory testing program.

Recommendation 13

Government institutions should generally collect personal genetic information only if specific statutory authority exists for the collection. This rule should apply whether the information becomes available through mandatory testing or through a person volunteering personal genetic information or volunteering to be tested.

The remainder of this part discusses the restrictions placed by the Act on the method of collection, and the use and disclosure of personal information. It also discusses rights of access to the information. **The discussion in the remainder of this part assumes, therefore, that the initial collection of personal genetic information was lawful.**

(2) Direct collection

In general, the *Privacy Act* requires personal information to be collected directly from the individual to whom it relates. Subsection 5(1) reads:

A government institution shall, wherever possible, collect personal information that is intended to be used for an administrative purpose directly from the individual to whom it relates except where the individual authorizes otherwise or where personal information may be disclosed to the institution under subsection 8(2).

Subsection 5(1) therefore permits collection other than direct collection in three situations:

- if direct collection is not possible;
- if the individual authorizes collection other than direct collection; or
- if the institution is entitled to receive the personal information under certain disclosure provisions of the Act (subsection 5(1), for example, would allow a government institution to collect personal information

indirectly if an Act of Parliament or regulation permits another government institution to disclose the information to the first institution.)⁹

This direct collection requirement applies to genetic testing. Except in the three situations outlined immediately above, personal genetic information must be collected directly from the individual to whom it relates. Even if it is possible to identify a genetic characteristic of one person from a test of a relative, the genetic information should, if possible, be collected directly from that person, not the relative.

It is also possible that indirect collection of highly sensitive genetic information could violate *Charter* privacy protections. Even if the person being tested has consented to the test, it may be unlawful to use that test process to "search" the genome of another person.

(3) Informing about the purpose of collection

Subsection 5(2) of the Act requires in general that government institutions tell persons why their personal information is being collected:

5(2) A government institution shall inform any individual from whom the institution collects personal information about the individual of the purpose for which the information is being collected.

The person need not be told the purpose of the collection in two other circumstances identified in subsection 5(3): where informing might result in the collection of inaccurate information or where it might defeat the purpose or prejudice the use for which the information is collected. Neither exception would likely arise with genetic testing. Information collected through a technically accurate genetic test will not become inaccurate simply because the person is told the purpose of the collection. Nor will it defeat the purpose or prejudice the use.

Note that if the information is not collected from the individual, there is no obligation to tell the purpose of the collection. For example, a genetic test of a parent (direct collection from the parent) might also disclose a certain or likely genetic trait in a child (indirect collection). Because the information is collected directly from the parent, not the child, only the parent must be told the purpose of the collection.

The potential unfairness of not telling a person the purpose of the collection can be avoided. As a policy, all persons about whom genetic information is being collected, even through the test of another, could be told the purpose of the collection. This policy would perhaps be cumbersome, but it would be fair. We strongly encourage its adoption.

Recommendation 14

Government institutions should tell persons why personal genetic information about them is being collected, even if they have no right under subsection 5(2) of the *Privacy Act* to be told.

(iii) Retention and disposal of personal genetic information

Subsection 6(1) of the Act imposes retention requirements for personal information that has been used for an administrative purpose (that is, where the information has been used in a decision making process that directly affects the individual).¹⁰ The information must be retained for a period set out in the Act's regulations. Subsection 4(1) of the *Privacy Regulations*¹¹ generally requires retention for at least two years:

Personal information concerning an individual that has been used by a government institution for an administrative purpose . . . shall be retained by the institution

- (a) for at least two years following the last time the personal information was used for an administrative purpose unless the individual concerned consents to its disposal; and

(b) where a request for access to the information has been received, until such time as the individual has had the opportunity to exercise all his rights under the Act.

Once genetic samples are taken from an individual and identified as belonging to the individual (normally by labelling the sample), they become personal information under the Act. Both the genetic sample and the information obtained by analyzing the sample must be retained for the period required by the regulation.

If the information or sample has not been used for an administrative purpose, there is no retention requirement. It may be disposed of at any time or kept for any period.

However, the Act and Regulations do not specify how long information may be kept. A government institution might theoretically keep genetic information and samples indefinitely. Subsection 6(3) of the Act contains only a broad directive on disposal:

A government institution shall dispose of personal information under the control of the institution in accordance with the regulations and in accordance with any directives or guidelines issued by the designated minister in relation to the disposal of such information.

The *Privacy Regulations* contain no directions on disposal that are relevant to disposing of personal genetic information.

As technology advances, samples collected for one purpose will inevitably tempt the custodians to analyze them further for another purpose. Thus, a test that originally generated only limited information could be supplemented over time by more advanced (and more intrusive) tests. These tests would generate ever-increasing amounts of highly personal genetic information about the person tested and his or her relatives.

A blood spot taken at birth for routine neonatal testing could, if retained, be used to identify thousands of different genetic traits over a person's lifetime. Apart from the situations discussed below, the sample should be disposed of as soon as possible. In this way, no sample will be left in the government's possession to invite future clandestine testing.

Instead of retaining the sample, the preferred solution in most cases is to retain only the information generated by testing the sample. It is sound privacy policy to dispose of the genetic information (especially the sample) as soon as its retention is no longer required by the *Privacy Regulations*. There should also be a clear legal obligation to do so, not simply the broad obligation stated in subsection 6(3). A strict limit should be placed on the period of retention of personal genetic information, whether or not used for an administrative purpose.

Several exceptions to this general rule might be necessary. Genetic samples taken from the scene of a crime should not be disposed of before the crime is "solved" and all trial and appeal processes have been exhausted. There may even be merit in retaining the sample from the scene longer, in case genetic technology will evolve to permit more accurate forensic DNA analysis. Retaining it longer could also be useful in extraordinary cases, such as that of David Milgaard.¹²

Nor should disposal be automatic if there is no second chance to obtain the genetic sample (for example, if the person from whom the sample was taken has been cremated¹³ or has disappeared) and there may be a legitimate need for genetic information about that person in the future.

It would likely not be necessary (depending on the risk of random mutations) to retain the genetic samples taken from an accused for more than two years after the trial. If the accused wished later to challenge the initial analysis of his or her genetic sample, he or she could simply give another sample.

A second exception to the requirement of early disposal occurs with samples taken for genetic monitoring. Monitoring seeks to identify genetic changes that may occur from exposure to chemicals, radiation or other influences.

A genetic sample taken after the exposure may not give an accurate picture of the person's genetic makeup before the exposure. It is therefore necessary to retain the pre-exposure genetic sample in case the person wishes to have it re-tested or have additional tests performed on it.

A third exception relates to the "unlinking" process in epidemiological research. A genetic sample may be unlinked so that it cannot be identified with its donor or a genetic relative. Once identifying information is removed from the sample, it will not be "personal information". It will be "anonymous". The *Privacy Act* will no longer apply; thus, strictly speaking, this scenario is not an example of an exception to the Act, but rather is a circumstance to which the Act does not apply. For the sample to lose its status as personal information, however, it must become impossible to link it with its donor. This would permit leaving some information with the sample (for example, the date the sample was taken, the city, the age of the donor), but the information in aggregate must not permit identifying an individual.¹⁴

Recommendation 15

A strict time limit should be placed on retaining personal genetic information (including samples), whether or not the information has been used for an administrative purpose. If information is allowed to be kept for extended periods under exceptional circumstances, extraordinary care must be taken to ensure that it is used only for purposes for which it was collected or for a consistent purpose.

(iv) Accurate, complete and current information

Subsection 6(2) of the Act seeks to ensure that personal information used by government institutions is accurate, current and complete. It reads:

A government institution shall take all reasonable steps to ensure that personal information that is used for an administrative purpose by the institution is as accurate, up-to-date and complete as possible.

This report does not pretend to be a scientifically thorough analysis of the science and technology of genetic testing. Therefore, it cannot assess the accuracy of tests that seek to identify genetic traits. But history and hindsight have taught that "foolproof" scientific techniques are often oversold. This will almost certainly hold true for aspects of genetic testing. Figuring out which combinations of the three billion base pairs of nucleotides (and factoring in environmental influences) will give rise to certain traits or disorders will leave enormous room for unjustified speculation. Inevitably, this will lead to error as scientists try to determine the extent to which human beings are determined by their genes.¹⁵

Applied to genetic testing, the "accuracy" requirement of the Act has at least two aspects. The first is the technical accuracy of the test. Does the test accurately identify the presence of a given gene or a genetic marker? Among the factors to be considered are the technical qualifications of the person(s) administering the test, the possibility that the test subject's genetic sample was contaminated by foreign genetic material (perhaps due to unclean testing equipment), incorrect reading of technical indicators by technicians, and transcription errors. Among the most common technical errors may be the inadvertent switching of samples through mislabelling. All the technical expertise in the world can be nullified by this one lapse.

