HUMAN-NONHUMAN CHIMERAS: A REGULATORY PROPOSAL ON THE BLURRING OF SPECIES LINES

Abstract: The chimera of modern biotechnology is defined broadly as a single organism composed of a mixture of materials from two or more organisms possessing distinct genetic backgrounds. Unlike the United States, which does not regulate chimeras directly, Canada has responded to the unregulated pursuit of chimera technology by banning certain chimeras as part of comprehensive legislation designed to regulate human reproductive technologies. In 2004, the Canadian Parliament passed the Assisted Human Reproduction Act despite criticism urging greater legislative justification for the Act's provisions and modification to its statutory definitions. Because current regulatory mechanisms in the United States, including patent law and administrative oversight, fail to regulate chimera technology, the United States should enact new legislation, using Canada's legislation as a model, to prohibit embryonic chimeras and to regulate other human-nonhuman combinations. Unregulated biotechnology threatens to disrupt legal and social institutions; therefore, the United States must make a balanced effort now to protect the public interest.

INTRODUCTION

The Chimera of ancient Greek mythology was a fire-breathing beast with a lion's head, goat's body, and dragon's tail that ravaged the kingdom of Lycia until the hero, Bellerophon, destroyed it.[1] The chimera of modern biotechnology is defined broadly as a single organism composed of a mixture of materials from two or more organisms possessing distinct genetic backgrounds.[2] The mythological origin of the term reflects not only the multispecies composition of chimeras, but also their potential, as products of unbridled technological innovation, to generate disruption and confusion in society.[3]

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[1] THOMAS BULFINCH, THE AGE OF FABLE (1855), *reprinted in* BULFINCH'S MYTHOLOGY 3, 117–18 (Random House 1993).

[2] Henry T. Greely, *Defining Chimeras . . . and Chimeric Concerns*, 3 AM. J. BIOETHICS, Summer 2003, at 17, 17–19 (recommending an exhaustive taxonomy to aid the analysis of ethical concerns presented by various forms of chimeras).

[3] *See* Jason Scott Robert & Françoise Baylis, *Crossing Species Boundaries*, 3 AM. J. BIOETHICS, Summer 2003, at 1, 9 (discussing ethical aspects of creating chimeras followed by responses from over two dozen commentators). *But see* Robert Streiffer, *In Defense of the*

Chimeras were once merely the fantastic creations of science fiction; however, rapid advances in genetics, cloning, and embryology have resulted in the blurring of species lines, including our own species, *Homo sapiens*.[4] In particular, recent advances in the development of chimeras have led to the creation of a variety of organisms with both human and animal components.[5]

Despite these scientific developments and the expanding discussion of chimeras among bioethicists, legal discourse has not explored thoroughly the implications of this emerging technology.[6] In the United States, there is no regulatory body prepared to address the specific legal and ethical issues that chimeras present.[7] The Food and Drug Administration (the "FDA") has not extended its regulatory reach to embryonic chimeras,[8] although it has made a controversial claim of jurisdiction over human cloning.[9] Furthermore, present efforts to regulate federally funded research, such as President George W. Bush's limitation on the creation of new stem cell lines, do not encompass chimera technology directly, or private biotechnology research generally.[10] Likewise, internal methods of biotechnology regulation, including self-policing organizations and institutional review boards, have proven to be insufficient regulators of biotechnology.[11]

Unlike the United States, Canada responded to the unregulated pursuit of chimera technology by banning certain human-nonhuman

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Moral Relevance of Species Boundaries, 3 AM. J. BIOETHICS, Summer 2003, at 37, 37 (asserting that Robert and Baylis offer no empirical evidence to support their claim that the existence of chimeras would introduce inexorable moral confusion).

[4] *See* Robert & Baylis, *supra* note 3, at 1, 4–6. The existence of species lines, however, is biologically problematic. *See infra* notes 266–267 and accompanying text.

[5] Robert & Baylis, *supra* note 3, at 4; *see infra* notes 42–70 and accompanying text.

[6] *See* A.M. Chakrabarty, *Crossing Species Boundaries and Making Human-Nonhuman Hybrids: Moral and Legal Ramifications*, 3 AM. J. BIOETHICS, Summer 2003, at 20, 21.

[7] *See* ERIK PARENS & LORI P. KNOWLES, THE HASTINGS CTR., REPROGENICS AND PUBLIC POLICY: REFLECTIONS AND RECOMMENDATIONS 17 (Supp. 2003), *available at* http://thehastingscenter.org/pdf/reprogenetics_and_public_policy.pdf.

[8] *See id.* at 12.

[9] *See* Gregory J. Rokosz, *Human Cloning: Is the Reach of FDA Authority Too Far a Stretch?*, 30 SETON HALL L. REV. 464, 511–12 (2000) (asserting that despite the benefits of agency regulation, FDA jurisdiction over cloning is unlikely to survive a serious challenge).

[10] *See* President George W. Bush, Address to the Nation on Stem Cell Research from Crawford, Texas, 37 WEEKLY COMP. PRES. DOC. 1149, 1151 (Aug. 9, 2001), http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2001_presidential_documents&docid=pd13au01_txt-9.pdf.

[11] *See* Lori A. Alvino, Note, *Who's Watching the Watchdogs? Responding to the Erosion of Research Ethics by Enforcing Promises*, 103 COLUM. L. REV. 893, 901–09 (2003) (suggesting that administrative regulations governing federally funded research on human subjects and oversight by institutional review boards provide inadequate safeguards).

combinations as part of comprehensive legislation designed to regulate human reproductive technologies.[12] The Canadian Parliament passed the Assisted Human Reproduction Act (the "AHR Act") in 2004,[13] despite criticism urging greater legislative justification for the Act's provisions and modification to the statutory definitions.[14] In contrast, legislators in the United States have struggled to reach a consensus on embryo research and human cloning, but have yet to address chimeras specifically.[15] The United States, therefore, should confront the pressing issues arising from the creation of novel beings by implementing legislation modeled after Canada's AHR Act.[16]

This Note weighs the arguments for and against regulating the creation of various types of chimeras,[17] evaluates opportunities to regulate chimeras within existing institutions,[18] and examines Canada's AHR Act as a possible model for legislation in the United States.[19] Part I of this Note explains the science behind chimera creation as it pertains to the complex definitional issues inherent in regulation.[20] Part II of this Note sets forth some of the ethical and legal arguments in support of and in opposition to the regulation of chimeras.[21] Part III examines the potential use of existing legal mechanisms to regulate chimeras, including patent law, the FDA, and existing laws.[22] Part IV analyzes

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[12] *See* Assisted Human Reproduction Act, ch. 2, 2004 S.C. (Can.) (received Royal Assent on Mar. 29, 2004), *available at* http://www.hc-sc.gc.ca/english/pdf/protection/ahr/C-6_4_RA.pdf.

[13] *Id.* For an overview of the Canadian legislative process, see generally SENATE ET AL., INSIDE CANADA'S PARLIAMENT: AN INTRODUCTION TO HOW THE CANADIAN PARLIAMENT WORKS 1, 26 (2002), *available at* http://www.parl.gc.ca/Information/library/inside/pdf/inside-canada-parliament-e.pdf. To become law in Canada, a bill first must be introduced in either the Senate or the House of Commons. *Id.* The bill then passes through the first reading, second reading, committee stage, report stage, and third reading in each house. *Id.* Following Royal Assent by the Governor General, the bill becomes law. *Id.*

[14] *See* Timothy Caulfield, *Symposium on Bill C-13: The Assisted Human Reproduction Act*, 11 HEALTH L. REV. 3, 3 (2002) (reflecting general themes of symposium).

[15] *See* PARENS & KNOWLES, *supra* note 7, at 17.

[16] *See* Stuart A. Newman, *Averting the Clone Age: Prospects and Perils of Human Developmental Manipulation*, 19 J. CONTEMP. HEALTH L. & POL'Y 431, 462 (2003) (suggesting a bright-line rule to prohibit genetic and cellular manipulations of human embryos); Lauren Cirlin, Comment, *Human or Animal: A Resolution to the Biotechnological Blurring of the Lines*, 32 SW. U. L. REV. 501, 519–20 (2003) (recommending that Congress decide whether to allow or prohibit human-nonhuman chimera research).

[17] *See infra* notes 71–95 and accompanying text.

[18] *See infra* notes 96–207 and accompanying text.

[19] *See infra* notes 208–249 and accompanying text.

[20] *See infra* notes 26–70 and accompanying text.

[21] *See infra* notes 71–95 and accompanying text.

[22] *See infra* notes 96–207 and accompanying text.

Canada's AHR Act and describes the critical debate surrounding this legislation.[23] Part V addresses the constitutional and legal implications of modeling legislation in the United States after the AHR Act including scientific expression under the First Amendment, the concept of personhood, and protection for chimeras under the Thirteenth Amendment.[24] Finally, Part VI argues that because current mechanisms fail to regulate chimera technology, the United States should enact legislation, using Canada's AHR Act as a model, to prohibit the use of human gametes and embryos to make chimeras.[25]

I. Scientific Technology and the Production of Chimeras

Regulators must understand and reference the underlying biotechnology to develop coherent and useful definitions of chimeras.[26] Moreover, scientific understanding reveals how rapid advances in biotechnological techniques shape the ethical and legal discourse regarding chimera regulation.[27] For example, complex biotechnology enables scientists to increase the human composition of chimeras dramatically, thus dismantling traditional concepts of species and personhood.[28] As a result, biotechnological differences suggest that certain technology may contravene the public welfare and human dignity, whereas other technology generates less concern.[29]

A. *Traditional Methods for Crossing Species Boundaries*

Scientists have been crossing species boundaries for decades by transferring specific genes[30] and other materials from one species to

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[23] *See infra* notes 208–249 and accompanying text.

[24] *See infra* notes 250–296 and accompanying text.

[25] *See infra* notes 297–387 and accompanying text.

[26] *See* President's Council on Bioethics, Human Cloning and Human Dignity: An Ethical Inquiry 37–55 (2002) [hereinafter Human Cloning and Human Dignity] (emphasizing the importance of accurate terminology to prevent distortion and ambiguity in the discussion of human cloning), *available at* http://www.bioethics.gov/reports/cloningreport/pcbe_cloning_report.pdf.

[27] *See* Robert & Baylis, *supra* note 3, at 1.

[28] *See id.* at 4–5; Michael D. Rivard, Comment, *Toward a General Theory of Constitutional Personhood: A Theory of Constitutional Personhood for Transgenic Humanoid Species*, 39 UCLA L. Rev. 1425, 1431 (1992) (asserting that present doctrines cannot address issues of personhood raised by emerging technology involving novel humanoid organisms).

[29] *See* Greely, *supra* note 2, at 19; Josephine Johnston & Christopher Eliot, *Chimeras and "Human Dignity"*, 3 Am. J. Bioethics W6, W6–7 (2003), *at* http://mitpress.mit/edu/journals/ajob/3/3/w6.pdf.

[30] A gene is "[t]he functional and physical unit of heredity passed from parent to offspring. Genes are pieces of DNA, and most genes contain the information for making a

another.[31] Conventional technologies include animal breeding to produce hybrids, such as mules;[32] interspecies organ donation;[33] and genetic recombination techniques.[34] Interspecies organ donation, or xenotransplantation, emerged several decades ago as an attempt to remedy the insufficient number of human organ donors.[35] Researchers hope that, in the future, specially bred animals will provide an abundant supply of organs for human recipients.[36]

Scientists modify donor animals using genetic engineering techniques such as genetic recombination, which involves the transfer of genes from one species to another.[37] Scientists have used recombinant DNA techniques to express human proteins in lower life forms, including bacteria.[38] Subsequent innovations have allowed scientists to

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specific protein." NAT'L HUMAN GENOME RESEARCH INST., TALKING GLOSSARY OF GENETIC TERMS, *at* http://www.genome.gov/glossary.cfm?key=gene (last visited Apr. 1, 2004). DNA, or deoxyribonucleic acid, is the primary genetic material of most organisms. Eileen Morin, *Of Mice and Men: The Ethics of Patenting Animals*, 5 HEALTH L.J. 147, 149 (1997). DNA is the component of genes that may be spliced and recombined in various ways in genetic engineering. *Id.*

[31] *See* NAT'L BIOETHICS ADVISORY COMM'N, CLONING HUMAN BEINGS: REPORT AND RECOMMENDATIONS OF THE NATIONAL BIOETHICS ADVISORY COMMISSION 1 (1997), *available at* http://www.georgetown.edu/research/nrcbl/nbac/pubs/cloning1/cloning.pdf; Rokosz, *supra* note 9, at 472 (discussing the process of using bacteria to replicate human DNA and manufacture proteins); *infra* notes 35–36 and accompanying text.

[32] Mules are hybrids of male donkeys and female horses that may occur naturally without ethical concern. Greely, *supra* note 2, at 19.

[33] *See infra* notes 35–36 and accompanying text.

[34] *See infra* notes 37–41 and accompanying text; *see also* David Castle, *Hopes Against Hopeful Monsters*, 3 AM. J. BIOETHICS, Summer 2003, at 29, 29 (suggesting conventional and unconventional chimeras raise the same ethical concerns to varying degrees).

[35] Fritz H. Bach et al., *Ethical and Legal Issues in Technology: Xenotransplantation*, 27 AM. J.L. & MED. 283, 284–85 (2001). Several patient deaths in the 1960s and 1970s stalled scientists' initial efforts to harvest organs from animal donors for use as substitutes for human organs. *Id.* Research accelerated in the 1980s following advances to prevent organ rejection, including new drugs to suppress the immune system and procedures to modify donor animals genetically. *Id.*

[36] *See id.* at 285.

[37] *See* Robert P. Merges, *Intellectual Property in Higher Life Forms: The Patent System and Controversial Technologies*, 47 MD. L. REV. 1051, 1053 (1988); Morin, *supra* note 30, at 149; Rivard, *supra* note 28, at 1434–36. Scientists have developed several recombination techniques, including microinjection, cell fusion, electroporation, and retroviral infection. Morin, *supra* note 30, at 149. In the most common technique, microinjection, scientists insert foreign genes from one animal directly into the DNA of another animal, called a host. Merges, *supra* at 1054. A portion of the inserted DNA will be taken into the host nucleus and will integrate with the host DNA, thereby expressing the desired protein. *Id.*

[38] *See* Greely, *supra* note 2, at 19. The public's moral ambivalence toward the creation of bacteria-human chimeras may result from these chimeras' relative invisibility and dissimilarity to human beings. *See id.*

engineer uniquely human susceptibilities into mammals.[39] For example, by the late 1980s, scientists refined recombinant DNA technology to create mice that expressed human proteins[40] and mice that contained entire human immune systems.[41]

B. *Modern Techniques to Create Chimeras*

Recent advances in biotechnology have expanded the potential to blend species beyond the limits of traditional transplantation and genetic recombination techniques.[42] Innovations in stem cell research, embryology, and cloning enable scientists to create modern chimeras, which increasingly blur the line between human and animal.[43]

1. Fusing Stem Cells and Embryos to Produce Chimeras

The narrow scientific definition of chimera is an organism that has at least two different populations of cells, which are genetically distinct and originated from different fertilized eggs.[44] Scientists typically create chimeras by mixing stem cells[45] (or embryos) from one

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[39] *See* Merges, *supra* note 37, at 1053–55. An example of this technique is described in the first patent of a multicellular organism, known as the "Harvard Mouse," issued to Philip Leder in 1988. *See* U.S. Patent No. 4,736,866 (issued April 12, 1988); JoAnne Eichelberger Seibold, Note, *Can* Chakrabarty *Survive the "Harvard Mouse"?*, 2 U. FLA. J.L. & PUB. POL'Y 81, 81–83 (1998–1999) (describing a mouse engineered to contain cancer-causing genes not normally found in mice). Following the success of the Harvard Mouse, scientists engineered thousands of transgenic mice, which were discarded after their use in experimental studies of cancer, HIV, and illnesses requiring animal research models. Merges, *supra* note 37, at 1055; Mark Sagoff, *Transgenic Chimeras*, 3 AM. J. BIOETHICS, Summer 2003, at 29, 29.

