Commons Science and Technology Committee: Inquiry into Bioengineering in the UK

Response by the Wellcome Trust

December 2009

1. The Wellcome Trust is the largest charity in the UK. It funds innovative biomedical research, in the UK and internationally, spending over £600 million each year to support the brightest scientists with the best ideas. The Wellcome Trust supports public debate about biomedical research and its impact on health and wellbeing.
2. We welcome the opportunity to respond to this consultation. It is imperative that the funding and regulatory environment in the UK continues to foster the development and application of new technologies, maintaining the UK's globally competitive edge in existing and emerging fields of research. In our response, we make some general comments to address the questions asked by the Committee, in each of the three areas of research identified in the call for evidence.
3. Bioengineering is of course a much wider field than the three areas highlighted by this inquiry - encompassing healthcare innovations in, for example, prosthetics, cochlear implants, and biomaterials. In June 2009, the Wellcome Trust and the Engineering and Physical Sciences Research Council announced joint funding of £41 million to support four new Centres for Biomedical Engineering – which will support multidisciplinary teams bringing together biomedical scientists, clinicians and engineers to address key healthcare needs. Bioengineering exemplifies the need for interdisciplinary research and training: addressing the existing barriers in the UK to academic career progression of individuals whose expertise spans diverse disciplines represents an overarching challenge in developing the field.
4. In regard to the three areas identified by the inquiry, we believe that lessons can be drawn from the experiences in both genetic modification (GM) and stem cell research in the UK to inform future strategies in the emerging area of synthetic biology and other new biotechnologies. We believe three key issues need to be addressed:

    a. **Funding:** there must be a commitment to long term funding from the public and private sectors, especially for translational research, early stage product development and capacity building;

    b. **Appropriate Regulation:** regulatory frameworks at UK, EU and international levels must be proportionate and fit for purpose to:

    - remain flexible to accommodate fundamental research and translational applications and to respond to future scientific developments:
    - facilitate scientific research, whilst maintaining a robust ethical and regulatory framework which maintains public confidence in science and scientists; and
    - minimise bureaucracy and associated costs of undertaking research.

c. **Public Engagement:** there is a need to develop early-stage public engagement strategies around new technologies, which bring together scientists, the public and policy makers to discuss emerging technologies and associated ethical issues.

Genetic Modification

5. This area of research has flourished since the 1980s and the UK has been a world leader in the field. The technology is being utilised in the development of biomedical therapies: for example, genetic modification of animals has enabled the development of new treatments for leukaemia and more effective drugs for diabetes.

6. A facilitative and efficient regulatory framework for use of genetically modified animals for fundamental research and clinical trials of therapeutics is crucial if the UK is to maintain its competitive edge in this field. Regulation of animal research, including genetically modified animals should not inhibit the use of such animals or impose increased levels of bureaucracy which increases the time and cost of research in the UK, making it less competitive. The UK needs to be careful that national and European regulatory provisions do not result in additional research burden without animal welfare benefits.

7. The Academy of Medical Sciences has recently launched a working group looking at the use of 'Animals containing human material' to explore current and future research trends, possible therapeutic outcomes from such research and the ethical issues and societal views surrounding such research. The working group will also identify any gaps in current regulations which govern such research. Early exploration of such issues should help in ensuring any future research is carried out within a robust ethical and regulatory framework which has public support for both the research and its therapeutic products.

8. Lessons must be learned from the experience of genetically modified crops regarding the need for early engagement between scientists, the public and policy makers. The introduction of GM crops has struggled against public misconceptions about "Frankenstein foods", confusion about the underlying science, and a lack of clarity about where the risks and benefit lie. Interestingly, Sense about Science has launched a fresh public discussion about GM – 'Making Sense of GM' - in an attempt to address public questions and misconceptions around GM technology[1]. As they note, continued public interest in the issue is demonstrated by the fact that there have been more Google searches on genetically modified crops in the past two years in the UK than anywhere else in the world.

9. This is an area that the UK and Europe will need to tackle imminently, especially as the issue of food security and food shortage become more and more pressing in both low and middle income countries. For example, the Nuffield Council of Bioethics published a report on the use of GM crops in developing countries in 2003, concluding that there is a moral imperative for making GM crops readily and economically available to people in developing countries who want them. While recommending that research into GM crops should be directed towards the needs of small-scale farmers in developing countries, the Council also stressed that the possible costs, benefits and risks associated with particular GM crops can only be assessed on a case by case basis.

