FARM ANIMAL TO ANIMAL FARM:
The Legal Implications of Human-Pig Chimeras and Xenotransplantation

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I. INTRODUCTION

It is highly likely that animals, particularly pigs, will undergo genetic code insertions during their embryonic stage to produce human-compatible organs farmed for xenotransplantation. The process will create a human-pig chimera—an organism that is technically a pig but contains human DNA. While this process holds promise for addressing organ shortages and curbing human organ trafficking, it will undoubtedly spark vigorous debates about the animals' living conditions, the regulatory roles of U.S. agencies, and whether or not these animals should receive enhanced legal protections due to them possessing human genetic information.

The ethical line between humans' use of animals and cruelty towards them has generated extensive case law and philosophical inquiry. While there is no straightforward answer, the need for humane treatment of animals is evident. Although farming pigs for organ transplantation provides numerous advantages, treating these animals with the utmost care and respect is essential.

The next decade will likely witness significant advancements in xenotransplantation, accompanied by challenging debates, essential legislation, and legal disputes. This paper will explore regulatory schemes and other legal rights that will be central to this new endeavor.

As of this writing, all fifty states have enacted animal anti-cruelty statutes.[1] In addition, the Federal government enacted the Animal Welfare Act ("AWA"), one of the most prominent federal animal anti-cruelty statutes. However, the Act regulates animal cruelty regarding lab animals and does not regulate the meat or farming industries.[2] Since these pigs are essentially farmed, albeit in a lab, the AWA does not specifically protect these animals. Due to this

[1] *See Anti-Cruelty: Related Statutes*, Animal Legal & Historical Center, http://www.animallaw.info/statutes/topicstatutes/sttoac.htm (last visited Nov. 1, 2023).
[2] *See* 7 U.S.C.S. § 2131 (LexisNexis 1985).

ambiguous legal status of these animals, legal disputes have emerged between federal and state authorities concerning whether the Food and Drug Administration ("FDA"), the United States Department of Agriculture ("USDA"), or individual states should regulate these animals. The disputes hinge on whether the animals are farmed or used for medical purposes. The use of animal parts could be considered agricultural products destined for human consumption and sustenance, although the animals are raised in a lab and used for medical purposes. This juxtaposition opens debate on whether the animals fall under FDA medical product jurisdiction or align with agriculture and livestock farming covered by state law and the USDA.

In general, the FDA regulates medical and pharmaceutical animal use,[3] and the USDA oversees agriculture.[4] Each agency has varying responsibilities based on the species of animals.[5] This paper will explore the idea that xenotransplant animals, specifically human-pig chimeras, should constitute a distinct animal category with interagency oversight because they are raised like farmed livestock but fulfill a medical purpose.

This emerging technology offers significant benefits. Therefore, an absolute ban would be counterproductive, especially since pig farming will persist for the foreseeable future. Nonetheless, this technology treads closely to a realm of philosophical and ethical concerns that could evolve into significant legal implications. As a result, regulatory frameworks must be carefully developed and scrutinized as thoroughly as possible prior to implementation.

Following this brief introduction, Part II of this paper will address man's use of animals in a historical and religious context. Part III will delve into the scientific process behind creating the human-pig chimera. Part III continues with the pros and cons of xenotransplantation, the

[3] U.S. Food and Drug Admin., https://www.fda.gov/ (last visited Nov. 10, 2023).
[4] *See generally Laws and Regulations*, USDA, https://www.usda.gov/our-agency/about-usda/laws-and-regulations (last visited Nov. 10, 2023).
[5] *FDA and USDA Food Regul.*, Registrar Corp, https://www.registrarcorp.com/resources/fda-usda-food-regulations. (last visited Nov. 10, 2023).

living conditions that must be utilized to ensure healthy organs, and reasons why pigs are best suited for xenotransplantation.

Next, this comment will present current law and Federal agency responsibilities that regulate these animals in Part IV. First, a brief history of animal protection legislation is discussed followed by the current agency responsibilities and legal status of chimeras. Lastly, Part IV will propose new regulations and decipher the best suited agency to deal with this emerging technology.

Part V, the final section of the comment, will address philosophical and legal considerations, such as personhood, constitutional standing, informed consent, and other legal rights, in the event these animals acquire human cognitive abilities through accidental or purposeful genetic brain modification. The question posed in Part V will explore whether introducing human DNA into a non-human animal gives heightened legal protection, surpassing their classification as mere property used for agriculture and medical research.

To conclude Part V, the comment will present policy and regulatory suggestions that ensure prevention of genetic modification to chimeric brains. These recommendations include addressing interagency coordination and potential Congressional legislation for the appropriate use of this technology.

II. A BRIEF HISTORY OF HUMAN ANIMAL USE IN SOCIETY AND RELIGION

Approximately 2.5 million years ago, early humans began to occasionally eat meat, which gradually became a main staple of the human diet.[6] Around 11,000 BCE, there was a significant shift in human society as we gradually transitioned from the traditional

[6] Tess Joosse, *Meet the Scientist Studying How Humans Started Eating Meat*, NAT'L MUSEUM OF NAT. HIST. SMITHSONIAN MAG (Dec. 9, 2021), https://www.smithsonianmag.com/blogs/national-museum-of-natural-history/2021/12/09/meet-the-scientist-studying-how-humans-started-eating-meat.

hunter-gatherer lifestyle and embraced agriculture and animal husbandry—marking a pivotal moment in human history.[7] By 6000 BCE, early civilization had domesticated most farm animals we are familiar with today,[8] and practiced agriculture in every major continent except Australia.[9] The paleontological record shows that humans have consistently used animals for sustenance and that animal use was pivotal in expanding civilization. Additionally, many species depend on differing species for their own sustenance. The hierarchy of animal use for survival has always existed and is a core tenet of life on earth.

The Bible and Qur'an have referenced the creation of animals for human use. In the Bible, God said, "Let us make man in our image, after our likeness: and let them have dominion over the fish of the sea, and over the fowl of the air, and over the cattle, and over all the earth, and over every creeping thing that creepeth upon the earth."[10]

The Qur'an classifies humans as superior to animals and occupying a privileged status.[11] As part of this privilege, as "Earth's conscientious stewards, humans are responsible for protecting and serving each other and the ecosystem."[12] This framework mandates that humans have a responsibility to care for and protect animals as "vicegerents."[13]

Throughout history, there has been a deep respect for animals used for sustenance and in religious rituals.[14] Prehistoric societies and modern hunters and farmers shared this reverence for

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[7] *History of Agriculture*, Food System Primer, https://foodsystemprimer.org/production/history-of-agriculture (last visited Oct. 1, 2023).
[8] *See* David. R. Montgomery, Dirt: The Erosion of Civilizations, 34–44 (2nd ed. 2012).
[9] *Id.* at 36.
[10] *Genesis* 1:26 (King James).
[11] *See* Engy Abdelkader, *Animal Protection Theory in U.S. and Islamic Law: A Comparative Analysis with A Human Rights Twist*, 14 UCLA J. Islamic & Near E. L. 45, 46 (2015).
[12] *See Id.*
[13] *See Id.*
[14] Bernard E. Rollin, *Ethical and Societal Issues Occasioned by Xenotransplantation*, 10 Animals 1695-1715, 1697 (2020).

