

LEGAL ISSUES PERTAINING TO CLONING

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I wish to thank the Embassy for inviting me to participate in this Biomedical Day and to share the program with so many distinguished representatives of the scientific, business, academic, and political communities.

The legal issues respecting cloning are many – I could probably take up all of the allotted time merely listing them.

Our time is better spent, however, looking at the most pressing legal issue, and that is legislating the issue. There is a lot of legislation being proposed. I will concentrate on the administration's bill in response to the National Bioethics Advisory Committee's Report ("NBAC Report"). Recurring themes in my analysis are simply that our leaders need more education on this subject. This subject does not merit a rush to judgment or hysterical overreaction. In other words, "just because science can, does not mean it should."

Jeff Goldblum, the hero scientist in *Jurassic Park*, makes this statement playing today's stereotypical hero, espousing an us-versus-them mentality – that is, government and citizens versus the evil scientist. This seems to be the mentality that has developed respecting cloning in the wake of Dr. Wilmut's announcement that he had successfully cloned a sheep, named Dolly.

I believe that the seeming emergency activity in the wake of Dolly is a result of this us-versus-them attitude. That attitude is a result of a lack of education and knowledge on the part of many decision makers.

One reason I say this is the fact that it seems to be mutually agreed upon (even among scientists) that there is no place for human cloning in our society at this time. It is doubtful that any scientists

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are likely to attempt human cloning for a long time. Why then is there this great urgency to pass a ban on human cloning before the matter has been analyzed from a legal prospective?

I

There are several bills, including an administration bill, which have been winding their way through Congress, in response to the NBAC Report. In addition, a number of foreign countries have taken action to prohibit cloning. The European Union and several other countries, including Germany, Denmark, Australia, Spain, and the U.K. already have laws or are preparing laws to forbid human cloning.

In addition, France, Argentina, China, and Japan have indicated an intention to deter efforts to clone humans, as have the forty Council of Europe countries and the World Health Organization.

In June the G7 (i.e., U.S., Japan, Germany, England, France, Italy, and Canada) collectively endorsed a worldwide legislative ban on human cloning. The Biotechnology Industry Organization (BIO), an organization of 700 companies, has stated its agreement with those comments presented to the NBAC that:

- (1) cloning animals (let alone humans) is very difficult and at best is only capable of being performed by a very small number of scientists in the world;
- (2) the scientists who have the capability for this research are a small community well known to each other; and,
- (3) according to these scientists' own testimonies presented to the NBAC none are likely to attempt human cloning in the foreseeable future.

In light of this information, what is the urgency in passing a ban at this time? Is not a ban unwarranted?

The threat of cloning is not so great that it is worth the risk that vital research will be undermined. BIO has stated publicly that it does oppose potential use of somatic cell nuclear transfer technology to create a human child. It also has stated that it does not believe that somatic cell nuclear transfer can or should be applied to human beings.

Furthermore, BIO recommended that the NBAC endorse a continuation of the current voluntary moratorium of the cloning of human beings in lieu of any federal or state law or regulation regarding the use of somatic cell nuclear transfer technology.

Drafting a statute that does not unintentionally prohibit vital biomedical research is very difficult. Even though the NBAC suggests a

sunset provision, that is not adequate protection against the immediate damage which will result from a poorly drafted statute.

In addition, policing a prohibition is not something that can be done easily. The technology can be practiced anywhere, and policing operations will be difficult if not impossible. A ban in the U.S. is likely to lead to offshore cloning as well as underground or "back alley" cloning research. Yet if the U.S. continues the moratorium, the U.S. might become the offshore site for those scientists of other countries with stricter regulation of cloning research.

I should point out that a moratorium did not work in the past for *in vitro* fertilization. When *in vitro* fertilization was first made possible, it was controversial; there was not then nor is there now federal funding for it. Yet, despite the controversy, the practice of *in vitro* fertilization has grown without particular regulation or oversight.

On the other hand, germ-line gene therapy has been the subject of an effective moratorium. The performance of such genetic treatment has been possible, but no one has conducted those experiments because there is a lack of consensus for them today. There is no legislation – only a scientific debate and a decision. All involved recognize the enormous potential for the ability to manipulate genes. The ethical boundaries that were established by self-regulation other than by law for the use of germ-line therapy have been useful and effective.

