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**THE “CATCH-22” OF XENOTRANSPLANTATION:
COMPELLING COMPLIANCE WITH LONG-
TERM SURVEILLANCE**

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I. INTRODUCTION

Xenotransplantation, a promising therapy using animal-to-human transplants, comes with numerous risks. These risks necessitate that xenotransplant recipients consent to long-term surveillance. However, long-term surveillance might be invasive, might compromise recipients’ privacy interests, and might warrant the need for third-party consent. A successful long-term surveillance program must be constitutional and effective, but thus far, the law relating to xenotransplantation is underdeveloped and current statutes are inadequate to enforce consent to long-term surveillance.

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This comment will analyze and discuss the legal issues regarding informed consent and xenotransplantation. Part II will provide the scientific background required for understanding the risks raised by xenotransplantation and will illustrate the necessity of monitoring xenograft recipients long-term. Part III will explore the problems raised by compelling long-term surveillance, indicating that while active compliance is crucial, significant obstacles hinder obtaining such compliance. Part IV will analyze the difficulties inherent in obtaining third-party consent. Part V will address the current legal and regulatory framework at both state and federal levels, demonstrating that such framework insufficiently addresses the legal issues implicated by xenotransplantation. Part VI will evaluate proposed solutions, including strategies implemented in dealing with other communicable diseases, and will suggest measures for effective, xeno-specific legislation. The paper will conclude with recommendations for addressing the immediate obstacles confronting xenotransplant clinical trials and will point out areas requiring further development before such trials may be safely conducted.

II. XENOTRANSPLANTATION OFFERS A POTENTIAL SOLUTION TO ORGAN DONATION SHORTAGES BUT INTRODUCES SIGNIFICANT MEDICAL AND LEGAL CONCERNS.

The number of patients awaiting an organ donation vastly exceeds the number of available organs.¹ As of September 2006, the list of persons awaiting an organ donation numbered over 92,000, as compared to only 7,500 available donors.² During 2004 over 6,000 patients died while awaiting an organ.³ Some estimates show that only five percent of the organs needed are actually made accessible for transplantation.⁴ The distressing disparity between need and availability has led researchers to consider the possibility of animal-

¹ “[T]he United Network for Organ Sharing (UNOS) is a non-profit, scientific and educational organization that administers the nation’s only Organ Procurement and Transplantation Network. . . .” UNITED NETWORK FOR ORGAN SHARING, U.S. TRANSPLANTATION DATA, [hereinafter UNOS], <http://www.unos.org/whoWeAre/> (last visited Oct. 10, 2006).

² UNOS, <http://www.unos.org/data/default.asp?displayType=usData> (last visited Sept. 10, 2006).

³ NAT’L KIDNEY FOUND., 25 FACTS ABOUT ORGAN DONATION AND TRANSPLANTATION, <http://www.kidney.org/news/newsroom/fsitem.cfm?id=30> (last visited Sept. 11, 2006) [hereinafter 25 FACTS].

⁴ Marilia Cascalho et al., *Xenotransplantation and the Future of Renal Replacement*, 15 J. AM. SOC’Y NEPHROLOGY 1106, 1106 (2004).

to-human transplants, or xenotransplantation.⁵ According to the FDA, xenotransplantation is the implant or transfer of cells or tissue from nonhuman, animal sources into human recipients.⁶ The definition includes human cells grown *ex vivo* in contact with animal proteins or cells.⁷

Many in the medical field view xenotransplantation as a viable solution to the shortage problem.⁸ Several factors contribute to the desirability of xenographic cells over human tissues: increased availability, lower cost, and decreased likelihood that the xenograft will turn cancerous (a concern with allotransplants).⁹ Furthermore, research offers some hope that xeno-technology will prove useful in areas other than transplantation, such as alleviating conditions not customarily treated by organ transplant or providing an alternative source of stem cells.¹⁰

It is well known that tissue transplants between humans easily transmit viral diseases such as HIV, Creutzfeldt-Jakob Disease, and hepatitis from the donor to the recipient.¹¹ This same potential for transmission also applies to xenotransplants and raises serious health concerns about the possibility of xenoses (also called xenozoonoses), diseases resulting from the transmission of an infectious agent from an animal organ to a human recipient.¹² Xenoses

⁵ See 25 FACTS, *supra* note 3.

⁶ CTR. FOR BIOLOGICS EVALUATION & RES., U.S. DEP'T OF HEALTH & HUMAN SERVS., U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: SOURCE ANIMAL, PRODUCT, PRECLINICAL AND CLINICAL ISSUES CONCERNING THE USE OF XENOTRANSPLANTATION PRODUCTS IN HUMANS (2003), <http://www.fda.gov/cber/gdlns/clinxeno.pdf> [hereinafter FDA GUIDANCE FOR INDUSTRY].

⁷ *Id.*

⁸ See *Transplanting Animal Organs Could Soon Be A Reality*, SCI. DAILY, Sept. 10, 2005 (adapted from a news release by Imperial College London), <http://www.sciencedaily.com/releases/2005/09/050910090133.htm> (last visited Jan. 4, 2007).

⁹ One doctor commented that “despite the risks, xenotransplantation may be the best hope we have for dealing with the current transplant shortage.” *Id.*; Cascalho, *supra* note 4, at 1109.

¹⁰ The Guideline mentions putative uses such as “epilepsy, chronic intractable pain syndromes, insulin dependent diabetes mellitus and degenerative neurologic diseases such as Parkinson’s disease and Huntington’s disease.” CTR. FOR BIOLOGICS EVALUATION & RES., U.S. DEP'T OF HEALTH & HUMAN SERVS., U.S. FOOD & DRUG ADMIN., PHS GUIDELINE ON INFECTIOUS DISEASE ISSUES IN XENOTRANSPLANTATION, 1 (2001), <http://www.fda.gov/cber/gdlns/xenophs0101.pdf>; Stefan Lovgren, *Pig Stem Cells To Be Used to Grow Human Organs?*, NAT'L GEOGRAPHIC NEWS, Feb. 15, 2005, http://news.nationalgeographic.com/news/2005/02/0215_050215_transplant.html (last visited Jan. 4, 2007).

¹¹ PHS GUIDELINE ON INFECTIOUS DISEASE ISSUES IN XENOTRANSPLANTATION, *supra* note 10, at 15.

¹² Naveen Atray et al., *Xenotransplantation*, eMEDICINE, May 17, 2004, <http://www.emedicine.com/med/topic3715.htm>.

are unpreventable when infectious agents remain undetected in the host animal by virtue of remaining asymptomatic, but become virulent once transferred to the human host.¹³ Biological characteristics in humans might increase the infectious agent's viability, and current biotechnology cannot detect all possible transmissible agents carried by animal-donor tissues.¹⁴ These factors elevate the risk to transplant recipients, their close contacts, and the community at large.

The AIDS epidemic represents a prime example of this scenario.¹⁵ Though non-virulent in chimpanzees, the HIV-1 virus proved highly infectious in humans.¹⁶ Technology lacked the ability to detect and study the virus, making the situation all the more frightening when the first AIDS cases appeared in the human population.¹⁷ This fear of pathogen transmission to human recipients led to the rejection of nonhuman primates as donors, and shifted the focus to pigs as the primary donor animal.¹⁸ However, pig organs pose the analogous concern that undetected porcine endogenous retroviruses (PERV) might be transmitted to humans, thereby causing disease.¹⁹

Long-term surveillance, which provides the medical community with the capacity to recognize, study, and treat zoonoses as they occur, must be established as an immutable condition of xenotransplant clinical trials.²⁰ The World Health Organization advisory group defines surveillance of a xenogeneic infection or disease event as:

[T]he structured collection, reporting, analysis and interpretation of a xenogeneic infection/disease event. It is dependent on the ability

¹³ SEC'Y'S ADVISORY COMM. ON XENOTRANSPLANTATION, U.S. DEP'T OF HEALTH & HUMAN SERVS., REPORT ON THE STATE OF THE SCIENCE IN XENOTRANSPLANTATION, iii (2004), http://www4.od.nih.gov/oba/SACX/reports/Sci_draft_030905.pdf [hereinafter REPORT ON THE STATE OF THE SCIENCE IN XENOTRANSPLANTATION]; see PHS GUIDELINE ON INFECTIOUS DISEASE ISSUES IN XENOTRANSPLANTATION, *supra* note 10, at 15.

¹⁴ PHS GUIDELINE ON INFECTIOUS DISEASE ISSUES IN XENOTRANSPLANTATION, *supra* note 10, at 16.

¹⁵ *Id.*

¹⁶ REPORT ON THE STATE OF THE SCIENCE IN XENOTRANSPLANTATION, *supra* note 13, at iii.

¹⁷ *Id.*

¹⁸ *Id.* at iv.

