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THE CLONE WARS: THE GROWING DEBATE OVER FEDERAL CLONING LEGISLATION

As readers of science fiction are well aware, the term "clone" refers to asexually produced offspring, that is, offspring produced by a process of cell-division which does not begin with the union of two sex cells. A clone is the genetic twin of the cell donor. Propagation of plants by this method is, of course, commonplace, but mammalian reproduction in this fashion would indeed be a revolutionary accomplishment, with profound and disturbing implications.¹

Introduction

¶ 1 As is evident from this footnote from a 1979 District Court opinion, "cloning" is not a novel concept, and in fact, experiments with tadpoles date back as far as the 1950s. However, experiments involving humans have not been attempted to date. In fact, scientists thought human cloning was impossible until February 22, 1997, when a sheep named "Dolly"² was born at the Roslin Institute in Scotland.³ Dolly's birth shocked the scientific community and led to vigorous debate about whether this technology could or should be applied to humans.

¶ 2 Despite the fact that the cloning controversy has been around for some time, human cloning was not seriously contemplated until Ian Wilmut and his colleagues at the Roslin Institute cloned the first mammal through the use of a novel scientific development called "nuclear transfer technology."⁴ The production of this clone was accomplished by transferring the udder cell of a six-year-old all-white adult Welsh Mountain sheep into a Scottish Blackface ewe's egg from which the DNA had been removed.⁵ Scientists facilitated the combination between the udder cell and the enucleated egg using electric charge. The resulting fused cell grew into an embryo with the entire nuclear genetic material derived solely from the udder cell.⁶

¶ 3 Dolly's creation immediately led to discussions of the possibilities of human cloning. In the same issue of *Nature* in which Dr. Wilmut's paper was published, an editorial suggested that "cloning humans. . . [would likely be possible from] . . . one [to] ten years from now."⁷ In fact, soon after Dolly's announcement, Randal Wicker, head of the Cloning Rights United Front in New York, stated that he had contacted a scientist rumored to be "developing human cloning technology," stating that cloning is "part of the reproductive right of every human being."⁸ Infertility researchers and physicians imagine that breakthroughs made possible through cloning could be the answer to many individuals' battles with infertility.⁹

¶ 4 After cloning of the first mammal, cloning of a human became a realistic and foreseeable possibility and led immediately to concerns about both the ethical

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and legal implications of human cloning. In March of 1997 following the announcement of the birth of Dolly, President Clinton issued a moratorium that would ban the use of federal funds for any project involving human cloning.¹⁰ In addition, President Clinton asked the newly appointed National Bioethics Advisory Commission (NBAC) to address the ethical and legal issues surrounding human cloning and to determine if there were any "Federal [causes of] action to prevent its abuse."¹¹ After a thorough evaluation of all available scientific information, the NBAC agreed that human cloning likely posed significant risks to a potential fetus and/or child.¹² These concerns led the NBAC to conclude that "at this time it is morally unacceptable for anyone in the public or private sector, whether in a research or a clinical setting, to attempt to create a child using. . . cloning."¹³ The NBAC concluded that the ban on using federal funds for human cloning research using somatic cell nuclear transfer should continue and urged all scientific investigators voluntarily to comply with this moratorium.¹⁴ The NBAC also recommended that Congress enact legislation prohibiting all research toward the creation of a child using somatic cell nuclear transfer; however, the Commission did emphasize that its recommendation should be limited such that the prohibition should not interfere or limit important areas of scientific research.¹⁵

¶ 5 With these recommendations in mind, President Clinton asked private researchers to voluntarily refrain from human cloning research¹⁶ and almost simultaneously several bills were introduced in Congress.¹⁷ In August of 1997, Clinton proposed a voluntary five-year moratorium on human cloning in the United States. In March, 1998, approximately 64,000 biologists and physicians signed the moratorium. State legislators introduced several bills to ban cloning in response to this controversy. On October 4, 1997, the California legislature adopted a law that created a five-year moratorium on the creation of a child through cloning.¹⁸ Also reacting to the news of the possibility of cloning mammals Michigan adopted a bill banning human cloning on June 3, 1998.¹⁹

¶ 6 In addition to several of the state legislatures a number of professional organizations have expressed sentiments that the cloning of humans is ethically unacceptable. The NBAC conducted surveys of a number of medical organizations including the American Medical Association, the World Medical Organization, and the World Health Organization, all of which indicated that they would support a ban on human cloning.²⁰ In fact, the majority of the 32 scientific organizations surveyed by the NBAC indicated that they would oppose the procedure.²¹ Certain religious groups have also indicated that they would support bans on human cloning; in particular, the Vatican stated that a "person has the right to be born in any human way . . . [Adding that the Vatican urges states to] immediately pass laws that ban the application [of this technology to] humans."²²

