Crossing the Immunological Barrier

A man sits shaking on an airplane. Sweat soaks his face, his arms and legs shake uncontrollably. Within hours of landing in California, the man lies dead, and hundreds of people are infected with the same mysterious virus. In another scenario, a teenage boy unknowingly sells drugs laced with a deadly viral strain. Terrorists threaten to release the virus to the nation, causing the entire population to be eradicated within days.

These are the respective premises of the movie *Outbreak* and the television show, *24*. Hollywood has always been fascinated by such apocalyptic themes. Biological weapons and viruses are prevalent instruments used to create movies and shows that depict chaos and mass destruction. Until September 11, 2001, the majority of people viewed these depictions as highly exaggerated dramas. However, when the towers crumbled in New York City, the public was faced with a frightening possibility.

News shows, magazines, and even the U.S. President, made dire predictions about biological threats to national security. Most of the viruses that the government worried about were animal disease strains. Anthrax, SARS, Monkey pox, West Nile virus… the list goes on and on. But what is the likelihood of these diseases causing widespread illness and deaths? This is the question experts are faced with today. This is also the inspiration for writing this article.

The questions surrounding animal importation and diseases are varied and complex. In fact, Hollywood's portrayal of the problem is only one minor element of the issue. This article is divided into four sections. First, the article provides a brief background of problem. Second, the article discusses xenotransplantation and its risk of

spreading diseases. Third, international trade laws are discussed in light of public health concerns. Lastly, the article summarizes the findings of this article and introduces possible prevention and control strategies.

Part One: Background of Zoonotic Diseases

"Zoonoses" is the term used to describe the transmission of animal disease to humans through either airborne or physical contact.[1] The dangers of zoonoses are numerous. Often, the diseases that animals carry are latent and harmless while residing in their bodies. However, once they are transmitted to humans, they may mutate into dangerous or even deadly illnesses. Since animals carry pathogens that humans do not possess, human immune systems are not well-equipped to deal with the onslaught of new, foreign diseases. [2] For example, Macaque herpes is harmless to Macaque monkeys, but lethal to human beings.[3] Similarly, Ebola outbreaks in Sudan, Zaire and the U.S. have been linked to crossing the animal to human immunological barriers. [4] Most recently, the world watched as the latest evidence of cross-barrier viruses proved deadly when Europeans digested meat infected with Foot and Mouth Disease (FMD).[5]

FMD is an extremely virulent disease because it can flourish in almost any condition. [6]FMD can be transmitted via saliva, feces, mucus, milk, tissue, urine, blood or air. Unlike mad cow disease, with which it is most often confused, FMD is usually

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[1] Morgan, Frank. *Babe, the magnificent donor? The perils and promises surrounding transplantation*. 14 J. Contemp. Health L. and Policy 127.
[2] *Id.*.
[3] *Id.*
[4] *Id at *5*.
[5] *Id*
[6] Cooper, Kelly Dickinson. *Trade and Environment: Foot and Mouth Disease Outbreak in Europe Raises Environmental Concerns and Causes Economic Loss*. 2001 Colo. J. Int'l Envt'l and Policy 59.
[6] *Id.*

harmless and rare among humans. Nevertheless, its impact upon world politics was felt in February 2001, when the first case was confirmed in the England. Soon after, exports on alllive animals, meat and dairy products were banned. Farmers across the continent began the mass slaughter of infected animals, and crops were burned to prevent further outbreaks. So while FMD is not as physically damaging to humans as BSE, the consequences of the disease are still severe.

BSE is a prion disease discovered and documented by Nobel Laureate Stanley Prusiner.[7] Prion cells are present in all vertebrates, but in BSE, they mutate and slowly erode brain cells. BSE is a degenerative neurological disorder that is common in bovine.[8] Since its origin is unknown, it was initially difficult to recognize the disease during the first ten years of its outbreak. It was not until Europeans began to die tragically in 2001 that the world learned of mad cow disease. BSE's human form is Creutzfeld-Jakob disease (CJD).[9] CJD has caused ninety-four human deaths in Europe in recent years.[10] This occurred when humans ate meat from cows that were infected with BSE.[11] Humans infected with CJD suffer from loss of memory, tremors, hallucinations, weakness, and eventually cannot talk or walk. There is no known cure for the disease.

At the moment, BSE is considered to be a European problem, since there are no known cases in the United States. This is mainly due to the United States' quick prevention strategies. Soon after the outbreak was confirmed to be linked to meat, the United States banned its importation. Nevertheless, the possibility that such a disease could permeate our borders has raised several concerns about the efficacy of food and animal centers.

