Those engaged in moral discourse about public policy, however, must move beyond such personal considerations, however deeply felt, and develop coherent arguments that will persuade many others to accept a particular point of view. As a result, it is useful to formulate moral convictions in ways that most people can understand and reflect upon. In a pluralistic society, there is no easy way to determine when and which governmental interventions are warranted. No algorithm clearly indicates whether the arguments for governmental intervention in a particular situation are stronger than the arguments against such interventions. Instead, we must engage in moral discourse, debate, and argument in a process of public deliberation. Although closure must be reached, and decisions made, even if there is no consensus, our society has only just begun to reflect seriously on the possibility of creating children through somatic cell nuclear transfer. It may be premature to come to closure on some issues because so little time has been devoted to the issue.

Thus, the ethics of making policy, as opposed to the ethics of cloning itself, requires us to return to the guidelines set forth by scholars such as Gutmann and Thompson: are the moral concerns sufficiently strong to justify prohibition or regulation? If so, is the price we pay in the form of constraints on personal liberty or the abridgement of legally protected rights acceptable? Can individual cases be treated as exceptions? Or will making exceptions create more problems, in the form of intrusive inquiries into people's motives, for example, such that making the exceptions causes more harm than good?

It is not possible to answer these questions with certainty. But some help can be obtained by looking at existing law governing efforts to create children in this manner, and at the possible policies that might be adopted to govern this technology.

Conclusions

In summary, the Commission reached several conclusions in considering the appropriateness of public policies regarding the creation of children through somatic cell nuclear transfer. First and foremost, creating children in this manner is unethical at this time because ~~of~~ president insufficient evidence that such techniques are effective and safe. Even if concerns about safety are resolved, however, significant concerns remain about the negative impact of the use of such a technology on both individuals and society. Public opinion on this issue may remain divided. Some people believe that cloning through somatic cell nuclear transfer will always be unethical because it undermines important social values and will always ~~retain the potential to cause~~ risk psychological or other harms to the resulting child. In addition, although the Commission acknowledged that there are cases for which the use of such cloning might be considered desirable by some people, overall these cases were insufficiently compelling to justify proceeding with the use of such techniques. Finally, the Commission was not persuaded by objections to a prohibition against such cloning which were based, in part, on the expectation that its use is unlikely to be widespread and, in part, on the belief that many of the assumed harms are purely speculative.

indicates that such techniques

Finally, many scenarios of creating children through somatic cell nuclear transfer are based on the serious misconception that selecting a child's genetic makeup is equivalent to selecting the child's traits or accomplishments. A benefit of more widespread discussion of such cloning would be a clearer recognition that a person's traits and achievements depend heavily on education, training, and the social environment, as well as on genes. Should this type of cloning proceed, however, any children born as a result of this technique should be treated as having the same rights and moral status as any other human being.

Clearly, there is a need for further public deliberation on the serious moral concerns raised by the prospect of cloning human beings. As the Commission proceeded in its review, the members learned from listening to the public and to each other. Many important issues remain unclear or unresolved, such as whether there is a moral right to freely make procreative decisions, even if those decisions include creating a child through somatic cell nuclear transfer. The Commission believes that it is essential to try to understand the diverse reactions to such cloning and the ethical arguments for and against various policies regarding its use. This report is only the beginning of a public process to assess the impact of this new technology.

References

Annas, G.J, "Regulatory models for human embryo cloning: The free market, professional guidelines, and government restrictions," *Kennedy Institute of Ethics Journal* (4)3:235-249, 1994.

Brock, D., "Cloning Human Beings: An Assessment of the Ethical Issues Pro and Con," paper prepared for NBAC, 1997.

Brock, D.W. "The non-identity problem and genetic harm," *Bioethics* 9:269-275, 1995.

Cahill, L., Testimony presented to the National Bioethics Advisory Commission, March 13, 1997.

Chadwick, R.F., "Cloning," *Philosophy* 57: 201-209, 1982.

Coleman, "Playing God or playing scientist: A constitutional analysis of laws banning embryological procedures," *27 Pacific Law Journal* 1331, 1996.

Duff, N., "Theological Reflections on Human Cloning," Testimony presented to the National Bioethics Advisory Commission, March 13, 1997.

Etzioni, A., *The Moral Dimension* (NY: The Free Press, 1990).

Feinberg, J., "The child's right to an open future," in *Whose Child? Children's Rights, Parental Authority, and State Power*, W.Aiken and H. LaFollette (eds.) (Totowa, NJ: Rowman and Littlefield, 1980).

Glendon, M.A., *Rights Talk* (New York: The Free Press, 1991).

Gutmann, A., and D. Thompson, *Democracy and Disagreement* (Cambridge, MA: Belknap Press, 1996).

Jonas, H., *Philosophical Essays: From Ancient Creed to Technological Man* (Englewood Cliffs, N.J.: Prentice-Hall, 1974).

Kass, L., "Why We Should Ban the Cloning of Human Beings," Testimony presented to the National Bioethics Advisory Commission, March 13, 1997.

Keveles, D.J., *In the Name of Eugenics* (Cambridge, MA: Harvard University Press, 1995).

Meilaender, G., "Remarks on Human Cloning to the National Bioethics Advisory Commission,

Testimony presented to the National Bioethics Advisory Commission, March 13, 1997.

Macklin, R., "Why We Should Regulate—But Not Ban—the Cloning of Human Beings," Testimony presented to the National Bioethics Advisory Commission, March 14, 1997.

Macklin, R., "Splitting embryos on the slippery slope: Ethics and public policy," *Kennedy Institute of Ethics Journal* 4: 209-226, 1994.

Mill, J.S., *On Liberty* (Indianapolis, IN: Bobbs-Merrill Publishing, 1859).

National Institutes of Health, *Report of the Human Embryo Research Panel* (Bethesda, MD: National Institutes of Health, 1994).

Nussbaum, M.C., "Nature, function, and capability: Aristotle on political distribution," in *Oxford Studies in Ancient Philosophy,* Julia Annas and Robert H. Grimm (eds.) Supp. 1988.

Nussbaum, M.C., "Aristotelian social democracy," in *Liberalism and the Good* 203, R. Bruce Douglass, et al., (eds.), pp. 217-226, 1990.

Parfit, D., *Reasons and Persons* (Oxford: Oxford University Press, 1984).

Posner, R, *Sex and Reason* (Cambridge, MA: Harvard University Press, 1992).

Radin, M., "Reflections on Objectification," *65 Southern California Law Review* 341 (November 1991).

Radin, M., "The Colin Ruagh Thomas O'Fallon Memorial Lecture on Personhood," 74 *Oregon Law Review* 423 (Summer 1995).

Rhodes, R. "Clones, harms, and rights," *Cambridge Quarterly of Healthcare Ethics* 4:285-290, 1995.

Robertson, J.A., "A Ban on Cloning and Cloning Research is Unjustified," Testimony Presented to the National Bioethics Advisory Commission, March 14, 1997.

Robertson, J.A., "The question of human cloning," *Hastings Center Report* 24:6-14, 1994.

Robertson, "The scientist's right to research: A constitutional analysis, *51 Southern California Law Review 1203*, 1977.

Rothenberg, K., Testimony before the Senate Committee on Labor and Human Resources, March 12, 1997.

1 Schwartz, H., *The Culture of Copy* (New York: Zone Books, 1996).

APPENDIX A: GLOSSARY[1]

Blastocyst: the developing preimplantation embryo, beginning about 4 days after fertilization. The blastocyst consists of a sphere of cells made up of an outer layer of cells (the trophectoderm), a fluid-filled cavity (the blastocoel), and a cluster of cells on the interior (the inner cell mass).

Blastomere: each of the cells produced when the fertilized egg cleaves into 2, then 4, 8, and 16 cells.

Blastomere separation: a technique by which a jelly-like substance called the zona pellucida is removed from around a two-to eight-cell embryo, or morula, and the embryo is incubated in a special solution so that the blastomeres separate and fall apart. The blastomeres are then cultured separately.

***Cellular cloning:** the process by which cells are derived from the soma, or body, and are grown in tissue culture in a laboratory. The genetic makeup of the resulting cloned cells, or cell line, is identical to that of the original cell.

Chromosomes: nucleic acid-protein structures in the nucleus of a cell. Chromosomes are composed chiefly of DNA, the carrier of hereditary information. Chromosomes contain genes, working subunits of DNA that carry the genetic code for specific proteins, interspersed with large amounts of DNA of unknown function. A normal human somatic cell contains 46 chromosomes; a normal human gamete contains 23 chromosomes.

Clone: A precise copy of a molecule, cell, or individual plant or animal.

Cytoplasm: the contents of a cell other than the nucleus. Cytoplasm consists of a fluid containing numerous structures that carry out essential cell functions.

Differentiation: the process whereby an unspecialized early embryonic cell acquires the features of a specialized cell such as a heart, liver, or muscle cell.

---

[1]Most of the definitions were excerpted from the National Institutes of Health *Report of The Human Embryo Research Panel* (Washington, DC: U.S. Government Printing Office, 1994).

*Indicates definitions not found in the Embryo Panel Report -- these were definitions that were readily culled from the text of this report.

Diploid: a cell or tissue having two chromosome sets, as opposed to the haploid situation of eggs and sperm which have only one chromosome set.

DNA: Deoxyribonucleic acid, found primarily in the nucleus of cells. DNA carries the instructions for making all the structures and materials the body needs to function.

Egg: the mature female gamete; also called ovum, or oocyte.

