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TEXT:
Attached is chapter 1 as an attachment and as text. I am faxing it to Dr. Dumas as I write. If anyone else wants it faxed, please let Sean Simon or Rob Tanner know (301-402-4242). H2K

INTRODUCTION

The idea that humans might someday be cloned-created from a single 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. The technique involved transplanting the genetic material of an adult sheep, apparently obtained from a fully differentiated somatic (non-reproductive) cell into an egg from which the nucleus had been removed. The resulting birth of the sheep, named Dolly, on July 5, 1996 appears to mark yet another milestone in our ability to control, refine, and amplify the forces of nature.

The Scottish sheep experiment was different from prior attempts to create identical offspring from a single pair of adult animals. It used a cloning technique, referred to in this report as "somatic cell nuclear transfer," to produce an animal that was a genetic twin of an adult sheep. Put another way, Dolly contained the genetic material of only one parent. This technique of transferring a nucleus from a somatic cell into an egg is an extension of experiments that had been ongoing for over 40 years. The fact that somatic cells could be "reprogrammed," or that the genetic complement of the cell could be reactivated well into the chronological life of the cell, is what sets this experiment apart from prior work.

For some time, scientific evidence has suggested that the genetic material contained in differentiated somatic cells might direct the formation of healthy fertile adult animals, but its capacity to do so remained unproved (DiBernadino, 1997). The Roslin experiment, therefore, was a significant scientific event with potentially profound implications since it brings us closer to the possibility of developing a capacity to clone human beings in an asexual manner. Although for the past ten years scientists have routinely cloned sheep and cows from embryo cells, this was the first successful experiment using the nucleus of a somatic cell to clone an animal that matured to a fully developed state.

The issues surrounding the cloning of human beings have long been the subject of periodic concern and debate among philosophers, scientists, ethicists, and others, particularly following the publication of Joshua Lederberg's 1966 article on cloning in the American Naturalist (Lederberg, 1966). Nevertheless, the impact of these most recent developments on our national psyche has been quite remarkable. Some commentators have

suggested that the furor aroused by the new possibility for cloning is out of proportion to most of the ethical, legal, and moral issues it raises, since these same issues have been raised by previous developments and are simply emerging again in a novel and striking form. At the same time it is important to acknowledge that human procreation by asexual means with a fully determined genetic profile is certainly unprecedented and some consider it to be a truly radical step. Perhaps these events also have captured our imaginations as symbols of a much older and deeper narrative that speaks to our concerns regarding the impact of science and technology on our moral lives and on long established cultural values.

While some scientists were surprised that the technical barriers of cell differentiation and development seemingly could be so easily overcome when using somatic cells as the source for nuclear transfer, the public-including many members of the scientific community-are responding to Dolly with a combination of fascination, hope for useful new understandings of human biology, and profound concern-even alarm-about the prospect of being able to create whole humans from a single somatic cell via nuclear transfer cloning techniques. Although much of the initial public reaction was one of fear, concern, and serious moral reservations about the potential use or abuse of this new technological capacity, a few voices were heard cautiously suggesting that a better understanding of cell dynamics in humans and animals might enable us to develop new cures for various diseases. Thus, it is important that we reflect not only on the dangers and ethical reservations but also on the potential human benefits from the use of this type of cloning that might arise in such areas as treating particular infertility problems, transplanting cells or tissues, or preventing certain genetically transmitted harms to offspring.

A few of the initial objections to this new type of cloning were either speculative or based on simple misunderstanding, for example, that cloning would allow for the instantaneous creation a fully grown adult from the cells of an individual. Other fears stemmed from the incorrect idea that an exact copy, although much younger, of an existing person could be made. This fear reflects an erroneous belief that one's genes bear a simple relationship to the physical and psychological traits that make up a perso n. Although genes provide the building blocks for each individual, it is the interactions between genes and the environment and the process of learning during the development of a child that result in each unique individual human. Thus the idea that nuclear transplantation cloning could be used to re-create exemplary people has no scientific basis and is simply false.

Other objections to nuclear transplantation cloning, however, are based on carefully articulated philosophical ideals, deep cultural commitments, or religious beliefs, and these deserve continuing and careful consideration. These objections reflect deeply held beliefs about the value of human individuality and personal autonomy, the meaning of family and the value of a child, and are based on views about the natural world, and limits to violating respect for human life and the integrity of the human species.

Many public leaders in the United States responded to the announcement about Dolly with immediate and strong condemnation of any attempt to clone human beings in this new manner. The reasons ranged from frightening

science fiction imagery to the judgment that the cloning of humans is a serious violation of basic human rights and human dignity. The reaction abroad was similar, with many nations seemingly ready-indirectly or directly-to prohibit the cloning of human beings in this new manner. Indeed, many international organizations such as UNESCO and the Council of Europe have a long-established and well-articulated concern that research and clinical applications in biology and genetics remain consistent with a fundamental commitment to human dignity and human rights. To date, Australia, Great Britain, Denmark, Germany, and Spain have enacted laws banning the cloning of human beings. Unfortunately, some of the deep concerns supporting such views and associated legislation are stated in vague or overly broad terms. The widespread public discomfort, even revulsion, about the cloning of human beings deserves the best articulation possible, a task which takes time and requires the considered reflections of diverse groups within American society and abroad.

Within days of the published report of the apparently successful cloning of a sheep in this new manner, President Clinton instituted a ban on federal funding for research related to cloning of human beings. In addition, the President asked the recently appointed National Bioethics Advisory Commission (NBAC) to address within ninety days the scientific, ethical, religious, 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 was enacted to restrict the creation of a child through somatic cell nuclear transfer.

Controlling Nature

Humankind's efforts to control nature date back as far as recorded history. In particular, domesticated plants and animals have been the mainstay of our agricultural heritage. Over time human mastery over nature often has been met, quite understandably, with opposition and concern, and frequently has been considered by some to be an affront to the natural order of things or by others to be at odds with interpretations of God's revealed word. Indeed many myths and legends, ancient as well as modern, deal directly with humankind's on-going struggle to ensure that the
benefits of our new technological capacities clearly outweigh the harms-both expected and unexpected. The idea that our growing technological mastery is filled with moral ambiguity and capable of both vast good and catastrophic evil is deeply embedded in many cultural traditions.

A prime example is the mythology of the Argo, the first ship, in classical Greek culture. The Greeks see the initial act of shipbuilding as both the origin of culture and the origin of decline. While sailing enables one to encounter other persons and other possibilities, it also brings marauders and war, and its very existence bespeaks the danger of unlimited human desire. Thus, the ability to build and sail boats is both a boon and a curse. Euripides' Medea starts with a lament about the trees that were

cut down to build the Argo and the other troubles that followed.

Would that the Argo had never winged its way to the land of Colchis.... Would that pine trees had never been felled in the glens of Mount Pelion and furnished oars for the hands of the heroes who at Pelias' command set forth in quest of the Golden Fleece.

Concern about our tools and technology has been greatly accelerated with the coming of modern industrialized societies. Is it possible, some now wonder, that our confidence in human competence and technology may be just another myth? How, some are now asking, can we save our souls and find some moral compass or moral limit to our desire to master everything and possess all? Only such limits, many would say, can save us from the moral ambiguity of our own cleverness.

In recent years, concern about humankind's control over nature has been particularly acute in relation to the new moral choices created by the stunning developments in the biomedical sciences, especially in the area of human reproduction. Although personal reproductive health is considered to be, in most cases, a private matter, ongoing controversies regarding the moral standing of human genetic material and particular human interventions in procreation have focused public attention on the ethical and legal implications of new reproductive techniques. In many cases, initial fears give way to cautious acceptance, but a wariness lingers that is easily reawakened with each new advance.

Artificial insemination by donor, for example, was considered a form of adultery when first introduced in the 1940s. It is now a widely used and accepted practice in the treatment of infertility, although some continue to have serious reservations. When prenatal diagnosis was introduced in the late 1960s, the public simultaneously welcomed the opportunity to prevent lethal disease in newborns but worried about the use of such techniques to select "vanity" characteristics or nonmedical traits in offspring. The birth of Louise Brown, conceived via in vitro fertilization, in 1978 was another dramatic event, providing a new and controversial means to parenthood. With all of these technical advances, there has been a continuing debate about safety, legality, ethical acceptability, and the government's right to intervene in private matters.

Research itself, not just its clinical application, has often sparked debate. For example, research involving human fetuses has been a subject of intense national debate and disagreement for over two decades (IOM, 1994). Federal research in this area continues to be restricted to that which has potential therapeutic benefit to the fetus, or involves no more than minimum risk to the fetus even if potential benefit to the mother can be demonstrated. Restrictions also remain regarding embryo research. Despite the cautious recommendations of the National Institutes of Health Human Embryo Research Panel (1994) that certain targeted and carefully regulated research using early human embryos be eligible for federal funds, in December 1994 the President directed NIH not to allocate federal funds for research programs that involved the creation of human embryos for research purposes. This issue was also addressed by Congress, which inserted language in the FY96 and FY97 appropriations bills that widened the presidential ban to prohibit virtually all human embryo research

conducted with federal funds. Work in this area continues in the United States, but it is largely limited to the private sector and takes place without any federal regulation.

Recombinant DNA research represents another example of controversy and intense debate: In the 1970s concerns about the safety of unintended release of recombinant organisms led to a voluntary research moratorium in the scientific community and the development of guidelines (Fredrickson, 1991). Similarly, until recently all experiments involving gene therapy (treatment of specific diseases by inserting human genes into human patients) have been subject to guidelines and review by a federal body.

As segments of human DNA or human cells became the focus of study and the objects of manipulation, their use as research materials raised increasingly important ethical issues about how these materials are obtained, transformed, and, in some cases, used to develop commercial products (OTA, 1987). Such research with human genetic material generates questions about respect for persons and the human body, and the value and moral status to be placed on cells and tissues.

Genetic and reproductive technologies also cause concern because of the specter of eugenics and of real or imagined social control through manipulation of human genes. Genetic control suggests broken taboos, and, in the words of Henry David Thoreau, implies that "men have become the tools of their tools"(Blank, 1981). While these concerns are often set against and partly attributable to a backdrop of fiction, fantasy, and misunderstanding, they are, more importantly, related to profound concerns regarding the nature of humankind and its relationship to other aspects of the natural world. When the bizarre and fantastic scenarios are removed, we are left with a myriad of reactions: sincere expressions of opposition; serious moral concerns; new hope for a better understanding of human biology and the prospect of combating currently untreatable afflictions; calls for more study; and guarded statements about the need for some measure of control (Macklin, 1994; 1997).

Controlling Science

For centuries the scientific community enjoyed a great deal of autonomy in directing and regulating its research agenda. Since mid century, however, demands for external regulation have increased, in part because much research, particularly in the biological sciences, is publicly funded and therefore requires some additional measure of accountability. More importantly, society has become more sensitive to concerns about the dangers-particularly to human participants-of the research itself and its future consequences. Further, our evolving moral sensibilities, together with the spectacular advances in biomedical science have generated new ethical concerns. As Bernard Davis of Harvard Medical School and others have noted, society sometimes seeks to regulate or restrict research when it poses the specters of dangerous or unfamiliar products, powers, or ideas (Davis, 1980).
The regulation of science has thus become part of the landscape, particularly for those who receive federal funds (OTA, 1986). In addition to environmental, health, occupational, and safety regulations, scientists must also comply with animal welfare and human subjects protections and

abide by restrictions and moratoria on specific types of research. Because science is both a public and social enterprise and its application can have profound impact, society recognizes that the freedom of scientific inquiry is not an absolute right. There are times when limits must be imposed, even if such limits are perceived as an impediment by an individual scientist. Limits on freedom of inquiry, however, must be justified, and impositions on such freedom should satisfy certain conditions-for example, that the limits are not arbitrary, that they emerge from the thoughtful balancing of costs and benefits, that they are not unnecessarily oppressive, that they do not lightly impinge on long established rights and freedoms, that there is some continuing public discourse with those affected by the ban, and that such limitations be open to reconsideration in the light of new information and new understanding.

Consideration of Ethical and Religious Perspectives

When the President asked NBAC to take up the issue of the cloning of human beings he admonished that "any discovery that touches upon human creation is not simply a matter of scientific inquiry, it is a matter of morality and spirituality as well." Although well aware that the United States Constitution prohibits the establishment of policies that are solely motivated by religious beliefs, NBAC shared the President's concern and sought out testimony about the cloning of human beings from leading scholars from a variety of religious traditions. In the same spirit NBAC also commissioned a background paper on the positions a number of religious traditions have taken or are considering on the cloning of human beings.

NBAC felt this was especially important because religious traditions influence and shape the moral views of many U.S. citizens and religious teachings over the centuries have provided an important source of ideas and inspiration. Although in a pluralistic society particular religious views cannot be determinative for public policy decisions that bind everyone, policy makers should understand and show respect for diverse moral ideas regarding the acceptability of cloning of human beings in this new manner.

Although some religious responses to the cloning of human beings through somatic cell nuclear transfer are tied tightly to particular scriptural texts or other faith communities, often these ideas can be stated forcefully in terms understandable and persuasive to all persons, irrespective of specific religious beliefs. For example, appeal may be made to a view of human nature or of human reason, rather than exclusively to a religious source of knowledge such as scripture or revelation.

NBAC also wanted to determine whether various religious traditions, despite their distinctive sources of authority and argumentation, reach similar conclusions about this type of human cloning. A convergence of views across these traditions, as well as across secular traditions, would be instructive, even if not necessarily determinative, for public policy.

While many Americans look to their religious faiths for moral guidance on issues, other sources of moral knowledge and insight are also important.

Many moral considerations that would be widely acknowledged as legitimate do not depend for their force on particular religious commitments or a specific philosophical outlook. For example, the conviction that it is wrong to harm a child is broadly shared among Americans. If you inquire why it is wrong to harm a child, people may give different answers. Some may refer to their religious or philosophical conviction that a child is a gift from God. Others may say that it is always wrong to harm an innocent person without some compelling reason. To many people, this is a bedrock principle of ethics, even if it has no single, universally acknowledged foundation in a specific religious tradition. Rather, it finds its foundation in many different understandings of morality, some religious, some secular. Moral ideas such as the obligation not to inflict harm on others are accessible to all Americans and, therefore, can provide a robust foundation for public policy where it is relevant.

America has a vibrant tradition of ethical dialogue in which all are invited to participate. What moral considerations deserve our attention and which are the most important in responding to a particular issue? These are questions that arise with every new controversy. Whether one's ethical beliefs come from theological commitments, philosophical study and debate, or from hard-won life experience, all voices should be welcome to the conversation, and all thoughtful views are entitled to a respectful hearing.

Policy makers need to consider a range of moral views when they try to determine whether a particular policy is ethically justifiable as well as politically feasible. A particular policy may not be politically feasible, for instance, if it evokes thoughtful, widespread and vigorous moral opposition. In such circumstances its social costs may outweigh its putative benefits, and additional education and deliberation may be required before new policies are put in place.

Consideration of Law and Public Policy

The public policy chosen with respect to the cloning of human beings via somatic cell nuclear transfer should reflect a keen knowledge of the science, our best judgments about the ethics of attempting such an experiment, and our traditions regarding limitations on individual actions in the name of the common good. Americans in this era, relative to earlier generations, have a wide interest in and substantial knowledge of science.
Nevertheless, in the weeks following the report of Dolly both the public and the media demonstrated a surprising lack of understanding of the science involved in cloning. NBAC believes that public debate about issues such as human cloning requires an even more educated populace. Science policy has become public policy, which can only be wisely decided by an informed nation.

American tradition has been to avoid prohibiting or regulating personal activities, absent a rational reason related to effects on others or society as a whole. Where the individual actions are expressions of fundamental rights, such as the right to free speech or the right to privacy, the reasons for limitation must be compelling, and the limitations made as minimal as possible.

The cloning of human beings in this new fashion appears to raise concerns about direct physical harms to the children who may result. This in itself is sufficient to justify a prohibition on such attempts at this time, even if such efforts were to be characterized as the exercise of a fundamental right 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.

In its discussion of potential policy options, the Commission considered the relative benefits of achieving an immediate prohibition through federal legislation on the cloning of human beings using somatic cell nuclear transfer techniques. It also considered more indirect means to deter such experiments.
Indirect, non-legislative options considered by the Commission include cooperation by the private sector, both research and clinical, in a moratorium on such experiments and/or clinical practice, and the continued prohibition of the use of federal funds to support such experiments. The American Medical Association and the World Medical Association, for example, have already called for such a moratorium on clinical activities.

The Commission also weighed, in terms of nuclear transplantation cloning, the potential impact of a possible legislative measure to extend basic human subjects protections to all research conducted in the United States. This would insure that any research efforts to clone a human in this manner would, along with all other research using human subjects, be covered by the twin protections of informed consent and appropriate scientific review to insure an ethically acceptable balance between risks and benefits. In light of the present state of animal research in this area, such protections should prevent such cloning research from going forward at this time.

Finally, NBAC recognized that cooperation with our foreign counterparts in the enforcement of any common elements of our respective policies could strengthen any of the measures adopted by the United States. Since science is a global endeavor, cooperation with our foreign counterparts would ensure consistency across borders and enhance public confidence in scientific research generally.

Process of NBAC and Organization of the Report

The results of NBAC's 90-day analysis are presented in this report. In its deliberations, NBAC focused its discussion on the science of the cloning of human beings using the somatic cell nuclear transfer technique, and the ethical, religious, legal, and regulatory implications of cloning human beings in this manner. To aid in these tasks the Commission invited testimony from an array of scientists, scientific societies, ethicists, theologians, and legal experts, and heard from a wide variety of interested parties during the public comment session at each meeting. In addition, it commissioned numerous background papers from recognized experts to inform its work.

This report consists of five chapters in addition to this one. Chapter Two describes the scientific developments which preceded and made possible the cloning of Dolly and speculates on potential applications of this and related technologies. Chapter Three outlines the numerous ethical concerns raised by the prospect of cloning human beings via somatic cell nuclear transfer. Chapter Four builds on the ethics discussion of Chapter Three by presenting some of the key themes in religious interpretations and evaluations of human cloning. Chapter Five discusses the legal and policy issues considered by the Commission as it pondered various recommendations.
The final section, Chapter Six, presents the recommendations made by the Commission in response to the President's request.

In many instances, the Commission found itself moving at a rapid pace in only partly charted waters. In those times it relied on its individual and collective wisdom, judgment, and moral foundations, and the advice of others. The Commission argued and debated the issues as it searched for appropriate formulations of the problem and the wisdom to suggest useful policy options. While the members of the Commission learned a great deal during its deliberations, it could not reach a resolution on all of the i ssues before it. Nevertheless, it was able to accomplish two things. First, it developed a set of recommendations, which are set out in chapter six. Second, it agreed that it was important to take a number of steps to ensure the continuation of an informed national discussion of these issues and other developments in the biomedical sciences and clinical practices that have an impact on our moral lives and cultural traditions.

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LEGAL AND POLICY CONSIDERATIONS

The public policy chosen with respect to cloning human should reflect both our best judgments about the ethics of attempting such an experiment and the our traditions regarding limitations on individual actions in the name of the common good. Cloning human beings appears to raise concerns about direct, physical harms to the children who may result. This in itself is probably 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 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. The prohibition on cloning human beings could be effectuated directly, through federal legislation, or indirectly, by way of a collection of efforts aimed at deterring such experiments. These efforts include cooperation by the private sector, both research and clinical, in a moratorium on such experiments; continued prohibition of the use of federal funds to support such experiments; and the extension of basic human subjects protections to all research in the United States. Cooperation with our foreign counterparts in the enforcement of any common elements of our respective policies could strengthen any of these measures.

* * * * * * * * * * * * *

The purpose of this chapter is to review existing and potential public policies, including legislation and regulation, with regard to the cloning of human beings. In this context, the current moratorium on the use of federal funds for the cloning of humans has provided a welcome opportunity for a more thoughtful analysis of the potential risks and benefits of human cloning, the current legal status of cloning, and the potential constitutional challenges that might be raised if new legislation is enacted to restrict such cloning.

Although the potential ability to clone human beings engendered a great deal of discussion —mostly heated objections—the formation of appropriate public policy with respect to cloning of human beings depends on more than the particular views of individuals and/or groups regarding the rights and wrongs of the cloning itself. It also depends on the traditions, customs, and principles of constitutional law that guide public policy making in the United States. These bear repeating and include such important factors as:

a) a presumption in favor of individual freedom of action, absent compelling 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, even though 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) accommodation of compelling individual need to deviate from the policy, wherever possible;

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

f) integration with common policies set in other nations, to the extent possible

The presumption in favor of individual freedom of action is not without its critics in America. Legal scholar Mary Ann Glendon, for example, has noted that an overly narrow approach that maintains a focus on rights to the exclusion of responsibility leaves us in a situation where "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 the 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.

Despite this presumption, however, many things are prohibited in the name, for example, of the common good. The liberty enshrined in American tradition and constitutional law is not, therefore, an unfettered liberty, but rather the ordered liberty of a social compact. To ensure the good order of society, frequently one person's liberty is limited when its exercise would serve to limit the liberty of another, or would otherwise undermine important constitutional 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. On this basis alone, efforts to clone human beings at this time 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.

There are many scientific reasons justifying a prohibition at this time, including: the potential for unacceptably high rates of developmental abnormalities in the embryos and fetuses; uncertainty regarding the "age" or "genetic clock" of the clone; the uncertain impact of hidden mutations in the adult somatic cell; and the largely unexplored technical difficulties of using this technique in humans without producing developmentally abnormal fetuses. In addition to all of this, of course, there are the potential psychological harms to the clone and systematic affronts to public values and morale. These latter concerns include issues surrounding the undermining of self/identity, human dignity, privacy, autonomy, and kinship relations of the cloned human being.

Laws Regarding Kinship Relations

With respect to kinship relations, current state laws addressing parentage—including paternity acts, surrogacy statutes, and egg donation statutes—are not broad enough to address the multitude of parentage issues raised by the process of cloning. Cloning 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 mitochondria. In addition, if the egg with the transferred nucleic material is implanted in a surrogate gestational mother, the child will have two other potential parents—the gestational mother[1], and if she is married, her husband.[2] There may also be intended rearing parents unrelated to the individual who is cloned.

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

As can be seen from this initial discussion, the familial relations associated with various cloning scenarios are complex. While this does not necessarily lead to harm, and while the law is capable of responding with new definitions that can capture the realities of the families that are created, these complications do lead many to wonder about the psychological effects there might be on the child involved. Further, because these harms will remain largely speculative no matter what the state of cloning research using non-human species, they will remain a substantial source of objection to cloning human beings even if physical safety concerns should be resolved.

Public and Private Values

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

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

Concerns about the potential impact of cloning human beings on public and private values and morale are harder to capture. 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, but these are incapable of serving as the sole basis for policymaking in a religiously diverse nation committed to separation of church and state.[3] Further, the absence of an agreed 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).