[40] Merges, *supra* note 37, at 1056. For example, in one experiment, researchers inserted the gene for the protein, tissue plasominogen activator (tPA), into female mice, which began secreting tPA in their milk. *Id.* The researchers then used the tPA as a clot dissolver for heart attack victims. *Id.*

[41] Greely, *supra* note 2, at 19. For example, the SCID-hu mouse contains a complete human immune system for the purpose of researching human immune functions. *Id.*

[42] *See infra* notes 43–70 and accompanying text.

[43] *See* Robert & Baylis, *supra* note 3, at 1, 6.

[44] COLO. STATE UNIV., CYTOGENETICS AND CHROMOSOMAL DISORDERS: MOSAICISM AND CHIMERISM, *at* http://arbl.cvmbs.colostate.edu/hbooks/genetics/medgen/chromo/mosaics.html (last updated Aug. 5, 1998). Mosaic organisms, like chimeras, possess genetically different cells. *Id.* For example, people with Turner's Syndrome often possess a mixture of normal cells and cells with chromosomal abnormalities. *Id.* Mosaicism differs from chimerism, however, because all of the cells in the organism originate from a single fertilized egg. *Id.*

[45] Stem cells are "undifferentiated multipotent precursor cells that are capable both of perpetuating themselves as stem cells and of undergoing differentiation into one or more specialized types of cells." HUMAN CLONING AND HUMAN DIGNITY, *supra* note 26, at 233.

species with early embryos of another species.[46] Each type of cell retains its own character, such that the resulting chimera is a combination of mismatched parts.[47] Because the DNA from each species ordinarily does not combine in this process, any offspring of the chimera will contain DNA from just one of the original species.[48]

An indeterminate number of people are born as natural human-human chimeras.[49] These chimeric people possess two types of cells containing different sets of DNA as a result of a rare genetic anomaly that is seldom detected.[50] Scientists have manipulated this process in animals to produce unnatural yet viable transgenic chimeras, beginning with a goat-sheep chimera, or "geep," in 1984.[51] Based on this success, scientists proposed injecting human stem cells into mouse embryos to test their pluripotency, or potential to develop into various types of tissues.[52] The researchers hypothesized that if the cells survived and became pluripotent, they then would contribute to the formation of all of the chimera's tissues, including germ line cells, which produce eggs and sperm.[53] Developmental biologists, however, were divided on whether it was ethical to add human cells to developing animal embryos.[54] Nevertheless, this theory was tested in 2004, when researchers

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[46] *See* Robert & Baylis, *supra* note 3, at 8.

[47] SARAH HARTWELL, HYBRID BIG CATS #1, *at* http://members.aol.com/jshartwell/hybrid-mammals.html (last visited Apr. 1, 2004).

[48] Rivard, *supra* note 28, at 1437.

[49] Helen Pearson, *Dual Identities*, 417 NATURE 1, 10–11 (2002). Typically, a chimeric person was destined to be born a twin. *Id.* at 10. Due to a developmental anomaly, cells from the twin became incorporated in the chimeric person's body in one of two ways: (1) either the twin was spontaneously aborted, leaving embryonic blood cells that became part of the chimeric person's bone marrow, or (2) the cells of the twin failed to separate at the embryonic stage, so the chimeric person was born with some somatic cells containing DNA from the twin. *Id.* Researchers have suggested that the incidence of natural human-human chimeras has increased with the advent of in vitro fertilization (IVF) techniques. *Id.* at 11.

[50] *Id.* at 10–11.

[51] *See* Carole B. Fehilly et al., *Interspecific Chimaerism Between Sheep and Goat*, 307 NATURE 634, 634–36 (1984). The "geep" was the first chimera created in the United States. *Id.* at 634. The structure of its legs and skull were goat-like, but it had the frame of a sheep with curly wool and patches of short, coarse hair. *See id.* at 635–36.

[52] Natalie DeWitt, *Biologists Divided over Proposal to Create Human-Mouse Embryos*, 420 NATURE 255, 255 (2002).

[53] *See id.*; Robert & Baylis, *supra* note 3, at 8.

[54] DeWitt, *supra* note 52, at 255. Ultimately, despite the ethical debate, scientists inserted neural stem cells from ten-week-old human fetuses into the brain of a live mouse, after which the human cells survived and populated various regions of the mouse brain. Lisa M. Krieger, *Treading New Ethical Ground, Scientists Put a Bit of Man into a Mouse*, MERCURY NEWS, http://www.siliconvalley.com/mld/siliconvalley/4700100.htm?template=contentModules/printstory.jsp (posted Dec. 9, 2002). Scientists had conducted other experiments grafting human embryonic stem cells onto early chick embryos. *See* Ronald S. Goldstein et al., *Integra-*

produced human-pig chimeras by injecting human stem cells into developing pig embryos.[55] The developing pigs contained both human and porcine cells, and surprisingly, some cells fused spontaneously to incorporate both human and pig DNA.[56]

2. Cloning to Produce Human-Nonhuman Embryos

Policymakers and ethicists often reference other interspecies combinations, such as hybrids, when discussing chimeras.[57] Hybrids are created when an egg and a sperm from different but closely-related species join to form a single zygote.[58] Although scientists create hybrids in the laboratory, they also combine material from different species into a single cell using cloning[59] techniques.[60] These human-nonhuman em-

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tion and Differentiation of Human Embryonic Stem Cells Transplanted to the Chick Embryo, 225 DEVELOPMENTAL DYNAMICS 1, 80–86 (2002).

[55] Brenda M. Ogle et al., *Spontaneous Fusion of Cells Between Species Yields Transdifferentiation and Retroviral Transfer in Vivo*, 18 FED'N AM. SOC'YS FOR EXPERIMENTAL BIOLOGY J. 548, 548–50 (2004) (condensed version available in print; full text of prepublication version published online Jan. 8, 2004, *available at* http://www.fasebj.org). In January 2004, scientists created human-pig chimeras by injecting human stem cells derived from adult bone marrow donors into forty-day-old pig fetuses. *Id.* Of the surviving human stem cells, about sixty percent became incorporated into the porcine tissue. *Id.*

[56] *See id.* Researchers did not anticipate that cells from each species would fuse in this manner to create hybrid cells with two sets of DNA. *See* Gaia Vince, NewScientist.com, *Pig-Human Chimeras Contain Cell Surprise*, *at* http://www.newscientist.com/news/news.jsp?id=ns99994558 (Jan. 13, 2004). The United States Patent and Trademark Office (the "USPTO") rejected a proposal to create human-nonhuman chimeras using a similar technique. *See infra* notes 107–121 and accompanying text.

[57] *See, e.g.*, Assisted Human Reproduction Act, ch. 2, §§ 3, 5(1), 2004 S.C. (Can.) (defining and regulating both hybrids and chimeras); Robert & Baylis, *supra* note 3, at 8–9 (featuring both hybrids and chimeras in bioethical discussion). Embryos produced through interspecies nuclear transfer fall within this Note's broad analysis of single biological entities composed of a mixture of materials from two or more organisms possessing distinct genetic backgrounds. *See supra* note 2 and accompanying text.

[58] HARTWELL, *supra* note 47. A zygote is "[t]he diploid cell that results from the fertilization of an egg cell by a sperm cell." HUMAN CLONING AND HUMAN DIGNITY, *supra* note 26, at 233. Diploid "[r]efers to the chromosome number in a cell, distinct for each species (forty-six in human beings)." *Id.* at 230.

[59] Cloning involves the insertion of DNA from a body cell (somatic cell) into an egg from which the nucleus has been removed. *See generally* HUMAN CLONING AND HUMAN DIGNITY, *supra* note 26, at 57–71. Scientists use chemicals or electricity to stimulate cloned embryos to begin dividing as would an egg fertilized by a sperm. *Id.* at 60. If scientists join a somatic cell nucleus from one species and an egg cell from another species, then each cell in the resulting organism will contain materials from both species. *Id.* at 58–59.

[60] *See* Robert & Baylis, *supra* note 3, at 8. Organisms produced using cloning techniques are not technically hybrids because they are not created from eggs and sperm. *See* HARTWELL, *supra* note 47. These organisms are not technically chimeras either, because all of their cells are genetically identical. *See* COLO. STATE UNIV., *supra* note 44.

bryos raise some of the same profound ethical questions as traditional chimeras.[61] For example, following the first human-nonhuman nuclear transfer[62] in 1998, President Bill Clinton indicated that he was "'deeply troubled'" by the human-nonhuman nuclear transfer and asked the National Bioethics Advisory Board to investigate the research.[63] In the procedure at issue, scientists at a private biotechnology company fused the nuclei of human body cells with cow eggs from which the nuclei had been removed.[64] Only one of the resulting embryos, which contained 99% human DNA from the transferred human nucleus and 1% cow DNA from the egg's mitochondria,[65] developed past the sixteen-cell stage.[66]

In 2003, scientists in China removed the DNA from the nuclei of rabbit eggs and replaced it with DNA from human body cells.[67] The scientists then allowed the embryos to develop for several days before

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[61] *See* Robert & Baylis, *supra* note 3, at 8.

[62] Nuclear transfer means "[t]ransferring the nucleus with its chromosomal DNA from one (donor) cell to another (recipient) cell. In cloning, the recipient is a human egg cell and the donor cell can be any one of a number of different adult tissue cells." PRESIDENT'S COUNCIL ON BIOETHICS, REPRODUCTION AND RESPONSIBILITY: THE REGULATION OF NEW TECHNOLOGIES 232, *at* http://www.bioethics.gov/reports/reproductionandresponsibility/_pcbe_prepub_reproduction_and_responsibility.pdf (forthcoming 2004) [hereinafter REPRODUCTION AND RESPONSIBILITY].

[63] *See* Transcript, Nat'l Bioethics Advisory Comm'n, 25th Meeting (Nov. 17, 1998), at 3, 99, *available at* http://www.georgetown.edu/research/nrcbl/nbac/transcripts/nov98/day_1.pdf. Professor Ralph L. Brinster, a veterinary scientist at the University of Pennsylvania, indicated that transgenic organisms produced through nuclear transfer are probably not chimeras. *Id.* at 102–03.

[64] *See* Jose E. Cibelli et al., *Somatic Cell Nuclear Transfer in Humans: Pronuclear and Early Embryonic Development*, 2 J. REGENERATIVE MED. 25, 25–31 (2001); *see also* Robert P. Lanza et al., *Human Therapeutic Cloning*, 5 NATURE MED. 963, 975 (1999) (discussing benefits of cow-human interspecies nuclear transfer research).

[65] Mitochondria are "[s]mall energy-producing organelles inside of cells." HUMAN CLONING AND HUMAN DIGNITY, *supra* note 26, at 232. Mitochondria replicate by creating a copy of their short mitochondrial DNA sequence, so that each of the two resulting mitochondria receives a copy. *Id.*

[66] *See* Lanza et al., *supra* note 64, at 975.

[67] Ying Chen et. al., *Embryonic Stem Cells Generated by Nuclear Transfer of Human Somatic Nuclei into Rabbit Oocytes*, 13 CELL RESEARCH 251–64 (2003), *available at* http://www.cell-research.com/20034/034-chzb.pdf; *see also* Carina Dennis, *China: Stem Cells Rise in the East*, 419 NATURE 323, 334–36 (2002). In the experiment, scientists removed the nuclei from human cells that were extracted from tissues discarded after surgeries on male and female children and adults. Rick Weiss, *Cloning Yields Human-Rabbit Hybrid Embryo*, WASH. POST, Aug. 14, 2003, at A04. The scientists then transplanted the nuclei into New Zealand rabbit eggs and allowed them to develop to the embryonic stage. *Id.* The rabbit DNA reprogrammed the human DNA to multiply and develop into embryos that contained both the nuclear human genome and mitochondrial rabbit DNA. *Id.*

they destroyed them.[68] Researchers claim that these techniques may yield embryonic stem cells, from which they hope to produce cells and tissues for human transplantation.[69] This research raises additional concerns, however, because if the experiments were continued, they might lead to the development of human-nonhuman beings.[70]

II. Ethical and Legal Justifications for Chimera Regulation

Notwithstanding concerns about the void of legal authority controlling the development of chimera technology in the United States, there is also no consensus about which, if any, chimeras should be regulated.[71] The arguments for and against the regulation of chimeras involve two traditions of Western philosophy.[72] The first philosophy, the deontological approach, evaluates the inherent rightness or wrongness of an action without regard to the consequences.[73] The second philosophy, the utilitarian approach, weighs the benefits and harms of an action without judging its morality.[74] Arguments for and against chimera regulation implicate both philosophies.[75]

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[68] Weiss, *supra* note 67, at A04. The researchers did not allow the embryos to live beyond fourteen days, which is in accord with the standard originally set forth by the United Kingdom's Report of the Committee of Inquiry into Human Fertilisation and Embryology (the "Warnock Report"). *See* Department of Health & Social Security, Report of the Committee of Inquiry into Human Fertilisation and Embryology, 1984, Cmnd. 9314, at 66, http://www.bopcris.ac.uk/img1984/ref2900_1_1.html; Weiss, *supra* note 67, at A04. The Warnock Report led to the United Kingdom's criminalization of experiments that involve putting human embryos into animal bodies or mixing human gametes with animal gametes without a license. *See* Human Fertilisation and Embryology Act, 1990, c. 37, §§ 3(3)(b), 4(1)(c) (U.K.), http://www.hmso.gov.uk/acts/acts1990/Ukpga_19900037_en_1.htm.

[69] *See* Lanza et al., *supra* note 64, at 975.

[70] *See id. But see* Janet L. Dolgin, *Embryonic Discourse: Abortion, Stem Cells, and Cloning*, 31 Fla. St. U. L. Rev. 101, 113–14 (2003) (suggesting that although nuclear transfer experiments reinforced public concern about the creation of human-nonhuman beings, such as a cow-person, the promise of embryonic stem cell research generated responses in favor of cloning for research purposes).

[71] *See infra* notes 205–207 and accompanying text (describing changes in the President's Council's interim recommendations to Congress regarding which types of chimera creations Congress should prohibit); *see also* Thomas A. Magnani, *The Patentability of Human-Animal Chimeras*, 14 Berkeley Tech. L.J. 443, 444–45 (1999) (recommending that "biotechnology should be regulated, *if at all*, by Congress directly") (emphasis added).

[72] Morin, *supra* note 30, at 168.

[73] *Id.*

[74] *Id.*

[75] *Id.*

A. *Deontological Arguments*

The primary ethical objections to making human chimeras are deontological.[76] Deontological arguments include, for example, emphasis on the dignity of humanity or stewardship over other beings.[77] In light of the special dignity afforded to the human embryo, deontologists might advocate a ban on chimeras made using human embryos.[78] Also, deontologists might object to some future uses of chimeras, which although purely speculative, indicate the type of unrestrained scientific experimentation that the government might intervene to prevent.[79] For example, researchers may create future human-nonhuman chimeras for nonmedical, elective purposes such as to delay aging and to enhance human capabilities.[80] These efforts to create chimeras for nontherapeutic purposes might raise deontological objections based on assertions of their intrinsic wrongness.[81]

B. *Utilitarian Arguments*

Utilitarians might find that the benefits of creating human-nonhuman chimeras for medical and pharmaceutical research outweigh any harmful results.[82] Human-nonhuman chimeras are increasingly valuable to pharmaceutical companies for studying the benefits of new drugs.[83] Currently, FDA regulations require pharmaceutical companies to test new drugs extensively on animals before they may be tested on humans; however, drugs that produce a beneficial effect

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[76] *See* Magnani, *supra* note 71, at 456–58 (criticizing patent law's moral utility test as applied to technology, because it weighs beneficial uses more heavily than abstract moral objections to chimeras).

[77] *See id.* at 457.

[78] *See* Samuel B. Casey & Nathan A. Adams IV, *Specially Respecting the Living Human Embryo by Adhering to Standard Human Subject Experimentation Rules*, 2 YALE J. HEALTH POL'Y, L., & ETHICS 111, 118–19 (2001) (suggesting that human embryos be given special respect in research and be subject to guidelines for human experimentation instead of policies for the use of human issues); Magnani, *supra* note 71, at 457.

[79] *See* Newman, *supra* note 16, at 457–61 (discussing the risks of unlimited human developmental manipulation).

[80] *See, e.g.*, Julian Savulescu, *Human-Animal Transgenesis and Chimeras Might Be an Expression of Our Humanity*, 3 AM. J. BIOETHICS, Summer 2003, at 22, 22–24 (advocating the creation of chimeras when there are rational reasons to do so or when genetic modification will improve human reasoning, because such purposes are expressions of humanity).

