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University of Arkansas School of Law
NatAgLaw@uark.edu ☎ (479) 575-7646

An Agricultural Law Research Article

**Baa, Baa, Cloned Sheep, Have you any Law?
Legislative Responses to Animal Cloning in
the European Union and the United States**

by

Stacy J. Ratner

Originally published in BOSTON COLLEGE INTERNATIONAL AND COMPARATIVE
LAW REVIEW
22 B.C. INT'L & COMP. L. REV. 141 (1999)

www.NationalAgLawCenter.org

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INTRODUCTION

Nearly a century ago, before the scientific technology that could make it a widespread practice began to emerge, the word *clone* came into English parlance.¹ In its simplest form, cloning refers to any process that produces genetically identical organisms.² Scientists and science fiction writers have long been captivated by the potential cloning holds for reengineering society.³ But the accelerated pace of cloning research in animals over the last two decades has resulted in a sudden dilemma for lawmakers.

In February 1997, Scottish researchers reported the first successful cloning of an animal from an adult cell.⁴ This event, and the cloned sheep named Dolly who resulted from it, inspired rapid and public reaction from governing bodies worldwide, including those of the European Union (EU) and United States (U.S.).⁵ Proposed cloning legislation in the EU specifically addresses the issues of animal cloning, building on a history of regulating ethical and humane treatment for animals used in scientific research.⁶ But legislation proposed by the U.S. reflects an ongoing failure to protect certain types of animals from

¹ The author would like to thank John Nann of the Boston College Law Library for his invaluable assistance with this Note. See THE COMPACT OXFORD ENGLISH DICTIONARY 272-73 (Clarendon Press 2d ed. 1991). The first recorded use of the word, spelled *clon*, was in 1903 in SCIENCE; *cloning* also made its debut in SCIENCE, in 1960. See *id.*

² See Marie A. DiBerardino & Robert G. McKinnell, *Backward Compatible*, THE SCIENCES, Sept./Oct. 1997, at 32.

³ See *id.*; M.Z. Ribalow, *Take Two*, THE SCIENCES, Sept./Oct. 1997, at 41.

⁴ See I. Wilmut et al., *Viable Offspring Derived from Fetal and Adult Mammalian Cells*, NATURE, Feb. 27, 1997, at 810-13.

⁵ See Nigel Williams & Elizabeth Pennisi, *Will Dolly Send In the Clones?*, SCIENCE, Mar. 7, 1997, at 1415.

⁶ See Commission Proposal for a European Parliament and Council Decision Concerning the 5th Framework Programme of the European Community for Research, Technological Development and Demonstration Activities, 1997 O.J. (C 173) 26 [hereinafter Proposed Framework Programme].

research exploitation, and does not satisfactorily address the ethical issues bound up with cloning animals.⁷

Part I of this Note examines the history of animal cloning and previous legislation concerning animal research in the EU and U.S., ending at the point where researchers successfully cloned an adult sheep and lawmakers saw a need for immediate legislation on the issues thus raised. Part II focuses on the EU and U.S. legislative responses, paying particular attention to the considerations prioritized by each and the ways in which these responses built on previous legislation. Part III compares and criticizes the two approaches based on their common assumptions. Finally, Part IV concludes that the U.S. approach to cloning legislation is insufficient, and suggests that a proposal incorporating elements of the EU's draft legislation would be preferable.

I. THE LABORATORY AND THE LEGISLATURE: SCIENTIFIC AND LEGAL BACKGROUND OF ANIMAL CLONING

A. A (Very) Brief History of Animal Cloning

The first animal cloning research, carried out in the 1890s, attempted to produce identical organisms by splitting animal embryos at early stages of development.⁸ More advanced work in the early 20th century explored the problem in terms of genetics, hypothesizing that the key to successful cloning lay in the switching process during differentiation.⁹ In 1952 animal cloning research leapt forward with the invention of a nuclear transfer procedure.¹⁰ Subsequent work with this technique led to the successful cloning of many species from embryonic nuclei.¹¹ But attempts to clone a new and identical animal from

⁷ See Human Cloning Research Prohibition Act, H.R. 922, 105th Cong. (1997); Human Cloning Prohibition Act, H.R. 923, 105th Cong. (1997); Fact Sheet on Cloning Prohibition Act of 1997, 105th Cong. (1997), available in 1997 WL 309844, at *1 [hereinafter Fact Sheet].

⁸ See DiBerardino & McKinnell, *supra* note 2, at 32.

⁹ See *id.* Differentiation is the stage of embryonic development at which cells begin to form different structures: skin, muscle, etc. During this stage, some genes in each cell are switched off and others are switched on, due to the actions of multiprotein complexes that help or inhibit the genes from acting as protein manufacture templates. See *id.*

¹⁰ See *id.* at 33. In this procedure, the nucleus from one frog's body cell is transplanted into the egg cell of another frog, where it is effectively reprogrammed to function as though it contains the original genes of the egg cell. The egg then continues through the normal stages of cell division, growth, development, and metamorphosis, resulting in a frog genetically identical to the original body cell donor. See *id.*

¹¹ See *id.* at 36.

the cells of an adult did not succeed.¹² This failure made the practical application of cloning research somewhat limited, since the real advantages of producing animal clones lie in the potential to recreate an adult animal whose genetic attributes are already known and are desirable to replicate.¹³