Finally, the instinctive distrust with which much of the American public greeted the prospect of cloning [cite to news articles/editorials/testimony/congressional statements] is necessarily a significant factor, as no suggested public policy can hope to gather support and compliance in the absence of either consensus or persuasive argumentation.

In addition, some worry that cloning may also have negative impacts on certain legal concepts. Pizzulli points out that "(a) privacy and autonomy might be severely attenuated in one known by himself or others to have a predetermined genetic identity; and (b) irrespective of personal and/or public knowledge of one's clonal origins, the technology of cloning might have macro-effects upon society by eroding the concept of individuality which is at the core of our notions of privacy and autonomy." (Pizzulli 19--). In addition to weakening an individual's sense of free will, cloning would "weaken the social constructs and political institutions that serve to foster the exercise of individual autonomy and to inhibit the coercive manipulation of individuals."

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

Members of the Commission could not evaluate 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

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[3] "[I]n order to be legitimate, the State's interest [in prenatal life] 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." Thomas Nagel, "Moral Epistemology," in Institute of Medicine, [Ruth Bulger, Elizabeth Bobby, Harvey Feinberg, eds.] Society's Choices: Social and Ethical Decision making in Biomedicine 201, 212 (1995).

all Americans. On the other hand, the collective force of these objections makes a strong prima facie case for a political judgment that cloning human beings would violate the deeply held views of many Americans.

But while such arguments may make a strong political case for prohibiting 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 go to school, sometimes the law demands a more compelling reason, as well as proof that the prohibition has been written as narrowly as possible so as to infringe upon individual as little as is necessary to accomplish the compelling state purpose.

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, as well as those so grounded in our culture and history as to be assumed by the public as beyond casual governmental interference.

Thus, to determine if the arguments put forth are sufficient to justify a prohibition legally, as well as politically, it is necessary to examine whether the choice to clone oneself would be viewed as a fundamental liberty. Since cloning 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.

Rights and Procreation

The right to make decisions about whether or not to bear children is constitutionally protected under the constitutional right to privacy[4] and the constitutional right to liberty.[5] The U.S. Supreme Court in 1992 reaffirmed the "recognized protection accorded to liberty relating to intimate relationships, the family, and decisions about whether to bear and beget a child,"[6] and a federal district court has indicated that this right to make procreative decisions encompasses the right of an infertile couple to undergo medically-assisted reproduction, including in vitro fertilization and the use of a donated embryo, stating:

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

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

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

> 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.[7]

Some commentators, such as Pizzuli, Robertson, and Coleman, argue that the Constitution could similarly protect the right to create a child through cloning, as it is not qualitatively different from the practice of medically assisted. Others disagree, deeming cloning to be "replication," rather than "reproduction."

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. Among those has been the assumption that it is interdependent, i.e., it involves 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 represents a form of genetic transfer horizontally between two persons within a genetic generation, such as between twins.

Whether cloning is best characterized as procreation or as something *sui generis [define please]* is a matter of debate, or at best, prediction. Thus, it is impossible to say with certainty whether it would be treated in law as a fundamental right. All that can be said at this time is that, 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.

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

- To continue the existing moratorium on federal funding of research on the cloning of human beings through nuclear transfer techniques, and to extend the intent of that moratorium to cover any effort to use federal funds for this technology in a clinical, i.e. non-research setting (e.g., reimbursement for medical care).

- 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 protections already in place for those enrolled in federally funded protocols.

- To facilitate public education and debate, in preparation for possible legislative

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[7] 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)

responses, if any, and to carry on a national discussion about the uses of 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.

Continue the Moratorium on the Use of Federal Funding for Cloning Human Beings

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. The continuation of this moratorium could encompass both federal research funds, such as those made available by HHS, 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 use via nuclear transplantation cloning to initiate pregnancies.[8]

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 both maternal and child health posed by this technology, it might be appropriate to condition receipt of these funds on the promise to prohibit such attempts within one's 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.

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 clone human beings. Compliance is likely to 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.

The closest analogy to a moratorium on cloning human beings may well be found in the moratorium, still in existence, on the use of germ line gene therapy, i.e., deliberate changes in

[8]The applicability of Medicare funds 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. [add cites to articles on post-menopausal pregnancy]

human DNA intended to be inherited. A decade ago, the consensus was that no one could do it 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, some voices pointed out that 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] RAC will not *at present* entertain proposals for germ line alternations" [emphasis added]. This turn of phrase says the door is closed but RAC might open it in response to an appropriate knock. This was a deliberate decision, as an outright ban was urged by the Council for Responsible Genetics (CRG) in 1985, but the RAC subcommittee elected to stick with its language. German and Danish law, by contrast, says that such intervention is a criminal act.

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.

Many scientific societies have already indicated to NBAC their support for such a moratorium; of XX societies contacted, XX clearly stated that they take the position that it is wrong at this time to attempt to clone human beings (cite to Carol's survey and the RAND summary]. It has been the case in the past that self-generated 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 the constitutional challenges, as they are most often relevant 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 cloning. 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. 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 [add cite to literature documenting failure of state boards].

No one has offered NBAC a good estimate of the number of laboratories that might be capable of attempting to clone a human being [is this true???], but W. Bruce Currie, a biologist at Cornell University, estimates that at least ten fertilization clinics in the United States have the technology (Begley, 19--).

If it were attempted, the only federal legislation clearly on point would be the Fertility Clinic Success Rate and Certification Act of 1992[9] which regulates assisted reproductive technology programs. It covers "all treatments or procedures which include the handling of human oocytes or embryos," and embryo laboratories—defined as facilities in which "human oocytes are subject to assisted reproductive technology treatment or procedures based on manipulation of oocytes or embryos which are subject to implantation." The Act requires assisted reproductive technology programs to report their pregnancy success rates to the Secretary of Health and Human Services for publication in an annual consumer guide. In addition, the Act requires that assisted reproductive technology programs identify the embryo laboratories that they rely on for lab work, for publication in the consumer guide. Finally, the Act requires the Secretary of Health and Human Services to develop a model program for the inspection and certification of embryo labs to be implemented by the states.

[9]42 U.S.C.A. § 263a-1 et seq. (Supp. 1996).

But despite this, and other arguably applicable state statutes,[10] there is no comprehensive protection at the state legislative level against dangerous applications of technology that could be used to try to clone a human being.

The threat of medical malpractice litigation does 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,

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[10]If cloning is considered to be a form of fertilization, questions arise regarding whether state laws setting standards for who may perform in vitro fertilization will cover the practice. There are fewer state laws specifically addressing the conduct of in vitro fertilization than addressing the conduct of fetal research. Although the impetus behind the in vitro fertilization laws was, for the most part, the regulation of the clinical practice of in vitro fertilization, the provisions are sometimes broad enough to regulate cloning researchers. Certain laws governing reporting, the qualifications of personnel, and so forth, will be applicable to researchers. A New Hampshire law, for example, requires counseling in advance of in vitro fertilization and limits the procedure to participants over age 21 (which, if applied to cloning could prohibit the use of DNA from a minor child). Pennsylvania has a reporting requirement which mandates that anyone performing in vitro fertilization file quarterly reports with the Department of Health describing such facts as the number of embryos destroyed and discarded and the number of women in whom embryos are implanted. Louisiana's law requires that in vitro fertilization shall only be undertaken by practitioners and facilities meeting the standards of the American College of Obstetricians and Gynecologists (ACOG) and the American Fertility Society (AFS) (currently, the American Society for Reproductive Medicine). La. Rev. Stat. Ann. § 9:128 (West 1991). Also, some states have statutes dealing with insurance reimbursement of in vitro fertilization for infertility. A few of those states mandate that, to be reimbursed, the in vitro fertilization procedure must be performed in facilities that meet the ACOG and AFS standards. See, e.g., Ark. Code Ann. § 23-86-118(d) (1992); Hawaii Rev. Stat. § 432:1-604(6) (1994); 215 ILCS 5/356m(b)(1)(c) (1993); Md. Ann. Code art. 48a §§ 477EE(6) and 470W (1994). The insurance-related provisions are unlikely to be applicable to cloning, since cloning will be denied coverage as being too experimental.

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. Membership in professional societies is voluntary, as is members' adherence to an organization's code of conduct and standards and participation in membership surveys.

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, and the World Medical Association has issued a similar statement. The result should be to deter efforts to use the technology, and to make redress against those who do use it somewhat easier, should there be public or private efforts to prove malpractice. 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.

A physician whose treatment complied with the standard of care in the field, i.e., conformed with that offered by the "reasonable prudent physician" under the same or similar circumstances, can rarely be found liable for medical malpractice. Statements issued by a relevant professional society are viewed as evidence of what a reasonably prudent physician might have done. Thus, current customs of practice protect physicians. A deficiency in the law is its assumption that customary medical practice adequately reflects scientific learning and otherwise represents appropriate public policy to be enforced by the courts against individual practitioners (Havighurst 1992).

Legislate Extended Human Subjects Protections

A third action that could be taken to prevent dangerous uses of cloning would be to extend human subjects protections, currently spelled out in regulations at 45 CFR Part 46, 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 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 OPRR in its presentation to NBAC at the first commission meeting, and, more recently, in its April 10, 1997 letter to the NBAC subcommittee on human subjects protections.

By extending protection to encompass all research settings, any person attempting to use cloning to produce a human child within the context of a systematic investigation (the federal definition of research) would be subject to IRB-style peer review and a basic risk/benefit balancing test. 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.

Advantages to this approach include its 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 new and unanticipated response to 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 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, oarticularly with regard to novel technologies (cite to transcripts of subcommittee meeting, esp the one in December 1996). 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, the protections outlined above regarding voluntary moratoria and professional society or disciplinary body statements must be used.

Finally, 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 can be considered. Indeed, such prohibitions are already being considered by a number of state legislatures (See Appendix XXX for a summary of state bills now pending) and will probably be adopted by a number of other countries or international bodies as well [cite to bartha's paper].

The advantages to a prohibition lie primarily in its comprehensive coverage and clarity, as it would cover both private and public work, in both research and clinical settings. By relying on a single statement of principle, there is no need to rely on the cooperation of diverse medical and scientific societies, or the actions of diverse IRBs, to accomplish one's goal. 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 squelch incipient commercial interest in use of the technology for infertility relief, thus removing a structural force that could otherwise lead to intense and premature pressure to attempt clinical application even before necessary research in animals has been completed. Finally, a clear prohibition on efforts to clone human beings could help to quell public anxieties with regard to the purely molecular and cellular applications that form the basis of much of contemporary biomedical science, and that continue to hold such promise for medical and scientific advance.

As a correlative benefit, federal legislation could displace the varied state legislative efforts now ongoing, some of which suffer from ambiguous drafting that could inadvertently the cellular and molecular cloning that is as noted above so important for contemporary biomedical science. Further, by unifying law at the national level, federal legislation could prevent "forum shopping," in which motivated researchers or clinicians are enticed to relocate to states where protections against dangerous uses of cloning are fewer.

On the other hand, 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 more liberally permit cloning than others. It would also prevent hinder experimentation with different legal regimes governing the technology, thus 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 compelling 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 might consider a legislative ban that includes a sunset provision. Such a 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 advantages—in terms of enhanced public confidence—that are gained by a legislative prohibition, it ensures that the question of cloning will be revisited 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 have matured.

A sunset provision, however, would have to include details explaining how and when the legislative ban would expire. An 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 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 medium for ongoing public education about the technology, as it develops, in order to

deepen and widen the discussions about the ethics of its use.

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

On December 15-18, 1996, in Strasbourg, France, at the Third Symposium on Bioethics of the Council of Europe on "Medically-Assisted Procreation and the Protection of the Human Embryo," 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". (CDBI/SPK(96) (22), p. 6). At the same meeting, J. Egozcue, the Spanish expert, in his report on "Research in Human Conceptuses" reiterated 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" (CIBD/SPK (96) (5), p. 7).

Recently, two international ethics committees, one governmental (UNESCO) and the other non-governmental (HUGO)were deliberately 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 is viewed by these nations and international organizations as incompatible with human dignity,

prohibitions under domestic law of the signatory countries will follow. Indeed, plans for such prohibitions have already been announced by Germany (cite to email with the article) and France (also cite to email with the article), and the U,K, reacted within days of Wilmut's announcement to tighten up its own existing law to ensure that efforts to clone a human being would be clearly prohibited (cite to email with article).

Since science and medicine are now transnational endeavors, the U.S. government could look for ways to cooperate with its foreign counterparts to enforce any common policies aimed to deter 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.

CONCLUSIONS

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States. These bear repeating and include such important factors as:\par
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}\pard \fi-720\li720\sl0\tx720
{\plain \f3 a)\tab a presumption in favor of individual freedom of
action, abse
nt compelling arguments to
the contrary based on the common good and the need to protect others
from harm
;\par
}\pard \sl0
{\plain \f3 \par
}\sect \sectd \sbknone\headery1440\linemod1\lineppage\linex576
{\header \pard \sl0
{\plain ~~CONFIDENTIAL~~ DRAFT -- MAY 15, 1997\par }}

\pard \s3\fi-720\li720\sl0\tx720
b)\tab the requirement that arguments against individual freedom of
action be m
ade in terms as
convincing and understandable as possible to all those who will be
affected, ev
en though
U.S. citizens are of various religious faiths and cultural traditions;
\par
\pard \sl0
\par
\pard \s3\fi-720\li720\sl0\tx720
c)\tab the requirement that liberty be constrained as little as needed
while se
rving the public
interest; \par
\pard \sl0
\par
\pard \s3\fi-720\li720\sl0\tx720
d)\tab accommodation of compelling individual need to deviate from the
policy,
wherever
possible;\par
\pard \sl0
\par
\pard \s3\fi-720\li720\sl0\tx720
e)\tab restraint in the exercise of federal powers with regard to areas
traditi
onally governed by
diverse state laws and policies; and\par
\pard \sl0
\par
\pard \s3\fi-720\li720\sl0\tx720
f)\tab integration with common policies set in other nations, to the
extent pos
sible\par
\pard \sl0
\par

\tab The presumption in favor of individual freedom of action is not without it
s critics in
America. Legal scholar Mary Ann Glendon, for example, has noted that an overly
narrow
approach that maintains a focus on rights to the exclusion of responsibility le
aves us in a
situation where \'93we can barely find the words to speak of indirect harms, cu
mulative injury, or
damages that appear only long after the acts that precipitated them\'94 (Glendo
n, 1991).
Nonetheless, from the writings of Locke to the writings of the United States Su
preme Court, the
American tradition has been to assume the freedom to act absent a specific, jus
tifiable
prohibition. This tradition is enshrined in the constitutional language of lib
erty used in case law,
ranging from freedom from unreasonable searches and seizures to freedom to refu
se medical
treatment.\par
\par
\tab Despite this presumption, however, many things are prohibited in the name,
 for example,
of the common good. The liberty enshrined in American tradition and constituti
onal law is not,
therefore, an unfettered liberty, but rather the ordered liberty of a social co
mpact. To ensure the
good order of society, frequently one person\'92s liberty is limited when its e
xercise would serve to
limit the liberty of another, or would otherwise undermine important constituti
onal values.\par
\par
\tab It is for this reason that an individual\'92s actions may be limited when
they would directly
harm another. This principle can be applied even when the harm will not be exp
erienced by a
currently living person. Thus, on occasion, American courts have recognized th
at even actions

taken prior to the conception of a child might lead to legal
responsibility for
 that child\'92s health
costs, if the actions were unreasonable and avoidable. On this basis
alone, ef
forts to clone
human beings at this time may well be inappropriate, since there is
widespread
consensus that
such a step would be dangerous and premature before a great deal of
further ani
mal research is
conducted.\par
\par
\tab There are many scientific reasons justifying a prohibition at this
time, i
ncluding: the
potential for unacceptably high rates of developmental abnormalities in
the emb
ryos and fetuses;
uncertainty regarding the \'93age\'94 or \'93genetic clock\'94 of the
clone; th
e uncertain impact of hidden
mutations in the adult somatic cell; and the largely unexplored technical
diffi
culties of using this
technique in humans without producing developmentally abnormal fetuses.
In add
ition to all of
this, of course, there are the potential psychological harms to the clone
and s
ystematic affronts to
public values and morale. These latter concerns include issues
surrounding the
 undermining of
self/identity, human dignity, privacy, autonomy, and kinship relations of
the c
loned human being.\par
\par
\pard \qc\sl0
{\plain \b\f3 Laws Regarding Kinship Relations}{\plain \f3 \par
}\pard \sl0
{\plain \f3 \par
}{\plain \f3 \tab With respect to kinship relations, current state laws
address
ing parentage\'97including
paternity acts, surrogacy statutes, and egg donation statutes\'97are not
broad
enough to address the
multitude of parentage issues raised by the process of cloning. Cloning
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 sm
all fraction of
DNA in the mitochondria. In addition, if the egg with the transferred nucleic
material is
implanted in a surrogate gestational mother, the child will have two other pote
ntial parents\'97the
gestational mother{*\bkmkstart BM_1_}{*\bkmkend BM_1_}{\super\fs19
\chftn {\f
ootnote \pard \sa240
{\plain \super\fs19 \chftn }{}{\plain }{\plain \f3\fs22 In many states, the wom
an 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, t
his holds true even when the
surrogate is gestating an embryo with no genetic relationship to her. Only in
Florida, New Hampshire,
North Dakota and Virginia do court-approved gestational surrogacy arrangements
result in the intended
parents\'97not the surrogate\'97 being viewed as the legal parents.}}}
}{\plain \f3 }{\plain \f3 , and if she is married, her
husband.{\super\fs19 \ch
ftn {\footnote \pard \sa240
{\plain \super\fs19 \chftn }{}{\plain }{\plain \f3\fs22 The latter will have ri
ghts (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 surrogat
e and her husband are the legal
parents of a child she has gestated regardless of their genetic contribution.}{
\plain \f3 }{\plain See, e.g., }{\plain \ulw Ariz.
Rev. Stat}{\plain . \'a7 25-218 (1996).}}}
}{\plain \f3 There may also be intended rearing
parents unrelated to the individual who is cloned.\par
}{\plain \f3 \par
}{\plain \f3 \tab The contributors to such cloning arrangements will have vario
us legal rights and
responsibilities with respect to the resulting child. Since the child is a twi

n to the cloned
individual, the latter\'92s parents could be recognized as legal parents.
They
 certainly would be
identified as the parents under DNA paternity testing. Yet, given that
they wi
ll likely have not
made the decision to create offspring (in fact, they may be dead at the
time th
eir own offspring is
cloned), it will often be unfair to designate them as the legal parents.
It is
 also not in keeping
with a perspective that considers pre-conception intent as a relevant
factor fo
r determining
parenthood in the context of assisted reproduction.\par
}{\plain \f3 \par
}{\plain \f3 \tab As can be seen from this initial discussion, the
familial rel
ations associated with various
cloning scenarios are complex. While this does not necessarily lead to
harm, a
nd while the law is
capable of responding with new definitions that can capture the realities
of th
e families that are
created, these complications do lead many to wonder about the
psychological eff
ects there might
be on the child involved. Further, because these harms will remain
largely spe
culative no matter
what the state of cloning research using non-human species, they will
remain a
substantial source
of objection to cloning human beings even if physical safety concerns
should be
 resolved.\par
}{\plain \f3 \par
}\pard \qc\sl0
{\plain \b\f3 Public and Private Values}{\plain \f3 \par
}\pard \sl0
{\plain \f3 \par
}{\plain \f3 \tab Concerns about the potential impact of cloning human
beings o
n public and private
values and morale are harder to capture. Americans share some but not
all of t
heir 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 prov
ide answers,
but these are incapable of serving as the sole basis for policymaking in a reli
giously diverse
nation committed to separation of church and state.{\super\fs19 \chftn {\footno
te \pard
{\plain \super\fs19 \chftn }{}{\plain }{\plain \f3\fs22 "[I]n order to be legit
imate, the State's interest [in prenatal life] must be secular; consistent with

the First Amendment the State may not promote a theological or sectarian intere
st. 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 Obs
tetricians 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 par
t and dissenting in part).\par
}}\pard \sa240
{}{\plain \f3\fs22 \tab When applied to ethical decision making, one philosophe
r 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 tru
th." Thomas Nagel, "Moral
Epistemology," in Institute of Medicine, [Ruth Bulger, Elizabeth Bobby, Harvey
Feinberg, eds.] Society's
Choices: Social and Ethical Decision making in Biomedicine 201, 212 (1995).}}}

{\plain \f3 }{\plain \f3 Further, the absence of an agreed methodology in moral philosophy or bioethics for resolving disputes among compe
ting ethical
theories and conflicting values means that no analytical argument can be persua

sive to every
person (Brock, 1995).\par
}{\plain \f3 \par
}{\plain \f3 \tab Finally, the instinctive distrust with which much of the Amer
ican public greeted the
prospect of cloning [cite to news
articles/editorials/testimony/congressional s
tatements] is
necessarily a significant factor, as no suggested public policy can hope to gat
her support and
compliance in the absence of either consensus or persuasive
argumentation.\par

}{\plain \f3 \par
}{\plain \f3 \tab In addition, some worry that cloning may also have negative i
mpacts on certain legal
concepts. Pizzulli points out that \'93(a) privacy and autonomy might be sever
ely attenuated in one
known by himself or others to have a predetermined genetic identity; and (b) ir
respective of
personal and/or public knowledge of one\'92s clonal origins, the technology of
cloning might have
macro-effects upon society by eroding the concept of individuality which is at
the core of our
notions of privacy and autonomy.\'94 (Pizzulli 19--). In addition to weakening
 an individual\'92s
sense of free will, cloning would \'93weaken the social constructs and politica
l institutions that
serve to foster the exercise of individual autonomy and to inhibit the coercive
 manipulation of
individuals.\'94\par
\tab All of the objections described above are, to a large extent, based upon p
redictions of the
widespread effects on society should cloning become a frequent practice. Thus,
 they are
arguments not only about the morality of cloning itself, but also about the nee
d to avoid cloning
even in arguably compelling cases, lest the accumulation of such individual cas
es lead to

widespread practice that could undermine, as many who testified have put it, th
e very meaning of
being human.\par
}{\plain \f3 \par
}{\plain \f3 \tab Members of the Commission could not evaluate each of these ob
jections, as they are
partly speculative, partly theological, and partly based on particular values o
r world views that
are commonly but nonetheless not universally shared by all Americans. On the o
ther hand, the
collective force of these objections makes a strong prima facie case for a poli
tical judgment that
cloning human beings would violate the deeply held views of many Americans.\par