[81] *See* Magnani, *supra* note 71, at 457. For example, an experiment involving human-human hermaphroditic chimeras produced strong ethical objections in relation to the relatively weak beneficial use of the research. *See infra* notes 350–352 and accompanying text.

[82] *See* Magnani, *supra* note 71, at 456.

[83] *Id.*

for animals may not produce the same effect in humans.[84] The creation of human-nonhuman chimeras would make this process more efficient, because researchers could evaluate the direct effect of new drugs on the human cells of chimeras.[85]

Human-nonhuman chimeras also offer promise in organ transplantation.[86] Humans are less likely to reject organs harvested from chimeras than from animal donors, because animal hearts and kidneys grown partly from human cells in chimeras would resemble the recipient's organs more closely.[87] Chimeras are also useful in studies of human development.[88] Given that scientists have already produced human-rabbit chimeras as sources of stem cells,[89] utilitarians might support adding pluripotent animal stem cells to developing human embryos to test for immunological resistance to disease.[90] Similarly, utilitarians might urge the isolation of gene sequences from animals resistant to diseases such as HIV for introduction into the human genome to confer HIV resistance.[91]

A more radical utilitarian approach might support creating chimeras for human genetic enhancement.[92] Researchers could add animal genes to the human genome to confer new traits or to delay aging; for example, increasing human night vision by adding genes from nocturnal animals or combating human telomere[93] degradation by adding genes from long-living creatures.[94] At the same time, the utilitarian approach necessitates acknowledging the risk that the pro-

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[84] *Id.*

[85] *See id.*

[86] *See id.*

[87] Magnani, *supra* note 71, at 456.

[88] *See id.*

[89] *See supra* notes 67–68 and accompanying text.

[90] *See* Savulescu, *supra* note 80, at 22.

[91] *See id.*

[92] For a discussion of enhancement, see generally PRESIDENT'S COUNCIL ON BIOETHICS, BEYOND THERAPY: BIOTECHNOLOGY AND THE PURSUIT OF HAPPINESS (2003), *available at* http://www.bioethics.gov/reports/beyondtherapy/beyond_therapy_final_report_pcbe.pdf, which analyzes the potential for biotechnology to enhance human health and performance.

[93] A telomere is "[t]he segment at the end of each chromosome arm which consists of a series of repeated DNA sequences that regulate chromosomal replication at each cell division. Some of the telomere is lost each time a cell divides, and eventually, when the telomere is gone, the cell dies." U.S. NAT'L LIBRARY OF MED. ET AL., GENETICS HOME REFERENCE: GLOSSARY, *at* http://ghr.nlm.nih.gov/ghr/glossary/telomere (published Mar. 26, 2004).

[94] *See* Savulescu, *supra* note 80, at 22.

posed experiments would introduce unpredictable and harmful animal genes into the human germ line.[95]

III. The Potential to Regulate Chimeras Through Existing Institutions

Although scientists have been creating human-nonhuman chimeras for several decades, advances in embryology and cloning have pushed this technology in new directions.[96] These unprecedented developments in biotechnology have generated public debate; however, most research involving early human life is unregulated,[97] aside from limitations on federal funding for stem cell research.[98] For example, there are no federal laws regulating privately funded embryo research[99] and no significant restrictions on human cloning or the pursuit of inheritable genetic modifications.[100]

A. *Chimera Regulation Through Patent Law*

Particularly in the area of intellectual property law, practitioners have urged Congress to resolve the debate over which forms of life are patentable.[101] The issue arose in the 1980 decision of the United States Supreme Court in *Diamond v. Chakrabarty*, which established

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[95] *See* Paul R. Billings et al., *Human Germline Gene Modification: A Dissent*, 353 The Lancet 1811, 1873–74 (1999) (asserting legal, ethical, and scientific justifications for prohibiting the genetic manipulation of germ cells, such as the absence of a clinical need and the risk of unpredicted effects that will persist in subsequent generations).

[96] *See* Robert & Baylis, *supra* note 3, at 1.

[97] *See* Reproduction and Responsibility, *supra* note 62, at 129 (discussing indirect regulation of assisted reproductive technologies); Discussion Document, President's Council on Bioethics: U.S. Public Policy and the Biotechnologies That Touch the Beginnings of Human Life: A Detailed Overview (June 13, 2003), http://www.bioethics.gov/background/biotechnology.html (concluding that the federal government has no meaningful regulation over the scientific manipulation of human embryos).

[98] *See, e.g.*, Bush, *supra* note 10, at 1151 (restricting federal funding for stem cell research to the use of existing cell lines).

[99] *See* Reproduction and Responsibility, *supra* note 62, at 132.

[100] *See* George J. Annas et al., *Protecting the Endangered Human: Toward an International Treaty Prohibiting Cloning and Inheritable Alterations*, 28 Am. J.L. & Med. 151, 168 (2002). Professor Annas recommends an international ban on reproductive cloning and inheritable germ line modifications. *Id.* at 151–52.

[101] *See* Cirlin, *supra* note 16, at 521 (indicating that the issue of patent protection for human-nonhuman chimeras will remain unresolved unless Congress intervenes); *Chimera Patent Application Holds Mirror to Biotech Society*, GeneWatch (Council for Responsible Genetics, Cambridge, Mass.), July 1998, at 2 [hereinafter GeneWatch] (Stuart Newman suggesting that the U.S. Supreme Court could resolve the patentability of human-nonhuman chimeras).

that a genetically engineered bacterium was a patentable invention.[102] The Court stated that Congress intended for patentable subject matter to "include anything under the sun that is made by man," but for it to exclude ideas as well as laws and processes of nature.[103] Despite arguments that this holding might lead to the patenting of a "gruesome parade of horribles," the Court indicated that Congress could make the determination of which lifeforms are not patentable.[104] The current debate involves those who believe that no one should possess the exclusive rights to living organisms,[105] including chimeras, and those who hope to secure patents on humans and nonhuman combinations for the generation of stem cells and tissues.[106]

1. The Role of United States Patent and Trademark Office in Patenting Chimeras

In the years since *Chakrabarty*, the U.S. patent system has become a maelstrom of controversy regarding human-nonhuman chimeras.[107] In 1997, cellular biologist Stuart Newman,[108] with support from biotechnology activist, Jeremy Rifkin,[109] filed an enterprising patent application to force the U.S. Patent and Trademark Office (the "USPTO") to decide whether chimeras containing up to fifty percent human DNA are patentable subject matter (the "Newman patent").[110] The application provoked immediate public debate over what it means to be human and whether the USPTO should be an arbiter of morality in biotechnology.[111] Rifkin and Newman's objective was not to create the chimeras, but rather to secure the exclusive right to the technology for twenty

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[102] 447 U.S. 303, 309 (1980) (holding bacteria designed to consume oil is patentable subject matter).

[103] *Id.* (quoting S. REP. No. 82-1979, at 5 (1952); H.R. REP. No. 82-1923, at 6 (1952)).

[104] *Id.* at 316, 318.

[105] *See* GENEWATCH, *supra* note 101, at 3 (describing the No Patents on Life movement).

[106] *See, e.g.*, World Intellectual Property Organization, Int'l Publ'n No. WO 98/07841 (published Feb. 26, 1998) (process patent for creating human-cow embryo); *see also supra* notes 64–66 and accompanying text.

[107] *See generally* Dashka Slater, *HuMouse™*, LEGAL AFFAIRS, Nov.–Dec. 2002, at 21, http://www.legalaffairs.org/issues/November-December-2002/feature_slater_novdec2002.html.

[108] Stuart Newman is a cellular biologist at New York Medical College and founding member of the Council for Responsible Genetics. *Id.*

[109] Jeremy Rifkin is an author and economist as well as the president of the Foundation for Economic Trends. *Id.* at 1.

[110] *See id.* at 22.

[111] *Id.* The chimeras described in the patent application include human combinations with mice, chimpanzees, pigs, and baboons. *Id.* at 1. The patent application suggests three methods for mixing human and animal embryos, which could be implanted in a human or animal uterus. *Id.* at 2.

years after the patent was granted, or, if the patent was denied, to reduce the economic incentive for others to develop chimeras.[112] The USPTO denied the patent application in 1999;[113] however, Newman and Rifkin have continued to appeal.[114]

Originally, the USPTO denied the Newman patent because it claimed that the invention "embrace[d] a human being."[115] When Newman and Rifkin asked the USPTO to identify the legal basis for banning their patent, the USPTO stated that the Newman patent would violate the Thirteenth Amendment, which forbids slavery and the ownership of human beings.[116] The USPTO has maintained that it will not grant patents on human life nor for the processes to create human life; however, it no longer relies on the Thirteenth Amendment as its reason.[117] Instead, the USPTO has revived the beneficial-utility doctrine, originally set forth by Justice Joseph Story, [118] which was used to deny patents on gambling devices and early medical frauds.[119] In denying the Newman patent, the USPTO interpreted the utility requirement to exclude inventions deemed to be "injurious to the well being, good policy, or good morals of society."[120] Accordingly,

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[112] *See* Slater, *supra* note 107, at 2.

[113] *See id.* at 27.

[114] *See* Aaron Zitner, *Patently Provoking a Debate*, L.A. TIMES, May 12, 2002, at A1.

[115] The USPTO initially rejected the Newman patent application, stating it "embraces a human being. In particular, applicant's claimed invention . . . is not limited to non-humans but rather includes within its scope a human being and as such falls outside the scope of protection." *See Patent Application Is Disallowed as 'Embracing' Human Being*, 58 PAT. TRADEMARK & COPYRIGHT J., June 17, 1999, at 203, 203. The USPTO regulations state that "[i]f the broadest reasonable interpretation of the claimed invention as a whole encompasses a human being, then a rejection under 35 U.S.C. 101 must be made indicating that the claimed invention is directed to nonstatutory subject matter." U.S. PATENT OFFICE, DEP'T OF COMMERCE, MANUAL OF PATENT EXAMINING PROCEDURE § 2105 (8th ed. 2001), *available at* http://www.uspto.gov/web/offices/pac/mpep/mpep_e8r1_2100_508.pdf.

[116] *See* U.S. CONST. amend. XIII; Slater, *supra* note 107, at 26; Zitner, *supra* note 114, at A1.

[117] *See* Nathan A. Adams, *Creating Clones, Kids & Chimera: Liberal Democratic Compromise at the Crossroads*, 17 NOTRE DAME J.L. ETHICS & PUB. POL'Y 71, 131 (2003).

[118] Lowell v. Lewis, 15 F. Cas. 1018, 1018–19 (C.C.D. Mass. 1817) (No. 8568) (seminal case in finding certain non-useful inventions unpatentable); Adams, *supra* note 117, at 131–32.

[119] *See generally* ROBERT P. MERGES ET AL., INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE 142–44 (3d ed. 2003).

[120] *See* Media Advisory, U.S. Patent & Trademark Office, Facts on Patenting Life Forms Having a Relationship to Humans (Apr. 1, 1998) (quoting Tol-O-Matic, Inc. v. Proma Product-und Marketing Gesellschaft M.b.H., 945 F.2d 1546, 1552 (Fed. Cir. 1991) (citing *Lowell*, 15 F. Cas. at 1019 (Story, J.))), http://www.uspto.gov/web/offices/com/speeches/98-06.htm; Adams, *supra* note 117, at 132.

by declaring certain human-nonhuman chimeras unpatentable, the USPTO appears willing to set normative standards for biotechnology.[121]

2. Absence of Public Morality in U.S. Patent Law

The moral utility doctrine, as implemented by the USPTO, differs from European patent laws, which explicitly address the moral status of the human embryo in biotechnology.[122] In 1998, the European Parliament and the Council of the European Union issued a directive that forbids patents on inventions that contravene the "ordre public," or public morality.[123] The Preamble to the Directive sets forth that "processes to produce chimeras from germ cells or totipotent cells of humans and animals, are obviously also excluded from patentability."[124] In contrast, the role of the embryo in U.S. abortion law[125] and the lack of public consensus on the moral status of the embryo[126] would complicate any attempt to model chimera regulation after the European patent system.[127]

3. The Role of Congress in Regulating Biotechnology Patents

In addition to policy decisions by the USPTO, Congress may use its statutory authority to withhold the issue of patents for certain dan-

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[121] *See* Adams, *supra* note 117, at 132 (presenting view that the USPTO may not be suited to making judgments about biotechnology); *see also* Duane Nash, *Recommended Response for Human Cloning Patent Applications*, 42 IDEA 279, 299 (2002) (asserting that under the U.S. Constitution, the regulatory role to discourage unwanted scientific developments belongs to Congress).

[122] *See* Council Directive 98/44, art. 6, 1998 O.J. (L 213) 13, 18 [hereinafter Council Directive 98/44], *available at* http://europa.eu.int/eur-lex/pri/en/oj/dat/1998/l_213/l_21319980730en00130021.pdf; *see also* Adams, *supra* note 117, at 123–27; Magnani, *supra* note 71, at 453–54.

[123] *See* Council Directive 98/44, art. 6.1, at 16. Under the Directive, technology that is offensive to the ordre public includes processes to clone humans, processes to alter the human germ line, commercial or industrial uses of human embryos, processes to genetically alter animals which cause unnecessary suffering without any substantial medical benefit, and the animals used in such processes. *Id.* art. 6.2, at 18–19.

[124] *Id.* para. 38, at 16.

[125] *See* Roe v. Wade, 410 U.S. 113, 156–59 (1973) (rejecting the view that embryos are legal persons in abortion context). For a comparison of abortion laws in the United States and Europe, see generally Teresa Nicholson, Comment, *European Abortion Law: An Analysis and Comparison of Abortion Law in the European Union and the United States*, 24 CUMB. L. REV. 573, 573–86 (1994).

[126] *See infra* notes 275–285 and accompanying text.

[127] *See* Magnani, *supra* note 71, at 457.

gerous technologies.[128] For example, under the Atomic Energy Act of 1954, the Department of Defense must review all patent applications regarding atomic energy to determine whether an invention has weapon potential.[129] If the invention only has defense-related potential, then the Department of Defense may assert a monopoly over the technology and may take the rights to the invention in exchange for compensation.[130] Congress has not considered chimeras to be of equal danger to atomic weaponry at this time.[131]

Nevertheless, in 2004, Congress passed a provision of the federal budget that prohibited the USPTO from issuing patents on human organisms.[132] The provision codifies the USPTO's current position against granting patents for genetically engineered human beings, fetuses, and embryos.[133] The provision, however, will not affect the patenting and marketing of DNA sequences, cell lines, stem cells, tissues, and other biological products of human origin.[134] In addition, the provision does not prevent scientists from seeking patents for processes to create biological products.[135]

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[128] *See, e.g.*, Atomic Energy Act of 1954, 42 U.S.C. § 2181 (2000). Similarly, Congress has withheld the issue of patents for sensitive national security information. *See* Invention Secrecy Act of 1951, 35 U.S.C. §§ 181–188 (2000).

[129] *See* 42 U.S.C. § 2181; Adams, *supra* note 117, at 132.

[130] *See* 42 U.S.C. § 2181; Adams, *supra* note 117, at 132.

[131] *See* Merges, *supra* note 37, at 1066–67 (contrasting nuclear weapons with recombinant DNA technology and concluding that a patent ban is appropriate for nuclear weapons because they have no alternative useful purpose and raise national security concerns rather than moral concerns, whereas biotechnology patents serve beneficial uses).

[132] Consolidated Appropriations Act of 2004, Pub. L. No. 108-199, § 634, 118 Stat 101 (stating succinctly that "[n]one of the funds appropriated or otherwise made available under this Act may be used to issue patents on claims directed to or encompassing a human organism"), *available at* http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=108_cong_public_laws&docid=f:publ199.108.pdf; *see also* Amy Fagan, *House Will Vote on Patent Ban for Human Life Forms; Biotechnology Firms Support Bill*, WASH. TIMES, Dec. 8, 2003, at A08.

[133] Rick Weiss, *Hill Negotiators Agree to Bar Patents for Human Organisms*, WASH. POST, Nov. 25, 2003, at A19. Representative David Weldon, a physician who sponsored the provision, stated that it would codify the USPTO's existing rule that human organisms are not subject to patents. *See id.* The Director of the USPTO confirmed that the provision's language "does not alter the USPTO policy on the nonpatentability of human life-forms at any stage of development and is fully consistent with our policy." Letter from James E. Rogan, Director, U.S. Patent and Trademark Office, to Hon. Ted Stevens, Chairman, Committee on Appropriations, U.S. Senate 2 (Nov. 20, 2003), *available at* http://www.nrlc.org/Killing_Embryos/Human_Patenting/WeldonamendUSPTO.pdf [hereinafter Rogan Letter].