II

The executive and legislative response, to date, regarding the cloning issue demonstrates that we need, as a society, to have a better public and political understanding of the significance of scientific discoveries.

President Clinton asked the NBAC, when the cloning development was reported, to advise him within 90 days as to whether or not the new technology should be even more tightly controlled than with a moratorium, prohibiting the allocation of federal funds for cloning of human beings. In June the Commission issued its report. It recommended that the cloning of a human being, whether financed publicly or privately, should be made a criminal offense. The White House then quickly proposed legislation in response to the NBAC recommendations.

Before analyzing that legislation, I should summarize the NBAC principal recommendations.

The National Bioethics Advisory Commission made the following recommendations for immediate action:

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

The NBAC further recommended that the legislation prohibit anyone from attempting, whether in a research or clinical setting, to create a child through somatic cell nuclear transfer cloning – and it emphasized the necessity of a sunset clause to allow for review within three to five years.

The NBAC also emphasized the importance of appropriate oversight bodies to continually evaluate and reevaluate somatic cell nuclear transfer technology and the ethical and social issues, and to report on its potential use to create human beings sometime prior to the expiration of a sunset period. Finally, the Commission recommended that any legislation be carefully written so as not to interfere with important areas of scientific research.

III

Against those recommendations, the administration proposed its Bill.¹

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 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.”

The bill provides a sunset provision, but this is not an adequate protection against the danger today, which will result from a poorly drafted statute. If there was an imminent probability that unethical and unsafe experimentation would begin on human beings, then there

¹ The excerpts presented by Mr. Fersko are from the Clinton administration proposed bill to be enacted as the “Cloning Prohibition Act of 1997.”

would be a need for swift action by our government. But the experimentation is not imminent and the ethical questions raised are more a result of the possible enactment of the bill, which could inhibit vital medical research, than by any actual ongoing activity.

I turn now to the bill itself. The problems begin with the title, "Cloning Prohibition Act." Yet, the bill does not prohibit all cloning.

SECTION 2. FINDINGS.

(B) (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.

In the findings section it is stated that cloning of human DNA sequences and cells, which raise neither the scientific nor the ethical issues that can arise from possible creation of children through somatic cell nuclear transfer techniques, should not be interfered with.

SECTION 2. FINDINGS.

(B) (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.

The findings section also states that cloning animals by somatic nuclear transfer does not raise the same issues implicated in attempting to create a child. Therefore, on the basis of these two statements alone the bill should not be titled the "Cloning Prohibition Act." Obviously, cloning other than to produce a child through somatic nuclear transfer is not prohibited.

A further incongruity arises out of the bill's definition of "cloning."

SECTION 4. DEFINITIONS.

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

Cloning is defined to mean "the production of a precise genetic copy of a molecule (including DNA), cell, tissue, plant animal or human." This definition is inclusive of more than somatic cell nuclear transfer. Given this broad definition of cloning and the title of the proposed law, the statute may be subject to interpretation in incongruous ways when compared with statements contained in the bill itself and could result in the prohibition of other important areas of research. It would be preferable to have a title that reflects the substance of the bill.

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.

Another subtle but significant problem in the purpose section (section 3), is a reference to a prohibition against "somatic cell nuclear transfer cloning." This use of the word "cloning" is misleading, because the bill prohibits a type of somatic cell nuclear "transfer" only and not cloning in general.

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.

In the prohibition section (section 5) it is stated that it is unlawful to use somatic cell nuclear transfer with the "intent" of "introducing" the product of that transfer into a woman's womb or in any way "creating" a human being. Are there two violations here? It seems that one violation might be "introducing," and the other might be "creating;" or, another interpretation may be that "introducing" and "creating" a human being are equivalent.

The bill may be read to the effect that "introducing" the product of somatic cell nuclear transfer into a woman's womb is one way of "creating" a human being. If this is a fair interpretation, this might be the first federal statute stating or implying that a fertilized embryo in a woman's womb is already a human being.

Another interpretation is that there are other ways of creating a human being besides "introducing" an egg into a woman's womb.