Embryo: the developing organism from the time of fertilization until significant differentiation has occurred, when the organism becomes known as a fetus.

Embryo transfer: the introduction of a preimplantation embryo into the uterus for growth and developnment.

Embryonic stem (ES) cells: primitive undifferentiated cells from the embryo that have the potential to give rise to a wide variety of specialized cell types.

Enucleated egg: an egg from which the nucleus has been removed.

Fertilization: the process whereby male and female gametes unite; it begins when a sperm contacts the outside of the egg and ends with the formation of the zygote.

Gamete: a mature sperm or egg.

Gene: a working subunit of DNA. Each of the body's 100,000 genes carries the instructions that allow the cell to make one specific product such as a protein.

Gene targeting: Generating a precise replacement of one gene for a different or altered gene.

Genome: the complete genetic makeup of a cell or gene.

Genetic imprinting: a biochemical phenomenon that determines, for certain specific genes, which one of the pair of identical genes, the mother's or the father's, will be active in that individual.

Germ cell: a sperm or egg, or a cell that can become a sperm or egg. All other body cells are known as somatic cells.

Inner cell mass (ICM): the cluster of cells inside the blastocyst, which gives rise to the embryo and ultimately the fetus.

***In vitro* fertilization (IVF):** an assisted reproduction technique in which fertilization is accomplished outside the body.

***Molecular cloning:** the process whereby identical fragments of DNA are produced by insertion of a DNA fragment into a host vector followed by amplification to produce many thousands of copies in a host cell, usually a bacterium.

Mutation: a change in DNA that alters a gene and thus the gene's product, leading in some cases to deformity or disease. Mutations can occur spontaneously during cell division or can be triggered by environmental stresses such as sunlight, radiation, and chemicals.

Nuclear transplantation cloning: a type of cloning in which the nucleus from a diploid cell is fused with an egg from which the nucleus has been removed. The DNA of the transplanted nucleus thus directs the development of a resulting embryo.

Nucleus: the cell structure that houses the chromosomes.

Oocyte: the mature female germ cell; the egg.

***Somatic cells:** those cells not destined to become sperm and egg cells.

Sperm: mature male reproductive cells.

Totipotent: having unlimited developmental capacity. The totipotent cells of the very early embryo have the capacity to differentiate into extraembryonic membranes and tissues, the embryo, and all postembryonic tissues and organs.

Zygote: the single-celled, fertilized egg.

Chapter Five

LEGAL AND POLICY CONSIDERATIONS

The public policies recommended with respect to the creation of a child using somatic cell nuclear transfer reflect the Commission's best judgment about both the ethics of attempting such an experiment and our view of traditions regarding limitations on individual actions in the name of the common good. At present, the use of this technique to create a child would be a premature experiment that exposes the developing child to unacceptable risks. This in itself is sufficient to justify a prohibition on attempts to clone human beings at this time, even if such efforts were to be characterized as the exercise of a fundamental right to attempt to procreate. More speculative psychological harms to the child, and effects on the moral, religious, and cultural values of society may or may not be enough to justify prohibitions in the future, and more time is needed for discussion of these concerns. The prohibition on cloning human beings via somatic cell nuclear transfer could be effectuated directly, through federal legislation, or indirectly, by way of a collection of efforts aimed at deterring such experiments. Such efforts could include voluntary cooperation by the private sector, both research and clinical, in a moratorium on such experiments, and a continued prohibition of the use of federal funds to support such experiments. Enhancement of protections for human subjects of medical research and cooperation with our foreign counterparts in the enforcement of any common elements of our respective policies could strengthen any of these measures.

* * * * * * * *

This chapter briefly reviews existing and proposed laws and policies that would affect efforts to clone human beings using somatic cell nuclear transfer, as well as the potential constitutional challenges that might be raised if such efforts are restricted.[1]

Almost immediately after the announcement of Dolly's birth, legislation was introduced in the Congress and in approximately a dozen states, aimed at prohibiting all or some research on human cloning (see Table 1). Some of the bills would prohibit the use of somatic cell nuclear transfer cloning to create a child; others would also, either deliberately or inadvertently, prohibit research on cloning human DNA sequences or cell lines. The current moratorium on the use of federal funds for cloning human beings in this manner has provided an opportunity for additional analysis of the potential risks and benefits of creating children through somatic cell nuclear

[1] To support the Commission's review, a commissioned paper, "The Current and Future Legal Status of Cloning" was prepared by Lori Andrews, Chicago-Kent College of Law. In addition, NBAC commissioned a review of research moratoria, "Do Research Moratoria Work?" prepared by Robert M. Cook-Deegan, and a review of international responses, "Cloning: An International Comparative Perspective," prepared by Bartha Knoppers, University of Montreal.

transfer, its current legal status, and the potential constitutional challenges that might be raised if new legislation is enacted to restrict such acts.

Laws Affecting Efforts to Clone a Human Being

At present, there is no law in the United States directly addressing attempts to create a child through somatic cell nuclear transfer, although a variety of state and federal laws and policies do have some application.

Federal Law

Federal law already requires that clinics using assisted reproduction techniques, such as *in vitro* fertilization, be monitored. The requirement would appear to apply, as well, to efforts to use somatic cell nuclear transfer cloning to create a child. This statute, the Fertility ~~Clinic~~ Success Rate and Certification Act of 1992,[2] covers all laboratories and treatments that involve manipulation of human eggs and embryos, and requires that rates of success at achieving pregnancies be reported to the Department of Health and Human Services (DHHS) for publication in a consumer guide. It also directs DHHS to develop a model program for inspection and certification of laboratories that use human embryos, to be implemented by the states.

As this statute is implemented, any clinic or laboratory involved in attempts to initiate pregnancies by somatic cell nuclear transfer cloning should be identifiable to the federal government, and the outcomes of its efforts known to the public. As states move to implement the inspection and certification aspects of the law, a mechanism would exist to prevent attempts to use the technology, if it is shown to be ineffective or dangerous for the tissue donor or resulting child.

Federal regulations governing the use of human beings in research also restrict the conduct or funding of any research aimed at cloning human beings. Research that is conducted with federal funds or at institutions that have executed a "multiple assurance agreement" with the federal government is subject to these regulatory provisions, aimed at ensuring that human subjects are not exposed to unreasonably risky experiments and are enrolled in research only after giving informed consent.[3] Enforcement of these protections lies primarily in the hands of "Institutional Review Boards," ["IRBs"] committees appointed by institutions (such as universities) where research is conducted. IRBs review experiments before people can be enrolled. To the extent that efforts to clone human beings take place at institutions subject to

---

[2] 42 U.S.C.A. Sec. 263a-1 et seq

[3] 45 C.F.R. Part 46

these regulations or in experiments funded by the federal government, any serious question about the physical harms that might result would make it difficult for such experimentation to be approved.

With regard to federal research funding, President Clinton announced in 1994 that the National Institutes of Health (NIH) should not finance any research that involves creating embryos solely for research that would result in their destruction.[4] Furthermore, Congress has passed prohibitions on the use of FY96 and FY97 funds appropriated to the Departments of Labor, Education, and HHS for any research that involves exposing embryos to risk of destruction for non-therapeutic research.[5] The net effect of these policies is to eliminate virtually all federal funding for research to perfect methods for cloning human beings, as even research aimed at initiating a pregnancy would probably involve the destruction of many embryos that fail to develop normally.

creating and destroying

State Laws

While these restrictions prohibit only federally funded research, a number of state laws regarding the management of embryos arguably could restrict even privately funded research.[6] By and large, however, states do not have legislation directly regulating assisted reproduction techniques, leaving state medical malpractice law as the primary means for regulating clinical application of the technology.[7]

---

[4]"Statement of the President on NIH Recommendations Regarding Human Embryo Research," U.S. Newswire (Dec. 2, 1994).

[5]P.L. 104-91 and P.L. 104-208.

[6]Ten states have laws regulating research and/or experimentation on conceptuses, embryos, fetuses or unborn children that use broad enough language to include early stage conceptuses.Fla. Stat. Ann. § 390.001(6) (West 1993); La. Rev. Stat. Ann. § 9:121 et seq. (West 1991); Me. Rev. Stat. Ann. tit. 22, § 1593 (West 1992); Mass. Gen. Laws Ann. ch. 112, § 12J (West 1996); Mich. Comp. Laws Ann. § 333.2685 et seq. (West Supp. 1997); Minn. Stat. Ann. § 145.421 (West 1989); N.D. Cent. Code § 14-02.2-01 (1991); N.H. Rev. Stat. Ann. § 168-B:15 (Supp. 1996); Pa. Cons. Stat. § 3216 (West Supp. 1996); R.I. Gen. Laws § 11-54-1 (1994).

[7]If cloning is considered to be a form of fertilization, questions arise regarding whether state laws setting standards for who may perform *in vitro* fertilization will cover the practice. Certain laws governing reporting, the qualifications of personnel, and so forth, will be applicable to researchers. A New Hampshire law, for example, requires counseling in advance of *in vitro* fertilization and limits the procedure to participants over age 21 (which, if applied to cloning, might prohibit the use of DNA from a minor child). Pennsylvania has a reporting requirement which mandates that anyone performing *in vitro* fertilization file quarterly reports with the Department of Health describing such facts as the number of embryos destroyed and discarded and the number of women in whom embryos are implanted. Louisiana's

Malpractice law operates most effectively when agreement exists within the medical profession about the indications and contraindications for a particular procedure, as well as about the methods by which the procedure is appropriately carried out. For an entirely new procedure, agreement on these points may be lacking, although sometimes consensus exists within the profession that any attempt to use a new procedure would be premature in light of the existing, pre-clinical data.