¹⁹ *Id.*

²⁰ See SEC'Y'S ADVISORY COMM. ON XENOTRANSPLANTATION, U.S. DEP'T OF HEALTH & HUMAN SERVS., INFORMED CONSENT IN CLINICAL RESEARCH INVOLVING XENOTRANSPLANTATION, 20 (2004), http://www4.od.nih.gov/oba/SACX/reports/IC_draft_030905.pdf; PHS GUIDELINE ON INFECTIOUS DISEASE ISSUES IN XENOTRANSPLANTATION, *supra* note 10, at 19, 21; Patrick S. Florencio & Erik D. Ramanathan, *Are Xenotransplantation Safeguards Legally Viable?*, 16 BERKELEY TECH. L.J. 937, 940 (2001) [hereinafter Ramanathan].

of detectors (health care providers, diagnostic laboratory workers and others) to identify and properly respond to xenogeneic infection/disease event occurrence. Surveillance serves as the basis for developing timely information about the event, which is, in turn, disseminated to those responsible for the event’s management.²¹

Without such monitoring, the development of diseases (from a PERV, for example) could go undetected and untreated, allowing the recipient to expose their community to a potentially virulent and lethal pathogen.²² Fundamentally, long-term surveillance requires that subjects submit to periodic monitoring for the duration of their lives,²³ a time span based on the long latency periods exhibited by other viruses known to infect human beings.²⁴

Current legislation requires that researchers involved in clinical trials obtain a participant’s informed consent before implementing any sort of long-term monitoring.²⁵ The concept of informed consent plays a foundational role in the American medical system: physicians and doctors perform an advisory role, while the patient makes the final decision regarding which course of treatment to pursue.²⁶ “[C]rucially, the ‘informed’ precedes the ‘consent’.”²⁷

Existing legislation on informed consent provides research subjects with the right to withdraw from a clinical trial at any point: “[p]articipation is voluntary . . . and . . . the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.”²⁸ But in xenotransplantation trials, the need for surveillance arguably outweighs the individual’s right to withdraw. Allowing a subject to drop out would handicap

²¹ WORLD HEALTH ORG., DEP’T OF COMMUNICABLE DISEASE SURVEILLANCE & RESPONSE, WHO GUIDANCE ON XENOGENEIC INFECTION/DISEASE SURVEILLANCE AND RESPONSE: A STRATEGY FOR INT’L COOPERATION AND COORDINATION, 5 (2001), http://whqlibdoc.who.int/hq/2001/WHO_CDS_CSR_EPH_2001.2.pdf.

²² See *id.* at 1; see also SEC’Y’S ADVISORY COMM. ON XENOTRANSPLANTATION, DEP’T OF HEALTH & HUMAN SERVS., ABOUT XENOTRANSPLANTATION, <http://www4.od.nih.gov/oba/sacx/aboutxeno.htm> (last visited Jan. 11, 2006).

²³ INFORMED CONSENT IN CLINICAL RESEARCH INVOLVING XENOTRANSPLANTATION, *supra* note 20, at iv.

²⁴ Infectious Disease Issues in Xenotransplantation, 68 Fed. Reg. 60,697–98 (Oct. 23, 2003).

²⁵ 21 C.F.R. § 50.25 (2006).

²⁶ Fritz H. Bach & Adrian J. Ivinson, *A Shrewd and Ethical Approach to Xenotransplantation*, 20 TRENDS IN BIOTECHNOLOGY 129, 129 (Mar. 2002).

²⁷ *Id.*

²⁸ 21 C.F.R. § 50.25(a)(8) (2006).

the scientific community's ability to track and treat the disease, thus subjecting the public to risk of infection.²⁹

To ensure that public health authorities are able to detect and isolate new infectious agents, it is essential for prospective xeno-transplantation research participants to be fully informed that their compliance with lifelong surveillance is critical and that failure to comply may, in some cases, necessitate the application of public health laws.³⁰

The unknown factor makes compliance crucial for xenotransplant recipients: any xenosis that develops is likely to be novel and might not physiologically present in ways scientists or health care personnel readily recognize.³¹ The best hope for tracking, studying the development of, implementing treatments for, and creating vaccines to combat such novel infectious agents lies in maintaining a record of periodic tissue samples from each recipient.³²

III. COMPELLING COMPLIANCE IS DIFFICULT IN A LONG TERM SURVEILLANCE PROGRAM.

Compliance with long-term surveillance requires recipients to actively participate in the monitoring program. The Public Health Service (PHS) advises informing potential transplant recipients that they will be asked to consent to fulfilling several lifelong expectations, the most important of these being their faithful adherence to regular physical examination and collection of tissue and blood specimens.³³ Xenotransplantation subjects will also need to consent

²⁹ INFORMED CONSENT IN CLINICAL RESEARCH INVOLVING XENOTRANSPLANTATION, *supra* note 20, at 20. The ability to monitor, diagnose, and treat xenographic diseases almost totally depends on recipient compliance. Transcript of Second Meeting of the SACX 22 (Jul. 3, 2001) (statement by Dr. Karren King, Member, SACX), http://www4.od.nih.gov/oba/sacx/transcripts/SACX7-3_transcript.pdf.

³⁰ INFORMED CONSENT IN CLINICAL RESEARCH INVOLVING XENOTRANSPLANTATION, *supra* note 20, at iv. The Secretary's Advisory Committee on Xenotransplantation to the President (SACX) was established by the Secretary of Health and Human Services to address the variety of problems associated with xenotransplantation, and to craft recommendations accordingly. SECRETARY'S ADVISORY COMM. ON XENOTRANSPLANTATION, DEP'T OF HEALTH & HUMAN SERVS., ABOUT THE SACX, <http://www4.od.nih.gov/oba/sacx/aboutsacx.htm> (last visited Jan. 11, 2006).

³¹ Ramanathan, *supra* note 20, at 971.

³² PHS GUIDELINE ON INFECTIOUS DISEASES IN XENOTRANSPLANTATION, *supra* note 10, at 35–36. *See also* Florencio & Ramanathan, *infra* note 109, at 118 (“The importance of the safeguards lies not in their ability to altogether prevent the emergence of infectious diseases—because they are incapable of doing so—but in their ability to provide the foundation for a rapid response to emerging infectious diseases.”).

³³ INFORMED CONSENT IN CLINICAL RESEARCH INVOLVING XENOTRANSPLANTATION, *supra* note 20, at 14.

to a number of other conditions: archiving these samples in a national (and eventually worldwide) database (where the data will be retained for fifty years); complying with behavior modification; continually informing close contacts and potential healthcare providers about the transplant; refraining from blood or tissue donations; and submitting their bodies for autopsy upon death.³⁴ These conditions require a level of patient adherence that has thus far proven extraordinarily difficult to ensure, due to both problems with predicting and controlling patient behavior and the potential for violating the individual's constitutional rights.³⁵

Experience with patients demonstrates that adherence to monitoring protocols decreases proportionately in asymptomatic patients, the further out the patient gets from treatment.³⁶ Overall, accurately predicting patient adherence remains largely unfeasible.³⁷ Certain dynamics such as severity of condition or patterns in patient behavior do allow limited predictions: patients with chronic conditions exhibit less compliance than those with acute conditions, and in general, as people begin to feel better adherence decreases.³⁸

It is the author's opinion that additional factors such as geographic location and inconvenience are also likely to influence patient behavior. In an increasingly mobile society, recipients might view required appointments at testing centers (for the purpose of taking tissue samples) every couple of years as significantly inconvenient. The hassle and expense of international travel would act as considerable deterrents to compliance, and even the inconvenience of traveling to a regional testing center located only a couple of hours away might effectively diminish some recipients' compliance. In addition, the desire to escape the obligation of periodic testing could possibly motivate some recipients to quietly remove themselves to more remote locations. Overall, both social factors and demographics have proven ineffective in predicting patient compliance, making it nearly impossible to forecast which subjects will remain faithful to long-term monitoring.³⁹

³⁴ *Id.* at ii-iii.

³⁵ Ramanathan, *supra* note 20, at 942-43 ("[H]uman behavior is the leading cause of emerging infectious diseases."). "Compulsory compliance . . . would require the relinquishment of certain civil liberties . . ." *Id.*

³⁶ Transcript of Second Meeting of the SACX, *supra* note 29, at 22.

³⁷ *Id.* See also Richard Coker, *Tuberculosis, Non-Compliance and Detention for Public Health*, 26 J. MED. ETHICS 157, 159 (2000).

³⁸ Transcript of Second Meeting of the SACX, *supra* note 29, at 22.

³⁹ *Id.*

The U.S. Department of Health and Human Services (DHHS) has recommended the creation of a national database for archiving tissue samples from xenotransplant recipients, and the World Health Organization (WHO) has expanded this concept, arguing for the establishment of a worldwide database.⁴⁰ The database would allow researchers increased access to information that would facilitate better monitoring for traveling recipients.⁴¹ Creation of a national database dictates that each country implement oversight systems for long-term monitoring. Given the likelihood that some xenotransplant recipients will travel or relocate internationally, long-term surveillance of these persons can only be accomplished if the destination country is capable of obtaining and archiving tissue samples.⁴² Less technologically and economically advanced countries lacking the resources to execute such a system raise the following dilemmas: (1) such countries might present something of a safe harbor for xenotransplant recipients, where recipients could escape the surveillance requirements; and (2) lack of ability to monitor and track might leave such countries unprotected against a disease that developed within their borders.⁴³

With several countries already conducting restricted clinical trials in xenotransplantation, including the U.S., Belgium, Spain, Germany, Mexico, and New Zealand, the geographical barriers that arise in relation to long-term surveillance are no longer problems of the future.⁴⁴ Advances in medical technology have enabled xeno-

⁴⁰ REPORT ON THE STATE OF THE SCIENCE IN XENOTRANSPLANTATION, *supra* note 13, at 1. WHO recommends that instead of creating a database *de novo*, a more efficient approach would seek to utilize "established resources: existing international surveillance systems, methodologies and tools." WORLD HEALTH ORG., DEP'T. OF COMMUNICABLE DISEASE SURVEILLANCE & RESPONSE, OECD/WHO CONSULTATION ON XENOTRANSPLANTATION SURVEILLANCE: SUMMARY, 5 (Oct. 26, 2001), http://whqlibdoc.who.int/hq/2001/WHO_CDS_CSR_EPH_2001.1.pdf [hereinafter OECD/WHO CONSULTATION]. The 57th World Health Assembly requested the collection of data on a global level for the purpose of assessing xenotransplants. Human Organ and Tissue Transplantation, *From the Eighth Plenary Meeting of the Fifty-Seventh World Health Assembly in Geneva*, 78 TRANSPLANTATION 493 (Aug. 27, 2004), available at <http://www.transplantation-soc.org/downloads/WHOfinal.pdf>.

⁴¹ WHO GUIDANCE ON XENOGENEIC INFECTION, *supra* note 21, at 1.

