Annex B

In the process of researching embryo definition this paper was found. It is largely concerned with the accurate terminology surrounding naming of cloning techniques. This was included as background information for thinking about definitions and terminology.

Definition of an embryo: Terminology paper

This staff working paper was discussed at the Council's February 2002 meeting. It was prepared by staff solely to aid discussion, and does not represent the official views of the Council or of the United States Government.

Staff Working Paper on Terminology

Introduction: The Importance of Careful Use of Names
There is a great deal of confusion about the terms used in discussing human cloning. There is honest disagreement about what names should be used, and there are also attempts to select and use terms in order to gain advantage for a particular moral or policy position. It is terribly important to try to be accurate and fair in the matter of language. Choice of names can decisively affect the way questions are posed, and hence how answers are given. Efforts to win the moral argument by Orwellian use of speech must be resisted. The issue is not a matter of semantics; it is a matter of trying to call things by their right names, of trying to fit speech to fact as best one can. We should not only stipulate the meanings we intend by our use of terms; we should also choose terms that most accurately convey the descriptive reality of the matter at hand. If this is well done, the moral argument can then proceed on the merits, without distortion by linguistic sloppiness or chicanery.

Many of the terms that appear in the cloning debate are confusing or are used in a confused manner. There are difficulties concerning the terms that seek to name the *activity* or *activities* involved: cloning, asexual reproduction, reproductive cloning, research cloning, therapeutic cloning, somatic cell nuclear transfer (or nuclear transplantation), nuclear transfer for stem cell research, nuclear transfer for regenerative medicine. There are difficulties concerning the terms that seek to name the *"product"* or *"products"* of the activities: cell, activated cell, clump of cells, reconstituted (or reconstructed) egg, zygote, embryo, human embryo, blastocyst, potential human being, human being, clone, person. And there are difficulties concerning the terms that seek to describe the *relation* between the "product" and the person whose somatic cell nucleus was transferred to produce "it": genetic copy, replica, genetically virtually identical, non-contemporary twin, clone.

Let us try to sort out the terms by beginning with the nature of the *activity* or the *deed* done in the activity of cloning. As a prelude to doing so, some general observations will be helpful. Although all aspects of an activity or action are relevant to understanding its full human meaning, when describing a deed we do

well to distinguish WHAT it is from both HOW it is done and WHY it is done. The act itself (WHAT) may be accomplished by a variety of means or techniques (HOW), and it may be undertaken for a variety of motives or purposes (WHY). To be sure, there is disagreement about the degree to which the motives or purposes of the agent are to be reckoned in the description of the act itself. For example, do the different motives make an act of "mercy-killing" different AS AN ACT from murdering a person or killing a murderer or killing someone in self-defense? Or are they all equally acts of homicide (killing of a human being) whose MORAL meaning we can then proceed to debate, if we wish, by attending not only to the act itself but also to the agent's motive and purpose? (See Meilaender comment on "Distinguishing Motive and Intention.") Though we do not wish to beg this question, the very existence of this disagreement suggests that we do well not to ignore the naked act itself, since it may well have a meaning independent of what moved the agent.

To illustrate: in vitro fertilization (IVF: the extra-corporeal -- *in vitro* = in glass -- merging of egg and sperm, creating a zygote that is the beginning stage of a new living being) is the WHAT. It is an act of "fertilization," of making fertile, of making the egg cell ready and able to develop into the human organism. This fertilization may be accomplished in at least two ways (HOW): by merely mixing egg and sperm, allowing the sperm to find and penetrate the egg, or by the technique of injecting individual sperm directly into the egg (a technique known as ICSI, intracytoplasmic sperm injection). And it may be done for the (proximate) purpose (WHY) of initiating a pregnancy, in turn for the (ultimate) purpose of providing a child for an infertile couple; or it may be done for the (proximate) purpose of providing living human embryos for basic research on normal and abnormal embryological development, in turn for the (ultimate) purposes of understanding human development or of discovering cures for diseases and producing tissues for regenerative medicine. Though the technique used or the purposes served may differ, in the crucial respect the act remains the same and bears a common intrinsic meaning: a human zygote, the first stage of a new human being, is intentionally produced outside the body with technical assistance.