B. *The Promise and Perils of Animal Cloning*

Animal cloning research is a controversial field. In general, proponents of animal cloning research rely on the potential it holds for advancement in the health and agricultural spheres.¹⁴ Those opposing animal cloning point to three threats: the exploitation of animals, the danger of limiting genetic diversity, and the implications of human cloning that follow from animal cloning research.¹⁵

The first significant benefits of animal cloning research include the potential applications of cloning for the improvement of human medicine.¹⁶ Animal cloning could be used to produce therapeutic human proteins in the milk of transgenic farm animal species; such proteins can be used to make drugs that combat health problems like blood deficiencies and cancer.¹⁷ A perennial source of organs for transplantation into humans could be created using cloned animals.¹⁸ Genetically identical animal clones could be used to model human disease

¹² See *id.*

¹³ See DiBerardino & McKinnell, *supra* note 2, at 36.

¹⁴ See *Human Cloning and Related Issues: Hearing Before the Subcomm. on Tech. of the House Comm. on Science*, 105th Cong. (1997), available in 1997 WL 410643 (statement of Lester M. Crawford, Director, Nat'l Ass'n for Biomedical Research) [hereinafter *Crawford Statement*].

¹⁵ See Gillian Handyside, *Commission, Euro-MPs Undecided on Animal Cloning*, THE REUTER EUR. COMMUNITY REP., Mar. 11, 1997, available in LEXIS, News Library, Wires File; Anjay Elzanowski & Derek M. Brown, *Animals, Not Humans, Should Be the Focus of the Ethics Debate on Cloning*, WASH. TIMES, June 19, 1997, at A18.

¹⁶ See *Cloning—Challenges for Public Policy: Hearing Before the Subcomm. on Pub. Health and Safety of the Senate Comm. on Labor and Human Resources*, 105th Cong. (1997), available in 1997 WL 136117 (statement of Harold Varmus, Director, National Institutes of Health, Department of Health and Human Services) [hereinafter *Varmus Statement*].

¹⁷ See *The Day Is Here for Laws on Human Cloning*, ATLANTA J. & CONST., Feb. 26, 1997, at 16A. The efficacy of such human protein drugs is already established, but the cost of producing them is high. See Tim Friend, *Cloning Animals for Healthier Humans*, USA TODAY, Feb. 25, 1997, at 6D; *Crawford Statement*, *supra* note 14. Since a much greater volume of protein drugs could be produced using cloned animals, the cost would drop and the drugs would become more widely available. See Friend, *supra*; *Crawford Statement*, *supra* note 14.

¹⁸ See Richard Orr, *In Support of Wider Animal Cloning*, U.S. Researcher Outlines Benefits, CHI. TRIB., Mar. 24, 1997, at 3; *Varmus Statement*, *supra* note 16; *Crawford Statement*, *supra* note 14. It has been suggested that organs from cloned animals are less likely to be rejected than those

and aid research into new and improved therapies.¹⁹ New pharmaceuticals could be tested on groups of animal clones without the fear of genetic make-up skewing the results.²⁰ Finally, studying the ways cells mutate in an age-diverse group of animal clones could provide valuable information on the aging process, leading to new treatments for cancer and Alzheimer's disease.²¹

The second key point for animal cloning proponents is the potential cloning holds for improving the agricultural industry.²² If researchers clone cows that have proven efficient at converting grain into meat, a whole herd of optimal beef cattle could be created.²³ Similar scenarios can be envisioned with sheep (better wool), dairy cows (more/better milk), and so forth. Pro-cloners also argue that animals themselves might benefit from animal cloning research.²⁴ Animals free from common diseases could be reproduced.²⁵ Fewer animals would be required in control groups for experiments if those used were clones.²⁶ Interesting but controversial ramifications for animal benefit include the area of endangered species: cloning animals in danger of becoming extinct might help to preserve their gene pool and eventually remove them from the endangered list.²⁷

The arguments against animal cloning begin with the premise that reproducing identical animals for their desirable genetic attributes is tantamount to exploitation, and therefore unethical.²⁸ According to this view, cloning reduces animals to "test tubes with tails" used chiefly

obtained from other humans, which adds to the advantage of this procedure. See *Varmus Statement*, *supra* note 16.

¹⁹ See *Crawford Statement*, *supra* note 14.

²⁰ See *ORT*, *supra* note 18, at 3.

²¹ See *Crawford Statement*, *supra* note 14.

²² See Ronald Kotulak, *Move Over Dolly: U.S. Firm Clones in New Way*, CHI. TRIB., Aug. 8, 1997, at 1.

²³ See Dennis Pollock, *Animal Cloning Stirs Farm Debate*, FRESNO BEE, Feb. 28, 1997, at C1. Long-term effects would include the eventual dropping of beef prices in the consumer market, since demand would remain steady while supply (and quality) escalated. See *id.*

²⁴ See *Crawford Statement*, *supra* note 14.

²⁵ See *Handyside*, *supra* note 15.

²⁶ See *Ethics of Cloning: Hearing Before the Subcomm. on Tech. of the House Comm. on Science*, 105th Cong. (1997), available in 1997 WL 109016 (statement of M. Susan Smith, Director, Oregon Regional Primate Research Center).

²⁷ See *id.*; Todd Ackerman, *Texans Strongly Oppose Human, Animal Cloning*, HOUSTON CHRON., May 17, 1997, at 33.

