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REPRODUCTIVE GENETICS 1991-2002: A SELECTED ANNOTATED LEGAL BIBLIOGRAPHY OF GENETIC TESTING, GENE TRANSFER AND REPRODUCTIVE CLONING

GAIL H. JAVITT, J.D., M.P.H.*

I. GENETIC TESTING/PRENATAL OR PREIMPLANTATION SCREENING AND SELECTION/NEWBORN SCREENING

Lori B. Andrews, *Prenatal Screening and the Culture of Motherhood*, 47 HASTINGS L.J. 967 (1996).

In this article policy recommendations are made regarding the regulation of fetal cell sorting (FCS) (an investigational form of prenatal testing that is not yet available clinically). FCS involves testing circulating fetal cells found in maternal blood. It is less invasive and poses fewer risks than other methods of prenatal testing (e.g., chorionic villus sampling or amniocentesis). The author raises two concerns: (1) doctors may routinely perform genetic testing on fetal cells in maternal blood without prior consent; and (2) states may mandate FCS to test for genetic defects in the fetus. Since many of the defects that can be tested for cannot be treated, such policies may encourage termination of pregnancy. In addition, mandatory testing means that the woman is required to learn genetic information about herself (e.g., that she has the gene for Huntington's disease) that she might not wish to know. Genetic test results also may influence how a parent interacts with a child after birth, and may lead to discrimination in insurance coverage or employment, and stigmatization of those with genetic disability and those who choose not to terminate pregnancy.

The author advocates against mandatory use of FCS. She cites several legal arguments in support of this proposed policy. These are: (1) right of medical privacy –e.g., not to know information about oneself; (2) Fourth Amendment right against unlawful search and seizure; (3) right to bodily integrity; (4) reproductive autonomy; and (5) right to make parenting decisions. Against these she weighs the potential state interests in mandating testing, and concludes that they do not

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outweigh the strong reasons to insist upon only voluntary FCS following obtaining informed consent from the patient by the physician.

April L. Cherry, *A Feminist Understanding of Sex-Selective Abortion: Solely A Matter of Choice?* 10 WIS. WOMEN'S L.J. 161 (1995).

The author addresses the challenge that sex-selective abortion poses to traditional feminist thinking about abortion rights. Whereas traditional feminist arguments favor promoting a woman's right and autonomy to choose abortion, sex-selection exposes the weakness in choice arguments, because the impact of individual choice in this case may be to harm women as a class, if female fetuses are selectively aborted. The author contends that the arguments that support other reproductive rights, e.g., contraception and non-selective abortion, do not necessarily support sex-selection. Whereas other reproductive rights give women control over whether and when to have children, sex-selection gives men greater control over women's reproduction and the sexual composition of future generations, and increases the risks of harm (discrimination, subordination) to all women. Thus, instead of eliminating subordination, sex-selection increases social, economic, political and reproductive exploitation. The author concludes that state restrictions on the availability of fetal sex-selection are both legally permissible and morally justified.

The author reviews demographic and sociological data indicating that worldwide fewer girls are born than boys, and discusses cultural practices and beliefs in non-Western countries (e.g., female infanticide) that account for this. She discusses how demographic data shows that more males than females are born in Western countries as well. Although in the U.S. relatively few abortions appear to be performed for sex-selection, studies indicate Americans also have a strong preference for male children. Further, it is hard to know whether sex-selection is occurring since women do not have to disclose the reason for abortion.

The dangers of sex-selection are that it will create a demographic imbalance and lead to a targeting of women's reproduction as a means of gender demographic politics. Sex-selection also creates distributive concerns, as only wealthier women will have access to the technology, so that females that are born will be "poorer and darker," exacerbating class inequalities.

The author analyzes the constitutionality of sex-selective abortion restrictions in light of legal precedent concerning abortion. *Roe v. Wade* recognized a fundamental right to privacy that encompassed a woman's right to abort a pre-viable fetus free of interference from the state. In *Planned Parenthood v. Casey*, however, the Supreme Court abandoned the position that legislative interference was presumptively invalid, and held instead that a regulation is unconstitutional only if it places a substantial or undue burden on access to abortion services. The Court rejected the "trimester" system established by *Roe* and held that the state's interest in the fetus extends to the entire pregnancy. Thus the state may enact

measures designed to persuade a woman to choose childbirth over abortion, provided those measures are intended to help the woman make an informed choice, and not hinder her free choice.

The author considers whether it would be constitutional for the state to prohibit sex-selective abortion, either by restricting access to information that a woman can have about sex-selection or by restricting what she can do with that information. She concludes that a court would likely find, under the *Casey* analysis, that such restrictions would not unduly burden the decision to abort or hinder a woman's free choice in doing so. She notes that two states, Pennsylvania and Illinois, [as of 1995] prohibit the use of abortion for the purpose of sex-selection.

Ellen Wright Clayton, *Screening and Treatment of Newborns*, 29 HOUS. L. REV. 85 (1992).

The author addresses circumstances when newborn screening should be performed. She contends that traditional legal analysis does not give sufficient attention to the subjective experiences of families with genetic screening and counseling. She advocates for an interdisciplinary approach that includes empirical analysis in the formulation of legal rules. Using such an analysis, she argues that society should resist efforts to require that newborns be tested for an ever-increasing number of conditions. She states that newborn screening can cause psychological and other harm to infants and families, and can have adverse social and legal consequences. Therefore, society should screen neonates only when children can derive substantial benefit from early detection and legislatures should ensure parental participation in the screening process.

Dena S. Davis, *Genetic Dilemmas and the Child's Right to an Open Future*, 28 RUTGERS L.J. 549 (1997).

The author discusses three issues made possible by genetic testing that pit the autonomy of parents against the best interest of their present or future children. These are: (1) disabled parents who seek to ensure that their children share their disability; (2) predictive testing of children for adult-onset disorders; and (3) sex-selection. She argues that the traditional "welfare of the child" analysis is insufficient because the norms of non-directiveness will value parental autonomy over child welfare interests. She proposes, instead, a balancing approach that recognizes the child's "right to an open future." Using this balancing approach, health care providers should not participate in the first or third scenarios, and should be extremely wary of permitting the second. She advocates the development of codes by professional organizations to implement these positions.

The author refers to Joel Feinberg, who believes that the "child's right to an open future" encompasses rights held by adults but which must be protected during childhood so that they may be exercised in adulthood. For example, the right to

reproduce would preclude sterilization of a child since that would eliminate the possibility of reproduction as an adult.

The author first discusses the scenario of deaf parents deliberately creating a deaf child. She reviews the arguments of Deaf activists who assert that deafness is not a disability but a distinct culture, as well as data demonstrating economic and educational inequalities between deaf and hearing people. She concludes that whether construed as a disability or a culture, deliberately creating a deaf child restricts that child's life opportunities (socially, economically, and professionally) and therefore violates the child's right to an open future. The author concludes that genetic counselors should not assist in that endeavor.

The author then discusses testing children for adult-onset diseases. She points to the fact that only fifteen percent of adults at risk for Huntington's disease have chosen to be tested as evidence that there is no consensus whether or not it is better to have the information. Since adults are permitted to make the decision for themselves, parents should not remove the decision from children, as this would not respect the child's right to an open future. The author states that there is a growing consensus in the United States against offering such tests for children.

Finally, the author discusses pre-implantation sex-selection (leaving aside the difficult issue of termination). She concludes that sex-selection limits the child's right to an open future by promoting gender role stereotyping and encouraging parents to invest heavily in having children of a particular sex. This combination of investment and stereotyping will make it difficult for the child to grow and develop in ways that are different from, or in conflict with, parental expectations. Health care providers should therefore not assist in sex-selection, and should refrain from disclosing the gender of the fetus.

Cara Dunne & Catherine Warren, *Lethal Autonomy: The Malfunction of the Informed Consent Mechanism within the Context of Prenatal Diagnosis of Genetic Variants*, 14 ISSUES IN L. & MED. 165 (1998).

The authors challenge the current approach of genetic counselors advising expectant mothers about the potential genetic defects of their fetuses. They contend that genetic counselors are unduly negative in counseling concerning genetic diseases, and that decision-making is therefore not informed. Specifically, counselors do not provide those they are counseling with information about or access to individuals living with the particular disability (e.g., retinoblastoma), but rather focus on statistics concerning death and disability.

The authors advocate abolishing causes of action for wrongful birth and life suits against providers for failing to offer particular tests (e.g., amniocentesis). They argue that such causes of action fail for inability to demonstrate causation and also are counter to public policy. They also suggest bringing "wrongful termination" suits in which situation who have terminated pregnancies based on one-sided information, sue providers for failing to have communicated all material

information that would have affected their decision. Finally, the authors recommend that genetic counselors be required to undertake training in disability issues, and that support foundations be included in the counseling process.

Susan M. Faust, *Baby Girl or Baby Boy? Now You Can Choose: A Look at New Biology and No Law*, 10 ALB. L.J. SCI. & TECH. 281 (2000).

The author reviews the history of sex-selection, explores the consequences of using it, addresses legal concerns focusing on whether there is a need for regulations, and offers suggestions on how the legislature should proceed. The author argues for limited regulation of sex-selection technologies that would uphold procreative liberties and also protect consumers. These goals could be achieved by applying “intermediate scrutiny” to proposed regulations; this level of scrutiny is used for the protection of “quasi-fundamental” rights.

Many theories exist regarding the potential consequences of sex-selection technology. Historically, studies indicate a strong preference for male children, and therefore one major consequence could be a predominantly male population. Societal consequences of a male dominated society are wide-ranging and difficult to predict, but could be especially significant for women and the elderly. The cost of sex-selection may produce a surplus of men in the upper classes. There is evidence to suggest that male preference may be subsiding overall, but the desire for a first-born son remains. Currently, however, it seems unlikely that the sex ratio will be significantly altered, since the only reliable method is favorable to female pre-selection. Furthermore, only a minority of couples will actually use sex-selection.

Some oppose sex-selection because they believe it is one more step down the “slippery slope” of human genetic manipulation, which could allow parents to design their ideal child. Others believe sex-selection may impose unfair gender expectations on the child, with long-term psychological consequences. Long-term medical consequences are a concern as well. One potential advantage of sex-selection cited by the author is that better family planning may lead to happier families and children who are more loved by their parents.

Although sex-selection is not currently regulated in the U.S., the author examines whether the government can constitutionally do so. First, it must be established whether individuals have a fundamental right to choose the sex of their child. The Supreme Court has determined that there is a fundamental right to marital privacy, which includes the right to procreate free from “unjustified intrusion by the State.” Although this right is well-established, it is unclear whether the fundamental right to procreation would include the right to predetermine the sex of one’s child.

If the Court does decide that the right to select the sex of one’s child is fundamental, it must apply the test of “strict scrutiny” in order to regulate it. If this right is found to be non-fundamental, the Court would apply the less stringent

“rational basis” test, which requires that regulation be rationally related to legitimate government interests. In the author’s view, the Supreme Court is unlikely to define sex-selection as a fundamental right; however, since it does involve procreation, the author suggests it be deemed a “quasi-fundamental” right. In this case, “intermediate scrutiny” would be applied, which requires that the state pursue an “important” objective in its regulations.

The author reviews other countries’ approaches to sex-selection technology. The European Council and Germany have prohibited medically-assisted sex-selection except when it is necessary to avoid a serious hereditary sex-related disease. In Canada, professional ethics codes forbid sex-selection, though these codes are not legally enforceable.

The author concludes that the U.S. has three options for sex-selection regulation. First, the legislature could enact an absolute prohibition on sex-selection practices. Second, the legislature could limit the circumstances under which sex-selection may be used. Third, the legislature could choose not to regulate sex-selection at all. The author believes a compromise regulatory approach could be taken that would ensure certain standards are met by fertility clinics, while not unreasonably interfering with the individual’s right to choose the sex of his or her child. Regulations should be examined under “intermediate scrutiny.”

Anny Huang, *FDA Regulation of Genetic Testing: Institutional Reluctance and Public Guardianship*, 53 FOOD DRUG. L.J. 555 (1998).

The author addresses the inadequacy of current governmental oversight of commercialized genetic testing services. She reviews the potential regulatory actors and concludes that the Food and Drug Administration (FDA) is in the best position to regulate genetic testing.

The author notes that commercialization of genetic testing is a fairly recent phenomenon, but the presence of biotechnology companies in the genetic testing arena is growing rapidly as the technology develops.

The author describes the potential harm from genetic testing. She explains that when used to diagnose a symptomatic individual, there are few differences between genetic tests and other methods of diagnosis. Predictive testing, however, offers only estimates and probabilities of risk. These tests may be available before the validity and reliability of their predictive value has been established. Furthermore, the genetic tests are often developed for more dangerous and severe ailments, which means that there are rarely effective treatments, cures or means of prevention. The author states that learning a positive genetic test result can be psychologically devastating, disrupt family relations, affect life decisions (marriage and children), and define personal identity and status within the community, potentially leading to conditions of inequity and intolerance. There have even been reported cases of suicide by otherwise healthy individuals after

learning of their genetic test results. Genetic testing has already enabled employers and insurers to genetically discriminate against individuals, and has facilitated “wrongful birth” suits against physicians who incorrectly perform genetic tests.

The author describes the current state of government oversight, which is a patchwork of federal and state regulation. Genetic tests that are sold to laboratories as “kits,” as well as “analyte specific reagents” (ASRs), are regulated by the FDA as medical devices. As with other medical devices, test kits and ASRs are classified according to their level of risk, with the degree of regulation based on the classification level. The author believes that most genetic tests should be classified as “Class III” which is the most stringently regulated class of medical devices. Like other medical devices, test kits and ASRs also must comply with specified labeling requirements and good manufacturing practices (GMPs).

On the other hand, the FDA does not regulate genetic testing services provided by clinical laboratories, nor does any other entity currently require a demonstration of safety and effectiveness of testing services provided by clinical laboratories. Rather, only the technical competence of the laboratory’s testing is regulated under the Clinical Laboratory Improvement Amendments (CLIA). Under CLIA, the laboratory must demonstrate only that it produces accurate and reliable identification of the target information.

The author opines that the FDA might not be eager to regulate genetic testing as a result of previous accusations of paternalism and attempts to protect the public from too much self-knowledge, and from concern about encroaching on the “practice of medicine.” Furthermore, almost any guidelines it issues will prompt passionate objections and criticism. In addition, although it is fairly uncontroverted that the FDA has some jurisdiction to regulate genetic tests under the Medical Device Amendments to the Federal Food, Drug & Cosmetic Act (FDCA), the boundaries of this jurisdiction are uncertain. First, there is the question of whether regulation of genetic testing services meets the “interstate commerce” requirement that is a prerequisite to FDA jurisdiction. Under the interstate commerce clause of the U.S. Constitution, Congress has the power to regulate commerce among the states. The FDCA has been established as a constitutional exercise of this power. The author finds that when genetic testing samples or patients cross state lines, or when the company has clinics in several states, Congress clearly has the power to regulate under the Commerce Clause. The question remains as to whether Congress can regulate solely regional test centers and nonprofit organizations. Second, there is the question of whether Congress delegated jurisdiction to the FDA to regulate genetic testing services. The FDA has asserted authority to regulate some genetic testing products as medical devices. To support its authority, the FDA must identify a device and the presence of interstate commerce. To accomplish this, the FDA has several alternatives: (1) regulate materials shipped in interstate commerce from which the genetic test is assembled; (2) regulate the genetic test itself; or (3) some combination of the two.

The author states that even though most people agree that there should be some authority to determine whether a genetic test has positive predictive value for the disorder being tested, different types of settings for genetic tests may be more susceptible to causing harms than others. Genetic testing may occur in several different contexts: (1) as part of a research study; (2) following a request by a physician (e.g., a symptomatic individual, person with family history of genetic disease, or prenatal diagnosis); (3) direct consumer access to a laboratory; and (4) home test kits. The potential risks from genetic testing are: (1) misinformation; (2) insufficient or unreliable information; and (3) information with low predictive value. In addition, there is the concern of dangerous information. The author believes that the problems of misinformation and defective information are greatest where "commercial interest, puffery, ready access by the public, and lack of independent review converge." On the other hand, an administrative agency should not prevent consumers from obtaining reliable self-knowledge, as this is the equivalent of "social policy making." Thus, the author would defer to the legislative process rather than administrative review.

