

Response to Science and Technology Committee Inquiry on Bioengineering

This is a response from the Economic and Social Research Council (ESRC) Centre for Social and Economic Research on Innovation in Genomics (the ESRC Innogen Centre), which is based at the University of Edinburgh and the Open University, and is part of the ESRC Genomics Network. The centre carries out research that connects the social with the life sciences. We have specific areas of expertise in the social and regulatory dimensions of synthetic biology, stem cells and GM crops, and we will address each of these areas in turn.

Members of staff in the Innogen Centre who have contributed to this response include: Prof Joyce Tait (synthetic biology, stem cells and GM crops), Dr Jane Calvert (synthetic biology), and Dr Sarah Parry (stem cells).

Summary of response

Synthetic biology, stem cells and GM all demonstrate the interconnections between scientific and technological developments on the one hand and social, ethical, regulatory and public concerns on other.

In the area of **synthetic biology** we highlight the importance of early-stage decisions on ownership and sharing for the development of the field, and argue that the UK's internationally competitive position can only be maintained through investment in interdisciplinary research.

We address the difficulty of the commercialisation of **stem cells** from two angles. First, our research on public engagement in stem cell research has shown that the ethical framings of commercialisation must be taken into account, particularly since potential commercial exploitation could stop individuals consenting to the donation of their tissue. Second, we argue that translation to tissue-based therapies is unlikely because of the uncertain regulatory environment, modelled on pharmaceuticals, with long time-scales and costs.

In the area of **GM crops**, Innogen research has shown that the current European system for developing and regulating biological approaches to food crop production is seriously flawed, and that what is needed is a policy-led strategic approach to the development of an effective governance system, with a more flexible and robust design.

Preliminary comment: bioengineering

1. We would like to raise a question concerning the use of the term 'bioengineering' in this Inquiry. Although this term sits comfortably with certain schools of synthetic biology that explicitly aim to make biology into an engineering discipline (see O'Malley et al. 2008), it does not fit as easily with some work in stem cells and GM. What is the benefit of using this term, and of putting work in GM and stem cells under its umbrella?

Synthetic biology

What is the UK's Research Capacity?

2. It is widely agreed that the USA is dominant in synthetic biology. A comparative study of levels of funding for synthetic biology in different countries would be valuable to assess the differences in national investments into the field.

How easy is it to translate and commercialise research?

3. Since synthetic biology is at an early phase of development, much of the research has not yet reached the stage of being translated or commercialised. In fact, some scientists working in synthetic biology say that investment in infrastructures and foundational technologies (such as DNA synthesis) is more important than commercialisation efforts at this early stage.
4. There is also concern among some synthetic biologists that the premature appropriation of interchangeable biological parts ('BioBricks') could lead to blocking patents and patent thickets, which could inhibit downstream research and innovation (see Calvert 2008, Rai and Boyle 2007). For these reasons, alternative ownership regimes which aim to facilitate innovation without restricting access to the technology are actively being discussed in the synthetic biology community. Some of the options being suggested are commons-based and open-source inspired, drawing parallels between synthetic biology and software development.
5. In this context, standard measures of innovative activity such as patent counts may not prove to be the most appropriate way to assess the development of the technology. It may not be productive to focus on translation and commercialisation to the exclusion of other facets of this nascent field, if the aim is to build UK capacity in the area of synthetic biology.

How do UK and International Regulations affect research and translation?

6. Most of the research in this area is still too early-stage to have a good understanding of its future translational needs. The area closest to market realisation is synthetic biofuels and here translation is hindered by uncertainty about government policies in the context of standard setting, CO₂ emissions targets and subsidies for particular kinds of outcome.

How can the UK maintain and grow its internationally competitive position?

7. Synthetic biology is an interdisciplinary field which brings together biologists, engineers, chemists and computer scientists. The field is also notable for the way in which social scientists, philosophers and lawyers have become involved 'upstream'. These interdisciplinary aspects of the field will need to be nurtured if synthetic biology is to flourish.
8. There are well-rehearsed problems with funding and rewarding interdisciplinary research (see McCarthy 2004), which are particularly relevant to synthetic biology. For example, synthetic biology does not fit neatly within the remit of one research council, meaning that continued cross-council funding will be required. Training students in synthetic biology will also be challenging, because they will have to acquire skills in a range of scientific and engineering disciplines, as well as learn to contribute to discussions of the social implications of their work. The established Doctoral Training Centres in Systems Biology may provide a good model here.

9. The UK Research Councils have been far-sighted in facilitating the involvement of social scientists in synthetic biology, through the seven funded Networks in Synthetic Biology and the Imperial//LSE Centre for Synthetic Biology and Innovation. It is important to maintain this involvement while the field grows and develops in the UK. This type of close engagement will mean that social scientists will not merely comment on the consequences of the research, but engage with the research as it proceeds, which could provide an opportunity for novel interdisciplinary work (Calvert and Martin 2009).
10. The UK has also taken the lead in initiating several public engagement exercises in synthetic biology (see Royal Academy of Engineering 2009). Although GM experiences have shown that we should not expect straight-forward and unproblematic results from these exercises, they provide important opportunities for on-going dialogue.

