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978-0-521-19576-8 - Xenotransplantation and Risk: Regulating a Developing Biotechnology

Sara Fovargue

Excerpt

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1 Introducing the issues

A day rarely passes without a media report which suggests that ‘miracle’ cures for some diseases and conditions are imminent. This ‘forward stampede’ which advocates new (bio)technologies may distract attention from other, less technological, problems and solutions¹ and, to fulfil its promise, a developing biotechnology must move from pre-clinical to clinical trials. At this point, the relationships between science, ethics and law are brought into sharp focus. Xenotransplantation not only highlights these relationships but also the (ab)use of non-human animals. This is not my focus here; rather, I am concerned with whether and how xenotransplantation, a developing biotechnology which *may* benefit an individual but inherently risks harming others, can be accommodated within existing legal and ethical structures and conventions. What is at issue is how to appropriately reconcile private benefit with collective risk.² The risks of xenotransplantation are such that it necessarily challenges accepted legal and ethical norms and existing regulatory structures may thus be ill-equipped to deal with it, but insufficient attention has been paid to these challenges by policy-makers and regulators to date. English law is my base but I draw on legal and ethical material from other jurisdictions where appropriate to explore how, if at all, the problems I identify have been addressed elsewhere. My analysis and discussions are thus not dependent on a legal system similar to England’s; my concerns and questions are relevant across the world because of the *global* nature of the issues and risks raised by this biotechnology.

What is xenotransplantation?

In England xenotransplantation is defined as ‘any procedure that involves the transplantation, implantation, or infusion into a human recipient of

¹ F. Schumacher, *Small is Beautiful* (London: Vintage, 1973), p. 128.

² E.R. Gold and W.A. Adams, ‘Reconciling Private Benefit and Public Risk in Biotechnology: Xenotransplantation as a Case Study in Consent’ (2002) 10 *Health Law Journal* 31, 32.

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either live tissues or organs retrieved from animals, or, human body fluids, cells, tissues or organs that have undergone *ex vivo* contact with live non-human animal cells, tissues or organs'.³ Work on this biotechnology has been motivated by the consistent gap between the demand for and supply of human organs available for transplantation.⁴ Pigs are currently the main focus as the source for these organs, and the hypothesis is that if pig organs are genetically engineered to minimise their rejection by humans, a never-ending supply of suitable organs, cells and tissues may be produced. The longest a human has survived with a non-human animal solid organ is nine months;⁵ however, this chimpanzee kidney

³ Department of Health (DH), *Xenotransplantation Guidance* (2006), p. 1 (at: www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_063074.pdf, accessed 16/03/11). Similarly, Australia – National Health and Medical Research Council (NHMRC), 'Animal to Human Transplantation Research (Xenotransplantation) – Definition: What is Animal to Human Transplantation' (2010) (at: www.nhmrc.gov.au/health_ethics/health/xeno.htm, accessed 16/03/11); Canada – Health Canada, Science & Research, 'Xenotransplantation' (2006) (at: www.hc-sc.gc.ca/sr-sr/biotech/about-apropos/xeno-eng.php, accessed 16/03/11); France – Comité Consultatif National d'Éthique pour les Sciences de la Vie et de la Santé (CCNE), *Opinion on Ethics and Xenotransplantation* (1999) No. 61, p. 2 (at: www.ccne-ethique.fr/docs/en/avis061.pdf, accessed 16/03/11); New Zealand – HRC (Health Research Council) Gene Technology Advisory Committee, *Guidelines for Preparation of Applications Involving Clinical Trials of Xenotransplantation in New Zealand* (2007), p. 3 (at: www.hrc.govt.nz/assets/pdfs/publications/Guidelines%20for%20Preparation%20of%20Applications%20Involving%20Clinical%20Trials%20of%20Xenotransplantation%20in%20NZ.pdf, accessed 16/03/11); Sweden – A Report by the Swedish Committee on Xenotransplantation, *From One Species to Another – Transplantation from Animals to Humans: Summary and Statutory Proposals* (Stockholm: Swedish Committee on Xenotransplantation, 1999) Swedish Government Official Report No. 1999: 120, Proposal for an act (2000: 000) for clinical trials on humans involving transfer of living biological material from animals (Xeno Licensing and Control Act), s. 1; Switzerland – Statement of Position of the SAMS (Swiss Academy of Medical Sciences), 'Medical–Ethical Principles of Xenotransplantation' (2001) 131 *Swiss Medical Weekly* 388, 389; US – US Department of Health and Human Services (DHHS), Food and Drug Administration (FDA), *PHS Guideline on Infectious Disease Issues in Xenotransplantation* (2001), p. 4 (at: www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Xenotransplantation/UCM092858.pdf, accessed 16/03/11); Council of Europe, *Report on the State of the Art in the Field of Xenotransplantation*, CDBI/CDSP-XENO (2003) 1, p. 9, ch. 4 (at: [www.coe.int/t/dg3/healthbioethic/activities/06_xenotransplantation_en/XENO\(2003\)1_SAR.pdf](http://www.coe.int/t/dg3/healthbioethic/activities/06_xenotransplantation_en/XENO(2003)1_SAR.pdf), accessed 16/03/11); World Health Organization (WHO), 'Xenotransplantation' (at: www.who.int/transplantation/xeno/en/, accessed 16/03/11).

