House of Commons
Trade and Industry Committee

UK Biotechnology Industry

Twelfth Report of Session 2002–03

Report, together with formal minutes, oral and written evidence

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The Trade and Industry Committee

The Trade and Industry Committee is appointed by the House of Commons to examine the expenditure, administration, and policy of the Department of Trade and Industry.

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Footnotes

In the footnotes of this Report, references to oral evidence are indicated by ‘Q’ followed by the question number. References to written evidence are indicated in the form ‘App’ followed by the Appendix number.
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List of written evidence
Summary

The UK has established itself as the leading biotechnology nation in Europe and remains second in the world, after the United States. However, many other countries are investing heavily in an effort to develop their own biotechnology capacity. The UK cannot afford complacency.

The UK’s world reputation in biotechnology is based on its long-established reputation for excellence in research in the biosciences in its universities, teaching hospitals and research institutes. However, such research is suffering from long term under-investment which could threaten the UK’s continued strength in biotechnology.

Many biotechnology companies have been founded on discoveries made through academic research. If the UK is to take advantage of the commercial applications of its academic research an efficient technology transfer process is required. At the moment that process is less developed here than it is in the USA. Whilst there are institutions where it is done well, and a steady improvement can be expected as expertise spreads, we are concerned at the variable quality. We recommend efforts to improve the technology transfer process nationwide through steps to promote best practice.

Biotechnology companies in the UK are less well funded than their competitors elsewhere. The Government’s support for commercial biotechnology is modest - many countries are targeting government funds at the sector. But we are not convinced that this public money will guarantee success. An adequate supply of venture capital is crucial to the continued success of biotechnology. The UK has a well developed venture capital sector but the timescales over which it is prepared to invest are not as long as the biotechnology firms generally require.

Biotechnology across the world is evidently suffering from the consequences of a bear market, but there are signs that this will bring about a period of consolidation in the sector which may prove beneficial in the long run. The positive effects of clusters can be seen in cities such as Cambridge, Boston or Munich. Young companies, in particular, can benefit from the concentration of biotechnology activity in a relatively small area. We are concerned, however, that efforts to create new clusters risk proving expensive failures and that competition between UK regions could potentially damage the UK’s biotechnology effort as a whole. We should be primarily concerned to reinforce the success of our most internationally competitive locations.

We have concerns over the shortage of management and intermediate skills in the sector. We recommend that the government, universities, RDAs, and the trade organisations work together to improve provision of training in these areas. Also, there is a shortage of biomanufacturing in the UK. Whilst this is not necessarily a problem at the moment, the development of biomanufacturing in other countries may deprive the UK of the potential additional value associated with this. The links between R&D and manufacturing in biotechnology may provide an opportunity for UK-based manufacturing in areas close to R&D centres.
1 Introduction

1. Biotechnology is the industrial application of biological processes. The biotechnology industry has been a source of both controversy and excitement over the last two decades. Whilst the origins of modern biotechnology lie in discoveries made in the post war years by figures such as James Watson and Francis Crick, commercial biotechnology emerged in the United States in 1970s. The UK was the next country to follow when commercial biotechnology developed here during the 1980s.

2. The USA’s early start established a lead in the field, both in technological and commercial terms, that it has maintained ever since. The UK has generally been considered to be in second place. However since the mid-1990s governments of many other countries have prioritised biotechnology and committed significant funding to develop their own biotechnology sectors. The German government, for instance, made an explicit commitment to catching and overtaking the UK as Europe’s biotechnology leader.1

3. With biotechnology such a focus of public policy in Germany, France, Canada, Singapore, Puerto Rico, Israel, and Ireland, amongst many others, fears have arisen that the UK may not be doing enough to nurture an industry seen to have such potential and may be in danger of jeopardising the advantages of its early start in the field. With this in mind we undertook an inquiry into the condition of the biotechnology industry in the UK, the challenges it faces, and the government policies designed to help it. The inquiry focuses, in particular, on the pharmaceutical or ‘red’ biotechnology sector, rather than the agricultural, ‘green’ biotechnology. Pharmaceutical biotechnology is the dominant branch of biotech activity in the UK, with a far greater number of companies involved in the sector;2 agricultural biotechnology is a different industry facing a different set of challenges and so we chose to restrict our focus. However, red biotechnology is a prime example of the sort of knowledge-driven industry that the government has been so keen to encourage and the lessons drawn here will be relevant to other high-technology industries making products with long gestation periods.

4. In the course of the inquiry we have taken evidence in Westminster from: the British Venture Capital Association; Bionow; the BioIndustry Association; Professor Peter Dunnill; the Association of the British Pharmaceutical Industry; Dr Greg Winter; Dr Jeff Skinner; Dr Ederyn Williams; Lord Sainsbury, Minister for Science and Technology and a DTI official; and the Investment Management Association. In addition we took oral evidence from: Scottish Enterprise; the Roslin Institute; Sir William Stewart; Pantherix; Cyclacel; Strakan; and Scottish Equity Partners in Edinburgh and from: the Eastern Region Biotechnology Initiative; Babraham Bioscience Technologies; Sense Proteomic; De Nova; and Acambis in Cambridge. We received written submissions from a range of individuals and institutions. In addition to the formal evidence sessions we undertook visits to Berlin and Munich in Germany, and to Boston, Washington and North Carolina in the United States. We are grateful to all those who contributed evidence to the inquiry or who helped

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1 The Scrip ‘German Biotech Companies Struggling in Bear Market’ No. 2794 (30 October 2002), p.16
2 According to figures prepared by the research consultancy Critical I for the DTI of almost 500 biotech companies in the UK, less than 20 % are involved in agricultural and environmental aspects of biotechnology.
with the visits. And finally, we would like to express our thanks to our Special Advisors, Mr John Hodgson, Dr Robin Fears and Mr Roger Quince.
2 Background

The UK Biotechnology Industry

5. Commercial biotechnology can be dated to the establishment of the first commercial biotechnology company, Genentech, in California in 1976. The first UK companies emerged in the early 1980s. Figures vary depending on the definitions adopted, but, according to figures prepared for the DTI, the UK currently has 481 companies. In 2001 the sector directly employed 23,650 people in the UK. In 2002 the UK biotechnology industry had a market capitalisation of £6.3 billion, accounting for 42% of the total market capitalisation of European biotechnology.

6. Because of its relatively early start, the UK has until recently been the largest biotechnology nation in Europe. But since the mid 1990s the Germany has channelled both federal and Länder money into its biotech sector. As a result, if judged by the number of companies at least, Germany could now claim to be challenging the UK as Europe’s foremost biotech nation; Ernst & Young figures show Germany to have the largest number of biotechnology firms in Europe with 360 to the UK’s 331. This deduction would be misleading, however. Regardless of the number of companies, the UK’s biotech industry is the most mature in Europe and its companies are larger. Germany has a high number of small companies at the very early stages of development. Germany has only 13 public companies, whereas the UK has 46. The list of biggest European biotechnology companies is dominated by UK firms. As a consequence, if judged by the value of the industry (‘market capitalisation’), revenues, the number of products in clinical trials, or numbers employed, the UK remains the largest biotechnology nation in Europe by some distance.

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3 Figures from Critical I for the DTI. The BioIndustry Association (BIA), the UK’s biotechnology trade association employs a looser definition of the sector to arrive at a figure of 550 companies in the UK (BIO 9). Ernst & Young give a figure of 331 companies: (Endurance: the European Biotechnology Report 10th Anniversary Edition, Ernst & Young, May 2003 (hereafter ‘Ernst & Young’)). Subsequent references are to the Critical I-DTI’s figures unless otherwise stated.

4 Ernst & Young, 2003, p.4. Critical I figures show the UK in the lead with 481 to Germany’s 430.

5 Ernst & Young, 2003, p.4

6 Ernst & Young, 2003, p.9

7 Ernst & Young, 2003, p.38
### The Biotechnology Industry in Selected Countries

<table>
<thead>
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<th>UK</th>
<th>Germany</th>
<th>France</th>
<th>USA</th>
</tr>
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<tbody>
<tr>
<td><strong>Revenue (£M)</strong></td>
<td>2,860</td>
<td>665</td>
<td>515</td>
<td>16,099</td>
</tr>
<tr>
<td><strong>Employees</strong></td>
<td>23,650</td>
<td>14,408</td>
<td>not available</td>
<td>141,000</td>
</tr>
<tr>
<td><strong>No. companies</strong></td>
<td>481</td>
<td>430</td>
<td>330</td>
<td>1,457</td>
</tr>
<tr>
<td><strong>No. public companies</strong></td>
<td>46</td>
<td>17</td>
<td>7</td>
<td>380</td>
</tr>
<tr>
<td><strong>R&amp;D Expenditure (£M)</strong></td>
<td>1,259</td>
<td>781</td>
<td>154</td>
<td>7,333</td>
</tr>
<tr>
<td><strong>IPOs 2001</strong></td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td><strong>IPOs 2002</strong></td>
<td>3</td>
<td>0</td>
<td>0</td>
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**Sources:** Ernst & Young; Critical I

7. In every country with a biotech industry, activity is concentrated in a relatively small number of geographical locations. In the United States the industry grew up in Boston and San Francisco and their surrounding areas. For the UK, and indeed for Europe, Cambridge has been the focus of biotechnology activity. But just as new centres of biotechnology have emerged in the USA, in places such as San Diego, Los Angeles, Seattle and North Carolina, so have they in the UK. As well as Cambridge and the Eastern region, Oxford, London, Manchester and Liverpool, York and Central Scotland all have significant levels of biotechnology activity.®

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® Biotechnology Clusters Report. Though whether these UK biotech locations constitute genuine ‘clusters’ is a debatable matter which is returned to in more detail in Chapter 6.
Distribution of Biotechnology firms by Region

<table>
<thead>
<tr>
<th>Region</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>East Midlands</td>
<td>16</td>
</tr>
<tr>
<td>East of England</td>
<td>89</td>
</tr>
<tr>
<td>London</td>
<td>65</td>
</tr>
<tr>
<td>North West</td>
<td>32</td>
</tr>
<tr>
<td>Northern Ireland</td>
<td>11</td>
</tr>
<tr>
<td>North East</td>
<td>12</td>
</tr>
<tr>
<td>Scotland</td>
<td>75</td>
</tr>
<tr>
<td>South East</td>
<td>111</td>
</tr>
<tr>
<td>South West</td>
<td>18</td>
</tr>
<tr>
<td>West Midlands</td>
<td>15</td>
</tr>
<tr>
<td>Yorkshire</td>
<td>21</td>
</tr>
<tr>
<td>Wales</td>
<td>12</td>
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Source: DTI

Departmental Competency for Biotechnology

8. Unlike countries such as Germany and Singapore, the UK did not create a biotechnology industry through design, but rather it evolved more gradually. A variety of government departments and agencies have responsibility for aspects of policy relating to the industry. The DTI is the government department which has oversight for the sector and its Bioscience Unit is ultimately responsible for the biotechnology sector as a whole. The DTI is also in charge of both overall policy relating to Small and Medium-sized Enterprises (SMEs) and, more broadly, economic competitiveness matters; and of promoting industry-related Research and Development (R&D) and technology transfer. In addition the DTI is the parent department for the Office of Science and Technology (OST), within whose remit lies overall science policy.9

9. Regulatory competency for much of the biotechnology activity in the UK rests with the Department of Health (DoH). Furthermore, through the NHS, it is the primary domestic customer for any treatments that the industry produces; and it also has a role in the clinical trials process which drugs need to go through before they can reach the market.

10. Although companies are increasingly emerging from the research departments of large pharmaceutical companies, the majority of small biotechnology firms have been a product of research conducted in the country’s universities and research institutes. As a result the Department for Education and Skills (DfES) has a role in respect of university policy and funding and the supply of scientists and technicians to the industry.

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9 Details of some of the schemes designed to help the biotechnology industry are discussed in Chapter 5.
One of the key policies to stimulate investment in R&D has been tax credits — potentially an important measure in such a research-intensive industry. The Treasury, therefore, is in charge of one of the most significant policy initiatives aimed at the sector.

