THE CHALLENGES OF GENETIC INFORMATION

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Summary

Genetic information shares many characteristics with other types of health information. Therefore, in dealing with the emerging concerns regarding genetic information, the first question policy makers need to address is the way in which genetic information is unlike other health information, posing problems that require a unique regulatory response. The combination of the following three elements constitutes the primary reason why we have to develop appropriate regulatory measures or adapt existing ones to deal specifically with the challenges of genetic information: the volume of information that can be extracted from one sample; the speed of testing; and its link with computer technology. These features do not raise new concerns so much as augment traditional concerns regarding the uses of health information. But even if these concerns are not in themselves new, the new contexts in which they are raised may require different types of responses, or additional responses, than those pertaining to more traditional health information.

1. Introduction

The futuristic movie GATTACA pictures the struggle of a 'genetic proletarian,' born out of a stubborn mother who refused to abort her genetically inferior fetus, towards the fulfillment of his life-dream of becoming a cosmonaut. In order to do so, he has to cheat the genetically monitored GATTACA society that performs regular DNA testing to systematically screen out people of his kind from any reasonable job and from insurance coverage. One of the scenes of the movie portrays the activities of a local "gene shop." Clients of this shop have a mouth swab to recuperate DNA traces of the person they just dated and kissed. The gene shop conducts a computerized DNA analysis on the spot, providing a summary genetic portrait of the potential partner they just 'caught.' On a one-page summary, clients get basic information about the person's behavioral traits, life-expectancy and potential progeny.
Obviously, a simple mouth swab and DNA analysis based on saliva currently cannot give us such detailed information and certainly not in a time span of three minutes, as suggested in the movie. Also, several scientific hurdles have to be overcome before we will be able to conduct simultaneous, and affordable, tests for a variety of conditions and traits. But even though the gene-shop scene is very much a caricature of genetic testing, it provides a strong metaphor both for what type of issues are likely to be raised by genetic testing and for why we have to be concerned about the social consequences of unbridled use by third parties. Research into the development of DNA chip and microarray technology is already taking place and in the near future will likely allow us to scan entire genes for the detection of a variety of mutations. Genetic tools will become faster, more efficient, and cheaper.

In this chapter, we will argue that the combination of the following three elements constitutes the primary reason why we have to develop appropriate regulatory measures or adapt existing ones:

- the volume of information that can be extracted from one sample;
- the speed of testing; and
- Its link with computer technology.

These are the main reasons, we argue, why genetic testing, if inappropriately used, can have detrimental social consequences. Other characteristics have been identified as making genetic information 'unique', but we will argue that many other types of health information share these characteristics. However, when combined with the three factors we identify, many of our traditional concerns regarding health information are augmented. In other words, the concerns raised by the advent of genetic testing are related more to what one can call an amplification of existing concerns about the use of health information than to the specificity of genetics. It is a matter of degree, or depth, more than a matter of newness. But even if these concerns are not in themselves new, the new contexts in which they are raised may require different types of responses, or additional responses, than those pertaining to more traditional health information.

This chapter aims at identifying the relative specificity of genetic information and analyzing the arguments invoked to support specific regulation and legislation that singles out genetics.

2. What is genetic information?

It is difficult to analyze the use of genetic information in a comprehensive manner without treating genetic information as a one-dimensional concept. However, one always has to keep in mind that genetic information can be obtained in a variety of ways and can refer to very different forms of health information. The genetic information referred to in this chapter is generally the information resulting from genetic research undertaken with new genetic technology developed in the last decades and that has led to the identification of specific associations between genes and genetic diseases and traits. It is this relatively new form of genetic information that much of the debate about the potential negative social impact of genetic testing focuses on. But the term genetic information also includes family history of disease, information from chromosomal testing and data gathered from twin studies, for example, all which have been used in research and in health care for the most part of the last century without receiving the same attention. In the debate over what constitutes genetic information, some even point out that all health information is to some extent genetic.