¶ 7 Despite the significant caution shown by many legislatures, scientists, and their associated professional organizations, there was still concern about individuals who did not subscribe to the same professional ethics and cautionary morals as the majority of the world. On December 5, 1997, a physicist named Richard Seed announced that he planned to attempt human cloning before Congress had a chance to enact a ban on this technology.²³ Subsequently, on January 20, 1998, the Food and Drug Administration (FDA) announced that it had jurisdiction to regulate human cloning and that it would now be a violation of federal law to try somatic cell transfer²⁴ on humans without first obtaining FDA approval.²⁵

¶ 8 The human cloning debate slowed during 1999 and the beginning of 2000. Then in August, 2000, a religious organization called the Raelian²⁶ movement announced that its company, Clonaid,²⁷ would make the first attempt at human cloning.²⁸ While the claims made by the Raelians may be dismissed as religious fanaticism, a more plausible announcement surfaced in January of 2001. Former University of Kentucky Professor Panayiotis Zavos²⁹ announced that he, in collaboration with Dr. Severino Antinori,³⁰ had plans to clone a human within a year. Likely the combination of religious fanaticism and two technically capable scientists led Congress to schedule hearings by the House Energy and Commerce Committee for March 27, 2001 in order to determine

whether Congress should place a ban on human cloning.³¹

What is Human Cloning?

¶ 9 Cloning is the transfer of the DNA³² from a donor cell into an egg cell that has had its nuclear DNA removed. The transferred DNA directs the enucleated egg cell to develop into a copy of the donor cell or organism. It is the transfer of the donor DNA that directs the cellular machinery present in the egg cell to transform itself into a "clone" of the donor cell. In the case of "Dolly" an adult mammary cell containing a copy of every gene needed to make "Dolly" was arrested at a cell cycle stage known as G0, or quiescence.³³ Following the synchronization of the donor and the egg cell, these two cells were placed in close proximity and then stimulated to re-enter the cell cycle by an electric shock. The electrical stimulation caused both cells to re-enter the cell cycle synchronously and the resulting fused cell began to divide and was implanted into a surrogate mother and carried to term.³⁴ The resulting lamb, "Dolly", was an exact copy³⁵ of the six-year old ewe that had contributed its DNA.

The Potential Benefits of Human Cloning

¶ 10 There are a number of significant health benefits that might become possible through the use of this technology. The first and most obvious use of this technology is for the generation of a child for infertile couples.³⁶ The child that would be created would not be a union of the cells from the two partners as would happen in normal coital reproduction but rather the child would have all of its genetic material donated from one of the partners. While this may not be an equivalent substitute for a child resulting from a union between zygotic cells from both partners, it might provide a more attractive option than simple adoption or IVF of an egg that comes from a genetically distinct donor mother. This technology also would be useful when both husband and wife are carriers³⁷ for a recessive genetic disease³⁸ but still desire to have some genetic link to their child.

¶ 11 In addition to providing another reproductive option, clones could be created to donate non-essential organs like kidneys or bone marrow.³⁹ In fact, this technology could be used to develop cells that would not be rejected by a transplant patient's immune system. Examples include production of Islets Cells to be transplanted into a diabetic, the production of healthy skin grafts for burn patients, or even the generation of an HIV therapy whereby cloned HIV resistant leukocytes replace the patient's immune system.⁴⁰

¶ 12 Despite some of the outlandish possibilities and the somewhat extreme points of view of a number of the proponents of human cloning, the technology does offer some significant and realistic possibilities for the treatment of disease. Accordingly any type of ban or regulation of this technology must be narrowly tailored so as not to inhibit a rational scientist from using this technology to search for cures.

The Risks of Human Cloning

¶ 13 Scientists have voiced concerns about the implications of applying nuclear transplantation cloning to humans. In fact, in the experiment that resulted in Dolly there were 277 attempts before a successful clone was developed.⁴¹ Harold Varmus, Director of the National Institutes of Health, testified before Congress that animal cloning is not scientifically ready to be applied to humans, with many questions that must be answered by further animal studies.⁴²

¶ 14 There is also some concern regarding the cellular age of cloned DNA.

