

# Reconciling Private Benefit and Public Risk in Biotechnology: Xenotransplantation as a Case Study in Consent

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## I. Introduction

All major technological advances have the potential to fundamentally change the social, economic, political and legal landscapes of those who adopt the benefits of innovation. While these advances may represent significant changes in knowledge or modes of behaviour, they nonetheless develop gradually. This progressive implementation is the cumulative effect of a multitude of discrete individual decision-making processes. Research is initiated into what appears to be a promising line of inquiry or may be a serendipitous by-product of other projects. Investment underwrites this activity, originating in either the public or private sector, for motives of either public health and welfare or profit and return on investment. The end-users of technology, the ostensible intended beneficiaries, accept or reject the applied products of research, either through a considered analysis of the benefits to be gained by adopting a new technology or in the hope that whatever the outcome, it is better than the current alternative. Thus, while appearing organic, technological development actually take place within the context of a multitude of decisions at the individual and aggregate levels, from the decision to invest initial resources in research and development, to the decision to commercialize, to the decision to adopt the products of commercialization. Each of these decisions is, at least in part, a reaction to not only a perceived need for technology to address a problem or improve productivity or standard/quality of life, but also to the acceptance of the fundamental changes that will occur as a result of implementation.

While these general thoughts apply to all new technologies, they take on heightened meaning with respect to biotechnology. Research and development in this field along with the concomitant commercialisation of the products of biotechnological innovation, present a unique challenge that we have not had to address in the past technological revolutions that we have weathered. Advancements in biotechnology have the potential to alter not just our environment but our physical embodiment as well. In altering not merely our social, cultural, economic or political environments, but the physical foundations of life itself, the decision to

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adopt a particular biotechnology may be irrevocable and the results irreversible. There can be no turning back from a decision to alter our biological destiny.

While biotechnology promises to change many aspects of our lives in terms of our relationship with nature and our physical environment, it is in the area of health care that we are most likely to feel the impact of irreversible innovation. To date, this impact has been subtle: we now manufacture, for example, some medications using genetically-modified microorganisms, we provide genetic tests, and we conduct research using our emerging knowledge of the human genome. But the potential of modern biotechnology stretches far beyond these early applications. For example, researchers are working on ways to match medications against a person's genetic make-up in order to reduce adverse reactions and maximize positive ones (pharmacogenetics<sup>1</sup>) and there has been some limited success (but also failure) in inserting non-mutated genes into the bodies of those suffering from genetic diseases (gene therapy). We may also soon have the ability to insert animal organs into human beings in order to replace diseased human organs. This is called xenotransplantation: the transplantation of an organ or tissues across species.

In each of the above examples, the health benefits to individual recipients of the products of biotechnological innovation are self-evident, although far from uncontroversial.<sup>2</sup> The appropriate balance between the benefits and risks of medical intervention in each individual case is a decision typically made within the confines and confidentiality of a doctor-patient relationship. The appropriate risk management strategies surrounding these decisions are institutionalized in the form of legal rules such as professional ethics, negligence and fiduciary duty. What remains unexamined is the distribution of benefits and burdens amongst various other stakeholders and even the wider population. The outcome of a cost-benefit analysis in relation to a given technological innovation may differ depending upon the unit of analysis. For an individual facing a life-threatening illness, the outcome of adopting innovation under circumstances of scientific uncertainty is likely to be positive, but for the wider population a negative outcome is a distinct possibility. Biotechnological innovation may indeed result in a benefit to the individual recipient, i.e., improvements in the quality or duration of life, but at the expense of increased risk to members of the public in terms of adopting innovation under conditions of scientific uncertainty.

Biotechnological innovation thus raises the question of the appropriate manner in which to reconcile private benefit with public risk. Assuming that a given biotechnological innovation is indeed a viable solution to a given health care

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<sup>1</sup> United States, *What is Pharmacogenetics?* (Bethesda: National Institute of General Medical Sciences, June 1999) online: National Institute of General Medical Sciences <[http://www.nigms.nih.gov/funding/pharmacogenetics\\_laysummary.html](http://www.nigms.nih.gov/funding/pharmacogenetics_laysummary.html)> (date accessed: 24 November 2000).

<sup>2</sup> In adopting advances in biotechnology to therapeutic use, concerns apart from the potential success of the treatment are inevitably engaged. For example, is the cost of treatment justified as an efficient or otherwise morally defensible use of resources? Does adoption of the technology violate ethical, moral or religious values? How should the benefits of the technology be distributed throughout the population?

problem in a specific instance, and that ethical issues can be addressed in a satisfactory manner, is the risk to the public acceptable? Are there spillover effects in the general population that must be taken into account in balancing the benefits and risks of a given medical innovation applied to individual circumstances? In particular, it should be noted that such spillover effects cannot necessarily be confined to national borders; in a world of increased mobility of both people and goods, an outbreak of infection or disease could easily become an epidemic of global proportions. Given the controversial nature of most innovations in biotechnology in general, and the risk to the greater public in particular, the implementation of biotechnological innovation is not simply an issue of consent within a doctor-patient relationship. Instead, a decision must be made within a given community as to whether to even allow the products of innovation to be applied.

Given the varied nature of the risks involved with biotechnology—health, social, and cultural—and the fact that a risk to public health cannot be confined to geopolitical borders, the concept of consent to the introduction of a new technology is difficult to articulate. In order to evaluate whether consent exists, we must address both normative and methodological challenges by defining what we mean by consent in the given context and how to determine whether such consent exists prior to taking any decision to implement new developments in biotechnology. Is consent simply a matter of applying existing principles of representative and deliberative democracy, in that consent may be inferred from the presence of duly enacted legislation? Does consent require the reconciliation of majority and minority interests through a process of judicial review with reference to constitutional requirements and guarantees? How should we identify a community with the necessary authority to provide consent? When faced with a dilemma in terms of reconciling private benefit with public risk, how should reconciliation be achieved?<sup>3</sup> Should individual states be permitted to proceed with unilateral implementation efforts, given that the risks of biotechnological innovations cannot be confined to territorial borders?

In this paper, we attempt to construct the necessary analytical framework in which issues such as these can be addressed, thereby bringing order to the difficult task of determining whether a given community has provided the necessary consent to implement controversial innovations in biotechnology. While we focus on one particular biotechnology, xenotransplantation, our general framework is applicable to the introduction of any new biotechnology whether in the health or even agricultural sector.

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<sup>3</sup>It is of course possible to define the potential benefits of xenotransplantation technology in aggregate terms, which would thereby engage a cost-benefit analysis that measured public benefit against public risk. This characterization, however, does not displace the equally acceptable characterization of the potential benefits of individual transplants as accruing wholly to the recipients, while the associated risks of zoonoses resulting from the transplant are externalized to the population at large.

We begin our analysis with the necessary assumption that in western liberal democracies at least, any decision as to the viability of biotechnological innovation will take into account informed public participation and discussion concerning the identification and assessment of associated benefits and risks. The debate will most likely be framed in terms of whether to proceed with a given technology, and if so, under what circumstances. The necessary public consultation could take any number of forms, including questionnaires, requests for comments, communication through letters, fax or email, or organized public forums. If the end result of the consultation process is a decision to proceed, then institutional design will necessarily follow in order to set into place the necessary regulatory framework and public health infrastructure for implementation.

Our concern is that if either the consultation process or the resulting institutional design is conducted in an ad hoc manner, i.e., without reference to a conceptual framework for the purposes of soliciting and assessing the legitimacy of the public's consent, then any decision to proceed with a new technology is likely to be ambiguous and thus undermine public confidence in the health care system and its administration. Similar difficulties arose when public authorities in Europe ignored the risk of "mad cow" disease and authorities in Ontario failed to ensure that drinking water was properly tested. If we do not know the right questions to ask, the process of collecting answers will at best waste valuable resources and at worst will fail to result in an appropriate (and therefore uncontested) balance between the competing interests involved. Significant deficiencies will not arise until later in the process and will be addressed in a reactive rather than proactive manner.

In an effort to address such concerns before they become problems, we attempt in this paper to provide the necessary guidelines to assist decision-makers in asking the right questions, of the right people, at the right times. We do so by analyzing consent as a function of the nature of the technology in question, the perceived individual benefits and associated collective costs. We have selected xenotransplantation as our case study, based on the timeliness of the issue; the Canadian Public Health Association has recently reported to the federal government on its public consultations designed to determine whether Canada should proceed with xenotransplantation, and if so, under what circumstances.<sup>4</sup> The Association concluded that, at present, Canadians are not prepared to proceed with the technology but may be in the future.<sup>5</sup>

In Part II of this paper, we set out the potential health benefits for recipients of xenotransplants, along with the associated risks to recipients and the wider

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<sup>4</sup>Canadian Public Health Association, *Animal-to-human transplantation: Should Canada proceed?: A public consultation on xenotransplantation* (Ottawa: Canadian Public Health Association, 2002) online: <<http://www.xeno.cpha.ca/english/finalrep/reporte.pdf>> (date accessed: 17 January 2002) [hereinafter Canadian Public Health Association].

<sup>5</sup>Letter from H. Ross & R. Van Tongerlo to the Canadian Minister of Health (7 January 2002), available in *ibid.*

population, addressing both scientific and ethical concerns. Our objective in this part is to demonstrate that the implementation of xenotransplantation technology cannot proceed in an ad hoc manner, but instead requires a collective decision to implement an institutional risk management structure capable of reconciling private benefits with public risks and potential ethical objections. It is within the design and operation of such an institutional structure that consent plays an important role; given that the risks of xenotransplantation technology cannot be internalized within transplant recipients alone, reconciliation of the costs and benefits of this technology requires consent on the part of others potentially at risk.

In Part III, we set out a conceptual framework for assessing the adequacy of consent within any proposed institutional risk management structure. We divide consent into three related, analytical levels: macro, mezzo and micro; and two contexts: domestic and international. The macro level is concerned primarily with normative definitions of consent, i.e., what consent means within a given community or the factors that must be present before consent is viewed as legitimate. The mezzo level works to formulate public policy within the context of a given biotechnological innovation by recognizing that risk management requires both discrete and continual decision-making. Accordingly, the mezzo level of an analysis of consent demarcates between threshold and process issues. The former entails the necessary consent to proceed with implementation of a given innovation, while the latter envisions a more sophisticated institutional structure for conditional consent that takes account of continual advances in the available store of knowledge. Finally, the micro level exists to operationalize consent by examining various methodologies by which public participation can be solicited and evidence of consent collected and examined.

It is important to note that in developing and articulating a conceptual framework sufficient to address the issue of consent, we are engaging in a process of procedural design rather than advocating for a specific substantive outcome. We are attempting to set out *ex ante* an appropriate methodology through which issues of consent can be examined for legitimacy, but we do not propose to predict *ex poste* outcomes concerning the adoption of xenotransplantation technology. Our modest contribution to the debate is to suggest that legitimate consent is more likely to be achieved by understanding consent as a necessary factor in reconciling private benefit and public risk and approaching the process of reconciliation in an organized fashion.

## **II. Xenotransplantation Technology: Identifying Benefits and Risks**

### **A. Private Benefits: Addressing Organ Donor Shortage Through Xenotransplantation**

Between 1988 and 1994, the number of Canadians waiting for solid organ transplants more than doubled. Nearly four percent of those awaiting a kidney transplant currently die before receiving that transplant. Approximately eight percent of those awaiting heart grafts and 11 percent of those awaiting liver grafts

similarly die prior to receiving the graft.<sup>6</sup> Other countries face similar scarcity. Japan and the United States report that nearly 5 and 10 people, respectively die every day while waiting for an organ transplant.<sup>7</sup> As waiting lists grow longer, we can only expect these statistics to increase. Given that Canadians lead generally healthy lives, do not frequently die of gunshot wounds, and do not have a high rate of traffic fatalities, we will not soon find an increase in the numbers of organs that are appropriate for transplant. While governments are taking measures to increase the rate at which Canadians donate their organs,<sup>8</sup> we still are unlikely to meet our growing needs.

One alternative for addressing this chronic organ shortage is xenotransplantation, the transfer of living cells, tissues or organs from one species to another, i.e., from animals to humans. This technique has the potential to address a critical worldwide shortage of healthy cells, tissues and organs for medical transplants. By transplanting healthy animal organs into humans, we can provide a sufficient number of organs to overcome the shortfall. Pigs are an especially attractive source for donor organs since their organ size and physiology are in many ways similar to those of humans. Moreover, pigs are relatively easy to breed: they mature early and can be bred in large quantities in highly controlled environments. The perceived benefits to individual recipients are obvious, as individuals on waiting lists for non-existent human organs could be treated instead with xenotransplants.

This is not to say that xenotransplantation does not face significant physiological and immunological barriers. Physiologically, humans and pigs differ in their blood properties and metabolisms.<sup>9</sup> We know, for example, that while porcine insulin can regulate blood sugar levels in humans, primates surviving with porcine kidney transplants have developed anemia.<sup>10</sup> Cross-species compatibility is especially difficult to evaluate given that only a few xenotransplants have survived for any prolonged period. It is reasonable, however, to expect that transplanted complex pig organs will present their human hosts with a number of significant deficiencies.<sup>11</sup> In addition to the physiological differences between pig and human organs, the transplant of porcine organs into a human being will present difficult immunological hurdles. A human body's immune system is very effective at identifying foreign surface proteins so that when an organ is transplanted—no

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<sup>6</sup>Canada, *Proposed Canadian Standard for Xenotransplantation* (Ottawa: Health Canada, July 1999) online: Health Canada <<http://www.hc-sc.gc.ca/hpb-dgps/therapeut/zfiles/english/bgtd/xenostde.html>> (date accessed: 27 December 2002) [hereinafter "Canadian Standard"].

<sup>7</sup>OECD, *Xenotransplantation: International Policy Issues* (New York: OECD 1999) at 18 [hereinafter OECD, *Xenotransplantation*].