As biotechnology is reliant on scientific discovery to provide the basis for new products, basic research is the foundation upon which the industry rests. Though a significant amount of research is funded by charities such as the Wellcome Trust, the Government is a major funder of basic research. This money is generally channelled via the research councils, the primary conduits being the Biotechnology and Biological Sciences Research Council (BBSRC) and the Medical Research Council (MRC).

Much of the competency for small business support now falls to the Regional Development Agencies (RDAs). In addition to generic support to SMEs, a number of RDAs have identified biotechnology as a key area for development and have implemented various schemes designed to encourage new companies or attract existing ones to their regions.

**Why Support Biotechnology?**

In relative terms the UK government has not committed massive amounts of public money to subsidising the biotechnology industry. However, this is not the case in a number of other countries which appear to regard biotechnology as a sector in need of significant public support. All pharmaceuticals development is highly research-intensive. It would normally take a decade or more to bring a drug through to market and the failure rate is very high, with only a small proportion of the discoveries that emerge from the laboratories making it through the pre-clinical experiments and the clinical trials stage. This means that it is also highly capital-intensive and the rate of expenditure of companies is very high.

As noted above, the industry is heavily dependent on a continuous stream of high quality basic research to provide the discoveries upon which commercial biotechnology is built. Government foots the bill for a high proportion of basic research across the industrialised world and so the state has a heavy involvement with the industry from its earliest stages. The sector is seen as a key strategic industry for the near future. On the one hand, countries are eager to establish themselves at the forefront of a technology that has the potential to yield a whole new generation of medicines. On the other, the rate at which the large pharmaceutical companies are delivering significant new drugs through conventional (i.e. chemical rather than biotechnological) research appears to have slowed. Moreover, the problems of drug resistance and of serious side-effects to chemical drugs have made new approaches, especially those looking to harness the human body's own defence mechanisms, more attractive. With its potential to provide a new stream of innovations in the pharmaceutical sector, the strategic importance of biotechnology will increase in the near future.

But it is not only the quantity of money that is significant but also the terms upon which it is available. Whereas most product development in conventional pharmaceuticals
is conducted by the very large multi-national corporations which dominate the sector, biotechnology companies are usually relatively small. Given that biotechnology companies have few tangible assets — their value lies in their scientific know-how — they have nothing to act as collateral to secure loans. Whilst the large pharmaceutical companies have the resources to overcome the high cost and long timeframes involved in drug development internally, the same is not true of the biotechnology sector. As a consequence the industry is highly reliant on venture capital. However, the timescales within which venture capital firms would normally expect to see some return on their investment are rather shorter than the timeframes within which a biotechnology firm could realistically be expected to deliver that return. Such mismatched timescales can prove a very real constraint on successfully bringing products through the development process and to market.

17. For these reasons, and although this takes different forms, the biotechnology sector is everywhere characterised by relatively high levels of state involvement. This is just as much the case in a ‘liberal’ economy such as the USA as it is in a ‘social market’ economy such as Germany’s where a greater degree of state involvement would be the norm. Governments have been keen to establish their nations at the forefront of an industry with such apparent potential. And because the lead-times for product development are so long and the risk of failure so high, they been persuaded that the market will not ensure the necessary levels of R&D and long-term investment. The industry clearly promises much — 19 of the almost 50 public biotechnology companies are making a profit and more will begin to do so in the coming years. However, it is not yet generally delivering value for money for investors. In the meantime, however, the government needs to determine the extent of market failure and social need in order to assess the extent to which public subsidy is necessary.

12 The funding problems of the biotechnology industry, including venture capital, are discussed in Chapter 5.
13 Critical I
3 Basic Research

Resources

18. It is through the emergence of scientific discoveries, primarily from academic institutions, that potential products and techniques for commercial biotechnology are identified. It is also at the level of basic research that government involvement and funding is at its most visible; despite the involvement of charitable foundations, government funding of basic research remains the bedrock of the industry.

19. That the UK was able to make an early start in commercial biotechnology is in no small part due to its traditional strength in research in the biosciences. UK universities and research institutes have established themselves at the forefront of biotechnology research; the MRC Laboratory of Molecular Biology in Cambridge (and its forerunners) alone has had 13 Nobel Laureates as members of its faculty.

20. Despite such a reputation there is a widespread feeling that this research excellence may be in jeopardy through long term underinvestment, both specifically in research funding, and more broadly, in the Higher Education (HE) infrastructure. There was a broad consensus in evidence that a healthy HE sector in general was a necessity for the continued success of the UK’s biotechnology industry. However, the impression was also given that there is something of a funding crisis in the UK HE sector and that this is reaching a stage where it could be detrimental to the quality and quantity of teaching and research, and, by implication, to the UK’s biotechnology industry.

21. The BIA’s submission claimed that “[u]nless quickly addressed, the chronic underfunding of research in UK universities will so degrade the infrastructure that it will precipitate another serious ‘brain drain’ to better funded facilities elsewhere, to the serious detriment of UK science and its support for biotechnology and related industries”.14 The Association of the British Pharmaceutical Industry (ABPI), the trade association of UK pharmaceuticals companies, bemoaned the condition of the HE infrastructure in their evidence: “The [UK] science base has suffered, in part, due to 20 years of underinvestment in basic infrastructure”.15 And the prognosis of one senior academic who has been active in biotechnological research at one of the country’s better resourced and most prestigious universities reinforced the pessimistic picture painted by the trade bodies: “I am more gloomy about the university situation than I have been in 35 years, and that is not because things have not been done recently, but the underinvestment is dire”.16

22. Despite these complaints, in many respects the HE system does appear to be justifying its reputation for excellence. For instance, OECD figures on citations put UK academics near the top of the league table — in the 19 most industry-relevant scientific disciplines, published research from the UK is some of the most highly cited and is significantly more

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14 App 4
15 App 14
16 Q 154 (Prof Dunnill)
so than work from either the USA or Germany. It also represents some of the 'best value', receiving more citations per dollar of public research funding spent.\textsuperscript{17}

23. That said, however, the concerns about the condition of the UK’s HE infrastructure appear well founded. While there has been an increase in funding in recent years, as a recent survey of UK competitiveness noted, it will take a prolonged period of investment “until the accumulated effect of years of under-investment in, for example, the university infrastructure will have been overcome”.\textsuperscript{18} The report cites OECD figures showing that between 1989 and 1999 public funding for R&D fell significantly further in the UK than in any other OECD economy.\textsuperscript{19} The sum of the BBSRC’s and the MRC’s expenditure on biotechnology is £241 million.\textsuperscript{20} The National Institutes of Health (NIH), the nearest US equivalent, does not separately identify expenditure on biotechnology but overall it has a budget of $23 billion of which 82\% is spent on R&D and research training.\textsuperscript{21} Even if only 10\% of the R&D/research training budget is spent on biotechnology, it is a considerably greater sum than the relevant UK research bodies are able to provide.

24. The UK’s research expertise in biotechnology has made its relative prominence in commercial biotechnology possible. The strength of the commercial biotechnology sector cannot be guaranteed merely by putting ever greater sums of public money into higher education and academic research. However, given the integral links between education and research and commercial biotechnology, it is hard to see how strength can be achieved and sustained in the latter without the former being adequately resourced.

**Focussing Research**

25. As well as the sums of money spent on research, there is the issue of how directive that funding should be: the best balance between directed research, which is explicitly tied to specific public policy ends, and ‘blue skies’ research, which allows scientists to develop their own research agenda, to a greater or lesser extent, without interference.

26. In the USA the majority of public money that funds biotechnology research is tied to matters of public health. The NIH, which spends billions of dollars each year on research involving biotechnology,\textsuperscript{22} awards funding under programmes targeting specific areas of public health such as cancer, heart disease or mental illness. Despite an increasing emphasis on ‘users’ in the grant application process, the UK research councils do not fund on this basis to the same extent.

27. Whilst a heavy reliance on funding tied to specific public policy goals would intuitively seem to be the route most likely to secure the most immediate returns, this is not necessarily the case. Applied research has to be built upon the more ‘blue skies’ research; it

\textsuperscript{17} OECD, *Benchmarking Industry-Science Relationships* (Paris, 2002), Fig. 5c, p.36


\textsuperscript{19} Ibid, Fig. 12, p.23

\textsuperscript{20} HC Deb, 26 June 2003, col 922W

\textsuperscript{21} Office of the Budget/NIH
is through progress in basic science that an understanding is reached from which more applied work can then develop. Applied and basic research are two sides of the same coin rather than distinct alternatives. Moreover, even where applied research is being conducted in an academic environment, any breakthroughs made are likely to require extensive further research until they can be used to develop new drugs or treatments. Even if research is directed it is highly unlikely to turn the universities and research institutes into a production line creating finished products. Money invested in academic research is not merely replicating or replacing research conducted in the commercial sector.

**Regulation of Research**

28. One area where we heard that the UK has a clear advantage over countries such as Germany and the USA is the regulatory framework within which biotechnology research is conducted. A major constraint on the development of biotechnology in Germany in the past, for instance, was the restrictive regulatory regime that made certain areas of research very difficult. Although regulation has been liberalised recently, the ban on stem cell research highlights the difficulties that still remain there. The United States has also undergone a high profile debate about stem cell research which, we were told, has reached a satisfactory conclusion. However, powerful lobbies there would like to see such research banned and certain states have imposed restrictions that are making research in the field difficult.

29. In contrast, the UK can be seen to have a comparatively liberal framework of regulation. Many of those we met on our visits to Germany and the USA were envious of the relative freedom enjoyed by British scientists. The prospect of tight restrictions being imposed on biotechnology research is seen by scientists as a real threat and it appears that they are prepared to move to avoid these restrictions. We were told of a prominent biotechnology research team that had abandoned Massachusetts for California for this reason. If tighter restrictions were imposed more generally in the USA, the UK would presumably prove a reasonably attractive alternative and a migration of research expertise could take place. However, the more liberal regime in the UK cannot be taken for granted and countries such as Singapore now form a genuine alternative. Regulation of aspects of biotechnology research has recently been discussed at European Union level and public opinion in a number of member states favours stricter regulation — or even outright bans — on some types of research. Whilst the UK has so far preserved its right to impose its own regulatory regime, pressure for the setting of standards at European level is likely to continue. Policies vary across the EU and it remains a contentious issue for some member states.

30. While we agree that regulation should set clear, ethical limits beyond which researchers should not be allowed to go, public opinion in the UK seems broadly content with the difficult ethical balance struck in the regime here. We would therefore oppose any attempt to tighten regulation here. We are aware that the Government takes the same view, but we wish to underline the importance of continuing vigilance; the regulatory environment for biotechnology research in the UK is a real source of advantage and must not be undermined by developments at the European level.
Conclusion

31. Excellence in research cannot in itself ensure commercial success in biotechnology but it does seem to us that its absence will preclude it. The UK has a fine tradition of research in biotechnology and has made good progress in translating some of this research into the commercial world. Levels of investment, however, remain a problem, with the UK spending less than its competitors on research and on the HE sector as a whole. Whilst the UK is still performing creditably, there must be some concern about the degree to which this can be sustained over the long term.
4 The Technology Transfer Process

32. Whilst excellence in research is a necessary condition for a flourishing biotechnology industry, it is not a sufficient one. Germany’s late start in commercial biotechnology and the fact that this start has required an extensive (and expensive) development strategy would seem to highlight the fact that, despite a well-respected and well-resourced research base, other factors are needed. The successful translation of the fruits of academic research into a commercial ‘product’ is, in the first instance, dependent on successful technology transfer mechanisms.

33. The realisation of this fact and a growing awareness of the commercial potential of much academic work has led to a spread of Technology Transfer Offices (TTOs) across UK universities. In comparison with the USA, however, the technology transfer process is very much less developed, a fact that is, perhaps, at the root of some of the reservations we have heard regarding their effectiveness.23

Why Commercialise?