Any type of regulation or legislation developed in the context of genetics will have to be attentive to the problem of defining what constitutes genetic information and how one can distinguish in fact, and as a matter of principle, the different types of genetic data. In order to highlight this problem, we will enumerate here some of the major differences between types of genetic information arising from the type of testing, the purpose and manner of collection of the information or sample, and the method of storage.

2.1 DNA Testing

In most current discussions, genetic information is understood as information resulting from the analysis of an individual's DNA. Startling developments in molecular genetics and DNA technology (closely linked also to developments in computer technology) over the last decades are directly responsible for what has been termed 'the genetic revolution'. When people talk about 'genetic information,' they are most likely thinking of information derived from the use of this new technology. Through the use of a variety of techniques such as electrophoresis, somatic cell hybridization, cytogenetic mapping, multiplexing, and radiation-induced breakage of chromosomes, scientists have been able to make physical maps of the human genome. The physical maps portray the position, size, order and numbering of base pairs in the different genes. Comparison of the maps of different people allows researchers to find specific mutations associated with genetic conditions or traits. Even when the mutation directly related to a genetic condition has not been identified, DNA techniques can be used to find markers for the disease. Markers are characteristic DNA sequences that enable scientists to determine whether a mutation present in that DNA region has been inherited or not. A variety of tests have been developed on the basis of these techniques. Currently available DNA-based genetic tests include tests for: Amyotrophic lateral sclerosis (Lou Gehrig's disease), Alzheimer disease, ataxia telangiectasia, inherited breast and ovarian cancer, Cystic Fibrosis, Duchenne muscular dystrophy, fragile X syndrome, Huntington's disease, myotonic dystrophy, sickle cell disease, thalassemia, Tay-Sachs disease and many other conditions.

2.2 Indirect Genetic Testing

Although some of the most spectacular advances in medicine have been obtained by DNA analysis, other forms of testing can clearly be identified as 'genetic tests.' The identification of phenotypic characteristics associated with genetic conditions such as cleft palate or Spina Bifida, for example, is a form of genetic testing. Testing can also occur at the chromosomal level. Chromosomal abnormalities can be detected, for example, through amniocentesis. Other forms of 'genetic tests' involve the testing of urine, blood or other body fluids to discover abnormal metabolite levels that are indicators of genetic disorders such as phenylketonuria (by measurement of phenylalanine in blood) or Lesch-Nyhan disease (by identification of high urinary uric acid levels). Finally, genetic disorders can be detected through measuring proteins, which are the products of genes. Defective genes often lead to identifiable deficiencies in protein production. The observation of mutant proteins can be used as a measurement to determine the presence of a genetic condition such as Tay-Sachs.

2.3 Family History

For a very long time, people have been aware of the fact that diseases are 'running in families' and have been involved in studying the familial character of diseases. Not only family physicians, but also interested third parties such as insurance companies have been aware of this and have been collecting information on people's family history of disease. Indeed, from time immemorial people have talked about people having a disease 'running in the family.' The history of behavioral genetics contains a remarkable example of a lay person's contribution to genetic research. The first association of a particular gene with a tendency to violence was established with crucial help from detailed records of a Dutch family's history of crime and violence, kept by one member of that family. Clearly, family history of disease is genetic information that can lead to the identification of 'at risk families', in which all members are identified at increased risk for developing certain conditions. For example, breast cancer, Huntington's disease, Tay Sachs, and some mental illnesses, have all been 'running in families' and people identified as members of these families have both benefited from knowing this (e.g. for making life choices, taking preventive action if possible, improved monitoring) as well as been harmed by it (e.g. being excluded from insurance, discriminated in employment, being stigmatized as members of diseased families, suffering emotionally).

2.4 Differentiation of Genetic Testing According to its Health Care Purpose and its Timing

Genetic testing can be differentiated according to why it is used in health care and at what stage.

- **Pre-natal diagnosis**

This is genetic testing that is being conducted before birth to determine whether a foetus is affected by or at risk for having a genetic disorder.

- **New-born screening**

New-born screening focuses on the identification of metabolic disorders in neonates, for which early treatment may be crucial to reduce the progression of the disease. New-born screening exists for a variety of conditions such as phenylketonuria, galactosemia and homocystinuria.