}{\plain \f3 \par
}{\plain \f3 \tab But while such arguments may make a strong political case for
prohibiting cloning,
American law occasionally demands more. Specifically, while any rational reaso
n will suffice
for government limitation of ordinary individual liberties, such as the right t
o drive or to go to
school, sometimes the law demands a more compelling reason, as well as proof th
at the
prohibition has been written as narrowly as possible so as to infringe upon ind
ividual as little as
is necessary to accomplish the compelling state purpose. \par
}{\plain \f3 \par
}{\plain \f3 \tab This is the case when fundamental liberties are at stake. Fu
ndamental liberties have been
defined by the Supreme Court as those that are specifically mentioned in the Co
nstitution, for
example, the right to free speech, as well as those so grounded in our culture
and history as to be
assumed by the public as beyond casual governmental interference.\par
}{\plain \f3 \par
}{\plain \f3 \tab Thus, to determine if the arguments put forth are sufficient
to justify a prohibition legally,
as well as politically, it is necessary to examine whether the choice to clone

```
oneself would be
viewed as a fundamental liberty.  Since cloning 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 \'93bearing and
begettin
g\'94 of children has been
characterized as a fundamental right.  \par
}{\plain \f3 \par
}\pard \qc\sl0
{\plain \f3 }{\plain \b\f3 Rights and Procreation}{\plain \f3 \par
}\pard \sl0
{\plain \f3 \par
}{\plain \f3 \tab The right to make decisions about whether or not to
bear chil
dren is constitutionally
protected under the constitutional right to privacy{\super\fs19 \chftn
{\footno
te \pard \sa240
{\plain \super\fs19 \chftn }{}{\plain }{\plain \ulw\f3\fs22 See}{\plain
\f3\fs2
2 , }{\plain \ulw\f3\fs22 e.g.}{\plain \f3\fs22 , }{\plain \ulw\f3\fs22
Griswol
d v. Connecticut}{\plain \f3\fs22 , 381 U.S. 379 (1965); }{\plain
\ulw\f3\fs22
Eisenstadt v. Baird}{\plain \f3\fs22 , 405 U.S. 438
(1972).}}}
}{\plain \f3  and the constitutional right to liberty.{\super\fs19 \chftn
{\foo
tnote \pard \sa240
{\plain \super\fs19 \chftn }{}{\plain }{\plain \ulw\f3\fs22 Planned
Parenthood
v. Casey}{\plain \f3\fs22 , 505 U.S. 833, 112 S.Ct. 2791 (1992).}}}
}{\plain \f3   The
U.S. Supreme Court in 1992 reaffirmed the \'93recognized protection
accorded to
 liberty relating to
intimate relationships, the family, and decisions about whether to bear
and beg
et a child,\'94{\super\fs19 \chftn {\footnote \pard \sa240
{\plain \super\fs19 \chftn }{}{\plain }{\plain \ulw\f3\fs20 Planned
Parenthood
v. Casey}{\plain \f3\fs20 , 505 U.S. 833, 112 S.Ct. 2791, 2810 (1992).
Early d
ecisions protected the
married couples\'92 right to privacy to make procreative decisions, but
later d
ecisions focused on individuals\'92 rights as
well.  The U.S. Supreme Court, in }{\plain \ulw\f3\fs20 Eisenstadt v.
Baird}{\p
```

lain \f3\fs20 , stated, \'93[i]f the right of privacy means anything, it is the
 right
of the }{\plain \ulw\f3\fs20 individual}{\plain \f3\fs20 , married or single, t
o be free from unwarranted governmental intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a chi
ld.\'94 }{\plain \ulw\f3\fs20 Eisenstadt v. Baird}{\plain \f3\fs20 , 405 U.S. 4
38,
453 (1972).}}}
}{\plain \f3 and a
federal district court has indicated that this right to make procreative decisi
ons encompasses the
right of an infertile couple to undergo medically-assisted reproduction, includ
ing }{\plain \ulw\f3 in}{\plain \f3 }{\plain \ulw\f3 vitro}{\plain \f3
fertilization and the use of a donated embryo, stating:\par
}{\plain \f3 \par
}\pard \li720\ri720\sl0
{\plain \f3 It takes no great leap of logic to see that within the cluster of c
onstitutionally
protected choices that includes the right to have access to contraceptives, the
re
must be included within that cluster the right to submit to a medical procedure

that may bring about, rather than prevent, pregnancy.{\super\fs19 \chftn {\foot
note \pard \sa240
{\plain \super\fs19 \chftn }{}{\plain }{\plain \ulw\f3\fs22 Lifchez v. Hartigan
}{\plain \f3\fs22 , 735 F.Supp. 1361 (N.D. Ill.), }{\plain \ulw\f3\fs22 aff\'92
d without opinion}{\plain \f3\fs22 , }{\plain \ulw\f3\fs22 sub nom.}{\plain \f3
\fs22 , }{\plain \ulw\f3\fs22 Scholberg v. Lifchez}{\plain \f3\fs22 , 914 F.2d 260 (7th Cir. 1990), }{\plain \ulw\f3\fs22
cert. denied}{\plain \f3\fs22 , 111 S.Ct. 787 (1991)}}}
}{\plain \f3 \par
}\pard \sl0
{\plain \f3 \par
}{\plain \f3 \tab Some commentators, such as Pizzuli, Robertson, and Coleman,
argue that the
Constitution could similarly protect the right to create a child through clonin
g, as it is not

qualitatively different from the practice of medically assisted. Others disagr
ee, deeming cloning
to be \'93replication,\'94 rather than \'93reproduction.\'94\par
}{\plain \f3 \par
}{\plain \f3 \tab To the extent that cloning invokes the choice to generate a c
hild, it is indeed procreative.
On the other hand, cases discussing procreative rights have always been premise
d on underlying
assumptions about the meaning of procreation. Among those has been the assumpt
ion that it is
interdependent, i.e., it involves the reproductive cooperation of a male and a
female, at least on
the biological level. Another assumption has been that it involves the transmis
sion of genes
vertically across a generation, that is, between a parent and child. Cloning r
epresents a form of
genetic transfer horizontally between two persons within a genetic generation,
such as between
twins.\par
}{\plain \fs22 \par
}{\plain \tab Whether cloning is best characterized as procreation or as someth
ing }{\plain \i sui generis [define
please] }{\plain is a matter of debate, or at best, prediction. Thus, it is im
possible to say with certainty
whether it would be treated in law as a fundamental right. All that can be sai
d at this time is that,
if it were to be treated as a fundamental right, then arguments against the pra
ctice based on
speculative psychological and social harms would be tested against the strictes
t scrutiny of the
judicial system.\par
}{\plain \par
}{\plain \tab It is against this backdrop that the Commission developed the fol
lowing policy options:\par
}{\plain \par
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{\header \pard \sl0
{\plain ~~CONFIDENTIAL.~~ DRAFT -- MAY 15, 1997\par }}

\pard \li720\sl0

\'20\'20To continue the existing moratorium on federal funding of
research on t
he cloning of
human beings through nuclear transfer techniques, and to extend the
intent of t
hat
moratorium to cover any effort to use federal funds for this technology
in a cl
inical, i.e.
non-research setting (e.g., reimbursement for medical care). \par
}\pard \sl0
{\plain \par
}\pard \li720\sl0
{\plain \'20To obtain the agreement of the private sector to abide by the
spiri
t of the federal
moratorium.\par
}\pard \sl0
{\plain \par
}\pard \li720\sl0
{\plain \'20To extend to all participants in research protocols the
protections
 already in place for
those enrolled in federally funded protocols.\par
}\pard \sl0
{\plain \par
}\pard \li720\sl0
{\plain \'20To facilitate public education and debate, in preparation for
possi
ble legislative
responses, if any, and to carry on a national discussion about the uses
of clon
ing
technology.\par
}\pard \sl0
{\plain \par
}\pard \li720\sl0
{\plain \'20To cooperate with our counterparts in other nations to
enforce any
common elements of
our respective policies regarding efforts to clone human beings.\par
}\pard \sl0
{\plain \par
}\pard \qc\sl0
{\plain \b Continue the Moratorium on the Use of Federal Funding for
Cloning Hu
man Beings}{\plain \par
}\pard \sl0
{\plain \par
}{\plain \tab The first, and simplest, of the policy options is to call
for a c
ontinuation and expansion of
the March 4 Presidential ban on the use of federal funds for cloning of
human b

eings. The
continuation of this moratorium could encompass both federal research
funds, su
ch as those
made available by HHS, as well as other federal payments. Thus, for
example, M
edicaid and
Medicare could make clear what is already widely assumed, to wit, that
they wil
l not pay for any
efforts to use via nuclear transplantation cloning to initiate
pregnancies.{\su
per\fs19 \chftn {\footnote \pard \sa240
{\plain \super\fs19 \chftn }{}{\plain }{\plain \f3\fs22 The applicability
of Me
dicare funds may not be apparent, but with the advent of post-menopausal
pregnancy via hormonal maintenance, Medicare unexpectedly became a public
insur
er with at least
theoretical obligations to pay for pregnancy care. [add cites to articles
on po
st-menopausal pregnancy]}}}
}{\plain \par
}{\plain \par
}{\plain \tab 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
being
s via nuclear
transplantation. For example, the federal government provides large
block gran
ts for maternal
and child health services. In light of the significant risks to both
maternal
and child health posed
by this technology, it might be appropriate to condition receipt of these
funds
on the promise to
prohibit such attempts within one\'92s institution. In the past, such an
appro
ach has been used with
regard to prospects for human gene therapy. Thus, in the 1980s,
institutions w
ere told that they
could receive federal funds for work on recombinant DNA therapy on the
conditio
n that no one
would attempt to use it in people until the specific application had been
revie
wed for its safety
and ethical acceptability by a specially created review body. Compliance
with t
hese conditions

has been excellent.\par
}{\plain \par
}\pard \qc\sl0
{\plain \b Appeal to the Private Sector for Adherence to the Intent of
the Fede
ral Moratorium \par
}{\plain \b On the Cloning of Human Beings}{\plain \par
}\pard \sl0
{\plain \par
}{\plain \tab 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 att
empt to clone human
beings. Compliance is likely to be high, especially within the research
commun
ity, which has a
history of successfully invoking voluntary moratoria even on exciting and
appea
ling innovations
such as gene therapy.\par
}{\plain \par
}{\plain \tab The closest analogy to a moratorium on cloning human beings
may w
ell be found in the
moratorium, still in existence, on the use of germ line gene therapy,
i.e., del
iberate changes in
human DNA intended to be inherited. A decade ago, the consensus was that
no on
e could do it
safely and reliably. Opinion split about the prudence of banning it. On
the o
ne hand, there
seemed little harm in banning it, with some prospect of public assurance
as a b
enefit. On the
other hand, some voices pointed out that if the technology evolved
sufficiently
, one might
imagine clinical scenarios, however rare, where it could be useful. \par
}{\plain \par
}{\plain \tab Policy on deliberate germ line intervention now varies from
barel
y permissive to
explicitly proscriptive. In the United States, \'93the [Recombinant DNA
Adviso
ry Committee]
RAC will not }{\plain \i at present}{\plain entertain proposals for germ
line
alternations\'94 [emphasis added]. This
turn of phrase says the door is closed but RAC might open it in response
to an

appropriate knock.
This was a deliberate decision, as an outright ban was urged by the
Council for
 Responsible
Genetics (CRG) in 1985, but the RAC subcommittee elected to stick with
its lang
uage. German
and Danish law, by contrast, says that such intervention is a criminal
act.\par

}{\plain \par
}{\plain \tab For ten years, RAC has had a }{\plain \i de facto}{\plain
ban on
 germ line gene therapy. If a concrete,
clinically defensible proposal is ever made, RAC can simply choose to
review th
e protocol if
need be. \par
}{\plain \par
}{\plain \tab Many scientific societies have already indicated to NBAC
their su
pport for such a
moratorium; of XX societies contacted, XX clearly stated that they take
the pos
ition that it is
wrong at this time to attempt to clone human beings (cite to Carol\'92s
survey
and the RAND
summary]. It has been the case in the past that self-generated moratoria
have
garnered less
resistance than governmentally imposed prohibitions. In addition, such
morator
ia avoid
governmental intrusion into the freedom of scientific inquiry via
legislative f
iat. Finally, and
perhaps counter-intuitively, a self-imposed moratorium may be more
durable, as
it is largely
immune from the constitutional challenges, as they are most often
relevant when
 individuals
challenge governmental\'97as opposed to private\'97limitations on
personal choi
ces.\par
}{\plain \par
}{\plain \tab On the other hand, a voluntary moratorium may not be
sufficient t
o deter the occasional
use of cloning. The history of infertility treatment\'97especially that
of in
vitro fertilization\'97

demonstrates that where there is a sizeable and well financed demand for a nove
l service, there
will be professionals willing to try to provide it. Sanctions against those wh
o 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 [add cite
to literature
documenting failure of state boards].\par
}{\plain \par
}{\plain \tab No one has offered NBAC a good estimate of the number of laborato
ries that might be
capable of attempting to clone a human being [is this true???], but W. Bruce Cu
rrie, a biologist at
Cornell University, estimates that at least ten fertilization clinics in the Un
ited States have the
technology (Begley, 19--).\par
}{\plain \par
}{\plain \tab If it were attempted, the only federal legislation clearly on poi
nt would be the Fertility
Clinic Success Rate and Certification Act of 1992{\super\fs19 \chftn {\footnote
 \pard \sa240
{\plain \super\fs19 \chftn }{}{\plain }{\plain \f3\fs22 42 U.S.C.A. \'a7 263a-1
 }{\plain \ulw\f3\fs22 et}{\plain \f3\fs22 }{\plain \ulw\f3\fs22 seq.}{\plain
\f3\fs22 (Supp. 1996).}}}
}{\plain which regulates assisted reproductive
technology programs. It covers \'93all treatments or procedures which include
the handling of
human oocytes or embryos,\'94 and embryo laboratories\'97defined as facilities
in which \'93human
oocytes are subject to assisted reproductive technology treatment or procedures
 based on
manipulation of oocytes or embryos which are subject to implantation.\'94 The
Act requires
assisted reproductive technology programs to report their pregnancy success rat
es to the
Secretary of Health and Human Services for publication in an annual consumer gu

ide. In
addition, the Act requires that assisted reproductive technology programs
ident
ify the embryo
laboratories that they rely on for lab work, for publication in the
consumer gu
ide. Finally, the
Act requires the Secretary of Health and Human Services to develop a
model prog
ram for the
inspection and certification of embryo labs to be implemented by the
states.\pa
r
}{\plain \par
}{\plain \tab But despite this, and other arguably applicable state
statutes,{\
super\fs19 \chftn {\footnote \pard \sa240
{\plain \super\fs19 \chftn }{}{\plain }{\plain \f3\fs22 If cloning is
considere
d to be a form of fertilization, questions arise regarding whether state
laws

setting standards for who may perform }{\plain \ulw\f3\fs22 in}{\plain
\f3\fs22
  }{\plain \ulw\f3\fs22 vitro}{\plain \f3\fs22 fertilization will cover
the pr
actice. There are fewer state
laws specifically addressing the conduct of }{\plain \ulw\f3\fs22
in}{\plain \f
3\fs22 }{\plain \ulw\f3\fs22 vitro}{\plain \f3\fs22 fertilization than
addres
sing the conduct of fetal
research. Although the impetus behind the }{\plain \ulw\f3\fs22
in}{\plain \f3
\fs22 }{\plain \ulw\f3\fs22 vitro}{\plain \f3\fs22 fertilization laws
was, fo
r the most part, the regulation
of the clinical practice of }{\plain \ulw\f3\fs22 in}{\plain \f3\fs22
}{\plain
 \ulw\f3\fs22 vitro}{\plain \f3\fs22 fertilization, the provisions are
sometim
es broad enough to regulate
cloning researchers. Certain laws governing reporting, the
qualifications of p
ersonnel, and so forth, will be
applicable to researchers. A New Hampshire law, for example, requires
counseli
ng in advance of }{\plain \ulw\f3\fs22 in}{\plain \f3\fs22 }{\plain
\ulw\f3\fs
22 vitro}{\plain \f3\fs22
fertilization and limits the procedure to participants over age 21}}}
}{\plain \pard \qj\fi-1440\li2160\sa240\tx2160
.\tab N.H. Rev. Stat. Ann. \'a7168-B:13 (Supp. 1993){\super\fs19 \chftn
{\footn

ote \pard \qj\sa240
{\plain \super\fs19 \chftn }{}{\plain (which, if applied to cloning could proh
ibit
the use of DNA from a minor child). Pennsylvania has a reporting requirement w
hich mandates that
anyone performing }{\plain \ulw in}{\plain }{\plain \ulw vitro}{\plain fertil
ization file quarterly reports with the Department of Health describing such facts as the number of embryos destroyed and discarded and the number of w
omen in whom embryos
are implanted.}}}
}{\plain \pard \qj\fi720\li2160\sa240\tx2160
. \tab 18 Pa. Cons. Stat. Ann. \'a73213(e) (1983).{\super\fs19 \chftn {\footnot
e \pard \qj\sa240
{\plain \super\fs19 \chftn }{}{\plain Louisiana\'92s law requires that }{\pla
in \ulw in}{\plain }{\plain \ulw vitro}{\plain fertilization shall only be un
dertaken by practitioners
and facilities meeting the standards of the American College of Obstetricians a
nd Gynecologists (ACOG)
and the American Fertility Society (AFS) (currently, the American Society for R
eproductive Medicine).
La. Rev. Stat. Ann. \'a7 9:128 (West 1991). Also, some states have statutes de
aling with insurance
reimbursement of }{\plain \ulw in}{\plain }{\plain \ulw vitro}{\plain fertili
zation for infertility. A few of those states mandate that, to be reimbursed,

the }{\plain \ulw in}{\plain }{\plain \ulw vitro}{\plain fertilization proced
ure must be performed in facilities that meet the ACOG and AFS standards.}{\pla
in \ulw
See}{\plain , }{\plain \ulw e.g.}{\plain , Ark. Code Ann. \'a7 23-86-118(d) (19
92); Hawaii Rev. Stat. \'a7 432:1-604(6) (1994); 215 ILCS
5/356m(b)(1)(c) (1993); Md. Ann. Code art. 48a \'a7\'a7 477EE(6) and 470W (1994
). The insurance-related
provisions are unlikely to be applicable to cloning, since cloning will be deni
ed coverage as being too
experimental.}}}
}{\plain there is no comprehensive

protection at the state legislative level against dangerous applications of tec
hnology that could be
used to try to clone a human being. \par
}\pard \qj\sa240
{\plain \par
}{\plain \tab The threat of medical malpractice litigation does provide some pr
otection 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 techn
ology 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\'92s behalf makes this, too, an inadequate
 means of policing the
clinical application of the technology.\par
}{\plain \par
}{\plain \tab Nonetheless, in order to bolster the effectiveness of a self-impo
sed moratorium on
cloning human beings, state authorities should be called on to tell their licen
sed practitioners that
this technology is not ripe for human application. Relevant clinical societies
 should be urged to
do the same. \par
}{\plain \par
}{\plain \tab 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 eth
ics governing
general behavior, as do the American Medical Association and the National Socie

ty of Genetic
Counselors. A professional organization can also survey its members and gather
data on new
techniques. Membership in professional societies is voluntary, as is members'
adherence to an
organization's code of conduct and standards and participation in membership su
rveys.\par
}{\plain \par
}{\plain \tab 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, and the W
orld Medical
Association has issued a similar statement. The result should be to deter effo
rts to use the
technology, and to make redress against those who do use it somewhat easier, sh
ould there be
public or private efforts to prove malpractice. Not only do such statements pr
ovide guidance to
practitioners directly, they also provide guidance to courts, which have increa
singly become
arbiters of whether a health care provider has met his or her professional obli
gations to a patient.\par
}{\plain \par
\tab A physician whose treatment complied with the standard of care in the fiel
d, i.e.,
conformed with that offered by the "reasonable prudent physician" under the sam
e or similar
circumstances, can rarely be found liable for medical malpractice. Statements
issued by a
relevant professional society are viewed as evidence of what a reasonably prude
nt physician
might have done. Thus, current customs of practice protect physicians. A defi
ciency in the law
is its assumption that customary medical practice adequately reflects scientifi
c learning and
otherwise represents appropriate public policy to be enforced by the courts aga
inst individual

practitioners (Havighurst 1992).\par
}{\plain \par
}\pard \sa240
{\plain \tab }{\plain \b Legislate Extended Human Subjects
Protections}{\plain
 \par
}{\plain \par
}{\plain \tab A third action that could be taken to prevent dangerous
uses of c
loning would be to
extend human subjects protections, currently spelled out in regulations
at 45 C
FR Part 46, 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
proje
ct assurance with the
government; those in trials using FDA-regulated investigational drugs,
devices,
 and biologics;
and those enrolled in trials sponsored by one of the 17 federal agencies
that h
ave adopted the
common rule for subject protection. This still leaves some number of
research
subjects
unprotected by federal law, as documented by OPRR in its presentation to
NBAC a
t the first
commission meeting, and, more recently, in its April 10, 1997 letter to
the NBA
C subcommittee
on human subjects protections. \par
}{\plain \par
}{\plain \tab By extending protection to encompass all research settings,
any p
erson attempting to use
cloning to produce a human child within the context of a systematic
investigati
on (the federal
definition of research) would be subject to IRB-style peer review and a
basic r
isk/benefit
balancing test. In light of the significant physical harms that are
expected b
ased on current data,
such research could not easily be approved until some compelling benefits
have
been shown.\par
}{\plain \par
}{\plain \tab Advantages to this approach include its flexibility over
time sho

uld information from
studies in other animals indicate that physical risks to humans are less
than e
xpected. More
importantly, this approach represents a new and unanticipated response to
techn
ological
innovations. Rather than addressing cloning alone, it sets the stage for
revie
w of any new
technology that has application in humans, by taking full advantage of
the exis
ting system of
decentralized IRB-review. In addition, it accomplishes other NBAC goals
regard
ing the
extension of basic human subjects protections.\par
}{\plain \par
}{\plain \tab This option does, however, suffer from several
disadvantages. Fi
rst, 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
criticis
m as inadequate
to the task, due to overwork, conflicts-of-interest, and the absence of
suffici
ent expertise,
oarticularly with regard to novel technologies (cite to transcripts of
subcommi
ttee meeting, esp
the one in December 1996). Finally, because the protections it offers
extend o
nly to those
enrolled in research protocols, it does not address experimental use of
this te
chnology that is
offered in a therapeutic or other non-research guise; for that setting,
the pro
tections outlined
above regarding voluntary moratoria and professional society or
disciplinary bo
dy statements
must be used.\par
}{\plain \par
}{\plain \tab Finally, if the foregoing options do not suffice to deter
dangero
us or premature efforts at
cloning, or if the more general societal harms are viewed as sufficiently
alarm
ing as to require

more dramatic attention, then a legislative prohibition can be considered. Ind
eed, such
prohibitions are already being considered by a number of state legislatures (Se
e Appendix XXX
for a summary of state bills now pending) and will probably be adopted by a num
ber of other
countries or international bodies as well [cite to bartha\'92s paper].
\par
}{\plain \par
}{\plain \tab The advantages to a prohibition lie primarily in its comprehensiv
e coverage and clarity, as
it would cover both private and public work, in both research and clinical set
tings. By relying
on a single statement of principle, there is no need to rely on the cooperation
of diverse medical
and scientific societies, or the actions of diverse IRBs, to accomplish one\'92
s goal. In addition,
legislative prohibitions offer the opportunity to draft significant penalties f
or violation, thus
increasing the deterrent effect enormously as compared to that offered by the o
ther measures
outlined above. Indeed, one of the strongest deterrent effects might be to squ
elch incipient
commercial interest in use of the technology for infertility relief, thus remov
ing a structural force
that could otherwise lead to intense and premature pressure to attempt clinical
application even
before necessary research in animals has been completed. Finally, a clear proh
ibition on efforts
to clone human beings could help to quell public anxieties with regard to the p
urely molecular
and cellular applications that form the basis of much of contemporary biomedica
l science, and
that continue to hold such promise for medical and scientific advance.\par
}{\plain \par
}{\plain \tab As a correlative benefit, federal legislation could displace the
varied state legislative

efforts now ongoing, some of which suffer from ambiguous drafting that could in
advertently the
cellular and molecular cloning that is as noted above so important for contempo
rary biomedical
science. Further, by unifying law at the national level, federal legislation c
ould prevent \'93forum
shopping,\'94 in which motivated researchers or clinicians are enticed to reloc
ate to states where
protections against dangerous uses of cloning are fewer.\par
}{\plain \par
}{\plain \tab On the other hand, there is a tradition in the United States of f
oregoing federal legislation
in areas traditionally reserved to the states. Direct regulation of family aff
airs and of medical
practice\'97both of which would be implicated in a legislative prohibition\'97r
epresents two such
areas. Thus, federal action could stifle the diverse policy responses of the s
tates, should some
states wish to more liberally permit cloning than others. It would also preven
t hinder
experimentation with different legal regimes governing the technology, thus per
haps obscuring
lessons that might be learned from long term observation of the experiences in
states with diverse
legislative responses to this technique.\par
}{\plain \par
\tab A legislative ban also would represent a strong obstacle to changes in pol
icy 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 cha
nge. Since the
applications of cloning for procreation are likely to be few, and the numbers o
f persons with a
compelling interest in pursuing this option similarly small, a legislative ban
might leave some
small number of persons with compelling needs nonetheless unable to pursue thei

r interests.\par
}{\plain \par
}{\plain \tab It is for this reason that one might consider a legislative ban t
hat includes a sunset
provision. Such a 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 advantages\'
97in terms of
enhanced public confidence\'97that are gained by a legislative prohibition, it
ensures that the
question of cloning will be revisited in the future, when scientific and medica
l questions have
been clarified, possible uses have been identified, and public discussion of th
e deeper moral
concerns about this practice have matured. \par
}{\plain \par
}{\plain \tab A sunset provision, however, would have to include details explai
ning how and when the
legislative ban would expire. An alternative to simply choosing an arbitrary n
umber of years,
which may or may not coincide with a moment at which significant new informatio
n about the
technology has emerged, would be the creation of a body charged with identifyin
g 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 decision
s, 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 it
s availability to
serve as a medium for ongoing public education about the technology, as it deve
lops, in order to
deepen and widen the discussions about the ethics of its use.\par
}{\plain \par

