**Xenortansplants - safety, reliability and ethics - Archive 1997 - Updated 1999.**

There are three fundamental questions to ask regarding the use of organs from "humanised" animals to treat medical disorders. Are they safe? Do they work? Are they ethically right to use?

## 1. Are xenotransplants safe?

The government position in January 1997 was that xenotransplants may be ethically sound in principle, but should be banned for now due to safety risks over possible transfer of animal viruses into humans. As a doctor involved for some years in the AIDS field, I have seen at first hand the global devastation from an animal virus that mutated into a human variant. HIV is already carried by one in 250 of the whole world's adult population, with one new infection every fifteen seconds. Many towns and cities in Africa have infection rates of over 25% while in Bombay alone, up to 800 new people are infected every night. Other viruses, perhaps with no obvious effects on their animal hosts, could also turn out to be highly dangerous to humans and may be difficult to detect. One of the most effective ways to force a mutation is to pass viruses from one species through another. This may be a very low risk, but such a mutation could have a completely unforeseen and catastrophic result. The government verdict was correct that xenotransplants are unsafe.

## 2. Do xenotransplants work?

Even well matched human to human transplants often fail. Therefore it is hardly surprising that animal organs have a far higher rejection rate, despite being taken from genetically modified animals. Media hype has given the impression that the technology is almost ready for use in humans but the reality is very different with unacceptably low rates of success in cross-species transfers. Xenotransplants do not work well enough yet to try on sick humans even if the safety issue can be overcome.

## 3. Are xenotransplants ethically acceptable?

Xenotransplants for humans rely on human genes being added to the animal in order to make the animal cells "feel" human enough to be accepted. Scientists involved always stress the tiny amount of human genetic material used but the process poses profound philosophical and religious questions. Is it right to blur the distinctives between animals and humans? Is there a limit morally that ought to be placed on the percentage of an animal that can be humanised? If so, what is it? Given monkeys and humans only differ by 15% in their genes, presumably a

transfer of just 0.2% could be highly significant, perhaps enough to give a monkey speech? We do not know the answers to these questions.. We now have the technology to produce a 50:50 mix of any mammals we like. Geep have already been born (combined sheep and goat). Humonkeys would be relatively simple to make. How many human genes does an animal have to have to gain human rights? And what about animal rights? One may argue that these questions are far removed from humanising a pig with a minute amount of human genetic material but the underlying issues will never go away.

**Xenotransplants are at present unsafe, unreliable and pose unresolved ethical questions. These questions need urgent debate because the speed of progress is likely to change views on safety and efficacy within five years.**

## More below on US response and latest information from Alix Fano, Campaign for Responsible Transplantation PO Box 2751 New York, NY 10163-2751 Tel. (212) 579-3477:

He writes: "On April 6th, the FDA published a 'Guidance for Industry' in the Federal Register on "Public Health Issues Posed by the Use of Nonhuman Primate Xenografts in Humans." In the guidance, the FDA again acknowledges the dangers of using nonhuman primates as donors in xenotransplants. Bottom line: "clinical protocols proposing the use of nonhuman primate xenografts should not be submitted to the FDA until sufficient scientific information exists addressing the risks posed by nonhuman primate xenotransplants."

Essentially, FDA is saying that it would not approve any primate xenografts at this time, but is encouraging further research on primates to study virus transmission to humans. FDA is NOT ruling out other species, like pigs, in xenotransplants.

1) Responsible health authorities would ban all xenotransplants outright, regardless of the species, particularly because of the threats of inter-species virus transmission.

2) Pigs are being considered as the source animal of choice for xenotransplants. But there is no evidence that pigs are any safer than nonhuman primates. We have plenty of evidence that pig viruses would be just as dangerous as nonhuman primate viruses (i.e. influenza, PERVs, paramyxovirus, and earlier this year, the Nipah (Hendra-like virus) in Malaysia that has resulted in hundreds of human infections, 98 human deaths, and 640,500 pigs slaughtered since March 20th1999).

3) The US should follow Europe’s lead. In January 1999, the Council of Europe, representing 40 European countries, recommended a world-wide ban on xenotransplants.

4) There are safer and more humane alternatives to xenotransplantation that are not being explored by regulatory authorities. These include aggressively promoting preventive medicine, and increasing human organ donation rates as many European countries have successfully done through various legislative schemes.

5) The US General Accounting Office published a report on Organ Donation in April 1998 which revealed an untapped donor pool of 150,000 people in the US. The Department of Health and Human Services should fully investigate the points made in that report before allowing xenotransplants to go forward."