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[7] Prusiner, Stanley. *The prion diseases*. Sci. Am 272: 70-77, 1995,2.
[8] *Id.*
[9] *Trade and Environment* at *2.
[10] *Id.*
[11] *Id.*

Bovine diseases are only one type of zoonoses. Other illnesses include West Nile Virus, dengue fever, anthrax and SARS. Since these are all infectious diseases, they are often classified as emerging infectious disease or EID. Examples of EID include typhoid, smallpox and malaria. These diseases are better documented and recognizable than zoonotic diseases because their existence dates to early existence. Thus, zoonoses poses a greater problem than regular infectious diseases because it is still an uncharted territory. As new diseases emerge, scientists work hastily to discover their origins, symptoms and how to contain them. In the meantime, the EID infects and spreads unhindered. Most importantly, zoonotic diseases pass human immune systems and take root within the human body. In most instances, this permeation occurs unintentionally through physical or airborne contact. However, in the case of xenotransplantation, permeation may occur willfully when patients subject themselves to this procedure.

Part Two: The Interesting Problem of Xenotransplantation

1. Background

Xenotransplantation is an innovative medical procedure in which tissues, organs, body fluids and cells from animals are transplanted into humans.[12] Xenotransplants perform the same functions as the human materials they replace. The procedure is intended as a solution to the shortage of human organs (allotransplants).[13] End-stage organ failure is

[12] Florenico, Patrick S. *Are xenotransplantation safeguards legally viable?* www.lawgenecentre.org/links/about.php?ID=925.
[13] Fishman, Jay. *Infection in xenotransplantation*. British Medial Journal, September 23, 2000 at 1.

the most critical health problem facing Americans today.[14] Currently, more than 65,000 people are on the national organ transplant waiting list.[15] Approximately 4,000 of them die annually while waiting for a suitable organ transplant.[16]

Heart failure cases provide another potent example of the insufficient supply of organ transplants. Heart failure kills four times more people than HIV infection.[17] The most effective remedy to heart failure is transplantation. Unfortunately, the demand for organ donations far exceeds its supply. It is estimated that only 2,000 human hearts are available annually for approximately 45,000 patients who could use them.[18] Given these statistics, it is little wonder that scientists have tried to devise alternatives to human organ donations. The most popular choice has been to turn to animals for organ donations.

2. History

Cross-species transplantation dates back to the early twentieth century, when kidney xenografts of rabbit, pig, goat, primate and lamb donors were used.[19] After a series of fatal procedures, however, scientists did not attempt further procedures until the 1950s. In 1954, Drs. Murray, Harrison and Merrill performed the first successful human kidney transplant between identical twins at the Brigham Hospital in Boston Massachusetts.[20] Twenty years later, the first successful heart transplant followed suit.[21] Unfortunately, the lives of these recipients were often not extended beyond a few days. In fact, the longest

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[14] *Xenotransplantation: risks, clinical potential and future prospects.* EID Volume 2, November 1, January-March 1996.
[15] See http://www.digitaltermpapers.com/view.php?url=/Business/Supply_and_Demand.shtml.
[16] *Id.*
[17] *Infection in xenotransplantation* at 3.
[18] *Id.*
[19] *Xenotransplantation: risks, clinical potential* at 4.
[20] *A Brief History of transplantation.* The Heart of the Matter newsletter. December 2003.
[21] *Id.*

survivor at that time was a newborn baby with hypoplastic left heart syndrome. "Baby Fae" received a mismatched ABO-blood group baboon heart that only functioned for 20 days.[22]

Initially, primates were the chosen donors because they are the most similar species to human beings. [23]Scientists hoped their anatomical structures would be so compatible that immune rejection would not occur. However, these attempts were largely unsuccessful.[24] Their failure was due to the fact that primates do not have Type O blood types (the universal donor) and cannot be bred in large colonies.[25] Additionally, numerous animal rights organizations decried the practice. They claimed it exploited animals that had similar structures, feelings and thought processes of human beings.

3. Using Pigs as Donors

Undeterred, scientists then looked to pigs for potential donorship. Pigs, particularly miniature swine, are most desirable because their organs are similar in size and anatomy to humans.[26] Additionally, they are abundant and generally accepted as a source of food, clothing and goods.[27] Therefore, the use of pigs does not garner the same level of controversy that primates do. In fact, the Nuffield Bioethics Committee concluded in its second report that using pigs was ethical while using primates was not. [28]

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[22] *Id.*
[23] *Id.*
[24] Jodi K. Fredrickson, *HE'S ALL HEART . . . AND A LITTLE PIG TOO: A LOOK AT THE FDA DRAFT XENOTRANSPLANT GUIDELINE.* 52 Food Drug L.J. 429 at*2
[25] *Xenotransplantation: risks, clinical potential* at *2.
[26] Professor Fritz H. Bach, *Ethical and Legal Issues in Technology: Xenotransplantation*. 27 Am. J.L. and Med. 283 at *2.
[27] *Id.*
[28] *Id* at 5.

