CLONING HUMAN BEINGS

The Current and Future Legal Status of Cloning

Commissioned Paper
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CONTENTS

PREFACE

> "Perhaps in recognition of the surrealistic circumstances they should have spelled it D-A-L-I, instead of D-O-L-L-Y."[1]

This response is quite representative of how most people reacted to the news that a team of Scottish scientists succeeded in cloning a mammal. On July 5, 1996, a sheep named Dolly was born in Scotland, the result of the transfer of the nucleus of an adult mammary tissue cell to the enucleated egg cell of an unrelated sheep, and gestation in a third, surrogate mother sheep.[2] Although for the past ten years scientists have routinely cloned sheep and cows from embryo cells,[3] this was the first cloning experiment which has succeeded using the nucleus of an adult cell.[4]

Shortly after the report of the sheep cloning was published, President Clinton instituted a ban on federal funding for human cloning.[5] This moratorium provides the opportunity for an analysis of the potential risks and benefits of human cloning, the current legal status of cloning, and the potential constitutional challenges that might be raised if new legislation is put into place to restrict cloning.

With the recent success in cloning an adult mammal, it is reasonable to start thinking about the feasibility and impact of human cloning. Many reproductive and genetic procedures, such as artificial insemination by donor, embryo transfer, in vitro fertilization, and preimplantation screening of embryos, were applied first in animals and then in humans. Animal husbandry is a precursor to clinical reality for humans, with the time of technology transfer to humans ever decreasing. If W. Bruce Currie, biologist at Cornell University, is correct, "[c]loning humans from adults' tissues is likely to be achievable any time from one to ten years from now,"[6] an estimate which was repeated by the journal *Nature*, which published the article about Dolly. Immediately after Dr. Wilmut announced to the world how Dolly was "conceived," Dr. Harold Varmus, the director of the National Institutes of Health, testified before a House subcommittee that the technology involved was "fairly simple."[7] Currie estimates that at least ten fertilization clinics in the United States have the technology which will allow such a feat; he did not, however, name these ten clinics.[8]

The executive summary briefly surveys the current and future legal status of cloning; the rest of this document develops this analysis. The paper then addresses the potential uses that could be made of cloning. The procedures to be used and their purposes are relevant to an analysis of whether human cloning falls within the reach of existing law. Discussion of the potential impact of cloning, which is relevant in determining the need for a legal policy and whether such a policy can be justified as a proper exercise of governmental power, is followed by that of the impact of existing laws on cloning, particularly state bans on embryo research. The next sections describe proposed federal and state laws regarding cloning; analyze whether federal legislation restricting or banning cloning can be challenged as not justified by the federal spending power or the federal power to regulate interstate commerce; analyze whether a ban on human

cloning might be subject to attack as violating scientists' alleged First Amendment right to scientific inquiry; and assess whether a ban on human cloning of complete individuals would violate an individual's or couple's constitutional right to privacy or liberty to make reproductive decisions. The paper then examines constitutional concerns, such as the Thirteenth Amendment prohibition on slavery and the nobility clause, that could restrict certain forms of cloning; analyzes who would be considered to be the legal parent(s) of the resulting child if an individual were cloned; addresses the human research constraints applicable to a child created through cloning; and addresses potential tort claims based on cloning. The final section addresses policy options in this area.

Throughout this paper, two types of cloning research are addressed. The first is research at the genetic, cellular, and tissue level which is not intended to create a cloned individual. Most of the scientists addressing human cloning research focus on this first type of research. The second type is research which is intended to create an individual. The latter type of research might be considered by some to be too remote and speculative to be worthy of serious policy analysis at this time. However, given the fact that much of the public and media discussion has focused on the cloning of whole individuals, a legal policy analysis would be deficient if it did not analyze whether existing and proposed laws would cover the cloning of whole individuals as well.

EXECUTIVE SUMMARY

This section—the executive summary—summarizes the analysis with respect to the most important legal issues that have been raised: Do existing laws ban the procedure? If human cloning were regulated or banned, could that policy be challenged as unconstitutional? If the cloning of a whole individual were allowed, who would be the legal parents?[9]

A. Potential State Restrictions on Cloning

Ten states have laws regulating research and/or experimentation on conceptuses, embryos, fetuses, or unborn children that use broad enough language to include early stage conceptuses.[10] However, several arguments could be made to suggest that most of the statutes should be construed narrowly so as not to apply to cloning. First, an argument can be made that since the experimental procedure is being done on an egg, not an embryo, fetus, or unborn child, the laws should not apply. By the time the embryo is created, the experimental procedure is completed. Second, two of the ten states define the object of protection—the conceptus (Minnesota) or unborn child (Pennsylvania)—as the product of fertilization. If transfer of nucleic material is not considered fertilization, these laws would not apply. Third, the laws of at least eight of the states banning embryo research are sufficiently general that they might be struck down as unconstitutionally vague.[11]

Two statutes have provisions that are particularly likely to be applied to cloning. In New Hampshire, a preembryo may not be allowed to develop beyond 14 days post-fertilization,[12] so cloning research may be permissible within the first 14 days of development. However, "no

preembryo that has been donated for use in research shall be transferred to a uterine cavity."[13] Thus, if a renucleated oocyte is considered to be a preembryo, it would be impermissible in New Hampshire to implant the resulting conceptus to create a child.

In Louisiana, the statute applies to an "in vitro fertilized human ovum . . . composed of one or more living human cells and human genetic material so unified and organized that it will develop in utero into an unborn child."[14] An entity meeting the definition cannot be cultured and farmed solely for research purposes,[15] which would prohibit cloning research to study gene function, cellular development, and so forth. Another provision specifically states that such an entity may be used "solely for the support and contribution of the complete development of human in utero implantation."[16] This creates the anomalous result that researchers could clone a whole individual in Louisiana, but could not do research ex utero on cloned cells.

B. Constitutional Concerns

If the federal government chooses to regulate or even ban cloning, that action might be challenged on a number of constitutional grounds—as not being justified under the commerce clause, as violating scientists' First Amendment freedom of inquiry, or as violating a couple's or individual's constitutional right of privacy or liberty to make reproductive decisions.

1. Reach of the Commerce Clause

Congress has the power to regulate interstate commerce, but states maintain the power to regulate intrastate activities that have little impact on interstate commerce. In 1995, the U.S. Supreme Court held, for the first time in almost 60 years, that Congress had adopted legislation that exceeded its authority under the commerce clause.[17] The facts at issue in that case, however, are distinguishable from the case of cloning. In that case, Congress had banned the possession of a firearm within 1000 feet of a schoolyard. The U.S. Supreme Court held that the law was not a proper exercise of federal power because the activity at issue did not affect interstate commerce, interfered with a traditional state activity (education), and had already been addressed by state laws in most states.[18] There is much more leeway for the federal government to regulate cloning. It is likely that some of the equipment or materials used in the cloning procedure will have moved in interstate commerce,[19] some of the individuals seeking cloning services will have traveled interstate to obtain those services,[20] some funding will have come from out of state,[21] some of the personnel may have been hired from out of state,[22] and some of the researchers may attend related conferences and classes out of state.[23] Moreover, if the federal government were to adopt a law on cloning, Congress could address the commerce clause concerns in the legislative history, which it failed to do in connection with the firearm ban at issue in *Lopez*. Congress' power to regulate cloning under the commerce clause would include a power to ban it.[24]

2. Right to Scientific Inquiry

Certain commentators have speculated that there might be a right of scientific inquiry protected by the First Amendment right to free speech. If the First Amendment protects a marketplace of ideas, it seems likely it would protect the generation of information that would be included in that marketplace. The U.S. Supreme Court has not directly addressed the right of scientific inquiry, but a lower federal court has suggested in *dicta* that scholars have a "right . . . to do research and advance the state of man's knowledge."[25] Other federal courts, however, have refused to recognize a First Amendment right of scientific inquiry.[26] And even if the First Amendment were found to be applicable to scientific inquiry, there is widespread agreement that the method of research could be regulated to prevent harms.

3. Right to Make Reproductive Decisions

The right to make decisions about whether to bear children is constitutionally protected under the constitutional right to privacy[27] and the constitutional right to liberty.[28] The U.S. Supreme Court in 1992 reaffirmed the "recognized protection accorded to liberty relating to intimate relationships, the family, and decisions about whether to bear and beget a child."[29] Early decisions protected married couples' right to privacy to make procreative decisions, but later decisions focused on the individual's rights. The U.S. Supreme Court, in *Eisenstadt v. Baird*,[30] stated, "[i]f the right of privacy means anything, it is the right of the *individual*, married or single, to be free from unwarranted governmental intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child."[31]

A federal district court has indicated that the right to make procreative decisions encompasses the right of an infertile couple to undergo medically assisted reproduction, including in vitro fertilization and the use of a donated embryo.[32] Some legal analysts have suggested that the constitutional right to make reproductive decisions free from unnecessary governmental intrusion covers the decision of a couple to undergo cloning.[33] However, other legal analysts have noted that the unprecedented step of creating a child with only one genetic progenitor would be such a fundamental change in the way humans "reproduce" that it would not be constitutionally protected.[34]

Even if a restriction on cloning were found to infringe upon an individual's or a couple's right to make reproductive decisions, the government could justify the restriction if it had a compelling state interest and the restriction furthered that interest in the least restrictive manner possible. The potential physical and psychological risks of cloning an entire individual[35] are sufficiently compelling to justify banning the procedure. Moreover, certain uses of cloning—such as creation of a clone as a source of spare organs—would likely be banned by the Thirteenth Amendment prohibition of slavery and involuntary servitude.

The use of cloned cells and tissue for research purposes other than the creation of a child would not be protected by the constitutional rights of privacy and liberty that protect reproductive

decisions. Consequently, a governmental regulation or ban of such research would not have to have such stringent justification. It would be constitutional so long as it was rationally related to an important governmental purpose. Under such an analysis, a court could uphold restrictions that require that sufficient animal research be done in advance. Moreover, it would be permissible to require the scientists proposing the research to have "the burden of proving that the research is vital, cannot be conducted any other way, and is unlikely to produce harm to society."[36]

C. Parenthood Issues

Current state laws addressing parentage, including paternity acts, surrogacy statutes, and egg donation statutes, are not broad enough to address the multitude of parentage issues raised by the process of cloning through nuclear transfer. The process of cloning will result in a child having genetic material from as many as four individuals: the person from whom the cell nucleus was derived, that individual's biological parents, and the woman contributing the enucleated egg cell which contains a small fraction of DNA in the mitochondria.[37] In addition, if the egg with the transferred nucleic material is implanted in a surrogate gestational mother, the child will have two other potential parents—the gestator and, if she is married, her husband. The latter will have rights (even though he has no biological connection to the child) based on the common law presumption that if a woman gives birth within marriage, her husband is the child's legal father, or in some states, based on specific statutes holding that the surrogate and her husband are the legal parents of a child she has gestated, regardless of their genetic contribution.[38] There may also be intended rearing parents unrelated to the individual who is cloned; this may occur when the cloned individual is deceased, a celebrity, or a favorite relative.

Various contributors in the cloning arrangements will have legal rights and responsibilities with respect to the resulting child. Since the clone is a twin to the cloned individual, the latter's parents could be recognized as legal parents. They certainly would be identified as the parents under DNA paternity testing. Yet, given that they will likely have not made the decision to create offspring (in fact, they may be dead at the time their own offspring is cloned), it seems unfair to designate them as the legal parents. It is also not in keeping with a perspective that considers preconception intent as a relevant factor for determining parenthood in the context of assisted reproduction.

In many states, the woman who gives birth is considered to be the legal mother and her husband the legal father of any resulting child. Under statutes in Arizona and Utah, this holds true even when the surrogate is gestating an embryo with no genetic relationship to her. Only in Florida, New Hampshire, North Dakota, and Virginia do court-approved gestational surrogacy arrangements result in the intended parents—not the surrogate—being viewed as the legal parents. However, these four states have leeway for denial of parenthood to people who clone. The laws allow only married individuals to contract with gestational surrogates (thus not applying to the unmarried individual who clones himself or herself). Virginia also allows judges the leeway to deny gestational surrogacy based on psychological examination of the intended parents. Some would argue that the desire to clone oneself is evidence of psychological disturbance.

The person who clones himself or herself could try to establish paternity (or maternity) under the state paternity statute. If such individuals are denied use of the provisions allowing "mothers" and "fathers" (because they do not seem to fit traditional conceptions of that role), they might be able nonetheless to go forward under the provisions in at least 13 states that allow "interested persons" to bring a paternity action.[39] Such an action could be challenged by one of the other rights holders, though, such as the cloned individual's parents or the gestational surrogate.

The state laws for blood testing to prove paternity may or may not be useful to the individual who wishes to prove he or she is the "parent" of his or her clone. The laws provide for a wide range of such tests—from HLA typing to DNA tests. If one of the less precise tests were used, the individual whose nucleic material was used might have a match that makes it appear that he or she is the "parent" and might be declared the legal parent on those grounds. However, if DNA testing were used, the nucleus provider would clearly have the pattern closer to that of a twin (a nearly 100% match) rather than a parent (50% match). It is not clear what a judge would make of such information. The legal standard for paternity is often a particular probability of being a parent. For example, in Mississippi, the blood test must show that there is a statistical probability of paternity of 98% or greater. So, the judge's ideas about paternity and parenthood, rather than the DNA test, would be determinative of whether the nucleus provider was declared the parent of the clone. The nucleus donor's claim to the rights and responsibilities of parenthood would be bolstered under doctrines and cases that give weight to preconception intent in recognizing legal parenthood.[40]

If a couple creates a child who is the clone of a loved one or an unrelated individual chosen for that person's valued traits, parenting rights would also be dispersed across individuals. If the wife carried the clone to term, the couple would be protected by legal presumptions assigning parenthood to the birth mother and her husband. If paternity testing were done, however, the parents of the cloned individual (and maybe the cloned individual himself or herself) might be able to assert rights to the child.

THE GOALS OF CLONING RESEARCH

A. How Is Cloning Performed?

"Cloning" is the manipulation of a cell from an animal or human in such a way that it grows into a copy of that animal with identical nucleic DNA.[41] The clone will not be 100% genetically similar because it will have mitochondrial DNA from the egg donor.[42] In the case of Dolly, an adult mammary cell which contains a copy of every gene needed to make the lamb was extracted and then starved of its nutrients in order for the cell to enter a quiescent state.[43] This cell was then fused with an enucleated egg cell—one in which the nucleus has been extracted—and an electric current was run through the fused cell, activating the dormant cell and causing it to begin to divide. These divided cells were then implanted into a surrogate mother and carried to term.[44]

B. What Are the Uses for Cloning Technology in Animals?

Dolly was not cloned primarily for scientific purposes, but rather for commercial ones. Dr. Wilmut and the Roslin Institute had created a means for sheep to be engineered to express pharmaceutical products in their breast milk. The company that funded the research, PPL Therapeutics, P.L.C. of Edinburgh, applied for a patent on the technique. Dr. Wimut's goal in creating Dolly was to find a method to produce "consistent" transgenic animals.[45] Dr. Wilmut has stated that his idea is to create one transgenically beneficial animal, for whatever scientific or commercial purposes, and then to clone that animal until a small herd is achieved,[46] where reproduction of the animal would be continued by alternative methods to avoid the problem of "species suicide." Cloning animals is seen as beneficial both to the pharmaceutical industry and to agriculture.

This notion of consistent animals is of particular importance to the pharmaceutical industry, where clones may prove to be the most beneficial.[47] Dr. Wilmut has stated that medically useful transgenic sheep and cows would be created, and those animals could then be cloned, thus creating walking biomedical factories.[48] The greatest area of promise in pharmacology seems to be in the area of genetically manipulating animals whose milk will contain useful proteins, such as blood-clotting amino acids to be used in treating hemophilia.[49] Dr. Wilmut states that the Roslin Institute "is confident that it will be possible within two or three years to produce farm animals that will produce in their milk proteins to treat human diseases."[50]

In addition, cloning may provide another method of reproducing cattle and sheep.[51] Increasing the cattle and sheep population could lead to an increase in the world's food supply by producing more milk from smaller herds. For example, cows could produce 30,000 to 40,000 pounds of milk per year as opposed to the average 13,000 pounds per year they now produce.[52] With herd sizes reduced, land which is currently used for cattle and sheep grazing could be devoted to raising grain and other crops.[53]

Another proposed benefit of cloning is the proliferation of champion breeding stock. Champion bulls, dogs, horses, and sheep would all serve to produce either more food and wool or greater contributions to human entertainment.[54] The proposition of cloning existing adults seems advantageous over embryo cloning—twinning—because in twinning, one is not absolutely certain of the sort of animal—or human—the twinned embryos will become. Accordingly, with this new nuclear transplantation technique, it is possible to clone only the "best" existing animals, or those with the most desirable traits. Once the desired animal is created, it is theoretically possible to make as many copies as desired.[55]

C. What Are the Proposed Uses for Cloning Research in Humans?

Many proposed uses of cloning technology in humans have been offered, ranging from the scientifically interesting through the medically useful to the bizarre. Cloning technology may be useful in understanding the mechanisms of disease and in developing treatments; in creating organ and tissue reserves; in creating children for individuals and couples; and in immortalizing oneself,

loved ones, or important individuals. It is likely that one or more of these will be attempted. "In science, the one rule is that what can be done will be done," said Rabbi Moses Tendler, professor of medical ethics at Yeshiva University.[56]

1. Disease Research and Treatment

Dr. Wilmut has stated that his objective in creating Dolly was merely to "build a better glass of milk."[57] However, the implications of his research might possibly benefit humans in additional ways. Cloning research technology could help increase understanding of how genes turn on and off and why cells divide, leading to potential treatments for genetic diseases, cancer, and neurological traumas. It could also help researchers to understand, and potentially reverse, the aging process.

Cloning research might lead to greater understanding of the intricacies of the cellular life cycle, potentially allowing control and manipulation of this cycle.[58] Cloning research, specifically nuclear transplantation, promises scientists the opportunity to learn how to "starve" mature, differentiated cells and reactivate their DNA, thus causing differentiated cells' genes to revert to their most primitive state.[59] By redirecting cells to act as they do in their embryological state, scientists can learn how to direct, or grow, these cells in the manner they wish, ultimately leading to control of the development of normal and abnormal cells.[60] Thus, cloning technology may lead scientists to discover why cancerous cells mutate, revert to an embryonic stage, and then uncontrollably divide.[61] Such technology might also allow researchers to go one step further and take differentiated cells from anywhere in a patient's body and redirect the cells into other sorts of cells, such as brain cells to treat Parkinson's disease or lung cells to treat cystic fibrosis.[62]

Cloning research might possibly lead to enhanced understanding of how genes operate and how they can be manipulated to cure and prevent diseases.[63] Neuroscience may also benefit from cloning techniques by enhancing understanding of why spinal cord tissue, brain tissue, and heart muscle do not regenerate after injury.[64]

Many of the questions that cloning research would address could also be addressed in other ways, however, so it is not known whether human cloning is necessary to provide these benefits.[65] One researcher has speculated, for example, that cloning research will have only a "modest role" in the field of developmental biology.[66]

2. Reproductive Technology

Cloning research may lead to greater insights into the mechanisms of human reproduction—for example, by enhancing understanding of the high rate of spontaneous abortions in natural situations.[67] Such research could lead to infertility treatments.

Beyond scientific research in cloned tissue, the cloning of complete individuals raises the potential for individuals to create children. Numerous forms of noncoital reproduction have

developed over the past two decades, including in vitro fertilization, egg donation, embryo donation, and surrogate motherhood. Some of the individuals who currently provide assisted reproductive services envision a role for cloning as well.

If both members of a couple are infertile, they may wish to clone one or the other of themselves.[68] If one member of the couple has a genetic disorder that the couple does not wish to pass on to a child, the unaffected member of the couple could be cloned. In addition, if both husband and wife are carriers of a debilitating recessive genetic disease and are unwilling to run the 25% risk of bearing a child with the disorder, they may seek to clone one or the other of them.[69] This may be the only way in which the couple will be willing to have a child that will carry on their genetic line. In the future, these couples might also wish to avail themselves of gene therapy on the resulting embryos, which is not currently possible, to eliminate undesirable hereditary genetic traits in their cloned children.[70] This combination of techniques would be similar to the ones that led ultimately to the creation of Dolly.

Charles Strom, director of genetics and the DNA laboratory at Illinois Masonic Medical Center, argues that the high rate of embryo death that has occurred in animal cloning should not dissuade people from considering cloning as a legitimate reproductive technique.[71] Strom points out that all new reproductive technologies have been marred by high failure rates, and that it is just a matter of time before cloning could be as economically efficient as any other form of artificial reproduction.[72]

Even people who could reproduce coitally may desire to clone for a variety of reasons. People may want to clone themselves, deceased or living loved ones, or individuals with favored traits. A wealthy childless individual may wish to clone himself or herself to have an heir or to continue to control a family business. Parents who are unable to have another child may want to clone their dying child.[73] This is not unlike the current situation in which a couple whose daughter died is making arrangements to have her cryopreserved in vitro embryo implanted in a surrogate mother in an attempt to recreate the daughter.[74]

Additionally, a person with favored traits could be cloned. Respected world figures and celebrities such as Mother Teresa, Michael Jordan, and Michelle Pfeiffer have been suggested as candidates for cloning. Less well-known individuals could also be cloned for specific traits. For example, people with a high pain threshold or resistance to radiation could be cloned.[75] People who can perform a particular job well, such as soldiers, might be cloned.[76] One biologist suggested cloning legless men for the low gravitational field and cramped quarters of a space ship.[77]

Others worry that immortalizing people will lead to an inherently discriminatory practice of selecting only the "best" to be immortalized.[78] For many people, the notion of cloning superior or important historical figures is simply too closely related to the practice of eugenics. Also, some believe that no one should be deciding which humans are worthy of cloning.[79] Would it be the scientists themselves,[80] or should government officials decide? Arthur Caplan, director of the

Center for Bioethics at the University of Pennsylvania, stated that history has taught us frightening lessons "from Nazi Germany to Bosnia, of the evils humans can do when they set values on one another according to biological or inherited traits."[81]

3. Organ and Tissue Reserve

Human cloning research might provide insights that could be valuable in the field of organ transplantation. National Institutes of Health director Dr. Harold Varmus stated that possibly one area of cloning research might provide methods of growing skin, which could then be used in grafting for burn victims and patients with skin-destroying diseases.[82] He explained that nuclear transplantation cloning technology, by enhancing an "understanding of how genes are turned off and on and how we can make different kinds of cell types, not whole human beings, but different kinds of human tissues for transplantation and for treatment of disease, offers tremendous prospects."[83]

Beyond basic scientific research and the development of a technology to create organs in vitro, it has been suggested that clones could be created to donate non-essential organs like kidneys and blood.[84] John Fletcher, former bioethicist from the National Institutes of Health, stated that "[i]t is hard to argue against the idea of a family's loving a child so much that it will happily raise another, identical child so that one of its kidneys or a bit of its marrow might allow the first to live. . . . The reasons for opposing this are not easy to argue."[85] More generally, John Robertson advocates cloning a "backup supply of embryos from which tissue or organs could be obtained if a tragedy befell a first child."[86]

It has been suggested that a person suffering from leukemia could be cloned, the resulting fetus's marrow could be extracted in utero, and then the cloned fetus could be aborted in utero, thus avoiding some of the fears that clones would be treated as second-class citizens.[87] Jeffrey Kluger argues that cloned organ banking is the ultimate realism of the Maoist Chinese belief that individuals are "uberorganistic," or a collection of multicellular parts to be die-cast as needed.[88] Cloning a person for an organ reserve would be futile if the resulting individual had the same diseased organ, however. But situations may arise in which an organ transplant may be needed as the result of injury or nongenetic illness.