[134] Weiss, *supra* note 133, at A19.

[135] *Id.*

As a result, this provisionary ban allows the USPTO to continue to address new or borderline issues, including chimeras.[136] The USPTO already grants patents on animals that have been modified to include a few human genes for the production of a human protein or antibody; however, it remains unclear under the provision which chimeras are so humanlike that they cannot be patented, such as the human-chimpanzee chimera described in the Newman patent application.[137] The USPTO Director stated that the provision gives "unequivocal congressional backing" for the USPTO's refusal "to grant any patent containing a claim that encompasses any member of the species Homo sapiens at any stage of development," which suggests that chimeras created from human embryos may not qualify for patent protection.[138] Nevertheless, in denying the Newman patent, the USPTO did not explain its determination that chimeras containing less than fifty percent human DNA encompass a human being and therefore are unpatentable.[139] Hence, the interpretive question remains: How many human gene sequences are needed for the USPTO to decide that a chimera is human?[140]

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[136] *See* 149 CONG. REC. E2234 (daily ed. Nov. 5, 2003) (statement of Rep. Weldon). Weldon explained that the patent ban does not affect the patentability of human-animal chimeras:

> What about an animal that is modified to include a few human genes so it can produce a human protein or antibody? What about a human/animal "chimera" (an embryo that is half human, half animal)? The fact is, these questions are not new. The USPTO has already granted patents on the former. It has also thus far rejected patents on the latter, the half-human embryo, because the latter can broadly but reasonably be construed as a human organism. The Weldon amendment does nothing to change this, but leaves the USPTO free to address new or borderline issues on the same case-by-case basis as it already does.

Id. (citations omitted).

[137] *See id.* The provision refers to the patenting of a "human organism" rather than the patenting of a "human being." *See* Pub. L. No. 108-199, § 634, 118 Stat. 101; 149 CONG. REC. E2234. Initially, this language raised suspicion among biotechnology groups, because although they accepted a ban on the patenting of "human beings," they feared that the language, "human organism," might be interpreted to mean a ban on the patenting of biotechnology derived from human beings, such as embryonic stem cells, prosthetics, and transgenic organisms. *See id.*; *U.S. Takes Further Steps to Prevent Patenting of Human Beings*, 23 BIOTECH L. REP., Feb. 2004, at 57, 57–58. Representative Weldon stressed that the language was not meant to affect existing policies. *See* 149 CONG. REC. E2235.

[138] *See* Rogan Letter, *supra* note 133, at 1.

[139] *See* Magnani, *supra* note 71, at 449–50; *supra* notes 107–121 and accompanying text.

[140] *See* Magnani, *supra* note 71, at 449–50. As described, the USPTO has not determined the percentage of human DNA that justifies patent prohibition. *See id.* The stance of

B. *Administrative Regulation of Biotechnology as a Model for Chimera Regulation*

Current administrative regulations, as applied to animal and human subject research, provide a starting point to determine whether biotechnology regulation in the United States may be expanded adequately to encompass chimeras.[141] Multiple federal agencies regulate the experimental and commercial uses of genetically modified animals.[142] In 1986, the Coordinated Framework for Regulation of Biotechnology (the "Framework") formalized this decentralized approach.[143] The agencies listed in the Framework are governed by almost a dozen federal statutes, regulations, and guidelines.[144] No single agency, however, provides for the comprehensive regulation of genetically modified or-

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the USPTO that it will not grant patents on human life raises the question of at what point a chimera is so humanlike that it cannot be patented. *See id.*

[141] *See* Reagan Anne Kulseth, Note, *Biotechnology and Animal Patents: When Someone Builds a Better Mouse*, 32 ARIZ. L. REV. 691, 709, 711–12 (1990) (recommending that administrative regulation provides adequate management of biotechnology, including human-nonhuman hybrids).

[142] OFFICE OF TECH. ASSESSMENT, 101ST CONG., NEW DEVELOPMENTS IN BIOTECHNOLOGY: PATENTING LIFE—SPECIAL REPORT 110 (1989), *available at* http://www.wws.princeton.edu/cgi-bin/byteserv.prl/~ota/disk1/1989/8924/8924.PDF; *see also* Kulseth, *supra* note 141, at 712–14 (describing the administrative regulation of animals, research procedures, and biotechnology products); Randy Vines, *The Regulation of Biotechnology*, BIOTECH. INFO., Pub. No. 443-006 (Va. Cooperative Extension, Blacksburg, Va.), May 2002, at 1–2, *available at* http://www.ext.vt.edu/pubs/biotech/443-006/443-006.pdf.

[143] *See* 51 Fed. Reg. 23,302–350 (June 26, 1986) (describing federal policies regulating the safety of biotechnology research and products). The Office of Technology Assessment (the "OTA") surveyed each agency listed in the Framework to determine the potential use and regulation of genetically altered animals. OFFICE OF TECH. ASSESSMENT, *supra* note 142, at 102–10. Congress closed the OTA on September 29, 1995. OFFICE OF TECH. ASSESSMENT, 104TH CONG., OTA ARCHIVE (Aug. 1996), http://www.access.gpo.gov/ota/.

[144] OFFICE OF TECH. ASSESSMENT, *supra* note 142, at 103–04. Nearly a dozen enabling statutes give authority to these agencies, with some products regulated by more than one agency. *See, e.g.*, Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136–136 (2000); Animal Welfare Act, *id.* §§ 2131–2159; Toxic Substances Control Act of 1976, 15 U.S.C. §§ 2601–2656 (2000); Lacey Act Amendments of 1981, 16 U.S.C. §§ 3371–3378 (2000); Virus-Serum Toxin Act, 21 U.S.C. §§ 151–159 (2000); Federal Food, Drug, and Cosmetic Act of 1938, *id.* §§ 301–397; Poultry Products Inspection Act, *id.* §§ 451–471; Federal Meat Inspection Act, *id.* §§ 601–695; Endangered Species Act of 1973, 53 U.S.C. §§ 1531–1544 (2000); *see also* INST. OF LAB. ANIMAL RES., NAT'L RESEARCH COUNCIL, GUIDE FOR THE CARE AND USE OF LABORATORY ANIMALS (7th ed. 1996), *available at* http://books.nap.edu/execsumm_pdf/5140.pdf; OFFICE OF LAB. ANIMAL WELFARE, NAT'L INSTS. OF HEALTH, PUBLIC HEALTH SERVICE POLICY ON HUMANE CARE AND USE OF LABORATORY ANIMALS (2002), *available at* http://grants2.nih.gov/grants/olaw/references/PHSPolicyLabAnimals.pdf.

ganisms, and none of the agencies address modern chimera technology directly.[145]

Under the Framework, the FDA, the Environmental Protection Agency, and the U.S. Department of Agriculture regulate the research, development, and approval of biotechnology products.[146] The Framework regulates these products according to their composition and proposed uses, rather than by their method of production.[147] As a result, cutting-edge biotechnology is subject to the same fragmented laws and policies that govern conventional products.[148]

1. The FDA's Legal Mandate as Applied to Biotechnology Regulation

The FDA has claimed authority over various forms of assisted reproductive technology,[149] although it has not added human-nonhuman chimeras specifically to its jurisdiction.[150] The FDA's legal mandate, as conferred by Congress under the Commerce Clause,[151] authorizes it to regulate the distribution of products linked to interstate commerce.[152] Although this mandate technically does not cover the direct regulation of biotechnology, the FDA may regulate a broad range of activities surrounding the distribution of biotechnology products.[153]

The Federal Food, Drug, and Cosmetic Act of 1938 (the "FFDC Act") and the Public Health Services Act (the "PHS Act") set forth the FDA's regulatory authority.[154] As an administrative agency, the FDA may interpret these enabling statutes to accommodate circumstances that Congress could not have predicted when originally drafting the statutes.[155] In general, by working within its charters, an agency has

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[145] *See* OFFICE OF TECH. ASSESSMENT, *supra* note 142, at 110.

[146] Vines, *supra* note 142, at 1. For example, the FDA regulates food products, human and veterinary drugs, and medical devices, and the U.S. Department of Agriculture supervises efforts to enhance and protect agriculture. *See* OFFICE OF TECH. ASSESSMENT, *supra* note 142, at 106–08.

[147] *See* Vines, *supra* note 142, at 1.

[148] *See id.*

[149] *See, e.g.*, Rick Weiss, *FDA to Regulate Certain Fertilization Procedures*, WASH. POST, July 11, 2001, at A02 (describing FDA's first effort to regulate the fertility field by overseeing ooplasmic transfer technique).

[150] *See* PARENS & KNOWLES, *supra* note 7, at 12.

[151] U.S. CONST. art. I, § 8, cl. 3.

[152] *See* REPRODUCTION AND RESPONSIBILITY, *supra* note 62, at 57; Rokosz, *supra* note 9, at 492–95.

[153] *See* Rokosz, *supra* note 9, at 493–94.

[154] Federal Food, Drug, and Cosmetic Act of 1938, 21 U.S.C. §§ 301–397 (2000); Public Health Service Act, 42 U.S.C. §§ 201–300 (2000).

[155] *See* Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837, 844–45 (1984) (suggesting that reviewing courts will defer to an agency's attempts to modernize

latitude to adapt to new challenges without requiring congressional authority or instruction for each situation.[156] As a consequence, an agency may respond to new technology without risking that additional legislation will disrupt existing policies.[157] Congress's deference to agencies, however, makes it difficult to predict which modernizing efforts a reviewing court will permit and which it will nullify.[158]

The FDA's jurisdiction includes one quarter of all consumer products and encompasses modern biotechnologies, such as tissue transplants, stem cell research, and human cloning.[159] Despite the limited expertise of FDA regulators in dealing with these emerging areas of technology, the FDA has not sought congressional assistance for an expansion of its statutory jurisdiction or for stronger administrative tools.[160]

The FFDC and PHS Acts provide three possible mechanisms for the FDA to assert jurisdiction over human-nonhuman chimeras and other forms of emerging biotechnology.[161] Chimeras may be "biological products" pursuant to the PHS Act.[162] Alternatively, chimeras may be "drugs,"[163] or the procedures used to create chimeras may be medical "devices" under the FFDC Act.[164] If the FDA has jurisdiction under these statutes and their implementing regulations, then it must approve an investigative new drug application before research may proceed.[165] Unauthorized research may be subject to criminal or civil sanctions.[166]

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unless it can be shown that Congress specifically prevented the agency from taking such initiative); Richard A. Merrill, *Human Tissues and Reproductive Cloning: New Technologies Challenge FDA*, 3 HOUS. J. HEALTH L. & POL'Y 1 (2002), *at* WL 3 HOUJHLP 1, at *1.

[156] *See* Merrill, *supra* note 155, at *1.

[157] *See id.*

[158] *Id.* at *2.

[159] *Id.*

[160] *Id.* at *3.

[161] Elizabeth C. Price, *Does the FDA Have Authority to Regulate Human Cloning?*, 11 HARV. J.L. & TECH. 619, 620 (1998); Rokosz, *supra* note 9, at 469–70.

[162] Public Health Service Act § 351, 42 U.S.C. § 262(i) (2000).

[163] Federal Food, Drug, and Cosmetic Act of 1938 § 201(g), 21 U.S.C. § 321(g)(1) (2000).

[164] Federal Food, Drug, and Cosmetic Act of 1938 § 201(h), 21 U.S.C. § 321(h).

[165] Price, *supra* note 161, at 620.

[166] *Id.* at 621; *see, e.g.*, 21 U.S.C. § 333(f) (setting civil penalty for violating device requirements of FFDC Act of up to $15,000 for each violation with a maximum of $1,000,000 per adjudication); 42 U.S.C. § 262(f) (setting fine of up to $500 or imprisonment of up to one year, or both, for violating biological products requirements of the PHS Act).

2. FDA Jurisdiction over Biotechnological Materials and Processes

Despite its broad discretion to interpret its charter, the FDA was reluctant to extend its jurisdiction to human tissues.[167] Although in the 1970s the FDA declared jurisdiction over porcine heart valves used in xenotransplantation as biological materials, the FDA did not extend its jurisdiction to human heart valves until many years later.[168] The FDA acknowledged that tissues could be regulated as drugs, medical devices, or biotechnology products; however, it did not commence regulation of human tissues until concerns about the transmission of infectious diseases, such as HIV, from donors to transplant recipients compelled it to assert its regulatory authority.[169]

The FDA was less hesitant to declare its jurisdiction over human cloning, which it claimed through a series of informal expressions made over several years, beginning with a remark in 1999 regarding cloning as a form of gene therapy.[170] Cloning, the FDA asserted, fell under its biologics regulations, which primarily involve human gene therapy and the medical manipulation and reinsertion of human cells.[171] The FDA suggested that it would regulate cloning for reproductive purposes but not necessarily cloning for biomedical research.[172] The FDA further stated that cloning to produce children

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[167] Merrill, *supra* note 155, at *9–52 (detailing the FDA's response toward regulation of human tissue transplants).

[168] *Id.* at *19–24.

[169] *Id.* at *14–15, 24–26.

[170] *See* Richard A. Merrill & Bryan J. Rose, *FDA Regulation of Human Cloning: Usurpation or Statesmanship*, 15 HARV. J.L. TECH. 85, 87–88 (2001); *see also* Richard A. Merrill, Remarks at Meeting of the President's Council on Bioethics, Session 5: Biotechnology and Public Policy: Role of the Food and Drug Administration (FDA) (Jan. 17, 2003), http://www.bioethics.gov/transcripts/jan03/session5.html. The FDA's claim to jurisdiction over cloning originated from statements Acting Commissioner Michael Friedman made on a radio call-in show in Washington, D.C. *Id.* The FDA backed up its assertion of jurisdiction through communications with institutional review boards, congressional testimony, and public statements. *Id.* Traditionally, the FDA asserts its authority by publishing a comprehensive discussion in the *Federal Register* which is available for public comment. *Id.* Accordingly, in support of its jurisdiction over cloning, the FDA pointed to two statements that representatives made in the *Federal Register*, one in 1993 regarding gene therapy and another in 1997 regarding tissue and cellular therapies. *Id.*; *see* Rokosz, *supra* note 9, at 487.

[171] *See* Rokosz, *supra* note 9, at 490.

[172] CHRISTIAN LEGAL SOC'Y & CHRISTIAN MED. & DENTAL ASS'N, COMMENTS ON STAFF WORKING PAPER NO. 8, AN UNNUMBERED STAFF WORKING PAPER ON REGULATING BIOTECHNOLOGIES, AND SELECTED TRANSCRIPTS OF THE PRESIDENT'S COUNCIL ON BIOETHICS 6 (2003) [hereinafter CHRISTIAN LEGAL SOC'Y], *available at* http://www.clsnet.org/clrfPages/advocacy/BioethicsComments.pdf.

would require filing an investigational new drug application,[173] but it was not prepared to grant such applications for cloning.[174]

C. *Assisted Reproductive Technology and Its Implications for Chimera Regulation*

In addition to regulation through patent law and agency oversight, governments traditionally regulate reproductive biotechnology using six general frameworks.[175] None of these regulatory mechanisms explicitly addresses chimeras; they serve as starting points for the regulation of novel biotechnology, however.[176] The first framework avoids broad legislation in favor of case by case judicial precedent, as exemplified by legal decisions regarding the disposition of frozen embryos.[177] This form of regulation, which often incorporates oversight by institutional review boards, is not comprehensive and varies by region.[178] Presently, the only case law applicable to chimeras pertains to the USPTO's denial of patents on human life.[179]

The second framework involves specific legislation for isolated issues, such as legislation to prohibit or restrict a particular technology.[180] The third scheme involves broader legislation directed at assisted reproductive technology and typically encompasses the treatment of embryos in research.[181] Canada's AHR Act is an example of broad assisted reproductive technology legislation that also encompasses chimeras.[182] The fourth regulatory scheme involves human sub-

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[173] *See* Merrill, *supra* note 155, at *1. Researchers use investigational new drug applications as exemptions from the requirement of prior FDA approval for marketing and distributing drugs for use in clinical trials. *Id.* at *4–6.

