House of Commons

Science and Technology Committee

Bioengineering

Seventh Report of Session 2009–10

HC 220

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We found that the UK has an excellent research base but is still failing to maximise its potential by translating research into wealth and health. Considering that the UK is emerging from a recession and a difficult economic climate still prevails, this is worrying. The road to economic recovery will depend, in part, on exploitation of the UK's research base, which in turn requires efficient translation to generate returns on investments.

Some areas of bioengineering, such as stem cells, have clearly benefited from strong Government leadership and support, backed up by generous levels of funding from both the public and private sectors. Others, such as genetically modified (GM) crops, are less well supported and funded. This is curious when GM crops are considered by the Government to be safe and offer potential benefits. GM crops are certainly the poor cousin in the bioengineering family, and we strongly urge the Government to signal its support for GM crops as well as improving the regulatory situation in Europe.

Regulation of bioengineering is complex but, on the whole, adequate in theory. However in practice problems arise and researchers have found that regulations inhibit research and translation, either because of regulatory complexity (stem cells) or a flawed operation of the regulatory process (GM crops). We have made recommendations to address these problems.

We found good indications that the UK is learning from past experiences in bioengineering when handling new emerging technologies, such as synthetic biology. The Government and Research Councils have recognised the value of synthetic biology early, and are providing funding. There is good activity in public engagement on synthetic biology. However we are concerned that while research is well funded there is not enough forethought about synthetic biology translation, for example developing DNA synthesis capability, which would provide the UK with an excellent opportunity to get ahead internationally. If this is not addressed, synthetic biology runs the risk of becoming yet another story of the UK failing to capitalise on a strong research base and falling behind internationally.

1 Introduction

Why bioengineering?

1. Bioengineering is the application of engineering principles or methods to biology or medicine. It could also be viewed as "turning ideas into reality" for biology and medicine.[1] Humans have a long history of engineering biological systems, for example agriculture developed about 10,000 years ago and formed the basis of modern civilisation. Since then, farmers have been applying selective breeding to food crops, a process further accelerated by the discovery of the role of genetics in plant breeding in the 20th century. Such bioengineering has resulted in the modern grains and vegetables that are familiar today yet would have been alien to our distant ancestors.[2] Similarly, for many thousands of years humans have been engineering medical devices and interventions—with various degrees of success—with the aim of improving health and prolonging life. The desire to manipulate biological systems is certainly not new, but over the last century the tools have become increasingly complex and sophisticated as our understanding of biology and medicine has matured.

2. The biological sciences encompass a wide range of disciplines and engineering is equally diverse. Bioengineering, the overlap between (at least) these two groups of disciplines, includes activities ranging from cellular-based research in tissue engineering to mechanical engineering-based applications such as orthopaedics. In this report on bioengineering, we are referring to a broad, highly interdisciplinary area overlapping science and engineering.

3. We chose bioengineering as an important topic for scrutiny for three reasons. First, the Government considers bioengineering to be amongst the strategically important enabling technologies for the 21st century.[3] This is partly because of its great economic, health and societal importance to the UK and partly because the UK has so far held an internationally competitive position in bioengineering, with a global lead in some areas.

4. Second, the powerful combination of the UK's global status in bioengineering and its actual and potential impacts on our society, means that bioengineering, as the Prime Minister might put it, virtually "picks itself"[4] as an area in which the Government should consider investing heavily. The Government has often expressed interest in the notion of selecting strategically important sectors for investment, a debate that has been particularly pertinent since the UK entered an economic downturn in 2008. Under the Haldane Principle the Government sets an over-arching strategy, while researchers themselves establish detailed priorities and apportion funding on the basis of peer review. Against the backdrop of the recession and possible funding cuts the Government has shown increased interest in using the discretion afforded by the Haldane Principle to identify strategic priorities, known to some as "picking winners". Lord Drayson sparked the debate in February 2009, when he asked in a speech:

1 Innovation, Universities, Science and Skills Committee, Fourth Report of Session 2008–09, *Engineering: turning ideas into reality*, HC 50–I

2 For example broccoli, a flowering mutant of kale, is thought to be only 500 years old.

3 Ev 55 [BIS, Defra and DH], para 1

4 Oral evidence taken before the Liaison Committee on 12 February 2009, HC (2008–09) 257–i, Q 41

> Given that this global economic downturn is radically and dramatically reshaping the relative and absolute economic strength of nations—and that other nations are making choices about which areas to focus on in order to drive future growth—shouldn't we do the same to boost the economic impact of our science base?[5]

One of the areas Lord Drayson has identified as a strategic priority is life sciences, which encompasses bioengineering. In February 2010, he said that "we have to be ruthless about establishing where we have competitive advantage and what are the sectors with the clear growth opportunities. This is where we have to invest: in space, digital, life sciences".[6] In his oral evidence to us he explained:

> There is no doubt that as a country the environment we face is economically much more challenging and we have to respond to it in a way that ensures we are clear about those areas of growth on which we shall depend in future. The solution to the reduction in debt is in large part growth […] We need to diversify our economy and therefore will rely on those areas with significant growth potential within life sciences. This is a very important area both scientifically and in terms of the potential for new businesses and jobs.[7]

In tight fiscal climates, tough funding choices have to be made and we wanted to scrutinise an area that, if investments become more focused towards sectors offering the UK a competitive economic advantage, is likely to be a good bet for strategic prioritisation.

5. Too often, potentially successful industries that germinate in the UK blossom elsewhere. During our 2008–09 *Engineering: turning ideas into reality* inquiry we, at that time the Innovation, Universities, Science and Skills (IUSS) Committee, explored case studies on nuclear engineering, plastic electronics engineering, geoengineering and engineering in Government.[8] The inquiry was wide-ranging and covered skills, innovation, policy implications of emerging technologies and the Government's use of engineering advice. Plastic electronics engineering was a technology where the UK had a competitive advantage and made significant investments in the early development stage, but lost the industry because the necessary investment for taking the technology to market came from abroad – this loss occurred over the course of our six-month inquiry. The third reason to look at bioengineering was therefore to see if in other engineering areas the UK was learning from past mistakes and ensuring that investment in research and development was not lost in translation.

The inquiry

6. We were interested both in the strength of the bioengineering research base and how good the UK is at translating that research into economic and societal benefits. Regulation

5 "Foundation for Science and Technology Lecture", Department for Innovation, Universities and Skills, 4 February 2009, www.dius.gov.uk

6 "Nairne lecture: "Science: where now?", Department for Business, Innovation and Skills, 11 February 2010, www.bis.gov.uk

7 Q 182

8 Innovation, Universities, Science and Skills Committee, *Engineering: turning ideas into reality*

is a key factor in enabling or inhibiting research and translation, and therefore we included the impact of regulations in our inquiry.

7. The diversity of bioengineering, from the point of view of scrutiny, was both a blessing and a curse. It provided us with a range of issues that could be explored, yet the scale of the area made it impossible to focus on bioengineering in detail. The relatively short time between the re-establishment of the Science and Technology Committee in October 2009 (in succession to the IUSS Committee) and the end of the Parliament further added to the constraints. We therefore decided to select three bioengineering topics to inform our inquiry. We chose genetically modified crops, stem cells and synthetic biology. Each topic brought different characteristics to help us focus our investigation into bioengineering research, translation and regulation.

- Genetic modification (GM) is a relatively mature technology. It has been used for many years as a tool in both medical and agricultural contexts. We considered the use of GM techniques in crops to be particularly interesting because of the controversy and varying acceptance of GM crops around the world as well as the initial world-leading position of the UK, which introduced Europe's first food product from GM plants (a tomato paste) in 1996.[9]

- Stem cell technology is less mature yet there is a complex regulatory system governing research and translation and it has been subject to recent legislative changes in the UK made through the Human Fertilisation and Embryology Act 2008. Again, the UK has held a world-leading position in stem cell research.

- Synthetic biology is an emerging technology area. It is widely considered to be a field that shows great promise, but is still mostly at the research stage. Successful development of synthetic biology would require robust regulations and support for translation.

Terms of reference

8. We invited written submissions on the following questions, as they related particularly to GM crops, stem cells and synthetic biology:

- What is the UK's research capacity?

- How easy is it to translate and commercialise research?

- How do UK and international regulations affect research and translation?

- How can the UK maintain and grow its internationally competitive position?[10]

9. We received 39 written submissions to the inquiry. We themed the evidence sessions to include one panel focussing on each of the questions above. On 6 January 2010 we held a session with two panels, one on research and the other on translation. On 20 January 2010

9 Ev 91 [Professor Mike Ferguson]

10 "Bioengineering: terms of reference", Science and Technology Committee Press Notice 9 of Session 2008-09, 4 November 2009

we took evidence from a panel on bioengineering regulations. On 27 January 2010 we heard from Lord Drayson, Minister for Science and Innovation, Dan Norris MP, Minister for Environment and Rural Affairs, and Dr Mark Bale, Deputy Director of Health, Science and Bioethics at the Department of Health, to discuss the UK's international position and Government policies.

10. On 15 December 2009 we visited some research facilities as part of the inquiry. We were hosted by the Centre for Stem Cells and Regenerative Medicine at University College London (UCL) and the Centre for Synthetic Biology and Innovation at Imperial College London. We would like to put on record our thanks to both centres for accommodating these visits and note that we were particularly struck by the enthusiasm of the researchers we encountered.

Structure of report

11. In the following chapters we consider basic research in bioengineering, the translation of research into products and the regulations affecting both. Chapter 2 tackles basic science and Chapter 3 considers translation. We are mindful that this common distinction between basic research and translational research is a false dichotomy and that, although some activities could be considered as one or the other, most span both camps or fall somewhere in between. Characterising this area as a spectrum with basic research at one end, translation in the middle and commercial application at the other is also simplistic and fails to recognise that the system is complex and often far from linear. We do not attempt to describe the bioengineering research and translation system here, but simply take this opportunity to note that we are mindful of the pitfalls of drawing a distinction between the two. Throughout the report and particularly in Chapter 4, where we discuss regulations that impact on bioengineering as a whole, we will attempt to break the artificial distinction wherever possible.

2 Basic research

12. In 2004 the Government published the *Science and Innovation Investment Framework 2004–2014*, in which it set the UK an ambitious goal to increase gross investment in research and development (GERD) as a proportion of GDP[11] from 1.69% in 2004 to 2.5% by 2014. In 2008 the UK spent 1.88% of GDP on GERD,[12] showing a relatively small increase since the framework's goal was set.

Research funding

13. As we have noted, bioengineering includes many disciplines, so it is difficult to define the boundaries of bioengineering research and therefore to compile definitive figures on funding. We can, however, examine some indicative figures from different funding sources.

Private and charity sector

14. A significant amount of bioengineering research is funded by the private and charity sectors. According to the 2009 R&D Scoreboard, an investigation of the performance of the top UK and global corporate investors in R&D during calendar year 2008, the 130 UK pharmaceuticals and biotechnology sector firms among the most active 850 companies in the UK invested £9.6 billion in R&D making the sector by far the largest investor in R&D.[13] The R&D Scoreboard includes R&D funded by UK companies, but not all of this is carried out in the UK. In contrast, the Business Enterprise R&D (BERD) data generated by the Office for National Statistics (ONS) focuses on R&D activity within the UK, independent of the source of funding, and excludes R&D carried out by UK companies in other countries.[14] Its 2008 figures show that the "pharmaceuticals, medical chemicals and botanical products" sector contributed £4.3 billion, or 27.2% of the total R&D investment in the UK.[15]

15. The charity sector is an important funding source for medical research, raising funds in a number of ways, for example through fundraising or investment portfolios. The Association of Medical Research Charities (AMRC) reported in 2008 that its 117 members had contributed over £5 billion to medical research over the preceding six years,[16] with over £935 million spent in 2008–09.[17] These figures include the contributions of the Wellcome Trust and Cancer Research UK, two of the world's largest charitable bodies funding medical research. The Wellcome Trust alone spends an estimated £600 million on

11 Gross Domestic Product

12 OECD Main Science and Technology Indicators 2009/2

13 "The 2009 R&D Scoreboard", *Department for Business, Innovation and Skills*, March 2010

14 "How is the Scoreboard compiled?", *Department for Business, Innovation and Skills*, www.bis.gov.uk

15 "UK Business Enterprise Research and Development 2008", *Office for National Statistics Statistical Bulletin*, 11 December 2009, www.statistics.gov.uk

16 "A very public benefit: 21 years of charity support for medical and health research and innovation", *Association of Medical Research Charities,* December 2008

17 "About us", *Association of Medical Research Charities,* May 2009, www.amrc.org.uk

biomedical research every year, although this tends to focus more on translational research.[18]

Public sector

16. The Government's Science, Engineering and Technology (SET) statistics indicate the state of science funding in the UK. These show that the Science Budget has grown significantly in ten years from £1.2 billion in 1997–98 to around £3.5 billion in 2008–09.[19] There are, however, signs that this growth may be coming to a halt. In December 2009, the Government announced in its 2010 Pre-budget report that it would seek to make £600 million of savings by cutting the higher education, science and research budgets.[20] How the axe will fall across these areas has not yet been clarified,[21] and our concerns on this issue led to us conduct a separate inquiry into funding cuts, on which we plan to report before the end of the session.[22]

17. Funding for basic research mainly flows through the Research Councils. As noted above, under the Haldane Principle the Government sets an over-arching strategy, while researchers themselves establish detailed priorities and apportion funding on the basis of peer review. In 2007–08, the Research Councils invested in the order of £110 million in bioengineering research.[23] Of the seven Research Councils, the Biotechnology and Biological Sciences Research Council (BBSRC), Medical Research Council (MRC) and Engineering and Physical Sciences Research Council (EPSRC) are the primary funders of bioengineering in the UK.