}\pard \qc\sa240
{\plain \b Cooperate With Other Nations in the Enforcement of Common Elements o
f Our Policies
Regarding Human Cloning}{\plain \par
}\pard \sa240
{\plain \par
}{\plain \tab On December 15-18, 1996, in Strasbourg, France, at the Third Symp
osium on Bioethics
of the Council of Europe on "Medically-Assisted Procreation and the Protection
of the Human
Embryo," 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 inclu
de the following:
. .. 3) cloning by nuclear substitution". (CDBI/SPK(96) (22), p. 6). At the s
ame meeting, J.
Egozcue, the Spanish expert, in his report on "Research in Human Conceptuses" r
eiterated that
"[o]ther lines of research are forbidden or even penalized, although in some ca
ses 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, parthen
ogenesis, the
production of chimeras, interspecies fertilization (with the exemption of the h
uman-hamster
system), any modification of the genome (or of the non-pathological genome, as
in the Spanish
law) and germ-cell therapy" (CIBD/SPK (96) (5), p. 7).\par
}{\plain \par
}\pard \qj\sa206\keep
{\plain \tab Recently, two international ethics committees, one governmental (U
NESCO) and the other
non-governmental (HUGO)were deliberately 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 in
ternational instrument
on the protection of the human genome" (1993).\par
}\pard \qj\sa206
{\plain \tab The preamble of UNESCO's proposed }{\plain \i Universal Declaratio
n on the Human Genome and
the Protection of Human Rights}{\plain recalls the universal principles of hum
an rights as found in the
international instruments and recognizes that: "research on the human genome an
d the resulting
applications open up vast prospects for progress in improving the health of ind
ividuals and of
humankind as a whole, but emphasiz[es] that such research should fully respect
human dignity and
individual rights....\'94\par
}{\plain \tab The International Ethics Committee of HUGO in its }{\plain \i Sta
tement on the Principled Conduct
of Genetic Research}{\plain was also concerned with research under the Human G
enome Project and Human
Genome Diversity Project generally, and not with any particular form of researc
h. However, the
}{\plain \i Statement}{\plain in its background principles refers to the "acce
ptance and upholding of human dignity and
freedom".\par
}{\plain \tab While easily dismissed as too broad and vague, these internationa
l approaches, which are
necessarily the result of compromise, may prove to be more inclusive than the n
arrow, scientific
definitions often found under national legislation. To the extent that cloning
 human beings is viewed
by these nations and international organizations as incompatible with human dig
nity, prohibitions
under domestic law of the signatory countries will follow. Indeed, plans for s
uch prohibitions have
already been announced by Germany (cite to email with the article) and France (
also cite to email

with the article), and the U,K, reacted within days of Wilmut\'92s
announcement
 to tighten up its own
existing law to ensure that efforts to clone a human being would be
clearly pro
hibited (cite to email
with article).\par
}{\plain \tab Since science and medicine are now transnational endeavors,
the U
.S. government could look
for ways to cooperate with its foreign counterparts to enforce any common
polic
ies aimed to deter
efforts to clone a human being. These could include agreement to enforce
one a
nother\'92s prohibitory
legislation where appropriate, as well as for the United States to affirm
its c
ommitment to some of
the international documents being pr{*\bkmkstart BM_2_}{*\bkmkend
BM_2_}epare
d.\par
}\pard \qc\sa206
{\plain \b CONCLUSIONS}{\plain \par
}{\plain to be written\par
}}

RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: Rachel E. Levinson (CN=Rachel E. Levinson/OU=OSTP/O=EOP [OSTP])

CREATION DATE/TIME: 9-JUN-1997 14:44:46.00

SUBJECT: bill and fact sheet

TO: nbac-members (nbac-members @ lists.princeton.edu @ inet [UNKNOWN])
READ:UNKNOWN

TEXT:
President's remarks will be sent separately. Note end of Section 9
regarding NBAC extension.

========== ATTACHMENT 1 ==========
ATT CREATION TIME/DATE: 0 00:00:00.00

TEXT:
TO THE CONGRESS OF THE UNITED STATES:

I am pleased to transmit today for immediate consideration and prompt en
actment the
"Cloning Prohibition Act of 1997." This legislative proposal would prohibit an
y attempt to create
a human being using somatic cell nuclear transfer technology, the method that w
as used to create
Dolly the sheep. This proposal will also provide for further review of the eth
ical and scientific issues
associated with the use of somatic cell nuclear transfer in human beings.

Following the February report that a sheep had been successfully cloned
using a new
technique, I requested my National Bioethics Advisory Commission to examine the
ethical and legal
implications of applying the same cloning technology to human beings. The Comm
ission concluded
that at this time "it is morally unacceptable for anyone in the public or priva
te sector, whether in a
research or clinical setting, to attempt to create a child using somatic cell n
uclear transfer cloning"
and recommended that Federal legislation be enacted to prohibit such activities
. I agree with the
Commission's conclusion and am transmitting this legislative proposal to implem
ent its
recommendation.

Various forms of cloning technology have been used for decades resulting
in important
biomedical and agricultural advances. Genes, cells, tissues, and even whole pl
ants and animals have
been cloned to develop new therapies for treating such disorders as cancer, dia
betes, and cystic

fibrosis. Cloning technology also holds promise for producing replacement skin
, cartilage, or bone
tissue for burn or accident victims, and nerve tissue to treat spinal cord inju
ry. Therefore, nothing
in the "Cloning Prohibition Act of 1997" restricts activities in other areas of
 biomedical and
agricultural research that involve: (1) the use of somatic cell nuclear transf
er or other cloning
technologies to clone molecules, DNA, cells, and tissues; or (2) the use of som
atic cell nuclear
transfer techniques to create animals.

The Commission recommended that such legislation provide for further rev
iew of the state
of somatic cell nuclear transfer technology and the ethical and social issues a
ttendant to its potential
use to create human beings. My legislative proposal would implement this recom
mendation and
assign responsibility for the review, to be completed in the fifth year after p
assage of the legislation,
to the National Bioethics Advisory Commission.

I urge the Congress to give this legislation prompt and favorable consid
eration.

WILLIAM J. CLINTON

THE WHITE HOUSE
June 9, 1997

A BILL

To prohibit any attempt to create a human being using
somatic cell nuclear transfer, to provide for further
review of the ethical and scientific issues associated
with the use of somatic cell nuclear transfer in human
beings, and for other purposes.

Be it enacted by the Senate and House of Representatives of
the United States of America in Congress assembled,
SECTION 1. SHORT TITLE. This Act may be cited as the "Cloning
Prohibition Act of 1997".
SECTION 2. FINDINGS.
(a) It has been reported that an adult sheep has been cloned
using a technique called somatic cell nuclear transfer, a form
of cloning.
(b) The National Bioethics Advisory Commission (NBAC) has
reviewed the scientific and ethical implications of this
technology's potential use to clone human beings.
(1) NBAC has found that:
(a) Somatic cell nuclear transfer technology may
have many applications for biotechnology, livestock

production, and new medical approaches including the production of pharmaceutical proteins and prospects for regeneration and repair of human tissues.

(b) However, the possibility of using somatic cell nuclear transfer for the purposes of creating a child entails significant scientific uncertainty and medical risk. Potential risks, known and unknown, could result in harm to a child.

(2) The NBAC concluded unanimously 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. The Commission's consensus is based on current scientific information indicating that this technique is not safe to use in humans at this point.

(3) Moreover, in addition to issues of safety, the Commission identified many additional serious ethical concerns which they agreed require a great deal more widespread and careful public deliberation before this technology may be used.

(4) NBAC recommended a continuation of the current moratorium on the use of Federal funds to support any attempt to create a child by somatic cell nuclear transfer, and an immediate request to all firms, clinicians, investigators, and professional societies to comply voluntarily with the intent of the Federal moratorium.

(5) NBAC further recommended that Federal legislation be enacted to prohibit anyone from attempting, whether in a research or clinical setting, to create a child through somatic cell nuclear transfer cloning.

(6) NBAC also recommended that the United States cooperate with other countries to enforce mutually supported restrictions on this activity.

(7) NBAC specified that the legislation should include a sunset provision and that, prior to the sunset date, an oversight body should review and report on the status of somatic cell nuclear transfer technology and the ethical and social issues associated with its use and recommend whether the prohibition should be continued.

(8) The Commission concluded that any regulatory or legislative actions undertaken to effect the foregoing prohibition should be carefully written so as not to interfere with other important areas of research, such as the cloning of human DNA sequences and cells, which raise neither the scientific nor the ethical issues that arise from the possible creation of children through somatic cell nuclear transfer techniques.

(9) The Commission also found that cloning animals by somatic cell nuclear transfer does not raise the same issues implicated in attempting to use the technique to create a child, and its continuation should only be subject to existing regulations regarding the humane use of animals.

(c) Biomedical research facilities, including those conducting

cloning, and reproductive services facilities affect interstate commerce.

SECTION 3. PURPOSES. The purposes of this Act are

(a) To prohibit any attempt to create a human being using somatic cell nuclear transfer cloning; and

(b) To provide for further review of the ethical and scientific issues associated with the use of somatic cell nuclear transfer in humans.

SECTION 4. DEFINITIONS.

(a) "Cloning" means the production of a precise genetic copy of a molecule (including DNA), cell, tissue, plant, animal, or human.

(b) "Somatic cell" means any cell of the body other than germ cells (eggs or sperm).

(c) "Somatic cell nuclear transfer" means the transfer of a cell nucleus from a somatic cell into an egg from which the nucleus has been removed.

SECTION 5. PROHIBITION. It shall be unlawful for any person or other legal entity, public or private, to perform or use somatic cell nuclear transfer with the intent of introducing the product of that transfer into a woman's womb or in any other way creating a human being.

SECTION 6. PROTECTED BIOMEDICAL RESEARCH. Nothing in this Act shall restrict other areas of biomedical and agricultural research, including important and promising work that involves:

(1) the use of somatic cell nuclear transfer or other cloning technologies to clone molecules, DNA, cells, and tissues; or

(2) the use of somatic cell nuclear transfer techniques to create animals.

SECTION 7. PENALTIES.

(a) Any person who intentionally violates Section 5 shall be fined the greater of $250,000 or two times the gross gain or loss from the offense.

(b) If a person is violating or about to violate Section 5, the Attorney General may commence a civil action in Federal district court to enjoin such violation.

(c) Any property, real or personal, derived from or used to commit a violation or attempted violation of Section 5, or any property traceable to such property, is subject to forfeiture to the United States in accordance with the procedure set forth in Chapter 46 of Title 18 of the United States Code.

(d) The Attorney General of the United States shall have exclusive enforcement authority under this Act.

SECTION 8. EFFECTIVE DATE.-This Act shall apply to somatic cell nuclear transfers performed within five years after the date of its enactment.

SECTION 9. NATIONAL BIOETHICS ADVISORY COMMISSION REPORT. No later than four and one-half years after the enactment of this Act, the National Bioethics Advisory Commission shall report to the President on (1) the state of the science of somatic cell nuclear transfer; (2) the ethical and social issues associated with the potential use of this technology in humans; and (3) the advisability of continuing the prohibition established by this

Act. The Commission is authorized to continue for five years from the date of enactment for this purpose and for other purposes as established in Executive Order 12975 and subsequent amendments to this order.

SECTION 10. RIGHT OF ACTION. Nothing in this Act shall be construed to give any individual or person a private right of action.

"CLONING PROHIBITION ACT OF 1997"

FACT SHEET

The President today transmitted to the Congress the "Cloning Prohibition Act of 1997." This legislative proposal would implement the key recommendation of the National Bioethics Advisory Commission for legislation to prohibit any attempt to create a human being using somatic cell nuclear transfer technology.

The National Bioethics Advisory Commission (NBAC) Report

President Clinton today accepted the NBAC's report on the possible cloning of human beings. In February, following reports of the successful cloning of a sheep, the President asked the NBAC to review the profound ethical issues raised by the possible cloning of human beings. Today, Dr. Harold Shapiro, Chair of the Commission and President of Princeton University, formally presented the report to the President.

The Commission found unanimously that it is morally unacceptable for anyone to attempt to create a child with the technology used to create Dolly the sheep. The NBAC reported that attempting to create a child using so-called somatic cell nuclear transfer cloning would pose great risks to the child and raise other ethical issues needing further discussion. The NBAC called for a moratorium on the use of the technique in humans.

The Commission also found that the new technology may have many agricultural and medical benefits, including the development of medicines, therapies for diseases such as cancer, cystic fibrosis, and diabetes, and prospects for repair and regeneration of human tissues. The NBAC concluded that the cloning of DNA, cells, tissues, and non-human animals --using

somatic cell nuclear transfer and other cloning techniques --is not ethically problematic when conducted in compliance with existing regulations and guidelines.

Cloning Prohibition Act of 1997

Acting on the Commission's key recommendation, President Clinton announced legislation banning the use of the new technology to clone human beings. Consistent with the NBAC's recommendation, the President's legislative proposal prohibits for five years the use of somatic cell nuclear transfer to create a human being and directs the NBAC to report to the President in four and a half years on whether to continue the ban. The proposal is carefully worded to ensure that it will not interfere with beneficial biomedical and agricultural activities.

Further Actions By The President

As recommended by the NBAC, President Clinton today also:

Reaffirmed that no Federal funds will be used to clone human beings. The President stated that the prohibition he put in place in March will remain in effect while his proposed legislation is pending.

Urged privately funded scientists and clinicians to adhere to the voluntary moratorium he called for in March. The President asked these professionals to work through their societies and associations to ensure that all adhere to the current voluntary ban while his proposed legislation is pending.

Pledged to work with other countries to enforce the prohibition. Several other countries, including Great Britain, Denmark, Germany, Australia, and Spain, have banned human cloning.

RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: Rachel_E._Levinson@oa.eop.gov (Rachel_E._Levinson@oa.eop.gov [UNKNOWN])

CREATION DATE/TIME: 9-JUN-1997 14:53:26.00

SUBJECT: bill and fact sheet

TO: nbac-members@lists.Princeton.EDU (nbac-members@lists.Princeton.EDU [UNKNOWN])
READ:UNKNOWN

TEXT:
Message Creation Date was at 9-JUN-1997 14:48:00

President's remarks will be sent separately. Note end of Section 9
regarding NBAC extension.

The following attachments were included with this message:

TYPE : FILE
NAME : 9INFO.TXT

Subject: 9INFO
MIME-version: 1.0
Content-type: TEXT/PLAIN; CHARSET=US-ASCII
A1-type: DOCUMENT
TO THE CONGRESS OF THE UNITED STATES:

I am pleased to transmit today for immediate consideration and prompt enactment the "Cloning Prohibition Act of 1997." This legislative proposal would prohibit any attempt to create a human being using somatic cell nuclear transfer technology, the method that was used to create Dolly the sheep. This proposal will also provide for further review of the ethical and scientific issues associated with the use of somatic cell nuclear transfer in human beings.

Following the February report that a sheep had been successfully cloned using a new technique, I requested my National Bioethics Advisory Commission to examine the ethical and legal implications of applying the same cloning technology to human beings. The Commission concluded 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" and recommended that Federal legislation be enacted to prohibit such activities. I agree with the Commission's conclusion and am transmitting this legislative proposal to implement its recommendation.

Various forms of cloning technology have been used for decades resulting in important biomedical and agricultural advances. Genes, cells, tissues, and even whole plants and animals have been cloned to develop new therapies for treating such disorders as cancer, diabetes, and cystic fibrosis. Cloning technology also holds promise for producing replacement skin, cartilage, or bone tissue for burn or accident victims, and nerve

tissue to treat spinal cord injury. Therefore, nothing in the "Cloning Prohibition Act of 1997" restricts activities in other areas of biomedical and agricultural research that involve: (1) the use of somatic cell nuclear transfer or other cloning technologies to clone molecules, DNA, cells, and tissues; or (2) the use of somatic cell nuclear transfer techniques to create animals.

The Commission recommended that such legislation provide for further review of the state of somatic cell nuclear transfer technology and the ethical and social issues attendant to its potential use to create human beings. My legislative proposal would implement this recommendation and assign responsibility for the review, to be completed in the fifth year after passage of the legislation, to the National Bioethics Advisory Commission.

I urge the Congress to give this legislation prompt and favorable consideration.

WILLIAM J. CLINTON

THE WHITE HOUSE
June 9, 1997

A BILL

To prohibit any attempt to create a human being using somatic cell nuclear transfer, to provide for further review of the ethical and scientific issues associated with the use of somatic cell nuclear transfer in human beings, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,
SECTION 1. SHORT TITLE. This Act may be cited as the "Cloning Prohibition Act of 1997".
SECTION 2. FINDINGS.
(a) It has been reported that an adult sheep has been cloned using a technique called somatic cell nuclear transfer, a form of cloning.
(b) The National Bioethics Advisory Commission (NBAC) has reviewed the scientific and ethical implications of this technology's potential use to clone human beings.
(1) NBAC has found that:
(a) Somatic cell nuclear transfer technology may have many applications for biotechnology, livestock production, and new medical approaches including the production of pharmaceutical proteins and prospects for regeneration and repair of human tissues.
(b) However, the possibility of using somatic cell nuclear transfer for the purposes of creating a child entails significant scientific uncertainty and medical

risk. Potential risks, known and unknown, could result in harm to a child.
(2) The NBAC concluded unanimously 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. The Commission's consensus is based on current scientific information indicating that this technique is not safe to use in humans at this point.
(3) Moreover, in addition to issues of safety, the Commission identified many additional serious ethical concerns which they agreed require a great deal more widespread and careful public deliberation before this technology may be used.
(4) NBAC recommended a continuation of the current moratorium on the use of Federal funds to support any attempt to create a child by somatic cell nuclear transfer, and an immediate request to all firms, clinicians, investigators, and professional societies to comply voluntarily with the intent of the Federal moratorium.
(5) NBAC further recommended that Federal legislation be enacted to prohibit anyone from attempting, whether in a research or clinical setting, to create a child through somatic cell nuclear transfer cloning.
(6) NBAC also recommended that the United States cooperate with other countries to enforce mutually supported restrictions on this activity.
(7) NBAC specified that the legislation should include a sunset provision and that, prior to the sunset date, an oversight body should review and report on the status of somatic cell nuclear transfer technology and the ethical and social issues associated with its use and recommend whether the prohibition should be continued.
(8) The Commission concluded that any regulatory or legislative actions undertaken to effect the foregoing prohibition should be carefully written so as not to interfere with other important areas of research, such as the cloning of human DNA sequences and cells, which raise neither the scientific nor the ethical issues that arise from the possible creation of children through somatic cell nuclear transfer techniques.
(9) The Commission also found that cloning animals by somatic cell nuclear transfer does not raise the same issues implicated in attempting to use the technique to create a child, and its continuation should only be subject to existing regulations regarding the humane use of animals.
(c) Biomedical research facilities, including those conducting cloning, and reproductive services facilities affect interstate commerce.
SECTION 3. PURPOSES. The purposes of this Act are
(a) To prohibit any attempt to create a human being using somatic cell nuclear transfer cloning; and
(b) To provide for further review of the ethical and

scientific issues associated with the use of somatic cell nuclear transfer in humans.

SECTION 4. DEFINITIONS.

(a) "Cloning" means the production of a precise genetic copy of a molecule (including DNA), cell, tissue, plant, animal, or human.

(b) "Somatic cell" means any cell of the body other than germ cells (eggs or sperm).

(c) "Somatic cell nuclear transfer" means the transfer of a cell nucleus from a somatic cell into an egg from which the nucleus has been removed.

SECTION 5. PROHIBITION. It shall be unlawful for any person or other legal entity, public or private, to perform or use somatic cell nuclear transfer with the intent of introducing the product of that transfer into a woman's womb or in any other way creating a human being.

SECTION 6. PROTECTED BIOMEDICAL RESEARCH. Nothing in this Act shall restrict other areas of biomedical and agricultural research, including important and promising work that involves:

(1) the use of somatic cell nuclear transfer or other cloning technologies to clone molecules, DNA, cells, and tissues; or

(2) the use of somatic cell nuclear transfer techniques to create animals.