⁴ In the UK, e.g., 3,706 transplants were performed between 1 April 2009 and 31 March 2010 but at 31 March 2010 7,997 people were registered on the active transplant list, 2,545 were temporarily suspended from transplant lists, and 552 patients died waiting for a transplant: NHS Blood and Transplant, *Activity Report 2009–2010, Transplant Activity in the UK* (2010), pp. 1, 3–4 (at: www.uktransplant.org.uk/ukt/statistics/transplant_activity_report/transplant_activity_report.jsp, accessed 16/03/11).

⁵ K. Reemtsma *et al.*, 'Renal Heterotransplantation in Man' (1964) 160 *Annals of Surgery* 384.

was not genetically engineered and the viability of a genetically engineered pig organ in a human is unknown. Clinical cellular xenotransplants have been performed,⁶ but a clinical xenotransplant of a genetically engineered solid organ has yet to be reported. This is my focus.

If genetically engineered solid organ xenotransplants are able to prolong and maintain life the individual recipient will have benefited. Society will also benefit from their return to work and increased productivity, minimising ill health and disease, confidence in science and medicine may increase, and ‘spin-offs’ from the biotechnology may develop.⁷ Xenotransplants may also be preferable to allotransplants (human-to-human transplants) by enabling operations to be timed for the patient’s benefit and not when an organ becomes available, reducing time in hospital, minimising the need for immunosuppression, providing an unlimited source of organs, and circumventing the difficulties of obtaining consent for donation.⁸ The initial immunological barriers to solid organ xenotransplantation *may* have been negotiated via the use of genetically engineered pigs, but other potential physiological and microbiological barriers have been identified and remain unaddressed, as discussed in Chapter 2.⁹ Of particular concern is the risk of transmitting infectious diseases across the species barrier and from the xeno-recipient to her close contacts, relatives *and* the wider public, causing pandemics.¹⁰ The risk of transmitting infectious diseases is widely acknowledged but there is no consensus on the nature, extent or degree of it. The diseases may be known, such as porcine endogenous retroviruses, and unknown; making it difficult to devise detection tests, respond to any infections, or monitor their existence and spread. Some diseases may be latent, with the length of this also unknown. Nevertheless, pre-clinical research into genetically engineered solid organ xenotransplantation continues,¹¹ even though other biotechnological advances, such as cloning and stem cells, have led the utility of this

⁶ R.B. Elliott *et al.*, ‘Live Encapsulated Porcine Islets from A Type 1 Diabetic Patient 9.5 Years after Xenotransplantation’ (2007) 14 *Xenotransplantation* 157.

⁷ P.D. Kumar, ‘Xenotransplantation in the New Millennium: Moratorium or Cautious Experimentation?’ (2000) 4 *Perspectives in Biology and Medicine* 562, 569.

⁸ NHMRC, *Discussion Paper – Xenotransplantation: A Review of the Parameters, Risks and Benefits* (2009), pp. 20–21 (at: www.nhmrc.gov.au/_files_nhmrc/file/about/committees/expert/gtrap/nhmrc_xeno_discussion_paper_website.pdf, accessed 16/03/11).