the animals they depended on. However, contemporary culture seems to have drifted away from showing proper respect because of cruel farming practices and medical research.[15]

In contrasting past versus modern animal care, Dr. B.E. Rollins stated:

> The singular beauty of animal care is that it was at once an ethical and prudential doctrine. It was prudential in that failure to observe husbandry inexorably led to ruination of the person keeping animals. Not feeding, not watering, not protecting from predators, not respecting the animals' physical, biological, physiological, and psychological needs and natures, meant your animals did not survive and thrive, and thus neither did you. Thus, no formally articulated animal ethic was needed. Animal husbandry in essence became the basis for what was the newly civilized society and the leisure time necessitated by the development of culture, as Thomas Hobbes pointed out in *Leviathan*.[16]

This societal transformation prompted Federal and State governments to enact anti-cruelty laws and animal testing standards.[17] While innovation in organ transplantation holds much promise, it is imperative we revere and respect the animals that we continue to use for our own survival.

III. EXPLANATION OF XENOTRANSPLANTATION AND HUMAN-PIG CHIMERAS

A. Xenotransplantation Defined

Xenotransplantation involves transferring living cells, tissues, or organs from one species into another species.[18] "Xeno" is derived from the Greek word for "foreigner."[19] Typically, humans are the intended recipients of organ xenotransplantation.[20] Previous human xenotransplant attempts have involved various organs, such as chimpanzee kidneys, livers, and hearts; baboon livers and hearts; as well as pig corneas and pancreases.[21] Unfortunately, past recipients of xenotransplants seldom experience long-term survival following the procedures.[22]

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[15] *Id.* at 1699.
[16] *Id.*
[17] *Id.* at 1700.
[18] *Xenotransplantation,* U.S. Food and Drug Administration, https://www.fda.gov/vaccines-blood-biologics/xenotransplantation (last visited Oct. 13, 2023).
[19] Rollin, *supra* note 17, at 1702.
[20] Rollin, *supra* note 17, at 1704.
[21] Rollin, *supra* note 17, at 1707.
[22] Rollin, *supra* note 17, at 1708..

However, that disappointing consequence is hopefully changing as successes in 2021 and 2023 have shown xenotransplantation recipients surviving for longer periods of time, with the hope that will translate to long-term survival.[23]

B. Human-Pig Chimera Defined

According to Greek mythology, a chimera is a creature that was a combination of different animals—usually it has lion's head, a goat's body, and a snake's tail.[24] However, in modern science, a chimera is an animal created in a lab that has cells or genes from two or more different species[25] that have not sexually reproduced.[26] Rather than sexual reproduction, the chimera organism has DNA taken from another species and inserted into their genetic code using DNA splicing techniques during fertilization or the embryonic development stage.[27]

For clarification, it is essential to distinguish between chimeras and hybrid organisms because they arise from different processes.[28] Hybrids result from the mating or sexual reproduction of individuals from separate species and they typically exhibit an equal mix of their parents' species in their genetic makeup.[29] Examples of hybrids include mules and ligers, both of which are not chimeric animals.[30]

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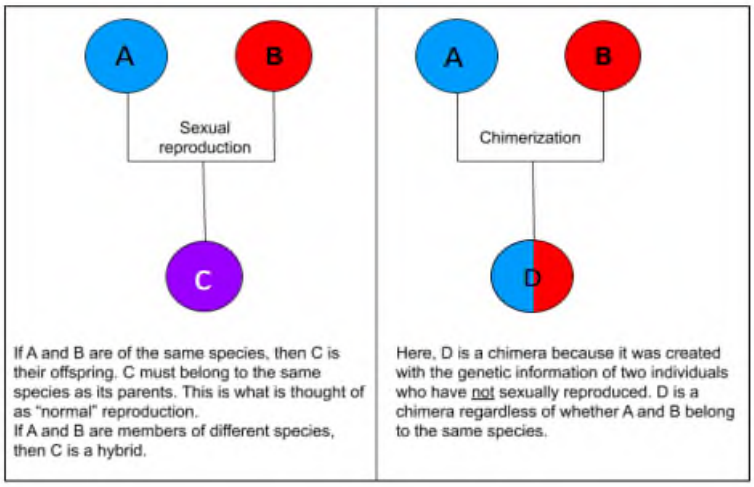
[23] Rollin, *supra* note 17, at 1702.
[24] Nicola Davis, *Human-Pig Embryos Q&A: How Would 'Chimeras' Make Transplant Organs*, THE GUARDIAN (Jun. 6, 2016), https://www.theguardian.com/science/2016/jun/06/human-pig-embryos-qa-chimeras-transplant-organs-scientists.
[25] *Id.*
[26] DR. HAKIM. K SABOOWALA, EXPLORING THE ETHICS OF ORGAN FARMING & INTERSPECIES CHIMERA: AN OVERVIEW, 25–40 (2020).
[27] *Id.* at 35.
[28] *Id.* at 38.
[29] *Id.*
[30] *Id.* at 40.



[31]

The concept of chimeric cells, which combine cells from two distinct species, has piqued the interest of scientists as a potential avenue for producing organs suitable for human transplantation.[32] One approach involves creating a chimera by combining a non-human animal embryo, often a pig, with human stem cells and allowing an embryo to develop. A second option for chimeric creation, often referred to as CRISPR, directly inserts targeted human organ genetic code into the pig embryo.[33]

Ethically complex gene-editing techniques like CRISPR, along with stem cell technologies, are frequently employed to create human-pig chimeras that cultivate human organs for transplantation.[34] Insertion of human organ code into the pig embryo using CRISPR is often preferred as it tends to be an easier process than human stem cell splicing.[35] CRISPR also helps to alleviate some of the ethical concerns of human stem cell use.[36] As the chimera matures, the

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[31] *Organ Farming and Interspecies Chimeras*, NYU LANGONE HEALTH (Jan. 5, 2022), https://med.nyu.edu/departments-institutes/population-health/divisions-sections-centers/medical-ethics/sites/default/files/medical-ethics-organ-farming-and-interspecies-chimeras.pdf.
[32] James Gallagher, *Human-Pig 'Chimera Embryos' Detailed*, BBC NEWS (Jan. 26, 2017), https://www.bbc.com/news/health-38717930.
[33] *Id.*
[34] Andrew T. Crane et al., *Interspecies Organogenesis for Human Transplantation*, 28 Cell Transplantation 1091-1105, 1092 (2019).
[35] *Id.* at 1100.
[36] *Id*. (Stem cell use is contentious due to the source of these cells, particularly embryonic stem cells, and concerns regarding the destruction of human embryos for their extraction).

patient can eventually receive a new, human-like, specifically targeted organ grown from the chimera.[37]

Using CRISPR, researchers first implant human donor genetic code into the pig embryo during the early stages of embryonic development—often referred to as the blastocyst stage.[38] Subsequently, the blastocyst is introduced into the womb of a female pig.[39] Although genetically foreign, the human cells are not rejected by the pig embryo because the embryo's immune system has not yet developed.[40] The pig embryo goes on to develop into a fetus with organ cells derived from the injected human cells.[41] If all proceeds as planned, the young chimera will be born and grow into a full size, healthy animal containing the targeted human-like organ.[42] Following birth, researchers typically conduct tests to verify that the animal possesses the correct human genetic material.[43]

It is important to note that the genetic information of the host and the donor do not blend. Rather, the chimera comprises cells with genetic traits from both the host and the donor.[44] With a chimera organ, the organ transplanted from the pig would primarily be composed of human cells, not pig cells.[45] If the testing and growth is successful then the chimera will be raised and later the organs harvested for human use. There have been significant strides in successful use of these animals, but it remains far from perfect. The longest a human recipient has survived from a heart xenotransplant is currently seven weeks.