<sup>8</sup>See, for example, R. Mackie & L. Priest, "Law targets organ donations" *The Globe and Mail* (17 November 2000) A5.

<sup>9</sup>See R. A. Weiss, "Xenotransplantation" (1998) 317 *BMJ* 931 [hereinafter Weiss]; H.G. Auchincloss & D.H. Sachs, "Xenogeneic Transplantation" (1998) 16 *AR Immunol.* 433 [hereinafter Auchincloss].

<sup>10</sup>*Ibid.* Kidneys synthesize a hormone called erythropoietin that is essential for regulating the production of red blood cells. Porcine erythropoietin does not function in humans, thus human recipients of pig kidneys would need to be treated with recombinant human erythropoietin.

<sup>11</sup>Auchincloss, *supra* note 9.

matter how well it is matched to its host—some degree of rejection will occur. The immunological barriers to xenografts differ from those between members of the same species (allografts) because of the greater molecular incompatibility between host and donor tissue.

Xenotransplantation encounters three distinct types of immunological rejection. The first and most violent form of rejection—called hyperacute rejection—is triggered by the fact that humans and pigs are such different species. Hyperacute rejection results from antibodies in the host attacking antigens on the xenograft. Pigs express a blood group antigen lacking in humans called galactose- $\alpha$  (1-3)galactose [ $\alpha$ Gal].<sup>12</sup> Natural human antibodies bind to the  $\alpha$ Gal sugar on the pig organ, destroying it within minutes of exposure to human blood. Second, xenotransplants face acute rejection. It occurs even between species far more similar than pigs and humans, typically within two to three days.<sup>13</sup> Little is known about acute rejection because, while it is similar to hyperacute rejection in that it is caused by antibodies to the  $\alpha$ Gal sugar, it involves a distinctly different process. Third, all transplants, whether from other species or from other humans, must overcome cell-mediated rejection to be successful. Because of the differences in species, xenografts face a significantly stronger risk of cell-mediated rejection than do allografts. This form of rejection again arises out of an attack by human T-cells on antigens protruding from the surface of the engrafted cells.

Research aimed at overcoming these immunological reactions continues. While the use of immunosuppressants to control cell-mediated rejection has had some success, it also presents undesirable risks such as drug toxicity and the inability of the recipient to fight off infection normally controlled by T-cell immunity.<sup>14</sup> Other measures being investigated include transplanting a large number of donor cells to overwhelm the human antibody attack<sup>15</sup> and creating transplant tolerance through a mixed bone marrow chimerism approach.<sup>16</sup> A final and more controversial technique to permit xenotransplantation is one based on genetic engineering. By genetically manipulating the donor pigs, we can create transgenic donor pigs whose organs either lack the enzyme that synthesizes  $\alpha$ Gal or possess human cell membrane proteins that inhibit the chain of events leading to rejection.<sup>17</sup>

Recent scientific developments suggest that we are close to developing technologies to overcome immunological rejection. One study using mice demonstrated that immunization with chimeric peptides blocked the strong T-cell immune response and prolonged the survival of porcine islet grafts in vivo, thus supporting

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<sup>12</sup> Weiss, *supra* note 9.

<sup>13</sup> Auchincloss, *supra* note 9.

<sup>14</sup> Weiss, *supra* note 9; Auchincloss, *supra* note 9.

<sup>15</sup> Auchincloss, *supra* note 9.

<sup>16</sup> *Ibid.*

<sup>17</sup> Weiss, *supra* note 9.

a chimerism approach to immunotherapy.<sup>18</sup> The recent cloning of pigs with the 1,3-galactosyl transferase gene knocked out moves us closer to the possibility of avoiding hyperacute rejection of pig organs in humans.<sup>19</sup> These pigs are genetically modified to not produce the galactose sugar on cell surfaces that is thought to be the principal cause of hyperacute rejection. Nevertheless, even this achievement leads to more questions. Some scientists wonder whether other sugars also trigger hyperacute rejection.<sup>20</sup> Coupled with this cloning achievement was the recent report of a cell-grafting approach designed to overcome the immunological problems of xenografting for axonal regeneration of spinal cord injuries. Scientists reported the development of transgenic pigs armed with the gene encoding a human complement-inhibitory protein (hCD59) that shows hope in addressing the problem of natural antibody reactivity.<sup>21</sup> These breakthroughs promise a means to clone genetically modified pigs with great precision.<sup>22</sup>

These recent developments make it not unreasonable to conclude that scientists may soon resolve many of the immunological problems associated with xenotransplantation, making it a genuinely practical treatment. Already, we can measure the survival of xenograft recipients in weeks rather than hours.<sup>23</sup> These individual benefits, however, come with concomitant public risks, not only medical risks beyond the concerns of the individual transplant recipient, but also issues of social and moral acceptability. If xenotransplantation is permitted to proceed in the absence of the consent of those subject to these public risks, then the private benefit to the individual recipient has in effect been underwritten by public costs in terms of the involuntary assumption of risk, notwithstanding that the results of a cost-benefit analysis in the aggregate may have resulted in a negative rather than a positive outcome. In order to understand the magnitude of these costs, it is necessary to examine in greater detail the nature and extent of public risks associated with xenotransplantation technology.

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<sup>18</sup>N.J. Rogers *et al.*, "Costimulatory Blockade by the Induction of an Endogenous Xenospecific Antibody Response" (2000) 1:2 *Nature Immunology* 163.

<sup>19</sup>D. Butler, "Xenotransplant experts express caution over knockout piglets" (2002) 415:6868 *Nature* 103 [hereinafter Butler]. See also I.A. Polejaeva, S. Chen & T.D. Vaught, "Cloned Pigs Produced by Nuclear Transfer From Adult Somatic Cells" (2000) 401:6800 *Nature* 86 and A. Onishi *et al.*, "Pig Cloning by Microinjection of Fetal Fibroblast Nuclei" (2000) 289:5482 *Science* 1188.

<sup>20</sup>Butler, *ibid.*

<sup>21</sup>T. Imaizumi *et al.*, "Xenotransplantation of Transgenic Pig Olfactory Ensheathing Cells Promotes Axonal Regeneration in Rat Spinal Cord" (2000) 18:9 *Nature Biotechnology* 949.

<sup>22</sup>Anonymous, "The Trials of Xenotransplantation" (2000) 406:6797 *Nature* 661.

<sup>23</sup>A transgenic pig heart was recently reported to have survived for more than a month in a baboon—a considerable achievement compared to previous post xenograft survival rates. See C.M. Vial *et al.*, "Life supporting function for over one month of a transgenic porcine heart in a baboon" (2000) 19:2 *J Heart Lung Transplant* 224.

## B. Public Risks: Medical, Social and Moral

Unfortunately, as we resolve the immunological and physiological problems associated with xenotransplantation, we face other risks. These relate to the possibility of animal viruses infecting the transplant recipient and spreading to the general population, the uneven social distribution of costs and benefits arising from xenotransplantation, and moral risks in terms of treatment of animals and the definition of what it means to be human.

### 1. Medical Risks

Xenotransplantation presents a risk of zoonoses whereby undetected animal viruses living in the donor tissue will infect the human recipient and thereafter spread to the general human population. The magnitude of this risk, however, is difficult to assess.<sup>24</sup> Evidence already exists that infectious agents in the form of porcine endogenous retroviruses (PERVs) can infect human cells in culture and that transplanting pig pancreatic islets into immunosuppressed mice may lead to widespread infection by PERVs.<sup>25</sup> Although infections are common even in allotransplantation and blood transfusions,<sup>26</sup> the infection concerns are more severe with xenotransplantation. The spread of these zoonotic infections may introduce entirely novel diseases that the human population has never before encountered and, consequently, has no means to combat.

Should a porcine virus infect a human host, we would be in a double bind. Not only would we not have the ability to treat the infectious disease, but the very procedures we use to make the xenotransplantation effective undermine our ability to fight the virus. This is so for two reasons.

First, the immune suppression needed to prevent rejection by the host will help viruses propagate and adapt. Since the human recipient of the xenograft will need to take immunosuppressing drugs for life, the recipient's immune system will not be able to combat viruses originating in the porcine tissue. This will give these viruses time to replicate and to slowly evolve to adapt to human beings. Should this adaptation occur, the virus would be able to successfully infect other human beings.

Second, the genetic modification of pigs presents a further risk of adaptation. In a sense, all of the cells within the genetically-modified pigs will be part human. This is because the genetic manipulation of the pig necessary to make it acceptable

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<sup>24</sup> A prime example is the HIV-1 virus, which probably came from chimpanzees. The worldwide AIDS epidemic may have been started by a single cross-species event or by the use of chimpanzee kidneys in Africa to create batches of poliovirus vaccine. See R.A. Weiss, "Xenografts and Retroviruses" (1999) 285 *Science* 1221 [hereinafter *Retroviruses*].

<sup>25</sup> L. J.W. Van Der Laan *et al.*, "Infection by Porcine Endogenous Retrovirus after Islet Xenotransplantation in SCID Mice" (2000) 407:6800 *Nature* 90 [hereinafter Van Der Laan].

<sup>26</sup> These viruses include HIV, hepatitis B and C, various herpes viruses, and tuberculosis. See *Retroviruses*, *supra* note 24.

for xenotransplantation relates to the presence or absence of pig and human antigens on the surface of pig cells. Because the genetically-modified porcine cells resemble, to some extent, human cells, pig viruses will have the opportunity to evolve the ability to enter human cells. That is, pig viruses will be able to make the jump from pig virus to part-pig, part-human viruses. Once we place a genetically-modified porcine organ in a human recipient, especially one taking immunosuppressants, the virus may be able to make the last jump, from a part-pig, part-human cell to a pure human cell.<sup>27</sup>

The risk of transferring pathogens from animal donors to human recipients is clearly a major concern in xenotransplantation. Industries involved in xenotransplantation research have already mobilized to reduce the risks associated with PERVs.<sup>28</sup> But despite the industry's concerted efforts to ensure the safety of xenotransplantation, the potential risks transcend both the individual recipient and geographical borders. The magnitude of the risk society bears in adopting this new technology is directly related to the probability of infection and to the severity of its consequences. Unfortunately, risk assessment is demanding and is inherently uncertain. The PERV case study ought to serve as an important caution to the threat of cross-species transmission of pathogens. We must accept that our methods of detecting infection are not clear cut<sup>29</sup> and that the risk of infection remains largely unquantified.

## 2. Social Risks

The potential health risks of xenotransplantation do not fall on the same people who receive the most benefit from them. While it is true that the transplant recipient has both the most to gain from xenotransplantation and the most to lose from infection, the health risk to the general population is not borne equally. Transplantation is, at the best of times, an expensive procedure. When combined with the costs of developing and using new immunological tools to combat rejection, the costs of xenotransplantation are substantial. On the assumption that health care resources are at the very least finite, a significant social risk exists that scarce resources may be disproportionately allocated to a relatively small number of individual recipients at the expense of the majority.

Social risks involving the allocation of resources also involve issues of distribution. Given the high costs of xenotransplantation, it will be a medical technique only available to any significant degree in developed nations.<sup>30</sup> When developing nations do not have sufficient funds to pay for routine vaccines and to deal with AIDS, they certainly will not have the resources to provide xenotrans-

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<sup>27</sup> Weiss, *supra* note 9.

<sup>28</sup> BioTransplant, for example, has bred a herd of miniature swine that are relatively free of transmissible PERVs. See K. Birmingham, "New Xeno Joint Venture" (2000) 18:11 *Nature Biotechnology* 1128.

<sup>29</sup> E. Dorey, "PERV Data Renew Xeno Debate" (2000) 18:10 *Nature Biotechnology* 1032.

<sup>30</sup> Distributional concerns also exist in states with privatized health care, given that seriously ill patients do not have universal access to expensive technology regardless of ability to pay.

plantation to their citizens. Xenotransplantation is truly a rich country treatment. While the benefits of xenotransplantation are limited to developed countries, however, the general health risk from infection by animal viruses is shared by all. Viruses respect no borders and are easily transported, as HIV and more recently SARS only too easily demonstrate. Should an animal virus infect a transplant recipient and that recipient transfers the infection to the general population, all countries in the world will face a similar potential epidemic. Even here, when we take into account the availability or resources to combat a new epidemic, risks are not equally shared. Developed countries have far greater resources to put into the fight against a new virus than do developing nations. The inequity between developed and developing nations with respect to the risks and benefits associated with xenotransplantation is a serious social concern.

### 3. Moral Risks

Xenotransplantation also gives rise to certain moral risks. These are fourfold. First, there is the obvious concern about the treatment of animals. While it is true that we commodify animals in food production for the purposes of basic survival, we would be adding an entirely new layer of commodification by growing animals, and more controversially, developing transgenic animals, for the sole purpose of harvesting their organs in an effort to treat human disease. In addition, since we will need to ensure that these animals are as pathogen-free as possible, we will have to isolate donor animals even more from their natural environments and subject them to painful, intrusive and often deadly experimentation.<sup>31</sup>

A second moral concern is whether xenotransplantation will change what it means to be human. Some commentators have suggested that a xenotransplant recipient may feel or may be treated as being less human because he or she harbours within him or herself an animal organ.<sup>32</sup> Apart from this individual psychological risk, others have noted that proponents of a “natural order” reject xenotransplantation technology on the basis that the transfer of animal organs into human transplant recipients is unnatural and in violation of the natural world.<sup>33</sup> Whether at the level of individual recipients or the larger community, how we conceive of ourselves as human beings is thus at stake.

A third, related concern is that, by making organs a commodity that patients can purchase, we will undermine the altruistic meaning of the act of donating an organ on death. Currently, the family of someone who dies in circumstances in

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<sup>31</sup> See, for example: A. Fano, “If Pigs Could Fly, They Would: The Problems with Xenotransplantation” in B. Tokar, ed., *Redesigning Life? The Worldwide Challenge to Genetic Engineering* (Montreal: McGill-Queen’s University Press, 2001) at 182–194.