⁹ G. Griffin and D. Muir, *Infection Risks in Xenotransplantation* (London: DH, 2001); J.M. Dobson, J.H. Dark, *The Physiology of Xenotransplantation* (London: DH, 2002).

¹⁰ D. Butler, ‘Last Chance to Stop and Think on Risks of Xenotransplants’ (1998) 391 *Nature* 320.

¹¹ See reports in *Xenotransplantation* (at: www.wiley.com/bw/journal.asp?ref=0908-665X, accessed 16/03/11).

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type of xenotransplantation to be questioned.¹² Despite these problems it has been suggested that a small number of clinical trials should be permitted in order to determine the nature and extent of these barriers and risks.¹³

Why focus on xenotransplantation?

I focus on xenotransplantation for two reasons; first, it is a developing biotechnology with profound inherent risks which go beyond the intended beneficiary. Performing an experimental procedure or embarking on clinical trials is always risky but when this involves a biotechnology which has the potential to prolong or save millions of lives with a market worth millions of dollars, the drive to clinically proceed may be irresistible. Indeed, '[t]he "technological imperative" to keep pushing back the barriers can place enormous strains on our legal and ethical institutions and frameworks of analysis. Yet the huge therapeutic potential requires us to embrace and confront these questions.'¹⁴ In the light of this, I use xenotransplantation as an example to explore *how* risks can be regulated and discuss the importance of public involvement in decision-making. One question which must be publicly considered is whether some risks are too great to take, despite their potential to prolong or save life, because of the need to protect public health from serious infectious diseases with uncertain and unknown consequences.

Secondly, the nature and extent of these risks are such that existing legal and ethical frameworks may not offer sufficient protection to xenorecipients and others. There has been a trend in many Western countries to base health care systems on concepts of individual autonomy and individual rights, but the implications of biotechnologies such as xenotransplantation support not only the calls for a rethinking of autonomy but also the suggestion that individual autonomy *cannot* be the central ethical principle in health care.¹⁵ More particularly, '[x]enotransplantation

¹² United Kingdom Xenotransplantation Interim Regulatory Authority (UKXIRA), *Third Annual Report September 1999–November 2000* (London: DH, 2001), para. 6.19.

¹³ A.S. Daar, 'Xenotransplantation: Three Questions to Advance the Discourse' (2000) *British Medical Journal* (at: www.bmj.com/content/320/7238/868/reply#bmj_el_7566, accessed 16/03/11).

¹⁴ D. Price, *Legal and Ethical Aspects of Organ Transplantation* (Cambridge University Press, 2000), p. 2.

¹⁵ N. Manson and O. O'Neill, *Rethinking Informed Consent in Bioethics* (Cambridge University Press, 2007); M. Brazier, 'Do No Harm – Do Patients Have Responsibilities Too?' (2006) 65 *Cambridge Law Journal* 397; A. Dawson and E. Garrard, 'In Defence of Moral Imperialism: Four Equal and Universal Prima Facie Principles' (2006) 32 *Journal of Medical Ethics* 200; O. O'Neill, *Autonomy and*

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raises issues such as the protection of the interests of future generations, the prevention of harm, the acceptance of some harm for the achievement of a “higher good”, or the supremacy of the freedom to choose (autonomy).¹⁶ The risks of xenotransplantation highlight the fact that we are interconnected individuals who are related to, interdependent and reliant on others. Thus, health care systems which are premised on legal and ethical notions of individual autonomy alone may not be appropriate for xenotransplantation with its potential to harm the intended beneficiary *and* others. However, there is a tendency to assume that such developments *can* fit into existing regulatory structures, an assumption I challenge.

Before setting out the themes which underpin this book I want to make it clear that I am not arguing that xenotransplantation is a viable solution to overcoming the shortage of human organs available for transplantation. In fact I would suggest that the science has not advanced sufficiently to merit clinical trials, and that there are other less risky alternatives.¹⁷ However, the fact that pre-clinical research continues, as do claims about the imminence of solid organ clinical trials,¹⁸ necessitates that the legal and ethical implications, ramifications, and realities of clinical xenotransplants are analysed.

