QUESTIONS ANSWERED:
Question 12 - Regulation

ANSWER:
[Please note that my response pertains to SNP-based genomewide DNA analysis, not to body imaging] Since autumn 2007, commercial companies have been offering individual genetic risk calculations over the internet. For fees starting at $399 these companies look at up to over a million points (single nucleotide polymorphisms, SNP) across the genome to assess their customers' individual genetic predispositions to various diseases, traits, carrier status, and drug responses. Consumer genomics – also known as personal genomics, or retail genomics –, differs from classical medical genetic testing in four main ways: First, instead of looking at the absence of presence of a particular mutation, it creates a large dataset which can be reanalysed when new research findings (suggesting a new correlation between a genetic marker and a phenotype) become available. Second, in contrast to classical medical genetic testing, which regularly takes place in a clinical context, consumer genomics does not involve any medical professionals. Information can be purchased and accessed on the internet. Third, as colleagues and I have argued elsewhere, the data provided by consumer genomics companies typically conveys medically relevant and non-medically relevant information at the same time (Prainsack et al 2008). Fourth, consumer genomics focuses on complex diseases and traits, which are caused by the interplay of various genetic and non-genetic factors. Many of these factors are yet unknown or unexplored. Thus, the predictive value of the genetic markers tested by consumer genomics companies is very small at best. For these reasons, the regulatory and ethical issues arising in connection with SNP-based genomewide testing are different from those in the field of 'classical' genetic testing for rare mutations. Regulatory efforts in many countries, however, have not yet recognized these differences and are still trying to target consumer genomics with regulatory instruments of the genetic era. For example, after years of deliberation, the German Parliament finally passed the Genetic Diagnosis Law (Gendiagnostik-Gesetz) last April. The law provides that genetic tests 'for medical purposes' may only be carried out by a physician, thereby banning all forms of direct-to-consumer (DTC) genetic testing which provide medically relevant information. This clearly pertains to the burgeoning market of consumer genomics as well. Interestingly, however, by the time of writing this response (July 2009), consumer genomics companies have not ceased to sell their services to German residents, nor to residents of other countries where DTC genetic testing for medical purposes is prohibited. The companies – such as 23andMe and Navigenics in California, and

deCODEme in Iceland - argue that the information they provide is not medical advice. On this basis they could claim that their customers are not affected from such bans. Another reason for why bans on DTC testing for medical purposes are regularly ignored is that they are notoriously difficult to enforce. It is practically impossible to punish a resident of Hamburg for purchasing a genetic test over the internet from a company based in the US, for example. Moreover, the US-based company would not be punishable on the basis of the German ban anyway. But should the ineffectiveness of such legal bans be a cause for concern? Perhaps it should not. The fear that individuals might be seriously but needlessly worried by their test results, or that they could engage in unhealthy behaviour as a result of assuming their genomes prevent them from cancer or other diseases, has not yet been supported by empirical evidence. Research on how individuals act upon results from genetic susceptibility testing suggests that significant and sustainable lifestyle changes are very rarely the result. In addition, genetic information seems no more likely to instigate lifestyle changes than other types of risk information (see, for example, Pearson 2008). Thus, the scenario that we will see masses of seriously worried and/or chain smoking and overeating genome-test consumers in the future is remote. Nevertheless, there are other reasons why consumer genomics deserves our attention. It is indicative of the ongoing individualisation of responsibility in the field of health care (Rose 2006). If people get sick when they could have prevented it, social and/or financial costs are the result. Thus, precaution and prevention play important roles in individual quests to increase health and prevent disease, also to control costs. The main danger posed by the increasing uptake of consumer genomics is not that patients are too simple-minded to understand the results. But individuals may feel pressed to spend their money on such tests as part of their individual duty to stay healthy when due to their low predictive value genome tests are singularly unsuitable for this task. And even when, perhaps very soon, personal genome analyses will be so inexpensive that cost would be insignificant to most people, the decision to get tested is still likely to have unintended consequences. For example, because test results are made available to consumers on the internet, the data cannot be irreversibly removed. Furthermore, although the predictive value of SNP-based genomic disease risk data is currently negligible, test-takers could still find themselves in a situation in which they need to disclose the data when buying certain life or other insurance policies (Prainsack 2008). Those are issues which need to be addressed by adequate regulation of the use of personal data in general, as they are not a particularity of consumer genomics. On the contrary, the special attention which health authorities and legislators have paid to consumer genomics so far has contributed a lot to its representation as a 'medical' genetic testing service in

the public domain. For this reason, legislators should abstain from any action that grants SNP-based genome testing services legitimacy as providers of medical information. References: Pearson H. Genetic testing for everyone. Nature 2008: 453/7195: 570-571. Rose N. The Politics of Life Itself: Biomedicine, Power, and Subjectivity in the Twenty-First Century. Princeton University Press, 2006. Prainsack B. What are the stakes? Genetic non-discrimination legislation and personal genomics. Personalized Medicine 2008: 5/5: 415-418. Prainsack B, Reardon J, Hindmarsh R, Gottweis H, Naue U, Lunshof JE. Misdirected Precaution. Nature 2008: 456/7218: 34-35.