However, the main obstacle with using pigs as donors for xenotransplantation is that all pigs are born with two copies of a gene that create a sugar molecule that attaches to cell surfaces.[29] This molecule, called alpha-1-galactose, is very similar to a bacterial sugar. Thus, when a pig organ is inserted into a human body, the human immune system releases antibodies to aggressively fight the foreign substance. This inevitably leads to rejection of the organ within a matter of minutes. [30]

In response to this problem, scientists have genetically altered pig organs to become more compatible with humans. In February 2003, a Wisconsin biotech firm, Infigen, claimed it had genetically engineered and cloned a litter of three miniature swine in which both copies of the gene that creates alpha-1-galactose-have been suppressed.[31] This recent development has major repercussions. Like the cloning of Dolly the sheep, it allows for the creation of more genetically engineered creatures. By creating pigs that can theoretically be transplanted into humans without being rejected, Infigen has leapt forward into a new age of transplantation. The consequences of this discovery are numerous. With them come increased responsibilities and legal concerns.

4. The procedure

The first step in the process of xenotransplantation is to find a suitable animal donor. Just as in allotransplantation (the procedure of transplanting organs from one human to another), recipients receive drugs after the transplant to reduce the risk of immune rejection. Unfortunately, the use of immunosuppression drugs makes the recipient

[29] *Id.*
[30] John Fauber, *Cloned piglets may be successful in human transplants, firm says*. The Milwaukee Journal Sentinel, February 28, 2003.
[31] *Id* at *1.

more susceptible to ordinary diseases. Usually, when an organ is transplanted, some level of rejection occurs despite the compatibility of the match. The use of non-human organs heightens the risk of such rejection. It also elevates the need for immonsupression drugs, which increases the recipient's chances of infection and illness. "[T]transplanting a non-human primate organ into a human recipient will require a greater level of immunosuppression in the recipient than the same procedure involving a human organ; and a pig organ will involve an even greater level of immunosuppression in the recipient than the organ from the non-human primate".[32]

Furthermore, the traditional barriers of skin, immune systems and gastrointestinal tracts that protect humans from the spread of infections are circumvented when xenotransplantation takes place. Thus, animal diseases are essentially imbedded into the natural make-up of a human being. Since pigs are vastly different than humans, the cross-species barrier that is being circumvented is so wide that the potential for diseases is greater.[33] One of the greatest risks to xenotransplantation with pig organs is that a pig virus may infect the human recipient and mutate. [34] The most potent virus that swine carry is porcine endogenous retroviruses (PERV). PERV belongs to the same family of retroviruses that cause AIDS. [35] Unlike other viruses that can be eliminated through breeding or raising pigs in a sterile environment, PERV is imbedded into the typical genetic makeup of pigs. Therefore, it is hereditary and cannot be suppressed like the gene that creates alpha-1-galactose. [36]

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[32] *Draft guidelines* at *3.
[33] Fano, Alix. *Of Pigs, Primates and Plagues* at http://www.mrmcmed.org/pigs.html. Physiological and anatomical differences between humans and pigs call into question the rationale for their use. These include differences in life-span, heart rate, blood pressure, metabolism, immunology, and regulatory hormones.
[34] *Ethical and Legal Issues* at *2
[35] *Id* at *2.
[36] *Cloned piglets* at *2.

The disease is even more dangerous because it is difficult to quantify the risks it poses to humans. Since no solid pig organ has yet been transplanted into a human, it is impossible to ascertain exactly what risks human may encounter. By the same token, it is also impossible to develop drugs or safeguards against such potential risks. In a worst case scenario, if solid pig organs are transplanted without safeguards, PERV and other diseases could not only infect the recipient's immune system but also all friends, family members, and others s/he may come in contact with.[37]

Even if the strictest safeguards are enforced, xenobiotechnology will always carry the risk of introducing and spreading zoonotic diseases. Besides PERV, pigs are known to have at least 25 diseases that can be transmitted to humans.[38] For instance, the deadly human influenza virus in 1918 that killed approximately 20 million people worldwide was a mutation of a swine flue virus. [39] Most recently, the "Nipah" virus, discovered in Malaysia in late 1998, spread from pigs to hundreds of humans.[40] This led to the mass slaughter of some one million pigs, as well as several dogs and horses.

Although many critics argue most claims about possible xenotransplant outbreaks are unsubstantiated, some facts are undisputed. Scientists know viruses can infect one organism while passing to another. They also know a virus that is harmless in one species may be lethal in another. HIV, the human immunodeficiency virus, is one example of this risk.[41] Many researchers believe HIV originated from primates.[42] These scientists believe

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[37] *Ethical and Legal issues* at *3.
[38] *Id.*
[39] *Of Pigs, Primates and Plagues* at *4.
[40] *Id.*
[41] *This Little Piggy Went to Market: The Xenotransplantation and Xenozoonoses Debate* 27 J.L. Med. & Ethics 137.
[42] *Id.*

HIV is a simian immunodeficiency virus(SIV) that crossed the species barrier in Africa.[43] If this is true, primates have never suffered the devastating effects of HIV that humans have. So HIV, like other cross-species viruses, is more dangerous in humans than in its original animal hosts. Similarly, monkey pox, Ebola and other viruses are prevalent among monkeys.[44] When they passed to human beings, though, the consequences have been terrible.

