Nuffield Council on Bioethics

28 Bedford Square London WC1B 3JS Telephone 020 7681 9619 Fax 020 7637 1712

30 April 2004

The Right Honourable The Chancellor of the Exchequer
Ten-year investment framework for science and innovation
Science & Industry Team
HM Treasury
1 Horse Guards Road
London SW1A 2HQ

Dear Chancellor,

The Nuffield Council on Bioethics is grateful for the opportunity to comment on the consultation, **Science and innovation: working towards a ten-year investment framework**.

The Council examines ethical questions raised by recent advances in biological and medical research, and has published Reports discussing ethical issues associated with: genetic screening; ownership of tissue; xenotransplantation; genetics and mental disorders; genetically modified crops; research on human stem cells; research related to healthcare in developing countries; patenting DNA; genetics and human behaviour and pharmacogenetics. Recommendations and conclusions from these publications that are relevant to the questions posed in the consultation document are attached at **Annex A**.

Developments in biomedicine and biology are taking place at an unprecedented pace. Public support for some of the potential applications of these advances is high. However, many people have also expressed unease about their possible implications. It is often observed that science moves so quickly that ethics has difficulty in keeping up. It is crucial that ethical, legal and social issues raised by the introduction of a new technology are considered from an early stage. Where necessary, appropriate regulation may need to be formulated, to ensure that the benefits of a new technology are maximised while the risks are minimised. Encouraging discussion and debate, from a balanced

and informed position, should help the public to regain trust in science and technology.

The Council aims to consider developments before problems arise, providing independent and timely guidance for policymakers and legislators. We therefore welcome the publication of this consultation.

Yours sincerely

Dr Sandy Thomas
Director

ANNEX A

Science and Innovation: working towards a ten year investment framework

A response from the Nuffield Council on Bioethics

Q4: In order to inform decisions on the future investment framework, and building on the Research Councils' extensive consultations with stakeholders, in what areas are there opportunities for the UK research base to excel and contribute to the economy and society, which might form the basis of future strategic research programmes over the next ten years?

The Nuffield Council welcomes the inclusion of research using stem cells and programmes to enhance genomics and proteomics on the list of priorities for future investment.

While the Council is not able to comment specifically on opportunities for the UK research base to excel and contribute to the economy over the next ten years, there are a number of areas the Council has identified where further research should be encouraged. These include:

Pharmacogenetics: ethical issues (2003)

- Pharmacogenetics could be used to improve the prescribing of existing medicines, whether by reducing the incidence of adverse reactions, or by restricting prescription to those patients likely to benefit... In some cases, the development of a test could make a significant contribution to improving the prescription of existing medicines. It is not clear that the private sector will be motivated to pursue pharmacogenetic research in relation to medicines not covered by patent protection. **We therefore recommend that efforts should be made to encourage pharmacogenetic research on existing medicines, where there is reason to believe that such research could significantly improve efficacy or safety. Funding and support should be made available within the public sector and public–private partnerships encouraged.** We welcome the recent announcement by the Department of Health that £4 million will be directed towards research in pharmacogenetics over the next three years (paragraph 3.26).

Genetics and human behaviour: the ethical context (2002)

- **We take the view that research in behavioural genetics has the potential to advance our understanding of human behaviour and that the research can therefore be justified. However, we note that it is important that those who fund research in this area should continue to fund research of a high calibre, should be transparent about their funding practices and should be aware of the potential for the abuse and misinterpretation of results. In addition, we**

recommend that research sponsors who intend to focus strategic funding in this area should pay careful attention to public concerns about the research and its applications (paragraph 11.17).

Mental disorders and genetics: the ethical context (1998)

- Despite considerable effort to date, genetic research has so far yielded little practical help in limiting the suffering of those with mental disorder… There seems little doubt that, over the next ten years, susceptibility loci will be identified and some of these will hold up to robust scientific scrutiny. These discoveries will certainly improve understanding of the causes of mental disorder, probably more by small incremental steps than major revolutions. **The full potential of these discoveries can only be realized if accompanied by a well-integrated and rigorous research programme covering social, developmental and other biological approaches to the understanding of mental disorder** (Paragraph 3.26).