The second aspect of "accuracy" is the interpretation of test results based on the scientific knowledge of the day. Genetics may have created a population of impatient geneticists and patients who are willing to assume that genetic discoveries are valid and that speculative theories contain established truths.

This office cannot evaluate scientific findings. If the "XYY" theory suggesting anti-social behaviour in males with an extra Y chromosome¹⁶ were first presented today, this office could not confirm or challenge it. But it can caution against uncritically accepting new science as fact.

Predictive values: Many genetic traits have only limited predictive value. Many disorders – the most common ones – are multifactorial (involving many genes and many environmental factors, such as exposure to cigarette smoke or

chemicals). Genetic testing to predict multifactorial disease is recognized as being scientifically complex.

A report by the U.S. Congress Office of Technology Assessment (OTA) states:

[I]t is the exception that the direct link between one gene, one locus, and one disease can be made. Most diseases are multifactorial and polygenic; i.e., several genes in combination with specific environmental factors act together to produce the disease state.¹⁷

Later, it states:

Combinations of genes encode complex aspects of the human phenotype, such as the immune response and cholesterol metabolism. Defects in one or more of these genes can cause diseases that may be exacerbated by environmental factors such as viruses, chemicals, and radiation; thus the term "multifactorial disease." Multifactorial diseases are far more common than single gene disorders. They include coronary artery disease, diabetes mellitus, multiple sclerosis, schizophrenia, epilepsy, allergic rhinitis, asthma, some forms of arthritis, and some forms of emphysema, to name a few.¹⁸

About genetic monitoring specifically, the OTA notes that most analysts agree that the ability to accurately interpret cytogenetic (chromosomal) test results at the individual level is questionable. They recommend that until the relationship between cytogenetic damage (damage to chromosomes) and disease is better understood, interpretation should be limited to the population level.¹⁹

These expressions of concern by various organizations emphasize the need for caution in accepting genetic findings as "fact".

To enhance "technical" accuracy, appropriately qualified persons must conduct the tests and analyze the results. This is not a task for the non-scientist.

Persons without the medical or scientific expertise to assess the information derived from genetic testing should not test or analyze the information.

Furthermore, if the analysis of the genetic test results is not current, an appropriately qualified person should determine whether the original assessment remains valid. This cannot be a hard and fast rule. Some genetic test results – those showing the presence of a monogenic disorder, such as Duchenne muscular dystrophy, or Huntington's disease, for example – will likely not need reassessment of their original validity. But assessments of the implications of other genetic traits are often much more tentative. Sometimes too, because of the possibility of random genetic mutations over time, it may be necessary to retest the person.

Files containing genetic test results should include a directive that the results of the test must be reassessed by an appropriately qualified person before use or disclosure. For example, a 25-year-old government file might identify a penitentiary inmate as a "super male" with an XYY chromosomal structure. The file might indicate that this genetic characteristic makes the inmate anti-social. Before this information is used today for an administrative purpose, it should be critically reassessed. The directive should also state that retesting may be necessary because of the possibility of random mutations.

One model for reassessment is found in the Treasury Board's *Interim Policy Guide: Access to Information Act and the Privacy Act*²⁰. Under the Guide, exemptions to the right of access to personal information permit disclosure to be withheld if it could reasonably be expected to be injurious to the interest specified in the exemption (for example, the information might damage the mental health of the individual). Information which has been protected from disclosure in the past should be reassessed when a new request for the information is received.

A similar scheme could prevent the use of outdated interpretations of genetic tests. Each use or disclosure of genetic test results should require a reassessment of the validity of the preceding analysis.

Previous uses and disclosures of the genetic test results should also be recorded. This will permit correction if necessary.

Recommendation 16

To enhance the accuracy and completeness of personal genetic information and to make it as up-to-date as possible, government institutions should ensure the following:

- 1. Only qualified persons should conduct genetic tests and interpret test results.**
- 2. Before "older" test results are used for an administrative purpose, a qualified person should critically reassess the interpretation of the results (and, if need be, the test process itself) to ensure that the testing method and results are supported by current medical and scientific thought. It may also be necessary to retest the subject because of the possibility of random mutations.**
- 3. Medical or scientific explanations about or qualifications of the information generated by genetic testing should accompany the test results in a person's file.**
- 4. If information generated by genetic testing (or the test process itself) is found to be inaccurate or outdated, a notation should immediately be entered on the affected person's file and any incorrect information corrected.**
- 5. Uses and disclosures of personal genetic information should be recorded to make it easier to correct all files containing incorrect information.**

Accuracy and Testing Genetic Relatives: Another accuracy issue stems from the use of genetic information about one person to identify genetic conditions or traits in a relative. Family members share many genetic traits. Still, concluding that one person has a given trait or disorder because it is present in a relative is risky, for two reasons:

- without a genetic test, there may be no certainty that the persons are natural relatives; a child is clearly the child of its mother only during pregnancy; there is no certainty at all about the child's relationship with its supposed father. Those using indirect testing should be required to state on the person's file the reasons for believing that the person being tested indirectly is in fact the natural genetic relative of the person actually tested, and their relationship; and
- even close relatives do not have identical genetic compositions. A child will inherit some genetic traits from each parent, thus making the child's genome a "composite" of that of each parent.²¹ Few specific genetic characteristics can definitely be said to pass from one generation to another. Traits carried in the mitochondrial DNA are among the few exceptions. The mitochondrial DNA of a child almost never varies from that of genetic relatives on the maternal side.²²

The collection of genetic information about a person indirectly from genetic information about a relative will also generally violate subsection 5(1) of the Act. It may violate the *Charter* as well.

Recommendation 17

To enhance accuracy and to meet the direct collection requirements of subsection 5(1) of the *Privacy Act*, genetic information about a person should be collected through a test of that person, not through the test of a person thought to be a genetic relative. Indirect testing should occur only if direct testing is not possible.

Government institutions collecting genetic information about a person indirectly through testing a relative should record the reasons for believing that the relative and the person are naturally related, and their relationship.

(v) Uses of personal genetic information

Section 7 of the Act restricts the use by government institutions of personal information. Personal information can be used for any purpose if the person to whom it relates consents. If the person does not consent, the information can be used in three ways only:

- for the purpose for which the information was obtained or compiled by the institution (subsection 7(a)),
- for a use consistent with that purpose (subsection 7(a)), or
- for a purpose for which the information may be disclosed to the institution under subsection 8(2) (subsection 7(b)). Subsection 8(2) identifies several situations where personal information can be disclosed by one institution to another.

The second use – consistent use – requires explanation. Consistent use is easiest to define in the negative. For example, if a blood spot were obtained for a routine medical diagnosis, it would not be a consistent use of the blood spot or information derived from it to use it in a criminal prosecution. Nor would it seem consistent to use the information to assess traits that might affect the person's employability.

At the other end of the scale, determining if a use is consistent becomes more difficult. If genetic samples assembled to determine the prevalence of a genetic trait in a small population were then used to determine the prevalence of another genetic trait, would that be a consistent use? Perhaps. Cases will need to be considered individually.

Because of the extreme sensitivity of most personal genetic information, heads of institutions should be required to review and approve consistent uses of the information. This goes beyond the strict requirements of the *Privacy Act*, but is justifiable as a measure to limit possibly inappropriate uses of this highly sensitive information. As subsection 9(3) of the *Privacy Act* requires, the head of the institution should notify the Privacy Commissioner of the consistent use.

Recommendation 18

"Consistent uses" of personal genetic information under the control of government institutions should require the personal approval of the head of the institution. As a policy, the decision should not be delegated.

(vi) Disclosure of personal genetic information

Subsection 8(1) states the general rule about disclosure of personal information. A government institution must not disclose personal information unless the person to whom it relates consents. Subsection 8(2), however, lists several exceptions, among them the following:²³

- disclosure for the purpose for which the information was obtained or compiled (for example, if the intention in collecting the information is to disclose it to the police, the disclosure to the police without the person's consent is proper);
- disclosure where a federal law or regulation permits disclosure;
- disclosure to comply with a warrant, subpoena or court order;
- disclosure to an investigative body;
- disclosure to foreign states or organizations of states under an agreement or arrangement;
- disclosure in the public interest; and
- disclosure for research.

Under paragraph 8(2)(m), the head of a government institution may disclose personal information where he or she decides it is in the public interest to do so, or where it would clearly benefit the individual to whom it relates. Similarly, disclosures to researchers under paragraph 8(2)(j) require the consent of the head of the institution. Other disclosures under subsection 8(2) do not require the consent of the head.

It is relatively easy for a government institution to disclose highly sensitive personal information under subsection 8(2). This continues to concern this office. The subsection is a sieve. For example, a government institution can agree or arrange to disclose personal genetic information to the government of a foreign state, an international organization of states, or any institution of any such government or organization for the purpose of administering any law. The affected individual's consent is not required, and there is no accountability to the individual. At best, the individual, if he or she knows about the disclosure, can seek to challenge it under the *Charter*.