State laws governing family relationships would also be applicable if efforts to clone human beings were successful. But paternity acts, surrogacy statutes, and egg donation statutes are not necessarily broad enough to address the kinship relationships involved in cloning human beings. The use of this technique would result in a child having as many as four individuals with claims to parental status based on some aspect of genetic connection: the person from whom the cell nucleus was derived, that individual's genetic parents, and the woman contributing the enucleated egg cell which contains a small fraction of DNA in the cytoplasmic mitochondria. In addition, if the egg with the transferred nucleic material is implanted in a gestational mother, the child will have two other potential parents: the gestational mother,[8] and if she is married, her husband.[9] Finally, the intended rearing parents could be unrelated to the individuals whose egg or nucleus was used, or to the gestational mother. The contributors to such cloning arrangements will have various, as yet ill-defined, legal rights and responsibilities with respect to the resulting child (Andrews, 1997).

Overall, existing law would severely restrict public funding for efforts to clone human beings; would monitor most efforts to clone human beings for safety and efficacy; and would discourage premature experimentation. It would not, however, prohibit all such efforts. Further, if an attempt to clone a human being were successful, then existing law would struggle to

---

law requires that *in vitro* fertilization shall only be undertaken by practitioners and facilities meeting the standards of the American College of Obstetricians and Gynecologists (ACOG) and the American Fertility Society (AFS) (currently, the American Society for Reproductive Medicine). La. Rev. Stat. Ann. § 9:128 (West 1991).

[8]In many states, the woman who gives birth is considered to be the legal mother and her husband the legal father of any resulting child. Under statutes in Arizona and Utah, this holds true even when the surrogate is gestating an embryo with no genetic relationship to her. Only in Florida, New Hampshire, North Dakota and Virginia do court-approved gestational surrogacy arrangements result in the intended rearing parents—not the surrogate— being viewed as the legal parents.

[9]The latter often will have rights (even though he has no biological connection to the child) based on the common law presumption that if a woman gives birth within marriage, her husband is the child's legal father, or in some states, based on specific statutes holding that the surrogate and her husband are the legal parents of a child she has gestated regardless of their genetic contribution. See, e.g., Ariz. Rev. Stat. § 25-218 (1996).

characterize the family relationships that ensue.

Constitutional Limitations on Policy Formulation

Although the potential ability to clone human beings by somatic cell nuclear transfer engendered a great deal of discussion,[10] the formation of appropriate public policy with respect to cloning of human beings in this manner depends on more than the potential benefits and harms of reproductive cloning itself. It also depends on the traditions, customs, and principles of constitutional law that guide public policy making in the United States. These include such important factors as:

---

[10]See, e.g., *Los Angeles Times*, February 25, 1997, page 6, "Next, Really Prolific Cows: Scientists Clone a Sheep, but We Needn't Fret the Doomsday Scenarios"; *The New York Times*, February 25, 1997, Section A; page 26; "Cloning for Good or Evil"; *The Houston Chronicle*, February 25, 1997, Outlook; page 19, "Dolly's birth is father to some worrying musings," Otis Pike; *The Record*, February 25, 1997, page L10, "Of Sheep and Men; Before Building a Better Beast, Think Twice; *The San Diego Union-Tribune*, February 25, 1997, page B-6, "Amazing breakthrough: Cloning of sheep has remarkable implications"; *Wall Street Journal*, February 25, 1997, Section A; page 22, "Review & Outlook: Listening to the Lamb"; *The Arizona Republic*, February 26, 1997, page B4, "Cloning Question; The Mysteries of Life"; *The Florida Times-Union*, February 26, 1997, page A10, "No need for panic"; *Miami Herald*, February 26, 1997, Section A; page 16, *"God's Work; Man's Hands"*; *The Morning Call*, February 26, 1997, page A16, "'Dolly' Opens New Vistas For Mankind"; *St. Petersburg Times*, February 26, 1997, page 14A, "Rules for cloning needed"; *The Buffalo News*, February 27, 1997, page 2B, "Ready or Not, Cloning Has Arrived; Don't Lose Time Banning it in Humans; *Dayton Daily News*, February 27, 1997, page 1a, "Animal Cloning Calls for Human Restraint"; *Philadelphia Inquirer*, February 27, 1997, page 19, "Don't Be Too Hasty With Laws on Cloning," by James K Glassman; *The San Francisco Examiner*, February 27, 1997, page A20, "Hello Dolly: The cloning of a lamb from a sheep cell opens up a new era of nervous jokes, profound questions and athletic opportunity"; *The Augusta (Ga.) Chronicle*, February 28, 1997, page A4, "Ban Human Cloning"; *The State Journal-Register* (Springfield, IL), March 2, 1997, page 16, "Cloning of sheep holds remarkable implications"; *The Baltimore Sun*, March 3, 1997, page 8A, "More of you and me?; Hello, Dolly: Replicating a sheep raises concerns about cloning humans"; *The Indianapolis News*, March 4, 1997, page A6, "Wolves in sheep's cloning"; *The Spokesman-Review* (Spokane, WA), March 7, 1997, page B6, "Cloning Tempts Our Darker Sides; Ban Research; We Won't Resist the Urge to Turn Humans into Instruments," D.F. Oliveria; *The Spokesman-Review* (Spokane, WA), March 7, 1997, page B6, "Cloning Offers Hope, Not Evil; Don't Be Afraid; Cloning Research Offers Hope to Solve Genetic Mysteries," Rebecca Nappi; *The Times-Picayune*, March 10, 1997, page B6, "Cloning Begets Questions"; *Dayton Daily News*, March 10, 1997, page 6A, "Fear of Clones Itself a Threat;" *The Orange County Register*, March 10, 1997, page B06, "Vital questions"; *Los Angeles Times*, March 13, 1997, page 8, "Don't Rush Anti-cloning Laws; Concerns Are Real, but Legislation Needs Expert Input;" *The Nashville Banner*, March 19, 1997, page A8, "Frist's note of caution; Don't be too hasty, he says, to pass law on cloning"; *The Nation*, March 24, 1997, No. 11, Vol. 264; Pg. 4; ISSN, "Irreplaceable ewe; cloning of a sheep;" Editorial, Hubbard, Ruth; *The New York Times*, April 1, 1997, page 22, "Cloning as an Anticlimax," Philip M. Boffey; Information Bank Abstracts, *Wall Street Journal*, May 2, 1997, page 14, "Will Cloning Beget Disaster?"

a) a presumption in favor of individual freedom of action, absent strong arguments to the contrary based on the common good and the need to protect others from harm;

b) the requirement that arguments against individual freedom of action be made in terms as convincing and understandable as possible to all those who will be affected, recognizing that U.S. citizens are of various religious faiths and cultural traditions;

c) the requirement that liberty be constrained as little as needed while serving the public interest;

d) allowing individual deviation from the applicable public policy when a compelling need is shown, whenever possible;

e) restraint in the exercise of federal powers with regard to areas traditionally governed by diverse state laws and policies; and

f) coordination with common policies set in other nations, where appropriate.

Liberty and Limited Federal Powers

The presumption in favor of individual freedom of action cannot be interpreted simplistically. A focus on rights to the exclusion of responsibility leaves us in a situation where, in the words of legal scholar Mary Ann Glendon, "we can barely find the words to speak of indirect harms, cumulative injury, or damages that appear only long after the acts that precipitated them" (Glendon, 1991).

Nonetheless, from the writings of Locke to the writings of the United States Supreme Court, the American tradition has been to assume a freedom to act absent a specific, justifiable prohibition. This tradition is enshrined in the constitutional language of liberty used in case law, ranging from freedom from unreasonable searches and seizures to freedom to refuse medical treatment. But the liberty enshrined in American tradition and constitutional law is not unfettered; rather, it is the ordered liberty of a social compact. To ensure the good order of society, one person's liberty may be limited when its exercise would limit the liberty of another, or would otherwise undermine important social values.

It is for this reason that an individual's actions may be limited when they would directly harm another. This principle can be applied even when the harm will not be experienced by a currently living person. Thus, on occasion, American courts have recognized that even actions taken prior to the conception of a child might lead to legal responsibility for that child's health

costs, if the actions were unreasonable and avoidable.[11]

On this basis alone, efforts at this time to create a child via somatic cell nuclear transfer may well be inappropriate, since there is widespread consensus that such a step would be dangerous and premature before a great deal of further animal research is conducted.

Morality and Public Policy Formulation

Concerns about the potential impact of cloning human beings through somatic cell nuclear transfer on public and private values and morale are quite real, but nonetheless difficult to articulate with precision. These ethical and theological concerns (as discussed in Chapter 3) focus on effects on self-identity, human dignity, privacy, autonomy, and kinship relations.

Americans share some but not all of their ethical and cultural traditions, and no single set of approaches that balances conflicting values in particular ways enjoys universal acceptance (Brock, 1995). Some theological analyses provide answers to their adherents, but these are incapable of serving as the sole basis for policy making in a religiously diverse nation committed to separation of church and state.[12] Further, the absence of an agreed upon methodology in moral philosophy or bioethics for resolving disputes among competing ethical theories and conflicting values means that no analytical argument can be persuasive to every person (Brock, 1995). Nonetheless, the instinctive distrust with which much of the American public greeted the prospect of cloning is necessarily a significant factor. No suggested public policy can hope to gather support and compliance in the absence of either consensus or persuasive argumentation.

