

Proposed regulation of human cloning: paving the way for degenerative disease therapeutics



'Biotechnology needs to face up to a growing number of ethical issues.'

Crispin Kirkman, Chief Executive Officer, BioIndustry Association (BIA)

The announcement in April 2001 by the Health Secretary, Alan Milburn, that the UK government will shortly be introducing legislation to ban human reproductive cloning, marks an important step in the regulation of bioscience. The BioIndustry Association (BIA) welcomes this announcement and is calling for this ban to be enforced throughout Europe and the rest of the world. A worldwide ban on human reproductive cloning would mean that vital research into degenerative diseases, such as Parkinson's disease, could be performed ethically and responsibly, as well as ensuring that such research would not be abused by a small minority for the purposes of human reproductive cloning.

Social responsibility

Scientific and technological developments are advancing so rapidly that society can barely keep pace with the complexities they bring. New science offers exciting possibilities in the discovery of cures for otherwise untreatable diseases, such as Parkinson's and Alzheimer's disease. However, at the same time, we recognize that, as a maturing industry, biotechnology needs to face up to a growing number of ethical issues. The danger is that the pace of scientific and medical advances will be decreased because the issues have not been debated openly and honestly. Clearly, part of the responsibility for ensuring that this debate takes

place rests with the industry. Regulation must address the risk issues associated with developing science, but must also ensure that advances can continue to be made. The public deserves an opportunity to play a part in framing any new rules; it also has a right to know how new regulations will resolve what it perceives to be the risks. Therefore, the challenge for industry and regulators is to achieve this crucial balance in what is an inherently risk-adverse society.

The Minister's announcement provides a welcome example of how regulation can allow the advancement of important research, but also set strict guidelines to ensure that boundaries are not crossed before society is ready. Britain has the toughest and best-developed regulatory environment for research involving human embryos. The Human Fertilization and Embryology Authority (HFEA), which was set up in 1990, only permits research using embryos of up to 14 days old and only under strictly defined criteria. The HFEA cannot and will not grant licences for human reproductive cloning, which would involve culturing the embryo past the 14-day period. The UK government's forthcoming legislation is intended to add further strength to an existing ban on human reproductive cloning.

Defining research

Research into regenerative therapies offers great hope to patients who are suffering from currently incurable diseases and conditions, such as diabetes, Parkinson's disease and spinal-cord injury. It is vital that we distinguish this important research using embryonic stem cells and cell nuclear replacement (CNR) techniques from the more unwelcome forays into human reproductive cloning. CNR is not the same as human reproductive cloning. Research in the laboratory using very early stage embryos consisting of a few hundred cells and no nervous system is quite different from culturing embryos past the 14-day period, implanting them in the womb, and attempting to take the pregnancy to full term. Whereas the former research technique offers hope to thousands of people suffering from incurable diseases, the latter is unethical, unnecessary

and should be banned worldwide. CNR is a vital research method that is essential to our understanding of how to reprogramme adult cells. If CNR is banned, then researchers will find it harder to develop treatments for patients, and desperately needed cures will either be delayed or will never materialize.

Restoring confidence

To ensure success and recognize the potential benefits of scientific research, we need to raise the nation's faith in the UK's outstanding science base and increase scientific awareness. General science education in the UK is not of a high standard – fewer people now study science beyond school level, and the understanding of even the most basic scientific concepts is at an all-time low. The public usually treats scientific advances with profound suspicion; however, the issue appears not to be so much an ingrained mistrust of science but the fact that the public is looking to regulators and the industry to provide the necessary safeguards. Recent events in the UK, particularly the bovine spongiform encephalopathy (BSE) crisis, have undermined public confidence in the provision of the necessary safeguards and there is a perception that science is being exploited for private-sector profit without proper consideration and concern for future generations. Therefore, scientists and industry must unite on this issue to ensure that the UK maintains its competitive edge in biotechnology.

Extending degenerative disease research

Until January 2001, research using stem cells was only permitted if it looked into the problems of infertility, miscarriage and congenital disease. Although important, such research did not cover many common diseases that affect even greater numbers of people in the UK and elsewhere. Backed by patient groups such as the Cancer Research Campaign, the British Heart Foundation and the Multiple Sclerosis Society, in a free vote the House of Lords and the House of Commons voted overwhelmingly in favour of extending the 1990 Human Fertilization and Embryology Act to permit stem-cell research into degenerative diseases. This decision, combined with the proposed legislation on human reproductive cloning, will allow science to advance in a vital area, and will also reinforce the need to control research in related areas for which society is not yet ready.

The challenge for the bioscience industry is now obvious: to ensure that the enormous potential of these developments is realised, that our understanding of them as a society is clear, and that we work with regulators to manage them in a responsible way.

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What do YOU think about current legislation on stem cell research in your country?

How do you think we can best regulate stem cell research without compromising the benefits that can be gained from this research?

Do you think banning human cloning goes far enough to prevent abuse of the new technologies and techniques available to us?

How do you think we can best communicate with the general public to allay their fears of these new scientific advances and gain their support?

Please send your comments to Dr Rebecca Lawrence, News & Features Editor,
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