Ursula Goodenough, a cell biologist from Washington University, raised an additional application of cloning—to allow reproduction without men.[89] If females cloned themselves, men would be "superfluous" in reproduction, leading to a world where men may eventually be phased out entirely—the ultimate "feminist utopia."[90] From the beginning of Wilmut's announcement of Dolly, commentators have discussed the implications of "virgin birth," or of a woman giving birth to her twin.[91] Ann Northrop, a columnist for the New York gay newspaper *LGNY*, says that nuclear transplantation is enticing to gays and lesbians because it offers them a means of reproduction and "has the potential of giving women complete control over reproduction."[92] "This is sort of the final nail in men's coffins. Men are going to have a very hard time justifying

their existence on this planet, I think. Maybe women may not let men reproduce," said Northrop.[93]

Also, Clone Rights United Front, a group of gay activists based in New York, have been demonstrating against the proposed New York legislation which would ban nuclear transplantation research and human cloning. They oppose such a ban because they see human cloning as a significant means of legitimizing "same-sex reproduction."[94] Randolfe Wicker founded the Clone Rights United Front in order to pressure legislators not to ban human cloning research, because he sees nuclear transplantation cloning as an inalienable reproductive right.[95] Wicker stated, "We're fighting for research, and we're defending people's reproductive rights. . . . I realize my clone would be my identical twin, and my identical twin has a right to be born."[96]

THE POTENTIAL IMPACTS OF CLONING

A. Problems in Application to Humans

There is widespread consensus that human cloning research should not be undertaken at this time. Before such a step is undertaken, further animal research is necessary. Princeton University biologist Dr. Shirley Tilghman has indicated that it is a long-term project to determine the risks in animals.[97]

There are many concerns about the potential danger of treatments based on cloning techniques and risks of cloning whole individuals. The high rate of laboratory deaths may suggest that cloning in fact damages the DNA of a cell, and scientists urge that Dolly should be closely monitored for abnormal genetic anomalies which did not kill her as a fetus but may have long-term harmful effects.[98] Dr. Wilmut warns that when thinking of applying nuclear transplantation as a means of human reproduction, one "shouldn't underestimate the difficulties of this [nuclear transplantation] research."[99]

It is unclear whether the animal research could be successfully generalized to humans. For example, all of the initial frog cloning experiments succeeded only to the point of the amphibian's tadpole stage.[100] In addition, some of the tadpoles were grossly malformed.[101] Thus, there is fear that initial trials in human nuclear transplantation would also meet with disastrous results.[102] Drs. Wilmut and Varmus, testifying before Congress, specifically raised the concern that animal-cloning technology is not scientifically ready to be applied to human cloning research, even if it were permitted, because there are technical questions which can be answered only by continued animal research.[103] Dr. Wilmut is specifically concerned with the ethical issue which would be raised by any "defective births" which may be likely to occur if nuclear transplantation is attempted with humans.[104]

In addition, if all the genes in the adult DNA are not properly reactivated, there might be a problem at a later developmental stage in the resulting clone.[105] Some differentiated cells

rearrange a subset of their genes. For example, immune cells rearrange some of their genes to make surface molecules.[106] That rearrangement could cause a problem for the resulting clone.

Moreover, human cloning research may not lead readily to treatments. In sheep embryos, the genes from the donor cell do not turn on until the egg has divided three or four times. In humans, by contrast, the genes turn on after two divisions. Although the difference may seem insignificant, Colin Stewart, from the National Cancer Institute, warns that the problem may lie in the fact that this rapid "turn-on time" may make it impossible to act quickly enough to catch the disease where its cancerous cells could be effectively and adequately quashed.[107] Additionally, for cancers which appear to be inheritable, such as the BRCA-1 mutation, there is no reason to assume that the cells will not mutate into other cancers or that the manipulation of the cancerous cells by these techniques will not further irritate the cells and worsen the original condition.[108]

Also, because scientists do not fully understand the cellular aging process, scientists do not know what "age" or "genetic clock" Dolly inherited.[109] On a cellular level, is she now a normal seven-month-old lamb, or is she six years old (the age of the mammary donor cell)?[110] Colin Stewart believes that Dolly's cells most likely are set to the genetic clock of the nucleus donor, and therefore are comparable to those of her six-year-old progenitor.[111] One commentator stated that if the hypotheses of a cellular, self-regulating genetic clock are correct, clones would be cellularly programmed to have much shorter life spans than the "original," which would seriously undermine many of the benefits which have been set forth in support of cloning—mostly agricultural justifications—and would psychologically lead people to view cloned animals and humans as short-lived, disposable copies.[112] This concern for premature aging has lead Dr. Sherman Elias, geneticist and obstetrician at the Baylor College of Medicine, to call for further animal testing of nuclear transplantation as a safeguard against subjecting human clones to premature aging and the potential harms associated with aged cells.[113]

The hidden mutations that may be passed on by using an adult cell raise concerns as well. "[Mutations are] a problem with every cell, and you don't even know where to check for them," writes Ralph Brinster of the University of Pennsylvania.[114] "If a brain cell is infected with a mutant skin cell, you would not know because it would not affect the way the cell develops because it is inactive. If you chose the wrong cell, then mutations would become apparent."[115]

Moreover, even if cloning were successful, it could lead to physical harm to the individual created, such as when the latter individual is subjected to physically invasive procedures to supply organs for transplants. Father Richard McCormick has said that to use a clone as a bank of potential organs and blood for donation is wrong; and one writer, Kenneth L. Woodward, called the practice an "inherently evil, morally unjustifiable intrusion into the human life."[116] Many feel that the manner in which a clone comes into existence should not affect the dignity or the rights the clone is granted. Therefore, notes Leon Kass, the clone should be treated as other humans are, and the notion of setting up a reserve of organs would be akin to slavery.[117]

B. Potential Psychological Impacts of Cloning Whole Individuals

There are concerns about the psychological impacts of cloning, both on the person whose DNA is used to create the clone and the resulting offspring. Psychologists worry that the mental health of the original may suffer from seeing himself or herself cloned. Many originals may feel that a clone would give them a second chance at life or an opportunity to change their own fate.[118] However, it could be too psychologically confusing and distressing for the originals to see themselves as children if they are not pleased about aging. Similarly, if the original sees the clone as a chance to correct fate, then the pressure placed on the clone would harm both the original and the clone.[119]

Mixing parental and twin roles could be psychologically harmful to the parent and the clone. "For the clonant to have as his parent the foreknower and creator of every one of his genetic predispositions might well make child adjustment exponentially more difficult," argues Francis Pizzulli.[120]

Thomas Murray worries about the self-identity of the clone when the clone finds out how he or she was conceived: "[H]uman beings tend to insist on finding meanings in relationships that it's not clear animals do."[121] Murray points out that an animal probably does not care about its conception, while a human does. It is often observed that adopted children feel a psychological compulsion to find their biological parents, for a number of reasons, including simple curiosity about their "genetic roots." Therefore, it is likely that human clones would experience the same compulsion to find the "original" from whom they were created. Just as "illegitimate children" historically were psychologically harmed and socially discriminated against, the children created by cloning might have problems, particularly where the replicant is ethically or religiously opposed to nuclear transplantation cloning. Similarly, in situations where a clone is created without the consent of the original, the potential rejection and hostility which the original may feel toward his or her cloned twin would be undeniably harmful to the clone's psyche.

Cloning could undermine human dignity by threatening the replicant's sense of self and sense of autonomy. Cloning represents the potential for "[a]buses of the power to control another person's destiny—both psychological and physical—of an unprecedented order. . . ."[122] Pizzulli points out that legal discussions of whether the replicant is the property of the cloned individual, the same person as the cloned individual, or a resource for organs all show how easily the replicant's own autonomy can be swept aside.[123]

Unlike a naturally occurring twin, the replicant "is *deliberately* infused with a *predetermined* genetic identity."[124] He is "saddled with a genotype that has already lived."[125] Pizzulli notes that "a clonant's genetic identity not only deprives him of a unique genotype but also has a detrimental impact upon his ability to experience a unique 'social environment' (i.e., physical and psychological stimuli that interact with his genotype subsequent to conception)."[126] Cloning, notes Pizzulli, "raises issues that go to the very nature of the individuality which is implicit in any legal order."[127] He points out, "[a]rguably a person cloned from a departed loved one has less chance of being loved solely for his own intrinsic worth."[128]

Another problem is that the clone has lost the ability to control disclosure of intimate personal information.[129] This may threaten the individual's self-image.[130] Studies of people's responses to genetic testing information show that learning genetic information about oneself (whether it is positive or negative information) can harm one's self-image.[131] The replicant individual may be made to feel that he or she is less of a free agent. Laurence Tribe argues that if one's genetic makeup is subject to prior determination, "one's ability to conceive of oneself as a free and rational being entitled to resist various social claims may gradually weaken and might finally disappear altogether."[132] Under such an analysis, it does not matter whether or not genetics actually determines a person's characteristics. Having a predetermined genetic makeup can be limiting if the person rearing the replicant, and/or the replicant, believes in genetic determinism.[133]

C. Potential Social Impacts of Cloning

Concerns have also been raised about the overall social impact of allowing people to create children through cloning. A general argument is made against cloning on the grounds that it is unnatural, but what is natural is historically bound and changes as technology becomes available. Contraception changed the natural assumption of the link between sex and procreation. Artificial insemination and in vitro fertilization further changed this assumption by showing that it was possible to procreate without sex. Joshua Lederberg argues that artificial reproduction is only as bizarre and new as sexual reproduction was at an earlier stage in evolution.[134] In addition, Joseph Fletcher has argued that the "natural" should not be privileged. He states:

> [L]aboratory reproduction is radically human compared to conception by . . . heterosexual intercourse. It is willed, chosen, proposed and controlled, and surely these are among the traits that distinguish *Homo sapiens* from others in the animal genus. . . . Coital reproduction is, therefore, less human than laboratory reproduction . . . with our separation of baby making from lovemaking both become more human because they are matters of choice, and not chance. This is . . . essentially the case for planned parenthood. I cannot see how either humanity or morality are served by genetic roulette.[135]

Even though labeling cloning as unnatural may not provide an appropriate policy reason to ban it, the social impacts of such a departure from the usual means of creating children must be factored into the policy analysis. There is concern that cloning will interfere with evolution. Because cloning promotes genetic uniformity, cloning increases the danger that a disease might arise in the future to which the resulting clones have no resistance.[136] George Johnson, professor of biology at Washington University, an evolutionist, opposes cloning because "genetic variation is the chief defense our species has against an uncertain future. If we strip ourselves of it, even partially, is to endanger our species."[137] What has allowed the human species to survive is genetic adaptation, and producing genetically identical humans would therefore be threatening to the species.[138] Also, it is not clear yet whether all or a high proportion of children created through nuclear transplantation will be sterile, which may affect the potential for humans to procreate in the traditional manner.[139] However, some commentators argue that if human cloning is restricted

to only very rare cases, then the evolution of the human species should not be stunted nor the human gene pool disturbed any more than the gene pool is currently affected by naturally occurring identical twins.[140]

Philippe Stroot, a spokesperson for World Health Organization, condemned human cloning as "ethically unacceptable"[141] because it threatens human evolution not only by destroying genetic diversity, but also by posing risks of transmitting diseases from the original to the clone, and, if transgenic manipulation is allowed, by transmitting diseases from animal species to humans.[142] Stroot stated that there are always concerns associated with medical technologies which involve the introduction of interspecies cells into one another, and that the potential for harm created by transgenic animals and humans must be closely monitored.[143] Future generations may be harmed if cloning is used extensively, since they would be limited only to the narrow range of acceptable genotypes left after a particular generation has instituted a cloning program.[144]

There are also concerns about the changes that cloning could bring to the institution of the family. Boston College theologian Lisa Sowhill Cahill is concerned with the commodification of human beings and their genes and the manipulation of human genetics to achieve more socially desirable children.[145] Allen Verhey, a Protestant ethicist at Hope College in Holland, Michigan, warns that cloning would desensitize society into regarding all children, particularly cloned children, as "products."[146]

A wide range of opponents—from Pope John Paul[147] to Senator Connie Mack to health law expert George Annas to Dr. Wilmut[148]—feel that nuclear transplantation cheapens not only the life of the clone but that of all humanity.[149] Opponents envision a world where clones are "cannibalized for spare parts,"[150] or are made solely for medical purposes, asked to donate their organs, and are then forever treated "like second class citizens."[151]

Cloning may also have negative impacts on legal concepts. Pizzulli points out that "(a) privacy and autonomy might be severely attenuated in one known by himself or others to have a predetermined genetic identity; and (b) irrespective of personal and/or public knowledge of one's clonal origins, the technology of cloning might have macro-effects upon society by eroding the concept of individuality which is at the core of our notions of privacy and autonomy."[152] In addition to weakening an individual's sense of free will, cloning would "weaken the social constructs and political institutions that serve to foster the exercise of individual autonomy and to inhibit the coercive manipulation of individuals."[153]

There have been religious arguments against cloning as well. Within the week after Dolly's story became public, the Vatican called for a global ban on cloning.[154] According to the Pontiff, the creation of life outside of marriage goes against God's plan. Additionally, according to the Pontiff, out of respect for animals, all cloning of animals should be abandoned as well.[155]

EXISTING LAWS THAT COULD RESTRICT CLONING

Are there existing state laws that would ban human cloning as either a scientific research technique to study cells and tissue or as a new means to create whole persons? The only existing legal regulation that speaks directly to cloning is the federal ban on cloning using federal funds. Proposed laws on the subject are under consideration,[156] but until they are passed, the analysis of whether a particular state restricts cloning requires scrutiny of statutes which were adopted for other purposes. In addition to the statutory precedents, criminal and tort law precedents in many states create an obligation on the part of scientists and clinicians to exercise due care when they undertake research or innovative therapy with respect to embryos and fetuses.[157] Moreover, constitutional principles must be considered in determining whether the application of such precedents to cloning is appropriate.[158]

A. State Statutes Governing Research on Embryos

There are ten states which have laws regulating research and/or experimentation on embryos, preembryos, fetuses, conceptuses, or unborn children which arguably may apply to cloning research.[159] The difficulty in discerning whether any of the states' regulations could reach cloning is primarily definitional. Each statute approaches the prohibited activities in a slightly different way, and thus a close analysis is necessary to determine whether cloning is within a particular statute's reach. Among the questions to be addressed are whether the cloning technique fits the definition of "research" or "experimentation"; whether the entity being researched upon fits the definition of Alive" and, depending on the state, "preembryo," "embryo," "fetus," "conceptus," or "unborn child"; and whether nucleic transfer can be considered to involve "fertilization."

Eight of the states prohibit some form of research on some product of conception, referred to in the statutes as a conceptus,[160] embryo,[161] fetus,[162] or unborn child.[163] An argument could be made that the experimentation is being done on an *egg*, not the product of conception, and thus these statutes should not apply. By the time the egg is renucleated, the experiment or research (which is prohibited) has already been completed. Since the statutes would not apply until after the cloning procedure is completed, it could be argued that the most protection these statutes supply would be protection from experimentation after the renucleation; it would not prevent the cloning itself.

The statutes are ambiguous. On the one hand, it could be argued that the statutes should not cover cloning, particularly since it was not within the original contemplation of the laws' drafters. On the other hand, it could be argued that the spirit of the legislation is to protect the beginning of human life and so the statutes would apply.[164]

The analysis is further complicated in states that define the term conceptus or unborn child as the product of "fertilization." Whether Minnesota's and Pennsylvania's statutes would apply to cloning turns on whether the term "fertilization" includes cloning. Minnesota's statute bans research on a "living conceptus," created in utero or ex utero, "from fertilization through 265

days thereafter."[165] Since fertilization is not defined, a court might turn to a dictionary definition: "the process of union of two germ cells whereby the somatic chromosome number is restored and the development of a new individual is initiated . . . ."[166] Cloning is not the union of two germ cells, but this process *does* restore the somatic chromosome number, *and* the development of a new individual is initiated. The two most important elements of fertilization are satisfied, and the third merely explains the only way previously known to accomplish the first two. Thus fertilization could be interpreted to include cloning. The 265-day period of coverage in the Minnesota statute potentially creates a loophole, though. If an embryo is created through cloning, it could be argued that if it is cryopreserved for 265 days after "fertilization," it could be experimented upon thereafter.

Pennsylvania prohibits nontherapeutic experimentation and nontherapeutic medical procedures on an "unborn child,"[167] which is defined as being an organism of the species of homo sapiens from fertilization to live birth.[168] Fertilization, in turn, is defined as the fusion of a human spermatozoa with a human ovum. Like Minnesota, then, the reach of the statute would depend in part on whether the definition of fertilization was stretched to cover nucleic transfer. Pennsylvania's law is open to an additional challenge. The statute's use of the term "unborn child" might allow for an argument that it should not be interpreted to cover cloning research which is not intended to lead to birth.

A further complication is presented by the fact that six of the statutes apply to "live" fetuses only.[169] Two of the statutes—Florida[170] and Maine[171]—do not define "live" but it is likely that a court would determine that the product of cloning research was live.

In the other four states that provide protection for "live fetuses," a fetus is defined as being "live" at that time when "in the best medical judgment of a physician, it shows evidence of life as determined by the same medical standards as are used in determining evidence of life in a spontaneously aborted fetus at approximately the same stage of gestational development."[172] Whether these statutes would apply to the new cloning technique is a medical determination. If they are to apply, Massachusetts, North Dakota, and Rhode Island would prohibit all research or experimentation,[173] while Michigan would prohibit only non-therapeutic research and experimentation.[174]

Some of the states that ban research and/or experimentation on fetuses have exceptions if the activity is necessary to preserve the life or health of the fetus.[175] An argument could be made that these statutes might create an exception for cloning whole individuals, because without the very procedure the statute would regulate, the fetus would not *be* alive to preserve. John Robertson argues that, in cloning, "the intent there is actually to benefit that child by bringing it into being so if one views it somehow as experimentation on the expected child I would think it should be classified as experimentation for its benefit and thus would fall within recognized exceptions when experimentation can occur."[176] However, a court would be unlikely to find such an argument persuasive; a court is likely to hold that the procedure needs to be therapeutic to an already existing fetus.

Two statutes have provisions that are particularly likely to be applied to cloning. The New Hampshire law does not allow a preembryo to develop ex utero past 14 days after fertilization, which would appear to allow cellular-level and genetic-level cloning research during that period. However, New Hampshire's statute prevents a "preembryo" that has been used for research from being transferred to a uterine cavity.[177] The statute's concern is clearly to prevent the birth of a researched-upon individual. New Hampshire's statute would completely ban cloning research that leads to a birth (until such time as there is an artificial womb perfected,[178] since the statute only prohibits implantation into a uterine cavity).

Louisiana has the most far-reaching statute. Louisiana's statute protects an "in vitro fertilized human ovum . . . composed of one or more living human cells and human genetic material so unified and organized that it will develop in utero into an unborn child."[179] Although the same arguments as above may be made about the definition of fertilization, they seem unnecessary because the definition of "in vitro fertilized ovum" is broad enough to include any human cells destined to become children. Accepting this interpretation, the entire statute applies to cloning. A renucleated oocyte is certainly one human cell and human genetic material, presumably alive, and so unified that it will develop into an unborn child. The Louisiana statute would bestow various rights upon the clone. Under the Louisiana statute, the resulting in vitro fertilized ovum can be used only for support and contribution of the complete development of human in utero implantation;[180] it cannot be cultured or farmed solely for research,[181] is deemed a juridical person,[182] must be given an identity,[183] can sue and be sued,[184] has a right to confidentiality,[185] is a biological human being which is not property,[186] may not be destroyed,[187] and is owed a high duty of care;[188] and all disputes regarding the in vitro fertilized human ovum shall be resolved in the best interest of the in vitro fertilized human ovum.[189]

The Louisiana statute specifies the relation of the resulting embryo to other persons and the duties owed by others to it. An in vitro embryo is not property.[190] If parents reveal their identities, their rights as parents of the fertilized ovum are preserved; otherwise, the physician or a court-appointed curator is its guardian.[191] The gamete donors owe the in vitro embryo a "high duty of care and prudent administration."[192] The donors may renounce their rights generally, in which case the embryo is placed for "adoptive implantationy," or in favor of a couple willing and able to accept the embryo.[193] Neither couple may pay or receive compensation to renounce parental rights.[194] Disputes involving the embryo are to be determined in the embryo's best interests.[195]

The physician who caused the in vitro fertilization is directly responsible for the embryo's safekeeping in vitro.[196] The physician, hospital, and clinic are not strictly liable for any screening, collection, conservation, preparation, transfer, or cryopreservation procedure undertaken in good faith. This immunity, however, appears to only apply to actions brought on behalf of an in vitro embryo as a juridical person.[197]

The Louisiana statuteq would severely limit or prevent some of the uses that have been suggested for cloning, such as cloning for body parts, and would settle the question of whether a clone is a

separate person or an extension of the original. It creates an anomalous situation, however, where research would be prohibited on cloned cells but there would be no specific ban on cloning a whole individual. The latter activity would seem to be permissible under the provision saying that an in vitro fertilized ovum may be used "solely for the support and contribution of the complete development of human in utero implantation."[198]

The states vary in the type of penalties they impose for violation of the fetal research laws. In some states, violation of the fetal research law is considered to be unprofessional conduct,[199] creating the potential for a physician/researcher who violates the law to lose his or her license to practice medicine. In other jurisdictions, the violation of such laws can subject the researcher to a fine and imprisonment.[200]

The Massachusetts statute creates an elaborate regulatory mechanism providing for public and private actions to enforce the law. When a proposal for research on fetuses is approved, the written approval by the Institutional Review Board must be filed with the local District Attorney.[201] The approval is open for public inspection. If the District Attorney believes that the proposed procedure is prohibited, he or she shall file a complaint, giving notice to the Commissioner of Public Health, who in turn gives notice to all licensed medical schools and other institutions in the state that may be affected by a judgment in the case.[202] The statute authorizes a broad class of people or institutions potentially affected by the judgment to intervene in the case.[203] The trial on the merits must be without a jury,[204] and any judgment must be published in newspapers and sent to licensed hospitals and medical schools.[205] There is also a procedure for researchers to bring a declaratory judgment action to determine whether a proposed procedure violates the provisions of the statute.[206]

In addition to questions of statutory interpretation, the state laws that have general bans on embryo research or experimentation may be challenged as unconstitutional for being impermissibly vague. Such laws have already been struck down in three states on those grounds. In *Lifchez v. Hartigan*, the ban on experimentation on embryos was unconstitutionally vague because it failed to define the terms "experimentation" and Atherapeutic."[207] The court pointed out that there are multiple meanings of the term "experimentation."[208] It could mean pure research, with no direct benefit to the subject. It could mean a procedure that is not sufficiently tested so that the outcome is predictable, or that departs from present-day practice. It could mean a procedure performed by a practitioner or clinic for the first time. Or it could mean routine treatment on a new patient. Since the statute did not define the term, it violated researchers' and clinicians' due process rights under the Fifth Amendment since it forced them to guess whether their conduct was unlawful.[209]

A similar result was reached by a federal appellate court assessing the constitutionality of a Louisiana law prohibiting nontherapeutic experimentation on fetuses in *Margaret S. v. Edwards*.[210] The appeals court declared the law unconstitutional because the term "experimentation" was so vague it did not give researchers adequate notice about what type of conduct was banned.[211] The court said that the term "experimentation" was impermissibly

vague[212] since physicians do not and cannot distinguish clearly between medical experimentation and medical tests.[213] The court noted that "even medical treatment can be reasonably described as both a test and an experiment."[214] This is the case, for example, " whenever the results of the treatment are observed, recorded, and introduced into the data base that one or more physicians use in seeking better therapeutic methods."[215]

A third case struck down as vague the Utah statute that provided that "live unborn children may not be used for experimentation, but when advisable, in the best medical judgment of the physician, may be tested for genetic defects."[216] The Tenth Circuit held that "[b]ecause there are several competing and equally viable definitions, the term 'experimentation' does not place health care providers on adequate notice of the legality of their conduct."[217] A petition for certiorari was filed in the U.S. Supreme Court in this case on March 18, 1997.