The prospect that highly sensitive personal genetic information might be traded with relative ease, not only to other governments in Canada, but across national borders, is frightening. It is particularly unsettling that there is no accountability to the persons whose sensitive personal information may be traded away.

We cannot in this report go into a lengthy analysis of subsection 8(2) and the ways to impose greater accountability and control on disclosures made under it. We intend to pursue changes to subsection 8(2) in another forum. For now, we recommend that as a policy the head of the institution be required to approve any disclosures of personal genetic information under paragraphs 8(2)(e) to (m). This would include the following disclosures:²⁴

- to an investigative body (paragraph 8(2)(e));
- to other governments or foreign organizations or institutions (paragraph 8(2)(f));
- to a member of Parliament (paragraph 8(2)(g));
- to officers or employees of the institution for internal audit purposes, etc. (paragraph 8(2)(h));
- to the National Archives (paragraph 8(2)(i));
- to associations of aboriginal people, Indian bands or government institutions researching or validating claims, disputes or grievances of aboriginal peoples (paragraph 8(2)(k));

- to government institutions wanting to collect debts from individuals or make payments to them (paragraph 8(2)(l));
- in the public interest, or where disclosure would clearly benefit the individual to whom it relates (paragraph 8(2)(m)).

As a policy, the consent of the head of the institution should also be required for disclosures of personal genetic information under the second part of paragraph 8(2)(a) – disclosures for a use consistent with the purpose for which the information was obtained or compiled by the institution.

This authority to consent under paragraphs 8(2)(a) and 8(2)(e) to (m) should, as a policy, not be delegated.

Recommendation 19

As a policy, the personal consent of the head of the institution should be required for disclosures of personal genetic information under paragraphs 8(2)(e) to (m) of the *Privacy Act*.

As a policy, the personal consent of the head of the institution should also be required for disclosures of personal genetic information under the second part of paragraph 8(2)(a) – disclosures for a use consistent with the purpose for which the information was obtained or compiled by the institution.

Note that subsection 8(2) states that the disclosures permitted by the *Privacy Act* are "[s]ubject to any other Act of Parliament". Other federal laws may enlarge or restrict the disclosure provisions of the *Privacy Act*. For example, a federal law could require or permit the disclosure of personal genetic information in circumstances that the *Privacy Act* alone would not permit. The law would take priority over the *Privacy Act* if there were a conflict between the two.

(vii) Access to one's own personal genetic information

The *Privacy Act* gives a person the right to see personal information about him or her contained in most government files.

Every individual who is present in Canada has a right of access to the following:

- (a) any personal information about the individual contained in a personal information bank; and
- (b) any other personal information about the individual under the control of a government institution and with respect to which the individual is able to provide sufficiently specific information on the location of the information as to render it reasonably retrievable by the government institution.

Subsection 12(2) gives the right to request correction of or annotations to information in personal information banks. This right arises only where the information is being used, has been used or is available for use for an administrative purpose.

The person affected may also require that institutions which have used the information be notified of the correction or annotation. Specifically, subsection 12(2) permits the person to do the following:

- (a) request correction of the personal information where the individual believes it contains an error or omission;
- (b) require that a notation be attached to the information indicating any correction requested but not made; and
- (c) require notifying any person or body to whom the information has been disclosed within the past two years of the correction or notation.

Section 12 access rights apply to personal genetic information, including the genetic sample from which the information was obtained. In most cases, the person requesting access would not want access to the sample; he or she could simply give another sample if another test was wanted. However, when the access relates to genetic monitoring, the person may want access to an earlier sample to show that his or her genetic makeup has or has not changed since that sample was taken. Government institutions should give access to genetic samples kept for genetic monitoring.

If a person wishes to have a sample retested, who pays? This office believes the government should pay. We took a similar position about retesting for evidence of drug use in our 1990 report, *Drug Testing and Privacy*. It is reasonable to have the government that took the information in the first place bear the cost of ensuring its accuracy through a re-test requested by the person affected.

Recommendation 20

The right of access to personal genetic information should include the right of access to the genetic sample from which information was derived. The government institution that authorized the original genetic test should bear the cost of retesting requested by the person to whom the information relates.

ENDNOTES

- (1) *Constitution Act, 1982*, section 8.
- (2) *Ibid.*, section 7.
- (3) R.S.C. 1985, c. P-21, s. 3.
- (4) Governments can of course violate privacy in ways other than by collecting information – for example, by police searches of a person or a person’s car or home.
- (5) See *Drug Testing and Privacy* (1990) at 22-23 and *AIDS and the Privacy Act* (1989) at 19.
- (6) It could still, however, violate *Charter* privacy rights. Even if it did not, valid ethical objections to the intrusion might be raised.

(7) Some exceptions will be warranted. For example, a foreign service officer might be genetically tested during treatment by a Health and Welfare physician. It would be appropriate for the physician to record this information on the person's medical file. Specific statutory authority should not be required for the collection of this information through testing, although the *Privacy Act* would restrict the uses of the information. Appropriate uses of information were discussed in Part II and are also discussed later in this part.

(8) Nor, in the unlikely event that it would happen, should a government institution collect personal genetic information just because a person volunteers to be tested. The section 4 requirement for collection must still be met.

(9) For example, personal information collected by one department to determine the health of a person could be disclosed to a second department for a use consistent with determining the health of the person. The second department would not be required to collect this information directly from the person.

(10) *Privacy Act*, s. 3, definition of administrative purpose.

(11) SOR/83-508.

(12) Unfortunately, it is almost impossible to say which cases are or will become extraordinary. An example of the dilemma of deciding when to dispose of forensic samples has arisen in the case of David Milgaard. Milgaard was convicted in 1970 for a 1969 rape and murder. He exhausted his traditional avenues of appeal in 1971, when the Supreme Court of Canada refused to hear his appeal. Milgaard continued to assert his innocence.

Normally, investigators dispose of exhibits after the exhibits are analyzed and appeals completed. Even if they don't, investigators may keep the exhibits in conditions that will allow the materials to deteriorate or become contaminated. In the Milgaard case, by chance, the investigators did not dispose of the exhibits that could be used for forensic DNA analysis.

In 1991, twenty years after Milgaard exhausted his appeals, the Minister of Justice asked the Supreme Court of Canada to decide whether the continued conviction of Milgaard was a miscarriage of justice. During the inquiry, the Court released the victim's clothing and other materials to see if genetic samples suitable for DNA analysis remained. (In 1988, Milgaard had obtained access to these items for DNA analysis. The procedures used in the analysis may have made the materials unsuitable for further DNA analysis.)

It becomes exceedingly difficult in light of the Milgaard case to identify when genetic samples related to a crime should be disposed of. Should they be kept for a period after the appeal process ends? The Milgaard situation suggests that they should. However, many cases might not warrant retaining the samples. This issue requires further consideration.

(13) It is still possible to perform genetic analysis on dead bodies, even ancient mummies, if genetic material remains intact. Researchers in the United States, for example, are ready to proceed with a project to determine genetically whether President Abraham Lincoln suffered a genetic condition known as Marfan's Syndrome. This would involve destroying a small part of the blood stains and bone fragments preserved by witnesses at the theatre where he was assassinated: *The Economist*, June 8, 1991 at 31. Significantly, the magazine suggested that performing the genetic test would invade his privacy.

(14) For an example of guidelines on unlinked, anonymous epidemiological surveys involving AIDS, see Federal Centre for AIDS Working Group on Anonymous Unlinked HIV Seroprevalence, "Guidelines on Ethical and Legal Considerations in Anonymous Unlinked HIV Seroprevalence Research", 143 *Canadian Medical Association Journal* 625 (1990). The guidelines dealt with anonymous unlinked HIV seroprevalence surveys, but many of the considerations discussed in the guidelines would apply to anonymous surveys based on genetic testing. Note as well the ongoing work of the Council for International Organizations of the Medical Sciences (CIOMS) on international ethical guidelines for epidemiological research and practice. CIOMS met in Geneva from November 7 to 9, 1990, to discuss proposed guidelines. Excerpts from the CIOMS guidelines appear in the Appendix.

(15) As an illustration of the almost unfathomable complexities of the human genome (and, hence, the potential for error in assessing the significance of certain of its elements), the Human Genome Project alone will consume thousands of person-years of research time over the next 15 years. (Note, however, the very recent claim that "complement DNA technology" [CDNA] may permit nearly all the genes in the genome to be found and sequenced in four or five years for \$10 million: *The Economist*, January 18, 1992 at 85-86. Even so, the genome remains extremely complex.)

(16) See D. Suzuki and P. Knutson, *Genethics: The Ethics of Engineering Life* (1988) at 141-59.