Many of the objections described above are based upon predictions of the widespread effects on society should this type of cloning become a frequent practice. Thus, they are arguments not only about the morality of cloning itself, but also about the need to avoid it even in arguably compelling cases, lest the accumulation of such individual cases lead to widespread practice that could undermine—as many who testified before NBAC have put it—the very

---

[11]See, e.g., Curlender v. Bio-Science Laboratories, 165 Cal. Rptr. 477 (Ct. App. 1980).

[12]"[I]n order to be legitimate, the State's interest ... must be secular; consistent with the First Amendment the State may not promote a theological or sectarian interest. Planned Parenthood of Southeastern Pennsylvania v. Casey, 112 S. Ct. 2791, 120 L.Ed 2d 674, 739 (1992) (Stevens, J. concurring in part and dissenting in part). See also Thornburgh v. American College of Obstetricians and Gynecologists, 476 U.S. 747, 778 (1986) (Stevens, J. concurring); see generally Webster v. Reproductive Health Services, 492 U.S. 490, 563-572 (1989) (Stevens, J., concurring in part and dissenting in part).

When applied to ethical decision making, one philosopher notes: "Morality's ambition is, or at least ought to be, to provide a system of conduct under which everyone can live with a sense of mutual justifiability. This follows from the conditions of political legitimacy. We do not live in a theocracy, where some people are thought to have a privileged and direct line to moral truth." (Nagel 1995)

meaning of being human.

Members of the Commission could not come to a common evaluation of each of these objections, as they are partly speculative, partly theological, and partly based on particular values or world views that are commonly, but nonetheless not universally, shared by all Americans. On the other hand, the collective force of these objections makes a strong *prima facie* case for a political judgment that creating a child in this manner would violate the deeply held views of many Americans.

Fundamental Liberties, Procreation and Cloning

But while such arguments may make a strong political case for prohibiting this type of cloning, American law occasionally demands more. Specifically, while any rational reason will suffice for government limitation of ordinary individual liberties, such as the right to drive or to operate a business, the Constitution demands a more compelling reason when a more important kind of right is infringed. Then, any limitation must serve a compelling purpose and must be drawn as narrowly as possible, so as to infringe upon individuals only as needed.

This is the case when fundamental liberties are at stake. Fundamental liberties have been defined by the Supreme Court as those that are specifically mentioned in the Constitution, for example, the right to free speech; those so deeply rooted in our culture and history as to be assumed by the public as beyond casual governmental interference; and those that are so basic they are necessary to a system of ordered liberty.

Thus, to determine if the arguments put forth are sufficient to justify a prohibition constitutionally, as well as politically, it is necessary to examine whether the choice to create a child via somatic cell nuclear transfer cloning would be viewed as a fundamental liberty. Since such cloning, if successful, would involve bringing children into the world, it is quite possible that one could characterize it as a form of procreation, for which the courts have carved out large areas of special protection since the "bearing and begetting" of children has been characterized as a fundamental right.

The right to make decisions about whether or not to bear children was first constitutionally protected under the constitutional right to privacy.[13] More recently, the Court has reaffirmed the "recognized protection accorded to liberty relating to intimate relationships, the

[13] See, e.g., Griswold v. Connecticut, 381 U.S. 379 (1965); Eisenstadt v. Baird, 405 U.S. 438 (1972). Early decisions protected the married couples' right to privacy to make procreative decisions, but later decisions focused on individuals' rights as well. The U.S. Supreme Court, in Eisenstadt v. Baird, stated, "[i]f the right of privacy means anything, it is the right of the individual, married or single, to be free from unwarranted governmental intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child." Eisenstadt v. Baird, 405 U.S. 438, 453 (1972).

family, and decisions about whether to bear and beget a child."[14] A federal district court has interpreted this right to make procreative decisions to include the right of an infertile couple to undergo medically assisted reproduction, including *in vitro* fertilization and the use of a donated embryo, stating:

> It takes no great leap of logic to see that within the cluster of constitutionally protected choices that includes the right to have access to contraceptives, there must be included within that cluster the right to submit to a medical procedure that may bring about, rather than prevent, pregnancy.[15]

Others take a narrower view of the Supreme Court's decisions about reproductive liberty. In this view, the Court merely aimed to protect bodily integrity from direct interference by the state (which would occur if the state compelled or prohibited abortions or contraceptive use) and particularly to ensure that the law not unduly burden women's choices. Thus interpreted, the Constitution would not guarantee individuals unfettered access to assisted reproductive technologies.

Commentators arguing over whether the Constitution should be interpreted to protect the right to create a child through somatic cell nuclear transfer thus begin by debating the present scope of procreative liberty, and then addressing whether or not this method is qualitatively different existing forms of medically assisted reproduction. Some argue that if the method can be used as a means to serve reproductive ends, it should be classified as procreation. Others disagree, deeming cloning with somatic cell nuclear transfer to represent a radical new step that should be classified as "replication," rather than "reproduction" (Annas, 1997; Kass; 1997; Macklin, 1997; Robertson, 1997).

To the extent that cloning invokes the choice to generate a child, it is indeed procreative. On the other hand, cases discussing procreative rights have always been premised on underlying assumptions about the meaning of procreation, for example, that it is interdependent, involving the reproductive cooperation of a male and a female, at least on the biological level. Another assumption has been that it involves the transmission of genes vertically across a generation, that is, between a parent and child. Cloning via somatic cell nuclear transfer represents a form of genetic duplication within an existing generation.

Whether cloning is best characterized as procreation or as something entirely new and different is a matter of debate, for which existing decisions by the U.S. Supreme Court offer only

---

[14] Planned Parenthood v. Casey, 505 U.S. 833, 112 S.Ct. 2791, 2810 (1992).

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

partial guidance. Thus, it is impossible to say with certainty whether somatic cell nuclear transfer cloning would be treated in law as a fundamental right. But if it were to be treated as a fundamental right, then arguments against the practice based on speculative psychological and social harms would be tested against the strictest scrutiny of the judicial system.

Policy Options

It is against this backdrop that the Commission developed the following policy options:

- To continue the existing moratorium on federal funding of any effort to create a child through somatic cell nuclear transfer, and to emphasize that the intent of this moratorium is to cover any effort to use federal funds for this technology whether in a clinical or research setting.

- To obtain the agreement of the private sector to abide by the spirit of the federal moratorium.

- To extend to all participants in research protocols the human subjects protections already in place for those enrolled in federally funded protocols.

- To prohibit efforts to clone human beings by federal statute.

- To facilitate public education and debate, in preparation for legislative action, if any, and to carry on a national discussion about the uses of somatic cell nuclear transfer cloning technology.

- To cooperate with our counterparts in other nations to enforce any common elements of our respective policies regarding efforts to clone human beings.

OPTION: Continue the Moratorium on the Use of Federal Funding for the Creation of a Child Using Somatic Cell Nuclear Transfer

The first, and simplest, of the policy options is to call for a continuation and expansion of the March 4 Presidential ban on the use of federal funds for cloning of human beings via somatic cell nuclear transfer. The continuation of this moratorium could encompass both federal research funds, such as those made available by the Department of Health and Human Services, as well as other federal payments. Thus, for example, Medicaid and Medicare could make clear what is already widely assumed, to wit, that they will not pay for any efforts to attempt to create a child via somatic cell nuclear transfer because, among other things, they do not pay for experimental

procedures.[16]

It may be worth exploring, as well, the feasibility of attaching conditions to the receipt of certain federal funds so as to extend the prohibition on cloning of human beings via nuclear transplantation. For example, the federal government provides large block grants for maternal and child health services. In light of the significant risks to the child's health posed by this technology, it might be appropriate to condition receipt of federal funds on the promise to prohibit attempts within a specific institution. In the past, such an approach has been used with regard to prospects for human gene therapy. Thus, in the 1980s, institutions were told that they could receive federal funds for work on recombinant DNA therapy on the condition that no one would attempt to use it in people until the specific application had been reviewed for its safety and ethical acceptability by a specially created review body. Compliance with these conditions has been excellent.

OPTION: Appeal to the Private Sector for Adherence to the Intent of the Federal Moratorium on the Cloning of Human Beings

An appeal can be made immediately to all portions of the private sector, and to all relevant societies of clinicians and researchers, urging them to forego any attempt to use nuclear transfer to create a child. Compliance could well be high, especially within the research community, which has a history of successfully invoking voluntary moratoria even on exciting and appealing innovations such as gene therapy. In another notable instance, scientists voluntarily suspended certain experiments using recombinant DNA technology in the 1970s, so that safety standards might be debated.

The closest analogy to a moratorium on cloning human beings may well be found in the existing moratorium on the use of germ line gene therapy, i.e., deliberate changes in human DNA intended to be inherited. A decade ago, the consensus was that no one could do gene therapy safely and reliably. Opinion split about the prudence of banning it. On the one hand, there seemed little harm in banning it, with some prospect of public assurance as a benefit. On the other hand, if the technology evolved sufficiently, one might imagine clinical scenarios, however rare, where it could be useful.

Policy on deliberate germ-line intervention now varies from barely permissive to explicitly proscriptive. In the United States, the Recombinant DNA Advisory Committee of the

---

[16]The applicability of Medicare (which generally pays for the care of persons aged 65 or older) may not be apparent, but with the advent of post-menopausal pregnancy via hormonal maintenance, Medicare unexpectedly became a public insurer with at least theoretical obligations to pay for pregnancy care. Furthermore, even if the female partner is not covered by Medicare, the male partner, from whom the somatic cell nucleus might be obtained, could be old enough to be a Medicare beneficiary.