⁴² See WORLD HEALTH ORG., ANIMAL TO HUMAN TRANSPLANTATION—FUTURE POTENTIAL, PRESENT RISK, May 2, 2005, available at <http://www.who.int/mediacentre/news/notes/2005/np08/en/index.html>.

⁴³ See *id.*; OECD/WHO CONSULTATION, *supra* note 40, at 27.

⁴⁴ Nelson Erlick, *Xenotransplantation Fact Sheet*, Author's Official Site, 2005, http://www.nelsonerlick.com/html/xeno_fact_sheet.html, (last visited Jan. 11, 2006); *Pig-cell transplant treatment denied*, N.Z. HERALD, May 21, 2005, http://www.nzherald.co.nz/section/story.cfm?c_id=5&objectid=10126694; Bioethics Council, *Xenotransplantation Should Be Allowed To Develop In New Zealand*, MED. NEWS TODAY, Dec. 18, 2005, http://www.mednewstoday.com/story.cfm?c_id=5&objectid=10126694.

transplant trials to move forward, accelerating the need to address these obstacles. Equipping researchers around the world with access to information from other xeno-clinical trials would be the first step toward making long-term surveillance of xenotransplant recipients possible, despite international travel. Although the WHO advisory group’s worldwide database proposition would indeed facilitate global communication between researchers, the creation of a National Xenotransplantation Database is still in the pilot phase.⁴⁵

The remaining obstacle to enforcing compliance with long-term monitoring involves potential violation of individuals’ constitutional rights under the Fourth and Fourteenth Amendments.⁴⁶ The Fourth Amendment protects individuals from “unreasonable searches and seizures” by the government; the crucial test lies in the “reasonableness” of the search or seizure.⁴⁷ *Skinner v. Railway Labor Executives’ Ass’n* laid out the test for “reasonableness”: a search should be “judged by balancing its intrusion on the individual’s Fourth Amendment interests against its promotion of legitimate governmental interests.”⁴⁸ The *Skinner* Court found that the Federal Railroad Administration’s authorization of policies for taking, and sometimes even requiring, employees to provide urine, blood, and breathe samples for the purpose of drug and alcohol testing constituted a “search.”⁴⁹ “Because it is clear that the collection and testing of urine intrudes upon expectations of privacy that society has long recognized as reasonable . . . these intrusions must be deemed searches under the Fourth Amendment.”⁵⁰ Under *Skinner*, the government may compel taking of bodily fluids and tissues when some

www.medicalnewstoday.com/medicalnews.php?newsid=35117 (The Toi te Taiao Bioethics Council of New Zealand agreed to allow xenotransplantation trials to proceed).

⁴⁵ Transcript of Fifth Meeting of the SACX 14 (Feb. 4, 2003) (statement of Dr. Eda Bloom), <http://www4.od.nih.gov/oba/sacx/transcripts/020403—Day%20%20Plenary%20Sessions.pdf>. The FDA, in conjunction with other Public Health Services agencies, is responsible for the development of the National Xenotransplantation Database, which will aid researchers in managing the long-term surveillance data that is collected. FDA GUIDANCE FOR INDUSTRY, *supra* note 6, at 52. Any national database would have to comply with the privacy requirements specified in the Health Insurance Portability and Accountability Act (HIPAA). INFORMED CONSENT IN CLINICAL RESEARCH INVOLVING XENOTRANSPLANTATION, *supra* note 20, at 18.

⁴⁶ Ramanathan, *supra* note 20, at 967–68.

⁴⁷ U.S. CONST. AMEND. IV; *Vernonia School Dist. 47J v. Acton*, 515 U.S. 646, 652 (1995).

⁴⁸ *Skinner v. Railway Labor Executives’ Ass’n*, 489 U.S. 602, 619 (1989) (quoting *Delaware v. Prouse*, 440 U.S. 648, 654 (1979)).

⁴⁹ *Skinner*, 489 U.S. at 617.

⁵⁰ *Id.*

“special need” justifies departure from the customary position of giving priority to the individual’s freedom.⁵¹

Compelling adherence to long-term surveillance, which requires taking tissue samples, constitutes an analogous situation, and is likely to also implicate the Fourth Amendment under the *Skinner* decision. Fourth Amendment violations require a state actor. Consequently, where xenotransplant clinical trials received federal funding, researchers collecting tissue samples would qualify as state actors. Because non-compliance with surveillance measures carries the potential of imposing significant health risks on the population at large, government funded researchers might argue a “special needs” case for justifying forced compliance with long-term monitoring. However, the extent to which long-term monitoring requirements would restrict individual freedom rises to a considerably greater degree than that required by one alcohol or drug test. The fact that the monitoring involves repeated, invasive procedures for the duration of the individual’s life would likely outweigh the argument of a legitimate government interest.⁵²

Compelling compliance with long-term surveillance also implicates the Fourteenth Amendment due to the potential violation of the fundamental right to privacy, granted under substantive due process.⁵³ Government actions impinging on a fundamental life, liberty, or property interest are subject to strict scrutiny: the means employed must be narrowly tailored to achieve a compelling government objective for such legislation to pass constitutional muster.⁵⁴ Forcing xenotransplant recipients to comply with long-term monitoring measures infringes on both fundamental privacy and liberty interests. It subjects persons to unwanted bodily invasion, intruding on both their person and their autonomy.

Assuming again that xenotransplant trials are government funded, and given the possibility of a widespread pandemic, an objective of preventing the spread of communicable diseases might constitute a compelling state interest. However, courts are not likely to find long-term surveillance measures “narrowly tailored.” The

⁵¹ *Id.* at 619.

⁵² *But see* Ramanathan, *supra* note 20, at 963, 968 (“... the advantage of saving one’s life through xenotransplantation should greatly outweigh the drawback of having to provide periodic serum samples. . . . Courts are likely to find that the intrusion on a transplant recipient’s privacy is minimal for several reasons.”).

⁵³ *Id.* at 968, 974.

⁵⁴ *Id.* at 969. *See generally* Lawrence v. Texas, 539 U.S. 558 (2003); Planned Parenthood v. Casey, 505 U.S. 833 (1992).

privacy and autonomy invasion necessitated by long-term surveillance would continue for the rest of recipients' lives. Lifelong surveillance would impair an individual's freedom to travel for any length of time, possibly even preventing a move overseas. Those eligible for a xenotransplant will already have reached end-stage organ failure, making it improbable that their state of health would allow them to go gallivanting around the world.⁵⁵ However, as advances in medical science tailor the xenograft to its human recipient, thereby decreasing compatibility problems, conceivably a person's health might be restored to the extent that he or she would be capable of international travel.

Issues about confidentiality and the possibility of “more narrowly tailored means” also weigh in favor of courts refusing to compel compliance. Long-term surveillance would require repeated disclosures of personal information regarding close contacts and family, disclosures that conflict with the individual's privacy right where personally identifiable medical information is involved. In addition, science advances rapidly. It acquires knowledge and develops new techniques, increasing the likelihood that less invasive and constraining monitoring techniques, such as periodic self-testing at home, will be developed in the near future. Due to the speculative nature and lack of time frame for developing “home test kits,” it is unlikely courts would allow a temporary system of forced compliance to stand until such kits are developed. Given these considerations, it is doubtful that enforcing recipients' consent to long-term monitoring would withstand strict scrutiny.⁵⁶

IV. THIRD PARTY CONSIDERATIONS.

Informed consent may also be required from a recipient's family, friends, and healthcare workers involved in the clinical trial or monitoring.⁵⁷ Both the Secretary's Advisory Committee on Xenotransplantation (SACX) and the PHS have raised the issue of third party consent. The SACX describes “intimate contacts” as “contacts of the recipients of xenotransplantation products . . . who have engaged in activities that could result in intimate exchange of body

⁵⁵ Transcript of Sixth Meeting of the SACX 14 (Feb. 24, 2004) (statement of Dr. Bill Scheckler), <http://www4.od.nih.gov/oba/sacx/Feb2004/Feb2004transcript.pdf>.

⁵⁶ *But see* Ramanathan, *supra* note 20, at 969.

⁵⁷ Transcript of Second Meeting of the SACX, *supra* note 29, at 2–4.

fluids, including blood or saliva, with the recipient.”⁵⁸ Obviously the primary concern revolves around the transmission of an infectious agent to an intimate contact, who could then unknowingly release it into the community.⁵⁹ In the interest of precaution, the PHS has recommended that intimate contacts consent to refraining from blood or other tissue donation.⁶⁰ Additionally, post-transplant surveillance may need to include intimate contacts and healthcare workers.⁶¹

Two significant hurdles hinder obtaining informed consent from these groups: the lack of any legal framework to obtain informed consent from a third party not participating in the clinical trial,⁶² and the fact that a person’s contacts and relationships change over time, making it potentially difficult to track “intimate contacts.”⁶³ Legislation governing informed consent in clinical studies mentions third party consent only where a subject’s youth or incapacity prevents her or him from granting consent, thus requiring a third party to consent on the subject’s behalf.⁶⁴ The SACX recommends that instead of the rigorous monitoring requirements imposed on xenotransplant recipients, close contacts would instead be asked to give only a “baseline sample” against which any future abnormalities could be compared.⁶⁵

The SACX acknowledged at its February 2004 meeting that obtaining informed consent from third parties did not appear viable on either a legal or logistical level.⁶⁶ One of the main deterrents was that as people’s contacts change over time, obtaining informed consent from those contacts would require revealing confidential medical information about the xenotransplant recipient to them, violating the recipient’s right to privacy.⁶⁷ The committee chose to pursue the education route instead, advocating a “consent team”

⁵⁸ INFORMED CONSENT IN CLINICAL RESEARCH INVOLVING XENOTRANSPLANTATION, *supra* note 20, at 22.

⁵⁹ PHS GUIDELINE ON INFECTIOUS DISEASE ISSUES IN XENOTRANSPLANTATION, *supra* note 10, at 16.