It should be noted, however, that the vagueness claim could be avoided if the state or federal government ban included more explicit language. For example, the proposed federal cloning ban, S. 368, would not be unconstitutionally vague. It prohibits "the replication of a human individual by the taking of a cell with genetic material and the cultivation of the cell through the egg, embryo, fetal and newborn stages into a new human individual."[218]

B. The Reach of Laws Governing In Vitro Fertilization and Assisted Reproductive Technology

Cloning procedures for reproductive purposes would be subject to the Fertility Clinic Success Rate and Certification Act of 1992,[219] which regulates assisted reproductive technology programs—defined as "all treatments or procedures which include the handling of human oocytes or embryos,"[220] and embryo laboratories—defined as facilities in which "human oocytes are subject to assisted reproductive technology treatment or procedures based on manipulation of oocytes or embryos which are subject to implantation."[221] The Act requires assisted reproductive technology programs to report their pregnancy success rates to the Secretary of Health and Human Services[222] for publication in an annual consumer guide.[223] In addition, the Act requires that assisted reproductive technology programs identify the embryo laboratories that they rely on for lab work[224] for publication in the consumer guide.[225] Finally, the Act requires the Secretary of Health and Human Services to develop a model program for the inspection and certification of embryo labs to be implemented by the states.[226]

If cloning is considered to be a form of fertilization, questions arise regarding whether state laws setting standards for who may perform in vitro fertilization will cover the practice. There are fewer state laws specifically addressing the conduct of in vitro fertilization than addressing the conduct of fetal research. Although the impetus behind the in vitro fertilization laws was, for the most part, the regulation of the clinical practice of in vitro fertilization, the provisions are sometimes broad enough to regulate cloning researchers. Certain laws governing reporting, the qualifications of personnel, and so forth, will be applicable to researchers. A New Hampshire law requires counseling in advance of in vitro fertilization and limits the procedure to

participants over age 21[227] (which, if applied to cloning could prohibit the use of DNA from a minor child). Pennsylvania has a reporting requirement which mandates that anyone performing in vitro fertilization file quarterly reports with the Department of Health describing such facts as the number of embryos destroyed and discarded and the number of women in whom embryos are implanted.[228] Louisiana's law requires that in vitro fertilization shall only be undertaken by practitioners and facilities meeting the standards of the American College of Obstetricians and Gynecologists (ACOG) and the American Fertility Society (AFS) (currently the American Society for Reproductive Medicine).[229] Some states have statutes dealing with insurance reimbursement of in vitro fertilization for infertility. A few of those states mandate that, to be reimbursed, the in vitro fertilization procedure must be performed in facilities that meet the ACOG and AFS standards.[230] The insurance-related provisions are unlikely to be applicable to cloning, since cloning will be denied coverage as being too experimental.

PROPOSED FEDERAL AND STATE STATUTES REGARDING CLONING

The announcement of Dr. Ian Wilmut's experiment led to the immediate introduction of federal and state bills to ban the practice of human cloning. Most do not suffer from the problem of unconstitutional vagueness, since the particular activity they ban—cloning—is explicitly described. However, it is described in different ways in the various bills, which could lead to definitional problems similar to those encountered in the fetal research laws as new variations of the technology are developed that may not exactly fit into the current cloning definition.

Federal legislation has been introduced, and bills have been proposed in at least 11 states (Alabama, California, Florida, Illinois, Maryland, Missouri, New York, New Jersey, Oregon, South Carolina, and West Virginia). The federal bill and two states' bills ban the use of governmental funds for cloning an entire individual.[231] The other nine states' bills ban cloning of an entire individual, no matter what the funding source. Only a few states' bills conceivably apply to cloning research not intended to create an entire individual. One bans research using cloned cells or tissue.[232] In addition, two other statutes might unintentionally ban such research. The South Carolina statute defines cloning as the creation of a human being and then bans the steps leading to it. It prohibits cloning by extracting the nucleus from any unfertilized egg and infusing into it DNA from any other cell.[233] Such a provision may restrict cellular research using cloning techniques because it might be difficult for a scientist to convincingly prove that he or she was not doing it to create an individual. West Virginia bans creation of a human "organism" through cloning, which might be interpreted to ban creation of tissue or an organ through cloning techniques.

Moreover, some of the statutes have loopholes since they only ban the creation of a "genetically identical" individual.[234] Since a donated egg is used to create the clone, the resulting individual will have some mitochondrial DNA that is not identical to that of the original individual. Thus, an argument could be made that the law would not apply because it does not create a "genetically identical" individual.

A. Federal Action

At the federal level, Senator Christopher Bond of Missouri introduced S. 368, a bill to ban the use of federal funds for research with respect to the cloning of a human individual. His bill defines cloning as "the replication of a human individual by the taking of a cell with genetic material and the cultivation of the cell through the egg, embryo, fetal, and newborn stages into a new human individual."[235] Thus, Senator Bond's bill would not prohibit federal funding of cloning research that did not result in a live birth. Researchers could clone human cells and allow the resulting entity to proceed through cell divisions to determine what influenced the turning on and off of certain genes. They apparently could also undertake cloning research to create human organs for transplant in the laboratory, so long as no new humans are born.

In addition, Representative Vernon Ehlers, on March 5, 1997, introduced H.R. 922 and 923. H.R. 922 provides that "[n]one of the funds made available in any Federal law may be expended to conduct or support any project of research that involves the use of a human somatic cell for the process of producing a human clone." H.R. 923 provides that "it shall be unlawful for any human person to use a human somatic cell for the process of producing a human clone." The latter bill has a civil penalty of $5,000, which, given the overall cost of cloning and the incentive to undertake the procedure for scientific and personal reasons, would probably not be enough to deter someone from cloning a person.

B. Alabama

State Senator John Amari of Alabama introduced S.B. 511, which prohibits the cloning of human beings.[236] Again, the definition of cloning is broad: "reproducing a being of like genetic constitution from a single somatic cell by repeated cell division."[237] Amari also introduced Senate Joint Resolution 58 requesting the U.S. Congress to prohibit cloning and urging other countries to prohibit the practice. The preamble of the joint resolution gave several reasons for the prohibition.

> "The creation of a human being is sacred and every person has the right to be born as the result of human reproduction."
>
> "The cloning of human beings could irreparably harm the dignity of human life and show an appalling lack of respect for human life."
>
> "The cloning of human beings could result in dangerous experiments with unfathomable consequences."

C. California

A bill was introduced in California by State Senator Johnston amending the human experimentation law to ban the cloning of a human being.[238] In addition, California State Senator

Dave Kelley introduced a Senate Joint Resolution[239] requesting the President and Congress "to act immediately and swiftly to ban, outlaw, and take all necessary means to prevent the cloning of human beings." The resolution points out that cloning human beings raises serious moral, ethical, legal, and other questions and that other countries ban cloning. The resolution also indicates that State Senator Kelley plans to introduce a bill banning cloning in California in the next legislative session.

D. Florida

Florida State Representative Villalobos introduced a bill to make it unlawful "to clone or attempt to clone the DNA of any human being."[240] This law would not just limit the cloning of a whole human being, or research involving nuclear transfer, but would restrict much existing scientific research in which cells are "cloned" or replicated through techniques that involve cell division.

E. Illinois

An Illinois bill, introduced by House Member Carolyn Krause, defines cloning as "the intentional manipulation of a human egg cell to make it genetically identical to another human being, living or dead."[241] The bill prohibits both human cloning and the use of public funds or property for human cloning.[242] It has an exception for in vitro fertilization, use of fertility-enhancing drugs, and certain other medical procedures that are not intended to create a genetically identical being.[243]

F. Maryland

In Maryland, State Representative Valderrama introduced a House Joint Resolution to ban state funding of cloning or cloning research that would "replicate a human being."[244] The resolution preamble asserts:

> The principles of industrial production and design, such as quality control, predictability, profitability, and efficiency, should never be allowed to apply to the production of humans.
>
> Social, ethical, and moral values should not be sacrificed in favor of the dubious potential benefits of scientific experimentation in human cloning.
>
> Cloning would tend to devalue human life or dehumanize mankind.

The resolution also points out that in a recently published poll, 90% of respondents favored prohibiting cloning by law.

G. Missouri

Representative Edwards-Pavia of Missouri introduced a bill forbidding the use of state funds for "the replication of a human person taking a cell with genetic material and cultivating such cell

through the egg, embryo, fetal and newborn stages of development into a new human being."[245] In addition to the limitations of coverage (it would not apply to cloning with private funds), it is ambiguous since it does not define "replication." It might be considered unconstitutionally vague since so many forms of reproduction (including coital) start with one cell (in most instances, the fertilized egg) and proceed through those stages of development.

H. New Jersey

The New Jersey bill, introduced by Assemblywoman Gell and Assemblyman Doria, takes an interesting approach and includes cloning within a broader bill regulating genetics. The bill makes it criminal to knowingly engage or assist, directly or indirectly, in the cloning of a human being, which is defined as "the replication of a human individual by cultivating a cell with genetic material through the egg, embryo, fetal and newborn stages into a new human individual."[246] (This again would create a problem with the definition of replication). The New Jersey bill also includes a number of provisions that would prevent an individual from being cloned without his or her consent. These provisions provide that, except in limited circumstances, an individual's DNA sample which has been used shall be destroyed upon the individual's request[247] and an individual's DNA sample used in research shall be destroyed upon completion of the project or withdrawal of the individual, unless the individual directs otherwise.[248]

I. New York

New York State Senator John Marchi has introduced a bill, S.B. 2877,[249] to criminalize human cloning and conspiracy to clone. Cloning is defined as "the growing or creation of a human being from a single cell or cells of a genetically identical human being through asexual reproduction."[250] The substantive provision prohibits cloning "by extracting the nucleus from any unfertilized human egg and infusing into such egg deoxyribonucleic acid from any other cell; or cloning a human being by any other measure or method."[251] The bill also provides that "[a] person is guilty of conspiring to clone when, the intentional conduct would result in the cloning of a human being, such person agrees with one or more persons to engage in or cause the cloning of a human being."[252] The Commissioner of Public Health or a departmental representative can enter into any workplace at a reasonable hour if there is reason to believe cloning is being conducted.[253] A parallel bill was introduced in the New York Assembly by Member of the Assembly Connelly.[254] Yet both bills may be problematic because of the language about a "genetically identical" individual.

J. Oregon

The Oregon proposal, sponsored by State Senator Lim, makes it "unlawful for any person to create a clone from a cell derived from a human being, including a fetus, embryo, or other product of conception."[255] The bill defines a clone as "an individual grown from a single somatic cell of its parent and genetically identical to the parent."[256]

K. South Carolina

State Representative Mason of South Carolina has introduced a bill that bans cloning and conspiracy to clone. The definition of cloning, though, has the same problem as the one in New York. Cloning is defined as "the growing or creation of a human being from a single cell or cells of a genetically identical human being through asexual reproduction."[257]

L. West Virginia

The West Virginia bill, introduced by State Senator Bailey, makes it "unlawful to use recombinant deoxyribonucleic acid (DNA) or recombinant ribonucleic acid (RNA) research and cell fusion, or other such genetic engineering technology, to engage in the manipulation or alteration of a human organism's genetic material to produce another human organism from that genetic material, more commonly referred to as cloning." The use of the term human organism, however, might be interpreted to include the creation of human tissue or organs, not just the creation of a whole individual.[258]

THE FEDERAL ROLE IN REGULATING CLONING

Because both President Clinton and various members of Congress have expressed concerns about human cloning of individuals—as have a majority of members of the public—federal action is being considered to ban the practice. Such an action would raise important questions of federalism and might be challenged as exceeding the federal government's authority. However, a close analysis of U.S. Supreme Court cases regarding federal powers provides justification for federal action in this area.

The states have traditionally regulated issues related to health care. For example, physicians and hospitals are licensed and regulated by state boards of medical examiners. Thus, at first glance, it would seem that cloning would be more appropriately regulated at the state level. However, despite this tradition of decentralization, the federal government may justify regulation of human cloning by linking such regulation to its spending power[259] and/or its power to regulate interstate commerce.[260]

The federal government currently regulates a variety of medical and scientific activities which are linked to government funding. In conjunction with its provision of Medicare funds, the federal government has required physicians to abide by certain regulations, such as by prohibiting certain forms of fraud and abuse.[261] Similarly, as a condition of receiving federal funds for scientific research, scientists must comply with federal regulations governing research.[262] Consequently, a federal ban on human cloning research with federal funds, as the President has currently promulgated, would be a permissible exercise of federal power.[263] However, regulation based on the spending power is insufficient to regulate research in the private sector, conducted with non-governmental funds. To be permissible, federal regulation of private research must be justified under the commerce clause.

The U.S. Constitution provides that Congress has the authority "to regulate commerce . . . among the several States. . . . [264] Court cases have held that the federal government has the power to regulate economic activities that substantially affect interstate commerce.[265] When Congress regulates medical and scientific activities pursuant to its commerce clause power, it often includes a jurisdictional element—a provision in the statute which indicates that it applies only to activities involving interstate commerce. One example is the National Organ Transplant Act, which provides, in part, that "[i]t shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce."[266] Even the proposed Human Research Subject Protections Act of 1997 contains a jurisdictional element in its definition of research facility: "any public or private entity, agency . . . or person that uses human subjects in research involving interstate commerce."[267]

Until recently, the Supreme Court endorsed a broad construction of the commerce clause. However, in 1995, for the first time in close to 60 years,[268] the Supreme Court held that Congress had passed a law that exceeded its authority under the commerce clause.[269] In *U.S. v. Lopez*, the Supreme Court held that the Gun-Free School Zones Act of 1990, prohibiting the possession of a firearm "at a place that the individual knows or has reason to believe, is a school zone,"[270] neither "regulate[d] commercial activity nor containe[d] a requirement that possession be connected in any way to interstate commerce."[271] Consequently, the law was struck down as exceeding the federal power to regulate.

Commerce clause case law concerns the basic principle that the Constitution creates a Federal Government of enumerated powers.[272] As James Madison wrote, "[t]he powers delegated by the proposed Constitution to the federal government are few and defined. Those which are to remain in the State governments are numerous and indefinite."[273] Federalism is central to our form of government. As the U.S. Supreme Court has pointed out, "[a] healthy balance of power between the States and the Federal Government will reduce the risk of tyranny and abuse from either front."[274] The nature of Congress' commerce power was first defined in *Gibbons v. Ogden*.[275] The commerce power "is the power to regulate; that is, to prescribe the rule by which commerce is to be governed. This power, like all others vested in Congress, is complete in itself, may be exercised to its utmost extent, and acknowledges no limitations other than are prescribed in the Constitution."[276]

In the "watershed"[277] case *NLRB v. Jones & Laughlin Steel Corp.*,[278] the Court sustained the directive of the National Labor Relations Board, issued pursuant to the National Labor Relations Act of 1935, that the defendant steel company desist from discriminating against employees on the basis of union membership and in other respects interfering with attempts to organize the company's employees. The Court held that intrastate activities that "have such a close and substantial relation to interstate commerce that their control is essential or appropriate to protect their commerce from burden and obstructions" are within Congress' power to regulate.[279] Subsequent decisions, recognizing the great changes that had occurred in the way business was carried on, indicate that Congress did not have to show that each transaction it

regulates has a substantial impact on commerce: "[w]here a general regulatory statute bears a substantial relation to commerce, the *de minimis* character of the individual instances arising under that statute is of no consequence."[280]

For example, in *U.S. v. Darby*,[281] the Court upheld the Fair Labor Standards Act stating:

> The power of Congress over interstate commerce is not confined to the regulation of commerce among the states. It extends to those activities intrastate which so affect interstate commerce or the exercise of the power of Congress over it as to make regulation of them appropriate means to the attainment of a legitimate end, the exercise of the granted power of Congress to regulate interstate commerce.[282]

Under this approach, intrastate activities were reached in *Hodel v. Virginia Surface Mining & Reclamation Assn.*,[283] *Perez v. U.S.*,[284] *Katzenbach v. McClung*,[285] and *Heart of Atlanta Hotel, Inc. v. U.S.*[286] At issue in those cases were the regulation of intrastate coal mining, intrastate extortionate credit transactions, restaurants utilizing substantial interstate supplies, and inns and hotels.

In some instances, the federal government was found to have power to regulate because of supplies which moved in interstate commerce.[287] In other instances, the key was that customers came from out of state. The Supreme Court has upheld the constitutionality of the Civil Rights Act of 1964[288] as applied to hotels[289] of seemingly "purely local character."[290] In holding that "the power of Congress to promote interstate commerce also includes the power to regulate the incidents thereof, including local activities . . . which might have a substantial effect upon . . . commerce,"[291] the Court reasoned that racial discrimination would burden interstate travel.[292]

In light of the contours of the federal commerce power as outlined by case law, the *Lopez* court affirmed three broad categories of legislation authorized by the commerce clause: (1) statutes regulating the use of the channels of interstate commerce; (2) laws governing "the instrumentalities of interstate commerce, or persons or things in interstate commerce, even though the threat may come only from intrastate activities"; and (3) statutes regulating activities "that substantially affect interstate commerce."[293]

In holding that "possession of a gun in a local school zone is in no sense an economic activity that might, through repetition elsewhere, substantially affect any sort of interstate commerce,"[294] the Court relied on a number of factors. First, the majority opinion repeatedly noted that the Gun-Free School Zones Act did not regulate any "commercial transaction or economic activity."[295] In *Lopez*, "neither the actors nor their conduct have a commercial character and neither the purpose nor the design of the statute have an evident commercial nexus."[296] Rather, the Gun-Free School Zones Act was "a criminal statute that by its terms had nothing to do with 'commerce' or any sort of economic enterprise."[297]

Second, the Gun-Free School Zones Act contained "no jurisdictional element which would ensure, through case-by-case inquiry, that the firearm possession in question affects interstate commerce."[298] Professor Deborah Merritt suggests that a jurisdictional element would have signaled that Congress was aware of its limits under the Commerce Clause and took those limits seriously.[299] The jurisdictional clause would have slightly narrowed the scope of federal prosecutions, making the federal interest more apparent.[300] By failing to include a jurisdictional element, "Congress almost dared the Court to find the statute unconstitutional."[301]

Third, the Court was influenced by the lack of express findings or legislative history. In fact, the Government conceded that "neither the statute nor its legislative history contains express congressional findings regarding the effects upon interstate commerce of gun possession in a school zone."[302] Although congressional findings or a legislative history are not prerequisites to sustaining a statute under the commerce clause, the majority noted that such findings or history would have enabled them "to evaluate the legislative judgment that the activity in question substantially affected interstate commerce, even though no such substantial effect was visible to the naked eye. . . ."[303] The Court wanted either Congress or the Solicitor General's office to articulate a rationale for the exercise of congressional power at issue.[304]

Fourth, the statute's link to education, an area traditionally regulated by the States,[305] was also significant. The Government argued that "the presence of guns in school poses a substantial threat to the education process by threatening the learning environment. A handicapped educational process, in turn, will result in a less productive citizenry. That, in turn, would have an adverse effect on the Nation's economic well-being."[306] The Court was troubled by this argument, which was based on a tenuous link between the presence of guns in schools and the Nation's economy. Acceptance of such an argument would imply that Congress could regulate almost all aspects of education.

Fifth, the statute's focus on gun possession also affected the Court's decision. The statute at issue was broadly drawn. As a result, it included some forms of gun possession that posed little, if any threat to school children.[307] A hypothetical situation posed by the Fifth Circuit which would fall under the prohibitions of the statute involved carrying an unloaded shotgun "in an unlocked pickup truck gun rack, while driving on a country road that at one turn happens to come within 950 feet of the boundary of the grounds of a one-room church kindergarten located on the other side of a river, even during the summer when the kindergarten is not in session."[308]

Furthermore, gun possession on school premises lacked the "aura of national urgency"[309] present in earlier cases endorsing a broad construction of the commerce clause.[310] Most states had already outlawed the possession of guns on school premises, and there were no findings, nor did the Government argue, that state and local officials were unable to enforce those laws.

Finally, the *Lopez* Court might have believed that in response to the Government's arguments, it simply had to set some limit to Congress' authority. The Government argued that violent acts affect the national economy by raising insurance rates; violent crimes affect the

economy by discouraging interstate travel; and guns disrupt education, reducing workforce skills and ultimately diminishing productivity.[311] In considering these arguments, the Court pointed out that if it were to accept them, it would be "hard pressed to posit any activity by an individual that Congress is without power to regulate."[312] Under the "costs of crime" reasoning, "Congress could regulate not only all violent crime, but all activities that might lead to violent crime, regardless of how tenuously they relate to interstate commerce."[313] Under the "national productivity" reasoning, "Congress could regulate any activity that it found was related to the economic productivity of individual citizens: family law (including marriage, divorce, and child custody), for example."[314] Under these arguments, it would be "difficult to perceive any limitation on federal power."[315]

Although *Lopez* reminds us that Congressional authority to regulate under the commerce power is limited, commentators suggest that the unique combination of factors at play in that case will readily distinguish it from future challenges. Nonetheless, it does raise a number of factors to be considered in determining whether Congress' commerce power extends to the regulation of cloning.

The first question is whether cloning is, in fact, commerce. Medicine initially was viewed as an altruistic, non-commercial endeavor. Hospitals were charitable institutions for the poor and were exempt from various rules that governed businesses. For example, tort suits against hospitals were prohibited on the ground of charitable immunity.[316] In recent years, hospitals have taken on more of the characteristics of business, characterized by revenues and expenditures in the millions of dollars.[317] The characterization of hospitals as businesses has justified the extension of such federal regulatory schemes as the Fair Labor Standards Act,[318] the National Labor Relations Act,[319] and the Sherman Act[320] to hospitals. Each of those acts specifically state that they apply only to interstate commerce.[321] Cases upholding the application of these regulatory schemes to hospitals reason that the purchase of medicine and supplies from out-of-state sources and reimbursement from out-of-state insurance companies and the federal government are sufficient to establish a substantial effect on interstate commerce.[322]

Providers challenging the federal regulation of cloning may argue that they provide their services for purely altruistic purposes—creation of organs, reproductive options—rather than economic gain. What if cloning were provided without charge? Sperm is provided without charge at the Repository for Germinal Choice in Escondido, California (the Nobel Prize Sperm Bank) due to the owner's interest in attempting to upgrade the intelligence of the next generation. A similar entity could be established to allow people to raise clones of talented individuals. Nevertheless, an organization does not have to be a commercial enterprise to affect interstate commerce.[323]

What if it were alleged that cloning did not have a *substantial* impact on interstate commerce? Such an argument has already been made in the medical setting, when individual dentists challenged the application of Title III of the Americans with Disabilities Act to their practices as unconstitutional under the commerce clause.[324] Title III prohibits discrimination on

the "basis of disability . . . by any person who owns, leases, . . . or operates a place of public accommodation."[325] Private entities are considered public accommodations "if the operation of such entities affect commerce."[326] In *Abbott v. Bragdon*,[327] the defendant argued that because the practice of dental medicine occurs purely intrastate, it did not substantially affect commerce and thus was beyond Congress' regulatory authority under the commerce clause.[328] The court found that

> if the Defendant's purchase of supplies and equipment from out of state, receipt of payments from out of state insurers and credit card companies, and attendance of classes and conferences out of state by themselves do not substantially affect interstate commerce . . . those commercial activities taken together with the activities of other dentists similarly situated, have an effect on interstate commerce substantial to fall within the reach of congressional authority under the Commerce Clause.[329]

The court concluded that an "economic enterprise that trades in interstate commerce, even one centered on filling cavities," is sufficiently tied to commercial activity.[330] In fact today "[t]here is little doubt that health care providers are subject to the congressional commerce authority and, therefore, the Congress can opt to impose regulatory controls or federal policy conditions on the activities of those providers. . . ."[331]

The Food and Drug Administration (FDA) under the Food, Drug, and Cosmetic Act,[332] which regulates drugs and medical devices, also provides a precedent for considering cloning to involve interstate commerce. The Food, Drug, and Cosmetic Act prohibits:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.