Q12: What should the role of Government be in improving the interaction between science and society? Are there areas where Government could improve the promotion of science in society? How can we improve public confidence in the Government's use of science? What should we be aiming to achieve in this area in the next ten years?

Ethical, legal and social issues raised by developments in medicine and biology are of direct concern to society and should be discussed from an early stage. The Government should continue to seek expert advice before the introduction of a new technology, and address the concerns of the public through open debate and discussion. It is particularly important that the government advisory committees should continue to have consumers and advisers on ethics as full members. The crucial requirement for such bodies is that they are expert and independent and have the means and authority to obtain thorough analysis of any question which they think needs deeper investigation. **(*Genetically modified crops: ethical and social issues*** (1999) paragraph 8.25**)**

The Council recognises the importance of the role of committees such as the Human Genetics Commission (HGC) and the Agricultural and Environmental Biotechnology Commission (AEBC) in addressing the concerns of the public, and has directed a number of recommendations made in its Reports to these groups.

The Government's response to public concerns about xenotransplantation provides a good illustration of the benefits of seeking timely advice and establishing an appropriate regulatory framework. In 1995 the Council concluded that the development of xenotransplantation should continue, subject to rigorous regulation to ensure protection for potential human recipients and care for animal welfare. In the same year, the Department of Health set up an Advisory Group on the ethics of xenotransplantation which made a number of detailed recommendations to regulate developments in animal-to-human transplants. Acting on advice from both these groups, the Government established the UK Xenotransplation Interim Regulatory

Authority (UKXIRA) in 1997 which ensures that issues and potential risks are addressed as the science develops.

To maintain public confidence, it may sometimes be necessary for the Government to introduce appropriate regulation and monitoring to ensure that the benefits of a new technology are maximised while the risks are minimised. The Council has, for example, made a number of specific recommendations about the regulation of genetic tests, particularly those sold directly to the public. The questions addressed by these tests include very sensitive areas of personal and family vulnerability, and there is considerable potential for exploitation of the anxieties and aspirations of members of the public. In novel areas of science, most people are unlikely to be well placed to make informed judgements.

In the case of genetic tests, there is currently no specific legalisation in place that would provide a regulatory mechanism for assessing the efficacy or reliability of a test. This applies even to genetic tests for diseases, as well as to the hypothetical tests for genetic influences on behavioural traits. This may mean that, without appropriate safeguards, consumers may be at risk of exploitation through misleading marketing practices. In the Report, ***Genetics and human behaviour: the ethical context*** *(2002),* **we welcome the consideration by the Human Genetics Commission (HGC) of genetic tests supplied directly to the public and recommend that both the public and private provision of such tests, if they are developed, should be stringently monitored and regulated as necessary** (paragraph 13.55).

The Government also has a role to play in ensuring that the public are provided with clear and balanced information about new technologies. The Council has specifically recommended, for example, initiatives to provide independent and impartial information about new genetic tests, to patients and health professionals, including GPs and pharmacists, should be encouraged (***Pharmacogenetics: ethical issues*** (2003) paragraph 5.7). The Council is currently examining ethical issues raised by research involving animals. This is a topic that people feel very deeply about, and the Council notes the Government's steps to increase transparency and openness in the area.

'*GM nation?*', the Government's initiative in 2003 to broaden discussion about the introduction of genetically modified crops in the UK, provided a framework that encouraged wider debate of the issues. The Council contributed to the discussion with a follow-up publication on ***The use of genetically modified crops in developing countries***. Opportunities such as this, which promote discussion and debate from an informed position, should help the public to strengthen trust in science and technology.

