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.

Dr W Nichols, Saudi Arabia

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

Although directing medications to sub groups of the population may appear to be detrimental for the pharmaceutical companies financially, the decrease in profits due to the decreased potential market should be to a large extent be offset by savings during research and development.

Savings may be realized through:

- Making research more efficient
- Allowing drugs to be approved which would be otherwise be blocked because of adverse reactions in a sub group of the population, by contra indicating their prescription to this sub group.
- Reducing the possibility of patients suffering severe adverse reactions would also reduce legal liability suites against the pharmaceutical companies.
- a minority genotype A in one population might be the majority genotype in another population and given the global nature of most pharmaceutical companies, the potential loss from the minority population can be offset by the majority population. The existence of totally unique genotypes will probably be restricted to only a few highly inbred populations and then not necessarily extend to the entire genome.

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

Initially support may be needed to do group specific research, and the term "orphan drug" may be redefined; but it is probable that the "orphan drugs" of one population will be the main stream drug for another, and this should help provide the companies with sufficient profit to allow them to continue.

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

In my opinion pharmacogenetic testing should be included as part of standard protocol design in all trials.

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 should be available only through a medical practitioner

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

It should be theoretically possible to identify genotypically those individuals who would react adversely to the medication and to exclude their suitabuility for taking the drug. If any of these patients chose to ignore the warnings they would then be liable for their own actions.

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?
Yes, but only if any potential adverse reactions were not very severe life threatening.

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?
Ideally every patient should obtain the best possible treatment, however where there are budget restrictions there cost benefit decisions have to be made as with any other medication or treatment.

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?.13
As with many new treatments availability of pharmacogenetic drugs may initially appear in the affluent private sector, but there should be a filter through which will benefit all sectors. The majority of genotypic differences are not related to social strata of bank balance.

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?
Genetic information for the purpose of pharmacogenetic analysis should be subject to the same storage, confidentiality and feedback as other kinds of genetic information.

Q10 What level of anonymity should be accorded to genetic information stored as part of research in pharmacogenetics?
Genetic information should be at least double coded.

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

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donor be restricted to allow usage only for specific kinds of research?
Full informed consent should be obtained for a range of pharmacogeneic tests.

Q12 Do you think that researchers should provide individual feedback about
genetic information obtained from participants in research in pharmacogenetics?
Whether individual feedback was provided or not would depend on the nature of the research, and the degree of reliability which could be attached to the pharmogenetic trait being studied.

Q13 What, in your view, would be appropriate methods of regulating scope, storage and access with respect to pharmacogenetic information used in clinical practice?
Genetic information for the purpose of pharmacogenetic analysis should be subject to the same storage, confidentiality and feedback as other kinds of medical information.

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?
Pharmacogenetic testing shares the same ethical and legal issues raised by the use of other forms of genetic testing, primarily problems related to the heritability of genetic material, so that other members of the family may be directly effected by a result.

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?
Testing should be restricted to testing for response to medicines unless direct consent is obtain for other types of research.

Q16 What implications do you think pharmacogenetic tests might have for family members?
As in disease susceptibility studies information on one individual may have direct implications to other family members. If potentially life threatening reactions are involved the physician would be morally obliged to inform the effected family members, but only after extensive genetic counseling had occurred.

Q17 In your view, are controversies likely to arise about who ultimately decides which treatment is prescribed in light of a pharmacogenetic test?
Only if pharmacogenetic testing is restricted to elite medicine, the trickle down effect to all strata must be allowed to occur.

Q18 Should patients be able to refuse a genetic test to determine response to medicines but still expect to receive a prescription?
Counselling should avoid the situation where a patient would refuse testing. However if the test were to indicate a patients life threatening reaction to the

treatment then the medication should not be given without the test, cases to find degree of efficacy however could still be treated.

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?

No

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?

No, not for the majority of genes
Widespread study should result in how many factors are in fact shared
And that no one racial or ethnic group will be able to be established as being genomicaly superior, each group having its own problems many of which are shared!