<sup>32</sup> See, for example: F.H. Bach, A.J. Ivins & C. Weeramantry, “Ethical And Legal Issues In Technology: Xenotransplantation” (2001) 27:2-3 *Am. J.L. & Med.* 283 at 294-95; M.A. Clark, “This Little Piggy Went To Market: The Xenotransplantation and Xenozoonose Debate” (1999) 27:2 *J.L. Med. & Ethics* 137 at 140.

<sup>33</sup> J.M. Kress, “Xenotransplantation: Ethics and Economics” (1998) 53:2 *Food & Drug L.J.* 353 at 372.

which he or she can donate an organ can console themselves that the death of their loved one resulted in some good: the priceless giving of life. We, as a society, must evaluate whether the meaning of this act of donation will be undermined by the existence of a market in organs.<sup>34</sup>

A fourth moral concern is based on religious faith. A number of religions consider pigs to be unclean. We must therefore consider the religious implications of transplanting a pig organ into a human being. While many religions, such as Judaism and Islam, permit the violation of certain of their rules in order to achieve the higher good of protecting life, the theological implications of xenotransplantation will need to be worked out.<sup>35</sup>

As this brief examination has illustrated, xenotransplantation raises a host of medical, social, and moral questions that have no easy or immediate answers. Further, the answers themselves may change as society evolves and as our scientific knowledge of the medical risks increases. Nevertheless, with the likelihood that xenotransplantation will soon be technically available, we need to decide whether we wish to use this technology.

### III. Consent to Innovation: Avoiding Involuntary Assumption of Risk

As the above discussion demonstrates, xenotransplantation faces important technological hurdles and presents substantial health, social, and cultural risks to humanity. While scientific research will have to tackle the technological impediments to implementing the benefits of xenotransplantation, it will never be able to assure us that xenotransplantation poses no risk to us. The idea of deciding to accept the risks inherent in any innovative technology as the necessary price for the benefits to be achieved involves, at some level, consent on the part of those from whom the price is to be extracted. The purpose of this analysis is, therefore, to describe a conceptual framework within which society can decide whether to accept these risks for the sake of the potential benefit and if so, how to manage them.<sup>36</sup>

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<sup>34</sup>R.M. Titmuss, *The Gift Relationship: from human blood to social policy* (London : Allen & Unwin, 1970) [hereinafter Titmuss].

<sup>35</sup>"Pig Organs Okay with Muslims, Jews" *The National Post* (17 August 2000) A17.

<sup>36</sup>We have made two necessary and logically prior assumptions in setting out our conceptual model of consent. First, we have assumed that the state has a significant role to play in regulating xenotransplantation technology for the purposes of protecting and enhancing health and social welfare. Second, we have assumed that public participation and consent is a necessary component of state regulation in this area. We readily concede that the first assumption indicates our rejection of a wholly free market model as a suitable mechanism for meeting public health objectives, and that our second assumption is based upon a western liberal democratic view of a state's internal political process. We do not attempt within this analysis to address private regulation of xenotransplantation technology, nor do we attempt to apply this conceptual framework to other representative political systems, e.g. to authoritarian or theocratic regimes, apart from the necessity of addressing consent within the context of international law.

Our analytical approach to the issues raised by xenotransplantation proceeds on the assumption that in circumstances where the adoption of a given biotechnology results in private benefit with unidentified and unknown risks to the public, an involuntary assumption of these risks is inappropriate. Accordingly, our analysis focuses on the concept of consent as the necessary mechanism for reconciling private benefits with public risk. We do not claim that this approach is exhaustive of all the issues, nor that this approach is superior in terms of reaching the most viable solution to any potential problems. Instead, our chosen analytical framework is intended to highlight the potential for discrepancy between the promised benefits of biotechnology, which in the case of xenotransplantation can be viewed as accruing to individual transplant recipients, and the potential externalities in terms of the risks borne by the wider population.<sup>37</sup> Reconciling these private benefits and public risks requires that we pay particular attention to the institutional design of a risk management structure capable of balancing the competing interests involved.

Design issues are further complicated by the fact that the risks associated with xenotransplantation, particularly those associated with xenozoonoses, cannot be confined to geopolitical borders. States cannot necessarily protect their own domestic welfare calculus from the unilateral actions of other states that may not have reached an identical assessment of the optimal balance between costs and benefits. There exists a very real possibility that while one state's internal decision-making process may result in a prohibitive attitude towards xenotransplantation on the basis that the benefits do not outweigh the associated risks, other states may adopt a more permissive approach better suited to their own internal requirements in any number of areas, including the significant factor of the state's level of economic development.<sup>38</sup> Accordingly, in the international arena, the possibility of an involuntary assumption of risk remains.

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<sup>37</sup> It is certainly true that individual benefits can be aggregated into the wider population *ab initio*, and could be used to offset to discounting factor produced by aggregate risk. For example, we could define the potential benefits of xenotransplantation technology with reference to aggregate increases to social welfare and public health, which would thereby engage a cost-benefit analysis that measured public benefit against public risk. This characterization, however, does not displace the equally acceptable inquiry into consent that arises with the characterization of the potential benefits of individual transplants as accruing wholly to the recipients, while the associated risks of xenozoonoses resulting from the transplant are externalized to the population at large. But such an analysis, while analytically acceptable, does not place in as sharp a relief the issue of private benefit and public consent that must be addressed.

<sup>38</sup> One can imagine a "race to the bottom" scenario whereby a state may adopt a permissive regime in the face of otherwise unacceptable risks in order to attract foreign direct investment. Participation in such a race is not necessarily limited to developing or least-developed states. Several commentators have discussed the application of "race to the bottom" theory and regulatory arbitrage in relation to environmental regulation, an area that is analogous in many respects with regulation to protect public health. See, for example: R.L. Revesz, "Federalism and Environmental Regulation: A Public Choice Analysis" (2001) 115:2 Harv. L. Rev. 553. For a general discussion of the "race to the bottom" scenario, as well as a critique of Revesz' arguments, see, for example: R.L. Revesz, "Federalism and Interstate Environmental Externalities" (1996) 144:6 U. Pa. L. Rev. 2341; R.L. Revesz, "Rehabilitating Interstate Competition: Rethinking the "Race to the Bottom" Rationale for Federal Environmental Regulation" (1992) 67 N.Y.U. L. Rev. 1210; K.H. Engel & S.R. Saleska, "Facts Are Stubborn Things": An Empirical Reality Check in the Theoretical Debate Over the Race-to-the-Bottom in State Environmental Standard-Setting" (1998) 8 Cornell J.L. & Pub. Pol'y 55; J.E. Krier, "On the Topology of Uniform Environmental Standards

In order to develop an institutional design capable of meeting the challenges as set out above, we need to analyze consent in accordance with a conceptual framework that permits both a systematic and normative assessment of the various alternatives for balancing private benefits and public risks within domestic and international contexts. Our suggested framework divides the rather unwieldy notion of consent in the abstract into three discrete, analytical levels of assessment, macro, mezzo and micro, based on the nature of the decision that must be taken at a particular point in the process of adopting (or declining to adopt) the products of biotechnological innovation in general, and xenotransplantation technology in particular. We then apply our analysis at each of these levels within each of the domestic and international contexts. The focus throughout is procedural rather than substantive, in that the purpose of the analysis is to articulate an appropriate methodology for achieving consent in a given set of circumstances, rather than to determine whether consent is in fact legitimate in the context of xenotransplantation.

Briefly stated, the macro, mezzo and micro levels of analysis relate respectively to the tasks of defining what is meant by the concept of consent in a given community, formulating public policy in relation to the kind of consent required in the context of a given biotechnological innovation, and determining the operational methods for ascertaining consent, or lack thereof, within a given population's public and political processes. Note that while the macro level of analysis is concerned with normative definitions of consent, it is not our intention to conduct a lengthy examination of the available literature across a multitude of disciplines relating to the legitimacy of any given notion of consent in any particular context. Our objective is simply to set out the macro level of analysis as a necessary component of the procedural framework in which discussion and debate is to take place. Similarly, we do not intend to address the empirical issues involved in assessing the appropriate mechanisms for obtaining consent as anticipated by the micro level of analysis, our objective again being simply to set out an appropriate procedural framework rather than assess potential substantive outcomes. Our discussion will focus primarily on the mezzo level of analysis and it is here that we will set out what we view as significant elements of a decision-making process addressing the adoption of xenotransplantation technology.

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in a Federal System — And Why It Matters" (1995) 54:4 Md. L. Rev. 1226; R.B. Stewart, "Environmental Regulation and International Competitiveness" (1993) 102:8 Yale L.J. 2039; R.B. Stewart, "International Trade and Environment: Lessons from the Federal Experience" (1992) 49:4 Wash. & Lee L. Rev. 1329; S. Williams, "Panel IV: Culpability, Restitution, and the Environment: The Vitality of Common Law Rules" (1994) 21:2 Ecology L.Q. 549; T.W. Merrill, "Panel III: International Law, Global Environmentalism, and the Future of American Environmental Policy" (1994) 21:2 Ecology L.Q. 485.

## A. The Macro Level: Defining Consent

At the macro level of analysis, the question of consent is primarily ontological in nature, in that the issue for determination is the definition of consent in a given community. At the domestic level, the legitimacy of consent should be assessed with reference not only to the norms of the internal political system, but also in relation to the nature of the risks involved in adopting a particular technology and the complexity of the issues involved. Given that our analysis is focussed on process rather than substantive outcomes, our intention in this section is merely to set out the requirement for a normative assessment of consent as the initial step in reconciling private benefit and public gain and to highlight the necessity of a contextual approach to this question. For those readers wishing a more detailed summary of different normative approaches to notions of consent within a given community, please refer to Appendix A: Normative Assessment of Consent.

Given that adopting xenotransplantation involves the risk of zoonoses and that this risk cannot be contained within traditional geopolitical borders, the issue of consent at the macro level cannot be confined to a domestic analysis. States are unlikely to reach uniform results in terms of the cost-benefit analysis of adopting xenotransplantation technology. What is more likely is that the internal decision-making process will result in a variety of approaches, ranging from outright prohibition to wholesale acceptance. The relevant question for determination then becomes whether states adopting a prohibitive approach are able to protect themselves from the possible spillover effects originating in states adopting a permissive approach. At this point, normative assessment of consent is less significant than an account of positive international law.

### 1. Domestic Consent: Political Legitimacy and Contextual Analysis

The first task for decision-makers is to settle upon an acceptable normative baseline for the construction of the concept of consent in the context of biotechnological innovation and implementation in a given community.<sup>39</sup> The most logical focal point to begin this analysis is with reference to the requirements and norms of the relevant political system. For example, in Western liberal democracies, consent may amount to nothing more than the adoption of the existing structures of governance, whereby a legislative body is presumed to represent majoritarian preference when enacting legislation.<sup>40</sup> Democratic systems of governance may in some cases also rely on majoritarian preference as expressed through devices such

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<sup>39</sup>Of course, this does raise the logically prior question and perhaps inevitably recursive question of who decides who decides, in that we must first arrive at a mechanism for consenting to the normative baseline before we can assess consent in the given context. This is a question without answer and we propose none here. Through this article, we merely contribute our views on how to select mechanisms of consent.

<sup>40</sup>In its simplest formulation, democracy is nothing more than rule by the people. Few commentators in this area, however, would limit the concept of democracy to this rather populist notion. See, for example: A. Gutman, "Democracy" in R.E. Goodin & P. Pettit, eds., *A Companion to Contemporary Political Philosophy* (Oxford: Blackwell Publishers, 1993) at 411–419.

as referenda, rather than indirectly through representative or deliberative democracy. In constitutional democracies, wherein a division of power exists between the legislative and judicial branches, majoritarian preference may be constrained by protection of minority rights, in which case consent is identified by reference to implementing legislation on a conditional basis, the understanding being that all legislative enactments are subject to judicial review for conformity with constitutional requirements.

How consent is defined, however, and what type of consent is most desirable in a given situation, depends not only upon the norms of a given political regime, but also upon what values are implicated in relation to a given technology and the magnitude of the associated risks. The legitimacy and depth of consent depends heavily on the surrounding circumstances. The more significant an issue – in the view of those from whom consent is sought – the higher the form of consent ought to be. Xenotransplantation 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). The technology also raises the possibility of significant risks to public health that are irreversible in nature. Accordingly, the magnitude of the potential benefits and risks of xenotransplantation militate against forms of consent based purely on electoral power.<sup>41</sup> Consent in these circumstances would be at best illusory, given the highly technical nature of the field and the necessity of public education in understanding the relevant issues.<sup>42</sup> In these circumstances, contingent consent may be more suitable, i.e., a citizen complies with a government’s decision if that government is perceived to be trustworthy and other citizens seem to be consenting.<sup>43</sup> In other words, formulation of public policy cannot proceed without the informed participation of other citizens in the decision-making process, notwithstanding the powers delegated to the elected representatives.

## 2. *International Consent: Regulatory Diversity and Spillover Effects*

International perspectives illustrate the potential for regulatory diversity in adopting either a permissive or prohibitive approach to developments such as xenotransplantation technology. Moral and ethical concerns regarding biotechnology are likely to vary widely among states, as are assessments of the nature and extent of the benefits and risks involved. For example, the European public may favour application of biotechnology in medicine, but is opposed, on ethical grounds, to the cloning of animals and Genetically Modified (GM) foods.<sup>44</sup> In Japan

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<sup>41</sup> See generally M. Levi, *Consent, Dissent and Patriotism* (Cambridge: Cambridge University Press, 1997) [hereinafter Levi].

<sup>42</sup> The results of the Canadian Public Health Association consultations demonstrates the enormous difference in public response depending on the level of information provided to those responding. See Canadian Public Health Association, *supra*, note 4.