18. The Government told us that it aimed "to maintain the UK as a world leader in stem cell research and development".[24] It pointed out that funding for stem cell research had doubled "from about £30 million in 2005–06 to more than £60 million in 2007–08".[25] The Research Councils contributed more than two thirds of this funding in the past year (£47 million),[26] and according to Pfizer Ltd, 59% of this Research Council funding (approximately £28 million) was for basic research.[27] The Government also has its eye on emerging technologies too and told us that it "wants to develop and exploit the UK's capability in Synthetic Biology".[28] The Research Councils explained that they are

18 Ev 174, para 1

19 "SET Statistics", *Department for Business, Innovation and Skills*, www.dius.gov.uk

20 "Securing the recovery: growth and opportunity: Pre-budget report", *HM Treasury*, December 2009

21 Science and Technology Committee, Sixth Report of Session 2009–10, *The impact of funding cuts on science and scientific research*, HC 335

22 "The impact of spending cuts on science and scientific research: terms of reference", Science and Technology Committee Press Notice 11 of Session 2009-10, 13 January 2010

23 Ev 9, para 5

24 Ev 56, para 2.4

25 Ev 57, para 2.15

26 Q 3

27 Ev 118

28 Ev 56, para 2.2

developing a "solid programme" in synthetic biology, with expenditure in 2007–08 of around £20 million.[29]

19. The importance placed on funding for GM crops was tougher to analyse. The Government's position was reasonably clear: they stated that "the need to improve global food security to feed an estimated population of nine billion people by 2050 is a major challenge. The potential contribution that GM can make as part of a "tool kit" should be considered".[30] The Government said that the total UK public spend on food and farming research, provided by the BBSRC, the Department of Environment, Food and Rural Affairs (Defra) and the Department for International Development (DfID), was about £350 million a year. Departmental expenditure tends to support research that is aligned with specific policy aims (see paragraph 60), while Research Council funding mainly focuses on basic plant and crop science.[31] The BBSRC's spend in the area of plant and crop science, which is wider than bioengineering, was £66.4 million in 2007–08.[32] As a tool, genetic modification (GM) has a relatively long history of use in bioengineering research.[33] RCUK informed us that expenditure on GM research by the Research Councils in 2007–08 was around £140 million.[34] This covered animals, humans and other organisms as well as plants.[35] However, narrowing down to GM crop research, the Government told us that "at present the amount of public funding specifically for GM crop-related research is relatively limited." This "limited" amount was not quantified.[36]

20. The Government's acknowledgement that GM crop research funding is "relatively limited" contrasts with its position that GM should be considered as part of a "tool kit" to improve global food security, a significant international challenge. We return to the assessment of GM crops when we examine regulations in Chapter 4.

21. **Bioengineering is an important component of the UK research base and basic research is relatively well funded. We detected, however, some tension between government priorities and funding support in the area of GM crop research. This may be a healthy manifestation of the Haldane Principle or a situation peculiar to GM crops, but we invite the Government to consider whether its overall strategy on the differential levels of funding in key strategic areas is a cause for concern.**

Research excellence

22. The Department for Business, Innovation and Skills (BIS) surveys the international comparative performance of the UK research base. The most recent report, published in September 2009, concluded that:

29 Ev 12, para 20

30 Ev 55, para 2.6

31 Ev 78

32 Ev 55, para 2.19

33 Ev 15, para 33

34 Ev 14, para 32

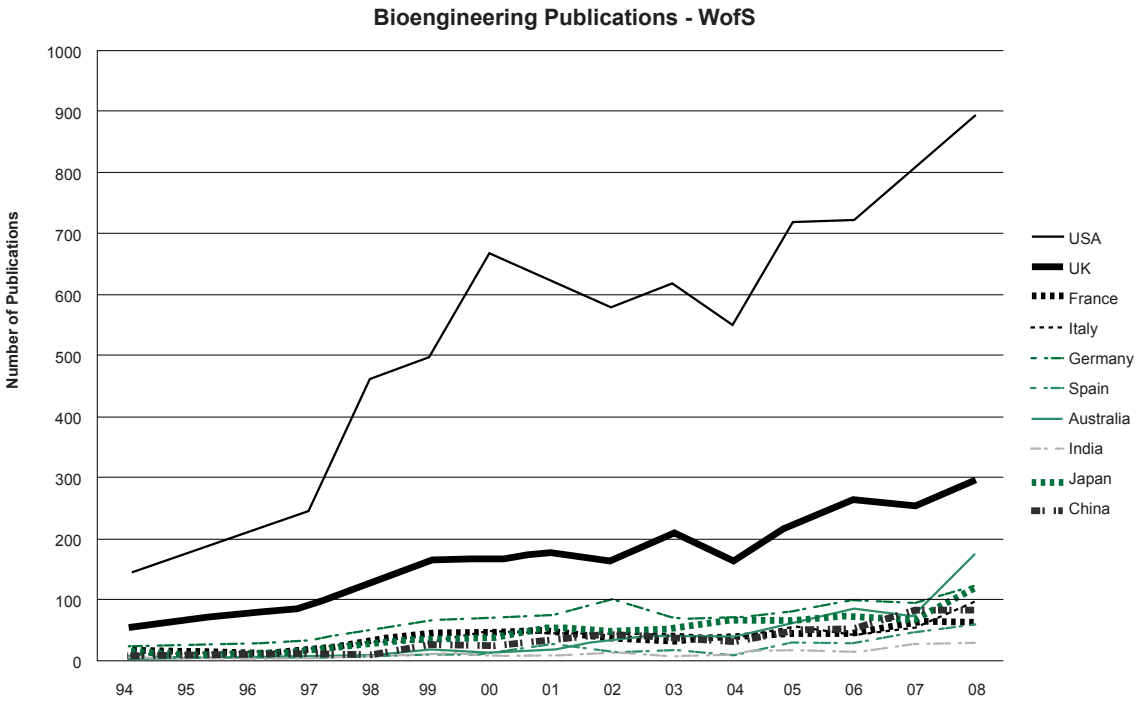
35 Ev 15, Annex 1

36 Ev 78

> The UK exhibits strong relative international performance in terms of sustainable achievement and productivity and continues to support a more consistent performance than most countries across fields of research. It is strong overall in the natural sciences and, on indicators where it has been second to the USA, it has maintained a close trail of moved into first place over the last few years.[37]

23. An example of where the UK has overtaken the USA is in its average citation impact,[38] which is greater than the USA's in the clinical, health and biological sciences. Overall, the BIS report shows that the UK generally excels in bibliometrics such as citation impact and share of world research papers.[39] Imperial College told us that "the UK is second only to the US in terms of publications relating to bioengineering",[40] as illustrated by Figure 2.

Figure 2: Bioengineering and biomedical engineering peer reviewed research publications (from Web of Science, search terms: bioeng* OR biomedical eng* OR medical eng*)[41]



24. The Government pointed out that the UK is considered to be a global leader in stem cell research,[42] and according to the UK National Stem Cell Network, research capacity is strong and growing.[43] We asked Professor Sir Martin Evans, who won the 2007 Nobel prize for his work on embryonic stem cells, whether he thought the UK's stem cell research base was healthy and he replied:

37 "International comparative performance of the UK research base", Department for Business, Innovation and Skills, September 2009

38 Citation impact is the ratio of citations per paper.

39 "International comparative performance of the UK research base", Department for Business, Innovation and Skills, September 2009

40 Ev 8, para 2.1

41 Ev 8

42 Ev 55, para 2.24

43 Ev 116, para 2.1

> I think intellectually it is pretty good. Obviously, we had something of a start here but it was a start at a low level. There is now worldwide an enormous amount of activity and interest and a huge amount of money has been put in elsewhere, for instance, in California, but I think we are in reasonably good shape.[44]

25. Similarly, the Royal Academy of Engineering, in their written submission, stated that "the UK currently holds a strong position in synthetic biology research".[45] Professor Richard Kitney, Co-Director of the Centre for Synthetic Biology and Innovation at Imperial College, was of a similar view, stating that "as far as the academic research side of synthetic biology is concerned we are number two in the world at the moment, the US being the leader".[46]

26. The National Institute of Agricultural Botany (NIAB) told us that:

> The UK has a traditionally strong plant science base in both universities and research institutes, particularly in the field of basic plant genetics in which the UK remains a world-leading authority.[47]

Professor Mike Ferguson, Dean of Research at the College of Life Sciences in the University of Dundee, concurred with this view, stating that:

> The UK has an excellent and vibrant research base in basic plant science despite limited research funding, with many laboratories routinely using (and improving) GM techniques and making fundamental discoveries that could be applied to crop improvement.[48]

27. The majority view is that the UK has an overall excellent bioengineering research base. We identified two threats to this position: funding cuts and international competition. We have already noted the threat of £600 million cuts at paragraph 16. The Council for Science and Technology (CST), in its report *A vision for UK research*, published in March 2010, pointed out that "the UK's leading position in research—currently second only to the United States [...] is under threat from major investments being made by existing and emerging economic powers."[49] The CST linked this threat to cuts and recommended that:

> The first step is for Government to continue to prioritise research funding against other competing financial pressures, against the background of public expenditure constraints. Prioritisation must not compromise the need for the UK to maintain a broad research base—the need to ensure capacity. At the project level, funding should be determined solely by the excellence of the research proposal itself.[50]

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44 Q 2

45 Ev 153, para 2

46 Q 40

47 Ev 104, para 5

48 Ev 91

49 Council for Science and Technology, *A vision for UK research*, March 2010

50 Council for Science and Technology, *A vision for UK research*, March 2010, page 5

28. The CST's belief in the need to ensure research capacity chimed with concerns that the UK will lose the benefit of the strong investments made in the science base over the past decade. For example, Sir Martin Evans told us:

> I think we have done very well over the last few years, particularly the last decade, and if we suddenly cut that we will lose all that benefit. The trouble is that in science you cannot just turn it on and off like a tap. You lose the people and you lose the facilities. That does not mean, of course, that science should not take its share of the burden, but I think we should also look to trying to use the benefits of the science we have and the science base we have for economic benefit and not look at it merely as a pit to spend money in but also as a cash cow to get money out of.[51]

Conclusions

29. **The UK is a world leader in basic research in bioengineering. But there is no room for complacency, particularly when faced with the dual threats of funding cuts and increasing international competition. Excellence in research is an investment for the UK's future, and it requires a long-term, sustained commitment to funding from the Government. Funding cuts to bioengineering, and indeed most areas of science and engineering, would risk throwing away the investment the Government has already made over the past 10 years. It would be foolhardy to take away that support now and lose out on the future benefits of past investment. We are concerned that the UK would not maintain an internationally competitive position in bioengineering if funding for basic research was cut, even in the short-term.**

51 Q 48

3 Translating research

Background

30. The translation of basic bioengineering research to commercial operation is usually an expensive and lengthy process. For example, it can cost an agribusiness approximately £150 million to bring a product to market and the process can take 10 years.[52] Medical applications can have similar requirements: we were told that it can take "hundreds of millions" of pounds[53] and up to 17 years to bring a stem cell-based product to market.[54]

31. With a timescale running into decades, the cost of translating bioengineering research is high. Yet translation is of crucial importance; without successful translation it is impossible to reap benefits from investments in basic research. The CST report summarised the UK's key weakness, stating:

> The UK's international position in research is not matched by its position in terms of productivity growth or innovative performance. [...] It is widely recognised that the weakness of UK research policy has been in translating research outputs into economic and social benefit, and [...] this needs to be addressed urgently.[55]

32. A shortfall in funding to sustain products through the long translational phases to commercial operation is often colourfully characterised as the "valley of death", where many potential applications fall before they ever reach the commercial stage.