SECTION 7. PENALTIES.

(a) Any person who intentionally violates Section 5 shall be fined the greater of $250,000 or two times the gross gain or loss from the offense.

(b) If a person is violating or about to violate Section 5, the Attorney General may commence a civil action in Federal district court to enjoin such violation.

(c) Any property, real or personal, derived from or used to commit a violation or attempted violation of Section 5, or any property traceable to such property, is subject to forfeiture to the United States in accordance with the procedure set forth in Chapter 46 of Title 18 of the United States Code.

(d) The Attorney General of the United States shall have exclusive enforcement authority under this Act.

SECTION 8. EFFECTIVE DATE.-This Act shall apply to somatic cell nuclear transfers performed within five years after the date of its enactment.

SECTION 9. NATIONAL BIOETHICS ADVISORY COMMISSION REPORT. No later than four and one-half years after the enactment of this Act, the National Bioethics Advisory Commission shall report to the President on (1) the state of the science of somatic cell nuclear transfer; (2) the ethical and social issues associated with the potential use of this technology in humans; and (3) the advisability of continuing the prohibition established by this Act. The Commission is authorized to continue for five years from the date of enactment for this purpose and for other purposes as established in Executive Order 12975 and subsequent amendments to this order.

SECTION 10. RIGHT OF ACTION. Nothing in this Act shall be construed to give any individual or person a private right of

action.

"CLONING PROHIBITION ACT OF 1997"

FACT SHEET

The President today transmitted to the Congress the "Cloning Prohibition Act of 1997." This legislative proposal would implement the key recommendation of the National Bioethics Advisory Commission for legislation to prohibit any attempt to create a human being using somatic cell nuclear transfer technology.

The National Bioethics Advisory Commission (NBAC) Report

President Clinton today accepted the NBAC's report on the possible cloning of human beings. In February, following reports of the successful cloning of a sheep, the President asked the NBAC to review the profound ethical issues raised by the possible cloning of human beings. Today, Dr. Harold Shapiro, Chair of the Commission and President of Princeton University, formally presented the report to the President.

The Commission found unanimously that it is morally unacceptable for anyone to attempt to create a child with the technology used to create Dolly the sheep. The NBAC reported that attempting to create a child using so-called somatic cell nuclear transfer cloning would pose great risks to the child and raise other ethical issues needing further discussion. The NBAC called for a moratorium on the use of the technique in humans.

The Commission also found that the new technology may have many agricultural and medical benefits, including the development of medicines, therapies for diseases such as cancer, cystic fibrosis, and diabetes, and prospects for repair and regeneration of human tissues. The NBAC concluded that the cloning of DNA, cells, tissues, and non-human animals --using somatic cell nuclear transfer and other cloning techniques --is not ethically problematic when conducted in compliance with existing regulations and guidelines.

Cloning Prohibition Act of 1997

Acting on the Commission's key recommendation, President Clinton announced legislation banning the use of the new technology to clone human beings. Consistent with the NBAC's recommendation, the President's legislative proposal prohibits for five years the use of somatic cell nuclear transfer to create a human being and directs the NBAC to report to the President in four and a half years on whether to continue the ban. The proposal is carefully worded to ensure that it will not interfere with beneficial b iomedical and agricultural activities.

Further Actions By The President

As recommended by the NBAC, President Clinton today also:

Reaffirmed that no Federal funds will be used to clone human beings. The President stated that the prohibition he put in place in March will remain in effect while his proposed legislation is pending.

Urged privately funded scientists and clinicians to adhere to the voluntary moratorium he called for in March. The President asked these professionals to work through their societies and associations to ensure that all adhere to the current voluntary ban while his proposed legislation is pending.

Pledged to work with other countries to enforce the prohibition. Several other countries, including Great Britain, Denmark, Germany, Australia, and Spain, have banned human cloning.

RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: Rachel E. Levinson (CN=Rachel E. Levinson/OU=OSTP/O=EOP [OSTP])

CREATION DATE/TIME:24-JUN-1997 14:37:50.00

SUBJECT: two versions

TO: cludlam (cludlam @ bio.org @ inet [UNKNOWN])
READ:UNKNOWN

TEXT:
first is WP, second is ASCII DOS text

Let me know if you have a problem reading either one and we'll get you a
disk========== ATTACHMENT 1 ==========
ATT CREATION TIME/DATE: 0 00:00:00.00

TEXT:
Unable to convert ARMS_EXT:[ATTACH.D29]MAIL40643547Q.116 to ASCII,
The following is a HEX DUMP:
========== END ATTACHMENT 1 ==========

========== ATTACHMENT 2 ==========
ATT CREATION TIME/DATE: 0 00:00:00.00

TEXT:

A BILL

To prohibit any attempt to create a human being using somatic cell nuclear transfer, to provide for further review of the ethical and scientific issues associated with the use of somatic cell nuclear transfer in human beings, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,
SECTION 1. SHORT TITLE. This Act may be cited as the "Cloning Prohibition Act of 1997".
SECTION 2. FINDINGS.
(a) It has been reported that an adult sheep has been cloned using a technique called somatic cell nuclear transfer, a form of cloning.
(b) The National Bioethics Advisory Commission (NBAC) has reviewed the scientific and ethical implications of this technology's potential use to clone human beings.
(1) NBAC has found that:
(a) Somatic cell nuclear transfer technology may have many applications for biotechnology,

livestock production, and new medical approaches including the production of pharmaceutical proteins and prospects for regeneration and repair of human tissues.

(b) However, the possibility of using somatic cell nuclear transfer for the purposes of creating a child entails significant scientific uncertainty and medical risk. Potential risks, known and unknown, could result in harm to a child.

(2) The NBAC concluded unanimously 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. The Commission's consensus is based on current scientific information indicating that this technique is not safe to use in humans at this point.

(3) Moreover, in addition to issues of safety, the Commission identified many additional serious ethical concerns which they agreed require a great deal more widespread and careful public deliberation before this technology may be used.

(4) NBAC recommended a continuation of the current moratorium on the use of Federal funds to support any attempt to create a child by somatic cell nuclear transfer, and an immediate request to all firms, clinicians, investigators, and professional societies to comply voluntarily with the intent of the Federal moratorium.

(5) NBAC further recommended that Federal legislation be enacted to prohibit anyone from attempting, whether in a research or clinical setting, to create a child through somatic cell nuclear transfer cloning.

(6) NBAC also recommended that the United States cooperate with other countries to enforce mutually supported restrictions on this activity.

(7) NBAC specified that the legislation should include a sunset provision and that, prior to the sunset date, an oversight body should review and report on the status of somatic cell nuclear transfer technology and the ethical and social issues associated with its use and recommend whether the prohibition should be continued.

(8) The Commission concluded that any regulatory or legislative actions undertaken to effect the foregoing prohibition should be carefully written so as not to interfere with other important areas of research, such as the cloning of human DNA sequences and cells, which raise neither the scientific nor the ethical issues that arise from the possible creation of children through somatic cell nuclear transfer techniques.

(9) The Commission also found that cloning animals by somatic cell nuclear transfer does not raise the

same issues implicated in attempting to use the technique to create a child, and its continuation should only be subject to existing regulations regarding the humane use of animals.

(c) Biomedical research facilities, including those conducting cloning, and reproductive services facilities affect interstate commerce.

SECTION 3. PURPOSES. The purposes of this Act are

(a) To prohibit any attempt to create a human being using somatic cell nuclear transfer cloning; and

(b) To provide for further review of the ethical and scientific issues associated with the use of somatic cell nuclear transfer in humans.

SECTION 4. DEFINITIONS.

(a) "Cloning" means the production of a precise genetic copy of a molecule (including DNA), cell, tissue, plant, animal, or human.

(b) "Somatic cell" means any cell of the body other than germ cells (eggs or sperm).

(c) "Somatic cell nuclear transfer" means the transfer of a cell nucleus from a somatic cell into an egg from which the nucleus has been removed.

SECTION 5. PROHIBITION. It shall be unlawful for any person or other legal entity, public or private, to perform or use somatic cell nuclear transfer with the intent of introducing the product of that transfer into a woman's womb or in any other way creating a human being.

SECTION 6. PROTECTED BIOMEDICAL RESEARCH. Nothing in this Act shall restrict other areas of biomedical and agricultural research, including important and promising work that involves:

(1) the use of somatic cell nuclear transfer or other cloning technologies to clone molecules, DNA, cells, and tissues; or

(2) the use of somatic cell nuclear transfer techniques to create animals.

SECTION 7. PENALTIES.

(a) Any person who intentionally violates Section 5 shall be fined the greater of $250,000 or two times the gross gain or loss from the offense.

(b) If a person is violating or about to violate Section 5, the Attorney General may commence a civil action in Federal district court to enjoin such violation.

(c) Any property, real or personal, derived from or used to commit a violation or attempted violation of Section 5, or any property traceable to such property, is subject to forfeiture to the United States in accordance with the procedure set forth in Chapter 46 of Title 18 of the United States Code.

(d) The Attorney General of the United States shall have exclusive enforcement authority under this Act.

SECTION 8. EFFECTIVE DATE.-This Act shall apply to somatic cell nuclear transfers performed within five years after the date of its enactment.

SECTION 9. NATIONAL BIOETHICS ADVISORY COMMISSION REPORT. No later than four and one-half years after the enactment of this Act, the National Bioethics Advisory Commission shall report to the President on (1) the state of the science of somatic cell nuclear transfer; (2) the ethical and social issues associated with the potential use of this technology in humans; and (3) the advisability of continuing the prohibition established by this Act. The Commission is authorized to continue for five years from the date of enactment for this purpose and for other purposes as established in Executive Order 12975 and subsequent amendments to this order.

SECTION 10. RIGHT OF ACTION. Nothing in this Act shall be construed to give any individual or person a private right of action.========== END ATTACHMENT 2 ==========

A BILL

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Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

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(1) NBAC has found that:

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including the production of pharmaceutical proteins and prospects for regeneration and repair of human tissues.

(b) However, the possibility of using somatic cell nuclear transfer for the purposes of creating a child entails significant scientific uncertainty and medical risk. Potential risks, known and unknown, could result in harm to a child.

(2) The NBAC concluded unanimously 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. The Commission's consensus is based on current scientific information indicating that this technique is not safe to use in humans at this point.

(3) Moreover, in addition to issues of safety, the Commission identified many additional serious ethical concerns which they agreed require a great deal more widespread and careful public deliberation before this technology may be used.

(4) NBAC recommended a continuation of the current moratorium on the use of Federal funds to support any attempt to create a child by somatic cell nuclear

transfer, and an immediate request to all firms, clinicians, investigators, and professional societies to comply voluntarily with the intent of the Federal moratorium.

(5) NBAC further recommended that Federal legislation be enacted to prohibit anyone from attempting, whether in a research or clinical setting, to create a child through somatic cell nuclear transfer cloning.

(6) NBAC also recommended that the United States cooperate with other countries to enforce mutually supported restrictions on this activity.

(7) NBAC specified that the legislation should include a sunset provision and that, prior to the sunset date, an oversight body should review and report on the status of somatic cell nuclear transfer technology and the ethical and social issues associated with its use and recommend whether the prohibition should be continued.

(8) The Commission concluded that any regulatory or legislative actions undertaken to effect the foregoing prohibition should be carefully written so as not to interfere with other important areas of research, such as the cloning of human DNA sequences and cells, which raise neither the scientific nor the ethical issues that

arise from the possible creation of children through somatic cell nuclear transfer techniques.

(9) The Commission also found that cloning animals by somatic cell nuclear transfer does not raise the same issues implicated in attempting to use the technique to create a child, and its continuation should only be subject to existing regulations regarding the humane use of animals.

(c) Biomedical research facilities, including those conducting cloning, and reproductive services facilities affect interstate commerce.

SECTION 3. PURPOSES.—The purposes of this Act are—

(a) To prohibit any attempt to create a human being using somatic cell nuclear transfer cloning; and

(b) To provide for further review of the ethical and scientific issues associated with the use of somatic cell nuclear transfer in humans.

SECTION 4. DEFINITIONS.

(a) "Cloning" means the production of a precise genetic copy of a molecule (including DNA), cell, tissue, plant, animal, or human.

(b) "Somatic cell" means any cell of the body other than germ cells (eggs or sperm).

(c) "Somatic cell nuclear transfer" means the transfer

of a cell nucleus from a somatic cell into an egg from which the nucleus has been removed.

SECTION 5. PROHIBITION.—It shall be unlawful for any person or other legal entity, public or private, to perform or use somatic cell nuclear transfer with the intent of introducing the product of that transfer into a woman's womb or in any other way creating a human being.

SECTION 6. PROTECTED BIOMEDICAL RESEARCH.—Nothing in this Act shall restrict other areas of biomedical and agricultural research, including important and promising work that involves:

(1) the use of somatic cell nuclear transfer or other cloning technologies to clone molecules, DNA, cells, and tissues; or

(2) the use of somatic cell nuclear transfer techniques to create animals.

SECTION 7. PENALTIES.—

(a) Any person who intentionally violates Section 5 shall be fined the greater of $250,000 or two times the gross gain or loss from the offense.

(b) If a person is violating or about to violate Section 5, the Attorney General may commence a civil action in Federal district court to enjoin such violation.

(c) Any property, real or personal, derived from or used

to commit a violation or attempted violation of Section 5, or any property traceable to such property, is subject to forfeiture to the United States in accordance with the procedure set forth in Chapter 46 of Title 18 of the United States Code.

(d) The Attorney General of the United States shall have exclusive enforcement authority under this Act.

SECTION 8. EFFECTIVE DATE.-This Act shall apply to somatic cell nuclear transfers performed within five years after the date of its enactment.

SECTION 9. NATIONAL BIOETHICS ADVISORY COMMISSION REPORT.—No later than four and one-half years after the enactment of this Act, the National Bioethics Advisory Commission shall report to the President on (1) the state of the science of somatic cell nuclear transfer; (2) the ethical and social issues associated with the potential use of this technology in humans; and (3) the advisability of continuing the prohibition established by this Act. The Commission is authorized to continue for five years from the date of enactment for this purpose and for other purposes as established in Executive Order 12975 and subsequent amendments to this order.

SECTION 10. RIGHT OF ACTION.—Nothing in this Act shall be construed to give any individual or person a private right

of action.

RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: Rachel E. Levinson (CN=Rachel E. Levinson/OU=OSTP/O=EOP [OSTP])

CREATION DATE/TIME:31-JUL-1997 16:41:06.00

SUBJECT: Ehlers Cloning bill

TO: Jeffrey M. Smith (CN=Jeffrey M. Smith/OU=OSTP/O=EOP @ EOP [OSTP])
READ:UNKNOWN

TEXT:
---------- Forwarded by Rachel E. Levinson/OSTP/EOP on
07/31/97 04:40 PM ----------

Rachel E. Levinson 07/31/97 04:20:50 PM

Record Type: Record

To: Lucia A. Wyman/WHO/EOP
cc: Clifford J. Gabriel/OSTP/EOP
Subject: Ehlers Cloning bill

H.R. 922 states that federal funds may not be used to conduct or support any research that includes the use of human somatic cell nuclear transfer technology to create an embryo. Our bill language would extend the prohibition to the private sector and would prohibit somatic cell nuclear transfer with the intent of introducing the product of that transfer into a woman's womb or in any other way creating a human being. We stayed away from the issue of embryo research, as did the National Bioethics Advisory Commission. Our language is not perfect but does try to make clear a very narrow scope so as not to impede biomedical and agricultural research.

The current Congressional ban on embryo research already covers Ehlers scope. His vagueness is a source of concern to the biotech, pharmaceutical and reproductive biology research communities.

I will fax you an article on the mark up.

RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: Jeffrey M. Smith (CN=Jeffrey M. Smith/OU=OSTP/O=EOP [OSTP])

CREATION DATE/TIME:31-JUL-1997 18:08:48.00

SUBJECT: Re: Ehlers Cloning bill

TO: Rachel E. Levinson (CN=Rachel E. Levinson/OU=OSTP/O=EOP @ EOP [OSTP])
READ:UNKNOWN

TEXT:
Thanks for sending off to Lucia -- again. Can you send me a copy of the article you mention... for my files. Thanks.

Rachel E. Levinson 07/31/97 04:42:50 PM

Record Type: Record

To: Jeffrey M. Smith/OSTP/EOP
cc:
Subject: Ehlers Cloning bill

---------- Forwarded by Rachel E. Levinson/OSTP/EOP on 07/31/97 04:40 PM ----------

Rachel E. Levinson 07/31/97 04:20:50 PM

Record Type: Record

To: Lucia A. Wyman/WHO/EOP
cc: Clifford J. Gabriel/OSTP/EOP
Subject: Ehlers Cloning bill

H.R. 922 states that federal funds may not be used to conduct or support any research that includes the use of human somatic cell nuclear transfer technology to create an embryo. Our bill language would extend the prohibition to the private sector and would prohibit somatic cell nuclear transfer with the intent of introducing the product of that transfer into a woman's womb or in any other way creating a human being. We stayed away from the issue of embryo research, as did the National Bioethics Advisory Commission. Our language is not perfect but does try to make clear a very narrow scope so as not to impede biomedical and agricultural research.

The current Congressional ban on embryo research already covers Ehlers scope. His vagueness is a source of concern to the biotech, pharmaceutical and reproductive biology research communities.

I will fax you an article on the mark up.

RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: stipton@asrm.com (stipton@asrm.com [UNKNOWN])

CREATION DATE/TIME:20-JAN-1998 21:34:05.00

SUBJECT: Adhoc: ASRM cloning info - (long)

TO: adhoc@aamcinfo.aamc.org (adhoc@aamcinfo.aamc.org [UNKNOWN])
READ:UNKNOWN

TEXT:
Greetings,

We have gotten requests from a number of AHG members for our cloning legislation. Accordingly, below you will find our press release, our legislative package, and a summary of proposed federal legislation.

Sean Tipton
ASRM
202-863-2494

EMBARGOED UNTIL 12 a.m. January 20, 1998

Contact: Heather E. Kowalski
202/863-2439

Hkowalski@asrm.com

Reproductive Medicine Group Vows to Help Ensure No Human Cloning

(Washington, DC)-The American Society for Reproductive Medicine (ASRM) announced today that they have drafted model legislation to prohibit human cloning.

Speaking on behalf of the Society's 9,500 members, which includes leading researchers and practitioners in reproductive medicine and infertility, Executive Director J. Benjamin Younger, MD reiterated the group's strong opposition to human cloning.

"ASRM has stated since the announcement of Dolly's birth in March that we oppose using this technology to clone a human. Since October 1997 our organization has also been participating with other scientific groups representing more than 64,000 scientists in a voluntary five-year human

cloning moratorium. We have done these things in an effort to make it clear that legitimate scientists who are engaged in actual infertility research, are not and will not use this technology to clone a human being," he said.

Younger further outlined the importance of using carefully crafted language in any legislation so that important reproductive research is not hampered. "It is important that in passing a cloning prohibition, future research into infertility and many other debilitating diseases is not in any way impeded. Only through research can we find improved techniques and treatments that will help the more than 6 million Americans who suffer the pain of not being able to bear a child."

MORE

As a medical and scientific organization, ASRM is eager to work with policy makers to ensure that accurate definitions of cloning technology are used in any legislation. In the proposed ASRM legislation it will be unlawful for any person to create a human child by transferring the nucleus from a somatic cell of an existing or previously existing person into an oocyte from which the nucleus has been removed. The legislation also protects other areas of biomedical and agricultural research, is time limited, and would preempt state laws.

Younger concluded that while a human cloning prohibition is needed, it should not be hastily drafted. "We have seen a poorly worded piece of legislation passed in California, which in essence, closes the door on promising research because it uses an overly broad definition of cloning. We must work together to ensure that in our effort to make human cloning illegal we do not sentence millions of people to needless suffering because research and progress into their illness cannot proceed."

The American Society for Reproductive Medicine (ASRM) has more than 9,500 members who are devoted to advancing knowledge and expertise in reproductive medicine and biology, including obstetricians-gynecologists, urologists, endocrinologists, research scientists, medical technologists, and allied health professionals.

# # #

Model Cloning Prohibition Language *

CLONING PROHIBITION AND RESEARCH PROTECTION ACT

SECTION 1. PROHIBITION. It shall be unlawful for any person to create a human child using somatic cell nuclear transfer.

SECTION 2. DEFINITIONS. For the purposes of this section, the following definitions apply:
(a) "somatic cell nuclear transfer" means transferring the nucleus of a somatic cell of an existing or previously existing human child or adult into an oocyte from which the nucleus has been removed;
(b) "the creation of a human child" means implanting into the uterus the product of somatic cell nuclear transfer technology for gestation and subsequent birth;
(c) "somatic cell" means a mature, diploid cell;
(d) "oocyte" means the female germ cell, the egg;
(e) "nucleus" means cell structure that houses the chromosomes, and thus the genes; and
(f) "gestation" means the period during which an embryo develops, inside the uterus, into a fetus that is ready to be born.

SECTION 3. PREEMPTION OF STATE LAWS. This law shall preempt any state law
that imposes on individuals or institutions any limitations with respect to nuclear transfer, human cloning, cloning of molecules, DNA, cells, and tissues, or the use of nuclear transfer techniques to develop animals, or to related research.

SECTION 4. PROTECTED BIOMEDICAL RESEARCH. Nothing in this Act shall restrict other areas of biomedical and agricultural research, including but not limited to important and promising work that involves:
(a) the use of somatic cell nuclear transfer or other cloning technologies, to clone molecules, DNA, cells, and tissues; or
(b) the use of somatic cell nuclear transfer techniques to develop animals.

SECTION 5. EFFECTIVE DATE. This Act shall apply to somatic cell nuclear transfer performed after the date of its enactment.

SECTION 6. REAUTHORIZATION. The prohibition in this legislation shall expire five years from the effective date.

SECTION 7. NATIONAL BIOETHICS ADVISORY COMMISSION REPORT. No later than four and one-half years after the enactment of this Act, the National Bioethics Advisory Commission shall report to the President on
(a) the state of the science of somatic cell nuclear transfer;
(b) the ethical and social issues associated with the potential use of this technology in humans; and
(c) the advisability of continuing the prohibition established by this Act. The Commission is authorized to continue for five years from the date of enactment for this purpose and for other purposes as established in Executive Order 12975 and subsequent amendments to this order.

SECTION 8. RIGHT OF ACTION. Nothing in this Act shall be construed to give any individual or person a private right of action.

SECTION 9. PENALTIES.
(a) Any person who intentionally violates Section 1 shall be fined the greater of $250,000 or two times the gross gain or loss from the offense.