When Dolly was born she had inherited the cellular DNA of a six-year-old ewe.⁴³ Would this mean that when Dolly has her first birthday she will be 1 year old or 7 years old? One commentator stated that, if the hypotheses of a cellular self-regulating genetic clock are correct, clones could be programmed at a cellular level to have a much shorter life-span than the "original" from which they were cloned.⁴⁴ Dr. Sherman Ellis, a geneticist and obstetrician at the Baylor College of Medicine, agrees that, because of this fear of premature aging, further testing in animal models is required in order to ensure that all of the safety concerns have been addressed before scientists move on to attempt cloning humans.⁴⁵

¶ 15 Additionally, the history of animal studies involving cloning seems to caution scientists against attempting human cloning before they determine and address all major obstacles and potential problems. Early studies with frogs met with only mixed success, sometimes resulting in "grossly . . . genetically deformed adults"⁴⁶ More recently, when the Grenada Corporation in Texas began the cloning of cattle from differentiated embryonic stem cells, a number of gross abnormalities resulted, including abnormal birth weight, cardiovascular dysfunction, and respiratory abnormalities.⁴⁷ Many of these calves were born with genetic disorders, and between 18-20% of the calves were still-born.⁴⁸

¶ 16 Subsequent to the creation of Dolly Ian Wilmut's group attempted to create cloned transgenic⁴⁹ sheep that had the ability to produce Human Clotting Factor IX.⁵⁰ In this experiment, the group successfully completed 425 DNA transfers into enucleated egg cells. Of these 425 attempted IVFs only fourteen resulted in pregnancy and only six lambs were born. Similar to the problem mentioned above in the cloned-cattle, several of these sheep were born abnormally large.⁵¹

¶ 17 The low success rates observed in the animal studies raise serious concerns that initial trials of human cloning via nuclear transplantation may lead to disastrous consequences. Dr. Wilmut expressed concern regarding the ethical dilemmas surrounding creation of an abnormal human.⁵² Responding to Richard Seed's intent to clone a human within two years, Dr. Wilmut stated "with people, the possibility of 276 failures, many of which would involve miscarriages, sounds horrific and raises huge ethical concerns."⁵³

What Legal Mechanisms Are Available to Regulate Cloning?

¶ 18 Rapid development of cloning technology makes regulation by current law difficult at best. The two general areas of law that pose the best possibility of providing regulation are the Food & Drug Administration (FDA) and state laws regulating embryo research. However, these legal systems were not designed to deal with the problems inherent in cloning technology and, accordingly, the laws are an inadequate fit. Additionally, Congress would be wise to pay attention to the drafting problems associated with both of these regulatory schemes if they determine that legislating a federal ban on human cloning is an appropriate course of action.

¶ 19 Human cloning relates technologically to *in-vitro* fertilization, which has been around for almost twenty years. The state laws created to address the concerns inherent in IVF do have some considerable cross application to cloning. States such as Michigan⁵⁴ and California⁵⁵ have passed laws specifically prohibiting cloning; however, other states may simply assume that their laws regulating embryo research reach the type of potential misconduct present in human cloning technology. Ten states have legislation regulating research and/or experimentation on conceptuses, embryos, fetuses, or unborn children that use broad enough language to potentially encompass cloning research.⁵⁶ However, arguments that these statutes do not cover nuclear transplantation cloning are far from foreclosed.

¶ 20 As an example eight of the ten states having legislation prohibiting embryo research do so by prohibiting research on a product of conception.⁵⁷ Proponents of research argue that these statutes do not cover cloning research because the actual research is performed on the egg rather than a product of conception. Because the conceptus develops after the fusion of the donor cell and the enucleated egg, the "research" is complete by the time the product of the cloning would be subject to these laws.⁵⁸

¶ 21 One of the other hurdles that many state laws face in regulating cloning research are the definitional problems affecting their application and their scope. Because bans on embryonic research are described in differing ways in most of the bills and because of the rapid advancement in the science involved with this technology, much cutting edge research would fall outside of state bans.⁵⁹ One example of the type of definitional problems that face the state legislation are bills that have been introduced in five states which ban the creation of "genetically identical" individuals.⁶⁰ The wording of this definition is probative of the lack of scientific understanding behind these prohibitions. Because the most prevalent and successful cloning technique right now is "nuclear transplantation cloning,"⁶¹ a clone generated with this type of technique would not be subject to these laws as the clone would have mitochondrial DNA that comes from the egg cell and nuclear DNA that comes from a donor cell, thereby resulting in a clone that is not technically "genetically identical" to either the egg or the donor cell.

¶ 22 Of even greater concern is that some of the state laws may soon be outpaced by the rapid progress of this science. This problem becomes clear when one examines the California ban in light of the developments of nuclear transplantation technology. The California law prohibits the transferring of a nucleus from a human cell into another human cell.⁶² However, developments in this technology might enable an unethical scientist to circumvent this law's prohibition through the use of alternative techniques that would not technically fall under the definitional limitations of the law. An example of such circumvention can be imagined in light of the discovery by scientists at the University of Wisconsin, who published results indicating that cow eggs can serve as incubators for nuclear DNA of other mammalian species.⁶³ Potential violators could circumvent the law by transplanting the human DNA into an enucleated cow egg cell. This research at the University of Wisconsin makes clear the importance of precision in defining cloning proscriptions. Ten of the eighteen states that have proposed legislation to ban cloning would also suffer from the same definitional problems that would affect the California law.⁶⁴ In contrast to these states, the Michigan law bans human cloning using a human or non-human egg.⁶⁵

¶ 23 These arguments are not meant to imply that all of these proposed state laws are defective but rather to highlight the need for scientific understanding and to underscore the mandate of precision in defining the proscribed technique or research. One example of a law that seems to reach far enough to encompass this technology is the legislation in New Hampshire. Here, a researched-upon pre-embryo may not be transferred to a uterine cavity.⁶⁶ Accordingly, if a cell that results from nuclear transplantation cloning is considered a pre-embryo, it would be impermissible to implant the resulting embryo into a uterine cavity to create a child.

