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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List of questions

Q1 What do you think will be the likely economic impact of pharmacogenetics on the development of new medicines?

That the pharmaceutical industry will carefully research the likely market size before developing any new drug, and favour will be given to the largest potential markets. Also new drugs for limited potential markets will have an associated much larger price tag which then may be prohibitive to healthcare organisations!

Q2 Do you think that further regulatory measures will be needed to encourage the development of clinically desirable but economically unprofitable medicines?

This would be the logical method to control the pharmaceutical industry ? in the form of development grants or research underwritten by government. However this has not worked to date, giving the simple example of lack of research into simple antiviral, anti-bacterial or anti-protozoal drugs for the Third World.

Q3 In your view, should pharmacogenetic testing of participants in trials be a regulatory requirement for the development of medicines in the future?

No. Testing should be part of the voluntary consent process. It could be possible that non-tested participants could form another arm of a trial, and thus act as a control group.

Q4 Who should be responsible for providing a pharmacogenetic test? For individual therapy, should tests be available directly to patients over the counter or on the internet, or should they only be available through medical practitioners as part of a decision about the use of a prescribed medicine?

Tests without any desired backup or counselling could create public alarm etc. However, it will be difficult (?impossible) to regulate simple blood/smear tests – particularly if there is easy profit to be made. One possible method could be to prohibit the transport of body tissue via the postal system, but how this could be policed in practice??

Q5 What will be the implications of pharmacogenetics for pharmaceutical companies and providers of healthcare regarding legal liability for adverse reactions?

Hopefully the same stringent MCA controls will be maintained for the recording of adverse reactions for any new medical products. The fact that patients have been pharmacogenetically tested as suitable for the product

should not detract from their present legal rights if adverse reactions are subsequently found.

Q6 Should medicines which have been developed for administration in conjunction with a pharmacogenetic test be distributed to countries in which testing facilities are not available?

As stated in your paper; a patient population for a medicine is the total population with the clinical symptoms, not just who the drug companies deem eligible. Thus medicines should be available to all populations with symptoms and so potential benefit.

Q7 How should predictions of efficacy and safety, as well as cost, be integrated in deciding whether to provide a particular treatment to patients in (a) a public healthcare system, and (b) a private healthcare system?

An important principle could be that patients within the public healthcare system should not be used as "guinea-pigs" i.e. take all the risk for research into a new treatment, which subsequently is only available in the private sector. Thus if a new treatment is licensed on a country's formulary after being researched on "public patients", then it should be made available (integrated) into both healthcare systems equally.

Q8 Do you think the application of pharmacogenetics might exacerbate inequalities in the provision of healthcare? Is it likely to challenge the principle of solidarity that lies at the basis of the provision of national healthcare in the UK? Will the benefits of pharmacogenetics only be affordable or available to the wealthy?

See Q7 answer. Similarly if research is performed on patients in less wealthy countries, then it should be mandatory on the pharmaceutical company to make the drug available in those countries as well as wealthy countries, with relevant pricing structures. The risk taken for the research to take place should be shared equally by all the population likely to benefit – otherwise inequalities will immediately occur.

Q9 In your view, is the storage of genetic information for the purpose of pharmacogenetic analysis categorically distinct from storage of other kinds of genetic information, for example information about susceptibility to disease?

Fundamentally any storage of genetic information for whatever reason should be made crystal clear to the individual submitting the genetic sample. If the level of anonymity or identifiability is made clear to the individual, then it is up to the individual to consent or

otherwise to donating the sample. There should be no local or national rules for this, as it is a matter for individual consent. There ought to be stringent and transparent regulations laid down so that the individual could gain compensation if the genetic information is used for any other purpose than that consented to.

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Q10 What level of anonymity should be accorded to genetic information stored as part of research in pharmacogenetics?

There is no universal rule for this. If there is some potential benefit for genetic information to be passed back to the individual, then this should be made clear on the consent form. Thus the level of anonymity is dependent on the purpose of use for the genetic information. As long as this is 100% clear on the consent form, then the level of anonymity is up to the individual to decide on to agree to or not. If the subject then finds the information has been used for other purposes, then there ? ought to be simple statutory law for the individual to claim. e.g. if this affected their insurance premium, then the level of compensation should equal the loss of financial cover. i.e. punitive to the drug company to be equivalent to life cover lost x £million?

Q11 What kinds of consent should be required for the collection of samples for research in pharmacogenetics? Should pharmaceutical companies which collect samples in the course of research in pharmacogenetics be able to use such samples for any purpose, or should consent of the donor be restricted to allow usage only for specific kinds of research?

The usual rules of informed consent should apply. If samples are to be used for any other purpose, then this should be explicit on the consent form. The consequences of consenting for "any purpose" should be crystal clear and perhaps questioned twice on the consent form. This potentially could include shared information with the police or criminal investigation computers.??

Q12 Do you think that researchers should provide individual feedback about genetic information obtained from participants in research in pharmacogenetics?

This will be specific to the research in question. If feedback could potentially be beneficial, then this should be explained and offered. If not beneficial, then the reasons for this should be explained and anonymity offered.

Q13 What, in your view, would be appropriate methods of regulating scope, storage and access with respect to pharmacogenetic information used in clinical practice?

In principle storage and access should be made explicit on the consent form. In practice, patients rarely understand the whole

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consequences of the research but should NOT BE DISADVANTAGED. Perhaps there ought to be an overall clause to state: ?? " If in the future you are found to be uninsurable as a result of this research, or your level of cover is reduced to £X,000000, then you will receive the equivalent level of compensation." ????????

Q14 Do you think that the ethical and legal issues raised by the use of pharmacogenetic tests in primary care differ from those raised by other forms of genetic testing? What about non-genetic tests, such as tests for cholesterol?

The ethical and legal issues surrounding pharmacogenetic tests are no different (in theory) with any forms of genetic tests.

Q15 What might be the psychological implications for individuals of pharmacogenetic tests? Are such tests likely to reveal information that is of relevance outside the context of testing for response to medicines?

Again this is specific to the test in question. There are always psychological implications to genetic questions. If such tests reveal further medical implications, then this should automatically be part of the information on the consent form.

Q16 What implications do you think pharmacogenetic tests might have for family members?

Where the genetic relevance is known and agreed and consented, then relevance for other family members is irrelevant. (assuming Q15 true)

Q17 In your view, are controversies likely to arise about who ultimately decides which treatment is prescribed in light of a pharmacogenetic test?

This is a minefield. The decision could be between physician, surgeon, cytologist, haematologist, pain clinician, palliative care, etc. Controversies are almost **certain** to arise.

Q18 Should patients be able to refuse a genetic test to determine response to medicines but still expect to receive a prescription?

NO – assuming proper explanation

Q19 Do you think that the providers of health insurance should have access to pharmacogenetic information? What about other parts of the insurance industry, for example life insurance?

Only if specifically consented. If not, then wide 100% negation. If then ***negated by law****: my answer would be that any access to genetic information is ok* ***as long as*** *any subsequent financial implication from this information will be fully compensated for.*

Q20 Do you think that pharmacogenetics will increase the likelihood of the grouping of patients according to racial or ethnic groups for medical purposes? If so, what might be the ethical and social implications of such an outcome?.

Such drug treatment advance will automatically benefit certain ethnic groups. As long as *ALL* ***groups are equally represented by any research, then ok. If any ethnic issue becomes relevant, then further medical research will become imperative.***