Q14: What are the research aspirations and funding plans of the medical charities over the coming next decade? How best can Government and charity funders work together to enhance the impact of their complementary research efforts on national and global health outcomes and contribute to the development and maintenance of a sustainable UK science base?

The Council is concerned that the consultation document contains no mention of research to address the needs of those in developing countries (see also Nature editorial, Vol 428, 25 March 2004 p.351). The Council published a Report, ***Genetically modified crops: ethical and social issues***, in 1999, and has recently returned to the topic with a follow-up Discussion Paper, ***The use of genetically modified crops in developing countries***. This Paper reviews recent scientific evidence and developments in policy, regulation and trade in order to re-assess the recommendations and conclusions of the 1999 Report. The Council has made the following recommendations and would urge the Government to consider the importance of such research when setting its science framework for the next ten years:

- We are clear that **in particular cases, GM crops can contribute to substantial progress in improving agriculture, in parallel to the (usually slow) changes at the socio-political level. GM crops have demonstrated the potential to reduce environmental degradation and to address specific health, ecological and agricultural problems which have proved less responsive to the standard tools of plant breeding and organic or conventional agricultural practices. Thus, we affirm the conclusion of our 1999 Report that there is an ethical obligation to explore these potential benefits responsibly, in order to contribute to the reduction of poverty, and to improve food security and profitable agriculture in developing countries** (paragraph 4.48).

- The majority of successful applications of GM crops have been developed by industry for commercial agriculture in developed countries. In contrast, most research on GM crops that may have potential for developing countries continues to be undertaken by publicly-funded organisations. A major concern which we expressed in our 1999 Report was the neglect of a serious issue: the risk that gains from GM crops will not be brought to bear on the needs of poor people in developing countries. We also concluded that GM crop technology was unduly concentrated on the crops and farm systems of industrialised countries. **We therefore affirm the recommendation made in our 1999 Report that genuinely additional resources be committed by the UK Department for International Development (DFID), the European Commission, national governments and others, to fund a major expansion of public GM-related research into tropical and sub-tropical staple foods, suitable for the needs of small-scale farmers in developing countries. In determining which traits and crops should be developed, funding bodies should be proactive in consulting with national and regional bodies in developing countries to identify relevant priorities** (paragraphs 6.16-6.17).

The Council has also discussed the importance of externally-sponsored research in developing countries in its Report, ***The ethics of research related to healthcare in developing countries*** (2002):

- The burden of disease in the majority of developing countries is enormous. The active participation of many agencies will be required if change is to be achieved. Despite the great need for research to determine which forms of intervention in developing countries are most effective, the capacity of those countries to conduct relevant research is severely limited. It is vital therefore that the public and private sectors in developed countries should sponsor research to help bridge this gap. (Chapter 3 and Paragraph 10.7)

Q16: In light of the second Wanless Report, where are the weaknesses in public health research capacity? How can we improve the links between academics and deliverers of public health, to ensure a strong evidence base both on causality and on effective, well targeted interventions? How should the roles of the various research bodies be better coordinated in relation to public health, to ensure the public health research requirements are met in a structured and coherent way?

The Council recognises the increasing importance of considering ethical, social and legal issues raised in the area of public health. The Council will hold a Workshop on the ethics of public health in July 2004, which will consider how the balance should be struck between individual choice and community benefit.

Q20: Are there barriers facing business and the science base in effective engagement with EU research programmes? How can the UK more effectively influence and benefit from EU research funding and policies? In what ways can action at Community level add value to UK science and innovation policies? How can national and community funding complement each other more effectively?

Within Europe there are diverse attitudes, for example to embryo research in general and the derivation of stem cells through therapeutic cloning in particular. Many countries have debated the ethical issues and some, like the UK, have decided that research on embryos, with appropriate legislation, can be morally justified. It is important to acknowledge that different countries have different social and cultural perspectives and to allow countries to adopt their own guidelines to restrict or regulate the research to reflect these views.