¶ 24 As an administrative agency with jurisdiction, the FDA provides an alternative form of regulation on human cloning.⁶⁷ FDA guidelines cover products that contain cells that have been substantially altered through "more than minimal" manipulation.⁶⁸ These regulations may not technically extend to cover human cloning. But if they do extend that far, they do not require prior approval if a patient's cells are being used for his or her own reproductive purposes.⁶⁹

Should Congress Federally Ban Human Cloning?

¶ 25 After holding hearings on March 27, 2001, several Congressmen

proposed legislation to prohibit human cloning within the United States. Senator Sam Brownback said, "[t]here is no need for this technology to ever be used with humans."⁷⁰ Senator Brownback is one of the primary supporters for the legislation in the House and Senate that would make it a federal crime to clone a human, or to participate in human cloning or import human clones to the United States. Under the proposed legislation, violators would receive up to 10 years in prison and a minimum \$1 million fine.⁷¹ Likewise, Representative Dave Weldon, one of four physicians serving in Congress, stated, "[t]he scientists who created Dolly had over 200 attempts before Dolly was born, [t]he prior attempts resulted in malformed, sickly creatures that had to be euthanized. We cannot allow this scenario to play out with humans."⁷² White House spokesman Ari Fleischer said on March 27, 2001, that President Bush will work with Congress on a federal statute that bans human cloning.⁷³ With the debate already at the highest level of national discourse, Congress must carefully consider numerous factors in ratifying or rejecting the considered legislation.

Congress Must Consider Both Technological Issues and the Failures of State Laws

¶ 26 The opposition to the federal ban by the religious fanatics should provide ample evidence that some sort of action is mandated and the testimony by prominent scientists and ethicists would seem to be a vote of confidence in Congress's ability to draft appropriately tailored legislation. While this technology appears to have many applications for the development of cures for a number of different diseases, the potential for abuse cries out for regulation. The task for Congress in drafting a federal ban on human cloning is to prohibit the use of this technology for the generation of entire human clones without substantially affecting scientists who merely want to use this technology in their research for cures for disease. Clearly, a federal ban could be drafted to achieve these goals; however, the drafters would have to have an appreciation for the intricacies of the science underlying this technology so as not to draft overly broad prohibitions while still being able to encompass all of the possible abuses in the use of this technology for the cloning of an entire human being.

Conclusion

¶ 27 Human cloning is clearly an issue with little middle ground. Moral concerns argue both for and against both sides of the issue, while the high failure rates of the technologies involved raise the grim specter of likely genetic defects in any rounds of experimentation and testing. Yet the enormous health benefits offered by cloning, as well as the age-old scientific lure of human cloning simply *being there*, already led numerous scientists and private groups to proclaim their efforts to perfect the technology, with varying degrees of realism. It is the concern over this stampede of scientists and research groups that may lead Congress to pass legislative regulation to shore up the bulwark of State law, but any such legislation must be cautiously tailored to avoid the negative effects of a complete ban, yet avoid the dangers of unregulated cloning efforts and abuse.

By: John Garvish

Footnotes

1. See *Bromhall v. Rorvik*, 478 F. Supp. 361, 363 n.1 (E.D. Pa. 1979) (alteration from original to emphasize the lack of belief that human cloning would ever be a possibility).