[174] *See* CHRISTIAN LEGAL SOC'Y, *supra* note 172, at 2. Although the FDA may require screening, registration, and similar mechanisms, it probably cannot prevent cloning to produce children altogether. *Id.* Cloning to produce children may not be a health-related treatment for disease pursuant to the FDA's biologics, drugs, and device authority. *See id.*; Rokosz, *supra* note 9, at 469–70.

[175] Lori Knowles, The Hastings Ctr., Remarks at Meeting of the President's Council on Bioethics, Fourth Meeting: Session 1: Regulation 2: Genetic and Reproductive Technologies: International Models (June 20, 2002), http://www.bioethics.gov/transcripts/jun02/june20session1.html.

[176] *See id.*

[177] *Id.*; *see, e.g.*, Davis v. Davis, 842 S.W.2d 588, 604 (Tenn. 1992) (holding that husband's interest in avoiding parenthood following divorce outweighed wife's interest in frozen embryos).

[178] Knowles, *supra* note 175.

[179] *See generally supra* notes 101–140 and accompanying text.

[180] *See* Knowles, *supra* note 175.

[181] *Id.*

[182] *See generally* Assisted Human Reproduction Act, ch. 2, 2004 S.C. (Can.).

ject research legislation, which includes the use of embryos, fetal tissue, and human beings.[183] This framework includes institutional review boards and a group of regulatory statutes for research on human subjects, known as the Common Rule.[184] The fifth scheme involves the formation of an advisory panel or commission which typically develops a regulatory scheme.[185] The AHR Act provides for such an advisory panel in regard to stem cell technology.[186] Finally, the most common regulatory framework currently being applied to biotechnology is a combination of schemes.[187]

1. The Deliberations of the President's Council on Bioethics

Like Canada, the President's Council on Bioethics (the "President's Council") incorporated chimeras into its discussions of assisted reproductive technologies in the United States.[188] Beginning in 2002, the President's Council devoted considerable resources to examining the governance of biotechnologies that "touch the beginnings of human life."[189] Suggesting the need to overhaul existing regulatory institutions and create new regulatory authorities, the President's Council admitted that it was far from able to offer clear recommendations regarding major institutional reforms.[190]

In 2003, the President's Council examined assisted human reproduction and explored whether legislation could be tailored to include new technology such as chimeras.[191] The only federal law cur-

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[183] Knowles, *supra* note 175.

[184] *See* Protection of Human Subjects, 45 C.F.R. § 46 (2001), *available at* http://www.access.gpo.gov/nara/cfr/waisidx_99/45cfr46_99.html. The Common Rule, a collection of protocols originated in the 1970s, provides a regulatory framework for all federally funded research on human subjects. Michael J. Malinowski, *Choosing the Genetic Makeup of Children: Our Eugenics Past-Present, and Future?*, 36 CONN. L. REV. 125, 165–68 (2003).

[185] Knowles, *supra* note 175.

[186] *See* Assisted Human Reproduction Act §§ 21–44.

[187] Knowles, *supra* note 175.

[188] *See* REPRODUCTION AND RESPONSIBILITY, *supra* note 62, at 132. In Canada, policymakers originally conceived the AHR Act in the context of assisted reproductive technology. *See supra* notes 220–224 and accompanying text.

[189] *See* REPRODUCTION AND RESPONSIBILITY, *supra* note 62, at xxxix–xl.

[190] *See id.* at 207; President's Council on Bioethics, Session 5: Biotechnology & Public Policy: Proposed Interim Recommendations, I (Sept. 5, 2003), http://www.bioethics.gov/transcripts/sep03/session5.html (Chairman Leon Kass remarking during introduction to session).

[191] *See* Staff Working Paper, President's Council on Bioethics, U.S. Policy and the Biotechnologies that Touch the Beginnings of Human Life: Draft Recommendations (Sept. 5, 2003), http://www.bioethics.gov/background/bpprecommend.html [hereinafter Sept.

rently in place to regulate assisted human reproduction is the Fertility Clinic Success Rate and Certification Act of 1992, which does not encompass chimeras directly.[192] The President's Council recognized the need to "flesh out what these [terms] mean . . . and [the] disagreement about chimera."[193] The President's Council's commitment to formulating clear definitions of chimeras reflects the debate over the definitions contained in Canada's AHR Act, which is discussed further in Part IV.[194]

In its deliberations, the President's Council discussed the need to respect the humanity of procreation by preserving a reasonable boundary between humans and nonhumans during the early stages of life.[195] Because no public institutions are responsible for setting appropriate limits for these rapidly advancing technologies, the President's Council urged Congress to adopt targeted restrictions on several well-defined activities.[196] The Council recommended collecting these measures in a "Reproduction and Responsibility Act," which would acknowledge the need for a moratorium on certain practices until the public

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2003 Recommendations] (recommending a clear boundary between humans and animals in procreation).

[192] Fertility Clinic Success Rate and Certification Act of 1992, 42 U.S.C. §§ 263a-1 to -7 (2000); *see* Lars Noah, *Assisted Reproductive Technologies and the Pitfalls of Unregulated Biomedical Innovation*, 55 FLA. L. REV. 603, 614–15 (2003) (describing role of Centers for Disease Control under the Fertility Act in monitoring assisted reproductive technology, which did not involve reporting adverse events). The President's Council recommended that Congress modify the Fertility Act to include reporting requirements for "Innovative Techniques" including novel and experimental procedures. Sept. 2003 Recommendations, *supra* note 191. The President's Council suggested that assisted reproductive technology facilities should report the "extent to which technologies are tested in animals." *Id.* This contemplated language, however, did not address human-nonhuman chimeras specifically. *See id.*

[193] Transcript, President's Council on Bioethics, Session 6: Biotechnology & Public Policy: Proposed Interim Recommendations, II (Sept. 5, 2003), http://www.bioethics.gov/transcripts/sep03/session6.html.

[194] *See infra* notes 208–249, 339–381, and accompanying text.

[195] *See* Staff Working Paper, President's Council on Bioethics, Biotechnology and Public Policy: Biotechnologies Touching the Beginnings of Life: Draft Recommendations (revised) (Jan. 15, 2004), http://www.bioethics.gov/background/bppinterim.html [hereinafter Jan. 2004 Recommendations]; Staff Working Paper, President's Council on Bioethics, Biotechnology and Public Policy: Biotechnologies Touching the Beginnings of Life: Defending the Dignity of Human Procreation (Oct. 16, 2003), http://www.bioethics.gov/background/bpp_defend_dig.html [hereinafter Oct. 2003 Recommendations]; Transcript, President's Council on Bioethics, Session 2: Toward a "Richer Bioethics": Chimeras and the Boundaries of the Human (Oct. 16, 2003), http://www.bioethics.gov/transcripts/oct03/session2.html [hereinafter Oct. 2003 Session].

[196] *See* REPRODUCTION AND RESPONSIBILITY, *supra* note 62, at 219.

and legislators have had an opportunity to debate the appropriate governance of these technologies.[197]

2. The President's Council's Recommendations

In 2004, following its review and analysis, the President's Council concluded that the creation of human-nonhuman chimeras raises unique challenges to the character of human procreation.[198] The President's Council distinguished various contexts in which scientists create chimeras, opining that there is nothing inherently objectionable about mixing human and animal tissues.[199] In the context of therapy and preventative medicine, the President's Council endorsed xenotransplantation, animal-derived pharmaceuticals, and the insertion of animal genes into humans or human fetuses to prevent disease.[200]

In the context of procreation, the President's Council recommended two prohibitive rules to establish boundaries where it deemed the ethical concerns most acute and the need for bright-line rules most reasonable.[201] First, it recommended that Congress "[p]rohibit the production of a hybrid human-animal embryo by fertilization of human egg by animal sperm or of animal egg by human sperm."[202] The President's Council explained that it did not want to judge the humanity or moral worth of a hybrid entity, and it did not want this ambiguously human life to have nonhuman ancestors.[203] Second, the President's Council recommended that Congress "[p]roscribe the transfer, for any purpose, of any human embryo into the body of any member of a non-human species," explaining that humans should be placed only in human wombs.[204]

The President's Council initially discussed three provisions;[205] however, it omitted a recommendation prohibiting the combination of human and nonhuman embryos.[206] Some members suggested that this prohibition was premature because the President's Council had not

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[197] *Id.*

[198] *Id.*

[199] *See id.* at 222.

[200] *Id.* (expressing reservations about the inheritable genetic modification of eggs and sperm).

[201] REPRODUCTION AND RESPONSIBILITY, *supra* note 62, at 222.

[202] *Id.* at 223.

[203] *Id.* at 222.

[204] *Id.* at 222–23.

[205] *Compare* Jan. 2004 Recommendations, *supra* note 195, *with* Oct. 2003 Recommendations, *supra* note 195.

[206] Oct. 2003 Recommendations, *supra* note 195.

considered sufficiently the potential scientific benefits of embryonic chimeras.[207]

IV. Canada's AHR Act as a Legislative Model for Chimera Regulation in the United States

In 2002, the President's Council examined Canada's efforts to regulate reproductive technologies.[208] Canada's AHR Act reflects a decade-long effort to address the moral and ethical issues surrounding assisted reproductive technology, while promoting scientific and medical research.[209] To satisfy the dual goals of resolving ethical concerns and developing useful science, the AHR Act covers activities that are completely prohibited[210] and those that are subject to regulatory control.[211] The creation of various forms of chimeras and hybrids is prohibited under the AHR Act.[212]

A. *Canada's Collectivist Approach Contrasted with the United States' Individualist, Rights-Based Approach to Biotechnology*

The communitarian Canadian approach to assisted reproductive technology is unlike the rights-based approach to biotechnology in the United States.[213] Differences between the two ideological frameworks originate from the United States' heritage of rugged individualism and regulatory suspicion, in contrast with Canada's historical and geographic reliance on ordered control and governmental guidance.[214]

These historical differences influence the Canadian and United States' approaches to the regulation of novel biotechnology.[215] For

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[207] *See* Transcript, President's Council on Bioethics, Sessions 3 & 4: Biotechnology and Public Policy: Proposed Interim Recommendations, III and IV (Oct. 16, 2003), http://www.bioethics.gov/transcripts/oct03/session3_4.html.

[208] *See* Knowles, *supra* note 175.

[209] *See* Angela Campbell, *Defining a Policy Rationale for the Criminal Regulation of Reproductive Techniques*, 11 Health L. Rev. 26, 26–30 (2002); *see also* Monique Hébert et al., Parliamentary Research Branch, Library of Parliament, Bill C-6: Assisted Human Reproduction Act 20 (2004), *available at* http://www.parl.gc.ca/37/3/parlbus/chambus/house/bills/summaries/c6-e.pdf.

[210] Assisted Human Reproduction Act, ch. 2, §§ 5–9, 2004 S.C. (Can.).

[211] *Id.* §§ 10–19.

[212] *See id.* § 5(1)(i)–(j).

[213] *See* Alison Harvison Young, *New Reproductive Technologies in Canada and the United States: Same Problems, Different Discourses*, 12 Temp. Int'l & Comp. L.R. 43, 53 (1998).

[214] *See id.* at 50.

[215] *See id.* at 53. The Canadian government set forth its policy of setting boundaries for the use of assisted reproductive technologies in a 1993 report. *Id.* The report recommended legislation with criminal sanctions for the pursuit of certain new reproductive

example, Canada has developed a stronger concept of public interest than the United States.[216] As a result, Canadian society is more accepting than the United States of a broad and active role for the government in promoting its public interest.[217] Consequently, the assumption that the government should change social conditions for the better has characterized policies regulating reproductive technology in Canada.[218] The United States, in contrast, has been less receptive to governmental interference in science and the marketplace, which has led to an absence of biotechnology regulation.[219]

B. *Legislative History in Defining Chimeras in Canada's AHR Act*

The legislative history of the AHR Act explains its emphasis on the regulation of chimeras created from human embryological materials and its exclusion of other types of chimeras.[220] Bill C-6 originated from guidelines issued in March 2002 by the Canadian Institutes of Health Research (the "CIHR"), Canada's main federal funding agency for health research.[221] The CIHR guidelines addressed cloning and human embryo experimentation as well as the creation of embryological chimeras.[222]

Subsequent to the passage of the CIHR guidelines, the Canadian Parliament released the AHR Act to regulate various forms of fertility

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technologies, including human-nonhuman hybrids, and recommended the formation of a regulatory and licensing body. *Id.*

[216] *See id.*

[217] *See id.*

[218] *See* Young, *supra* note 213, at 44.

[219] *See id.* at 82. The United States retains traditional tort and contract remedies. *See* REPRODUCTION AND RESPONSIBILITY, *supra* note 62, at 118–19; Young, *supra* note 213, at 82. These legal regimes, however, have not been applied to human-nonhuman chimeras. *See* REPRODUCTION AND RESPONSIBILITY, *supra* note 62, at 118–19; Young, *supra* note 213, at 82.

[220] *See* Jason Scott Robert, *Regulating the Creation of Novel Beings*, 11 HEALTH L. REV. 14, 14 (2002) (explaining the AHR Act's primary emphasis on assisted reproductive technology and secondary emphasis on human embryo research); *see also* Françoise Baylis, *Betwixt and Between Human Stem Cell Guidelines and Legislation*, 11 HEALTH L. REV. 44, 44 (2002) (describing AHR Act's origin as legislation to regulate various aspects of infertility treatment).

[221] Canadian Institutes of Health Research, Human Pluripotent Stem Cell Research: Guidelines for CIHR-Funded Research § 7.4, http://www.cihr-irsc.gc.ca/e/publications/1487.shtml (updated Apr. 9, 2004) [hereinafter CIHR Guidelines] (serving as a precursor to the AHR Act).

[222] *Id.* Specifically, the guidelines prohibited CIHR funding for the following four activities: (1) creating embryos for research purposes, (2) using nuclear transfer to develop stem cells, (3) mixing human or nonhuman cells with a human embryo or fetus to create a chimera, and (4) mixing human stem cells with a nonhuman embryo or fetus to create a chimera. *Id.*; Baylis, *supra* note 220, at 44.

treatment.[223] Although the AHR Act was designed to regulate in vitro manipulation of human embryos, it also encompassed some of the embryo and stem cell research guidelines propounded by the CIHR.[224] Notably, the AHR Act established a licensing system for embryo experimentation,[225] an area of research that continues to be heavily debated in the United States.[226] Under the AHR Act, the CIHR will grant licenses to researchers allowing them to utilize in vitro embryos, if the CIHR is convinced that the research could not be completed using stem cells or cells from other sources.[227] These controversial licensing and research provisions require that Canada form an oversight committee to provide a national ethics review of all stem cell research.[228]

According to the legislation's objective to regulate assisted human reproduction,[229] the AHR Act addresses only embryonic combinations of both chimeras[230] and hybrids.[231] Section 5(1)(i) of the AHR

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[223] Bill C-56, An Act Respecting Assisted Human Reproduction, 37th Parl., 1st Sess. (2002) (Can.) (1st reading May 9, 2002), http://www.parl.gc.ca/37/1/parlbus/chambus/house/bills/government/C-56/C-56_1/C-56TOCE.html (last visited Apr. 8, 2004); Baylis, *supra* note 220, at 44. The Canadian Health Minister first introduced the AHR Act as Bill C-56 in the House of Commons in May 2002. Baylis, *supra* note 220, at 44. When Bill C-56 was an Order Paper and under consideration for Royal Assent, Parliament was prorogued so that all pending bills were automatically removed. Baylis, *supra* note 220, at 44. *See generally* HOUSE OF COMMONS (CAN.), PRÉCIS OF PROCEDURE ch. 17 (last revised Nov. 2003), http://www.parl.gc.ca/information/about/process/house/precis/chap17-e.htm (setting forth the process for prorogation, which ends a parliamentary session, and the subsequent reintroduction of bills). In October 2002, the House of Commons withdrew Bill C-56 and reintroduced it as Bill C-13. Baylis, *supra* note 220, at 44. Finally, the AHR Act was introduced in February 2004 into the Canadian Senate as Bill C-6. *See generally* Assisted Human Reproduction Act, ch. 2, 2004 S.C. (Can.).

[224] Baylis, *supra* note 220, at 44.

[225] *See* Assisted Human Reproduction Act § 40(2).

