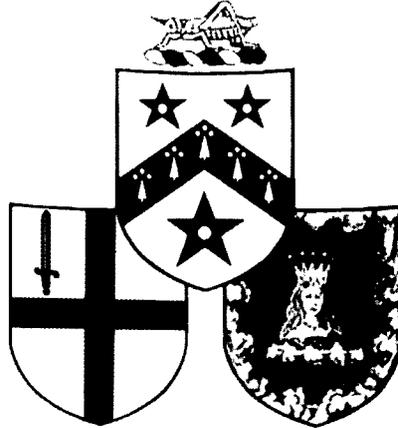


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**CONFLICT AND CONSENSUS IN THE AGE
OF THE NEW GENETICS**

Lecture 4

**PHARMACOGENOMICS: REVOLUTION IN HEALTH
CARE**

by

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GRESHAM COLLEGE

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Pharmacogenomics – a revolution in health care?

Professor Hilary Rose and Professor Steven Rose

Over the past few years, and in several countries, proposals have been developed to create broad population-wide data-bases incorporating individuals' health and DNA records. The intentions are stated to relate both to improved health management and also to aid 'gene hunting' to identify genes associated with a variety of common diseases. This lecture will discuss both the implementation and implications of such proposals, focussing on perhaps the most well developed and controversial, that taking place in Iceland. So it will focus on the Icelandic story, based on Hilary's own research there over the last couple of years. The full story is now in press, and when it is published, copies will be made available, if appropriate on the Gresham web site.

From 1998, when most of the public learnt for the first time about Health Sector Databases it was in the context of the Iceland conflict, headlined by much of the media as 'Iceland sells its people's genome'. To many, not least Icelanders themselves, it read as if Brave New World had finally arrived and was now being driven through at high speed. Some three years later it is clear that whatever was happening on this extremely small Nordic island was not some bizarre one-off phenomenon, but had to be understood as part of a much wider move by the big pharmaceutical companies, venture capital and the state towards predictive medicine and pharmacogenomics. Iceland may be the first example of pharmacogenomics in action, even though it was never spoken as such in any of the debates and discussions, but always by the softer term, the Health Sector Database (HSD), but unquestionably it is not going to be the last.

This continuing controversy operates at two very different levels, the 'ethical' and the 'technological'. By 'ethical' I mean all those doubts raised as to whether this immense biotechnological innovation is socially responsible, by 'technological' I mean does it, within its own terms, work? Within Europe, this is the first time that such a major biotechnological innovation affecting the entire medical care system and indeed its related research structure, has been introduced with such a central role given to the private sector. This development changes who gets to judge 'Does it work?' for in this new context the judgement is made primarily by the market itself. Given the down turn in confidence in the new economy during 2000 as reflected in sliding shares, it is clear that what ever the confidence of the innovators, investors whether high risk venture capitalists or lower risk share investors are less enthused than they were. Here we are less concerned with the impersonal judgement of markets but rather with the 'ethical' issues, as Icelanders themselves understand them.

Even while the media was reporting the fierce divisions within the Icelandic health care and biomedical research communities, and feeling troubled by the proliferating ethical and policy issues, global players not least SmithKline Beecham (SKB) were making not dissimilar proposals for the UK. There were important differences of approach; thus the SKB proposals differentiated themselves from the Icelandic deCode model in two key ways. First, eschewing the raw market model they suggested that new hybrid structures between the state and the market were likely to be a more appropriate way of proceeding. Second, seeing the bitter professional fights within Iceland, they emphasised the need to work slowly and consensually, bringing all the constituencies on board.

Later in 1999 the British public learnt from the television programme Newsnight of discussions between the Wellcome Trust and the MRC for what appeared to be yet another not dissimilar health data-base for the UK. Although in the event, these Wellcome / MRC discussions looked more likely to produce a large epidemiological study rather than a population based health data

base on the Icelandic model, the interest in linking genetic profiles and health, illness and indeed behaviour was now on the cards. Similar projects are reported from Canada, Estonia, Scandinavia and elsewhere.