Dozens of such infections have been documented in journal articles of the last decade. The major problem with zoonoses is that it creates unforeseeable health risks for both the recipients and the general public. The basic structure of these diseases lends itself to mass outbreaks. Since the diseases are often latent and highly contagious, it is easy for an infected individual to spread the disease to family, friends and community members. Also, the fact the procedure is so new makes it is difficult to evaluate exactly how great this risk is.

5. Prevention and Control

These sobering facts have led this author to conclude that xenotransplantation undermines any real efforts to control infectious diseases. With the increased awareness of animal diseases, the potential for outbreaks has become a very serious possibility. Thus, the need for legally viable safeguards against these dangers is substantial. In order to minimize the possibility of more outbreaks, the federal government must increase its regulation of xenotransplantation.

[43] *Of Pigs, Primates and Plagues* at *4.
[44] *Id.*

In 1996, the Centers for Disease Control (CDC), the Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS) published a set of guidelines for xenotransplantation.[45] It suggested all xenotransplantation procedures should be regulated under new FDA investigational new drug regulations and informed consent laws.[46] However, the FDA has not yet adopted these guidelines. Nonetheless, the guidelines are useful when trying to determine what safeguards can be placed on xenotransplantation.

The guidelines suggest the federal government should provide for specially designated teams that monitor data, tissue storage and surveillance. It also recognizes the need for government regulated clinical facilities, protocol reviews, informed consent regulations and the maintenance of animal donor populations. [47] Such prevention strategies are an important step, but pose several legal and ethical dilemmas.

a. Surveillance

Most commentators agree that any attempt to control the spread of infectious disease requires a surveillance system. However, it is important to recognize such a system would not prevent the spread of disease on its own. Due to the nature of these diseases, many infections can spread, undetected, even under the most rigorous surveillance system. Furthermore, a system designed to monitor the progress and movement of individual recipients could clash with basic fundamental rights. For example, the rights to travel, movement and privacy would necessarily be infringed by such a system. These rights have been historically recognized and honored bythe U.S judicial system.

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[45] See U.S. Dep't of Health and Human Services, PHS Guidelines on Infectious Disease Issues in Xenotransplantation, at http://www.fda.gov/cber/gdlns/xenophs0101.pdf (January 19, 2001)
[46] *Id.*
[47] *Id.*

In *Apetheker v. Secretary of State*, for example, the U.S. Supreme Court held the right to travel was a fundamental right protected by the due process clause of the 5th Amendment.[48] It further stated: "freedom of movement across frontiers in either direction, and inside frontiers as well, was a part of our heritage. Travel abroad, like travel within the country, may be as close to the heart.as the choice [] to eat, wear or reads".[49] On the other hand, *Zemel v. Rusk* recognized the government's right to restrict some travel when flood, pestilence or other natural disasters threaten public safety.[50] Therefore, when the risks of a disease are obvious, the government should be allowed to limit an individual's 1st Amendment and due process rights. However, the true dilemma occurs when the risks of a disease are speculative. In these cases, the government cannot justify its actions without ample proof of its necessity. This is the dilemma xenotransplantation poses. This also explains the FDA's current reluctance to impose a surveillance program that may infringe upon these rights. Until further research is conducted, it is difficult for the government to implement preventive programs that will honor case precedent.

In recognition of the need to impose public safety measures, the United Kingdom has adopted guidelines for a surveillance system that can serve as a model for the United States.[51] The UK proposal enables quick detection, management and investigation of possible infectious diseases emerging from xenotransplantation. It requires recipients to agree to: (a) regular samples of bodily fluids that are then tested for disease; (b) refrain from donating blood, organs or tissues; (c) register their name and address on a national registry at all times; (d)post-mortem analysis; and (e) divulge all confidential information

[48] 378 U.S. 500; 84 S. Ct. 1659.
[49] *Id.*
[50] 85 S. Ct. 1271; 14 L. Ed. 2d 179
[51] *Are xenotransplantation safeguards* at 5.

to health care officials.[52] Theoretically, such a model could help stop the spread of infectious animal diseases. However, can any government really sustain such an extensive program? Considering the procedural and monetary logistics involved, one has to ask whether such a system would place an undue burden upon individuals and the government. Also, how can such a proposal be reconciled with constitutionally guaranteed rights?

2. Informed Consent

Proponentsof xenotransplantation argue the balance between protecting individual constitutional rights and the duty to maintainpublic health can be achieved through comprehensive informed consent procedures. . Even a cursory look at health law cases would illustrate, however, that informed consent is not such a simple alternative. Informed consent in other areas of health law, such as drug testing, abortion and clinical trials, has often resulted in complex and protracted litigation. This is partly due to the vulnerability of patients who purport to give their informed consent. As sick and desperate individuals, many patients do not possess the sound mind or body to givetheir consent . A patient's debilitated condition exposes his/her susceptibility and vulnerability. Often the patient's desire to recover from the disease clouds any rational judgment. In short, a patient who is dying from organ failure and suffering from excruciating pain may consent to almost anything to recover from his/her fate. Under such circumstances, can any informed consent be legitimate?