(b) The adulteration or misbranding of any food, drug, device, or cosmetic in interstate commerce.

(c) The receipt in interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.[333]

Although "it is well settled that Congress has the power, under the commerce clause of the Federal Constitution, to condemn the interstate transportation"[334] of drugs and devices that violate the Act, manufacturers continue to challenge this authority,[335] and the power of the FDA is continually upheld. This is because it can generally be shown that some part of the drug or device—an ingredient, a container, or a package—has passed in interstate commerce. Along those lines, *U.S. v. 39 Cases*,[336] held that a drug manufactured in one state for distribution in the same state was subject to the provisions of the Act because component ingredients were shipped in interstate commerce to the manufacturer. The court reasoned that "it would be a strained

interpretation to say that each 'drug' component falls within the jurisdiction of the Act, being shipped in interstate commerce, but, when compounded together to form another 'drug,' the finished product is not being held for sale after shipment in interstate commerce."[337] To so interpret the Act would create a loophole at the expense of public protection.[338]

In 1980, Congress passed a law regulating the interstate sale, barter, or exchange of blood, blood components, or blood derivatives, unless "such . . . blood, blood component or derivative . . . has been propagated or manufactured and prepared at an establishment holding an unsuspended and unrevoked license issued by the Secretary [of Health and Human Services] to propagate or manufacture, and prepare such . . . blood, blood component or derivative. . . ."[339] The regulation of the biological components involved in cloning would be a logical expansion of this power.[340] In fact, if the cloning was done with DNA from blood, it would have to comply with this law.

If an entity that undertook cloning claimed that it operated exclusively intrastate, using supplies, equipment, and personnel from the state, it might claim to be exempt from the reach of federal law. This is similar to the claim of researchers in California working under the California AIDS Vaccine Research and Development Grant Program,[341] which provides funds to the private sector for the development of an AIDS vaccine "until the Federal Food and Drug Administration (FDA) approves the clinical testing of an AIDS vaccine on humans."[342] In establishing this program, the California legislature permitted AIDS vaccines to be tested in the state without being subject to FDA requirements. Under the program, the vaccine is manufactured by a California company for use in California on California residents. Despite this justification, it is not likely that the regulation of an AIDS vaccine and its clinical trial would be viewed by courts as an intrastate activity and therefore beyond Congress' reach. Rather, the federal government has probably not decided to step in and regulate the program under the federal Food and Drug Act because, as one commentator suggests, that opposition to the program would be "akin to political suicide."[343] Given the pervasive and immediate threat AIDS poses to the public health of our nation, no politician would "want to appear to be standing in the way of people receiving experimental treatments, even if unproven and unsafe."[344]

Cloning research and services do not evoke the same policy justifications as does access to an AIDS vaccine. Although cloning research could provide bone marrow, organs, and even children to infertile couples, those concerns are not as pervasive as is the threat of AIDS. Furthermore, there are alternatives to cloning for obtaining organs and for treating infertility.

Post-*Lopez* cases challenging the constitutionality of the Freedom of Access to Clinic Entrances Act (FACE)[345] may provide guidance in determining whether federal regulation of human cloning would survive similar constitutional challenges. FACE prohibits the physical obstruction, injury, or interference "with any person because that person is or has been . . . obtaining or providing reproductive services;"[346] the physical obstruction, injury, or interference "with any person lawfully exercising or seeking to exercise the First Amendment right of religious freedom at a place of worship;"[347] and the intentional destruction of a reproductive health services

facility or a place of worship.[348] Congress derived its authority to enact FACE from its authority to regulate activities that substantially affect interstate commerce.[349] Cases sustaining the constitutionality of the Act under the commerce clause hold that unlike the Gun-Free School Zones Act at issue in *Lopez*, FACE regulates commercial activity—the provision of reproductive health services.[350] Furthermore, such cases hold that the provision of reproductive health services substantially affects interstate commerce based on the following congressional findings: (1) reproductive health facilities acquire equipment, medicine, medical supplies, surgical instruments and other necessary medical products from other states;[351] (2) "individuals travel interstate to obtain and provide reproductive services;"[352] (3) "obstruction of facilities decreases the overall availability of reproductive health services nationwide;"[353] and (4) "obstruction of facilities is a nationwide problem that is beyond the control of individual states."[354] Because FACE regulates a commercial activity that substantially affects interstate commerce, as supported by congressional findings, it is a legitimate exercise of Congress' commerce power.

Congressional findings similarly justify the enactment of the Fertility Clinic Success Rate and Certification Act of 1992,[355] which requires that assisted reproductive technology programs report their pregnancy success rates to the Secretary of Health and Human Services for publication in an annual consumer guide and that the Secretary develop a model program for the certification of embryo laboratories to be implemented by the states. This legislation arose in response to the absence of regulation in "one of the fastest growing areas of health care."[356] The drafters sought to protect "vulnerable" couples from a field "ripe for exploitation."[357] In addition, the legislative history points out that the government had to "step in" because the regulation of clinics could not be left to voluntary guidelines created by professional societies such as the American Society for Reproductive Medicine, since those clinics causing the most problems were unlikely to comply with voluntary programs. The Fertility Clinic Success Rate and Certification Act does not adopt substantive provisions directly regulating clinics, but rather calls for the secretary to develop model guidelines for states to adopt, if they desire.[358] This form of implementation suggests that Congress contemplated commerce clause concerns in the direct regulation of in vitro fertilization (IVF) laboratories.

However, under case law addressing the constitutionality of FACE, it is likely that Congress could directly regulate those facilities that provide cloning as a reproductive service. First, the provision of reproductive health services is a commercial activity.[359] The test that will be used to determine whether Congress has the authority to regulate cloning performed with private funds is "whether a rational basis existed for concluding that [the] regulated activity sufficiently affected interstate commerce."[360] Second, cloning facilities are likely to substantially affect interstate commerce in some of the same ways that the facilities at issue in the FACE cases do. For example, cloning facilities are likely to acquire equipment, medicine, medical supplies, surgical instruments, and other necessary medical products from other states. *U.S. v. Dinwiddie* points out that the commerce clause allows regulation of a health care facility if its patients are "in interstate commerce."[361] It is likely that some of the patients coming to cloning clinics will travel interstate. By one estimate, there are 10 clinics in the United States that may be able to provide

these services,[362] and, consequently, people in other states would have to cross state lines to obtain the services.

Having out-of-state employees and purchasing out-of-state equipment also makes a business subject to the commerce clause.[363] In addition, cloning providers will share information and research findings in a national arena, requiring attendance at national classes and conferences. Under *Abbott*, traveling to and attendance at national conferences may be sufficient to satisfy the "substantially affects" requirement.[364] Furthermore, those human beings who result from cloning will have the right to travel. Finally, cloning is an issue of national concern. Like IVF, cloning is "ripe for exploitation" (often with the same potential consumers—infertile couples). The legal, physical, psychological, and sociological issues implicated by cloning are even less familiar to the public than those raised by IVF.

The activity of cloning is further distinguishable from the activities at issue in *Lopez* because it does not affect an area where there is a history of state regulation and where states have regulated extensively. Unlike lower school education, which is provided at a local level, cloning would generally be provided by a limited number of facilities around the country that draw personnel and patients from a national market. In addition, few states have regulated the conduct of human research.[365] Such research has primarily been funded and regulated at the federal level. In *Lopez*, 40 states had already acted to ban the possession of guns near schoolyards.[366] With respect to cloning, states do not yet have a legal scheme in place to deal with the issue.[367] In fact, state legislatures have introduced bills calling on the federal government to address the issue.[368]

Cloning research which does not create full human beings may not "substantially affect" interstate commerce in the same way as reproductive cloning. However, the research facilities are likely to participate in an interstate market of supplies, scientists, and information, and thus be within the reach of federal law.

If a federal law were adopted, it would be important to provide a sufficient legislative history to indicate how cloning would affect interstate commerce, to establish why cloning is of national importance, and to document state legislative actions specifically asking for the federal government to intervene in this area.

IS THERE A RIGHT OF SCIENTIFIC INQUIRY?

If Congress (or a state) were to adopt a ban on human cloning, questions would arise as to its constitutionality. Specifically, a question would arise regarding whether scientists have a constitutional right of inquiry that could serve as the basis of a constitutional challenge to such a restriction.

There is no doubt that scientific inquiry has been an enduring American value. The framers of the Constitution discussed the sacred nature of scientific inquiry.[369] The Constitution established a system of patents to promote scientific invention.[370] Historically, scientific theories

have been protected because of the great social import the United States places on the "sanctity of knowledge and the value of intellectual freedom."[371]

In fact, Senator Tom Harkin has defended cloning research by explicitly stating that scientists have the right to research and that there are not "any appropriate limits to human knowledge. None, whatsoever. . . . To my friends Senator Bond and President Clinton who are saying 'Stop, we can't play God,' I say 'Fine. Take your ranks alongside Pope Paul V who in 1616 tried to stop Galileo.'"[372] Senator Harkin argues that any government ban or limitation on human cloning research is essentially an "attempt to limit human knowledge [which is] demeaning to human nature."[373] Harkin also stated that human cloning "is right and proper . . . [because] it holds untold benefits for humankind in the future."[374]

Although there is no specifically enumerated right to research in the U.S. Constitution, certain commentators argue that support for such a right could be derived from the Fourteenth Amendment right to personal liberty[375] and the First Amendment right to free speech.[376] This right to research consists of the freedom to pursue knowledge.[377] The strongest claims have been made for a First Amendment right of scientific inquiry. The U.S. Supreme Court in *Branzburg v. Hayes* specifically analogized the information function performed by academic researchers to that performed by the press.[378] If the First Amendment protects a marketplace of ideas, it seems likely that it would protect the generation of information that will be included in the marketplace. The U.S. Supreme Court has protected the precursors to speech in a variety of settings,[379] such as extending First Amendment protection to the financing of speech[380] and the gathering of news[381] as necessary precursors to speech itself.

There is extensive discussion *in dicta* of a right of inquiry. The Supreme Court stated in *Meyer v. Nebraska*[382] that the right to liberty guaranteed by the Fourteenth Amendment encompassed freedom to "acquire useful knowledge . . . and generally to enjoy those privileges long recognized at common law as essential to the orderly pursuit of happiness by free men."[383] A federal district court similarly suggested that scholars have a "right . . . to do research and advance the state of man's knowledge."[384] But what does that "right" consist of? It is clear that the right of scientific inquiry protects access to existing information. For example, that federal court opined *in dicta* that obscenity laws could not be applied to prohibit the Kinsey Institute from studying obscene materials.[385] However, other court cases specifically reject the idea that a fundamental right of scientific inquiry exists.[386] These cases are relevant because they held that there is no fundamental right of medical researchers to conduct medical research on fetuses.

Even if scientific inquiry were found to be protected by the Constitution, certain restrictions would be permissible. Regulation would not be permissible if it were solely undertaken to restrict the generation of new knowledge. However, the government could regulate to protect against compelling harms (such as the psychological, physical, and social risks of cloning of whole individuals), so long as the regulation is no more restrictive on speech than is necessary to further that interest.

The freedom to pursue knowledge is distinguishable from the right to choose the method for achieving that knowledge, since the method itself may permissibly be regulated.[387] Although the government may not prohibit research in an attempt to prevent the development of new knowledge, it may restrict or prohibit the means used by researchers which intrude on interests in which the state has a legitimate concern.[388]

Therefore, both the federal government and the states may regulate the researcher's methods in order to protect the rights of research subjects and community safety.[389] Research may be restricted, for example, to protect the subject's right to autonomy and welfare by requiring informed, free, and competent consent.[390] This is in keeping with other permissible restrictions under the First Amendment. In cases where "speech" and "nonspeech" elements are inextricably bound up in the conduct, "a sufficiently important governmental interest in regulating the nonspeech element can justify incidental limitations on First Amendment freedoms."[391] Thus, where the government can prove that restrictions on cloning and cloning technology are sufficiently important to the general well-being of individuals or society, such restrictions are likely to be upheld as legitimate, constitutional governmental actions, even if scientists were held to have a First Amendment right of scientific inquiry.[392]

THE RIGHT TO MAKE REPRODUCTIVE DECISIONS

The right to make decisions about whether or not to bear children is constitutionally protected under the constitutional right to privacy[393] and the constitutional right to liberty.[394] The U.S. Supreme Court in 1992 reaffirmed the "recognized protection accorded to liberty relating to intimate relationships, the family, and decisions about whether to bear and beget a child."[395]

Early decisions protected married couples' right to privacy to make procreative decisions, but later decisions focused on individuals' rights as well. The U.S. Supreme Court, in *Eisenstadt v. Baird*,[396] stated, "[i]f the right of privacy means anything, it is the right of the *individual*, married or single, to be free from unwarranted governmental intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child."[397]

A federal district court has indicated that the right to make procreative decisions encompasses the right of an infertile couple to undergo medically-assisted reproduction, including in vitro fertilization and the use of a donated embryo.[398] *Lifchez v. Hartigan*[399] held that a ban on research on conceptuses was unconstitutional because it impermissibly infringed upon a woman's fundamental right to privacy. Although the Illinois statute banning embryo and fetal research at issue in the case permitted in vitro fertilization, it did not allow embryo donation, embryo freezing, or experimental prenatal diagnostic procedures. The court stated:

> It takes no great leap of logic to see that within the cluster of constitutionally protected choices that includes the right to have access to contraceptives, there must be included within that cluster the right to submit to a medical procedure that may bring about, rather than prevent, pregnancy. Chorionic villi sampling is similarly protected. The cluster of constitutional choices that includes the right to

> abort a fetus within the first trimester must also include the right to submit to a procedure designed to give information about that fetus which can then lead to a decision to abort.[400]

Some commentators argue that the Constitution similarly protects the right to create a child through cloning. As Pizzulli points out, "[i]n comparison with the parent who contributes half of the sexually reproduced child's genetic formula, the clonist is conferred with more than the requisite degree of biological parenthood, since he is the sole genetic parent."[401]

John Robertson argues that cloning is not qualitatively different from the practice of medically assisted reproduction and genetic selection that is currently occurring.[402] Consequently, he argues that "cloning . . . would appear to fall within the fundamental freedom of married couples, including infertile married couples to have biologically related offspring."[403] Similarly, June Coleman argues that the right to make reproductive decisions includes the right to decide in what manner to reproduce, including reproduction through, or made possible by, embryo cryopreservation and twinning.[404] This argument could also be applied to nuclear transplantation by saying that a ban on cloning as a method of reproduction is tantamount to the state denying one's right to reproductive freedom.

In contrast, George Annas argues that cloning does not fall within the constitutional protection of reproductive decisions. "Cloning is replication, not reproduction, and represents a difference in kind, not in degree in the way humans continue the species."[405] He explains that "[t]his change in kind in the fundamental way in which humans can 'reproduce' represents such a challenge to human dignity and the potential devaluation of human life (even comparing the 'original' to the 'copy' in terms of which is to be more valued) that even the search for an analogy has come up empty handed."[406]

If a constitutional right to clone was recognized, any legislation which would infringe unduly upon this fundamental right would be subject to a "strict standard" of judicial review.[407] Legislation prohibiting the ability to clone or prohibiting research would have to further a compelling interest in the least restrictive manner possible in order to survive this standard of review.[408]

The potential physical and psychological risks of cloning an entire individual[409] are sufficiently compelling to justify banning the procedure. The notion of replicating existing humans seems to fundamentally conflict with our legal system, which emphatically protects individuality and uniqueness.[410] Banning procreation through nuclear transplantation is justifiable in light of the sanctity of the individual and personal privacy notions that are found in different constitutional amendments and protected by the Fourteenth Amendment.[411]

One could argue that a ban on cloning would "preserve the uniqueness of man's personality and thus safeguard the islands of privacy which surround individuality."[412] These privacy rights are implicated through a clone's right to "retain and control the disclosure of

personal information—foreknowledge of the clonant's genetic predispositions."[413] Catherine Valerio Barrad argues that courts should recognize a privacy interest in one's DNA because science is increasingly able to decipher and gather personal information from one's genetic code.[414] The fear that potential employers and health insurers may use private genetic information discriminatorily is not only a breach of privacy of the original DNA possessor, but any clone "made" from that individual.[415] Even in cases where the donor waives his privacy rights and releases genetic information about himself, the privacy rights of the clone are necessarily implicated due to the fact that the clone possesses the exact same genetic code.[416] Thus, the legal system would have to devise strategies to deal with the privacy issues of donors and clones.[417] In particular, laws would need to be created to effectively deal with situations where either the original's or the clone's genetic information is released without the prior consent of the other individual sharing that genetic code. This argument also evokes the Fifth Amendment's protection of a "person's ability to regulate the disclosure of information about himself."[418]

The government could also assert a compelling interest in protecting against social harms. For example, the government could assert an interest in preserving evolution and forbid cloning because it could lessen diversity in society.[419] The government may also assert an interest in diversity as a cultural good independent of its value for evolution.[420]

The use of cloned cells and tissue for research purposes other than the creation of a child would not be protected by the constitutional rights of privacy and liberty that protect reproductive decisions. Consequently, a governmental regulation or ban of such research would not have to have such stringent justification. It would be constitutional so long as it was rationally related to an important governmental purpose.

CONSTITUTIONAL LIMITS TO CLONING

While a First Amendment right of scientific inquiry or a constitutional liberty or privacy argument might be seen as protecting cloning, other constitutional provisions may limit the use of cloning.

A. Thirteenth Amendment Concerns

Cloning a whole individual whose genetic constitution is known in advance may create a form of "genetic bondage"[421] that runs afoul of the U.S. Constitution's Thirteenth Amendment prohibition on slavery.[422] To the extent that a cloned individual would be limited in his or her freedom based on expectations about his or her genetic makeup, being a clone can be seen as creating a badge of slavery. A clone's autonomy might be limited where his or her genetic traits and predispositions are already known.[423] Intentionally producing people whose genetic predispositions are known undermines the theory of free will, and courts have held that infringement on free will and civil liberty may be prohibited by the Thirteenth Amendment.[424] Bans or restrictions on cloning would be justifiable where the government could prove that cloning is inconsistent with the notion of free will, and that such an erosion of the free will would result in grave societal harms.[425]

Laurence Tribe has noted that cloning "will profoundly affect what it means to be a human being and will do so in ways that matter whether or not particular 'abuses' ever take place."[426] Francis Pizzulli points out that a ban on cloning individuals would likely be constitutional since it is not based on a religious rationale but on "the valid secular purpose of safeguarding a normative view of human identity," resting upon the personal privacy and individual autonomy values of the Thirteenth and Fourteenth Amendments.[427] "Implicit in the prohibition of clonal humans is the rationale that certain types of humans ought not to exist, either because they have inalienable rights to nonexistence or because their presence would erode important social values."[428]

Additionally, the creation of persons to be used as "spare" parts for transplantation would not only be socially repugnant,[429] but be violative of the clone's Thirteenth Amendment rights against involuntary servitude.[430] The clone's right to bodily integrity and personal property rights are also violated by the notion of spare organ-part banking.[431]

B. Nobility Clause

The United States was formed with a rejection of British values that certain special privileges should attach based on one's blood lines. To that end, the U.S. Constitution, art. I, § 9, cl. 8 states, "No title of nobility shall be granted by the United States." State constitutions, too, have such provisions. The Alabama constitution provides, "No title of nobility, or hereditary distinction, privilege, honor, or emolument, shall ever be granted or conferred in this State." An 1872 Alabama case interpreted this provision in the following way:

> To confer a title of nobility, is to nominate to an order of persons to whom privileges are granted at the expense of the rest of the people. It is not necessarily hereditary, and the objection to it arises more from the privileges supposed to be attached, than to the otherwise empty title or order. These components are forbidden separately in the terms "privilege," "honor," and "emolument," as they are collectively in the term "title of nobility." The prohibition is not affected by any consideration paid or rendered for the grant. Its purpose is to preserve the equality of the citizens in respect to their public and private rights.[432]

In an innovative legal analysis, Francis Pizzulli suggests that the values underlying the nobility clause could render unconstitutional a positive eugenics program.[433] If certain individuals are given the right by the government to clone based on their genetic makeup (such as top scientists, political leaders, musicians, or athletes), it might be viewed as creating a class of nobility.[434] At the very least, letting only certain individuals have access to cloning due to their purported genetic distinction would violate the idea of "equality of citizens in respect to their . . . private rights."[435]

Even if the nobility provisions of the federal and state constitutions do not directly apply,[436] they signal an important set of values against creating a supposed hereditary elite which can be used as a public policy argument against cloning whole individuals. However, the nobility

provisions would not serve as a bar to cloning cells, tissue or organs in vitro unless, of course, only individuals of a particular genetic background were allowed to clone a spare organ for themselves.

WHO IS THE PARENT IN CLONING?*

Traditionally, "family" referred to the nuclear family—a household consisting of a husband, a wife, and their children. That traditional view of family, though, is continually being challenged. Divorce, homosexuality, and single parenthood create family structures far different from the traditional concept of family. Additionally, the use of assisted reproductive technologies, including the use of gamete or embryo donors as well as surrogates has lead to familial configurations not contemplated just a few decades ago.

Are these recent family structures and methods of family building any less valuable than the traditional nuclear family created through coital reproduction? The question has not been fully answered—in part, because the answer requires society to consider what values "family" represents and what it means to be a parent. Using the nuclear family as a model, the law has very clearly defined rights and obligations based on one's status as a parent.

> Parents have the right to custody of their child, to discipline the child, and to make decisions about education, medical treatment, and religious upbringing. Parents assign a child a name. They have a right to the child's earnings and services. They decide where the child will live. Parents have a right to information gathered by others about the child and may exclude others from that information. They may speak for the child and may assert or waive the child's rights. Parents have the right to determine who may visit the child and to place the child in another's care.
>
> . . . Parents must care for their child, support him financially, see to his education, and provide him proper medical care.[437]

These rights and obligations, though, become less clear when the roles of mother and father are not as obvious as when a couple produces a child through coital reproduction. Methods of collaborative reproduction necessitate reconsidering what it means to be a parent. Is parenthood defined by biology, genetics, intention, or rearing? These types of questions will need to be answered when sorting out the rights and responsibilities of the potential parents if an individual is cloned.

Current state laws addressing parentage, including paternity acts, surrogacy statutes, and egg donation statutes, are not broad enough to address the multitude of parentage issues raised by the process of cloning through nuclear transfer. The process of cloning will result in a child's having genetic material from as many as four individuals: the person from whom the cell nucleus

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*This section was prepared by Nanette R. Elster, J.D., M.P.H.

was derived, that individual's biological parents, and the woman contributing the enucleated egg cell which contains a small fraction of DNA in the mitochondria. In addition, if the egg with the transferred nucleic material is implanted in a surrogate gestational mother, the child will have two other potential parents—the gestator and, if she is married, her husband. The latter will have rights—even though he has no biological connection to the child—based on the common law presumption that if a woman gives birth within marriage, her husband is the child's legal father, or in some states, specific statutes that provide the surrogate and her husband are the legal parents of a child she has gestated regardless of their genetic contribution.[438] There may also be intended rearing parents unrelated to the individual who is cloned, such as when the cloned individual is deceased, a celebrity, or a favorite relative.

