CLONING HUMAN BEINGS

Cloning: An International Comparative Overview

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CONTENTS

INTRODUCTION

The cloning of the sheep called Dolly involved a different technique than that used in embryo twinning or splitting. In "Dolly," a quiescent *adult* mammary cell was placed in the *unfertilized* ovum of a sheep whose nucleus had been removed. This was followed by the transfer of the *subsequent embryo* into a surrogate mother sheep, its normal division as an embryo, and then by the birth of a sheep genetically identical to the donor (except for the mitochondrial DNA which came from the ovum donor). (*Nature*, 1997, vol. 385, February 27, 810-1)

Two months earlier (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 had 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).

The scope of this international, comparative study on "human" cloning covers the last decade (1986–96) of laws, bills, and official policy statements on the legal and ethical issues with regard to research in human genetics and new reproductive technologies. While it includes international,[1–5] regional (Europe),[6–12] and national coverage[13–37] of these issues, it excludes the United States and animal cloning and does not cover legislation on human tissues generally. International and regional positions will be treated in a first part (I) followed by the division of the different national positions covering 13 countries into five categories in the second part (II): (1) legal prohibitions on research on gametes and/or embryos; (2) legal prohibitions on embryo twinning; (3) legal prohibitions specific to the cloning technique used in the creation of "Dolly"; (4) recommendations on cloning as found in bills, policy statements, or ethical guidelines; and finally, (5) recent government actions in relation to "Dolly."

INTERNATIONAL POSITIONS

Recently, two international ethics committees, one governmental (UNESCO)[1] and the other nongovernmental (HUGO),[2] were deliberately created for the study of the ethical, legal, and social issues surrounding human genetics. Neither has an explicit statement on cloning. 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, as well as the prohibition of all forms of discrimination based on genetic characteristics." In particular, article 4 foresees the need for scientific research, but such research should have therapeutic aims. It provides that: "[r]esearch, which is necessary to the progress of knowledge, is part of the freedom of thought. Its applications, especially in biology and genetics, should relieve suffering and improve the health of individuals and the well being of humankind as a whole" and that "[b]enefits from advances in biology and genetics should be made available to all, with due regard to the dignity and rights of each individual." Moreover, article 5 maintains that: "[n]o research applications should be allowed to prevail over the respect for human dignity and human rights, in particular in the fields of biology and genetics." These provisions taken together would disallow any form of genetic research such as cloning when interpreted by a signatory country to run afoul of their purpose and scope.

A universal declaration, when adopted, is an international statement of principles that eventually may become part of customary law and so have force of law, but *ab initio* serves a hortatory function and is meant to guide nations in their domestic legislation. Absence of specific provisions on cloning, however, does not mean that the positions taken (which must by reason of their origin and vocation be general in nature) are without normative value and impact. They apply therefore to the legitimacy of cloning as a research endeavor.

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." The deliberate creation of a clone could well fall within the purview of concerns enumerated therein, including the possible "reduction of human beings to their DNA sequences and attribution of social and other human problems to genetic causes" referred to in its preamble.

While easily dismissed as too broad and vague, these international approaches which are necessarily the result of compromise may, as we shall see, prove to be more inclusive than the narrow, scientific definitions often found under national legislation.

Turning to the Council of Europe and then to the European Union, November 26, 1996 saw the adoption by the Council of Europe (40 countries) of the *Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine*.[6] Upon signature, this *Convention* is binding upon member states. Again, even though there is a chapter on the "Human genome" (Chapter 4), no mention is made of cloning. Article 2 of the *Convention*, however, states:

> "Parties to this Convention shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine." Moreover, like the proposed UNESCO *Declaration*, "[s]cientific research in the field of biology and medicine shall be carried out freely, subject to the provisions of this *Convention* and the other legal provisions ensuring the protection of the human being" (article 15).

It is also important to note that earlier recommendations of the Council of Europe either covered medical research and reproductive technologies in general or were "subject specific," that is, covered cloning. Beginning with the latter, that is medical research with human beings, in 1990, the Council stated in its preamble to *Medical Research on Human Beings*[8] that "medical research should never be carried out contrary to human dignity." It also maintained that such research "should take into account ethical principles" and that "[a]ny medical research which is unplanned, or contrary to any of the preceding principles, or in any other way contrary to the ethics or law, or not in accordance with scientific methods in its design and cannot answer the questions posed should be prohibited or, if it has already begun, stopped or revised, even if it poses no risk to the person(s) undergoing the research" (article 16).