Of the potential federal agencies that could regulate genetic testing, which include the Centers for Disease Control and Prevention, the Center for Medicare and Medicaid Services, and the FDA, the author concludes that the FDA is the most appropriate body because it already has implemented regulations for genetic test kits, and the issues raised are similar to those raised by other FDA regulated products. The FDA therefore has the necessary institutional expertise, and creating a new agency would not increase efficiency.

Ruth Hubbard, *Predictive Genetics and the Construction of the Healthy III*, 27 SUFFOLK U. L. REV. 1209 (1993).

The author cautions against over-reliance on genetic information as a means of predicting health and illness. She argues that health and illness are not only biological phenomena but also social ones. While the function of a DNA segment may be predictable in a narrow way, e.g., in specifying the composition of a protein, knowing the composition or location of chromosomes does not specify the individual. She states: "[w]e are not the expression of our genes We are the expression of everything that goes on inside and around us from the moment each one of us is conceived, or even before." Predictive genetic tests cannot provide information about the severity of an illness, because of other biochemical and environmental factors that may be present. Moreover, predictive testing of a fetus cannot provide information about what kind of person that fetus will grow up to be or the significance of the mutation in the child's life or the life of those around him. How the child integrates into the family's life is dependent on factors external to the genetic information, but foreknowledge of a genetic problem may change the family's behavior from the outset. Those who know more about a

disability tend to be less likely to want a fetus tested or to terminate a pregnancy, because they realize the limitation of genetic “predictions.” She concludes :

To look at health and illness through the lens of genetics distorts our priorities by drawing attention away from the many biological, psychological, social, and economic factors that affect our health and play a part in generating disease or preventing its development Looking at our genes does not help to change these circumstances and may make things worse by making us fatalistic about our future health. Furthermore, genetic predictions of ill health create a new class of “patients” who are coming to be referred to as the asymptomatic or healthy ill....This kind of geneticization not only debilitates people by needlessly increasing dependence upon the scientific and medical professions but may get in the way of our family relationships and of our obtaining an education, a job, or health insurance.

Abby Lippman, *Prenatal Genetic Testing and Screening: Constructing Needs and Reinforcing Inequities*, 17 AM. J.L. AND MED. 15 (1991).

The author explores the social implications of the “geneticization” of disease as manifested by the emphasis on prenatal genetic testing, and in particular its implications for women. She defines “geneticization” as “an ongoing process by which differences between individuals are reduced to their DNA codes, with most disorders, behaviors, and physiological variations defined, at least in part, as genetic in origin.” It refers as well to “the process by which interventions employing genetic technologies are adopted to manage problems in health.” She states that this is a reductionist view, in which genetic determination is emphasized, and also one that promotes scientific control over the body. She urges a questioning of assumptions underlying the increased use of prenatal testing, and an examination of the societal implications.

The author focuses on prenatal diagnosis, which she terms a “ritual” of pregnancy, at least for white, middle-class women in North America, as a demonstration of geneticization, as it is “the most widespread application of genetic technology to humans today.” She states that the justifications offered by proponents of genetic testing are: (1) a public health rationale, (e.g., a way to reduce birth defects in the population); (2) reproductive autonomy (e.g., increasing women’s choices and control over reproduction); and (3) reassurance and avoidance of distress.

The author challenges these justifications, arguing that they are incomplete and not the only possible construction of the social impact of genetic testing. For example, while genetic testing increases “control,” whose control does it increase? It is not necessarily the woman’s, rather it could give others (e.g., insurance companies) more control to dictate certain actions based on the test results (e.g., termination). Furthermore, genetic testing is based on the rationale that “certain

fetal conditions are intrinsically not bearable.” She also contends that the “need” for genetic testing is socially constructed, and is based on the parameters of testing technology. This is reinforced by societal expectations of women to have healthy babies, and by our labeling of certain groups (e.g., women over 35). Thus our perception of what is an imperfect fetus, and therefore what can be terminated, is based on what is diagnosable at a given time and based on social expectations. Similarly, genetic testing allows science to define for society what is normal and abnormal, which will change as technology evolves. Additionally, she questions why “reassurance” is perceived as requiring the offering of genetic knowledge, as opposed to better nutrition, access to support services, assistance to care for a child with a disability, or medications to treat a genetic disorder.

Michael J. Malinowski & Robin J. R. Blatt, *Commercialization of Genetic Testing Services: The FDA, Market Forces, and Biological Tarot Cards*, 71 TUL. L. REV. 1211 (1997).

The authors advocate the development of regulatory safeguards for predictive genetic testing to ensure that it is used only when it carries scientifically valid predictive value, and in a context in which providers understand the technology’s limitations and provide accurate interpretation and counseling. They propose increased regulatory restrictions on the availability of genetic testing, in conjunction with more “gate-keeping” by physicians, through the development of professional standards. This keeps tests from being offered commercially before sufficient information about their positive predictive value is known. They also advocate more regulation of clinical laboratories and more attention to the role of institutional review boards (IRB) in developing genetic tests.

The authors state that the discovery of genetic alterations linked to health conditions often occurs before therapies have been developed for those conditions and also before the clinical significance of the alteration within an individual can be assessed. Nevertheless, there is a big push by commercial and academic genetic testing laboratories to offer genetic testing services to the public, with potentially harmful results. Offering these tests serves several functions: (1) generation of revenue to fund research and development; (2) amassing data regarding the predictive value of a test in the general population, leading to the ability to sell it in a noninvestigational context; (3) obtaining samples for gene sequencing; (4) accelerating development of more marketable diagnostics and therapeutics; and (5) increasing familiarity, acceptability, and demand for such tests among physicians and the public, so that they become part of the standard of medical care and are eligible for insurance coverage.

The authors identify the lack of federal regulation for genetic tests, and lack of physician knowledge about genetics and genetic testing (e.g., knowledge about how to interpret) as problematic. While the FDA regulates the production of reagents, probes, and test kits, the agency does not regulate reagents produced in-

house by labs (known as “home brews”). Also, while the Health Care Finance Administration [now CMS] oversees clinical laboratories under the Clinical Laboratories Improvement Amendments (CLIA), the oversight extends only to requiring labs to demonstrate the analytical validity of tests and components, not the clinical validity. Thus, there is no requirement that the test be shown to actually predict anything related to a patient’s health, only that it correctly identify the presence of a particular genetic sequence. According to the authors, oversight of genetic testing services is essentially left to market forces, legal liability, and the judgment of primary care physicians. Lack of FDA oversight also means the FDA does not regulate the marketing claims made by providers of the tests (e.g., in advertising). Given that the tests are subject to misinterpretation, ensuring the accuracy of information provided to consumers is critical.

Anthony S. Niedwiecki, *Science Fact or Science Fiction? The Implications of Court-Ordered Genetic Testing Under Rule 35*, 34 U.S.F. L. REV. 295 (2000).

The author discusses Federal Rule of Civil Procedure 35 (Rule 35), which permits court-ordered physical or psychological testing if “good cause” exists and if the person subject to the exam has put his or her condition “in controversy.” He examines the way in which courts have used Rule 35 to order genetic testing, and the ramifications of such orders. He compares court ordering of genetic tests to court-ordered HIV tests. The author proposes an analysis that courts should follow when ordering genetic tests.

Courts have ordered genetic tests in a variety of civil lawsuits, e.g., medical malpractice and claims of injury to a child because of exposure to chemicals during pregnancy. Defendants have wanted to show that the claimed injury resulted from a genetic disorder and not the alleged wrongdoing. Courts have reasoned that the intrusion of these tests is minimal, but have not taken into account possible privacy issues or psychological risks associated with genetic tests. The author argues that before courts order genetic tests, they should understand the types of tests available, how they work, and the types of information they produce.

The author states that the implications of a “positive” genetic test result vary widely depending on what is tested for. For example, a person who tests positive for Huntington’s disease will go on to develop the disease, but the test cannot predict when onset of the disease will begin or its duration (onset to death). In contrast, the genetic test for Alzheimer’s disease (ApoE) has very low predictive value. While people with two e4 alleles have an 8-10 times greater risk of developing Alzheimer’s, many people with those alleles do not develop it. Similarly, the BRCA genes are associated with increased risk of breast and ovarian cancer, but do not indicate if or when a cancer will develop. Nevertheless, a positive test result for all these tests will inform an individual of the likelihood that they will die without necessarily providing a remedy.

The author looks at court-ordered HIV testing and its implications for genetic testing. Some courts have ordered HIV testing when a plaintiff has sought future damages, on the theory that plaintiff raised the issue of future earning potential and HIV would lead to shortened life expectancy. Other courts have refused to do so, reasoning that the information was too attenuated to be relevant. HIV testing has also been ordered in child custody cases, and in cases where one party fears having been exposed. Some have argued that HIV should be treated differently from other communicable diseases (e.g., special protections such as anonymity) while others have argued it is no different from other communicable diseases. Similar views could be applied to genetic testing as well, depending on whether one thinks that genetic information is unique or similar to other medical information.

The author contends that every disease has some unique characteristics that make it distinct from other diseases, and therefore every test will provide a different type of information. Courts should examine the unique characteristics of each disease-test combination when considering the need for ordering a test under Rule 35, and consider both what information the specific test will produce and the potential consequences of the information, what the author terms an “examination of the examination.” This examination should consider the consequences of learning the results, e.g., learning that one has an incurable disease, the potential loss of insurance, potential for the DNA to be used in another context in the future, and the impact of the information on other family members. The risks of ordering testing should be weighed against the probative value of the information in a particular situation.

Vicki G. Norton, *Unnatural Selection: Nontherapeutic Preimplantation Genetic Screening and Proposed Regulation*, 41 UCLA L. REV. 1581 (1994).

The author addresses the potential for abuse of “preimplantation genetic screening” (PGS), e.g., its use for nontherapeutic, eugenic purposes. She states that current federal statutes and regulations do not apply to PGS, and state laws regulating fetal experimentation likely do not apply to the early embryo. She recommends that Congress and state legislatures should pass laws banning nontherapeutic PGS, and contends that such laws would be constitutional.

The author first describes the laboratory techniques involved in PGS. She then addresses whether “nontherapeutic” PGS should be regulated. She includes in the nontherapeutic category selection of embryos for cosmetic and performance traits, and selecting an embryo to help an existing child. While the high cost of PGS/IVF means that it is likely that the initial demand for the procedure will be small, costs may decrease over time, and interest may grow as more genes are identified.

The author identifies several ethical problems with nontherapeutic PGS, some of which are shared by prenatal testing and nontherapeutic selective abortion. These are: (1) potential for discrimination, e.g., based on gender or racial

characteristics; (2) parents viewing children as a means to an end rather than as an end in and of themselves, with the associated risk of exploitation of offspring, e.g. for financial gain; (3) misallocation of resources if parents who can have a healthy baby without PGS use the technique; (4) creation of a genetically elite class; (5) favoritism of a “selected” over a non-selected child; (6) backlash against therapeutic use of PGS; and (7) decrease in genetic diversity.

Jason Christopher Roberts, *Customizing Conception: A Survey of Preimplantation Diagnosis and the Resulting Social, Ethical, and Legal Dilemmas*, *DUKE L. & TECH. REV.* 12 (2002), at <http://www.law.edu/journals/dltr/articles/2002dltr0012.html>.

The author reviews ethical objections that have been raised regarding the use of preimplantation genetic diagnosis (PGD). These objections are related to concerns about: (1) the moral status of the embryo; (2) late-onset disorders, and the possibility that a cure may in the future be developed; (3) the effect on those with disabilities of screening out embryos with disabilities (e.g., message of inferiority); (4) gender discrimination and disrespect to embryos if PGD is done for sex-selection; and (5) use of PGD to select traits not related to specific illness or that involves complex behavior characteristics. The author concludes that policies are needed to ensure safety and appropriate use of PGD.

John A. Robertson, *Genetic Selection of Offspring Characteristics*, 76 *B.U. L. REV.* 421 (1996).

The author examines the issue of genetic selection of offspring characteristics. Using a reproductive rights framework, the author concludes that there is a presumptive right to select or shape offspring characteristics prior to birth, because the ability to make these decisions has a strong impact on the decision of whether or not to reproduce. This right encompasses the reproductive freedom and autonomy to select offspring characteristics as well as to refrain from selecting offspring characteristics. The state may interfere with procreative liberty only if it can demonstrate compelling, tangible harm to others. Such assertion of harm must be evaluated using “strict scrutiny”, and not simply a “rational-basis review”. With the possible exceptions of cloning and genetic diminishment, the author concludes that the state cannot prohibit pre-selection techniques because the potential assertions of harm are insufficient to outweigh individual procreative liberty interests.

The author states that the basis for asserting a rights claim for pre-birth selection derives from the recognized liberty interest in making decisions regarding reproduction. The right to choose whether or not to have offspring entails the right to information and technologies that facilitate having or not having a child in particular circumstances. The scope of the right depends on: (1) the centrality or materiality of the specific characteristic to the reproductive decision; and (2) the

nature, severity, and probability of the harms or untoward effects that flow from the selection efforts.

The author then examines the materiality of several different circumstances of prebirth selection: (1) avoidance of offspring with a disability; (2) late-onset genetic disease and susceptibility traits; (3) gender selection; (4) other nonmedical traits; (5) germ-line gene therapy; (6) nontherapeutic enhancement; and (7) cloning. He states that the “objective materiality of some traits to reproductive decisions will attenuate as we move from genes for severe genetic disease to susceptibility genes to genes for hair and eye color, and from negative to positive methods of selection...” He states that “...at some point the divergence from what most people view as central to reproductive meaning will diminish the perceived importance of the reproductive interest at stake, and indicate that selection on that basis should not be part of procreative liberty.” He concedes that drawing the line between protected and unprotected interests will be difficult.

The author next focuses on the potential harms from prebirth selection strategies. He concludes that preconception methods of selection do not present harms significant enough to justify state prohibition or restriction. In particular, carrier screening and sperm sorting do not present harms significant enough to warrant governmental restriction. With respect to prenatal diagnosis and abortion, he identifies discomfort with abortion for non-serious or non-medical reasons as stemming from “symbolic moral costs” of destroying potential life. These symbolic costs do not outweigh the right to make reproductive choices. Next he examines concerns arising from the discriminatory impact of prenatal selection. He distinguishes between state interference with prebirth decisions and state encouragement of certain practices. Regarding gender selection, he states that concerns regarding population imbalance may be sufficient to permit government limitations on the practice. But, he disagrees that gender selection is inherently discriminatory towards women. Addressing harms to children, he concludes that most efforts at prebirth selection will cause no harm to children.

Sonia Mateu Suter, *The Routinization of Prenatal Testing*, 28 AM. J.L. & MED. 233 (2002).

The author discusses the “routinization” of prenatal genetic testing, meaning the current state of prenatal medicine in which genetic testing has become commonplace. She states that this routinization is concerning because it has impoverished the informed consent process, undervalued the emotional and psychological ramifications of prenatal testing, and contributed to an inability to discuss the moral dimensions of reproductive technology. This routinization is in contrast to the adult-onset disease context, in which much more restraint and caution have been used. She argues that the same level of caution and restraint should apply in the context of prenatal genetic testing.

The author first reviews the history of genetic counseling for both prenatal testing and adult-onset disorders. Whereas specific guidelines and recommendations have been developed for adult-onset conditions, with the aim of addressing the potential for psychological harms and insurance/employment consequences, the same “healthy skepticism” has not emerged in the prenatal testing context.

The author next discusses the “routinization” of reproductive genetic testing. She states that prenatal screening (looking at high risk groups) has become the norm, and most women choose prenatal genetic testing when it is offered— those who reject it are asked “why not.” She posits several explanations for how this has come about. First is simply the availability of the technology. Second, the values underlying genetic counseling indirectly promote screening/testing, as do health professionals interested in finding out more about the condition of the pregnancy. While genetic counselors adhere to a code of “non-directiveness,” they focus on the value of choice which requires information, and have a preference for more information. As a group, they also favor testing for themselves. These values may unconsciously be transmitted to patients. Other health professionals tend to be directive by nature, and not able to understand that someone would reject additional information. Third, many patients undergo testing because of the belief that it is part of being a “good parent,” a belief reinforced by popular literature on pregnancy and by physicians themselves. Patients also pursue genetic testing for reassurance and a sense of control, which may include the desire for a “perfect” child and discomfort with disabilities or with the costs of raising a disabled child. Fourth, the law has influenced the routinization of testing with its requirement of informed consent and the liability risk to providers for failing to offer tests if parents subsequently have a child with a genetic defect.