34. Recent studies of competitiveness have stressed the role of the education system in fostering growth and innovation and, in a climate where all public expenditure is scrutinised for value for money, for its contribution to the general economic well-being of the nation.24 The economic contribution of the university system was a theme recently addressed by the Secretary of State for Education and Skills.25

35. We did find some anecdotal evidence that in academia, straying from the path of ‘pure research’ to become involved in its application in a commercial context was frowned upon.26 But this is decreasingly a problem, and, as UK universities have become aware of the potential to commercialise some of their research, it seems that the academic community has begun to be more enthusiastic; and it may be that the problem will soon be trying to dissuade researchers from trying to commercialise inappropriate work.

36. Relatedly there are fears that technology transfer might be regarded by HE institutions as a means of substantially increasing their income and by governments as a means of gaining a readily identifiable return on public expenditure in this area. It is true that successful commercialisation of technology can create quite large sums of money for the originating scientist, naturally an appealing prospect to those used to an academic’s salary. But it was emphasised to us that the primary motivation for technology transfer is to make full use of the practical applications of a scientific discovery.

37. Neither are the returns to the host institution liable to be that significant. It is certainly true that some institutions have earned significant sums from their commercialisation activity. But these are the exception — notable returns to the institution are more likely to

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23 Q 577 and Q 582 (Dr Winter)
25 P. Baty ‘Clarke lays into useless history’, Times Higher Education Supplement (May 9 2003), p. 2
26 Q 33 (BVCA)
be in the form of the increased cachet that it brings rather than huge profits. As one witness put it: “it is highly unlikely that we are going to do deals which will generate huge amounts of money for the institution…Most of the leading universities are doing it because it is expected as part of their mission and because they see it as enhancing their reputation and reinforcing their status as a leading research institution”.27 Even in the United States, where commercialisation of research is a more established practice, the amounts of revenue are limited. Whilst Universities such as Stanford and MIT have earned quite large revenues from their technology transfer activities, they are unusual. Furthermore, whilst the revenues of some universities may look impressive, they may be less so when seen in the context of their overall turnover. For instance, we were told that Duke University in North Carolina, a prestigious university with a strong research profile in the life sciences, earned $4.5 million dollars in 2001 from licensing their technology. However the university has $7 billion dollars of assets and in the same year raised $340 million dollars in externally funded research. Typically, universities in the United States with a successful research commercialisation record could expect to add 3-4% to their total research income.28 Clearly then, the commercialisation income, whilst no doubt welcome, is not fundamental to university finances in the United States. It should also be noted that any significant returns to Universities on their technology transfer activities are likely to be derived from a very small number of their projects. The MRC Laboratory of Molecular Biology earned £18 million in one year from their commercialised research, but this was attributable to two patents.29 A recent report on university technology transfer noted that the majority of UK universities received little or no income from licensing.30

Technology Transfer Offices

38. A reflection of the greater emphasis on commercialisation in British academia has been the establishment of technology transfer offices throughout the university sector. A Bank of England study found that, though a relatively recent phenomenon — the mean date of establishment was 1995 — all the Universities in their study had established technology transfer offices.31

39. The role of technology transfer offices is not only to commercialise their university’s research, but also to alert scientists within the university to the possibility that their research may have commercial applications — “…a little bit of encouraging when educating to the possibilities”.32 Furthermore, because academics are likely to lack the expertise to negotiate the commercialisation process successfully, it is vital that the technology transfer offices are able to provide appropriate advice and support, either directly, or through having access to networks of specialists who can be brought in.

40. Commercialisation is not simple. It is not sufficient for the science to be of a high standard. The research also has to offer the possibility that it can be developed to make a

27 Q 599 (Dr Williams)
28 Q 596 (Dr Williams)
29 Q 580 (Dr Winter)
32 Q 587 (Dr Skinner)
new product, or produce an old one more efficiently, on a commercial scale and at a significant rate of return on the considerable investment that is inevitably required. The technology transfer office has a clear role in advising on the commercial attractiveness of research.

41. The property rights to the science also need to be clearly established through adequate patenting. Without this the research will prove commercially worthless as it will lose any exclusivity of use, with companies free to exploit it at will. Patenting is a sophisticated activity and we heard evidence of poorly constructed patents undermining the commercial potential of some technology.\textsuperscript{33} Patenting may be an area where the technology transfer offices cannot provide the detailed knowledge required in most areas and may be better served by bringing in outside experts.\textsuperscript{34}

42. One of the crucial questions to be answered once the decision to commercialise a piece of science has been taken is over what form that commercialisation should take. The two main routes available would be to offer it to existing companies under a licence or to establish a new, spin-out company to work on developing its commercial application.

43. Licensing technology to an existing company is appealing because of the comparative ease of the process. Tasks associated with spinning out a company such as raising capital or finding suitable premises are avoided. However, the possibility of licensing a piece of technology is dependent on a suitable interest in that technology being shown on the part of existing companies. We heard that in some instances companies had been put off licensing technology by the excessively high prices that some universities were charging.\textsuperscript{35} If this is the case then it is obviously a concern. The new technology that emerges from universities is unlikely to be in an advanced stage of development and the company that licenses it will probably have to do a considerable amount of further work to establish whether it genuinely has any commercial application at all. Under these circumstances it seems unrealistic to demand a particularly high price for licences. But if such situations have arisen, they are probably due to inexperience on the part of the technology transfer staff. The technology transfer staff who gave evidence to us said that the price of licences for the universities’ technology were determined by how much companies were willing to pay for them, and that they had never lost a licensing deal through arguments over prices.\textsuperscript{36} Inevitably that means that some licences that have been bought cheaply have yielded very high returns and, with the benefit of hindsight, it may be that the university might have held out for a better deal. But many licences will yield no return at all to the company and, given the level of development of the technology and the high risk nature of the industry, we would not expect the universities to be losing licensing deals through excessive price demands.

44. A further problem with licensing is that, in order to be attractive to a company, the technology has to be at a reasonably advanced stage of development and it is difficult for university-based scientists to develop their research to this stage.\textsuperscript{37} Even where a licence is

\textsuperscript{33} Q 545 (ABPI)
\textsuperscript{34} Q 612 (Dr Skinner)
\textsuperscript{35} Q 334 (Strakan)
\textsuperscript{36} Q 595 (Dr Skinner)
\textsuperscript{37} Q 586 (Dr Winter)
taken up by a company, a considerable amount of further research is required to develop its commercial application, research in which it would generally be desirable for the originating scientist to be involved. But with an international market in intellectual property it is quite possible for the licensing company to be based in a different area, or even country, making such post-licence collaboration with the originating scientist very difficult.\footnote{Q 594 (Dr Williams)}

45. For reasons such as these, licensing, despite the apparent simplicity of the process, is frequently not a viable route for commercialising a given piece of technology. As a consequence the spin-out route, despite the level of difficulty and high risk involved, is often the preferred option. Under such circumstances the technology transfer office will need to help the scientist with business plans with a view to attracting finance.\footnote{Sources of finance for biotechnology companies are discussed in more detail in the next chapter.} Some technology transfer offices have close links with individual venture capital (VC) companies — we saw evidence of this in the United States where there are many more regionally based VC firms with close relationships with the universities in their locale, but we also note recent developments such as the one at Kings College of the University of London.\footnote{King’s College London Press Release (14 May 2003)} In some instances the universities are able to provide their own finance for their spin-out companies, though in the UK the funds available are very limited — in the United States we spoke to universities with quite considerable venture funds available for their spin-out companies. The availability of adequate finance is fundamental to the possibility of successful commercialisation and without a sufficient quantity, the technology transfer process will stall.\footnote{We do however also note the perils of making it ‘too easy’ to start up companies. These are discussed in more detail in the next chapter.}

46. Some universities are also able to offer their spin-out companies accommodation of some sort and specially designed ‘incubator space’ is increasingly to be found on campuses. This can be a real help to spin-out companies — not only can it remove the pressure of trying to find affordable space from the fledgling company but it can also help the originating scientists to direct the company’s research efforts whilst maintaining links with their originating department. This has two obvious benefits. First, scientists are more likely to be enthusiastic about starting up a new firm in a high risk sector where the chances of failure are great if the possibility of keeping their post at their parent department remains. We have seen that many universities in the United States offer very flexible employment contracts to their research staff to allow them to devote a certain amount of time to commercialisation activities. It seems in the UK some universities are better at this than others.\footnote{Q 461 (Sense Proteomic)} Secondly, in the circumstances where those involved with the new company are inexperienced in business, having spent their working lives in academia, being based on campus can ease the transition.

47. The range of skills required to commercialise research successfully is obviously quite broad. As well as, ideally, having a good understanding of the basic science, the technology transfer office staff also need to have some business expertise, spanning areas from finance to law. The level of efficiency with which technology transfer offices carry out the functions
required of them is evidently variable. On the one hand we heard complaints about them, and even the technology transfer professionals themselves noted how few really good technology transfer offices there are within UK universities.\(^{43}\) On the other hand, as noted above, the UK is commercialising an increasing quantity of its scientific research and it is doing so at a lower cost than either the USA or Germany. Such variations in quality as there are between university technology transfer offices seems, in large part, to be a reflection of the relative lack of expertise of a majority of technology transfer staff. This can be expected to improve gradually as experienced staff spread through the HE sector, leaving the good offices to take up posts at those with less of a commercialisation track record.\(^{44}\) We welcome schemes to promote best practice such as the one in the West Midlands.\(^{45}\)

48. **The reports of variable quality led us to question the need for in-house technology transfer offices at all: could not the technology transfer activities be contracted out, perhaps with the good units taking over the less good?** Whilst not ruling out this route, we were persuaded that good in-house technology transfer units were preferable. They can take a longer term approach, perhaps working with researchers over a period of time to develop the commercial potential of their work; they are more able to monitor their university’s research activities for commercial potential and build links with particularly research-active faculties, and they can develop their institution’s technology transfer activities over time. Furthermore, in so far as there is a variable quality amongst the technology transfer offices and that this is owing to a lack of experienced personnel, contracting out will do nothing to alleviate this shortage, especially as, in a survey of technology transfer offices, they claimed that the main hindrance on their ability to commercialise more technology was a lack of staff. If they have not got sufficient staff to fulfil the potential of their own institutions, they are unlikely to be able to take on the technology transfer responsibilities of others. Specialists can, and it seems are, brought in for specific projects. But even if universities were to make greater use of them, an in-house technology transfer staff would still be required, as their liaison point at the very least, but also to fulfil the sort of long term role mentioned above.

**Intellectual Property Rights**

49. The technology transfer process in the USA is considerably more developed than in the UK and in evidence references were made to the greater entrepreneurialism there.\(^{46}\) Technology Transfer in the USA was given huge impetus by the Bayh-Dole Act of 1980. Prior to this, federally funded research, including that funded by the National Institutes of Health (NIH), went largely uncommercialised. This was because technology developed through Government-funded research was only available for licence on a non-exclusive basis, thereby undermining any commercial incentive a company might have in developing it. At the most basic level the Bayh-Dole Act simplified the commercialisation process by establishing a single intellectual property policy throughout the government departments. It gave the institutions carrying out federally funded research the rights to

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\(^{43}\) Q 601 (Dr Williams)

\(^{44}\) Q 603 (Dr Williams)

\(^{45}\) Ibid.

\(^{46}\) Eg Q 34 (BVCA)
exploit that research themselves. It also gave small firms the right to license federally held patents and thus promoted links between these firms and universities.

50. The impact of the Bayh-Dole Act in the USA seems to have been considerable. Not only did it significantly simplify the process of commercialisation, it also gave a direct incentive to the universities and research institutes to do so. But it also significantly raised the profile of the commercialisation process and increased awareness of the possibility of technology transfer. Universities responded by setting up technology transfer offices in very substantial numbers.\(^47\) As a result of the Bayh-Dole Act, commercialisation in the USA is now done on a very large scale and with a level of resources that we do not have in Europe.

