REPORT[1]

Introduction

The report,[2] in 1997, of the live birth of Dolly the sheep, which resulted from transfer of an embryo formed by the process of somatic cell nuclear transfer (SCNT), also known as cell nuclear replacement (CNR), stunned the world. For the first time, a mammalian embryo had been produced from adult somatic cells (in that case, mammary cells of a sheep), rather than by the union of gametes (i.e., sperm and egg), transferred to the uterus of an adult sheep, and gone on to live birth. Almost immediately, speculation arose as to when this technique would be utilized to clone a human being.[3]

SCNT is a process by which the full complement of nuclear DNA (i.e., containing diploid, or paired, chromosomes), is

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[1] In the drafting of the Recommendation, a deliberate attempt has been made to keep the language relatively general, so as to provide some general guidance and direction for courts, legislatures, and policy-makers, without committing the American Bar Association to an overly specific position or positions in the face of unique and unanticipated fact situations that are almost sure to arise in the future. Given the present state of the art in the technology of reproductive cloning from adult somatic cells, considerations of medical safety and propriety alone are sufficient to adopt a position against human reproductive cloning as defined in Part I of the Recommendation. The Recommendation is not intended to restrict the American Bar Association from reconsidering its position at some undetermined time in the future, should significant changes in technology and in moral and ethical precepts occur.

[2] Wilmut I, et al: Viable offspring derived from fetal and adult mammalian cells, NATURE 1997;385:810-813.

[3] The resulting embryo, in a sense, is not a "true" clone, in that mitochondrial, or cytoplasmic, DNA from the recipient egg remains as part of the embryo, and only the nuclear DNA from the somatic cell becomes only the nuclear DNA of the embryo.

removed from a somatic, differentiated cell of one organism, and injected into an ovum, or egg, from which the nuclear DNA (containing haploid, or unpaired, chromosomes) has been removed. The newly formed cell takes on the characteristics of an embryo and has the potential to develop into a live born organism, given the proper conditions of transfer into the body of a female, gestation, and live birth.

However, preceding the birth of Dolly, DNA had been transferred into 277 enucleated oocytes, which resulted in 29 embryos, which were implanted into 13 sheep, without success. More recently, there have been several reports that indicate that organisms born as a result of this technique may have significant genetic and other defects, the commonest abnormalities being fetal overgrowth, defective placentas, respiratory distress, and cardiac abnormalities.[4]

Reproductive or "baby" cloning

There is a recent report of the formation of human embryos using SCNT.[5] In addition, there are groups and individuals who have announced plans to clone human beings with the use of SCNT.[6]

A recent article in Science indicates that reproductive cloning in higher primates is impossible with current techniques.[7] Apparently, proteins critical to chromosome

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[4] Editorial, Biological uncertainties about reproductive cloning, LANCET 2001;358:519.

[5] Cibelli JB, et al, Somatic Cell Nuclear Transfer in Humans: Pronuclear and Early Embryonic Development. J REGENERATIVE MED 2001;2:25-31.

[6] Human Clone's Birth Predicted, WASHINGTON POST, May 16, 2002, p. A08. *See also* http://news.bbc.co.uk/1/hi/health/3406129.stm (last visited 1/18/04).

[7] Vogel, G, Misguided Chromosomes Foil Primate Cloning, SCIENCE 2003;300:225; Simerly, C, et al, Molecular Correlates of Primate Nuclear Transfer Failures, SCIENCE 2003;300:297.

distribution are removed with the egg nucleus, causing unequal chromosome segregations in the newly formed cells. Indeed, it may be that this same phenomenon, but less severe, in lower mammals, explains the problems that have occurred, even in the lower mammals that have been cloned. Nonetheless, given the present rate of scientific progress, it is still very likely that the technical problems will be overcome within a few years, and that efforts to clone adult human beings will in fact be successful at some point.

There is clearly a "market" for reproductive cloning. People who have lost a child, or other loved one, see cloning as a way to "bring back" that person. Others may see cloning themselves as a way to achieve immortality, or simply as a way to perpetuate their genomes, for reasons difficult for others of us to understand. Others may see reproductive cloning, or "baby cloning" as simply one of many new techniques of assisted reproduction, like *in vitro* fertilization, that will eventually become a standard form of treatment for infertility, and which will expand the scope of treatments that enable couples to have children who are biologically related to both of the couple. For instance, a same-sex female couple, where one partner is incapable of producing her own eggs, may wish to have a child by means of SCNT, using the enucleated cytoplasm of the egg of one, that has been injected with the nuclear DNA of a somatic cell of the partner who is unable to produce eggs. Or, in a male-female couple where the husband is incapable of producing sperm, nuclear DNA from the somatic cell of the husband could be injected into the egg of the wife. Simply put, men or women who cannot produce gametes, would be able to have genetic offspring.