The law has, in one instance, led directly to alteration in the standard of care. In the early 1980s, the American College of Obstetricians and Gynecologists (ACOG) recommended against routine screening of maternal serum AFP, arguing that it was of “uncertain value” because of the high false positive rate. ACOG stated it should not be routinely offered unless there were adequate safeguards. But, in 1985 ACOG reversed course based on liability concerns and stated that every patient should be advised of the availability of the test, which in practice has often meant persuasion to have the test.

The author then examines the societal costs of routinization. She states that the goal of promoting patient choice has become “more a hope than a reality,” because patients often feel they have no choice but to accept testing, because this is the societally-sanctioned action. Because of the absence of choice, patients are not prepared for the serious questions that may be presented by test results. The decision to test becomes divorced from considerations of these larger implications. In particular, the issue of pregnancy termination is rarely discussed before testing is conducted, nor is the possible trauma associated with therapeutic abortion, or the

anxiety associated with testing. The author asserts that providers' failure to "tie important considerations to the decision to begin prenatal testing is quite simply a failure of informed consent."

Routinization also obscures the moral dimensions of testing, including its implications for attitudes towards the disabled and the eugenic aspects of individual decisions to terminate a pregnancy, choices that may be societally determined. These issues are worthy of moral deliberation but this does not occur because testing has become routinized.

Patients should be urged to consider the difficult choices they may be faced with and the psychological ramifications and moral dimensions of these choices before testing is undertaken.

Suzanne P. Tomlinson, *Genetic Testing for Cystic Fibrosis: A Personal Perspective*, 11 HARV. J.L. & TECH 551 (1998).

The author, an attorney who has cystic fibrosis (CF), criticizes a 1997 National Institutes for Health Consensus Statement recommending that all pregnant couples or couples planning a pregnancy be tested for the gene that causes (CF). She raises the concern that testing will lead to a reduction of the number of individuals with CF and will undermine incentives to cure the disease. In addition, requiring that CF testing be offered may convey the message that it is unacceptable to bear a child with a preventable defect, thereby reducing parental choice rather than enhancing it.

The author raises several specific criticisms to the expert panel's recommendations: (1) while the panel phrased the goal of testing in terms of providing information to help people make informed decisions, the "true goal of reducing the number of affected births" was never stated; (2) the panel did not recommend newborn screening for CF, which it should have if the goal were to improve health outcomes of those affected with CF; (3) the panel discussed the cost-effectiveness of testing, e.g., of avoiding CF-affected offspring, undermining the claim that they were not encouraging selective termination or sending a negative message to those with CF; (4) the variable nature of the disease makes it impossible to know how severely someone with CF will be affected, so that some CF fetuses will be terminated even though they might not have been severely affected; and (5) some populations are at very low risk for CF, so that the clinical sensitivity in these populations is likely to be less precise, leading to a greater risk of uninformative testing and/or improper conclusions.

The author states that, to use CF testing in a responsible manner, health professionals and the public must be educated about the variable nature of the disease and the fact that new treatments are enabling those with CF to live longer, healthier lives. The decision to forego testing should remain a voluntary option. Those who choose not to terminate a CF pregnancy should be supported and not stigmatized.

Robert Wachbroit & David Wasserman, *Patient Autonomy and Value-Neutrality in Nondirective Genetic Counseling*, 6 STAN. L. & POL'Y REV. 103 (1995).

The authors argue that the commitment to non-directiveness by genetic counselors requires respect for patient autonomy but not value neutrality. While these two concepts are often linked, the authors argue that they are independent concerns. Whereas respect for autonomy requires the counselor to ensure that the patient's choices concerning genetic diagnoses are informed and voluntary and reflect the patient's own values and interests, value-neutrality serves as an undue constraint on the counselor's interaction with the patient, and impedes the goal of ensuring voluntary, informed choices.

The authors review arguments that have been made in favor of value neutrality. These are that: (1) it is necessary to avoid the taint of eugenics; (2) it is required by respect for autonomy, since (a) the counselor's value judgments would enjoy spurious scientific authority, (b) the expression of values could lead to coercive actions, (c) the autonomy of patients seeking genetic testing is particularly fragile, and (d) the social pressure on these patients is particularly great.

The authors offer arguments refuting all of these claims. Further, they contend that value neutrality is impossible, since both autonomy and promoting genetic testing reflect underlying values.

The authors argue that it is difficult to know how to best respect a patient's autonomy in an individual case, since the influences on that person will vary. The inability to express the counselor's values or to explore with the patient the basis for the patient's preferences will hinder the process of helping the patient make an informed, voluntary choice.

II. GENETIC MODIFICATION/ENHANCEMENT

George J. Annas, *The Man on the Moon, Immortality, and Other Millennial Myths: The Prospects and Perils of Human Genetic Engineering*, 49 EMORY L.J. 753 (2000).

The author advocates a moratorium on at least some human gene transfer experiments and an international treaty banning specific "species-altering" techniques and species-endangering experiments. He states that unauthorized species-altering research, such as xenotransplantation, embryo research, and artificial organs, are "crimes against humanity" and "terrorist acts" if they are conducted in the absence of a democratically authorized social warrant.

The author argues that altering human nature undermines both human dignity and human rights, and ultimately destroys the fundamental belief in human equality. The author explains that Homo sapiens could develop into two species: (1) the standard-issue human beings, who would be seen as savages to be

slaughtered and subjugated; and (2) the new, genetically-enhanced neo-humans. The author states that human dignity and equality are likely to be protected only if science is accountable to democratic institutions, and is “transparent enough so that international deliberation can take place before irrevocable species threatening experiments are conducted.” He advocates building international institutions as sturdy as the United Nations and the proposed International Criminal Court to protect human rights.

The author warns that without oversight, the market will define what it means to be a “better” human. Of additional concern is the fact that biotechnology corporations, which have eternal life, limited liability, and no allegiance to any government, are leading the way to “better” humans. He warns that one should look beyond the stated motives for exploration, whether outward-looking (e.g., space) or inward-looking (e.g., genetics). The author suggests that professionals in law and medicine should work together to enhance human rights and health. Furthermore, non-governmental organizations (NGOs) must play a more central role in world affairs in order to prevent commercial interests from being the primary motive for science and experimentation. The author believes that an international movement will be stronger if rooted in human rights, rather than medical ethics.

Roberta M. Berry, *Genetic Enhancement in the Twenty-First Century: Three Problems in Legal Imagining*, 34 WAKE FOREST L. REV. 715 (1999).

The author proposes that we use “legal imagining” to both advance our understanding of the issues surrounding genetic enhancement and to agree upon the appropriate method for resolving the ethical, legal, and public policy issues. Legal imagining examines hypothetical problems from the lawyer’s perspective. The author states that it is very important to choose the appropriate method for analyzing the issues because once chosen, there are only a limited range of persuasive arguments and potential resolutions.

The author posits a future world in which gene therapy and genetic enhancement are commonplace. She presents scenarios that raise questions relating to injuries to offspring from genetic enhancement and the liability implications of such harms, resentment by enhanced offspring for having been enhanced, and athletic competition between the genetically enhanced and the unenhanced.

The author concludes that any choice-worthy methodology must consider the following three concerns: (1) safeguarding the best interests of children; (2) the motivation for genetic enhancement and potential harms; and (3) the implications of genetically upgrading offspring in pursuit of a competitive edge. The author warns that “once humankind is put in play, the world around us can change quickly and dramatically, in ways very hard to predict or control, and for good.”

Therefore, we must analyze genetic enhancement through a method that permits us to imagine such a world and cope with the unimaginable consequences.

Judith A. Cregan, *Light, Fast, and Flexible: A New Approach to Regulation of Human Gene Therapy*, 32 MCGEORGE L. REV. 261 (2000).

The author identifies problems in the current regulation of human gene therapy, and suggests five possible regulatory changes to address them. The author discusses the role of the National Institutes of Health (NIH) and the Food and Drug Administration (FDA) in overseeing gene therapy research. She also describes the role of tort law, specifically the tort of failure to provide informed consent and the theory of strict product liability.

The author states that the two significant problems facing the public in gene therapy clinical trials are: (1) lack of informed consent and researcher conflicts of interest; and (2) potential for public availability of confidential patient information. There are additional concerns with the agencies that regulate gene therapy trials: (1) inadequate researcher compliance in reporting adverse events in clinical trials; (2) unsuccessful oversight of the informed consent process; and (3) lack of resources or jurisdiction to effectively police rapidly changing clinical trials. Furthermore, an overlap in jurisdiction between the FDA and the Recombinant DNA Advisory Committee (RAC) of the NIH has fueled confusion and an interagency rivalry. Finally, there is a tension between the gene therapy industry's need to protect and capitalize upon proprietary information and the government's need for this information to be included in adverse event reports to the FDA and NIH in order to protect patients.

The author suggests that, rather than attempting to regulate gene therapy within the existing regulatory framework, we ask what regulatory framework would work best now. She states that the following are requirements for the new regulatory structure: (1) scientific expertise that paces the industry; (2) authority to make and enforce regulations; (3) flexibility to accommodate extremely rapid technological innovations; (4) input on regulations from persons with backgrounds in ethics, law, public policy, and public health to provide a balanced viewpoint; and (5) the ability to share scientific innovation while protecting proprietary information.

The author makes five specific proposals for regulatory change. These are: (1) the establishment of a standing Senate Subcommittee for biotechnology issues under the Senate Committee for Health, Education, Labor, and Pension; (2) moving the RAC under the Office of the Secretary of Department of Health and Human Services, with the authority to direct both the FDA and NIH regarding biotechnology issues; (3) increasing FDA resources for monitoring and enforcing biotechnology regulation; (4) establishing FDA regulations to mandate the appointment of independent patient advocates for patients considering participation

in gene therapy clinical trials; and (5) the enactment of a federal law prohibiting strict products liability for design defects in gene therapy products.

Leon R. Kass, *Triumph or Tragedy? The Moral Meaning of Genetic Technology*, 45 AM. J. JURIS. 1 (2000).

The author articulates four of his concerns about the flood of genetic technologies and the power they increasingly wield over humanity. He does not focus on specific technologies, but rather considers “the moral meaning of the entire enterprise.”

The author begins by defining what is different about genetic technology, compared to conventional medicine. First, genetic engineering makes changes that are transmissible to succeeding generations, and may even be used in the future to intentionally alter offspring through germ-line gene therapy. Secondly, genetic technology, in addition to being used therapeutically, may also be used for enhancement purposes, creating the possibility of new human capacities. The paradox, therefore, is that the current uses of genetic technology in medicine are familiar and noble, but genetic technology’s inherent differences could ultimately be used for unsettling purposes.

Second, the author raises the question of how much genetic self-knowledge is good for us.

The deepest problem connected with learning your own genetic sins and unhealthy predispositions is neither the threat to confidentiality and privacy nor the risk of so-called genetic discrimination in employment [sic] of insurance . . . it is, rather, the various hazards and deformations in living your life that will attach to knowing in advance your likely or possible medical future.

Having knowledge of one’s genetic predispositions may be even harder when the information provided by a test is less certain. The author considers with gravity “the threat that excessive genetic foreknowledge poses to human freedom and spontaneity,” and argues that we should never “violate the right to that ignorance which is a condition for the possibility of authentic action.”

Third, the author considers the power that scientists, geneticists, and the government may exert as a result of their expertise in these technologies. The author dismisses the claims that the technologies they are developing are neutral, and emphasizes the coercion and loss of freedom that will be experienced by most people as a result. “[I]f any one age really attains, by eugenics and scientific education, the power to make its descendants what it pleases, all men who live after it are the patients of that power.”

Finally, the author focuses on the concerns about human dignity. He emphasizes that genetic technology and scientific teachings about human life are not morally and humanly neutral, but rather, are “pregnant with their own moral meaning.” He breaks down the assault on human dignity into four aspects. First,

using new genetic therapies is frequently called “playing God.” “Determining who shall live and who shall die—on the basis of genetic merit—is a godlike power already wielded by genetic medicine.” Second, turning procreation into a laboratory process may lead to the manufacture and commodification of children, whose genetic traits can be selected for and manipulated. Third, the author posits that the standard of health is being deconstructed by new genetic technology, making it difficult to define what is normal and healthy, causing problematic medicalization of traits, and obscuring the meaning of enhancement. Most scientists will say that their goal is merely the reduction of pain and suffering, but the author believes they have an underlying motive: “Hidden in all this avoidance of evil is nothing less than the quasi-messianic goal of a painless, suffering-free, and, finally, immortal existence.” Finally, the author suggests that if we succeed at obtaining mastery over our genes, it may end in tragedy for the human race, in the form of an undermining of our self-conception as “free, thoughtful, and responsible beings.”

Angela Liang, *Gene Therapy: Legal and Ethical Issues for Pregnant Women*, 47 CLEV. ST. L. REV. 61 (1999).

The author addresses whether a pregnant woman could, legally or ethically, be forced to undergo gene therapy for the benefit of a fetus she is carrying, if such technology were feasible. She concludes that courts should not impose gene therapy on pregnant women.

The author reviews state case law concerning maternal refusal of treatment in the context of unborn and born children. Courts generally consider four state interests when they determine whether to override competent medical treatment decisions: preserving life; preventing suicide; maintaining the ethical integrity of the medical profession; and protecting third parties. Not all of these interests are directly applicable to *in utero* gene therapy. The courts may also take into account the manner in which a court order may be enforced. Most courts will not override a pregnant woman’s refusal of medical treatment needed solely for the benefit of her fetus. The fetus cannot have rights superior to those of its mother, because the law will not treat the fetus as a separate entity. However, it may be acceptable, where a balancing test is properly used, to compel a pregnant woman to undergo a medical procedure against her will. Such cases have previously involved life-threatening decisions late in pregnancy.

The author presents three reasons not to mandate *in utero* gene therapy. First, a policy that mandates gene therapy would place an undue burden on pregnant women and violate the Equal Protection Clause of the Fourteenth Amendment. Being forced to undergo an intrusive medical procedure would violate the woman’s right to bodily integrity. Furthermore, the Pregnancy Discrimination Act declares that discrimination because of pregnancy is essentially sex discrimination. Second, mandatory *in utero* gene therapy may have a disproportionately

discriminatory effect on women and minorities, as eugenics programs have historically done. Conversely, discrimination may occur against those of lower socio-economic status, who are unable to afford gene therapy procedures. Third, from a public policy standpoint, it will be impossible to determine which "abnormalities" should be "fixed." Concepts of quality of life and suffering are subjective. Additionally, there is a gray area in what is considered a "disability," and it will become increasingly difficult to distinguish between gene therapy and genetic enhancement. For all these reasons, parents must retain the decisional autonomy in determining whether *in utero* gene therapy on a fetus is appropriate or desirable.

Maxwell J. Mehlman, *The Law of Above Averages: Leveling the New Genetic Enhancement Playing Field*, 85 IOWA L. REV. 517 (2000).

The author explores two potential negative consequences of genetic enhancement: (1) an increase in social inequality; and (2) competition for scarce resources between the enhanced and unenhanced. He makes several recommendations to mitigate these consequences.

The author defines genetic enhancement as a genetic intervention that: (1) is "undertaken for the purpose of improving a characteristic or capability that, but for the enhancement, would lie within what is generally accepted as a 'normal' range for humans," or (2) "installs a characteristic or capability that is not normally present in humans." The author's definition encompasses: (1) somatic enhancements in adults and children; (2) pre-conception enhancement; (3) selective abortion; (4) embryo selection; and (5) germ-line enhancement. He also includes DNA recombination to make pharmacological products (e.g., rDNA-derived human growth hormone).

The author contends that the inequality and unfairness issues presented by genetic enhancement may be unprecedented. This is because of: (1) the likely cost of enhancement; (2) the technology's ability to alter traits that are currently unalterable, such as intelligence, charisma etc.; (3) its ability to alter traits is more powerful and more long-lasting, and it may permit wholesale, rather than particularistic, alterations; and (4) some traits may be passed on to future generations, creating a genetic aristocracy (or "genobility") or even a "master race."