*As of January 19, 1998 endorsed by:

American Pediatric Society
American Society for Reproductive Medicine
Association of Medical School Pediatric Department Chairman
Society for Pediatric Research
Society for the Study of Reproduction

Summary of Current Cloning Legislation

HR 922 (Ehlers) Would prohibit federal funds for cloning research.
Status: Reported out of House Science Committee, referred to House Commerce Committee

ASRM analysis: ASRM supports a cloning prohibition, not a ban on research. What should be prohibited is the creating of a clone of an existing or previously existing human being. A prohibition on cloning research would adversely impact many other areas of research. This bill also contains incorrect scientific definitions, is overly broad, and lacks a federal preemption clause or a sunset provision.

H.R. 923 (Ehlers) Would prohibit use of a somatic cell to make a human clone.
Status: Referred to House Commerce Committee

S 368 (Bond) Would prohibit federal funds for cloning research.
Status: Referred to Labor Committee, Public Health and Safety Subcommittee has held hearings on cloning, but not on this bill specifically.

Clinton Proposal: Would prohibit human cloning.
Status: Not yet officially introduced

ASRM analysis: The President has shown strong leadership on this issue, pointing out both the potential perils of human cloning at this time,

and the danger of an overly broad prohibition. The draft legislation released by the White House in June has many virtues including a sunset provision. The draft lacks a federal preemption and there are some technical problems in some places.

California Law: Prohibits human cloning by outlawing nuclear transfer into an egg.
Status: Law

ASRM analysis: This law points out the difficulty in writing legislation, and the need for a federal preemption clause. By passing the version of the bill from the Assembly, rather than the Senate, the words nuclear transfer "from any source" rather than "somatic cell" were used. Thus making further research into this promising new treatment for infertility illegal in California.

RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: subscriptions@washington-fax.com (subscriptions@washington-fax.com [UNKNOWN])

CREATION DATE/TIME:25-JAN-1998 23:07:18.00

SUBJECT: Washington Fax January 26, 1998

TO: subscriptions@washington-fax.com (subscriptions@washington-fax.com [UNKNOWN])
READ:UNKNOWN

TEXT:
January 26, 1998

SOME SCIENTISTS OK A "PROPERLY" WORDED LEGISLATIVE HUMAN CLONING BAN
OTHER PROMISING CLONING RESEARCH MUST BE PROTECTED, THEY SAY

A Chicago scientist's declaration that he wants to establish a clinic for the cloning of human beings has prompted some scientific leaders to rethink their initial position that legislation banning the cloning of a human being is not necessary.

Scientific leaders now say proposals such as Chicago scientist Richard Seed's are an indication cloning legislation is needed. But they still caution against passing laws that are hastily written and poorly worded, saying tight and unnecessary restrictions would deny many people beneficial medical treatments and services.

Seed's announcement has created a public outcry and sent elected officials at the state and federal level scrambling to establish laws prohibiting some cloning techniques.

Both President Clinton and the National Bioethics Advisory Commission have already declared a moratorium on human cloning. Their decision was reached after a group of scientists revealed they had used somatic cell techniques to clone the sheep known as "Dolly." (see Washington Fax 6/10/97)

At a Tuesday press conference, the American Society for Reproductive Medicine (ASRM) called the practice of cloning an existing human being "unacceptable."

Ralph Yount, Federation of American Societies for Experimental Biology (FASEB) president, issued a similar statement last week, and criticized any plans to clone a human being at the present time.

"Cloning a human being would be unethical and reprehensible," said Yount, a biochemistry and chemistry professor at Washington State University. "The techniques that created Dolly are unreliable: only one of 277 embryos actually produced a viable adult sheep, and it is not even known yet that Dolly will live a normal life span. Applying to human beings today the unreliable techniques which led to Dolly only last year would be unacceptable."

While a cloning prohibition is needed, such legislation should not be hastily drafted, said ASRM Executive Director Benjamin Younger, using a California cloning ban as an example.

"We have seen a poorly worded piece of legislation passed in California, which in essence, closes the door on promising research because it uses an overly broad definition of cloning," he said. "We must work together to ensure that in our effort to make human cloning illegal we do not sentence millions of people to needless suffering because research and progress into their illness cannot proceed."

ASRM introduced their own legislation Tuesday that would make it unlawful for "any person to create a human child by transferring the nucleus from a somatic cell of an existing or previously existing person into an oocyte from which the nucleus has been removed."

According to ASRM--which has more than 9,500 members who specialize in reproductive medicine and biology--their legislative model would protect other areas of biomedical and agricultural research. While their legislation would also be time-limited and preempt state laws, Younger said no one on Capitol Hill has yet been willing to cosponsor ASRM's bill.

The legislative model constructed by ASRM would place a five-year ban on human cloning, which is the same time frame proposed by President Clinton.

During the press conference Younger and ASRM legislative liaison Sean Tipton criticized House bill H.R.923, "The Human Cloning Prohibition Act." The bill, introduced by Vernon Ehlers, R-MI, who is a scientist, has been sent to the House Commerce Committee for referral. According to Tipton, the bill is poorly worded, and would prohibit beneficial research and practical medical applications. The bill also lacks a time period for future scientific and ethical review, Tipton said. He explained that if such a bill were passed, human cloning would be banned permanently, unless the law was repealed by Congress. (see Washington Fax 7/31/97)

Congress is also reviewing two bills that would prohibit federal funding for the cloning of humans. Both the House version, H.R.922, and its Senate counterpart, S.368, would also impose a civil money penalty not to exceed $5,000 on anyone breaking the cloning prohibition. According to ASRM, embryo splitting for infertility treatment should be allowed, but Ehler's bill, as currently written, would prohibit the practice.

Meanwhile the Food and Drug Administration has announced it will regulate any attempts to use high-level cell manipulation techniques that could lead to the cloning of a human being. According to FDA sources, this action would include taking legal action if necessary.

With 14 life science societies, FASEB is the largest coalition of biological and biomedical scientists in the United States. Their Public Affairs Executive Committee recently passed a resolution that closely resembles ASRM's.

While Dolly's unveiling last February raised concerns about human cloning, Biotechnology Industry Organization (BIO) President Carl Feldbaum said the

public has since learned the 20-year-old practice of cloning cells, genes and tissues can be beneficial to many people.

"While these techniques do not lead to the cloning of a human being, they do have promise, for example, to enable us to regenerate spinal cord tissue for accident victims and skin for burn victims," Feldbaum explained.
--John B. Everton

Compiled and Published by: WASHINGTON FAX: AN INFORMATION SERVICE
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Executive Editor: Shirley Haley

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E-mail: subscriptions@washington-fax.com

RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: Derecho Comparado <derecho_comparado@pjn.gov.ar> (Derecho Comparado <derecho_comparado@pjn.gov.ar> [UNKNOWN])

CREATION DATE/TIME:31-AUG-1998 16:52:15.00

SUBJECT: INT-LAW Once again, we need your help in Argentina

TO: law-france@amgot.org (law-france@amgot.org [UNKNOWN])
READ:UNKNOWN

TO: childri-L@nic.surfnet (childri-L@nic.surfnet [UNKNOWN])
READ:UNKNOWN

TO: intilex@abanet.org (intilex@abanet.org [UNKNOWN])
READ:UNKNOWN

TO: int-law@listhost.ciesin.org (int-law@listhost.ciesin.org [UNKNOWN])
READ:UNKNOWN

TEXT:
Dear all:
we are preparing a comparative law research work on surrogate parentship and would be thankful if you help us to access legislation and case law regarding:
1- who is the legal mother in your legal system: the genetic or the surrogate one?
2- are these contracts valid and judicially enforceable?
Thank you for any help that you can give us.
Best regards from Argentina

Mercedes urioste

--
Supreme Court of Argentina
Comparative Law Research and Library Secretary
Talcahuano 550 - 4to piso - of 4002
1013 Buenos Aires
Argentina
Phone: (54)(1) 370-4637
Fax : (54)(1) 373-7501
e-mail: derecho_comparado@pjn.gov.ar

RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: "Mr. Raffaele Ladu" <r.ladu@vr.nettuno.it> ("Mr. Raffaele Ladu" <r.ladu@vr.nettuno.it> [UNKNOWN])

CREATION DATE/TIME:31-AUG-1998 20:53:12.00

SUBJECT: Re: INT-LAW Once again, we need your help in Argentina

TO: int-law@listhost.ciesin.org (int-law@listhost.ciesin.org [UNKNOWN])
READ:UNKNOWN

TEXT:
This is the Italian answer to your questions:

1 - The one who gives birth to the baby;

2 - They are considered "contra bonos mores" and therefore not enforceable.

-----Original Message-----
From: Derecho Comparado <derecho_comparado@pjn.gov.ar>
To: int-law@listhost.ciesin.org <int-law@listhost.ciesin.org>;
childri-L@nic.surfnet <childri-L@nic.surfnet>; intilex@abanet.org
<intilex@abanet.org>; law-france@amgot.org <law-france@amgot.org>
Date: luned? 31 agosto 1998 21.41
Subject: INT-LAW Once again, we need your help in Argentina

>Dear all:
> we are preparing a comparative law research work on surrogate
>parentship and would be thankful if you help us to access legislation
>and case law regarding:
>1- who is the legal mother in your legal system: the genetic or the
>surrogate one?
>2- are these contracts valid and judicially enforceable?
> Thank you for any help that you can give us.
> Best regards from Argentina
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>
>Mercedes urioste
>
>--
>Supreme Court of Argentina
>Comparative Law Research and Library Secretary
>Talcahuano 550 - 4to piso - of 4002
>1013 Buenos Aires
>Argentina
>Phone: (54)(1) 370-4637
>Fax : (54)(1) 373-7501
>e-mail: derecho_comparado@pjn.gov.ar
>
>

>----
>int-law@listhost.ciesin.org : Use this address for postings and replies -
>Email text body 'unsubscribe int-law' to: majordomo@listhost.ciesin.org
>

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int-law@listhost.ciesin.org : Use this address for postings and replies -
Email text body 'unsubscribe int-law' to: majordomo@listhost.ciesin.org

RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: sgb@losgb.com (Sheldon G. Bardach) (sgb@losgb.com (Sheldon G. Bardach) [UNKNOWN])

CREATION DATE/TIME:25-FEB-1999 16:11:46.00

SUBJECT: Surrogate Mother

TO: law-lib@ucdavis.edu (law-lib@ucdavis.edu [UNKNOWN])
READ:UNKNOWN

TEXT:
Hi All!

I am involved in a new matter which requires me to become familiar with the law and forms involved in the establishment of a surrogate mother relationship for the carrying to term of an egg of the wife and fertilized by the husband (that makes three people). All the parties reside in the State of Californial. Has anyone had any experience in the area, and can anyone refer me to treatises, forms, etc.

TIA
Sheldon G. Bardach
Law Offices of Sheldon G. Bardach
11755 Wilshire Boulevard, Suite 1450
Los Angeles, CA 90025-1543
Tel: (310) 455-0500
Fax: (310) 455-7074
e-mail: sgb@losgb.com
web site: http://www.losgb.com

RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: "Dr. Eric Cassell" <ecassell@email.msn.com> ("Dr. Eric Cassell" <ecassell@email.msn.com> [UNKNOWN])

CREATION DATE/TIME: 5-APR-1999 14:31:35.00

SUBJECT: Stem cells from unimplanted embryos

TO: NBAC Members E-list <nbac-members@lists.Princeton.EDU> (NBAC Members E-list <nbac-members@lists.Princeton.EDU> [UNKNOWN])
READ:UNKNOWN

TEXT:
All,
Perhaps this will let be fuel for discussion of the stem cell issue.
Debate about fetal research revolved around whether the fetus is a person
or
not. Sometimes human being is used as a synonym for person. In the
political battles that have raged over this subject for these many years,
it
can appear to one group that the other is trying to dehumanize the embryo
?
with all that follows from that. To others, that the assignment of the
status of person to the embryo is an attack on the rights of women. It is
well known that these are unresolvable conflicts that depend solely on the
definition of words and not at all on objectively or scientifically
determinable fact. The conflict is important to NBAC as we consider
questions related to stem cells because of its political ramifications, but
the question of whether the embryo is a person or not does not require
resolution for us to move forward. It is sufficient, on the one hand, that
we acknowledge the strongly held belief of some that embryos are persons.
On the other hand, it is clear that stem-cell research provides the promise
of major advances in the treatment of many diseases and should be life
saving for children and adults. The question is not whether embryos are
persons, but under what conditions can stem cells be retrieved from embryos
even if they are persons.
As persons, embryo cannot give consent, consent can only be given by a
parent, the natural surrogates. Parents may consent to autopsy on their
children and parents may consent to the harvest of organs for
transplantation. This is analogous to retrieving stem cells from aborted
fetuses with the mother?s consent.
The more difficult issue is the embryo created in an in vitro fertilization
program that will not be implanted. If it is not implanted it cannot
continue to grow past a primitive cellular stage. It is, therefore, not
analogous to the living embryo in the uterus which is alive because it in
the uterus. An unimplanted early stage embryo is not a living creature in
any sense by which we use those words, living creature. It is may be alive
if carefully handled and it has the potential for development if it is
implanted. Just as the ovum has the potential to be a living creature if
it
is fertilized and implanted. There are no living early stage embryos that
can continue to live independently. Just as the amputated finger is still

alive shortly after amputation if carefully handled. It has potential to grow if its is reattached. Humans have rights, but the attribution to a piece of tissue that it is human is a biological statement about its genetic character, not about its rights in the human community. Because, it is only human tissue and nothing more if not implanted, ownership belongs with the donor of the ovum. No one questions that the decision to implant rests solely with the mother. Therefore it is also the mother?s decision not to implant. Like the contributor of any piece of tissue, the mother has the right to designate its use.

Because the unimplanted embryo is human it is an object of respect. For the same reason human embryos should never be created for trivial reasons. Creating embryos solely for obtaining stem-cells must balance respect for human tissue (in relation to the unimplanted embryo) against the principle of beneficence manifested by saving lives and reducing suffering as a result of stem cell research.

Eric Cassell

RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: preventionews@cdcnpin.org (preventionews@cdcnpin.org [UNKNOWN])

CREATION DATE/TIME:30-JUL-1999 15:18:08.00

SUBJECT: [CDC News] HIV/STD/TB Funding Information 07/30/99

TO: prevention-news@hattrick.qrc.com (prevention-news@hattrick.qrc.com [UNKNOWN])
READ:UNKNOWN

TEXT:
The following funding information has been recently added to the CDC National Prevention Information Network's (NPIN) Funding Database (http://www.cdcnpin.org/db/public/fundmain.htm). For more information about HIV, STD, and TB funding opportunities, please contact the CDC NPIN at 1-800-458-5231.

FUND TITLES:

Title: Generalist Physician Faculty Scholars Program 2000
Title: NICHD Small Grants Program
Title: Program to Establish/Operate Health Promotion and Disease Prevention Initiative Program for African Americans
Title: Grants for Education Programs in Occupational Safety and Health to Prepare Health Services Researchers

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Fund Title: Generalist Physician Faculty Scholars Program 2000.

Funder Name: Robert Wood Johnson Foundation

Fund Description: The Robert Wood Johnson Foundation's Generalist Physician Faculty Scholars Program offers four-year career development awards to outstanding junior faculty in medical school departments/division of family practice, general internal medicine, and general pediatrics. This program is intended to strengthen generalist physician faculty in the nation's medical schools by improving their research capacity while maintaining their clinical and teaching competencies. One hundred and one awards were made in the first seven years of the program (1993-1999). The Foundation has authorized continued recruitment through the year 2000, and will make up to 15 awards next year. Four-year grants of up to $240,000 will be made to sponsoring institutions to help cover the Scholars' salary and research costs. Scholars will be required to spend at least 40 percent of their time in research and other scholarly pursuits. In addition to receiving financial support, scholars have the opportunity to work with an outstanding group of senior academicians who serve on the National Advisory Committee. Scholars also participate in an annual meeting, which includes presentation and review of ongoing research and

discussion of a broad array of issues relevant to general academic medicine.

Inclusive Target Audience(s): 170 - Physicians , 689 - Medical Schools

Exclusive Target Audience(s): N/A

Fund Subject(s): Curriculum , Professional networks , Program development , Training

Fund Duration: 4 years.

Letter of Intent Date:
N/A

Application Deadline:
September 30, 1999 - 2/2000 - Interviews with National Advisory Committee.

Intended Award Date(s):
May 1, 2000

Project Start Date(s):
N/A

Amount Available: - Total: $240,000.00

Notes on the Funding Amount: Four-year grants of up to $240,000 will be made to sponsoring institutions to help cover the Scholars' salary and research costs. Scholars will be required to spend at least 40 percent of their time in research and other scholarly pursuits. Grant funds may be used for a portion of the Faculty Scholar's salary, research assistance, medical student summer stipends, travel, and other direct expenses essential to carry out the Faculty Scholar's proposal. Grants are made to sponsoring institutions.

Number of Funds Expected to be Awarded: 15

Fund Location (Eligibility): Location unrestricted. (United States)

Fundee, Geographic Location (Eligibility): Location unrestricted. (United States)

Fundee, Other Eligibility: To be eligible for nomination a candidate must (1) be a physician who is a U.S. citizen, (2) be a full-time junior faculty member in family practice, general internal medicine, or general pediatrics, (3) provide evidence of research skills (research fellowship or equivalent training or experience), (4) have at least two papers published in peer-reviewed journals, (5) demonstrate excellence as a teacher, and (6) show a clinical commitment to generalism by caring for a defined panel of patients.

Fundee, Other Restrictions: The Program nominations are made by the deans of a four-year, fully accredited U.S. medical school (allopathic

or osteopathic). A school may submit only one nomination per year and have only two physicians in the program at any one time.

Fund Products: N/A

Fundee, Type of Support: Scholarships -- to individuals , Technical assistance

Fundee, Inclusive Target Organizations: IND - Individual

Fundee, Exclusive Target Organizations: N/A

Application Procedure Contact Person: Evan Charney
http://www.rwjf.org
University of Massachusetts Medical School
Worcester Foundation Campus
222 Maple Avenue
Shrewsbury, MA 01545
508-845-2641
508-845-2644 - FAX

Application, Type of Information Required:
Address requests for applications and all inquiries to Evan Charney, MD, University of Massachusetts Medical School, Worcester Foundation Campus, 222 Maple Avenue, Shrewsbury, MA 01545; call 508-845-2641; or fax 508-845-2644.

Fund Note: N/A

Fund Identification Number: 1419

Fund Title: NICHD Small Grants Program.

Fund Number: PAR-99-126

Funder Name: US Department of Health and Human Services
Public Health Service
National Institutes of Health
National Institute of Child Health and Human Development

Fund Description: The National Institute of Child Health and Human Development (NICHD) announces the continuation of its Small Grants Program, first published in February 1996. Several modifications to the program are introduced in the current announcement. The program will continue to provide limited financial support for new biomedical and behavioral research projects relevant to the NICHD mission in population science; reproductive science; pregnancy and birth; human growth and nutrition; normal and atypical development; pediatric, adolescent, and maternal HIV/AIDS; genetics and teratology; developmental biology; and medical rehabilitation research. This program will use the NIH small grant (R03) award mechanism. The NICHD Small Grant (R03) Program is

designed to provide support for projects requiring minimal funding for limited periods of time. Proposed research must be relevant to the mission of the Institute as represented by its program areas. Program areas for the Center for Population Research include Contraceptive Research, Demographic and Behavioral Science, and Reproductive Sciences. Program areas for the Center for Research for Mothers and Children include Child Development and Behavior; Developmental Biology, Genetics, and Teratology; Endocrinology, Nutrition, and Growth; Mental Retardation and Developmental Disabilities; Pediatric, Adolescent, and Maternal AIDS; and Pregnancy and Perinatology. Program areas for the National Center for Medical Rehabilitation Research include Behavioral Sciences and Rehabilitation Engineering, Biological Sciences, and Clinical Practices. Examples of the types of projects suited to the R03 mechanism include Pilot or Feasibility Studies, Innovative Research, Development of Research Methodology, Applied Research, High Risk/High Payoff Studies, Development of New Research Technology, and Reanalysis of Existing Data. The NICHD is particularly interested in supporting small grants submitted by new investigators, that is, investigators who have never before been Principal Investigator on an NIH research grant.

Inclusive Target Audience(s): 306 - Adolescents , 314 - Children , 390 -

Women

Exclusive Target Audience(s): N/A

Fund Subject(s): Adolescents , Behavioral research , Children , Clinical

research , HIV prevention , Nutrition , Pediatric AIDS , Rehabilitation , Women

Fund Duration: Up to 2 years.

Letter of Intent Date:
N/A

Application Deadline:
October 1, 1999
February 1, 2000
June 1, 2000

Intended Award Date(s):
N/A

Project Start Date(s):
N/A

Notes on the Funding Amount: The NICHD small grant is a $50,000 per year direct cost award. Support may be requested for $50,000 (direct costs) for one year or $100,000 (direct costs) for two years. These grants may not be renewed.

Fund Location (Eligibility): Location unrestricted. (United States)

Fundee, Geographic Location (Eligibility): Location unrestricted. (United States)

Fundee, Other Eligibility: Applications may be submitted by domestic, for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. Foreign institutions and organizations are not eligible for the NICHD small grant. Racial/ethnic minority individuals, women, and persons with disabilities are encouraged to apply as Principal Investigators. The NICHD also encourages applications from new investigators.

Fundee, Other Restrictions: It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH-supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. It is also the policy of NIH that children (i.e., individuals under the age of 21) must be included in all human subjects' research conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them. NICHD small grant support is for new projects only; competing continuation applications will not be accepted. An R03 grant may not be used to supplement research projects already being supported or to provide interim support for projects pending review. Simultaneous submission of both small grant and traditional research grant applications on the same topic will not be accepted. Small grant support may not be used for thesis or dissertation research.

Fund Products: N/A

Fundee, Type of Support: Program development , Research

Fundee, Inclusive Target Organizations: CNY - County
CTY - City
EDU - Educational Organization, Institution
FED - Federal
FPF - For Profit
HSP - Hospital
MIN - Minority Owned
NPF - Non Profit
RCH - Research Institution
STA - State
WOM - Woman Owned

Fundee, Exclusive Target Organizations: N/A

Application Technical info Person: Steven Kaufman
Center for Population Research
Contraception and Reproductive Health Branch
Building 61E, Room 8B13, MSC-7510
Bethesda, MD 20892 -7510
301-496-4924

301-480-1972 - FAX

Application, Type of Information Required:
Applicants must use Form PHS 398 (rev. 4/98). Application kits are available from the Division of Extramural Outreach and Information Resources, National Institutes of Health, 6701 Rockledge Drive, MSC 7910, Bethesda, MD 20892-7910, by calling (301) 435-0714, or by e-mailing grantsinfo@nih.gov. Contact funder for additional application instructions.

Fund Note: This program announcement replaces PA-96-025, NICHD Small Grants Program. This program announcement uses "Modular Grant" and "Just-in-Time" procedures.

Fund Identification Number: 1420

Fund Title: Program to Establish/Operate Health Promotion and Disease Prevention Initiative Program for African Americans.