Furthermore, informed consent laws work best with known diseases that can predict known outcomes. In such cases, physicians can thoroughly explain a diagnosis and the patient's options. The patient can then research and weigh those options intelligently.

[52] *Id.*

In the case of xenotransplantation, however, this is not possible. A patient essentially would place his/her life in the hands of a scientist who also cannot assess the risks associated with the procedure. First, there is no conclusive scientific data about the side effects of xenotransplantation. Even its success at prolonging one's life is not guaranteed. Second, its impact upon public health has not yet been ascertained. Therefore, a patient may be subjected to regular tests, scrutiny and surveillance without fully understanding the associated consequences.

Patients' Rights

The informed consent doctrine is premised on the patient's right to know and the right to self-determination. In the instance of xenotransplantation, both rights are infringed. First, a physician has a duty to inform the patient of the nature of a proposed procedure, its nature and risks. Second, a patient has the right to accept or forgo treatment after reviewing the information. As stated earlier, this process cannot occur with xenotransplantation. Unless more is learned about this clinical procedure, it is impossible to gain informed consent.

Nuremburg Code

The notion of informed consent was developed after World War II, when the world learned that Nazis had performed experimental medical procedures on unwitting prisoners. During the Nuremburg trials in December 1946, sixteen German defendants were prosecuted for war crimes and crimes against humanity during the Nazi reign and convicted by an American court. The greatest legacy of those trials was the creation of the

Nuremberg Code, a set of ten principles laid out by the judges who decided the case. [53]The Nuremberg Code is significant worldwide because it directly limits the purpose and effects of human experimentation. After the horrors of unregulated medical experimentation were revealed, the Western nations agreed that such a Code was vital to preventing further cruelty against human beings.

The first principle of the Nuremberg Code asserts "the voluntary consent of human subjects is absolutely critical". [54]For the aforementioned reasons, this tenet of the Code is violated by the advent of xenotransplantation clinical trials. Informed consent cannot be achieved in such a volatile environment. Given the experimental nature of the procedure, the risk of preying on vulnerable patients is great. Xenotransplantation may give patients false hope about their recovery. This pretense may propel patients to consent to procedures they normally would not agree to. Also, insufficient date prevents physicians from fully explaining the risks of consequences. As a result, informed consent cannot be achieved.

Additionally, xenotransplantation violates the second Nuremberg principle. That principle states any experiment should "yield fruitful results for the good of society".[55] As explained, transplanting pig (and other animal) organs into human beings erodes the natural barrier between human and animal species. Thus, disease and infection are given full reign of the human immune system. The consequences of this transplantation are enormous since the diseases that humans may acquire are highly dangerous and contagious. Thus, recipients, their families, friends and society are put at risk when xenotransplantation takes place.

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[53] Wendy K. Mariner. *Public Confidence in Public Health Research Ethics*. HHS, PHS, Public Health Reports, January, 1997.
[54] *Nuremberg Code* at http://www.med.umich.edu/irbmed/ethics/Nuremberg/NurembergCode.html.
[55] *Id.*

Each of the Nuremberg Code principles is nullified by the participation of humans in the xenotransplant clinical trials. Nowadays, the Nuremberg Code is not used as decisive legal authority. Nevertheless, it serves as a guidepost for national regulations on experimental procedures. Critics argue the Code, and its principles, restrict the advancement of biotechnology. Scientists feel particularly constricted by the first and second principles of the Nuremberg Code. Experimental procedures are always uncertain explorations into unknown realms. Thus, they argue adherence to these principles hinders their development.

Nevertheless, the Nazi experiments and the recent Tuskegee controversy should demonstrate the need to abide by the Nuremberg principles.[56] In order to maintain human dignity and integrity, it is vital that world governments adopt some semblance of the Nuremberg Code in their supervision of experimental procedures.

b. Third Party Consent

Even if patients are able to give their informed consent, it would be impossible to obtain consent from all third parties involved. A xenograft recipient not only places himselfin danger of infection, but all those s/he comes in contact with as well. Thus, by the definitions of human rights laws, every third party who may be exposed to an infectious disease must consent to such a risk.[57] Otherwise, an unconsented exposure to health risks would violate the tenets of the Nuremberg Code, the 1964 U.N. Helsinki Declaration and other declarations.