51. We are not convinced, however, that attempting to replicate the measures contained in the Bayh-Dole Act would have the same impact in the UK. In the USA the Bayh-Dole Act was introduced to increase the exploitation of publicly funded research in the context where regulations were acting as a deterrent to this. We received no evidence suggesting that a similar pool of unexploited technology exists here as a result of government regulations on the use of its intellectual property. However, we do suspect that the change in the IPR regulations that the Bayh-Dole Act brought about was only part of the reason for its success — its main contribution may have been the increased awareness among academics and companies about the potential of university based science and the enthusiasm for commercialisation it created amongst leading research universities. There has clearly been an increase in the UK’s technology transfer effort in recent years. Our impression is that the UK is still some way behind the USA in this area. However, this is as a result of a relative lack of experience and expertise, and a relative lack of resources, rather than as a result of constraints imposed by government regulations.

**Conclusion**

52. The USA has a clear lead in the size, and also the sophistication, of its technology transfer effort. Some Universities, such as MIT and Stamford, have gained very large incomes from their commercialisation activities. But even at institutions where the revenues from such activities were much smaller, we were impressed by the commitment to transferring their research into the commercial world and making the most of any potential applications that it might have.

53. The UK’s technology transfer process is less developed than the USA. In many ways it appears to be developing in the right direction. We applaud the efforts that have been made on the part of UK universities to increase the benefits to the public through commercial exploitation of scientific discoveries. Although too many technology transfer staff may lack expertise, this will improve over time. However, in the meantime, efforts to promote best practice must be made. Whilst recognising the independence of universities and the sensitivity of individual government departments to incursions into their territory, we think that there may be a role for the relevant

sectoral units in the DTI — in this case the Bioscience Unit — in bringing representatives from the various technology transfer offices together with industry representatives in order to exchange best practice and to obtain a clearer idea of what industry wants from the offices. Furthermore, efforts to inform and incentivise scientists in the possibility of commercialising their research must continue.
5. Business Finance & Development

54. The UK has a fine tradition of biotechnology research and is improving its capacity to translate that research into commercial applications. But commercialisation is only the beginning of the process and a vibrant biotechnology sector relies on thriving companies as much as it does on a flourishing research community. After the excitement surrounding biotechnology firms that reached its peak in 2000, the sector everywhere has experienced problems — it seems capital is far harder to come by for biotechnology firms than it was a few years ago, and where it is available it is possibly on worse terms too. The public markets seem, to all intents and purposes, closed to new biotechnology firms.

55. Central government in the UK has not invested public money as heavily in biotechnology firms as have many other countries. In Germany and the USA we heard of considerable state-level public money being available too. Whilst some Regional Development Agencies (RDAs) do have schemes to support and encourage biotechnology, they are not on a comparable scale.48

56. The absence of government support could be regarded as a good sign — that the UK biotechnology sector is able to survive without extensive public support and subsidy. However we received evidence that the private support infrastructure is not without its problems either — for instance the quantity and quality of venture capital on offer. It would be a matter of considerable concern if UK companies were faced with the twin obstacles of market failure and a lack of public support (at least in comparison with competitor countries).

Government Support

57. As noted in our introductory chapter, the biotechnology industry is characterised by high levels of state involvement. The level of support varies in its nature and its extent but is highest at the earliest stage of company formation and development and diminishes thereafter.

58. In the UK there are a variety of schemes that biotechnology firms can access. Few actually involve direct financial support. This contrasts with Germany where we heard of quite extensive funding being given to small biotech firms. In the UK the LINK scheme, run by the Office of Science and Technology (OST), provides funds over two or three years for joint projects between universities and business. LINK support for bioscience is estimated at £10 million per annum.49 The DTI’s SMART scheme provides up to £150,000 to Small and Medium sized Enterprises (SMEs) to develop new high technology products and processes. Because an SME is defined as a company with fewer than 250 employees, biotechnology firms, which are mostly relatively small, can access this. SMART awards totalled £35 million in 2002 with approximately 10% going to biotechnology firms.50

48 Eg Q 176 (Scottish Enterprise). Scottish Enterprise is the equivalent to the RDAs in England.
49 DTI provisional estimates.
50 Ibid.
59. There are other schemes that provide advice and mentoring rather than funds. BIOWISE is an on-line information service that promotes awareness of biotechnology and its potential. The Biotechnology Mentoring and Incubator Challenge (BMI) provided mentoring and advice to fledgling biotechnology businesses. But it also offered a subsidy, through matched funding, for building biotechnology incubator space. The Biotechnology Enterprise Platform Challenge (BEP) provided £5 million to establish several centres with a portfolio of intellectual property in particular fields with a view to establishing collaboration between them and other institutions working in those area. Both BMI and BEP are closed to new applications.

60. The University Challenge Fund (UCF) has provided money to help establish a number of companies. UCF, funded jointly by the DTI, the Wellcome Trust and the Gatsby Charitable foundation, was a competition for universities and research institutes to gain part of the £45 million available to establish seed funds to help high technology spin-out companies by investing up to £250,000 in commercialisation activity from their institution. 37 universities and research institutes won funds, either independently or as part of consortia, ranging between £1 million and £4.5 million. They were also required to contribute 25% in matched funds. Several witnesses expressed concern that the UCF funds will not be recapitalised in future. It is our impression that the scheme has proved popular. According to some provisional figures it is estimated that UCF has provided £3.613 million to some 25 biotechnology firms in 2001 and 2002.

61. There are also various schemes run by RDAs, many of which have identified biotechnology as a priority. These include networking and mentoring schemes, regional venture capital funds, incubator development, and, in Scotland, the Proof of Concept fund aimed at providing development funds to encourage commercialisation.

62. In comparison with the other countries we visited these schemes are small. Germany, for instance, provides seed funding and extensive help for start-up companies through matched funding for private venture capital as well as guarantees for private venture firms investing in biotechnology companies. In the United States, the level of involvement by the individual states was striking. A number of states are investing considerable amounts of money to try to establish biotechnology clusters. For instance, Michigan has committed $1 billion – $50 million per annum over 20 years — to develop biotechnology in the Detroit area. Kentucky, Wisconsin and Florida, to name only a few, have committed considerable funds to try to attract established biotechnology companies to their regions. We spoke to a representative of the Maryland Department of Business and Economics who told us of their extensive range of funds for biotechnology. They have various schemes providing equity investment and grants to small firms, and seed funds to spin-outs, and would, at any one time, have around 40 companies in their biotechnology portfolio.

63. In their written submission, the BIA suggested that government funding provided useful, though small, quantities of money. However, for the most part, for the companies we spoke to at least, government funding played a negligible role in their establishment and

51 App 4
52 Critical I provisional estimates.
53 App 6
The need for a well-funded research base was reiterated to us frequently by the companies. However, there seemed no particular appetite for public subsidies or grants to companies and, as will be discussed below, the main request was for better private funding.

It should also be noted that there is also the very real danger of making it too easy to start new firms; Germany would appear to provide a good example of this. From the mid-1990s, Germany introduced a variety of measures to establish itself as a leading biotechnology nation. Given its late start in commercial biotechnology, this took the form of the policies to help spin-out and start-up companies noted above. As a consequence a lot of companies were established in Germany in a very short space of time and difficulties have arisen from this. Germany's venture capital market is small — it has not traditionally been a significant source of finance there. It seems that with the establishment of so many biotechnology companies in so short a time, the demand for venture capital has outstripped its supply. Whilst this problem has been exacerbated by other economic difficulties in Germany, it highlights the need not only for an efficient technology transfer process, but also for the subsequent private infrastructure, such as a developed venture capital market, to sustain these new companies.

The German government sought to reduce the risk associated with biotechnology to try to attract venture capitalists to invest in the sector. This worked initially. However, as the companies have grown, we were told that there are increasing reservations in both government and industry circles about whether many of the companies are commercially viable and should have attracted funding at all. In contrast, the dominance of private venture capital in the UK ensures that a careful scrutiny of the company is undertaken at an early stage and a certain level of quality control is maintained. Whilst the problems of the German biotechnology sector can in part be seen as a reflection of the current business climate there, nonetheless they are also a result of the very rapid growth of small companies and, with the reduction of risk, a lack of scrutiny of those small companies. Not only have too many companies been formed for the private capital sector to sustain, companies have been formed that probably should not have been, with technology with little commercial viability and without the levels of necessary management expertise in place.

R&D tax credits are widely used across the world to provide a stimulus to innovation. They were introduced in the UK in 2000. Under the UK scheme, SMEs have been entitled to a tax credit on their non-capital R&D expenditure over £25,000 at 150%. Or, if the company is not making a taxable profit, as is the case with most biotechnology firms, losses can be surrendered to the Exchequer in return for a cash payment of 24% of total, eligible R&D spend. The scheme was estimated to provide £150 million of support to R&D activity in the UK. European State Aid rules confine the scheme to SMEs but an R&D tax incentive for larger firms is to be introduced. It is to be hoped that this will diminish the perverse incentive inherent in the existing scheme, no doubt recognised by the Government, to restrict company employee numbers in order to remain eligible for the tax credit.

The scheme was amended under the 2003 budget. The threshold was lowered from £25,000 to £10,000; the range of staff whose costs could be included was increased; and SMEs in receipt of government grants other than state aid, who were excluded from the
scheme under EU state aid rules, will be eligible for some support under the scheme for larger businesses. Some ICT costs for new companies are also now included.

68. R&D tax credits are evidently popular and their extensions welcomed.\textsuperscript{55} Research has suggested that R&D tax credits do boost R&D activity nationally. The Institute for Fiscal Studies notes that R&D expenditure is increased by subsidies such as tax credits — a 10% reduction in the cost of R&D can lead to an increase of 1% in the short terms and as much as 10% in the longer term.\textsuperscript{56} However, it was pointed out to us that similar schemes on a more generous scale have been adopted in other countries such as the USA; so while welcome, the tax credits in themselves will not necessarily make the UK more popular as a centre for biotechnology.\textsuperscript{57} It also seems that the application process is complicated and bureaucratic.

**Venture Capital**

69. The biotechnology industry relies on venture capital for its survival. In a sector dominated by firms with little in the way of tangible assets to act as collateral for loans — their intellectual property and the know-how of their staff are their primary assets — and which require a considerable quantity of money to sustain themselves, venture capital provides the main route of funding. Given this, any shortcomings in the provision of venture capital in the UK will have a considerable, detrimental impact.

70. The British Venture Capital Association (BVCA) — the venture capital trade association — has 160 members. Of those 16 have biotechnology as their only or primary focus and another 22 invest in biotechnology. In 2002, BVCA members invested £58 million in biotechnology companies out of a venture capital investment of £5.5 billion — about 1.2%. This was down from 2001 figures of £68 million invested in biotechnology out of a total of £4.7 billion — about 1.4%. Interestingly, the total number of biotechnology companies invested in was actually greater in 2002 – 75 companies rather than the 57 backed in 2001 — which implies that the venture capitalists are putting up less per biotechnology investment than in previous years.\textsuperscript{58}

71. As well as supplying the core finance for the bulk of biotechnology firms, venture capital firms have also provided valuable advice to the companies they invest in. In a relatively young industry dominated by scientists, it seems that experienced, good quality management is scarce.\textsuperscript{59} Venture capitalists would normally put a non-executive director with extensive management experience on the board of the companies in which they invest.\textsuperscript{60}

\textsuperscript{55} App 4
\textsuperscript{56} Rachel Griffith, *How Important is R&D for Economic Growth & Should the Government Subsidise it?* Institute for Fiscal Studies Briefing Note No. 12 (October 2000)
\textsuperscript{57} App 4
\textsuperscript{58} BVCA, *BVCA Report on Investment Activity 2002* (2002). These figures capture investment by BVCA members only. In evidence the BVCA was confident that venture capital investment activity by non-members was not significant and that their data provided a reliable picture of the UK venture capital market: Q 3.
\textsuperscript{59} Eg Q 684 (IMA)
\textsuperscript{60} Qq 18 (BVCA) and 363 (Scottish Equity Partners)
72. When venture capitalists are looking at a potential investment they require certain criteria to be met. They need to be sure that the science upon which the company is based is sound; that the intellectual property is properly protected; they are increasingly looking for a portfolio of potential products or a platform technology that can be used as a basis for a variety of products; they look for a good management team and a clear strategy for the company; and finally they look for a clear ‘exit point’ — an obvious moment when the venture capitalists will be able to recoup their investment, through a trade sale or an initial public offering (IPO) on the Alternative Investment Market (AIM) for example — usually within seven years of the initial investment.  