C. Pros and Cons of Using Chimeric-Pigs for Xenotransplantation

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[37] *Id.* at 1103.
[38] *Id.*
[39] *Id.* at 1096.
[40] *Id.* at 1101.
[41] Crane et al., *supra* note 34, at 1099.
[42] *Id.*at 1105.
[43] *Id.* at 1093.
[44] Julian Koplin & Dominic Wilkinson, *Moral Uncertainty and The Farming of Human-Pig Chimeras*, 45 J. Med. Ethics 440, 440 (2019).
[45] *See Id.*

i. The Pros

Firstly, the United States faces a chronic organ shortage, which xenotransplantation could significantly address.[46] Over 110,460 patients are currently awaiting organ transplants, with a median wait time of nearly five years.[47] Tragically, about twenty individuals die per day while on the transplant waiting list.[48] The existing transplantation system relies on healthy, functional human organs, which makes it impossible to meet the overwhelming demand.[49]

Encouraging public organ donation, while necessary, cannot singularly resolve this crisis due to the sheer number of people in need. Non-essential living organ donation (such as kidney donation) offers another strategy. However, this approach has limitations since only a small number of people choose to donate organs while alive.[50] To effectively address the organ shortage, xenotransplantation technology could be coupled with organ donation practices to save countless lives. However, ensuring humane and respectful treatment of the sacrificial animal is vital.

Secondly, xenotransplantation could decrease the trafficking of humans for organ removal ("THBOR"). THBOR often involves exploiting individuals for their organs through coercion, deception, or taking advantage of vulnerabilities such as financial problems.[51] Due to the shortage of legally obtained organs, the global illegal organ trade is estimated to generate

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[46] Jeffrey J. Whyte & Randall S. Prather, *Genetic Modifications of Pigs for Medicine and Agriculture*, 78 MOLECULAR REPRODUCTION AND DEVELOPMENT 879, 880 (2011).
[47] *Id*.
[48] *Human Trafficking for the Purposes of Organ Removal: UNODC Regional Consultation Addresses One of the Least Known but Growing Forms of Trafficking Worldwide*, UNITED NATIONS: OFFICE ON DRUGS AND CRIME (Aug. 10, 2022), www.unodc.org/unodc/en/human-trafficking/glo-act2/Countries/human-trafficking-for-the-purposes-of-organ-removal_-unodc-regional-consultation-addresses-one-of-the-least-known-but-growing-forms-of-trafficking-worldwide.html.
[49] *Id*.
[50] *Id*.
[51] *Id*.

approximately *$1.5 billion annually* from roughly 12,000 illegal transplants.[52] It is believed that around 10% of all transplants fall under this criminal category.[53] THBOR has severe repercussions for human security, primarily affecting the most vulnerable groups like the unemployed, homeless individuals, and migrants.[54] Xenotransplantation has the potential to dismantle the illegal organ trade and ultimately safeguard countless vulnerable people.

A third benefit of chimeric transplantation is its avoidance of the controversies linked to embryonic stem cells.[55] A contentious aspect of stem cell research involves the utilization of human embryos, which may include cells from aborted fetuses or surplus embryos donated by fertility clinics.[56] This issue is circumvented when using pig chimeras created with genetic insertion techniques like CRISPR.[57]

Lastly, chimeric-pig technology has applications beyond organ transplantation, such as treating cardiovascular disease, cystic fibrosis, Alzheimer's, spinal muscular atrophy, paralysis, and diabetes,.[58] Chimeric animals can also be utilized for the incubation of human compatible living biological products, such as insulin or bone marrow.[59]

ii. The Cons

While the potential benefits of xenotransplantation are substantial, concerns arise regarding the possible transmission of known and unknown infectious agents to recipients and their close contacts.[60] One public health concern is the possibility of cross-species infection by

[52] Juan Gonzalez et al., *Organ Trafficking and Migration: A Bibliometric Analysis of an Untold Story*, 17 INT'L J. ENVIRONMENTAL RSCH. & PUB. HEALTH 3204, 3205 (May 2020).
[53] Susan Maginn, *Organ Trafficking Facts*, THE EXODUS ROAD (Jan. 16, 2023), https://theexodusroad.com/organ-trafficking-facts/.
[54] *Id.*
[55] *Division of Medical Ethics*, NYU LANGONE HEALTH, https://med.nyu.edu/departments-institutes/population-health/divisions-sections-centers/medical-ethics/ (last visited Nov. 15, 2023).
[56] *Id.*
[57] *Id.*
[58] Whyte & Prather, *supra* note 45, at 881–84.
[59] Whyte & Prather, *supra* note 45, at 882.
[60] Xenotransplantation, *supra* note 18.

retroviruses, which may remain dormant and lead to disease years after implantation.[61] Making matters worse is that identifying new infectious agents with current techniques may also prove challenging.[62]

However, the risk associated with transferring infectious microorganisms, as highlighted in the 2003 FDA guidance and subsequent World Health Organization ("WHO") consensus documents, has been extensively studied.[63] These studies have shown that the risk is either less likely than previously believed or manageable through better donor selection and recipient management strategies.[64] Consequently, the cost-benefit ratio of pig-to-human xenotransplantation of organs and tissues has significantly evolved in the last decade, as recognized by the FDA, and is presently viewed as a net positive.[65] Nonetheless, the viral contagion risk persists.[66] Prudent regulatory schemes and well thought out safety standards will be essential before this technology becomes widely used.

Finally, some scientists are concerned that human cells might not only develop the pig's pancreas or heart but other organs such as the brain.[67] Potential brain modification raises questions about whether the pigs could develop human-like characteristics.[68] Altering a pig's brain to exhibit human behaviors or physical traits would ignite a profound philosophical and legal debate, prompting discussions on informed consent, equal protection, and the reconsideration of animals' status from property to personhood.[69] Section IV of this paper, "Emerging Legal Issues with Human-Pig Chimera Brain Activity" provides a further discussion.

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[61] *Id.*
[62] *Id.*
[63] David K.C. Cooper et al., *Regulation of Clinical Xenotransplantation—Time for a Reappraisal*, 101 TRANSPLANTATION 1766, 1767 (2017).
[64] *Id.* at 1768.
[65] *Id.*
[66] *Id.*
[67] Koplin & Wilkinson, *supra* note 43, at 440–46.
[68] *Id.*
[69] *Id.* at 445.