²⁸ See Dave Brett Wasser, *Cloning Raises Question of Whether We Have Right to Exploit Animals*, WASH. TIMES, Mar. 2, 1997, at B2; Rod Fee, *Well . . . hello, Dolly! Assessing the Impact of Cloning*, SUCCESSFUL FARMING, May 15, 1997, at 49.

for the advantage of factory farming.²⁹ Using animal clones to test medical theories, develop human protein drugs, and supply organs for human use is similarly exploitative, since it creates animals whose sole purpose is to serve mankind and who are routinely killed in furtherance of that objective.³⁰ Opponents of animal cloning also argue that the status of pet animals is in jeopardy: the possibility of creating identical clones of pets could reduce them to the functional and emotional equivalent of replaceable toys.³¹

The second argument against animal cloning is that it will limit genetic diversity of livestock.³² The disadvantages of limited genetic diversity in farm animals include susceptibility of a whole herd to new strains of infectious diseases and the cessation of selective breeding.³³ Limiting genetic diversity is of particular concern as applied to endangered species; some genetic diversity seems essential for the survival of such animals.³⁴ Moreover, efforts to protect endangered species by cloning could be expensive enough to cut into funding that would otherwise be used to preserve natural habitats for those species.³⁵

Although these arguments are of great import to those concerned with animal welfare, the renewed public alarm about animal cloning is largely attributable to the potential it presents for human cloning.³⁶ Cloning research could be the first step towards genetically reengineering a society of desirable people: this savors of eugenics, and raises a host of ethical, social, moral, and religious issues that cannot be resolved to the satisfaction of all parties.³⁷

C. *Hello Dolly: A Scientific Breakthrough and Its Legislative Effects*

On February 27, 1997, researchers at Scotland's Roslin Institute reported the successful cloning of a lamb from the udder cells of an

²⁹ See Fee, *supra* note 28, at 49 (quoting People for the Ethical Treatment of Animals (PETA)).

³⁰ See Wasser, *supra* note 28, at B2.

³¹ See Elzanowski & Brown, *supra* note 15, at A18. Efforts towards reproducing pets are already being undertaken: The Missyplicity Project, for example, is a privately funded research group whose exclusive aim is to clone the pet dog of a wealthy individual. See *The Missyplicity Project* (visited Sept. 24, 1998) <<http://www.missyplicity.com>>.

³² See Handyside, *supra* note 15.

³³ See Pollock, *supra* note 23, at C1.

³⁴ See Jon Cohen, *Would-Be Cloners Face Daunting Hurdles*, SCIENCE, May 30, 1997, at 1330.

³⁵ See Jon Cohen, *Conservation Biology: Can Cloning Help Save Beleaguered Species?*, SCIENCE, May 30, 1997, at 1329.

³⁶ See Peter G. Brown, *What Hath Wilmut Wrought?*, THE SCIENCES, Sept./Oct. 1997, at 4.

³⁷ See *Will Cloning Beget Disaster?*, WALL ST. J., May 2, 1997, at A14.

adult ewe.³⁸ "Dolly," as the new lamb was named, inspired a continuing storm of news coverage: writers and speakers on both sides of the animal cloning debate used the breakthrough as a point of discussion, while the media and many governments focused on the questions Dolly raised about the possibility of human cloning.³⁹

In the EU and U.S., a need for immediate cloning legislation was perceived.⁴⁰ Reports to both the EU and the U.S. government on the issue of cloning research were produced in an extremely compressed time span, and proposed legislation was drafted immediately upon receipt.⁴¹

D. *Prior Legislation on Animal Research*

New animal cloning legislation in both the EU and U.S. rests to a large extent on the previous legal standing of animals in those societies.⁴² EU and U.S. legislation on animal research subjects generally attempts to balance two major concerns: the indispensability of animals to many kinds of scientific research and an instinctive compassion for animals in modern society.⁴³ However, EU legislation tends to focus more sharply on the necessity of treating animal research subjects in an ethical and humane way.⁴⁴ U.S. legislation, though it cites humane treatment as a motivating force, contains exceptions particularly pertinent to animal cloning and does not provide nearly as much protection overall.⁴⁵

In the EU, Council Directive 86/609, designed to protect animals used for experimental and other scientific purposes, came into effect in 1986.⁴⁶ Member States have been steadily harmonizing their use of research animals with the stated objectives of this legislation.⁴⁷ In ad-

³⁸ See Wilmut et al., *supra* note 4, at 810-13.

³⁹ See Kenneth L. Woodward, *Today the Sheep . . . Tomorrow the Shepherd?*, NEWSWEEK, Mar. 10, 1997, at 60.

⁴⁰ See Handyside, *supra* note 15; Williams & Pennisi, *supra* note 5, at 1415.

⁴¹ See Human Cloning Research Prohibition Act, H.R. 922, 105th Cong. (1997); Human Cloning Prohibition Act, H.R. 923, 105th Cong. (1997); Proposed Framework Programme, *supra* note 6, at 26; Fact Sheet, *supra* note 7.

⁴² See CHERYL RAE NYBERG ET AL., LABORATORY ANIMAL WELFARE 147-48 (1994).

⁴³ See *id.*

⁴⁴ See Council Directive 86/609 of 24 November 1986 on the Approximation of Laws, Regulations and Other Administrative Provisions of the Member States Regarding the Protection of Animals Used for Experimental and Other Scientific Purposes, 1986 O.J. (L 358) 1-28.