33. The Government has long been aware of this problem and in 2006 the Government commissioned Sir David Cooksey to produce *A review of UK health research funding*. The Cooksey review concluded that "the UK is at risk of failing to reap the full economic, health and social benefits that the UK's public investment in health research should generate".[56] The review argued that researchers are in fact disincentivised to develop the findings of basic research.[57] The review refined the valley of death for health research, identifying two specific gaps:

- translating ideas from basic and clinical research into the development of new products and approaches to treatment of disease and illness; and
- implementing those new products and approaches into clinical practice.[58]

34. In this report we look at levers to improve translation: in this chapter, funding and the role of the NHS; and, in the following chapter, regulation.

52 Ev 27, para 4.3

53 Q 89

54 Q 62

55 Council for Science and Technology, *A vision for UK research*, March 2010, page 6

56 HM Treasury, *A review of UK health research funding*, December 2006, page 3

57 HM Treasury, *A review of UK health research funding*, December 2006, page 37

58 HM Treasury, *A review of UK health research funding*, December 2006

Who should fund translation?

35. When we asked Lord Drayson whose responsibility it was to fund the translation of bioengineering research into commercial applications, he responded:

> it is the responsibility of government to enable effective translation. It is for entrepreneurs and investors to see the market potential and therefore to do that work; it is for Government to continue to fund research on the basis of excellence having a clear sense of how that excellent science can be translated to ensure it works better in the United Kingdom than in other countries of the world.[59]

36. The question of who should fund translation is not as clear-cut as who should fund basic research, where it is generally accepted that the public sector has a significant role to play. With market potential and a commercial return there should be an incentive for the private sector to identify potential products and to fund translation to commercial production. As the plastic electronics example highlighted, however, the position is more complex and the private sector often needs further incentivisation.[60]

Private sector funding

Venture capital

37. One main source of private funding is venture capital (VC). Typically this is capital provided for early-stage, high-potential growth companies in the interest of generating a return through, for example, stock market flotation or sale of the company.

38. Sir John Bell, Chairman of the Office for the Strategic Coordination of Health Research (OSCHR),[61] told us that "the venture capital industry and the biotech sector are cyclical" and that:

> We are at the bottom of a cycle at the moment and there is very limited investment available, in part because of the terrible financial conditions that have existed for the past few years, but also in part because of the fact that venture capital companies investing in biotech have not been particularly successful for their investors.[62]

39. Professor Chris Mason, Professor of Regenerative Medicine Bioprocessing at University College London (UCL), considered that the problem was deeper, and told us that "the general view from the venture capital community is that the biotech model, in general, is broken and there is no model for stem cells and cell therapies".[63] Many areas of bioengineering are unappealing to venture capitalists because the long-term nature of the translation process results in delayed returns on VC investment, making investment a

59 Q 209

60 Innovation, Universities, Science and Skills Committee, *Engineering: turning ideas into reality*

61 The role of OSCHR is discussed further at paragraph 49.

62 Ev 181 [Professor Sir John Bell], para 13

63 Q 60

high-risk option. Professor Peter Raymond, Director of Medcell/Novathera,[64] summarised the problem in his written submission, with specific reference to stem cells, stating:

> It is virtually impossible to find finance for translational development, because it is expensive, high risk and very time consuming. VCs are looking for a 100% return on their investment in 5 years and the current perception is that stem cells and other areas of regenerative medicine will not deliver for at least 10 years. In addition, the VC Community is very jaundiced in its view of biotechnology because success has been so limited.[65]

40. Lord Drayson held a similar view, telling us that:

> There is a lack of venture capital funding in this area in Europe and a lack of clarity in the minds of entrepreneurs and investors as to how they can take this ground-breaking research and develop it into viable businesses in a timescale that is fundable.[66]

Industry

41. Because of the costs involved in translating stem cell research into applications, some consider that the pharmaceutical industry, with a history of taking products to market, has an important role to play.[67] The traditional pharmaceutical approach towards drug development has been the "blockbuster" approach of producing generic drugs. Developing autologous,[68] patient-personalised treatments, a possible future for cell-based therapies, would require the pharmaceutical industry to radically rethink its "blockbuster" approach. Professor Mason confirmed that "autologous cell therapies may not be that attractive to big pharma".[69] Sir Martin Evans explained the reason was that:

> the long-term future of many of the proposed stem cell based therapies will be a personalised medicine because these are transplant [...] and what you really want is to have a transplant which is a perfect match for the patient. A perfect match, of course, is the patient's own cells. […] That goes completely against the main pharmaceutical companies' blockbuster approach to a business model and I think that is one of the reasons why many of the big pharma have been quite slow in coming into this area[70]

42. The Northeast England Stem Cell Institute (NESCI) suggested additional reasons for why "the pharmaceutical industry has limited interest in playing its 'usual' role of financing development and of acting as a sponsor in clinical trials" for cell-based, patient-specific treatments:

64 A spin out company from Imperial College using stem cells, now operating as MedCell Biosciences.

65 Ev 85, para 2

66 Q 185

67 For example, Ev 85

68 That is, where a patient's own cells or tissue is used in treatment.

69 Q 61

70 Q 18

- Compared to established medicines, the manufacture of cell therapy requires a different type of expertise—it is not easily scalable, it cannot easily be outsourced and it often needs to be linked to a particular hospital location;
- Intellectual property in this field is not easily allocated to a particular formula or molecule. The patent landscape is diverse, complex and largely untested;
- Most stem cell therapies are historically more closely related to clinical transplantation, an area which historically has not interfaced much with industrial R&D;
- Stem cell therapies are often linked to the expertise of the pioneering academic/clinical team. This tacit knowledge cannot be easily transferred to allow production or distribution remotely; and
- Many stem cell therapies are likely to be very expensive not just to develop but also to produce on a routine basis. It is not certain that these costs will be met by healthcare systems. Industry will not invest significantly in the development of these therapies until the reimbursement route is clear.[71]

43. Despite these concerns, Professor Kell, Chief Executive of BBSRC, told us that:

> the evidence is that we have been able to attract some very good people and significant funding from international pharmaceutical companies, such as Pfizer, which has put £100 million into Cambridge[72]

In 2008, Pfizer Ltd created Pfizer Regenerative Medicine, a new research unit co-located in the Cambridge (UK) and the USA. The centre focuses on stem cells and modulators of regenerative processes.[73] Pfizer Ltd told us that:

> The pharmaceutical industry can provide a lot of experience to overcome [issues such as poor pivotal trial design and an evolving rather than established regulatory landscape] and guide the development of regenerative medicines and new tools in a way that ensures they are commercialised and made available to patients.[74]

44. Moreover, despite its reliance on the "blockbuster" approach, the pharmaceutical industry may soon have to develop other business models. The Government's 2009 *Life Sciences Blueprint*[75] pointed out that:

> The pharmaceutical sector is facing a patent "cliff", equivalent to $140 billion in sales, as several blockbuster drugs come off patent over the next few years, and must in any case look to new business models to replenish its pipeline.[76]

71 Ev 110

72 Q 5

73 Ev 118

74 Ev 119

75 We discuss the Office for Life Sciences in more detail at paragraph 57.

76 Office for Life Sciences, *Life Sciences Blueprint*, July 2009, page 9

45. When we asked Lord Drayson whether the pharmaceutical sector should develop business models around service-based, personalised cell therapy treatments, he replied:

> Yes, I do, but for them to be able to do that there must be an understanding of the changes which will take place and a realistic sense of the timescales, speed of adoption, the potential risks and benefits and the regulatory framework. All of these things impact on the likelihood of investment.[77]

46. There was a marked contrast between industries to support stem cell and GM crop translation. Despite the difficulties outlined, the pharmaceutical sector has a strong presence in the UK. Of the six major global companies involved in agricultural biotechnology, none has its headquarters in the UK.[78] Syngenta, whose headquarters are in Switzerland, has a crop research facility based in Berkshire although it does not carry out GM research in the UK any more. In 2004, Syngenta was one of the last major companies to relocate its GM facilities, a move that was hailed as the "final nail in the coffin for GM research in the UK".[79] It appears that there is virtually no industry in the UK to support the translation of GM crops.

47. **We conclude that the private sector cannot on its own fund the translation of basic bioengineering research to commercial operation, particularly in the case of GM crops, where the private sector is virtually non-existent in the UK. Venture capitalists alone are not capable of providing the sustained long-term investment in bioengineering to achieve the economic and societal benefits the UK needs. The position of the pharmaceutical industry is less certain. We consider that the pharmaceutical sector's need to develop new business models is an opportunity to embrace new bioengineering technologies based on, for example, patient-personalised cell-based therapies.**

Public sector funding

48. We now consider whether the public sector can and should bridge the bioengineering translation gap. The Government has a number of mechanisms for encouraging, coordinating and funding translation of bioengineering research, particularly in the medical field.

Office for the Strategic Coordination of Health Research

49. The 2006 Cooksey review examined health research in the UK and made recommendations to ensure that publicly funded health research was carried out in the most effective and efficient way, facilitating rapid translation of research findings into health and economic benefits.[80] A key recommendation was to set up an Office for the Strategic Coordination of Health Research (OSCHR) that would take an overview of budgetary division and research strategies of both the MRC and National Institutes for

77 Q 203

78 Ev 96, para 12

79 "Last biotech moves GM research to US", *Times Higher Education*, 2 July 2004

80 "Cooksey proposes reform of medical research", HM Treasury press notice, 6 December 2006

Health Research (NIHR),[81] a move that we have scrutinised in the past.[82] Professor Sir John Bell has told us that in the stem cell area, the MRC—on behalf of the OSCHR partners—has established a Translational Stem Cell Research Committee (TSCRC) to fund research that will drive stem cells towards application, both clinically and in disease modelling and drug discovery. Since the TSCRC was launched in 2008, it has awarded £11.5 million through its response mode funding route and targeted initiatives.[83]

50. We asked Professor Mason whether the setting up of OSCHR had made an impact in stem cell translation and he responded "it is possibly too early" to tell.[84]

51. **We recommend that in October 2010 the Government provide our successor committee with an assessment of the effectiveness of the Office for the Strategic Coordination of Health Research in facilitating rapid translation of research findings into health and economic benefits.**

Technology Strategy Board

52. A body with a wider remit is the Technology Strategy Board (TSB), which was originally established in 2004 as an advisory board to guide the Government's Technology Strategy. In 2006, plans were announced for the TSB to be given a wider role and to operate as a Non-Departmental Public Body (NDPB). The TSB in its current form was established on 1 July 2007.[85] The TSB's role is to stimulate technology-enabled innovation in the areas which offer the greatest scope for boosting UK growth and productivity. The activities of the TSB are jointly supported and funded by BIS and other government departments, the devolved administrations, regional development agencies and research councils.[86]

53. The TSB achieves its aims through a range of initiatives, which include:

- Collaborative R&D programmes—designed to assist industrial and research communities to work together on R&D projects in strategically important areas;
- Innovation platforms—identifying barriers to meeting societal challenges, mapping possible routes to overcoming the barriers and aligning activities to support innovative solutions;
- Knowledge transfer networks—national networks in a specific field of technology or business application bringing together stakeholders to stimulate innovation through knowledge transfer;
- Knowledge transfer partnerships—enabling companies to obtain knowledge of strategic competitive importance, from the further/higher education sector or from a research and technology organisation; and

81 Ev 176, para 5

82 Science and Technology Committee, Third Report of Session 2006–07, *The Cooksey Review*, HC 204

83 Ev 180, paras 3–4

84 Q 67

85 "About us: FAQs", *Technology Strategy Board*, www.innovateuk.org

86 *As above*

- The Small Business Research Initiative—this uses Government procurement to drive innovation, resulting in a fully funded development contract between a small company and a Government department.[87]

54. In September 2009, the TSB launched a Regenerative Medicine Programme, with £18 million promised to support key areas of commercial R&D and the development of cutting edge R&D partnerships. The TSB told us that "three Research Councils, MRC, BBSRC and EPSRC, will provide additional funding of at least £3.5m".[88] Professor Mason told us that, while the TSB's initiative was welcome, and it:

> will start to help move products potentially across that valley [of death...], [£]18 million is still a tiny amount when we consider that really to get one biotech product all the way through we are talking about hundreds of millions. It is a kick-start, but it is not across the valley; it starts us out, it is a mini-pier, but then we need something to take us forward.[89]

55. In October 2009 the TSB also announced an Innovation Platform focused on Sustainable Agriculture and Food, which seeks to increase the productivity of crops and livestock and, simultaneously, decrease the environmental impact of the industry. The development and use of GM technologies in addressing agriculture and food challenges is included in the scope of the Innovation Platform, [90] which seeks to invest up to £75 million over the next five years.[91] The National Institute of Agricultural Botany told us that this TSB Innovation Platform (along with other measures) had "helped strengthen links between public research and commercial plant breeding sectors".[92] The TSB has however acknowledged that:

> we expect businesses to comply with UK and EU regulatory and legal obligations, and in the area of GM it may be difficult for UK-based GM projects to provide competitive business cases showing UK wealth generation given the current EU position on GM crops.[93]

We return to the EU position on GM crops in chapter 4.