D. Why Use Pigs?

Baboons and pigs have been recommended as preferred choices for xenotransplantation hosts.[70] Baboons, while more biologically similar to humans than pigs, face logistical challenges due to their limited population, high maintenance costs, and the general societal pressures against primate research.[71] Furthermore, our knowledge about baboons is relatively limited when compared to pigs, and new legislation has been passed in the last twenty years that restricts primates from being used for medical research. Additionally, baboons also take many years to reach adulthood while pig growth is much faster.[72] On the other hand, pigs, although more distantly related to humans on the evolutionary tree, share crucial biological similarities in terms of size, anatomy, and physiology.[73] Pigs also pose a lower risk than baboons of transmitting zoonotic pathogens to human transplant recipients.[74]

Even more advantageous is a pig's practicality.[75] Due to extensive infrastructure dedicated to pork production, they are already bred efficiently and cost-effectively.[76] The legal and ethical objections to pig slaughter for medical purposes have been generally minimal due to farming practices, especially when compared to primates.[77] Additionally, pigs are polytocous, regularly giving birth to multiple offspring in a single pregnancy, which makes them efficient for the incubation of chimeric embryos.[78] All in all, "pigs represent an excellent choice for chimera research due to their biological compatibility and logistical advantages."[79]

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[70] Rollin, *supra* note 14, at 1700.
[71] *Id.* at 1699.
[72] *Id.* at 1697.
[73] *Id.* at 1703.
[74] *Id.* at 1702 (Xenotransplantation from primates to humans poses a higher risk of transmitting animal-borne diseases than pigs because primates and humans are so closely linked and easily share zoonotic disease. Pigs and humans tend not to share communicable diseases because our genetics are much further removed).
[75] *Id.* at 1696.
[76] Whyte & Prather, *supra* note 45, at 881–84.
[77] *Id.* at 884.
[78] *Id.* at 889.
[79] Rollin, *supra* note 14, at 1705.

E. The Living Conditions of Human-Pig Chimeras

Utilizing pigs in xenotransplantation research or organ cultivation is likely to contravene well-established agricultural guidelines for animal care and welfare.[80] These modern guidelines emphasize environments that align with the animal's natural behaviors and physiological requirements.[81] Unfortunately, current technology does not allow pigs intended for xenotransplantation to be housed outdoors or within groups.[82]

Scientists must raise these chimeric pigs in environmental conditions significantly different from traditional farming practices.[83] They need to be housed more akin to laboratory animals in controlled, sterile environments that reduce the chances of pathogen spread to maintain their health.[84] The chimeric pigs need to be isolated to procure healthy organs. Also, in many situations, the immune systems of these animals must be suppressed to preclude the development of problems with the chimeric organ.[85] This furthers the practice of isolated lab housing.

These conditions could arguably appear to be an improvement over modern, mass-production agricultural settings in terms of animal health, but the conditions still fail to adequately address the biological and psychological needs of the animals.[86] Consequently, these animals may experience enhanced care when compared to mass produced farm animals, but their overall well-being is likely to be compromised due to their isolation.[87] We must develop a system where these animals are treated humanely and not kept in isolation.

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[80] *Id.*
[81] L. Syd M. Johnson, *Xenotransplantation: Three Areas of Concern*, THE HASTINGS CENTER (Jan. 19, 2022), https://www.thehastingscenter.org/xenotransplantation-three-areas-of-concern/.
[82] *Id.*
[83] Rollin, *supra* note 14, at 1700.
[84] *Id.* at 1710.
[85] *Id.*
[86] *Id.*at 1706.
[87] *Id.* at 1708.

These practices will undoubtedly be a contentious issue for our legal system. The agencies that will regulate the management of these animals remain to be determined. However, effective regulation has the potential to drive innovation; thus, reducing the necessity of raising pigs in a laboratory setting. Implementing effective regulations for the living conditions of xenotransplant animals could encourage scientists to create human-pig chimeras that could be housed in more humane environments.

If the scientific and medical communities faced reasonable governmental pressures concerning the care of these animals, these pressures could stimulate advancements in the technology. These advancements might eventually allow the chimeras to transition from laboratory settings to outdoor environments alongside other animals. The shift of human-pig chimeras to natural environments may take time for scientists to achieve, but it is an ethical necessity. Providing these animals with conditions closer to their natural habitats is a goal we should aim to achieve.

A simple legislative proposal could lead Congress or the USDA to create a regulation stating that pig populations should not be kept in isolation. This simple regulatory law could theoretically encourage scientists to create a pig chimera that is resistant to zoonotic diseases and organ rejection. Once scientists achieve this, the next step could involve reintroducing these chimeras to natural environments.

IV. APPLICABLE FEDERAL ANIMAL LAWS AND AGENCY POWERS

A. Animal Welfare Act History and Animal Protection History

In 1966, Public Law 89–544, also known as the Laboratory Animal Welfare Act, was enacted by Congress in response to public concern about pets being stolen for research.[88] This law established minimum standards for the care, housing, sale, and transport of various animals

[88] Bruce A. Wagman, Sonia Waisman & Pamela D. Frasch, Animal Law: Cases and Materials, 639–54 (2019).

in the possession of animal dealers or laboratories.[89] The Act also mandated licensing for cat and dog dealers, research facilities, and the identification of dogs and cats to prevent theft.[90] In 1970, the law was amended and renamed the Animal Welfare Act ("AWA"), broadening its coverage to include other warm-blooded animals used in research, exhibition, or the pet trade.[91]

In 1972, the Secretary of Agriculture excluded birds, mice, rats, horses, and farmed animals from the AWA's definition of "animal."[92] This exclusion was successfully challenged in court in 1992 but later vacated on grounds of standing in 1994.[93] Further developments on this issue continue and the definition of "animal" continues to change.[94] With the use of chimeric animals, the definition of animals will need further development, especially since these animals contain human DNA.

The Improved Standards for Laboratory Animals Act of 1985 further strengthened the AWA standards by enhancing care for laboratory animals, increasing enforcement, mandating training for animal handlers, and establishing Institutional Animal Care and Use Committees.[95] In 1998, a legal challenge arose regarding the exclusion of rats, mice, and birds from the AWA's protection.[96] A settlement in 2000 required the USDA to undertake rulemaking on the regulation of these animals. However, this agreement was superseded in 2001 by the Agricultural Appropriations Act.[97]

In 2002, the federal Farm Security and Rural Investment Act ("FSRIA") included an amendment excluding certain birds, mice, and rats bred for research from the AWA definition of

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[89] *Id.*
[90] *Id.* at 644.
[91] *Id.*
[92] *Id.* at 645.
[93] *Id.*
[94] Wagman & Frasch, *supra* note 88, at 646.
[95] *Id.*
[96] *Id.* at 653.
[97] *Id.* at 648.