With so many contributors—biologic, genetic, and social—determining who shall assume the parental rights and obligations of the resulting child is very difficult not only from a legal standpoint but also from scientific, psychological, and sociological perspectives. In the cloning scenario, it is unclear which of the contributors is responsible for raising and supporting the resulting child. If parenthood is not clarified, there may be situations in which either the state will bear the responsibility or the child will be caught in a legally complicated, protracted custody battle.[439]

In attempting to determine the parentage of a clone it is going to be necessary to not only consider states' paternity laws, but also any state laws that address parentage in the context of egg donation and surrogacy. There are two types of surrogacy—traditional and gestational. Traditional surrogacy involves a woman agreeing to be inseminated with sperm from the intended father (or a donor), carrying the resulting child to term, and relinquishing all parental rights to the child to the intended father and his wife if he is married. In that situation, the surrogate is providing the egg (which includes mitochondrial DNA and nucleic DNA) and is gestating the fetus. Gestational surrogacy typically involves a woman agreeing to carry an embryo created through in vitro fertilization of the egg and sperm of the intended parents or a donated egg and/or sperm and relinquishing the child to the intended parents. The distinction between the two forms of surrogacy is that with gestational surrogacy, the woman who carries the child to term contributes no genetic material. Currently, at least 34 states have laws addressing artificial insemination by donor,[440] but only 5 states have laws dealing specifically with parentage in egg donation.[441] While 22 states have laws addressing surrogacy,[442] only 8 of those address parentage.[443]

Whether and how these laws might apply to cloning is a complex matter. Under the artificial insemination laws, if a man provides sperm for artificial insemination of a consenting woman and her consenting husband, that couple and not the sperm donor are the legal parents.[444] Because statutes specifically use the term "sperm" or "semen," they arguably do not influence the situation in which a man provides DNA rather than sperm.

The egg donation laws are more likely to be applicable, even though the egg being used in cloning has only mitochondrial DNA, not nucleic DNA. In the five states having egg donation

legislation, the donor is *not* considered to be the mother of the resulting child. Four of the states' statutes specifically assert that the donor has no parental rights or obligations with respect to the resulting child.[445] The Texas statute likely results in the same outcome, but it addresses the issue of legal parentage only from the perspective of the intended parents. It reads, in part:

> If a husband consents to provide sperm to fertilize a donor oocyte by in vitro fertilization or other assisted reproductive techniques and the wife consents to have a donor oocyte that has been fertilized with her husband's sperm, pursuant to his consent, placed in her uterus, a resulting child is the child of both of them.[446]

The language of this statute is significant in the cloning context, because unlike the other four states' laws on egg donation, the Texas statute does not state that the donor relinquishes all parental rights. This law stresses that the intended parents would only be the legal parents if the donated egg is fertilized with the husband's sperm. So, this would not be broad enough to rule out the donor of the enucleated egg as a potential parent in the cloning scenario. The law leaves unanswered the question of the donor's rights and obligations if the egg is not fertilized with the recipient's husband's sperm as would be the case with cloning. One might argue that if a donated egg is enucleated and a nucleus transferred to it, the egg donor may have not only parental rights to a resulting child but also parental obligations such as support.

The surrogate mother laws also figure into the analysis. Although eight states do have statutory presumptions regarding parentage determinations in surrogacy, the states differ over whether the surrogate and her husband are presumed to be the parents or whether the biological father and his wife are presumed to be the parents. Laws in Arizona, North Dakota, and Utah presume that the surrogate and her husband are the legal parents of the child, whereas laws in Arkansas, Florida, Nevada, New Hampshire, and Virginia presume that the genetic father and his wife are the legal parents of the child. Of the eight states, only Arkansas' and Nevada's statutes do not apply to both traditional and gestational surrogacy. The Arkansas statute only covers traditional surrogacy. Because the presumption under the Arkansas statute is that the intended father and his wife are the child's parents, it is likely that the same presumption would apply to gestational surrogacy where both of the intended parents would have a genetic link to the child, but the issue of parentage when donor gametes are used is not certain. The Nevada statute, though, only applies to gestational surrogacy, leaving the determination of parentage in a contested, traditional surrogacy arrangement unresolved.

Florida and New Hampshire impose specific age requirements concerning who can participate in surrogacy arrangements. In Florida, all participants must be 18 or older,[447] and in New Hampshire, all participants must be 21 or older.[448] North Dakota defines both a gestational carrier and a surrogate as "adult woman,"[449] which presumably imposes an age requirement at least for the surrogate.

Another restriction found in the surrogacy statutes which may be even more limiting to cloning than an age requirement is a requirement that the intended parents be married. If marriage

is a requirement and the statute does apply to cloning situations, single individuals interested in cloning themselves would not be able to use the mechanisms of the statute to assert parental rights as an intended parent. Florida, Nevada, New Hampshire, and Virginia specifically define intended parents as being married. In addition, North Dakota[450] uses the terms *husband* and *wife* rather than *intended mother* and *intended father*, which implies that participants need to be married in order for the statute to apply. Other requirements which may limit applicability to cloning include the requirements of the Virginia statute that all participants must undergo a home study and must all meet applicable standards of fitness for adoptive parents.[451]

Three states have additional restrictions regarding recognition and approval of surrogacy contracts which may further limit their applicability to instances of cloning especially by a single male. In Florida, it must be determined by a licensed physician that "[t]he commissioning mother cannot physically gestate a pregnancy to term; . . . gestation will cause a risk of harm to the physical health of the commissioning mother; or . . . will cause a risk of harm to the health to the fetus."[452] Both New Hampshire's and Virginia's statutes have similar requirements that the intended mother be unable to carry the child without risk to herself or the fetus.[453] Virginia's statute differs slightly from New Hampshire's and Florida's in that it also takes into account risks to the psychological health of the mother or fetus. For a surrogacy contract to be approved in Virginia, the intended mother must be "infertile . . . unable to bear a child or . . . unable to do so without unreasonable risk to the unborn child or to the physical *or mental health* of the intended mother or child."[454]

In states that do not have laws addressing a specific reproductive technology, it is necessary to turn to a state's parentage act which may not clearly resolve the question of who is the child's legal mother. In California, for example, the parentage act would find that both the woman who gestates a child and the woman who contributes her genetic material are the child's legal mothers. One section of the act provides that "(a) Between a child and the natural mother, [the parent and child relationship] may be established by proof of her having given birth to the child, . . ."[455] suggesting that the gestator is the mother. Another section, though, allows for the use of a blood test to establish maternity,[456] based on a genetic relationship suggesting that the woman who provided her genetic material is the mother.

The California Supreme Court was confronted with resolving this conundrum in *Johnson v. Calvert*,[457] a gestational surrogacy case in which the surrogate asserted her parental rights to the child. The court resolved the case by looking to the parties' intent, which had been memorialized in a contract. The agreement clearly indicated that the intent of all the parties was for the man and woman whose sperm and egg formed the embryo to be the legal parents of the child. Based on this clearly expressed intent, the court found that the mother of the child was the woman who had contributed her genetic material. If a written contract had not expressed the parties' intent, the outcome of this case may have been different, as California does not have a statutory presumption of parentage in the context of surrogacy. The result may also have differed if donor eggs had been used rather than the eggs of the intended mother. The court would have

had to decide whether gestation, genetic contribution, or intent is determinative of the legal status of motherhood. This is precisely the type of decision that may be necessary if cloning does occur.

The court in *Johnson* gave significant weight to intent, which may indicate a willingness to consider preconception intent in other settings. One legal scholar, Marjorie Schultz, argues that "because parenting involves long-term and multi-faceted commitment, personal intention seems a desirable basis for selecting between two biological claimants who are arguably equally situated."[458] Shultz points out, "[a]s in other arenas of policy, private ordering need not be absolute; particular regulatory constraints on private ordering might be adopted."[459]

Some states have essentially codified the recognition of intent in collaborative reproduction. The surrogacy law in Virginia, for example, provides an elaborate scheme for ultimately recognizing parental intent. The law provides for judicial approval of surrogacy contracts. The law specifies that in order to be judicially approved, specific issues must be addressed in the contracts. Additional requirements for approval include that all parties must have counseling, the surrogate must be married and have had at least one pregnancy and live birth, and at least one of the intended parents is expected to be the child's genetic parent.[460] The statute clearly lays out what is necessary for a court to approve a surrogacy arrangement and legally recognize the intent of the parties.

The state parentage acts, which were cited in *Johnson v. Calvert*, create additional issues with respect to cloning. Every state has a specific statute setting forth presumptions about paternity. Under these legitimacy statutes, a husband of a woman who bears a child during marriage or within a certain number of days after termination, separation, or dissolution of the marriage is presumed to be the father and has legal responsibilities for the child.

The statutes, however, present problems with respect to cloning. First, some states allow exceptions to the presumption of paternity if the husband is sterile. In those states, an infertile husband who wants to be considered the legal father of a clone born to his wife (either using his or her DNA) may not be able to assert paternity under the statute.

Moreover, the statutes create a problem for people wanting to establish parenthood to a clone gestated by a surrogate. Even when the statutory presumption of the surrogate's husband's paternity is rebuttable, the statutes governing paternity do not always provide a mechanism for the biological father to assert his paternity. The genesis of the paternity statutes was to allow a woman to assert that a particular man was the father of her child and to allow her to bring a legal proceeding to compel that man provide child support. To that end, all the statutes allow a mother, expectant mother, or representative of the mother to initiate a paternity action. Some additionally allow the child or a guardian, conservator, or child's best friend or representative to initiate such an action.[461] Some statutes also allow certain public officials, such as state public welfare officials or housing officials, to bring a paternity action (for example, in cases where the state will have to make welfare payments on the child's behalf if a father is not identified to support the child).

Far fewer states have a specific provision for a man wanting to be recognized as the legal father to establish his paternity. While over 19 states specifically provide such a mechanism, in some states a man asserting fatherhood can do so only if there is no presumed father. In those states, the man providing the DNA for the clone may be able to bring a paternity action when an unmarried surrogate bears his child, but not when a married surrogate does so. However, the man providing the sperm may also be able to initiate a paternity action under a provision providing simply for actions by the "father," which is common in at least nine states.[462]

In at least 13 states, there is also a provision for "interested parties" to bring a paternity action, and three states have a provision to allow a relative to bring a paternity action.[463] Arguably, the father could bring a paternity action as an interested party or relative.

However, if there is a provision allowing the "presumed" or "alleged" father to bring a paternity action, the man providing the DNA probably will not be able to use that provision to bring a paternity action if the surrogate changes her mind. He is not the presumed father (if the statute provides that a woman's husband is the presumed father). He is not the "alleged" father either (since the surrogate is not alleging he is the father).

In establishing paternity, states differ in the type of proof they statutorily specify as admissible. In at least 45 states, blood tests can be used.[464] In the District of Columbia, for example, "[a] conclusive presumption of paternity shall be created upon a genetic test result and an affidavit from a laboratory . . . that indicates a 99% probability that the putative father is the father of the child and the Division shall enter a judgment finding the parentage of the child."[465] Similarly, a Tennessee statute provides that "[a]n individual is conclusively presumed to be the father of a child if blood, genetic, or DNA tests show that the statistical probability of paternity is 99% or greater."[466] In contrast, some states find there is a *rebuttable* presumption of paternity even if a 99% probability has been shown under certain circumstances. In Michigan, for example, "[i]f 2 or more persons are determined to have a probability of paternity of 99% or higher, paternity shall be presumed for the person with the higher probability."[467] In Mississippi, there is a rebuttable presumption "affecting the burden of proof, of paternity, if the court finds that a probability of paternity, as calculated by the experts qualified as examiners of genetic tests, is ninety-eight percent (98%) or greater. This presumption may only be rebutted by a preponderance of the evidence."[468]

Some tests used to establish paternity are so general (for example, those tests based on blood type), that a man contributing his nucleic material to create a clone may be found to have a 98 or 99% probability of being the child's father. Other types of tests are so specific, however, that they would identify a nucleic donor as a twin rather than as a father of the child. Thus, it is unclear whether an individual seeking to be considered the parent of a child created with his DNA would be able to use current legal mechanisms to do so.

There is no uniformity among the states concerning the laws governing sperm donation, egg donation, or surrogacy; and there continues to be some uncertainty in assigning parentage in

disputed arrangements. The applicability of these laws to cloning will present even more confusion. Cloning through nuclear transfer presents at least 13 possible parental configurations ranging from as few as 3 possible legal parents to as many as 10.

Surrogacy, egg donation, and sperm donation statutes attempt to address the question of parentage when reproduction occurs with the assistance of individuals other than or in addition to the man and woman seeking to have a child. Cloning, though, unlike collaborative, non-coital reproduction, or even traditional sexual reproduction, may be accomplished with as few as one participant. One woman could transfer nucleic material from one of her cells to her own enucleated egg cell and have the resulting "embryo" transferred to her uterus for gestation. Yet, even in this scenario, parentage issues are raised with which existing laws are ill equipped to deal. For example, if this woman sought child support, her own father and mother may have a legal obligation to support the child because existing paternity testing would find them to be the child's genetic parents. Yet, the woman, too, would be presumed to be the child's mother based on the common law presumption that the woman who gives birth is the legal mother.[469] It is unlikely that in this scenario her maternity would be challenged; however, if it were, the parentage determination would be complicated. In addition to the legal confusion raised by even this most simplistic cloning scenario raises, there are equally baffling psychological and sociological issues raised by the issue of a woman giving birth to her identical twin.[470]

In another possible cloning scenario, cloning may more closely approximate family building in the traditional sense, where a man and woman contribute genetic material to form an embryo which the woman carries to term, than currently accepted and practiced forms of collaborative reproduction. For example, consider a husband and a wife who have chosen to have a child, but the wife has a genetic disease she does not want to pass on to her offspring. To avoid the possibility of passing on this disease, the couple decides to transfer nucleic material from one of the husband's cells to the wife's enucleated egg cell and then transfer the resulting embryo to the wife's uterus. Unlike egg donation or traditional surrogacy, which would accomplish the couple's goal of not passing on the wife's genetic disease to their offspring, cloning allows the couple to reproduce using its own genetic material without the contribution of a third party. In terms of genetics, the husband's parents will also be the resulting child's parents and, in fact, the husband will be the child's twin. If a highly specific paternity test were to be performed, the husband could have a nearly 100% genetic match with the child. This may be indicative that he is not the child's father, "since no two people, aside from identical twins, have the same genetic composition."[471] He may have the intent to be the child's father, and if the child is born during the marriage, he will be presumed to be the child's legal father; but if his status is challenged, a paternity test could reveal that he is the child's identical twin and this may rebut the presumption.

In some states, "[e]ven if the presumption of paternity has been successfully overcome, a party may be stopped from questioning paternity under certain circumstances . . . includ[ing] situations where the parties involved have, by their conduct, accepted the man as the father of the child in question."[472] This is yet another way in which the law currently recognizes intent in the parenting context. This illustrates that in this cloning situation closely akin to traditional family

building, it is possible that the husband and wife choosing to create a child through cloning will be recognized as the child's legal parents, so long as neither of them challenges the other's status.

If a couple creates a child who is the clone of a loved one or an unrelated individual chosen for his or her valued traits, parenting rights would also be dispersed across individuals. If the wife carried the clone to term, the couple would be protected by legal presumptions assigning parenthood to the birth mother and her husband.[473] If paternity testing were done, however, the parents of the cloned individual (and maybe the cloned individual himself or herself) would be able to assert rights to the child.

Even a cloning arrangement which closely resembles traditional reproduction, as between a husband and wife, presents confounding questions not resolvable under existing law. The examples discussed are the simplest potential parental configurations possible in human cloning, yet they raise very profound issues. Existing laws may not effectuate the desired outcome of cloning arrangements and could leave unanswered many questions, including who can make childrearing decisions, who must support the child, who has a right to the child's earnings, and from whom can the child inherit. This confusion about family roles and relationships and the uncertainty of current law to address these issues may present serious psychological, sociological and legal risks for all parties involved in a cloning arrangement.

The matters become even more complicated when a man decides to clone himself by having his DNA fused with a donor egg and gestated by a surrogate. His parents might be viewed as the legal parents of the resulting child. In most states, the egg donor could assert a parental right. In addition, the surrogate generally would have a claim to the child. This would occur either under existing paternity statutes that indicate that the woman who gives birth to the child is the legal mother or, as in Arizona and Utah, where a gestational surrogate and her husband are considered to be the legal parents. Only in Florida, New Hampshire, North Dakota, and Virginia would an "intended" parent (in this case the man cloning himself) possibly have a superior claim to that of the surrogate. But these statutes would not help the man if he were not married.

There are two other likely scenarios in which a surrogate would participate in the cloning situation.[474] One scenario would involve an infertile couple who wants to have a genetically related child. The wife, having had a hysterectomy, cannot carry a child but can still produce eggs. Her husband is sterile, so they decide to fuse her egg cells with his nucleic material and have the resulting embryo gestated by a surrogate. In the second scenario, the wife has had a hysterectomy and oophorectomy, and so the gestator also contributes the egg cell, which is fused with the husband's nucleus.

The first situation resembles gestational surrogacy since the surrogate is contributing no genetic material. As such, the laws in Florida, New Hampshire, North Dakota, and Virginia would likely recognize the intended parents as the child's legal parents.[475] However, the law of North Dakota relies on the parentage act to determine paternity and maternity in gestational surrogacy, and under such analysis the probability of parentage must be 95% or higher.[476] Although, using a

DNA test, there would be greater than a 95% "match" with the intended father, courts might view the test results as indicating twinning, not parenthood. And because the intended mother is only contributing mitochondrial DNA, she would not be a greater than 95% match. The statutes in Arizona and Utah would provide that the surrogate and her husband are the child's legal parents.

Based on a 1994 Arizona Court of Appeals decision, though, this presumption of maternity under the Arizona law is rebuttable. In *Soos v. Superior Court of the State of Arizona*,[477] a married couple entered into a gestational surrogacy contract. During the pregnancy the wife filed for dissolution of the marriage and requested shared custody of the unborn children. The husband asserted that he was the biological father under the existing statute and the surrogate was the legal mother; as such, he asserted that the wife had no standing to request custody. When the triplets were born, the husband was named as the father and took custody. The wife subsequently challenged the constitutionality of the applicable statute. The court found the statute unconstitutional and held that "[b]y affording the Father a procedure for proving paternity, but not affording the Mother any means by which to prove maternity, the State has denied her equal protection of the laws."[478] Therefore, in Arizona, although there is a presumption of maternity in favor of the surrogate, this presumption is rebuttable.

In the second scenario, which resembles traditional surrogacy because the egg of the gestator is utilized, Arizona, North Dakota, and Utah have statutes that would recognize the surrogate and her husband, if she is married, as the child's legal parents. Arkansas statute would be inapplicable because it specifically refers to the surrogate as having been artificially inseminated. It would seem unlikely that the term "inseminated" would include the process of nuclear transfer. Similarly, the law of New Hampshire, which requires one of the intended parents to be a gamete provider, gamete being defined as ovum or spermatozoa,[479] would also be inapplicable. The laws of Florida and Virginia would both find that the intended parents are the child's legal parents.

The examples discussed reflect the difficulty of applying existing law to this new and unprecedented technology. Other assisted reproductive technologies were also not amenable to existing law; therefore, over time, statutes addressing the unique issues raised by such practices have been and continue to be enacted. However, as is seen by the dearth of surrogacy and egg donation statutes, the law does not keep pace with the technological developments. And given the widespread opposition to cloning complete individuals, it will be unlikely that legislators will rush to develop paternity, maternity, or "clonerity" statutes for this new realm which may be considered to be a tacit acceptance of the procedure.

HUMAN RESEARCH IMPLICATIONS

If cloning of an entire individual does occur, there will be extensive scientific and public curiosity about the resulting individual. Consequently, the procedure may be performed as part of a research protocol that would involve observational, psychological, and medical testing on the resulting individual to assess whether physical and psychological development are affected by the

process of cloning. If the resulting individual is a competent adult, he or she would have a clear right to refuse to participate in any follow-up research and would be protected by the federal regulations governing human research, if the research is federally funded, as well as various state laws governing human research, no matter what the source of funding.[480] When the resulting individual is a minor child, however, questions arise regarding what types of research are permissible and who may consent to the child's participation in research.[481]

The previous section discussed the necessity of determining legal parentage of a child born through cloning in order to assess the rights and obligations of all contributors with respect to the child. One reason that parentage must be determined at the outset of a cloning arrangement is to determine who has the responsibility for consenting to medical treatment for the embryo, fetus, and child. Included within that responsibility is the right to consent to medical research involving the child.

The medical and psychological effects of cloning on embryos, fetuses, and resulting children are unknown; therefore, observation and medical testing on the embryo, fetus, and child would likely be necessary to make an assessment of these effects. There will likewise be interest in the psychological implications of taking nucleic material from one child in order to create another child or children. This situation may be similar to the situation in which parents consent to transplantation of an organ from one child to the child's sick sibling, which has been found to be legally permissible.[482]

In general, "competent individuals should not be used in research without their informed and voluntary consent."[483] In fact, the first principle of the Nuremberg Code states that "The voluntary consent of the human subject is absolutely necessary." Similarly, the Federal Regulations provide that "[n]o investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or *the subject's legally authorized representative*."[484] In addition, the section which pertains specifically to research on children requires that the parents or guardians and the child "assent."[485]

The requirement of parental consent will be difficult to satisfy if the child is a clone. Who is responsible and authorized to consent for the child? Which contributor(s) has the child's best interests in mind? Are there ever situations in which research on children should not be done despite parents' authorization? "As a general rule parents, as the natural guardians of their children, have the authority, and even the duty, to consent to medical care on behalf of their children," according to Leonard Glantz.[486] One reason that parents have this authority is that "parents are best able to determine what is in their child's best interest. . . ."[487]

In addition, parents are liable for the support of their children, and this could increase greatly in the event of a physician's error.[488] However, this may not always be appropriate.[489] The parents themselves may not comprehend the purpose or nature of an experiment. Or they may be unduly coerced to participate in research by the researchers and clinicians who helped create the

child, especially in the context of cloning, where this is the only way for the couple to have a genetically related child. Parents' feelings of responsibility to a first child may influence their decision to allow experimentation on a clone, particularly in order to have a "reserve" of organs or bone marrow available if the child should become ill.[490] In some cases, parents may be induced to consent to their children's participation by undue incentives.[491] In a California case,[492] a member of a university Institutional Review Board (IRB) disapproved of a research protocol which permitted parents to consent to their children's participation in nontherapeutic research. He resigned from the IRB and brought a legal action to bar the use of normal, healthy infants as controls in an asthma research project. Apparently, the children were to be injected with drugs and the parents were to receive $300 per year for their children's participation. The case alleged that it would be child abuse for parents to consent to nontherapeutic research on their infants. A trial judge denied the motion for a preliminary injunction, and the case was not pursued any further.[493] It is not inconceivable that incentives such as this may be used to convince parents to consent to their children born through cloning to be the subjects of research. Additionally, parents may be provided with various incentives to consent to cloning of an existing child.

There are limits to what parents can volunteer their children for. The Supreme Court stated in *Prince v. Massachusetts*,[494] that "[p]arents may be free to become martyrs themselves, but it does not follow that they are free in identical circumstances to make martyrs of their children before they reach the age of full and legal discretion when they can make that choice for themselves."[495]

Past a certain age, a mature child should be allowed to decide whether or not he or she wants to assume the risks of an unknown therapy.[496] For example, a child of 12 with a potentially terminal illness such as leukemia may be more capable than the parents of deciding whether or not to participate in an experimental research program.[497] Additionally, a child of 12 may be able to decide whether or not he or she wishes to be cloned in order to have an available bone marrow donor. It is the child's identity which could be compromised. Moreover, there is a question of whether the child whose DNA is used would have parental obligations toward the clone at some time in the future.