⁶⁰ *Id.* at 5.

⁶¹ *Id.* at 19.

⁶² INFORMED CONSENT IN CLINICAL RESEARCH INVOLVING XENOTRANSPLANTATION, *supra* note 20, at iv; Transcript of Sixth Meeting of the SACX (statement of Dr. Robyn Shapiro), *supra* note 55, at 10.

⁶³ INFORMED CONSENT IN CLINICAL RESEARCH INVOLVING XENOTRANSPLANTATION, *supra* note 20, at 22.

⁶⁴ 45 C.F.R. § 46.402 (2005); 21 C.F.R. §§ 50.3, 50.24 (2005).

⁶⁵ Transcript of Second Meeting of the SACX (statement of Lou Marzella), *supra* note 29, at 7.

⁶⁶ Transcript of Sixth Meeting of the SACX (statement of Robyn Shapiro), *supra* note 55, at 10.

⁶⁷ *Id.*

which would help instruct close contacts on the health risks posed to them by the xenotransplant recipient, and the need to abstain from certain activities such as tissue donation or unprotected sex.⁶⁸

In contrast, the United Kingdom requires informed consent from the recipient’s family members, despite the fact that this would disqualify subjects whose family members refuse to give their consent.⁶⁹ Whether the United States chooses to proceed without requiring per se informed consent from intimate contacts, consent to obtain the baseline sample and any subsequent samples required for monitoring purposes must at some point be obtained from the recipient’s close contacts. Given their close interaction with xenotransplant recipients, healthcare workers would also need to consent to some form of long term monitoring, including periodic collection of biological samples.⁷⁰

Policy makers for xenotransplantation argue that informed consent may be required from yet another third party, the general public. If we consider it unethical to subject patients to risks to which they have not consented, is it not just as unethical to place such risks on a community at large?⁷¹ The reality, though, is that public consent is difficult, if not impossible to obtain, and in the opinion of this author, is unnecessary. Several factors contribute to the difficulty of obtaining some sort of “societal consent”: the nature of the topic and the science involved are sophisticated; most risks cannot be ascertained with any degree of probability; and a method that would accurately reflect society’s views would be complex to design.⁷² At the very least, precautionary measures warrant educating the public with valid and accurate information,⁷³ but relatively few proposals exist for implementing an educational program.

The SACX has advised that a more practical approach may be to focus on educating communities regarding the medical and ethi-

⁶⁸ Transcript of Sixth Meeting of the SACX (statement of Dr. Harold Vanderpool), *supra* note 55, at 13.

⁶⁹ Transcript of Sixth Meeting of the SACX (statement of Dr. David Cook), *supra* note 55, at 11.

⁷⁰ Transcript of Sixth Meeting of the SACX (statement of Robyn Shapiro), *supra* note 55, at 10; INFORMED CONSENT IN CLINICAL RESEARCH INVOLVING XENOTRANSPLANTATION, *supra* note 20, at 22.

⁷¹ See Bach, *supra* note 26, at 129–30.

⁷² T.A. Caulfield & G.B. Robertson, *Xenotransplantation: Consent, Public Health and Charter Issues*, 5 MED. L. INT’L 81, 90 (2001).

⁷³ PHS GUIDELINE ON INFECTIOUS DISEASES IN XENOTRANSPLANTATION, *supra* note 10, at 2–3; Atray, *supra* note 12.

cal aspects of xenotransplantation.⁷⁴ However, the committee abdicates responsibility of this task and recommends that another “appropriately constituted advisory committee” be established to address the issue.⁷⁵ The SACX did suggest preliminary steps for informing the public: providing opportunities for the public to engage in open dialogue on xenotransplantation, requiring that members of the advisory group be accessible for interviews, and asking the advisory group to remain well-informed regarding developments in xenotransplantation trials to facilitate the accurate dissemination of information to the community.⁷⁶ Other recommendations include creating informational resources about xenotransplants and increasing interaction with similar international groups.⁷⁷

Xenotransplantation does not necessarily warrant obtaining public consent, despite the public’s risk of contracting disease from the recipient. The public is exposed daily to numerous health risks, yet no consent is required. For example, bad pollution practices might increase a community’s risk of cancer, but the polluting entity is not required to secure “community consent.” Likewise, the public is exposed to virulent agents everyday by persons secretly or unknowingly infected with HIV, yet no public consent must be obtained for them to move about freely in the community. And community consent is not required when persons who have been treated for tuberculosis or Ebola virus are released back into the community. Granted, the means for diagnosing and treating these diseases are well known, while the presentation of a potential xenozoonosis remains an event yet to be seen.⁷⁸ But not everyone in the general public understands the necessity of taking precautions to protect themselves from contracting AIDS or tuberculosis.⁷⁹ If public consent is not required for other circumstances that jeopard-

⁷⁴ Transcript of Sixth Meeting of the SACX (statement of Robyn Shapiro), *supra* note 55, at 10.

⁷⁵ INFORMED CONSENT IN CLINICAL RESEARCH INVOLVING XENOTRANSPLANTATION, *supra* note 20, at v.

⁷⁶ *Id.* at vii.

⁷⁷ *Id.*

⁷⁸ See CTRS. FOR DISEASE CONTROL, SPECIAL PATHOGENS BRANCH, EBOLA HEMORRHAGIC FEVER (2006), <http://www.cdc.gov/ncidod/dvrd/spb/mnpages/dispages/ebola.htm>; CTRS. FOR DISEASE CONTROL, DIVISION OF TUBERCULOSIS ELIMINATION: QUESTIONS AND ANSWERS ABOUT TB (2005), <http://www.cdc.gov/nchstp/tb/faqs/qa.htm>. See generally REPORT ON THE STATE OF THE SCIENCE IN XENOTRANSPLANTATION, *supra* note 13, at iii.

⁷⁹ See generally AM. SOC. HEALTH ASS’N, LEARN ABOUT STIs/STDs, STD/STI STATISTICS: FAST FACTS (Oct. 9, 2006), http://www.ashastd.org/learn/learn_statistics.cfm; USAID: REDUCING THE THREAT OF INFECTIOUS DISEASES OF MAJOR PUBLIC HEALTH IMPORTANCE: USAID’S INITIATIVE TO PREVENT AND CONTROL INFECTIOUS DISEASES, at 1 (Mar. 1998), http://www.usaid.gov/our_work/global_health/id/idstrategy.pdf.

ize the public's health, by analogy neither should it be required for xenotransplantation. Assuming a zoonosis would be passed by the regular vectors of transmission, people are already educated to understand the importance of basic, preventative health measures. Today, educating the public on matters of health and safety is often largely a function of the public school system.⁸⁰ For example, by the time most children leave elementary school they know not to have unprotected sex or share needles. Obtaining public consent to xenotransplantation should not pose yet another roadblock to implementing clinical trials. Rather than trying to tackle the complex obstacles to obtaining societal consent, a more feasible route might be simply utilizing the educational programs already in place.

V. EXISTING LEGISLATION IS INADEQUATE TO ENFORCE INFORMED CONSENT

Federal statutes governing informed consent requirements in clinical research provide specific measures for obtaining a research study participant's consent and guidance for regulatory oversight.⁸¹ Several conditions must be satisfied before human subjects can be used in research.⁸² In addition, informed consent must be obtained in written form, approved by the appropriate Institutional Review Board (IRB), and the agreement to participate in the study may be revoked at any point if the subject so chooses.⁸³ However, federal law fails to define what constitutes "legally effective" consent, and is silent with regard to enforcing participants' consent to long-term surveillance measures.⁸⁴ Furthermore, the statute omits any mention of situations where the participants jeopardize public health by withdrawing from the study or refusing to comply with monitoring procedures to which they have already consented.⁸⁵

Regulatory oversight of all xenotransplantation clinical trials belongs to the Food and Drug Administration (FDA), an agency of

⁸⁰ See THE CTR. FOR HEALTH & HEALTH CARE IN SCHOOLS, POLICY & PROGRAM, <http://www.healthinschools.org/policy.asp> (last visited Feb. 6, 2006).

⁸¹ See generally 21 C.F.R. § 50 (2005); FDA ORG., U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/opacom/7org.html> (last visited Jan. 12, 2006).

⁸² The subject must voluntarily agree to participate, any unwarranted influence or coercion must be minimized, the subject may not be required to waive any legal rights, and unambiguous language that releases or appears to release the researcher from negligence liability cannot be used. 21 C.F.R. § 50.20 (2005).

⁸³ §§ 50.25, 50.27.

⁸⁴ See generally § 50.

⁸⁵ *Id.*

DHHS.⁸⁶ The FDA controls all clinical investigations, and requires that investigations be subject to review by IRBs that meet the FDA's approval.⁸⁷ In addition, DHHS created the SACX in 1997 to "consider the full range of complex scientific, medical, social, and ethical issues, and the public health concerns raised by xenotransplantation" and advise the Secretary of Health and Human Services on "policy and procedures."⁸⁸

The FDA, the PHS, and the SACX have all issued reports providing guidance on various aspects of xenotransplantation.⁸⁹ The reports also make appropriate recommendations for dealing with informed consent issues and risks to intimate contacts and the general public.⁹⁰ However, the reports supply only guidance, and as such, they may be ignored without legal consequences.

The PHS Guideline on Infectious Disease Issues in Xenotransplantation advocates extensive counseling procedures to ensure that recipients grasp the extent of the responsibilities accompanying the choice to participate in a clinical trial.⁹¹ Participants should be educated concerning the risk of infection from a xenograft, the risk of transmitting an infectious agent to close contacts or other susceptible persons, the need to report unexplained illnesses, possible isolation of the recipient should he or she develop an infection, the significance of adhering to long term surveillance measures, and the responsibility of keeping researchers informed as to the recipient's location and contact information.⁹²

The Guideline also outlines the participant's duty to educate their intimate contacts about the risk of zoonosis, behaviors that may facilitate the transmission of any zoonotic agent from the

⁸⁶ Public Health Service Act, 42 U.S.C. §§ 262, 351 (2005); Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321 et. seq. (2005). The Investigational New Drug Act gives the FDA regulatory control over clinical trials. 21 C.F.R. § 312.2 (2005).

