THE RIGHT TO GENETIC DISOBEEDIENCE: THE ICELAND CASE

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On 17 December 1998 the Icelandic Parliament (Althingi), by 37 votes out of 63, passed a law authorizing the collection and processing of the medical and genetic data of the entire population of the island by private profit-making companies. Behind the general and abstract wording of the licence granting procedure there is a very clear situation: the deCode genetics firm, set up with the help of U.S. capital by the Icelandic geneticist Kari Stefansson and which has already signed a deal for the use of research results with the pharmaceutical firm Hoffman-La Roche, which aims to develop and place on the market medicines for the treatment of twelve common diseases. This law merely has the appearance of a general piece of legislation but is in reality a very particular measure. And, reflecting on this well, it could not be otherwise, given that all the medical records of Iceland are a non-renewable single good.

Under the project all Icelandic hospitals and treatment centres will be connected to a single network which links up to a central computer. All data collected by doctors from their patients will flow into this database as well as all the data already amassed on the deceased population (which have been available in detailed form for the last few decades at the public health service), genealogical data kept for a long time at churches scattered over the country and data on blood and tissue samples. deCode genetics will buy the right to use the data stored in the database for twelve years for profit making purposes. For its part, it must bear the costs of data collection and database construction, pay the Icelandic authorities the costs for preparation of the licence and a yearly fee for its application, including the work of the Ethical Committee and any access of the Health Minister to the database. The 270.000 inhabitants of Iceland are a source of great interest to geneticists since they all descend from one single progenitor group which settled on the island around 1000 years ago. As there has been very little contact with other peoples, strong homogenous characteristics have been preserved. Human groups with strong common characteristics, “original populations” or “historically interesting isolated peoples” are the subject of study in order to be able to understand the development and genesis of common diseases and develop gene therapies.

The novelty in the Icelandic case lies not in the interest of geneticists nor in the collection of data by means of information technology but in the absolutely unheard of fact that a sovereign parliament has authorized a private firm to collect all data on the medical history and biological constitution of its own citizens, to process it and to use it for profit-making purposes with a virtually total exclusive right. The affair has given rise to an extremely heated debate both on the island and throughout the world.

Supporters of the project, first of all deCode genetics, and, in a “highly incestuous way”, the Icelandic government, argue that the database will benefit medical research with the discovery of new genes and therapies and that the method of collection complies with international data protection law. They further maintain that Icelandic scientific research and, in general, employment on the island will benefit.

The front of opponents is gathered together in MANNVERND, an organization which may be found on the WEB as the Association of Icelanders for Ethics in Science and Medicine. It is fighting against a law which it considers
an attack on human rights, privacy and ethical, scientific and commercial standards.

Numerous doctors have formally declared that they will not collaborate with the database. The Icelandic Medical Association (IMA) has opposed the project right from the start and, in its congress of October 1999, denounced the violation both of the principle of informed consent and of the trust between doctors and patients and vindicated the duty of doctors to ensure that these laws are respected. The World Medical Association (WMA) has sided with the Icelandic doctors, drawing irritated reactions from the Health and Social Security Minister. Anders Milton, WMA spokesperson, has denounced inadequacies in the coding system since the collection of a great mass of information on a limited number of people, as are the inhabitants of the island, does not rule out the possibility that individuals could be identified. Furthermore, even an individual refusal to supply data only stops the entry of new data and not the handling of data already on the database.

The authoritative geneticist Richard Lewontin, in his significantly entitled article “People Are Not Commodities”, which appeared in The New York Times on 23 January 1999, and in other papers of his raises numerous criticisms. Firstly, there is “an immense gap between what the public has been told about the database and its reality, a gap large enough to be visible even from thousands of miles away”. The informed consent procedure is a complete reversal of the standard demanded in medical research. Here it is not the person who asks for the data who must obtain consent but the individual who has the burden of requesting exclusion from the database, receiving no explanation of the uses to which these data may be put, so much so that it may be predicted that only “politically sophisticated” Icelanders will demand exclusion. The rhetoric on Icelandic nationality spouted by deCode genetics and its founder, Kari Stefansson, is also misleading given that the company was set up with the capital of U.S. firms. Lewontin finally criticizes the information monopoly logic which limits the access of scientists and health institutions, the secret contracts, the conflicts of interest and asks that Iceland be boycotted and excluded from international scientific cooperation.