56. **We recommend that the Government provide our successor committee with an update in October 2010 assessing the effectiveness of the Technology Strategy Board's Sustainable Agriculture and Food Innovation Platform in improving the translation of GM crop technology.**

87 "Technology Strategy Board: driving innovation", *Technology Strategy Board*, www.innovateuk.org

88 Ev 121, para 11

89 Q 89

90 Ev 122, para 17

91 "Sustainable agriculture and food initiative aims to increase productivity", Technology Strategy Board press release, 13 October 2009

92 Ev 106, para 27

93 Ev 122, para 17

Government Office for Life Sciences

57. In January 2009, the Government Office for Life Sciences (OLS) was created, with a focus on improving the UK operating environment for pharmaceutical, medical technology and medical biotechnology industries.[94] After a six-month review period, the OLS produced the 2009 Life Sciences Blueprint, outlining "a package of actions to transform the UK environment for life sciences companies".[95] Having realised the difficulties of obtaining VC funding, the Government made a commitment, in the blueprint, to "invest £150 million alongside private sector investment on an equal basis, with the aim of leveraging enough private investment to build a £1 billion, 10-year VC Fund".[96] This VC fund, now known as the "UK Innovation Investment Fund" will provide funding for digital, ICT and advanced manufacturing as well as life sciences.[97] The VC fund will "invest government money on the same terms as investors".[98] When we asked Lord Drayson about the Government's progress in developing this fund, he told us that the life of the fund had been extended from 10 to 15 years,[99] and that:

> We announced the fund in principle seven months ago and to date have raised £325 million. I think the fact we have already raised more from the private sector than the government has invested in arguably the toughest funding market conditions to raise funds since the 1930s reflects that we have the structure right. As of yesterday [26 January 2010] the first closing took place and that money is now starting to flow into the market.[100]

58. **We welcome the Government's venture capital fund, the UK Innovation Investment Fund, and commend its success to date in raising funds in a tough fiscal climate. We request that the Government provide our successor committee by October 2010 with a breakdown showing how funds will be allocated, particularly how much will be available to the life sciences sector.**

Departmental expenditure

59. Finally, we consider the role of government departments themselves in funding translation. For obvious reasons departmental expenditure tends to favour applied research that is aligned with the department's policy priorities. Departmental civil R&D investment fell by 40% from £2.1 billion in 1986–87 to £1.3 billion in 2007–08.[101]

60. The Government said that between 2007 and 2009, the NIHR and DH have spent over £8 million on stem cell clinical research and development.[102] Defra's current baseline for

94 "Office for Life Sciences", Department for Business, Innovation and Skills, www.bis.gov.uk

95 "Life Sciences Blueprint", Office for Life Sciences, July 2009

96 "Life Sciences Blueprint", Office for Life Sciences, July 2009, page 22

97 "Life Sciences 2010: Delivering the blueprint", Office for Life Sciences, January 2010, page 45

98 Q 208

99 Q 207

100 Q 208

101 "SET statistics", Department for Business, Innovation and Skills, November 2009

102 Ev 57, para 2.17

expenditure on food and farming research, (excluding animal health and welfare), is around £29 million per annum, including the Department's contribution to the TSB's Sustainable Agriculture and Food Initiative. In 2008–09 Defra funded £0.88 million on research into the risk assessment of GM organisms and coexistence issues and £0.35 million on a limited number of Defra projects on crop improvement involving in part the development of GM model or crop plants. [103]

61. The Government has told us it recognises the "potential for GM technology to offer a range of benefits over the longer term".[104] Again we note a curious discrepancy between the Government's recognition of the potential benefits of GM crops and the limited R&D funding available through departments. **We recommend that the Government consider increasing funding for applied research into GM crops. As it aligns with Defra's policy objectives on global food security, we suggest that this increased funding could be provided, at least in part, through Defra's R&D budget**.

Conclusions on funding for translation

62. Translation does not happen in a single step. While we have kept our scrutiny broadly focused, we have become aware of distinctions between early and late stage translation as we consider the role of various funders. For example, Professor Mason explained that:

> it is generally recognised globally that public money is now required to drive through this first translational stage through phase 1 and phase 2, which is when the products show real value. By the end of phase 1 they show safety, by the end of phase 2 they show efficacy; therefore if you can get to the end of phase 2 there is a large hike in the value, let us say, of that particular product.[105]

Sir John Bell held a similar view that "in the pharmaceutical and biotech sector, we are likely to have to carry things further in the public domain before we spin them out".[106] He told us that:

> The Academy of Medical Sciences ran a roundtable discussion on this subject a year ago which involved Lord Drayson and a range of international venture capitalists, public sector funders and policy makers. The major conclusion from that meeting was [...] that we do need to find a better way to keep inventions in universities longer so that they have a much more likely chance of being successful when they are spun out, based on better evidence of both efficacy and safety. This is a model that I know some American universities have taken up rather aggressively and I believe needs also to be pursued in the UK.[107]

However he drew a line, cautioning that:

103 Ev 58, para 2.20

104 Ev 61, para 3.17

105 Q 60

106 Ev 181, para 12

107 Ev 181, para 13

> It is not realistic to believe that the public sector can carry a full stem cell clinical programme systematically from basic science all the way through Phase 3 studies and regulatory approval. This is likely to be extraordinarily expensive for even a single stem cell population, well beyond the capabilities of the public sector purse. Nor should the public sector be expected to carry this load.[108]

63. **In early stage translation, we argue that the Government has a greater duty than the private sector to bridge the gap, particularly in areas that align with policy priorities. More funding should be provided by the public sector for the early stages of translation. In stem cells, for example, this would be until the stage where it is possible for products to demonstrate evidence of safety and efficacy.**

64. **The Government is right to intervene to bridge the so called "valley of death" between basic research and commercial production. But if it is serious about doing so, funding for translation should be much greater. As a starting point for debate, we propose that if the Government were serious about translation in the same way that it is serious about basic research, the funding for translation would be increased to at least the same order of magnitude.**

The role of the NHS in translation

65. The NHS is arguably the first customer for a new medical application and can provide a bridge to global markets.[109] In February 2009, Lord Drayson called the NHS "our clear competitive advantage". He stated that:

> No other country has [...] a healthcare system so universally appreciated as the UK's. This is a major advantage for us as a nation [...] providing the lever to create a world lead in medical research—and from this a world lead in the life sciences industry: pharma and biotech. In turn, they can provide the growth and jobs that will help to rebalance our economy and fund future public investments, such as in scientific research.[110]

66. In June 2008 the Government published *High Quality Care for All*, a review of the NHS, which included the aim of:

> Ensuring that clinically and cost effective innovation in medicines and medical technologies is adopted. [The NHS] will strengthen the horizon scanning process for new medicines in development, involving industry systematically to support better forward planning and develop ways to measure uptake. For new medical technologies, [the NHS] will simplify the pathway by which they pass from development into wider use, and develop ways to benchmark and monitor uptake.[111]

108 Ev 181, para 11

109 Ev 117, para 3.5

110 "Foundation for Science and Technology Lecture", Department for Innovation, Universities and Skills, 4 February 2009, www.dius.gov.uk

111 "High quality care for all", Department of Health, June 2008, p13

67. When we asked Lord Drayson how the UK could make the best use of the NHS to be a global leader in medical research he explained that the Government is "actively addressing this and that is the whole thinking behind the Office for Life Sciences and the blueprint".[112] During our inquiry, we identified two key difficulties with the adoption of new technologies, particularly stem cell-based therapies, into the NHS. First, the UK National Stem Cell Network (UKNSCN) said that NHS Commissioners were slow to embrace new therapies that might displace more conventional medicines and treatments.[113] Second, the UKNSCN said that there were not enough "clinician-researchers" engaged in translational research which inhibited understanding of how to translate a technology from the laboratory to the clinic.[114]

68. Taking autologous cell therapies as an example, we asked Lord Drayson how the NHS could adapt to assist translation. He replied:

> we need to recognise that autologous treatment requires a different type of relationship between the healthcare system and the company that is providing that service. That will need different types of business models and will require business people and their investors to understand how that will provide income in future. Therefore, they need certainty and clarity from NHS policies that the NHS will be an early adopter of these techniques. The NHS needs to signal that if these technologies become available the NHS will be a good place for them to be applied to give people confidence to invest and translate these new therapies from research into clinical applications.[115]

69. The NHS therefore has a role to provide a market "pull" for new technologies. In the long-term, the NHS must be in a position to adopt more sophisticated autologous and personalised medicines and therapies. It is not a completely new concept: for example in-vitro fertilisation (IVF) operates on a patient-personalised basis and has been available on the NHS for years, (albeit subject to a "postcode lottery").[116] However the NHS, like the pharmaceutical industry, mostly operates with a "blockbuster" approach which is unsuitable for the adoption of autologous and patient-personalised therapies.

70. **We agree with Lord Drayson that the NHS gives a competitive advantage to the UK. It is therefore essential that this advantage is fully exploited to assist the translation of bioengineering therapies such as those based on autologous stem cells.**

71. **The Government is working on improving NHS adoption of novel technologies through various initiatives. However we are concerned that improving NHS culture and attitudes towards novel technologies is being neglected. We recommend that the Government produce a strategy for the NHS which will ensure: (1) that institutional inertia and adherence to conventional models of healthcare does not inhibit the introduction of new technologies and (2) that the NHS develops greater strengths in**

112 Q 201

113 Ev 117, para 3.5

114 Ev 117, para 3.6

115 Q 202

116 "Key facts on infertility, IVF and NHS provision", British Fertility Society, February 2005, www.britishfertilitysociety.org.uk

clinician-researcher collaborations to facilitate the translation of technologies from the laboratory to the clinic.