⁸⁷ 21 C.F.R. § 56.103(b) (2005).

⁸⁸ ABOUT THE SACX, *supra* note 30; *see also* INFORMED CONSENT IN CLINICAL RESEARCH INVOLVING XENOTRANSPLANTATION, *supra* note 20, at vii (SACX is to make recommendations to the DHHS on policy and procedures).

⁸⁹ *See generally* REPORT ON THE STATE OF THE SCIENCE, *supra* note 13; INFORMED CONSENT IN CLINICAL RESEARCH INVOLVING XENOTRANSPLANTATION, *supra* note 20; FDA GUIDANCE FOR INDUSTRY, *supra* note 6; PHS GUIDELINE ON INFECTIOUS DISEASES IN XENOTRANSPLANTATION, *supra* note 10.

⁹⁰ *See generally* REPORT ON THE STATE OF THE SCIENCE, *supra* note 13; INFORMED CONSENT IN CLINICAL RESEARCH INVOLVING XENOTRANSPLANTATION, *supra* note 20; FDA GUIDANCE FOR INDUSTRY, *supra* note 6; PHS GUIDELINE ON INFECTIOUS DISEASES IN XENOTRANSPLANTATION, *supra* note 10.

⁹¹ PHS GUIDELINE ON INFECTIOUS DISEASES IN XENOTRANSPLANTATION, *supra* note 10, at 20–21.

⁹² *Id.*

recipient to the other person, and the need for intimate contacts to report unexplained illnesses to the research team.⁹³ Yet, the document expressly disclaims any legal authority and stops short of making any further recommendations for ensuring compliance with monitoring: “[This guideline] is intended to provide general guidance to local review bodies evaluating proposed xenotransplantation clinical protocols and . . . does not create or confer any rights for or on any person and does not operate to bind PHS or the public.”⁹⁴

In September of 2004, the SACX issued two reports for public comment: The Report on Informed Consent in Clinical Research Involving Xenotransplantation and The Report on the State of the Science in Xenotransplantation.⁹⁵ According to the Informed Consent Report (IC Report), informed consent requires disclosure, comprehension, and voluntariness: “(1) disclosure of relevant information on the part of researchers through discussions and materials; (2) comprehension by prospective research participants; and (3) voluntariness on the part of prospective research participants.”⁹⁶ Informed consent entails educating subjects that their compliance with “public safety measures” (involving, for example, long-term monitoring, the possible need for isolation, and autopsy upon death) is vital, as well as obtaining their agreement to comply with such measures.⁹⁷ The IC Report recommends establishing a “consent team” as part of the research protocol to assist in educating the participants and their intimate contacts on informed consent issues and relevant behavior modifications.⁹⁸ Participants should also be advised that if an infectious event occurs and they refuse to comply with surveillance measures, the state can invoke public health laws to deal with the situation.⁹⁹ However, the SACX acknowledges that most state public health laws only apply once an individual manifests signs of infection.¹⁰⁰

The crux of being prepared to deal with an infectious event lies in the researchers’ access to periodic tissue samples, allowing them

⁹³ *Id.* at 20.

⁹⁴ *Id.* at 12.

⁹⁵ See REPORT ON THE STATE OF THE SCIENCE, *supra* note 13; INFORMED CONSENT IN CLINICAL RESEARCH INVOLVING XENOTRANSPLANTATION, *supra* note 20.

⁹⁶ INFORMED CONSENT IN CLINICAL RESEARCH INVOLVING XENOTRANSPLANTATION, *supra* note 20, at ii.

⁹⁷ *Id.* at vi.

⁹⁸ *Id.* at 6.

⁹⁹ *Id.* at 20.

¹⁰⁰ *Id.* at 21.

to study and track disease development.¹⁰¹ Thus, the application of public health laws to enforce isolation and quarantine of the infected individual would occur too late to prove helpful. Participants' compliance is most crucial before the onset of any disease is apparent. The IC Report concludes by admitting that current state laws are inadequate to enforce such compliance, and by recommending that legislatures review and amend state laws as necessary to enforce compliance.¹⁰²

The Supreme Court has validated the use of state public health laws to enforce vaccinations to protect against the spread of disease.¹⁰³ Additionally, state courts have endorsed the use of isolation and quarantine measures under the state's police power to protect the community from persons infected with a communicable disease.¹⁰⁴ Looking to state public health laws provides one putative avenue for dealing with noncompliance; however, the SACX fails to offer any guidance on legislative amendments that would compel compliance without making public health laws unconstitutional.¹⁰⁵

Before the advent of modern medicine, the state's authority to take drastic measures to prevent epidemics was vital to maintaining health and order in the community.¹⁰⁶ The advancement of medicine in preventing, treating, and controlling the outbreak of disease has decreased the danger of widespread infection in the population, rendering the use of public health laws that infringe on individual

¹⁰¹ See INFORMED CONSENT IN CLINICAL RESEARCH INVOLVING XENOTRANSPLANTATION, *supra* note 20, at iv, 20; GUIDELINE ON INFECTIOUS DISEASES IN XENOTRANSPLANTATION, *supra* note 10, at 19.

¹⁰² See INFORMED CONSENT IN CLINICAL RESEARCH INVOLVING XENOTRANSPLANTATION, *supra* note 20, at 20–21.

¹⁰³ *Jacobson v. Commonwealth of Massachusetts*, 197 U.S. 11, 38 (1905) (using a rational basis test to uphold a Massachusetts law allowing cities to mandate smallpox vaccinations).

¹⁰⁴ See *Ex Parte Dillon*, 186 P. 170, 171–72 (Cal. App. 2d 1919) (acknowledging the state's right to use isolation and quarantine where the state had reasonable basis to believe the person was infected with a communicable disease); *Duncan v. City of Lexington*, 244 S.W. 60, 61 (Ky. 1922) (affirming the power granted by state law to effect isolation and quarantine of prostitutes carrying a contagious form of syphilis); *City of New York v. Antoinette R.*, 630 N.Y.S.2d 1008, 1011–12 (N.Y. App. Div. 1995) (upholding forced detention of a patient with active tuberculosis when the patient refused to comply with monitoring responsibilities). *But see Best v. Bellevue Hosp. New York, NY*, 115 Fed. App'x. 459, 461 (2d Cir. 2004) (patient with active tuberculosis claimed hospital illegally detained him, violating his Fourth and Fourteenth Amendment rights, and appellate court decided in his favor on procedural grounds).

¹⁰⁵ See generally REPORT ON THE STATE OF THE SCIENCE, *supra* note 13; INFORMED CONSENT IN CLINICAL RESEARCH INVOLVING XENOTRANSPLANTATION, *supra* note 20.

¹⁰⁶ See Toni Locy, *Quarantine Laws Being Updated*, USA TODAY, Apr. 2, 2003, http://www.usatoday.com/news/health/2003-04-22-quarantine_x.htm.

freedoms almost obsolete.¹⁰⁷ Indeed, a number of cases involving public health laws enforcing vaccination or isolation and quarantine date back to the early 20th century.¹⁰⁸

As xenotransplantation trials go forward, state public health laws will once again become vital in protecting societal health from the risks posed by xenotransplantation. Discussions in the scientific and political arenas suggest that such public health laws constitute the best avenue for enforcing compliance with long-term surveillance.¹⁰⁹ However, the current outdated status of public health laws makes them ineffective for dealing with a xenotransplant recipient’s non-compliance with monitoring efforts.¹¹⁰

Texas’ public health laws provide a prime example. The Communicable Disease Prevention and Control Act (CDPCA) seeks to prevent the spread of contagious diseases in the population by conferring authority on the Texas Board of Health, the Texas Department of Health, and the Commissioner to take action in the event of such circumstances.¹¹¹ The CDPCA grants the Board broad powers in the interest of protecting the public health, including the power to order mandatory testing of individuals suspected of being infected with a “reportable disease.”¹¹² Duties allocated to the Board under the CDPCA include exercising its power to control the spread of disease, enacting regulations as needed to enforce the CDPCA, imposing “control measures” (i.e. isolation and quarantine) on a person, animal, location, or thing as needed, and taking action to stop the introduction of a disease into the state.¹¹³ The Board determines which diseases qualify as “reportable diseases,” what constitutes ex-

¹⁰⁷ *Id.*

¹⁰⁸ See, e.g., *Jacobson v. Massachusetts*, 197 U.S. 11 (1905); *Ex Parte Dillon*, 186 P. 170 (Cal. App. 2d 1919); *Duncan v. City of Lexington*, 244 S.W. 60 (Ky. 1922).

¹⁰⁹ See INFORMED CONSENT IN CLINICAL RESEARCH INVOLVING XENOTRANSPLANTATION, *supra* note 20, at iv, vi, 16, 20–21; Patrik S. Florencio & Erik D. Ramanathan, *Legal Enforcement of Xenotransplantation Public Health Safeguards*, 32 J.L. MED. & ETHICS 117, 119 (2004) [hereinafter “Florencio & Ramanathan”].

¹¹⁰ Transcript of Sixth Meeting of the SACX (statement of Robyn Shapiro), *supra* note 55, at 11 (commenting on the efficacy of current health legislation for compelling compliance with surveillance measures: “For the most part, our public health laws are very old, and they do not fit well with [the asymptomatic recipient who simply fails to comply with the surveillance instructions]”); Florencio & Ramanathan, *supra* note 109, at 119 (“As currently formulated, however, the generally applicable public health law provisions in most jurisdictions in the United States . . . are inadequate to enforce xenotransplantation surveillance.”).