2. See John Arlidge, *Scientists 'Able to Create Human Clone,'* GUARDIAN (London), Feb. 26, 1997, at 6, available in 1997 WL 2368146. (discussing the cloning of "Dolly" where Dr. Wilmut revealed that "the world's first cloned animal was named after singer Dolly Parton, because the cell used to create her came from the 'impressive mammaries' of another sheep.")
3. I. Wilmut et al., *Viable Offspring Derived From Fetal and Adult Mammalian Cells*, 385 NATURE 810, 813 (1997).
4. In "Nuclear Transplantation Cloning", the nucleus of a donor cell is transplanted into an enucleated egg cell; however, the egg cell still has its own mitochondrial DNA. Accordingly, while the cloned cell is 99% identical to the donor cell it is not technically genetically identical as some of the cloned DNA comes from the enucleated egg cell despite the absence of a nucleus.
5. See Wilmut et al. *supra* note 3; See also Gina Kolata, *With Cloning of a Sheep, the Ethical Ground Shifts*, N.Y. TIMES, Feb. 24, 1997, at A8.
6. See *id.*
7. *Caught Napping by Clones*, 385 NATURE 753 (1997). See David Masci, *Cloning Humans Sparks Debate Advisory Panel to Report Thursday on Issues and Give Guidelines*, PITT POST-GAZETTE, May 25, 1997, at A15 (noting the general agreement among scientists that cloning of a human has come into the realm of possibility and adding that it is likely to occur within the next decade); *but see* Sharon Begley, *Spring Cloning*, NEWSWEEK, June 30, 1997, at 82, 83 (stating that, given what scientists have learned involving the problems associated with animal cloning in the three months following "Dolly", the timeframe put forth in *Nature* looks circumspect).
8. *Questions for: Randolfe Wicker*, N.Y. TIMES, May 25, 1997, at 18. Another group that has also made claims regarding their ability to perform human cloning are the Raelians. A Canadian religious group, the Raelians formed Clonaid, a company to provide customers with a chance to be cloned for a fee of \$ 200,000 per attempt (obviously with no guarantees). See also *Vatican Says No to Human Clones, Because Only God Can Make A Soul*, BIOTECHNOLOGY NEWSWATCH July 7, 1997, at 4. (noting that the possibility is real and some people believe that the technology is ready for application to humans.) In fact, two families are said to have approached the Roslin Institute seeking to clone relatives who are dead or dying. See *id.*; Mike Santangelo, *Doctor Isn't Sheepish: U.S. Will Soon Clone Humans*, NEWSDAY, Oct. 21, 1997, at C3.
9. See Gina Kolata, *For Some Infertility Experts, Human Cloning is a Dream*, N.Y. TIMES, June 7, 1997, at 8. The application of cloning technology to infertility problems seems promising. As opposed to *in-vitro* fertilization ("IVF"), if cloning technologies were to be applied to an infertile woman, doctors would not have to give that woman the powerful drugs that are needed to force the production of eggs. *Id.* In fact, some women with ovarian failure have requested that the DNA from one of their husband's cells be added to a donor's egg from which the DNA had been removed in order to produce clones of the husband (i.e. nuclear-transplantation cloning). *Id.*
10. See Katharine Q. Seelye, *Clinton Bans Federal Money for Efforts to Clone Humans*, N.Y. TIMES, Mar. 5, 1997, at A13.
11. Gina Kolata, *Little-Known Panel Challenged to Make Quick Cloning Study*, N.Y. TIMES, Mar. 18, 1997, at C1. See generally *Cloning Symposium*, 38 Jurimetrics J. 1 (1997) (critiquing the NBAC report from several perspectives).
12. See *Cloning Symposium*, *supra* note 11 at 108.

13. See *id.*

14. *Id.* at 109.

15. See generally National Bioethics Advisory Commission, Cloning Human Beings 13-22 (June 1997) at 109.

16. Seelye, *supra* note 10, at A13.

17. See Gina Kolata, *Commission on Cloning: Ready-Made Controversy*, N.Y. TIMES, June 9, 1997, at A12. There have been a number of new legislative efforts to ban human cloning recently probably in response to Richard Seed's announcement that he intended to open a cloning clinic despite the fact that this physicist lacks the funds, the training, or a formal institutional affiliation to perform the cloning. See also Sheryl Gay Stolberg, *Small Spark Reignites Debate on Human Cloning*, N.Y. TIMES, Jan. 19, 1998, at A11.

18. See Act of Oct. 4, 1997, 1997 Cal. Stat. 688.

19. See Act of June 3, 1998, 1998 Mich. Pub. Acts 108, *bill text available in Westlaw*, at 1997 MI H.B. 864 (SN); Act of June 3, 1998, 1998 Mich. Pub. Acts 109, *bill text available in Westlaw*, at 1997 MI H.B. 4846 (SN); Act of June 3, 1998, 1998 Mich. Pub. Acts 110, *bill text available in Westlaw*, at 1997 MI H.B. 4962 (SN); Act of June 3, 1998, 1998 Mich. Pub. Acts 111, *bill text available in Westlaw*, at 1997 MI H.B. 5475 (SN) 7 MI H.B. 5475 (SN); see also Engler Signs Legislation to Ban Human Cloning, GRAND RAPIDS PRESS, June 4, 1998, at A20.

20. See Letter from President William J. Clinton to Dr. Harold Shapiro, Chairman, National Bioethics Advisory Commission (Feb. 24, 1997) *reprinted in NATIONAL BIOETHICS ADVISORY COMMISSION, CLONING HUMAN BEINGS: REPORT AND RECOMMENDATIONS OF THE NATIONAL BIOETHICS ADVISORY COMMISSION*, at 99 (1997).

