Key Legal Issues: Determining the Rise of Geoethics as the Optimum Analytical Paradigm

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The key legal issues surrounding xenotransplantation depend on the magnitude of the social problem that the procedure addresses. A significant social problem exists because none of the alternatives to xenotransplantation can fully address the demand of an aging population for an adequate supply of vital organs. This latent demand will be expressed as a patient's right to xenotransplantation, once it is shown to be safe and effective. For this right to be accepted legally it must be demonstrated that xenotransplantation is consistent with respect for animal life, is affordable by health care systems, and does not jeopardize public health. These three hurdles are surmountable provided that an international organization ensures donor herd practices, xenograft access procedures and xenogeneic disease monitoring and control practices meet specified standards. Because the risks of xenotransplantation are distributed globally, the legal issues go beyond bioethics into a new discipline of geoethics.

Introduction

A latent demand for organ transplantation exists that is considerably larger than the extant demand constrained by screening criteria to better match allograft availability. It is estimated that the latent demand for organs is at least five times greater than that reflected on current waiting lists.[1] An important share of the end stage organ failure market is likely to be addressable by xenografts notwithstanding the concomitant development of mechanical devices and regenerative medicine solutions. Improved organ donation rates, procurement procedures and allocation policies will help reduce the gap between organ demand and supply, but can not satisfy the latent demand for thoracic organs. Marketplace-type procedures for addressing excess demand for organs are anathema to public policy.

A right to health care is generally recognized in domestic and international law.[2] This right is not absolute, but is subject to countervailing interests such as resource availability and considerations of public health. The right to health care emanates from the expectation of society for its members to function as productive citizens. The just allocation of health care services within limited resources is controversial. However, health care rationing systems tend to rank transplantation procedures as a high priority, with Oregon's 1999 explicit rationing system listing heart, lung, liver and kidney transplants as priority numbers 158, 445, 110 and 109, respectively, out of 744 possible treatments and a funding cut-off at priority number 574. Even if a medical procedure cannot be afforded for all in need of it, a just solution is to provide some affordable number of the procedures on a non-discriminatory basis. Consequently, it can be expected that patients will demand a right to xenotransplantation, as a life-saving measure, as the procedure is shown to be safe and effective. A right to xenotransplantation spawns unique legal issues.

Discussion

Recognition of a private right to xenotransplantation, consistent with budgetary resources, has the potential to conflict with two public concerns—that animals be treated with respect, and that the public health not be endangered.

Animal Law Issues. Animals do not have rights in the same sense as humans do, because animals are not capable of complying with the countervailing

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obligations that accompany all human rights. However, due to the phylogenetic proximity of higher animals and humans, there is a consensus in society that all sentient life is entitled to a measure of respect. A pluralistic society needs to provide considerable flexibility to its members in terms of how, precisely, to accord animals respect. However, the society can reasonably set forth some boundaries, as it does for other essentially spiritual questions, such as religious practices and abortion.[3] In today's law those boundaries proscribe gratuitous violence toward animals, such as the intentional infliction upon them of distress.[4]

Consequently, the animal law issue for xenotransplantation is satisfied by ensuring that the donor animals are not caused distress during their breeding or sacrifice. It should be noted that this legal resolution is not "specist" because the animals are not being sacrificed for being animals. Instead, distress to sentient beings overall is being minimized by saving sentient beings who fear their impending death (humans) with the sacrifice of sentient beings who are not aware of their impending death (pigs), and who are not caused distress during their life.

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Public Health Law Issues. In theory, xenotransplantation public health concerns are addressable via applicability of the type of isolation and containment procedures that were agreed upon at the Asilomar Conference for the management of genetically modified organisms.[5] However, the application of Asilomar-type procedures to xenotransplantation requires an extended analysis because the world community is now more organized than it was in 1975, and more aware of zoonotic health threats due to the AIDS pandemic and "mad cow" disease. Jurgen Habermas and other legal theoreticians have provided a template for the regulation of risks that affect disparate parties.[6] In essence, the moral stance is to negotiate the consent of those to whom a risk will be passed prior to creating the risk.

Habermasian ethics effectively requires an international treaty to be negotiated among governmental and relevant non-governmental entities prior to the clinical implementation of xenotransplantation. The likely outcome of such a globally participative norm-setting process would be a new global enforcement organization for xenotransplantation (GEOX). Such an organization would accomplish the richer nations' concerns of ensuring there are strict xenogeneic infectious risk minimization procedures in place, no rogue xenotransplant centers, and a worldwide sentinel surveillance system for xenozoonotic (and other) emerging viral threats. But, through treaty-making negotiations, such an organization would also accomplish the poorer nations' concerns, and those of many NGOs. These concerns will likely center on being provided with the financial means of achieving basic health care in exchange for participating in a surveillance network, and being provided with some right of access to xenotransplantation operations in the richer countries.

The World Bank has estimated the cost of implementing health care stations throughout developing countries in the range of $10 per capita annually.[7] This translates to approximately $10 billion annually for implementation in countries with less than one doctor per thousand people. This sum, which would also cover GEOX xenograft program certification expenses, can be self-financed via a $20,000 tax on each xenograft, assuming ultimate annual xenotransplantations totalling 175,000 in each of the US and Europe, 50,000 in Japan and 100,000 in the rest of the world.

The Geoethical Paradigm. Traditional principles of bioethics work well when treatment largely affects a single patient. Xenotransplantation, however, is a therapy with potential xenozoonotic consequences to the world's population. At this macrocosmic level of medicine, geoethics is needed over bioethics. There are three geoethical principles:

1. those who may shoulder risks must help shape, through their representatives, the risk-producing regime;
2. those who may feel risks are entitled to benefits from the risk-producing activity; and
3. risk-producing activities should self-finance independent assurance of compliance with global norms.

Key legal issues frame a conflict between private and public interests in xenotransplantation. However, the technology offers a pathway to take human health care to a new level of optimization. A geoethical implementation of xenotransplantation ensures that it will relatively benefit most those who are least well off, and at the same time provide maximum assurance that risks to public health are minimized. A geoethically derived legal regime for

xenotransplantation helps create a society that, in its endless quest for improvement, constitutes the raison d'etre Kant envisioned as "the destined final end, the highest moral perfection to which the human race can attain."[8]

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