<sup>43</sup> Margaret Levi is credited with the enunciation of this form of consent. See Levi, *supra* note 41 at 29.

<sup>44</sup> G.Gaskell, N. Allum & M. Bauer, “Biotechnology and the European Public” (2000) 18:9 *Nature Biotechnology* 935.

the opposite is true: the application of xenotransplantation is less acceptable than GM foods.<sup>45</sup> Other countries take still different approaches.<sup>46</sup>

Given the risk of zoonoses, the potential for regulatory diversity in the adoption of xenotransplantation will be of concern to states deciding upon a prohibitive approach to this technology. The risk of inadvertent infection does not end with the xenotransplant recipient, but extends as well to the risk of subsequent secondary transmission of infection by the recipient to the wider population. Absent a practical or legal method for confining not only the xenotransplant recipient, but also any person in contact with the recipient to a geopolitical territory, a state cannot fully internalize all of the risks of proceeding from xenotransplantation technology. Accordingly, prohibitive states have legitimate concerns regarding the potential spillover effects from permissive states.

While the macro level of analysis within a given state is concerned with the definition of consent in a given community, consent between states is more a matter of positive law than normative assessment. While the interactive and progressive development of domestic and international norms is acknowledged, the international legal system, despite commentary to the contrary, remains focused on the sovereign state as the relevant subject of international law. International law's foundational premise, the sovereign equality of all states, transforms the definition of consent from a normative assessment into a positive analysis. Given the legal status of states as juridical equals, state consent is required to establish an international norm, whether through conventional or customary international law.<sup>47</sup> The focus on sovereign states to the exclusion of other international actors has been subject to challenge,<sup>48</sup> as has the emphasis on formal consent.<sup>49</sup> Nonetheless, while the macro level of analysis anticipates that within liberal democracies at the very least, states are both able and likely to define consent with reference to normative

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<sup>45</sup>D.Macer & M.A. Chen Ng, "Changing Attitudes to Biotechnology in Japan" (2000) 18:9 Nature Biotechnology 945.

<sup>46</sup>See, for example: S.H. Priest, "US Public Opinion Divided over Biotechnology?" (2000) 18:9 Nature Biotechnology 939; E.F. Einsiedel, "Cloning and its Discontents — a Canadian Perspective" (2000) 18 Nature Biotechnology 943; T.J. Hoban "Public Perceptions and Understanding of Agricultural Biotechnology" (October 1999), online: <<http://usinfo.state.gov/journals/ites/1099/ijee/bio-hoban.htm>> (date accessed: 23 September 2000); Canadian Biotechnology Secretariat, "Public Opinion Research into Biotechnology Issues" (January 2000), online: Industry Canada <<http://strategis.ic.gc.ca/SSG/bh00257e.html>> (date accessed: 23 September 2000).

<sup>47</sup>State consent in conventional international law is evidenced by a state becoming a party to an international convention. State consent within customary international law is somewhat more difficult to identify, as these norms are established by both state practice and *opinio juris*, *i.e.*, acting out of a sense of compulsion. Some norms of customary international law, known as *jus cogens*, are considered to bind states regardless of consent. These norms, however, are few in number and not relevant to this analysis.

<sup>48</sup>See, for example: T. J. Biersteker & C. Weber, eds., *State Sovereignty as a Social Construct* (Cambridge: Cambridge University Press, 1996); O. Schachter, "The Decline of the Nation-State and its Implications for International Law" (1997) 36:1-2 Colum.J. Transnat. L. 7; K. Knop, "Re/Statements: Feminism and State Sovereignty in International Law" (1993) 3:2 Transnat'l L. & Contemp. Probs. 293.

<sup>49</sup>Positive accounts of international law are challenged by the progressive development of universal norms predicated upon notions of natural law, *i.e.*, human rights.

concerns, the constraint of sovereign equality limits the definition of consent at the international level to a positive account of international law.

Given these constraints, the question for determination is not the level of consent required, but whether a state may proceed to adopt a permissive approach to xenotransplantation technology in the face of opposition from states adopting a prohibitive approach on the basis that the technology poses unacceptable transboundary risks. Neither conventional nor customary international law contains any clear prohibition to constrain the internal decision-making process of states in choosing to adopt a permissive approach to xenotransplantation technology. Instead, states wishing to protect themselves from spillover effects may seek to rely on an increasingly significant principle within international environmental law known as the precautionary principle.

Stated in the simplest of terms, the precautionary principle is a decision-making tool for risk management under conditions of scientific uncertainty. The objective is to prevent long-term externalization of costs in favour of short-term internalization of benefits. Given that the principle addresses the reconciliation of competing interests in the benefits and costs of adopting new technology, it would seem well-suited to the task of reconciling prohibitive and permissive approaches to xenotransplantation at the international level. The difficulty is that the legal status of the precautionary principle is somewhat uncertain. Not only does controversy exist as to whether the precautionary principle constitutes a binding rule of customary international law (as opposed to an emerging norm), but there is no consistent definition of the principle.

One of the most well-known articulations of the precautionary principle as it applies to matters of biotechnology is contained within the Preamble of the 1992 United Nations Convention on Biological Diversity.<sup>50</sup> The Preamble adopts a somewhat awkward double negative in stating that “where there is a threat of a significant reduction or loss of biological diversity, lack of full scientific certainty should not be used as a reason for postponing measures to avoid or minimize such a threat”. Provisions within the Convention for the negotiation and adoption of an international biosafety protocol led to the negotiation of the Cartagena Protocol on Biosafety in January, 2000.<sup>51</sup> The Biosafety Protocol, as it is known, establishes an international regime governing trade in living modified organisms, or LMOs, defined in the Protocol as “any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology”.<sup>52</sup>

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<sup>50</sup> *United Nations Convention on Biological Diversity*, 5 June 1992, 31 I.L.M. 818.

<sup>51</sup> *Cartagena Protocol on Biosafety to the Convention on Biological Diversity*, 29 January 2000, 39 I.L.M. 1027.

<sup>52</sup> *Ibid.*, Art. 3(g).

The significance of the Protocol is that not only does it represent the first international agreement addressing risk management in the field of biotechnology, but it also explicitly acknowledges the precautionary principle in several key provisions. For example, the Preamble states that the parties “[r]eaffirm[] the precautionary approach” to environmental protection. Articles 10 and 11 expressly permit parties to rely on the precautionary principle to prohibit the import of LMOs, indicating that scientific certainty is not required prior to acting to avoid or minimize potential associated risks.<sup>53</sup> The scope of the Protocol, however, is actually quite narrow as it applies only to transboundary movement of LMOs. A state adopting a prohibitive approach to xenotransplantation could seek to rely on the Protocol to prevent the importation of transgenic animals intended for use as xenotransplants. The state is more likely, however, to regulate the activity directly by prohibiting persons within its territorial borders from engaging in xenotransplantation activity such that the import of transgenic animals is unlikely to occur.

Absent conventional law on point, states seeking to contain potentially harmful spillover effects from states adopting a permissive approach to xenotransplantation would need to rely on the precautionary principle as a norm of customary international law. The difficulty with this approach is that the legal status of the principle is uncertain.<sup>54</sup> Not only does disagreement exist as to whether the precautionary principle has become part of customary international law, but the content of the norm appears to vary depending upon the context in which it is used. As one commentator has aptly noted, “as the precautionary principle advances into law, it is increasingly frustrating that there is no convergence either as to what it means, or as to what regions of action (environment, public health) it is supposed to apply”.<sup>55</sup>

It is not necessary for the purposes of this analysis to debate the legal status of the precautionary principle. It is sufficient to note that given the presence of debate, states cannot with any degree of certainty rely on the precautionary principle to constrain the internal decision-making processes of other states from adopting xenotransplantation technology. Reconciliation of private benefits for permissive states and the potential for the involuntary imposition of public risk on prohibitive states must take place through instruments of cooperation rather than coercion. Obtaining consent under these circumstances is a function of the mezzo level of analysis, discussed in the following section.

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<sup>53</sup> *Ibid.*, Arts. 10, 11.

<sup>54</sup> In *114957 Canada Ltée (Spraytech, Société d'arrosage) v. Hudson (Town)*, 2001 SCC 40, paras. 30–32, Justice L'Heureux-Dubé, writing for the majority, referred to commentary setting out arguments in favour of the status of the precautionary principle as a norm of customary international law, but did not go so far as to affirm the statement of the Supreme Court of India that the precautionary principle is “part of the Customary International Law”.

<sup>55</sup> C.D. Stone, “Is There a Precautionary Principle?” (2001) 31:7 *Env'tl. L. Rep.* 10790 [hereinafter Stone].

## B. The Mezzo Level: Formulating Public Policy

The outcome of an analysis at the macro level of consent is a definition of the type and level of consent required in order to justify a decision to adopt a biotechnological innovation under conditions of moral and scientific uncertainty. The relevant question for determination at the domestic level is whether the existing political structure of governance is sufficient to consent to a public assumption of risk in order to benefit individual transplant recipients, or whether a more active consultation process is necessary. While we have tried to avoid reaching substantive conclusions in setting out this procedural methodology, it seems fairly uncontroversial that given the complexity of the issues and the nature of the risk, some degree of public consultation will be required in order for consent to adopt xenotransplantation technology can be considered legitimate.<sup>56</sup> At the international level, however, the issue of consent is framed more as an issue of positive law than a matter of normative assessment and a substantive determination is necessary. The constraints imposed by sovereign equality within the international legal order do not preclude discussion and debate, but they are sufficient to permit individual states to adopt a permissive approach to xenotransplantation technology, notwithstanding the objections of prohibitive states concerned with potential spillover effects from the risk of zoonoses. Despite the clear risk that one country's decision to proceed with xenotransplantation has on its neighbours and the international community in general, there are no obvious mechanisms to override state sovereignty and provide the opportunity for international consent. Accordingly, public policy formation at the international level must rely on more informal mechanisms of consensus-building.

Once we agree that some form of public participation is required before proceeding with xenotransplantation, we must move down a level and ask to what the public is consenting and which general approaches to gaining that consent are appropriate. This is the mezzo level of consent and the one that we explore in the most depth in this article.

As we illustrated in Part II, xenotransplantation gives rise to social, ethical, and scientific risks. Given the dissimilarities between these risks, we start from the proposition that a single consent mechanism may not be appropriate with respect to all risks. Rather, we suggest that risks can be divided into two categories: those for which consent can be given on an almost once-and-for-all basis and those for which continuous consent is required. We call the former type of decision a threshold issue and the latter a process issue. The mezzo level of consent thus involves differentiating risks between threshold and process issues.

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<sup>56</sup> See, generally: P. Slovic, "Perceived Risk, Trust, and Democracy" (1993) 13:6 Risk Analysis 675 [hereinafter Slovic]; J.A. Bradbury, K.M. Branch & W. Focht, "Trust and Public Participation in Risk Policy Issues" in G. Cvetkovich & R.E. Lofstedt, eds., *Social Trust and the Management of Risk* (London: Earthscan Publications Ltd., 1999) at 117 [hereinafter *Social Trust*]; R.E. Kasperson, D. Golding & J.X. Kasperson, "Risk, Trust, and Democratic Theory" in *Social Trust*, *ibid* 22.

The logic behind the division of consent into threshold and process issues relates to the level of dependence that different risks have on information, whether of a scientific or of a social science nature. Where risks are moral, as opposed to factual or, more likely, where our information base surrounding a particular risk is relatively stable, the public is in a position to provide its consent for all activity falling within that risk. For example, where the decision to proceed is based on a social consensus that some activity is morally acceptable, the public need only arrive at the conclusion once rather than each time the risk is presented. Of course, we agree that this is an oversimplification: society's moral principles change over time, but a society's morals are relatively slow to change – at least in comparison with changes in its scientific knowledge – and thus, for the purposes of this article, we assume they are stable. We accept, however, that even consent to cross a threshold issue may be subject to re-examination over the long term.

While positive threshold decisions – that is, decisions to cross the threshold – take on a once-and-for-all nature (subject to our discussion above), the same is not necessarily true of decisions not to cross the threshold. A decision not to move forward may be made for several reasons. At one end of the spectrum are those reasons based on firm moral principles. Decisions made for these reasons are unlikely to change, at least in the short term. But a decision not to proceed may be based on other factors that are subject to change, such as inadequate administrative, legal, or regulatory infrastructure or a total lack of information. In such cases, the risks are either not managed or are unmanageable given current knowledge. Since public acceptance of high risk technology strongly parallels trust and confidence in risk managers,<sup>57</sup> the improbability of effective risk management is likely to result in a decision not to proceed with the technology at the present time.<sup>58</sup>

Process issues involve uncertainty. Even should a society decide to proceed with xenotransplantation, that decision will depend on the society's level of knowledge about the medical and social risks posed by xenotransplantation. That is, a decision to proceed with a particularly risky technology, such as xenotransplantation, will depend on certain assumptions about the degree and nature of the medical risk of cross-species infection and of the social risk of inequitable distribution of risks and benefits.<sup>59</sup> In these circumstances, it is not only impracticable, but also unfair to demand once-and-for-all consent to xenotransplantation. The public will and should demand the opportunity to monitor progress in the state of medical and social knowledge and to have the ability to withdraw its consent at any time. Thus, consent for process issues is a process of knowledge accumulation, public scrutiny, and a mechanism to continue or withdraw consent to further activity in the area.

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<sup>57</sup> C.G. Brunk, L. Haworth & B. Lee, *Value Assumptions in Risk Assessment: A Case Study of the Alachlor Controversy* (Waterloo, Ont: Wilfrid Laurier University Press, 1991).

<sup>58</sup> The results of the study conducted by the Canadian Public Health Association can probably be best interpreted as a decision not to proceed until an acceptable risk management regime can be implemented. See Canadian Public Health Association, *supra*, note 4.