- **Pre-symptomatic testing**

This is carried out on healthy individuals to determine whether they carry a genetic mutation that increases their likelihood of developing a genetic condition. It aims at determining people's future health risks, and generally does not relate to their present health status. The predictive character of the tests will vary according to the type of disorder tested for, but the term pre-symptomatic testing is generally used for more 'determinant,' late-onset genetic conditions. These are the traditional conditions in which a positive test result indicates a very high likelihood of future illness. A paradigm example is Huntington's disease, a dominant, single-gene disorder.

- **Diagnostic genetic testing**

In its strictest sense this form of testing aims at confirming a particular diagnosis through a genetic test. Lesch-Nyhan disease, for example, can be diagnosed by conducting an enzyme assay. Conducting a genetic test likely will become a standard part of many diagnoses. In the domain of mental health care, for example, there is an expectation that genetic research will promote more accurate diagnosis and better treatment targeted at subcategories of mental health disorders that are currently not clearly discernible because of the lack of precise clinical tools.

It is important to note that genetic research and diagnostic genetic testing may impact on the typology of a disease. For example, new research indicates that some people who carry the cystic fibrosis gene may have none of the most severe expressions of the disease. It shows that some mutant genes tend to be not associated with the traditional pulmonary disease of CF (i.e. early onset of progressive bronchiectasis). However, people having the mutant gene may suffer from related health problems also associated with cystic fibrosis such as pancreatitis and reproductive problems, in particular in the form of absence of vas deferens in men. These men might previously not have been diagnosed as having cystic fibrosis. With the advent of genetic testing, a specific genetic cause of their infertility or pancreatitis can be established. Genetic testing can thus have a profound impact on the diagnosis of health problems.

It should be said that the term genetic diagnostic test is also used more broadly to define all genetic tests aiming at the identification of the 'genetic status' of specific individuals, as contrasted with genetic screening.

- **Genetic screening**

This refers to those tests that are conducted on populations with the aim of determining which individuals are sufficiently at risk of having a specific disorder so that further, more specific testing should be undertaken. These tests therefore must be sufficiently specific to allow some form of definite diagnosis, including genetic diagnosis, that may

warrant therapeutic intervention. This would include, for example, pre-symptomatic testing such as BRCA1&2 testing, which may be the basis for a decision to undergo a preventive mastectomy.

- **Carrier testing**

This is conducted to find out whether a person is carrying one copy of a recessive genetic disorder. Carrier testing can assist couples in making reproductive decisions, since it allows them to determine the risk that their offspring will inherit two copies of a mutant gene and thus be at risk for developing the condition.

- **Susceptibility testing**

This can refer to testing that leads to the identification of a genetic mutation that makes people more susceptible to developing a disease when exposed to certain environmental hazards. For example, certain tests can identify those people who carry the gene for ataxia telangiectasia. They are more likely to develop cancer when exposed to high levels of radiation. This form of susceptibility testing will likely become a focus of debate in the context of employment. Susceptibility testing has also been used to refer to detecting genetic mutations that indicate an increased likelihood of developing a condition such as Alzheimer's. The difference with pre-symptomatic genetic testing would consist here of the lower level of predictability. Finally, susceptibility testing can also refer to tests that can identify whether a person is more likely either to respond well to particular drug treatments, or to suffer from more severe side-effects. This form of susceptibility testing is related to a new area of research, pharmaco-genomics, which offers prospects of more individually tailored drug treatments.

2.5 Identification Purposes: Forensic DNA and Military DNA banks

DNA is now widely used to identify tissue samples such as hair, skin particles, blood and so on, left at the scene of a crime or found attached to clothing, vehicles or other instruments used by potential suspects. The technique used to match the DNA of these samples with the DNA of identified suspects or victims is different from DNA sequencing undertaken for health care purposes. It is also unlikely that tissue or samples from a crime scene could be used to identify genetic traits or conditions. The way these samples are collected, and the often minimal amount of usable DNA that is discovered in this way makes these samples unfit for uses other than identification. Issues raised by the use of forensic samples are therefore often very specifically connected to criminal law and evidence. Nevertheless, while crime scene samples may not be fit for uses other than mere identification, law enforcement agencies have started to establish DNA banks of convicted offenders, missing persons and unsolved cases as well as population frequency databases for comparison. Samples in these databases, collected in more clinically reliable circumstances, could be used for further testing. For the same purposes of potential identification, the United States military is now one of the largest collectors of DNA samples.