Prior to the adoption of the 1996 Council of Europe *Convention*, a 1989 *Recommendation on the Use of Human Embryos and Fetuses in Scientific Research*[10] provided that "[t]he removal of *cells* (author's emphasis), tissues, or embryonic or fetal organs, or of the placenta or the membranes, if live, for investigations other than of a diagnostic character and for preventive or therapeutic purposes shall be prohibited" (Appendix D.9). The general tenor of this text, covering the fetus and the embryo however, would lead one to conclude that it was "embryonic cells" that were envisaged (see explanatory paragraphs 3 to 7). This may be because an earlier "cloning-specific" recommendation of 1986, *Use of Human Embryos and Fetuses for Diagnostic, Therapeutic, Scientific, Industrial and Commercial Purposes*,[12] which defined cloning as "the creation of identical human beings by cloning or any other method, whether for race selection purposes or not" (section 14(A)(iv)), without further explanation, had already recommended to governments of its member states that such a technique be forbidden.

Another "cloning-specific" recommendation by the Council of Europe can be found in an 1989 information document entitled *Principles in the Field of Human Artificial Procreation*.[11] This information document was originally to be a recommendation but was not adopted by the Council of Ministers, since two member states disapproved of assisted conception techniques. It would have prohibited "[t]he use of techniques of artificial procreation to create identical human beings by cloning or by any other method . . ." (principle 20). Then in 1994, the Parliamentary Assembly of the Council of Europe in its recommendation on the protection of patentability of material of human origin asked that "techniques for cloning" be prohibited (article 13iii(b)).[7]

Turning now to the resolutions of the European Parliament of the European Union, the first *Resolution on the Ethical and Legal Problems of Genetic Engineering*[9] was adopted in

1989. It maintained that "[t]he European Parliament as regards clones, considers that the only possible response to the possibility of producing human by cloning and to experiments with a view to the cloning of humans must be to make them a criminal offence" (article 41).

Finally, three statements of international non-governmental organizations bear mention here. The first is that of the International Law Association in its 1988 *Resolution on Reproductive Technologies and the Protection of the Human Person*.[5] The position of the association was that "[c]onsidering the dignity inherent in all human beings, . . . any research or manipulation of human genetic material shall be for *therapeutic* purposes and shall be subject to the approval and control of an ethics committee" (article 1) (author's emphasis). Penal sanctions were asked for. Similarly, the 93rd Inter-Parliamentary Conference of 1995, in its wish to promote "universal principles and rights," mentioned "the inviolability of the human body and the intangibility of the genetic heritage of the human species."[4] Finally, the 1996 *Charter on Sexual and Reproductive Rights* of the International Planned Parenthood Federation[3] also mentions the right to human dignity and access to "safe" and "acceptable" reproduction technologies (article 103) without further definition.

At the international level, then, there is no doubt that respect for human dignity and respect for the intangibility of the human body, its constituent parts, reproductive tissues, and even down to the cell(s) are irreparably linked. While the need for, and value of, research involving humans are reaffirmed, both the proposed UNESCO *Declaration* and the European *Convention* would limit such research in the "genetic arena" to *therapeutic* interventions. These two overarching instruments implicitly refute human cloning. This is underscored not only by the more specific prohibitions on cloning, as found in the recommendations and resolutions just examined, but by national positions.

NATIONAL POSITIONS

Before turning to the specific positions found in the thirteen countries under study, it is important to emphasize that like the international instruments just examined, the objectives of these national positions are largely similar. Indeed, the stated object of the majority is to protect the dignity of all persons in relation to uses of human genetic materials.[17,20,28,33,34,35] Cloning is seen as "diminish[ing] the value of human individuality"[18,34] and as "violat[ing] basic norms of respect for human life"[19] and the "integrity of the human species."[24]

(1) Research on Embryos

Some countries with legislation on new reproductive technologies restrict such techniques to the use of "viable cells" in order to achieve pregnancy" (Austria, France)[16,23] and "to avoid the transmission to a child of a particularly serious disease" (France, Spain).[23,31] Four countries prohibit experimentation with fertilized eggs (Norway)[28] or with human embryos (France),[23] or experiments which have as their purpose "developing methods for achieving potentially hereditary genetic effects" (Sweden),[32] that is, to "develop certain characteristics" (Switzerland).[33] It is interesting to note, however, that while research with fertilized ova and with embryos are

explicitly mentioned, no country has prohibited by specific mention in law research on unfertilized gametes, and so, at first glance, the "Dolly" technique might not be prohibited. Yet, as just mentioned, if research on fertilized ova or embryos generally, or the legitimate applications of the techniques of medically assisted procreation which involve the prior obtaining of ova and sperm are themselves severely constrained to the therapeutic purposes mentioned above, cloning could well be understood to be excluded from the ambit of licit practice.

