



Submission from: Friends of Animals, Inc.
Lee Hall, Legal Director
777 Post Road
Darien CT 06820
United States
Tel: 610.964.0090
Fax: 610.964.9152

To: Secretariat, Animal Welfare Committee (AWC)
National Health and Medical Research Council
NHMRC (MDP 33)
GPO Box 9848
CANBERRA ACT 2601
Via e-mail: research@nhmrc.gov.au

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INTRODUCTION

Established in 1957 as a non-profit corporation under the laws of the state of New York, Friends of Animals is amongst the most well-established and reputable animal advocacy groups in the United States. Our areas of research, advocacy, and ethical education include environmental and food supply issues, genetic engineering, and philosophical and legal personhood.

In this submission we formally respond to the National Health and Medical Research Council's "Animal Welfare Committee's Guidelines for the creation, breeding, care and use of genetically modified and cloned animals for scientific purposes, Draft consultation document 2005" (hereinafter "Draft Guidelines").

The "integrity" and the "nature" of nonhuman animals may be affected by genetic modification or cloning, observes the Council in the Preamble to the Guidelines. Changes may include how such animals interact with other animals and the environment. The Council states: "Such changes (both expected and unexpected) have major ethical significance."

We agree, and believe that Australia should follow that statement to its logical conclusion, and disallow the cloning of nonhuman as well as human beings. We further state that genetic modification of nonhuman beings for human purposes is ethically unacceptable, for the reasons below.

ON THE PREAMBLE TO THE DRAFT GUIDELINES

In the Preamble, the Council points out that the issues covered in the draft include the creation and use of “laboratory animals, agricultural animals and companion animals developed and used for scientific purposes.” Insofar as the Draft Guidelines refer here to pets as a research goal, we note that the use of cloning to create pets, show, or racing animals is downright frivolous. The obvious point of it, as used in the United States by one firm, Genetic Savings & Clone, has been the five-figure sum that the company charges for a cloned pet.

The main uses of genetically modified and cloned animals, however, are expected to be in biomedical research, xenotransplantation, the production of pharmaceutical proteins, and increasing productivity of farm animals and other animals used for lucrative purposes. We’ll cover these proposed or potential uses in this statement.

Although Friends of Animals would agree that organ donation and human health are important causes, the best and safest answer is public education, disease prevention, and a good system for human organ donation; and the issue of cloned or deliberately genetically modified animals have enormous ethical ramifications -- with regard to human health, the state of the world’s ecology, and the interests of nonhuman animals. Those ramifications are being given relatively little attention as science and commerce become increasingly intertwined.¹

Moreover, as noted above and below,² the interests represented by the research are not always public health.

Animal Welfare: The Draft Guidelines Fall Short

Scientists often cannot weigh the harms of animal cloning research against the benefits of that research. They can only speculate. Mark Westhusin, lead cloning researcher with Texas A&M University, puts the point bluntly: "It's slow, painstaking work to get little bitty pieces of information that you hope will one day help and improve the technology."³

Furthermore, as the Council’s Draft Guidelines concede, “increased use of genetically modified animals can create a dilemma” under “the principles of the 3Rs, particularly

¹ For example, Monsanto is a leading corporation buying access to genetic information regarding nonhuman animals. See Rachel Melcer, “Monsanto Sees Joint Effort Producing The Super Pig”, *St. Louis Post-Dispatch* (8 Jun. 2004), available electronically at: <http://monsanto.co.uk/news/ukshowlib.phtml?uid=7860> More information on this connection -- between e.g., Australian genetic science and Monsanto -- appears on the Gene Technology Act 2000 website, www.ogtr.gov.au.

² See page 2 (on pets) and page 8 (on agribusiness) of this statement.

³ Juan A. Lozano, “Texas A&M Leads World in Cloning Animals”, Associated Press (17 Jul. 2005) (quoting Mark Westhusin, lead researcher with the A&M cloning team). Texas A&M is the world's first academic institution to clone six species in six years: cattle, a boer goat, pigs, a deer, a horse and a cat. *Ibid.*

Reduction,” as set out in the Code of Practice for the Care and Use of Animals for Scientific Purposes [hereinafter “Code”]. In fact, it’s more than a dilemma. The proposed research would be antithetical to the principle of reduction. The Council states with certainty that “the number of genetically modified animals created for scientific purposes has increased with new technologies.”

What the Council does not know is whether the use of genetically modified animals *will* eventually decrease the number of animals used for scientific purposes *if* they lead to improved models of disease – although the Council says it *may*.

Thus, as the Council observes, researchers don't know how genetically modified animals would affect the total number of animals used for scientific purposes. The creation and use of the animals -- both now and indefinitely -- is obviously contrary to the spirit of at least one of the Council’s own core welfare principles.