While there has been considerable debate over the religious, moral, and ethical aspects of the use of SCNT, or similar techniques, as a means of reproduction, the overriding consideration for the present and for the near future, given the present-day state of the art, ought to be that this is a form of human experimentation that is fraught with significant risk of producing disease and suffering in its subjects, with relatively little or no potential benefit to society or humankind.

Parentage and other legal issues

While attempts at human reproductive cloning are today considered by virtually all responsible scientific and medical organizations as unsafe, if even possible at this stage, it is almost a certainty that someone, somewhere, will eventually produce live birth of a human clone by means of SCNT or some other technique that produces an embryo cell with the potential to develop into a human being, with a genome identical, or nearly identical to, and derived from, an existing human being. In that event, there will inevitably be novel issues regarding the legal status of the subject human being, including parentage.

The American Medical Association (AMA) has defined "human cloning" as "the application of somatic nuclear transfer technology to the creation of a human being that shares all of its nuclear genes with the person donating the implanted nucleus." The AMA further declares that physicians should not participate in human cloning at this time because of the risk of physical harms, as well as psychosocial harms. It also notes that more thought is required on a societal level regarding how to construct familial relations.[8] The AMA's view is consistent with the Recommendation, and indeed, seems to invite subparagraph 3) of the Recommendation (Lines 37 and 38). The American Society for Reproductive Medicine has opposed reproductive cloning from the beginning.[9] The Section of Family Law's Model Act (Model Assistive Reproductive Technologies Act) will address the determination of parentage in human clones.[10]

To illustrate how courts may be become befuddled in determining issues of parentage when novel biological techniques are used to produce children, one need look no

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[8] Council on Ethical and Judicial Affairs, Code of Medical Ethics: Current Opinions with Annotations, American Medical Association, 2002-2003 Edition, §2.147.

[9] Ethics Committee Report: Human somatic cell nuclear transfer (cloning), Fertil Steril 2000;74:873-876. See also http://www.asrm.org/Media/misc announcements/cloning/asrmpositioncloning.html (last visited 12/8/03).

[10] A draft and supporting monograph is available at http://www.abanet.org//family/home.html, under "Reports" (art_monograph.doc) last accessed 8/6/03).

further than a recent case[11] which involved a married couple who arranged for transfer of an embryo formed by egg and sperm from neither of them, into a gestational mother who was not genetically related to the embryo. During the pregnancy, the couple divorced, and the trial court ruled that neither was the parent of the child later born to the gestational mother and also ruled that the gestational mother was not the child's mother either. Eventually reason prevailed and both of the couple who arranged for the embryo transfer and contracted with the surrogate were held to be the child's legal parents. Parentage issues relating to human clones are likely to be even more difficult to decide, and guidance in the form of ABA policy would assist in helping courts reach sensible decisions in the first instance.

Consider the legal problems that may occur if a clone isn't quite what was expected. Perhaps the person or persons who arranged for the cloning to occur intended for the clone to be the same person as its progenitor (person from whom the nuclear genome was obtained). Or maybe the scientist who carried out the cloning process was simply interested in producing a human clone, without giving a thought to who the child's parents would be. Suppose the clone had serious genetic or developmental defects, and the persons who originally intended for the clone to be their child then decided that they did not want to have the clone as their child, and perhaps even tried to have it destroyed, claiming it was not really a human being.

The Uniform Parentage Act of 2002 provides for gestational agreements. Since, at least given the present state of the art, birth of a human clone would require a gestational mother, it would seem most appropriate to determine parentage of a human clone using this scheme. In the absence of a valid gestational agreement under the UPA, the child's mother would be the woman who gave birth to the child. If the woman were married, her spouse would be the other parent. This is also consistent with the provisions of the UPA.

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[11] Jaycee B. v. Superior Court, 42 Cal. App. 4th 718(1996), *rev.* 49 Cal. Rptr. 2d, 694, 22 FLR 1174 (Ct. App. 1996), and In re Marriage of Buzzanca, 72 Cal. Rptr. 2d 280 (1998), 24 FLR 2019 (3/17/98).