The author makes several proposals to mitigate the inequality and unfairness of genetic enhancement. First, addressing inequality, he suggests implementing a system of licensing for enhancements, whereby licenses are granted under the condition that enhanced people employ their abilities in a pre-defined, socially beneficial manner. Failure to live up to the terms of the license would lead to loss of access to the enhancements or their benefits. Other penalties would be imposed for misuse of the enhancements. Enhancements would be genetically "tagged" to distinguish them from unlicensed "black market" enhancements. Second, he

suggests an enhancement “lottery,” in which everyone would be entered into a lottery, and the winners would be entitled to resources to purchase the maximum package of enhancements available in the private market. To qualify, they would have to become licensed. Third, he suggests a ban on germ-line enhancement. Addressing unfairness specifically, he discusses the possibilities of “leveling up” or “leveling down.” The former would entail giving at least some of those who were not genetically enhanced some countervailing benefit, such as money or another desirable resource. It could also take the form of laws akin to antidiscrimination laws so that the unenhanced had equal access to employment. The latter would entail preventing enhanced people from taking advantage of their enhancements when competing with the unenhanced. For example, the enhanced might be required to disclose the fact of their enhancement or information gained as a result of the enhancement. Society could also prohibit non-beneficial interactions, such as those in which enhanced athletes compete against the unenhanced.

The author responds to potential challenges that the proposals would constitute significant infringements on liberty and privacy by stating that these costs are better than the alternatives in which a “struggling genetic underclass” is “locked into subservience by a ruling, self-perpetuating, genetic aristocracy” or a “prolonged period in which the promise of genetic advances is lost amid mounting social chaos.”

Emily Marden & Dorothy Nelkin, *Displaced Agendas: Current Regulatory Strategies for Germline Gene Therapy*, 45 MCGILL L.J. 461 (2000).

The authors argue that current regulatory processes in place to address concerns over germ-line gene therapy focus on clinical efficacy and risk, while neglecting social and ethical concerns. The authors advocate for the development of new forums for public debate, in order that society may become aware of and able to participate in discussions regarding the bioethical concerns of germ-line gene therapy.

The authors identify three motivations that drive the interest in germ-line gene therapy: (1) scientific hubris; (2) commercial interests; and (3) media hype. First, scientists often make exaggerated claims that their discoveries will cure diseases and revolutionize medicine. This hubris drives an unrealistic optimism, misleads the public, and makes thoughtful ethical debate difficult. Secondly, commercial interests promote new developments like germ-line gene therapy, and this also precludes consideration of whether they should be used. Thirdly, the media tends to amplify the hype over new technology. These three factors together push acceptance of new technology, without consideration of the associated social and ethical concerns.

The author states that germ-line gene therapy poses many social and ethical concerns. First, there are the long-term safety issues, which may not be known for

many years. Second, the impact on future generations, who are obviously unable to consent to therapy, is grave. Third, germ-line gene therapy “represents an addiction to the notion of progress.” Preimplantation genetic diagnosis already accomplishes what germ-line gene therapy would seek to do— it is not really necessary, given that viable alternatives already exist.

The authors argue that existing regulation is not adequate to meet the challenges posed by the new technology. Neither the Food and Drug Administration nor the National Institutes of Health, the two most obvious regulatory bodies, is equipped to address social and ethical aspects of new developments. In contrast, Europe addresses germ-line gene therapy as a social and ethical issue through the broader framework of international human rights law. A 22-nation convention has ruled out any uses of germ-line gene therapy, while allowing genetic manipulation for the purposes of prevention, diagnosis, or therapy.

Joseph M. Rainsbury, *Biotechnology on the RAC – FDA/NIH Regulation of Human Gene Therapy*, 55 FOOD & DRUG L.J. 575 (2000).

The author describes the historical development of federal oversight of gene therapy, and discusses whether this history can provide a model for regulating other controversial emergent biotechnologies. He concludes that federal oversight of human gene therapy clinical trials has been a “regulatory success story,” and that the National Institutes of Health Recombinant DNA Advisory Committee (RAC) has been a key component of this success, by providing an open forum for intelligent deliberation about the risks and benefits of gene therapy. The author concludes “although the RAC provides an excellent institutional model for quelling irrational fears about misunderstood technologies, it may not be robust enough to shepherd the more socially divisive medical innovations from the laboratory to the clinic.”

III. CLONING

Mona S. Amer, *Breaking the Mold: Human Embryo Cloning and Its Implications for a Right to Individuality*, 43 UCLA L. REV. 1659 (1996).

The author addresses legal issues arising from the technique of “blastomere separation.” The author considers whether children created from this procedure have property rights over the other cloned embryos by virtue of their shared genetic identity and whether these rights could permit them to prevent the use of the remaining cloned embryos. She concludes that children created through this procedure do have property rights in their DNA code, and that these rights should permit the exclusion of others from using the remaining cloned embryos to produce additional children.

Blastomere separation permits separating an embryo at the blastomere stage in order to produce several genetically identical embryos. It is essentially a technique for cloning. It has been used for many years in cattle, but research in humans in the early 1990s by researchers at George Washington University was discontinued following objections by scientists and ethicists.

The author examines whether property rights exist in a cloned embryo by a person with identical DNA using the traditional indicia of a property right, which are the rights to possess, control, exclude others from, dispose of, receive profits from, and destroy the object at issue. While property rights ordinarily may exist in DNA under this framework, when applied to a first-born child seeking to exert a property right over frozen cloned embryos, they would seem to preclude such an assertion, since the embryos are not within the control of the first-born. In other words, the DNA no longer has the incidents of property. The author finds this result dissatisfying, however, since it seems that science dictates when DNA is and is not property.

The author seeks other ways by which a right to exclude others from use of cloned embryos could be asserted. She examines whether the DNA could be considered to be a body part of that person. In *Moore v. Regents of the University of California*, the court held that the plaintiff did not maintain a property interest in cells removed from his body and used to develop a cancer cell line. The court reasoned that (1) the proteins produced by the cells do not vary from one person to the next; and (2) the scientists added value to the cells to make them patentable, such that the cell line differed from the original cells. The author seeks to distinguish *Moore* from the cloned embryo situation. First, the DNA in the cloned embryo is distinct from the general population, and second, no additional alterations are performed by the scientists such that the DNA differs from that of the first child. Also, while the court in *Moore* seemed concerned with not hindering scientific advance, prohibiting the implantation of a cloned embryo would not appear to do so.

The author then explores underlying values that are threatened by permitting use of cloned embryos. She argues that human dignity could be reduced when clones of existing people are created. Individuals may view themselves as commodified and as having less worth. Society may similarly view them as having less value. The law currently recognizes an individual's interest in protecting his/her identity and in individuality. The right of publicity, which prohibits unauthorized appropriations of a persons' name, face, voice, or other characteristics, embodies the societal interest in individuality. The author contrasts identical twins from a later born clone and argues that the latter raises concerns not present in the former circumstance. She argues that the right to individuality is more significant than a parent's right to procreate and that, moreover, courts have recognized that when there is a dispute between co-owners of embryos, the right of

the person who does not want to use the embryos for procreation is greater than the right of the person who does (e.g., *Davis v. Davis*).

Lori B. Andrews, *Is There a Right to Clone? Constitutional Challenges to Bans on Human Cloning*, 11 HARV. J.L. & TECH. 643 (1998).

The author analyzes whether a federal ban on reproductive cloning would violate the U.S. Constitution. Specifically, she addresses whether such a ban would: (1) infringe on scientists' right to scientific inquiry; (2) violate the right to privacy or the liberty interest in making reproductive decisions; or (3) exceed the federal spending power or the federal power to regulate interstate commerce. The author concludes that human cloning could permissibly be restricted based on compelling potential harms to the clone or to society as a whole.

The author first reviews the potential negative physical and psychological harms to the cloned human, as well as the potential negative societal impacts of cloning. She then reviews federal and state efforts to regulate human cloning.

Concerning the question of infringement on the constitutional right of scientific inquiry, she states that the United States has historically protected scientific inquiry because of the great social import placed upon knowledge and intellectual freedom. Support for this right may be derived from the Fourteenth Amendment right to personal liberty and the First Amendment right to free speech. But, cloning is sufficiently analogous to embryo research—for which restrictions have been upheld—so that restrictions placed upon it should likewise not be considered protected by a right of scientific inquiry. Even if human cloning research were protected by the Constitution, the government may regulate the researcher's methods in order to protect the rights of research subjects and community safety.

Concerning the right to make reproductive decisions, the author identifies the rights that have been recognized relating to procreation and contraception, but finds that cloning is too qualitatively different from normal reproduction and assisted reproduction to assume the same constitutional protections apply. Furthermore, even if a court were to recognize a constitutional right to clone, legislation infringing upon this right would be permissible if it were narrowly tailored to further a compelling state interest. She identifies several such interests, including the potential physical and psychological risks of cloning, the interest in preserving genetic diversity, and the potential for creating "genetic bondage" in contravention of the Thirteenth Amendment prohibition of slavery. The author disagrees with those who say the potential psychological and social harms from cloning are too speculative to permit a government ban against cloning. She analogizes cloning to incest, and argues that both may be banned because they permit an exercise of excessive power of parents over children.

Finally, the author argues that federal regulation of cloning is constitutionally permitted through the spending power and the power to regulate interstate

commerce. The author argues that case law would support a view of cloning as a form of commerce and that such activity would affect interstate commerce. Furthermore, cloning is not traditionally an area of state regulation, and few states have regulated the conduct of human research.

George J. Annas, *Human Cloning: A Choice or an Echo?* 23 U. DAYTON L. REV. 247 (1998).

The author discusses the subject of choice within the context of cloning, and concludes that choice is an insufficient rationale for cloning. "Duplicating yourself is sterile, self-absorbed, and ultimately destructive. Moreover, creating a clone in your own image is to curse your child by condemning it to be only an echo." Cloning is a crime against the clone because it deprives the clone of authentic growth and the right to ignorance about its future. It is hypocritical to argue that cloning, which limits the liberty and choice of the clone, can be justified on the basis that cloning expands the liberty and choices of cloners. All human children deserve "the right to live an uncharted life, a life filled with choices they must make themselves, not choices forced on them by another's fixation on duplicating or copying parts of an already-lived life."

The author urges enactment of a federal statute prohibiting commerce in human embryos. He opposes a "market model" of regulation, because the market ideology is profit maximization. Professional standards would be appropriate if they were meaningful, but fertility specialists have bypassed the research phase and proceeded directly to clinical practice. Furthermore, research protocols are often reviewed only by local Institutional Review Boards (IRBs). The IRBs generally have no special expertise, are composed primarily of other researchers, meet in secret, and generally approve whatever projects their colleagues want to perform. The current practice is to provide consumer-patients with whatever they want and can afford rather than to develop a professional model that sets meaningful standards. There has been little federal activity to regulate cloning. The author attributes the lack of oversight of reproductive technologies generally to the Reagan and Bush administrations' anti-abortion agenda. The author believes that the time has come to move beyond an advisory committee and establish a regulatory commission, such as a federal Human Experimentation Agency (HEA) with both rule-making and adjudicatory authority. The new regulatory panel must be broad-based and composed almost exclusively of non-researchers and non-physicians so that it reflects public values. Furthermore, the HEA should transfer to human cloning proponents the burden of proving an important societal purpose for such an experiment before it is permitted, rather than imposing on regulators the burden of proving that there is a compelling reason not to approve it.

Barry Brown, *Human Cloning and Genetic Engineering: The Case for Proceeding Cautiously*, 65 ALB. L. REV. 649 (2002).

The author contends that governmental efforts to prohibit human cloning will not prevent people from attempting it, and therefore argues for the imposition of a “more logical framework” that acknowledges the inevitable advances being made in the science of human cloning. The author recommends that the science be allowed to proceed “to test and experiment as long as the research and therapeutic protocols for such actions are consistent with the highest standards we currently expect for all human research.” By becoming less anxious about the science, realistic discussion about the main issues—who will choose, and who will pay—can be held. According to the author, the legislative response so far has been reactionary, since it has focused on complete bans. Such bans will be unenforceable and fail to protect the public. Thus, he advocates establishing a “supportive but firm regulatory environment for overseeing and controlling that research” and requiring “the complete disclosure of the empirical and clinical processes.”

Michael Broyde, *Cloning People: A Jewish Law Analysis of the Issues*, 30 CONN. L. REV. 503 (1998).

The author analyzes cloning technology from a Jewish law perspective. The author begins with the premise that new technologies are neither categorically permitted nor categorically prohibited but must be evaluated in light of Jewish law. Cloning, like other reproductive technologies, raises two competing imperatives, one which encourages assisting those who need help in reproducing and the other which advocates conservatism regarding sexual activity. The author contends that cloning is fundamentally a form of assisted reproduction, and should be made available to those individuals in need of assisted reproduction.

The author contrasts Jewish and American law in that the former holds familial status questions to be immutable, and seeks merely to discover parentage, whereas the latter views them as determinable by a court. The author then considers who would be the legal parents of a clone under Jewish law. He states that the gestational mother would be considered the legal mother of a clone, even if there were no genetic connection. He notes that there is debate among Jewish legal scholars regarding the possibility of having more than one legal mother, and states that some rabbinic authorities would also recognize the donor of the egg and/or genetic material as the legal mother. At the least, a female genetic donor would be considered the legal mother for the purpose of prohibitions on sexual relationships with family members. Regarding the identity of the father, the author states that if a male contributed the genetic material for the clone he would be the legal father. He notes a difference of opinion in Jewish law regarding whether paternity can arise in the absence of a sexual relationship, e.g., whether a male fulfills his obligation to procreate absent a sexual relationship, but states that the vast majority

of rabbinic authorities rule that children produced by non-sexual means are the legal children of the inseminator. By analogy, if the genetic donor of the clone were male, he would be considered the legal father.

The author also considers the religious identity of the clone. Jewish law considers the mother's religious identity to determine the child's identity. Thus if the gestational and genetic mothers are different, the child's religious identity would depend on which mother was viewed as the legal mother.

The author then discusses how Jewish law determines whether something has human status. Jewish law provides that a person who is born from the womb of a woman is considered human. Thus a clone would be considered human since it would meet this criterion. If this criterion were not met (e.g., if there were artificial incubators), other provisions of Jewish law would likely require considering whether the clone was functionally human, e.g., whether it had human attributes and human intellectual ability.

The author then examines whether cloning is permissible, prohibited, or a good deed. There are several categories of activities within the Jewish law, those that are obligatory (such as the requirement for a male to reproduce and have at least one boy and one girl), those that are commendable but not obligatory, those that are permissible, those that are discouraged, and those that are prohibited. Thus the central question is whether cloning fulfills the obligation to be fruitful and multiply. This in turn depends on whether fulfillment of this obligation requires the mixing of genetic material from a man and a woman. The author posits that cloning could potentially fulfill the obligation. For example, if cloning were the only way by which a man could procreate, it could arguably be considered a fulfillment of this requirement. Since women are not obligated to procreate under Jewish law, a woman clonor would be committing a religiously neutral act. In either event, the author states that he has not identified any "intrinsic grounds found in Jewish law to prohibit cloning." He states that Jewish law "does not view the death of pre-embryos in the process of attempted implantation as violative of Jewish law." He notes that a rabbinic authority might temporarily prohibit cloning as a prophylactic rule if there were concerns that clones would be mistreated, but this is different from saying that cloning is intrinsically forbidden. While cloning is "far less than the ideal" means of reproduction under Jewish law, if it is the only method it would appear acceptable from a Jewish law perspective.

Dena S. Davis, *Religious Attitudes Toward Cloning: A Tale of Two Creatures*, 27 HOFSTRA L. REV. 509 (1999).

The author examines the differences in theological perspectives regarding cloning through the lens of two stories, one a novel by Mary Shelley and one a Jewish legend about the Golem of Prague. Frankenstein is essentially a cautionary tale about humans attempting to "play God" as an act of hubris and without the willingness to take responsibilities for the consequences of their creations. In

contrast, the creation of the “golem” by Rabbi Loeb in the 16th century was consistent with divine directives and was done in partnership with God, for the purpose of protecting life. The author posits that these two stories serve as contrasting paradigms that reflect the two strains of religious thought regarding cloning. Under the first view, humans place themselves in a perilous position when they exceed appropriate boundaries of human endeavors and act in contravention to God’s will. Cloning is wrong under this view because creation is properly in the province of the divine, and it is dangerous because human beings are fallible and self-interested, and will be powerless to set limits on their creations. Under the second view, humans are co-creators with God and have a duty to act to improve human life and relieve suffering. Cloning is consistent with this co-creator relationship, and it can be appropriately constrained and used for purposes consistent with these duties. The author concludes that these contrasting views are driven not only by theology but by “a fundamentally optimistic or pessimistic view of the world and of human motivation.”