In addition, the Council observes, producing newly genetically modified animals means that many animals are used to produce the few animals that lead to a genetically modified strain. This, although researchers do not know if the creation of these animals will lead to *any* “improved models of disease”. Therefore, the Guidelines’ stated intent to weigh the “predicted scientific or educational value of the project against the potential effects on the welfare of the animals”⁴ is not possible.

Animal Rights: A Serious Valuation of Nonhuman Animals’ Inherent Interests

In the Preamble of the Draft Guidelines, the Council points out that spontaneous mutation may occur naturally, but that underscores the reality that mutations induced in a lab are not natural occurrences. Or, in the Council’s terms: “An induced mutation by genetic modification is a man-made alteration in the genetic code.”⁵

What we know today as the science surrounding induced genetic modification is, relatively, a scientific novelty. In 1951, Rosalind Elsie Franklin explained how the discovery of DNA had cracked the code of individual life. Two decades later, U.S. biochemists inserted DNA from a toad into an E.coli bacterium. In a 1976 letter to the magazine *Science*, Dr. Erwin Chargaff would ask, "Have we the right to counteract irreversibly the evolutionary wisdom of millions of years, in order to satisfy the ambition and curiosity of a few scientists?"⁶

⁴ “Animal Welfare Committee’s Guidelines for the creation, breeding, care and use of genetically modified and cloned animals for scientific purposes, Draft consultation document 2005” (hereinafter “Draft Guidelines”), Section 2.1 (vi), “Consideration of proposals to create or use genetically modified or cloned animals”.

⁵ See Draft Guidelines”, Section 4.1, “Steps involved in the creation of genetically modified animals”.

⁶ Erwin Chargaff, "On the Dangers of Genetic Meddling," *Science*, vol. 192, no. 4243 (4 Jun. 1976), at pages 938, 940.

In the 1980s, after the U.S. Supreme Court decided that a genetically altered bacterium could be patented,⁷ the marketing of genes became a multi-billion dollar industry. Yet from a moral perspective, the global society has not achieved consensus on whether conscious beings should be the objects of such applications. Brazil, India, and Norway, for example, have declined to grant patents to plants and animals.⁸

Notably, even in the United States, with regard to animals, the legal landscape varies. In the preface to the casebook *Wildlife Law*, Professors Dale Goble and Eric Freyfogle observe that "[e]nvironmental law, once focused on direct threats to human health, now is concerned with assaults on non-human life." This suggests that law is poised to make room for a recognition of the value of nonhuman lives unto themselves.

The Draft Guidelines do not anticipate this recognition. They dismiss the concept that a nonhuman consciousness implicates inherent value -- not merely the valuation calculated through the subjective observations and interests of human users, but on its possessor's own terms.

Between Human and Nonhuman life: No Bright Line

Bioethicists who see animal cloning as a necessary step to creating human stem cell lines typically decline to view this as paving the way for human clones.⁹ An ethical borderline between humans and all others seems unclear, however, when an international team of experimenters, adding weight to decades of field observations, reports that nonhuman primates develop distinct cultural traditions,¹⁰ and when we learn that the manufacture of tools has been observed in both apes and several bird species.¹¹

And when a panel of 22 scientists, lawyers, and philosophers recently debated, for more than a year, the wisdom of inserting human stem cells into monkey brains, the team's

⁷ In 1980, in the 5-4 decision in *Diamond v. Chakrabarty*, 447 U.S. 303, the U.S. Supreme Court decided that a genetically altered bacterium could be patented. In 1988, Harvard University patented the "OncoMouse," a rodent susceptible to cancer.

⁸ See Emily Marden, "The Neem Tree Patent: International Conflict over the Commodification of Life", 22 *BC Int'l & Comparative Law Review* 279 (1999), at page 279.

⁹ Lest it be thought that there is no slippery slope here, it should be noted that by 1991, about a decade after the holding in *Diamond v. Chakrabarty* allowing the patenting of life, the U.S. Court of Appeals for the Federal Circuit would uphold patenting on human genes.

¹⁰ See Helen Briggs, "Chimpanzee Culture 'Confirmed'", *BBC News* (22 Aug. 2005) (citing research published in the online edition of *Nature*), available electronically at: <http://news.bbc.co.uk/2/hi/science/nature/4166756.stm>

¹¹ W.C. McGrew, "Chimpanzee Material Culture: Implications for Human Evolution" (Cambridge University Press; 1992).

scientists weren't sure how to ethically separate humans from other primates.¹²

At least in reference to primates, the panel's conclusions, reported in the July 15 issue of the journal *Science*, cast significant uncertainty on the Council's statement¹³ that "[t]he mainstream research and community position is ... that the relative higher intrinsic value of humans allows some use of animals in research for the advancement of human health and well being."