[226] *See* PARENS & KNOWLES, *supra* note 7, at 9 (discussing societal disagreement about the use of embryos in research).

[227] *See* Assisted Human Reproduction Act § 40(2); HÉBERT ET AL., *supra* note 209, at 18.

[228] *See* Assisted Human Reproduction Act §§ 21–22.

[229] *See* HEALTH CANADA, PROPOSALS FOR LEGISLATION GOVERNING ASSISTED HUMAN REPRODUCTION: AN OVERVIEW 4 (2001) (describing guiding legislative principles), *available at* http://www.hc-sc.gc.ca/english/pdf/reproduction/repro_over.pdf.

[230] In accord with the narrow scientific meaning, the AHR Act defines a chimera as "(a) an embryo into which a cell of any non-human life form has been introduced; or (b) an embryo that consists of cells of more than one embryo, foetus or human being." Assisted Human Reproduction Act § 3. This definition of chimera covers both human-nonhuman chimeras and human-human chimeras. *Id.*

[231] The AHR Act defines a hybrid as:

> (a) a human ovum that has been fertilized by a sperm of a non-human life form; (b) an ovum of a non-human life form that has been fertilized by a human sperm; (c) a human ovum into which the nucleus of a cell of a non-human life form has been introduced; (d) an ovum of a non-human life form

Act prohibits creating chimeras or transplanting chimeras into either human beings or nonhuman life forms.[232] Section 5(1)(j) prohibits creating hybrids for the purpose of reproduction or transplanting a hybrid into either a human being or a nonhuman life form.[233] Sections 5(2) and 5(3) prohibit anyone from offering or advertising the performance of any of the prohibited activities, or paying, or offering to pay, someone else to do so.[234]

C. *Criticism of the AHR Act: Definitional and Criminal Issues*

The AHR Act generated considerable controversy in Canada, because the government provided few formal documents or statements to justify the statutory ban.[235] Furthermore, the AHR Act generated confusion over the scope and purpose of the definitions of chimera and hybrid.[236] The AHR Act takes a broad position in regard to human-nonhuman hybrids, prohibiting both traditional hybrid combinations of eggs and sperm as well as transgenic organisms created using nuclear transfer techniques.[237] Additionally, the definition of hybrid contains a catch-all provision to encompass variations of hybrids not presently contemplated.[238] The prohibition, however, applies only to hybrids created for reproductive purposes.[239] Presumably, scientists may create hybrids for research or any other purposes.[240]

In contrast, the AHR Act adopts a narrow position on the prohibition of human-nonhuman chimeras, describing only two possibilities: (1) the insertion of nonhuman cells into human embryos, and

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> into which the nucleus of a human cell has been introduced; or (e) a human ovum or an ovum of a non-human life form that otherwise contains haploid sets of chromosomes from both a human being and a non-human life form.

Id.

[232] *Id.* § 5(1)(i).

[233] *See id.* § 5(1)(j).

[234] *Id.* § 5(2)–(3).

[235] *See* Caulfield, *supra* note 14, at 3–4.

[236] *See* Baylis, *supra* note 220, at 45 (describing definitional exclusion of human-to-nonhuman and animal-to-animal chimeras); *see also* Matthew Herder, *Donate a Definition*, 11 HEALTH L. REV. 40, 40–41 (2003) (describing other definitional deficiencies in the AHR Act).

[237] Assisted Human Reproduction Act §§ 3, 5(1)(j); *see* Robert, *supra* note 220, at 16. The AHR Act prohibits the creation of hybrids in at least four ways: (1) human ovum/nonhuman sperm, (2) non-human ovum/human sperm, (3) somatic cell nuclear transfer ("SCNT") with a human enucleated egg/nonhuman nucleus, and (4) SCNT with a nonhuman enucleated egg/human nucleus. Assisted Human Reproduction Act §§ 3, 5(1)(j).

[238] Assisted Human Reproduction Act §§ 3, 5(1)(j); *see* Robert, *supra* note 220, at 15.

[239] *See* Assisted Human Reproduction Act §§ 3, 5(1)(j); Robert, *supra* note 220, at 14.

[240] *See* Robert, *supra* note 220, at 14.

(2) the insertion of cells from another human (at any stage of development including other embryos)[241] into human embryos.[242] Notably, the AHR Act does not encompass the transfer of human stem cells into nonhuman embryos in its definition of chimera.[243] In addition, the AHR Act does not address the movement of tissues or organs between humans and animals.[244] Although the Canadian government did not offer detailed explanations for its chosen definitions, the narrow definition of chimera likely resulted from the limited objective of the legislation: to regulate human reproductive technology.[245]

Critics of the AHR Act find its criminal sanctions, which carry maximum penalties of $500,000 or ten years in prison, to be unduly harsh.[246] The original CIHR guidelines never inflicted financial penalties on researchers for noncompliance, but instead simply withheld research funding.[247] Moreover, critics claim that researchers should not face large fines and jail terms in their efforts to further scientific knowledge.[248] Conversely, supporters of the AHR Act argue that sanctions would encourage researchers to act ethically and carefully when engaging in stem cell research and related experiments.[249]

V. Implications of Legislation to Regulate Chimeras in the United States Using the AHR Act as a Model

A legislative prohibition on biotechnology similar to Canada's AHR Act might raise constitutional issues in the United States.[250] For

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[241] The definition of chimera attempts to prevent all human-human embryonic chimeras. *See* Assisted Human Reproduction Act § 3. According to the statute, researchers may not create chimeras by adding an embryo, fetus, or human being. *See id.* Technically, however, a researcher can still create a chimera using two pronuclei, which are pre-embryonic combinations of egg and sperm before they fuse into a mononuclear zygote. Hilary White, Campaign Life Coalition, A Final Critique of C-13, at 20 (2003), *available at* http://www.lifesite.net/features/stemcellembryo/c13finalcritique.pdf. For a discussion of embryological development, see Bruce M. Carlson, Human Embryological & Developmental Biology 32 (1999).

[242] Assisted Human Reproduction Act § 3; *see* Robert, *supra* note 220, at 16.

[243] *See* Assisted Human Reproduction Act § 3. The CIHR guidelines, however, originally included this provision. *See* CIHR Guidelines, *supra* note 221, § 7.4.6; Robert, *supra* note 220, at 16; *supra* note 222 and accompanying text.

[244] *See* Assisted Human Reproduction Act § 3.

[245] *See supra* note 220, and accompanying text.

[246] *See* Assisted Human Reproduction Act §§ 60–64; Baylis, *supra* note 220, at 45.

[247] CIHR Guidelines, *supra* note 221, § 7.4; Baylis, *supra* note 220, at 45.

[248] Baylis, *supra* note 220, at 45–46.

[249] *Id.*

[250] For a comprehensive analysis of constitutional issues raised by biotechnology, which are beyond the scope of this Note, see generally Lori B. Andrews, *Is There a Right to Clone?*

example, prohibiting the creation of certain human-nonhuman chimeras might implicate the First Amendment and the Thirteenth Amendment.[251] Nevertheless, given the rapid progression of biotechnology, legislation would permit public deliberation about the role of scientific research, the concept of personhood, the moral status of the embryo, and the future of human-nonhuman chimeras.[252]

A. *Chimeras as Scientific and Artistic Expression Under the U.S. Constitution*

Opponents to the regulation of chimeras may assert that there is a First Amendment free speech right and a Fourteenth Amendment right to engage in scientific inquiry.[253] In 1923, the U.S. Supreme Court stated in dicta in *Meyers v. Nebraska* that the Fourteenth Amendment grants the right "to acquire useful knowledge."[254] Nevertheless, courts subsequently have not found a deeply rooted constitutional interest in scientific inquiry.[255]

Scientific research, however, is a foundation for the exchange of ideas, and might be entitled to the same constitutional protection as the distribution of scientific information.[256] Although disseminating scientific information is inherently communicative, scientists would need to show that scientific research is likewise expressive as symbolic conduct.[257] The First Amendment protects expressive conduct if the

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Constitutional Challenges to Bans on Human Cloning, 11 HARV. J.L. & TECH 643 (1998); John A. Robertson, *Liberty, Identity, and Human Cloning*, 76 TEX. L. REV. 1371 (1998); Cass R. Sunstein, *Is There a Constitutional Right to Clone?*, 53 HASTINGS L.J. 987 (2002). *But see generally* Clarke D. Forsythe, *Legal Perspectives on Cloning: Human Cloning and the Constitution*, 32 VAL. U.L. REV. 469 (1998).

[251] *See infra* notes 253–265, 289–291, and accompanying text.

[252] *See* REPRODUCTION AND RESPONSIBILITY, *supra* note 62, at 271–72 (discussing the benefits of targeted legislative prohibitions).

[253] Adams, *supra* note 117, at 108.

[254] 262 U.S. 390, 399 (1923); Adams, *supra* note 117, at 111.

[255] *See* Adams, *supra* note 117, at 110; Andrews, *supra* note 250, at 661–64. Instead, some courts have set limits on scientific inquiry. *See, e.g.*, Wynn v. Scott, 449 F. Supp. 1302, 1322 (N.D. Ill. 1978), *aff'd sub nom.* Wynn v. Carey, 599 F.2d 193 (7th Cir. 1979) (finding no scientific right to experiment on fetuses). Furthermore, the government may regulate research methods to protect the rights of research subjects and community safety. *See* Andrews, *supra* note 250, at 663–64.

[256] Adams, *supra* note 117, at 108.

[257] *See id.* at 108–09.

conduct is intended to convey a particularized message, and if it is likely that those who view the message will understand it.[258]

Chimera creation, in particular, may straddle the line between scientific inquiry and artistic expression.[259] For example, images of mice with artificial human ears growing on their backs have been described as "the most symbolically-charged recent depictions of biomedical experimentation and its challenge to the category 'human.'"[260] In addition, artists have recognized the potential for creative expression through transgenics.[261] For example, one artist produced a green-fluorescent-protein rabbit with DNA derived from a jellyfish.[262] The artist has announced his plans to produce a glowing dog by the same technique and, likewise, to create human-nonhuman chimeras as potential art.[263] The artist explained that his work is defined not only by the scientific creations themselves, but also by their roles in society.[264] Given the expressive aspects of creating chimeras, courts may be forced to make decisions about emerging biotechnology on the basis of the First Amendment.[265]

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[258] *See* Spence v. Washington, 418 U.S. 405, 414–15 (1974) (displaying American flag superimposed on peace symbol was form of expression); Adams, *supra* note 117, at 109 (noting that biological research might not meet this standard of expression).

[259] *See, e.g.*, Eduardo Kac, *Transgenic Art*, 6 LEONARDO ELEC. ALMANAC (Dec. 18, 1998), *at* http://mitpress2.mit.edu/e-journals/LEA/ARTICLES/TRANSART/transart.html. *See generally* THE EIGHTH DAY: THE TRANSGENIC ART OF EDUARDO KAC (Dan Collins & Sheilah Britton eds., 2003).

[260] Sarah Franklin, *Drawing the Line at Not-Fully-Human: What We Already Know*, 3 AM. J. BIOETHICS, Summer 2003, at W25, W25, *at* http://mitpress.mit.edu/journals/ajob/3/3/W25.pdf. The "ear" was an artificial scaffold that was nourished by the mouse's skin cells. Joseph D'Agnese, *Brothers with Heart*, 22 DISCOVER, July 2001, at 40.

[261] Jeremy Rifkin, *Dazzled by the Science: Biologists Who Dress up Hi-Tech Eugenics as a New Art Form Are Dangerously Deluded*, THE GUARDIAN, Jan. 14, 2003, at 17, http://www.guardian.co.uk/comment/story/0,3604,874312,00.html (critical analysis of transgenic art and artistic aspects of modern biotechnology innovations). *But see* EUGENE THACKER, AESTHETIC BIOLOGY, BIOLOGICAL ART, at http://art-design.smsu.edu/acm/contextin/fall_03/thacker/thacker_print.html (responding to Rifkin's comments regarding transgenic art) (last visited Apr. 7, 2004).

[262] *See* EDUARDO KAC: TELEPRESENCE, BIOTELEMATICS, AND TRANSGENIC ART 101–31 (Peter T. Dobrila & Aleksandra Kostic eds., 2000), *reprinted in* Eduardo Kac, *GFP Bunny*, 36 LEONARDO 97, 97 (2003), *available at* http://www.ekac.org/gfpbunny.html#gfpbunnyanchor.

[263] *See* Kac, *supra* note 259.

[264] *See* Kac, *supra* note 262, at 98–100. The group, Critical Art Ensemble, presents performance art called GenTerra in which the audience participates in a decision involving the release of benign transgenic bacteria. *See generally* GENTERRA, *at* http://www.critical-art.net/biotech/genterra/ (last visited Apr. 7, 2004).

[265] *See* Adams, *supra* note 117, at 109–10. The claim of artistic expression through chimeras relates to the First Amendment claim to religious expression through biotechnology. *See id.* at 107; *see also* U.S. CONST. amend. I. Cults such as the Raelians have developed

B. *Animal Rights Debate*

Despite arguments that species are constantly changing and that human beings have been crossing species lines for years in agriculture and selective breeding, critics assert that scientists should not create chimeras because biotechnology should not disrupt individual species.[266] Regardless of whether the concept of species is simply a biological construct,[267] animals often suffer for the advancement of science.[268] Researchers will continue to employ genetic engineering and other biotechnology techniques on animals to study human disease, to develop pharmaceuticals, and to improve food and organ sources.[269] Notwithstanding these beneficial opportunities, some animal rights organizations continue to oppose biotechnology developments, including the patenting of life forms.[270]

The exploitation of human-nonhuman chimeras raises unique concerns, because unlike other animal research subjects, these chimeras are partially human.[271] Human beings are no longer defined solely by genetic composition.[272] The Human Genome Project, which sequenced the DNA of a small number of individuals, revealed the genetic similarity of human beings to one another and to other species.[273] Consequently, the ethical debate regarding how to regulate chimera requires characterizing personhood.[274]

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technology around this claim. *See* Adams, *supra* note 117, at 109; *see also* THE RAELIAN MESSAGE, *at* http://www.rael.org/english/index.html (last visited Apr. 1, 2004).

[266] *See* Magnani, *supra* note 71, at 457–58.

[267] *Id.* at 458; *see also* Robert & Baylis, *supra* note 3, at 3–4, 5 n.8 (discussing lack of scientific consensus on how to define species).

[268] *See* Morin, *supra* note 30, at 176.

[269] *See id.* at 177–80.

[270] *See id.* at 176.

[271] *See* Cynthia B. Cohen, *Creating Human-Nonhuman Chimeras: Of Mice and Men*, 3 AM. J. BIOETHICS, Summer 2003, at W3, W3–5, *at* http://mitpress.mit.edu/journals/ajob/3/3/w3.pdf. *But see* Magnani, *supra* note 71, at 456 (indicating the overall value of research involving chimeras in comparison to research involving other animal subjects); Morin, *supra* note 30, at 177 (noting that transgenic animals may become superior research models, which would lessen suffering by reducing the number of organisms needed in experiments).

[272] *See* Robert & Baylis, *supra* note 3, at 4. Despite a variety of biological attributes that might be uniquely human, scientific evidence alone cannot define species adequately. *See id.* at 4–5. Some commentators have suggested that the "notion of human uniqueness is a myth or a convenient and comforting fabrication by human beings." Kimberly A. Urie et al., *The Humane Imperative: A Moral Opportunity*, 3 AM. J. BIOETHICS, Summer 2003, at W20, W20, *at* http://mitpress.mit.edu/journals/ajob/3/3/w20.pdf.

[273] *See* Robert & Baylis, *supra* note 3, at 4.

[274] Linda MacDonald Glenn, *Biotechnology at the Margins of Personhood: An Evolving Legal Paradigm*, 13 J. EVOLUTION & TECH. 1, 42 (2002), *at* http://www.jetpress.org/volume13/

C. *The Moral Status of the Human Embryo*

Legal and regulatory issues in modern biotechnology often depend on determining the "moral status"[275] of the embryo.[276] The embryo in utero is not a "person" under the Fourteenth Amendment according to the 1973 U.S. Supreme Court decision in *Roe v. Wade*; however, that decision may not bear on the status of a living human embryo ex utero, where there is no imperative to consider fetal and maternal rights together.[277] Courts have held that living human embryos occupy an interim position between person and property that entitles them to "special respect" because of their potential to become human life.[278]

In regard to human cloning, President George W. Bush has declared his support for legislative proposals to ban all human cloning.[279] Congress, however, has not been able to reach a consensus.[280] The debate involves the process of nuclear transfer, which may be

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glenn.pdf (proposing a person-property continuum to evaluate personhood and to arrive at common legal understanding to apply to new intelligent life).