¹¹¹ TEX. HEALTH & SAFETY CODE ANN. §§ 81.001, 81.041, 81.081–.082 (Vernon 2003).

¹¹² §§ 81.004, 81.041, 81.050.

¹¹³ §§ 81.004, 81.021, 81.081–.082.

posure, and the procedures for reporting.¹¹⁴ Reporting obligations covered by the Act require persons such as healthcare providers, parents or guardians, school officials, and pertinent laboratory management personnel to report individuals infected with a “reportable disease.”¹¹⁵

The Act requires reporting of communicable diseases, but mandatory reporting is impossible where a zoonosis remains undetected. Thus, the mandatory reporting provision is useless with regard to compelling xenotransplant recipient compliance with long-term testing. First, the types of disease that can trigger mandatory testing are limited to the list of “reportable diseases” compiled by the Board.¹¹⁶ Reporting of any potential xenozoonosis would therefore qualify as mandatory only if the “reportable diseases” list were amended to include infections caused by zoonotic agents.¹¹⁷ Additionally, only certain public service personnel may request mandatory testing of an individual to ascertain whether they are infected with a contagious disease.¹¹⁸ To request testing, an official must believe that exposure has put him or her at risk of contracting the disease, and provide reasons in an affidavit.¹¹⁹ The degree of

¹¹⁴ §§ 81.041, 81.050.

¹¹⁵ § 81.042.

¹¹⁶ TEX. HEALTH & SAFETY CODE ANN. § 81.003(8) (“‘Reportable disease’ includes only a disease or condition included in the list of reportable diseases.”). Texas Administrative Code defines “reportable diseases” as follows:

For purposes of this section ‘reportable disease’ means communicable diseases and health conditions required to be reported . . . including: acquired immune deficiency syndrome (AIDS); amebiasis; anthrax; botulism—adult and infant; brucellosis; campylobacteriosis; chancroid; chickenpox; Chlamydia trachomatis infection; cholera; cryptosporidiosis; dengue; diphtheria; ehrlichiosis; encephalitis; Escherichia coli 0157:H7; gonorrhea; Hansen’s disease (leprosy); Heamophilus influenzae type b infection, invasive; hantavirus infection; hemolytic uremic syndrome (HUS); hepatitis, acute viral; human immunodeficiency virus (HIV) infection; legionellosis; listeriosis; Lyme disease; malaria; measles (Rubeola); meningitis; meningococcal infection, invasive; mumps; pertussis; plague; poliomyelitis, acute paralytic; rabies in man; relapsing fever; Rocky Mountain spotted fever; rubella (including congenital); salmonellosis, including typhoid fever; shigellosis; streptococcal disease, invasive Group A; syphilis; tetanus; trichinosis; tuberculosis; tuberculosis infection in persons less than 15 years of age; typhus; Vibrio infection; viral hemorrhagic fevers; and yellow fever. This list of diseases may change from time to time.

28 TEX. ADMIN. CODE § 122.3 (2006). TEX. HEALTH & SAFETY CODE ANN. § 81.041 lists actions the Board may take in response to “reportable diseases.”

¹¹⁷ See TEX. HEALTH & SAFETY CODE ANN. §§ 81.041, 81.043 (Vernon 2003); 28 TEX. ADMIN. CODE § 122.3 (2006).

¹¹⁸ TEX. HEALTH & SAFETY CODE ANN. § 81.050 (Vernon 2003).

¹¹⁹ *Id.*

uncertainty with xenozoonosis would thwart any attempt to instruct public officials on signs indicating a zoonotic infection. Finally, the greatest need for compliance with long-term surveillance is during the period before or leading up to a possible infection, enabling researchers to track the development of the infectious agent.¹²⁰ Without symptoms indicating the presence of a contagious disease, officials would have no grounds for suspecting the person constituted an exposure risk.

The CDPCA also confers on state health officials the authority to adopt “reasonable and necessary” control measures to avert the spread or influx of disease within the state.¹²¹ Officials must predicate such actions upon a “reasonable cause to believe that an individual is ill with, has been exposed to, or is the carrier of a communicable disease”¹²² Control measures include a variety of restrictive actions, ranging from compelling immunization or detention, to isolation, quarantine and administration of medicine.¹²³ Refusal to voluntarily comply with control measures will subject a person to court order, provided the health official has reasonable grounds for suspecting that the person’s infection represents a direct risk to the community’s health.¹²⁴

Despite the broad discretion afforded state health officials under the CDPCA, many of the reasons mentioned above regarding the law’s effective application also apply to these provisions: they lack the capacity for enforcing xenotransplant study participants’ compliance with long-term surveillance.¹²⁵ First, the Act fails to apply during the time period when surveillance measures are most crucial—before infection has manifested itself such that health officials have “reasonable cause” to believe the individual is ill.¹²⁶ In the situation where the person is asymptomatic and no infection that poses a threat to public health can be clearly established, the Act does not allow for the use of control measures, such as quarantine or isolation.¹²⁷

Second, the procedures for implementing control measures when the person demonstrates non-compliance are time consuming

¹²⁰ See Ramanathan, *supra* note 20, at 946–47.

¹²¹ TEX. HEALTH & SAFETY CODE ANN. § 81.083 (Vernon 2003).

¹²² § 81.083.

¹²³ § 81.082(f).

¹²⁴ § 81.083(e).

¹²⁵ § 81.083(b)

¹²⁶ *Id.*

¹²⁷ §§ 81.082, 81.083.

and cumbersome. Before control measures may be enforced with non-compliant persons, a court order must be obtained and a written copy delivered personally or by certified mail to the infected individual.¹²⁸ The suspected individual retains the right to counsel and a jury trial, and once appointed, the attorney may cause further delay by requesting documents and information.¹²⁹ Unless otherwise specified under the Act, the person remains at liberty until the conclusion of the hearing, allowing her or him to continue to expose others to infection.¹³⁰ Once the case reaches trial, the jury determines (1) “if the person is infected with or is reasonably suspected of being infected with a communicable disease that presents a threat to the public health,” and (2) whether the person “has refused or failed to follow the orders of the health authority.”¹³¹ Should a person develop a xenozoonosis, these unwieldy procedures would obstruct any aggressive measures required to successfully treat the individual, locate other persons in the community infected by exposure, and arrest the spread of disease. Refusal to comply with any of the CDPCA’s provisions carries criminal consequences, but since the greatest need for enforcing compliance occurs before the Act applies, these consequences are irrelevant.¹³²

VI. EVALUATION OF STRATEGIES FOR DEALING WITH ANALOGOUS RISKS PRESENTED BY OTHER DISEASES, AND PROPOSED SOLUTIONS.

The breadth of informed consent required by xeno-transplantation poses several novel dilemmas. First, the need for adherence to long-term surveillance directly conflicts with federal regulations that prohibit the waiver of any legal rights and that require the subject be free to withdraw from the study at any time.¹³³ Proposed statutes or changes in existing legislation must withstand constitutional scrutiny, or they will be invalidated by the courts, leaving the public unprotected and the scientific community hampered in its

¹²⁸ TEX. HEALTH & SAFETY CODE § 81.083(c).

¹²⁹ §§ 81.050(f), 81.160, 81.170.

¹³⁰ § 81.160. A motion for protective custody may be granted where public health officials have reason to believe the individual qualifies for protective custody. § 81.161.

¹³¹ § 81.170(f).

¹³² See, e.g., §§ 81.049, 81.087.

¹³³ INFORMED CONSENT IN CLINICAL RESEARCH INVOLVING XENOTRANSPLANTATION, *supra* note 20, at 20.

efforts to study and track disease development.¹³⁴ Second, the need for consent from third parties such as intimate contacts and health-care workers calls for new protocols and regulations because none currently exist.¹³⁵ Third party compliance with long-term monitoring also implicates possible violations of constitutional rights.¹³⁶ Finally, the public health concerns raise difficult considerations: is it possible to obtain “societal consent”?¹³⁷ Does the public’s interest in safety and health at some point override the individual’s autonomy and constitutional rights?

Thus far, proposed solutions for enforcing compliance include using contract law to bind recipients to their consent to monitoring, amending existing public health laws to include xeno-specific provisions, implementing a system of rewards and punishments to motivate compliance, and relying on counseling and education to impress upon xenotransplant recipients the necessity of continued, periodic testing.¹³⁸

A. Contract Law

Under principles of contract law, the process of informed consent would be viewed as a contract binding the participant to the specific performance of complying with surveillance measures.¹³⁹ However, several problems with this course of action make it impractical. One inherent difficulty lies in the fact that current federal law reserves to research subjects the right to withdraw from a clinical trial at any point.¹⁴⁰ Another lies in the question of whether contract law could overcome the concept of “self-determination” fundamental to our notion of informed consent.¹⁴¹ According to SACX, “self-determination” is the concept that “prospective subjects have a right to make free and autonomous “yes” or “no” choices with respect to their becoming involved in medical research.”¹⁴² One “yes” on a subject’s part would bind him or her to a lifestyle of re-

¹³⁴ Ramanathan, *supra* note 20, at 940, 946–47.

¹³⁵ INFORMED CONSENT IN CLINICAL RESEARCH INVOLVING XENOTRANSPLANTATION, *supra* note 20, at iv.

¹³⁶ See Ramanathan, *supra* note 20, at 951.

¹³⁷ See Caulfield, *supra* note 72, at 90.

¹³⁸ Florencio & Ramanathan, *supra* note 109, at 118–19.

¹³⁹ *Id.* at 119.

¹⁴⁰ 21 C.F.R. § 50.25(8) (2005).

¹⁴¹ Ramanathan, *supra* note 20, at 949.