"The intrinsic value of animals is recognised," states the Council, "in that research use is conditional on safeguarding animal welfare in the research process and justifying or minimising any harm to them. This "intrinsic value" is a more difficult notion to pin down than the Council suggests in the Draft Guidelines. No bright line can be drawn anywhere, if a consciousness is the key factor. Whether humans have greater intrinsic value remains, even by the Council's own acknowledgement, "an issue for debate on the ethics of use of animals for research purposes."¹⁴

In the Preamble of the Draft Guidelines, the Council observes that "[t]he potential impact of genetic modification on the welfare of animals raises special concerns", and that "recommendations on how best to manage the potential impact of genetic modification on the welfare of animals, and the associated monitoring requirements, are outside the scope of the *Code*." We agree; and some of those concerns cannot be ameliorated by codification of the practice.

Applying embellishments to the existing Code does not mitigate, for example, the concern about creating, using instrumentally, and using with implications of unprecedented severity, animals who, once conscious of their lives, have individual value unto themselves. Implicated here are deeper questions than administrative law or animal cruelty law can reach.

ON THE DRAFT GUIDELINES

The Scope of the Guidelines: Endangered Species

The Animal Welfare Committee's Draft Guidelines¹⁵ apply to the production of hybrid animal species, such as those that may arise in a program to preserve an endangered

¹² The report's lead author is Mark Greene, formerly of Johns Hopkins University and now a professor at the University of Delaware. A brief summary in lay terms is supplied in Robert Roy Britt, "Stem Cell Research With Monkeys Sparks Debate: Grafting Human Cells Into Animals' Brains Seen Having Ethical Ramifications", *LiveScience* (14 Jul. 2005), available electronically at: <http://www.msnbc.msn.com/id/8572943/>.

¹³ See "Preamble: Ethical and welfare issues related to the production and use of genetically modified and cloned animals" of the Draft Guidelines.

¹⁴ See *Ibid*.

¹⁵ Draft Guidelines, Section 1, "The Scope of These Guidelines".

species by cross species nuclear transfer. The speculative claim that laboratory scientists could prevent extinctions arguably comprises the strongest claim from the viewpoint of consideration for the entire biocommunity. Yet the utilitarian framework applied here misses the value of individual, implicated lives of the many test subjects that will not repopulate the natural biocommunity. For the eventually resulting animals -- those presumably able to repopulate -- the laboratory framework, because it does not address habitat degradation or other causes of accelerated extinction, is poised to defeat its own purpose and, at the same time, to "counteract irreversibly the evolutionary wisdom of millions of years."

Welfare Issues

Much cloning takes place within research primarily geared to agricultural relevance. If cloned dairy products were to hit the market, beginning, for example, with milk and veal from the cows' first-generation offspring, some may enquire about human safety, but cruelty prosecutions will be reserved for unusual cases of gratuitous harm.

The Council acknowledges the "potential for any genetic modification to cause unexpected pain or distress to animals and that a welfare problem may appear only after the project is at a relatively advanced stage, such as in second or later generations of genetically modified animals" -- yet merely cautions Animal Ethics Committees to "be aware of the potential."¹⁶ There is no framework to deal with harm caused to future generations, once out of the labs. Nor could they. Animal cruelty statutes have traditionally had no bearing on industrially useful practices, no matter how painful.

Under the Draft Guidelines' own expectations, animal health, welfare, breeding or lifespan may be affected.¹⁷ Further, in addition to the suffering and death¹⁸ caused in experiments regarding illness generally,¹⁹ cloning undeniably causes additional and severe suffering in many of the surrogate mothers and in the clones, who face disproportionate risks of organ failure, attention deficits, and severe birth defects.

Use and Problems with Genetic Modification of Animals and Xenotransplantation

The voice of animal advocates should not be dismissed. Over the past two decades, animal advocacy has sparked a new awareness. In January 2003, the European Parliament

¹⁶ Draft Guidelines", Section 2.2", "Welfare Issues".

¹⁷ Draft Guidelines", Appendix 4; Animal Details; Section 13, "Humane euthanasia and experimental endpoint criteria".

¹⁸ See Draft Guidelines", Appendix 4; Animal Details; Section 8, "Genetic alteration; Affected organs/tissues".