Themes

Risk

Risk, its nature, understanding of it, the possibility of explaining and then regulating it, is central to this book because much is still unknown and uncertain about xenotransplantation. In Chapter 2 I discuss the potential risks involved in the biotechnology and in Chapter 6 I explore some suggestions for managing, controlling and regulating them. One of the problems is that ‘[i]n the absence of hard data,

Trust in Bioethics (Cambridge University Press, 2002); D. Beylveled and R. Brownsword, *Human Dignity in Bioethics and Biolaw* (Oxford University Press, 2001), ch. 2.

¹⁶ Gold and Adams, ‘Reconciling Private Benefit’, 46.

¹⁷ See, e.g., J.K. Mason and G.T. Laurie, *Mason & McCall Smith’s Law and Medical Ethics* (8th edn, Oxford University Press, 2011), ch. 17; J. Herring, *Medical Law and Ethics* (Oxford University Press, 2010), ch. 8; E. Jackson, *Medical Law: Text, Cases and Materials* (Oxford University Press, 2010), ch. 11.

¹⁸ E.g., R.N. Pierson *et al.*, ‘Current Status of Xenotransplantation and Prospects for Clinical Application’ (2009) 16 *Xenotransplantation* 263; D.K.C. Cooper *et al.*, ‘Recent Advances in Pig-to-Human Organ and Cell Transplantation’ (2008) 8 *Expert Opinion in Biological Therapeutics* 1.

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attempts to assess risks and develop a rational policy are exercises in reasoned speculation',¹⁹ and these questions need addressing:

[h]ow can we appraise and predict such unknown health risks? What kind of balance ideally should be struck between our obligations to accept some risk to ourselves in order to benefit designated individuals or groups of individuals whose lives might be sustained through our actions, and our obligation to protect and foster the health of the community – locally, nationally, and internationally? And if a biomedical procedure with the characteristics of xenotransplantation is clinically initiated, with what kinds of precautions, surveillance, social controls, and regulations should it be surrounded?²⁰

Where the risks are unidentifiable or latent until a biotechnology is clinically in use, effective risk management will be difficult if not impossible to attain. There may be ways to regulate risk, such as a moratorium or via the precautionary principle, but will these strategies appropriately safeguard public health while also offering the possibility of benefit to individuals in need? Xenotransplantation raises questions about acceptance and understanding of uncertainty and risk, personally and to others, questions which it may not be possible to address prior to its clinical introduction. We are not experienced in assessing risks and benefits which go beyond the individual; thus, 'the key question today is how to develop an ethics discourse adequately evaluating the balance between a low (or unknown) risk of occurrence of an adverse event against the enormous negative consequences should that event come to pass'.²¹ These issues are explored in Chapters 2 and 5.

The public

The lack of knowledge about the risks of xenotransplantation may have an impact on public confidence in and an understanding of science, both of which are crucial because of these risks. British experiences of the Bovine Spongiform Encephalopathy (BSE) crisis and the introduction of genetically modified (GM) crops highlight the importance of such confidence, trust and understanding, and the risks of xenotransplantation are such that public consultation and engagement is

¹⁹ L. Chapman, 'Speculation, Stringent Reasoning and Science' (1999) 77 *Bulletin of the World Health Organization* 68, 69.

²⁰ R.C. Fox and J.P. Swazey, *The Courage to Fail – A Social View of Organ Transplants and Dialysis* (New Brunswick, NJ: Transaction, 2002), pp. xviii–xix.

²¹ A.S. Daar, 'Xenotransplantation – Science, Risk and International Regulatory Efforts', in T.A. Caulfield and B. William-Jones (eds.), *The Commercialization of Genetic Research – Ethical, Legal and Policy Issues* (New York, NY: Kluwer Academic, 1999), pp. 129, 130.

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crucial. However, traditionally, only the consent of the individual recipient is required to an experimental procedure or to authorise a person's involvement in a clinical trial, rather than a more general 'community consent'. There is thus little space for wider considerations and discussions. However, the risks of xenotransplantation require public participation and involvement in decision-making processes as this is a novel biotechnology,²² and genetically engineered solid organ xenotransplants should not be performed without this because '[t]he public must be able to make informed choices with regard to practices which could endanger the future of our species and the principle of human dignity'.²³ Yet the value of such consultation may be limited if public understanding of risk along with the means of expressing it are poor or similarly restricted. I discuss ways to address these points in Chapter 2.