(17) U.S. Congress, Office of Technology Assessment, *Genetic Monitoring and Screening in the Workplace*, OTA-BA-455 (Washington, D.C.: U.S. Government Printing Office, October 1990) at 191.

(18) *Ibid.* at 195.

(19) *Ibid.* at 9. Restricting the interpretation to the population level would mean that chromosomal changes in any one person would not be used to predict the future health of that person. The information might be useful in making some predictions for future health within a large group.

(20) At 83.

(21) Some limited conclusions can be reached with certainty; if both parents are carriers of the cystic fibrosis gene, their child has a one-in-four chance of having cystic fibrosis.

(22) A child's version of one region of mitochondrial DNA almost never varies from that of his or her mother, brothers, sisters, grandmother, maternal aunts and uncles and other genetic relatives on the maternal side: U.S. Congress, Office of Technology Assessment, *Genetic Witness: Forensic Uses of DNA Tests*, OTA-BA-438 (Washington, D.C.: U.S. Government Printing Office, July 1990) at 51. While mitochondrial DNA is therefore useful in identifying family relationships (as with children in Argentina who disappeared in the 1970s), it contains only limited genetic material – some 16,500 base pairs of nucleotides.

(23) See subsection 8(2) for the precise language.

(24) Personal genetic information is of course unlikely to be disclosed in some of the circumstances described.

Part IV

Regulating the Private Sector

By venturing into the privacy of human genomes, geneticists are not simply satisfying, as some would insist, their own insatiable scientific curiosities. Whether they recognize it or not, they are also creating new opportunities for others to harness this scientific knowledge – for good or for ill – in ways that will influence the lives of human beings.

Knowing this, each of us must be willing to do more than simply applaud each startling new breakthrough in molecular genetics that is announced in newspaper headlines. We must also be willing to play a part in monitoring those who might seek to use discoveries in genetics for personal, political or economic leverage in the endlessly shifting balances of power that are the inevitable consequence of scientific knowledge and its application.

David Suzuki and Peter Knudtson, *Genethics: The Ethics of Engineering Life* (1988) at 180.

Privacy regulation of the private sector is not as fully developed as regulation of government. The federal *Privacy Act* and equivalent provincial privacy laws do not apply to the private sector. Nor does the *Charter of Rights*.

Still, limited protections do exist against private sector intrusions. Several provinces¹ have enacted legislation making invasion of privacy a "statutory" (created by statute) tort. In some countries, the common law (law that has evolved through court judgments) tort concept of invasion of privacy has evolved to protect privacy from intrusions by government or the private sector. However, whether a common law tort of invasion of privacy exists in Canada remains a subject of debate.

Certain professionals – health care workers and lawyers, for example – must maintain in confidence the information they receive from clients or patients. In provinces that have developed common law rules on privacy, the private sector may be subject to these rules.

Broad notions of ethics may also offer some privacy protection – for example, the ethical duties of beneficence (the duty to help others) and non-maleficence (the duty to do no harm) and the principle of autonomy.² Often these will dictate that certain aspects of peoples' lives should not be exposed to the public. Although ethics cannot be enforced like laws, the members of a civilized society should generally accept them as guidelines for conduct.

All said, the private sector has at least as much leeway as government, and likely significantly more, to intrude on personal privacy. Information collection technology that once was financially viable only for government now sits on the desks of thousands of businesses. The drive for competitiveness and efficiency heightens the enthusiasm of businesses for employee and client selection and surveillance techniques. The growing biotechnological testing industry in North America has created additional pressure to test – for AIDS, drug use and, now, genetic traits – through its marketing efforts.

The very availability of intrusive technology seems to whet mankind's appetite for its use. In the process, privacy - that important right to be left alone - becomes a casualty. Two earlier reports from this office, *AIDS and the Privacy Act* and *Drug Testing and Privacy*, spoke of our concern about the impact of these testing technologies on privacy. Genetic technology has appeared alongside these and other intrusive biotechnological developments and threatens to surpass them all in its ability to intrude.

Governments holding information about a person suggesting a genetic risk of antisocial behaviour may earmark the person for special surveillance by police forces, schools and other government institutions. Private sector bodies armed with this speculative information might become equally oppressive, if in different ways. Employers might deny employment. They might employ the person, but only in positions that do not involve trust. They might refuse to

promote the person. Insurers might refuse to insure. Credit granting agencies may refuse to extend credit.

In this report we have recommended that government not collect genetic information that could be used to suggest criminal or anti-social tendencies. We do not want persons with that genetic makeup to be stigmatized by possibly inaccurate information. Society must protect its citizens from stigmatization by the private sector too.

In short, governments have no monopoly on oppression or discrimination through the collection, use and disclosure of personal genetic information. And the private sector is subject to few of the legislative safeguards that help protect persons against government intrusions.

Perhaps the private sector is largely benevolent, composed of good corporate citizens. But benevolence can be vulnerable to fear, prejudice, irrationality and the blind drive for efficiency. We have seen all these in the calls by some private sector employers for HIV antibody testing. We have seen prejudice and the blind drive for efficiency combine to justify intrusions through drug testing. We will inevitably see the call for genetic testing for similar reasons: to find a better class of worker or one more resistant to workplace hazards; to insure only the best risks; to grant credit only to those with no genetic risks that may prevent them from meeting their obligations.

Such private sector intrusiveness is hardly new. In the early part of this century, the Ford Motor Company of Detroit had a sociological department with scores of investigators. The investigators entered workers' homes to see that no one drank to excess, that sex lives were unblemished, houses were clean, and off-duty hours were profitably spent. The penalty for non-compliance was dismissal.³ Professor David Linowes suggests that this information may have been more intrusive than the information being sought today (although with the emergence of genetic and other biotechnological testing, his observation may no longer hold). Today, however, personal information can be easily assembled, then transmitted around the world in an instant.⁴ And with the globalization of economic activity, flows of information across borders are increasing.

Few will challenge the desirability of employers choosing the best employees. And insurance premiums for healthy persons will be lower if insurers choose only the best risks. Taken individually, decisions by employers and insurers to employ biotechnology to their advantage may appear logical. On a societal level, however, they are not. Nor are they necessarily humane.

At some point in our drive for efficiency, the dictates of economics and our thirst for technological fixes must yield to more fundamental social values. Among them, and most germane to this office, is respect for individual dignity and privacy.

Significantly, a 1989 Office of Technology Assessment survey of medical monitoring in the U.S. workplace identified strong support for a government role in regulating genetic screening in the private sector. Sixty-one per cent of the health officers responding to a survey of U.S. corporations, utilities and unions agreed with the notion that "government agencies should provide guidelines for genetic screening of job applicants and employees". Sixty per cent agreed that government agencies should provide guidelines for genetic monitoring of employees. In companies currently using such genetic tests, the majority of health officers (71 per cent) agreed that government agencies should provide guidelines.⁵

There are also pragmatic reasons for regulating the private sector. The unified Europe of the 1990's will exert a powerful influence on international business practices. Already evident in Europe is a strong commitment to public and private sector data (privacy) protection. Pressure is building there for non-European Community members to harmonize their data protection laws with those of EEC countries.

In European eyes, Canada fails to provide adequate private sector data protection. Companies based in Canada who wish to do business in Europe may not be able to transmit personal data out of Europe to Canada unless Canada offers equivalent private sector data protection. As an indicator of the importance of EEC data protection laws in international business, there is for the first time some suggestion even in the United States that the private sector will encourage Congress to pass privacy controls for the private sector. Thus,

private sector privacy regulation may be necessary for international competitiveness – a reversal of the thinking that privacy *intrusions* are necessary for competitiveness.

This situation could require Canada to make the private sector subject to privacy laws. Voluntary respect for individual privacy, even industry-wide voluntary codes of conduct, simply will not appease Europe.

Since this office was established in 1983, we have observed government and private sector activities that affected the privacy of Canadians. We are satisfied that the *Privacy Act*, provincial privacy laws and the *Charter* have helped to protect Canadians from prying governments.

We now recommend the next step – that the federal government explore, with the private sector and with other levels of government, the implementation of policies or laws to improve privacy protection in the private sector.

Recommendation 21

The federal government should explore, with the private sector and with other levels of government, the implementation of policies or laws to improve privacy protection in the private sector.

ENDNOTES

- (1) British Columbia, Saskatchewan, Manitoba, Newfoundland and Quebec (through the *Quebec Civil Code*).
- (2) For a study of some ethical implications related to genetics generally, see B. Knoppers, *Human Dignity and Genetic Heritage: A Study Paper* prepared for the Law Reform Commission of Canada (1991).
- (3) David F. Linowes, *Privacy in America: Is Your Private Life in the Public Eye?* (University of Illinois Press, 1989) at 31.
- (4) *Ibid.*.
- (5) U.S. Congress, Office of Technology Assessment, *Medical Monitoring and Screening in the Workplace: Results of a Survey - Background Paper*, OTA-BP-BA-67 (Washington, D.C.: U.S. Government Printing Office, October 1991) at 38.