⁴⁵ See 7 U.S.C. §§ 2131-2159 (1992).

⁴⁶ See Council Directive 86/609, 1986 O.J. (L 358) 1-28.

⁴⁷ See *id.* at 27-28.

dition to specifying conditions under which experimentation animals must be kept, the EU directive emphasizes the need to limit animal experimentation as much as possible and to consider the welfare of the individual animal when designing experiments.⁴⁸ Underlying this legislative slant is a concern with the ethical aspects of animal use for research. As the Economic and Social Committee noted, "[a]nimal experimentation is an activity with moral content. Use of animals needs to be stringently justified. Hence a balance must be struck between the interests of science, industry, public health and animal health in terms of animal use."⁴⁹ Under the EU legislation, an animal is "any live non-human vertebrate, including free-living larval and/or reproducing larval forms, but excluding foetal or embryonic forms."⁵⁰

The primary U.S. legislation controlling the use of animals for research is found in Title 7 of the U.S. Code.⁵¹ There, Congress states that regulation of animals and activities is necessary "to insure that animals intended for use in research facilities . . . are provided humane care and treatment."⁵² The precise specifications for such "humane" treatment are not laid out in this statute, however; they are left to the discretion of the Secretary of Agriculture.⁵³ Basic U.S. legislation thereby evinces a concern with the treatment of research animals without providing any real guidelines for researchers.⁵⁴ But the real difference between the U.S. and EU approaches lies in their very different definitions of the word "animal."⁵⁵ Under U.S. legislation, the term "animal" means:

[A]ny live or dead dog, cat, monkey (nonhuman primate mammal), guinea pig, hamster, rabbit, or such other warm-

⁴⁸ See *id.* at 1.

⁴⁹ Opinion on the Proposal for a Council Directive on the Protection of Animals Used for Experimental and Other Scientific Purposes, 1986 O.J. (C 207) 4.

⁵⁰ Council Directive 86/609, art. 2(a), 1986 O.J. (L 358) 1.

⁵¹ See 7 U.S.C. §§ 2131-2159 (1992).

⁵² See 7 U.S.C. § 2131 (1992).

⁵³ See 7 U.S.C. § 2132(b) (1992).

⁵⁴ See 7 U.S.C. § 2131 (1992). This purposeful vagueness stems from Congressional desire to provide researchers, particularly medical ones, with maximum autonomy. As the Committee on Agriculture put it, this legislation "establishes by law the human ethic that animals should be afforded the basic creature comforts," but also "recognizes the responsibility and specifically preserves the necessary domain of the medical community. . . . [I]t in no manner authorizes the disruption or interference with scientific research or experimentation. . . . [T]he research scientist still holds the key to the laboratory door." H.R. REP. NO. 91-1651, at 2 (1970), *reprinted in* 1970 U.S.C.C.A.N. 5103, 5103.

⁵⁵ See 7 U.S.C. § 2132(g) (1992); Council Directive 86/609, art. 2(a), 1986 O.J. (L 358) 1.

blooded animal . . . intended for research, testing, [or] experimentation . . . but such term *excludes* . . . *livestock or poultry used or intended for use for improving animal nutrition, breeding, management, or production efficiency, or for improving the quality of food or fiber.*⁵⁶

Under such a definition, the animals most likely to be affected by cloning research—livestock, cloned to improve the overall quality of meat, milk, or wool—are not protected in any way.⁵⁷

II. LAW IN THE NEW ERA: POST-DOLLY PROPOSALS

Immediately following the Dolly announcement, the EU and U.S. began the process of drafting new legislation to address the issues raised.⁵⁸ Both sets of proposals reflect an acknowledgment of limited governing power in the arena of scientific research and a sense that scientific progress may in some ways be unlegislable.⁵⁹ However, there is a marked difference between the EU and U.S. responses, which follows from their respective positions on laboratory animal welfare.⁶⁰ In the EU, concern with ethical ramifications applies to animals as well as people.⁶¹ But in the U.S., the ethics of animal cloning are not addressed by proposed legislation—because, perhaps, the primary objectives and subjects of animal cloning research have already been neatly exempted from existing research animal welfare statutes.⁶²

A. *Legislative Response in the EU: Ethics Above All*

The power of the EU Council to affect cloning research among the member states is founded on Article 100 of the Treaty of Rome, which gives it the authority to issue directives that directly affect the estab-

⁵⁶ 7 U.S.C. § 2132(g) (1992) (emphasis added).

⁵⁷ *See id.*

⁵⁸ *See* Human Cloning Research Prohibition Act H.R. 922, 105th Cong. (1997); Human Cloning Prohibition Act, H.R. 923, 105th Cong. (1997); Proposed Framework Programme, *supra* note 6, at 26; Fact Sheet, *supra* note 7.

⁵⁹ *See* H.R. 922; H.R. 923; Proposed Framework Programme, *supra* note 6, at 26; Fact Sheet, *supra* note 7.

⁶⁰ *See* NYBERG ET AL., *supra* note 42, at 147–48.