Public consultations are becoming more common in England,²⁴ and while they can be criticised for limited publicity and appealing to respondents with vested interests, difficulties or concerns about such consultations should not be used as excuses not to engage in them. Experiences of and lessons from public consultations in other areas and jurisdictions must be drawn on to improve what will always be an imperfect exercise, and in Chapter 2 I discuss how public debate and consultation on biotechnologies can be encouraged, while acknowledging that this will not be straightforward given that where ethically sensitive topics are concerned consensus is unlikely. Nevertheless, the public need to be involved in the decision-making process surrounding xenotransplantation because they are, essentially, being *expected* to accept risks to themselves without specifically consenting to them. If some form of participatory decision-making is not possible, it is important to consider whether a biotechnology which inherently risks public health should be introduced.

Regulating risk

Having set out the risks involved in xenotransplantation and the importance of public involvement in decisions to accept such risks,

²² J. Wilsdon and R. Willis, *See-through Science: Why Public Engagement Needs to Move Upstream* (London: Demos, 2004), p. 12.

²³ N. Lenoir, 'Biotechnology, Bioethics and Law: Europe's 21st Century Challenge' (2006) 69 *Modern Law Review* 1, 5.

²⁴ E.g., DH, 'Consultations' (at: www.dh.gov.uk/en/Consultations/Liveconsultations/index.htm, accessed 16/03/11); Human Fertilisation and Embryology Authority (HFEA), 'Consultations & Reviews of Policy' (at: www.hfea.gov.uk/122.html, accessed 16/03/11).

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I explore how law regulates risk in two contexts. First, in Chapter 3 I consider how experimental procedures and medical research are defined and regulated, and discuss which category the first genetically engineered solid organ xenotransplant will fall into. This is important because while medical research in the form of clinical trials is now statutorily regulated in England,²⁵ regulation of the former is less clear. I consider whether the current regulatory regimes are appropriate in the light of the risks of xenotransplantation, and then discuss selecting the first recipients. This matters because the needs and demands of those who are desperately ill must be balanced with the wider demands of society; for health protection and medical advances. I explore whether the suggested first recipients (those with no other hope) will be adequately safeguarded when deciding to receive a xenotransplant under existing regulatory schemes. I also introduce some issues explored further in Chapter 5 regarding whether the principle of autonomy supports allowing people to sacrifice themselves in the (limited) hope of gaining some benefit to themselves, but with the more likely outcome of providing information for future generations. I question whether the extraordinary risks of xenotransplantation mean that individual autonomy *must* be legally limited with regard to this biotechnology. Essentially, can A's need for a xenotransplant outweigh B and C's need not to have their health and life jeopardised?

Secondly, in Chapter 4, I discuss how risk is regulated by considering the regulatory schemes which have been proposed and adopted for *in vitro* fertilisation (IVF), gene therapy and xenotransplantation. These biotechnologies have all stretched the limits of and, to some extent, changed or led to questions about the boundaries of science and what it is to be human. Thus, alongside a country's general regulatory framework on experimental procedures or medical research, a further layer of specific regulation has been considered or introduced for these developing biotechnologies. I explore how these schemes were devised and implemented, and highlight the problems of regulating *developing* biotechnologies. These regulatory issues are important because there is a concern that ethical discussions and debate occur too late in the regulatory process, when the move from laboratory to the hospital seems inevitable and unstoppable. Furthermore, where the risks of a biotechnology go beyond the individual, I suggest that public involvement in regulatory decision-making is essential and any regulatory body must encourage this.

²⁵ The Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004 No. 1031.