Although reproductive cloning is illegal in a number of jurisdictions, and almost certainly will be made so by any legislative body that speaks to the issue in the next few years, it will be attempted by someone, somewhere.[12] Nonetheless, there is some sentiment that any ban on reproductive cloning should be time-limited.[13] Attempts to ban reproductive cloning in the Unites States Congress and

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[12] For an update of state laws regulating cloning, see: http://www.kentlaw.edu/islt/StateCloningLegislation.pdf (last accessed 8/1/03). Another source of current prohibitions on reproductive cloning can be found at http://www.glphr.org/genetic/genetic.htm (last accessed 4/8/04). New legislation in Canada, which became law on 3/29/04 (http://www.parl.gc.ca/PDF/37/3/parlbus/chambus/house/bills/government/C-6_3.pdf, last accessed 4/9/04) prohibits human cloning and defines a human clone as

"an embryo that, as a result of the manipulation of human reproductive material or an in vitro embryo, contains a diploid set of chromosomes obtained from a single - living or deceased - human being, foetus or embryo."

In Congress (See ASRM News, Vol. 37, No. 2, Summer, 2003), H.R. 534 The Human Cloning Prohibition Act of 2003 (Weldon, R-FL) cleared Judiciary before a hearing. This bill would ban (criminalize) *all* cloning, including therapeutic cloning. S.B. 303 The Human Cloning Ban and Stem Cell Research Protection Act of 2003 (Hatch, Feinstein, Specter, Kennedy, and Harkin) outlaws SCNT for reproductive cloning, and provides criminal penalties. It protects therapeutic cloning with Federal oversight. S.B. 303, The Human Cloning Ban and Stem Cell Research Protection Act of 2003 (Hatch, Feinstein, Specter, Kennedy, and Harkin) outlaws SCNT for reproductive cloning, and provides criminal penalties. It protects therapeutic cloning with Federal oversight.

[13] Robertson JA, Human Cloning and the Challenge of Regulation. N ENGL J MED 1998;339:119-122. See also,[Knesset] Panel to reconsider ban on human cloning, HAARETZ, 1/13/04, http://www.haaretzdaily.com/hasen/spages/382293.html (last visited 1/19/04)

in the United Nations have been stalled by political issues relating to attempts by certain factions to include a ban on therapeutic cloning.[14] This phenomenon is unlikely to occur in the ABA, because the ABA has already approved a resolution that would permit therapeutic cloning.[15] The sponsors and supporters of the proposed resolution do not, in any way, intend it to affect the position taken on therapeutic cloning, and explicitly support in its entirety Resolution 117B, adopted on August 13, 2002. The primary purpose of this Recommendation is to assure that any living being that is born as a result of attempts to produce a human being by means of reproductive cloning is a separate and distinct person from its progenitor, and is guaranteed the full panoply of rights that accrues to any other person.

The 1992 Revision of the Model State Vital Statistics Act and Regulations recommends the following definition of **live birth**. This definition is based on the definition promulgated by the World Health Organization in 1950 and revised in 1988 by a working group formed by the American Academy of Pediatrics and the American College of Obstetricians and Gynecologists. The revision added clarifiers to help determine what should be considered a *live birth*:

> "Live Birth" means the complete expulsion or extraction from its mother of a product of human conception, irrespective of the duration of pregnancy, which, after such expulsion or extraction, breathes, or shows any other evidence of life such as beating of the heart, pulsation of

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[14] U.N. Puts Off Human-Clone Ban Amid Demands by U.S., Vatican, WALL STREET JOURNAL, Friday, November 7, 2003, p. A3.

[15] Resolution 117B, approved by the ABA House of Delgates, August 13, 2002 reads: "RESOLVED, that the American Bar Association opposes governmental actions that would a) prohibit scientific research conducted for therapeutic purposes, including research involving cell nuclear transfer that is not intended to replicate a human being, provided that such research is conducted in conformity with accepted research, ethical, and legal safeguards; or b) penalize individuals or research entities that participate in such research."

> the umbilical cord, or definite movement of voluntary muscles, whether or not the umbilical cord has been cut or the placenta is attached. Heartbeats are to be distinguished from transient cardiac contractions; respirations are to be distinguished from fleeting respiratory efforts or gasps.[16]

While some may contend that an "embryo" produced by SCNT is not "a product of human conception," one must keep in mind that the foregoing definition was not formulated with the idea of applying it to human reproductive cloning. Its use in the setting of human reproductive cloning is considered appropriate.

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[16] See http://www.cdc.gov/nchs/data/misc/itop97.pdf (last accessed 3/20/04).