73. It was emphasised to us that these timescales were not absolute and that some companies have been funded for considerably longer than this. However, venture capitalists would normally expect to see at least a viable exit strategy in the foreseeable future within this timeframe. Whilst the five to seven year timeframe represents a longer period than venture capitalists would commit funds to in other industries, nonetheless it does create certain problems in biotechnology. Bringing a drug to market can take 10 to 12 years or more; but with the shorter timeframes favoured by the venture capitalists, there is a danger that companies will either find themselves short of cash at an important stage of development, or pushed towards research programmes with the prospect of more immediate returns.  

74. Though an IPO may be a possibility at this stage (i.e. after about seven years) under certain circumstances, there is a high likelihood, especially given the drop in confidence in biotechnology firms that the public markets have experienced in recent years, that it will not. A trade sale may also be a possibility, though this is dependent on finding a buyer from the large pharmaceutical firms and may not be an appealing prospect to the company itself. Furthermore, under such circumstances there would be a high possibility that any return on the technology that did eventually emerge would go abroad.  

75. This problem with the funding cycle for biotechnology firms is not exclusive to the UK. In the United States we heard complaints about a funding ‘valley of death’ that companies experience after a couple of rounds of venture capital funding. However, the sums of money invested by venture capitalists in the USA are far larger and this would presumably alleviate the problem. Anecdotal evidence from the founder of a Cambridge-based biotechnology company was that the quantities invested in a single company by USA venture capitalists might be up to 10 times larger.  

76. In the UK not only is the quantity of money invested smaller, but it would normally also be given in tranches. British venture capitalists usually put in place certain benchmarks by which the progress of a company in which they have invested can be measured — subsequent instalments of money would be contingent on these benchmarks being met. The BIA felt that this was a serious constraint on companies’ ability to act strategically and

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61 Q 9 (BVCA)  
62 Q 14 (BVCA)  
63 This is discussed in more detail below, paragraphs 84–91.  
64 Biotechnology firms’ business strategies are discussed below, paragraphs 92–97.  
65 Q 439 (De Novo). BVCA evidence would seem to confirm this: Q 20 (BVCA)
to respond to new situations swiftly.\textsuperscript{66} It would also, presumably, make companies tend to concentrate on meeting the next performance target rather than focussing on longer term goals.

77. The BVCA conceded that the tendency not to invest such large sums of money, and to pay the money in tranches, could slow the development of the company in which they are investing. However they considered this a necessary consequence of the smaller venture capital funds, relative to the United States, that their members are working with: “we are managing much smaller funds here than in the United States, so we have less ability to chuck in very large amounts of capital.”\textsuperscript{67}

78. The UK venture capital market does not seem to be geared to providing finance to the smaller, early stage biotechnology firms. In the USA we heard that specialist venture capital firms exist who focus on providing seed capital and finance to very early stage firms, and who look to exit by passing the company on to the mainstream venture capitalists. The UK does not seem to have this level of specialisation amongst its venture capital firms.\textsuperscript{68} That UK venture capital firms do not focus on early stage companies was confirmed by the BVCA.\textsuperscript{69} The focus on more developed companies is evident in the BVCA’s list of investment criteria mentioned above: a portfolio of different products and an experienced management team are unlikely to be characteristic of companies at the earliest stage of development.

79. There are several reasons for neglect of the early stage companies by the venture capitalist firms. The perceived risk associated with these types of firm is one. The perception is that many young biotechnology companies will not survive and that they are most likely to fail in their early stages — despite the greater sums of money involved, later stage companies are seen as a less risky prospect because their R&D is at a more advanced stage and consequently a clearer picture of their prospects can be gained.\textsuperscript{70}

80. But there are other practical issues, as well, that act as disincentives to venture capitalists thinking of investing in these companies. For instance they do not like to deal with such small sums of money: “Very early stage investing (seed round investing, as we would call it) as it is typically characterised is a…very, very difficult area for the traditional VC community to get involved in…because it is putting very small amounts of capital to work. If you need to make a myriad of investments of very small amounts you have a huge portfolio and you get into problems with the business model”.\textsuperscript{71} This is exacerbated by the tendency of venture capitalists to invest as part of a syndicate of venture capitalist firms. In order to spread their risk, venture capitalists often syndicate their investments so the amounts of money available would normally be too big for the earliest stage companies.

\textsuperscript{66} App 6
\textsuperscript{67} Q 20 (BVCA)
\textsuperscript{68} One venture capital firm we spoke to, Scottish Equity Partners, was originally set up by Scottish Enterprise to provide venture capital to small firms. Scottish Enterprise felt that this was an area inadequately served by the mainstream venture capital firms.: Q 381.
\textsuperscript{69} Q 30 (BVCA)
\textsuperscript{70} Ibid.
\textsuperscript{71} Ibid.
One venture capitalist firm we spoke to, who specialise in early stage investments, claim to be having difficulty finding partners to syndicate with.\textsuperscript{22}

81. We have also heard that venture capitalists are having to concentrate their resources on their existing portfolio of companies rather than look to finance new ones. Companies that gained their first round of venture capital funding a few years ago require subsequent rounds of finance. However, with the enthusiasm about the sector amongst investors reduced from its levels in the late 1990s, and with less confidence that the venture capital funds will remain plentiful, venture capitalists’ priority is to maintain the flow of money to companies in which they have already invested rather than to take on new ones.\textsuperscript{73} This is exacerbated by the current ‘bear market’ in the high technology sector which makes biotechnology IPOs extremely difficult. With this exit route closed off, venture capitalists are faced with the prospect of continuing to fund companies with quite substantial sums of money, where, under different circumstances, they would normally have expected to have already had their return. This clearly presents problems for companies at earlier stages of development who are trying to raise their first round of venture capital and may even spread to affect companies looking for a second round of finance.

82. Moreover, venture capital does seem a parochial industry and there is nothing to suggest that gaps in its domestic supply will be filled from abroad. We heard that even established clusters such as Raleigh-Durham in North Carolina have to work hard to persuade venture capitalists from California and Massachusetts to take an interest in their region.

83. The UK venture capital market does not serve the smaller firms well. As a response to this, government money has been concentrated on seed and early stage funding through schemes such as the UCF. Whilst government measures to increase the flow of funds into venture capital would seem appealing, the problems of Germany should serve as a warning. Increasing expertise in university Technology Transfer Offices may in time provide more attractive prospects for venture capitalists. However, even if better companies are spun out the ‘structural’ factors that deter the venture capitalists from becoming involved in the earliest stages would remain. The regional venture capital funds that are currently being established may provide valuable support in the absence of private funding. We received no evidence as to whether — and if so how — small biotechnology firms are using such funds; and, in any case, the funds are too new for any firm conclusions about their usefulness to be drawn yet. However it is important that the rigorous scrutiny of new investments and strict commercial criteria that one would expect from private venture firms is maintained by these public funds.

**The Public Markets**

84. The conventional route by which venture capitalists have sought to exit their biotechnology investments has been either through trade sales or through IPOs. Whilst trade sales remain a popular option, the impression we gained was that most of those founding biotechnology firms aspire to take their companies public. To date some 51 UK

\textsuperscript{22} Q 379 (Scottish Equity Partners)

\textsuperscript{73} R. Arnold & S. Smart, ‘Funding Discoveries – 50 Years and Beyond’, *Business Weekly* (March 2003)
biotechnology companies have floated, accounting for 48% of the European total. However the experience has not been without its problems and the market is, in effect, closed to new biotech IPOs.

85. This is partly a reaction to the general collapse of technology share prices, and, more specifically, to the overpricing and subsequent falls in biotechnology share prices: “During 2000 we had obviously a huge technology boom and tech investors and telecoms investors were looking for the next big thing and thought it was biotech. So valuations got pushed up to unsustainable levels.”74 But there seems to be more to the current scepticism with which the markets view biotechnology firms than a simple reaction to overpricing.

86. The markets have clearly responded to the performance of the biotechnology companies that have floated. Whilst some are either beginning to deliver profits or bring drugs to the market, or at least hold out the promise of doing so in the medium term, others are apparently failing to live up to the expectations that investors had of them at the time of floatation. To some extent this has been true of biotechnology companies the world over, but it seems to be more so of European firms — one of the Investment Management Association representatives that we saw, who had considerable experience of the biotechnology market, said, “I think it is fair to say that as far as the UK biotech sector is concerned it would be difficult to argue that it has been an area where you could make successful long term investments. There is a shortage of companies that have come public and have really become international class successful”.75

87. To emphasise that this is a specifically European, rather than general biotechnology sector, problem, one UK biotechnology fund invests 80% of their total money in North America76 — “the reason why this is the case is because there are a lot of very successful biotech companies in the US which could be seen as role models for the emerging ones, whereas there are not the same success stories in the UK”.77

88. One reason for the relative failure of the British, and indeed European, public biotechnology companies can be discerned from our evidence. A criticism made to us was that too many companies have floated too early during biotechnology’s ‘boom’ years. IPO has been viewed by biotechnology companies very much as a further stage in the development process — after two or three rounds of venture capital finance, IPOs have been seen as merely the next step in raising cash to continue the development process. These companies could therefore be some five years or more away from a finished product at the time of flotation; and with an extensive, expensive and hazardous clinical trials process to be negotiated, the chances of failure are still high. It does appear that, in the excitement that surrounded the biotechnology sector, companies were allowed to float at too early a stage of their development.

89. The result of this is a gloomy outlook for many public biotechnology companies. Some successes notwithstanding, many are still trading below their cash balances; in effect, their technology is considered by the markets to be worth less than nothing. A Financial Times

74 Q 680 (IMA)
75 Q 669 (IMA)
76 S. Johnson, ‘Are Ailing Funds About to Leave the Sickbay?’, Financial Times – Money (16 March 2002)
77 Q 676 (IMA)
article noted that: “Investors have lost patience with tales of dizzying scientific achievements and want to start seeing results”.78 Whilst in many instances investors have been aware that they have been investing in potential, clearly they are now demanding some prospect of this potential being realised.

90. The realisation of this has prompted fund managers to become more stringent in the criteria that they apply to potential biotechnology investments. They are now looking for companies with drugs in late stage (i.e. stage II or III) of clinical trials, a portfolio of drugs in the pipeline, experienced management drawn from big pharma or the financial sector, and sufficient cash reserves to take the company through the inevitable fluctuations in the market — “if you put those attributes together it is fair to say that at the stage of development that we are here in the UK there are relatively few companies that would satisfy these criteria”.79

91. There are other factors that have not helped UK biotechnology firms in the public markets. It seems that the markets have taken a dim view of companies that have had to return to the markets on several occasions to try to raise more capital. This has been exacerbated by constraints on public companies trying to raise private money. It seems US firms that have floated may have benefited from instruments such as Private Investment in Public Equity (PIPE) that allow them to turn to private capital during a lean period, whereas in the UK they are prevented from doing this by anti-dilution rules.80 However, these difficulties, whilst no doubt constraining, do not seem to be fundamental to the plight of biotechnology firms on the public markets. This, it seems, is far more attributable to the quality of the companies themselves, or at least the stage of development at which they had floated.

**Business Development**

92. The difficulties that biotechnology firms have had with the public markets would seem to have significant implications for the preferred model of development that has apparently been dominant in the minds of both biotechnology entrepreneurs and managers and of the majority of venture capital investors. The pioneering US biotechnology firms such as Genentech and Amgen have apparently set the course that others have aspired to follow — from start-up, through venture capital-funded development to floatation. It seems to us that this is not a model that is appropriate in all cases, regardless of the aspirations of those involved.