In the autumn of 1999 the first acts for the preparation of the agreement, i.e. the access of deCode genetics to the data of 30 patients at Reykjavik hospital without their consent, provoked strong reactions from some Members of Parliament and the Director General of Public Health. They invited the government to revise its decision. Some private citizens have already warned the hospital against giving third parties their data, threatening to remove the data from the hospital.

**An Impossible Privacy**

The Iceland case, the only one of its kind, is not as easy to tackle and criticise as may seem at first sight. There are numerous aspects to the affair. One of these is that of individual liberty to choose whether or not to participate in the data base by giving data: the question of genetic and medical data privacy.

Icelandic law, as most critics stress, does not provide in any point for the need for the informed consent of the people whose data are taken and handled. This is not simple chance. The notes to the law clearly state that “It would take great effort, time and money to gain consent from every individual” and that it is therefore preferable to adopt a coding system which makes the data anonymous and which cannot be reconstructed later except with a decoding key. It is therefore preferable to make the information non-personalized rather than adopt the principle of consent to data collection. The latter would allow greater possibilities for
study, but would be faced with numerous refusals. The will of the directly interested parties is therefore reduced to a “non-consent” form, to a request to opt out. The effectiveness of the system of (non)decoding has a decisive bearing on this question: it should make it impossible to connect anonymous data to its original subjects. The technical question is much debated in that the decoding key, as has been noted, must actually be in continuous use to allow new data to be added, errors to be corrected and links between health data and genetic and genealogical data to be set up.

More generally speaking, however, the critical point is the possibility of doing without consent. According to some critics, on the basis of European data protection law, the exception to the principle of consent to data collection cannot be justified simply because non-decoding and non-diffusion after handling are guaranteed. However this criticism could fall down, as could the argument of violation of informatics self-determination for lack of consent, should the deCode genetic project be deemed a statistical epidemiological study, a type of study for which European law does not require consent provided that anonymity is assured.

As regards the main concern that information about an individual may fall into the hands of groups who could use it for their own interests, such as insurance companies and employers, the Ministry of Health and Social Security of Iceland has reassured everybody declaring that, in the case of the Icelandic database, connecting individual data “cannot be regarded as reasonably possible without substantial effort”. However there are those who argue that, because of its “highly incestuous” relationship with deCode genetics, the Icelandic government would maintain that the database was anonymous even if it were not so or if it were much less anonymous that the government would have people believe.

In other words, if the deCode genetics project may be classed as an epidemiological study and if the decoding system is guaranteed to be adequate, all criticisms as to consent could prove to be weak.

The principle of consent and its violation are also relevant from another point of view. So far we have spoken of consent to the taking and handling of data. It’s a very different matter if we speak of consent to experimental treatment of the person, according to medical standard. On this point the Icelandic law is rather ambiguous. On the one hand it is precise, taking care to regulate a matter outside ordinary or experimental medicine (Art.2), but on the other hand it uses notions such as patient (Art.8) or doctor. This point is delicate in that some data are acquired within a therapeutic doctor-patient relationship but they will go into the database in a context which is not in the slightest therapeutic or medical, if not in an extremely indirect way and, anyhow, not for those supplying the data.

In the Icelandic case, not asking for consent could therefore constitute a serious breach of international law on research, but only if the project is considered to be research on human beings. If, however, it is only statistical epidemiological research on data and not on people this argument too could be very fragile.

The doubt remains, therefore, that individual protection offered by international treaties and domestic law on genetic and medical data privacy and clinical experimentation on humans are not an adequate and sufficient perspective in such a case as this, in which the past and present data of an entire people are at stake.

Science and monopolies (a new twist to an old problem)

The database project may be examined not only from the standpoint of single individuals but also from that of its
intrinsic scientific correctness or ethicalness. This is the freedom of research and research ethics angle. There has been no substantial criticism of the scientific correctness of the database project and there seems to be no doubt that a project of this kind will be useful per se.

However, the database is to be set up and run for the declared aim of financial profit. Therefore the study and research aspects could fall into second place behind the pure and simple exploitation of data. *deCode genetics* has replied to the perplexity of the Icelandic scientific community by stating that the goals and limits of the database are laid down in the law. Furthermore, they argue that the database will increase research opportunities for Icelandic scientists who will be able to access data and attract funds and scientists to Iceland. However, this defence does not take into account the fact that scientists who want to access the database may do so only on condition that they do not use or divulge information in any way which has an adverse effect upon the licensee’s commercial interests (this is stated in the notes to the law). It is highly likely that any research carried out by universities or other public centres will be detrimental to the interests of the licensee. The question is whether the database represents a new kind of attack on scientific freedom or whether it is simply, from a commercial perspective, “a new twist to an old problem”, that of the relationship between science and economic interests. The new twist could be the monopoly conferred on *deCode genetics*.