This issue of Health Sector Databases or pharmacogenomics is of potentially profound significance for the whole shape and direction of health care. The promises being made to 'us', both as citizens and patients are immense, but science and technology have made huge promises before, and things have sometimes gone badly wrong. Britain like most Northern and Western European countries has had very good experience of managing and regulating biomedical innovation, not least human embryological research and IVF. These matters have been seen to require sensitive management, and have been given the time to develop an ethical consensus between all the stakeholders. But culturally sensitive as they are, neither embryological research then (it changes today with the possibility of therapeutic cloning) nor IVF, have had the immense significance for economy and society of either nuclear or the new genetics. The stakes of the current proposals, not least the promises concerning the potential of health databases are culturally and economically high.

There is a distinct irony to recent developments in pharmacogenomics. This potentially immense innovation, actively pursued by global pharmaceutical companies and venture capital, requires as its precondition a universal health care system. Only the old welfare states have universal health care records; marketised medical care systems exclude many from health insurance. Although those excluded from health-care insurance may (or may not) receive reasonable emergency care, they are by definition also excluded from cradle-to-grave regular care and their concomitant medical recording systems. Not for the first time the relationship between the organisational structures of health care provision and the development of genetics comes into visibility and importance. For pharmacogenomics only the old welfare states offer what they speak of in their depoliticised language as a 'good' population. However, what constitutes 'good' is fluid. Thus, while deCode emphasises the smallness (275,000) and homogeneity of Iceland as 'good', SKB sees the 59 million of the socially and genetically diverse UK as an even better 'good' population, and the Wellcome MRC study envisaged a sample of 500,000. The 'good' population for pharmacogenomics seems, providing there are universal medical care and recording systems plus well cared for tissue banks, remarkably flexible.

In the lecture, I will trace the history of the Icelandic conflict, the role played by the company, deCode, which 'bought' the data-base and the responses of both the professional critics of deCode's plans and of the lay people whom I have interviewed. I will argue that the deCode, and related initiatives, can be seen as not just the 'commodification of nature' but also as 'the commodification of virtual nature' – of information about people.

The commodification of nature, whether of green or human nature, is scarcely new. Some non-industrialised cultures have seen, and still see, nature as morally active and thus outside commodification; others have admitted restricted commodification. Land, sweet water, access to hunting and fishing, have long been subject to property claims. (For that matter there is little that is innovative about slavery, prostitution, or wet-nursing.) The advent of capitalist modernity and continuous technological innovation has intensified the commodification of nature. Even though within economics commodities are treated as 'taken for granted' objects, subject to supply and demand, the social birth of a commodity is typically surrounded by intense moral debate. Today the countries of the South challenge the North with biopiracy in the North's relentless drive to commodify both indigenous nature and indigenous knowledge of nature. A powerful symbol of this moral and political conflict is the patenting by Sequana of a genetic profile associated with asthma that is very strongly present among the tiny population of Tristan da Cunha. Sequana makes money from these poor island people, who gave body samples but who have received

nothing. Today medical records and tissue samples are being fought over. Endlessly squirreled away in hospitals and clinics, is it ethically appropriate for these to be mined and commodified or are privacy and confidentiality more important cultural values? For that matter will the digitalisation of information – as some analysts have proposed- serve to sweep away those concepts of privacy developed in a non digital era?