Translation of emerging technologies

72. In contrast to GM and stem cell technology, synthetic biology is at an early stage and the UK is not currently in a position to translate synthetic biology research, although we were told that in the USA some translation is already occurring.[117] Notwithstanding that the technology was at an early stage, the view was put to us that developing a DNA synthesis capability would enable the UK to become a world leader in synthetic biology translation.[118] Dr Alastair Elfick, Director of the Centre for Biomedical Engineering at the University of Edinburgh, explained that "to date researchers have had the ability to edit genomes" but that the future would be one where "we will be able to write function into genomes".[119] This step change from editing to writing genome function is what DNA synthesis technology would enable synthetic biology researchers to achieve. Dr Elfick continued:

> Such is the current, and future, value of DNA synthesis that the UK cannot be found to be in a position where this capacity is sub-contracted. A national initiative to develop cheaper, faster, longer, high-fidelity DNA synthesis would put the UK firmly at the front of this new industrial revolution. [...] We should not be put in a position where we try to build a new industry on top of out-sourced foundations.[120]

73. We are aware that £2.5 million of funding to develop DNA synthesis technology was recently announced by ITI Life Sciences, part of Scottish Enterprise.[121] Lord Drayson told us the TSB would address business models and strategic planning in synthetic biology.[122] We explored with Lord Drayson whether the TSB would support the development of DNA synthesis and he explained that:

> It will, but one must be measured in recognising that this has been described as a phase that moves from reading to writing the genetic code of life. That is a big deal which has some major ethical considerations. We need to be very clear about what that presents in terms of risks and challenges and go through an effective public engagement process to ensure that this does not get ahead of where the general public is in terms of the perception of the balance of risks and benefits.[123]

74. Although we agree that public engagement is important, Lord Drayson's answer was slightly unsatisfactory in indicating a commitment from Government to support the development of DNA synthesis capability. **Given that there is widespread consensus that developing a national DNA synthesis capability would put the UK at the forefront of**

117 Ev 153 [Royal Academy of Engineering]

118 For example Ev 170 [Royal Society of Chemistry], para 1

119 Ev 103

120 *As above*

121 "ITI Life Sciences invests £2.5m in R&D programme to advance efficiency of synthetic biology", ITI Life Sciences, www.itilifesciences.com

122 Q 199

123 Q 200

synthetic biology translation and what some consider to be the next industrial revolution, we recommend that the Government should invest in a national initiative to develop this capability. We consider that the Technology Strategy Board should manage this programme.

Conclusions on translation

75. **Translation of research is widely recognised as a persistent weakness in the UK, a view we share. While the UK has an excellent research base, the all-too common message is that we are missing opportunities to capitalise on the investments in the research base.**

76. **The barriers to translation of bioengineering extend beyond funding. However increasing funding for translation would be one way for the Government to signal its commitment to improving translation in the UK, irrespective of any strategic prioritisation debate.**

77. **The pharmaceutical sector, despite the difficulties we found, can provide valuable expertise and funding to enable translation, including in the area of stem cells. However both the pharmaceutical sector and the NHS primarily operate under a "one size fits all" approach to medicines, which will make it difficult to translate and integrate autologous stem cell therapies into clinical practise. New business and operational models will be required.**

4 Bioengineering regulation

78. Bioengineering activity must be regulated where there are concerns over health, safety or ethics to be addressed. On the one hand regulations have to provide a framework to ensure occupational, environmental and public safety while, on the other, allow innovative research and development to occur. As Professor Kell noted, "the key [...] is to recognise and welcome the importance of good regulation whilst seeking to ensure that it is proportionate and things do not get held up unnecessarily".[124]

79. In this chapter we examine first how regulations are developed, with particular focus on the value of public engagement and on the influence of Europe. Because bioengineering encompasses a range of activities, it is difficult to generalise when discussing regulations that tend, by nature, to be highly specific to the activity in question. Therefore the second part of this chapter examines separately the regulations applying to releases of GM crops into the environment and the regulatory system governing stem cell research and translation. Within these two examples we have aimed to establish what works well and where improvements should be made.

Developing regulation

Public engagement

80. Most fields of bioengineering will impact directly on people's lives in some way, from the medicines they use to the food they eat. Because it manipulates biological systems, bioengineering is sometimes viewed uneasily, and the use of bioengineering has led to some of the most intense controversies in modern science. Bioengineering tends to generate ethical concerns and anxieties in ways that other fields of science and engineering do not, and therefore policy-makers cannot ignore the public debate if their proposals on regulation are to be well received. The Government's Science and Society initiative includes an expert group on "Science and trust", which recently published a report highlighting the importance of public engagement, stating:

> Evidence shows that the public is overwhelmingly supportive of ensuring that risks are adequately understood and regulated before new technologies are commercialised. As a recent expert group report for the European Commission argued, the governance crisis associated with the innovation of certain new technologies relates to questions of risk and uncertainty, specifically the perceived failure of regulators to take account of public values and the full range of uncertainties.[125]

81. The issue of public acceptance came up in our inquiry most notably to illustrate the contrast between embryonic stem cell regulation and the development of GM crop technology, on which we have already noted there has been public opposition. The general view was that in developing amendments to the Human Fertilisation and Embryology

124 Q 25

125 "Science and Trust expert group report and action plan: Starting a national conversation about good science", Department for Business, Innovation and Skills, March 2010

(HFE) Act in 2008, a process that our predecessor committee played a key role in,[126] public views were appropriately included. As Sir Martin Evans put it, "that was a long and arduous process which did basically take the public with it".[127] Professor Lisa Jardine, chair of the Human Fertilisation and Embryology Authority (HFEA) commented that "this country has been in the position of being able to conduct embryonic stem cell research [...] because parliamentarians have charged us with that responsibility, because the public [...] trusts us in this regard".[128] She continued:

> We do have the advantage of starting with [...] primary legislation which is extremely clear that we are custodians on behalf of both Parliamentarians and the general public. Listening to my colleagues, that is the strong feeling that I have; that we have a very clear remit in having to take the public with us. It is absolutely fundamental to what we do. That may have helped us to take it on board from the beginning.[129]

82. We have one concern about Professor Jardine's comments. The HFEA is a regulatory body set up by Parliament to regulate based on legislation passed by Parliament. It has a duty to make certain information publicly available but it should not develop regulation in response to public opinion, therefore its remit does not extend to taking the public with it—that is the role of Parliament.

83. With GM crops, in contrast, Lord Drayson's view was that "both Government and industry clearly got it wrong in terms of not engaging with the public in an effective way about the technology".[130] He added that:

> we learned a lot about GM foods the hard way and that lesson was applied very successfully in the field of stem cells where we created a competitive advantage for the United Kingdom internationally. We were able through much better public engagement to bring the public with us and enable Parliament to establish a regulatory framework to provide us with a world lead in stem cell research.[131]

Highlighting the success of the regulatory approach to human embryo research, Sir Martin Evans suggested:

> Perhaps something of that sort is needed again to take the public with the GM crop issue. The public needs to know that it has been properly looked at, that we do have regulation in this country which retains our safety but allows our advance.[132]

84. Many of those who provided written submissions to the inquiry suggested that the ongoing lack of public acceptance of GM crops stems partly from a failure of Government to signal publicly its interest.[133] This brings us to the issue of public awareness, which is

126 Science and Technology Committee, Fifth Report of Session 2004–05, *Human Reproductive Technologies and the Law*, HC 7–I

127 Q 37

128 Q 108

129 Q 166

130 Q 182

131 As above

132 Q 38

133 For example, Ev 126 [Royal Society of Edinburgh], para 15

different from public engagement. Public engagement seeks to explore public opinions and concerns, and often raises more questions than answers. It is a vital part of developing good policies and regulations and explaining them. Public awareness activity, in contrast, is more of a one-way process that aims to inform and becomes particularly important when controversies or concerns about a technology arise.

85. The history of GM crops in the UK is rather a sorry tale of public misconceptions defeating the evidence and, taking Lord Drayson's point, it shows how Government got it wrong by not engaging effectively with the public.[134] When we asked the Minister, Dan Norris, about the Government's position on GM crops, he stated "the most important thing will always be safety when it comes to GM and GM crops".[135] The Government's position on GM crops was set out in 2004, following a review of public opinion and essentially states that "the Government takes a precautionary approach and we will only agree to the commercial cultivation of a GM crop if we are satisfied that it is safe" and that "the only sensible approach is to assess each GM crop on an individual case-by-case basis".[136]

86. When we asked the Minister what Defra was doing to raise public awareness of the benefits of GM crops he struggled to name a specific initiative. Eventually he stated that "every time we are asked about it we will say we think it is safe".[137] He also told us he was "sure" that Defra's website would say the same thing.[138] Unfortunately, we could not find on Defra's website a clear statement of the Government's belief in the overall safety of GM crops, although it did say that the Government "has concluded that there is no scientific case for a blanket ban on the cultivation of GM crops in the UK".[139] The Minister told us that:

> there is an issue about communication with the public and public understanding. We want the public to be in a much better place than it has been in the past to make informed decisions about issues surrounding GM. Without doubt what the media have presented to many members of the public are the understandable concerns but they have not necessarily promoted the benefits that GM brings.[140]

He added that "companies face a challenge in coming forward with GM products that have much clearer benefits for society and the individual" and that "companies need to make that case and come forward".[141]

87. When we suggested that, companies aside, the Government had not made the case for GM crops, the Minister told us that:

134 Q 182

135 Q 187

136 "GM crops–frequently asked questions", Department for Environment, Food and Rural Affairs, 24 August 2009

137 Q 216

138 Q 217

139 "GM crops", *Department for Environment, Food and Rural Affairs,* 24 August 2009

140 Q 187

141 *As above*

> there are potential benefits and we have to make the case. I am sorry that you do not believe we are making the case strongly enough, but it is certainly not because we do not want to. We make that case all the time in speeches every week, sometimes every day. We are very clear that trials need to be conducted and there are significant potential benefits to be gained from GM crops and GM in general. [...] you are right to say that it is difficult to go from a place where there are no huge obvious benefits to the individual and society and the benefits go to farmers and producers. That gap has to be filled and we are determined to try to do that. I do not think I can be clearer than that.[142]

88. While the Government recognised the difficulties of conducting GM crop field trials in the UK, it did not make the link between public anti-GM sentiment and its own policy of sitting complacently on the fence, failing adequately to convince the public either of the need for or safety of GM crops. **In our view it is not just the responsibility of companies or the media to make an evidence-based case for GM crops to the public, but the responsibility of the Government too. We consider that the Government, and particularly Defra, is emphasising the importance of safety without informing the public that it considers GM crops to be generally safe.**

89. **We welcome the Minister's positive attitude towards raising public awareness about the potential benefits of GM crops, but we believe that stronger leadership is necessary. The Government, and particularly Defra, should actively lead the public debate on this issue by stating its belief in the overall safety and potential benefits of GM crops on the Defra website and in relevant publications and speeches. It should also facilitate ways for GM crop researchers to engage with the public about the benefits of their research.**

90. Part of our inquiry focused on synthetic biology, particularly on whether lessons had been learned from past experiences in bioengineering. The potential of synthetic biology has been described as "close to unlimited"[143] although Lord Drayson cautioned against over-hyping the potential of synthetic biology, stating that "in the past we have seen certain types of science where excitement has led to hype, over-promise and unrealistic timescales which then create a backlash against the science or lack of understanding of the balance of risks and potential benefits".[144] Lord Drayson told us that:

> at the early stage of the emergence of a new field, which is where we are at with synthetic biology, one is grappling with ways of defining both the science itself and also the way in which it can be applied when the community is still unclear about the potential applications. Therefore, the role of government is to ensure that it remains up to date given that the field is changing very rapidly and that what we have learned in the past from previous types of ground-breaking scientific research is applied[145]

91. We were interested in whether the lesson about the importance of effective public engagement had been learned by the synthetic biology community. Professor Kitney

142 Q 221

143 Q 41 [Professor Douglas Kell]

144 Q 197

145 *As above*

described two separate studies, the first conducted by the Royal Academy of Engineering and the second jointly organised by the BBSRC and EPSRC.[146] Professor Kell told us that aside from these two studies, RCUK funding for synthetic biology this year included "about £0.5 million […] on the public engagement activities directly".[147]

92. There has been mixed success with public engagement in the past, with GM crops commonly viewed as a situation where the UK got it wrong, and stem cell regulation as an exemplar of how things should be done. It is commendable that public engagement in synthetic biology is well underway before the technology has even captured the public imagination. **We are pleased to discover that public engagement has been considered an early priority by those working in synthetic biology research and policy. This commitment indicates that lessons are being learned from past experiences.**

Influence of Europe

93. Many of the regulations affecting bioengineering are derived from EU Directives, for example, the Genetically Modified (Contained Use) Regulations 2000, which were the implementation of European Directive 98/81/EC.[148] These regulations govern most laboratory research on GMOs (including GM crop research and synthetic biology). Another example concerns the translation of bioengineering into health applications, which is affected by the UK's Medicines for Human Use (Clinical Trials) Regulations 2004, implementing the Clinical Trials Directive 2001/20/EC.[149]

94. We have touched on the relationship between EU Directives and science in the past, for example when we looked at scientific advice informing the EU Physical Agents (Electromagnetic Fields) Directive.[150] The impact of Europe on UK science is a theme that has repeatedly arisen in our past inquiries, particularly the implementation of EU Directives into UK legislation. Most recently it arose during our Evidence check inquiry into homeopathy, where we scrutinised the MHRA's implementation of an EU Directive into a new licensing scheme for homeopathic products. **The impact of Europe, particularly EU Directives, on UK science and engineering is a subject worthy of further scrutiny; one that we hope our successor Science and Technology Committee may take up as a stand-alone inquiry.**

95. In the following section we examine in more detail the impact of EU regulation on GM crop releases.

146 Q 42

147 *As above*

148 Directive 98/81/EC modified Council Directive 90/219/EEC of 23 April 1990 on the contained use of genetically modified micro-organisms

149 "Implementation of the Clinical Trials Directive in the UK", *Medicines and Healthcare products Regulatory Agency*, 15 January 2010, www.mhra.gov.uk

150 Science and Technology Committee, Fourth Report of Session 2005–06, *Watching the Directives: Scientific advice on the EU Physical Agents (Electromagnetic Fields) Directive*, HC 1030

Regulation of GM crop releases

96. Most of the comments we received on the regulatory regime applying to GM crops focussed on the release of GM crops for field trials or for commercial purposes. There were no complaints on the Genetically Modified (Contained Use) Regulations 2000,[151] which govern GM research in the laboratory. As research moves out of the laboratory, GM crops are affected by the Genetically Modified Organisms (Deliberate Release) Regulations 2002, the result of implementing European Directive 2001/18/EC. These regulations set out the procedures for considering all applications to release GMOs for research, either as:

- Part B releases, for research purposes such as field trials of GM crops; or
- Part C releases, for commercial releases such as the cultivation of crops.