The science-economic interests question remains open also if we examine it in the light of the Universal Declaration on the Human Genome and Human Rights, adopted on 11/11/97 by the General Conference of UNESCO (henceforth the UNESCO Declaration). The Declaration obliges states “to ensure the intellectual and the material conditions favourable to the free conduct of research in the human genome” (Art.11). Obviously, everything hinges on the definition of research activity and on its relations with profit-making business activity. However, if the work of *deCode genetics* is considered as research activity it would undoubtedly be protected under the UNESCO Declaration and the law of the Icelandic Parliament would be almost a necessary piece of legislation. However, it is maybe a little too much to link a positive obligation on the part of the state to favour a certain type of research and, what is more, to legitimise a research monopoly by this general principle of research freedom. If we begin to reason in this way, debatable operations such as the Icelandic project not only risk becoming legitimate but paradoxically the more cautious legislative choices adopted by other states could be contrary to the Declaration, such as the Swiss Confederation with its restrictive bill on genetic data.

Furthermore the UNESCO Declaration forbids profit being made from the human genome but only *in its natural state* (Art. 4: “The human genome in its natural state shall not give rise to financial gains”), evidently omitting from the ban all gains arising from an increase in value due to human activity, even that of a private company operating by monopoly. The *deCode* project, also considered in the light of research freedom, could get round the scrutiny of criticisms based on the UNESCO Declaration.

The UNESCO Declaration throws up some further questions which need to be analysed. The statements on research and treatment regarding the individual genome are based on a consolidated cluster of ideas and principles which are expressly referred to in the preparatory work. These are the principle of dignity, the right to equal treatment, rejection of all discrimination, the principle of solidarity between peoples and states, the right of all to live in decent conditions and to benefit from the advantages of scientific progress.
We may ask ourselves, therefore, if these rights and principles are respected in the Icelandic case. For example, can we be sure that Icelanders are not being discriminated against with respect to the citizens of other states or that Icelanders as a whole are not being discriminated against as regards other peoples? Can it be ruled out with certainty that the premise itself of the project (the genetic homogeneity of the population) may feed some form of racial or social prejudice? And that this will not be fuelled by careless handling of the data?

It is not easy to find satisfactory answers simply using the UNESCO Declaration, with its inevitable generalness and limits.

**The Right to Genetic Disobedience**

The question which the international treaties and domestic laws on genetic and medical privacy cannot tackle lies in this: all the members of an entire people and the institutions they have given themselves are facing the interests of the international genetic industry. At this level the fundamental question of the pact between citizens, society and state may be asked.

We need to return to the Icelandic law and grasp its double content. On the one hand it is a law that makes it possible to have a “private licence” to handle the medical and genetic data of the population. On the other hand it guarantees that the Health Minister has access to the database and to the acquisition of data for compiling health reports, planning and policy making (Art. 5 point 7).

Health Minister access is the noble part of the project which should also justify, from the point of view of public interest in the health of the community, the debatable assignment of the licence to deCode. However, leaving deCode out of the equation, it is doubtful whether a Health Minister has general indiscriminate power of this kind, without specifying any purpose. Of course the law states that the goal is to develop new and improved methods of achieving better health, prediction and diagnosis and treatment of disease as well as seeking the most economic ways of operating health services (Art. 10). But these are objectives or general ideas or are, in their turn, much debated. We need only consider the temptation of eugenic policies which could spring from the availability of this mass of data linked to disease prediction. The prospect of improving public health, therefore, does not justify anything. Limits need to be laid down which stop the rights and interests of the individual and the community itself being violated (in the name of the wellbeing of the community). It must never be forgotten that the declared aim of all the U.S. and northern Europe eugenic legislation, at the beginning of the 20th century and then in Germany, was to improve society. And, as for today, we cannot forget that international law sometimes limit the possibility of access or refusal to supply personal data actually referring to the concept of public health.

In other words, ministerial power of access to data and to develop health plans, based on elements which allow disease prediction (and therefore on genetic data), appears to be itself a source of concern and requires that limits be fixed. It cannot be per se considered as something beneficial and safe which can legitimise the deCode project.