"animal."[98] The FSRIA also addressed the use of cats and dogs in federal research, requiring independent reviews and reports by the National Institute of Health and USDA.[99]

The history of the AWA illustrates Congress's commitment to fostering medical innovation via animal testing while concurrently safeguarding the humane treatment of the animals involved. There is a delicate balance between promoting medical progress and respecting animal welfare, but it is evident that governmental regulatory agencies struggle with exact definitions and protections.

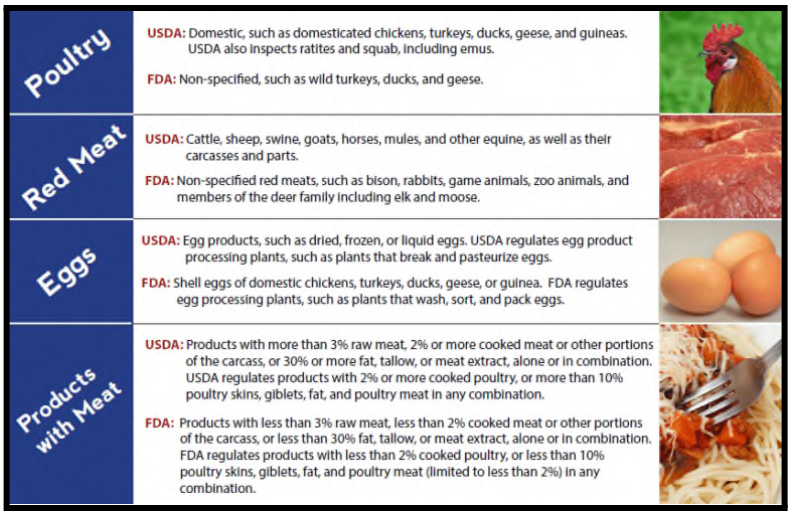
Humans are presently the stewards of the planet, and it is our responsibility to act in a manner that honors this stewardship. Technological advancements pave the way for new frontiers in science but also urge us to navigate these uncharted territories with thoughtful consideration and responsibility.

B. Differing Agency Control

The FDA and the USDA have complex, overlapping rules for different animal species used in food and medical products. Simplifying these regulations could reduce government red tape and help streamline responsibilities. However, with human-pig chimeras, the boundaries are further blurred. Congress or administrative agencies need to create a clear framework for managing these undefined animals.

The chart below provides a brief overview of the varying administrative authorities concerning species differentiation:

[98] *Id.*
[99] *Id*.



[100]

i. United States Department of Agriculture ("USDA")

The USDA is a federal regulatory authority tasked with supervising farming and agriculture across the United States.[101] Essentially, the USDA plays a crucial role in ensuring that meat consumed by the American public remains safe and uncontaminated from the moment an animal, like a pig, comes into existence through its preparation for cooking and consumption.[102]

Moreover, the USDA informs the public about various topics, including nutrition recommendations, biotechnology developments, and disease risks.[103] It is important to highlight that the USDA has the sole authority over animals not exposed to medications or drugs during their entire life—from birth to slaughter.[104] Whereas animals that are exposed to drugs and medications fall under the FDA's jurisdiction.[105] This regulatory aspect can be confusing for

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[100] *FDA and USDA Food Regulations*, Registrar Corp, https://www.registrarcorp.com/resources/fda-usda-food-regulations/ (Picture showing differing agency responsibilities by livestock species. Although, this is for meat products it shows the confusing set up between animal species) (last visited Nov. 2023).
[101] *See generally Laws and Regulations*, USDA, https://www.usda.gov/our-agency/about-usda/laws-and-regulations. (last visited Nov. 2023).
[102] *Id.*
[103] *Id.*
[104] *Id.*
[105] *Id.*

chimeric pigs because genetic modification may not be categorized as a drug exposure although it is technically a medical procedure.

The USDA's supervision encompasses cattle, sheep, *swine*, goats, horses, mules, and other equine animals, including regulating their carcasses and parts.[106] This aspect is interesting for animal organ use because the organs are technically animal parts.

A pressing question emerges: should chimeric pigs, which have undergone genetic modification from birth and give rise to subsequent generations, be categorized as livestock for farming and human consumption, or should they be regarded as animals treated with pharmaceuticals?

It is important to point out that the USDA typically has a less stringent approach to animal welfare regulation when compared to the FDA. Consequently, if our objective is to ensure the humane treatment of these specific animals, it may be more appropriate for the FDA to have jurisdiction over this category of animals.

ii. United States Food and Drug Administration ("FDA")

The FDA, a part of the Department of Health and Human Services ("HHS"), regulates a wide range of products, including food, drugs, vaccines, biological products, medical devices, and animal-related items, with a crucial role in overseeing genetically modified pigs used in food products.[107] Xenotransplantation use is technically not food although the animal parts are still being put into human bodies and used by humans. However, this juxtaposition brings up jurisdictional questions as to who governs chimeric pigs used for xenotransplantation.

[106] *Id.*
[107] *What FDA Does and Does Not Regulate*, FDA (Feb. 23, 2023), https://www.fda.gov/animal-veterinary/animal-health-literacy/what-fda-does-and-does-not-regulate (last visited Nov. 10, 2023).

Additionally, the FDA promotes public health by regulating innovations that improve medication effectiveness, safety, and affordability.[108] It also provides the public with accurate, science-based information for using medicines and foods.[109]

The FDA assumes authority in regulating pharmaceutical use on animals destined as food products.[110] This jurisdiction covers swine that undergo drug treatment from birth to slaughter.[111] In this capacity, the FDA ensures that all animal drug use is safe for the animal's welfare and the eventual human consumption of food products derived from these animals.[112]

This conundrum leads to interagency conflict between the USDA and FDA. One might argue that chimeric pigs used for xenotransplantation are more aligned with pig-derived agricultural products rather than medical research. Nevertheless, it is essential to consider that they are being introduced into the human body and are vital in sustaining human health, which is analogous to food consumption. Fortunately, as discussed next, there have been regulatory developments during the Trump and Biden Administrations.

iii. Current Interagency Issues and Guidance Between the USDA and FDA

On December 14, 2020, during the Trump Administration, the FDA approved genetically modified ("GM") pigs for food production and medical products, named GalSafe Pigs.[113] The FDA outlined that they would regulate any intentional genomic alterations ("IGAs") in animals to ensure safety for the animals and those consuming food from them.[114] These IGAs would undergo premarket oversight, whether intended for food or pharmaceutical production and other

[108] *Id.*
[109] *Id.* at 2.
[110] *Id.* at 3.
[111] *Id.*
[112] *Id.*
[113] Kathleen M. Sanzo & Maria Kalousi-Tatum, *USDA's Proposal to Take Back Regulatory Oversight of GM Animals from FDA Remains Viable Despite Change in Administration*, Morgan Lewis (June 22, 2021), https://www.morganlewis.com/blogs/welldone/2021/06/usdas-proposal-to-take-back-regulatory-oversight-of-gm-animals-from-fda-remains-viable-despite-change-in-administration.
[114] *Id.*

useful products.[115] Labeling food that came from GM animals would then fall under the responsibility of the USDA.[116]

However, just several weeks later, there was a significant disagreement.[117] The USDA wanted more oversight of IGAs and released an Advanced Notice of Proposed Rulemaking ("ANPRM") titled Regulation of the Movement of Animals Modified or Developed by Genetic Engineering.[118] Under the ANPRM, the USDA would be responsible for establishing "a flexible, risk- and science-based regulatory framework for the regulation of certain animals modified or developed using genetic engineering that is intended for agricultural purposes" in consultation with the FDA.[119] The USDA would be responsible for determining whether GM animals are safe to eat, monitoring the meat of GM animals as part of the food supply, and reviewing the safety and efficacy of IGAs and their impact on the environment.[120] This verbiage of "agricultural purposes" poses problems for xenotransplantation pigs because it remains unclear whether they are medical products or farmed livestock.

