Xenotransplantation—caution, but no moratorium

To the editor—The authors of your February 1998 issue commentary, argue that clinical studies in the field of xenotransplantation should be halted. While we agree with the need for caution and risk assessment in this or any other new therapy, we disagree with the call for a new, national committee.

In calling for a new national committee, the major justification offered by Bach *et al.* is that the public needs to be fully advised about the risks of xenotransplantation so that they can participate in a national or international debate to determine whether or not clinical studies should proceed. This is a surprising justification given that the very issues they are raising have been addressed in public meetings by several other well-informed groups over the past few years. These groups have included the U.S. Food and Drug Administration (FDA) and the Institute of Medicine of the U.S. National Academy of Sciences (IOM).

The authors acknowledge that the FDA has "already established a broadly constituted advisory committee, including both expert scientists and lay representatives". Their explanation of why they are now proposing another, much less well-defined "national committee" to ask the same questions, is that there are "unique aspects of public risk associated with xenotransplantation." This is the very reason why the FDA got involved in the first place. It is difficult for us to understand why these authors wish to ignore the patient and thorough deliberations of previous advisory groups and call for a new, ill-defined group to repeat the process.

Xenotransplantation is currently seen as the most promising, near-term solution to a severe shortage of human tissues and organs. As with any new therapy, there are likely to be risks associated with xenotransplantation and we are certainly in favor of assessing those risks with the greatest of care, both through preclinical studies and through well-controlled clinical trials. However, while there is strong precedent for halting medical practices which are known to confer injury and risk, the halting of a medical practice for which risk has not yet been assessed would create a dangerous precedent. In fact, there is no way to assess that risk adequately without such clinical trials. Indeed, similar decisions are made routinely in the use of new antibiotics. Each such agent has a clear impact on bacterial flora and poses a risk to the general public through the potential for emergence of new, drug resistant bacterial strains. We rely on local Institutional Review Boards and the FDA to assure efficacy and safety of the drugs being tested, and do not consider it necessary to convene new national bodies to consider the ramifications of their use. Such a practice would undoubtedly lead to unnecessary delays and avoidable loss of life.

We therefore think it important to clarify that not all members of the transplantation community back the call for a moratorium on well-controlled, clinical research on xenotransplantation.

DAVID H. SACHS, ROBERT B. COLVIN, A. BENEDICT COSIMI, PAUL S. RUSSELL, MEGAN SYKES
Harvard Medical School
Transplantation Biology Research Center
Massachusetts General Hospital
East Building 149-5102, 13th Street
Boston, MA 02129, USA

CHRISTOPHER G. A. MCGREGOR
Mayo Medical Center
Rochester, MN 55905

JEFFREY L. PLATT
Departments of Surgery, Immunology and Pediatrics
Medical Sciences Research Building, Box 2605
Duke University Medical Center
Durham, NC 27710

Bach et al. reply—Sachs and colleagues make three arguments. The first two are that (i) the very issues we are raising have been discussed in public meetings for years, and (ii) the national committee we are proposing be formed would ask the same questions that the FDA has already asked. The signatories are wrong on both of these counts.

(i) Individuals from the public who have attended FDA meetings have not participated in any process such as the one we propose. There is a crucial difference between allowing a few hundred people to attend a meeting during which they are primarily lectured to, and organizing a committee such as the one we suggest that is both carefully constituted to represent the major segments of our society and the relevant disciplines, and the members of which educate

To the editor—I am a co-author of the February issue commentary that proposed a moratorium on human xenotransplantation[1]. Because certain of the concerns raised in that commentary have been addressed, I no longer feel that a moratorium is necessary.

The unique risk of xenotransplantation is the potential spread of infection from another species not only to the recipient but also to others who were not involved in the clinical decision to undertake the transplantation[2]. Our paper proposed that a mechanism be created to involve the public in the on-going review of information regarding the safety of xenotransplantation. As a part of a four year long evaluation, the Food and Drug Administration (FDA) and other agencies of the United States Public Health Service (USPHS) have directed careful and open discussions about xenotransplantation, focusing attention on the potential risk of infection to the organ recipient and to the community at large. Much new information and an agenda for future research have been developed through this process.

The recent federal xenotransplantation conference (U.S. Department of Health and Human Services, "Developing U.S. Public Health Policy in Xenotransplantation," January 21–22, 1998, Bethesda, Maryland, USA) included a proposal by the USPHS for the formation of a national Xenotransplantation Advisory Committee to include scientists, physicians, ethicists, lawyers and members of the lay public. The charge to this oversight committee is similar to that proposed by our commentary: to enhance the safety and public awareness of xenotransplantation while allowing clinical trials to advance. In the meantime, existing review mechanisms will assure that each proposed protocol includes the evaluation of all human subjects for known infectious agents potentially associated with interspecies transplantation.

The risks of xenotransplantation are not zero. Ultimately, these risks can only be measured in clinical trials. I now believe that the potential benefits of xenotransplantation justify a cautious advancement of such studies. Data assembled as a result of such experiments will allow informed decisions about whether the risks are worth taking.

JAY A. FISHMAN
Massachusetts General Hospital
Boston, MA, 02114, USA
email: jfishman@helix.mgh.harvard.edu