Part V

Conclusion

The issues spawned by genetic testing do not fit neatly into the jurisdictional divisions created by Canadian constitutional law. They cross federal and provincial lines, sometimes involving the shared powers of the federal and provincial governments. Often they do not distinguish between the public and private sectors. Therefore to suggest that amendments to the *Privacy Act* alone will resolve privacy problems associated with genetic testing is simplistic.

The privacy of Canadians is protected, although incompletely, by a hodge-podge of legislation (provincial and federal), constitutional documents (the *Charter*) and common law (such as the tort of invasion of privacy, to the limited extent it may exist in Canada). Beyond that, only policies, ethics and a sense of "decency" protect our privacy. Enhancing the protection of personal genetic information may require a similarly varied approach.

In this report, we have identified the need to regulate both the private and public sectors in their handling of genetic information. There are several options for doing this, alone or in combination with others:

For federal government institutions:

- entrenching a constitutional right to privacy in the *Charter*;
- enhancing the *Privacy Act* to protect personal genetic information acquired by federal government institutions;
- specific legislation governing federal government institutions (thus overriding the general provisions of the *Privacy Act* in matters of genetics);
- encouraging policies that increase individual control over personal genetic information.

For provincial government institutions:

- entrenching a constitutional right to privacy in the *Charter*;

- enhancing provincial equivalents to the *Privacy Act* to protect personal genetic information acquired by provincial government institutions;
- specific legislation governing provincial government institutions (thus overriding the provisions of general provincial privacy laws in matters of genetics);
- encouraging policies that increase individual control over personal genetic information.

For non-government (private sector) bodies:

- enactment by provincial governments of a tort of invasion of privacy generally (four provinces have done so already) or a specific tort of invasion of genetic privacy ;
- detailed legislation limiting the use of genetic testing in the private sector (possibly a joint federal-provincial exercise);
- government encouragement of the private sector to set policies that respect individual control over personal genetic information;
- extending a constitutional right to privacy to relations in the private sector.

The recommended approaches

A single-pronged approach to resolving privacy issues relating to genetic testing will not do. We propose that federal and provincial governments and the private sector work towards the following:

(a) including explicit privacy protection, in the form of a right to privacy, in the *Charter of Rights*. An explicit constitutional right to privacy will offer both a legal and a philosophical base for protecting genetic privacy;

(b) reviewing the *Privacy Act* and strengthening its provisions. The Act must evolve, not only to protect personal genetic information, but to meet the privacy protection challenges not foreseen when it

was first enacted. Provinces with laws regulating privacy should also be encouraged to review and strengthen them;

(c) legislating to regulate specific aspects of genetic testing, such as forensic DNA analysis;

(d) legislating, adopting policies, or both, on private sector intrusions into genetic privacy; and

(e) fostering respect for genetic privacy. Restraint should be the guiding concept, even if laws otherwise permit intruding into the human genome.

Recommendation 22

Federal and provincial governments and the private sector should work towards the following:

- (a) including explicit privacy protection, in the form of a right to privacy, in the *Charter of Rights*;**
- (b) reviewing the *Privacy Act* and strengthening its provisions;**
- (c) legislating to regulate specific aspects of genetic testing, such as forensic DNA analysis;**
- (d) legislating, adopting policies, or both, federally and provincially, to regulate private sector intrusions into genetic privacy; and**
- (e) fostering respect for genetic privacy.**

Lesser measures simply will not stave off abuses of personal genetic information through genetic testing. Canadians should benefit from the immense medical promise of genetic technology, but not by sacrificing their private souls along the way.

Part VI

Summary of Recommendations

Recommendation 1

The Government of Canada should study the following:

- the extent to which government institutions and private sector organizations have collected, retained and disposed of personal genetic information, including genetic samples, and their anticipated activities in this area;
- the purposes of the collections;
- who had, has or will have access to the information or samples;
- the uses, past, present and future of the information or samples;
- the privacy protections provided or to be provided for the information or samples; and
- the situations in which the information has been, is being or will be disclosed to other persons or organizations.

Recommendation 2

Persons should have a reasonable expectation of genetic privacy. There should be no mandatory genetic testing at the behest of the state (except in strictly limited circumstances in criminal investigations) or the private sector.

Governments and the private sector should not oblige persons to learn their genetic traits or disorders.

Recommendation 3

Employers should in general be prohibited from collecting personal genetic information about job applicants or employees through mandatory or voluntary genetic screening. However, employers should be permitted to

screen employees or applicants who volunteer for the screening if the employees or applicants retain absolute control over the genetic samples and any related personal information.

Recommendation 4

Employers should in general be prohibited from collecting personal genetic information about employees through mandatory or voluntary genetic monitoring. However, employers should be permitted to genetically monitor employees who volunteer for monitoring if the employees retain absolute control over the genetic samples and any related personal information.

Recommendation 5

1. As a general principle there should be no denial of services or benefits to a person who refuses to undergo genetic testing to obtain a service or benefit. The person should be permitted to provide justifiably required information through testing other than genetic testing if he or she wishes. The person should also have the option of refusing to be tested at all, although this may result in the loss of the service or benefit.
2. The type of information gathered by service or benefit providers through genetic testing should be strictly controlled. Even if the provider can legally collect this information, no new types of information should be collected through genetic testing without a thorough review of the ethics and human rights implications of the additional collection.
3. Service or benefit providers should collect and use only the genetic information needed to tell whether the person meets the required standard.

Recommendation 6

Government institutions should generally not collect, use or disclose personal genetic information relating to the reproductive process, whether through mandatory or voluntary genetic screening.

Recommendation 7

Personal genetic information relating to reproduction that is collected by government institutions providing medical care should be used only to inform a person's own decisions about reproduction. This information should not be used for any other purpose.

Recommendation 8

Personal genetic information collected by government institutions or private sector physicians providing ordinary medical care should be used only to inform a person's own decisions about medical care. This information must not be used for any other purpose.

Recommendation 9

In criminal investigations, suspects should be compelled to provide genetic samples only if specific statutory authority, such as proposed by the Law Reform Commission of Canada, authorizes the mandatory collection.

Recommendation 10

Mandatory analysis (whether RFLP analysis or genetic screening) of a suspect's genetic sample should be limited to suggesting or confirming the identity of a suspect, or exonerating the suspect. Genetic screening should not be used to suggest psychological characteristics of the suspect.

Recommendation 11

Governments should not establish banks of genetic samples of convicted persons or the general population for criminal justice purposes. Governments

should not establish genetic databases of the general population for criminal justice purposes.

Genetic databases containing identification information about persons convicted of crimes involving serious violence should not be assembled for criminal investigations or prosecutions without

- (a) further study of the privacy and other human rights implications and
- (b) specific authorizing legislation, if the study finds the database to be acceptable.

If genetic databases are to be found acceptable, they should be used only for identification. The information contained in a genetic database and any genetic samples related to the crime should not be used to try to identify other characteristics that may have a genetic link, such as personality.

Recommendation 12

Wherever possible, genetic research should use anonymous, unlinked genetic samples or information to preserve anonymity.

Recommendation 13

Government institutions should generally collect personal genetic information only if specific statutory authority exists for the collection. This rule should apply whether the information becomes available through mandatory testing or through a person volunteering personal genetic information or volunteering to be tested.

Recommendation 14

Government institutions should tell persons why personal genetic information about them is being collected, even if they have no right under subsection 5(2) of the *Privacy Act* to be told.

Recommendation 15

A strict time limit should be placed on retaining personal genetic information (including samples), whether or not the information has been used for an administrative purpose. If information is allowed to be kept for extended periods under exceptional circumstances, extraordinary care must be taken to ensure that it is used only for purposes for which it was collected or for a consistent purpose.

Recommendation 16

To enhance the accuracy and completeness of personal genetic information and to make it as up-to-date as possible, government institutions should ensure the following:

1. Only qualified persons should conduct genetic tests and interpret test results.
2. Before "older" test results are used for an administrative purpose, a qualified person should critically reassess the interpretation of the results (and, if need be, the test process itself) to ensure that the testing method and results are supported by current medical and scientific thought. It may also be necessary to retest the subject because of the possibility of random mutations.
3. Medical or scientific explanations about or qualifications of the information generated by genetic testing should accompany the test results in a person's file.
4. If information generated by genetic testing (or the test process itself) is found to be inaccurate or outdated, a notation should immediately be entered on the affected person's file and any incorrect information corrected.
5. Uses and disclosures of personal genetic information should be recorded to make it easier to correct all files containing incorrect information.