National Institutes of Health [RAC] "will not *at present* entertain proposals for germ line alterations" [emphasis added]. This turn of phrase conveys that the RAC is not prepared to approve such experiments now, but it invites researchers to submit protocols that might offer an acceptable risk/benefit balance. This was a deliberate decision, as an outright ban was urged by the Council for Responsible Genetics (CRG) in 1985, but the RAC elected to stay with its language. German and Danish laws, by contrast, say that such germ-line intervention is a criminal act. Thus, for ten years, RAC has had a *de facto* ban on germ line gene therapy. If a concrete, clinically defensible proposal is ever made, RAC can simply choose to review the protocol if need be (Cook-Deegan 1997).

Many scientific societies have already indicated to NBAC their support for a moratorium on efforts to use somatic cell nuclear transfer cloning to create a child. Of 32 societies contacted, the majority stated that they take the position that it is wrong at this time to attempt to clone human beings.[17] The World Medical Association, representing clinicians around the world, has also endorsed a moratorium.[18] Historically, moratoria have garnered less resistance than governmentally imposed prohibitions. In addition, such moratoria avoid governmental intrusion into the freedom of scientific inquiry via legislative fiat. Finally, and perhaps counter-intuitively, a self-imposed moratorium may be more durable, as it is largely immune from constitutional challenges, which are more often successful when individuals challenge governmental—as opposed to private—limitations on personal choices.

On the other hand, a voluntary moratorium may not be sufficient to deter the occasional use of somatic cell nuclear transfer cloning. No one has offered NBAC a good estimate of the number of laboratories that might be capable of attempting to use somatic cell nuclear transfer to create a child, but W. Bruce Currie, a biologist at Cornell University, estimates that at least ten fertility clinics in the United States have the technology (Begley 1997). The history of infertility treatment—especially that of *in vitro* fertilization—demonstrates that where there is a sizeable and well financed demand for a novel service, there will be professionals willing to try to provide it. Indeed, the professional societies in the infertility field have not joined the A.M.A. in its statement that efforts to use somatic cell nuclear transfer cloning to create a child are unacceptable at this time. Further, sanctions against those who try to provide the service prematurely are weak. State medical licensing authorities, for example, are not as vigorous in their prosecution of medical violations as they could be (Grad & Marti 1979; Hogan 1983).

---

[17]To receive input on scientific and professional society views about cloning of human beings, NBAC commissioned the Critical Technologies Institute of RAND to request informal input from relevant organizations, of which 32 responded. "Views of Scientific Societies and Professional Associations on Human Nuclear Transfer Cloning Research," by Elisa Eiseman, May 1997.

[18]"Global Group Urges a Voluntary Ban on Human Cloning," *Chicago Tribune*, May 12, 1997, p. 16.

As mentioned previously, if somatic cell nuclear transfer cloning were attempted, the only federal legislation clearly on point would be the Fertility Clinic Success Rate and Certification Act of 1992 which regulates assisted reproductive technology programs. But despite this and arguably applicable state statutes, there is no comprehensive protection at the federal or state legislative levels against dangerous applications of technology that could be used to try to clone a human being in this manner.

The threat of medical malpractice litigation might provide some protection against premature application of a risky technology, but it too is lacking. Since the very people who request the service most urgently are the ones who would hold the privilege of suing for malpractice, it is unlikely that many suits would be brought, even if the technology were to prove tragically flawed for human application. And even though the child himself or herself would hold an independent right to sue for injuries incurred through premature use of the technique, the limited range of legal actions, and the need for someone other than the parents to be motivated to obtain authority to sue on the child's behalf, makes this, too, an inadequate means of policing the clinical application of the technology.

Nonetheless, in order to bolster the effectiveness of a self-imposed moratorium on cloning human beings, state authorities should be called on to tell their licensed practitioners that this technology is not ripe for human application. Relevant clinical societies should be urged to do the same. Professional societies can set voluntary, informal standards for professional behavior, require members to participate in continuing professional education to maintain active membership status, or require periodic examination. They can have codes of ethics governing general behavior, as do the American Medical Association and the National Society of Genetic Counselors. A professional organization can also survey its members and gather data on new techniques.

On the other hand, membership in professional societies is voluntary, as is members' adherence to an organization's code of conduct and standards. Moreover, no professional organization that represents *in vitro* fertilization clinicians and scientists has publicly expressed its opposition to such cloning attempts.

Still, it is notable that the American Medical Association has already stated to NBAC that it is not an acceptable form of medical practice to attempt to clone human beings through somatic cell nuclear transfer; the World Medical Association and the World Health Organization have issued similar statements. The result should be to deter efforts to use the technology, and to make redress against those who do use it somewhat easier, should malpractice suits be filed. Not only do such statements provide guidance to practitioners directly, they also provide guidance to courts, which have increasingly become arbiters of whether a health care provider has met his or her professional obligations to a patient.

OPTION: Legislate Extended Human Subjects Protections

A third action that could be taken to prevent dangerous uses of cloning would be to extend existing human subjects protections to all persons in the United States. At the moment, these protections extend only to those persons enrolled in research trials at institutions that have executed a multiple project assurance with the government; those in trials using Food and Drug Administration (FDA)-regulated investigational drugs, devices, and biologics; and those enrolled in trials sponsored by one of the 17 federal agencies that have adopted the common rule for subject protection. This still leaves some number of research subjects unprotected by federal law, as documented by the NIH Office for Protection from Research Risks in its presentation to NBAC at the first commission meeting, and, more recently, in an April 10, 1997 letter to the NBAC subcommittee on human subjects protections.

By extending protection to encompass all research settings, any researcher attempting to use nuclear transfer cloning to produce a human child within the context of a "systematic investigation" (which is the federal definition of research) would be subject to Institutional Review Board (IRB) review of the risks, the benefits, the adequacy of the consent, and the justice of human subject selection. In light of the significant physical harms that are expected based on current data, such research could not easily be approved until some compelling benefits have been shown.

An advantage to legislatively extending human subjects protection rather than relying solely on prohibitory legislation or a voluntary ban on cloning human beings is flexibility over time, should information from studies in other animals indicate that physical risks to humans are less than expected. More importantly, this approach represents a robust response to new and unanticipated technological innovations. Rather than addressing cloning alone, it sets the stage for review of any new technology that has application in humans, by taking full advantage of the existing system of decentralized IRB review. In addition, it accomplishes other NBAC goals regarding the extension of basic human subjects protections.

This particular legislative option does, however, suffer from several disadvantages. First, because it requires legislative action, it cannot be implemented immediately. Further, it depends on the decentralized IRB review system, which itself has been subject to much criticism as inadequate to the task, due to overwork, conflicts of interest, and the absence of sufficient expertise, particularly with regard to novel technologies.[19] Finally, because the protections it offers extend only to those enrolled in research protocols, it does not address experimental use of this technology that is offered in a therapeutic or other non-research guise; for that setting, e.g., a stand-alone infertility clinic, the protections outlined above regarding voluntary moratoria and professional society or disciplinary body statements must be used, or a legislative prohibition must be adopted.

---

[19]See transcripts of NBAC Human Subjects Subcommittee meeting, December 16, 1996.

OPTION: Legislative Ban on the Use of Somatic Cell Nuclear Transfer to Create a Child

If the foregoing options do not suffice to deter dangerous or premature efforts at cloning, or if the more general societal harms are viewed as sufficiently alarming as to require more dramatic attention, then a legislative prohibition may be needed. Indeed, such prohibitions are already being considered by a number of state legislatures and will probably be adopted by a number of other countries or international bodies as well (Knoppers, 1997).

The advantage to federal legislation—as opposed to state-by-state laws—lies primarily in its comprehensive coverage and clarity, as it would cover both private and public work in both research and clinical settings. Besides ensuring interstate uniformity, a federal law would relieve the need to rely on the cooperation of diverse medical and scientific societies, or the actions of diverse IRBs, to achieve the policy objective. As an additional benefit, federal legislation could displace the varied state legislative efforts now ongoing, some of which suffer from ambiguous drafting that could inadvertently prohibit the important cellular and molecular cloning research describe in Chapter Two of this report. Further, by unifying law at the national level, federal legislation could prevent "forum shopping," in which researchers or clinicians are enticed to relocate to states where protections against dangerous uses of cloning are fewer.

In addition, legislative prohibitions offer the opportunity to draft significant penalties for violation, thus increasing the deterrent effect enormously as compared to that offered by the other measures outlined above. Indeed, one of the strongest deterrent effects might be to inhibit incipient commercial interest in the use of the technology for infertility relief, thus removing a structural force that could otherwise lead to intense and possibly premature pressure to attempt clinical application before necessary research in animals has been completed.

Finally, a clear prohibition on efforts to create a child through nuclear transfer could help to quell anxieties with regard to the purely molecular and cellular techniques, also called "cloning," that form the basis of much of contemporary biomedical science, and that continue to hold such promise for medical and scientific advance without raising the same ethical issues as those associated with creating a child.

On the other hand, there are some drawbacks to federal legislation. There is a tradition in the United States of foregoing federal legislation in areas traditionally reserved to the states. Direct regulation of family affairs and of medical practice—both of which would be implicated in a legislative prohibition—represents two such areas. Thus, federal action could stifle the diverse policy responses of the states, should some states wish to be more liberal in permitting nuclear transfer to create a child. It would also hinder experimentation with different legal regimes governing the technology, perhaps obscuring lessons that might be learned from long term observation of the experiences in states with diverse legislative responses to this technique.