(2) Embryo Twinning

Often countries with an explicit prohibition on human cloning cover embryo splitting or twinning, but not the "Dolly" technique. An example of this is the 1995 *Infertility Treatment Act* of the state of Victoria in Australia.[14] It bans cloning as well as the attempt to clone with penal sanctions, but defines cloning as "to form, outside the human body, a human embryo that is genetically identical to another embryo or person" (article 3). Similarly, the 1990 *German Embryo Protection Law*[25] also prohibits "artificially caus[ing] a human embryo to develop with the same genetic information as another embryo, fetus, living person or deceased person" (article 6(1) (again with penal sanctions). Depending on how the phrase "causes a human embryo to develop" is interpreted, this definition may or may not cover "Dolly." Paradoxically, the 1990 *Human Fertilization and Embryology Act*[37] of the United Kingdom, which proscribes "replacing a nucleus of a cell of an *embryo* with a nucleus taken from a cell of any embryo, person or subsequent development of an embryo" (article 3(3)(d)) (emphasis added) may also not be inclusive. The 1995 Code of Practice of the Human Fertilization and Embryo Authority repeats this definition in its list of activities that are prohibited by law. It adds that it "will not license research projects involving embryo splitting with the intention of increasing the number of embryos for transfer" (article 10.5).

Irrespective of whether such precise scientific definitions include the Dolly technique, it is clear that in these countries the intent was to prohibit human cloning. The potential limits of the precise legal provisions, however, point to the danger of using scientific definitions in a legislative text.

(3) "Dolly" Technique

Two countries have legislation that simply prohibits research on the creation or production of "genetically identical human beings" (Denmark, Spain)[21,22,30] without further definition. Such legislation is sufficiently broad to be inclusive of both embryo twinning and the "Dolly" technique by concentrating on "the result" rather than the technique itself.

(4) Bills, Policy Positions, and Ethical Guidelines

Of the thirteen countries under study, only Canada[17] and Switzerland[34] currently have bills on reproductive technologies. The Canadian bill would make it a criminal offense to "manipulate an ovum, zygote or embryo for the purpose of producing a zygote or embryo that contains the same genetic information as a living or deceased human being, or, zygote, embryo or fetus" (article

4(1)(a)). This bill, which would *inter alia* cover the "Dolly" technique, has passed first reading and is broader in its scope than the report of the Canadian Royal Commission on New Reproductive Technologies,[14] which had recommended "the prohibition of human zygote/embryo research related to cloning" (rec. #184). In Switzerland, the current federal bill on medically assisted procreation proposes criminal sanctions for "the artificial creation of genetically identical beings"[34] (article 2(n)) (author's translation) and again would be inclusive in scope.

Other countries have either study papers prohibiting the "production of genetically identical individuals,"[29] or describing the creation of genetically identical preembryos (twinning)[27,35] and recommending its prohibition,[36] or codes of ethics in the same vein. Examples of the latter are found in Australia, where the 1996 National Health and Medical Research Council ethical guidelines[13] considered as ethically unacceptable "experimentation with the intent to produce two or more genetically identical individuals" (guideline 11.3). These guidelines apply in the states where there is no relevant legislation (guideline 6.1). This recent statement follows a 1982 position[15] that also considered as ethically unacceptable "[c]loning experiments designed to produce from human tissues viable or potentially viable offspring that are multiple and genetically identical" (no 8). Another example is in Canada, where parallel to the bill before Parliament just described, three research councils are preparing a *Code of Conduct for Research Involving Humans*[20] that would simply state that "cloning of human beings [is] ethically unacceptable" (article 16.10). It is interesting to note that while a 1993 Norwegian report[29] recommended to Parliament the prohibition of the "production of genetically identical individuals" (p. 33), the 1994 Norwegian law on the medical use of biotechnology[28] simply prohibits "research on fertilized eggs" (article 3-1).

Government Actions

On March 4, 1997, the Italian Ministry of Health established a three-month moratorium on cloning research in humans and animals.[26] On June 26, 1996, the President and Chancellor of the Swiss Confederation, in a message[35] on both a new popular initiative on new reproductive technologies and the recently proposed federal bill,[34] reiterated his country's position against the "artificial creation of genetically identical beings."

CONCLUSIONS

Either indirectly or directly, all of the international and national sources have focused their attention on the issue of cloning. Some limited themselves to broader statements of the principles of human rights in the need to preserve human dignity and integrity; others circumscribed the goals, scope, and type of medical research involving human beings and the new reproductive technologies; while other more direct prohibitions on cloning either addressed embryo twinning techniques or simply mentioned the prohibition on the creation of identical human beings and thus, in the latter case directly covered the Dolly technique. The latter approach, which proscribes the goal rather than the technique, avoids the pitfalls and confusion of ambiguous or too precise legislation.

Irrespective of the route chosen, the gambit of approaches symbolizes the difficulties inherent in legislating with regard to scientific advances, especially in a prospective fashion. The criminal law is a vehicle that sanctions behaviors that are considered morally reprehensible in a given society. "Crimes," however, require definition for the sake of certainty, and so techniques that we can only "imagine" may in their very description escape sanction. Human rights legislation seeks to guarantee and promote the well-being of persons and humanity but its actualization in the scientific context is difficult. Ethical guidelines fulfill both a principled and self-regulatory function but are often without sanction. Depending on the technology under scrutiny and jurisdictional issues, different legal tools and approaches are available. The problem lies in our limited understanding of present and future scientific advances. "Dolly" is but another lesson in humility.

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