Some commentators suggest that where children are capable of assessing information and comprehending the nature and consequences of acting as a research subject, they should be allowed to consent or withhold consent independent of their parents.[498] However, the states which provide statutorily for the participation of minors in research require the co-consent or sole consent of the parent or guardian.[499] Additionally, the federal regulations also outline requirements for permission by parents and assent by the child, where appropriate.[500]

Some commentators argue that children should never be used as research subjects in nontherapeutic experiments[501] because of the problems involved in obtaining informed consent and the possibility that the child's parents or the researcher could be subject to criminal liability for child abuse.[502] Others argue that experiments with children are absolutely essential as results cannot be obtained by other methods or means of study.[503] They would permit such research

where there is an institutional review board review and approval, parental authorization, and the informed consent of the minor when he or she is capable.[504]

The research that may be performed on children born through cloning may be considered to be nontherapeutic research as there is no direct benefit to the child who is the clone. The child would be a research subject in order to observe how the cloning process may affect physical, mental, and psychological development. Some of these analyses could be done without any physically invasive procedures, while others would require intervention.

Under the federal research regulations, research on children involving only minimal risk is allowed so long as the IRB finds that adequate provisions are in place for soliciting the child's assent and permission of the child's parents or guardian.[505] Assent is defined as the child's affirmative agreement to participate and does not include failure to object.[506] Both the child's assent and the parent's or guardian's permission are required under all circumstances. If the research involves greater than minimal risk, but may potentially benefit the child, the IRB must additionally determine that the risk is justified by the anticipated benefit to the child and that the anticipated benefit is at least as favorable to the child as available alternatives.[507] Research that involves greater than minimal risk, and no direct benefit, but is likely to provide knowledge about the subject's disorder is permitted if the IRB determines that the risk is only slightly more than minimal and the procedure is reasonably similar to the established treatment.[508] Where the research is directed toward the alleviation or prevention of a serious children's illness, but is not otherwise approvable, it nevertheless may be conducted if the Secretary of Health and Human Services (after consultation with a panel of experts[509] and the opportunity for public review and comment) determines that the research will be conducted in accordance with sound ethical principles.[510]

The statutes of at least two states contain provisions regarding the use of children as experimental subjects.[511] Virginia requires the informed consent of the child's guardian in addition to the child's consent where the child is capable of giving such consent.[512] New York requires consent of the child's parents or guardians with the approval of an IRB.[513]

Cloning research presents a unique type of research on children because presumably healthy children will be observed and experimented upon to determine how the cloning procedure affected them. It is likely that the testing of such children will be extensive. Even those aspects of the research that do not require physical interventions (such as observation and questionnaires) might be harmful to the child by emphasizing his or her dissimilarity to other children. Forcing a clone child to become a research subject, even with his or her parents' consent, might be stigmatizing and emotionally disturbing to the child.

POTENTIAL TORT CLAIMS BASED ON CLONING

If an entire individual is created by cloning, that individual might be able to bring wrongful life actions against the individual who caused him or her to be brought into being or the scientists

and/or physicians who served as facilitators. Wrongful life cases have succeeded in a few jurisdictions.[514] The claim in such cases is that a child would rather not have been born than have been born with a particular disability. Cases to date have found breaches of duties to the child's parents. For example, in *Curlender v. Bio-Sciences,* the parents were erroneously told by a genetic testing laboratory that the father did not carry the gene for Tay-Sachs when he did, leading to the creation of a child with Tay-Sachs, who successfully sued the laboratory for wrongful life.[515] The court in that case said *in dicta* that the child would also have had a cause of action against her parents for not aborting her. Under that logic, parents are seen as having a duty to future offspring not to give birth to a child with serious disabilities. Some commentators argue similarly that choosing to give birth to a child with a serious disability should be analogized to the parent maiming a child through child abuse.[516]

Some commentators argue that clones would have actions in tort against their creators for "wrongful life" because of their lack of "uniqueness" and invasion of their privacy.[517] Recently, John Robertson argued that because nuclear transplantation cloning denies clones their right to personal privacy and alleged constitutional right to unique genes, it is likely that many would be so psychologically harmed that they would prefer to not have been born at all.[518] Another commentator responded to this concern by arguing that if the legal system allowed clones to bring wrongful life suits, these suits would further undermine notions of human autonomy by reinforcing the idea that humans are machines which are controlled merely by their genes.[519] Replicants whose claimed harm is that their autonomy has been limited—by having a predetermined genotype, by having the value of their talents devalued, by the overcreation of clones of their genotype—would be unlikely to show that they have been so seriously limited so as to be considered to be a wrongful life.

The analysis is more complex when a sterile individual clones himself or herself to have a genetically related child. The child created with the limitation of sterility might be able to claim that that disability is significant enough to be considered to be a wrongful life. Similarly, it might be argued that replicants have been wronged by being denied their uniqueness and by having their future options limited by genetic predetermination. However, it is unlikely that such a claim would give rise to an action for wrongful life, since courts that do recognize such claims limit them to situations in which the child is seriously disabled. A boy who was born "illegitimate" was not allowed to sue his father for wrongful life.[520] And a court speculated that, with respect to deafness, "it seems quite unlikely that a jury would ever conclude that life with such a condition is worse than not being born at all."[521]

The replicant of a cloned individual might also have a cause of action based on tort or property grounds for the creation of too many genetically identical versions which diminish his or her right to distinctiveness. Pizzulli explains the issue in the following way:

> While a given genotype may have been proved to be eminently successful, his duplicate may be relatively unfit *because he is a duplicate*. That is, there is little place for a duplicate genotype in a society which places a premium on uniqueness

and individuality. A duplicate genotype is therefore relatively lacking in fitness, with respect to the posited social/moral environment and is therefore relatively lacking in social worth.[522]

POLICY OPTIONS

This paper was prepared to aid the National Bioethics Advisory Commission in assessing the range of legal options that are possible in the regulation of human cloning. An analysis of existing laws found that there are few statutes that would apply to human cloning. A few states' restrictions on embryo research may apply to cloning,[523] and a federal law would require that clinics offering human cloning as a form of assisted reproductive technology would have to identify themselves and report success rates to the Secretary of Health and Human Services.[524] There is clearly a need for policies addressing human cloning.

In May 1971, Dr. James Watson, the Nobel Prize winner for co-discovering the structure of DNA, authored a seminal article for *Atlantic Monthly* called "Moving Toward the Clonal Man." He explained how cloning could be done and he tried to alert ethicists and scientists that the realization of human cloning was "a matter far too important to be left solely in the hands of the scientific and medical communities.[525] President Clinton has assigned the task of making recommendations about cloning to the National Bioethics Advisory Commission, with the admonition that "any discovery that touches upon human creation is not simply a matter of scientific inquiry, it is a matter of morality and spirituality as well."[526]

This paper has addressed the potential barriers that may have blocked federal attempts to regulate human cloning, such as constitutional challenges based on the commerce clause, scientists' First Amendment right of inquiry, or individuals' or couples' privacy or liberty rights to make reproductive decisions. In each case, it has been shown that human cloning could permissibly be restricted.

Thus, the National Bioethics Advisory Commission does not face undue restrictions in the range of recommendations it could consider. It would be constitutionally permissible to enact a federal ban on creating individuals through human cloning. There is widespread public support for such a ban. Already such prohibitions have been proposed in Congress and 11 states. No legislator has proposed a bill to permit the process.

It would also be permissible to enact restrictions on scientific research on cloned tissue, cells, or organs. Such research is not constitutionally protected as part of reproductive decision making, so governmental regulation or ban of such research would not have to have stringent justifications. Regulation of human cloning research would be constitutional so long as it was rationally related to an important governmental purpose. Under such an analysis, a court could uphold restrictions that require that sufficient animal research is done in advance. Moreover, it would be permissible to require the scientists proposing the research to have "the burden of

proving that the research is vital, cannot be conducted any other way, and is unlikely to produce harm to society."[527]

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APPENDIX A: POTENTIAL PARENTAL CONFIGURATIONS IN HUMAN CLONING

By Nanette R. Elster, J.D., M.P.H.

	CONTRIBUTORS	POTENTIAL PARENTS
I	Intended Mother's Egg Intended Mother's Nucleus Intended Mother as Carrier	1. Intended Mother 2. Intended Mother's Mother 3. Intended Mother's Father [4. Intended Mother's Husband]
II	Donor's Egg Intended Mother's Nucleus Intended Mother as Carrier	1. Egg Donor 2. Intended Mother 3. Intended Mother's Mother 4. Intended Mother's Father [5. Intended Mother's Husband]
III	Donor's Egg Intended Father's Nucleus Intended Mother as Carrier	1. Egg Donor 2. Intended Father 3. Intended Father's Mother 4. Intended Father's Father 5. Intended Mother
IV	Intended Mother's Egg Intended Father's Nucleus Gestational Carrier	1. Intended Mother 2. Intended Father 3. Intended Father's Mother 4. Intended Father's Father 5. Gestational Carrier [6. Gestational Carrier's Husband]
V	Donor's Egg Intended Mother's or Intended Father's Nucleus Gestational Carrier	1. Egg Donor 2. Intended Mother or Intended Father 3. Intended Mother's or Intended Father's Mother 4. Intended Mother's or Intended Father's Father 5. Intended Mother's or Intended Father's Spouse 6. Gestational Carrier [7. Gestational Carrier's Husband]
VI	Intended Mother's Egg Intended Father's Nucleus Intended Mother as Carrier	1. Intended Mother 2. Intended Father 3. Intended Father's Mother 4. Intended Father's Father
VII	Donor's Egg Intended Mother's or Intended Father's Nucleus Donor as Carrier	1. Egg Donor/Carrier [2. Carrier's Husband] 3. Intended Mother or Intended Father 4. Intended Mother's or Intended Father's Mother 5. Intended Mother's or Intended Father's Father [6. Intended Mother's or Intended Father's Spouse]

APPENDIX A: POTENTIAL PARENTAL CONFIGURATIONS IN HUMAN CLONING (continued)

VIII	Donor A's Egg Donor B's Nucleus Intendend Mother as Carrier	1. Egg Donor 2. Nucleus Donor 3. Nucleus Donor's Mother 4. Nucleus Donor's Father 5. Intended Mother [6. Intended Father]
IX	Donor A's Egg Donor B's Nucleus Gestational Carrier	1. Egg Donor 2. Nucleus Donor 3. Nucleus Donor's Mother 4. Nucleus Donor's Father 5. Gestational Carrier [6. Gestational Carrier's Husband] 7. Intendend Mother [8. Intended Father]
X	Donor A's Egg Donor A's Nucleus Gestational Carrier	1. Donor A 2. Donor A's Mother 3. Donor A's FAther 4. Gestational Carrier [5. Gestational Carrier's Husband] [6. Intended Mother] [7. Intended Father]
XI	Donor A's Egg Donor B's Nucleus (Donor born thru egg and sperm donation) Gestational Carrier	1. Donor A 2. Donor B 3. Donor B's egg donor 4. Donor B's sperm donor 5. Donor B's Legal Mother 6. Donor B's Legal Father 7. Gestational Carrier [8. Gestational Carrier's Husband] [9. Intended Mother] [10. Intended Father]
XII	Intended Mother's Egg Dodnor Nucleus (from the child of the Intended Mother and the Intended Father) Intended Mother as Carrier	1. Intended Mother 2. Nucleus Donor 3. Intended Father
XIII	Intended Mother's Egg Donor's Nucleus Donor as Carrier	1. Intended Mother 2. Nucleus Donor 3. Nucleus Donor's Mother 4. Nucleus Donor's Father [5. Nucleus Donor's Spouse]

Endnotes

1. *All Things Considered*, Cloning roundtable, R. Seigel, L. Wertheimer (hosts), D. Rosenberg, R. Portilo, T. Peters, L. Kass (guests), February 24, 1997 (transcript on file with author).

2. M. Specter, A new creation: The path to cloning—A special report, *The New York Times*, March 3, 1997, p. A1.

3. In 1993, embryologists at George Washington University split human embryos, making twins and triplets. See K. Sawyer, Researchers clone human embryo cells; Work is small step in aiding infertile, *The Washington Post*, October 25, 1993, A4. These embryos were not implanted into a woman for gestation. This procedure is distinguishable from cloning by nuclear transfer.

4. S. Begley, Little lamb, who made thee?, *Newsweek*, March 10, 1997, 53-57. See also I. Wilmut, A.E. Schnieke, J. McWhir, A.J. Kind, and K.H.S. Campbell, Viable offspring derived from fetal and adult mammalian cells, *Nature*, 385:810-813, 1997.

5. Transcript of Clinton's remarks on cloning, *U.S. Newswire*, March 4, 1997.

6. Begley, supra note 4.

7. National brief—Washington D.C.: NIH director plays down cloning effect, *Los Angeles Times*, February 27, 1997, A9.

8. Begley, supra note 4.

9. Although these are the most pressing legal issues raised, the rest of this paper goes beyond these issues to address other legal concerns, such as the human subjects' concerns regarding research on a clone, the application of the nobility clause of federal and state laws to cloning, and the liability issues associated with cloning whole individuals.

10. Fla. Stat. Ann. § 390.001(6) (West 1993); La. Rev. Stat. Ann. § 9:121 et seq. (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 et seq. (West Supp. 1997); Minn. Stat. Ann. § 145.421 (West 1989); N.D. Cent. Code § 14-02.2-01 (1991); N.H. Rev. Stat. Ann. § 168-B:15 (Supp. 1996); Pa. Cons. Stat. § 3216 (West Supp. 1996); R.I. Gen. Laws § 11-54-1 (1994).

11. Three other states' fetal research bans—those of Illinois, Louisiana, and Utah—have already been struck down on those grounds.

12. N.H. Rev. Stat. Ann. § 168-B:15(1) (Supp. 1996).

13. N.H. Rev. Stat. Ann. § 168-B:15(2) (Supp. 1996).

14. La. Rev. Stat. Ann. § 9:121 (West 1991).

15. Id., § 9:122.

16. Id.

17. *U.S. v. Lopez*, 514 U.S. 549, 115 S.Ct. 1624 (1995).

18. Over 40 states have laws outlawing firearms on or near school grounds. *U.S. v. Lopez*, 115 S.Ct. 1624, 1641 (1995) (Kennedy and O'Connor, JJ., concurring).

19. See, e.g., *Daniel v. Paul*, 395 U.S. 298 (1969); *Perez v. U.S.*, 402 U.S. 146 (1971); *U.S. v. 62 Packages*, 48 F.Supp. 878 (W.D. Wisc. 1943); *U.S. v. Undetermined Number of Unlabeled Cases*, 21 F.3d 1026 (10th Cir. 1994).

20. *U.S. v. Dinwiddie*, 76 F.3d 913 (8th Cir. 1996), cert. denied, 117 S.Ct. 613 (1996); *U.S. v. Wilson*, 73 F.3d 675 (7th Cir. 1995); *Heart of Atlanta Motel v. U.S.* 379 U.S. 241 (1964).

21. *Abbott v. Bragdon*, 912 F.Supp. 580 (D. Me. 1995), aff'd, F.3d, 1997 WL 85096 (1st Cir. 1997).

22. *U.S. v. Wilson*, 73 F.3d 675 (7th Cir. 1995).

23. *Abbott v. Bragdon*, supra note 21.

24. Lottery Case, 188 U.S. 321 (1903) (the power to regulate under the interstate commerce clause includes the power to prohibit).

25. *Henley v. Wise*, 303 F.Supp. 62 (N.D. Ind. 1969).

26. *Margaret S. v. Edwards*, 488 F.Supp. 181, 220-221 (E.D. La. 1990). See also *Margaret S. v. Treen*, 597 F.Supp. 636 (E.D. La. 1984), aff'd sub. nom. *Margaret S. v. Edwards*, 794 F.2d 994 (5th Cir. 1986); *Wynn v. Scott*, 449 F.Supp. 1302 (1978), aff'd, sub. nom., *Wynn v. Carey*, 599 F.2d 193 (7th Cir. 1979).

27. See, e.g., *Griswold v. Connecticut*, 381 U.S. 379 (1965); *Eisenstadt v. Baird*, 405 U.S. 438 (1972).

28. *Planned Parenthood v. Casey*, 505 U.S. 833, 112 S.Ct. 2791 (1992).

29. *Planned Parenthood v. Casey*, 505 U.S. 833, 112 S.Ct. 2791, 2810 (1992).

30. 405 U.S. 438 (1972).

31. *Eisenstadt v. Baird*, 405 U.S. 438, 453 (1972).

32. *Lifchez v. Hartigan*, 735 F.Supp. 1361 (N.D. Ill.), aff'd without opinion, sub nom., *Scholberg v. Lifchez*, 914 F.2d 260 (7th Cir. 1990), cert. denied, 498 U.S. 1069 (1991).

33. J. Robertson, Statement to the National Bioethics Advisory Commission, March 14, 1997, 83.

34. G. Annas, Testimony on Scientific Discoveries and Cloning: Challenges for Public Policy, before the Subcommittee on Public Health and Safety, Committee on Labor and Human Resources, United States Senate, March 12, 1997, 4.

35. See the discussion of risks, *infra* in Part II.

36. These standards were suggested by George Annas in Senate testimony. George Annas, testimony on Scientific Discoveries and Cloning: Challenges for Public Policy, before the Subcommittee on Labor and Human Resources, United States Senate, March 12, 1997.

37. Approximately .01 percent of our DNA is encoded outside the nucleus or mitochondrial DNA. S. Tilghman, Statement to the National Bioethics Advisory Commission, March 13, 1997, 170-171. The clone will have mitochondria from the egg. It may also have mitochondria from the cell that was used to provide the nucleic DNA. Id. 171. For more information about mitochondrial DNA, see J.M. Shoffner, Maternal inheritance and the evaluation of oxidative phosphorylation, *Lancet*, 348:1283-1288, 1996.

38. See, e.g., Ariz. Rev. Stat. § 25-218 (1996).

39. L.B. Andrews, Alternative reproduction, in S.B. Schatkin (ed.), *Disputed Paternity Proceedings*, vol. 2, New York: Matthew Bender, 1990, § 30.02, 30-11.

40. M.M. Shultz, Reproductive technology and intent-based parenthood: An opportunity for gender neutrality, 1990 *Wisc. L. Rev.* 297 (1990); *Johnson v. Calvert*, 851 P.2d 776 (Cal. 1993) (en banc), cert. denied, 114 S.Ct. 206 (1993) and cert. dismissed 114 S.Ct. 374 (1993).

41. Begley, supra note 4.

42. Tilghman, supra note 37, 172.

43. T.H. Maugh II, Brave new world, *Los Angeles Times*, February 27, 1997, B2.

44. See id.; see also P.N. Spotts, R. Marquand, A lamb ignites a debate on the ethics of cloning, *The Christian Science Monitor*, February 26, 1997, 3; see also F.C. Pizzulli, Note, Asexual reproduction and genetic engineering: A constitutional assessment of the technology of cloning, 47 *S. Cal. L. Rev.* 476, 483 (1974).

45. Begley, supra note 4, 55.

46. Testimony of Ian Wilmut, Federal Document Clearing House Congressional Testimony, March 12, 1997.

47. Cloning of sheep has remarkable implications, Copley News Service, February 24, 1997.

48. L. Reibstein, G. Beals, A cloned chop, anyone?, *Newsweek*, March 10, 1997, 58.

49. S. Stolberg, Sheep clone researcher calls for caution science, *Los Angeles Times*, March 1, 1997, A18.

50. See G. Kolata, Scientists urge senators not to rush to ban human cloning, *The New York Times*, March 13, 1997, B11 (testimony of Ian Wilmut before the Senate hearings on cloning, March 12, 1997).

51. Begley, supra note 4.

52. Id.

53. J.M. Nash, The age of cloning, *Time*, March 10, 1997, 62-65.

54. Id.

55. P. Kendall, W. Neikirk, Cloning breakthrough a large step on much larger road, *Chicago Tribune*, February 25, 1997, 1. See also, Maugh, supra note 43.

56. J. Gross, Thinking twice about cloning, *The New York Times*, February 27, 1997, B1.

57. Begley, supra note 4.

58. Kolata, supra note 50; see also Don't rush anti-cloning laws, *Los Angeles Times*, March 13, 1997 (Governor Pete Wilson commenting that he would not consider a bill banning cloning human research if it would hinder "important" biotechnology research designed to fight cancer, AIDS, and other diseases).

59. Kolata, supra note 50; see also Pizzulli, supra note 44.

60. Kolata, supra note 50.

61. Begley, supra note 4.

62. Kolata, supra note 50.

63. Maugh, supra note 43; see also Stolberg, supra note 49.

64. C. Krauthammer, A special report on cloning, *Time*, March 10, 1997, 60; see also Stolberg, supra note 49.

65. Id.

66. Tilghman, supra note 37, 169.

67. Kendall, supra note 55.

68. H. Wray, J.L. Sheler, T. Watson, The World after cloning, *U.S. News and World Report*, March 10, 1997, 59.

69. J. Katz, *Experimentation with Human Beings*, New York: Russell Sage Foundation, 1972, 977.

70. Maugh, supra note 43; see also, J. Laurence, Regulations are relatively liberal, *The Times*, February 26, 1997.

71. Stolberg, supra note 49.

72. Id.

73. W. Gaylin, We have the awful knowledge to make exact copies of human beings, *New York Times Magazine*, 56(March 5):48, 1972.

74. Kolata, Medicine's troubling bonus: Surplus of human embryos, *New York Times*, March 16, 1997, 1; Fox on Trends (Fox Television), March 19, 1997.

75. J.B.S. Haldane, Biological possibilities for the human species in the next thousand years, in *Man and His Future*, G. Wolstenholme (ed.), 1963, 337, cited in Pizzulli, supra note 44, 490 n. 66.

76. Fletcher, Ethical aspects of genetic controls, *N Eng J Med*, 285:776, 779, 1971.

77. Haldane, supra note 75, 354-355, cited in Pizzulli, supra note 44, 520.

78. J. Kluger, Will we follow the sheep?, *Time*, March 10, 1997, 67.

79. Gross, supra note 56 (comments by Father Richard McCormick).

80. *All Things Considered*, supra note 1 (comments of Leon Kass).

81. Id. (equating the decision of who to immortalize as not dissimilar to the activities in Nazi Germany and the historical legal racism that inflicted our country); see also S. Schmickle, Cloning debate full of mystery and wonder, *Star Tribune*, March 2, 1997, 14.

82. See NIH director plays down cloning effect, *Los Angeles Times*, February 27, 1997, A9.

83. Id.

84. Kluger, supra note 78.

85. Id.

86. Robertson Statement, supra note 33, 86.

87. Krauthammer, supra note 64.

88. Kluger, supra note 78.

89. Nash, supra note 53.

90. C.P. Gilman, *Herland*, New York: Pantheon Books, 1979.

91. Nash, supra note 53.

92. A. Manning, Pressing a 'right' to clone humans, some gays foresee reproduction option, *USA Today*, March 6, 1997, D1.

93. L. Schilinger, Postcard from New York, *The Independent* (London), March 16, 1997, 2 (discussion of the Clone Rights United Front demonstrations in New York to dissuade New York legislators from passing a bill that would make human cloning research a felony).

94. Manning, supra note 92.

95. Id.; see also Schilinger, supra note 93.

96. Schilinger, supra note 93.

97. Tilghman, supra note 37, 173.

98. See Nash, supra note 53; see also Spotts and Marquand, supra note 44.

99. See Stolberg, supra note 49 (Ian Wilmut warning against prematurely banning all cloning research; from testimony before the Senate hearings on cloning research, March 12, 1997).

100. The law and medicine, *The Economist*, March 1, 1997, U.S. ed., 59; see also Pizzulli, supra note 44, 484 (citing Briggs and King, Transplantation of living nuclei from blastula cells into eucleated frogs' eggs, *Proc Nat Aca Sci, U S A*, 38:455, 1952).

101. Pizzulli, supra note 44, 484, 487.

102. Id., 487.

103. P. Recer, Sheep cloner says cloning people would be inhumane, Associated Press, March 12, 1997 (reported testimony of Dr. Ian Wilmut and of Dr. Harold Varmus before the Senate, March 12, 1997, regarding the banning of human cloning research).