93. With finance becoming harder to find and the public markets not a realistic option, at least for the time being, companies may have to reassess their development strategy. However this may have positive results for the health of the sector.

94. We were told on several occasions that there are too many small companies in Europe. This was most obviously the case in Germany in the wake of the aggressive drive to

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79 Q 670 (IMA)
80 Q 682 (IMA)
encourage spin-out companies. But it is also the case in Britain too.\textsuperscript{81} If City investors are looking for larger companies with a portfolio of products at late stage development in their pipeline, this may give a spur to merger and acquisitions (M&A) activity. Because of the shortage of capital, a period of consolidation through M&A activity has been predicted for some time but has, as yet, failed to materialise on the scale deemed necessary.\textsuperscript{82} The process is not straightforward; indeed it is genuinely difficult to find two companies whose research strengths are genuinely complementary and which are suitable to join together. However, such a development holds the potential to improve the health of the sector substantially, leaving fewer but larger companies with a broader range of research and with more potential products in their pipelines.

95. Encouraging M&A activity could help with both pre- and post-IPO sectors of the biotechnology industry. For those private companies still relying on VC funding, M&A activity can boost the product pipeline, deepen cash reserves, and spread the quality management in the sector less thinly, all of which would improve the chances of a successful IPO, judged by the criteria that the fund managers are evidently using. For floated companies the stronger product pipeline would improve their chances of bringing a successful product to market.

96. Obstacles to this process do not seem insurmountable. The most obvious difficulty is finding two companies with a good match between their research. Beyond this, hesitancy on the part of the company managers seems to play a role: “Managements have been reluctant to give up the dream as long as some cash remains in the company”.\textsuperscript{83} Some may also feel that their companies are undervalued in the current market and try to hold out for a better price. Others may be unwilling to give up the autonomy of directing their own company.

97. It may be that investors in both public and private biotechnology firms will need to be more proactive in this consolidation process. We have heard that some venture capitalists have begun to pressure the firms in which they have invested into mergers and we would expect to see more of this. But beyond straightforward M&A activity there are signs that companies are coming up with new and seemingly mutually beneficial ways of working together. A good example would be the recent link-up between Roche, a large pharmaceutical company, and the biotechnology firm Antisoma. Roche, in acquiring the rights to Antisoma’s oncology drugs pipeline for a five year period in return for cash and a small equity stake, have effectively contracted their oncology R&D to Antisoma for five years. Given the apparent reluctance of the large pharmaceutical companies to acquire biotechnology firms and, indeed, their tendency to increasingly spin out their own small biotechnology firms, it may be that this sort of relationship is something that will occur more frequently. We have been told that there are signs of this as the biotechnology companies look for new ways to secure a flow of cash into the company in a depressed market. This sort of activity may strengthen the sector. However, it remains to be seen

\textsuperscript{81} Q 684 (IMA). See also G. Dyer, “Companies Need to Wake Up and Smell the Coffee”, \textit{Financial Times} (12 November 2002)

\textsuperscript{82} R. Arnold & S. Smart, ‘Funding Discoveries – 50 Years and Beyond’, \textit{Business Weekly – DNA Supplement} (April 2003)

\textsuperscript{83} \textit{Ibid.}
whether this is a long-term development or whether it is only a short term response to a
difficult climate.

Conclusions

98. There are a number of highly successful UK biotechnology companies and more will
emerge in the coming years. However, it seems that less money is available from all
sources for biotechnology companies in the UK than in the USA. Government support
in its various forms, venture capital and angel funding, are all on a fraction of the scale
that they are in the USA. Meanwhile fund managers are more likely to invest the money
they control in the American biotechnology companies than British ones.

99. There was little support for extensive government subsidy for commercial
biotechnology in the UK. It is not clear that it will make better biotechnology
companies. However, there was a consensus that, without a suitably funded higher
education and academic research infrastructure, the UK’s bioscience strength will be
undermined and it will lose the basis of a successful and vibrant commercial
biotechnology sector.

100. Perceiving market failure in the earliest stages of company formation, government
policy has been targeted at facilitating the commercialisation process. Support in this
area has been considerably less than in both the USA and Germany. But, as the German
case highlights, it is possible to make it too easy to start a biotechnology company. The
companies have to be based around commercially viable technology, and there needs to
be an adequate private equity market to develop and sustain the companies once they
are established.

101. Venture capital provides the backbone of biotechnology funding and the UK has
the most developed venture capital sector after the United States. Nevertheless, in
comparison with the USA at least, the venture capital funds are smaller and the amount
of money they are prepared to commit to each investment is smaller. A further
difficulty seems to be that the venture capitalists are looking to exit long before the
companies are developed enough to be an appealing prospect for the public markets.
With the public markets closed to new biotechnology offerings, it may be that venture
capitalists will have to wait longer before exiting and perhaps take a more proactive role
in encouraging some consolidation in the sector, both of which could potentially
strengthen it.

102. The public market seems to have been the route that most of those involved in the
biotechnology industry aspire to. However, it is evidently not always the most suitable
option. Companies have approached IPO as merely another stage in the development
process, but the conditions under which public companies operate are very different.
Public companies face a much more volatile climate than private companies and are
subject to far greater pressure to deliver some tangible success. It is clear that not all
those companies which aspire to the public markets, or indeed all those that have
already floated, have been ready for the harsher climate there.

103. The quality and quantity of finance available to biotechnology companies is a
crucial factor in the success or failure of the UK biotechnology industry. Whilst UK
companies fare better than those in many other countries, they are certainly disadvantaged in comparison with their American counterparts who have access to larger funds and who consequently have larger amounts of money made available to them. Moreover, we have found evidence that UK investors are keener to invest in US biotechnology companies than they are to invest in domestic ones. The perception, at least, is that the US companies are superior to, and have better quality management than, those from Britain or the rest of Europe. This belief also helps to explain the relative shortage of investment for UK biotechnology companies. To the extent that this perception is true, it is a cause for concern. Investors are under no obligation to support a sector that they feel is too risky for them. But the role of government is to ensure a favourable regime so that investors are not deterred. Beyond this, it is the companies that must prove themselves viable commercial propositions in order to secure investment.
6 Clusters

104. The concept of ‘clusters’ and their contribution to economic growth has been most closely associated with the Harvard academic Michael Porter and his work has evidently found resonance within the DTI.84 In 1999 the Minister for Science published a report, *Biotechnology Clusters*, which set out the benefits of clusters in promoting the UK’s biotechnology sector.85

105. A cluster can broadly be characterised as a geographical concentration of companies, service providers, suppliers and, at least in the case of a high technology industry such as biotechnology, research (in practice a university or research institute) in a particular industry. Under the cluster concept, these all compete with each other but also provide a mutually beneficial climate in which to develop, which in turn stimulates further company formation, the provision of services or research activity.

106. *Biotechnology Clusters* identified ten critical factors for cluster development —

i) Strong science base
ii) Entrepreneurial culture
iii) Growing company base
iv) Ability to attract key staff
v) Availability of finance
vi) Premises and infrastructure
vii) Business support services and large companies in related industries
viii) Skilled workforce
ix) Effective networks
x) Supportive policy environment86

107. These factors are both the result of a critical mass of biotechnology in a given location but also stimuli to further activity and thus, it is argued, a virtuous circle is established where the benefits of a concentration of biotechnology activity gives rise to further activity.87

108. We wanted to find about the benefits of clusters from those with first hand experience of them so we undertook visits to Edinburgh and Cambridge in the UK, Munich and Berlin in Germany, and Boston and Raleigh-Durham in North Carolina in the USA. The

85 *Biotechnology Clusters*, DTI (August 1999)
86 Ibid.; App 2
87 Eg Q 43 (BVCA)
transcripts of the meetings we had in Edinburgh and Cambridge are appended to this report.\textsuperscript{88} Our witnesses reiterated the importance of many of the factors listed in the DTI’s report, but also that the importance can be overstated and that there can be negative aspects of being located in a cluster.

109. Many of the companies based in a cluster may have been spun out of one of the universities or research institutions at the core. They may have started life in a university-owned incubator facility and then perhaps, as they grew, graduated to a nearby science park. The proximity of the parent department allows some continuing collaboration between faculty and the company researchers, potential employment opportunities for the department’s post-doctoral researchers and a more general interaction between industry and academia.

110. But successful clusters will not comprise local spin-outs alone. Whilst a high degree of company formation is a key characteristic of a successful cluster, companies are located there which have no particular links to the area or the research institutions in it. They are attracted to the cluster by the resources it provides but also perhaps by the ‘buzz’ of being situated in a location with so much biotechnology activity occurring, and even by a desire to reap the reputational benefits of the cluster’s brand name.\textsuperscript{89}

111. As well as technology transfer from the research institutions in the centre of the cluster in the form of licensing or spin out activity, knowledge transfer can also occur on a more informal basis through face-to-face contact between those working for the various companies and research centres.\textsuperscript{90} With the regular face-to-face interaction that clusters make possible, this more informal knowledge transfer can take place on a regular basis in a way that would not be possible to the same degree over larger geographical areas.

112. A particular appeal of clusters, we found, was that, with the concentration of biotechnology in a relatively confined location, there is a burgeoning specialist labour market. Companies based in clusters can normally recruit people with the necessary scientific skills with relative ease. The universities, around which the clusters tend to develop, can provide a steady stream of doctoral and post-doctoral researchers to work in the companies. From the perspective of the individual scientist, the appeal of being based in a cluster is also clear. Given the volatile nature of the biotechnology sector and the high attrition rates amongst companies, scientists located in areas with substantial biotechnology activity know that, in the event of such a company failing, a new opportunity will not be far away.\textsuperscript{91} Larger, more established clusters may also have a large pharmaceutical company presence — we saw this in Cambridge, Boston, Raleigh-Durham and Munich, for instance. Whilst, according to our sources, there was limited interaction between the large pharmaceutical and the smaller biotechnology firms, again the large pharmaceutical companies provide a source of recruitment for scientists and also for management.\textsuperscript{92}

\textsuperscript{88} Qq 165–383 and 385–509  
\textsuperscript{89} Q 315 (Strakan)  
\textsuperscript{90} Biotechnology Clusters, DTI (August 1999), Para 1.4  
\textsuperscript{91} Q 288 (Pantherix)  
\textsuperscript{92} Q 490 (Acambis)
113. Given the concentration of biotechnology firms, specialist premises are likely to be available in clusters. Fitting out premises to make them suitable for biotechnology work can be costly — specialist drainage and ventilation systems are required, for instance. Given this cost, developers are unlikely to be willing to provide specialist accommodation unless they see a continuing demand for it. With the high concentration of firms in clusters and long term demand guaranteed by the high levels of new company formation, a developer is more likely to be willing to provide the sort of suitably furnished premises required. (However, even in the well-known biotechnology centres like Cambridge and Munich, some public sector involvement in the provision of such premises is normal: in the case of Cambridge the lead has been taken by colleges such as St John’s and Trinity; in Munich it has been the land government).

114. One of the key factors that makes a cluster more than just a concentration of firms is the presence of an associated service sector. As a biotechnology firm, being located in a substantial cluster means being close to a variety of specialist services that can be drawn upon. For instance, clusters may also be home to venture capital firms and, though less often in Europe, to a number of business angels. As investors it makes commercial sense to locate in an area with a steady stream of investment opportunities. As we have already noted, venture capital investing seems parochial by inclination so the presence of a significant venture capital community is a considerable asset. As well as venture capitalists and angels, the concentration of biotechnology ensures a supply of other services such as lawyers with particular expertise in intellectual property and regulatory matters as well as a range of consultants that can offer help to growing companies.93

115. The concentration of biotechnology-related activity in an area can increase awareness of the sector’s special difficulties among local policy makers, and thereby contribute to a more sympathetic policy climate. With the economic importance of the biotechnology cluster and the scope for a formal organisation to represent it, the lobbying power of those involved in the sector is increased. As an example, we heard how effective this had been in improving the policy climate for biotechnology in the Boston area.