⁶¹ *See* Parliament Resolution on Cloning Animals and Human Beings, 1997 O.J. (C 115) 93; Opinion of the Group of Advisers on the Ethical Implications of Biotechnology (GAEIB) to the European Commission on Ethical Aspects of Cloning Techniques, May 28, 1997, at 6 [hereinafter GAEIB Report]; Proposed Framework Programme, *supra* note 6, at 26.

⁶² *See* H.R. 922; H.R. 923; S. 368, 105th Cong. (1997); Fact Sheet, *supra* note 7.

lishment or functioning of the common market.⁶³ Unfortunately, the EU's power to legislate may stop short of the ability to ban cloning.⁶⁴ It can withhold funding for cloning research, ask the Member States' governments to impose penalties on anyone defying such a ban, or reject patents that might lead to cloning techniques, but its direct power to regulate scientific research is limited to patented drugs and does not extend to cloning.⁶⁵

In addition to these limitations, EU legislators face a growing sense that it is too late to interfere with animal cloning, and that the technology and the promise the process holds for improving human life cannot be stopped.⁶⁶ As the director of the Roslin Institute claims, "the genie [of animal cloning] is out of the bottle and nobody is going to stop it The technology works and the knowledge explosion will happen."⁶⁷ The combination of its own limitations and the popular pragmatic view helped the EU to shorten its consideration of animal cloning.⁶⁸ European Parliament debate in March 1997 produced a resolution by the next month; at the end of May 1997, the Group of Advisers on the Ethical Implications of Biotechnology (EU-GAEIB) submitted its report on the ethics of cloning to the European Commission, and in June 1997 the Commission published a proposal including legislation on animal cloning.⁶⁹ These documents largely reflect the same concern with animal welfare demonstrated in earlier EU legislation for the protection of animal research subjects.⁷⁰

From the beginning, an emphasis on ethics characterized the EU approach to new legislation.⁷¹ Reactions to Dolly and the appropriate response to her creation were varied, but ethics were at the center of debate on both sides of the issue.⁷² The Parliament's Resolution was

⁶³ See TREATY ESTABLISHING THE EUROPEAN COMMUNITY, Feb. 7, 1992, O.J. (C 224) art. 100 (1992), [1992] 1 C.M.L.R. 573 (1992).

⁶⁴ See Robin Herman, *European Bioethics Panel Denounces Human Cloning*, WASH. POST, June 10, 1997, at Z19.

⁶⁵ See *id.*

⁶⁶ See *Animal Cloning Is "Out of the Bottle,"* IRISH TIMES, Mar. 22, 1997, at 11.

⁶⁷ See *id.*

⁶⁸ See *id.*; Herman, *supra* note 64, at Z19.

⁶⁹ See Parliament Resolution on Cloning Animals and Human Beings, *supra* note 61, at 94; GAEIB Report, *supra* note 61; Proposed Framework Programme, *supra* note 6, at 26.

⁷⁰ See Parliament Resolution on Cloning Animals and Human Beings, *supra* note 61, at 94; GAEIB Report, *supra* note 61; Proposed Framework Programme, *supra* note 6, at 26.

⁷¹ See *Remarks of Kenneth Collins, Verbatim Report of Proceedings (Provisional Edition) of March Part Session on Cloning Animals and Human Beings* (visited Oct. 10, 1997) <<http://www.db.europarl.eu.int/dg7-b>>.

⁷² See *id.*

accordingly drafted to address the "new ethical ground" broken by cloning.⁷³ A focus on ethics and animals was the theme of the EU-GAEIB's May opinion: though it found that animal cloning "is likely to add to our understanding of biological processes . . . and hence may contribute to human well-being," the EU-GAEIB nonetheless stated firmly that such research "is ethically only acceptable if carried out with strict regard to animal welfare," when "the aims and methods are ethically justified and when it is carried out under ethical conditions."⁷⁴ Finally, the Commission's proposal for animal cloning legislation is based on ethics.⁷⁵ The current status of animal cloning in the EU is that it will be permitted "only for objectives which are justified on ethical grounds and to the extent that the operations involved are effected on an ethical basis."⁷⁶

B. *Legislative Response in the U.S.: Humans First, the Rest Nowhere*

Like the EU, the U.S. government saw that the news of Dolly's creation required immediate legislative attention.⁷⁷ The power of the federal government to act on the issue is, however, similarly subject to limitations; while it can ban federal funding for a specific type of research, it has not historically been able to regulate what researchers may do in private labs supported by private funding.⁷⁸ Moreover, a sense of inevitability as to the continued practice of animal cloning has characterized much of the legislative discussion on the issue; as one Congressman put it, "the history of science is the history of the dominance of science and technology, and Presidents and Congresses do not have the power to defy it."⁷⁹

Speed was the priority in legislating cloning research; the House and Senate each introduced legislation within a week of the Dolly announcement, though the bills dealt only with human cloning.⁸⁰ The

⁷³ See Parliament Resolution on Cloning Animals and Human Beings, *supra* note 61, at 93.

⁷⁴ See GAEIB Report, *supra* note 61, at 6.

⁷⁵ See Proposed Framework Programme, *supra* note 6, at 26. The European Parliament criticized the first version of the text, claiming it did not take sufficient account of ethical concerns; the Commission was therefore forced to redraft it into a more ethically centered and acceptable form. See *EU Joins World Debate on Animal Cloning*, ANP ENGL. NEWS BULL., Feb. 28, 1997, available in LEXIS, News Library, Wires File.

