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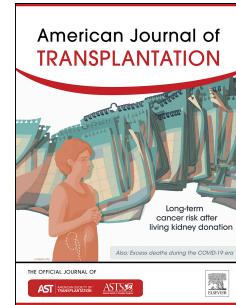
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Xenotransplantation and Lifelong Monitoring

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To the Editor:

We read with interest the report from Adams et al. regarding the FDA meeting on regulatory expectations for xenotransplantation. [1] Within the report, Adams et al. offer a meeting summary of 7 topics that the joint American Society of Transplant Surgeons/American Society of Transplantation committee on xenotransplantation identified as important for xenotransplantation research. We applaud the inclusion of ethical considerations as one of the 7 topics, and since the discussion of ethical considerations is admittedly brief, we want to pinpoint the challenges posed by requiring lifelong surveillance. The authors note:

[1] In the case of early-phase xenotransplant trials long-term monitoring for zoonotic infection may be needed to protect the public health and may require that xenotransplant trial recipients consent to lifelong follow-up.[2]

The tension, as Adams et al. describes, is that an ethical tenet of research with human participants is that subjects have the right to withdraw completely from a study without penalty. However, the potential for xenozyoonotic infection have led researchers and organizations to highlight the need—or even the requirement—for long-term or lifelong surveillance.

The authors advise that a potential solution to the risk of xenozyoonosis is to require participants to consent to lifelong surveillance (Table 2). However, informed consent does not guarantee compliance, because an individual may refuse to comply with surveillance requirements for any number of reasons. What is needed of xenotransplant research, for this to be practicable, is something that binds participants to lifelong surveillance and is enforceable through legal procedures and/or police powers. In the United States (US), there is no legal precedent for mandatory lifelong surveillance of otherwise healthy individuals. While the US Supreme Court has ruled that individual rights can be suspended in the interest of public health when the risks are subject to scientific assessment, there is no legal precedent for mandated surveillance of individuals who do not show signs of illness [3]. Public health laws also tend to

be specific, directed to particular communicable diseases, and some state health codes allow for measures to be taken to prevent spread of a contagious disease *but only when informed of its presence* [4]. In order for an individual's rights to be overridden by the government, there needs to be proof that an individual is sick with a contagious disease and poses a risk to public health. But, as it currently stands, the risk to public health of xenozoonosis is too unspecific and unknown to be legislated. This is an important discussion that needs a definitive conclusion before formal clinical trials begin.

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Declaration of interests

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:

Daniel J. Hurst reports a relationship with New York University that includes: consulting or advisory. If there are other authors, they declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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