¹⁴² INFORMED CONSENT IN CLINICAL RESEARCH INVOLVING XENOTRANSPLANTATION, *supra* note 20, at 3.

stricted freedoms, and the desperation of a subject's position would likely interfere with his or her ability to rationally appreciate the gravity of giving consent.¹⁴³

Finally, with whom would the subject be contracting—the institution conducting the research or perhaps the federal government?¹⁴⁴ Would the relevant entity be able to enforce the contract in the courts?¹⁴⁵ Because no case law exists regarding an agreement to both render lifelong performance and relinquish civil rights, an informed consent contract would be an issue of first impression for the courts. Such a contract would essentially require participants to relinquish their civil rights to bodily integrity and privacy, specifically the rights to refuse unwanted bodily touching and unwanted medical treatment.¹⁴⁶

It is doubtful that courts would find constitutional a contract with the government host institution or society, given both the recipients' disparate bargaining power and the fact that the contract requires recipients to contract away their civil rights.¹⁴⁷ The inequality in bargaining positions might also lead courts to invalidate such contracts on grounds of unconscionability.

B. Xeno-Specific Public Health Legislation

Public health laws specifically addressing xenotransplantation provide another venue for enforcing long-term compliance with monitoring. In the 1990s, New York enacted tuberculosis laws in response to outbreaks of tuberculosis in the community.¹⁴⁸ These laws provide one illustration of disease-specific public health legislation.¹⁴⁹ Asymptomatic carriers who were noncompliant with follow-up treatments were thought to be the source of infection in the population.¹⁵⁰ The new legislation allowed the use of police power by New York's public health officials to forcibly detain patients who quit complying with treatment measures.¹⁵¹ The risk to the public's

¹⁴³ Most recipients are likely to be very ill and desperate—their lives depend on obtaining a transplant. CAMPAIGN FOR RESPONSIBLE TRANSPLANTATION, WHAT'S WRONG WITH XENO?, <http://www.crt-online.org/wrong.html> (last visited Jan. 12, 2006).

¹⁴⁴ See Ramanathan, *supra* note 20, at 950–51.

¹⁴⁵ *Id.* at 951.

¹⁴⁶ *Id.*

¹⁴⁷ *Id.*; CAMPAIGN FOR RESPONSIBLE TRANSPLANTATION, *supra* note 143.

¹⁴⁸ Coker, *supra* note 37, at 157.

¹⁴⁹ *Id.*

¹⁵⁰ *Id.*

¹⁵¹ *Id.*; see also NY PUB. HEALTH § 2120 (McKinney 2005).

health justified the use of coercive techniques because it was impossible to determine who would develop the disease.¹⁵²

Similar legislation could be enacted to compel compliance with long-term surveillance measures. The main difference between the tuberculosis statutes that New York enacted and possible xenotransplant-specific legislation lies in basing the law’s applicability on the individual’s health status. Whereas New York’s laws applied once the person was known to be infected with tuberculosis, xeno-specific legislation would need to apply to all xenotransplant recipients, regardless of the individual’s state of health.

Xeno-specific public health laws could grant the government power to enforce compliance with lifelong surveillance, either through withholding certain benefits, or by increasing local public health officials’ police power to isolate and detain non-compliant individuals. Forced detainment in other public health contexts is based on the rationale that the person presents a sufficient risk to society to justify elevating the public good over the individual good.¹⁵³ The same argument applies where xenotransplant recipients might risk the health of the entire community by refusing to adhere to monitoring protocols.

Legislative attempts to deal with the public health threat represented by avian influenza (flu viruses that infect birds, also caused by a zoonotic agent¹⁵⁴) are pertinent when considering xeno-specific legislation. Though no laws have been passed that specifically address the prevention of an avian flu outbreak or the resulting response, forthcoming legislation in this area holds promise for guiding the drafting of similar xeno-specific legislation. Issues related to the threat of an avian influenza pandemic mirror the concerns raised by non-compliant xenotransplant recipients. For example, scientists cannot predict which strain of flu virus infecting birds could eventually cause a pandemic, the risks that specific viruses pose to humans, or the magnitude of infection should an outbreak occur.¹⁵⁵ Similarly, unpredictable factors prevent forecasting

¹⁵² Coker, *supra* note 37, at 157–58; see also *Antoinette R.*, 630 N.Y.S.2d at 1016–17; *City of New York v. Doe*, 205 A.D.2d 469 (N.Y. App. Div. 1994) (clear and convincing evidence standard must be met when showing failure to comply with monitoring and treatment).

¹⁵³ Coker, *supra* note 37, at 158–59.

¹⁵⁴ CTRS. FOR DISEASE CONTROL & PREVENTION, DEP’T OF HEALTH & HUMAN SERVS., AVIAN INFLUENZA (BIRD FLU): TRANSMISSION OF INFLUENZA A VIRUSES BETWEEN ANIMALS AND PEOPLE (Oct. 17, 2005), <http://www.cdc.gov/flu/avian/gen-info/transmission.htm>.

¹⁵⁵ *Bio-Security Coordination for Agricultural Products: Testimony Before the S. Subcomm. on Research, Nutrition and General Legislation*, 109th Cong. 15–16 (2006) WL 52804 (F.D.C.H.) (Jan.

the development of xenoses.¹⁵⁶ Ongoing surveillance measures are also advocated: the DHHS argues that year-round surveillance of flu developments is crucial for prompt detection and for maintaining the preparedness to deal with a flu pandemic.¹⁵⁷ One suggestion before the Committee on House Government Reform involved developing a “population-based surveillance among adults hospitalized with influenza.”¹⁵⁸

The premise behind this suggestion is that “timely case reporting constitutes the backbone of the early warning system for detecting the emergence of a pandemic virus.”¹⁵⁹ States are currently in the process of developing flu preparedness plans, and due to the similarities between a possible flu pandemic and the spread of a xenosis, adaptation of bird flu legislation to xenotransplantation issues holds promise.¹⁶⁰

Many legal scholars, including those advising the President on the SACX, lean towards xenotransplantation-specific public health legislation as the most viable resolution to the legal dilemmas posed by informed consent.¹⁶¹ Current state public health legislation is inadequate to effectively address the myriad complex legal problems raised by informed consent.¹⁶² Most public health laws allow forced quarantine and isolation only upon proof by clear and convincing evidence that the individual is (1) infected, (2) the disease is contagious, and (3) the disease is fatal enough to create a public health

9, 2006) [hereinafter *Bio-Security Coordination*] (statement of Alex Azar, Deputy Sec. of the Dep't of Health & Human Servs.).

¹⁵⁶ See *supra* text accompanying notes 13–14.

¹⁵⁷ See *Bio-Security Coordination*, *supra* note 155, at 15–16.

¹⁵⁸ *Flu Season Preparation: Testimony Before the H. Comm. on H. Government Reform*, 109th Cong. 4 (2005) WL 1541438 (F.D.C.H.) (Jun. 30, 2005) [hereinafter *Flu Season Preparation*] (statement of James W. LeDuc, Ph.D., Dir., Div. of Viral and Rickettsial Diseases Nat'l Ctr. for Infectious Diseases).

¹⁵⁹ *Avian Flu—Part I, Testimony Before the Comm. on H. International Relations*, 109th Cong., 2005 WLNR 19686686 (Dec. 7, 2005) (statement of Dr. Margaret Chan, Assistant Director-General, World Health Org.).

¹⁶⁰ Newly developed plans include xeno-relevant aspects, such as utilizing surveillance measures and inhibiting infection in the community. *Flu Season Preparation*, *supra* note 158, at 2.

¹⁶¹ INFORMED CONSENT IN CLINICAL RESEARCH INVOLVING XENOTRANSPLANTATION, *supra* note 20, at iv; see also *The Cultural, Spiritual and Ethical Aspects of Xenotransplantation: Animal-to-Human Transplantation: What Are The Risks?*, TOI TE TAIAO: THE BIOETHICS COUNCIL, Jan. 2005, <http://www.bioethics.org.nz/publications/xeno-discussion-jan05/html/page8.html>; Ramanathan, *supra* note 20, at 957.

¹⁶² Ramanathan, *supra* note 20, at 957.

emergency.¹⁶³ As noted above, Texas’ Health Code contains no provision for dealing with an individual who potentially carries an infectious disease when exposure to the agent cannot be reasonably proven.¹⁶⁴ It is doubtful that judicial backing to enforce conformity would be available, except where an “immediate threat from a communicable disease” exists.¹⁶⁵ This means the infection must be highly contagious, as well as carry the potential of causing a large number of fatalities or disabilities due to its virulence, before judicial enforcement would be an option.¹⁶⁶

To be effective, xeno-specific state legislation must withstand constitutional scrutiny. Such laws would aim to prevent and curtail the spread of infectious and pathogenic diseases in the population at large, but requiring a person to submit to periodic monitoring procedures infringes on the individual’s fundamental rights to privacy and bodily integrity. Laws violating an individual’s substantive due process rights, such as the right to privacy, invoke strict scrutiny.¹⁶⁷ As noted above, strict scrutiny requires a compelling state interest and that the means employed be narrowly tailored to the state’s goal in passing the law.¹⁶⁸ The right to refuse unwanted touching and the right to autonomy over one’s person remain deeply rooted in the American concept of privacy.¹⁶⁹

Despite the fact that xenotransplantation holds the potential to save thousands of lives every year, it is doubtful courts would find that the ends justify such infringement on the individual’s autonomy. Courts are reticent to introduce another class of exceptions that strip citizens of their constitutional rights,¹⁷⁰ and that is exactly what such a law would do. Refusing to uphold the government’s power to enforce compliance, the courts would probably find instead that clinical trials should be halted until a means could be

¹⁶³ *Id.* at 957–58. Texas Health and Safety Code only allows the use of measures such as detention, restriction, isolation, or quarantine, to facilitate implementation of a “public health program or policy,” or in the event that an individual has been exposed to or carries a communicable disease. TEX. HEALTH & SAFETY CODE ANN. § 81.082 (Vernon 2005).

