A LEAP OF FAITH? SANCTIONING XENOTRANSPLANT CLINICAL TRIALS

ABSTRACT. Introducing a new medical technique, procedure or drug to the public via clinical trials is risky at the best of times. When the trial involves a biotechnology which holds out the promise of prolonging, if not saving, life the push to move from the laboratory to clinical trials may be hard to resist. In this article I explore whether the regulatory scheme for clinical trials in the UK is able to accommodate developing technologies by considering how the current legal and ethical frameworks determine when a procedure such as xenotransplantation should proceed to trials. In particular, I discuss whether basing our regulatory schemes on the principles espoused in the Declaration of Helsinki offer sufficient protection to those who may be affected by xenotransplant trials – the recipient, their health-care workers, close contacts and, unusually, the wider public. I question whether it is possible for a technology to be approved for clinical trials when allowing such trials may benefit the individual but ultimately negatively impact on society as a whole.

KEY WORDS: clinical trials, organs, regulation, risk, therapeutic benefit, xenotransplantation

INTRODUCTORY REMARKS

Since Murray’s transplant of a kidney from one twin to another in 1954, Starzl’s liver transplant in 1963, and Barnard’s heart transplant in 1967,1 transplant programmes throughout the world have been hindered by one common problem: the demand for organs far exceeds the supply of suitable donated human organs.2 Suggested ways of increasing the number of human organs available for transplantation have included encouraging living donation, using non-


2 Between 1 April 2003 and 31 March 2004 2,854 solid organ transplants were performed in the UK; however, 7,236 people were registered on the solid organ transplant list: NHS UK Transplant, Transplant Activity in the UK 2003–2004 (2004), p. 7.
heart beating donors, elective ventilation and adopting a presumed consent scheme. The use of artificial organs has also been explored, and recent developments in cloning and stem cell technologies have increased interest in these areas. Each of these alternatives raise legal and ethical issues, many of which have been explored elsewhere.

Prior to the allotransplants (human-to-human) mentioned above, initial transplantation work involved xenotransplantation (the transplantation of organs, cells or tissues from one species to another), and attention has refocused on this area since the mid-1990s and the production of genetically engineered non-human animals which would help to overcome some of the inherent biological barriers to xenotransplantation. Experimentation into xenotransplantation continues today, and many countries have established, or are establishing, bodies to regulate this developing technology. In the UK, the United Kingdom Xenotransplantation Interim Regulatory Authority (UKXIRA) was instituted in 1997 to, amongst other things, monitor and approve clinical trial applications, and it has considered, but not approved, four applications since its inception.

Clinical trials of cell and tissue

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4 See, for example, the studies listed in Xenotransplantation 11/5 (2004).


7 Two applications were received in 1998 but it is unclear whether they were for cell, tissue or whole organ trials: UKXIRA, Second Annual Report September 1998–August 1999 (London: DH, 2000), paras. 3.15–3.20; one application was received in 1999, again the nature of the application is uncertain: UKXIRA, Third Annual Report September 1999–November 2000 (London: DH, 2001), paras. 4.3–4.4; and the application in 2003 concerned a temporary bio-artificial liver system: UKXIRA, The UKXIRA Fifth Annual Report (London: DH, 2004), paras. 2.3–2.5.