[56] *Public Confidence* at *1.
[57] See Nuremberg Code, principle 1.

c. Temporary Solution

Given these problems, a moratorium must be placed on xenotransplantation procedures until the risks of infectious disease can be assessed and controlled. Without such a moratorium, the government places its citizens at risk of contracting dangerous infectious diseases. While the benefits of xenotransplantation are clearly recognizable, the risks of such a procedure are too great to proceed. Nonetheless, the issue of xenotransplantation is just one facet of the problem of animal infectious diseases.

Part Three: International Trade Laws

1. Public Health, Economy and Migration

While a discussion of xenotransplantation is mostly hypothetical at this stage, the global impact of animal infectious diseases is documented proof of the need for control and prevention. As stated, disease outbreaks can have far-reaching consequences on global trade and economy. When a disease like mad-cow disease infects the human population, prices in food, medicine and stocks plummet. Other areas of public health are also affected. For example, when FMD infected the meat in Europe, surgical centers in New York suffered.[58] Since that outbreak, surgical centers couldn't receive blood donations from Europe so their blood supply has seriously diminished. [59] Additionally, when FMD outbreaks ravaged European countries, the United States Department of Agriculture placed

[58] Schwartz, Carolyn A. *Impact of Livestock Animal Disease Outbreaks on International Trade*. 8 ILSA J. Int'l & Comp. L 255.
[59] *Id.*

a ban on all live animal and meat imports. This widespread ban resulted in an economic loss of $250 million.[60]

The USDA, CDC, the National Institute of Health (NIH) and the FDA, work together to protect Americans from diseases associated with animals. Although the aforementioned disease pose significant threats to a person's well-being, other diseases are dangerous economically. For example, FMD is economically disastrous for underdeveloped nations. Since a FMD vaccine is available, many countries can implement extensive vaccination programs for their livestock. However, such a program can cost billions of dollars. Therefore, it is almost impossible for developing countries to employ. However, if these countries decide not to vaccinate its animal population, it faces embargos from other countries and a loss of its entire trade supply.[61]

2. NAFTA and GATT

International trade with the United States is governed by both NAFTA (North American Free Trade Agreement) and GATT (General Agreement on Tariffs and Trade). With the adoption of these treaties, the trade of livestock and livestock products among member nations has grown.[62] The main concern with this increase is that animal diseases will spread faster and wider as a result. Since the implementation of NAFTA and GATT naturally heighten the risk of animal importation disease, this article must explore these treaties.

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[60] *Id.*
[61] *Id.*
[62] Looney, J.W. *The effect of NAFTA(and GATT) on animal health laws and regulations.* Oklahoma Law Review, Vol. 48:367.

During the Tokyo round of GATT negotiations in the 1970s, member nations agreed to devise a "Standards Code" that would help nations adopt international standards to suit their needs.[63] The result of the conference was two agreements which are in existence today. The Agreement on Technical Barriers to Trade ("TBT") requires that regulations have a legitimate objective that is not "trade restrictive". SPMS (Sanitary and Phytosanitary Measures) instructs members to protect human or animal life from the spread of disease.[64] Nations, including the United States, use SPMS as justification for laws they impose against certain animals or products.

Both treaties contain provisions about SPMS that could potentially affect the migration of animals from one country to another. SPMS measures are defined as any measure applied to "protect animal or plant life or health within the territory of the Member from risks…"[65] All SPMS measures must be based on scientific evidence that supports the level of protection the Member chooses.[66] However, these stricter "scientific requirements" are not always met when the US imposes embargos on particular animals or by-products.

Risk Assessment and Scientific Requirement

NAFTA and GATT allow Member states to determine their own levels of protection from public health risks. However, this level must be justified by sound scientific evidence that the risk is viable and imminent. The levels of protection must also be based on "risk assessment". This means Members must evaluate the likelihood of entry

[63] Sykes, Alan O. *Exploring the need for international harmonization: domestic regulation, sovereignty and scientific evidence requirements: a pessimistic view*. 3 Chi. J. Int'l L. 353.
[64] See GATT, art. 1, III(4).
[65] *Id.*
[66] NAFTA, Section B: SPMS measures, art. 712(3), Dec. 8-17, 1993; GATT Doc. MTN/FA II-A1A-4(Dec. 15, 1993)

and the spread of disease.[67] Such a test was intended to prevent one country from unfairly placing embargoes upon another. In the spirit of free trade and democracy, the treaties hoped to eradicate prejudices and politics from the arena of international trade. In light of animal importation and diseases, however, the requirements for scientific evidence can be problematic. For those Members concerned about adhering to NAFTA and GATT, bans on foreign animals and substances can only be placed after extensive scientific evidence is gathered, documented and approved. Naturally, this poses a dilemma for a country faced with an emergency situation.