Fund Number: Program Announcement 99148

Funder Name: US Department of Health and Human Services
Public Health Service
Centers for Disease Control and Prevention

Fund Description: The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year FY 1999 funds for a cooperative agreement program to establish a health promotion and disease prevention initiative program for African Americans. This program addresses the "Healthy People 2000" priority area Education and Community-Based Programs. The program relates as well to recommendations of the 1985 Secretary's Task Force Report on Black and Minority Health, and the Department of Health and Human Services' (DHHS) initiatives to eliminate disparities in health status among racial and ethnic minorities. The purpose of the cooperative agreement is to assist a National or Regional Minority Organization (NRMO) to establish or operate the following three components: a Health Program Unit, a Speakers Bureau, and a National Health Network. The cooperative agreement will enable the grantee to use the three components for the following: (1) Health Program Unit to implement prevention strategies to improve the health of African Americans by targeting the leading causes of excess deaths in this population, and to increase the utilization of health care resources by African Americans; (2) National Health Network to assist minority organizations to expand their internal and external organizational networks, and to facilitate the dissemination of health promotion and disease prevention information to African Americans; (3) Speakers Bureau consisting of health professionals and other professionals to provide oral presentations on salient health promotion and disease prevention topics relating to African Americans at national, State, and local meetings. Other organizations, including community-based and national/regional organizations which serve primarily African

Americans should have ready access to the Speakers Bureau to assist in improving disease prevention and health promotion in their areas.

Inclusive Target Audience(s): 200 - Community Service Professionals , 230 - Educators , 310 - Blacks/African Americans

Exclusive Target Audience(s): N/A

Fund Subject(s): Blacks , Community health education , Community programs , Health planning , HIV prevention

Fund Duration: Up to 5 years.

Letter of Intent Date:
N/A

Application Deadline:
September 7, 1999

Intended Award Date(s):
N/A

Project Start Date(s):
September 30, 1999

Amount of Fund:
- Minimum: $100,000.00

Notes on the Funding Amount: It is anticipated that a minimum of $100,000 will be available in FY 1999 to fund one award.

Number of Funds Expected to be Awarded: 1

Fund Location (Eligibility): Location unrestricted. (United States)

Fundee, Geographic Location (Eligibility): Location unrestricted. (United States)

Fundee, Other Eligibility: Eligible applicants are NRMOs that principally serve the African-American population. The African-American community is targeted with this activity because of a critical need to eliminate disparities in health that currently exist among African Americans. Eligible applicants must meet the following criteria: (1) have been granted tax-exempt status under Section 501(c)(3), as evidenced by an Internal Revenue Service (IRS) determination letter; (2) have a governing body or board that is composed of more than 50% African Americans; (3) have a minimum of 12 months documented experience in operating and centrally administering a coordinated public health or related program serving the African-American population within a major portion or region (multi-state or multi-territory) of the United States through its own offices, organizational affiliates, or the participation of other minority organizations; (4) have a specific charge from the Articles of Incorporation or Bylaws or a resolution from its governing body or board to operate nationally or regionally (multi-state or multi-

territory) within the United States and its territories, i.e., Virgin Islands, Puerto Rico, Guam; (5) have agreements with their participating affiliates and chapters that their respective governing body or board is composed of 50% or greater African-American membership.

Fundee, Other Restrictions: Public Law 104-65 states that an organization described in section 501(c)(4) of the Internal Revenue Code of 1986 that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, cooperative agreement, contract, loan, or any other form.

Fund Products: N/A

Fundee, Type of Support: Cooperative agreements ,
Program development ,
Program evaluation

Fundee, Inclusive Target Organizations: CBO - Community Based Organization
IRS - IRS 501 (c)(3) Organization
MIN - Minority Owned

Fundee, Exclusive Target Organizations: N/A

Application Procedure Contact Person: Albertha Carey
http://www.cdc.gov
Grants Management Branch
Procurement and Grants Office
Centers for Disease Control and Prevention
2920 Brandywine Road, Room 3000
Atlanta, GA 30341 -4146
770-488-2735

Application Technical info Person: Yvonne Lewis
Centers for Disease Control and Prevention, Room 4326
1600 Clifton Road, NE, M/S D39
Atlanta, GA 30333
404-639-7220

Application, Type of Information Required:
Call 888-GRANTS4 (888-472-6874) to request an application kit and receive additional written information.

Fund Note: N/A

Fund Identification Number: 1421

Fund Title: Grants for Education Programs in Occupational Safety and Health to Prepare Health Services Researchers.

Fund Number: Program Announcement 00012

Funder Name: US Department of Health and Human Services
Public Health Service
Centers for Disease Control and Prevention

Fund Description: The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2000 funds for training grants in occupational safety and health. This program addresses the "Healthy People 2000" priority area of Occupational Safety and Health. The purpose of this program is to train health services researchers in the field of occupational safety and health. Programs should train researchers to examine the impact of the organization, financing, and management of preventive, clinical, and rehabilitative occupational health services and indemnity policies on the delivery, quality, cost, access to, and outcomes of such services.

Inclusive Target Audience(s): 117 - Researchers , 500 - Health Services Providers

Exclusive Target Audience(s): N/A

Fund Subject(s): Occupational health and safety

Fund Duration: Up to 5 years.

Letter of Intent Date:
September 24, 1999

Application Deadline:
November 30, 1999

Intended Award Date(s):
N/A

Project Start Date(s):
July 1, 2000

Amount Available: - Total: $500,000.00

Amount of Fund:
- Minimum: $150,000.00
- Maximum: $200,000.00
- Average: $165,000.00

Notes on the Funding Amount: Approximately $500,000 is expected to be available in FY 2000 to fund three awards. It is expected that the average award will be $$165,000, ranging from $150,000 to $200,000.

Number of Funds Expected to be Awarded: 3

Fund Location (Eligibility): Location unrestricted. (United States, the District of Columbia, or US Territory)

Fundee, Geographic Location (Eligibility): Location unrestricted.

(United States, the District of Columbia, or US Territory)

Fundee, Other Eligibility: Any public or private educational or training agency or institution that has demonstrated competency in the occupational safety and health field and/or health services research and is located in a State, the District of Columbia, or U.S. Territory, is eligible to apply for a training grant. For existing Educational Resource Centers (ERC) or Training Project Grants (TPG) that will be requesting supplemental funding, it is imperative to include the present grant number, so it may be processed as a supplement.

Fundee, Other Restrictions: Public Law 104-65 states that an organization described in section 501(c)(4) of the Internal Revenue Code of 1986 that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, cooperative agreement, contract, loan, or any other form.

Fund Products: N/A

Fundee, Type of Support: Program development

Fundee, Inclusive Target Organizations: EDU - Educational Organization, Institution

Fundee, Exclusive Target Organizations: N/A

Application Procedure Contact Person: Sonia Phelix
http://www.cdc.gov
Grants Management Branch
Procurement and Grants Office, Announcement 00012
Centers for Disease Control Prevention (CDC)
2920 Brandywine Road, Room 3000
Atlanta, GA 30341 -4146
770-488-2724

Application Technical info Person: Bernadine Kuchinski
Office of Extramural Coordination and Special Projects
National Institute for Occupational Safety and Health
Centers for Disease Control and Prevention (CDC)
1600 Clifton Road, NE, Mailstop D-40
Atlanta, GA 30341
404-639-3342

Application, Type of Information Required:
Call 888-GRANTS4 (888-472-6874) to request an application kit and receive additional written information.

Fund Note: N/A

Fund Identification Number: 1422

If you have information about your organization's conference or funding

opportunities that you would like included in the NPIN databases and/or in the weekly e-mail announcements, please send it via e-mail to info@cdcnpin.org

The PreventioNews Mailing List is maintained by the National Prevention Information Network (NPIN), part of the Centers for Disease Control and Prevention's National Center for HIV, STD, and TB Prevention. Regular postings include the Prevention News Update, conference announcements, funding opportunities, select articles from the Morbidity and Mortality Weekly Report series, and announcements about new NPIN products and services.

To subscribe to the mailing list, send a blank message to preventionews-subscribe@cdcnpin.org
To remove your name from the mailing list, send a blank message to preventionews-unsubscribe@cdcnpin.org

Please send all e-mail inquiries to info@cdcnpin.org

RECORD TYPE: FEDERAL (NOTES MAIL)

CREATOR: preventionews@cdcnpin.org (preventionews@cdcnpin.org [UNKNOWN])

CREATION DATE/TIME:13-AUG-1999 15:18:09.00

SUBJECT: [CDC News] HIV, STD, and TB Funding Information 08/13/99

TO: prevention-news@hattrick.qrc.com (prevention-news@hattrick.qrc.com [UNKNOWN])
READ:UNKNOWN

TEXT:
The following funding information has been recently added to the CDC National Prevention Information Network's (NPIN) Funding Database (http://www.cdcnpin.org/db/public/fundmain.htm). For more information about HIV, STD, and TB funding opportunities, please contact the CDC NPIN at 1-800-458-5231.

FUND TITLES:

Title: HIV/AIDS Surveillance and HIV Incidence and HIV Prevalence Studies: Notice of Availability of Funds. Part I. Core HIV/AIDS Surveillance.
Title: HIV/AIDS Surveillance and HIV Incidence and HIV Prevalence Studies: Notice of Availability of Funds. Part II. Supplemental Surveillance Projects.
Title: HIV/AIDS Surveillance and HIV Incidence and HIV Prevalence Studies: Notice of Availability of Funds. Part III. HIV Incidence and HIV Prevalence Studies.
Title: Grants for Education Programs in Occupational Safety and Health to Prepare Health Services Researchers: Notice of Availability of Funds for Fiscal Year 2000.
Title: Milken Family Foundation: General Fund Announcement.
Title: Nathan Cummings Foundation: Health Program
Title: Biomedical Methods to Prevent Sexual Transmission of HIV: Special Targeted Request for Proposal.

Correction to: NICHD Small Grants Program.

Fund Title: HIV/AIDS Surveillance and HIV Incidence and HIV Prevalence Studies: Notice of Availability of Funds. Part I. Core HIV/AIDS Surveillance.

Fund Number: Program Announcement 00005

Funder Name: US Department of Health and Human Services
Public Health Service
Centers for Disease Control and Prevention

Fund Description: The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2000 funds to monitor the HIV epidemic through HIV/AIDS Surveillance and HIV Incidence and HIV Prevalence Studies. This program addresses the "Healthy People 2000" priority area(s) for HIV Prevention. Approximately $48 million is available under this announcement to support the following program activities: Part I. Core HIV/AIDS Surveillance; Part II. Supplemental Surveillance Projects; and Part III. HIV Incidence and HIV Prevalence Studies. The national HIV/AIDS surveillance system is the primary source of population-based information on persons with HIV/AIDS in the United States. The primary purposes of the Core HIV/AIDS Surveillance Program (Part I) are to (1) monitor the incidence and prevalence of HIV infection, and HIV-related morbidity (including AIDS) and mortality in adults, adolescents, and children; (2) monitor perinatal HIV-exposure in infants; (3) monitor behaviors related to HIV testing, risks/exposure to HIV infection, and access to care in at-risk and infected populations; (4) identify changes in trends of HIV transmission; and (5) assist State and local health departments to use these data as a guide for allocation of most federal resources for HIV treatment, care, and other services provided to HIV-infected persons and affected communities, and for prevention and treatment services planning and evaluation. The purpose of providing cooperative agreement funds for the core HIV/AIDS Surveillance program is to assist State and local public health departments in (1) implementing and conducting HIV case surveillance in all States and territories, (2) evaluating the performance of HIV/AIDS surveillance systems, and (3) implementing projects to supplement the information available through HIV and AIDS case reporting to enhance and extend the ability of States and local areas to plan for public health resources and programs.

Inclusive Target Audience(s): 116 - Planners , 117 - Researchers , 636 - Local Government Agencies , 638 - State Government Agencies

Exclusive Target Audience(s): N/A

Fund Subject(s): Adolescents , Children , Morbidity and Mortality , Persons with AIDS , Surveillance

Fund Duration: Up to 3 years.

Letter of Intent Date:
N/A

Application Deadline:
October 1, 1999

Intended Award Date(s):
N/A

Project Start Date(s):
January 1, 2000

Amount Available: - Total: $28,000,000.00

Amount of Fund:
- Minimum: $4,000.00
- Maximum: $4,000,000.00

Notes on the Funding Amount: Approximately $28 million is available in FY 2000 to fund approximately 65 awards. Awards are expected to range from $4,000 to $4,000,000.

Number of Funds Expected to be Awarded: 65

Fund Location (Eligibility): United States, including the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau; and Chicago, Houston, Los Angeles, New York City, Philadelphia, and San Francisco.

Fundee, Geographic Location (Eligibility): United States, including the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau; and Chicago, Houston, Los Angeles, New York City, Philadelphia, and San Francisco.

Fundee, Other Eligibility: Assistance will be provided only to the health departments of States or their bona fide agents, including the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau, and the six independently-funded city health departments of Chicago, Houston, Los Angeles, New York City, Philadelphia, and San Francisco.

Fundee, Other Restrictions: N/A

Fund Products: N/A

Fundee, Type of Support: Conferences/seminars ,
Program development ,
Program evaluation ,
Technical assistance

Fundee, Inclusive Target Organizations: PHD - Public Health, Social Services Department

Fundee, Exclusive Target Organizations: N/A

Application Procedure Contact Person: Van Malone
Mailstop E-15
http://www.cdc.gov
Grants Management Branch
Procurement and Grants Office
Centers for Disease Control and Prevention (CDC)

Room 3000, 2920 Brandywine Road
Atlanta, GA 30341 -4146
770-488-2733

Application Technical info Person: Joe Posid
Surveillance Branch
Div. of HIV/AIDS Prevention-Surveillance and Epidemiology
Centers for Disease Control and Prevention
1600 Clifton Road, Mailstop E-47
Atlanta, GA 30333
404-639-2976

Application, Type of Information Required:
Submit the original and two copies of PHS 5161-1 (OMB Number 0937-0189). Forms are available at www.cdc.gov/od/pgo/forminfo.htm, or in the application kit. Contact the "Application Procedure Contact Person" in this record for additional information.

Fund Note: The highest preference will be given to applicants with at least one Ryan White Title I Eligible Metropolitan Area (EMA) and that have HIV case reporting as of the due date of this cooperative agreement application. The second preference will be given to applicants that have HIV case reporting as of the due date of this cooperative agreement application, but do not have at least one Ryan White Title I EMA. The third preference will be given to applicants with at least one Ryan White Title I EMA. That do not have HIV case reporting, but anticipate having implemented HIV case reporting by January 1, 2001; and the fourth preference will be given to all other applicants.

Fund Identification Number: 1426

Fund Title: HIV/AIDS Surveillance and HIV Incidence and HIV Prevalence Studies: Notice of Availability of Funds. Part II. Supplemental Surveillance Projects.

Fund Number: Program Announcement 00005

Funder Name: US Department of Health and Human Services
Public Health Service
Centers for Disease Control and Prevention

Fund Description: The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2000 funds to monitor the HIV epidemic through HIV/AIDS Surveillance and HIV Incidence and HIV Prevalence Studies. This program addresses the "Healthy People 2000" priority area(s) for HIV Prevention. Approximately $48 million is available under this announcement to support the following program activities: Part I. Core HIV/AIDS Surveillance; Part II. Supplemental Surveillance Projects; and Part III. HIV Incidence and HIV Prevalence Studies. The national HIV/AIDS surveillance system is the primary

source of population-based information on persons with HIV/AIDS in the United States. The primary purposes of the Supplemental Surveillance Projects (Part II) are to allow an increasing number of recipients the ability to better translate the implications of HIV/AIDS surveillance trend data for national, State, and local prevention and care programs, and enhance the utility of data from supplemental surveillance projects (e.g., SHAS) by using population-based methods of data collection to characterize infected populations and assess the impact of the HIV epidemic in the United States. As part of their three-year plan, grantees should indicate the year(s) in which they intend to conduct any of the supplemental surveillance projects described below: (1) Monitoring HIV-related morbidity and causes of mortality: (a) Adult/Adolescent Spectrum of Disease (ASD) project or (b) Survey of HIV Disease and Care; (2) Interview projects to supplement "core" surveillance activities: (a) SHAS (Supplement to HIV/AIDS Surveillance) or (b) New Supplemental Interview Projects; and (3) Enhanced Surveillance for Perinatal Prevention.

Inclusive Target Audience(s): 116 - Planners , 117 - Researchers , 636 - Local Government Agencies , 638 - State Government Agencies

Exclusive Target Audience(s): N/A

Fund Subject(s): Adolescents , Children , Health care , Morbidity and Mortality , Persons with AIDS , Surveillance

Fund Duration: 3 years.

Letter of Intent Date:
N/A

Application Deadline:
October 1, 1999

Intended Award Date(s):
N/A

Project Start Date(s):
January 1, 2000

Amount Available: - Total: $7,000,000.00

Notes on the Funding Amount: Approximately $7 million is available in FY 2000 to fund supplemental surveillance projects. (1) Approximately $3.2 million is currently available for monitoring HIV-related morbidity and causes of mortality (ASD and Survey of HIV Disease and Care). CDC would like to fund up to 9 ASD awards for up to 3 years. Over the course of the three-year project period, CDC would also like to fund up to 20 Survey of HIV Disease and Care awards (approximately seven different grantees each year) for 1 or 2 years (contingent on availability of funds). (2) Approximately $2,000,000 is currently available for interview projects to supplement "core" surveillance data (SHAS and New Supplemental Interview Projects). CDC would like to fund up to 12 awards for continuation SHAS for up to 3 years. Over the

course of the three-year project period, CDC would also like to fund up to 30 awards for New Supplemental Interview Projects to supplement HARS (approximately ten different grantees each year) for 1 or 2 years (contingent on availability of funds). (3) Approximately $1,800,000 is available to fund up to 30 awards for up to 3 years for Enhanced Surveillance for Perinatal Prevention.

Fund Location (Eligibility): United States, including the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau; and Chicago, Houston, Los Angeles, New York City, Philadelphia, and San Francisco.

Fundee, Geographic Location (Eligibility): United States, including the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau; and Chicago, Houston, Los Angeles, New York City, Philadelphia, and San Francisco.

Fundee, Other Eligibility: Assistance will be provided only to the health departments of States or their bona fide agents, including the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau, and the six independently-funded city health departments of Chicago, Houston, Los Angeles, New York City, Philadelphia, and San Francisco. Additional eligibility criteria applies for activities for which an applicant wish to submit an application under this part (Part II).

Fundee, Other Restrictions: N/A

Fund Products: N/A

Fundee, Type of Support: Program development ,
Program evaluation ,
Research

Fundee, Inclusive Target Organizations: PHD - Public Health, Social Services Department

Fundee, Exclusive Target Organizations: N/A

Application Procedure Contact Person: Van Malone
http://www.cdc.gov
Grants Management Branch
Procurement and Grants Office
Centers for Disease Control and Prevention (CDC)
Room 3000, 2920 Brandywine Road, Mailstop E-15
Atlanta, GA 30341 -4146
770-488-2733

Application Technical info Person: Joe Posid
Surveillance Branch
Div. of HIV/AIDS Prevention-Surveillance and Epidemiology
Centers for Disease Control and Prevention
1600 Clifton Road, Mailstop E-47
Atlanta, GA 30333
404-639-2976

Application, Type of Information Required:
Submit the original and two copies of PHS 5161-1 (OMB Number 0937-0189). Forms are available at www.cdc.gov/od/pgo/forminfo.htm, or in the application kit. Contact the "Application Procedure Contact Person" in this record for additional information.

Fund Note: Following are general funding preferences that will affect decisions for monitoring HIV-related morbidity and causes of mortality (ASD, Survey of HIV Disease and Care), and interview projects to supplement "core" surveillance activities (SHAS, New Supplemental Interview Projects): (1) Highest preference will be given to applicants that have at least one Ryan White Title I Eligible Metropolitan Area (EMA) and have HIV reporting as of the due date of the application. (2) Second preference will be given to applicants that have HIV reporting as of the date of the cooperative agreement application, but do not have at least one Ryan White Title I EMA. (3) Third preference will be given to applicants that have at least one Ryan White Title I EMA, do not have HIV reporting, but anticipate having implemented HIV reporting by January 1, 2001. (4) Fourth preference will be given to all other applicants.

Fund Identification Number: 1427

Fund Title: HIV/AIDS Surveillance and HIV Incidence and HIV Prevalence Studies: Notice of Availability of Funds. Part III. HIV Incidence and HIV Prevalence Studies.

Fund Number: Program Announcement 00005

Funder Name: US Department of Health and Human Services
Public Health Service
Centers for Disease Control and Prevention

Fund Description: The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2000 funds to monitor the HIV epidemic through HIV/AIDS Surveillance and HIV Incidence and HIV Prevalence Studies. This program addresses the "Healthy People 2000" priority area(s) for HIV Prevention. Approximately $48 million is available under this announcement to support the following program activities: Part I. Core HIV/AIDS Surveillance; Part II. Supplemental Surveillance Projects; and Part III. HIV Incidence and HIV prevalence Studies. The national HIV/AIDS surveillance system is the primary source of population-based information on persons with HIV/AIDS in the United States. The primary purposes of the HIV incidence and

prevalence studies are to (1) measure HIV incidence and prevalence in HIV risk populations, and in certain health care settings and geographical areas; and (2) to analyze and disseminate data obtained from currently-funded surveys to assist in evaluating the impact of HIV prevention efforts. Eligible applicants may apply for any or all of the eight activities proposed under this program announcement: (1) Data Analysis and Information Dissemination, (2) Evaluation of Current Estimates and Plan for Prospective Study of HIV Incidence and Characterization of Recently HIV-Infected Persons within Geographically-Defined Settings, (3) HIV Incidence and Prevalence Surveys (DTC, STD, YMS, and YWS), (4) HIV Incidence Studies of Illicit Drug Users in the Correctional System, (5) Use of the Sensitive/Less Sensitive Assay (S/LS, also known as the "detuned assay") to Measure HIV Incidence in Prospective or Retrospective Studies, (6) Laboratory testing using the Sensitive/Less Sensitive Assay, (7) Sentinel Surveillance for Variant and Drug Resistant Strains of HIV (SSVRS), and (8) Other studies of significance in measuring HIV incidence and prevalence and risk behaviors in specific risk populations, geographic areas, or other sentinel sites/populations.