21. See *id.* at 97. One predictable but notable exception is the infertility professional societies, who indicated that they would not advocate joining this ban.

22. *Id.* at 56.

23. See Marilyn Marchione, *Cloning Research Could Offer Great Benefits, Some Experts Say*, MILWAUKEE J. SENTINEL, Jan. 19, 1998, at 1.

24. Somatic Cell Transfer was the method used to produce Dolly by the Ian Wilmut at the Roslin Institute.

25. See Rick Weiss, *Human Clone Research Will Be Regulated*, WASH. POST, Jan. 20, 1998, at A1 (available at <http://www.junkscience.com/news/fdaclone.htm>).

26. The Raelian Movement is a religious organization that is based in Canada that believes that all life on Earth was created by extraterrestrials in their own image using genetic engineering. This religious movement is being lead by a former French sports journalist named Rael, who was visited by these extraterrestrials in the early 1970s. During their visit the extra-terrestrials told him to go out and establish an embassy in order to welcome the aliens back to Earth. See <http://www.rael.org>.

27. Clonaid is the Company that the Raelian movement established through their venture capital group in order to fulfill their mission of cloning humans. Currently they offer a number of services including *ovulaid*, *clonaid*, *insuraclone*, and *clonapet*. (The website is not specific about what each service involves but they are

to some degree self-explanatory. However, the website has already established a pricing structure for each of the particular services.) See <http://www.clonaid.com>.

28. See Miriam Falco, *Cloning Experts to tell House committee pros, cons*, March 28, 2001. (<http://www.cnn.com/2001/HEALTH/03/27/cloning.reality/index.html>).

29. Dr. Zavos is a former University of Kentucky professor that specializes in infertility.

30. Dr. Severino Antinori is an Italian invitro fertilization (IVF) specialist that has been known to push the envelope of what is possible with IVF. Nearly seven years ago Dr. Antinori implanted a fertilized egg into a 62-year old grandmother. See *id.*

31. See *supra* note 30.

32. DNA stands for Dextyribonucleic Acid and its ordered sequence in a long chain polymer is essentially a genetic blueprint that determines every characteristic about a cell or individual (i.e. eye color, skin color, attached ear lobes).

33. See Thomas H. Maugh II, *Brave New World*, L.A. TIMES, Feb. 27, 1997, at B2.

34. See *id.*; see also Francis C. Pizzulli, Note, *Asexual Reproduction and Genetic Engineering: A Constitutional Assessment of the Technology of Cloning*, 47 S. CAL. L. REV. 476, 483 (1974); Peter N. Spotts & Robert Marquand, *A Lamb Ignites a Debate on the Ethics of Cloning*, CHRISTIAN SCI. MONITOR, Feb. 26, 1997 at 3.

35. "Exact Copy" is used in a liberal sense as the egg cell would contribute the mitochondrial DNA for the resulting clone and any other factors, including the environment, that might affect development are not taken into consideration.

36. See Herbert Wray et al., *The World After Cloning*, U.S. NEWS & WORLD REP., Mar. 10, 1997, at 59.

37. A couple in which both partners are carriers for a recessive genetic disorder will not display any outward symptoms of the genetic disease themselves. Each partner will have another functional gene (thus the term "carriers") that will serve to complement his or her partial deficiency (i.e. the recessive allele). However, under simple Mendelian Genetics, the probability of one of their children getting both recessive alleles would be 25%. Because a number of these recessive genetic disorders can be life threatening, cloning might be the only way that a particular couple could be guaranteed that their child would not suffer from the recessive genetic disorder. However, this argument assumes that cloning will not introduce any other genetic mutations or cause any other unforeseen complications, an assumption that, as yet, I am not sure it safe to make.

38. Examples of recessive genetic disorders that commonly affect humans are Tay Sachs, Sickle Cell, Cystic Fibrosis, and Hemophilia.

39. See Jeffrey Kluger, *Will We Follow the Sheep?*, TIME, Mar. 10, 1997, at 66, 70.

40. Stem Cell Research seems to be leading to the development of potential cures for a number of other diseases. In a study conducted by Wakayama, et al. entitled *Differentiation of Embryonic Stem Cell Lines Generated from Adult Somatic Cells by Nuclear Transfer* from the April 27, 2001 issue of SCIENCE, it seems that potential treatments for Parkinsons Disease (caused by a deficiency of Dopamine) and Diabetes (caused by Islet cells that no longer produce insulin) might be a possibility through the use of a type of human cloning at a cellular level.