104. Id. (comments of Dr. Ian Wilmut, testifying that as of yet he does not know of "any reason why we would want to copy a person. I personally have still not heard of a potential use of this technique to produce a new person that I would find ethical or acceptable.").

105. Tilghman statement, supra note 37, 146.

106. Id., 147.

107. Recer, supra note 103.

108. Nash, supra note 53.

109. Recer, supra note 103.

110. Id.; see also Nash, supra note 53.

111. See Recer, supra note 103; see also J. Laurence, and M. Hornsby, Warning on human clones, *The Times*, February 23, 1997; see also, Whatever next?, *The Economist*, March 1, 1997, 79 (discussing the problems associated of having mitochondria of egg interact with donor cell).

112. Hello Dolly, *The Economist*, March 1, 1997, 17 (discussion of the pros and cons of aging research which could result from nuclear transplantation cloning); cf. T. Monmaney, Prospect of human cloning gives birth to volatile issues, *Los Angeles Times*, March 2, 1997, A2 (comments of Dr. Elias).

113. Monmaney, supra note 112.

114. Nash, supra note 53.

115. Id. See also Tilghman, supra note 37, 145 (discussing the problem of mutations).

116. Gross, supra note 56; see also K.L. Woodward, Today the sheep. . ., *Newsweek*, March 10, 1997, 60.

117. *All Things Considered*, supra note 1; see also J. Coleman, Playing God or playing scientist: A constitutional analysis of laws banning embryological procedures, 27 *Pac. L.J.* 1331, 1351 (total ban on embryological procedures violates the Constitution); see also Pizzulli, supra note 44, 489 (cloning "subhumans" solely for organs would lead society to view clones as "manufactured arrangements of cells" whose civil liberties would be infringed).

118. Krauthammer, supra note 64, 61.

119. R. Wright, Can souls be xeroxed?, *Time*, March 10, 1997, 73; see also Krauthammer, supra note 64.

120. Pizzulli, supra note 44, 510 (citation omitted).

121. *Talk of the Nation*, February 24, 1997 (transcript on file with author).

122. Pizzulli, supra note 44, 497.

123. Id., 492.

124. Id., 509.

125. Id., 509 (citation omitted).

126. Id., 509 (citation omitted).

127. Id., 499 (citation omitted).

128. Id., 503 n.140.

129. Id., 512.

130. Id., 514. Pizzulli points out that a person's self-image may be at odds with an "objective" description of himself or herself (id.), and that overestimation of abilities might spur one to achieve goals otherwise thought unattainable (id., 515).

131. For a review of the studies, see L.B. Andrews, Prenatal screening and the culture of motherhood, 47 *Hastings L.J.* 967 (1996).

132. L. Tribe, Technology assessment and the fourth discontinuity: The limits of instrumental rationality, 46 *S. Cal. L. Rev.* 617, 648 (1973).

133. There is much evidence of the widespread belief in genetic determinism. See, e.g., D. Nelkin, S. Lindee, *The DNA Mystique: The Gene as Cultural Icon,* New York: W.H. Freeman & Company, 1995.

134. Pizzulli, supra note 44, 499 (citation omitted). Such an argument, however, ignores the role of having a culture of thinking; reflective individuals who can react to and are influenced by such a change.

135. Fletcher, Ethical aspects of genetic controls, *New Eng J Med,* 285:776, 781, 1971.

136. G.B. Johnson, What rights should a cloned human have? *St. Louis Post-Dispatch*, March 20, 1997, B7.

137. Id.

138. Genesis the sequel, *Newsday*, March 9, 1997, G1.

139. Id.

140. Bader, M., Threats from cloning shouldn't be overstated, *Portland Oregonian*, March 9, 1997, A8 (arguing that as long "[a]s the human gene pool is intact, humans will be able to adapt to the extent that is within their overall makeup to do so.").

141. Who agrees cloning has research benefits, *The Times-Picayune*, March 12, 1997, A8 (the World Health Organization has condemned human cloning as "ethically unacceptable," but warns that other cloning research could be medically beneficial and therefore should continue.).

142. Id.

143. Id.

144. Pizzulli, supra note 44, 529.

145. Gross, supra note 56.

146. Id.

147. Vatican calls for a global ban on cloning, Reuters North American Wire, February 26, 1997.

148. Kolata, supra note 50.

149. Kluger, supra note 78.

150. Amer, M.S., Comment: Breaking the mold: Human embryo cloning and its implications for a right to individuality, 4 *UCLA L. Rev.* 1659, 1666 (1996) (citing Elmer-Dewitt, P., Cloning: Where do we draw the line?, *Time,* November 8, 1993, 65).

151. Id.

152. Pizzulli, supra note 44, 498.

153. Pizzulli, supra note 44, 524-25.

154. Vatican calls for a global ban on cloning, Reuters North American Wire, February 26, 1997.

155. Id.

156. There are currently bills introduced in Alabama, California, Florida, Illinois, Maryland Missouri, New Jersey, New York, Oregon, South Carolina, West Virginia and in the U.S. Congress. See S.B. 511 (Ala. 1997); S.B. 1344 (Cal. 1997); H.B. 1237 (Fla. 1997); H.B. 1829 (Ill. 1997); H.B. 2235 (Ill. 1997); H.J.R. 28 (Md. 1997); H.B. 824 (Mo. 1997); A.B. 2849 (N.J. 1997); A.B. 5383 (N.Y. 1997); S.B. 2877 (N.Y. 1997); S.B. 1017 (Ore. 1997); H.B. 3617 (S.C. 1997); S.B. 410 (W. Va. 1997); S. 368, 105th Cong., 1st Session (1997); H.R. 922, 105th Cong., 1st Session (1997); H.R. 923, 105th Cong., 1st Session (1997).

157. For a discussion of these precedents, see Andrews, L.B., The legal status of the embryo, 32 *Loy. L. Rev.* 357 (1986).

158. See Parts VII and VIII, infra.

159. Fla. Stat. Ann. ’390.001(6) (West 1993); La. Rev. Stat. Ann. ’9:121 et seq. (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 et seq. (West Supp. 1997); Minn. Stat.

Ann. ’145.421 (West 1989); N.D. Cent. Code ’14-02.2-01 (1991); N.H. Rev. Stat. Ann. 168-B:15 (Supp. 1996); 18 Pa. Cons. Stat. ’3216 (West Supp. 1996); R.I. Gen. Laws § 11-54-1 (1994).

160. Minn. Stat. Ann. § 145.421 (West 1989).

161. Mich. Comp. Laws Ann. § 333.2685 (West Supp. 1997).

162. Fla. Stat. Ann. § 390.001(6) (West 1993); Me. Rev. Stat. Ann. tit. 22, § 1593 (West 1992); Mass. Gen. Laws Ann. ch. 112, § 12J (West 1996); Mich. Comp. Laws Ann. § 333.2685 et seq. (West Supp. 1997); N.D. Cent. Code § 14-02.2-01 (1991); R.I. Gen. Laws
§ 11-54-1 (1994).

163. 18 Pa. Cons. Stat. § 3216 (West Supp. 1996).

164. Also note that few of the states which have research/experiment statutes are among the group (small but growing fast) of states which have introduced legislation to ban cloning. This situation lends itself to argument from both sides as well. On one hand, these states may assume that their current statute would cover cloning and a new statute would be duplicative. On the other hand, the lack of legislative action may indicate satisfaction with unregulated cloning.

165. Minn. Stat. Ann. § 145.421 (West 1989).

166. *Webster’s Third New International Dictionary, Unabridged,* Springfield, MA: Merriam Webster, Inc., 1986.

167. 18 Pa. Cons. Stat. § 3216 (West Supp. 1996).

168. 18 Pa. Cons. Stat. § 3203 (West Supp. 1996).

169. Fla. Stat. Ann. § 390.001(6) (West 1993); Me. Rev. Stat. Ann. tit. 22, § 1593 (West 1992); Mass. Gen. Laws Ann. ch. 112, § 12J (West 1996); Mich. Comp. Laws. Ann. § 333.2685 et seq. (West Supp. 1997); N.D. Cent. Code § 14-02.2-01 (1991); R.I. Gen. Laws
§ 11-54-1 (1994).

170. Fla. Stat. Ann. § 390.001 (West 1993).

171. Me. Rev. Stat. Ann. tit. 22, § 1593 (West 1992).

172. Mass. Gen. Laws Ann. ch. 112, § 12J(a)(I) (West 1996); Mich. Comp. Laws. Ann. § 333.2687 (West Supp. 1997) (the Michigan statute protects "embryo, fetus, or neonate," but the definition of the group is the same: "best medical judgment of a physician."); N.D. Cent. Code § 14-02.2-01(4) (1991); R.I. Gen. Laws § 11-54-1(c) (1994).

173. Mass. Gen. Laws Ann. ch. 112, § 12J(a)(I) (West 1996); N.D. Cent. Code § 14-02.2-01(1), (3) (1991); R.I. Gen. Laws § 11-54-1(c) (1994).

174. Mich. Comp. Laws Ann. § 333.2685 et seq. (West Supp. 1997).

175. See Mass. Gen. Laws Ann. ch. 112 § 12J(a)(I) (West 1996) (creating exception to preserve the life or health of the fetus or mother); Mich. Comp. Laws Ann. § 333.2685(1) (West Supp. 1997) (creating exception for therapeutic procedures); Minn. Stat. Ann. § 145.422 (West 1989) (creating exception to preserve the life or health of the fetus or mother and for "experimentation which verifiable scientific evidence has shown to be harmless to conceptus"); 18 Pa. Const. Stat. § 3216 (West Supp. 1996) (allowing therapeutic procedures); R.I. Gen. Laws § 11-54-1 (1994) (creating exception to preserve the life or health of the fetus or mother).

176. Robertson Statement, supra note 33, 94.

177. N.H. Rev. Stat. Ann. 168-B:15 (Supp. 1996).

178. Zorn, E., 'Brave new world' awaits debaters of abortion rights, *Chicago Tribune*, March 9, 1997, B1.

179. La. Rev. Stat. Ann. § 9:121 (West 1991).

180. La. Rev. Stat. Ann. § 9:122 (West 1991).

181. Id.

182. La. Rev. Stat. Ann. § 9:123 (West 1991).

183. La. Rev. Stat. Ann. § 9:124 (West 1991).

184. Id.

185. Id.

186. La. Rev. Stat. Ann. § 9:126 (West 1991).

187. La. Rev. Stat. Ann. § 9:129 (West 1991).

188. La. Rev. Stat. Ann. § 9:130 (West 1991).

189. La. Rev. Stat. Ann. § 9:131 (West 1991).

190. La. Rev. Stat. Ann. § 9:126 (West 1991).

191. Id.

192. La. Rev. Stat. Ann. § 9:130 (West 1991).

193. Id.

194. Id.

195. La. Rev. Stat. Ann. § 9:131 (West 1991).

196. La. Rev. Stat. Ann. § 9:127 (West 1991).

197. La. Rev. Stat. Ann. § 9:132 (West 1991).

198. La. Rev. Stat. Ann. § 9:122 (West 1991).

199. See, e.g., Cal. Bus. & Prof. Code § 2254 (West Supp. 1997).

200. See, e.g., N.M. Stat. Ann. § 24-9A-6 (1994) (providing for imprisonment for up to one year or the payment of a fine up to $1,000 or both).

201. Mass. Gen. Laws Ann. ch. 112, § 12J(a)(VI) (West 1996). An Institutional Review Board's reasonable, well-documented written approval provides a complete defense to criminal prosecution of the researcher. Id.

202. Mass. Gen. Laws. Ann. ch. 112 § 12J(b)(I).

203. Mass. Gen. Laws. Ann. ch. 112 § 12J(b)(III).

204. Mass. Gen. Laws. Ann. ch. 112 § 12J(b)(VI).

205. Mass. Gen. Laws. Ann. ch. 112 § 12J(b)(VII).

206. Mass. Gen. Laws. Ann. ch. 112 § 12J(b)(VIII).

207. 735 F.Supp. 1361, 1364 (N.D. Ill. 1990), aff'd without opinion, sub nom., *Scholberg v. Lifchez*, 914 F.2d 260 (7th Cir.), cert. denied, 498 U.S. 1068 (1991).

208. Id., 1364-65.

209. Id., 1364.

210. 794 F.2d 994 (5th Cir. 1986).

211. Id., 999.

212. Id.

213. Id. A concurring judge found this analysis to be contrived and opined that the provision was not unconstitutionally vague. Id., 1000 (Williams, J., concurring). Instead, he suggested that the prohibition was unconstitutional because "under the guise of police regulation the state has actually undertaken to discourage constitutionally privileged induced abortions." (Id., 1002, citing *Thornburgh v. American College of Obstetricians and Gynecologists*, 106 S.Ct. 2169, 2178 (1986)). The concurring judge pointed out that the state had "failed to establish that tissue derived from an induced abortion presents a greater threat to public health or other public concerns than the tissue of human corpses [upon which experimentation is allowed]." Id. Moreover, the state had not shown a rational justification for prohibiting experimentation on fetal tissue from an induced abortion, rather than a spontaneous one. Id.

214. *Margaret S. v. Edwards*, 794 F.2d 994, 999 (5th Cir. 1986).

215. Id.

216. Utah Code Ann. § 76-7.3-310.

217. *Jane L. v. Bangerter*, 61 F.3d 1493 (10th Cir. 1995).

218. S. 368, 105th Congress, 1st session, § 1(B) (1997).

219. 42 U.S.C.A. § 263a-1 et seq. (Supp. 1996).

220. 42 U.S.C.A. § 263a-7(1) (Supp. 1996).

221. 42 U.S.C.A. § 263a-1(b) (Supp. 1996).

222. Id.

223. 42 U.S.C.A. § 263a-5 (Supp. 1996).

224. 42 U.S.C.A. § 263a-1(a)(2) (Supp. 1996).

225. 42 U.S.C.A. § 263a-5 (Supp. 1996).

226. 42 U.S.C.A. § 263a-2 (Supp. 1996).

227. N.H. Rev. Stat. Ann. § 168-B:13 (Supp. 1993)

228. 18 Pa. Cons. Stat. Ann. § 3213(e) (1983).

229. La. Rev. Stat. Ann. § 9:128 (West 1991).

230. See, e.g., Ark. Code Ann. § 23-86-118(d) (1992); Hawaii Rev. Stat. § 432:1-604(6) (1994); 215 ILCS 5/356m(b)(1)(c) (1993); Md. Ann. Code art. 48a §§ 477EE(6) and 470W (1994).

231. 1997 Mo. H.B. 824 (introduced March 6, 1997); Md. H.J.R. 28 (introduced March 20, 1997).

232. Fla. H.B. 1237 (introduced March 7, 1997).

233. South Carolina H.B. 3617 § 16-17-745(B) (introduced March 11, 1997). A similar provision exists in New York Assembly Bill 5383 (introduced March 4, 1997).

234. 1997 N.Y.S.B. 2877 (introduced February 26, 1977); 1997 N.Y.A.B. 5383 (introduced March 4, 1997); 1997 Ill. H.B. 2235 § 5 (introduced March 10, 1997).

235. S. 368, 105th Congress, 1st session, § 1 (B) (1997).

236. The bill was introduced on March 4, 1997.

237. S.B. 511 § 1. Anyone who "intentionally, knowingly, or recklessly" clones a human being is guilty of a Class B felony. Id., § 2.

238. Cal. S.B. 1344 (introduced March 11, 1997).

239. This was introduced on March 4, 1997.

240. Fla. H.B. 1237 (introduced March 7, 1997).

241. 1997 Ill. H.B. 2235 § 5 (introduced March 10, 1997).

242. Id., § 10.

243. Id., § 5.

244. Md. H.J.R. 28 (introduced March 20, 1997).

245. Mo. H.B. 824 (introduced March 6, 1997).

246. N.J.A.B. 2849 § 1 (introduced March 24, 1997).

247. Id., § 2(b).

248. Id., § 2(c).

249. S.B. 2877 (introduced on February 26, 1997).

250. Id., § 4825.

251. Id., § 4826. Such actions are a Class D felony. Id., penal law § 125.70.

252. Id., Penal Law § 105.18. This is a Class B felony. Id.

253. Id., § 4827.

254. 1997 N.Y.A.B. 5383 (introduced March 4, 1997).

255. Ore. S.B. 1017 § 1 (introduced March 19, 1997).

256. Id., § 2.

257. S.C.H.B. 3617 § 16-17-45(A).

258. W.Va. S.B. 410 (introduced March 21, 1997).

259. U.S. Const. art. I, § 8, cl. 1.

260. U.S. Const. art. I, § 8, cl. 3.

261. See, e.g., 42 U.S.C.A. § 1395nn(b)(2)(B) (1995).

262. 45 C.F.R. § 46.201 et seq. (1996).

263. Transcript of Clinton remarks on cloning, U.S. Newswire, March 4, 1997.

264. U.S. Const., art. I, § 8 cl. 3.

265. *U.S. v. Lopez*, 115 S.Ct. 1624, 1630 (1995).

266. 42 U.S.C.A. § 274e (1991).

267. Human Research Subject Protections Act of 1997, S. 193 § 3(9) (1997).

268. *Carter v. Carter Coal Co.*, 298 U.S. 238 (1936) (holding provisions of the Bituminous Coal Act of 1935 regarding minimum wages, wage agreements, and collective bargaining unconstitutional on the basis that mining constituted "production," which is an "antecedent" of, not a part of, "commerce").

269. *U.S. v. Lopez*, 115 S.Ct. 1624 (1995).

270. 18 U.S.C. § 922 (q)(1)(A). The term "school zone" is defined as "in, or on the grounds of, a public, parochial or private school" or "within a distance of 1,000 feet from the grounds of a public, parochial or private school." 18 U.S.C. § 921(a)(25).

271. *Lopez*, 115 S.Ct., 1626.

272. U.S. Const., Art. I, § 8.

273. *Lopez*, 115 S.Ct., 1626 (citing The Federalist No. 45, pp. 292-293 [C. Rossiter ed. 1961)].

274. *Gregory v. Ashcroft*, 501 U.S. 452, 458 (1991).

275. 9 Wheat. 1, 189-90 (1924).

276. Id., 196.

277. *Lopez*, 115 S.Ct., 1628.

278. 301 U.S. 1 (1937).

279. Id., 37.

280. *Maryland v. Wirtz*, 392 U.S. 183, 197 n. 27 (1968).

281. 312 U.S. 100 (1941).

282. *U.S. v. Darby*, 312 U.S. 100, 118 (1941).

283. 452 U.S. 264 (1981).

284. 402 U.S. 146 (1971).

285. 379 U.S. 294 (1965).

286. 379 U.S. 241 (1964).

287. For example, in *Daniel v. Paul*, 395 U.S. 302 (1969), the U.S. Supreme Court held that an Arkansas amusement facility isolated on a country road nonetheless affects interstate commerce because a substantial portion of the food served at the snack bar (Id., 1701) moved in interstate commerce as well as the "sources of amusement" which included paddle boats leased from an Oklahoma company and a juke box which was manufactured out of state and played records manufactured out of state (Id., 1702).

288. 42 U.S.C.A. § 2000a (1994).

289. *Heart of Atlanta Motel, Inc. v. U.S.*, 379 U.S. 261 (1964).

290. Id., 358.

291. Id.

292. Id., 355-358.

293. *Lopez* 115 S.Ct., 1629-1630. In affirming regulation of activities that "substantially affect" interstate commerce, the Lopez court established that consistency with prior case law required a test that analyzed whether the regulated activity "substantially affects" interstate commerce as opposed to whether it "affects" interstate commerce.

294. *Lopez* 115 S.Ct., 1634.

295. Id., 1625, 1630-1641.

296. Id., 1640 (Kennedy, J., concurring).

297. Id., 1630-1631.

298. Id., 1631.

299. Merritt, D.J., Commerce!, *94 Mich. L. Rev.* 674, 696 (1995).

300. Id., 696.

301. Id.

302. *Lopez*, 115 S.Ct., 1631.

303. Id., 1632.

304. Merritt, supra note 299, 689 n. 65.

305. *Lopez,* 115 S.Ct., 640-641 (Kennedy, J., concurring).

306. Id., 1632.

307. Merritt, supra note 299, 701.

308. Id., 693 n. 74 (citing *U.S. v. Lopez,* 2 F.3d 1342, 1366 (5th Cir. 1993), aff'd., 115 S.Ct. 1624 (1995)).

309. Merritt, supra note 299, 703.

310. See for example, *NLRB v. Jones & Laughlin Steel Corp.,* 301 U.S. 1 (1937) (responding to severe worker dissatisfaction and a series of violent strikes) and *Perez v. U.S.*, 402 U.S. 146 (1971) (responding to the perception that organized crime was too far flung for state law to handle).

311. *Lopez,* 115 S.Ct., 1632.

312. Id.

313. Id.

314. Id.

315. Id.

316. This changed in 1957 in the landmark case, *Bing v. Thunig,* 163 N.Y.S. 2d 3, 143 N.E. 2d 3 (N.Y. 1957).

317. Wing, K.R., A.M. Silton, Constitutional authority for extending federal control over the delivery of health care, 57 *N.C. L. Rev.* 1423, 1470 (1979).

318. 29 U.S.C.A. § 203(S)(1)(B) (Supp. 1997) (establishing minimum wage and working condition requirements for certain defined employers engaged in interstate commerce).

319. 29 U.S.C.A. § 152(14) (Supp. 1997) (imposing collective bargaining requirements on employers engaged in interstate commerce).

320. 15 U.S.C.A. § 1 et seq. (1973).

321. 29 U.S.C.A. § 203(b) (1978) (FLSA); 29 U.S.C.A. § 152(b) (1973) (NLRA); 15 U.S.C.A. § 12 (Supp. 1996) (Sherman Act).

322. *Hospital Building Co. v. Trustees of Rex Hospital*, 425 U.S. 738 (1976) (holding that hospital had sufficient nexus with interstate commerce to invoke federal jurisdiction of Sherman Act). See also *Summit Health, Ltd. v. Pinhas*, 111 S.Ct. 366 (1991) (holding that jurisdictional elements of the Sherman Act were satisfied because ophthalmological services affect interstate commerce; because physicians and hospitals serve nonresident patients, they receive Medicare payments, and peer review proceedings routinely distributed across state lines affect doctors' employment opportunities throughout the Nation).

323. *National Organization of Women, Inc. v. Scheidler*, 510 U.S. 249, 114 S.Ct. 798, 803-806, 127 L.Ed.2d 99 (1994); *Wilson v. U.S.*, 73 F.3d 675 (7th Cir. 1995), cert. denied, 117 S.Ct. 47 (1996).

324. *Abbott v. Bragdon*, 912 F.Supp. 580 (D. Me. 1995), aff'd., 107 F.3d 934, 1997 WL 85096 (1st Cir. 1997); *U.S. v. Morvant*, 898 F.Supp. 1157 (E.D. La. 1995).

325. 42 U.S.C.A. § 12182(a) (1995).

326. 42 U.S.C.A. § 12181(7) (1995).

327. 912 F.Supp. 580 (D. Me. 1995), aff'd., ——F.3d ——, 1997 WL 85096 (1st Cir. 1997).

328. *Abbott v. Bragdon*, 912 F. Supp. 580, 593 (D. Me. 1995), aff'd., —— F.3d ——, 1997 WL 85096 (1st Cir. 1997).

329. Id.

330. Id., 594.

331. Wing and Silton, supra note 317, 1471.

332. 21 U.S.C.A. § 321 et seq. (1972).

333. 21 U.S.C.A. § 331 (1972).

334. *U.S. v. 62 Packages*, 48 F.Supp. 878 (W.D. Wisc. 1943).