Stem Cells

10. The UK has been a world leader in stem cell technologies as evidenced by the award of the 2007 Nobel prize for medicine to Sir Martin Evans FRS for his work in stem cells. The Wellcome Trust has recognised the potential of this field: over the last five years, we have provided £36 million for stem cell research in animals and £6.2 million on stem cell research in humans, including a £2.7 million translational award to the Scottish National Blood Transfusion Service to attempt to derive synthetic blood from human embryonic stem cells.

[1] http://www.senseaboutscience.org.uk/index.php/site/project/16/

11. It is therefore imperative that UK maintains its funding for both fundamental and translational research and retains its leading edge in this field. Initiatives such as Stem Cells for Safer Medicine[2] and the Technology Strategy Board's competition in regenerative medicine will facilitate translation of stem cell research into therapeutic products, and should receive continued support. This is a field in which the UK has enjoyed a competitive edge over the US – but this is now under threat following the amendments to the US federal policy on human embryonic stem cell research and the injection of significant new funding for this research.

12. The development of the regulatory framework governing stem cell technologies in the Human Fertilisation and Embryology Act (2008) can be seen as an exemplar of how scientists can engage with the public and policy makers early to ensure appropriate legislation is produced.

13. The Trust worked with other medical research organisations and the Science Media Centre to encourage scientists to explain stem cell technology and its potential benefits through various fora at the early stages of development of the regulatory framework and throughout the Parliamentary process. The Trust facilitated ethical debates across various religious groups on the subject which provided a space for both sides of the debate to be heard and an opportunity for the public to better understand the science and its associated ethical issues.

14. Part of the success of the public engagement strategy resulted from the involvement of clinical researchers in providing real examples of how the technology might be applied in practice. The use of narrative examples can help the public to picture the potential impact of such technologies and the ethical questions they raise.

15. With regard to translational stem cell research, the regulation of clinical trials of somatic cell therapies as medicinal products requires streamlining, clarification and simplification of the various EU regulations of the field. Particular clarification is required as to how somatic cell therapies which are not deemed to be Advanced Therapy Medicinal Products by the European Medicines Agency (EMEA), are regulated by the MHRA. Regulation needs to be risk based and proportionate to avoid increasing bureaucracy and cost in undertaking trials in the UK and the EU in stem cell based therapies.

16. The provision of intellectual property protection for products derived from human embryonic stem cells is also an area of ongoing international debate. It is vital that this position is clarified as soon as possible.

17. To support the research landscape, Government should take action to implement the recommendations of the Biosciences Innovation and Growth Team (BIGT) review including:

    - taking a leadership role in improving the Clinical Trials Directive which is currently under review; and
    - developing a vision for the future evolution of global biopharmaceutical regulation.

Synthetic Biology

18. This is an exciting emerging field in biological research, with promising applications in drug development, diagnostics, and chemical synthesis through to biosensor development, stem cell engineering and carbon capture. The field raises a number of ethical and regulatory questions which need to be explored in discussion with the public to enable appropriate development of regulation of the field, and to maintain public confidence in the science and resulting applications.

19. The Royal Academy of Engineering reviewed the field in its report on '*Synthetic Biology: scope, applications and implications'* in May 2009. It highlighted how much attention has been given to synthetic biology in the US, such as the £16m funding of a dedicated Synthetic Biology Centre (synBERC) at UC Berkeley and UCSF, by the National Science Foundation. In the UK

[2] http://www.sc4sm.org/

however, the field is only just beginning to establish itself – with very modest funding commitments to date.

20. The Wellcome Trust held a Frontiers Meeting in November 2008 to identify training needs for biologists and physical scientists in development of emerging biotechnologies. This resulted in the Trust providing £300,000 to support students taking part in the Internationally Genetically Engineered Machine (iGEM) competition. This programme will involve undergraduates from a number of disciplines including basic science, veterinary or medical degree, social science and philosophy students with an interest in ethics. The Research Councils have also recognised the potential of this field, through their support for 'networks' for synthetic biology research groups.
21. Through the Royal Society's Synthetic Biology Policy Coordination Group and other forums, there is an active ongoing dialogue between stakeholders working in this field. These discussions have recognised the vital need to engage early with the public, and several encouraging activities have been developed to begin this work.

Future vision

22. To ensure the UK remains globally competitive in emerging bioengineering technologies, the Government will need to maintain a competitive research environment for fundamental research in such technologies, along with coordinated strategies for the ethical review of such technology, early public engagement and the development of facilitative regulatory frameworks.