The response reproduced above 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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I have read the Nuffield Council on Bioethics' consultation paper on pharmacogenetics and would like to respond to the questions listed at the end of that document.

1 I think pharmacogenetics has the potential to speed up the development of new drugs for at least some subgroups of the populations in developed countries, although some of these new medicines may then only be licenced for use in these subgroups.

2 Yes.

3 As a minimum, it would be sensible to issues strong encouragement to pharmaceutical companies to store DNA samples from those involved in trials of new drugs in case of serious adverse drug reactions.

4 Pharmacogenetic testing should, in my view, be vailable only through a medical practitioner because such test results may well convey prognostic information as well as providing guidance about the choice of therapy - and unanticipated information may also emerge after the tests have been performed (such as the association between apoE alleles and dementia).

5 They will have to collect evidence more thoroughly and over a longer period - but will have an incentive to do so because highly effective drugs with serious adverse effects on a few will hopefully then be made safely available to the majority of the population.

6 Yes - as long as the appropriate tests are available over the internet and as long as very clear guidance accompanies the drug in the relevant local languages. There may well be problems with this policy but I think this would be preferable in practice to any attempt to have the drugs supplied to these countries.

7 There should be a public regulatory or licencing body that assesses the evidence and sets appropriate standards of care applicable to the health sector as a whole.

8 The application of pharmacogenetics has the potential to increase inequalities in the provision of healthcare within the UK, especially if its use within the NHS is rstricted on spurious grounds (e.g. through the demand for an unattainable standard of evidence of improved outcomes, leading to rationing in the guise of quality assurance). This should therefore reinforce our determination to protect the principles of the NHS in the rapidly changing circumstances of the present.

9 NO - I think it is likely that the two types of information will overlap extensively.

10 Full anonymisation will not be possible because of the importance of tracking clinical effectiveness of the drugs and adverse outcomes.

11 Consent of the research participants for the use of these samples should be resticted to specific kinds of research only - to those relevant to the disease for which they are being treated and to the treatment.

12 No - not usually - but if the research generates a validated and clinically useful test that would be relevant to the health care of the research parricipants then they should be informed of that as a group, and the test should be made available to these individuals through a CPA-accredited laboratory even before it becomes available through standard clinical laboratories.

13 The laboratories offering such tests should be subject to accreditation amnd quality assurance in relation to their data handling as well as technical proficiency, in both the NHS and private spheres. Samples and records of the results should be retained indefinitely in case (A)

further, more accurate testing becomes available or (B) an adverse drug reaction occurs in the individual.

14 NO. In particular, I do NOT think that pharmacogenetic tests are likely to be very much simpler in their implications than other genetic tests - and "genetic tests" are not all carried out on DNA, so that a cholesterol test can be a genetic test as much as a "diet- guidance" test). Primary care staff who come to use pharmacogenetic tests will need to be aware of the possble complex ramifications of the test results.

15 There are likely to be 'untreatable' or otherwise poor-prognosis groups identified through pharmacogenetic tests, with implications for the individual and perhaps for family members too.

16 Variable - these results may indicate which family members are more likely to develop the same condition or to respond well or badly to the available therapies.

17 Differences are perhaps more likely to arise in the context of private insurance schemes where the insurer may constrain the choice of drugs. Within NHS primary care, there is likely to be patient involvement in the decisions as models of shared decision making gain support.

18 Yes - but they may then be eligible for a narrower range of drug treatments if the risk of an ADR is substantial without testing.

19 At present and in the near future - NO. But this will need to be watched - and if pharmacogenetic testing becomes widespread on the basis of good evidence that it results in better outcomes then
YES, although it may then be necessary to regulate so as to prevent insurance companies weighting policy premiums (or refusing policies) on the basis of such information.

20 It might do so but I hope it will not because such categories are likely to be much less useful for predicting drug responses than the SNPs etc that are included in the genome screens seeking alleles associaed with differential drug responsiveness. The categories of attributed ethnicity - whether self-attributed or based on the professional's assessment of physical appearance - are likely to correlate poorly with pharmacogenetically-relevant genetic variation once the major genes such as G6PD, haemoglobin S and porphyria have been accounted for.