A legislative ban also would represent a strong obstacle to changes in policy as scientific information develops. While it is true that a ban could always be removed by a vote to repeal the prohibition, such an effort would take a strong interest group lobbying for change. Since the applications of cloning for procreation are likely to be few, and the numbers of persons with a strong interest in pursuing this option similarly small, a legislative ban might leave some small number of persons with compelling needs nonetheless unable to pursue their interests.

It is for this reason that one should consider a legislative ban that includes a sunset provision. It is notoriously difficult to draft legislation at any particular moment that can serve to govern the rapid and unpredictable advances of science. Some mechanism, such as a sunset provision, is needed to ensure an opportunity to re-examine the early judgement made today about the effects of somatic cell nuclear transfer cloning. A sunset provision would dictate that the prohibition expire, either automatically after a certain period of years, or upon declaration by some sort of review body set up for this purpose. While the inclusion of a sunset provision risks losing some of the public confidence gained by a legislative prohibition, it ensures that the question of cloning will be revisited by the legislature in the future, when scientific and medical questions have been clarified, possible uses have been identified, and public discussion of the deeper moral concerns about this practice has matured.

A sunset provision, however, would have to include details explaining how and when the legislative ban would expire. One alternative to simply choosing an arbitrary number of years, which may or may not coincide with a moment at which significant new information about the technology has emerged, would be the creation of a body, either immediately, or at a specific time (e.g., one year) prior to the date of the sunset. This body could then be charged with identifying the moment, if ever, when the ban ought to be repealed. The details of who should set up such a body, how its members should be appointed, the criteria by which it would render its decisions, and the tasks it should undertake in order to monitor the technology are crucial for the design of this sort of sunset provision. One advantage to the creation of such a body, however, is its availability to serve as a forum for ongoing public education about the technology, as it develops, in order to deepen and widen the discussions about the ethics of its use.

OPTION: Cooperate With Other Nations in the Enforcement of Common Elements of Our Policies Regarding Human Cloning

Since science and medicine are now transnational endeavors, the U.S. government could look for ways to cooperate with other nations and international bodies to enforce any common policies aimed at deterring efforts to clone a human being. These could include agreement to enforce one another's prohibitory legislation where appropriate, as well as for the United States to affirm its commitment to some of the international documents being prepared. Indeed, plans

for such prohibitions have already been announced by Germany and France,[20] and the United Kingdom is examining its own existing law to ensure that efforts to clone a human being would be clearly prohibited. European opinion seems unanimous on this point, and 20 countries associated with the Council of Europe have called for such a ban,[21] an idea endorsed by the World Health Organization.[22]

In addition, two international ethics committees, one governmental (UNESCO), and the other a committee of the non-governmental Human Genome Organization (HUGO) have been created for the study of the ethical, legal and social issues surrounding human genetics. Neither has an explicit statement on cloning, but the UNESCO International Bioethics Committee has as its mandate, "the preparation of an international instrument on the protection of the human genome" (1993).

The preamble of UNESCO's proposed *Universal Declaration on the Human Genome and the Protection of Human Rights* recalls the universal principles of human rights as found in the international instruments and recognizes that: "research on the human genome and the resulting applications open up vast prospects for progress in improving the health of individuals and of humankind as a whole, but emphasiz[es] that such research should fully respect human dignity and individual rights . . . "

The International Ethics Committee of HUGO in its *Statement on the Principled Conduct of Genetic Research* was also concerned with research under the Human Genome Project and Human Genome Diversity Project generally, and not with any particular form of research. However, the *Statement* in its background principles refers to the "acceptance and upholding of human dignity and freedom."

While easily dismissed as too broad and vague, these international approaches, which are necessarily the result of compromise, may prove to be more inclusive than the narrow, scientific definitions often found under national legislation. To the extent that cloning human beings via somatic cell nuclear transfer is viewed by these nations and international organizations as incompatible with human dignity, prohibitions under domestic law of the signatory countries will follow, either by legislative intiative, as mentioned above, or by interpretation of existing laws and policies.

---

[20]Emma Thompson, "Germans and French Press for Worldwide Ban on Human Cloning," *The Herald* (Glasgow), April 30, 1997, p. 14.

[21]Gile Tremlett, "Twenty European Countries Sign International Convention," *The Times* (U.K.), April 5, 1997.

[22]"Health Agency Says Cloning of Humans Unacceptable," *Chicago Tribune*, May 15, 1997.

For example, in December 1996, the renowned biologist Dr. Anne McLaren of the United Kingdom stated in her report on "Research on Embryos in Vitro: The Various Types of Research" that "[a]reas of research that are widely regarded as ethically unacceptable and often prohibited by law include the following: . . . 3) cloning by nuclear substitution." (Convention, 1996). At the same meeting, the Spanish expert J. Egozcue stated in his report on "Research in Human Conceptuses" that "[o]ther lines of research are forbidden or even penalized, although in some cases they may correspond to extremely useful models for the study of some special situations, that do not carry with them any danger, menace or unethical load. Among them are cloning, parthenogenesis, the production of chimeras, interspecies fertilization (with the exemption of the human-hamster system), any modification of the genome (or of the non-pathological genome, as in the Spanish law) and germ-cell therapy."

Nations as diverse as Argentina, China, and Japan have indicated an intention to deter efforts to clone human beings using somatic cell nuclear transfer. When joined with their European counterparts, these nations represent a global trend to avoid reproductive applications of this technology.

References

Andrews, L., "The Current and Future Legal Status of Cloning," paper commissioned by the National Bioethics Advisory Commission, April 1997.

Annas, G., Testimony before the Subcommittee on Public Health and Safety, of the Senate Labor and Human Resources Committee, March 12, 1997

Begley, S., "Little Lamb, Who Made Thee?" *Newsweek*, March 10, 1997, pp. 53-57.

Brock, D., "Public moral discourse," in *Society's Choices: Social and Ethical Decision Making in Biomedicine,* Ruth Bulger, Elizabeth Bobby, Harvey Feinberg, (eds.)(Washington, D.C.: National Academy Press, 1995).

Cook-Deegan, R.M., "Do Research Moratoria Work?" paper commissioned by the National Bioethics Advisory Commission, April 1997.

Glendon, M.A., *Rights Talk* (New York: The Free Press, 1991).

Hogan, G., "The effectiveness of licensing: History, evidence, and recommendations," *7 Law and Human Behavior* 117 (1983).

Grad, F., and N. Marti, *Physician Licensure and Discipline: the Legal and Professional Regulation of Medical Practice* (New York: Matthew Bender, 1979).

Leon Kass, Testimony before the National Bioethics Advisory Commission, March 14, 1997

Bartha Knoppers, "Cloning: An International Comparative Perspective," paper commissioned by the National Bioethics Advisory Commission, April 1997.

Ruth Macklin, Testimony before the National Bioethics Advisory Commission, March 14, 1997.

Thomas Nagel, "Moral Epistemology," in *Society's Choices: Social and Ethical Decision Making in Biomedicine,* Ruth Bulger, Elizabeth Bobby, Harvey Feinberg, (eds.)(Washington, D.C.: National Academy Press, 1995).

John Robertson, Testimony before the National Bioethics Advisory Commission, March 14, 1997.

Table 1: Proposed Legislation Pertaining to Cloning Human Beings

Federal Legislation:

S. 368, a bill to ban the use of federal funds for research with respect to the cloning of a human individual, defined as "the replication of a human individual by the taking of a cell with genetic material and the cultivation of the cell through the egg, embryo, fetal, and newborn stages into a new human individual."

H.R. 922, providing that "[n]one of the funds made available in any Federal law may be expended to conduct or support any project of research that involves the use of a human somatic cell for the process of producing a human clone."

H.R. 923, providing that "it shall be unlawful for any human person to use a human somatic cell for the process of producing a human clone."

State Legislation:

Bills that ban the use of governmental funds for any research using cloned cells or tissue:

Alabama [A.B. 1082 (introduced April 23, 1997)]

Bills that ban the use of governmental funds for cloning an entire individual:

Missouri [1997 Mo. H.B. 824 (introduced March 6, 1997)]

Maryland [Md. H.J.R. 28 (introduced March 20, 1997)]

Bills that ban cloning an entire individual, regardless of funding source:

Alabama [S.B. 511 (introduced March 7, 1997)]

California [Cal. S.B. 1344 (introduced March 11, 1997)]

Illinois [1997 Ill. H.B. 2235 § 5 (introduced March 10, 1997)]

Illinois [1997 Ill. S.B. 1829 (introduced March 7, 1997)]

New Jersey [N.J.A.B. 2849 § 1 (introduced March 24, 1997)]

New York [1997 S.B. 2877 (introduced February 26, 1997)]

North Carolina [S.B. 782 (introduced April 10, 1997]

Oregon [Ore. S.B. 1017 § 1 (introduced March 19, 1997)]

West Virginia [W. Va. S.B. 410 (introduced March 21, 1997)]

Bills that explicitly ban any research using cloned cells or tissue:

California [A.B. 1251 (introduced February 28, 1997)]

Florida [Fla. H.B. 1237 (introduced March 7, 1997)]

Bills that might unintentionally ban research using cloned tissue or cells:

South Carolina [H.B. 3617 § 16-17-745(B) (introduced March 11, 1997)]

New York [Assembly Bill 5383 (introduced March 4, 1997)]

Chapter Six

RECOMMENDATIONS OF THE COMMISSION

With the announcement that an apparently quite normal sheep had been born in Scotland as a result of somatic cell nuclear transfer cloning came the realization that, as a society, we must yet again collectively decide whether and how to use what appeared to be a dramatic new technological power. The promise and the peril of this scientific advance was noted immediately around the world, but the prospects of creating human beings through this technique mainly elicited widespread resistance and/or concern. Despite this reaction, the scientific significance of the accomplishment, in terms of improved understanding of cell development and cell differentiation, should not be lost. The challenge to public policy is to support the myriad beneficial applications of this new technology, while simultaneously guarding against its more questionable uses.