Does this mean that a human being has already been created when an egg is fertilized outside of the womb – as with *in vitro* fertilization?

The use of the word “intent” in this prohibition section is also troubling. The law focuses on somatic cell nuclear transfer “with the intent of introducing the product of that transfer into a woman’s womb . . .” Instead, the statute should focus on the final act of creating a human being. If it is agreed that a violation only occurs with the act of using somatic cell nuclear transfer technology to create a human being, then “intent” should not be relevant. Without an act there should be no violation – regardless of “intent.” This is the only way that absurd results can be avoided. In this regard, I should point out that the recent protocol to the European Bioethics Convention on this subject simply prohibits creation of a human being genetically identical to another human being, whether living or dead.

Under the current language of the bill a person can be found liable because he intended to create a human being but, in fact does not, while a person who did not intend to create a human being, but who later introduces the cell into a woman’s womb will not be liable. There could also be circumstances where a person will not be liable if that person had no intent to introduce the product of the somatic cell transfer into a woman’s womb but a third party does. Finally, there is the situation that could be created that simply because a person announces an intent to use this technology she can be liable even though she made no attempts and discovers that it would be impossible for her to do so.

What evidentiary standard would be necessary to prove requisite intent of an individual? Would it be sufficient to demonstrate that an introduction or creation took place? And how does one prove “intent” when the alleged perpetrator is not a person but a “legal entity” (e.g., universities or nonprofit foundations)? What evidence will be necessary to prove the “intent” of an “entity”?

SECTION 3. PURPOSES.

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Perhaps the drafters of the bill mean to prohibit “attempts” to create a child which happen to be unsuccessful. The word “attempt” is used in the purposes section. While “attempt” does involve a specific act

rather than a mental state, and thereby does facilitate a correct determination of the existence of a violation, this language may still prohibit research. Every act of research may be characterized as an "attempt." The only way to avoid this effect is to focus on the final act of creating a child not the mere use of somatic cell nuclear transfer.

SECTION 4. DEFINITIONS.

- (b) "Somatic cell" means any cell of the body other than germ cells (eggs or sperm).
- (c) "Somatic cell nuclear transfer" means that transfer of a cell nucleus from a somatic cell into an egg from which the nucleus has been removed.

It is critical that the definitions in this bill be correct and precise. Unfortunately, the definition of somatic cell nuclear transfer is not precise. The bill makes it unlawful to "perform or use somatic cell nuclear transfer" for certain purposes. The definition, however, of a somatic cell excludes cells which are "germ cells (eggs or sperm)." Then the bill defines "somatic cell nuclear transfer" to mean the transfer of a cell nucleus from a somatic cell to an egg from which the nucleus has been removed. The term "egg" is not defined in the draft. Did the drafters mean to use the word "egg" or should they have used another term?

Defects in these definitions not only cause confusion, but limit the effectiveness of section 6 (the savings clause to protect research) which makes reference to these definitions.

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 6 is the critical and very necessary savings clause attempting to protect other areas of biomedical research. However, it is strange that this protection of vital research is not mentioned in the purposes section (section 3). This inclusion would reduce the chance that the statute would be enforced in ways which would inhibit the use of cloning techniques for beneficial purposes.

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 7 should scare all of us. Section 7 provides penalties.

Subsection (a) provides, “any person who intentionally violates section 5 (see Figure 6) shall be fined the greater of \$250,000 or two times the gross gain or loss from the offense.” Subsection (c) provides, “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”

These Draconian penalties combined with the vagueness of the description of the prohibition in Section 5 (see Figure 6) are very likely to chill and discourage valuable research – and how will confiscation be handled? If the violation occurs at a company, would the statute allow confiscation of the entire company, even if only one researcher was involved? No funding agency would dare fund a project that seems to be even vaguely connected to this risk.

I submit that the existence of even a narrowly crafted statute will have a chilling effect far beyond its specific terms. The penalty section mentions a possible payment of “two times the gross gain or loss from the offense.” The concept of imposing a fine based on “gross gain” and “gross loss” presumably refers to gross revenues and gross expenses respectively. A precedent for imposing a fine this way is unheard of.

