

# **Comments Submitted to the National Health and Medical Research Council (NHMRC), Canberra, Australia, on “Draft Guidelines for Clinical Xenotransplant Research”**

September 6, 2002

## **SUMMARY**

It appears as though the decision to proceed with xenotransplantation clinical trials has already been made in this guideline, despite the NHMRC’s claims that it wants a “vigorous public discussion” on the technology. This is unethical and undemocratic. Thus, the question: “Why do we need to consider xenotransplantation,” should be reframed as follows: “Should we consider xenotransplantation at all?”

This guideline states that the demand for organs in developed countries is growing at 15% per year but fails to ask why or what can be done to reverse this unsustainable trend. Studies, including a noted Australian study, confirm that diet, physical inactivity, alcohol consumption, smoking, obesity, hypertension and socioeconomic factors are responsible for the overwhelming number of chronic diseases everywhere. Numerous (Australian and American) studies recommend making prevention a high priority of governments and healthcare institutions. This guideline makes absolutely no mention of the important role of prevention in health maintenance – a glaring oversight.

In addition, although some 60% of Australians support organ donation, only 26% become organ donors. Studies show that many more organs are available for transplant than are being accessed through existing organ procurement efforts; but this guideline pays too little attention to the reasons for poor organ donor rates or how they can be improved, and it neglects the need for research in this area. More importantly, while it promotes the potential benefits of xenotransplantation, it discredits virtually every available alternative to xenotransplants with the use of defeatist language, which ought to be eliminated from this guideline.

This guideline fails to minimally address the serious animal welfare concerns inherent in xenotransplantation, and fails to mention the extreme suffering endured by animals, particularly higher primates, involved in xenotransplantation research (see documentation enclosed with CRT submission). As such, it is disheartening that the NHMRC calls for more gruesome pig-to-primate experiments to be conducted in Australia. Hundreds of these experiments have already been conducted around the world with dubious outcomes. Researchers admit that nonhuman primates are poor models for humans, and that pig-to-primate experiments yield limited, if any, useful information that is relevant to the safety or efficacy of xenotransplantation in humans. Numerous factors involved include: complex species differences between nonhuman primates and human beings, the invasive nature of the experimental

protocols themselves which impair the collection of meaningful data, and the fact that these studies cannot assess risk. As such, pig-to-primate experiments should not be conducted in Australia, contracted out by the government, or condoned by the NHMRC.

This guideline outlines several criteria that must be met in order for xenotransplantation to be considered “ethical.” An example is that the research must “serve the common good,” though how xenotransplantation fulfills this, or any of the other, criteria is never explained.

It is clear from this guideline that the NHMRC has not prepared a cost-benefit analysis to determine the true cost of xenotransplant procedures and their impact on Australia’s health care system and economy. Rather than say that all the costs associated with xenotransplantation “cannot be predicted,” the NHMRC would do well to confront these issues now as it may realize that the technology is not economically feasible.

Although environmental concerns are never raised in the context of xenotransplantation, they should be addressed by the NHMRC. The adverse environmental and public health impacts of large-scale animal based agriculture operations have been well-documented. Xenotransplant pig breeding facilities will likely add to these impacts. How will facilities breeding pigs for xenotransplantation impact local communities? How will they deal with the thousands of tons of manure generated by their facilities? How will they, or hospitals, dispose of the remains of thousands of genetically modified animals? The guideline states that they will be disposed of by “appropriate methods,” but these are not discussed.

The NHMRC acknowledges that xenotransplantation could cause the emergence of a novel and potentially untreatable human infection. CRT has enclosed a voluminous array of journal articles to support this contention. However, the real implications of possible harm to people are ultimately ignored because the NHMRC has outlined a plan for the conduct of clinical xenotransplant trials and described surveillance and risk management procedures.

But studies show that our hospitals are ill-equipped to deal with the most basic infection control, patient care, and technical procedures. The World Health Organization has stated that our public health and regulatory systems are underfunded and over-burdened. CRT has called attention to the inadequacy of U.S. regulation of xenotransplantation through press releases and reports, and is currently suing the U.S. Food and Drug Administration to obtain records on side-effects and deaths in clinical xenotransplant trials. This should be of concern to the NHMRC since the U.S. is often viewed as a model for other countries to follow.

The NHMRC has a mandate to “raise the standard of individual and public health throughout Australia.” Xenotransplantation is inconsistent with that mandate. CRT believes that the NHMRC should honor the Precautionary Principle which states that people have a duty to take anticipatory action to prevent harm. When an activity poses threats to human health or the environment, precautionary measures should be taken to avoid that risk. And before using a new and potentially dangerous technology, decision-makers have an obligation to examine a full range of non-harmful alternatives,

including the alternative of doing nothing. In other words, some technologies pose too great a risk and should not be pursued.

Before considering a technology as extreme, dangerous, expensive and inhumane as xenotransplantation, the NHMRC should:

- Review the findings contained in *Preventing Chronic Disease* (see enclosed), which states that “effective action on prevention is . . . a high priority.”
- Based on the findings in the above report and in the medical literature, launch health promotion policies to reduce the incidence of chronic organ disease in Australia, thereby reducing the number of people on transplant waiting lists.
- Exhaust all avenues for increasing the supply of human organs.
- Fully examine, and allocate resources to, the range of available alternatives to xenotransplantation.
- Include the public in every stage of the decision-making process, through public forums, community meetings, frequent polling, and the like, and be honest about the risks and problems inherent in xenotransplantation.

CRT strongly believes that Australia now has the opportunity to set an example for the rest of the world. CRT urges the NHMRC to enact a moratorium on human clinical xenotransplantation trials, ban all animal-based xenotransplantation research now, and place a hold on the development of these draft xenotransplantation guidelines until it has conducted extensive public consultations.

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