⁷⁶ See Proposed Framework Programme, *supra* note 6, at 26.

⁷⁷ See Andy Coghlan, *Cloning Report Leaves Loophole*, NEW SCIENTIST, June 14, 1997, at 7.

⁷⁸ See *id.*

⁷⁹ 143 CONG. REC. E608 (daily ed. Apr. 9, 1997) (statement of Rep. Hamilton).

⁸⁰ See H.R. 922, 105th Cong. (1997); H.R. 923, 105th Cong. (1997); S. 368, 105th Cong. (1997).

two proposed House bills prohibit the use of Federal funds for human cloning research and the use of human somatic cells, imposing a civil penalty of no more than \$5000 for anyone who performs such work.⁸¹ The Senate bill likewise prohibits the use of Federal funds for research "with respect to the cloning of a human individual."⁸² No mention of animal cloning research appears in any of this proposed legislation.⁸³ President Clinton later introduced his own proposal, the Cloning Prohibition Act of 1997, based on a report prepared by the National Bioethics Advisory Commission (US-NBAC).⁸⁴

Both the EU-GAEIB and the US-NBAC reports address the ethical issues connected to cloning research.⁸⁵ However, the bases of assumption about animal cloning research, on which the US-NBAC report is founded, reflect a legislative complacency not present in the EU documents.⁸⁶ Having first observed that a consideration of human cloning would be advantaged by the passing of time, since that would "allow for the accrual of data from animal experimentation," the US-NBAC report flatly concludes that "research on cloning animals . . . does not raise the issues implicated in attempting to use this technique for human cloning, and its continuation should only be subject to existing regulations regarding the humane use of animals and review by institution-based animal protection committees."⁸⁷ The lack of any language related to the ethical nature of animal cloning research and the stated willingness to rest on previous legislation are characteristic of the U.S. approach, and reflect a canny and close reading of the relevant U.S. Code provisions.⁸⁸ Farm animals such as sheep and cows, which are the obvious first choices for cloning, are already exempt from mandated humane treatment.⁸⁹ And researchers working to clone farm animals for better meat or superior wool can claim double protection under the current statutory language, for such efforts certainly

⁸¹ See H.R. 922; H.R. 923. For the purposes of these bills, "human somatic cells" seem to be cells containing the essential nuclear material for human replication.

⁸² See S. 368.

⁸³ See *id.*; H.R. 922; H.R. 923.

⁸⁴ See Fact Sheet, *supra* note 7.

⁸⁵ See NATIONAL BIOETHICS ADVISORY COMMISSION, CLONING HUMAN BEINGS: REPORT AND RECOMMENDATIONS 63-86 (1997) [hereinafter NBAC REPORT].

⁸⁶ See *id.*

⁸⁷ *Id.* at iii, iv.

⁸⁸ See 7 U.S.C. § 2132(g) (1992).

⁸⁹ See *id.*

seem to fall under the category of "improving the quality of food or fiber."⁹⁰

Armed with the conclusions of the US-NBAC report, President Clinton submitted his Cloning Prohibition Act of 1997 to Congress in June 1997.⁹¹ This proposed legislation did not specifically address the cloning of animals, preferring to maintain a focus on the technology's eventual human applications.⁹² As the President said, "nothing in the Act restricts. . .the use of somatic cell nuclear transfer techniques to create animals."⁹³ A lack of restrictions on the use of animals in cloning research is entirely in keeping with previous U.S. legislation: to impose such restrictions would actually mean adding protection for a class of animals (those used to further medical and agricultural research) purposely exempted by Congress.⁹⁴

III. SIMILAR THEMES AND STRIKING DIFFERENCES: THE NEW CLONING PROPOSALS

A. *Common Postulates on Cloning Legislation*

In comparing the EU and U.S. approaches to animal cloning legislation, three basic assumptions common to both sets of legislation become apparent.⁹⁵ These are: that the benefits of animal cloning outweigh its disadvantages, that animal cloning should be regulated by the government, and that there is a clear dividing line between cloning animals and cloning humans.⁹⁶

Given the vast promise that animal cloning holds for medical and agricultural advances and the leadership positions occupied by the EU and U.S. in these fields, it is perhaps not surprising that both governing bodies have resisted attempts to ban animal cloning in light of its advantages.⁹⁷ Both the EU-GAEIB and US-NBAC reports pay special attention to the promise of animal cloning; the EU-GAEIB notes that

⁹⁰ See *id.*

⁹¹ See Fact Sheet, *supra* note 7.

⁹² See 143 CONG. REC. H3638 (daily ed. June 10, 1997) (message from Pres. Clinton).

⁹³ *Id.*

⁹⁴ See 7 U.S.C. § 2132(g) (1992).

⁹⁵ See H.R. 922, 105th Cong. (1997); H.R. 923, 105th Cong. (1997); Proposed Framework Programme, *supra* note 6, at 26; Fact Sheet, *supra* note 7.

⁹⁶ See H.R. 922; H.R. 923; Proposed Framework Programme, *supra* note 6, at 26; Fact Sheet, *supra* note 7.