41. See Wilmut et al., *supra* note 3, at 811.

42. See Recer, *supra* note 50.

43. See Wilmut et al., *supra* note 3, at 811.

44. See *Hello Dolly*, *ECONOMIST*, Mar. 1, 1997, at 17 (discussing the pros and cons of aging research which could result from nuclear transplantation cloning); see also Terence Monmaney, *Prospect of Human Cloning Gives Birth to Volatile Issues*, *L.A. TIMES*, Mar. 2, 1997, at A1. (noting that the "age" of someone's DNA is not fully understood and that many potential problems need to be examined. Stating that some biologists have "wondered if the DNA from an aged donor would give rise to a clone with a brand-new lease on life -- or one that was already old, a sort of newborn oldster").

45. See *id.*

46. See Francis C. Pizzulli, Note, *Asexual Reproduction and Genetic Engineering: A Constitutional Assessment of the Technology of Cloning*, 47 *S. CAL. L. REV.* 476, 484-485 (1974).

47. See *Horizon: Dawn of the Clone Age* (BBC television broadcast, Sept. 10, 1997), transcript available at <http://www.bbc.co.uk/science/horizon/cloneagetrans.html>.

48. See *id.*

49. A "Transgenic" animal is one that expresses a gene from another species. In this example the expression was of a human protein involved in blood clotting (Factor IX). The deficiency of Human Clotting Factor IX is what causes hemophilia.

50. See Angelika E. Schnieke et al., *Human Factor IX Transgenic Sheep Produced By Transfer of Nuclei from Transfected Fetal Fibroblasts*, 278 *SCIENCE* 2130, 2130 (1997). See also *Cloned Transgenic Lambs Produce Clotting Factor in Milk*, *BIOTECHNOLOGY NEWSWATCH*, Jan. 15, 1998, at 5.

51. See Nick Thorpe, *Scientists Baffled By Oversized Sheep Clones*, *SCOTSMAN*, July 28, 1997, at 1; see also Steve Connor, *"Giant" Lambs Put Future of Cloning in Doubt*, *SUNDAY TIMES* (London), July 27, 1997, at 5.

52. See Recer *supra* note 50 (quoting Dr. Wilmut as stating, "I don't see any reason why we would want to copy a person. I personally still have not heard of a potential use of this technique to produce a new person that I would find either ethical or acceptable").

53. *Cloning: Scientist's Plan to Clone Human Sparks Outrage*, *HEALTH LINE*, Jan. 8, 1998, available in *LEXIS News Library, Medical & Health Materials File* (quoting Wilmut).

54. See *supra* note 20.

55. See *supra* note 18.

56. See Fla. Stat. §390.0111(5) (1997); La. Rev. Stat. Ann. §9:121-:122 (West 1991); Me. Rev. Stat. Ann. tit. 22, §1593 (West 1992); Mass. Gen. Laws Ann. ch. 112, §12J (West 1996); Mich. Comp. Laws Ann. §333.2685 -- .2692 (West 1992); Minn. Stat. §145.421 -- .422 (1994); N.D. Cent. Code §14-02.2-01 to 14-02.2-02 (1991); N.H. Rev. Stat. Ann. §168-B:15 (1994); Pa. Cons. Stat. Ann. §3216 (West Supp. 1998); R.I. Gen. Laws §11-54-1 (1994).

57. A product of conception is defined as either a conceptus (See Minn. Stat. Ann. §145.421 (1994)), embryo (See Mich. Comp. Laws Ann. §333.2685 -- .2690 (West Supp. 1997)), fetus (See Fla. Stat. §390.0111(5) (1997); Me. Rev. Stat. Ann. tit. 22, §1593 (West 1992); Mass. Gen. Laws Ann. ch. 112, §12J (West 1996); Mich. Comp. Laws Ann. §333.2685 -- .2690 (West 1992); N.D. Cent. Code §14-02.2-01 to 14-02.2-02 (1991); R.I. Gen. Laws §11-54-1 (1994)), or unborn child (See 18 Pa. Cons. Stat. Ann. §3216 (West Supp. 1998)).

58. The laws in Minnesota and Pennsylvania prohibit research on conceptus and unborn children, respectively, which are the product of fertilization. If nuclear transplantation cloning is not defined as fertilization, this type of research could fall outside the scope of these laws for this reason as well. See Minn. Stat. Ann. §145.421 (1994); 18 Pa. Cons. Stat. Ann. §3216 (West Supp. 1998).