Then, on January 13, 2021, just days before the Biden Administration took office, a Memorandum of Understanding ("MOU") between the USDA and HHS was signed.[121] The MOU transferred the oversight of GM animals "intended for agricultural purposes (i.e., human food, fiber, and labor)" from the FDA to the USDA under the Animal Health Protection Act, the Federal Meat Inspection Act, and the Poultry Products Inspection Act.[122]

Under the MOU, the FDA would continue to have authority over IGAs intended for any purpose "other than agricultural use," including biopharmaceuticals, xenotransplantation, and

[115] *Id.*at 3.
[116] *Id.*
[117] *Id.* at 2.
[118] *Id.*
[119] *Id.*at 1.
[120] *Id.*
[121] *Id.*
[122] *Id.*at 1.

gene therapies.[123] However, despite industry support for this change, advocates from animal welfare, public health, and the environment wanted the FDA to maintain oversight over GM animals used for food production.[124] They argue that the MOU undermines the FDA's ability to protect public health because the USDA typically has less expertise with genetic engineering processes.[125]

The FDA continues to regulate GM animals used in agriculture and medicine.[126] Whether the USDA's attempt to regulate GM agriculture will succeed remains uncertain. There will certainly be some agency overlap in assessing the safety of genetic modifications for food, drugs, and human tissue. Due to this overlap, the agencies should collaborate and share their scientific expertise to evaluate this new technology and its potential impact on humans.

States will likely have a say in determining which federal agency is better suited to establish standards and enforce regulations due to their heavy involvement in livestock regulation. The timeline for a decision on the ANPRM and the Biden administration's stance on the proposed rules remain unclear.[127]

C. Further Legislative and Agency Proposals

In the past five years, significant deliberation has taken place regarding these animals' governance in ensuring their safe utilization for human purposes while protecting their sanctity.[128] Although the xenotransplantation technology remains nascent, it is encouraging that governmental entities are proactively addressing what is poised to become a new category of medicinal products.

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[123] *Id.*
[124] *Id.*
[125] *Id.* at 2.
[126] *Id.*
[127] *Id.*
[128] *What FDA Does and Does Not Regulate*, FDA, https://www.fda.gov/animal-veterinary/animal-health-literacy/what-fda-does-and-does-not-regulate (last visited November 17, 2023).

Presently, regulatory initiatives are coming from within the administrative agencies of the Executive branch.[129] Nevertheless, there is a discernible need for legislative action from Congress to address the unique challenges posed by these animals. It is especially important for Congress to enact legislation because the demarcation between chimeric animals should be decided through a democratic process involving the public rather than being solely determined through the deliberation of Executive branch agencies.

This comment proposes that Congress create new legislation that classifies animal chimeras as their own separate organisms and require the FDA and USDA to develop new guidelines regarding animals being farmed for medical products. To effectively navigate this regulatory landscape, Congress could contemplate assigning the FDA with new regulatory responsibilities or recommend establishing an entirely new agency department with interconnected roles involving FDA and USDA representatives.

This comment advocates that the FDA is better equipped to oversee the health and viability of these animals due to their familiarity with medical research animals. While the USDA specializes in agriculture and food production, the FDA's expertise lies in understanding laboratory conditions and genetic processes. Moreover, the FDA already possesses knowledge in enforcing medical laboratory standards through the AWA. The chimeric animal aligns more closely with the FDA's mission. Additionally, the FDA's expertise primarily concerns itself with the production of safe medical products for humans, whereas the USDA's focus is on food production.

If completely new legislation is at an impasse, Congress could consider amending the AWA as a legislative avenue for protecting chimeric pigs even though the AWA predominantly focuses on animal medical testing. Considering the shared attributes encompassing living

[129] *Id.*

conditions, medical and laboratory utilization, and aspects like slaughter, there is a conceivable prospect for the AWA to undergo an amendment to encompass the regulation of chimeric pigs. The USDA could remain a potential regulator of husbandry and agricultural guidance. However, it is clear the FDA currently possesses a more advanced and nuanced understanding of matters relating to laboratory environments and medical procedures. Regardless of new legislation, or amendments to existing statutes, it is most likely that the FDA is in the best position to regulate this burgeoning industry.

Also, state livestock regulations could assume a crucial role in this discussion, as the classification of chimeric pigs as livestock or federally regulated medicinal products is still unclear. One potential solution is to have the individual states assume responsibility for ensuring humane living conditions for these animals, similar to the state oversight of livestock, while simultaneously allowing federal regulators to monitor scientifically sound practices for raising pigs to ensure no risk to recipients.

V. EMERGING LEGAL ISSUES WITH HUMAN-PIG CHIMERA BRAIN ACTIVITY

A. Accidental (or Purposeful) Human-Pig Chimera Brain Modification

The potential for using pigs to grow human organs raises ethical concerns about the accidental (or purposeful) integration of human cells into pig brains because it could lead to increased human attributes and blur the boundary between humans and non-human animals.[130] This blurring raises questions about our own human identity within the scientific and philosophical communities that are concerning.[131]

If a human-animal chimera exhibited advanced human-like cognitive abilities or behaviors, it would likely prompt discussions about legal recognition of personhood and

[130] John D. Loike, *Should Human-Animal Chimeras Be Granted "Personhood"?*, THE SCIENTIST (May 23, 2018), https://www.the-scientist.com/news-opinion/opinion-should-human-animal-chimeras-be-granted-personhood-36664.
[131] *Id.*

challenge our conventional views of animals. Granting these animals personhood status, rather than their current legal designation as property, would raise other pertinent legal issues. These include considerations like legal standing[132] and informed consent[133] for medical procedures. The involvement of these animals in clinical drug trials or medical procedures would then fall under human legal rights rather than solely animal rights. As a precautionary measure, regulations that prohibit genetic modifications affecting the brain should be enforced.

Several serious inquiries, but certainly not all, raised by scholars and scientists pertaining to such transformed animals include:

- Could we utilize and detain a captive pig exhibiting human behavior or physical attributes?
- Could we still use the pig for medical purposes?
- Could we kill the animal? Would it be murder?
- Is there a percent composition of human neurons incorporated into an animal's brain that renders such a chimera human?[134]
- Does using human gametes to create a healthy animal classify the resulting offspring as human?[135]

B. Legal Issues Regarding Human-Pig Brain Modification

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[132] Legal standing essentially assesses whether an individual or entity has a sufficient connection or stake in a case to bring a lawsuit or participate in legal proceedings. It typically involves three key components: **Injury or Harm:** Demonstrating that the party has suffered or will suffer a direct and specific injury or harm due to the action or issue being addressed; **Causation:** Establishing a clear link between the injury claimed and the defendant's actions or the legal issue at hand; **Redressability:** Showing that a favorable court decision could address or remedy the claimed injury or harm. Animals currently lack legal standing in most jurisdictions, meaning they cannot bring lawsuits or participate directly in legal proceedings due to their inability to represent themselves in court without human guardians or representatives. Efforts to grant legal standing to animals involve debates about recognizing their interests and welfare within the legal system.

