

Report on ‘The Regulation of Genetics Outside the State’

ESRC Centre for Analysis of Risk and Regulation (LSE) and
the ESRC Centre for Genomics in Society (University of Exeter)

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We were pleased to welcome forty participants to the Crossmead Centre in Exeter for this workshop. The first talk was a very interesting presentation by Stuart Hogarth from the Institute of Public Health, Cambridge University. He discussed the debate about how to regulate genetic testing. Central to this debate have been arguments about the relative importance of statutory forms of regulation and other forms of control. The pressure group GeneWatch UK and the consumer group Which? (formerly the Consumer's Association) are amongst the strongest advocates of tighter statutory regulation of genetic testing in the UK. So far their efforts to achieve this goal have met with little success. He explained that if they have perhaps failed as regulatory advocates, they nevertheless been effective regulatory agents by having an impact on the practice of commercial genetic testing. His paper explored the tactics they have adopted in seeking to influence the practice of commercial genetic testing.

Dr Filippa Corneliussen from the BIOS centre at the London School of Economics then gave a presentation on how the technology used in biomedical R&D is as applicable to biological warfare and bioterrorism as to the promotion of human well-being. This dual-use nature of biomedical technologies is most ambivalent in commercial enterprises as this is where the technologies are most intensively exploited and the investments in both intellectual property and highly specialised equipment are most substantial, she explained. So what guidelines do companies have when developing technologies to prevent misuse? Filippa's research has shown the current regulations put in place to manage work with biological agents in the lab intended to prevent accidental infections/releases and unauthorised acquisitions of biological agents are not being adhered to effectively. She argued that a new set of regulatory measures are needed to prevent the actual techniques and knowledge generated through biomedical R&D from being misused. It is as yet unclear, however, exactly what form these measures should take.

Dr Carlos Novas, of BIOS, at the London School of Economics then introduced us to a history of genetic testing for Huntington's. Due to the widespread professional concerns about the potential psycho-social effects, especially suicide, amongst persons who had their genetic future revealed, the paper charted how a number of clinicians developed an empirical programme of psychological testing and research to assess the impact of predictive testing on clients and to develop appropriate counselling and ethical guidelines. The harms and benefits of offering this test were not found exclusively in the principled reason of bioethics, alternatively, it was grounded in a criterion of truthfulness achieved through a process of empirical psychological experimentation – this could be referred to as the scientific rationalisation of ethics. The knowledge and experience gained in providing predictive genetic testing for HD has not been confined to this illness alone, rather it has

served as an exemplar of how these types of tests ought and should be offered for other late onset genetic diseases.

Dr Paula Saukko, of Egenis also talked about Genetic testing. This she explained, has been deemed exceptional and requiring special safety measures, such as pre-test counselling, because it predicts future illnesses and may fuel psychological anxiety and social discrimination. As of late Human Genetics Commission has suggested that not all genetic tests, such as susceptibility tests, are exceptional, because their implications for individuals are less significant. To examine what happens when genetic testing is conducted in non-exceptional, mainstream clinical practice Paula conducted qualitative interviews with doctors (n=9) and patients (n=42) on their experience of direct referral for a genetic test for susceptibility to deep vein thrombosis without the involvement of specialist genetic services. Patients and doctors did not consider the test predictive or the condition immutable, and patients were not anxious but nonchalant about the test. A subgroup of less educated patients, however, were poorly informed about the test, its results and implications or were unaware of having had the test, which compromised informed consent and the utility of the test. Both doctors and patients expressed concerns about the potential use of the test results by insurance companies and employers. Policy discussion on exceptionalism has focussed on identifying a priori features of genetic tests that render them exceptional or less exceptional. The presentation argued that policy should be informed by an analysis of how genetic testing works not in principle but in practice. The findings of our study suggest that non-exceptional, direct referral to a susceptibility test is not without its problems and different models of service provision should be tried and developed.

The next day Dr Jane Calvert, also of Egenis gave a presentation on the patent system and how it has been affected by genomics. She explained that it has led to more sophisticated understandings of gene function, and it has opened the way for informational DNA patenting. DNA patents are increasingly attempting to claim sequences in computer-embodied form. As well as raising interesting questions about the patentability of information, these patents are particularly problematic for the academic genomics community, which attaches great importance to the free availability of information. Dr Alain Pottage, from the Department of Law, at the London School of Economics then talked about whether patent law is necessarily 'technology- specific', or whether we are making a difficult transition towards a 'post-industrial' patent system. Questions of this sort express the widespread feeling that patent law is no longer able to define with precision what forms of application of knowledge should be patentable, and that as a result it is resorting to arbitrary criteria of 'utility' in determining patentability. To the extent that machines were once the paradigmatic form of invention, the contrast between industrial machinery and informatic inventions offers a way of exploring this sentiment.

In the final session, Dr Alf Game, of the Biotechnology and Biological Sciences Research Council addressed whether or not a particular area of scientific opportunity or research need is pursued. This is determined by many factors other than the availability of funding and the existence of a permissive regulatory framework. Through consideration of a number of specific examples - incontinence and sexual dysfunction; comparative human genomics; crop science; stem cells - he explored the complex range of economic, political, social and cultural factors which can determine why some areas of research develop and prosper, whilst others of apparently similar importance do not.

Finally, Dr Christophe Bonneuil, of the Centre Koyré for the History of Science, CNRS, Paris and INRA-TSV. Gave an information dense talk on the transatlantic GM debate, which traditionally displays ‘sound science’ versus ‘precaution’.

Combining theoretical tools and concepts from Social Studies of Science and from the sociology of social problems, public policies and risk, Christoph accounted for the contrasts in research dynamics across the Atlantic in terms of trans-arena interactions between:

Interplay and competition between different disciplines, epistemological cultures and groups within the scientific arena and advisory bodies and the various and changing ways GMOs have been framed as a problem by different regulators in the policy arena. This session provoked lively debate and was followed by a much appreciated wine reception before delegates made their way. It is hoped that the workshop can provide a platform for further collaboration between the two centres.