116. But locating a company in a thriving biotechnology cluster is evidently not without its negative aspects. A frequent complaint that we heard in relation to places like Cambridge in the UK and Boston in the US was the relative shortage, and consequently the very high cost, of accommodation. Whilst there is more likely to be a stock of specialist premises in areas such as these, demand for them will be very high. We were told of a shortage of science park space that was confining companies to incubators for longer than necessary. This in turn was creating a logjam in incubator space.

117. Clearly, a supportive planning regime can help ease some of the pressure by making new build or the conversion of existing premises easier. However, in the most successful clusters, space will always be at a premium and command a high price. This has led to clusters spreading outwards. The Boston cluster spreads out some miles beyond the city; whilst the Scots biotechnology cluster is focussed in Edinburgh, it spreads across the central belt to Glasgow and north to Dundee; and the Cambridge cluster has spilled over into neighbouring counties. However the size of a cluster seems to be a matter of

93 Q 489 (Acambis)
perception. In the USA cluster boundaries were effectively defined by flying or driving times and whether a meeting could be attended or a visit made without the need for an overnight stay. In the UK it seems that the boundaries are defined by commuting distances so the pressure on accommodation here is likely to continue.

118. Whilst the burgeoning labour market for scientists may well be an appealing aspect of locating in a cluster, it could be viewed as a mixed blessing. Whilst recruitment in clusters may be much easier, it is likely that staff retention will be much harder as there will be regular opportunities to move on. Some of the companies we spoke to in Scotland felt that an advantage of being based away from the Cambridge region was the greater ease of retaining staff.94

119. The main benefits of clustering lie in knowledge transfer, support services and labour supply. It was pointed out to us that these benefits are felt most strongly by small, young companies. Once a company has reached a certain stage in its development, it will not necessarily gain as much from a cluster location as it once did. Of course there may be little point in moving. However, such companies are not tied to a particular location: “I do not think it matters where you are located because there are no borders in the biotech industry”.95

120. Numerous regions in a number of countries seem to be trying to develop biotechnology clusters, but the most successful ones in places like Cambridge, Boston or San Francisco have developed as a result of a coincidence of factors rather than as the result of deliberate design and public policy. It is clear that clusters can be hindered by policy — obstructive regulatory or planning regimes, for example. But the extent to which they can be created through design is less clear. The cluster concept provides a good description of the factors involved in the success of biotechnology in certain regions. It does not, however, necessarily provide a blueprint for establishing biotechnology elsewhere.

121. With this in mind we are concerned that too many areas have targeted biotechnology as an industry to cultivate. Not only may considerable sums of public money be wasted in trying to force into existence local biotechnology companies, but also rivalry between regions may adversely affect those with existing strengths in the sector thus undermining the success of biotechnology in the UK as a whole.

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94 Q 315 (Strakan)
95 Q 313 (Cyclacel)
7 Other Issues

122. A number of other issues emerged that could be considered to impact on the success of the UK’s commercial biotechnology sector but which do not fall under the company finance and development issues discussed above.

Skills

123. A particular complaint that we heard related to the range of skills displayed by those working in the biotechnology sector. The problem is not with the scientific training but a concern that some of the more ‘practical’ skills appear to be in short supply.

124. As noted earlier, witnesses expressed concern on several occasions that the standards of management within the biotechnology sector were poor —

“a real constraint [on the growth of biotechnology] is in terms of experienced management to take the companies on.”

“I think on the whole that the management of the UK biotech companies has not been as good as certainly some of the people I meet and we do most of the US investing. A lot of people I meet running the American biotech companies are of the highest quality both as scientists and as managers. I am sorry to say that I have not, even on the relative size of the economy basis, met as many outstanding managers in the UK sector”.

125. Despite these comments, this is not a complaint that is peculiar to the UK — we heard it made about biotechnology companies in Germany and the United States too. It is perhaps inevitable in a sector dominated by scientists who have moved out of laboratories and into board rooms without any experience of business and sometimes without any management training: “As an academic you have not got a clue what is going on. You have been cocooned in a university like this and shielded from the real world. It is very, very difficult; it is cut-throat and it is real”. Fund managers said that they looked for a management team drawn from large pharmaceutical firms or the financial sector. As yet it may be that the majority of biotechnology companies are too small to attract such people in large numbers, and as the sector in the UK matures presumably the calibre of management it can attract will improve. But if the quality of management is hindering the development of the sector, it is a matter that requires attention.

126. An academic scientist who had founded a biotechnology company told us that he had received advice on aspects of starting and running a company from a variety of sources, including the DTI and also at a series of seminars run by a Cambridge-based consultancy.

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96 Q 395 (Dr Solomon)
97 Q 684 (IMA)
98 Q 468 (Dr Dean); see also Q 268 (Pantherix)
99 Q 670 (IMA)
Companies would also normally receive support from their venture capital investors who would usually appoint a non-executive director to the company board.

127. A gradual improvement can be expected as the sector matures but it would not seem sensible to leave this entirely to chance. Whilst the advice given by venture capitalists is clearly useful and the government already has a programme of general advice and training for those running SMEs, biotechnology companies face starker problems than firms in many other sectors and it would be desirable for more extensive management training to be available.

128. We recommend that the Government and the BIA, perhaps together with the biotechnology specialists in the RDAs, look into ways to provide some systematic training in management. Given that so many companies are spun out of universities, they could also clearly play a role in this. Biotechnology is a high risk industry and some failures are inevitable. However, with better quality management these failures can be kept to a minimum.

129. Another area of concern was the lack of suitably skilled technicians. Whilst the image of the biotechnology industry may be of highly qualified staff with doctorates, conducting cutting edge research, the reality is that there is a considerable amount of work that does not require academic expertise of doctoral standard so much as good quality technical skills. We heard concern expressed about the shortage of suitably qualified people to perform such roles. Biomanufacturing, in particular, is an area which has substantial needs for technician-grade staff: “One of the key constraints on [biomanufacturing] is skills.”100 The shortage of technicians is, of course, a reflection of the UK’s wider shortage of intermediate level skills that we noted in our Third Report of Session 2001-02.101

130. Again this would appear to be an area where the Department for Education and Skills should be working with bodies such as the BIA, the RDAs and the LSCs to ensure the adequacy of training provision. We heard that Scottish Enterprise was working with local colleges with a view to increasing the provision of technician training. We applaud this and would encourage other regions to consider similar initiatives.

Biomanufacturing

131. At the moment the UK, in common with the rest of Europe, has a limited biomanufacturing capacity to complement its R&D capacity. One witness went so far as to say that, without biomanufacturing capacity on an adequate scale, the UK ran the risk of losing much of the value of its research.102 But the lack of manufacturing was also acknowledged more widely.103

132. Manufacturing may lack some of the glamour associated with R&D work but it is central to the process — biomanufacturing is, at the moment at least, less concerned with...
producing final products for market than with producing materials for further R&D, methods of drug delivery and tools for drug production. There is also a need for small quantities of finished products for trials purposes.

133. With this in mind, it seems to be advantageous to have manufacturing capacity located in reasonable proximity to where the research is taking place. It appears that much of the less sophisticated manufacturing is being attracted abroad to places such as Ireland and Puerto Rico where there is a generous public subsidy for it. But with the boundaries between biomanufacturing and R&D so blurred, there is clear advantage to co-location.104

134. As discussed above, we have heard that there is an inadequate supply of skilled staff. We also heard that, in some areas at least, a shortage of suitable, affordable accommodation could cause difficulties.105 However, the core of the problem seems to be a matter of economics — there is a small demand for most of the manufactured product, which is nonetheless costly to produce. The infrastructure requirements are also quite expensive.106 All this makes investment in this area a risky prospect, and one witness noted: “Venture companies do not like doing it...it is not a sector that one really likes to get into”.107 There is investment taking place in this area — we were told of a £70 million investment in a leading edge plant being established in the North East by Avecia for instance.108 And it may be that as the sector matures it becomes a more commercially appealing prospect. While raising the lack of manufacturing capacity as a concern, our witnesses did not suggest what should be done. It may anyway be too early to tell whether the lack of biomanufacturing will significantly limit the growth of the biotechnology industry in the UK, and also whether there is a market failure that the Government may need to address. Whilst much pharmaceutical manufacturing has moved abroad, this is not yet the case with biomanufacturing. The UK has the potential to retain it. Government and the RDAs should ensure that there are no obstacles to the establishment and retention of adequate biomanufacturing capacity accessible to the major R&D centres.

Trials

135. Before a drug can reach market the hurdle of clinical trials must be cleared. Most drugs will fail these trials and only a handful will make it to market. Trials are also a test of a company’s financial endurance — they seem to occur at a stage of company development where venture funds are drying up. But with the high failure rate associated with the early stages of the trials process, biotechnology firms have little appeal for other sources of capital at this stage

136. We took little evidence specifically on the trials process; however certain issues did arise from our wider investigations. We heard anecdotal evidence that companies are being pressured by their venture capital investors into entering products under development for clinical trials too soon; the venture capitalists’ exit possibilities will be improved if the companies in which they invest have at least succeeded in the first stage of clinical trials.

104 Q 659 (Lord Sainsbury)
105 Q 396 (Dr Solomon)
106 Q 148 (Professor Dunnill)
107 Ibid.
108 Q 663 (DTI)
However, premature trialling is clearly detrimental to the company’s research and to its finances and is a matter of concern if it is occurring on a significant scale.

137. We also heard, again anecdotally, that the interface between those involved in research and those involved in trials is not as smooth as it should be. Trials are expensive though the costs are not transparent, and they are frequently not completed to the agreed timetable. It was suggested to us that the NHS could be a considerable asset as a conductor of trials. However, at the moment the need for companies to negotiate terms for trials separately with each hospital trust creates difficulties; the system is currently too fragmented to allow the potential benefits of a National Health Service to be realised at the moment.

138. Having not inquired into the matter systematically we do not feel able to do any more here than air some of the concerns that were expressed to us. Ultimately, whilst it clearly imperative that drugs are subjected to thorough trials, a long and drawn out process merely diverts resources away from more innovative aspects of R&D. Anything that can be done to smooth the process, without reducing necessary protection, should be welcomed.