How would the case of a researcher acting without authorization be handled? Would the firm or university where the researcher is employed be penalized?

One recommendation which may give some certainty is the establishment of a mechanism that would enable scientists to secure opinions regarding the scope, interpretation, and possibly enforcement of the law with respect to specific research projects. These opinions could be published (with appropriate safeguards not to compromise

confidentiality) and would be similar to No-Action Letters of the SEC.

The administration's bill does not include a preemption clause. It would be a good idea, considering the possibilities for differential interpretation and enforcement of state laws and the chilling effect this could have on research. Furthermore, there could be forum shopping. In effect, scientists might move from state to state in search of a location with the least restrictive statute.

SECTION 8. EFFECTIVE DATE.

This act shall apply to somatic cell nuclear transfers performed within five years after the date of its enactment.

Finally, the effective date of the bill in section 8 seems to include both an effective date and a sunset provision by stating that "this Act shall apply to somatic cell nuclear transfers performed within five years after the date of its enactment." It would be clearer if the effective date and the sunset provisions were stated separately to avoid confusion.

IV

The NBAC Report recommended education, but the bill does not mention education. Education is most crucial if there are to be rational judgments made with respect to these cloning issues.

A final issue that I would raise with respect to the administration's bill is that it seems to be lacking in the whole area of scientific freedom. The United States Constitution, Article 1, Section 8, Clause 8, mandates "promoting the progress of science and useful arts." This congressional ban on cloning is a threat to all scientific freedom. Except for outlawing biological weapons, the federal government has never before moved to declare a whole area of scientific inquiry out of bounds. This sets a negative precedent whereby Congress could become a self-appointed police looking at all scientific endeavor.

V

Time does not permit an analysis of the other bills which have been introduced in Congress. I will simply mention the bills and a couple issues respecting them.

Senator Bond introduced S368 in the Senate on February 27, 1997. The strengths of that bill are that it limits prohibition to federally

funded research only, and it distinguishes between human cloning and human genetic engineering. However, it does not include a sunset provision, it does not contain a preemption clause, and it does not include a savings clause to protect other important research.

Congressman Ehlers introduced two other bills in March of 1997, and without going into all of the specific problems with the bills, including the amendment in the nature of a substitute which was offered in July of 1997 by Congressman Ehlers, it is interesting to note that in a recent amendment to HR922, the prohibition on the use of federal funds does not extend to the prohibition of human cloning research in the private sector and it does contain a section that requires the National Research Council to report back to Congress within five years on implementation of the act in terms of the effect it will have had on research.

BIO believes that the definition of the term "somatic cell" is a better definition in HR922, but of particular interest is the fact that the bill as amended focuses on a prohibition against cloning to produce an embryo as opposed to focusing directly on the cloning of a child. This is unlike many of the other bills. The issue of embryo research was studied extensively in 1994 and 1995 and the debates of that time led to the enactment of the last two labor HHS appropriations bills with a broad ban on the funding for embryo research. The fiscal 1998 NIH appropriations bill has a similar ban included in it.

The fear of the Biotechnology Industry Organization with respect to the Ehlers Bill is that it focuses on embryo and fetal tissue research and that it would have the effect of bringing up the whole controversy over the right to life or the right to choose and the definition of when life begins and other intractable debates. Thus, this bill seems to be a vehicle for relitigating in the congress and elsewhere the embryo research issue, rather than being a bill focused on human cloning.

An additional amendment to the Ehlers Bill was offered by Congressman Lynn Rivers on July 29, 1997, changing the nature of the prohibition and modifying the definitions so that they were technically accurate and focusing the issue on the cloning of human beings rather than on embryos. That amendment, however, was rejected, and on August 1 an amendment was accepted, saving essentially other areas of scientific research not specifically prohibited by the proposed act.

VI

Certain other legal issues surround these bills and the cloning issues.

The 13th Amendment to the United States Constitution prohibits slavery. If scientists had a patent to clone humans, the scientists

would essentially own the cloned individual. However, it could be argued that a patent holder could merely sell the patent rights to the invention without actually selling the cloned person, and in this way neither the personal autonomy nor the equal protection rights of the cloned person would be violated.