Stem cells

What is the UK's Research Capacity?

11. The UK's research capacity in the area of stem cells is excellent.

How easy is it to translate and commercialise research?

12. Findings from our project 'The Social Dynamics of Public Engagement in Stem Cell Research' indicate that the issue of commercialisation is far from straightforward. Drawing on focus group data with diverse citizens and discussions in public debates we found that the issue of commercialisation must not be reduced to one of technical or financial concerns but must take into account ethical framings of commercialisation. That is, it must allow for questions about whether commercialisation should occur and, if so, commercialisation of what?
13. One aspect of commercialisation concerns the donation of eggs, embryos and tissue for stem cell research. At present, all tissue is donated without financial remuneration to the donor. Our research findings indicate that many potential donors are concerned about individuals or organisations making a profit out of the research to which they have donated tissue. Parry's (2006) research has shown that potential egg and embryo donors were keen that any therapeutic applications arising from stem cell research should be available on the NHS rather than only to those who could afford them. Similarly, we heard from nurses based in a fertility clinic that couples ceased to donate their eggs or embryos once the consent form indicated the potential for commercial exploitation of the research findings. A central point here is that the donation of tissue that might be incorporated into stem cell products potentially raises a troubled sense of ownership for donors. This illustrates that a commercial agenda for stem cell research may have material consequences in terms of gaining access to the required tissue on which this developing field rests.
14. Significantly, in two public events organised on the topic of commercialisation ("Commercialisation – Developing stem cell applications: What role for the private sector?"), we found that experts in the field of stem cell research and publics alike had limited understanding of the complex processes involved in commercialisation. It is, therefore, important to generate debate not only about the implications of commercialisation but also the processes by which new products are developed in the private sector.

How do UK and International Regulations affect research and translation?

15. Stem cell technology is at a crucial stage in translation to practical application, as tissue-based therapies and also as aids to toxicity testing for drug discovery. UK policies have created an excellent environment for a flourishing research community, but is on the verge of losing this advantage when it comes to commercialisation. Application to toxicity testing is the area where most large and small companies see immediate opportunities for commercial development. Many small companies and scientists that started out aiming to develop tissue-based therapies have now moved their immediate focus to this area, the reason being the lack of lengthy and expensive regulatory requirements.
16. A factor which is making successful translation to tissue-based therapies increasingly unlikely in the UK is the EU decision to regulate such therapies by a mechanism similar to that for pharmaceuticals, with a likely timescale of 10 years and a cost of at least £500 million. Given expected development processes, regulatory uncertainties and the scale of potential markets, it is unlikely that any company will want to invest in such applications. And the state would not be able to support such costs. Recent major investments in the tissue therapy area from the UK Technology Strategy Board are unlikely to have the expected impacts while these constraints remain in place.

GM crops

What is the UK's Research Capacity?

17. In the GM area, capacity has almost entirely disappeared.

How easy is it to translate and commercialise research?

18. It is difficult for a variety of reasons, all related to policy and governance issues (see next question).

How do UK and International Regulations affect research and translation?

19. Innogen research has shown that the current European system for developing and regulating biological approaches to food crop production is seriously flawed and is likely to lead to ever-increasing disadvantages for European agriculture, particularly if commodity food prices continue to rise and climate change increasingly disrupts crop production globally. These disadvantages are also already evident in many developing countries.
20. The current systemic failure of the European regulatory system for GM crops has a complex background, including missed policy opportunities and a failure to build evidence-based approaches to risk governance. This is having a serious impact on today's innovation environment for biological approaches to enhance food crop production. A similar impact on future generations of biological research will be inescapable if there is not a policy-led strategic approach to the development of an effective governance system. This will require a more flexible and robust design in the face of 21st Century opportunities to benefit from biological discoveries and, on the negative side, to cope with global climate change and a changing financial environment.

All three areas

How can the UK maintain and grow its internationally competitive position?

21. In terms of regulation, many options could be implemented by the UK acting alone, e.g.: target setting and standard setting and local policies to support sustainable development of biofuels from synthetic biology advances; and facilitating ethical and safe curation of stem cell lines in the UK without inhibiting commercial involvement in development.
22. Other options will require co-ordinated action at EU level, for example: policy initiatives that could facilitate safe development of stem cell therapies within an affordable financial envelope and an acceptable timescale; support for EU initiatives to encourage investment in GM crop developments that could deliver societal or environmental advantages, or, failing that, support for allowing individual countries to pursue their own research agendas in the development of GM crops.

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