Much of the negative reaction to the potential application of such cloning in humans can be attributed to fears about harms to the children who may result, particularly psychological harms associated with a possibly diminished sense of individuality and personal autonomy. Others express concern about a degradation in the quality of parenting and family life if children's physical development were no longer as unpredictable, especially if parents were to confuse the predictability of certain of their children's physical characteristics with the predictability of their personality and character. And virtually all people agree that the current risks of physical harm to children associated with somatic cell nuclear transplantation cloning justify a prohibition at this time on such experimentation.

In addition to concerns about specific harms to children, people have frequently expressed fears that a widespread practice of somatic cell nuclear transfer cloning would undermine important social values by opening the door to a form of eugenics or by tempting some to manipulate others as if they were objects instead of persons. Arrayed against these concerns are other important social values, such as protecting personal choice, particularly in matters pertaining to procreation and child rearing, maintaining privacy and the freedom of scientific inquiry, and encouraging the possible development of new biomedical breakthroughs.

As somatic cell nuclear transfer cloning could represent a means of human reproduction for some people, limitations on that choice must be made only when the societal benefits of prohibition clearly outweigh the value of maintaining the private nature of such highly personal decisions. Especially in light of some arguably compelling cases for attempting to clone a human being using somatic cell nuclear transfer, the ethics of policy making must strike a balance between the values society wishes to reflect and issues of privacy and the freedom of individual choice.

To arrive at its recommendations concerning the use of somatic cell nuclear transfer techniques, NBAC also examined long-standing religious traditions that often influence and guide citizens' responses to new technologies. Religious positions on human cloning are pluralistic in their premises, modes of argument, and conclusions about human cloning. Nevertheless, several major themes are prominent in Jewish, Roman Catholic, Protestant, and Islamic positions, including responsible human dominion over nature, human dignity and destiny, procreation, and family life. Religious thinkers argue that the use of somatic cell nuclear transfer cloning to create a child would be intrinsically immoral and thus could never be morally justified; they usually propose a ban on such human cloning. Some other religious thinkers contend that human cloning to create a child could be morally justified under some circumstances but hold that it should be strictly regulated in order to prevent abuses.

The public policies recommended with respect to the creation of a child using somatic cell nuclear transfer reflect the Commission's best judgments about both the ethics of attempting such an experiment and our view of traditions regarding limitations on individual actions in the name of the common good. At present, the use of this technique to create a child would be a premature experiment that exposes the developing child to unacceptable risks. This in itself is sufficient to justify a prohibition on cloning human beings at this time, even if such efforts were to be characterized as the exercise of a fundamental right to attempt to procreate. More speculative psychological harms to the child, and effects on the moral, religious, and cultural values of society may be enough to justify prohibitions in the future, but more time is needed for discussion of these concerns.

Beyond the issue of the safety of the procedure, however, NBAC found that concerns relating to the potential psychological harms to children and effects on the moral, religious, and cultural values of society merited further reflection and deliberation. Whether upon such further deliberation our nation will conclude that the use of cloning techniques to create children would be allowed or should be permanently banned is an open question. Time is an ally in this regard, allowing for the accrual of further data from animal experimentation, enabling an assessment of the prospective safety and efficacy of the procedure in humans, as well as granting a period of fuller national debate of ethical and social concerns. The Commission therefore concluded that there should be imposed a period of time in which no attempt is made to create a child using somatic cell nuclear transfer.

Within this overall framework the Commission came to the following conclusions and recommendations.

I. The Commission concludes that at this time it is morally unacceptable for anyone in the public or private sector, whether in a research or clinical setting, to attempt to create a child using somatic cell nuclear transfer cloning. We have reached a consensus on this point because of insufficient information on the safety and effectiveness of this method in humans. Indeed, we

believe it would violate important ethical obligations were clinicians or researchers to attempt to create a child using these particular technologies, which are likely to involve substantial risk to the fetus and/or potential child. Moreover, in addition to safety concerns, many other serious ethical concerns have been identified, which require much more widespread and careful public deliberation before this technology may be used.

The Commission, therefore, recommends the following for immediate action:

- A continuation of the current moratorium on the use of federal funding in support of any attempt to create a child by somatic cell nuclear transfer.

- An immediate request to all firms, clinicians, investigators, and professional societies in the private and non-federally funded sectors to comply voluntarily with the intent of the federal moratorium. Professional and scientific societies should make clear that any attempt to create a child by somatic cell nuclear transfer and implantation into a woman's body would at this time be an irresponsible, unethical, and unprofessional act.

II. The Commission further recommends that:

- Federal legislation should be enacted to prohibit anyone from attempting, whether in a research or clinical setting, to create a child through somatic cell nuclear transfer cloning. It is critical, however, that such legislation include a sunset clause to ensure that Congress will review the issue after a specified time period (three to five years) in order to decide whether the prohibition continues to be needed. If state legislation is enacted, it should also contain such a sunset provision. Any such legislation or associated regulation also ought to require that at some point prior to the expiration of the sunset period, an appropriate oversight body will evaluate and report on the current status of somatic cell nuclear transfer technology and on the ethical and social issues that its potential use to create human beings would raise in light of public understandings at that time.

III. The Commission also concludes that:

- Any regulatory or legislative actions undertaken to effect the foregoing prohibition on creating a child by somatic cell nuclear transfer should be carefully written so as not to interfere with other important areas of scientific research. In particular, no new regulations are required regarding the cloning of human DNA sequences and cell lines, since neither activity raises the scientific and ethical issues that arise from the attempt to create children through somatic cell nuclear transfer, and these fields of research have already provided important scientific and biomedical advances. Likewise, research on cloning animals by somatic cell nuclear transfer does not raise the issues implicated in attempting to use this technique for human cloning, and its continuation should only be subject to existing regulations regarding the humane use of animals and review by

institution-based animal protection committees.

- If a legislative ban is not enacted, or if a legislative ban is ever lifted, any effort to use the somatic cell nuclear transfer technique to create a child should be preceded by controlled research that is governed by the twin protections of independent review and by existing standards regarding protection of human subjects, including informed consent.

- The United States Government should cooperate with other nations and international organizations to enforce any common aspects of their respective policies on the cloning of human beings.

IV. The Commission also concludes that different ethical and religious perspectives and traditions are divided on many of the important moral issues that surround any attempt to create a child using somatic cell nuclear transfer techniques. Therefore, we recommend that:

- The federal government, and all interested and concerned parties, encourage widespread and continuing deliberation on these issues in order to further our understanding of the ethical and social implications of this technology and to enable society to produce appropriate long-term policies regarding this technology should the time come when present concerns about safety have been addressed.

V. Finally, because scientific knowledge is essential for all citizens to participate in a full and informed fashion in the governance of our complex society, the Commission recommends that:

- Federal departments and agencies concerned with science should cooperate in seeking out and supporting opportunities to provide information and education to the public in the area of genetics, and on other developments in the biomedical sciences where these affect important cultural practices and commitments.

News Release

PhRMA

FOR IMMEDIATE RELEASE
June 7, 1997

Contact: Alixe Glen
(202)835-3460

PhRMA Applauds Bioethics Commission for Recognition of the Importance of Genetic Research

Expresses Concern on Legislative Recommendation

Washington, D.C. – While the National Bioethics Advisory Commission has recommended legislation to ban the cloning of entire human beings, it also recognized that genetic research is critically important to both individual patients and the public health. The Commission therefore urged that any legislation must be very narrowly drawn so that vital biomedical research can continue.

"Pharmaceutical companies are discovering medicines that help and heal human beings" said Alan F. Holmer, President, Pharmaceutical Research and Manufacturers of America (PhRMA). "Genetic research has already proved a powerful tool in the search for cures, leading to effective medicines to treat AIDS, cystic fibrosis, diabetes, heart attack and stroke, and hemophilia. Any legislative prohibition on the cloning of entire human beings must not jeopardize biomedical research that involves the cloning of human genes, cells or tissues."

Scientists at PhRMA companies use human genes, cells and tissues to discover new medicines. To help the patients of today and tomorrow with unmet medical needs this research must be allowed to continue. We urge the President to oppose any legislation that would impede invaluable biomedical research that involves cloning technology but not the cloning of entire human beings.

"Genetic research is an immeasurably valuable tool for improving peoples' lives. For the sake of patients – and the sake of generations to come – genetic research must continue. Our member companies conduct genetic research for the purpose of improving human health. And we endorse an informed public dialogue on all aspects of genetic research," Holmer stated.

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, happier, healthier and more productive lives. Investing nearly $19 billion this year in discovering and developing new medicines, PhRMA companies are leading the way in the search for cures.

###

PhRMA Internet Address: http://www.phrma.org

To: Elizabeth Drye

From: Dr. Harold T. Shapiro

6 pages (incl. cover)

C2/-

Fact Sheet

Transmit

Still.