Elliot N. Dorff, *Human Cloning: A Jewish Perspective*, 8 S. CAL. INTERDISC. L.J. 117 (1998).

This article considers the moral and theological issues surrounding human cloning from a Jewish perspective. The author recommends that human cloning be regulated but not banned, allowing cloning to proceed for medical research which aims to cure diseases. The author believes that cloning must be properly supervised and restricted in order to avoid some of its inherent dangers and potential for abuse. The author believes this could be accomplished by professional self-regulation. He also emphasizes the need to make cloning restrictions international.

The author first addresses the moral issues, beginning with who would be cloned. Cloning is most likely to be used by the rich and famous. As a result, cloning may increase socioeconomic disparities and may also be open to economic exploitation. Additionally, because the person to be cloned would be chosen based on his or her characteristics, cloning “denies the sacred character of human life depicted in Jewish tradition, transforming it instead to fungible commodities on the human marketplace to be judged by a given person’s worth to others.” Similarly, determinations about “good” and “bad” products of cloning would increase the objectification of human life. Although cloning is open to abuses, including eugenic purposes, it is itself morally neutral, and it promises some morally legitimate medical benefits. The author agrees that it would be harder for a clone to establish his or her identity, but the clone’s independence must be acknowledged and respected.

Next, the author addresses theological issues, such as how cloning forces us to think about basic principles regarding our relationship to God and God’s universe. We are God’s partners in the ongoing act of creation when we improve the human lot in life, but at the same time, we are not God: “we must strike a

balance, then, between our actions and God's." The Jewish tradition's high value on human life requires that steps be taken to heal when possible. "[T]he physician, in Jewish theology, is God's agent in accomplishing that task, and so use of the medical arts is not only permissible, but required." Therefore, an assessment of human cloning would depend on its use, and if it is intended to advance medical research or cure infertility, "it has a proper place in God's scheme of things."

The author considers the threat to individual identity that cloning poses. Ironically, the author believes that cloning could be "theologically very healthy, for it refocuses our attention on the rabbinic doctrine that we are not equivalent to our bodies." The uniqueness of cloned individuals would demonstrate the complex interacting roles of nature and nurture in determining whom a person is, demonstrating that people are much more than their collective genes.

Cloning poses a danger of self-idolization, in that it threatens to "undermine our humility and our sense as limited creatures." Cloning does this in two ways. First, it makes it possible to reproduce asexually. Children "represent a piece of our hold on eternity" and "our strongest tie to the future," and sexual reproduction requires both partners to participate with another in the creation of a child. Cloning, however, contributes to self-idolization, by allowing a person to independently perpetuate his/her genes and attempt to achieve immortality. Mortality, in fact, is beneficial, in that it "curbs our arrogance."

Nanette Elster, *Who is the Parent in Cloning?*, 27 HOFSTRA L. REV. 533 (1999).

The author explores the legal questions that would surround parentage and legal custody of a clone, if one were to be created in the United States. She concludes that it will be difficult to apply existing law to this new technology, and that the law does not generally keep pace with technological developments. The lack of uniformity of state laws will further complicate the situation. Cloning also challenges traditional definitions of family, and raises many questions in addition to ones focused on parentage and legal custody

New methods of reproduction require reassessment of the meaning of parenthood. Current laws are not adequate to address cloning in the context of parenthood. A cloned child may have genetic material from as many as four individuals—the person from whom the nucleus was derived, the biological parents of the nucleus donor, and the donor of the enucleated egg, which contains mitochondrial DNA. In addition, cloning raises questions about the parental status of the gestational mother and her husband. Many state laws presume that the man who is married to the woman giving birth is the father. Likewise, there may be parents who have no biological connection to the child who intend to raise the child.

In attempting to determine parentage of a clone, it will be necessary to look at state laws relating to paternity, surrogacy, and egg donation. Laws dealing with sperm donation are unlikely to be applicable since no sperm is involved in cloning.

Egg donation laws may be applicable, even though the egg donor's nuclear component is not used. A few state laws provide that egg donors do not have parental rights or obligations with respect to the resulting child. The wording of a statute may create ambiguities in the cloning context.

Surrogacy laws also may be applicable. State statutes differ regarding who are the presumptive parents in a surrogacy relationship. Surrogacy laws requiring marriage of the intended parents may preclude cloning by those who are not legally married, such as same sex couples, or single individuals. Other provisions in some surrogacy laws may also pose barriers to cloning.

In the absence of technology-specific laws, state parentage statutes must also be considered. These laws, however, may give more than one person legal rights and obligations to the cloned child (e.g., both the genetic and gestational mother). State paternity laws may make it difficult for a man who has contributed the genetic material to create a clone to establish paternity if the surrogate is married to another man.

Parentage laws may also potentially create a legal obligation for the parents of the DNA donor, since they would also be the genetic parents of the clone.

Matthew B. Hsu, Note, *Banning Human Cloning: An Acceptable Limit on Scientific Inquiry or an Unconstitutional Restriction of Symbolic Speech?*, 87 GEO. L.J. 2399 (1999).

The author addresses whether legislation banning human cloning would violate the constitutional right to free expression guaranteed by the First Amendment. He argues that human cloning is an expressive activity deserving of First Amendment protection, and that a ban on cloning would be an unconstitutional restriction of free speech.

The First Amendment protects not only written and verbal communication but also expressive conduct or symbolic speech. Conduct is protected if there is "an intent to convey a particularized message" that is likely to be understood by those receiving it. The message need not be the only, or even primary, purpose of the activity. But, where speech and non-speech elements are combined, government restrictions on the non-speech element that have an incidental suppressive effect on the speech elements may be permitted if the government's interest is sufficiently important. Under the four part test articulated in *United States v. O'Brien*, symbolic speech may be restricted if: (1) it is within the constitutional power of the government; (2) it furthers an important or substantial government interest; (3) the government interest is unrelated to the suppression of free expression; and (4) the incidental restriction of First Amendment freedoms is no greater than is essential to the furtherance of that interest.

The author argues that scientific experimentation is a form of expressive conduct. Just as a scientific paper outlining a procedure or theory for cloning expresses an idea, so too the conduct of an experiment to demonstrate the validity of the procedure is also an expression of that procedure or theory. "Scientists engage in experimentation for the purpose of expressing ideas, whether it is to prove or disprove a particular idea. Because a cloning experiment would also test a hypothesis, it should also be considered symbolic speech." Cloning research could also express ideas about the most effective method for cloning, and the acceptable scope of scientific inquiry.

Since cloning contains expressive elements, the question under the *O'Brien* test is whether the government interest in banning it is rationally related to those expressive elements. Arguments in support of a ban have claimed that cloning would damage human dignity, allow scientists to play God, and destroy human individuality. The author argues that these justifications seek to suppress the expression of a contrary idea about human nature and are therefore constitutionally impermissible. Other arguments against cloning are premised on concerns about the health and safety of cloned children. The author believes these concerns are overstated, since few people will use the procedure, and the procedure will cease to be used if birth defects occur. The author similarly believes that alleged psychological harms to children are overstated. The author contends that such arguments are pretexts, as there are many situations in which children's physical and psychological well-being are at risk and in which Congress does not act. In addition, a permanent ban precludes the possibility that the technique might one day be proven to be safe. The author also presents and dismisses other concerns about cloning, such as the potential negative social consequences and potential threat to genetic diversity.

Elizabeth Price Foley, *Human Cloning and the Right to Reproduce*, 65 ALB. L. REV. 625 (2002).

The author discusses whether the constitutional right to reproduce protects an individual's right to produce a child using cloning techniques, and if so, under what circumstances this right may be exercised. Taking a step-by-step approach, the author analyzes the right to reproduce in general, the right to reproduce through non-coital means, and finally the right to reproduce asexually through cloning.

The author first discusses whether there is a positive right to reproduce. Whereas the United States Supreme Court has clearly indicated that humans have the right *not* to reproduce, the Court has only inferred that there is a positive right *to* reproduce. The author notes that although early case law suggested that the right to reproduce was grounded in the penumbral right to privacy, recent cases have suggested that the right is instead found in the liberty interest of the Fourteenth Amendment's Due Process Clause. The author contends that the Supreme Court's case law establishes a positive right to reproduce through sexual intercourse.

According to the author, case law supports the conclusion that the right to reproduce extends to non-coital reproduction. While regulation of non-coital reproduction is permissible, within certain boundaries, the author argues that a complete ban against the use of non-coital reproduction methods would be unconstitutional.

Finally, the author argues that, speculative fears aside, there is no sufficient reason to treat asexual reproduction, like cloning, differently under the law merely because it does not require the union of sperm and egg. There is no evidence that this type of reproduction presents any more harm than sexual reproduction and the end result is the same, the birth of a child. The affirmative right to reproduce should include the right to bear or beget biologically related offspring. The author concludes by discussing how a court might approach the question of whether the constitutional protections for procreation would extend to asexual reproduction. The result would depend on how a court framed the right at issue. While a court would be unlikely to recognize a “right to asexual reproduction” as meriting constitutional protection, a court might recognize a right to procreation generally and afford varying degrees of protection depending on the method used.

Elizabeth Price Foley, *The Constitutional Implications of Human Cloning*, 42 ARIZ. L. REV. 647 (2000).

The author examines current laws that may prevent abuses of cloning and also the constitutionality of imposing a ban on human cloning. She concludes that current laws are sufficient to regulate cloning, and a ban may not be constitutional.

The author reviews the common fears concerning human cloning: organ “farming” for spare parts, slavery, and “waste” embryos. She contends that current laws are sufficient to prevent these potential abuses from human cloning. First, clones are born and would be “persons” and would enjoy full protection of the laws to the same extent as any other person. Clones, therefore, could not be used as forced organ donors, since laws against battery and murder would prohibit such conduct. Nor could clones be forced into slave labor, since the Thirteenth Amendment protects all persons from slavery and involuntary servitude.

Another concern that has been raised is the high number of embryos it requires to produce a successful clone. The author argues that the often-cited statistic that it took 277 attempts to create Dolly the sheep is misleading, since most of those did not even get to the cell-division stage. Of 29 embryos implanted in 13 different ewes, one successful birth occurred. In addition, the problem of “waste” embryos is not unique to cloning, and in fact is quite prevalent as a consequence of assisted reproductive technologies. There is legal precedent concerning the status of frozen embryos that could be applied to cloned embryos as well.

The author then explores constitutional impediments to laws banning human cloning. First, it could be asserted that scientific research constitutes “speech,” and

is therefore subject to protection under the First Amendment. It could be argued that cloning research constitutes “expressive conduct” that conveys the message that cloning is “normatively worthwhile and technologically possible.” If such research were determined to be subject to the protection of the First Amendment, only a compelling government interest could justify its suppression.

Second, the Due Process Clause prohibits governments from depriving any individual of “life, liberty, or property without due process of law.” The right to procreate has been recognized as a fundamental liberty interest by the Supreme Court, but the context was limited to sexual reproduction. The few lower court cases regarding artificial reproductive technologies (ART) indicate that pursuing assisted reproduction methods is also considered a fundamental liberty interest. The Supreme Court has not had occasion to consider this. In addition, there is the question of whether cloning is similar enough to other ARTs to be subject to the same protections, assuming they were applicable.

Third, the Equal Protection Clause prohibits invidious discrimination by the government. The success of an equal protection challenge to cloning would depend on whether cloning was viewed as a fundamental right. If it were, only a compelling governmental interest could justify discriminating between those who desire to procreate through cloning and those who use other methods; if it were not, the government would need only a “rational basis” to prohibit cloning.

If cloning is found to be a fundamental right, the government must demonstrate a compelling interest to prohibit it. The government might try to justify a ban based on an interest in: (1) preserving the traditional family; (2) protecting personal autonomy and privacy; (3) preserving the sanctity of human life; (4) protecting the health and safety of human embryos; and (5) preserving human genetic diversity. The author identifies weaknesses within all of these arguments.

Clarke D. Forsythe, *Human Cloning and the Constitution*, 32 VAL. U. L. REV. 469 (1998).

The author opposes human cloning on both societal harm and moral grounds. Human cloning proceeds on a cramped, artificial, and impersonal view of human beings and reflects the dehumanizing instinct of Aldous Huxley’s *Brave New World*. The impersonal instinct that fosters the intent to control the genetic destiny of one’s progeny comes from the same instinct that treats the human being as just a clump of cells.

The author argues that the destruction of a human embryo outside the womb would constitute homicide. Further, *Roe v. Wade* and its progeny do not create any constitutional exception for such activity. Federal and state legislatures therefore may ban human cloning without infringing on constitutional rights.

To support this argument, the author traces the history of common law protection of human life. He states that while “for most scholars, the legal and

moral status of the unborn human being begins and ends with *Roe v. Wade*,” there is in fact a long tradition of common law protection of the unborn through the law of homicide. According to the author, this legal tradition protected all human life, and not just “persons,” meaning that it protected both born and unborn. While *Roe v. Wade* created an exception to the extent that the law could not interfere with a woman’s right to terminate pregnancy, protection of the unborn was normal under common law. A review of the common law also shows a dynamic relationship between law and medicine with regard to the status and protection of the unborn child. “The law always considered the offspring of human parents to be a human being, and the law considered the unborn child to be a human being whenever it could be determined to be alive. Evidence of life— a living human being— was what was important for legal protection, not ‘personhood.’” The common law placed significance on two biological phenomena, quickening and live birth.

Also, according to the author, tort law has increasingly recognized the right to recover for prenatal injuries. “Today, at least thirty-six jurisdictions allow wrongful death actions for a *stillborn* child, while a dwindling minority of eight to ten states reject the action.”

Based on his review of common law, the author argues that “[c]ausing the death of human embryos outside the body, even though created through the fertilization of eggs *in vitro*, constitutes homicide under basic homicide law in effect in every state.”

The author next argues that the Supreme Court’s substantive due process decisions relating to family law and reproduction do not encompass using technology for asexual reproduction, and in particular, for cloning. These cases recognize limited privacy interests in marital coital reproduction, in protecting traditional family relationships and protecting “negative” liberties such as the right to refuse medical treatment. These cases recognize rights that are “deeply rooted in the common law.” Furthermore, the reproduction-related cases are premised on coital reproduction, and cannot be extended to extracorporeal reproduction. The author states that “[n]o broader constitutional liberty in ‘procreation’ encompasses a right to use technology to clone human embryos *in vitro*.” The author construes *Roe v. Wade* as protecting only a “negative” right to terminate pregnancy free of governmental intrusion, and not a broader “positive” reproductive liberty. *Roe* therefore would not constrain intervention by the state to prevent harm to extracorporeal embryos since such an action would not interfere with a woman’s liberty to seek abortion.

Henry T. Greely, *Banning “Human Cloning”: A Study in the Difficulties of Defining Science*, 8 S. CAL. INTERDIS. L.J. 131 (1998).

The author reviews definitions of human cloning that have been crafted by various legislatures and regulatory bodies seeking to ban the procedure. The author is critical of many of them because they are ambiguous, reflect a lack of

scientific understanding, fail to take into account certain potential procedures, and betray ulterior motives. The author offers an administrative solution to this problem, which is to delegate the task of defining cloning to an expert regulatory body that can both craft the initial definition and then update it as the science evolves.

Leon R. Kass, *Why We Should Ban the Cloning of Human Beings*, 4 TEX. REV. L. & POL. 41 (1999).

The author advocates for a legislative ban on human reproductive cloning, stating that “cloning is a serious evil, both in itself and in what it leads to.” He cautions that cloning is neither copying nor exactly like natural twinning. Unlike natural twinning, the clone will arise by deliberate design, with the entire genetic make-up pre-selected by the parents and/or scientists. While there is no immediate worry of mass-scale production of clones, cloning could become more than a marginal practice at fertility clinics based on free reproductive choice. The author states that society’s widespread repugnance to cloning is the intuitive result of our wisdom and belief that cloning defiles our given nature and social relations. Furthermore, we sense that cloning is a radical form of child abuse.