[275] Moral status is "[t]he standing of a being or entity in relation to other moral agents or individuals. To have moral status is to be an entity toward which human beings, as moral agents, have or can have moral obligations." HUMAN CLONING AND HUMAN DIGNITY, *supra* note 26, at 233.

[276] *See* Adams, *supra* note 117, at 147–48; Casey & Adams, *supra* note 78, at 112 (discussing special respect doctrine for human embryos); Zitner, *supra* note 114, at A1 ("We as a society are ambivalent about the moral status of the embryo. That's why this [debate] has been going on for a long time, and why no one wants to try to sort it out." (quoting Professor Arthur L. Caplan of University of Pennsylvania)).

[277] *See* 410 U.S. 113, 158 (1973); Casey & Adams, *supra* note 78, at 118–19. *But see* Doe v. Shalala, 862 F. Supp. 1421, 1426, 1429 (D. Md. 1994) (denying embryo standing to represent class of embryos suing to enjoin federally funded research because an embryo is not a "person").

[278] *See* Davis v. Davis, 842 S.W.2d 588, 597 (Tenn. 1992) (concluding that embryos "are not, strictly speaking, either 'persons' or 'property,' but occupy an interim category that entitles them to special respect because of their potential for human life"); *cf.* Kass v. Kass, 696 N.E.2d 174, 181 (N.Y. 1998) (holding that embryos are not persons for constitutional purposes, but declining to address whether embryos are entitled to special respect); Oct. 2003 Recommendations, *supra* note 195 (referring to the "special respect owed nascent human life—and even, if to a somewhat lesser degree, to egg and sperm, in view of their standing as the potential seeds of a new child and of a new human generation").

[279] *See* JUDITH A. JOHNSON, CONG. RESEARCH SERV., LIBRARY OF CONG., HUMAN CLONING 11 (2003), *available at* http://www.usembassy.it/pdf/other/RL31358.pdf; Bush, *supra* note 10, at 1150 (declaring strong opposition to cloning).

[280] *See* JUDITH A. JOHNSON, CONG. RESEARCH SERV., LIBRARY OF CONG., STEM CELL RESEARCH 15–17 (2003), *available at* http://www.usembassy.it/pdf/other/RL31015.pdf (describing proposed human cloning and stem cell legislation); Bryn E. Floyd, Comment, *Regulation of Stem Cell Research: A Recommendation That the United States Adopt the Australian Approach*, 13 PAC. RIM L. & POL'Y J. 31, 32–33 n.12 (2004).

used to create cloned human embryos as well as human-nonhuman embryos.[281] Opponents of a complete ban on human cloning generally approve of using nuclear transfer to create embryos, provided the embryos are not used for reproductive purposes.[282] Those in favor of a ban on human cloning generally believe that a partial ban, prohibiting only cloning to produce children, would be impossible to enforce; therefore, pragmatic and ethical concerns require a complete ban on human cloning.[283]

Embryos, unlike chimeras, are entirely human, yet the United States has not prohibited their manufacture or destruction in human cloning and embryo research.[284] Therefore, until legislators reach a consensus on the moral status of the living human embryo, which contains the potential to become a human being and from which all human beings develop, any attempt to define and regulate human-nonhuman chimeras will remain complicated.[285]

D. *The Moral Status of Chimeras: Beyond Regulation*

In the absence of legislation or as a result of renegade science, human-nonhuman chimeras may be inevitable.[286] In response, the courts and legislatures will need to decide the status of transgenic creatures and determine how to classify them on a scale between person and property.[287] The classification of chimeras as human would restrict their legal use in scientific research.[288] In fact, the prospective treatment of human-nonhuman chimeras may resemble the history of racial classification in the United States.[289] Indeed, if chimeras are human, then committing them to scientific experimentation

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[281] *See* JOHNSON, *supra* note 279, at 4; *see also supra* note 60.

[282] *See* Adams, *supra* note 117, at 85–86 (describing biotechnology industry's view).

[283] *See id.* at 106.

[284] *See* JOHNSON, *supra* note 280, at 18.

[285] *See* Adams, *supra* note 117, at 148–49.

[286] *See* Newman, *supra* note 16, at 460, 462–63 (suggesting that society is moving toward "an era of lifelike artifacts" in which it will need to determine the legal status of humanoid creations); *see also* Linda MacDonald Glenn, *A Legal Perspective on Humanity, Personhood, and Species Boundaries*, 3 AM. J. BIOETHICS, Summer 2003, at 27, 27 (indicating that further scientific advances may result, intentionally or unintentionally, in chimeras with superior intelligence to existing nonhuman animals).

[287] *See* Glenn, *supra* note 286, at 28; *see also* Glenn, *supra* note 274, at 42.

[288] Cirlin, *supra* note 16, at 507–08.

[289] *See* David Wasserman, *Species and Races, Chimeras, and Multiracial People*, 3 AM. J. BIOETHICS, Summer 2003, at W13, W13–14, *at* http://mitpress.mit.edu/journals/ajob/3/3/w13.pdf.

would be a form of servitude in violation of the Thirteenth Amendment[290] and also would violate their First Amendment right of freedom of association.[291]

The question remains whether chimeras would be treated as animals even if they consist almost entirely of human DNA.[292] The constitutional difficulties arise not only in patent law, but in terms of what types of research would infringe on personhood.[293] Due to the imprecise definition of human being supplied by the courts, legislators, and agencies, the rights afforded to human-nonhuman chimeras will depend on a determination of their humanity.[294] These questions are admittedly esoteric,[295] but the law must consider now the legal ramifications of the creation of new "species" of chimera.[296]

VI. The Legal Aspects of Adopting Legislation Similar to Canada's AHR Act to Regulate the Creation of Chimeras in the United States

To prevent the unrestricted development of human-animal chimeras, the United States should pass legislation similar to Canada's AHR Act.[297] Existing institutions are not equipped to regulate this emerging biotechnology.[298] By enacting clearly defined legislation, Congress may address the legal and ethical complexities presented by human-nonhuman chimeras, while continuing to promote medical and scientific advances.[299]

A. *Existing Regulatory Mechanisms Do Not Encompass Chimera Technology*

The President's Council suggested that existing institutions cannot regulate sufficiently the creation of various types of human-

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[290] U.S. Const. amend. XIII; Cirlin, *supra* note 16, at 507.

[291] U.S. Const. amend. I; *see* Cirlin, *supra* note 16, at 507.

[292] *See* Magnani, *supra* note 71, at 449–50.

[293] *See* Cirlin, *supra* note 16, at 507.

[294] *See* Rivard, *supra* note 28, at 1441–45; *supra* notes 275–285 and accompanying text.

[295] *See* Sagoff, *supra* note 39, at 29. This discussion is abstract in the sense that the creation of a living, hybrid creature is unlikely at this time. *See id.* Sagoff asserts that, outside mythology, no proposed scientific project raises such moral ambiguities and challenges to moral intuitions about what it means to be human or the species concept of *Homo sapiens*. *Id.*

[296] *See* Chakrabarty, *supra* note 6, at 21; *see also* Glenn, *supra* note 286, at 28.

[297] *See* Assisted Human Reproduction Act, ch. 2, §§ 3, 5(1)(i)–(j), 2004 S.C. (Can.).

[298] *See supra* notes 96–197 and accompanying text.

[299] *See* Reproduction and Responsibility, *supra* note 62, at 222–23 (recommending legislation to create a reasonably separate boundary between humans and nonhumans in assisted reproductive technologies).

nonhuman chimeras.[300] Patent law, agency regulation by the FDA, and other regulatory mechanisms are not equipped to deal adequately with human-nonhuman chimera technology.[301]

1. Patent Law Is an Insufficient Means of Regulating Biotechnology

In the area of patent law, Congress recently affirmed the USPTO's authority to deny patents pertaining to human life; however, it remains unclear whether the USPTO will deny patents on certain human-nonhuman chimeras.[302] Patent law cannot completely regulate biotechnology because scientists may decide to pursue certain technologies regardless of whether the products or processes are patentable.[303] Also, patent protection is limited to twenty years, after which technology enters the public domain.[304] Furthermore, patent law should be morally neutral, because it was designed to reward inventors of desirable inventions rather than to regulate or prohibit undesirable technology.[305] Therefore, the USPTO may lack authority and resources to limit patents on technology to develop human-nonhuman chimeras.[306]

Nevertheless, there is an underlying concern about the commodification of human life[307] in biotechnology patents in the United States.[308] Patent law could be used to declare some biotechnology to be unpatentable subject matter because these technologies pose significant risks to human dignity.[309] Some threats to human dignity have benefits to technology, science, and medicine that outweigh any

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[300] *See id.* at 176–81.

[301] *See id.*

[302] *See supra* notes 132–140 and accompanying text.

[303] Nash, *supra* note 121, at 299.

[304] 35 U.S.C. § 154(a)(2) (2000); Nash, *supra* note 121, at 300.

[305] *Id.*

[306] *See id.* at 300.

[307] Commodification "is the treatment of human beings or body tissues and substances as commodities—as means to an end, not as ends in themselves. Thus commercialization includes commodification, but commodification need not entail profit motive." PAUL SZABO, THE ETHICS AND SCIENCE OF STEM CELLS 115 (2002), *available at* http://www.paulszabo.com/images/pdf_books/Microsoft%20Word%20-%20BKStem1.pdf.

[308] *See* David B. Resnick, *Patents on Human-Animal Chimeras and Threats to Human Dignity*, 3 AM. J. BIOETHICS, Summer 2003, at 35, 35.

[309] *Id.* Violations of human dignity are distinct from threats to human dignity. *Id.* Violations to human dignity occur when one treats a whole human being, or part of a human being closely connected to the whole human being, as a commodity with only a market value. *Id.* In contrast, threats to human dignity occur when one engages in a practice that could lead to violations to human dignity. *Id.* According to these definitions, patents on human gametes and stem cells are threats to human dignity. *Id.*

harms.[310] In these instances, such patents should be permitted if careful attention is paid to the laws and policies that apply to the practices involved, with a goal of minimizing threats to human dignity.[311]

Then again, a policy of allowing patents with the goal of minimizing threats to human dignity should not apply to close cases involving human-nonhuman chimeras.[312] For example, it is difficult to distinguish a human embryo from a human embryo with a few animal genes.[313] In this case, by asserting a compelling interest in protecting human dignity, the government may eliminate the need to decide whether these chimeras are human because they are close enough to raise concerns.[314] This analysis still poses the difficult question of deciding when a chimera is "humanlike" enough to be unpatentable, but this is less difficult than deciding whether a chimera is "human" at all.[315] In comparison, the moral utility test in patent law is not particularly useful in a patent application for human-nonhuman chimeras, because the utilitarian arguments would inevitably outweigh the deontological arguments in the patent forum.[316] Therefore, the debate over the patentability of chimeras will continue in the USPTO until either Congress or the U.S. Supreme Court intervenes to set clear boundaries on the patentability of humanlike life forms.[317]

2. The FDA Lacks Jurisdiction to Regulate Chimeras

The USPTO's refusal to issue patents for chimeras that are less than fifty percent human does not eliminate the ability of researchers to pursue this controversial technology.[318] Therefore, legislators should intervene with regulations to prohibit certain human-nonhuman chimeras in order to protect and promote the public interest.[319] Any effort by the FDA to declare jurisdiction over chimeras would route this technology into a regulatory system without the benefit of a public debate

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[310] *Id.*

[311] *Id.* When human-nonhuman chimeras are not clearly humanlike, then their creation is less threatening to human dignity, and the USPTO should grant patents for such chimeras. *Id.* at 36.

[312] *See id.*

[313] Resnick, *supra* note 308, at 36.

[314] *Id.*

[315] *Id.* at 35.

[316] *See* Magnani, *supra* note 71, at 456.

[317] *See id.*

[318] *See* Nash, *supra* note 121, at 299.

[319] *See* REPRODUCTION AND RESPONSIBILITY, *supra* note 62, at 208–09.

in Congress.[320] Furthermore, it is likely that those planning to produce human-nonhuman chimeras would support FDA jurisdiction as a less restrictive alternative to legislation, because FDA oversight might not foreclose controversial chimera research regardless of public opposition.[321] Consequently, FDA jurisdiction would absolve Congress of its role in resolving the unprecedented ethical issues raised by chimeras.[322]

An additional limitation to FDA jurisdiction is the FFDC Act's requirement that information about the process of product design and the results of clinical trials must remain confidential during the approval process.[323] This process, which takes place in secrecy, does not permit a public discussion about the safety and significance of the relevant biotechnology.[324] Moreover, FDA jurisdiction inhibits the creative resolution of broad public questions involving ethics and human values.[325] Therefore, although the FDA has not stated explicitly whether the creation of chimeras falls within its jurisdiction, the FDA should not assert its regulatory authority over chimera technology.[326]

Notwithstanding these disadvantages, if chimera technology may be classified as a drug, medical device, or biological product, then the FDA legally could assert its regulatory authority over the research and development of chimeras.[327] Already, the FDA has declared its jurisdiction over xenotransplantation, primarily under its biologics authority.[328] In 2003, the FDA issued comprehensive guidelines for the transfer of

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[320] *See* Merrill & Rose, *supra* note 170, at 146 (suggesting that the FDA's assertion of jurisdiction over human cloning preempted the public discussion of moral and ethical issues); *see also* Merrill, *supra* note 155, at *82.

[321] *See* Merrill, *supra* note 155, at *74 (suggesting that biotechnology industry might favor FDA regulation because of concern that a legislative ban would be either too broad or too restrictive); *see also* Rokosz, *supra* note 9, at 490 (indicating biotechnology industry's belief that the FDA has authority over human cloning and that legislation is unnecessary).

[322] *See* Price, *supra* note 161, at 628.

[323] *See* Merrill, *supra* note 155, at *6–8.

[324] *See id.*

[325] *See* Merrill & Rose, *supra* note 170, at 146, 148.

[326] *See* Parens & Knowles, *supra* note 7, at 12 (recommending against the FDA's exclusive mandate over technologies such as human cloning and ooplasm transplantation).

[327] *See* Price, *supra* note 161, at 621; *see also* 21 U.S.C. § 321(g)(1), (h) (2000) (describing drugs and devices); 42 U.S.C. § 262(i) (2000) (describing biological products).

[328] *See* Ctr. for Biologics Evaluation & Research, U.S. Food & Drug Admin., Guidance for Industry: Source Animal, Product, Preclinical, and Clinical Issues Concerning the Use of Xenotransplantation Products in Humans 7 (Apr. 2003), *available at* http://www.fda.gov/cber/gdlns/clinxeno.pdf; Letter from Jay P. Siegel, Director, Office of Therapeutics Research and Review of the Center for Biologics Evaluation and Research (Mar. 8, 2002) (advising practitioners of FDA jurisdiction over xenotransplantation), *available at* http://www.fda.gov/cber/ltr/humemb.pdf; *see also* 21 U.S.C. § 321(g)(1), (h).

cells, tissues, and organs from nonhuman organisms, or from living nonhuman biological materials, into humans.[329] Although the FDA recognized the benefits of this technology for transplant recipients, it expressed concern about the spread of infectious disease and the formation of new viruses in the general human population.[330] The potential for disease transmission or genetic abnormalities could prompt the FDA to regulate human-nonhuman chimeras similarly to its regulation of porcine heart valves or human heart valves used in transplantation.[331]

It is unlikely, however, that Congress intended for the FDA to have jurisdiction over chimera creation, because this might exceed the FDA's authority under its enabling statutes.[332] In light of *FDA v. Brown & Williamson Tobacco Corp.*, in which the U.S. Supreme Court, in 2000, rejected the FDA's interpretation of its enabling statute to encompass tobacco, other courts may take a similar stance on the FDA's assertion of jurisdiction over human embryos and biotechnology.[333]

Nevertheless, the FDA maintains that existing laws provide both jurisdiction and sufficient means of control over certain biotechnologies.[334] The courts, in accord, have not voided any FDA initiatives in biotechnology.[335] Given the tendency of courts to yield to FDA control in biotechnology, judicial decisions may not provide an accurate measure of whether the FDA has exceeded its regulatory reach or failed to extend its reach far enough.[336] More specifically, the judiciary may not evaluate whether the FDA moved too hesitantly toward emerging technologies and whether the impact of the FDA's regulations lagged behind developing technology.[337] Therefore, even if the FDA or another regulatory body had the authority to regulate chimeras, legislation would still be appropriate.[338]

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[329] *See* CTR. FOR BIOLOGICS EVALUATION & RESEARCH, *supra* note 328, at 1.