Inclusive Target Audience(s): 116 - Planners , 117 - Researchers , 636 - Local Government Agencies , 638 - State Government Agencies

Exclusive Target Audience(s): N/A

Fund Subject(s): Behavioral research , Health care , Information dissemination , IV drug users , Surveillance

Letter of Intent Date:
N/A

Application Deadline:
October 1, 1999

Intended Award Date(s):
N/A

Project Start Date(s):
N/A

Amount Available: - Total: $13,000,000.00

Notes on the Funding Amount: Approximately $13 million is available in FY 2000 to fund all awarded activities under Activities 1-8 listed below. Activity 1: Data Analysis and Information Dissemination - Approximately $3,000,000 is available in FY 2000 to fund approximately 20 awards. It is expected that the average award will be $150,000, ranging from $100,000 to $300,000. Activity 2: Evaluate Current Estimates and Plan for Prospective Study of HIV Incidence and Characterization of Recently HIV-Infected Persons within Geographically-Defined Settings - Approximately $750,000 is available in FY 2000 to fund 3-5 awards. It is expected that the average award will be $250,000, ranging from $175,000 to $325,000. Activity 3: HIV Incidence and Prevalence Surveys (DTC, STD, YMS, YWS) - Approximately

$3,500,000 is available in FY 2000 to fund approximately 14 awards. It is expected that the average award will be $250,000, ranging from $100,000 to $400,000. Activity 4: HIV Incidence Studies of Illicit Drug Users in the Correction System - Approximately $750,000 is available in FY 2000 to fund up to 3 awards. It is expected that the average award will be $250,000, ranging from $200,000 to $300,000. Activity 5: Use of the Sensitive/Less Sensitive Assay (S/LS, also known as the "detuned assay") to Measure HIV Incidence in Prospective or Retrospective Studies - Approximately $1,875,000 is available in FY 2000 to fund up to 15 awards. It is expected that the average award will be $125,000, ranging from $100,000 to $175,000. Activity 6: Laboratory testing using the Sensitive/Less Sensitive Assay - Approximately $1,200,000 is available in FY 2000 to fund approximately 6 awards. It is expected that the average award will be $200,000, ranging from $150,000 to $250,000. Activity 7: Sentinel Surveillance for Variant and Drug Resistant Strains of HIV (SSVRS) - Approximately $900,000 is available in FY 2000 to fund approximately 9 awards. It is expected that the average award will be $100,000, ranging from $70,000 to $120,000. Activity 8: Other studies of significance in measuring HIV incidence and prevalence and risk behaviors in specific risk populations, geographic areas, or other sentinel sites/populations - Approximately $1,000,000 is available in FY 2000 to fund approximately 3 awards. It is expected that the average award will be $330,000, ranging from $275,000 to $375,000. Funding estimates may vary and are subject to change. Continued support in future years will be based on the availability of funds and success in demonstrating progress toward achievement of objectives.

Fund Location (Eligibility): United States, including the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau; and Chicago, Houston, Los Angeles, New York City, Philadelphia, and San Francisco.

Fundee, Geographic Location (Eligibility): United States, including the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau; and Chicago, Houston, Los Angeles, New York City, Philadelphia, and San Francisco.

Fundee, Other Eligibility: Assistance will be provided only to the health departments of States or their bona fide agents, including the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau, and the six independently-funded city health departments of Chicago, Houston, Los Angeles, New York City, Philadelphia, and San Francisco.

Fundee, Other Restrictions: N/A

Fund Products: N/A

Fundee, Type of Support: Management development ,
Program development ,
Research ,
Technical assistance

Fundee, Inclusive Target Organizations: PHD - Public Health, Social Services Department

Fundee, Exclusive Target Organizations: N/A

Application Procedure Contact Person: Van Malone
http://www.cdc.gov
Grants Management Branch
Procurement and Grants Office
Centers for Disease Control and Prevention (CDC)
Room 3000, 2920 Brandywine Road, Mailstop E-15
Atlanta, GA 30341 -4146
770-488-2733

Application Technical info Person: Don Mixon
Prevention Services Research Branch
Div. of HIV/AIDS Prevention - Surveillance and Epidemiology
Centers for Disease Control and Prevention
1600 Clifton Road, Mailstop E-46
Atlanta, GA 30333
404-639-2080

Application, Type of Information Required:
Submit the original and two copies of PHS 5161-1 (OMB Number 0937-0189). Forms are available at www.cdc.gov/od/pgo/forminfo.htm, or in the application kit. Contact the "Application Procedure Contact Person" in this record for additional information.

Fund Note: N/A

Fund Identification Number: 1428

Fund Title: Grants for Education Programs in Occupational Safety and Health to Prepare Health Services Researchers: Notice of Availability of Funds for Fiscal Year 2000.

Fund Number: Program Announcement 00012

Funder Name: US Department of Health and Human Services
Public Health Service
Centers for Disease Control and Prevention

Fund Description: The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2000 funds for training grants in occupational safety and health. This program addresses the

"Healthy People 2000" priority area of Occupational Safety and Health. The purpose of this program is to train health services researchers in the field of occupational safety and health.

Inclusive Target Audience(s): 117 - Researchers

Exclusive Target Audience(s): N/A

Fund Subject(s): Occupational health and safety , Training

Fund Duration: Up to 5 years.

Letter of Intent Date:
September 24, 1999 - Optional.

Application Deadline:
November 30, 1999

Intended Award Date(s):
N/A

Project Start Date(s):
July 1, 2000

Amount Available: - Total: $500,000.00

Amount of Fund:
- Minimum: $150,000.00
- Maximum: $200,000.00
- Average: $165,000.00

Notes on the Funding Amount: Approximately $500,000 is expected to be available in FY 2000 to fund three awards. It is expected that the average award will be $165,000, ranging from $150,000 to $200,000.

Number of Funds Expected to be Awarded: 3

Fund Location (Eligibility): Location unrestricted. (United States & US Territory)

Fundee, Geographic Location (Eligibility): Location unrestricted. (United States & US Territory)

Fundee, Other Eligibility: Any public or private educational or training agency or institution that has demonstrated competency in the occupational safety and health field and/or health services research and is located in a State, the District of Columbia, or U.S. Territory, is eligible to apply for a training grant. For existing Educational Resource Centers (ERC) or Training Project Grants (TPG) that will be requesting supplemental funding, it is imperative to include the present grant number, so it may be processed as a supplement.

Fundee, Other Restrictions: Public Law 104-65 states that an

organization described in section 501(c)(4) of the Internal Revenue Code of 1986 that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, cooperative agreement, contract, loan, or any other form.

Fund Products: N/A

Fundee, Type of Support: Program development , Program evaluation

Fundee, Inclusive Target Organizations: EDU - Educational Organization, Institution

Fundee, Exclusive Target Organizations: N/A

Application Procedure Contact Person: Sonia Phelix
2920 Brandywine Road, Room 3000
http://www.cdc.gov
Grants Management Branch
Procurement and Grants Office
Announcement 00012
Centers for Disease Control and Prevention (CDC)
Atlanta, GA 30341 -4146
770-488-2724

Application Technical info Person: Bernadine Kuchinski
Office of Extramural Coordination and Special Projects
National Institute for Occupational Safety and Health
Centers for Disease Control and Prevention (CDC)
1600 Clifton Road, NE, Mailstop D-40
Atlanta, GA 30341
404-639-3342

Application, Type of Information Required:
Call 888-GRANTS4 (888-472-6874) to request an application kit and receive additional written information.

Fund Note: N/A

Fund Identification Number: 1429

Fund Title: Milken Family Foundation: General Fund Announcement.

Funder Name: Milken Family Foundation

Fund Description: The Milken Family Foundation announced the funding opportunities to build human resources through programs in four major areas: (1) Education - to reward educational innovators, stimulate creativity among students, involve parents and other citizens in the school system, and offer opportunities to the disadvantaged students; (2) Health Care and Medical Research - to make the benefits of both

basic and highly advanced health care available to those who need them; (3) Community Services - to support programs and facilities that meet the essential needs at the neighborhood level; and (4) Human Welfare - to meet the compelling needs of the disadvantaged.

Inclusive Target Audience(s): 100 - Health Professionals , 117 - Researchers , 230 - Educators , 378 - Students, Young Adults

Exclusive Target Audience(s): N/A

Fund Subject(s): Community programs , Health care , Public education , Research , Schools , Student health programs

Letter of Intent Date:
N/A

Application Deadline:
N/A

Intended Award Date(s):
N/A

Project Start Date(s):
N/A

Amount of Fund:
- Average: $25,000.00

Notes on the Funding Amount: Each Milken Educator Award carries with it an unrestricted award of $25,000.

Fund Location (Eligibility): United States; primarily in the Los Angeles, CA area.

Fundee, Geographic Location (Eligibility): United States; primarily in the Los Angeles, CA area.

Fundee, Other Eligibility: N/A

Fundee, Other Restrictions: N/A

Fund Products: N/A

Fundee, Type of Support: Building/renovation ,
Conferences/seminars ,
General/operating support ,
Research ,
Scholarships -- to individuals

Fundee, Inclusive Target Organizations: IND - Individual

Fundee, Exclusive Target Organizations: N/A

Application Procedure Contact Person: Julius Lesner

http://www.mff.org
The Milken Family Foundation
1250 4th St., 6th Fl.
Santa Monica, CA 90401 -1353
310-998-2800
310-998-2828 - FAX

Application, Type of Information Required:
Submit letter or proposal to the funder for initial approach. Contact funder for more information.

Fund Note: N/A

Fund Identification Number: 1430

Fund Title: Nathan Cummings Foundation: Health Program.

Funder Name: Nathan Cummings Foundation

Fund Description: The Nathan Cummings Foundation's health program is committed to improving the quality of life at its beginning and at its end by supporting humane patient-centered care that provides comfort and caring, as well as cure. This program is grounded in an expanded view of health that recognizes the importance of family and the link between physical health and psychological, spiritual, social, economic, and environmental factors. The foundation supports projects geared towards low-income pregnant women and children under six that (1) increase awareness and acceptance of policies and practices by healthcare professionals and policymakers who support the foundation's holistics philosophy, and (2) increase implementation of such policies and practices by healthcare providers. The foundation also supports projects geared towards individuals who are dying that (1) support patient empowerment, especially by improving communication; (2) support family and other informal caregivers by improving the programs, services, and information available to them; and (3) increase the attention paid to the inner life/spiritual needs of people who are dying and their family or other informal caregivers.

Inclusive Target Audience(s): 314 - Children , 366 - Low Income Persons , 390 - Women , 400 - Persons With AIDS , 445 - HIV Positive Persons

Exclusive Target Audience(s): N/A

Fund Subject(s): Health care , Medical treatments , Mental health , Social services

Letter of Intent Date:
N/A

Application Deadline:

N/A

Intended Award Date(s):
N/A

Project Start Date(s):
N/A

Fund Location (Eligibility): Location unrestricted. (United States)

Fundee, Geographic Location (Eligibility): Location unrestricted. (United States)

Fundee, Other Eligibility: The foundation supports (1) state-based public interest organizations, and (2) national organizations that provide information and technical assistance to national and state-based public interest organizations and policymakers.

Fundee, Other Restrictions: In its core programs, the Foundation does not contribute to endowments, debt reduction, capital campaigns, capital construction, equipment purchases, or museum collections acquisitions. The Foundation makes a limited number of grants abroad and only in specifically defined areas.

Fund Products: N/A

Fundee, Type of Support: Program evaluation , Technical assistance

Fundee, Inclusive Target Organizations: STA - State

Fundee, Exclusive Target Organizations: N/A

Application Procedure Contact Person:
http://www.ncf.org
The Nathan Cummings Foundation
1926 Broadway, Suite 600
New York, NY 10023 -6915
212-787-7300
212-787-7377 - FAX

Application, Type of Information Required:
Send the Foundation a two to three-page letter of inquiry. Contact funder for additional instruction.

Fund Note: N/A

Fund Identification Number: 1431

Fund Title: Biomedical Methods to Prevent Sexual Transmission of HIV: Special Targeted Request for Proposal.

Funder Name: American Foundation for AIDS Research

Fund Description: The American Foundation for AIDS Research (amfAR) announces the availability of special targeted-research grant support for awards of up to $75,000, plus not more than 20% for indirect costs, for basic research in biomedical methods to prevent the sexual transmission of HIV. amfAR invites letters of intent (LOIs) for research projects in the following areas: (1) exploration of innovative approaches to specific anti-HIV microbicides or microbicides capable of blocking STDs associated with facilitation of HIV infection; (2) research in microbicidal biotherapeutics in prevention of HIV transmission; (3) role of mucosal humoral and/or cullular immunity in blocking transmission of cell-free and cell-associated HIV, and differences in mucosal immunity in intestinal vs. vaginal tissues; (4) role of hormones and cytokines in facilitating or impeding mucosal HIV transmission; and (5) design of experimental models to test the validity of microbicides. Proposals may involve any and all of these topics discussed above, as well as other issues not specifically raised here, but within the field of microbicide research.

Inclusive Target Audience(s): 117 - Researchers , 376 - Sex Partners

Exclusive Target Audience(s): N/A

Fund Subject(s): Epidemiological research , HIV prevention , Sexual behavior , Sexually transmitted diseases

Fund Duration: 1 year, with the possibility of renewal for a 2nd year

Letter of Intent Date:
September 15, 1999 - No later than 5:00 pm.

Application Deadline:
October 26, 1999 - Approximate date for full application. An LOI pre-application must be submitted and approved prior to submission of a grant application.

Intended Award Date(s):
January 1, 2000

Project Start Date(s):
N/A

Amount of Fund:
- Maximum: $750,000.00

Notes on the Funding Amount: The maximum amount for a Research Grant under this targeted funding initiative is US $75,000 in direct costs, plus not more than 20% for institutional indirect costs, for a total maximum award of US $90,000.

Fund Location (Eligibility): Location unrestricted.

Fundee, Geographic Location (Eligibility): Location unrestricted.

Fundee, Other Eligibility: Grants are awarded only to national or international nonprofit institutions. Members of the Foundation's Scientific Advisory Committee are eligible, provided they comply with the Foundation's policies regarding the avoidance of conflicts of interest, of which they are duly informed. Applicants need not be American citizens, and there are no restrictions as to age, color, creed, gender, handicap, marital status, medical condition, national origin, parental status, political affiliation, race, religion, or sexual orientation.

Fundee, Other Restrictions: Grants applications will not be accepted from for-profit entities. Grants are not made to individuals. Members of the Foundation's Board of Directors are not eligible as investigators in Foundation-supported research.

Fund Products: N/A

Fundee, Type of Support: Research

Fundee, Inclusive Target Organizations: INT - International
NPF - Non Profit

Fundee, Exclusive Target Organizations: FPF - For Profit
IND - Individual

Application Procedure Contact Person: Abbey Chernela
American Foundation for AIDS Research
Program Office
120 Wall Street, 13th Floor
New York, NY 10005 -3902
212-806-1696
212-806-1601 - FAX

Application, Type of Information Required:
For an LOI application form or additional information, contact American Foundation for AIDS Research (amfAR), Grants Department, 120 Wall Street, 13th Floor, New York, NY 10005-3902; call (212) 806-1696; fax (212) 806-1601; or email grants@amfar.org. The LOI forms may also be downloaded from website http://www.amfar.org. The original LOI and 8 copies should be submitted to the address above.

Fund Note: N/A

Fund Identification Number: 1432

Correction to: NICHD Small Grants Program.

There was a correction to the contact information for this funding

announcement. The correct information follows.

Fund Number: PAR-99-126

Funder Name: US Department of Health and Human Services
Public Health Service
National Institutes of Health
National Institute of Child Health and Human Development

Fund Description: The National Institute of Child Health and Human Development (NICHD) announces the continuation of its Small Grants Program, first published in February 1996. Several modifications to the program are introduced in the current announcement. The program will continue to provide limited financial support for new biomedical and behavioral research projects relevant to the NICHD mission in population science; reproductive science; pregnancy and birth; human growth and nutrition; normal and atypical development; pediatric, adolescent, and maternal HIV/AIDS; genetics and teratology; developmental biology; and medical rehabilitation research. This program will use the NIH small grant (R03) award mechanism. The NICHD Small Grant (R03) Program is designed to provide support for projects requiring minimal funding for limited periods of time. Proposed research must be relevant to the mission of the Institute as represented by its program areas. Program areas for the Center for Population Research include Contraceptive Research, Demographic and Behavioral Science, and Reproductive Sciences. Program areas for the Center for Research for Mothers and Children include Child Development and Behavior; Developmental Biology, Genetics, and Teratology; Endocrinology, Nutrition, and Growth; Mental Retardation and Developmental Disabilities; Pediatric, Adolescent, and Maternal AIDS; and Pregnancy and Perinatology. Program areas for the National Center for Medical Rehabilitation Research include Behavioral Sciences and Rehabilitation Engineering, Biological Sciences, and Clinical Practices. Examples of the types of projects suited to the R03 mechanism include Pilot or Feasibility Studies, Innovative Research, Development of Research Methodology, Applied Research, High Risk/High Payoff Studies, Development of New Research Technology, and Reanalysis of Existing Data. The NICHD is particularly interested in supporting small grants submitted by new investigators, that is, investigators who have never before been Principal Investigator on an NIH research grant.

Inclusive Target Audience(s): 306 - Adolescents , 314 - Children , 390 - Women

Exclusive Target Audience(s): N/A

Fund Subject(s): Adolescents , Behavioral research , Children , Clinical research , HIV prevention , Nutrition , Pediatric AIDS , Rehabilitation , Women

Fund Duration: Up to 2 years.

Letter of Intent Date:

N/A

Application Deadline:
October 1, 1999
February 1, 2000
June 1, 2000

Intended Award Date(s):
N/A

Project Start Date(s):
N/A

Notes on the Funding Amount: The NICHD small grant is a $50,000 per year direct cost award. Support may be requested for $50,000 (direct costs) for one year or $100,000 (direct costs) for two years. These grants may not be renewed.

Fund Location (Eligibility): Location unrestricted. (United States)

Fundee, Geographic Location (Eligibility): Location unrestricted. (United States)

Fundee, Other Eligibility: Applications may be submitted by domestic, for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. Foreign institutions and organizations are not eligible for the NICHD small grant. Racial/ethnic minority individuals, women, and persons with disabilities are encouraged to apply as Principal Investigators. The NICHD also encourages applications from new investigators.

Fundee, Other Restrictions: It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH-supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. It is also the policy of NIH that children (i.e., individuals under the age of 21) must be included in all human subjects' research conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them. NICHD small grant support is for new projects only; competing continuation applications will not be accepted. An R03 grant may not be used to supplement research projects already being supported or to provide interim support for projects pending review. Simultaneous submission of both small grant and traditional research grant applications on the same topic will not be accepted. Small grant support may not be used for thesis or dissertation research.

Fund Products: N/A

Fundee, Type of Support: Program development , Research

Fundee, Inclusive Target Organizations: CNY - County
CTY - City
EDU - Educational Organization, Institution
FED - Federal
FPF - For Profit
HSP - Hospital
MIN - Minority Owned
NPF - Non Profit
RCH - Research Institution
STA - State
WOM - Woman Owned

Fundee, Exclusive Target Organizations: N/A

Application Procedure Contact Person: Diane Watson
http://www.nichd.nih.gov/contacts/r03pacontacts.htm
Grants Management Branch
Building 61E,, Room 8A01 MSC-7510
Bethesda, MD 20892 -7510
301-496-5001
301-402-0915 - FAX

Application, Type of Information Required:
Applicants must use Form PHS 398 (rev. 4/98). Application kits are available from the Division of Extramural Outreach and Information Resources, National Institutes of Health, 6701 Rockledge Drive, MSC 7910, Bethesda, MD 20892-7910, by calling (301) 435-0714, or by e-mailing grantsinfo@nih.gov. Contact funder for additional application instructions. For inquiries regarding programmatic issues: http://www.nichd.nih.gov/contacts/r03pacontacts.htm . For the NIH guide for Grants and Contracts: http://www.nih.gov/grants/guide/ .

Fund Note: This program announcement replaces PA-96-025, NICHD Small Grants Program. This program announcement uses "Modular Grant" and "Just-in-Time" procedures.

Fund Identification Number: 1420

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preventionews-subscribe@cdcnpin.org
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CREATION DATE/TIME:13-SEP-1999 11:26:03.00

SUBJECT: RESEARCH NETWORK SEEKS PATIENTS FOR INFERTILITY STUDY

TO: HHSPRESS@LIST.NIH.GOV (HHSPRESS@LIST.NIH.GOV [UNKNOWN])
READ:UNKNOWN

TEXT:
National Institutes of Health

National Institute of Child Health and Human Development

NEWS RELEASE

FOR IMMEDIATE RELEASE
Monday, September 13, 1999

Contact:
Robert Bock
(301) 496-5133

RESEARCH NETWORK SEEKS PATIENTS FOR INFERTILITY STUDY

Scientists at a research network funded by the National Institute of Child Health and Human Development (NICHD) are seeking infertile couples for a study to investigate whether taking a sample of endometrial tissue is useful for diagnosing and treating infertility.

"There is a strong need for effective infertility treatments, and this need may result in the use of therapies that haven't been tested in clinical trials," said NICHD Director Duane Alexander, MD. "The purpose of this study--and the NICHD network, in general--is to provide the rigorous evaluation that patients and their physicians need to make informed decisions."

Endometrial biopsy--removing a small tissue sample from the lining of the uterus--is often conducted as a part of infertility testing, explained Donna Vogel, M.D., Ph.D., of NICHD's Reproductive Sciences Branch. However, little scientific information exists as to whether the practice actually leads to a better choice of treatment. Both fertile and infertile women may be eligible for the study if they are between 25 and 39 years old and have regular menstrual cycles of between 24 and 34 days.

NICHD's National Cooperative Reproductive Medicine Network

is designed to carry out large, multicenter clinical trials in the areas of male and female infertility and reproductive diseases and disorders, Dr. Vogel added.

"By studying large numbers of patients enrolled in common protocols, answers will be provided more rapidly than by individual centers acting alone," she said.

The first study conducted by the NICHD network found that, for certain kinds of infertility, the combination of hormonally inducing ovulation, followed by inseminating with the partner's sperm directly into the uterus, resulted in more pregnancies than did several other techniques. The study appeared in the January 21 issue of the "New England Journal of Medicine". A news release describing the study is available on the NICHD website at http://www.nih.gov/nichd/, "NICHD Network Identifies Most Effective of a Series of Infertility Treatments."

Those wishing to volunteer for the endometrial biopsy study may contact the following centers:

University of Pennsylvania
Philadelphia, Pennsylvania
Peg Crowner, RN
215-662-2935

The University of Rochester
Rochester, New York
Germaine Santoriello, RN
716-273-2088
716-273-2090

Baylor College of Medicine
Houston, Texas
Adele Dana, RN
Beverly Feldman, RN
713-798-7549

Brigham and Women's Hospital
Boston Massaachusetts
Kathleen Walsh, RN
Heather Nicholls, RN
617-732-4258

University of Alabama
Birmingham, Alabama
Velria Willis, RN
205-801-8217

University of Louisville
Louisville, Kentucky
Pat Swanson, RN
502-629-3830 x1404

Magee-Women's Hospital
Pittsburgh, Pennsylvania
Maureen Lockard, RN
412-641-4736

The NICHD is one of the Institutes comprising the National Institutes of Health, the Federal government's premier biomedical research agency. NICHD supports and conducts research on the reproductive, neurobiological, developmental, and behavioral processes that determine and maintain the health of children, adults, families, and populations. The NICHD website, www.nichd.nih.gov, contains additional information about the Institute and its mission.