It is worth noting that genetically modified organisms are patentable (*Diamond v. Chakrabarty*, 447 U.S. 303 (1980)), but the patent claims that are protected are not to newly formed discovered natural phenomena, but rather to "non-naturally occurring manufacture or composition of matter – a product of human ingenuity having a distinctive name, character and use." Essentially, these are patentable because the micro-organisms are created as a result of human ingenuity and research and are not naturally occurring products of nature.

Cloning also implicates reproductive freedom and the question of just how far that freedom extends. It can be argued that this right extends beyond noncoital reproduction through cloning. Of course, if a right to procreate and the right to have children are analogous, does that mean that a right to avoid offspring through abortion or contraception and the right to destroy embryos through cloning research are also analogous? This opens up the debate on the question of when life begins and the significance of that answer.

We enjoy a system of ordered liberty. One person's liberty may be limited only when its exercise would limit the liberty of another. An individual's actions may be limited when the harm to another is not necessarily a currently living person. This alone may render creating a child through somatic cell nuclear transfer inappropriate. Thus, ultimately, it will have to be decided whether or not creating a child via somatic cell nuclear transfer cloning would be viewed as a fundamental liberty. Therefore, federal court decisions have included *in vitro* forms of fertilization and other forms of medically assisted reproduction within the right to make reproductive decisions. Some would argue that cloning is not reproductive but rather replication. On the other hand, others will argue that cloning is procreative, at least to the extent that it involves the choice to generate a child.

As you can see, shaping up at some point in time is a debate as to whether somatic cell nuclear transfer cloning is to be treated as a fundamental right.

In this regard, at least one court has held that the right to procreate is not as significant as the right not to procreate. In *Davis v. Davis*, 842 S.W.2d, 588 (Tenn. 1992) cert. Den. 507 U.S. 911 (1993), the court held for the divorced father of two frozen embryos, essentially saying that "the party wishing to avoid procreation should prevail." Particularly important in that case was the fact that the other party

had a reasonable possibility of achieving parenthood by means other than use of the frozen embryos in question. The court was concerned over the father remaining ignorant or unable to control his parental status.

Taking this one step further, one could argue that there is an analogous situation when someone does not know whether he has been or will be cloned and does not have control over it. So, perhaps the right to procreate will be found not as significant as another party's right to individuality. That is, the right not to be cloned could clearly outweigh the right to procreate.

This debate over the legal status of the embryo also resurfaces when the issue of "harvesting" is added to the abortion and cloning debate. If cloning is deemed acceptable, then embryos could be created this way. One of the many benefits that could result would be that blood stem cells could be harvested for leukemia patients. However, this also means that embryos could be cloned, solely to be disseminated, much like car parts. Some fear both liberal abortion laws and liberal cloning laws for fear of harvesting.

Of course, getting to the bioethical issues also raises issues respecting the separation of church and state. The NBAC, during its 90-day period of investigation prior to its report to the president, heard from religious leaders and academic theologians on how to make a determination on how to incorporate into the NBAC report religious-based objections to the cloning of human beings.

There are also fascinating new litigation possibilities that may appear if human beings are ever cloned. Can a person prevent a clone of himself from being created? What should the default rules be? Should we have "do not clone" orders fashioned, similar to "do not resuscitate orders"?

Perhaps there will be malpractice actions for negligent cloning, since there are so many things that could go wrong.

If a scientist clones a particular person too many times, perhaps it will result in a diminished worth of the clone as an individual. (There will be a lot of people with similar talents and qualities). This could result in giving a clone a cause of action because he is an unemployed lawyer and the market is flooded with others possessing his same talent and exact genetic make-up.

Legal systems uphold rights to personal freedom and liberty; thus often one may sue for an unauthorized picture of oneself in a television commercial or a newspaper advertisement. Would this mean that a person X can sue because a person Y was cloned from X's cells? This may be an extreme example of an unauthorized appropriation of face and voice.

CONCLUSION

All of these issues must be considered when considering the best course of action to take regarding cloning, and obviously those who are making the decisions need to have all the necessary information. I end where I began – so I repeat that if anything is an emergency since Dr. Wilmut's announcement that he cloned a sheep named Dolly, it is education regarding the subject, rather than legislation.