Cont [redacted]
- pres ✓
- Elena ✓
- Todd
- Leg Affairs ✓
-

O Dept. - Damon

Event - Elena/Laura

EXECUTIVE SUMMARY

The idea that humans might someday be cloned—created from a single somatic cell without sexual reproduction—moved further away from science fiction and closer to a genuine scientific possibility on February 23, 1997. On that date, *The Observer* broke the news that Ian Wilmut, a Scottish scientist, and his colleagues at the Roslin Institute were about to announce the successful cloning of a sheep by a new technique which had never before been fully successful in mammals. The technique involved transplanting the genetic material of an adult sheep, apparently obtained from a differentiated somatic cell, into an egg from which the nucleus had been removed. The resulting birth of the sheep, named Dolly, on July 5, 1996, was different from prior attempts to create identical offspring since Dolly contained the genetic material of only one parent, and was, therefore, a "delayed" genetic twin of a single adult sheep.

This cloning technique is an extension of research that had been ongoing for over 40 years using nuclei derived from non-human embryonic and fetal cells. The demonstration that nuclei from cells derived from an adult animal could be "reprogrammed," or that the full genetic complement of such a cell could be reactivated well into the chronological life of the cell, is what sets the results of this experiment apart from prior work. In this report we refer to the technique, first reported by Wilmut, of nuclear transplantation using nuclei derived from somatic cells other than those of an embryo or fetus as "somatic cell nuclear transfer."

Within days of the published report of Dolly, President Clinton instituted a ban on federal funding related to attempts to clone human beings in this manner. In addition, the President asked the recently appointed National Bioethics Advisory Commission (NBAC) to address within ninety days the ethical and legal issues that surround the subject of cloning human beings. This provided a welcome opportunity for initiating a thoughtful analysis of the many dimensions of the issue, including a careful consideration of the potential risks and benefits. It also presented an occasion to review the current legal status of cloning and the potential constitutional challenges that might be raised if new legislation were enacted to restrict the creation of a child through somatic cell nuclear transfer cloning.

The Commission began its discussions fully recognizing that any effort in humans to transfer a somatic cell nucleus into an enucleated egg involves the creation of an embryo, with the apparent potential to be implanted in utero and developed to term. Ethical concerns surrounding issues of embryo research have recently received extensive analysis and deliberation in our country. Indeed, federal funding for human embryo research is severely restricted, although there are few restrictions on human embryo research carried out in the private sector. Thus, under current law, the use of somatic cell nuclear transfer to create an embryo solely for research purposes is already restricted in cases involving federal funds. There are, however, no current federal regulations on the use of private funds for this purpose.

The unique prospect, vividly raised by Dolly, is the creation of a new individual

genetically identical to an existing (or previously existing) individual—a "delayed" genetic twin. This prospect has been the source of the overwhelming public concern about such cloning. The Commission recognizes that any creation of embryos for research purposes alone raises serious ethical issues. However, these ethical issues have already been extensively discussed, and the use of somatic cell nuclear transfer to create embryos raises no new issues in this respect. The unique and distinctive ethical issues raised by the use of somatic cell nuclear transfer to create children relate to, for example, serious safety concerns, individuality, family integrity, and treating children as objects. Consequently, the Commission focused its attention on the use of such techniques for the purpose of creating an embryo which would then be implanted in a woman's uterus and brought to term. It also expanded its analysis of this issue to encompass activities in both the public and private sector.

In its deliberations, NBAC reviewed the scientific developments which preceded the Roslin announcement, as well as those likely to follow in its path. It also considered the many moral concerns raised by the possibility that this technique could be used to clone human beings. Much of the initial reaction to this possibility was negative. Careful assessment of that response revealed fears about harms to the children who may be created in this manner, particularly psychological harms associated with a possibly diminished sense of individuality and personal autonomy. Others expressed concern about a degradation in the quality of parenting and family life.

In addition to concerns about specific harms to children, people have frequently expressed fears that a widespread practice of somatic cell nuclear transfer cloning would undermine important social values by opening the door to a form of eugenics or by tempting some to manipulate others as if they were objects instead of persons. Arrayed against these concerns are other important social values, such as protecting the widest possible sphere of personal choice, particularly in matters pertaining to procreation and child rearing, maintaining privacy, and the freedom of scientific inquiry, and encouraging the possible development of new biomedical breakthroughs.

To arrive at its recommendations concerning the use of somatic cell nuclear transfer techniques to create children, NBAC also examined long-standing religious traditions that guide many citizens' responses to new technologies and found that religious positions on human cloning are pluralistic in their premises, modes of argument, and conclusions about human cloning. Some religious thinkers argue that the use of somatic cell nuclear transfer cloning to create a child would be intrinsically immoral and thus could never be morally justified. Other religious thinkers contend that human cloning to create a child could be morally justified under some circumstances, but hold that it should be strictly regulated in order to prevent abuses.

The public policies recommended with respect to the creation of a child using somatic cell nuclear transfer reflect the Commission's best judgments about both the ethics of attempting such an experiment and our view of traditions regarding limitations on individual actions in the name of the common good. At present, the use of this technique to create a child would be a

premature experiment that would expose the fetus and the developing child to unacceptable risks. This in itself is sufficient to justify a prohibition on cloning human beings at this time, even if such efforts were to be characterized as the exercise of a fundamental right to attempt to procreate.

Beyond the issue of the safety of the procedure, however, NBAC found that concerns relating to the potential psychological harms to children and effects on the moral, religious, and cultural values of society merited further reflection and deliberation. Whether upon such further deliberation our nation will conclude that the use of cloning techniques to create children should be allowed or permanently banned is, for the moment, an open question. Time is an ally in this regard, allowing for the accrual of further data from animal experimentation, enabling an assessment of the prospective safety and efficacy of the procedure in humans, as well as granting a period of fuller national debate on ethical and social concerns. The Commission therefore concluded that there should be imposed a period of time in which no attempt is made to create a child using somatic cell nuclear transfer.[1]

Within this overall framework the Commission came to the following conclusions and recommendations.

I. The Commission concludes that at this time it is morally unacceptable for anyone in the public or private sector, whether in a research or clinical setting, to attempt to create a child using somatic cell nuclear transfer cloning. We have reached a consensus on this point because of insufficient information on the safety and effectiveness of this method in humans. Indeed, we believe it would violate important ethical obligations were clinicians or researchers to attempt to create a child using these particular technologies, which are likely to involve substantial risks to the fetus and/or potential child. Moreover, in addition to safety concerns, many other serious ethical concerns have been identified, which require much more widespread and careful public deliberation before this technology may be used.

The Commission, therefore, recommends the following for immediate action:

- A continuation of the current moratorium on the use of federal funding in support of any attempt to create a child by somatic cell nuclear transfer.

- An immediate request to all firms, clinicians, investigators, and professional societies in the private and non-federally funded sectors to comply voluntarily with the intent of the federal moratorium. Professional and scientific societies should make clear that any attempt to create a child by somatic cell nuclear transfer and implantation into a woman's

[1] The Commission also observes that the use of any other technique to create a child genetically identical to an existing (or previously existing) individual would raise many, if not all, of the same non-safety-related ethical concerns raised by the creation of a child by somatic cell nuclear transfer.

body would at this time be an irresponsible, unethical, and unprofessional act.

II. The Commission further recommends that:

- Federal legislation should be enacted to prohibit anyone from attempting, whether in a research or clinical setting, to create a child through somatic cell nuclear transfer cloning. It is critical, however, that such legislation include a sunset clause to ensure that Congress will review the issue after a specified time period (three to five years) in order to decide whether the prohibition continues to be needed. If state legislation is enacted, it should also contain such a sunset provision. Any such legislation or associated regulation also ought to require that at some point prior to the expiration of the sunset period, an appropriate oversight body will evaluate and report on the current status of somatic cell nuclear transfer technology and on the ethical and social issues that its potential use to create human beings would raise in light of public understandings at that time.

III. The Commission also concludes that:

- Any regulatory or legislative actions undertaken to effect the foregoing prohibition on creating a child by somatic cell nuclear transfer should be carefully written so as not to interfere with other important areas of scientific research. In particular, no new regulations are required regarding the cloning of human DNA sequences and cell lines, since neither activity raises the scientific and ethical issues that arise from the attempt to create children through somatic cell nuclear transfer, and these fields of research have already provided important scientific and biomedical advances. Likewise, research on cloning animals by somatic cell nuclear transfer does not raise the issues implicated in attempting to use this technique for human cloning, and its continuation should only be subject to existing regulations regarding the humane use of animals and review by institution-based animal protection committees.

- If a legislative ban is not enacted, or if a legislative ban is ever lifted, clinical use of somatic cell nuclear transfer technique to create a child should be preceded by research trials that are governed by the twin protections of independent review and informed consent, consistent with existing norms of human subjects protection.

- The United States Government should cooperate with other nations and international organizations to enforce any common aspects of their respective policies on the cloning of human beings.

IV. The Commission also concludes that different ethical and religious perspectives and traditions are divided on many of the important moral issues that surround any attempt to create a child using somatic cell nuclear transfer techniques. Therefore, we recommend that:

- The federal government, and all interested and concerned parties, encourage widespread

and continuing deliberation on these issues in order to further our understanding of the ethical and social implications of this technology and to enable society to produce appropriate long-term policies regarding this technology should the time come when present concerns about safety have been addressed.

V. Finally, because scientific knowledge is essential for all citizens to participate in a full and informed fashion in the governance of our complex society, the Commission recommends that:

- Federal departments and agencies concerned with science should cooperate in seeking out and supporting opportunities to provide information and education to the public in the area of genetics, and on other developments in the biomedical sciences, especially where these affect important cultural practices, values, and beliefs.