97. We consider Part B releases first. Professor Chris Pollock, Chairman of the Advisory Committee on Releases to the Environment (ACRE), explained that applications for research releases (Part B releases) do not have to be approved at EU level and informed us that they "are decided entirely at home, and we have a system for approving such releases which works quickly and works effectively".[152] The 2002 Deliberate Release Regulations require that:

> a person who makes an application for a consent to release genetically modified organisms shall, not more than ten days after he sends that application to the Secretary of State, cause to be published in a national newspaper to be specified by the Secretary of State a notice containing the following information—
>
> (a) the name and address of the applicant;
>
> (b) the general description of the organisms to be released;
>
> (c) the location and purpose of the release; and
>
> (d) the intended date or dates of the release.

The Regulations further require that "an applicant for consent shall ascertain from the Secretary of State the level of detail on the location of the release which will be placed on the register and shall include the same level of detail in the notice to be published" as outline above.[153] So while the EU Directive sets the objective that field trial locations have to be publicly released, the UK Government has discretion regarding the level of detail required on locations.

98. The Agricultural Biotechnology Council told us that "current UK Government legislation requires those conducting GM crop trials to release a six figure grid reference to disclose the exact location of the trial".[154] They stated that "this process is enabling anti-

151 The Genetically Modified Organisms (Deliberate Release) Regulations 2002 (No. 2443)

152 Q 142

153 Genetically Modified Organisms (Deliberate Release) Regulations 2002 (SI 2002/2443), Reg 12(3)

154 Ev 167, para 3.2

biotech groups to actively target those hosting the trials or in many cases attempt to destroy the trial site itself".[155] They told us that:

> This makes the UK a challenging place to conduct GM trials in terms of cost and risk to the project, compared with many other countries in Europe and elsewhere in the world. It is worthy of note that of over 100 applications for field trials made across Europe in 2009, none were applied for in the UK (although one small trial did take place on the back of a 2008 application). This is potentially putting the UK at risk of being left behind since it is critical to test specific GM traits in UK growing conditions and develop locally adapted UK crop varieties incorporating these traits.[156]

99. The difficulty of carrying out field trials in the UK was a factor in Syngenta's decision to relocate their GM crop functions abroad. Dr Ray Elliott, Head of Strategic Projects at Syngenta, explained that:

> although the regulatory system is actually reasonably onerous it is workable; the issue was that most of the field trials that were put down in the UK were being vandalised and destroyed, that was the first point, so you could not actually generate the data to get your material through the regulatory system.[157]

100. The Government has told us that it is "taking steps to address the threat of vandalism".[158] The Government is:

> seeking to facilitate the hosting of GM trials at suitable sites that can provide greater security if required (including, if appropriate, through funding of security costs for eligible projects by BBSRC), and will continue to work with the police to ensure that, whilst peaceful protest can proceed, property is protected and those who engage in criminal activity are prosecuted.[159]

101. The Minister (Dan Norris MP) confirmed that the Government "would consider financing the security component of the trials" for academic research.[160] In 2009 a field trial was successfully conducted by Leeds University in nematode-resistant potatoes. The security cost (including fencing and 24-hour guards) was provided by the BBSRC[161] and cost approximately £100,000.[162] Dr Elliot confirmed that in the Leeds case "the security costs were almost as much as doing the trial."[163]

102. **We condemn the destruction of properly approved GM crop field trials and recognise that in the face of organised disruption the Government has to provide**

155 Ev 167, para 3.2

156 *As above*

157 Q 71

158 Ev 79

159 Ev 61, para 3.17

160 Q 211

161 *As above*

162 Q 72

163 Q 73

increased funding for GM crop field trial security. We recommend that Government continue to fund security for GM crop field trials.

103. The regulatory requirement to disclose the exact location of field trial raises a broader issue. In drafting legislation, the Government's hands were not tied by the EU Directive; it had, and still has, some leeway on disclosure details for the locations of GM crop field trials. We consider that while transparency and freedom of information are important, they must be balanced with the need to obtain relevant information on how GM crops perform in UK environments. **We recommend that the Government consider amending the Genetically Modified Organisms (Deliberate Release) Regulations 2002 to remove the requirement that researchers publicly disclose the six-figure grid reference location of planned field trials, in order to assist GM crop field trials and reduce the burden of security costs. This may involve a reinterpretation of either the level of detail on location or the extent to which the information should be made public.**

104. Once researchers have conducted field trials and gathered data on GM crop applications, they may wish to progress the application towards commercial cultivation. Advice to the Government on applications for commercial cultivation is provided by the Advisory Committee on Releases to the Environment (ACRE). ACRE, a scientific advisory committee that reports to Defra, conducts an independent scientific assessment and advises on the potential risks for human health and the environment. ACRE's assessment is necessary because under EU legislation, GM organisms (such as seeds) and food or feed products will not be approved for trial release or marketing unless a risk assessment indicates that human health and the environment will not be compromised.[164] When ACRE and Defra are satisfied with safety, the application is sent to Europe. Once approved at the European level by the European Food Standards Agency (EFSA), the GM application "can be imported, and if the consent conditions permit, cultivated anywhere in the EU, subject to other applicable legislation on seeds, pesticides and food and animal feed".[165]

105. We heard that there are problems with the EU regulatory system. The Government explained that:

> the EU regulatory system does not operate effectively, with lengthy delays in the approval of new GM products (especially GM crops for cultivation in the EU). This acts as a disincentive to R&D and plans for commercial introduction. The Government is pressing for the EU regime to be improved, so that quicker decisions can be reached on GM products without compromising safety.[166]

106. Specifically, the problem is that GM crops do not get approval at EU level even if ACRE and EFSA have approved the applications. This blockage in the approval process was aptly termed by the NIAB as "regulatory constipation".[167] Professor Chris Pollock, Chairman of ACRE, told us that the blockage was due to non-evidential factors and that it

164 Ev 64, para 4.24

165 "Genetically modified organisms: the regulatory process", Department for Environment, Food and Rural Affairs, 2 November 2009, www.defra.gov.uk

166 Ev 61, para 3.17

167 Ev 105, para 14

"occurs after EFSA has produced its opinion and occurs in those cases where EFSA has said there is no evidential basis to prevent cultivation".[168]

107. **The EU regulatory regime on the release of GM crops for commercial purposes is adequate, but operates dysfunctionally in practice, with blockages in the EU approval process occurring for political reasons.**

108. We asked the Minister what the Government was doing to change the regime. He told us "we are in constant dialogue about it because we are unhappy about it" but beyond that we unable to obtain an answer on our question about the approval of applications for the cultivation of GM crops.[169] We found scant evidence that the Government was trying to improve the EU approval process and little indication that this was even a priority. **We are disappointed that the Government told us it was pressing for change to the EU regime but was unable to provide us with the evidence that it is doing so. We recommend that the Government provide us with concrete details of how it is pressing for the EU regime to be improved and what the outcomes of its actions have been to date.**

109. A final concern about the EU approval process was raised by the NIAB, who highlighted to us "the potential implications of discussions currently taking place at an EU-level to introduce socio-economic criteria as part of the EU GM crop approval process".[170] These proposals have been suggested by the Dutch Government. The NIAB considered that the introduction of such criteria would be disproportionate as similar criteria were not applied to other novel or established technologies, would introduce further uncertainty into the system and introducing "arbitrary, opinion-based or politically-motivated criteria" would be contrary to free market principles.[171] When we asked the Minister about these proposals, he replied:

> I suspect that if you have a subjective measure or criterion like socio-economic benefit it creates the potential for even more delay. [...]The Dutch proposals are at such an embryonic stage that it is hard to take any position on them until we hear more.[172]
>
> Anything that could potentially speed up the situation would be very welcome, but if it was not thought through properly or it inadvertently added to delay or made no change it would be unwelcome.[173]

110. **We recommend that the Government keep our successor committee updated on proposals from the Dutch Government which may contain the introduction of socio-economic criteria as part of the EU GM crop approval process, and explain the UK Government's position on these proposals as they develop.**

168 Q 129

169 Qq 230–232

170 Ev 105, para 20

171 Ev 105, para 21

172 Q 235

173 Q 236

111. **While public engagement is important in developing regulations, we believe that the introduction of socio-economic criteria into the GM crop approval process is unwarranted and inappropriate in what should be an evidence-based process. We recommend that the Government oppose the introduction of socio-economic criteria into the GM crop approval process at the EU level.**

Regulatory system for stem cell research and translation

112. Even where a regulatory system has implemented the relevant EU legislation and ticked the box of incorporating public opinion, it must still be workable, or as the Northeast England Stem Cell Institute put it:

> Just because some research is theoretically permitted in law does not mean that the regulatory framework enables or facilitates research, if the opportunity costs of engaging with the regulatory framework are prohibitive.[174]

113. We touched upon this issue when we explored the regulatory system for stem cell research and translation. The regulatory system for stem cell research and translation primarily involves three agencies:

- The Human Fertilisation and Embryology Authority (HFEA), regulating embryo research;
- The Medicines and Healthcare products Regulatory Agency (MHRA) regulating stem cell treatments defined as a 'Medicinal product'; and
- The Human Tissue Authority (HTA) regulating treatments containing tissues or cells that are not considered as 'medicinal products' by the MHRA.

114. The HFEA has oversight where embryos are created and used in the derivation of human embryonic stem (ES) cell lines. Its remit ceases when the embryo is destroyed,[175] at which point the HTA's remit begins. The HTA also regulates the use of adult stem cells. The MHRA regulation applies when a cell therapy is intended to be a "medicinal product" (MP) or an "investigational medicinal product" (IMP).[176] Often more agencies are involved—for example, for a stem cell therapy derived from embryonic stem cells that could be used to treat Parkinson's disease, a research establishment would require:

- A licence from the HFEA;
- A licence from the HTA;
- Approval from a research ethics committee (REC); and

174 Ev 111, para 3.1

175 Usually after 14 days

176 Ev 124, para 11

- The approval of the local National Health Service Research and Development (NHS R&D) office.[177]

In addition, to bring the product to market a researcher would also need to:

- obtain approval from the UK Stem Cell Bank to deposit the stem cell line in that bank;
- obtain approval for animal testing from the Home Office Animal Licensing Directorate;
- engage with the MHRA about testing cells in MHRA-approved labs (before clinical trials begin) and then get MHRA approval for clinical trials; and
- after successful clinical trials, apply to the European Medicines Agency (EMEA) to obtain Marketing Authorisation to use the therapy as a standard treatment.

