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Editorial

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UK cash for gene therapy: Government pledges support

On 24 June, the new Secretary of State for Health, Dr John Reid, announced the publication of the genetics White Paper,[1] which aims to pave the way for the integration of genetics into mainstream healthcare in England. Along with a raft of new proposals comes £50 million – reassuringly described as 'new money' – to support NHS genetics services and research. Interestingly, a slice of the cash is to be served up directly to the gene therapy community.

A £2.5 million boost will be given over 5 years to support cystic fibrosis gene therapy research, while single-gene disorders are to receive 'up to £3 million' between them, in an attempt to plug the gaps left by industry in some of the less lucrative disease areas. A further £4 million has been earmarked for improving access to gene therapy vector production, which will be important once the Clinical Trials Directive[2] comes into play in May 2004. Although the paper does not reveal exactly how and where this money is to be spent, the sum is intended to cover the vector requirements for NHS research and treatment over 5 years. A National Biomanufacturing Facility[3] is already being constructed on Merseyside in the UK, and is due to be on stream in early 2005. The issue of the long-term safety of vectors also receives attention, as seen recently in the US, but details are scant as to the likely extent of investment in infrastructure to cover life-long clinical monitoring.[4]

Along with these specific provisions for gene therapy, the paper spells out plans for broader investment in genetics services. NHS genetics laboratories, for example, are to receive a £18 million upgrade in readiness for an expansion in genetic testing, and 50 new clinical training posts for genetics counsellors are to be funded for 5 years. On the back of this, targets are laid down to reduce genetic testing times by 2006: no longer than 8 weeks, for example, for unknown mutations in a large gene. Indeed, Peter Greenaway of the UK Department of Health says, 'The aspiration is to deliver genome-wide scans within this time-frame, and develop training schemes for the service to exploit this information.' Hence, there will be a £7 million push behind the increased use of genetics-based services in primary care in England, and training and education is to be made more widely available to non-specialists. Of relevance to gene therapy investigations is a new Genetics Visiting Fellowships Fund of £1.25 million to support both training abroad and invitations to international experts.

For the first time, a University Chair and department in pharmacogenetics will be established and £4 million is to be ploughed into pharmacogenetic research on existing drugs. In connection with this, the Human Genetics Commission is being asked to report by the end of 2004 on the case for screening babies at birth and storing their genetic information to facilitate tailored health later in life. Perhaps predictably, it was this aspect of the paper that received much of the media attention in the days immediately following its launch.

Jayne Spink of the Gene Therapy Advisory Committee believes that the Government now 'clearly acknowledges gene therapy's potential to substantially improve patient care. These funds will boost translational research and remove barriers and bottlenecks to clinical trials.' Dr Len Seymour, current President of the British Society for Gene Therapy, agreed that there are 'some disease settings where scientific developments have been fast, and progress is now clearly limited by cash for translation. This strategic investment should serve as a stimulus to accelerate the whole field forward.'

Inevitably, there are criticisms that the investment, although substantial, is inadequate. Professor Adrian Thrasher, of the Institute of Child Health in London, and head of the team that conducted Britains's first successful gene therapy trials for children with immunodeficiency, said the money was not enough. 'We are pleased to see this initiative,' he said, 'but to get this on track the Government will have to invest a lot, lot more.' There will be arguments about the targeting of funds between basic research into mechanisms and methodology *versus* clinical applications. Professor Charles Coutelle, of Imperial College London, said 'To avoid the dangers of hype for gene therapy, what is necessary is very sound, basic research and focus only on translational targets will not help.' There will also be differences of opinion over the timescale for judging the impact of the new investment. The programme is due to be reviewed in just 3 years, but the White Paper recognizes that the promise of gene therapy will not be realized for at least another 5 years, and that with the current rate of development we cannot expect the first licensed gene therapeutics to come on stream for perhaps 10 years.

Such development will inevitably raise social and ethical questions, and the Government tackles the tricky topic of the public's perception of genetics by promising a 'genuine dialogue'. We can hope that this gets off to a

better start than did the recent GM debate.[5] Among several measures being proposed to reassure the public is a new piece of legislation outlawing the 'theft' of DNA or, in other words, the testing of a person's DNA without their consent. There is also concern over the potential for exploitation of genetics research, and the mechanisms for its regulation. Patents are vital in encouraging innovation and competitiveness in the biotechnology sector on which the future of gene therapy heavily depends. To examine this issue in detail, the Department of Health has commissioned an independent study into the impact and management of intellectual property rights and genetics within the healthcare sector.

The goals being put forward are mainly long-term and we will have to wait and see what happens when the current pot of money dries up in a few years' time, as the baton for much of the funding will be passed to the NHS Trusts whose budgets have to reflect the full spectrum of priorities for the health of the nation. Cancer, heart disease, Alzheimer's and other degenerative conditions do not appear to be recognized for new gene therapy funding in this initiative despite their enormous burden on the population. However, we believe that the integrated approach shown in the White Paper is a welcome example of joined up thinking and good news for both patients and clinical scientists. We hope that it will encourage more investigators to translate promising therapies into the clinic and attract new investment from both public and private sectors for the development of gene therapy.

References

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