<sup>59</sup> Slovic, *supra* note 56 at 675; P. Slovic, "Perception of Risk" (1987) 236:4799 *Science* 280 at 283.

In general, threshold issues relate to the morality of xenotransplantation, that is, the intrinsic acceptability of using animal organs for transplantation into humans. If the technology is too viscerally or morally objectionable in and of itself, or if xenotransplantation presents too high a risk to the environment or human and animal life under any circumstances, or if it overly challenges our concepts of what it is to be human, then no further analysis is needed: the technology does not pass the threshold of *a priori* acceptability.<sup>60</sup> Only if this threshold is traversed do we need to address questions of risk management and monitoring that form the foundation for process consent.

The mezzo level thus works to formulate public policy within the context of a given biotechnological innovation by recognizing that risk management requires both discrete and continual decision-making. Accordingly, the mezzo level of an analysis of consent demarcates between threshold and process issues. The former entails the necessary consent to proceed with implementation of a given innovation, while the latter envisions a more sophisticated institutional structure for conditional consent that takes account of continual advances in the available store of knowledge. By differentiating between these issues, we provide a structure around which we can implement particular mechanisms of consent at the micro level.

## **a) Domestic**

### **(1) Threshold Issues**

#### *i. Deontological Threshold*

Before proceeding to implement xenotransplantation, we must ask whether the technology, and the conditions necessary for its development are inherently unacceptable (i.e., wrong in and of themselves). At this junction, the benefits offered by xenotransplantation are not relevant since we focus on unacceptable risk and not cost-benefit analysis. We need only ask if there is something involved in this technology that is so inherently wrong, offensive or otherwise socially unacceptable that we ought not to even consider its application in society.

Without approval of the deontological risks posed by xenotransplantation, we cannot move on. If the moral risks of proceeding are unacceptable, then we have no need to address process issues or to create an international framework for consultation or cooperation. Any state that decides not to cross the deontological threshold can simply decide not to permit the technology to be developed or used

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<sup>60</sup>Looking at the specific attributes of xenotransplantation technology is important. This is because even when people assume that certain technology, such as gene technology, is associated with relatively high risks and unknown consequences, they do not reject biotechnology altogether; instead acceptance of the particular technology varies according to the *type* of application. For example, generally applications involving plants are viewed as more acceptable than those involving animals. See: M. Siegrist, "The Influence of Trust and Perceptions of Risks and Benefits on the Acceptance of Gene Technology" (2000) 20:2 Risk Analysis 195 [hereinafter Siegrist].

within its borders. International cooperation may be needed, however, should the state wish to convince its neighbours not to engage in xenotransplantation. Nevertheless, a state is not dependent on international consensus to implement a ban on xenotransplantation.

Similarly, a decision to cross the deontological threshold does not trigger any need for international cooperation. A decision at this point does not involve a decision to actually use the technology: to do so, the public would need to consent to both other threshold issues as well as to provide consent to process issues.

While open to debate, deontological issues are not subject to revision with increasing scientific knowledge. These issues, as outlined earlier, are straightforward even if their resolutions are not. Does xenotransplantation challenge the basic integrity and intrinsic value of the human person or the human species? If we accept animals as sources of food or for medical experiment, is it acceptable to use animals as a source of organs? Even if we find that cross-species transplantation is acceptable, there is considerably more hesitation over the use of genetic engineering, especially across species barriers.<sup>61</sup> In determining whether xenotransplantation crosses the deontological threshold, we must also take into account the different cultural and religious views that may exist in a particular nation. Definitive interpretations of religious prohibitions are elusive and not every person of the same faith will share the same values.

Affirmation of xenotransplantation at the deontological level is a necessary, but not a sufficient, condition to permitting the use of this technology. There are still social and scientific issues that need to be addressed. We turn to these next.

#### *ii. Consequential Threshold (Moral)*

Our willingness to accept xenotransplantation depends not only on whether the technology is socially acceptable in and of itself but also on the extent to which we are willing to embrace the effects that the technology will have on society. The consequential threshold requires us to ask whether accepting the technology in society will produce undesirable effects that we reasonably ought to avoid creating or at the very least discourage.

On the surface, there is a resemblance between the consequential threshold and process issues. Although in both cases, we focus on the consequences of implementing the technology rather than on the morality of the technology itself, the consequential threshold does not involve a cost-benefit analysis whereas process issues do. In other words, the consequential threshold involves an examination of the risks that are consequent on xenotransplantation without regard to the

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<sup>61</sup>Industry Canada, "Public Opinion Research into Biotechnology Issues" (January 2000), online: Industry Canada <<http://strategis.ic.gc.ca/SSG/bh00257e.html>> (date accessed: 23 September 2000); see generally: Siegrist, *supra* note 60.

benefits. There are certain consequences of certain forms of technology that, no matter the benefits, are not acceptable. In this way, the consequential threshold resembles the deontological threshold.

The consequential threshold thus involves a determination of whether the consequences of implementing a technology are so grave that, regardless of any benefits, the technology is unacceptable. These consequences may take on one of two forms.

First are those consequences that give rise to moral risk. Will xenotransplantation undermine the altruism that is currently the basis of the gift relationship in organ donation? Richard Titmuss, several decades ago, outlined the threat that paid donations posed for altruism by converting a 'gift of life' into a 'gift of dollars.'<sup>62</sup> Therefore, if one of the consequences of xenotransplantation is a reconceptualization of the gift relationship in a negative manner, ought we to permit it? Another concern relates to discrimination. Even if we determine that xenotransplantation passes the deontological threshold, some groups in society may so oppose the technology as to harass or do worse to those who agree to undertake the treatment. We must therefore ask whether xenotransplantation poses a substantial risk that those who oppose it will stigmatize or ostracize those who undertake the procedure? While there are dangers in permitting a minority to dictate the behaviour of the remainder of society, public disorder is an important consideration in adopting any technology.

Second, the consequences of accepting xenotransplantation may present unacceptably high or unmanaged risk to human or animal health, or to the environment. Consent will be withheld if the public feels that the risks of the technology are so high or are so difficult to manage that no amount of benefit justifies acceptance of that technology. While a decision to traverse the consequential threshold does not mean an outright acceptance of xenotransplantation and may not even lead to its implementation, it does involve an acceptance that, from that point on, consent ought only to depend on a cost-benefit analysis. In other words, a decision to cross this threshold should only be made if there is some benefit that could outweigh the risks of proceeding with the technology.

The preceding survey of issues that need to be addressed at the consequential threshold of consent is by no means exhaustive. Only a fuller debate will reveal if other consequences of xenotransplantation need to be addressed as threshold issues. These consequences need not actually be proven to exist: the fear of their arising may be sufficient to halt further enquiry into the adoption of xenotransplantation. In effect, it is this characteristic of these consequences – that they are sufficient without further knowledge to arrest further activity – that makes these consequences a threshold issue.

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<sup>62</sup> See generally: Titmuss, *supra* note 34.

As with the deontological threshold, no international consensus is required to make a decision at the consequential threshold. Approval of xenotransplantation at this level does not mean that the technology will actually be put into practice; all that it means is that we need to ponder other aspects of using the technology further.

### *iii. Legal Threshold*

As we discussed above, part of the decision to be made at the consequential threshold was whether there existed an appropriate administrative, legal, or regulatory regime to manage the risks presented by the technology. Because of the importance the public attaches to risk management and its faith in those managers, we separate issues relating to the construction of that regime out from the general discussion of the consequential threshold.

In order to attain public support for xenotransplantation at the consequential threshold, the public will need to be satisfied that an appropriate legal infrastructure exists to account for the particular risks posed by this technology.<sup>63</sup> This infrastructure can take one of three forms. We can establish *ex ante* rules that set out boundaries of xenotransplantation, we can establish rules for adjusting negative consequences of xenotransplantation *ex poste*, or we can combine *ex ante* and *ex poste* measures. The choice that we make between these measures depends on both the probability and magnitude of the possible harm, particularly irreversible harm. *Ex poste* regulation of harmful activity typically involves measures such as tort law, or civil and criminal penalties, that are not applied until after the harm occurs. In contrast, *ex ante* measures are more precautionary in nature in that they seek to address risk before harm occurs, typically through regulatory standards governing a potentially harmful activity. *Ex ante* measures may seem preferable to *ex poste* measures, given that many of the risks associated with xenotransplantation are irreversible; damages or penalties would presumably be an insufficient remedy in response to alterations of our biological heritage. *Ex ante* regulation, however, also carries an associated risk of excessive regulation in that much beneficial activity may be unnecessarily prohibited. The question becomes one of institutional competence in that *ex ante* regulation presumes that the state is best placed to avert harm, while *ex poste* measures assume that private actors have superior information and thus are more capable of avoiding harm.<sup>64</sup>

Since public consent is unlikely in the absence of a regulatory mechanism, the legal framework within which xenotransplantation would take place is critical to attaining consent. Thus, the choice between governance strategies becomes a threshold issue. Without such a strategy, public consent is likely to be elusive. While there is a clear symbiotic relationship between national and international

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<sup>63</sup> Most people do not have detailed knowledge of biotechnology generally, or xenotransplantation technology specifically. One way people cope with this lack of knowledge is to rely on social trust to reduce the complexity of risk management decisions. That is why confidence in laws and trust in the managers and scientists is so important. See Siegrist, *supra* note 60 at 196.

<sup>64</sup> Stone, *supra* note 55.

governance structures, we assume here that domestic concerns can be isolated and domestic solutions implemented even in the absence of international consensus. We turn to international consensus later in this article.

While we do not intend to describe a particular governance structure that will best address the competing concerns rising out of xenotransplantation, we will describe some of the principles that any such structure ought to incorporate. That is, whatever regime a country adopts, there are general principles that remain constant. We survey these below.

A central principle of law is that the person receiving the benefits of a given activity should internalize the burdens associated with that activity.<sup>65</sup> It is economically inefficient to permit one person to receive all the gains from an activity and another to suffer the costs. In such circumstances, the beneficiary will over-indulge in the activity since he or she does not bear the costs of that activity. Thus, legal regimes tend to cause the beneficiary of an activity to internalize the costs of that activity. This internalization may take one of several forms, including direct suffering of the harm, payment of compensation to those suffering the harm, or payment to the state equal to the cost of the harm.

Unfortunately, it is far from clear how we could apply the principle of beneficiary pays to xenotransplantation. As we described earlier, although the transplant recipient will certainly suffer the most immediate risk, everyone in the world is potentially at risk from this procedure. In addition, as a medical procedure, xenotransplantation must be evaluated within the context of the entire health care sector. Given the severe market failure existing within this system<sup>66</sup> and the fact that most developed countries have some form of public medical system, the market does not provide an efficient mechanism through which to readjust unequal distributions of risks and benefits. Together, these factors argue against any mechanism that relies primarily on market forces to ensure equity between the beneficiaries of xenotransplantation and those put at risk by it.

While recognizing the limitations of market mechanisms to appropriately balance economic, social, and health factors, we need not entirely ignore legal mechanisms that take advantage of market forces. In this regard, the Learned Hand rule that balances the probability and severity of harm on the one hand against the costs of adequate precautions against those harms and the social utility of xenotrans-

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<sup>65</sup> This principle is formulated in various ways, but includes the concept of polluter-pays. For example, the polluter-pays principle requires that the costs of pollution should be borne by the person responsible for causing the pollution and consequential costs. Among the practical implications of the polluter-pays principle is its allocation of economic obligations in relation to environmentally damaging activities, particularly in relation to liability. See P. Sands, *Principles of International Environmental Law, Volume I: Frameworks, Standards and Implementation* (Manchester: Manchester University Press, 1995) at 213-217.

<sup>66</sup> See generally: R.G. Evans, *Strained Mercy, The Economics of Canadian Health Care* (Toronto: Butterworths Toronto, 1984).

plantation on the other, as well as the placement of legal responsibility for harm on the party most able to prevent the harm at the lowest cost, may play important roles in formulating *ex poste* rules to regulate xenotransplantation. Procedural rules such as reversing the onus of proof onto the alleged tortfeasor and imposing strict liability on those carrying out the procedure may also be appropriate.

Like all consequential threshold issues, the selection of the basic structure and balance achieved by the choice of legal regime will be a precondition to further inquiry into the implementation of xenotransplantation. More so than other consequential threshold issues, there is a significant benefit to international cooperation in the development of the legal regime. Since the potential harms of xenotransplantation are unlikely to be restricted to a single country, regulatory and liability regimes will need to explicitly address cross-boundary harms.

## (2) Process Issues

It would be unrealistic and unfair to assert that public consent can be restricted to a “go” “no-go” decision at the threshold level. While deontological and consequential issues are of high importance, public satisfaction that these issues have been appropriately addressed is not sufficient to implement xenotransplantation. None of the threshold issues, it must be remembered, engaged in a cost-benefit analysis. While we would never argue that cost-benefit analysis should be the only test that we apply to xenotransplantation, we argue that it is an important factor in building public acceptance of the technology. As discussed earlier, the public is unlikely to accept a technology in the absence of appropriate risk assessment and management to ensure the safe and ethical implementation of xenotransplantation.

Unlike threshold issues, both risk management and cost-benefit analysis are dependent on facts. As we discussed earlier, science is short of hard facts with respect to the risks posed by xenotransplantation for both potential transplant patients and for the general public. In the absence of firm scientific evidence of the safety of xenotransplantation, it may be difficult to convince the public to support this technology. The experience with Bovine Spongiform Encephalopathy (hereinafter BSE), in which scientists assured the public that the disease could not pass from cows to humans,<sup>67</sup> has substantially eroded public confidence in the accuracy of scientific prediction in the absence of experimental evidence.