Challenges to legal and ethical norms

The risks of xenotransplantation require a reconsideration of general and specific regulatory schemes *and* challenge accepted legal and ethical norms, especially those premised on individual consent. The precedence given to autonomy in many Western countries has been questioned,²⁶ and some developing biotechnologies further highlight the difficulties with this legal and bioethical principle, particularly in prioritising it over other concepts. Xenotransplantation thus requires a review of the balance between the autonomy of the individual and community interests in public health. While ‘*intense individualism* – possible individualism to the exclusion of any real sense of community’²⁷ has been in evidence in areas such as euthanasia and reproductive technologies, ‘respecting the rights of the individuals who make up a society, important as this is, is not always sufficient to protect the society itself. Sometimes, in carefully justified instances, to do so we must give priority to the needs of the community over the claims of individuals.’²⁸ Given the risks, xenotransplantation is a developing biotechnology where individual autonomy should not automatically rule; rather, a more communitarian and public health perspective is appropriate where ‘the acceptability of an action is to be judged by the goodness or badness of its effect not on an individual *per se* but on persons as interdependent units of society’.²⁹ Thus, while the exercise of individual autonomy may lead to self-fulfilment, ‘there is a social dimension to life which is potentially equally enriching. Autonomy must be qualified by the legitimate interests and expectations of others ...’³⁰

However, as discussed in Chapter 5, in many countries involvement in experimental procedures, medical research, and/or medical practice generally only require the consent of the individual concerned. I explore whether existing consent practices in England are legally and ethically sufficient and appropriate for xenotransplantation; consider the process of obtaining consent; and whether ‘first-party’ consent offers sufficient protection where a biotechnology exposes the recipient *and* others to risks. Consenting to a genetically engineered solid organ xenotransplant will involve two layers: (i) to the experimental procedure or clinical trial; and (ii) to the surveillance and monitoring regime, considered in Chapter 6, which is necessary because of the risks. This dual consent

²⁶ Above, n. 15.

²⁷ M.A. Sommerville, ‘Searching for Ethics in a Secular Society’, in *Ethics of Science and Technology, Explorations of the Frontiers of Science and Ethics* (Paris: UNESCO, 2006), p. 22, emphasis in original.

²⁸ *Ibid.*, p. 23. ²⁹ Mason and Laurie, *Mason & McCall Smith’s*, p. 7. ³⁰ *Ibid.*, p. 8.

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raises a number of questions including whether consent will be required from xeno-recipients *and* others such as their contacts and relatives, whether if the former but not the latter consent the recipient's involvement is prohibited, and whether the accepted right to withdraw from a clinical trial can remain in this context. Furthermore, first-party consent as currently conceived may not adequately safeguard and protect the third parties affected by the xenotransplant, particularly with regard to complying with the surveillance regime. Thus, obtaining 'third-party' consent from contacts, relatives and relevant health professionals to the post-xenotransplant surveillance regime also needs to be considered, and introducing this will set xenotransplantation further apart from other biotechnologies, medical research and treatments. However, the legal and ethical implications of xenotransplantation have not been seriously considered to date despite the fact that 'many of the proposals which are being considered by the policy making community are not consistent with current legal frameworks'.³¹

I thus suggest that 'a decision must be made within a given community as to whether to even allow the products of innovation to be applied'.³² If it is not possible to implement a system for this, then the clinical introduction of xenotransplantation needs careful consideration; specifically, how should, or can, potentially competing interests be balanced? Is it a choice between individual autonomy, choice and independence, and public health, protection and societal benefit? Given the risks, might xenotransplantation be a biotechnology which people *should not* be able to consent to because while the potential benefit is to the individual, the risks are to society?

Public health and global concerns

Xenotransplantation highlights the global nature of advances in health, risk,³³ and some issues and problems with identifying and monitoring risks internationally. For example, if genetically engineered solid organ xenotransplants are prohibited in country V, will a patient be prevented from having the operation in country X or Y and, if so, how will this occur? If such xeno-tourism cannot be prevented, will it be possible to minimise the risks to the xeno-recipient and others? Some consulates hold records on their citizens who seek medical treatment overseas but as

³¹ T.A. Caulfield, G.B. Robertson, 'Xenotransplantation: Consent, Public Health and Charter Issues' (2001) 5 *Medical Law International* 81, 82.

³² Gold and Adams, 'Reconciling Private Benefit', 33.

³³ U. Beck, *Risk Society: Towards A New Modernity* (London: Sage, 1992).