¹⁶⁴ TEX. HEALTH & SAFETY CODE ANN. §§ 81.082, 81.083 (Vernon 2005).

¹⁶⁵ § 81.003.

¹⁶⁶ §§ 81.003, 81.083.

¹⁶⁷ Ramanathan, *supra* note 20, at 968–69 (citing *Planned Parenthood of Southeastern Pa. v. Casey*, 505 U.S. 833, 871 (1992)).

¹⁶⁸ *Roe v. Wade*, 410 U.S. 113, 155 (1973).

¹⁶⁹ *Vacco v. Quill*, 521 U.S. 793, 807 (1997); *Cruzan v. Dir., Mo. Dep’t of Health*, 497 U.S. 261, 278 (1990); *Griswold v. Connecticut*, 381 U.S. 479, 486 (1965).

¹⁷⁰ *Cruzan*, 497 U.S. at 278.

crafted to monitor the development of zoonoses without infringing on the recipient's constitutional rights.

Modification of prototypical public health laws, prepared in response to the threat of bioterrorism following the 9/11 events, offer the greatest potential for drafting xeno-specific laws. The Model State Emergency Health Plan Act (MSEHPA), created for the Center for Disease Control (CDC) in 2001, is designed to enable "early detection of a health emergency by authorizing the reporting and collection of data and records, and [to allow] for immediate investigation . . ." without unduly compromising individuals' civil rights and liberties.¹⁷¹ MSEHPA accomplishes this by focusing on achieving a balance between consideration for each citizen's rights and the "common good."¹⁷² This parallels the inherent balance required by xenotransplant legislation: xeno-specific laws must protect the public's health without unjustifiably violating the xenograft recipient's liberties.

MSEHPA also contains language applicable to safeguarding the public health where xenotransplantation is concerned: the phrasing allows action to be taken prior to the development of a xenozoonosis. For example, the Act acknowledges the need for states to have the capacity to respond to prospective or authentic health crises.¹⁷³ Non-compliant xenotransplant recipients would constitute a prospective health crisis due to the possibility of spreading an infectious agent. In addition, the Act specifies that it endeavors to prevent and manage grave threats to the public health.¹⁷⁴ With the potential for spreading a novel infectious agent, xenotransplant recipients would fall under the authority granted by the Act for the "manage[ment]" of public health threats.¹⁷⁵

Several of MSEHPA's provisions could be extrapolated for use in xeno-specific legislation. Section 302, which addresses tracking illnesses, gives public health authorities the power to investigate and implement control measures on persons who "may be potential causes of a public health emergency," which could include xeno-

¹⁷¹ THE CTR. FOR LAW & THE PUBLIC'S HEALTH AT GEORGETOWN & JOHNS HOPKINS UNIVS., THE MODEL STATE EMERGENCY HEALTH POWERS ACT: A DRAFT FOR DISCUSSION (Dec. 21, 2001), <http://www.publichealthlaw.net/MSEHPA/MSEHPA2.pdf>.

¹⁷² *Id.* at 6, 8 ("The rights of people to liberty, bodily integrity, and privacy must be respected to the fullest extent possible consistent with maintaining and preserving the public's health and security.").

¹⁷³ *Id.* at 6-7.

¹⁷⁴ *Id.* at 9.

¹⁷⁵ *Id.* at 6.

transplant recipients.¹⁷⁶ Section 602 authorizes officials to quarantine or isolate “any person whose refusal of medical examination or testing results in uncertainty regarding whether he or she has been exposed to or is infected with a contagious or possibly contagious disease or otherwise poses a danger to public health.”¹⁷⁷ Although section 602 applies only during public health emergencies, the language is pertinent to situations involving xenotransplant recipients who cease adhering to long-term surveillance requirements: refusal to be tested by the recipients “results in uncertainty” regarding the possibility of their carrying an infectious agent.

C. Punitive Measures Versus Rewards

Alternative solutions may offer further insight into possible solutions for compelling compliance. Proposed alternatives include withholding government or health services if the recipient becomes non-compliant, imposing fines for non-compliance, or providing some sort of financial remuneration as incentive to remain faithful to the surveillance measures.¹⁷⁸

Australia’s procedures for enforcing compliance with tuberculosis patients incorporate some of these propositions.¹⁷⁹ Australian law requires that boundaries placed on a non-compliant individual with tuberculosis comport with standards of legitimacy, legality and a minimal amount of restraint.¹⁸⁰ The first step for encouraging compliance involves counseling and education, friend and family support, and conducting an evaluation to determine the obstacles preventing the person from continued compliance with treatment.¹⁸¹ If these procedures prove ineffective, the individual receives letters warning him of the threat his actions pose to the community at large.¹⁸² In addition, financial incentives like compensation for inconvenience or provision of some amount of income are provided in a further attempt to encourage voluntary compliance.¹⁸³ Finally, if the individual remains uncooperative, an “assessment panel” re-

¹⁷⁶ THE MODEL STATE EMERGENCY HEALTH POWERS ACT, *supra* note 171, at 15.

¹⁷⁷ *Id.* at 26.

¹⁷⁸ Atray, *supra* note 12, at 15; Florencio & Ramanathan, *supra* note 109, at 119; Sanjaya N. Senanayake & Mark J. Ferson, *Detention for Tuberculosis: Public Health and the Law*, 180 MED. J. AUSTRAL. 573, 573 (June 2004).

¹⁷⁹ Senanayake & Ferson, *supra* note 178, at 573.

¹⁸⁰ *Id.*

¹⁸¹ *Id.*

¹⁸² *Id.*

¹⁸³ *Id.*

views the case and determines whether a court order for detention is needed.¹⁸⁴ Once the order is issued, the individual may protest.¹⁸⁵

Australia's system combining education, incentive, and legal compulsion offers some direction for crafting xeno-specific legislation. The SACX is already urging that researchers engage in extensive education and counseling of xenotransplant recipients and their intimate contacts.¹⁸⁶ Laws mandating such counseling could provide for the granting or withholding of health and medical treatment based on the individual's adherence to monitoring.¹⁸⁷ Because no fundamental right to medical treatment exists under the common law, the United States Constitution, or case law, this option is more likely to withstand judicial scrutiny. Further incentives could include financial compensation composed of installments paid each time the recipient presents for monitoring or the assurance that as long as the person complies with monitoring, all her or his medical costs, xenograft related or not, will be covered.

The main drawback to the Australian system is the lengthy judicial process required before compliance may be legally compelled.¹⁸⁸ This parallels one shortcoming in current United States public health laws. The length of time required to move through the court system could wind up negating the very reason for enacting the legislation: implementing an efficient means for dealing with non-compliant individuals without jeopardizing the disease monitoring process or the general public. In addition, lawsuits can drag on for years. Does the recipient's medical care remain suspended during that time because they are non-compliant? Continuing to provide healthcare removes the motivation to become compliant again, but suspending it would leave xenotransplant recipients to their own resources. This could result in a situation where a recipient seeks medical care from unaware health care workers, exposing both the workers and the general public to any disease the recipient is potentially carrying.

¹⁸⁴ Senanayake & Ferson, *supra* note 178, at 573.

¹⁸⁵ *Id.*

¹⁸⁶ INFORMED CONSENT IN CLINICAL RESEARCH INVOLVING XENOTRANSPLANTATION, *supra* note 20, at 28.

¹⁸⁷ See Florencio & Ramanathan, *supra* note 109, at 119–20.

¹⁸⁸ See Senanayake & Ferson, *supra* note 178, at 573.

VII. CONCLUSION

The risk of an infectious disease, transmitted via xenotransplantation and spread throughout the community, necessitates long-term surveillance measures. However, because adherence to such lifelong monitoring is likely to decrease over time, means for legal enforcement of compliance with monitoring will be critical to protecting the public's health. Current public health laws are inadequate to deal with the risks that public health non-compliance creates. Thus, the most viable solution lies in drafting xeno-specific legislation.

Modeling xeno-specific laws on proposed bioterrorism emergency health plans carries the greatest promise. Regulations governing compliance with tuberculosis patients can provide guidance for drafting laws, and any bird flu legislation that is eventually enacted would also prove insightful. It is noteworthy that because the threat to public health from xenotransplant recipients is unknown and unpredictable, the crucial language in any law seeking to protect the community from the spread or outbreak of an analogous disease situation will lie in how the statute addresses *potential* risks or threats. To withstand judicial scrutiny, such legislation must take into account the common law right to self-determination, as well as the individual's right to liberty and privacy under the Fourteenth Amendment.

Although model health plans and tuberculosis laws provide some direction, further progress is necessary for xeno-specific legislation to successfully compel compliance with long-term surveillance. Additional incentives for encouraging compliance still need to be developed. Means for educating the public regarding xenotransplantation, including the benefits and risks it offers, as well as precautionary measures people can take to protect themselves and facilitate disease detection, must be implemented before clinical trials proceed. Once laws and a method for disseminating information to the public are established, subsequent problems that must still be addressed include tracking recipients, evaluating the success of the legislation and educational programs, and making adjustments accordingly.

Other areas of remaining development include database development and third-party consent. The National Xenotransplantation Database needs to be developed and implemented with subsequent evaluation of its usefulness, success, and the feasibility of expanding it into a worldwide system. At a minimum, consent by intimate con-

tacts to the taking of a baseline sample should be included in xenolegislation. Ideally, a method for long-term monitoring and communication of information to a xenotransplant recipient's close contacts would be established.

Although the risks raised by xenotransplantation may appear insurmountable, informed law, guided by accurate and established scientific principles, is capable of adequately addressing those risks. "The reasonable man adapts himself to the world; the unreasonable one persists in trying to adapt the world to himself. Therefore all progress depends on the unreasonable man."¹⁸⁹

¹⁸⁹ George Bernard Shaw, *Maxims for Revolutionists: Reason*, BARTLEBY.COM, <http://www.bartleby.com/157/6.html> (last visited Jan. 7, 2007).