The therapy would therefore require approval or licensing from eight different organisations.[178]

115. With such a complex regulatory system for stem cells, we expected criticism. We received some—for example, the ESRC Centre for Genomics in Society (Egenis), suggested that it inhibits research.[179] Conversely, the Society for General Microbiology told us that "permissive legislation in the UK regarding stem cell research and restrictive legislation in other countries (e.g. US) have given the UK has a leading edge in this field".[180] Sir Martin Evans told us that:

> I think the whole of our approach in Britain to regulation in this area has been exemplary and has led the world. You may say it is a waste of time. No, it is not a waste of time. It has been an example of how things should be done.[181]

116. When we asked Professor Kell for his view on whether the regulatory system was good enough, he replied that "the broad answer is yes. The regulatory framework is complex because the science is complex and it is differentially complex at different parts of the translational pipeline".[182] We agree that regulatory complexity in the area of stem cell therapies is unavoidable.

117. The key issue is whether the complexity or the way the system operates in practice inhibits research and translation. We heard some views that the different parts of the system do not work together as well as they could, and that there were gaps and overlaps between the agencies. For example, Professor Mason told us that "as we move through the translation we now have the potential to drop the baton as we move through these various

177 "Therapeutic Use of Dopaminergic Neurons Purified from Chemically-Differentiated Human Embryonic Stem Cells", UK Stem Cell Tool Kit, Department of Health, www.sc-toolkit.ac.uk

178 "Therapeutic Use of Dopaminergic Neurons Purified from Chemically-Differentiated Human Embryonic Stem Cells", UK Stem Cell Tool Kit, Department of Health, www.sc-toolkit.ac.uk

179 Ev 93, para 7

180 Ev 108, para 7

181 Q 24

182 Q 25

regulatory agencies",[183] and that "what we need is that the boundaries are very well defined and there are clear mechanisms for handing over from one agency to another".[184] The Government is aware of this problem. We asked Dr Mark Bale, Deputy Director of Health, Science and Bioethics at the Department of Health, what was being done to simplify the system for researchers, and he explained that:

> In terms of simplifying the regulatory landscape that relies on long-term discussions at the European level because that is largely where the regulatory basis is now. We can simplify it in terms of ensuring that the different agencies align their processes and regimens and there is a larger government policy around better regulation.[185]

When we asked Dr Martyn Ward, Head of the Clinical Trials Unit at the MHRA, how regulatory agencies could work together, to provide a more seamless service, he responded:

> We are working with certainly the HTA more closely than perhaps the HFEA at the moment in establishing an MOU [memorandum of understanding] so that the overlaps are clear and that the roles and responsibilities between the two regulators are not doubled up [...] We are also working with them in relation to road shows–so we are planning.[186]

118. **Effective regulation in complex areas of bioengineering such as stem cell research and translation relies on efficient inter-agency coordination. We welcome the MHRA's and HTA's commitment to produce a memorandum of understanding. We recommend that other agencies—such as the HFEA—should engage in the process to eliminate regulatory overlaps and should be included in a memorandum of understanding with the HTA and MHRA.**

Navigating the system: guidance for researchers

119. Stem cell researchers may not have early enough dialogue with the regulators to foresee what will be required further in the translation process.[187] Dr Bale agreed that "we have to tackle researchers' understanding of the regulatory process".[188] In December 2009, the Government launched the Stem Cell Tool Kit, an online resource designed to help researchers navigate the regulatory process by answering a series of questions to generate a "route map".[189] Dr Bale explained that the Tool Kit:

> was launched in an attempt to provide a tailored and, if you like, real-time summary of what researchers needed to do depending on precisely how they proceeded with their research. One of the key factors is that stem cells have such great potential that they can go into any number of different routes for basic or clinical research. Because

183 Q 52

184 Q 53

185 Q 222

186 Q 117

187 Q 69

188 Q 222

189 "UK Stem Cell Tool Kit", Department of Health, www.sc-toolkit.ac.uk

> they are so complex when one tries to map out the different regulatory routes it looks enormously complicated, but it can be simplified into a few key yes/no questions as the researcher proceeds.[190]

120. In our view the Government's intention in launching the Stem Cell Tool Kit is commendable. It must be to the advantage of researchers if the complexity of the regulatory system can be distilled into a simple format. The Tool Kit was launched during the course of our inquiry and its impact remains to be seen. The DH told us that its impact will be monitored quarterly and feedback will be sought from researchers.[191] **We welcome the development of the Stem Cell Tool Kit and recommend that the quarterly reports on its impact, including a summary of researchers' feedback, are published.**

International harmonisation of regulations

121. Harmonising UK regulations with those of Europe and the USA can facilitate the penetration of overseas markets by UK researchers. Professor Mason informed us, in respect of stem cells, of the need for a joined up approach with other countries, particularly linking up the UK regulatory bodies with the European Medicines Agency (EMEA) and Food and Drugs Administration (FDA) in the USA.[192] He commented that British companies often have their "eye firmly placed on the American market"[193] and that "harmonisation would be good for all patients everywhere in that it would accelerate the rate of getting products to market".[194]

122. Dr Martyn Ward, Head of the Clinical Trials Unit at the MHRA, told us that "we are part of a European network" and that "we support and are part of what is happening in Europe under common legislation, so we are completely joined up in that respect".[195] Representatives from the MHRA work on the assessments of products at the EMEA and sit on their committees. Dr Ward also told us that:

> FDA is independent, clearly, but there are bilateral agreements between both ourselves, and the EMEA and the FDA and dialogue regularly occurs between the EMEA and FDA and the Committee for Advanced Therapies (CAT)[196] has a bi-monthly dialogue with the FDA. At a more practical level, clinical trials approval, we have had one example, for instance, of an early stage gene therapy trial where it was approved in the UK, taken across the water to the FDA and the FDA, because they were aware of the fact that we had approved it, asked us for our opinion and we provided a comprehensive report.[197]

190 Q 222

191 Q 223

192 Q 52

193 Q 69

194 Q 69

195 Q 120

196 The CAT is a committee of the EMEA, whose purpose is to assess Advanced Therapy Medicinal Products (ATMPs) and give its opinions on whether therapies should be granted marketing authorisations.

197 Q 120

123. When asked whether this type of arrangement could be formalised to streamline the process of taking therapies to overseas markets, Dr Ward replied that "the legislation is co-ordinated at European level; so any sort of formalisation would need to be done at the European level."[198] He explained that "it has not been done"[199] and that "at the moment it is such an early stage that we just do not have the experience to know how to do this."[200] We asked the Government about this and Dr Bale told us at the oral evidence session that there is a "major network called the International Committee on Harmonisation [ICH] which looks at the technical requirements in different jurisdictions in the US, Europe and Japan and other countries".[201] We were informed in a supplementary memorandum that, although some of the ICH's guidance relevant to stem cells has been adopted by the EMEA and FDA, the ICH was currently not planning any work on stem cells in the future.[202]

124. **The UK is part of a global market and international competitiveness in bioengineering will be enhanced by access to European and American markets. We are keen to see more formalisation, or planning for formalisation, between international regulatory agencies. We recommend that the MHRA should lead on behalf of the UK in working with the EMEA and FDA to develop regulatory harmonisation, particularly for stem cell-based therapies.**

198 Q 122

199 Q 123

200 Q 124

201 Q 225

202 Ev 81

5 Conclusions

125. This inquiry allowed us to revisit subject matter, such as stem cells and GMOs, that we had explored in previous inquiries, while also looking at new, exciting technologies such as synthetic biology. As one of the last inquiries we conducted in this Parliament, it was particularly appropriate that we brought together past topics with new. As is commonly the case, we felt that the many strands within the inquiry could have alone been the basis of separate inquiries, although equally we found it valuable to explore the various issues together in a light-touch manner to get a broad picture of the UK's position in bioengineering.

126. We found that scrutinising stem cells, GM crops and synthetic biology brought a useful focus to inform our inquiry. Our key finding in the area of stem cells was that the regulatory system, although robust, could be in practice difficult for researchers to navigate and could be streamlined further. The case of GM crops was murkier; we found that the Government's position on GM crops and public research funding was unsatisfactory given the Government's views on the safety and potential benefits of GM crops. The regulatory system in Europe was viewed as a major inhibitor to research and translation and we have urged the Government to rectify the situation. The importance of public engagement was raised, and on a more positive note, we found that the synthetic biology community is already on top of the game with public engagement activities.

127. Many organisations and individuals, such as the CST and Sir David Cooksey, have stressed the importance of maintaining the UK's capacity in basic research while increasing the UK's focus on improving exploitation of that research. Having seen the strengths the UK has in basic bioengineering research coupled with weaknesses in translation, we are inclined to agree. **Rising competition from abroad means that the UK simply cannot become complacent about its international standing in bioengineering.**

128. With the threat of funding cuts looming overhead, the UK may have to make difficult decisions in the near future about research prioritisation. We are in favour of such a debate as long as it is conducted appropriately: the Government must be clear with the research community about the goals and format of such a debate—openness is crucial. While it is inappropriate to prioritise basic research funding in this manner, given that the sources of scientific breakthroughs are often unpredicted, we consider that there is scope for strategic prioritisation in the more applied, translational research areas. **We consider that the UK is clearly a world leader in bioengineering, and in the spirit of making the most of the UK's strengths, bioengineering would be a strong contender for strategic prioritisation. This would, however, require the Government to address the UK's key weakness in exploiting basic research, an area where, although much progress has been made, more action is required.**

Conclusions and recommendations

Basic research

1. Bioengineering is an important component of the UK research base and basic research is relatively well funded. We detected, however, some tension between government priorities and funding support in the area of GM crop research. This may be a healthy manifestation of the Haldane Principle or a situation peculiar to GM crops, but we invite the Government to consider whether its overall strategy on the differential levels of funding in key strategic areas is a cause for concern. (Paragraph 21)

2. The UK is a world leader in basic research in bioengineering. But there is no room for complacency, particularly when faced with the dual threats of funding cuts and increasing international competition. Excellence in research is an investment for the UK's future, and it requires a long-term, sustained commitment to funding from the Government. Funding cuts to bioengineering, and indeed most areas of science and engineering, would risk throwing away the investment the Government has already made over the past 10 years. It would be foolhardy to take away that support now and lose out on the future benefits of past investment. We are concerned that the UK would not maintain an internationally competitive position in bioengineering if funding for basic research was cut, even in the short-term. (Paragraph 29)

Funding translation

3. We conclude that the private sector cannot on its own fund the translation of basic bioengineering research to commercial operation, particularly in the case of GM crops, where the private sector is virtually non-existent in the UK. Venture capitalists alone are not capable of providing the sustained long-term investment in bioengineering to achieve the economic and societal benefits the UK needs. The position of the pharmaceutical industry is less certain. We consider that the pharmaceutical sector's need to develop new business models is an opportunity to embrace new bioengineering technologies based on, for example, patient-personalised cell-based therapies. (Paragraph 47)

4. We recommend that in October 2010 the Government provide our successor committee with an assessment of the effectiveness of the Office for the Strategic Coordination of Health Research in facilitating rapid translation of research findings into health and economic benefits. (Paragraph 51)

5. We recommend that the Government provide our successor committee with an update in October 2010 assessing the effectiveness of the Technology Strategy Board's Sustainable Agriculture and Food Innovation Platform in improving the translation of GM crop technology. (Paragraph 56)

6. We welcome the Government's venture capital fund, the UK Innovation Investment Fund, and commend its success to date in raising funds in a tough fiscal climate. We request that the Government provide our successor committee by October 2010 with

a breakdown showing how funds will be allocated, particularly how much will be available to the life sciences sector. (Paragraph 58)

7. We recommend that the Government consider increasing funding for applied research into GM crops. As it aligns with Defra's policy objectives on global food security, we suggest that this increased funding could be provided, at least in part, through Defra's R&D budget (Paragraph 61)

Conclusions on funding

8. In early stage translation, we argue that the Government has a greater duty than the private sector to bridge the gap, particularly in areas that align with policy priorities. More funding should be provided by the public sector for the early stages of translation. In stem cells, for example, this would be until the stage where it is possible for products to demonstrate evidence of safety and efficacy. (Paragraph 63)

9. The Government is right to intervene to bridge the so called "valley of death" between basic research and commercial production. But if it is serious about doing so, funding for translation should be much greater. As a starting point for debate, we propose that if the Government were serious about translation in the same way that it is serious about basic research, the funding for translation would be increased to at least the same order of magnitude. (Paragraph 64)