Recommendation 17

To enhance accuracy and to meet the direct collection requirements of subsection 5(1) of the *Privacy Act*, genetic information about a person should be collected through a test of that person, not through the test of a person thought to be a genetic relative. Indirect testing should occur only if direct testing is not possible.

Government institutions collecting genetic information about a person indirectly through testing a relative should record the reasons for believing that the relative and the person are naturally related, and their relationship.

Recommendation 18

"Consistent uses" of personal genetic information under the control of government institutions should require the personal approval of the head of the institution. As a policy, the decision should not be delegated.

Recommendation 19

As a policy, the personal consent of the head of the institution should be required for disclosures of personal genetic information under paragraphs 8(2)(e) to (m) of the *Privacy Act*.

As a policy, the personal consent of the head of the institution should also be required for disclosures of personal genetic information under the second part of paragraph 8(2)(a) – disclosures for a use consistent with the purpose for which the information was obtained or compiled by the institution.

Recommendation 20

The right of access to personal genetic information should include the right of access to the genetic sample from which information was derived. The government institution that authorized the original genetic test should bear the cost of retesting requested by the person to whom the information relates.

Recommendation 21

The federal government should explore, with the private sector and with other levels of government, the implementation of policies or laws to improve privacy protection in the private sector.

Recommendation 22

Federal and provincial governments and the private sector should work towards the following:

- (a) including explicit privacy protection, in the form of a right to privacy, in the *Charter of Rights*;
- (b) reviewing the *Privacy Act* and strengthening its provisions;
- (c) legislating to regulate specific aspects of genetic testing, such as forensic DNA analysis;
- (d) legislating, adopting policies, or both, federally and provincially, to regulate private sector intrusions into genetic privacy; and
- (e) fostering respect for genetic privacy.

Appendix

Activities in Other Countries Relating to Genetic Testing

This appendix outlines some - and only some - of the approaches to genetic testing in member countries of the Council of Europe and in the United States. It refers to draft guidelines on epidemiological research prepared for a 1990 meeting of the Council for International Organizations of Medical Sciences. It also reproduces sections of a position paper on genetic testing prepared by the Council for Responsible Genetics. Beyond these national and international efforts lies an abundance of literature on various aspects of genetics. A bibliography supplied at a recent conference on the legal, ethical and social implications of the Human Genome Project lists almost 850 articles and books.¹ Most were published within the last three or four years; many dealt with genetic testing.

Council of Europe

The Council of Europe, based in Strasbourg, is an intergovernmental organization established after the Second World War. Its goal is to achieve a greater unity between democratic countries in Europe. Membership consists of all the European Community countries, the Scandinavian countries, Switzerland, Austria, Iceland, Liechtenstein, Turkey, Cyprus, Malta, San Marino and Hungary.

In June 1990, the Committee of Ministers of the Council of Europe adopted a recommendation on prenatal genetic screening, prenatal genetic diagnosis and associated genetic counselling.² The Committee recommended that member states adopt legislation to conform with the principles contained in the recommendation.

The Committee defined prenatal genetic screening in part as "screening tests carried out to identify from among the general population of apparently healthy individuals, those at risk of transmitting a genetic disorder to their

offspring" [In this report, such screening programs are called pre-conception screening].

It defined prenatal diagnosis as "tests used to confirm or exclude whether an individual embryo or foetus is affected by a specific disorder".

Among the principles (and their accompanying commentaries) of privacy interest are the following:

Principle 2: Prenatal genetic screening and/or prenatal genetic diagnosis tests undertaken for the purpose of identifying a risk to the health of an unborn child should be aimed only at detecting a serious risk to health of the child.

.....

Principle 6: Prenatal genetic screening and prenatal genetic diagnosis may only take place with the free and informed consent of the person concerned.

Special care is needed for legally incapacitated persons to ensure that they should not be denied access to prenatal genetic screening and prenatal genetic diagnosis on account of the legal incapacity and that their legal representative or an authority or a person designated under national law should be consulted on their behalf. Prenatal genetic screening or prenatal genetic diagnosis should not be carried out when the person to undergo tests objects.

Principle 7: When prenatal genetic screening and prenatal genetic diagnosis is offered routinely this by no means does away with the requirement of free and informed consent.

.....

Principle 9: In order to protect the woman's freedom of choice she should not be compelled by the requirements of national law or administrative practice to accept or refuse screening or diagnosis. In particular, any entitlement to medical insurance or social allowance should not be dependent on undergoing these tests.

Commentary on Principle 9: Principle 6 requires that the consent of the woman should be free. This free nature should not be reduced or done away with either by direct or indirect influences. Principle 9 is intended to prevent both situations which might result from particular provisions of national law or administrative practice or from conditions attached to entitlement to medical insurance or social allowance. If for instance refunding of medical expenses connected with a pregnancy of social allowances to be given to [a] pregnant woman depend upon the pregnant woman's undergoing certain prenatal tests, the free nature of the consent to undergo these tests becomes prejudiced.

Principle 10: No discriminatory conditions should be applied to women who seek prenatal screening or diagnostic testing or to those who do not seek such tests, where these are appropriate.

Principle 11: In prenatal genetic screening, prenatal genetic diagnosis or associated genetic counselling personal data may only be collected, processed and stored for the purposes of medical care, diagnosis and prevention of disease and research closely related to medical care. Such data should be collected, processed and stored in accordance with the Convention for the protection of individuals with regard to automatic processing of personal data and the Committee of Ministers' Recommendation No. R (81) 1 on regulations for automated medical data banks.

Commentary on Principle 11: Genetic data are particularly sensitive and confidentiality must be assured. It is essential that its collection should be restricted and strictly controlled. The only justification for collection and storage of these data is for medical use. Therefore the Principle restricts collection of genetic data to purposes of medical care, diagnosis, prevention of disease and research. While genetic data collected in accordance with these Principles may be used for research purposes connected with medical care, the same principle restricts prenatal screening and prenatal diagnostic testing to detection of serious diseases. Furthermore when genetic data is collected or stored for research purposes such research must be related to medical care and prevention of disease. The data subject must be informed when data is to be used for research purposes.

Long-term conservation of genetic data is justified on a number of grounds, in particular when these data concern several generations or when a disease may not appear until late in life. Particular consideration should be given to strict security systems necessitated by the long-term storage of such data.

Principle 12: Any information of a personal nature obtained during prenatal genetic screening and prenatal genetic diagnosis must be kept confidential.

Commentary on Principle 12: In order to safeguard the privacy of individuals and to take full account of the personalised nature of genetic data, geneticists and any other persons who have access to genetic data collected or stored during prenatal genetic screening or prenatal genetic diagnosis must respect their confidentiality.

Principle 13: The right of access to personal data collected pursuant to prenatal genetic screening and prenatal genetic diagnosis should be given only to the data subject in the normal manner required for personal health data in accordance with national law and practice. Genetic data which relate to one member of the couple should not be communicated to the other member of the couple without free and informed consent of the former.

Principle 14: Where there is an increased risk of passing on a serious genetic disorder, access to preconception counselling and, if necessary, premarriage and preconception screening and diagnostic services should be readily available and widely known.

Law and practice concerning genetic screening in various Council of Europe member countries

In August 1990, the Council of Europe's Ad Hoc Committee of Experts on Bioethics published a bulletin briefly outlining the genetic screening activities of various member countries.³ Most screening related to the reproductive process – pre-conception, pre-natal and neonatal.

The following country-by-country description of practices relating to genetic testing is drawn from this bulletin. Additional information about practices in

the United States is drawn from other material. There may be some lack of clarity in the information summarized from the bulletin because the contents of the bulletin itself depended on the clarity of information received from individual countries.

Given the speed with which developments in genetics are proceeding, some of the information contained below may already be outdated.

Austria

Prenatal diagnosis is generally available for pregnant women. Such procedures are not compulsory and, with the exception of ultrasonographic examinations, are not routinely administered.

Genetic examination and counseling services are funded publicly. Section 132c (1) of the *General Social Security Act* provides that prenatal diagnosis is one of the benefits rendered by the health insurance schemes. Under section 4 of the Ordinance of the Federal Minister of Health and Environmental Protection of May 20, 1981, concerning Urgent Measures for Maintaining Public Health, Fed. Law Gazette N 274/1981, the following persons are eligible for the above measures:

- 1) persons who are suspected of having a genetic disease or chromosomal anomaly;
- 2) parents who want children or where pregnancy has already commenced, if
 - a. one child or several children have already been born with a genetic disease, a chromosomal anomaly, an open neural tube defect . . . or other severe defects;
 - b. close relations or the parents themselves have a genetic disease or chromosomal anomaly or if there is suspicion of such defects;
 - c. the mother is older than 35 and the father older than 50;

- d. there have already been several miscarriages or still-births that can be explained neither gynecologically, andrologically nor endocrinologically;
- e. the partners are related by blood; or
- f. mutagenic or teratogenic defects are suspected.