Scientific evidence regarding the various potential risks posed by xenotransplantation can be expected to grow over the coming years. While it may never be

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<sup>67</sup> See, for example: N. Phillips, J. Bridgeman & M.A. Ferguson-Smith, *The BSE inquiry: Return to an Order of the Honourable House of Commons, Volume 8* (London: Stationery Office, 2000), online: The BSE Inquiry <<http://www.bse.org.uk/report/volume8/toc.htm>> (date accessed: 28 February 2002) which extensively chronicles the evolution of knowledge leading to the identification of new variant Creutzfeldt- Jakob Disease in humans (“vCJD”). The causal link between vCJD and BSE was initially concluded to be remote; even as of February 1996, scientists stated that there was “no scientific evidence that BSE can be transmitted to humans and that eating beef causes CJD,” at para. 5.173.

possible to assert the absolute safety of this technology, our appreciation and ability to assess the risks posed will grow. Science encountered a similar phenomenon with respect to genetic engineering. While initial concerns over the safety of the technology led to a voluntary moratorium in the 1970s over its use, it did not take long for scientists to demonstrate the safety of the technology and, importantly, of the safeguards they used to minimize the risks posed.<sup>68</sup>

Given the present lack of scientific evidence and the expected growth of our scientific knowledge, we must develop mechanisms of consent that are flexible enough to adjust to our changing state of knowledge. We need, in effect, a continual consent process rather than a once-and-for-all consent mechanism. Such a process will ensure that the level of consent given matches, to the extent possible, the knowledge we possess of the risks and benefits brought about by xenotransplantation. This process must also recognize, however, that there will always be some degree of uncertainty, some unquantifiable hazard that will never be removed.

Essentially, a consent process must involve the construction of a flexible yet efficient decision-making body that, through its constitution, rules and decisions, provides the public with a transparent means to ensure that its will is being followed. Such bodies are not easy to construct. They can too easily become hostage to interest groups that represent only a minority within society, be that minority strongly in favour or strongly opposed to the technology.<sup>69</sup> Nevertheless, without such a body, it will be hard to convince the public that those in charge of managing the risks of xenotransplantation are taking appropriate measures to protect the public.<sup>70</sup>

Whether embodied in an actual administrative board or otherwise, the consent process can be expected to deal with a number of issues that involve a mixture of science, health policy, and ethics. Since all concerns that are fact independent should have been addressed at the threshold level, the issues remaining will be significantly fact dependent and thus difficult to predict in advance. Nonetheless, we can expect consent process issues to relate to a number of different areas of risk. The first is the risk of infection and transmission of disease from animals to humans. The second involves risks faced by the transplant patient in terms of his or her consent and the privacy of his or her medical records. Third are general health policy issues, especially those related to the allocation of often scarce health resources to various diseases and their treatments.

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<sup>68</sup> See generally: *Regulation of Recombinant DNA Research: Hearings Before the Subcomm. on Science, Technology, and Space of the Senate Comm. on Commerce, Science, and Transportation, (1977) 95th Cong., 1st Sess.*

<sup>69</sup> R.E. Lofstedt & T. Horlick-Jones, "Environmental Regulation in the UK: Politics, Institutional Change and Public Trust" in *Social Trust*, *supra* note 56, 73

<sup>70</sup> For a discussion of the factors influencing the success of such a body and the challenges it faces, see: D. Metlay, "Institutional Trust and Confidence: A Journey into a Conceptual Quagmire" in *Social Trust*, *supra* note 56, 100.

Although we examine the above categories of risk in more detail below, one should note the diversity of these risks. A consequence of this heterogeneity is that no one mechanism or body will be institutionally or epistemologically capable of managing all of the risks presented. A better approach would be to allocate responsibility for these various risks among several boards, agencies, or legal institutions. For example, we could establish a scientific body to determine questions of medical risk of infection, the court system to deal with issues of consent and discrimination, and publicly controlled administrative boards to deal with the allocation of resources. In cases of uncertainty, it would most likely be the courts that would determine jurisdiction.

The essence, then, of process consent, is to allocate responsibility over a given domain of knowledge to a body, whether already in existence, such as the courts, or new, such as a scientific board, with expertise or experience at dealing with questions in that domain. Combined with transparency and the clear elucidation of rules, such a solution to building consent is most likely to bring about public confidence in the system and hence in xenotransplantation. Of course, acceptance at the process consent level depends on first having achieved threshold consent as described in the previous section.

#### *i. Risk of Infection*

Perhaps the most significant scientific risk of xenotransplantation is that of zoonosis: the risk of an infective agent moving from an animal to a human being. The transplantation of animal organs, tissues, or cells into a human being increases the risk of such an infection given the increased proximity of the infectious agent to a human host. Given that the human host will be immunologically compromised due to anti-rejection medication, the risk for infection is increased. Viruses such as PERVs, which are endemic to pigs, are but an example of infectious agents that may cross species boundaries more readily when tissue has been transplanted into a human host. The fear is not simply that the transplant recipient will become infected – which may be a risk that can be more appropriately considered under the rubric of informed consent – but that that recipient may pass the infection onto others in the general human population.<sup>71</sup>

As discussed earlier, knowledge about cross-species infection is extremely limited. Our experience with BSE certainly demonstrates the possibility of such infection even when unanticipated.<sup>72</sup> Once we add in the effects of the insertion of human genetic material coding for important immunological cellular components, such as sugar molecules, the dangers of cross-species infection become even more unpredictable.<sup>73</sup> Different infectious agents may act differently from one another;

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<sup>71</sup> Van Der Laan, *supra* note 25.

<sup>72</sup> D. Derbyshire, "CJD Deaths are Rising by a Third Every Year", The Telegraph Group (4 August 2000), online: <<http://www.telegraph.co.uk/>>

<sup>73</sup> *Canadian Standard*, *supra* note 6.

an activity that is safe in respect of one virus may not be for another. Our understanding of cross-species infection and barriers to that infection can only grow.<sup>74</sup>

Given the scientific complexities involved with parsing through current and future scientific data relating to cross-species infection, the consent process adopted to address issues relating to risk of infection must have the ability to address advances in scientific knowledge. Nevertheless, the public may not have faith, particularly after its experience with BSE, in having decisions in this domain allocated solely to a group of mainstream scientific experts. At the same time, one would not like decisions to be made by those who failed to convince the public at the threshold level not to proceed with xenotransplantation. Once the appropriate level of public consent has been given to this procedure, the goal should be to implement the technology in as responsible a manner as possible.

*ii. Health and Privacy of Transplant Recipients*

So far, the length of survival for recipients of xenografts has been poor. Therefore, anyone undergoing xenotransplantation in the near future will only be doing so under experimental protocols. Given the high risk of these experiments to both the transplant recipient and the general population, care must be taken to ensure the adequacy of the protocols, the monitoring of infection in recipients, the procedures to address unanticipated infection such as quarantine, and, especially given these complications, informed consent procedures. With such severe and unquantifiable risks as these, ethics committees may find it difficult to approve experimental protocols. To solve this difficulty, there may be a need for national or, better yet, international standards regarding experimental protocols in this area.

Whatever mechanism is developed or used to address issues of informed consent and risk management within the confines of a particular protocol, attention must also be given to issues of long-term monitoring and privacy. As discussed earlier, xenotransplant recipients may face discrimination by virtue of having undertaken the procedure. Thus, tight control is needed with respect to the identities and well-being of recipients. At the same time, given the potential risk that recipients pose for the general public – if, as may turn out to be the case, animal viruses can infect human beings – it is imperative that transplant recipients be carefully monitored for a long period of time. Protecting privacy while remaining vigilant for any signs of infection will be a difficult balance to maintain. Nevertheless, public consent to xenotransplantation will be unlikely if an appropriate balance is not attained.

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<sup>74</sup>“Healthy Cattle may Still Harbour BSE” (2000) 406:6799 Nature 929.

*iii. Allocation of Resources*

Any medical procedure, especially an expensive one such as xenotransplantation, brings forth the question of resource allocation. Resource allocation can occur at the patient level (is there a more cost effective means to attain the same result?) and at the systemic level (is this the most fair and cost effective way to allocate limited resources among various patients suffering from various diseases?).

Like all transplantations, xenotransplantation promises to be expensive. In addition to the ordinary costs of transplantation are the costs of the animal organ (payments to human beings for their organs being illegal) and the extra costs of immunosuppressing medications to deal with acute rejection. It is likely that only the most developed of countries will be able to afford these costs and undertake the monitoring involved with such transplantations. Even in these countries, the high costs of the procedure are likely to challenge already strapped public health care systems. While xenotransplantation promises savings in the costs of dialysis, donor maintenance, and elective versus emergency surgery, it is unclear whether these savings could ever offset the costs of breeding, maintaining and monitoring animal herds; patent and licensing fees; the cost of purchasing organs from commercial resource producing companies; and increased ongoing patient monitoring costs. While cost is not the only relevant issue to consider, it certainly is important if the result of the accepting xenotransplantation is the denial of less expensive treatments to others in the medical system.

While the recipient of a xenograft must obviously consent to the transplantation, the health risks posed by that transplantation may offset the benefits accruing to the recipient. Any health procedure that causes more harm than it cures is unlikely to be one that a properly working resource allocation system would long countenance. Thus, while informed consent may be sufficient to deal with individual risks of infection, it is insufficient to justify imposing a burden on the general public and the health care system.

**(3) Process Summary**

We have used xenotransplantation here as an example through which to illustrate the complexity of process consent for any new technology. Consent at this level will depend on many factors, including public interest and involvement with the particular technology, the probability and severity of the risks presented, our knowledge concerning that risk, and public faith in existing risk management structures.

Although we have sketched out the concerns that need to be addressed at the process consent level and have even suggested some mechanisms that may be able to act as vehicles for that consent, we do not claim to have fully set out either the concerns or the options. Our goal was simply to suggest that special, flexible, and transparent mechanisms are needed to address the specific problems related to lack of clear and stable scientific knowledge.

**b) International**

As noted in the discussion above, given the requirement for formal consent in the international legal order and the lack of a legal mechanism by which prohibitive states can constrain the activity of permissive states in relation to xenotransplantation technology, a more cooperative approach to risk management is required. Formation of public policy could begin with monitoring the activity of permissive states and disseminating the increasing store of scientific knowledge in relation to xenotransplantation technology. The dissemination of information is critical, as states will need to respond to new calculations of benefit and risk as xenotransplantation technology develops further. The sharing of information will also assist the internal decision-making process of states that as yet have not committed to either a permissive or prohibitive approach to xenotransplantation. It is also possible that states having either rejected or adopted xenotransplantation technology may reverse an initial decision in light of new information. Subsequent experience could indicate, for example, that one of the most significant objections against xenotransplantation, the risk of xenozoonoses, has been either over- or underestimated.

The nature of the risks associated with xenotransplantation technology are such that voluntary cooperation can be expected, and that informal monitoring practices could eventually develop into binding norms of either customary or conventional international law. While permissive activity within states cannot be constrained in the absence of binding international legal norms, even permissive states would have an incentive to participate in an international, coordinated approach to monitor and address the potential spillover effects from adopting xenotransplantation technology. Given the scientific uncertainty associated with risks such as xenozoonoses, it is unlikely that the internal decision-making process of any state will result in unqualified and unconditional acceptance of the technology, i.e., xenotransplantation is likely to be subject to a regulatory regime presumed sufficient to manage the inherent risks while still taking advantage of the perceived benefits.<sup>75</sup> Within permissive states, the assessment of the appropriate level of regulatory oversight is bound to differ. Accordingly, permissive states implementing high levels of regulatory constraints would still perceive a risk of spillover effects from states implementing what would be perceived as less than optimal risk management structures. Just as prohibitive states must rely on cooperative institutions to address involuntary assumption of risk in relation to permissive states, so must permissive states with stringent precautions in place rely on these same mechanisms to address the involuntary assumption of risk in relation to other permissive states adopting a less precautionary approach to implementation.

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<sup>75</sup> See WHO Secretariat, *Report of OECD/WHO Consultation of Xenotransplantation Surveillance*, World Health Organization, Geneva, Switzerland, 4-6 October, 2000 WHO/CDS/CSR/EPH/2000.1, online: WHO Document Centre <<http://www.who.int/emc-documents/zoonoses/whocdscsreph20011c.html>> (date accessed: 16 February 2002) (noting that "current national frameworks have established very high benchmarks for safety") [hereinafter *Xeno Surveillance*].

Organized cooperative efforts towards institutionalizing risk management of xenotransplantation do exist at the international level. The World Health Organization initiated a consultation process among its Member states in October 1997, and subsequently released a summary report of the results and recommendations. The WHO acknowledged the potential benefits of the technology, but expressly indicated in the report that the recommendations are not meant to either encourage or discourage the adoption of xenotransplantation technology. In terms of developing guidelines and public policy in this area, Member states were encouraged to focus on the assessment and management of risk in certain key areas: (a) identifying infectious agents; (b) preventing transmission of zoonoses from xenografts; (c) evaluating and managing any zoonoses occurring in xenotransplantation recipients; and (d) preventing or managing secondary transmission of zoonotic infections.<sup>76</sup>

Further international consultation took place in October 2000 in the form of a joint initiative of the WHO and the Organization for Economic Cooperation and Development.<sup>77</sup> The focus of the consultation was xenotransplantation-associated infective disease surveillance at both the domestic and international levels. The conclusion reached by participants in the consultation was that, given the reality of clinical trials already taking place and the associated risk of xenogeneic pathogens, an international system of surveillance for xenotransplantation-associated infectious diseases was a necessity. The primary objectives of an international monitoring system would be: (a) rapid detection and reporting of xenotransplant-derived infectious disease events; (b) sharing of information and cooperation; and (c) facilitating xenogenic disease event verification and coordination of responses. The participants favoured linking national registration and surveillance systems over the development of a truly international institution of regulatory oversight and called upon international organizations such as the WHO and the OECD to assume a leadership role in the progressive development of an effective international surveillance network.