335. See, e.g., M-D-D-I Reports, "The Gray Sheet" (March 17, 1997) (referring to lawsuit challenging FDA's policy on PET radiopharmaceuticals).

336. 192 F.Supp. 51 (E.D. Mich. 1961). See also *U.S. v. Undetermined Number of Unlabeled Cases*, 21 F.3d 1026 (10th Cir. 1994) (holding that urine and saliva specimen containers used in HIV-testing are subject to FDA regulation).

337. 39 Cases, 192 F.Supp., 52.

338. Id.

339. 42 U.S.C.A. § 262(a) (Supp. 1997).

340. The proposed Human Tissues Safety Act of 1996, S. 2195, would bring within FDA regulation "human tissue," which is defined as "a collection of similar human cells which is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of a disease or condition in a human or for reproduction." If the Food, Drug, and Cosmetic Act were amended to include the regulation of human tissue, it is likely that embryos that result from cloning would fall within the proposed definition of "human tissue."

341. Cal. Health & Safety Code § 121200 (1996).

342. Id.

343. Rivas, M.S., The California AIDS initiative and the Food and Drug Administration: Working at odds with each other?, 46 *Food Drug Cosm. Law J.* 107, 125 (1991).

344. Id.

345. 18 U.S.C.A. § 248 (1994).

346. 18 U.S.C.A. § 248(a)(1)(1994).

347. 18 U.S.C.A. § 248(a)(2)(1994).

348. 18 U.S.C.A. § 248(a)(3)(1994).

349. *U.S. v. Wilson*, 73 F.3d 675, 680 (7th Cir. 1995).

350. *Cheffer v. Reno*, 55 F.3d 1517, 1520 (11th Cir. 1995).

351. Id., 1520; Wilson 73 F.3d, 681.

352. Cheffer, 55 F.3d, 1520; Wilson, 73 F.3d, 681 (holding unique scarcity of certain reproductive health services necessitates substantial interstate travel).

353. Cheffer, 55 F.3d, 1520; Wilson, 73 F.3d, 682.

354. Cheffer, 55 F.3d, 1520; Wilson, 73 F.3d, 680-682.

355. 42 U.S.C.A. § 263a (Supp. 1996).

356. 138 Cong. Rec. H5349-01 (1992).

357. Id.

358. 42 U.S.C.A. § 263a-2(b) (Supp. 1996).

359. Cheffer, 55 F.3d, 1520.

360. Lopez, 115 S.Ct. 1629 (1995).

361. *U.S. v. Dinwiddie*, 76 F.3d 913, 919 (8th Cir. 1996), cert. denied, 117 S.Ct. 613 (1996). The court noted that "[s]ubstantial numbers of women travel across state lines to obtain reproductive-health services." Id. (citation omitted).

362. This estimate is from Dr. W. Bruce Currie, biologist at Cornell University. Begley, supra note 4.

363. *U.S. v. Robertson*, 514 U.S. 669 (1995).

364. A legislative assistant in Senator Glenn's office suggested that the national exchange of research results justifies Congress' authority under the commerce clause to regulate the use of human subjects in all research, including those projects that do not receive federal funding. See proposed Human Research Subject Protections Act of 1997, S. 193.

365. See Andrews, L., *Medical Genetics: A Legal Frontier*, Chicago: American Bar Foundation, 1987, chapter 3.

366. *Lopez*, 115 S.Ct., 1641 (Kennedy, J., concurring).

367. Some states have proposed laws, however. See, e.g., N.Y. S.B. 2877 (February 26, 1997); Al. S.B. 511 (March 4, 1997).

368. California S.J.R. (March 4, 1997).

369. Francione, G.L., Experimentation and the marketplace theory of the First Amendment, 136 *U. Pa. L. Rev.* 428-429 (1987).

370. One of the powers of the legislative branch under the patents and copyrights clause of the U.S. Constitution is [t]o promote the Progress of Science and useful Arts, by securing for limited times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries. U.S. Const. Art. I, § 8, cl. 8.

371. Coleman, supra note 117, 1386-1387.

372. Stolberg, supra note 49.

373. Sen. Tom Harkin, D-Iowa, today said that he is investigating President Clinton's authority to ban federal spending for human cloning research, *Congress Daily*, March 12, 1997.

374. Recer, supra note 103 (testimony of Senator Tom Harkin before the Senate hearings on cloning research on March 12, 1997).

375. Robertson, J., The scientist's right to research: A constitutional analysis, 51 *S. Cal. L. Rev.* 1203-1279, 1213 (1977). Robertson argues that the right to participate as a research subject is protected by the Fourteenth Amendment's right to privacy as recognized in *Roe v. Wade*, 410 U.S. 113 (1973). This right arises from an individual's privacy interest in autonomous decision-making concerning the use of his or her body in an experiment designed to further medical knowledge or to be of personal benefit. Id.

376. Id., 1212. Coleman argues that "[v]arious Supreme Court decisions, read together, seem to acknowledge a freedom to conduct research which is anchored in the freedom of speech." Coleman, supra note 117 (citations omitted). See also *Roth v. United States*, 354 U.S. 476, 484 (1957) (noting that the Continental Congress cited scientific advancement as a reason for protecting freedom of the press); see also *Sweezy v. New Hampshire*, 354 U.S. 234, 250 (1957) (noting that "[t]eachers and students must always remain free to inquire, to study and to evaluate, to gain new maturity and understanding; otherwise our civilization will stagnate and die.").

377. Robertson, supra note 375, 1204.

378. *Branzburg v. Hayes*, 408 U.S. 665, 705 (1972).

379. Coleman, supra note 117, 1338.

380. *Buckley v. Valeo*, 435 U.S. 765 (1978).

381. Branzburg, 408 U.S., 681-682.

382. 262 U.S. 390 (1923).

383. Id., 399.

384. *Henley v. Wise*, 303 F.Supp. 62 (N.D. Ind. 1969).

385. Id., 67.

386. Margaret S. I, 488 F.Supp. 181, 220-221 (E.D. La. 1980). See also *Margaret S. v. Treen*, 597 F.Supp. 636 (E.D. La. 1984), aff'd sub. nom *Margaret S. v. Edwards*, 794 F.2d 994 (5th Cir. 1986); *Wynn v. Scott*, 449 F.Supp. 1302, 1322 (N.D. Ill. 1978), aff'd sub nom., *Wynn v. Carey*, 599 F.2d 193 (7th Cir. 1979).

387. Robertson, supra note 375, 1212.

388. Id., 1253.

389. Id., 1254.

390. Id., 1256.

391. *U.S. v. O'Brien*, 391 U.S. 367, 376-377 (1968).

392. Id.

393. See, e.g., *Griswold v. Connecticut*, 381 U.S. 379 (1965); *Eisenstadt v. Baird*, 405 U.S. 438 (1972).

394. *Planned Parenthood v. Casey*, 505 U.S. 833, 112 S.Ct. 2791 (1992).

395. *Planned Parenthood v. Casey*, 505 U.S. 833, 112 S.Ct. 2791, 2810 (1992).

396. 405 U.S. 438 (1972).

397. *Eisenstadt v. Baird*, 405 U.S. 438, 453 (1972).

398. *Lifchez v. Hartigan*, 735 F.Supp. 1361 (N.D. Ill.), aff'd without opinion, sub nom., *Scholberg v. Lifchez*, 914 F.2d 260 (7th Cir. 1990), cert. denied, 111 S.Ct. 787 (1991).

399. 735 F. Supp. 1361 (N.D. Ill. 1990), aff'd without opinion, sub nom., *Scholberg v. Lifchez*, 914 F.2d 260 (7th Cir. 1990), cert. denied, 498 U.S. 1068 (1991).

400. Id., 1377 (citations omitted). The court also held that the statute was impermissibly vague because of its failure to define "experiment" or "therapeutic." Id., 1376.

401. Pizzulli, supra note 44, 550.

402. Robertson statement, supra note 33, 83. This seems to be a reversal of Robertson's earlier position that cloning "may deviate too far from prevailing conception of what is valuable about reproduction to count as a protected reproductive experience. At some point attempts to control the entire genome of a new person pass beyond the central experiences of identity and meaning that make reproduction a valued experience." Robertson, J., *Children of Choice: Freedom and the New Reproductive Technologies*, Princeton, NJ: Princeton University Press, 1994, 169.

403. Id.

404. Coleman, supra note 117.

405. Annas, G.J., Human cloning, *ABA Journal*, May 1997.

406. Annas, G., Scientific Discoveries and Cloning: Challenges for Public Policy, testimony before the Subcommittee on Public Health and Safety, Committee on Labor and Human Resources, United States Senate, March 12, 1977, 4.

407. See, e.g., *Griswold v. Connecticut*, 381 U.S. 479 (1965); *Eisenstadt v. Baird*, 405 U.S. 438 (1972); *Roe v. Wade*, 410 U.S. 113 (1973); *Planned Parenthood of Southern Pennsylvania v. Casey*, 505 U.S. 833 (1992).

408. See *Lifchez v. Hartigan*, 735 F.Supp. 1361 (N.D. Ill.), aff'd without opinion, sub nom. *Scholberg v. Lifchez*, 914 F.2d 260 (7th Cir. 1990), cert. denied, 498 U.S. 1068 (1991).

409. See the discussion of risks, supra in Part II.

410. Mauro, T., Sheep clone prompts U.S. panel review, *USA Today*, February 25, 1997, A1.

411. Pizzulli, supra note 44, 502

412. Id., 512.

413. Id.; see also, Amer, supra note 150.

414. Valerio Barrad, C.M., Comment, Genetic information and property theory, 87 *Nw. U. L. Rev.* 1037, 1050 (1993).

415. Id.

416. Id.

417. See Amer, supra note 150, 1669 n. 50; see also A wolf in sheep's cloning? Fantasies abound about what cloning animals means to the human race, *The Edmonton Journal*, March 2, 1997.

418. See Amer, supra note 150.

419. Pizzulli, supra note 44, 557. "[L]arge-scale cloning of a limited number of genotypes would decrease the adaptive potential of man." Id., 560.

420. Id., 559.

421. This useful term was introduced by Francis Pizzulli, supra note 44, 481.

422. Under the Thirteenth Amendment of the U.S. Constitution, "[n]either slavery nor involuntary servitude, except as punishment for crime whereof the party shall have been duly convicted, shall exist within the United States, or any place subject to their jurisdiction." U.S. Const. Amend. 13, § 1.

423. Pizzulli, supra note 44, 515.

424. Id., 517-522.

425. Id.

426. Tribe, supra note 132, 649.

427. Pizzulli, supra note 44, 583.

428. Id., 493.

429. Kluger, supra note 78, 70 (Varmus commenting that human cloning is repugnant to the American public).

430. Pizzulli, supra note 44, 525-527.

431. Id.

432. *Horst, Mayor, & Co., et al. v. Moses*, 48 Ala. 129, writ dismissed, 82 U.S. 389 (1872).

433. Pizzulli, supra note 44, 581.

434. Pizzulli poses a counter argument—"That granting a talented person the right to clone on the basis of his genetic constitution is based on a claim of personal merit, and that it does

not necessarily follow that he is being accorded preferential treatment on the basis of his ancestry." Id., 580 n. 503.

435. Id. If legislatures were to enact laws regarding who could be cloned, this would also likely run afoul of state constitutional provisions prohibiting special legislation.

436. Lest it be thought that an argument based the nobility clause is far-fetched, it should be noted that the nobility clause has been revitalized by recent scholarship applying it to issues of affirmative action and political activity. See, e.g., Lobsenz, J.E., Bakke, Lochner, and law school: The nobility clause versus a republican form of medicine, 32 *Me. L. Rev.* 1 (1980) and Eisgruber, C.L., Political limits and the powers of government, 44 *UCLA L. Rev.* 1297 (1994).

437. King, A.E., Solomon revisited: Assigning parenthood in the context of collaborative reproduction, 5 *UCLA Women's L.J.* 329 (1995).

438. See, e.g., Utah Code Ann. § 76-7-204 (1995).

439. See, e.g., In re Baby M., 537 A.2d 1227 (N.J. 1988).

440. See, Andrews, L.B., N.R. Elster, Legal issues in fertility management, in *Infertility in the Male*, 3rd ed., L.I. Lipshultz, S.S. Howards (eds.), St. Louis: Mosby Year Book, 1997, 476-484, 477.

441. Fla. Stat. Ann. § 742.14 (West Supp. 1997); N.D. Cent. Code § 14-18-04 (Michie 1991); Okla. Stat. Ann. tit. 10 § 555 (West Supp. 1997); Texas Family Code § 151.102 (1996); Va. Code Ann. § 20-158 (Michie 1995).

442. Ariz. Rev. Stat. Ann. § 25-218 (1991); Ark. Code Ann. § 9-10-201 (Michie 1993); D.C. Code Ann. § 16-401 et seq. (Supp. 1996); Fla. Stat. Ann. §§ 63.212, 742.15 (West 1985 and Supp. 1997); Ind. Code Ann. § 31-8-2-1 (West Supp. 1996); Iowa Code Ann. § 710.11 (West 1993); Ky. Rev. Stat. Ann. § 199.590 (Michie 1995); La. Rev. Stat. Ann. § 9:2713 (West 1991); Mich. Comp. Laws Ann. § 722.851 et seq. (West 1993); Neb. Rev. Stat. § 25-21-200 (1989); Nev. Rev. Stat. § 126.045 (Michie Supp. 1995); N.H. Rev. Stat. Ann. § 168-B:16 (1994); N.Y. Dom. Rel. Law § 121 et seq. (McKinney Supp. 1997); N.D. Cent. Code § 14-18-05 (1991); Tenn. Code Ann. § 36-1-102146 (1996); Utah Code Ann. § 76-7-204 (1995); Va. Code Ann. § 20-160 (Michie 1995); Wash. Rev. Code Ann. § 26.26.210 et seq. (West Supp. 19976); W. Va. Code § 48-4-16 (1996); Wisc. Stat. Ann. § 69.14(h) (West 1990); Wyo. Stat. Ann. § 35-1-410(d) (1997).

443. Ariz. Rev. Stat. Ann. § 25-218 (1991); Ark. Code Ann. § 9-10-201 (Michie 1993); Fla. Stat. Ann. § 742.16 (West Supp. 1997); Nev. Rev. Stat. Ann. § 126.045 (Michie 1995);

N.H. Rev. Stat. Ann. § 168-B:16 (1994); N.D. Cent. Code § 14-18-05 (1991); Utah Code Ann. § 76-7-204 (1995); Va. Code Ann. § 20-158(D) (Michie 1995).

444. See, e.g., Conn. Gen. Stat. § 45a-774 (1994); 750 ILCS 40/3 (1996) and Wash. Rev. Code § 26.26.050 (1996).

445. Fla. Stat. Ann. § 742.14 (West Supp. 1997); N.D. Cent. Code § 14-18-04(1) (1991); Okla. Stat. Ann. tit. 10 § 555 (West Supp. 1997); Va. Code Ann. § 20-156 (Michie 1995).

446. Texas Fam. Code Ann. § 151.102(a) (West 1996).

447. Fla. Stat. § 742.15 (West Supp. 1997).

448. N.H. Rev. Stat. Ann. § 168-B:17(I) (1994).

449. N.D. Cent. Code § 14-18-01 (1991).

450. N.D. Cent. Code § 14-18-03 (1991).

451. Va. Code Ann. § 20-169 (Michie 1995).

452. Fla. Stat. § 742.15(2) (West Supp. 1997).

453. N.H. Rev. Stat. Ann. § 168-B:17 (1995); Va. Code Ann. § 20-160 (Michie 1995).

454. Va. Code Ann. § 20-160 (Michie 1995) (emphasis added).

455. Cal. Fam. Code § 7610 (1994).

456. See, Cal. Fam. Code §§ 7550, 7650 (1994).

457. 19 Cal. Rptr. 2d 494 (1993).

458. Shultz, supra note 40, 332. Another legal commentator, also espousing an intent-based allocation of parenthood, articulates the value of such a private ordering approach to assigning roles in collaborative reproduction. She explains that:

> The benefits of private ordering in general, and in the context of collaborative reproduction in particular are many. Privatization of familial relationships advantages all members of the family; it protects the best interests of the child and furthers the adults' autonomy. Allocation of parental status by prebirth agreement clarifies adult-child relationships from the beginning of the child's life. It enables intending parents to

> exercise parental authority and receive legal recognition of their functional status throughout the course of the child's life. It provides certainty to the child and structure to the family. Moreover, it ensures that relationships within families of consent have been thought out and planned, through negotiation and compromise.

King, supra note 437.

459. Shultz, supra note 40, 370.

460. Va. Code Ann. § 20-160 (1996).

461. See discussion of specific states' approaches in Andrews, L.B., Alternative reproduction, in *Disputed Paternity Proceedings*, vol. 2, S.B. Schatkin (ed.), New York: Matthew Bender, 1990, § 30.02, 30-11.

462. Id., 30-11.

463. Id.

464. Id., 30-12.

465. D.C. Code § 16-2343.1(e) (1996).

466. Tenn. Code Ann. § 24-7-112 (1996).

467. Mich. Stat. Ann. § 25.496 (1996).

468. Miss. Code Ann. § 93-9-27 (1996).

469. See, e.g., Schiff, A.R., Solomonic decisions in egg donation: Unscrambling the legal conundrum of legal maternity, 80 *Iowa L. Rev.* 265, 267 (1995) (opining that the presumption would establish legal parenthood for a woman who gave birth using a donated egg in the context or currently used forms of collaborative reproduction).

470. These issues are discussed supra in Section IIIB.

471. Schatkin, S.B. (ed.), *Disputed Paternity Proceedings*, 4th ed., vol. 1, New York: Matthew Bender, 1990.

472. Faust, H., Challenging the paternity of children born during wedlock: An analysis of Pennsylvania law regarding the effects of the doctrines of presumption of legitimacy and

paternity by estoppel on the admissibility of blood tests to determine paternity, 100 *Dick. L. Rev.* 963, 964 (1996).

473. See, e.g., Cal. Fam. Code § 7610.

474. A third but unlikely scenario is possible which would occur when the egg cell of the intended mother is fused with the nucleic material of the gestator.

475. The law in Nevada is not applicable, though, because it specifically states that the egg and sperm must be from the intended parents, but in this scenario, there is no sperm contributed by the intended father.

476. A blood test could reveal that the intended father is the twin brother of the child. "In the analysis of a typical paternity case, exhibiting approximately 40 bands in the two DNA fingerprints of the child, there will be approximately 17 maternal specific bands, 17 paternal specific bands, and 6 to 8 bands shared between the mother and alleged father and/or the mother, child and alleged father." Schatkin, supra note 473, 118-131 (footnote omitted).

477. 897 P.2d 1356 (1994).

478. Id., 1361.

479. N.H. Rev. Stat. Ann. § 168-B:1 (1996).

480. See Andrews, L.B., *Medical Genetics: A Legal Frontier,* 1987, chapter 3.

481. For a discussion of the use of children as research subjects, see Glantz, L., The law of human experimentation with children, in *Children as Research Subjects: Science, Ethics, and Law,* M.A. Grodin, L.H. Glantz (eds.), New York: Oxford University Press, 1994, 122; Grodin, M.A., J.J. Alpert, Children as participants in research, *Pediatric Clinics of North America*, vol. 35, Philadelphia: W.B. Saunders Co., 1980, 1389-1401, 1390; Levine, R., Children as research subjects, in *Children and Health Care,* Kopelman, Moskop (eds.), Norwell, MA: Kluwer Academic Publishers, 1989; Levine, R., *Ethics and Regulation of Clinical Research,* Baltimore: Urban and Schwartzenberg, 1981, 156.

482. See, e.g., *Hart v. Brown*, 289 A.2d 386 (1972).

483. Brock, D.W., Ethical issues in exposing children to risks in research, in *Children as Research Subjects: Science, Ethics and Law,* M.A. Grodin, L.H. Glantz (eds.), New York: Oxford University Press, 1994, 81.

484. 45 C.F.R. § 46.116 (1996) (emphasis added).

485. 45 C.F.R. § 46.408 (1996).

486. Glantz, supra note 483, 104.

487. Id.

488. Andrews, L., *Medical Genetics: A Legal Frontier*, Chicago: American Bar Foundation, 1987, 44-45.

489. Rozovsky, F.A., *Consent to Treatment: A Practical Guide*, Boston: Little, Brown & Co., 1984, 540.

490. The difficulties with this, including its possible violation of the Thirteenth Amendment, are discussed in this paper supra, Part IX.

491. Andrews, supra note 490, 45.

492. *Nielsen v. Board of Regents*, Civ. No. 665-049 (Super. Ct. San Francisco, Cal. filed August 23, 1973).

493. Andrews, supra note 490, 45.

494. 321 U.S. 158 (1944).

495. Id., 170.

496. Rozovsky, supra note 491, 540.

497. Id.

498. Id., 541.

499. N.Y. Pub. Laws. Ann. § 2442 (McKinney's 1996); Va. Code Ann. § 32.1-162.18 (1996 Supp.).

500. 45 C.F.R. § 46.408 (1996).

501. Levine, supra note 483, 157.

502. Woody, Legal and ethical concepts involved in informed consent to human research, 18 *Cal. W. L. Rev.* 50, 63-64, 72 (1981).

503. Christoffel, T., *Health and the Law: A Handbook for Health Professionals,* New York: Free Press, 1982, 293.

504. Id.

505. 45 C.F.R. § 46.404; § 46.408 (1986).

506. 45 C.F.R. § 46.402(b) (1986).

507. 45 C.F.R. § 46.405 (1986).

508. 45 C.F.R. § 46.406 (1986).

509. 45 C.F.R. § 46.407(b) (experts from disciplines such as science, medicine, education, law, or ethics).

510. 45 C.F.R. § 46.407(b)(2)(ii) (1986).

511. Supra note 501 (N.Y. and Virginia).

512. Va. Code Ann. § 32.1-162.18 (1996 Supp.).

513. N.Y. Public Health Law § 2442 (McKinney 1985).

514. For a general discussion of such claims, see Andrews, L.B., Torts and the double helix: Legal and ethical issues raised by the Human Genome Project, 29 *Houston L. Rev.* 149, 155-157 (1992). It should also be noted that at least seven states (Indiana, Minnesota, Missouri, North Dakota, Pennsylvania, South Dakota, and Utah) have adopted statutes to prohibit an individual from bringing a wrongful life suit. Id., 160 n. 54.

515. *Curlender v. Bio-Science Lab.*, 165 Cal. Rptr. 477 (Ct. App. 1980).

516. Shaw, M., Conditional prospective rights of the fetus, 5 J. L. Med. 63, 99 (1984).

517. Id., 537l; see also Brodie, I., Clinton acts swiftly to avert abuse of breakthrough, *The Times,* February 26, 1997 (citing that the clone would have an action for wrongful life based on its denial of uniqueness).

518. Robertson, J., Genetic selection of offspring characteristics, 76 *B.U. L. Rev.* 421, 437 (1996).

519. Pizzulli, supra note 44, 541.

520. *Zepeda v. Zepeda*, 190 N.E.2d 849, 859 (Ill. App. Ct. 1963), cert. denied, 379 U.S. 945 (1964).

521. *Turpin v. Sortini*, 643 P.2d 954, 962-963 (Cal. 1982).

522. Pizzulli, supra note 44, 543 n. 320.

523. See in particular the discussion of the Louisiana and New Hampshire laws in Part IV, supra.

524. 42 U.S.C.A. § 263a-1 et seq. (Supp. 1996).

525. Safire, W., Clonalities, *The New York Times*, February 27, 1997, A23.

526. Transcript of President Clinton's remarks on cloning, U.S. Newswire, March 4, 1997.

527. These standards were suggested by George Annas in Senate testimony. Annas, G., Scientific Discoveries and Cloning: Challenges for Public Policy Testimony, before the Subcommittee on Labor and Human Resources, United States Senate, March 12, 1997, 8.