The response reproduced below was submitted further to a consultation held by the Nuffield Council on Bioethics on its Report: *Pharmacogenetics- ethical issues*, during November 2002 – February 2003. The views expressed are solely those of the respondent(s) and not those of the Council.

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Q1 The likely economic impact of pharmacogenetics on the development of new medicines will have implications for the costs of personalised drugs and therefore the budget management pressures for Primary Care Organisations in due course. PCTs will have to balance the cost/benefit of personalised medication for some against less effective alternative for others and weight these against more general service priorities.

Q2 In terms of developing 'orphan' drugs at a research stage some sort of regulation and/or incentive will be necessary. Assuming such medication becomes available it is likely to be disproportionately expensive. At a local level, without national guidance (I don't think it needs regulation) to temper the variation between what is and is not available under the NHS will widen. Economically pressurised PCTs are likely to be pressurised choosing between high cost individual drugs and those more broadly targeted.

Q3 I don't know enough about the regulations of drug trials to know whether such testing requires regulation in order to happen. It seems vital that such trials should happen if the use and application is to be personalised.

Q4 I know there are mixed views on this with many clinicians preferring a gate-keeper type system, thereby requiring GPs/Primary Care Centres to initiate and record tests. As far as access to medication on the NHS is concerned I support this position.

Q5 I can't see why the legal liabilities would differ from those currently. The same advice/warnings etc would be offered with – hopefully – reduced side affects and therefore risks.

Q6 I would have thought the overall aim of pharmacogenetics is to aline the patient and drug more closely and therefore testing would be an integral part of the therapy.

Q7 In the Public system the National Institute of Clinical Excellence could set standards on the use of pharmacogenetics with the CHI (or equivalent) reviewing application on the policies. In truth I am not sure the public health service focuses very closely on efficacy and cost of drugs as they are currently licensed so am unsure about a distinction with personalised medication. In terms of safety, again the same systems of clinical governance and adverse reporting could apply.

The private system will develop in response to demand. The issue for the public system is to ensure access to quality information and to try to encourage those using a private option to share appropriate medical information.

Q8 There is a risk that phamacogenetics could focus treatment to those whose genes respond. The real risk therefore is at a policy level in deciding whether,

should such therapies be available in the NHS, it will be acceptable for a clinician/PCT to refuse treatment to somebody whose genes and not believed to be susceptible. My guess is that this will not. The drive therefore has to be to ensure therapeutic options are available for all and the best information about outcomes is made available. Perhaps this will be an important area for professional education.

Q9 Personally I don't make a distinction between commercial analysis and disease investigation although I think the real issue is getting properly informed consent from people.

Q10 Again a personal view, I think anonymity or not, should be something discussed with the person giving consent to a sample. I imagine it to be of benefit to the commercial industry to promote anonymity, and to avoid the complex ethical issues of how/what/if to handle the discovery of personal information that may be of interest to the individual. In essence I would like to see the option of anonymity to rest with the individual when consent is given.

Q11 In reality very few people understand, at this point, what they are giving consent to. Consent is still a very difficult issue and perhaps one that would benefit from a more broad discussion with the public generally.

Q12 I believe the individual should be given the option, when giving consent, to have feedback about genetically significant information if they choose to.

Q13 I am unable to offer a view to this question

Q14 The ethical issues are only different if the use of testing is to deny access to a form of therapy. The positive advantage perhaps is that patients might be protected from adverse affect and damage. There are however enhanced issues about information and choice in primary care.

Q15 the psychological implications for the individual are going to be different. If managed well, it offers more choice about the use of medication and side affects. It also perhaps opens up a broader focus on preventative strategies in those cases where results are probabilistic.

Q16 The implications for families will depend on the accuracy of pre-disposition probabilities and will need to be considered on an individual family basis. In broad terms I don't see that this will be of the same significance as single gene tests.

Q17 I think the policies will need to be clear about who is making the ultimate decision, and the parameters within which these are made. Ultimately in our system the decision will be clinical but we will need to decide for example, whether a person who refuses to take a genetic test is automatically excluded

from a certain therapy on the NHS. Central regulation will be very important to protect patients from arbitrary decision-making.

Q18 My personal view on this depends on how well accepted the accuracy of the test and the intervention are believed to be. Essentially with increase pressure on resource and technological advance in therapies such pressure is, in my opinion, inevitable.

Q19 No – I think access to personal information for insurance purposes must rely on consent between the individual and the insurance company.

Q20 My understanding of gene behaviour suggests susceptibility to pharmaceutical intervention is likely to be population specific and therefore there are very real ethical and racial issues resting behind this technology. Perhaps the safeguard is in the research guidelines in ensure such variations are properly researched. The other safeguard is in the monitoring of access. This area is likely to be of most concern to the public.