Activities such as these consultation processes initiated by the WHO and the OECD do not amount to a binding, formal agreement concerning risk management of xenotransplantation at the international level. The participation of the scientific community in these consultation processes, however, particularly those from permissive states in which clinical trials are already underway, does indicate that the necessary incentive exists among even permissive states to elevate the issue of risk management to the international level. Given time, there is every possibility that the aspirational recommendations contained within the consultation reports will form the basis of binding international agreement, whether through the express

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<sup>76</sup> See *Report of WHO Consultation on Xenotransplantation*, World Health Organization, Geneva, Switzerland, 28-30 October, 1997 WHO/EMC/ZOO/98.2, online: WHO Document Centre <<http://www.who.int/emc-documents/zoonoses/whocdscsreph20011c.html>> (date accessed: 16 February 2002).

<sup>77</sup> *Xeno Surveillance*, *supra* note 75.

provisions of an international convention or as a reflection of state practice within customary international law.

### **C. The Micro Level: Methodology for operationalizing participation and consent**

Having achieved an operational definition of consent at the macro level of analysis and formulated guidelines for public policy under conditions of scientific uncertainty at the mezzo level, the task at the micro level of analysis is to operationalize consent through specific institutional mechanisms of participation and consultation. In other words, it is time to translate the theory of the mezzo level into practice at the micro level through actual consultation with members of the public.

Domestically, various mechanisms exist for obtaining public participation and consent to new technology. As each option is applied to threshold or process concerns in the xenotransplantation context, the models present corresponding advantages and disadvantages. Depending upon the specific public policy objective, and whether the objective implicates threshold or process concerns, some models of participation may be of more assistance than others. In general, however, the efficacy of any given model should be assessed on its ability to incorporate public concerns into the policy and management of xenotransplantation, with particular reference to:

- the dissemination of competing viewpoints;
- the ability to focus dialogue between public and private interests; and
- the identification of common and complementary objectives.

An exhaustive assessment of the possibilities for institutional design is beyond the scope of this analysis. Set out in Appendix B, however, is a summary of the more recognizable models of public participation and consent, at least as they are found in liberal democracies. The salient features of each model are set out, along with a brief assessment of the relevance of each model in relation to either threshold or process issues and to the ability to respond to the three concerns set out above. A caveat is in order, in that it would be counterproductive to view these models of domestic participation and consent in isolation from the progressive development of international norms in relation to xenotransplantation technology. The process of consent at the domestic and international levels is necessarily a bidirectional process; activity at the international level will affect the identification of key issues and concerns within domestic policy, just as domestic interests will set the agenda for discussion at the international level.

The operationalization of consent at the international level is a more problematic issue. As discussed above, prohibitive states cannot prevent permissive states from adopting xenotransplantation technology, notwithstanding the potential for adverse spillover effects. There is reason to expect, however, that cooperation

can, to some extent, take the place of coercion. On the basis of enlightened self-interest alone, even permissive states would presumably prefer multilateral agreement to unilateral decision-making, given the level of scientific uncertainty associated with the risk of zoonoses. International surveillance is in the interests of both prohibitive and permissive states alike, as permissive states cannot exclude the possibility of negative spillover effects on their own populations. Perhaps more importantly for the purposes of this analysis, however, is that the process of consent in the international legal order is limited in scope to the participation of nation states. The formal process of consent in international law necessarily assumes that states are monolithic in perspective, i.e., that the legitimate government of any given state is presumed to represent the unconditional consent of its population to either prohibit or adopt xenotransplantation technology, or in the latter case, to determine relevant threshold and process issues.

Accordingly, the operationalization of consent at the international level in relation to nation states allows for only two basic options of institutional design: the development of either conventional or customary international law. Given the necessity for risk management under conditions of scientific uncertainty and the necessity of rapid response to the spread of infection from zoonoses should this risk materialize, customary international law is unlikely to be of assistance. Instead, what is required at the micro level is an international agreement to create an institutional structure capable of providing regulatory oversight of domestic implementation and management of xenotransplantation technology.<sup>78</sup> At a minimum, regulatory oversight would include a system of surveillance and notification based upon objective criteria of circumstances amounting to an adverse spillover effect. A more comprehensive regime would also impose universal minimum standards of precaution upon the domestic regulatory system governing xenotransplantation. Given that process issues remain relevant at the international level, the institutional structure should also allow for operational changes in response to new information.

Given the irrevocable nature of these spillover effects, however, the prevailing legal focus on the nation state to the exclusion of other actors within international law is to be discouraged. International organizations often explicitly recognize the necessity of public participation, particularly from non-governmental organizations, and have provisions in their constituting documents dictating the scope of such relationships.<sup>79</sup> Any international efforts to establish a legal regime to regulate xenotransplantation technology should consider its implications for the common genetic heritage of the global citizenry and provide for public participation in the process. At a minimum, the views of key players from industry and the

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<sup>78</sup> One possible legal regime would include a protocol negotiated under the United Nations Convention on Biological Diversity to manage the risks and allocate the benefits of xenotransplantation technology.

<sup>79</sup> *Charter of the United Nations*, Article 71, online: UN <<http://www.un.org/Overview/Charter/chapte10.html>> (date accessed: 16 February 2002).

medical and research communities should be solicited for the purposes of developing objective scientific assessments of risk.

As with the operationalization of consent in the domestic sphere, it is beyond the scope of this analysis to examine each of the many possibilities for institutional design of international regulatory oversight of xenotransplantation technology. Nor is it possible to provide an exhaustive blueprint for public participation in the process. We have set out, however, in Appendix B, a brief summary of the various possibilities for non-governmental participation in the progressive development of international norms, along with certain specific examples of formalized institutional processes. It is important to note, however, that there is currently no institutional model of formal public participation at the international level. Opportunities for public consultation are generally limited to submissions from international non-governmental organizations rather than private citizens and such input is non-binding. Given that the activities of nation states in relation to this technology could result in irrevocable harm and an alteration of the course of our collective genetic destiny, it would be worthwhile to reconsider the viability of formal public participation in an international binding decision-making process.

#### **IV. Conclusion**

The goal of our examination in this article is to articulate the need for different consent mechanisms to address different types of concerns and risks. As our discussion demonstrated, the case of xenotransplantation provides us with an excellent model through which to discuss consent given the mixture of difficult ethical, social, and scientific problems this technology presents to society. Further, since xenotransplantation may soon be a viable option to address the human organ shortage, a study of consent mechanisms is of vital importance. Governments and international bodies have already begun consultation processes in order to assess public support for this technology. We therefore hope that the insights provided in this article may be helpful in assessing the appropriateness of these consultation processes and in constructing new ones.

Xenotransplantation is also interesting because of the international nature of the risks that it presents. As we discussed in this article, xenotransplantation presents health risks not only to transplant recipients and the countries in which they reside, but to the international community. This permits us to explore the possibility for attaining international consent to xenotransplantation and the international mechanisms available for achieving that consent. Unfortunately, as our discussion has demonstrated, the international law commitment to individual state sovereignty stands in the way of an international approach to xenotransplantation. Nevertheless, opportunities exist for international cooperation, particularly in respect of the sharing of scientific information.

The primary outcome of our examination is that consent ought properly to be thought of as a multi-layered enterprise. We have sketched out three conceptions of consent: macro, mezzo, and micro consent. Macro consent involves a determination of the ethical obligation to obtain consent and the nature of that consent. On

a scale from complete acquiescence to fully informed consent, the macro level of consent sets out the general principles under which public consent is required. Mezzo consent takes as its starting point the macro decision concerning the type of consent required and determines the general nature of the consent mechanism required to address each of the particular ethical, social, and scientific risks presented. The micro level of consent involves the actual selection of consent mechanisms to implement the mezzo level decision concerning the nature of the mechanism required.

In our view, the mezzo level of consent has been under-examined. We suggested that consent issues at the mezzo level be divided between threshold issues and process issues. Threshold issues can be determined, more or less, independently from fact and do not involve a cost-benefit analysis. Only if the threshold is crossed, do we consider process issues: issues relating to the actual implementation of the chosen technology. Process consent is attained by the selection of a publicly acceptable consent mechanism that will often take the form of an administrative board or of a court with expertise in the relevant domain.

Through our examination of xenotransplantation, we have argued that there is a need to separate out issues concerning the ethical or social wisdom of xenotransplantation from decisions concerning the management of scientific, ethical, or social risks arising out of this procedure in particular circumstances. The public may be more comfortable with providing its once-and-for-all consent to large ethical and social issues if it is assured that a process exists to ensure that operationalization of the decision to accept the technology is done in a responsible and fair manner.

How far the case study of xenotransplantation is directly exportable to other technologies we leave for future studies. Nevertheless, we argue, the general structure of consent and its implementation from theory, to mechanism design, to mechanism selection, provides a strong basis from which to address issues of consent.

## Appendix A: Normative Assessments of Consent

- a. *Acquiescence under duress*:<sup>80</sup> The application of duress can be subtle and is not acceptable in a democracy.<sup>81</sup>
- b. *Habitual obedience*:<sup>82</sup> Consent is predicated on a sense of obligation rather than voluntary choice and generally entails lack of information concerning alternatives.
- c. *Pragmatic acquiescence*: Consent is a function of an inability to imagine counterfactual circumstances or alternatives and the knowledge that acquiescence is less problematic than resistance.<sup>83</sup>
- d. *Ideological consent*: Consent is both informed and compelled by a given ideology or moral code, wherein ideology is a reflection of a person's position in society.<sup>84</sup>
- e. *"I ought to"*: Consent is based somewhat on ideology, in that conformity proceeds from a sense of obligation and typically coincides with a given norm.<sup>85</sup>
- f. *Opportunistic obedience*: Consent or conformity is influenced by the promise of rewards and raises the possibility of consent even in the face of personal ideological opposition.<sup>86</sup>
- g. *Informed consent*: Particularly relevant in fiduciary relationships, consent is legitimate only to the extent that it is based on complete and accurate information (circumstances difficult to achieve in relation to technology involving a high degree of scientific uncertainty).  
h. *Not objecting*: Consent operates as a lack of deviation from a default position, although access to information is problematic in these circumstances,<sup>87</sup> e.g., the case of deCode Genetics in Iceland.<sup>h</sup>
- i. *Contingent consent*: Citizens will comply with regulation or prescription only to the extent that they perceive the government as trustworthy and are satisfied that other citizens are consenting as well. The citizen is also presumed to do a cost-benefit analysis, and if the cost is too high, will not consent.<sup>88</sup>
- j. *Positive permission based on complete information*: This is the highest possible threshold for ascertaining consent, requiring that a citizen have access to the necessary information to make an informed decision. Note, however, that in conditions of scientific uncertainty, positive permission based on complete information may be unattainable.

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<sup>80</sup>P.H. Partridge, *Consent and Consensus* (London: Pall Mall Press, 1971) at 32 [hereinafter Partridge].

<sup>81</sup>C.W. Morris, *The Social Contract Theorists* (Lanham, Md.: Rowman & Littlefield, 1999) at 130.

<sup>82</sup>Partridge, *supra* note 74 at 33.

<sup>83</sup>D. Held, *Models of Democracy* (Stanford: Stanford University Press, 1996) at 194 [hereinafter Held].

<sup>84</sup>*supra* note 41 at p. 30.

<sup>85</sup>Held, *supra* note 49 at 194.

<sup>86</sup>Levi, *supra* note 41 at 28.

<sup>87</sup>*Ibid.* at 17.

<sup>88</sup>*Ibid.* at 29.

## Appendix B: Operational Models of Participation and Consent

### 1. Threshold Models

The following models are appropriate for consideration of xenotransplantation “snapshot” issues wherein the public is presented with single-issue questions that are not fact-dependant, thus allowing a snapshot of public opinion to be identified:

- a. *Referendum*: Electors are asked to vote directly on a particular issue and the results are generally intended to be binding on the government. Potential disadvantages include a tyranny of the majority to the detriment of minority interests and a disruption to representative government responsible for informed decision-making.<sup>89</sup> The technique is valid for disseminating viewpoints, but it does little to focus dialogue on xenotransplantation, as referendums are often adversarial models with two distinct sides. A referendum is useful, however, at the threshold level as the majority opinion on a particular issue, i.e., whether the use of pig organs for human transplant recipients is acceptable, can be determined.
- b. *Opinion Survey*: A researcher polls a group of individuals with a questionnaire to determine their opinion on certain issues. Advantages include the ability to deal with a representative sample size as opposed to the population as a whole, data is easy to collect, and the results can be analyzed quickly. Disadvantages include the narrow scope permitted by the questionnaire format and the absence of related questions.<sup>90</sup> Surveys do little to focus dialogue as the parties are not brought together for the purposes of interactive discussion and the scope of questions is necessarily narrow. On the other hand, an opinion survey can direct attention to specific questions that lead to an understanding of common objectives, and public views and opinions on specific questions and issues can be quickly ascertained
- c. *Consensus conferences*: Also known as citizen’s panels or study panels, these involve a conference where non-expert citizens (typically 12-25 persons) participate in a debate on a relevant issue. The participants draft a paper at the end of the conference summarizing the results and recommendations. Advantages of this approach include the ability to provide in-depth education, the interactive setting, and the relatively quick turnaround time for deliberative results. Disadvantages include the

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<sup>89</sup> M.O. Dickerson & T. Flanagan, *An Introduction to Government and Politics*, 4<sup>th</sup> ed. (Toronto: Nelson Canada, 1994) at 198 and Scottish Parliament, “Involving Civil Society in the Work of Parliaments” online: <<http://www.scotland.gov.uk/government/devolution/cpsp-00.asp>> (date accessed: 11 July 2000).

<sup>90</sup> OECD, “Biotechnology and the Public” online: OECD <[http://www.oecd.org/dsti/sti/s\\_t/biotech/act/consultations.htm](http://www.oecd.org/dsti/sti/s_t/biotech/act/consultations.htm)> (last modified: 10 November 1999) [hereinafter *OECD Public*].

small sample size and that the model has no direct impact on policy.<sup>91</sup> The model does, however, provide a wonderful opportunity to disseminate competing viewpoints as background papers can cover a wide range of opinions and concerns on a new technology. As well, dialogue between public and private interests can be engaged during the debates, the result being that it will be possible to identify common ground between these often competing interests. The drafted report can also contribute to further public information once disseminated, particularly in terms of identifying complementary objectives between public and private interests and other groups with opposing objectives.