There is no law concerning genetic screening in children and adults.

Cyprus

Neonatal testing is carried out for phenylketonuria and hypothyroidism. These tests are done as part of a program to prevent mental defects. All newborn infants are tested. The test is done free of charge at one private centre financed by the government of Cyprus. Counselling of the parents about the purpose and benefits of the test is invariably done before the test is carried out.

A national registry for malignant tumours is in the process of being established. When ready, surveillance of families at risk for hereditary malignant tumours will be possible.

Screening for thalassemia also occurs.

Denmark

Specific rules about screening pregnant women and newborn children are contained in 1985 guidelines from the National Board of Health. These guidelines treat the question of hygiene during pregnancy and birth-assistance. During the pregnant woman's first health analysis, health care providers try to determine if the family has hereditary diseases which "necessitate" proper genetic analysis.

Finland (has observer status with the Council of Europe)

A Bill on Patient's Rights has been prepared by the Ministry of Social Affairs and Health.

The Committee on Legal Protection in Health Care proposed in 1983 that a bill on patients' rights be introduced in the Parliament. Some, including the medical profession, opposed the bill. Time seems to have worked in favour of the bill and now a slightly modified version has been prepared and circulated for comments. The bill was to have been debated in Parliament in the autumn of 1990 [the report does not state whether the bill was in fact debated].

The bill deals with several issues, including:

- patient's admission to health care
- patient's right to appropriate care and treatment
- patient's right to information
- patient's right to self-determination
- protection of privacy
- a special method for appeals
- founding of a system of patient ombudsmen, who would give information about patients' rights and assist patients in making appeals.

There is no law concerning genetic screening carried out on children and adults. The only "genetic screening" of children is that for hypothyresis in newborns.

Federal Republic of Germany

In the Federal Republic of Germany there is widespread discussion about the use of methods of genetic diagnosis (genome analysis) in very different areas of application. While, on one hand, Germans do not want a legal vacuum to emerge in this field, they also do not want to unduly restrict research. So far there are no specific legal regulations on the use of human genome analyses in the Federal Republic.

(i) Screening of newborns

To date, the mass screening of newborns sponsored by government or paid for by health insurance has been restricted to metabolic disorders where early treatment can prevent an outbreak of the disease or where severe consequences can be avoided or diminished (cystic fibrosis, phenylketonuria, galactosaemia, hypothyresis). Medical legislation requires the consent of the parents for these tests. Until now it was assumed that the general consent of the pregnant woman (or future parents) to diagnostic measures carried out on their child also included the above mass screenings.

(ii) Employees

Experts start from the assumption that the predictive value of DNA analyses in employment is low. Accordingly, its application is not yet important in Germany. To date, genome analysis has been important only for the following hereditary diseases and predispositions: N-acetyl-transferase-polymorphism; glucose-6-phosphate dehydrogenase deficiency; and alpha-1-antitrypsin deficiency.

(iii) Insurance

The insurance industry is at present still "reserved" about DNA analysis. The question of the extent to which and under what restrictions testing should be used is still under discussion.

(iv) Genetic analysis for use in court

"DNA fingerprinting" is used to evaluate biological traces (blood, secretions and hair) as an additional investigative method in criminal proceedings. Various courts (higher regional courts and regional courts) have approved of the use of genetic fingerprints as admissible evidence under the current laws on criminal procedure.

To clarify the law, however, a legal basis should be established for DNA fingerprinting. The prerequisites and restrictions connected with the implementation of the technique would be clearly stated in the *Code of Criminal Procedure*. To this end, the federal Minister of Justice has submitted a

discussion draft of a regulation on genetic fingerprinting. This is currently being considered.

The current *Code of Civil Procedure* does not contain any explicit provisions about the admissibility and suitability of DNA fingerprinting as evidence. In civil proceedings, the new investigative method can mainly be used to determine family relationships (for example, paternity). Whether the use of DNA fingerprinting for this purpose is permissible under current law must still be thoroughly researched. In practice, DNA fingerprinting has not yet gained considerable importance in civil court proceedings.

Greece

All newborns are examined for phenylketonuria, G-6-Pd deficiency and congenital hypothyroidism. If there is a problem, counselling is offered. Parents respond very positively, follow the doctors' instructions and go regularly to Athens for the follow-up, even if they live in remote parts of the country.

Voluntary examination for the detection of carriers of various heterozygous hemoglobinopathies is offered to everybody.

Other genetic tests (e.g. karyotypes) may be performed on single persons or members of a family when there is a problem.

Italy

As yet, there no one national law on genetic screening. However, the majority of the regions have passed regional laws about screening for genetic-metabolic diseases.

The Ministry of Health is now considering a national law that will provide for mandatory screening.

Selective screening for families at risk is provided for progressive muscular dystrophy, certain metabolic diseases, haemophilia, polycystic kidney disease, ataxia-telangiectasia, galactosaemia, cystic fibrosis and thalassemia.

Luxembourg

Genetic testing itself is not regulated. Luxembourg's current law on abortion prohibits it in principle. However, it may be permitted in certain cases, notably where a serious risk exists that the child will be born with a serious malady, physical deformity or mental disability.

Switzerland

Newborns have been screened since 1965.

Turkey

In the seven (university) centers located in the largest cities, the main service offered is post-natal chromosome analysis. In one, some metabolic screening is also carried out. All try to give genetic counselling and diagnosis of genetic diseases. So far, there is no one trained in clinical genetics, and patients are treated in other clinics, such as endocrinology, gynecology and pediatrics.

In Turkey there is no experience with mass screening for carrier status of common diseases, but neonatal screening for metabolic disorders has been carried out in a faculty in Ankara. There is a need for legislation to protect children and adults against abuses in human genetics. One of the problems might be sex selection, which attracts many because of the general tendency to prefer male children in the country.

United Kingdom

There are no statutes with regard to genetic screening of children and adults. The practice of genetic screening of children and adults is largely for the medical profession to determine on the basis of scientific evidence. It is for

the practitioner and the individual concerned to discuss whether and what types of screening should be offered depending on the circumstances and the risks and benefit of the particular test to be used. Guidance is available both from departmental and professional sources – for instance the medical Royal Colleges and professional societies. For some conditions national screening programmes are arranged through the National Health Service. However screening is arranged it would be for individuals to decide whether to consent to participate on the basis of professional advice.

United States

There are a multitude of studies and laws dealing with genetic testing in the United States. [Some have been discussed elsewhere in this report.]

Screening during reproduction: All 50 states routinely screen all newborn infants for PKU and hypothyroidism. Many screen for sickle cell diseases as well. Until recently, parental consent was not requested, but now a few states require seeking consent.

With many persons starting to offer screening for cystic fibrosis, the National Institutes of Health convened an expert panel to consider the issue and provide advice. The panel noted that the current test identifies only about 70 per cent of patients or carriers and that tests to detect the other 30 per cent are expected in the next two years. Accordingly, the panel recommended against routine screening of pregnancies or for carriers at this time, and that the present test be used for prenatal diagnosis only when there is a family history of the disease.⁴

Sickle cell anemia was the focus of considerable attention in the United States in the 1970s. At least 20 states eventually passed laws requiring sickle cell screening. These laws were aimed at newborns, schoolchildren, marriage licence applicants and prison inmates.⁵ In some cases, testing led to discrimination by employers and insurers, prompting laws in some states prohibiting discrimination on the basis of sickle cell disease or sickle cell trait. Since the mid-1970's many state laws requiring sickle cell screening have been repealed.⁶

Genetic privacy: One bill directed at protecting the privacy of personal genetic information warrants specific mention.

In September 1990, Bill H.R. 5612 – the *Human Genome Privacy Act* – was introduced in the House of Representatives. The bill proceeded no further. However, on April 24, 1991, a modified version of the bill was introduced as H.R. 2045. The more recent bill is virtually identical to H.R. 5612, except that it does not contain certain enforcement sections contained in the earlier bill.

Sec. 2.(b) of H.R. 2045 describes its purpose:

- 2.(b) The purpose of this Act is to provide an individual with certain safeguards against the invasion of personal genetic privacy by requiring agencies, except as otherwise provided by law, to –
 - (1) permit an individual to determine what records pertaining to him or her are collected, maintained, used, or disseminated by such agencies;
 - (2) permit an individual to prevent records pertaining to him or her obtained by such agencies for a particular purpose from being used or made available for another purpose without his or her consent;
 - (3) permit an individual to gain access to records, to have a copy made of any or all portion thereof, and to correct or amend such records;
 - (4) collect, maintain, use, or disseminate any record of identifiable personal genetic information in a manner that assures that the information is current and accurate for its intended use, and that adequate safeguards are provided to prevent any misuse of such information;
 - (5) permit exemptions from the requirements with respect to genetic records maintained anonymously for research purposes only; and

- (6) be subject to civil suit and criminal penalties for any damages which occur as a result of negligent, willful, or intentional action which violates any individual's rights under this Act.