[133] Informed consent refers to the process where an individual voluntarily agrees to participate in a specific activity or treatment after being provided with comprehensive information about the potential risks, benefits, and alternatives involved. This concept ensures that individuals make informed and autonomous decisions regarding their involvement, especially in medical procedures or research. As of now, informed consent as typically understood in human contexts is not directly applicable to animals. Animals do not have the cognitive ability to provide informed consent in a human-like manner.

[134] Loike, *supra* note 130.

[135] *Id.*

Human-animal chimeras, a blend of human and animal elements, do not neatly align with existing legal frameworks that define the rights of these two categories. Maintaining legal distinctions between animals and humans is crucial, especially as we continue to use them for food and medical purposes. For instance, there is a consensus on upholding the difference between consuming farm animals and cannibalism, and the same analog will need to be held if we are procuring organs from animals that have human DNA. This comment proposes that genetic modification and use of chimera organs is legally and ethically moral, but only if there is no brain modification. As soon as a chimera develops any human cognitive abilities then these animals would cross a line into human legal status and could no longer be utilized or killed.

Human-animal chimeras will likely remain in a gray area for the immediate future given their varying levels of human genetic information.[136] While discovering solutions will undoubtedly prove challenging, creating policy advancements on chimera-related issues must be made if we intend to use this technology. There must be strict regulatory controls on the genetic modification process with avoidance of any opportunity for brain modification. Congress should delineate clear and stringent rules rather than permitting administrative agencies to determine policies that may be vulnerable to elected political parties and societal trends that ebb and flow.

i. Personhood Following Enhanced Brain Activity Due to Human DNA Insertion

The question arises as to whether human-pig chimeras, which possess a combination of human and pig genetic material, should be considered legal "persons" entitled to constitutional protections under the 14th Amendment. This raises fundamental questions about the definition of personhood and whether it extends beyond the human species. Among the conditions that

[136] *Organ Farming and Interspecies Chimeras*, NYU GROSSMAN SCH. OF MED., https://med.nyu.edu/departments-institutes/population-health/divisions-sections-centers/medical-ethics/sites/default/files/medical-ethics-organ-farming-and-interspecies-chimeras.pdf (last visited November 2023).

"apply to personhood are rationality, consciousness, the attitude or stance taken by society, capacity for reciprocity, capability for verbal communication, and a self-consciousness."[137] Further, the Fourteenth Amendment is particularly relevant as it addresses issues of equal protection under the law and the definition of citizenship.

The Fourteenth Amendment states that no state shall "deprive any person of life, liberty, or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws."[138] The term "person" in this context has historically been understood to apply to human beings, but the legal landscape may need to adapt to emerging technologies and scientific advancements, such as the creation of human-animal chimeras. Courts will need to take the definition of personhood into serious reconsideration because chimeric pigs will contain human DNA. However, and even more importantly, if chimeric pigs developed human brain activity, then the legal status of these animals would need to be further considered. This comment proposes that at some point there is an ethical line that would be breeched if these pigs were transformed too much, and as such, the modified pigs would subsequently deserve heightened legal protections.

If human-pig chimeras were granted personhood status, there could be implications for their treatment and bodily rights. Issues related to their creation, use in research, and potential exploitation would need careful legal consideration. This would also bring up equal protection considerations. If personhood is granted, then it may require our government and country to grant legal rights to these animals. This might include considerations such as the right to life,

[137] Frederick J. White, *Personhood: An Essential Characteristic of the Human Species*, 80 The Linacre Quarterly 74, 78 (2013) (quoting Dennett D. C., *Brainstorms: Philosophical Essays on Mind and Psychology,* The MIT Press 269-271 (1981)).
[138] U.S. Const. amend. XIV, § 1.

freedom from inhumane treatment, and other legal rights akin to those granted to human individuals.

Additionally, the concept of personhood often includes the right to liberty.[139] If the chimeras possess a level of self-awareness and autonomy, legal challenges may emerge regarding their confinement, use in research, or any restrictions imposed on their freedom and liberty.

Lastly, the Fourteenth Amendment not only guarantees equal protection, but also addresses citizenship rights.[140] If chimeras were to attain a certain level of personhood, questions might arise about their eligibility for citizenship and their associated rights and responsibilities.

The legal framework most likely needs to be addressed through legislative action due to the unique challenges posed by such intense advancements in biotechnology. New laws and regulations could be required to establish a comprehensive and ethically sound regulatory framework.

The use of pig chimeras will likely become very complex with prudent oversight required by disciplined leaders. The ethical issues could easily spin out of control if a pig developed human traits. Clearly defined restrictions must be established before the technology becomes too sophisticated. This comment is not proposing an outright ban on xenotransplant use, but rather stringent thresholds for DNA modification. I, however, would firmly advocate for an outright ban on any genetic brain modification until it is more completely understood.

Another legal proposal might entail Congress or judges redefining the definition of persons as any organism that contains a certain amount of human specific DNA. If there was a percentage threshold that delineated the line between personhood and property status, then there could be laws developed that held the percentage of human DNA modification to a certain level.

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[139] *Id*.
[140] *Id*.

ii. Informed Consent Following Enhanced Brain Activity Due to Human Genetic Insertions

One vital issue in medical treatments and studies is informed consent. Humans, or their consent proxy, are obliged to provide informed consent before undergoing such procedures. However, this rule does not extend to animal subjects due to their legal status as property and inability to efficiently communicate with humans. Although there are guidelines for humane treatment, animals are legally allowed to be killed and used for medical procedures without informed consent.[141] A human-animal chimera leaning more toward an "animal" would also lack the capacity to give informed consent.[142] Yet, many find it ethically unsettling to treat a partly human entity with equal legality as natural animals. In general, the status of chimeras is undefined in the law due to the nature of their novel existence in this area of science.[143] Legal scholars who view the law as dependent upon categorizations anticipate an inevitable lapse in legislation due to the potential blurring of personhood lines with human-animal chimeras.[144]

Additionally, if chimeras were deemed to have human-like attributes, their need for legal guardianship might be considered, particularly when their communication with humans is hindered. This could involve establishing mechanisms to protect the rights and interests of these animals, similar to guardianship laws established for individuals with limited capacity. It seems that if these animals were given heightened personhood status, then a guardianship mechanism would have to be developed. This would most likely completely hinder these pigs use in medical research or organ harvesting as informed consent cannot be used to end your own life.