⁹⁷ See Handyside, *supra* note 15; Orr, *supra* note 18, at 3.

cloning "farm animals may prove to be of medical and agricultural as well as economic benefit," while the US-NBAC points out that animal cloning "promises to provide great practical benefit in terms of improved livestock, improved means of producing pharmaceutical proteins, and prospects for regeneration and repair of human tissues."⁹⁸ On this point, then, both sets of legislation are in agreement: despite the troubling issues of genetic diversity and animal exploitation, cloning research with animals is advantageous enough to merit continued practice.⁹⁹

The second common perspective in proposed EU and U.S. legislation is the idea that the governing body can and should regulate animal cloning research to the extent of its limited abilities.¹⁰⁰ On this point, the EU displays a greater propensity to legislate precise terms and conditions than does the U.S., which prefers to leave the specifics of regulation to administrative agencies and (perhaps) internal control by the researchers.¹⁰¹ But neither the EU nor the U.S. seems willing to leave animal cloning entirely in the hands of the private biotechnology sector.¹⁰² This reticence may be a function of the belief that animal cloning is the first step towards human cloning, and that governments cannot afford to give up their grasp on the issue because they must maintain the power to legislate on its human applications.¹⁰³

Although both the EU and U.S. see animal cloning research as the top of the slippery slope towards human cloning, they nevertheless maintain that a clear and divisive line exists between these two types of research.¹⁰⁴ The line is not one of technique, since the same somatic cell transfer process used to create Dolly could be used to clone human beings.¹⁰⁵ Rather, the boundary between animal and human cloning

⁹⁸ See GAEIB Report, *supra* note 61, at 6; NBAC REPORT, *supra* note 85, at 34.

⁹⁹ See GAEIB Report, *supra* note 61; NBAC REPORT, *supra* note 85, at 34.

¹⁰⁰ See H.R. 922; H.R. 923; Proposed Framework Programme, *supra* note 6, at 26; Fact Sheet, *supra* note 7.

¹⁰¹ See 7 U.S.C. § 2132(b) (1992). The U.S. attitude may reflect the influence of American scientists, some of whom formed a panel arguing that animal cloning research should be "allowed to continue without government interference." Michael Lasalandra, *Scientists Urge Open-Minded Cloning Legislation*, BOSTON HERALD, Mar. 11, 1997, at 10.

¹⁰² See H.R. 922, 105th Cong. (1997); H.R. 923, 105th Cong. (1997); Proposed Framework Programme, *supra* note 6, at 26; Fact Sheet, *supra* note 7.

¹⁰³ See GAEIB Report, *supra* note 61, at 6; NBAC REPORT, *supra* note 85, at i.

¹⁰⁴ See GAEIB Report, *supra* note 61, at 7; NBAC REPORT, *supra* note 85, at iv.

¹⁰⁵ See Kotulak, *supra* note 22, at 1.

research is drawn from prevailing moral, religious, and ethical views of humans' role in engineering nature.¹⁰⁶

B. *Dividing Lines and an Unshared Complacency*

Despite these similarities, there are two striking points of contrast between the EU and U.S. proposals: the conviction that previous legislation on animal treatment is (U.S.) or is not (EU) sufficient to cover the new advances in cloning research, and the concept that ethics should (EU) or should not (U.S.) play a critical part in the continuing development of animal cloning legislation.¹⁰⁷

In undertaking to draft new proposed legislation specifically on animal cloning, the EU recognizes a responsibility to react thoughtfully to changing technology, thus attempting to address the needs and concerns of society as breakthrough research comes to the fore.¹⁰⁸ By contrast, the U.S.'s view that previous legislation will suffice seems shortsighted; critics of the US-NBAC report charge that interest in animal cloning will only intensify, and that the report's failure to address the subject is a major drawback.¹⁰⁹

A similar willingness to reexamine and clarify prior attitudes on the ethics of animal research distinguishes the EU reaction to cloning from that of the U.S.¹¹⁰ In the EU vision, the dividing line between animal and human cloning research includes ethical considerations on both sides: animal cloning may not raise quite the same moral and religious issues as human cloning, but it does pose its own set of ethical dilemmas and must therefore be ethically justified.¹¹¹ Proposed U.S. legislation, however, indicates that ethical considerations are of little import in animal research, and thus concludes that existing legislation drafted in the 1970s will be adequate to address the situation.¹¹²

¹⁰⁶ See Woodward, *supra* note 39, at 60.

¹⁰⁷ See Proposed Framework Programme, *supra* note 6, at 26; NBAC REPORT, *supra* note 85, at iv.

¹⁰⁸ See GAEIB Report, *supra* note 61, at 6-7; Proposed Framework Programme, *supra* note 6, at 26.

¹⁰⁹ See National Bioethics Advisory Commission Reports on Human Cloning, PR NEWSWIRE, June 18, 1997, available in Westlaw, ALLNEWSPLUS database.

¹¹⁰ See GAEIB Report, *supra* note 61, at 3-5, 6-7.

¹¹¹ See *id.*; Proposed Framework Programme, *supra* note 6, at 26.

¹¹² See NBAC REPORT, *supra* note 85, at iv.

IV. FOLLOW THE LEADER: SUGGESTIONS FOR FUTURE U.S. LEGISLATION

U.S. legislation has chosen to pass over the ethical issues associated with animal cloning, but popular opposition to this legislative complacency has been growing.¹¹³ In the EU, however, the demonstrated effort to consider the ethical ramifications of animal cloning and hence protect animals from exploitation is a response to popular feeling, and thus likely to meet with general approval.¹¹⁴ The common U.S. and EU conclusion that animal cloning's advantages outweigh its dangers is valid, but must be supported by effective legislation if those dangers are to be permanently avoided.¹¹⁵ The U.S. ought, therefore, to adopt legislation similar to the EU's, and not rest on laws passed in an era when somatic cell nuclear transfer techniques for cloning mammals were only a distant possibility.