The proposed law would protect genetic information about living individuals only.⁷ It defines genetic information as "any information that describes, analyses, or identifies all or any part of a genome identifiable to a specific individual".⁸

The law would generally not apply to the private sector. It would restrict the actions of "agencies" of the U.S. federal government only. "Agency" is defined as "any executive department, military department, Government corporation, Government controlled corporation, Government contractors, or Government grantees maintaining genetic information pursuant to Federal contracts and/or grants or other establishment in the executive branch of the Government (including the Executive Office of the President), or any independent regulatory agency".⁹

Council for Responsible Genetics

The Council for Responsible Genetics is based in Boston. It is a national organization of scientists, public health advocates, trade unionists, women's health activists and others. The following excerpts are taken from a statement prepared by the Council's Human Genetics Committee.¹⁰ Although the analysis in the statement appears to be based primarily on American law, many of the issues apply equally to genetic testing in Canada.

As [genetic] tests become simpler to administer and their use expands, a growing number of individuals will be labelled on the basis of predictive genetic information. This kind of information, whether or not it is eventually proved correct, will encourage some sectors of our society to classify individuals on the basis of their genetic status and to discriminate among them based on perceptions of long-term health risks and predictions about future abilities and disabilities. The use of predictive genetic diagnoses creates a new category of individuals who are

not ill, but have reason to suspect they may develop a specific disease some time in the future: the healthy ill.

.....

[Employment testing] Basing employment decisions on genetic status opens the door to unfounded generalizations about employee performance and increases acceptance of the notion that employers need to exercise such discrimination in order to lower labor costs.

.....

The need for laws to protect the privacy of genetic information can be illustrated by the secrecy with which employers may use medical information.... Although it might be possible to challenge an employer's hiring practices which discriminate on the basis of medical status, it is very difficult to document such discriminatory practices.

.....

[Insurance testing] Insurers also face strong economic incentives to identify individuals perceived to be at increased risk for ill health in the future.

.....

Without legislation mandating that all insurers cover populations at risk without discrimination, those who do provide comprehensive coverage are at a financial disadvantage.

.....

Data banking increases the risk that genetic information will be used in ways that violate individual privacy and encourage irresponsible genetic epidemiology. To examine the full impact of genetic data banking we need to answer three questions: (a) What information is stored; (b) who has access to the information; and (c) how can such information be used?

Council for International Organizations of Medical Sciences (CIOMS)

CIOMS operates under the auspices of the World Health Organization and UNESCO. Its predecessor was formed in 1949, and CIOMS took its present name in 1952. Its goals include promoting international activities in the field of medical sciences and serving the scientific interests of the international biomedical community in general.

CIOMS is at present developing guidelines for ethical review procedures for epidemiological research and practice. The CIOMS Steering Committee completed its final draft, *International Guidelines for Ethical Review of Epidemiological Studies*, in 1991. The guidelines address privacy concerns in part and will be relevant for epidemiological research in many fields, including genetics and genetic testing.

The reader will see that one major ethical concern is how to avoid stigmatizing groups through epidemiological research.

I. Introduction

1. These Guidelines are intended for the guidance of investigators, health policy-makers, members of ethical review committees, and others in dealing with ethical issues that arise in epidemiology. They may also assist in the establishment of standards for ethical review of epidemiological studies.
2. The Guidelines are an expression of concern to ensure that epidemiological studies observe ethical standards. These standards apply to all who undertake any of the types of activity covered by the Guidelines. Investigators must always be held responsible for the ethical integrity of their studies.
3. Epidemiology is defined as the study of the distribution and determinants of health-related states or events in specific populations, and the application of this study to control of health problems.

IV. Ethical Principles Applied to Epidemiology

.....

3. Minimizing Harm

3.1 Causing harm and doing wrong

Investigators planning studies will recognize the risk of causing harm, in the sense of bringing disadvantage, and of doing wrong, in the sense of transgressing values.... It is wrong to regard members of communities only as impersonal material for study even if they are not harmed.

.....

Ethical review [of epidemiological studies] must always assess the risk of subjects or groups suffering stigmatization, prejudice, loss of prestige or self-esteem, or economic loss as a result of taking part in a study. Investigators will inform ethical review committees and prospective subjects of perceived risks, and of proposals to prevent or mitigate them. Investigators must demonstrate that the benefits outweigh the risks for both individuals and groups.

.....

3.2 Preventing harm to groups

Epidemiological studies may inadvertently expose groups as well as individuals to harm, such as economic loss, stigmatization, blame, or withdrawal of services. Investigators who find sensitive information that may put a group at risk of adverse criticism or treatment should be discreet in communicating and explaining their findings. When the location or circumstances of a study are important to understanding the results, the investigators will explain by what means they propose to protect the group from harm or disadvantage; such means include provisions for confidentiality and the use of language that does not imply moral criticism of subjects' behaviour.

3.3 Harmful publicity

Conflict may appear between, on the one hand, doing no harm and, on the other, telling the truth and openly disclosing scientific findings. Harm may be mitigated by interpreting data in a way that protects the interests of those at risk, and is at the same time consistent with scientific integrity. Investigators should, where possible, anticipate and avoid misinterpretation that might cause harm.

.....

4. Confidentiality

Research may involve collecting and storing data relating to individuals and groups, and such data, if disclosed to third parties, may cause harm or distress. Consequently, investigators should make arrangements for protecting the confidentiality of such data by, for example, omitting information that might lead to the identification of individual subjects, or limiting access to the data, or by other means. It is customary in epidemiology to aggregate numbers so that individual identities are obscured. Where group confidentiality cannot be maintained or is violated, the investigators should take steps to maintain or restore a group's good name and status.

Information obtained about human subjects is generally divisible into:

Unlinked information, which cannot be linked, associated or connected with the person to whom it refers; as this person is not known to the investigator, confidentiality is not at stake and the question of consent does not arise.

Linked information, which may be:

- anonymous, when the information cannot be linked to the person to whom it refers except by a code or other means known only to that person, and the investigator cannot know the identity of the person;
- non-nominal, when the information can be linked to the person by a code (that does not include personal identification) known by the person and the investigator; or
- nominal or nominative, when the information is linked to the person by means of personal identification, usually the name.

Epidemiologists discard personal identifying information when consolidating data for purposes of statistical analysis. Identifiable personal data will not be used when a study can be done without personal identification - for instance, in testing unlinked anonymous blood samples for HIV infection. When personal identifiers remain on records used for study, investigators should explain to review committees why this is necessary and how confidentiality will be protected. If, with the consent of individual subjects, investigators link different sets of data regarding individuals, they normally preserve confidentiality by aggregating individual data into tables or diagrams. In government service the obligation to protect confidentiality is frequently reinforced by the practice of swearing employees to secrecy.

ENDNOTES

- (1) The bibliography was supplied with materials assembled by the Health Law and Policy Institute of the University of Houston for a conference entitled "Legal and Ethical Issues Raised by the Human Genome Project". The conference took place in Houston, March 7 - 9, 1991. The bibliography, dated February 14, 1991, was compiled by Michael S. Yesley of the Los Alamos National Laboratory.
- (2) *Recommendation No (90) 13 of the Committee of Ministers to Member States on Prenatal Genetic Screening, Prenatal Genetic Diagnosis and Associated Genetic Counselling* (adopted by the Committee of Ministers on 21 June 1990 at the 442nd meeting of the Ministers' Deputies); contained in Council of Europe, Ad Hoc Committee of Experts on Bioethics (CAHBI), *Information Document: Prenatal Genetic Screening, Prenatal Genetic Diagnosis and Associated Genetic Counselling* (Strasbourg, 30 July 1990. Document reference: ACAHBIINF903).
- (3) Council of Europe, Ad Hoc Committee of Experts on Bioethics (CAHBI), *News on Bioethics* No. 1 (1990) (Strasbourg, August 29, 1990. Document reference: ACAHBIINF904).
- (4) Council of Europe, Ad Hoc Committee of Experts on Bioethics, *supra* note 3 at 21-22.
- (5) U.S. Congress, Office of Technology Assessment, *Genetic Monitoring and Screening in the Workplace*, OTA-BA-455 (Washington, D.C.: U.S. Government Printing Office, October 1990) at 41-42.
- (6) *Ibid.* at 42.
- (7) Sec. 101.(3) defines "individual" to mean a living individual.
- (8) Sec. 101.(2). This definition would appear **not** to include the actual sample of genetic material as "genetic information".
- (9) Sec. 101.(1).
- (10) The entire statement is reproduced in *Issues in Reproductive and Genetic Engineering*, Vol. 3 (1990) at 287-295.