We come, therefore, to the central point of a law which gives a private licence to the total heritage of medical and genetic data of the entire Icelandic people, past (from when the data first became available), present and future. The problem is whether a resource of this kind, non-repeatable and non-renewable, can be considered a resource of the state, of its representative institutions, of the nation or of the individual
citizens. Who, of all these, has the power to dispose of this resource?
The limits within which health institutions may operate have already been mentioned but the elective assemblies, what is more deciding by majority, certainly do not have unlimited powers. No theory of political representation includes the possibility of granting, for profit making purposes, goods of such a personal nature of the entire population. In short, it is a radical problem. If the state is recognised as having the power to assign personal data for commercial purposes by means of a contract, individual citizens must first be recognised as having the same right (and with this there may not be any problems). It must then be asserted that citizens, by uniting in a society, have given up the right to their own heritage of medical and genetic data. A reference to this can be found in Hobbes’ *Leviathan* where he deals with the argument of if and what man may renounce:

The motive and end for which this renouncing and transferring of right is introduced is nothing else but the security of a man’s person, in his life and in the means of so preserving life as not to be weary of it [...] sovereignty by institution is by covenant of every one to every one; and sovereignty by acquisition, by covenants of the vanquished to the victor, or child to the parent; it is manifest that every subject has liberty in all those things the right whereof cannot by covenant be transferred. I have shown before, in the fourteenth Chapter, that covenants not to defend a man’s own body are void. Therefore, if the sovereign command a man, though justly condemned, to kill, wound or maim himself; or not to resist those that assault him; or to abstain from the use of food, air, medicine or any other thing without which he cannot live; yet hath that man the liberty to disobey ix.

In the case of Iceland there is certainly no direct danger against which individuals or a society have to defend themselves, such as would be the case in a defensive war. The law is not even a majority decision on a health policy for a present defence against disease, which, although it should respect some inalienable individual rights, is justified by the current interest of public health and of citizens. In the Iceland case the public interest is future, merely possible and secondary and indirect with respect to a profit-making business.

It may be concluded that the Icelandic state and its Parliament have disposed of the heritage of the citizens without having the power to do so. The problem, therefore, is what the consequences are of a statement of this nature, considering that the decision was taken by a democratically elected Parliament. The actions of doctors opposed to cooperation, the criticisms of Icelandic associations and scientists, the warnings of individual citizens against using their data are, in this light, acts of denunciation of the state’s lack of power to dispose of data in this way and a vindication of the fundamental right to one’s own person, history and expression. In a word, demonstrations of the *right to disobey*.

But if the Icelandic people claim rights for the simple fact of existing and if these rights today have a value beyond the purely national (as is always the case in this field) we need to ask if and what response the Icelandic case may have in the international community and what the risks will be. It is certain that if the two perspectives which explain the Icelandic affair best are the violation of the antitrust law and the right to disobedience this means that genetics, its research and applications, raise problems the solution to which must be found in economics and politics rather than in ethics or law. And this is a matter of some import.
NOTES

i The numerous stances of the authoritative scientist and those of other scholars and associations may be found on the website www.mannvernd.is. The official voice of deCode is www.database.is.

ii “Clearly it would cost great effort, time and money to gain consent from every individual in a data collection envisaged here. This finance could otherwise be used to ensure confidentiality and build up the dispersed databases”: Bill on a Health Sector Database. Notes to the Bill, Section III, 3, paragraph 3 in http://brunnur.stjr.is/interpro/htr/htr.nsf/pages/gagnagr-ensk.

iii Bogi Andersen, Einar Arnason, Skuli Sigurdsson, KAFKAESQUE ETHICS FOR POST-MODERN VIKINGS? E-mail of 23 August 1999, in www.bmj.com The authors are Bogi Andersen, professor of medicine at the University of California, San Diego; Einar Arnason, professor of evolutionary biology and genetics at the University of Iceland and Skuli Sigurdsson, science and technology historian at the Humboldt University of Berlin.


v Council of Europe, RECOMMENDATION N.R (97) 5: Art. 12: “Scientific research. 12.1 Whenever possible, medical data used for scientific research purposes should be anonymous. Professional and scientific organisations as well as public authorities should promote the development of techniques and procedures securing anonymity. 12.2 However, if such anonymisation would make a scientific research project impossible, and the project is to be carried out for legitimate purposes, it could be carried out with personal data on condition that: a. the data subject has given his/her informed consent for one or more research purposes […] In line with European law Legislative Decree 30/7/99, no. 281, rules out the need for consent when the handling of data “is intended only for purposes of scientific or statistical research”. In other words consent seems to be indispensable only if there is no anonymity.


vii Bogi Andersen, Einar Arnason, Skuli Sigurdsson, op.cit.