[330] *See id.* at 2.

[331] *See supra* notes 167–169 and accompanying text.

[332] *See* Rokosz, *supra* note 9, at 512–13; *see also* Federal Food, Drug, and Cosmetic Act of 1938, 21 U.S.C. §§ 301–397; Public Health Service Act, 42 U.S.C. §§ 201–300; Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837, 844 (1984).

[333] *See* 529 U.S. 120, 126 (2000); Rokosz, *supra* note 9, at 513.

[334] *See* Merrill, *supra* note 155, at *2.

[335] *See id.* at *3. *But see Brown & Williamson*, 529 U.S. at 126 (voiding FDA jurisdiction over tobacco).

[336] *See* Merrill, *supra* note 155, at *3.

[337] *See id.*

[338] *See* REPRODUCTION AND RESPONSIBILITY, *supra* note 62, at 191.

B. *Canada's AHR Act as a Model for Legislation Regulating Chimeras in the United States*

Unlike regulation by federal agencies, patent law, and federal funding, legislation directly regulating the creation of human-nonhuman chimeras would apply to all research in the private and public sectors.[339] Research would be governed by one set of rules rather than by separate standards for federal or private funding.[340] This would eliminate any encouragement to move research to the private sector.[341]

1. Definitional Concerns: Which Chimeras Should Be Regulated?

In adopting legislation similar to Canada's AHR Act, the United States must resolve complex definitional issues that have led to criticism of the AHR Act.[342] Congress must determine which chimeras to prohibit and then frame the terminology to include only the chimeras being targeted.[343] Legislation modeled after the AHR Act should refine the Act's comprehensive definition of hybrid and develop a more inclusive definition of chimera that incorporates all chimeras made using human embryos.[344] Interspecies organisms that do not fall within the statutory language should be evaluated using several factors, including, but not limited to (1) the types of biological materials combined, (2) the relationship between the combined organisms, (3) whether the combination occurs naturally or through human intervention, and (4) at which point in development the combination occurs.[345] This evaluation could be accomplished by a new regulatory body.[346]

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[339] *See* Baylis, *supra* note 220, at 45.

[340] *Id.*

[341] *See id.*

[342] *See supra* notes 235–245 and accompanying text.

[343] *See supra* notes 235–245 and accompanying text. The definition of chimera set forth in the AHR Act is underinclusive. *See* Assisted Human Reproduction Act, ch. 2, §§ 3, 5, 2004 S.C. (Can.). This Note proposes that Congress adopt a more specific definition of chimera as discussed *infra* notes 344–373 and accompanying text. For a discussion of the need for precise definitions in legislation to regulate biotechnology, see HUMAN CLONING AND HUMAN DIGNITY, *supra* note 26, at 37–55 (discussing the definition of human cloning); Herder, *supra* note 236, at 40–42 (discussing the definition of embryo donor).

[344] *See* Robert, *supra* note 220, at 15–16.

[345] *See* Greely, *supra* note 2, at 17 (proposing broad criteria to evaluate chimeras).

[346] *See* REPRODUCTION AND RESPONSIBILITY, *supra* note 62, at 188–89 (proposing a new regulatory agency of the executive branch to oversee biotechnology).

a. *Animal-to-Animal Chimeras*

Despite ethical concerns about designing new creatures solely for human exploitation, animal-animal chimeras may be excluded from a reasonable legislative definition of chimeras.[347] The President's Council discussed the creation of animal-animal chimeras in detail, but these chimeras pose no significant ethical issues because they contain no human components and do not impinge on the concept of personhood.[348] Consequently, any regulatory definition of chimera including animal-animal chimeras would be accurate scientifically but would be overinclusive if the focus of legislation is biotechnology involving nascent human life.[349]

b. *Human-to-Human Chimeras*

In contrast to animal-animal, the scientific community has shunned the creation of human-human chimeras in the laboratory.[350] For example, researchers criticized a 2003 experiment that combined male and female human embryos into a single hermaphroditic human-human chimera.[351] These artificial chimeras raise moral concerns because of their minimal utility, their unnaturalness, and their adverse effect on human dignity.[352] Both the AHR Act and the President's Council's interim recommendations contain provisions banning the creation of some human-human embryos.[353] Therefore,

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[347] *See* Robert, *supra* note 220, at 16; *see also* Oct. 2003 Session, *supra* note 195.

[348] *See* Oct. 2003 Session, *supra* note 195; Greely, *supra* note 2, at 19.

[349] *See* Robert, *supra* note 220, at 16.

[350] *See* Tabitha M. Powledge, The Scientist, *Mixed-Sex Embryo Controversy: Scientific Skepticism and Ethical Criticism of Chimera Research Presented in Spain*, *at* http://www.biomedcentral.com/news/20030708/01 (July 8, 2003). For example, University of Pennsylvania Professor Arthur Caplan stated that the use of human embryos to create human-human chimeras for research was the inevitable product of years of under-regulation of the reproductive technology industry. *See id.*

[351] *See id.* At the 2003 meeting of the European Society of Human Reproduction and Embryology (the "ESHRE"), Norbert Gleicher of the Center for Human Reproduction in Chicago and New York reported that he had merged a cell from a male embryo with a female embryo and had grown the hermaphrodite hybrid in a lab for six days before destroying it. Norbert Gleicher & Y.X. Tang, *Blastomere Transplantation as a Possible Treatment*, Abstracts of the 19th Annual Meeting of the ESHRE, Madrid, Spain (July 1, 2003), *available at* http://humrep.oupjournals.org/cgi/reprint/18/suppl_1/XVIII57.pdf. The ESHRE and other scientists immediately condemned Gleicher's research, claiming that it was both scientifically and ethically objectionable. Powledge, *supra* note 350.

[352] *See* Greely, *supra* note 2, at 17–19.

[353] *See* Assisted Human Reproduction Act, ch. 2, §§ 3, 5(1)(i), 2004 S.C. (Can.); REPRODUCTION AND RESPONSIBILITY, *supra* note 62, at 222–23.

chimera regulation should prohibit explicitly the creation of all human-human chimeras at the embryonic level.[354]

c. *Nonhuman-to-Human Chimeras*

The AHR Act also prohibits the transfer of nonhuman cells to human embryos to form chimeras.[355] These nonhuman-human combinations raise strong ethical considerations because they utilize developing human embryos.[356] Although the President's Council decided not to recommend a ban on the combination of human and nonhuman embryos, Congress nevertheless should prohibit the creation of these nonhuman-human chimeras.[357] This is because they violate human dignity and the doctrine of special respect for human embryos and they could lead to the development of new humanlike species for scientific exploitation.[358]

The AHR Act does not address non-embryonic transfers from nonhumans to humans; however, these transfers should be considered by a regulatory body that can balance the various factors.[359] Although many of these transfers are widely accepted, some pose unique ethical concerns.[360] In the area of xenotransplantation, the placing of pig heart valves in human beings caused some initial concern among recipients; however, this transplant procedure is now regulated and accepted.[361] The public is not likely to object to the development of other single organ transplants from animals into human beings.[362] Yet, if a human were to receive many organs from a nonhuman, or if it were possible to transfer a single vital organ from a

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[354] *See* REPRODUCTION AND RESPONSIBILITY, *supra* note 62, at 225 (recommending ban on human-human chimeras but only for the purposes of reproduction). The AHR Act prohibits the creation of a human clone by any technique, including nuclear transfers. Assisted Human Reproduction Act § 5(1)(a). *But see id.* § 40(2) (allowing licensed use of in vitro human embryos); *supra* notes 225–227 and accompanying text.

[355] Assisted Human Reproduction Act, ch. 2, §§ 3, 5(1)(i), 2004 S.C. (Can.). The AHR Act also prohibits the artificial transfer of nonhuman nuclei to human cells for reproduction. *Id.* §§ 3, 5(1)(j).

[356] *See* Greely, *supra* note 2, at 19.

[357] *See* REPRODUCTION AND RESPONSIBILITY, *supra* note 62, at 222–23.

[358] *See* Johnston & Eliot, *supra* note 29, at 6–7; *supra* notes 275–296.

[359] *See* Assisted Human Reproduction Act § 3; *supra* notes 345–346 and accompanying text.

[360] *See supra* notes 76–81, 275–296, and accompanying text.

[361] Greely, *supra* note 2, at 19. Transferring nonhuman parts into human beings is troubling to many people because of the practical fear of the passage of disease through the transfer. *See id.* Animal rights proponents also object to such transfers as violations of species integrity. *See id.*

[362] *Id.*

similar species (such as a primate brain) into a human, then concern might arise as to whether the resulting organism was really human.[363] Thus, chimeras made by moving nonhuman parts into human beings raise concerns when the transfer is significant enough to cast doubts on the humanity of the recipient.[364] The AHR Act, by definition, does not cover this mode of chimera creation; nevertheless, the United States should consider creating a new regulatory body to evaluate these transfers.[365]

d. *Human-to-Nonhuman Chimeras*

Neither the AHR Act nor the recommendations of the President's Council prohibit the transfer of human stem cells to nonhuman embryos.[366] Generally, medical and scientific uses of chimeras are less objectionable than the creation of chimeras for art or curiosity;[367] however, any transfer of human embryonic cells to developing nonhumans presents the same ethical concerns as nonhuman-to-human chimeras and should be restricted.[368]

On a non-embryonic level, the public generally accepts scientific and medical practices involving the transfer of human material to animals, such as in the creation of transgenic mice.[369] A research proposal to create a mouse with human neurons in its brain received publicity, but did not generate much disapproval.[370] A research proposal transferring human brain tissue into a *primate*, however, would cause more serious ethical concerns because of the similarities between the two species.[371] Thus, chimeras made by moving human parts into nonhuman beings raise concerns when the transfer is significant enough to cast doubts on the humanity of the recipient.[372] This research should also be reviewed by a new regulatory body.[373]

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[363] *Id.*

[364] *Id.* at 17, 19.

[365] *See* Assisted Human Reproduction Act, ch. 2, § 3, 2004 S.C. (Can.); REPRODUCTION AND RESPONSIBILITY, *supra* note 62, at 188–89.

[366] *See* Assisted Human Reproduction Act §§ 3, 5; REPRODUCTION AND RESPONSIBILITY, *supra* note 62, at 222–24.

[367] Greely, *supra* note 2, at 19.

[368] *See* Johnston & Eliot, *supra* note 29, at 6–7; *supra* notes 275–296.

[369] *See* Greely, *supra* note 2, at 19. The ethical concerns are more prominent if the human stem cells are inserted into the brains or reproductive organs of animals. *See id.*

[370] *See id.*; Krieger, *supra* note 54.

[371] Greely, *supra* note 2, at 19; *see also* Glenn, *supra* note 274, at 39 (presenting a hypothetical in which human vocal chords are transplanted into a chimpanzee).

[372] *See* Greely, *supra* note 2, at 19.

[373] *See* REPRODUCTION AND RESPONSIBILITY, *supra* note 62, at 188–89.

2. Addressing Criticism of the AHR Act

The United States should adopt Canada's approach to regulating chimera technology, particularly because the strong consideration of individual rights in the United States would mitigate any rigidity in the Canadian collectivist view.[374] Any legislative attempt to regulate chimera technology, however, must articulate recognition of the opposing views on this issue.[375] In Canada, the government's insufficient justification for the AHR Act disappointed even its supporters.[376] Therefore, the United States should acknowledge the mechanical differences between various chimeras and the unique ethical issues they pose in framing legislation.[377]

In adopting legislation similar to the AHR Act, policymakers must decide whether to create an administrative body for oversight of chimera technology and whether to utilize criminal law to limit potentially harmful technology.[378] Proposed bills to ban human cloning have included criminal sanctions; therefore, the criminalization of scientific activity is not without precedent.[379] The inadequacy of the patchwork regulations under the Consolidated Framework strongly suggests the need for a single overseeing body to address novel biotechnology.[380] Ultimately, the success of legislation to regulate chimera technology will depend on effective enforcement through criminal sanctions, a regulatory agency, or both.[381]

3. Chimera Regulation Would Not Violate the U.S. Constitution

The regulation of the creation of human-nonhuman embryonic chimeras would not violate the First Amendment, because biotech-

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[374] *See* Young, *supra* note 213, at 85.

[375] *See* Caulfield, *supra* note 14, at 3.

[376] *See id.* at 3–4.

[377] *See id.*

[378] *See* Campbell, *supra* note 209, at 29 (arguing that a regulatory body would suggest that questionable activities are acceptable and would lack democratic responsiveness and accountability, whereas criminal regulation would be the most effective way to deal with harmful biotechnology). *But see* Timothy Caulfield, *Bill C-13 The Assisted Human Reproduction Act: Examining the Arguments Against a Regulatory Approach*, 11 HEALTH L. REV. 20, 20–23 (2002).

[379] *See* JOHNSON, *supra* note 280, at 16–17.

[380] *See supra* notes 142–148 and accompanying text.

[381] *See generally* REPRODUCTION AND RESPONSIBILITY, *supra* note 62, at 188–89 (discussing the potential to create a new regulatory agency to oversee biotechnology in the United States, but noting the complexity of establishing such an agency); Angela Campbell, *A Place for Criminal Law in the Regulation of Reproductive Technologies*, 10 HEALTH L.J. 77, 95–100 (2002) (justifying criminal law as a useful regulatory tool for Canadian biotechnology).

nology regulation does not hamper freedom of speech or religion, as there is no fundamental right to scientific inquiry.[382] Accordingly, general viewpoint-neutral regulation of expression in biotechnology is permissible under rational basis review.[383]

To the extent chimera creation is expressive conduct and regulation is not viewpoint neutral, regulation must satisfy strict scrutiny if it is not narrowly tailored.[384] In this regard, a law prohibiting the creation of chimeras would have to serve a compelling state interest and must not suppress free expression;[385] however, to the extent that chimera research is expressive, it may be commercial speech, subject to intermediate scrutiny.[386] Although the U.S. Supreme Court has held that scientific investigations are not generally commercial, recent efforts to showcase transgenic art suggest commercial, non-scientific reasons to create chimeras.[387]

Conclusion

With rapid developments in biotechnology blurring the lines between species and calling into question what it means to be a human person, human-nonhuman chimeras are no longer products of science fiction. Congress has been unable to reach a consensus on the regulation of biotechnology involving completely human subjects, such as human cloning and embryo research. As a result, scientists continue to create chimeras with increasing quantities of human tissues and genetic materials without limitation. The debate has found an audience in the patent system, but resolution of complex moral and scientific issues is better left to a public forum. Furthermore, chimera regulation cannot be accomplished effectively through existing legislation or regulatory agencies such as the FDA.

Consequently, the United States should consider legislation to regulate the production of certain types of chimeras, particularly human-nonhuman embryonic chimeras. Legislation would not raise any

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[382] U.S. Const. amend. I; *see* Adams, *supra* note 117, at 108.

[383] *See id.*

[384] *See id.* at 110.

[385] *See id.*

[386] *See id.* at 111–12.

[387] *See* Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, 425 U.S. 748, 762 (1976) (finding some commercial speech to be within First Amendment protection); *see also* Oct. 2003 Recommendations, *supra* note 195 (Dr. William Hurlbut suggesting that individuals might have commercial motivations to create genetic anomalies); Adams, *supra* note 117, at 110.

insurmountable constitutional issues with regard to scientific expression and would avoid the constitutional issues that will arise if scientists develop new species of humanlike chimeras. The United States should follow Canada's approach in preparing legislation to regulate chimera production. In adopting legislation modeled after Canada's AHR Act, the United States should reexamine its individualist approach to biotechnology and consider the critical definitional and ethical issues in regulating chimeras. Unregulated biotechnology, like the Chimera of Lycia, threatens to disrupt legal and social institutions; therefore, the United States must make a balanced effort now to protect the public interest.

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