The first step taken by the U.S. should be the drafting of language specifically addressing the issue of animal cloning. This language should begin by redefining the term "animal" in connection with cloning research, and the new definition should be considerably broader than the narrow categories of 7 U.S.C. § 2132(g): farm animals should certainly be included, since they are and will likely continue to be the primary subjects of cloning research.

Once it has extended its protection to animals as a general class and not just those listed in prior legislation, a newly proposed U.S. law on animal cloning should pattern itself after the EU's model of ethics and genetic diversity. It could achieve this by limiting or prohibiting funding for animal cloning research for those experiments and processes not carried out for an ethical end and in an ethical manner. Nothing in this concept would limit the useful applications to which animal cloning will most probably be put. Transgenic drug production, for example, would further the higher good of advancing medical treatment without endangering or altering the lives of the cloned animals

¹¹³ See Wasser, *supra* note 28, at B2; Ackerman, *supra* note 27, at 33; Elzanowski & Brown, *supra* note 15, at A18.

¹¹⁴ See Claire Smith, *Kirk Study Warns Against Mass Animal Cloning*, SCOTSMAN, May 12, 1997, at 2.

¹¹⁵ Some countries, like Italy and Indonesia, have chosen to ban all research into animal cloning due to fear that human cloning research will be the inevitable next step. While this reaction is perhaps understandable, it seems ill-considered: the possible agricultural and medical benefits animal cloning could provide merit continued research, which can theoretically be controlled by careful legislation. See *Italy Moves to Ban Animal and Human Cloning*, REUTERS NEWS SERVICE,

involved; similarly, if cloned animals would produce better beef or wool, fewer animals would be needed to satisfy the demand for these commodities and the total number of animals exploited for the human good would be lessened.

A new definition of "ethical" as it applies to animal cloning research should be at the heart of such legislation. This definition could include the criteria suggested in the EU-GAEIB report: "the duty to avoid or minimize animal suffering," "the duty of reducing, replacing and when possible refining the experimentation adopted for the use of animals in research," "the lack of better alternatives," and "human responsibility for nature and the environment, including biodiversity."¹¹⁶ These standards are lower than those applied in an ethical consideration of human cloning. This is acceptable, however, for the argument here is not that human and animal cloning research must be subject to the same exacting ethical scrutiny, but merely that the U.S. must make a meaningful effort to consider the ethics of animal cloning research and must not be content to leave the issue unaddressed. This is of particular importance in light of the U.S.'s unique position: its resources have recently permitted it to take the lead in cloning research, making it all the more important for it to define the frontiers within which such research must be conducted.¹¹⁷

By proposing draft legislation parallel to that of the EU, and quite possibly by improving on it through a more precise definition of "ethical" as applied to animal research, the U.S. could protect legitimate animal cloning while at the same time improving current legislation on the protection of animals used for research.¹¹⁸

CONCLUSION

Animal cloning is the result of much important research over the last century, and the vast promise it holds for scientific advancement as well as for practical applications in the fields of medicine and agriculture has never been clearer. Concurrent with its possibilities, though, are the significant dangers of exploitation and a lack of genetic diversity among animal species. Legislators in the EU and U.S.

Mar. 5, 1997, available in LEXIS, News Library, Wires File; *Indonesia to Set Up Special Team to Mull Cloning Ethics*, AGENCE FRANCE PRESSE, Mar. 8, 1997, available in 1997 WL 2073223.

¹¹⁶ See GAEIB Report, *supra* note 61, at 6-7.

¹¹⁷ See Kotulak, *supra* note 22, at 1; *Moo-ve Over Dolly: Company Clones a Bull*, OMAHA WORLD-HERALD, Aug. 7, 1997, at 1, available in 1997 WL 6312863.

¹¹⁸ See 7 U.S.C. § 2131(g) (1992).

were quick to recognize the need for new legislation on the issue, particularly in light of the growing feasibility it presents for human cloning. The EU response is the better considered and more complete of the two: by focusing specifically on animal cloning and incorporating a primary concern with ethics and biodiversity into its statutory language, the EU proposal ensures that animal cloning research towards worthwhile ends can continue while simultaneously protecting against the dangers posed by the technology. The total lack of any cloning legislation specific to animals in the U.S. reflects the current unprotected status of most of its research animals.

In order to satisfy the growing opposition to the practice, the U.S. should propose legislation modeled on that of the EU, and should promote international debate on the issue by refining the all-important definition of the word "ethical" in this context. Such legislation would aid in the protection of biodiversity and guard against the exploitation of animals without limiting the desirable advances promised by cloning research. Furthermore, it would serve as a model for those countries still undecided on the issue of how to treat animal cloning, bringing a better definition of "ethical" into world use and thus furthering the interests of both researchers and animal-rights activists. Dolly, and the cloned animals to come after her, may well hold the key to many of the world's pressing medical and agricultural problems. It is up to the U.S. to follow the lead of the EU in making sure that legislation exists to protect the ways in which we use these animals, thus ensuring an ethical balance between human and animal concerns.

Stacy J. Ratner