**Animal Rights Activism**

139. A serious concern of those involved in the UK biotechnology sector is the activities of some of the more extreme elements of the animal rights movement. Though these have been particularly heavily concentrated on Huntingdon Life Sciences, where staff and even investors have been targeted, the perception is that this is a wider problem for biotechnology firms throughout the UK as a whole. This has the potential to frighten off foreign biotechnology companies who might be considering the UK as a location, foreign investors from becoming involved here, and even young people from pursuing a career in bioscience.109

140. Last year there was tightening of company legislation designed to give some greater protection to directors under threat of attack. Before advocating further measures we would like to judge the effectiveness of the recent measures. We recommend a wider review of company law to see whether investors in vulnerable companies could be similarly protected. We support moves to make a more concerted attempt to explain the necessity of animal experimentation in drug development and to raise awareness of its benefits.110

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109 Eg Qq 100 (BIA), 403 (Dr Solomon), and 517 (ABPI)
110 Q 102 (BIA)
Conclusions and recommendations

Resources for basic research

1. The UK’s research expertise in biotechnology has made its relative prominence in commercial biotechnology possible. Excellence in research cannot in itself ensure commercial success in biotechnology but it does seem to us that its absence will preclude it. The strength of the commercial biotechnology sector cannot be guaranteed merely by putting ever greater sums of public money into higher education and academic research. However, given the integral links between education and research and commercial biotechnology, it is hard to see how strength can be achieved and sustained in the latter without the former being adequately resourced. Levels of investment remain a problem, with the UK spending less than its competitors on research and on the HE sector as a whole. Whilst the UK is still performing creditably, there must be some concern about the degree to which this can be sustained over the long term. (Paragraphs 24 and 31)

Regulation of research

2. While we agree that regulation should set clear, ethical limits beyond which researchers should not be allowed to go, public opinion in the UK seems broadly content with the difficult ethical balance struck in the regime here. We would therefore oppose any attempt to tighten regulation here. We are aware that the Government takes the same view, but we wish to underline the importance of continuing vigilance; the regulatory environment for biotechnology research in the UK is a real source of advantage and must not be undermined by developments at the European level. (Paragraph 30)

Technology transfer

3. The USA has a clear lead in the size, and also the sophistication, of its technology transfer effort. Some Universities, such as MIT and Stamford, have gained very large incomes from their commercialisation activities. But even at institutions where the revenues from such activities were much smaller, we were impressed by the commitment to transferring their research into the commercial world and making the most of any potential applications that it might have. The UK’s technology transfer process is less developed than the USA. In many ways it appears to be developing in the right direction. We applaud the efforts that have been made on the part of UK universities to increase the benefits to the public through commercial exploitation of scientific discoveries. (Paragraphs 52 and 53)

Increasing commercial exploitation of IP

4. We are not convinced that attempting to replicate the measures contained in America’s Bayh-Dole Act would have the same impact in the UK. In the USA the Bayh-Dole Act was introduced to increase the exploitation of publicly funded research in the context where regulations were acting as a deterrent to this. We received no evidence suggesting that a similar pool of unexploited technology exists here as a result of government regulations on the use of its intellectual property. However, we do suspect
that the change in the IPR regulations that the Bayh-Dole Act brought about was only part of the reason for its success — its main contribution may have been the increased awareness among academics and companies about the potential of university based science and the enthusiasm for commercialisation it created amongst leading research universities. There has clearly been an increase in the UK’s technology transfer effort in recent years. Our impression is that the UK is still some way behind the USA in this area. However, this is as a result of a relative lack of experience and expertise, and a relative lack of resources, rather than as a result of constraints imposed by government regulations. (Paragraph 51)

**Technology Transfer Offices**

5. The reports of variable quality led us to question the need for in-house technology transfer offices at all: could not the technology transfer activities be contracted out, perhaps with the good units taking over the less good? Whilst not ruling out this route, we were persuaded that good in-house technology transfer units were preferable. Although too many technology transfer staff may lack expertise, this will improve over time. However, in the meantime, efforts to promote best practice must be made. Whilst recognising the independence of universities and the sensitivity of individual government departments to incursions into their territory, we think that there may be a role for the relevant sectoral units in the DTI — in this case the Bioscience Unit — in bringing representatives from the various technology transfer offices together with industry representatives in order to exchange best practice and to obtain a clearer idea of what industry wants from the offices. Furthermore, efforts to inform and incentivise scientists in the possibility of commercialising their research must continue. (Paragraph 48 and 53)

**Funding of biotechnology companies**

6. There are a number of highly successful UK biotechnology companies and more will come through in the coming years. However, it seems that less money is available from all sources for biotechnology companies in the UK than in the USA. Government support in its various forms, venture capital and angel funding, are all on a fraction of the scale that they are in the USA. There was little support for extensive government subsidy for commercial biotechnology in the UK. It is not clear that it will make better biotechnology companies. (Paragraphs 98 and 99)

7. Perceiving market failure in the earliest stages of company formation, government policy has been targeted at facilitating the commercialisation process by concentrating on seed and early stage funding through schemes such as the UCF. Support in this area has been considerably less than in both the USA and Germany. But, as the German case highlights, it is possible to make it too easy to start a biotechnology company. The companies have to be based around commercially viable technology, and there needs to be an adequate private equity market to develop and sustain the companies once they are established. (Paragraphs 83 and 100)


**Availability of Venture Capital funding**

8. Venture capital provides the backbone of biotechnology funding and the UK has the most developed venture capital sector after the United States. Nevertheless, in comparison with the USA at least, the venture capital funds are smaller and the amount of money they are prepared to commit to each investment is smaller. A further difficulty seems to be that the venture capitalists are looking to exit long before the companies are developed enough to be an appealing prospect for the public markets. Moreover, we have found evidence that UK investors are keener to invest in US biotechnology companies than they are to invest in domestic ones. The perception, at least, is that the US companies are superior to, and have better quality management than, those from Britain or the rest of Europe. The result is that the UK venture capital market does not serve small biotechnology companies well. (Paragraphs 101, 103 and 83)

9. Increasing expertise in university Technology Transfer Offices may in time provide more attractive prospects for venture capitalists. However, even if better companies are spun out the ‘structural’ factors that deter the venture capitalists from becoming involved in the earliest stages would remain. Investors are under no obligation to support a sector that they feel is too risky for them. The role of government is to ensure a favourable regime so that investors are not deterred. Beyond this, it is the companies that must prove themselves viable commercial propositions in order to secure investment. (Paragraphs 83 and 103)

10. Whilst government measures to increase the flow of funds into venture capital would seem appealing, the problems of Germany should serve as a warning. The regional venture capital funds that are currently being established may provide valuable support in the absence of private funding. We received no evidence as to whether — and if so how — small biotechnology firms are using such funds: and, in any case, the funds are too new for any firm conclusions about their usefulness to be drawn yet. However it is important that the rigorous scrutiny of new investments and strict commercial criteria that one would expect from private venture firms is maintained by these public funds. (Paragraph 83)

**Flotation or M&A?**

11. The public market seems to have been the route that most of those involved in the biotechnology industry aspire to. However, it is evidently not always the most suitable option. Companies have approached IPO as merely another stage in the development process but the conditions under which public companies operate are very different. Public companies face a much more volatile climate than private companies and are subject to far greater pressure to deliver some tangible success. It is clear that not all those companies who aspire to the public markets, or indeed all of those that have already floated, have been ready for the harsher climate there. With the public markets closed to new biotechnology offerings, it may be that venture capitalists will have to wait longer before exiting and perhaps take a more proactive role in encouraging some consolidation in the sector, both of which could potentially strengthen it. (Paragraphs 101 and 102)
Clusters

12. We are concerned that too many areas have targeted biotechnology as an industry to cultivate. Not only may considerable sums of public money be wasted in trying to force into existence local biotechnology companies, but also rivalry between regions may adversely affect those with existing strengths in the sector thus undermining the success of biotechnology in the UK as a whole. (Paragraph 121)

Skills

13. We recommend that the Government and the BIA, perhaps along with the biotechnology specialists in the RDAs, look into ways to provide some systematic training in management. Given that so many companies are spun out of universities, they could also clearly play a role in this. Biotechnology is a high risk industry and some failures are inevitable. However with better quality management these failures can be kept to a minimum. (Paragraph 128)

14. We note concerns about a shortage of suitably qualified technicians. Again this would appear to be an area where the Department for Education and Skills should be working with bodies such as the BIA, the RDAs and the LSCs to ensure the adequacy of training provision. We heard that Scottish Enterprise was working with local colleges with a view to increasing the provision of technician training. We applaud this and would encourage other regions to consider similar initiatives. (Paragraph 130)

Biomanufacturing

15. It may be too early to tell whether the lack of biomanufacturing will significantly limit the growth of the biotechnology industry in the UK, and also whether there is a market failure that the Government may need to address. Whilst much pharmaceutical manufacturing has moved abroad, this is not yet the case with biomanufacturing. The UK has the potential to retain it. Government and the RDAs should ensure that there are no obstacles to the establishment and retention of adequate biomanufacturing capacity accessible to the major R&D centres. (Paragraph 134)

Clinical trials

16. Ultimately, whilst it clearly imperative that drugs are subjected to thorough trials, a long and drawn out process merely diverts resources away from more innovative aspects of R&D. Anything that can be done to smooth the process, without reducing necessary protection, should be welcomed. (Paragraph 138)

Animal rights activism

17. Last year there was tightening of company legislation designed to give some greater protection to directors under threat of attack. Before advocating further measures we would like to judge the effectiveness of the recent measures. We recommend a wider review of company law to see whether investors in vulnerable companies could be similarly protected. We support moves to make a more concerted attempt to explain the necessity of animal experimentation in drug development and to raise awareness of its benefits. (Paragraph 140)
Formal Minutes

Tuesday 15 July 2003

Members present:

Mr Martin O’Neill, in the Chair

Mr Roger Berry  Mr Andrew Lansley
Mr Jonathan Djanogly  Linda Perham
Mr Lindsay Hoyle  Sir Robert Smith

The Committee deliberated.

Draft Report (UK Biotechnology Industry), proposed by the Chairman, brought up and read.

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

Paragraphs 1 to 140 read and agreed to.

Summary agreed to.

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

Ordered, That the provisions of Standing Order No. 134 (Select Committees (reports)) be applied to the Report.

Ordered, That the Chairman do make the Report to the House.

Several Papers were ordered to be appended to the Minutes of Evidence.

Ordered, That the Appendices to the Minutes of Evidence taken before the Committee be reported to the House.

[Adjourned till Tuesday 9th September at Nine o’clock]
Witnesses

Tuesday 2 July 2002

Morning meeting

Mr John Mackie, British Venture Capital Association
Ev 1

Dr Linda Magee, Bionow, NWDA.
Ev 11

Tuesday 2 July 2002

Afternoon meeting

Dr Paul Drayson, Mr Crispin Kirkman, Mr Simon Best and Dr Paul Haycock
BiolIndustry Association.
Ev 17

Professor Peter Dunnill OBE, DSc, FREng, The Advanced Centre for
Biochemical Engineering, University College, London
Ev 29

Monday 15 July 2002

Morning meeting

Mr Ken Snowden and Mr Liam Fennell, Scottish Enterprise.
Ev 34

Professor Grahame Bulfield CBE, FRSE, Roslin Institute
Ev 42

Professor Sir William Stewart FRS, FRSE, The Royal Society of Edinburgh
Ev 48

Dr Chris Latham, Pantherix Limited
Ev 51

Monday 15 July 2002

Afternoon meeting

Mr Paul McBarron, Cyclacel
Ev 57

Mr Harry Stratford, and Mr Adrian Gardner, Strakan
Ev 60

Mr Calum Paterson, Scottish Equity Partners
Ev 66
Thursday 7 November 2002

Dr Jeff Soloman, Eastern Region Biotechnology Initiative  Ev 70

Dr David Hardman, Babraham Bioscience Technologies Ltd  Ev 76

Dr Roland Kozlowski, Sense Proteomic  Ev 80

Dr Philip Dean, De Novo Pharmaceuticals  Ev 80

Dr John Brown and Mr Nick Higgins, Acambis  Ev 84

Tuesday 19 November 2002

Dr Philip Wright, Dr Alexander Duncan and Dr Gill Samuels, ABPI  Ev 88

Dr Greg Winter, CBE, MRC Laboratory of Molecular Biology, Cambridge  Ev 97

Dr Jeff Skinner, UCL Ventures  Ev 102

Dr Ederyn Williams, Warwick Ventures  Ev 102

Tuesday 17 December

Lord Sainsbury of Turville and Dr Monica Darnbrough, Department of Trade and Industry  Ev 108

Mr Anthony Milford, Dr Joe Anderson, Mr Richard Saunders, and Mr Derek Bartlett, Investment Management Association  Ev 118
List of written evidence

1. Bionow (North West Development Agency) Ev 123
2. Department of Trade and Industry Ev 127
3. Professor Peter Dunnill, OBE, DSc, FREng Ev 134
4. BioIndustry Association Ev 136
5. Biotechnology and Biological Sciences Research Council Ev 161
6. British Venture Capital Association Ev 168
7. Medical Marketing International Group plc Ev 172
8. Medical Research Council Ev 174
9. LGC Limited Ev 177
10. PowderJect Pharmaceuticals plc Ev 178
11. BioIndustry Association (BIA) Ev 186
12. Wellcome Trust Ev 191
13. Eli Lilly and Co Ltd Ev 195
14. The Association of the British Pharmaceutical Industry Ev 196
15. Acambis plc Ev 209
16. ERBI Ev 211