The author finds four objections to human reproductive cloning. First, cloning involves unethical experimentation. Animal experiments indicate that there are grave risks of mishaps and deformities. Furthermore, since we cannot gain the consent of a future cloned child, we cannot ethically know whether human cloning is feasible. Second, cloning threatens the identity and individuality of the clone. In addition to being identical in genotype and appearance to another human being, the clone may also be the twin of his “father” or “mother.” The author suggests that there may be psychological ramifications as a result of the following hypothetical situations: (1) the clone of Mommy grows up to be the spitting image of the woman Daddy fell in love with; and (2) after divorce, Mommy may not love the clone of Daddy. Furthermore, a clone is saddled with a genotype that has already existed and therefore has expectations attached to it. There will be parental efforts to shape the clone after the original. Why else would they have cloned the original in the first place? The author warns that cloning also confounds lineage and social relations. For example, if a female child cloned from her “mother” desires a relationship with her “father,” she may seek out the father of her “mother.” Would “father/grandfather” be pleased to learn that the cloned child sought paternal attention and support from him? Furthermore, the clone is deliberately deprived of normal social identity. Not only does the child have only one “parent,” but in the case of self-cloning, the child is also the cloned individual’s twin. The result, the author states, is akin to incest— to be parent to one’s sibling. From then on, all other familial relationships will also be confounded. The author warns that society already confuses kinship and

responsibility for children due to the high rate of divorce, remarriage, adoption and non-marital childbearing.

Third, human cloning takes *in vitro* fertilization and genetic testing of embryos much farther by turning procreation into manufacturing. "With cloning, not only is the process in hand, but the total genetic blueprint of the cloned individual is selected and determined by the human artisans." Cloning would be a major step in making man another item of man-made creation. As opposed to natural procreation, clonal reproduction gives "existence to a being not by what we *are* but by what we *intend* and *design*." Through its will and creative prowess, the creator is inherently superior to the product. Scientists and prospective "parents" will adopt a technocratic attitude toward children, dehumanizing them, as they become their artifacts.

Fourth, cloning represents despotism over children and perversion of parenthood. The author states that when a couple chooses to procreate, they are not only saying "yes" to a child, but also to having whatever child they produce. Parents seek to guide their children by their own life lessons and hope that they will surpass their own limitations. The author explains that a child conceived of natural procreation contains the kind of genetic distinctiveness and independence that only corresponds with a never-before-enacted life. He cautions that some parents already try to live vicariously through their children. The author states that "whereas most parents normally have hopes for their children, cloning parents will have expectations." Cloning contradicts the open and forward-looking nature of the parent-child relationship because of the expectation that the blueprint of the last life will control the life to come. The author finds that cloning is despotic because it seeks to make one's children after one's own image and will.

The author urges that we follow those European nations and those states that have already enacted bans on human cloning. He warns that passing such regulation is not as simple as it may seem because of the vague term, "human being," and the issue of whether to include pre-implantation embryonic stages of human life. The author fears that the debate over embryo research will derail efforts to ban reproductive cloning. Thus, in an effort to find the middle ground, the author suggests the following type of legislative ban: "An individual shall not engage in an attempt to produce a human fetus and/or to generate for birth a human child by techniques of cloning (somatic cell nuclear transfer)."

The author acknowledges that his legislative proposal is without American precedent in the world of technology (though Britain and others have banned cloning, and we ban other types of "reproductive freedom" such as incest and polygamy). Although a ban may eventually be viewed as a mistake, for the time being it would place the burden of proof on proponents to show why cloning is imperative. The author notes that throughout American history, the technological imperative, to do what can be done, has probably served us well. However, in the context of cloning, we cannot continue to repair bad consequences after the fact.

The author concludes that a ban on cloning will not harm progress in the field of genetic science and technology, but rather reassure the public that scientists will proceed without violating deep ethical norms of humanity.

Katheryn D. Katz, *The Clonal Child: Procreative Liberty and Asexual Reproduction*, 8 ALB. L.J. SCI. & TECH. 1 (1997).

The author explores whether procreative freedom includes the right to reproduce by any means, including asexually, and examines the issues concerning parentage and legal relationships with the “clonal” child. She states that the “most difficult question regarding reproductive rights is whether we have a right to . . . create children with only one genetic parent.” However, cloning is “not as revolutionary as feared” since assisted reproductive technologies already permit the creation of children with only one legal parent, which the author terms “partial orphans.” Viewed through the “lens of procreative liberty,” cloning oneself “seems to be a logical extension of current practices using other reproductive technologies.” Indeed, cloning could eliminate some of the social and legal disputes that have arisen as a result of assisted reproductive technologies. It is unclear whether courts would protect the right to clone using the existing legal framework that affords some legal protection to reproductive decision-making. Deliberative bodies will need to decide whether the creation of “partial genetic orphans” is permissible, but should also realize “that clonal children are simply a replication of other mortal beings,” and should not make decisions based on misconceptions about the humanity of the clonal child.

Lori P. Knowles, *Science Policy and the Law: Reproductive and Therapeutic Cloning*, 4 N.Y.U. J. LEGIS. & PUB. POL’Y 13 (2000-01).

The author surveys the role of the law in shaping American bioethics and science policy. In particular, she emphasizes that law can help science policy to anticipate scientific developments, as well as take into account ethical concerns. The author uses the cases of reproductive and therapeutic cloning to illustrate her points.

Development of science policy in this country is problematic in several ways. First, ethical deliberations of new technologies generally begin only after the new technology is already in existence. Second, because the process of ethical consideration is inherently slow, immediate legislative response is not informed by these concerns. The result is that public policy is developed in a reactive and narrowly tailored manner. Another problem with the American system of developing science policy is that a different independent advisory body oversees each new scientific development. These advisory bodies have little interaction with each other, though the technologies they oversee may be related. “This isolation presents a significant weakness since the different bodies do not benefit

from each other's expertise, nor do they acquire a comprehensive picture of the state of the science at any given time."

The author believes the law should be used to promote flexibility and continued conversation about the issues. It can do this by structuring regulatory bodies that are responsive to change, and also by developing regulations. The lack of regulations in the reproductive technology field means "we respond to each new scientific development without the benefit of previously articulated commitments." The law can help fill this need.

Anne Lawton, *The Frankenstein Controversy: The Constitutionality of a Federal Ban on Cloning*, 87 KY. L.J. 277 (199899).

The author explores the question of whether Congress has the Constitutional power to ban human cloning. Specifically, she asks whether such a ban would be permitted under the Commerce Clause and whether the ban would implicate a fundamental right in violation of the Due Process Clause of the Fifth Amendment. The author concludes that Congress may ban cloning pursuant to its power to regulate interstate commerce, and that such a ban would not violate the Fifth Amendment Due Process Clause.

The Commerce Clause, contained in Article I of the Constitution, empowers Congress to "regulate Commerce with foreign Nations, and among the several States." Historically, the Supreme Court has adopted an expansive interpretation of interstate commerce, and has accorded significant deference to federal statutes enacted pursuant to the interstate commerce clause. In *United States v. Lopez*, the Court identified three categories of activities that Congress may regulate consistent with the Commerce Clause: (1) the use of the channels of interstate commerce; (2) the instrumentalities of interstate commerce; and (3) activities having a substantial relationship to interstate commerce.

The Court's decision in *Lopez* is counter to the general trend. In that case, the Court struck down the Gun-Free School Zones Act of 1990, which made it a crime to possess a gun in a school zone.

The author states that *Lopez* would not impede enactment of a federal law banning cloning. She argues that cloning is a commercial activity, since it may be used in conjunction with *in vitro* fertilization, which is a significant business enterprise. Further, research facilities conducting cloning utilize scientists, who will likely share information interstate. Finally, patients will likely travel across state lines to access cloning technologies, just as they do for other reproductive services.

Regarding the Due Process Clause, the author states that certain proactive activities, while not expressly recognized in the Constitution, have been held to be protected as fundamental liberty interests. The author argues that the Court would likely not recognize the right to clone as fundamental. She reviews cases such as *Bowers v. Hardwick* as evidence that the Court has avoided finding new

substantive rights by narrowly framing the particular question before it. In addition, the Court's pronouncements on abortion would likely also be significant to a review of a cloning prohibition. The Court's decision in *Planned Parenthood v. Casey* indicates discomfort by some on the Court with *Roe v. Wade's* treatment of abortion as a fundamental right. Some members of the Court view abortion as different from other fundamental rights because it involves the destruction of a fetus. Cloning similarly involves destruction of an embryo, but unlike abortion, does not implicate a woman's right to bodily integrity.

The Court could describe the asserted interest in cloning in two possible ways, and the way the interest is framed would influence the outcome. The Court could frame the interest as part of a decision to bear children, e.g., a right to procreation. Alternatively, the Court could describe the interest narrowly as the right to engage in cloning. The narrow construction would avoid the need to declare cloning a fundamental right. Even if the Court did view the right as fundamental, the author states that the Court would view a limitation on the right as compelling in light of the safety concerns raised by cloning.

Gilbert Meilaender, *Cloning in Protestant Perspective*, 32 VAL. U. L. REV. 707 (1998).

The author presents a Protestant theological view of cloning. He states that Protestants base their views of marriage and children on the creation story in the book of Genesis, which establishes a connection between the differentiation of the sexes and the begetting of a child. "[T]he child is a gift who springs from the giving and receiving of love." The author believes there are two ways to respond to this assertion: we may consider it wisdom that can guide our conduct, or we may consider it a limitation to our freedom and seek to transcend it. The author argues that the freedom to do the latter, to make and remake ourselves, while an important aspect of being human, is not what is most fundamental about us. It is surpassed by intrinsic truths about families, and the relationship between man and woman as ordered toward procreation.

Although the connection between sexual differentiation and procreation is mysterious, it can be explicated from two angles— for the good of the relationship, and for the good of the child. First, it is good for the relationship between man and woman because it reminds the couple that "[t]he act of love is not simply a personal project undertaken to satisfy one's own needs, . . . [but] a participation in a form of life that carries its own inner meaning." Second, maintaining the connection between the sexual relationship and procreation is also good for the child, because "[w]hen the sexual act becomes only a personal project, so does the child." But when a couple gives themselves to each other, a child is not the primary object; therefore, the child can always be considered a gift, the fruit of their shared love.

To further elucidate the distinction between making and begetting, the author draws upon the Nicene Creed, an important statement of Christian faith. Begetting, according to the author, implies an “equality of being.” Humans are “made by God through human begetting.” Because what we beget is like ourselves, we all have equal dignity, and cannot be put at each other’s disposal, like a cloned child to a parent.

The author distinguishes cloning from other forms of procreation which are separate from a sexual relationship between a man and a woman, believing cloning to be “a new and decisive turn in the road” in the understanding of a child as a product of the human will. The author believes the creation of human embryos for research is similarly problematic, as they are created solely for someone else’s purposes.

The author concludes by saying that Christians must live within the limits set by morality, and that the freedom to make and remake ourselves by cloning is one that ought to be limited.

Richard A. Merrill & Bryan J. Rose, *FDA Regulation of Human Cloning: Usurpation or Statesmanship?*, 15 HARV. J.L. & TECH. 85 (2001).

The authors analyze the legal and policy issues surrounding the Food and Drug Administration’s (FDA) assertion of jurisdiction to regulate human cloning. They conclude that the FDA’s authority over certain applications of cloning technology might be upheld by a court if challenged. However, they question the procedural mechanisms used by the FDA to assert jurisdiction. They also argue that the FDA’s “procedural shortcut” has had the effect of deflecting public debate concerning appropriate limits on cloning technology.

The authors describe the FDA’s steps to assert authority to regulate experimental attempts to clone a human being. They comment that the FDA pursued a “low profile” strategy to address this high profile issue, which could signal agency reluctance to get involved. The agency first indicated that it believed it had the authority to regulate cloning, and was prepared to do so, during an interview on public radio by an agency official. The FDA also asserted its jurisdiction to regulate human cloning experiments in a letter to Senator Kennedy at a time when he was sponsoring legislation to ban cloning. The agency also sent a letter to several hundred institutional review boards stating that clinical researchers using cloning technology, would be required to submit an investigational new drug (IND) application to the FDA, and that the FDA would not permit such investigations to proceed because of safety concerns. Finally, an FDA official testified before Congress regarding the FDA’s authority vis-a-vis cloning.

The authors point out that the FDA’s statements “left crucial questions unanswered” concerning what applications of cloning technology the agency

believed it had authority to regulate. The agency also made no provision for addressing the ethical and moral issues raised by cloning.

The FDA's statements made it clear that the agency was relying on its authority to regulate clinical studies of unapproved new drugs. But the authors point out, "the fact that the FDA claims authority is no guarantee that Congress has conferred it." The authors review the possible sources of authority from which the agency could draw in asserting jurisdiction over cloning. Looking at the FDA's requirements for new drugs, the authors note that, for any clinical experiment to be subject to the FDA authority under the Federal Food Drug and Cosmetics Act, three conditions must be met. First, the procedure must involve the administration of an "article." Second, the article must be within the definition of a "drug" or "device." Third, the article must be administered to a human subject. The authors note that the drug category might constitute an "awkward fit for procedures whose objective is to produce new human beings," nevertheless they concede that the FDA's legal theory could plausibly fit many applications of cloning and, additionally, would be subject to deference if challenged in court. However, they question whether the FDA's means of communicating its intended regulation of cloning comported with the Administrative Procedures Act (APA). They consider but reject the possible arguments that the FDA's pronouncements were statements of agency policy or interpretive rules, neither of which would be required to comply with notice and comment procedures. They state that the FDA's "unilateral declarations have not only stifled sponsors and researchers, but have also deflected public discussion of the serious questions surrounding the role, conduct, and oversight of cloning research."

The authors next consider the FDA's qualifications to consider the unique moral and ethical issues that cloning research would raise. They contrast the process followed in Great Britain with that followed in the U.S. "While Great Britain's approach encouraged public debate, the FDA's peremptory assertion of jurisdiction cut short public discussion and channeled into a closed regulatory process decisions about which experiments, if any, to allow." The authors, therefore, "question whether FDA jurisdiction is the best vehicle for fashioning a long-term policy for addressing the unique concerns generated by . . . the potential for human cloning."

James Lindemann Nelson, *Cloning, Families, and the Reproduction of Persons*, 32 VAL. U.L. REV. 715 (1998).

The author examines the impact that cloning may have on individuals and families by considering three different motivations for cloning: exclusion; replication; or affirmation. The author asserts that having biologically-related children is very significant to many people, perhaps as a "response to their sense of their boundedness in time, of their mortality." Additionally, the author posits that

biological connectedness may matter not just to parents, but to children as well; it is a vital part of a child's identity to know his/her biological roots.

Cloning for exclusion purposes would include an attempt to avoid a genetic disease or a lesbian couple who wishes to have a child without male involvement. Although cloning would dramatically restructure the family, the author does not see any reason that it is wrong in principle. Instead, he is concerned about who will have authority to determine the relationships in these families, and whose claims- parent or child- will trump.

Some may choose to clone for affirmation purposes, meaning to affirm a special relationship in some way, such as a widow cloning her dead husband to retain her link with him posthumously. The author states that while a clone's "claim that her very existence wronged her" under this circumstance does not hold weight, the clone may have a legitimate desire to form certain relationships. A parent who clones for affirmation purposes may find it difficult to assist in developing a child's sense of individuality.

The final scenario for which people may be motivated to clone is to replicate a certain individual, for example, to replace a deceased child, or create a genetically matched sibling for organ transplantation to another child. This scenario, especially, would make it difficult for parents to avoid forcing on a cloned child their expectations for his or her identity. However, as every child is to some extent burdened by parental expectations, the author believes that cloning, rather than posing an entirely new dilemma, "involves, rather, identifying clearly and vividly how cloning might heighten risks, as well as offer benefits."

The author concludes that cloning does not present an "ethical smoking pistol." Rather, it poses "a number of worrisome scenarios, and many concerns that need to be carefully balanced." In particular, cloning may increase our tendency toward biological and genetic determinism. Development of public policy for cloning will not be informed by definite principles; rather, a prudent, balanced judgment will have to be made, taking into account the unique ways that cloning could change our families and relationships.