For Iceland commodification is a fresh response to the old problem of protecting access to the fishing as their commons. The new risk to the industry however is through their own over-fishing, a phenomenon associated with larger boats and more efficient scientific techniques. The government has followed the usual regulatory mechanism of fishing quotas. These quotas can be held only by Icelanders and were originally allocated to those fishing in 1983. As time has gone on a fisheries version of share cropping has developed, following the emergence of large firms which dominate the market and gradually come to control most of the quota, with the result that smaller firms have to rent quota. This has given rise to sharp public criticism about both fairness and market domination by a few large firms. A legal case against the arbitrary allocation of quotas to those fishing at a given moment in history with no thought to the rights of future generations has met with success in the high court. The court struck the legislation down as unconstitutional. While this re-opens fishing rights to new fishers, the victory still leaves the quota problem untouched. Because quotas are set out in quantities of haddock, cod, and so forth problems arise if fishers catch too many of one species and cannot trade quota, then the fish must be thrown back or the fisher's quota license is in trouble. What was seen initially as scientifically managing the commons by commodification, first perversely produced an arbitrary and somewhat feudal structure of ownership, and secondly, as fishing remains vital to Iceland, has not resolved the basic resource management task. Scientifically managing high technology fishing through commodification has proved harder, both in constitutional and conservation terms, than was originally thought.

Debates around the commodification of nature are now entrenched in Icelandic culture, the narrative of the constitutional breach of fishing quotas is mobilised by the opposition to draw parallels with the database issue and its commodification of human bodies and information. By contrast protagonists of the database, also draw on the commodification narrative, they compare exploiting Iceland's genes as the country's equivalent of Norway's successful exploitation of its oil.

This general process of commodification within capitalist modernity is currently accelerating, powered both by the technosciences set to dominate the 21st century and also by the relentless energy of venture capital. These dual technosciences are biotechnology and informatics. Thus while the Icelandic controversy has been conceptualised as a further extension of the commodification of nature through biotechnology my own reading is that this is only partially the case. The most intense focus of the commodification process with the Health Sector Database is on information, albeit information about the human body. Biotechnology (using informatics) is bringing into existence an entirely new class of information -- genetic information -- but it is informatics itself which enables old forms of information, the medical records and the genealogies, to be brought into relation with the new, creating a historically new and marketable commodity.

My conclusions are that the Icelandic project has been steamrollered through and that, despite any potential commercial advantage this gives or appears to give, the strategy carries too many problems for both society and science. The climate for such high risk new technology projects has in fact deteriorated since the inception of deCode. The joint Blair/Clinton statement cast a question over limitless patenting. In early March (2000), the Nasdaq Biotech index began to slide down by more than 40% . Various biotech analysts from investment companies began to

speaking more cautiously of deCodes chances as they went to market in early June. The process has been so accelerated that it has never been possible to explore fully and calmly the fundamental question of what such a centralised database might or might not contribute to understanding the issues of health and disease. This is a serious deficit for the healthy development of genetics, public health, and democracy.

Popular support for the Icelandic HSD is understood as having two main sources; first, the popular support for the charismatic figure of deCodes CEO, who combines genetic nationalism with a narrative of science as technical and social progress; second, because its geographical location means that Icelanders have more to fear from nature than culture, Icelanders have a greater investment in the narrative of science as progress. It has been the intellectuals particularly in biomedical research, together with those sensitised to the politics of health and illness, notably patients with chronic disease and women influenced by feminism who have been most conscious of the risks as well as the potential gains posed by the HSD.

For those of us who observe rather than live with the HSD conflict, we have to be aware that legislation was necessary only because a purely market approach to genomics was adopted. In a more consensual, hybridised model of genomics, the innovation can be simply added on to the research and health policy agenda by experts. There is no moment when the very idea of a genomics data base can be accepted or rejected by democratic process. This expert-driven technological innovation is a conspicuous feature of the old welfare states, particularly Britain with its highly secretive political culture, which it is so painfully trying to move beyond. I would argue this old tradition is in need of serious challenge and overhaul. Thus it is the very fact of the Icelandic HSD legislation and the visibility of its processes which has exposed the immense innovation of genomics to vigorous public debate not just nationally but internationally. This conflict has served to put the ethical issues concerning the commodification both of bioinformatics and of nature as human tissue onto the international cultural and political agenda. Careful scrutiny of Iceland's highly visible conflict over commodification could help other countries increase both the transparency and the democratic accountability of their biomedical innovation.