As stated previously, the best solution is to completely avoid any of these issues by banning brain modification techniques. Strict regulatory processes must be developed to ensure

[141] Koplin & Wilkinson, *supra* note 43, at 440–46.
[142] *Id.*
[143] *Id.* at 442.
[144] *Id.* at 445.

that only targeted organs are produced inside the xenotransplant animal. This could be achieved by defining specific laboratory procedures that are known to only modify the animal for organ harvesting until further research has been developed. If there was any perceived human sentience or cognitive ability detected, then the particular animal could not be used for medical procedures since they could not give their informed consent.

iii. Constitutional Standing if Chimeric Animals Receive Personhood Status

Another issue is that of constitutional standing. In the United States, animals currently lack standing in courts due to their classification as property. While anti-cruelty and animal welfare laws exist, animals cannot initiate lawsuits.[145] However, if a genetically modified animal incorporated human DNA to the point of exhibiting human likeness or sentience, it would undoubtedly raise questions about increased protection. We could reach a point when an animal becomes "too human," and subsequently becomes eligible for constitutional standing and human legal rights.

Unlike some other federal animal protection laws, such as the Endangered Species Act,[146] the AWA does not include a "citizen suit provision" or otherwise provide a private right of action that would allow interested parties to sue for its enforcement.[147] Thus, lawsuits based on AWA violations typically are brought under the Administrative Procedure Act.[148] However, if animals were deemed as persons then lawsuits could be brought under the same mechanisms as a human being. Courts would undoubtedly have a difficult time navigating this. A judicial test might involve using genetic composition thresholds of modified animals that would create a defined

[145] *Id.*
[146] 16 U.S.C. §§ 1531–1543.
[147] *Id.*
[148] *Id.*

line between human and animal. Also, Congress could redefine the definition of persons as any organism that contains a certain amount of human specific DNA.

An argument against granting constitutional standing and enhanced legal rights is that the chimera, in its own mind, is purely animal.[149] In other words, it may not think of itself as human. Therefore, the same or nearly the same status as natural animals should remain.[150] However, this line of reasoning is short-sighted because the animal could start to develop a sense of personhood. There are no easy answers here, but the complexities of this issue will require thorough consideration by our country and society.

C. Proposals for Strict Regulation of Embryonic Brain Genetic Modification

Considerable research is underway on chimeras, and while specific applications seem like science fiction, they are within reach. Therefore, it is crucial to establish strict oversight on the scope of chimera research. Brain experimentation is a widely debated subject, and because our knowledge of how the brain works is currently so limited, it is probably unwise to explore this territory in a being as unique and unknown as an interspecies chimera. As a result, extensive constraints, if not an outright ban, should be used for the foreseeable future with regards to chimeric brain modification.[151] Congress should craft strict regulation in a bipartisan manner for the strongest protections. It would be more beneficial than rendering it to administrative agencies that often change their policies.

Congress should pass a bipartisan federal law that bans or severely restrains chimeric brain research to ensure robust protections. An executive order or agency regulation will not suffice; a congressional law is imperative. This prohibition should remain in place until the results of any brain modifications are comprehensively understood. For now, we should only

[149] *Id.*
[150] *Id.*
[151] *Id.*

employ precise scientific methods that exclusively modify the organ or medical product we need from the chimeric animal.

If Congress fails to enact legislation, then the President could establish a federal moratorium on chimeric brain modification due to the uncertainty surrounding the potential outcomes. These policies, however, could easily change as differing political parties are elected.[152] A fundamental principle in bioethics is the importance of cautiously proceeding in scientific endeavors that could lead to unforeseen consequences.[153]

Notably, several self-policing precautions are in place within the scientific community to prevent the creation of chimeras with human-derived neural tissue.[154] However, this comment argues for legal safeguards. Although, most scientific institutions only allow such experimentation with extremely prudent consideration, it is important that our government and society are also involved in these decisions.

VI. CONCLUSION

A 57-year-old patient with terminal heart disease successfully received a transplant of a genetically modified pig heart in January 2022.[155] This marked a historic surgery conducted at the University of Maryland Medical Center.[156] This groundbreaking procedure demonstrated that a genetically modified pig heart could function like a human heart without immediate rejection.[157] The patient experienced good cardiac function for nearly seven weeks but unfortunately passed away due to heart failure two months after the transplant.[158]

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[152] *Organ Farming and Interspecies Chimeras, supra* note 133.
[153] *Id.*
[154] *Id.*
[155] Deborah Katz, *UM Medicine Performs Historic Xenotransplantation*, UNIV. OF MD., BALT. (Jan. 11, 2022), https://www.umaryland.edu/news/archived-news/january-2022/um-medicine-performs-historic-xenotransplantation.php.
[156] *Id.*
[157] *Id.*
[158] Deborah Katz, *Lessons Learned from World's First Successful Transplant of Genetically-Modified Pig Heart into Human Patient,* UNIV. OF MD. SCH. OF MED. (June 30, 2023),

Researchers are still conducting studies to determine the cause of the heart failure but "found indirect evidence of antibody-mediated rejection based on histology, immuno-histochemical staining, and single-cell RNA analysis."[159] However, this surgery proved that xenotransplantation for patients needing heart transplants may be available soon.[160]

Another groundbreaking study published in *JAMA Surgery* in August 2023 showed genetically modified pig kidneys provided "life-sustaining kidney function" in a human for a planned seven-day study.[161] A brain-dead recipient received a human-pig kidney xenotransplantation with her family's consent, and almost immediately, the kidney functioned normally.[162] The genetically modified pig kidney produced urine rapidly and remained functional—confirming safe and effective xenotransplantation.[163]

In his paper, *A Brief History of Cross-Species Organ Transplantation*, Dr. David K.C. Cooper stated:

> The words of George Orwell in *Animal Farm* will be apposite to pig organ transplantation in humans. 'The creatures outside looked from pig to man, and from man to pig, and from pig to man again; but already it was impossible to say which was which.' I believe the same will one day be said for the doctor examining a patient with an organ transplant—the doctor will not be able to determine whether the organ is a [human transplant] or an [animal transplant]. Eventually, [human transplantation] will be of historic interest only.[164]

This emerging technology offers significant advantages. However, it is crucial to approach it with the utmost respect and consideration for the patients, the animals, the legal

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https://www.medschool.umaryland.edu/news/2023/Lessons-Learned-from-Worlds-First-Successful-Transplant-of-Genetically-Modified-Pig-Heart-into-Human-Patient-.html.

[159] *Id.*

[160] *Id.*

[161] Tyler Greer, *Pig Kidneys—For the First Time—Demonstrate "Life-Sustaining Kidney Function" in a Human*, Univ. of Ala. at Birmingham (Aug. 16, 2023), https://www.uab.edu/news/health/item/13712-new-study-pig-kidneys-for-the-first-time-demonstrate-life-sustaining-kidney-function-in-a-human.

[162] *Id.*

[163] *Id.*

[164] David K. Cooper, *A Brief History of Cross-species Organ Transplantation*, 25 Baylor Univ. Med. Ctr. Proc. 49, 55 (Jan. 2012).

ramifications, and the scientific ethics. Society will inevitably enter deep legal and philosophical discussions as this technology progresses.