Robert C. L. Moffat, *Cloning Freedom: Criminalization or Empowerment in Reproductive Policy?*, 32 VAL. U.L. REV. 583 (1998).

The author considers whether cloning should be criminalized, and concludes that cloning is not a big enough threat to justify limiting freedom by criminalizing this conduct.

First, the author argues that cloning does not pose a serious threat. The procedure, as a reproductive option, is a deterrent in itself because it is expensive, time-consuming, and emotionally and physically exhausting. Additionally, cloning for spare parts is more science fiction than fact. However, there are two instances in which cloning might be desirable: as a reproductive option when *in vitro* fertilization is impossible; and, when a younger clone of an existing sibling

may provide a perfect tissue match. But still, cloning, if available, would be utilized only by a very small number of people.

Second, the author argues that criminalizing cloning would be an unwarranted restriction of reproductive freedom. According to the author, the only justification for making behavior criminal is harm to others—that is the foundation of criminal law. The author asserts that it is difficult to determine who is harmed by cloning, and that not even the clone has a strong argument that he/she has been harmed. The author examines several applications of the harm principle. The claim of harm to oneself does not have any relevance with regard to cloning. Next, the author explores secondary harms, which are indirect, and may not injure a specific person, but rather the community as a whole. The author also rejects these claims as irrelevant to cloning. Lastly, the author considers public harms, which tend to be the most abstract and nonspecific of all. The author considers two theories of public harm that have been used to justify making cloning a crime. The social disintegration thesis posits that a society has a right and a need to enforce its existing morality; in this, it should obey its inner moral compass and feelings of repugnance. However, the author dismisses this idea: “Repugnance or disgust in many cases seems to be really just a form of temporary social hysteria.” The second notion of public harm is “public nuisance,” e.g., harm to the social fabric. The author posits that cloning critics focus too much on the biological nature of relationships, and that cultural factors play an important role, which reduces the impact that cloning may have. The author concludes that the harms of cloning are either too speculative or too weak to justify an “intrusion of criminal law into the realm of freedom and private autonomy.”

The author warns that criminalizing cloning may limit research freedom. “[P]ermitting political interference in the conduct of scientific research” may lead to the “totalitarian subjection of science to politics.” Most importantly, criminalizing all cloning would endanger basic scientific research on therapeutic cloning.

Duane Nash, *Recommended Response for Human Cloning Patent Applications*, 42 IDEA 279 (2002).

The author argues that the Patent and Trademark Office (PTO) should not invalidate patents pertaining to human cloning technology, including those pertaining to the cloning of human cells or tissues for therapeutic purposes (“therapeutic cloning”) and those pertaining to the cloning of a human being for reproductive purposes (“replicative cloning”).

The author discusses why patents for human cloning inventions should be permitted and enforced. First, human cloning inventions are patentable under United States law because: (1) they are patentable subject matter; (2) they possess sufficient utility; and (3) they are not precluded from satisfying the other patentability requirements. The United States Patent Act states that an invention

may be patented if it represents a “process, machine, manufacture, or composition of matter.” Courts have interpreted this to include biotechnology and the manipulation of living organisms. An early policy of precluding the patentability of medical and veterinarian therapies has since been overturned.

The author states that patent law should not be used as a means for regulating human cloning inventions. He finds no constitutional basis for using patentability to regulate cloning within Article I, Section 8, Clause 8 of the United States Constitution, which provides Congress with the power to “promote the Progress of Science and the useful Arts.” There is no discussion of discouraging unwanted science. The author states that the founding fathers most likely intended the regulatory role to rest with the legislature. The PTO lacks the expertise and resources necessary to hold hearings and weigh societal concerns regarding every new technology.

The author concludes by suggesting that the Department of Health and Human Services and the Food and Drug Administration are more appropriate forums for regulating human cloning. He urges that the following issues be given consideration: (1) who can perform cloning; (2) protection of a replicative clone; and (3) the rights of donors and an update of criminal law to incorporate transgressions within the field of human cloning.

Radhika Rao, *What’s So Strange About Human Cloning?* 53 HASTINGS L.J. 1007 (2002).

The author explores the motivations underlying the impulse to ban human cloning, and asks what the relationship of these motivations is to the question of whether a ban would be constitutional. The author cites three aspects of human cloning that produce “deep anxiety” among most of the public. First, cloning involves asexual, not sexual, reproduction. Moreover, cloning removes the requirement that sperm and egg be joined. Cloning therefore “frees individuals from the need to connect with others.” Second, cloning permits predetermination of genetic identity, leading to the fear that the clone would lose uniqueness and have a diminished sense of individuality. Third, cloning gives us the power to produce multiple copies of the same person, leading to the fear of “mass production of individuals with desired genotypes.”

The author then addresses whether the Constitutional right to privacy would protect cloning, and concludes that it would not. The author states that there are two ways to view the right to privacy, either as an individual right or as a relational or communitarian value. If privacy is an individual right, then there is no difference between cloning and any other reproductive act in terms of the level of protection it should receive. But, if the right of privacy protects relationships and not simply activities, then cloning may not be protected since it eliminates the need to form those intimate relationships. A ban on cloning would be fundamentally different from a ban on contraception or abortion, since the ban would be to protect

individual autonomy and equality, and not to diminish it. The author acknowledges the arguments that cloning could help enhance equality by enabling individuals from historically discriminated social groups to reproduce, but dismisses this argument as not likely to be the way the technology is actually used. The author concludes that there may be justifiable reasons to ban cloning: in order to protect the autonomy of the parents and the cloned person, to prevent objectification and commodification of cloned children, and to avoid creating new inequalities and discrimination.

Kurt A. Richardson, *Human Reproduction by Cloning in Theological Perspective*, 32 VAL. U.L. REV. 739 (1998).

The author presents a Christian theological perspective on the intent to clone a human being. He states that cloning as a method to reproduce whole human organisms possesses inherent moral flaws and legal contradictions that indicate “a violation of something basic in the created order.” Cloning should be rejected as a method of human reproduction because the procedures for perfecting the process would involve morally unacceptable conditions and produce morally unacceptable results. The improvements to reproduction that are sought through cloning, namely overcoming infertility and avoiding genetic disease, can be achieved through other technologies, specifically *in vitro* fertilization and gene therapy.

The belief that nature, and in particular human nature, is divinely created is a fundamental tenet of Christian theology, and informs the evaluation of issues affecting human life.

At the heart of the doctrine of creation is the identification of male and female humans as beings created in the image of God. This doctrine is the source not only of the notion of the incalculability of human value, but also of human responsibility to the entire created order.

The human soul requires both a healthy body and a healthy mind for its development, and reproductive cloning potentially conflicts with both these requirements. The clone would be biologically a twin of the person from whom the genetic material was taken, but would be younger. This would undermine healthy sibling and other family relationships. “Definitions of parenting and sibling relationships. . . cannot be sustained under such conditions.” Cloning disadvantages the cloned individual for the benefit of the person who wishes to be cloned. “Ultimately, the will to clone oneself, one’s spouse, another relative, or even some other extraordinary person, begins to strike one as more caprice than anything else.”

The inevitable “trial and error” that cloning will entail also makes it morally unrealizable. When human beings are involved, no errors should be tolerated. But in order to see if cloning were safe, ultimately a human clone would have to be created and followed throughout the life cycle. From a theological perspective,

cloning “violates the life of the child in a fundamental way, and thus should not be used for reproductive purposes.”

M. A. Roberts, *Cloning and Harming: Children, Future Persons, and the “Best Interest” Test*, 13 NOTRE DAME J.L. ETHICS & PUB. POL’Y 37 (1999).

The author examines the potential harms from human cloning. He states that, in order for the government to regulate cloning, it would have to demonstrate potential harms. The author warns against using an excessively broad standard to determine genuine harm. He distinguishes between indefinite and actual harms and argues that mere allegations of possible harm do not justify a ban on cloning.

The author also believes that cloning requires the consent of the person who is the source of the genetic material used to clone, just as consent is required for gamete donation. It is reasonable to want to retain a certain amount of control over one’s reproductive capacity, and harm would certainly be done to someone who was cloned without his or her knowledge, even if the harm is intangible. Therefore, cloning is permissible only if effective consent has been given.

A clear case can be made for the consent requirement when the source is an adult. When the source of the genome is a child, an embryo, or a future person, all of whom are incapable of providing consent, the issue of consent becomes more complex. Also, the potential for harm does not go away. To insure that the parent who requests the procedure is properly motivated and that the procedure would not harm the child, the author proposes that the “best interest” test be applied when the clone source is incapable of giving consent.

The fact that a genome can be collected “non-invasively” and without “bodily intrusion” does not mean harm cannot be done, nor does this preclude the need for the best interest test. The same standards that apply for adults must apply for non-consenting persons.

The author extends the best interest argument to cover production of clone multiples by embryonic cloning. In this case, the harm consists, as it did before, in finding oneself placed in the situation, without one’s consent, of existing as one of many rather than as one of one. The harm is suffered not only by the clone source, but also by each clone multiple.

The author upholds the “better to exist” defense of cloning, which states that although a clone may be harmed, it would certainly be better to exist that way, than to not exist at all. “Preventing the harm necessarily involves preventing the existence of that person. That is not in the person’s interests . . . existence as one of many is preferable to nonexistence.”

John A. Robertson, *Two Models of Human Cloning*, 27 HOFSTRA L. REV. 609 (1999).

The author presents an ethical analysis of cloning in which he makes two key distinctions. First, he distinguishes between therapeutic and reproductive cloning. Next, he distinguishes between reproductive cloning to overcome reproductive failure and reproductive cloning when sexual reproduction is possible.

Therapeutic and reproductive cloning employ similar techniques, but differ in their intended use. Therapeutic cloning refers to the extraction of stem cells from early embryos for research and potential therapies. Therapeutic cloning raises ethical concerns regarding the moral status of the embryo and the possibility that therapeutic cloning research will inevitably lead to reproductive cloning. However, the author does not believe either of these concerns should prevent research from moving forward.

In the case of reproductive cloning, the author states that it should be allowed in cases of reproductive failure, in order to help parents to have and rear a child with a genetic kinship. Only couples who are gametically infertile, and cannot be helped by conventional assisted reproductive technologies such as *in vitro* fertilization, and are also unwilling to use donated gametes or adopt a child, would likely be interested in cloning. The author refutes two arguments against cloning: first, that cloning will cause harm to resulting children; and second, that cloning will replace sexual reproduction as the primary form of reproduction, with disastrous consequences for the human race.

In the case of a couple who could reproduce sexually but choose not to, the author believes there is a much weaker case to be made for a right to clone. "They are not claiming a right to reproduce per se, but rather a right to select, control, or shape offspring characteristics . . . it is not the kinship connection alone which they seek, but rather a particular kind of genome or genetic relationship with the child." A couple may be motivated to clone out of sheer narcissism or out of the desire to have a clone of a particular person with a desirable genome, which implies a eugenic intent. "[T]he claim to use reproductive cloning in lieu of sexual reproduction hardly seems to be an aspect of procreative freedom as conventionally understood." The author would consider separately the cases of cloning a living or dead genetic child and cloning to produce a child with a tissue match to an existing child.

Distinguishing between these two circumstances of reproductive cloning has implications for cloning by homosexuals. For lesbians, cloning would allow reproduction without the need for a male. It would allow lesbian couples to have children who are genetically related only to one or both of them (and not a third party). In the case of lesbians, then, the question is not whether sexual reproduction is possible, but "whether her desire to reproduce without male involvement should be respected as much as any desire to have and rear

genetically-related children.” If so, cloning by lesbians might be perceived as reproductive failure because sexual reproduction is not feasible.

The case of cloning by gay males is different, because reproduction, sexual or asexual, requires a female to provide an egg and gestate. Cloning does not allow him a genetic relationship that he would otherwise be denied. Furthermore, it is impossible for both gay partners to be genetically related to the child. “The use of cloning by gay males would thus seem to be a case of seeking to have a child with a particular genome rather than having a child who is genetically connected at all.”

John A. Robertson, *Liberty, Identity, and Human Cloning*, 76 TEX. L. REV. 1371 (1998).

The author provides a comprehensive review of the science, ethics, and societal impacts of cloning technology, articulates scenarios when human cloning should be permissible, and considers the public policy questions raised by cloning.

The author states that cloning provides many potential benefits. Animal cloning serves many useful purposes and may be a boon to various biotechnology industries; it also has the potential to eliminate the genetic variation that confounds experiments. Cloning humans may allow treatment of infertile couples- including those who are gametically infertile- provide a source of matching organs and tissues, or replace deceased children.

The author discusses the various reasons cloning might be used, and how they fit into our concepts of procreative freedom and family creation. He also discusses whether cloning is an exercise in procreative liberty. The author defines procreative liberty as “the freedom to decide whether or not to have offspring.” As a deeply personal and intimate issue, freedom in making reproductive choices is a “deeply accepted moral value.” The author believes this extends to include the right to use assisted reproductive technology, and some right to choose characteristics, by either negative exclusion or positive selection. He states that there is a strong argument that some forms of cloning may also fall within the realm of procreative liberty, although he acknowledges that cloning is inherently different in the sense that it aims to produce a child with a particular set of genes. He views intention to rear the cloned child as key to determining whether procreative liberty is at stake.

The author addresses harms that may result from human cloning. The public response to cloning has been overwhelmingly negative, but the author suggests the claims of harm be analyzed as to whether they constitute a sufficient basis for the government to justify a complete ban. First, the author refutes the “wrongful life” argument, which asserts that out of concern for the welfare of the child, it is wrong to clone. The author denies that “preventing harm to offspring ever justifies preventing their birth altogether.” Next, the author articulates and rebuts each of seven potential harms resulting from human cloning, including: violation of human dignity, physical safety, threat to individuality, violation of autonomy,

objectification and instrumentalization of children; perversion of natural family and kinship ties, and eugenic practices.

The author also addresses the public policy questions raised by the prospect of cloning. He states that public policy must balance procreative freedom and a consideration of potential harms, through a combination of restrictions and regulations. Since cloning is currently still in the research and development phase, the most immediate policy question concerns whether to permit cloning for research purposes in animals and in humans. He argues that animal research is very informative and beneficial and should proceed without restrictions. The author does not see the need for a federal criminal law against all human cloning; to do that now would be rash, and it would set an unwise precedent for the future to invoke criminal law to settle bioethical issues.

When cloning has been proven to be safe and effective, policies may take the form of restrictions and regulations. Various restrictions may be made on who may clone and rear a cloned child. The author advocates against a complete ban on cloning in favor of a "limited ban with an exception where the parties requesting the cloning will also rear the child." He believes the rearing requirement "addresses the worst abuses of cloning." The author does not advocate for a ban on rearing a clone of oneself, believing the risks of harm to be minimal. However, he does draw the line at cloning and rearing one's parent. Finally, a ban on single women or men cloning could be enacted, and still allow married persons or those in two-partner committed relationships to clone.

Cloning policies may also take the form of regulations, which would be necessary to minimize the special risks that cloning poses. The first key regulatory issue is whether the source of DNA must consent, and the author upholds a consent requirement when the clone source is an existing person. However, he does not believe a child's consent is required. A second regulatory issue is whether the clone source's genetic parents should also consent, since cloning would give them, through no doing of their own, an additional genetic offspring. Regulatory policies addressing informed consent of the medical risks and social and psychological challenges posed to parents of clones should be developed. Additionally, the rearing rights and duties pertaining to cloned children need to be clarified. Defining relationships and legal status of all the parties involved will help normalize the relationships. A limit on the number of clones that can be produced with one person's DNA should be enacted—the author recommends three. Finally, "[a]n important issue in any regulatory approach is whether the professionals directly involved can be trusted. . . or whether a governmental agency is needed to oversee their practice." The decentralized system currently in use in the United States may need to be revamped as genetic technologies continue to develop.

Maura A. Ryan, *Cloning, Genetic Engineering, and the Limits of Procreative Liberty*, 32 VAL. U.L. REV. 753 (1998).