If a country is faced with an epidemic arising from xenotransplantation for example, it may be very difficult to obtain the requisite scientific evidence. Since such an epidemic has never occurred before, scientists would be hard pressed to speculate about the likelihood of its entry/departure into the country or its spread. Thus, by the definitions of NAFTA and GATT, the United States would not be justified in imposing a ban on travel or trade. So while the United States tries to sort out these logistics, infected persons or animals could move freely between countries, infecting others in their wakes. What international trade laws seem to ignore is most animal diseases insidiously creep into a human's immune system without timely detection. Thus, it is tremendously challenging for a Member to provide a "scientific requirement" every time it plans to contain a disease. The test posed by NAFTA and GATT illustrates the difficulty nations face when they balance their duty to protect their citizens while simultaneously obeying international trade agreements.

Furthermore, debates arise over whether such stringent scientific requirements are even necessary or prudent in this modern time of communicable diseases, increased travel

[67] *Id.*

and bioterrorism. Some critics of SPMS and other international laws believe scientific requirements actually endanger public welfare. For example, if a country receives a potential threat of an animal bearing a deadly disease, such as anthrax, it must first undergo a series of serious tests to prove such a threat is viable and imminent. Under the WTO, a member state must first prove the risks are scientifically approved.

While authorities undergo such tests, critics argue, the animal may continue to be imported into the US while a country tries to justify its ban. Such requirements may prove to be very costly to a country that is constantly deluged with imports. If each potentially harmful item must be a lengthy inspection before being banned from importation, the law may defeat its intended purpose. This article recognizes the need for scientific requirements to prevent discrimination among foreign suppliers. However, it proposes that this test must be considered within an international context.[68]

It is important to note that a regulation that restricts foreign trade in order to protect public health and welfare is generally given some level of discretion. The Appellate Bodies of most countries have respected the rights of member nations to determine their own risk levels.[69] Nonetheless, this risk assessment test forces Members to identify the disease and its consequences and prove its likelihood to spread via the banned product.

Australia-Salmon Case

This test was illustrated in the Australia-Salmon case. In that instance, Australia had developed a successful salmon industry. As a result, it banned the importation of

[68] See next section for full explanation.
[69] The World Trade Organization, Report of the Appellate Body, *Australia-measures affecting importation of salmon,* P125, WTO Doc. No. WT/DS18/AB/R (Oct. 20, 1998).

foreign salmon claiming it would infect domestic fish with certain diseases. [70] Canada challenged this ban, claiming it did not meet "risk assessment, as defined by the SPMS Agreement. Upon reviewing the charge, the Appellate Body considered factors listed within the SPMS Agreement. These factors state risk assessment m ust identify the disease, evaluate its likelihood of entry and determine the probability of its spread according to certain SPMS guidelines. [71] The Appellate Body concluded Australia met the first prong of risk assessment because it identified the diseases associated with the importation of foreign salmon. Nevertheless, Australia did not meet the second prong because it could not describe the likelihood of the disease entering and spreading within the nation.

Consequently, the Appellate Body in the Australia-Salmon case recognized that any regulation prohibiting free trade of goods and services without ample scientific proof of its adverse health effects may be classified as a "technical barrier of trade". These are domestic regulations that disadvantage or exclude foreigners from local markets.[72] The most obvious technical barrier to trade is a ban on foreign products that discriminates between various suppliers.[73] Facially nondiscriminatory regulations can also fall within this definition. For example, if a regulation requires foreign suppliers to undergo greater scrutiny, this may be classified as a technical barrier as well. Under this doctrine, facially discriminatory and nondiscriminatory regulations may have the same effect on international trade. Thus, the World Trade Organization has imposed obligations upon domestic regulations that extend beyond nondiscrimination requirements.

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[70] *Id.*
[71] *Id.*
[72] Sykes, Alan O. *Exploring the need for international harmonization: domestic regulation, sovereignty and scientific evidence requirements: a pessimistic view.* 3 Chi. J. Int'l 353
[73] *Id.*

3. The World Trade Organization (WTO) and Globalization

The WTO is the organization responsible for maintaining proper trade relations between Member nations. It was partly created to prevent such discriminatory behavior. Like its predecessor, GATT, the WTO intended to unify nations and equalize any disparities between suppliers. Essentially, the WTO forbids Members from discriminating against foreign suppliers.[74] One way it achieves this goal is by imposing the "scientific requirements" test.

While imposing this restriction on its Members, however, the WTO faces a tension between its respect for national sovereignty and its desire to unite Members. When it was originally devised, the WTO was touted as a regulatory system that was respectful of the sovereignty of each of its Member nations. In light of the growing problem of infectious diseases, the WTO cannot adhere to this original notion. Any meaningful scientific requirement regulation must necessarily infringe upon national sovereignty. If it does not, then the WTO and its agreements would be rendered meaningless.

Globalization

In order to reconcile these two duties, the WTO must redefine its concept of globalization. Globalization typically refers to a series of procedures that limit a state's ability to control actions within its own border.[75] Depending upon the status of an individual state, globalization can be viewed positively or negatively. For countries like the United States, globalization is generally a progressive step towards international cooperation, integration of financial markets and better foreign relations. For developing

[74] *Id.*
[75] Fidler, David P. *The globalization of public health: emerging infectious diseases and international relations*. www.larksongs.net/LawGlobSoc/pubhealth.htm.

countries, however, globalization can be viewed as a hindrance to national sovereignty, since it undermines their power over their own citizens. Moreover, unlike the United States, lesser nations do not have the power to challenge the WTO if a regulation does not suit their needs. Therefore, they are more obliged to follow global norms.