Although genetic testing is often conducted on samples that are collected for the purpose of a specified test, genetic information can also be extracted from sources that

were not provided with that aim. A couple of different scenarios are worth pointing out:

- **Guthrie blood spots**

Across Canada, Guthrie spots have been collected from generations of new-borns. These spots of dried blood, obtained through a little foot-prick at birth, are an excellent source of DNA. Most people are unaware that in many provinces, the cards containing these spots have been kept indefinitely and that this means that others do have a potential DNA profile of them.

- **Private DNA banks**

Many research centres and increasingly also private laboratories and pharmaceutical companies are setting up DNA banks. The samples in these banks are sometimes originally collected as anonymous samples, or are anonymized after collection. However, this does not mean that it would be impossible to connect these samples to their originators or family members, as we will discuss later. Other samples remain identified and are connected to clinical files for further research purposes.

- **Family DNA storage**

Several laboratories, hospitals and research centres offer, for payment, storage services for DNA of deceased family members. DNA stored this way can be helpful for family members who may later be interested in having an assessment of specific familial risks or may want to participate in genetic research.

- **Insurance companies**

As mentioned earlier, insurance companies have traditionally been involved in gathering information on family histories of disease. This information is kept on file and some of the information is shared with the Medical Information Bureau, a non-profit association to which more than 700 American and Canadian insurance companies subscribe. When people sign a waiver of confidentiality on an insurance application, it generally gives insurance companies the explicit right to share information with the MIB. The MIB does not store complete medical records, nor does it keep very detailed medical information on individuals. It does, however, register applicants with personal information and with a three-digit code that identifies medical factors which could affect insurability. Some state that the MIB records whether insurance has been denied, while others refute this claim. While detailed genetic information will not be kept by the MIB, clusters of diseases will be represented by general codes. For example, sickle cell, thalassemia and iron deficiency, will all fall under the code which represents 'anemia'. Huntington's disease will be classified as "a disorder of the nervous system." Insurance companies have also been involved in conducting HIV/AIDS testing. It does not seem impossible that they could develop an interest in obtaining blood samples and in keeping blood samples on file for purposes of risk assessment. In a way, a small blood sample would be a very concentrated source of health information that could be consulted when claims for payment are made.

- **Immigration**

Although there are no reports of immigration services using or keeping the results of specific genetic tests on file, some form of genetic information may be part of the health files of people who applied for landed immigrant status. Considering the highly predictive nature of some genetic tests and the potential implications for future health care costs, it does not seem implausible that some would defend the use of genetic testing in the context of immigration and the storage of DNA. Similar proposals have been made with respect to HIV/AIDS testing but are hopefully shelved after vocal criticism by various groups. Genetic testing has been used in immigration cases to determine parental links.

- **Employment**

In the context of employment, there are no reports of systematic compilation or use of genetic information, but it seems plausible that some genetic information may already be part of health files of employees. In the future, the further development of employment related genetic tests may push occupational health agencies and employers to store genetic information on individual employees.

2.6 Genetic Information Distinguished According to the Way it is Stored

Genetic information can also be distinguished on the basis of the way it is kept and expressed. As already suggested, genetic information can be contained in a blood sample, which then has to be further analyzed in order to release any of its secrets. Forensic DNA can be retraceable from objects, tissue or hair samples collected at crime scenes and stored by law enforcement agencies. Genetic information such as gene sequences can be available on paper or on computer files. It can be kept as a printout of a strip of DNA. Or it can be written out in the format of the sequences containing the four letters representing the chemical compounds that make up DNA. A family linkage study can be expressed in the form of a family diagram. Finally, results of genetic tests can be written down in medical files.

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