¹⁹ The Council does anticipate proposals to "produce genetically modified or cloned animals which are likely to suffer severe or prolonged distress." Draft Guidelines", Section 2.1 (iv)", "Consideration of proposals to create or use genetically modified or cloned animals".

mandated the end of most cosmetics testing on animals within the European Union by 2009, and, in a sort of grand legal boycott, ended European sales of cosmetics which have been tested on animals anywhere. British Liberal deputy Chris Davies declared, “This parliament, by a huge cross-party majority, has made clear that it will no longer accept that animals should be made to suffer for yet another product intended to flatter human vanity.”²⁰

Advocates have also acted in the public interest with regard to xenotransplantation. Recently, due to such action, a stack of confidential documents on xenotransplantation was released to the British press, following the defeat of an injunction obtained by drug companies.²¹ The documents, which chart the race to supply an unlimited supply of animal organs for medical purposes, reveal “a litany of failings” conducted in laboratories between 1994 and 2000.”²²

In 1995, Novartis’s former subsidiary company Imutran announced that it would be ready to transplant pig hearts into humans within a year, but, arguably because the connection of commerce and science leads to risks of puffery and secrecy, in this case the documents showed Novartis nowhere near that stated goal. Numerous deaths of primates were attributed to technical failures.²³

The British government’s mistakes in pushing the research on comes to light through these documents. An Imutran memo stated that the British government “will attempt to get the kidney transplants classified as ‘moderate,’ ensuring that it is easier for Imutran to receive a license and ignoring the ‘severe’ nature of these programmes.”²⁴ Government officials reassured Imutran on several occasions that a key licensing meeting would be a “rubber-stamping” exercise.

A striking finding revealed that the British government approved experiments with the intention of using sick babies as the first trial recipients for nonhuman hearts. History is replete with examples of dangerous experiments being performed on vulnerable subjects. In 1984, researchers performed an experimental baboon heart transplant on a dying “Baby Fae” with her mother’s questionable consent. Three weeks later, the baby died.²⁵

²⁰ Robin Pomeroy, “EU Bans Cosmetics Tested on Animals”, Reuters (17 Jan. 2003).

²¹ The release of this information was won by Uncaged Campaigns, an animal-rights group that defeated the pharmaceutical companies’ efforts to maintain secrecy. Uncaged pointed out the overwhelming public interest on a highly sensitive area of policy.

²² Mark Townsend, “Exposed: Secrets of the Animal Organ Lab”, *The Observer* (20 Apr. 2003).

²³ Ibid.

²⁴ Ibid.

²⁵ See George J. Annas, “Baby Fae: The ‘Anything Goes’ School of Human Experimentation”, *Judging Medicine*, at pages 385, 389 (1988).

Use and Problems with Cloned Animals

Cloning remains an inefficient process as well as an unethical process. Deaths and deformities are the norm.

Scientists at Texas A&M University in the United States, deemed the world's leading team after so far cloning a half-dozen species, say that 95 to 99 percent of cloning procedures fail.²⁶

Multiple piglets have been born without an anus and tail, for example --a fatal condition. Of A&M's surviving cloned animals deemed healthy, researchers themselves have acknowledged they don't know if they'll have problems later.²⁷

Similarly, the sibling clone of the much-vaunted, recently cloned puppy in Korea survived only three weeks.²⁸

The interests represented by the research are not always public health. A&M researchers, for example, are trying to create animals resistant to disease, particularly foot-and-mouth and mad cow disease. The interest here is financial -- to save animal agribusiness industry millions of dollars and increasing food production.²⁹ Significant to any weighing of interests, but not mentioned in the Draft Guidelines, is the reality that eating the flesh of cows is wholly unnecessary and probably problematic to human health.³⁰

CONCLUSION

Australia has commendably disallowed cloning of primates, both human and nonhuman. Friends of Animals appeals to Australians to take a leadership role in humanity's recognition of the intrinsic value and integrity of all animals.

Genetic modifications may occur naturally, as part of evolution. Deliberate genetic modification, however, is manipulative in the extreme, contrary to an ethic that seriously considers other animals' interests, and a set-up for disaster.

²⁶ Lozano, "Texas A&M Leads World in Cloning Animals" (note 3 above; citing Mark Westhusin and the A&M cloning team). The cloning is performed by embryonic transfer. Ibid.

²⁷ Ibid.

²⁸ Mark Henderson, "Give a Dog a Clone", *Times Online* (3 Aug. 2005), available electronically at: <http://www.timesonline.co.uk/article/0,,3-1720006,00.html>

²⁹ Lozano, "Texas A&M Leads World in Cloning Animals" (note 3 above).

³⁰ See, e.g., "Vegetarian Diets: Position Statement of The American Dietetic Association". According to the Association, "[s]cientific data suggest positive relationships between a vegetarian diet and reduced risk for several chronic degenerative diseases and conditions, including obesity, coronary artery disease, hypertension, diabetes mellitus, and some types of cancer."

Thus it is the position of Friends of Animals that Australia should disallow the cloning of nonhuman beings rather than codify a human prerogative to indulge in it.

We further state that genetic modification of nonhuman beings for human purposes is ethically unacceptable. The Council suggests that, “[w]here possible,” researchers should “study genetically modified embryos in vitro rather than implanting them in recipient animals.”³¹ If the Council followed what is ethical rather than what might be possible, it would avoid a path that presents extreme risks to human and nonhuman life and to our planet’s ecology.

³¹ “Draft Guidelines”, Section 4, “Refinement and Reduction”.