In the public health context, globalization creates several problems. Most public health experts agree that traditional notions of national sovereignty cannot coincide with the emergence of infectious diseases. [76] For example, globalization has caused historical borders between European countries to erode into a melting pot of Schengen states. The Schengen agreement enables the free travel and movement of citizens between all participating states. Rooted in the laudable ideas of unity and equality, the "Schengen area" was created when France, Germany, Belgium, Luxembourg and the Netherlands agreed to become a territory without internal borders in 1985.[77] The "Schengen area" took its name from the town in Luxembourg where the first agreements were signed. In 1997, this intergovernmental cooperation included 13 countries. More nations are continually added.

Adopted to create a stronger, more unified European unit, the "Schengen area" has been heavily criticized by traditionalists. Considered within the public health debate, the "Schengen Area" may provide fertile ground for infectious diseases to grow unhampered. Part of the Schengen agreement includes a removal of checks and inspections at common borders. These are now replaced by external border inspections. Consequently, travelers are only checked when entering and leaving the entire "Schengen Area". This may pose a problem since travelers within the area move between vastly different climates and

[76] *The globalization of public health at *6.* Many experts argue that the traditional distinction between national and international health has been blurred in light of recent developments. This blurring undermines an individual state's right to maintain its own health and safety standards.
[77] See http://europa.eu.int/scadplus/leg/en/lvb/l33020.htm.

conditions. Such a variety in temperatures and environments can breed more infections and diseases. Thus, the "Schengen Area" is the perfect illustration of the adverse effects that globalization has on public health and safety.

Another example of effects of globalization is the recent Severe Acute Respiratory Syndrome (SARS) epidemic. SARS is a viral respiratory illness that was first reported in Asia in February 2003.[78] Within a few months, the illness spread to more than two dozen countries in North America, South America, Europe, and Asia.[79] Due to increased surveillance and stricter border inspections, the SARS outbreak was successfully contained. Nevertheless, the quickness of its spread should serve as a grim warning to the WTO and its Members of the impact of globalization in the public health context.

Globalization has allowed dangerous pathogens to break the walls which once separated one nation from another. Infectious diseases have left illness and death in their wake. They follow no pattern and respect no borders. Now, even immunological barriers are eroded as cross-species diseases continue to spread. Thus, all species and nations are at risk of disease outbreaks. The spread of infectious diseases is no longer a problem confined to one nation. It must be addressed by an international community dedicated to maintaining the health of all persons, not just the citizens of any given country. This can only be achieved if the WTO, and other international organizations, make a concerted effort to protect public health and safety even at the expense of national sovereignty. Recognizing that the problem of animal diseases, and other infectious diseases, is a global problem is the very first step.

[78] http://www.cdc.gov/ncidod/sars/factsheet.htm.
[79] *Id.*

Conclusion

The issue of animal diseases touches upon several facets of health care law. Any discussion of zoonoses must explore the need for international cooperation and federal regulation of experimental trials. When discussing xenotransplantation, it is imperative that one recognize the risks involved in such a procedure. Thus, every government must undergo a risk-benefit analysis to determine whether xenotransplantation should proceed.

Undoubtedly, the goals of xenotransplantation are laudable. There is little question that the health care system is plagued by an organ donation shortage. Artificial organ transplants do not seem to be a viable option. Thus, animal organ donations may help fill this void. At no time does this article suggest that xenotransplantation cannot take place in the future. It only maintains that the procedure should not progress until adequate data and research are complied. A moratorium should be placed on xenotransplantation until the federal government and its state regulatory bodies have assessed all the risk involved and devised appropriate preventive measures. If we refuse to proceed in this cautionary manner, zoonotic outbreaks may be in our near future.

Given the widespread consequences of zoonotic diseases, international cooperation is critical. Even if one country adopts stringent prevention and control mechanism, it can still be susceptible to an outbreak. This is because citizens from that country can freely move to other less cautious nations. Loose regulations and mechanisms can allow people to pick up diseases as they move from one region to another. Hence, it is highly beneficial that an international network is established to prevent the spread of diseases. Infectious diseases do not discriminate between nations. They apply equally to every nation, person

and culture. They also affect all aspects of life. Disease outbreaks can undermine migration, world economy, public health and travel.

In short, it is vital for the integrity of our global system to devise a comprehensive course of action against the spread of zoonotic diseases. This can only be achieved once the WTO and all international organizations decide to place public health concerns above other matters. Once these organizations realize that national sovereignty can be reconciled with maintaining public health, the risk of zoonotic diseases can be significantly diminished.