59. During the last time that Congress addressed these issues in late 1997 and 1998, there were at least seven bills introduced into Congress and there were at least eighteen states that had introduced bills to ban human cloning. For the Congressional Bills See S. 1611, 105th Cong. (1998), also labeled S. 1602, 105th Cong. (1998); S. 1601, 105th Cong. (1998), also labeled S. 1599, 105th Cong. (1998); H.R. 3133, 105th Cong. (1998); S. 1574, 105th Cong. (1998); H.R. 923, 105th Cong. (1997); H.R. 922, 105th Cong. (1997); S. 368, 105th Cong. (1997); for the states as of April 1, 1998, there were bills introduced in Alabama, Connecticut, Delaware, Hawaii, Illinois, Kansas, Maryland, Minnesota, Mississippi, New Hampshire, New Jersey, New York, Ohio, Pennsylvania, Rhode Island, South Carolina, Tennessee, and Virginia. See S.B. 68, 1998 Reg. Sess. (Ala. 1998), S.B. 8, 1998 Reg. Sess. (Ala. 1998); H.B. 5475, 1998 Reg. Sess. Gen Assembly (Conn. 1998); S.B. 241, 139th Gen. Assembly, 2d Sess. (Del. 1998); H.B. 3206, 19th Leg. (Haw. 1998); S.B. 1243, 90th Gen. Assembly, 1997-98 Reg. Sess. (Ill. 1998); H.B. 2235, 90th Gen. Assembly, 1997-98 Reg. Sess. (Ill. 1997); H.B. 2846, 77th Leg., 1998 Reg. Sess. (Kan. 1998); H.B. 932, 1998 Reg. Sess. (Md. 1998); H.J.R. 11, 1998 Reg. Sess. (Md. 1998); S.B. 2423, 80th Reg. Sess. (Minn. 1998); H.B. 2730, 80th Reg. Sess. (Minn. 1998); H.B. 996, 1998 Reg. Sess. (Miss. 1998); H.B. 1658, 155th Sess., 2d Year (N.H. 1998); A.B. 329, 208th Leg. (N.J. 1998); A.B. 2849, 207th Leg. (N.J. 1997); S.B. 5993, 221st Leg. Sess. (N.Y. 1998); A.B. 9183, 221st Leg. Sess. (N.Y. 1998); S.B. 2877, 220th Leg. Sess. (N.Y. 1997); A.B. 5383, 220th Leg. Sess. (N.Y. 1997); H.B. 675, 122d Gen. Assembly, 1997-98 Reg. Sess. (Ohio 1998); S.B. 218, 122d Gen. Assembly, 1997-98 Reg. Sess. (Ohio 1998); H.B. 2128, 182d Gen. Assembly, 1997-98 Reg. Sess. (Pa. 1998); H.B. 7123, 1997-98 Leg. Sess. (R.I. 1998); H.B. 3617, 112th Gen. Assembly Sess. (S.C. 1997); S.B. 2295, 100th Gen. Assembly (Tenn. 1998); H.B. 2281, 100th Gen. Assembly (Tenn. 1998); H.B. 2198, 100th Gen. Assembly (Tenn. 1998); S.B. 2208, 100th Gen. Assembly (Tenn. 1998); H.B. 752, 1998 Sess. (Va. 1998).

60. The states that use the definition "genetically identical" are Illinois, Kansas, New York, South Carolina, and Tennessee, and their legislation is listed *supra* note 73.

61. See *supra* note 4.

62. See *supra* note 20.

63. See Robert Lee Hotz, *Cow Eggs Used as Incubator In Cloning Boon*, L.A. TIMES, Jan. 19, 1998, at A1.

64. The ten states with legislation that would suffer from the same definitional problems as that of California are Connecticut, Illinois, Minnesota, Mississippi, New Hampshire, New York, Ohio, Pennsylvania, Rhode Island, and Tennessee. See *supra* note 73 for proposed legislation.

65. See Act of June 3, 1998, 1998 Mich. Pub. Acts 108, *bill text available in* Westlaw, at 1997 MI H.B. 864 (SN), which prohibits "transferring the nucleus of a human somatic cell into an egg cell from which the nucleus has been removed or

rendered inert."

66. See N.H. Rev. Stat. Ann. §168-B:15(II) (1994).

67. See Weiss *supra* note 27; see also Senator Dick Armey's response to this story at <http://freedom.house.gov/library/technology/pr980120.asp> (stating that FDA regulation is not enough "Human cloning cannot be equated to manufacturing drugs. Human embryos, however they are created, are human beings. To assert that we need only regulate the practice of human cloning as if it is a drug, and not a process of creating life, is morally obtuse. This Congress will act to ban human cloning."); see also FDA letter asserting authority to regulate cloning posted at <http://www.fda.gov/oc/oha/irbletr.html>.

68. FDA, PROPOSED APPROACH TO REGULATION OF CELLULAR AND TISSUE-BASED PRODUCTS 6, 9 (1997) [hereinafter FDA Guidelines] (referring as an example to skin tissues for burn victims).

69. See FDA Guidelines, *supra* note 85, at Table I.

70. See McQueen *supra* note 90 (quoting Brownback).

71. See Anjetta McQueen, *Lawmakers Want Human Cloning Ban*, April 26, 2001 (http://dailynews.yahoo.com/hlx/ap/20010426/hl/human_cloning_3.html).

72. See McQueen *supra* note 90 (quoting Weldon).

73. See McQueen *supra* note 90 (quoting Fleischer).

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