- d. *Citizen juries*: These are similar to consensus conferences, in that a public panel debates an issue. The difference is that participants present information in an adversarial manner, i.e., each “side” presents its case. The “jury” then presents its findings to experts, who in turn draft a final report. The advantages of this model are similar to those associated with consensus conferences, including opportunities for further public education as viewpoints are disseminated through the final report. One significant disadvantage is that issues may be artificially compartmentalized due to the rigid adversarial structure of the presentations.<sup>92</sup> The adversarial model does not easily lend itself to discovering common ground. On the other hand, the adversarial structure brings the tension between dichotomous viewpoints into sharper relief, enabling a more precise understanding of the issues in conflict.
- e. *Focus groups*: Approximately 6 to 15 individuals from specific backgrounds are gathered together to discuss specific issues. A moderator ensures discussion remains on topic. Advantages of this approach include the ability to gain insights into people’s shared understandings and influences. Moreover, it is possible to create a group that reflects certain relevant interests, i.e., doctors, scientists, laypersons, etc. Disadvantages of this approach include the somewhat artificial setting and the influence of the moderator on the opinions of the participants.<sup>93</sup> In addition, there is less potential for public education as the discussion questions are normally narrow in focus and are not dependent upon consideration of background materials.

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<sup>91</sup> The Loka Institute, “Citizen Panels” online: The Loka Institute <<http://www.loka.org/pages/panel.htm>> (last modified: 11 April 2000) and R.E. Sclove, “Town Meetings on Technology” (July 1996) MIT Technology Review, online: The Loka Institute <<http://www.loka.org/pubs/techrev.htm>> (last modified: 22 November 1999)

<sup>92</sup> *OECD Public*, *supra* note 84; Jefferson Center, “The Citizen Jury Process,” online: <[http://www.jefferson-center.org/citizens\\_jury.htm](http://www.jefferson-center.org/citizens_jury.htm)> (date accessed: 10 July 2000); and Teledemocracy Action News Network, Auburn University, “Scientific, Deliberative Polling/Deliberative Democracy,” online: TANN <<http://www.auburn.edu/tann/tann2/project2.html#CITIZEN>> (date accessed: 11 July 2000).

<sup>93</sup> *OECD Public*, *ibid.*; J. Neilson, “The Use and Misuse of Focus Groups,” online: Jakob Nielsen’s Website <<http://www.useit.com/papers/focusgroups.html>> (date accessed: 11 July 2000), and A. Gibbs, “Focus Groups” in *Social Research Update* (1997) 19 University of Surrey, online: <<http://www.soc.surrey.ac.uk/sru/SRU19.html>> (date accessed: 11 July 2000).

- f. *Deliberative polling*: This approach combines deliberation in a small group discussion with random sampling. Participants are polled on a certain issue and then 200-300 people are sent background information and partake in a 2-3 day deliberation session. The advantages are the creation of a dialogue, public education and a representative sample. However, the narrowness of the questionnaire remains a disadvantage.<sup>94</sup> Dialogue between competing interests is achieved during the deliberation session, as both public and private interests can be represented in the search for common ground. The use of background information combined with deliberation provides an opportunity for common interests to become apparent.
- g. *Public hearings*: Public hearings solicit the views of people in various geographical locations as they advocate for their positions in a series of meeting-like sessions. The advantages of this approach include immediate feedback on politically salient issues and broad incorporation of different concerns. However, the lack of structure can make input difficult to consolidate and analyze. Dissemination of useful information is possible in that public notices are often posted, but the depth and quality of that information is not nearly as detailed as is the case with deliberative polling, consensus conferences or citizen juries (the latter models are provided with background information). There is limited opportunity for productive dialogue between competing interests as the presentations are made to a third-party board.
- h. *Working conversation model*: This is an educational model focused on providing background education for participants on new technologies. A series of conferences are held addressing various scientific and ethical topics. The goal is to educate participants who take the knowledge and apply it in various fora. The Einstein Institute for Science, Health and the Courts currently uses this model to educate judges who will be adjudicating and shaping the law for new technologies.<sup>95</sup> This model provides participants with background information and the ability to converse on contentious issues. Notwithstanding the advantages of this model in terms of the depth of coverage, significant disadvantages include the costs to participants or sponsors and limits to access for both financial and logistical reasons. A moderate level of dissemination of information is achieved using this model, as participants receive significant information that can be shared upon return to their home environments, e.g., in the case of judges, they can use it to bolster their decisions in new technology cases. Dialogue between public and private interests, however, may not be achieved as education, rather than debate or deliberation, is the primary focus. Similarly, discovering common

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<sup>94</sup>The Center for Deliberative Polling, "Executive Summary," online: CDP <<http://www.la.utexas.edu/research/delpol/bluebook/execs.html>> (last modified: 15 March 2000).

<sup>95</sup>F. Zweig & D.E. Cowdrey, "Educating Judges for Adjudication of New Life Technologies" (1999) 83:3 *Judicature* 157.

ground is difficult in an educational model, though it is possible for third parties to illuminate commonalities in a conference session.

## 2. Process Models

These models provide an organizational structure that allows for ongoing decisions and deliberations. The administrative structure behind these bodies encourages in-depth and constant consideration of the main concerns of xenotransplantation. Providing and maintaining these structures allows for continual public participation and consent on new technologies:

- a. *Advisory committees*: These committees are composed of experts in the field who review and make recommendations on specific problems. Expertise and easy administration are advantages of this model. Advisory committees, however, cannot dictate policy and are not representative of the public.<sup>96</sup> The ability to disseminate competing viewpoints is limited by the representation of such viewpoints on the committees. Accordingly, the scope of public participation and potential for information sharing is limited. Dialogue between public and private interests is promoted in this model, as long as both parties are represented on the committee. In addition, common objectives can be ascertained through careful deliberation between the experts. As an ongoing participatory model, while the composition of the committee is significant, this model does adequately provide a useful structure for process concerns.
- b. *House/parliamentary committees*: Elected government officials form a committee to consider a problem in depth. Experts, laypersons and activists make submissions for committee consideration. These types of committees are highly effective because they report to (and are a part of) the government's decision-making process and because they allow for the incorporation of many voices. However, in some cases participants are viewed as not sufficiently representative of the public.<sup>97</sup> In addition, the dissemination of competing viewpoints is limited to the perspectives of those participating on the committee. A satisfactory dialogue between public and private interests can be maintained as both "sides" are able to make submissions. As a process model, these committees have the advantage of proactive leadership, although in fact, governments typically create these committees in reaction to, rather than anticipation of, the implications of technological development.
- c. *Legislation*: Public participation and consent, once obtained, can be crystallized in legislation. An advantage of legislation is that public

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<sup>96</sup>European Union, "Transparency and Openness in Scientific Advisory Committees: The American Experience," online: <<http://www.europarl.eu.int/dg4/stoa/en/publi/167327/chap1.htm#b>> (date accessed: 11 July 2000), and New Zealand Government, "Occasional Paper 21: Crown Entities," online: <[http://www.ssc.govt.nz/documents/Occ\\_Paper\\_No21.htm](http://www.ssc.govt.nz/documents/Occ_Paper_No21.htm)> (date accessed: 11 July 2000).

<sup>97</sup>The Government of South Australia, "The Proceedings of Parliament," online: <<http://www.camtech.net.au/bright/proceed.htm>> (date accessed: 11 July 2000).

participation can be enshrined as a regulatory imperative. In addition, legislation typically provides a remedy for violations of the agreed upon norms. A significant disadvantage, however, is that legislation is necessarily fixed in time and thus provides little dynamic opportunity to respond to changes in the knowledge base associated with a given technological development. Legislation in and of itself it does not disseminate information, nor does it promote dialogue between public and private interests or find common objectives. However, these objectives can be achieved through the regulatory mechanism itself. As a process model, however, legislation is deficient to the extent that it is time-consuming to develop and implement.

- d. *Public hearings*: As described above, hearings are beneficial at the process stage, as they provide visible and ongoing entry points for public participation in addressing concerns incrementally as they arise. The disadvantage of public hearings at the process stage is that they tend to distract attention to “snapshot” issues and thus are not always a useful tool to address ongoing concerns.
- e. *Research ethics boards/hospital ethics committees*:<sup>98</sup> Multidisciplinary committees are of assistance in addressing ongoing moral and legal concerns under circumstances of scientific uncertainty in which subsequent developments alter the existing knowledge base. The format is sufficiently flexible to allow for continual review. The advantages and disadvantages will vary depending on procedural rules. For example, requiring public participation on a board or committee involves the citizenry in a meaningful way. However, depending on the procedural rules in place, a layperson may lack voting rights, and the deliberations and proceedings are often confidential. Procedural rules can be adjusted to address these concerns. For example, consensus seems to be the norm for university REBs.<sup>99</sup> One concern is that the dissemination of competing viewpoints is limited to those involved in the matter under review and that any dialogue between public and private interests is limited by the membership of any given committee. The articulation of common objectives is not the goal and is an unlikely outcome of these types of proceedings (ethics are often framed in terms of right or wrong). As a process model, review boards can provide an access point for quick consideration of different concerns of new technologies as they become available.

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<sup>98</sup> *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, online: NSERC <<http://www.nserc.ca/programs/ethics/english/policy.htm>> (last modified: 19 October 1999).

<sup>99</sup> Compiled by T. Leroux et al., in “The Feasibility of a National Canadian Advisory Committee on Ethics: Points to Consider” in *Canada Health Action: Building on the Legacy*, Papers Commissioned by the National Forum on Health, Vol. 5 (Sainte-Foy, Québec : Éditions MultiMondes, 1998) 439.

### 3. Opportunities for Public Consultation at the International Level

Despite recent initiatives, there is currently no legal model for formal public participation at the international level. Opportunities for public consultation are generally limited to submissions from international non-governmental organizations rather than private citizens, and such input is non-binding. Participation of NGOs in the development of binding international norms can occur in a variety of formats, including:<sup>100</sup>

- a. NGO representatives sent as delegates to international conferences to advise respective governments only and not free to conduct negotiations uninstructed by the government (*e.g.*, Cairo Population Conference);
- b. NGO representatives sent as delegates to international conferences to represent NGOs, and are free to conduct negotiations uninstructed by government (*e.g.* ILO);
- c. NGO representation at semi-public international conferences (*e.g.* IUCN);
- d. NGO membership in a formal (international organization's) advisory group; individuals are chosen for their expertise (*e.g.* UN Advisory Board on Disarmament Matters);
- e. NGO participation in the implementation of (international organization's) programs (*e.g.* assistance projects administered by the UN High Commissioner for Refugees);
- f. Opportunities for NGOs to participate in an international conference to draft a treaty;
- g. Opportunities for NGOs to participate on a preparatory committee for an international conference;
- h. Opportunities for NGOs to make presentations in special sessions in front of international organizations; and
- i. Membership of NGOs in international organizations; *e.g.* World Bank Inspection Panel (providing) a forum for citizens who oppose a bank-financed project because they believe it could negatively impact their rights or interests<sup>101</sup>

Specific institutional examples of public/NGO participation include:

- a. *The Sea Bed Authority*: Article 161 of United Nations Convention on the Law of the Sea outlines procedures and membership on the Sea Bed Authority. In particular, the Authority includes opportunities for geographical, political, and industrial representation. The innovative design

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<sup>100</sup>S. Charnovitz, "Two Centuries of Participation: NGOs and International Governance" (1997) 18 Mich. J. Int'l L. 183.

<sup>101</sup>See E. Hey, "The World Bank Inspection Panel: Towards the Recognition of a New Legally Relevant Relationship in International Law" (1997) 2 Hofstra L. & Pol'y Symp. 61.

of the Authority in respect to allocating legal responsibility to entities other than nation states shows some promise for increased public participation, notwithstanding the limited relevance of the Authority within international law.

- b. *World Trade Organization*: Dispute settlement in the WTO provides opportunities for public participation, both expressly as set out in Annex II, the Dispute Settlement Understanding, and in the body of case law interpreting the scope of involvement by NGOs.<sup>102</sup> This model is very process oriented and provides a forum for dispute resolution.
- c. *World Health Organization*: The WHO has provisions in its constitution and procedural regulations detailing its relationship with NGOs, e.g., permitting NGOs to submit memoranda to the Director General of the WHO.<sup>103</sup>
- d. *Environmental Treaties*: Various environmental treaties, such as the Rio Declaration on Environment and Development, provide for public participation in relation to certain key issues. For example, Principle 10 of the Declaration emphasizes appropriate access to information, opportunities to participate in decision-making processes and effective access to administrative proceedings, including redress and remedy.<sup>104</sup>

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<sup>102</sup>In *United States—Import Prohibition of Certain Shrimp and Shrimp Products (Complaint by Malaysia et al.)* (1998) WTO Doc. WT/DS58/R (Panel Report), online: WTO

<[http://www.wto.org/english/tratop\\_e/dispu\\_e/dispu\\_e.htm](http://www.wto.org/english/tratop_e/dispu_e/dispu_e.htm)> (date accessed: 15 February 2002), the panel ruled that the NGO briefs could not be accepted for the purpose of deliberations unless they were appended to the brief of one of the parties—in this case the U.S.

<sup>103</sup>*Principles Governing Relations Between the World Health Organization and Nongovernmental Organizations*, online: WHO <<http://www.who.int/ina-ngo/ngo/princ-e.htm>> (last modified: 8 May 2001).

<sup>104</sup>*Rio Declaration on Environment and Development*, 14 June 1992, 31 I.L.M. 876.