The role of the NHS

10. We agree with Lord Drayson that the NHS gives a competitive advantage to the UK. It is therefore essential that this advantage is fully exploited to assist the translation of bioengineering therapies such as those based on autologous stem cells. (Paragraph 70)

11. The Government is working on improving NHS adoption of novel technologies through various initiatives. However we are concerned that improving NHS culture and attitudes towards novel technologies is being neglected. We recommend that the Government produce a strategy for the NHS which will ensure: (1) that institutional inertia and adherence to conventional models of healthcare does not inhibit the introduction of new technologies and (2) that the NHS develops greater strengths in clinician-researchers collaborations to facilitate the translation of technologies from the laboratory to the clinic. (Paragraph 71)

Translation of emerging technologies

12. Given that there is widespread consensus that developing a national DNA synthesis capability would put the UK at the forefront of synthetic biology translation and what some consider to be the next industrial revolution, we recommend that the Government should invest in a national initiative to develop this capability. We consider that the Technology Strategy Board should manage this programme. (Paragraph 74)

Conclusions on translation

13. Translation of research is widely recognised as a persistent weakness in the UK, a view we share. While the UK has an excellent research base, the all-too common message is that we are missing opportunities to capitalise in the investments in the research base. (Paragraph 75)

14. The barriers to translation of bioengineering extend beyond funding. However increasing funding for translation would be one way for the Government to signal its commitment to improving translation in the UK, irrespective of any strategic prioritisation debate. (Paragraph 76)

15. The pharmaceutical sector, despite the difficulties we found, can provide valuable expertise and funding to enable translation, including in the area of stem cells. However both the pharmaceutical sector and the NHS primarily operate under a "one size fits all" approach to medicines, which will make it difficult to translate and integrate autologous stem cell therapies into clinical practise. New business and operational models will be required. (Paragraph 77)

Public awareness and engagement

16. In our view it is not just the responsibility of companies or the media to make an evidence-based case for GM crops to the public, but the responsibility of the Government too. We consider that the Government, and particularly Defra, is emphasising the importance of safety without informing the public that it considers GM crops to be generally safe. (Paragraph 88)

17. We welcome the Minister's positive attitude towards raising public awareness about the potential benefits of GM crops, but we believe that stronger leadership is necessary. The Government, and particularly Defra, should actively lead the public debate on this issue by stating its belief in the overall safety and potential benefits of GM crops on the Defra website and in relevant publications and speeches. It should also facilitate ways for GM crop researchers to engage with the public about the benefits of their research. (Paragraph 89)

18. We are pleased to discover that public engagement has been considered an early priority by those working in synthetic biology research and policy. This commitment indicates that lessons are being learned from past experiences. (Paragraph 92)

Influence of Europe on regulation

19. The impact of Europe, particularly EU Directives, on UK science and engineering is a subject worthy of further scrutiny; one that we hope our successor Science and Technology Committee may take up as a stand-alone inquiry. (Paragraph 94)

Regulation of GM crop releases

20. We condemn the destruction of properly approved GM crop field trials and recognise that in the face of organised disruption the Government has to provide

increased funding for GM crop field trial security. We recommend that Government continue to fund security for GM crop field trials. (Paragraph 102)

21. We recommend that the Government consider amending the Genetically Modified Organisms (Deliberate Release) Regulations 2002 to remove the requirement that researchers publicly disclose the six-figure grid reference location of planned field trials, in order to assist GM crop field trials and reduce the burden of security costs. This may involve a reinterpretation of either the level of detail on location or the extent to which the information should be made public. (Paragraph 103)

22. The EU regulatory regime on the release of GM crops for commercial purposes is adequate, but operates dysfunctionally in practice, with blockages in the EU approval process occurring for political reasons. (Paragraph 107)

23. We are disappointed that the Government told us it was pressing for change to the EU regime but was unable to provide us with the evidence that it is doing so. We recommend that the Government provide us with concrete details of how it is pressing for the EU regime to be improved and what the outcomes of its actions have been to date. (Paragraph 108)

24. We recommend that the Government keep our successor committee updated on proposals from the Dutch Government which may contain the introduction of socio-economic criteria as part of the EU GM crop approval process, and explain the UK Government's position on these proposals as they develop. (Paragraph 110)

25. While public engagement is important in developing regulations, we believe that the introduction of socio-economic criteria into the GM crop approval process is unwarranted and inappropriate in what should be an evidence-based process. We recommend that the Government oppose the introduction of socio-economic criteria into the GM crop approval process at the EU level. (Paragraph 111)

Regulatory system for stem cell research and translation

26. Effective regulation in complex areas of bioengineering such as stem cell research and translation relies on efficient inter-agency coordination. We welcome the MHRA's and HTA's commitment to produce a memorandum of understanding. We recommend that other agencies—such as the HFEA—should engage in the process to eliminate regulatory overlaps and should be included in a memorandum of understanding with the HTA and MHRA. (Paragraph 118)

27. We welcome the development of the Stem Cell Tool Kit and recommend that the quarterly reports on its impact, including a summary of researchers' feedback, are published. (Paragraph 120)

28. The UK is part of a global market and international competitiveness in bioengineering will be enhanced by access to European and American markets. We are keen to see more formalisation, or planning for formalisation, between international regulatory agencies. We recommend that the MHRA should lead on behalf of the UK in working with the EMEA and FDA to develop regulatory harmonisation, particularly for stem cell-based therapies. (Paragraph 124)

Conclusions

29. Rising competition from abroad means that the UK simply cannot become complacent about its international standing in bioengineering. (Paragraph 127)

30. We consider that the UK is clearly a world leader in bioengineering, and in the spirit of making the most of the UK's strengths, bioengineering would be a strong contender for strategic prioritisation. This would, however, require the Government to address the UK's key weakness in exploiting basic research, an area where, although much progress has been made, more action is required. (Paragraph 128)

Formal Minutes

Wednesday 17 March 2010

Members present:

Mr Phil Willis, in the Chair

Mr Tim Boswell	Dr Brian Iddon
Dr Evan Harris	Graham Stringer

The Committee considered this matter.

Draft Report (Bioengineering), proposed by the Chair, brought up and read.

Ordered, That the draft Report be read a second time, paragraph by paragraph.

Paragraphs 1 to 128 read and agreed to.

Summary agreed to.

Resolved, That the Report be the Seventh Report of the Committee to the House.

Ordered, That the Chair make the Report to the House.

Ordered, That embargoed copies of the Report be made available, in accordance with the provisions of Standing Order No. 134.

Written evidence was ordered to be reported to the House for printing with the Report.

[Adjourned till Monday 22 March at 4.00pm.

Witnesses

Wednesday 6 January 2010

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Professor Douglas Kell, Chief Executive, Biotechnology and Biological Sciences Research Council; **Professor Richard Kitney OBE FReng**, Co-Director, Centre for Synthetic Biology and Innovation, Imperial College, London; **Professor Sir Martin Evans**, Professor of Mammalian Genetics, Cardiff University. Ev 17

Dr. Ray Elliott, Head of Strategic Projects, Syngenta; **Professor Chris Mason**, Chair of Regenerative Medicine Bioprocessing, University College London. Ev 31

Wednesday 20 January 2010

Professor Lisa Jardine CBE, Chair, Human Fertilisation and Embryology Authority, **Dr Paul Logan**, Head of Policy, Hazardous Installations Directorate, Health and Safety Executive, **Professor Chris Pollock CBE**, Honorary Professor, University of Aberystwyth, and **Dr Martyn Ward**, Head, Clinical Trials Unit, Medicines and Healthcare products Regulatory Agency Ev 43

Thursday 29 November 2001

Lord Drayson, Minister for Science and Innovation, Department for Business, Innovation and Skills, **Dan Norris MP**, Minister for Rural Affairs and Environment, Department for Environment, Food and Rural Affairs, and **Dr Mark Bale**, Deputy Director of Health, Science and Bioethics, Department of Health Ev 67

List of written evidence

16	Imperial College London	Ev 1
17	John Innes Centre	Ev 122
18	National Institute of Agricultural Botany	Ev 104, Ev 106
19	NHS Blood and Transplant	Ev 161
20	Northeast England Stem Cell Institute	Ev 109
21	Office for Strategic Coordination of Health Research	Ev 176
22	Parkinson's Disease Society	Ev 151
23	Peter Raymond MBE	Ev 85
24	Pfizer Limited	Ev 118
25	Professor Chris Mason	Ev 26
26	Professor Mike Ferguson	Ev 91
27	Professor Sir John Bell	Ev 180
28	Research Councils UK	Ev 9
29	Royal Academy of Engineering	Ev 153
30	Royal Society of Chemistry	Ev 170
31	Royal Society of Edinburgh	Ev 126
32	School of Pharmacy & Biomolecular Sciences, Faculty of Science and Engineering, University of Brighton	Ev 112
33	Science and Technology Studies Unit, University of York	Ev 87
34	Scottish Centre for Innovation in Spinal Cord Injury	Ev 157
35	Society for General Microbiology	Ev 107
36	Syngenta	Ev 27, Ev 38
37	Technology Strategy Board	Ev 120
38	Wellcome Trust	Ev 174
39	UK National Stem Cell Network	Ev 116

List of Reports from the Committee during the current Parliament

The reference number of the Government's response to each Report is printed in brackets after the HC printing number.

Session 2009–10

First Report	The work of the Committee in 2008–09	HC 103
Second Report	Evidence Check 1: Early Literacy Interventions	HC 44 (HC 385)
Third Report	The Government's review of the principles applying to the treatment of independent scientific advice provided to government	HC 158-I (HC 384)
Fourth Report	Evidence Check 2: Homeopathy	HC 45
Fifth Report	The Regulation of Geoengineering	HC 221
Sixth Report	The impact of spending cuts on science and scientific research	HC 335
Seventh Report	Bioengineering	HC 220

Session 2008–09

First Report	Re-skilling for recovery: After Leitch, implementing skills and training policies	HC 48–I (HC 365)
Second Report	The Work of the Committee 2007–08	HC 49
Third Report	DIUS's Departmental Report 2008	HC 51–I (HC 383)
Fourth Report	Engineering: turning ideas into reality	HC 50–I (HC 759)
Fifth Report	Pre-appointment hearing with the Chair-elect of the Economic and Social Research Council, Dr Alan Gillespie CBE	HC 505
Sixth Report	Pre-appointment hearing with the Chair-elect of the Biotechnology and Biological Sciences Research Council, Professor Sir Tom Blundell	HC 506
Seventh Report	Spend, spend, spend? – The mismanagement of the Learning and Skills Council's capital programme in further education colleges	HC 530 (HC 989)
Eighth Report	Putting Science and Engineering at the Heart of Government Policy	HC 168–I (HC 1036)
Ninth Report	Pre-appointment hearing with the Chair-elect of the Science and Technology Facilities Council, Professor Michael Sterling	HC 887
Tenth Report	Sites of Special Scientific Interest	HC 717 (HC 990)
Eleventh Report	Students and Universities	HC 170–I (HC 991)

Session 2007–08

First Report	UK Centre for Medical Research and Innovation	HC 185 (HC 459)
Second Report	The work and operation of the Copyright Tribunal	HC 245 (HC 637)
Third Report	Withdrawal of funding for equivalent or lower level qualifications (ELQs)	HC 187–I (HC 638)
Fourth Report	Science Budget Allocations	HC 215 (HC 639)
Fifth Report	Renewable electricity-generation technologies	HC 216–I (HC 1063)
Sixth Report	Biosecurity in UK research laboratories	HC 360–I (HC 1111)
Seventh Report	Pre-legislative Scrutiny of the Draft Apprenticeships Bill	HC 1062–I

		(HC (2008–09)262)
First Special Report	The Funding of Science and Discovery Centres: Government Response to the Eleventh Report from the Science and Technology Committee, Session 2006–07	HC 214

Session 2007–08 (Continued)

Second Special Report	The Last Report: Government Response to the Thirteenth Report from the Science and Technology Committee, Session 2006–07	HC 244
Fourth Special Report	Investigating the Oceans: Government Response to the Science and Technology Committee's Tenth Report of Session 2006–07	HC 506 [incorporating HC 469–i]