The author contends that the reproductive rights paradigm- of which John Robertson is a leading proponent- is inadequate for defining the appropriate scope of moral obligations and relationships in assisted reproduction, in particular cloning and genetic selection of offspring characteristics. An account that makes individual autonomy the “only serious moral value” requiring consideration makes it difficult to judge some choices, such as intentionally diminishing a child’s genetic characteristics (for example, to create a deaf child) as morally unacceptable. Thus, the language of rights “fails to capture adequately the moral geography of assisted reproduction.” She argues that some other way of thinking about freedom in reproduction is needed, one that recognizes the importance of bodily integrity and of not being forced to reproduce, and simultaneously rejects the assumption that one is entitled to raise the child one desires.

This alternative account must necessarily draw on the “deeper religious, cultural, and moral traditions” that give moral meaning to human reproduction. “Only an account of offspring as potentially autonomous beings with a fundamental human dignity would explain why it is morally wrong to treat them as objects or things, or to manipulate genetic characteristics to serve personal reproductive goals.” Similarly, a reproductive rights account does not provide a basis for concluding that cloning should not be within the protected zone of reproductive liberty. “Rights talk” fails to “generate a satisfying ethic for assisted reproduction,” which demonstrates “the importance of shifting from an individual to a relational and social understanding of reproduction and shifting from a view of rights as claims against the community to a view of rights as mutual accountabilities.”

Lee M. Silver, *Popular Cloning Versus Scientific Cloning in Ethical Debates*, 4 N.Y.U. J. LEGIS. & PUB. POL’Y 47 (2000-01).

The author argues that the popular conceptualization of what it means to be a clone is inaccurate and leads to unfounded fears. Most of these fears “derive from aspects of the popular conceptualization of cloning that have no basis in reality.” Scientists contribute to this misunderstanding when they use imprecise or misleading language to discuss cloning. Fears that cloning can “make a copy” of a person are unfounded, because only the DNA can be copied, not the resulting individual. Cloned individuals will be born in the same way as non-cloned, and will have a unique identity and unpredictable future. This is because, while genes play an important role in development, they do not predetermine who the person will become. He predicts that people who clone for egomaniacal reasons “will quickly lose interest in cloning when they understand that not only will it not allow them to achieve immortality, but also they could end up with a child who will not obediently follow in their footsteps.” In addition, it would be just as wrong to use

a clone for an illegitimate purpose, such as a source of replacement body parts or warriors, as it would be to use a non-cloned individual.

According to the author, cloning can do no more than provide a person with a biologically-related child. Biological reproduction is a powerful if not well-understood desire shared by many in society and is recognized as a fundamental right by most democratic societies. Most people will have no interest in biological reproduction through somatic cell nuclear transfer (SCNT), but like other assisted reproductive procedures, it may provide infertile individuals a chance to have a biologically-related offspring. If the cloning procedure becomes routine, it may also offer lesbian couples and single women this opportunity as well, without having to use sperm of unknown origin or with potentially undesirable characteristics.

The author states that it would be unethical to use any reproductive technique, including SCNT, “unless data indicated that the procedure did not increase the risk of birth defects in live-born children.” It would also be unethical to use a procedure without disclosing information about safety and efficiency. He states that, given current information, using SCNT to produce a human would not be safe. But, given rapid advances in cloning technology, a safe protocol will likely be developed. This will raise questions regarding whether the use of SCNT to achieve pregnancy should be treated any differently from other assisted reproduction methods. The author rejects arguments that cloning is merely replication, and not reproduction, and that a cloned child will have limited opportunities, as unfounded. Similarly, he rejects the argument that cloning will confound normal understandings of family relationships as unsubstantiated, noting that there are many families today that are not bound by traditional genetic connections.

The author argues that, assuming human cloning is safe and efficient, society does not have a right to ask whether it should be allowed. “It is wrong to judge the validity of any safe approach to baby-making by where or how development begins. Instead, the validity should be judged by the love a parent gives to the child after he or she is born.”

Roy G. Spece, Jr. & Jennifer Weinzierl, *First Amendment Protection of Experimentation: A Critical Review and Tentative Synthesis/Reconstruction of the Literature*, 8 S. CAL. INTERDISC. L.J. 185 (1998).

The authors seek to offer a theoretical framework for First Amendment protection of scientific research and experimentation. They ask whether the “non-expressive” elements of experimentation might be protected under the First Amendment, and if so, whether state interests might nevertheless justify prohibitions of some experiments. They conclude that scientific research is protected under the First Amendment under two possible theories. They also examine governmental interests that might be offered to justify state prohibitions

of cloning or research related to it. In the case of cloning, they conclude that the government could demonstrate compelling interests in prohibiting such research as well as the absence of less restrictive means of preventing the asserted harms.

The authors first survey the legal literature that has looked at the question of First Amendment protection of research. After critiquing the existing literature, they offer a “synthesis and reconstruction” comprising two possible theories under which scientific research is protected. First, they posit that experimentation is an “integral part of a systemic process—the scientific method—that fits uniquely within the purposes, histories, and structures of the First Amendment and the marketplace of ideas.” They argue that there was a close relationship in the minds of the Framers of the U.S. Constitution between science and civil liberties. Also, the purpose and structure of the marketplace of ideas are analogous to the scientific method. Just as more speech is thought to be the remedy for bad speech, more data gathering and experimentation will provide new ways to explain nature. This does not mean that all experimentation is communicative, but rather it should be protected as a central part of a process that involves communication and conduct that is expressive in its search for the truth. Second, they posit that experimentation is “uniquely and powerfully facilitative of highly valued thought,” and should be protected by the First Amendment on that basis. They argue that experimentation is not simply a precursor to thought and speech but that the two are inextricably linked, such that experimentation yields further thought and speech, which in turn yields more experimentation. Furthermore, the particular thoughts and activities at issue are those with potential to benefit humankind.

The authors then examine the government interests that might warrant restrictions on research, and the level of scrutiny that courts should apply to such restrictions. They argue that where the government seeks to restrict particular types of experimentation to prevent the attainment of “forbidden knowledge,” such as how to clone humans, strict scrutiny should apply. The government would therefore be required to demonstrate a compelling interest in prohibiting the research. Where this is not the intention, they argue that an intermediate level of scrutiny should be applied, since experimentation is often associated with serious dangers that the government should have some latitude to regulate.

Cass R. Sunstein, *Is There a Constitutional Right to Clone?* 53 HASTINGS L.J. 987 (2002).

The author addresses whether there is a constitutional right to clone by comparing cloning to other activities that have been found both to have and to lack constitutional protections, including marriage, bodily integrity, and reproduction.

The author considers first whether the right to engage in reproductive cloning would be considered a fundamental right under the Due Process Clause, in which case the government can interfere only where there is a “compelling interest.” If there is no fundamental right, the government need to show only a “rational basis”

for restricting the activity. Some members of the Court have used a “traditionalism” test to determine if a right is fundamental. Under this test, the relevant question is: [I]s this right something that Anglo-American law traditionally protects? The author argues cloning would not be considered a right traditionally protected under the Due Process Clause, but goes on to point out several reasons why tradition should not be the test the Court uses.

The author explores other ways the Court might determine whether cloning is a fundamental right. He rejects the argument that cloning might be protected because it involves “intimate and personal” matters. He explores whether there is “a presumptive right against government intrusions into the decision of how and whether to produce children” but ultimately rejects that argument, arguing that the relevant precedent (concerning contraception and abortion) can be better explained by considering the intrusion on women’s bodies of bans on contraception and abortion, and the implications for women’s equality.

Concluding that it is unlikely the Court will find that a ban on reproductive cloning violates a fundamental right, the author points out that the government would only need to show a “rational basis” for a ban. The author discusses arguments the government offers for a ban on reproductive cloning. He describes three arguments as weak: Leon Kass’ “wisdom of repugnance,” the lessening of the worth of individuals, and concerns about genetic diversity. He considers three stronger arguments: (1) protecting against suffering and early death; (2) preventing psychological harm to the clone; and (3) concerns about the use and exploitation of human beings. He argues that even the strongest arguments would not be “compelling interests,” but that all would meet rational basis review.

Finally, the author explores issues related to therapeutic cloning. He quickly concludes that there is no fundamental right to engage in therapeutic cloning, but also points out that the arguments justifying a ban on therapeutic cloning are even weaker than those offered for a ban on reproductive cloning.

R. George Wright, *Second Thoughts: How Human Cloning Can Promote Human Dignity*, 35 VAL. U.L. REV. 1 (2000).

The author questions the common assumption that human cloning undermines the dignity of persons. He argues that cloning may actually deepen and enhance our appreciation of human dignity by defying a reductionistic view of the human person. Genetic tinkering, according to the author, will be shown to leave human dignity intact as an aspect of human beings that transcends their genomes.

According to the author, opponents of cloning argue that cloning will harm the clone’s dignity, privacy, and autonomy. Because knowledge of the clone’s genetic makeup will already be known, the clone’s privacy will be compromised. Autonomy will be restricted by the clone’s sense of having a closed, predetermined, or non-individualized identity. The author refutes the argument of

diminished autonomy by emphasizing the personhood of the clone, as unique and possessing the same mysterious human qualities that are impenetrable by science. The second objection the author addresses is the commodification of life, e.g., the idea that children will be manufactured as products. He admits that this sort of reductionism generally jeopardizes human dignity, but does not concede that cloning will cause this problem. A third objection against cloning is that it reduces individuality and threatens identity. The author points out that genetic identity does not guarantee true identity, because of the influence of environmental factors, both in and outside the womb. In addition, clones are likely to be different ages. The author argues that genetic uniqueness does not confer dignity. Once cloned, neither the progenitor nor the clone is genetically unique, yet the progenitor does not suddenly lose her dignity. Likewise, the dignity of identical twins is not in question. "Dignity is, at its deepest level, as much about something we share as about something we do not share."

The author argues further that cloning's potential for abuse does not, by itself, make it morally objectionable. He also rejects the notion that human cloning will lead to social inequalities. He points out that the advantages of the wealthy stem less from superior genetic endowments, and more from a broad range of environmental factors, including luck.

The author explores the concept of dignity using a Kantian approach. Kant taught that morality and humanity alone have dignity, and that morality is based on autonomy, which is based on consciousness. Dignity, as defined by Kant, is an intrinsic worth. In brief, the author argues that there is no reason to believe that clones will not be generally capable of the elements of Kantian dignity. Indeed, it is illogical to say that between two genetically identical persons, one is absent dignity.

Stephen J. Werber, *Cloning: A Jewish Law Perspective with a Comparative Study of Other Abrahamic Traditions*, 30 SETON HALL L. REV. 1114 (2000).

The author examines the perspectives on cloning of several different religious traditions. He states that the purpose is not to arrive at a consensus view, but rather to examine the variety of religious voices that should be included in a decision-making process. He states that while Judaism, Islam, and Christianity espouse different theological views and arrive at different conclusions, they share a concern for preserving the dignity of all human beings.

The author reviews three central Jewish tenets that support cloning, at least conceptually. These are the duties to procreate, save life and heal. Cloning is acceptable as a potentially new form of reproductive technology—a means of procreation consistent with the biblical mandate that we "be fruitful and multiply." The author disagrees with arguments opposing cloning because it eliminates genetic diversity, stating that the environmental influences upon a child "impose

differences and create a unique identity.” Thus, any human being created through cloning is fully individual and entitled to be treated with the respect and dignity showed any other person. Most Jewish ethicists say that cloning may change the process of reproduction, but the essence of the product remains the same. Additionally, a basic precept of Jewish law is that which is not prohibited is permitted.

Second, the duty to save life is so important that it can override other religious obligations. The author concludes that if the medical benefits of cloning can save lives, then Jewish law must recognize and accept cloning for this purpose.

Third, the duty to heal can be extended to cloning in the situation where cloning enables a doctor to heal another without causing the death of the clone. The author explains that “[h]aving a child is a wonderful blessed activity; having a child to save the life of another child is an even more blessed activity.” The Jewish tradition arguably places the creation of a child for the purpose of saving another on an equal or even higher moral plane than conceiving a child for the usual family objectives or to meet the duty to procreate. Furthermore, the potential that cloning has to prevent genetic diseases, especially Tay-Sachs disease, provides a compelling reason to support this technology. Current knowledge does not allow us to make a determination as to whether cloning would violate the precept of not causing harm to the mother, and therefore, there is no support for the conclusion that cloning violates Jewish law for this reason.

Based on this analysis, Jewish law permits a few tentative conclusions to be drawn regarding the propriety of human cloning:

- (1) [c]lones are fully human and must be treated with the full dignity accorded to all humans;
- (2) [a]lthough cloning is not the ideal means of reproduction, it is a mitzvah (good deed) in some circumstances and morally neutral in several other circumstances; and
- (3) [c]loning may be allowed for purposes of medical research or therapy.

A clone may not be used for the benefit of another, if that use could cause harm without the clone’s consent (e.g., organ donation). Finally, while Jewish scholarship recognizes the potential benefits of cloning, it also “reflects ambivalence in regard to the benefits and dangers of the cloning process on human values,” and views cloning as violating Jewish law if it results in the treatment of clones as a fungible commodity.

The author then reviews the positions of other “Abrahamic” traditions. He states that according to Islamic tradition, if cloning technology is used to benefit health, and proper care is taken to prevent harm, it is acceptable. It is the will of God, according to the Qu’ran, for “human beings to research, work, and understand the universe and then to draw conclusions that enable them to adopt methods and technology that serve God.”

Next, the author considers the position on cloning of various Christian traditions. The Catholic Church is unambiguously opposed to human cloning, as it

violates God's will regarding procreation, which is that every person be conceived out of love within the bond of marriage. Cloning also undermines the dignity of human beings, each of whom has a unique soul, because it instead views the person as a commodity. For these reasons concerning God's design for the family and the sanctity of human life, the Catholic Church strongly rejects any effort to clone human beings.

Various Protestant denominations reflect differing views on cloning. According to the author, mainline Protestant churches in general cautiously support cloning research, and even more cautiously approve human cloning. "The Christian recognition of creative freedom supports the pursuit of science when used to fulfill divine purposes and meets the correlative obligation of accountability." Therefore, assisted reproductive technologies can be viewed as projects undertaken with God-given ability to help humanity. However, the interests of children and the potential for eugenic misuse are of concern. Christian scholar Roger Shinn takes an opposing view. He makes five secular arguments against cloning, and also justifies rejection of cloning using the Creation stories.

The author examines the contrasting positions of two Lutheran scholars. Gilbert Meilaender argues that "sexual differentiation is ordered toward creation of offspring through the marital union" and that "by God's grace the child is a gift who springs from the giving and receiving of love." Furthermore, "a child should be a natural fruition of love rather than a chosen project." On the other hand, Ted Peters argues that cloning is not a threat to the dignity of the human person, because the "human soul, theologically speaking, is not formed from DNA as the phenotype is formed from the genotype." Therefore, "our dignity is not the result of identity or uniqueness" but rather comes from God's love for us. The two agree that children must always be considered as gifts, but Peters asserts that children who are not conceived the old-fashioned way are also gifts.

According to the author, the Methodist view emphasizes baptism to support its theological opposition to cloning. When Christians are baptized, they become part of the body of Christ; Christian bodies are, in a sense, "cloned" for this higher purpose. Additionally, cloning "wrongfully seeks to perfect that which has already been perfected in Christ."

The Greek Orthodox Church views cloning as immoral, as "humans are created in the image of God for a purpose willed by God." Orthodox teaching says that a clone would have a soul; thus, "the creation of a clone violates Orthodox tradition, but if a clone came into existence it would be treated as a human being." However, Orthodox Christianity opposes any use of cloning, because it is a violation of God's will for marriage and procreation, and it interferes with embryonic development and therefore human dignity. In fact, "these concerns are of such magnitude as to outweigh any life-saving potential therapeutic benefit."

Presbyterian perspectives on cloning differ according to the level of importance placed on genes in human individuality. Presbyterians see "human life

as a unique, non-repeatable journey through this mode of existence and into another that is more glorious and joyful,” emphasizing uniqueness and the soul. It permits human cloning for therapeutic uses, but rejects its use for replacing a person; however, it does not reject all human cloning outright, and instead asserts that currently, the weight of theological conviction is against the use of cloning.

Lastly, according to the author, the Southern Baptist perspective is that cloning “provides a powerful eugenic temptation that must be rejected by Christianity.” Southern Baptism is founded in the biblical mandates of dominion and stewardship, yet emphasizes the importance of humans playing their role. According to that view, it is wrong for humans to “play God,” since humans “are not the Creator, and the responsibility to assume control over the universe is not ours.”