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Editorial

Bridging the 'commercialisation gap' in Europe

Important questions about the future development of gene therapy remain unanswered. What are the main barriers to the process of converting today's science into tomorrow's technology? How might these obstacles be overcome? Which countries are best placed to reap the rewards promised by gene therapy? These matters are not traditionally raised in a scientific journal as they concern the worlds of commerce and public policy, yet they must be addressed by the scientific community if basic research is going to be successfully translated into new treatments.

In a major study for the European Commission,[1] we have tried to examine these issues by undertaking a broad survey of the development of gene therapy in Europe and the USA, and a detailed comparative analysis of the innovation process in the UK and the USA. The main finding of the research was that Europe lags some 3 to 5 years behind the USA in terms of both the clinical and commercial development of the technology. European clinical trials are generally at an earlier stage and firms are further from launching commercial products than their American rivals.

One factor explaining this is the sheer scale of the gene therapy research effort in the USA, which produces twice as many scientific publications and supports three times as many clinical trials as the whole of Europe. Interestingly, the overall pattern of clinical trials is the same and there are no major differences in the regulation of clinical research, with several European countries simply amending the RAC guidelines. In the area of clinical development the study identified a number of common barriers to translational research in both the USA and Europe. These included difficulties in getting access to research materials owned by firms and problems with the production of vectors for clinical trials sponsored by academics.

However, the main difference between EU states and the USA appears to lie in the way in which gene therapy is being developed by industry. This has created a 'commercialisation gap' in Europe, with basic research less intensively exploited, and fewer dedicated gene therapy firms created, than in the USA. This is a key issue, as it is essential to have an effective process of innovation linking academic research and industry. Only firms have the resources and expertise in production, regulatory affairs and clinical development, to translate gene therapy into new products for use in hospitals and clinics.

This European gap between academia and industry was clearly shown in the case study of the UK, where interviews with investigators revealed that they were less likely to be collaborating with a commercial partner, and where they did, it was often with an American company. In contrast, most leading researchers in the USA were working closely with domestic gene therapy firms. An important reason for this was the relative strength of the gene therapy industries. American gene therapy firms employ three times as many staff, are sponsoring five times as many clinical trials and are much better financed than the 12 dedicated firms in Europe. So although European investigators are keen to work with industry, they have fewer opportunities to do so. The result is that the European science base is less exploited than in the USA and a significant number of the benefits of public research are being exported abroad.

Another consequence of the commercialisation gap is that the pharmaceutical industry is making almost all its external investment in this area in North America. Since 1993, there has been a trend towards the integration of gene therapy into the pharmaceutical sector, with large companies investing heavily in acquisitions and alliances with small gene therapy firms. The lack of these firms in Europe is a major reason why large companies created 29 commercial collaborations related to gene therapy in the USA between 1992 and 1996, compared with only three in Europe. However, the pattern of financing presents a paradox, as European pharmaceutical companies have invested $1.4 billion in the American gene and cell therapy industries during this period, compared with just $140 million by their American counterparts. So although small American firms are leading the world in developing the technology and are actively exploiting the European science base, it is the European pharmaceutical industry which may ultimately benefit most from the successful development of gene therapy in the USA.

If Europe is to profit most from its publicly funded research, creating local jobs and building an internationally competitive gene therapy industry, then it must overcome the barriers to the commercialisation of its science base. There are three key areas which the research community and public policy makers need to address. First, there has to be a 'critical mass' of basic research in order to support a strong gene therapy industry. The size and concentration of US research is illustrated by the fact that the top five research centres working on gene therapy in the USA are directly comparable to the top five European countries, as measured by publications output and the number of clinical trials undertaken. Research from these five US institutes alone has helped established over 10 American gene therapy firms.

Coherent policies should therefore be established throughout Europe, such as those in Germany and France, to promote gene therapy as a national priority, with the emphasis on creating large centres of excellence. Second, the formal process of technology transfer has to be improved. Although significant progress has been made in this area in recent years, the sophisticated technology transfer programmes found in many US universities and research institutes are far less common in Europe. Governments need to give greater priority to this area and significantly increase investment in technology transfer initiatives. In addition, European academics should be given greater opportunities and incentives to exploit their research commercially.

Finally, the most important area for concerted action by government and industry is to assist the creation and development of new gene therapy firms. It is widely accepted that it is more difficult to start a new biotechnology company in Europe compared with the USA, although this is starting to change in the UK and Germany. Initiatives need to be developed to help the formation of new firms by improving access to seed capital, and providing start-up grants and technical assistance. In addition, established small companies also need support in the form of secure long-term finance and greater incentives to invest in research, to ensure they can grow and compete internationally. The adoption of Orphan Drug legislation in the EU would greatly help in this respect.

Research in the whole field of human genetics is unusual in being so closely tied to industrial innovation, and it is the USA which is leading the world in turning good science into promising technology.[2] If gene therapy is to realise its potential as a new therapeutic modality, then it is vital that Europe makes its full contribution in this area by overcoming the barriers to successful innovation and building stronger bridges between academia and industry.

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