As it happens, this fact is more or less accurately reflected in the descriptive terminology used for IVF. Interestingly enough, unlike the situation with cloning, no one distinguishes between "reproductive IVF" and "therapeutic IVF" or "research IVF," naming the activity or deed after the motive or purpose of the agent. This may reflect the accidental fact that IVF was initiated solely (or mainly) by people who were interested in using it to produce live-born children for infertile couples; the research use of "spare" embryos created by IVF came only later. But it happens that this common name is also descriptively apt: the deed is fertilization of egg by sperm, creating a living human zygote, the first stage of the development of a new human being.

It should be noted that, although we began by trying to describe the deed rather

than the product of the deed, the two aspects merged necessarily. The meaning of the act of "fertilization" falls forward onto the nature of the "object" that fertilization creates: the fertilized egg or zygote or earliest embryo. (By contrast, there is nothing in the name of the technique, "intracytoplasmic sperm injection," that even hints at the immediate result or goal of the intended injection.) Similar attention to the nature of the product may turn out to be indispensable for a proper characterization of the activity of cloning.

Cloning: Toward an Appropriate Terminology
Though much of the terminological confusion and controversy concerns the way to describe the different kinds of cloning practices that are envisioned, the term "cloning" itself is not without its own ambiguities. A "clone" (noun, from the Greek klon, "twig") refers to a group of genetically identical molecules, cells, or organisms descended from a single common ancestor, as well as to any one of the one or more individual organisms that have descended asexually from a common ancestor. "To clone" (verb) is to duplicate or create a genetic duplicate(s) of a molecule, cell, or individual organism. The replication of DNA fragments in the laboratory is called "DNA cloning." The propagation of single-cell lines in tissue culture is sometimes referred to as "cell cloning." Asexual propagations of bacteria or of plants by means of cuttings are instances of organismal cloning. Cloning of higher organisms is more complex: all cloning of vertebrate organisms must begin at the embryonic stages. Contrary to what some people imagine, cloning of amphibians or mammals (including human beings) is not the "Xeroxing" of an adult organism.

In the sense relevant here, "cloning" is a mode of asexual reproduction (parthenogenesis is another), the creation of a new individual not by the chance union of egg and sperm (from female and male individuals, the parents), but the creation of a new individual by some form of replication of the genetic make-up of a single individual. (The essence of sexual reproduction is not bodily intercourse but the fusion of male and female germ cells; thus IVF, though it takes place outside the body, is-biologically speaking-a form of sexual reproduction.) The WHAT of cloning is the activity of producing a clone, an individual or group of individuals genetically the same as the precursor that is being "replicated."[2]

In much of the current public discussion, we encounter a distinction between "reproductive" cloning and "therapeutic" cloning. The distinction is based entirely on the differing goals (the WHY) of the cloners: in the first case, the goal is the production of a cloned baby, in the second case, the development of treatments for diseases (suffered not by the clone, but by others). Both these terms have been criticized by partisans of several sides of the debate, and for understandable reasons.

Some object to the term "reproductive" cloning used as a term of distinction, because they argue that ALL cloning is reproductive: all cloning intends and issues in the creation of a living human embryo, a creature that is a new human

being in the (its) earliest stage of development or "reproduction." (This is a descriptive, not a normative point; it does not necessarily imply that such a being is fully human or "one of us," hence deserving of the moral and social protection accorded "persons.") The fact that only some of these embryonic cloned humans are wanted for baby-making purposes does not, in the view of these critics, alter this fact about their being.

Others object to the term "therapeutic" cloning for related reasons. The act of cloning may be undertaken with healing motives. But it is not itself an act of healing, nor does it issue in or effect a treatment or a cure (compare, in this respect, what used to be called "therapeutic abortion," an abortion undertaken in cases in which pregnancy was life-threatening to the pregnant woman and where abortion was therefore intended to save the woman's life). The prospective beneficiaries of any acts of cloning are, at the moment, purely hypothetical. And if medical treatments do eventually result, the embryonic clone produced in the process will never be the beneficiary of any therapy. On the contrary, this sort of cloning actually sacrifices the being that results from the act of cloning.

To avoid the misleading implications of calling any cloning "therapeutic," we might prefer the term "research" cloning, again indicating the purpose of the activity. Yet others find fault with this replacement. Because it appears to be a deliberate substitution for "therapeutic" cloning, it seems to imply that the scientists have abandoned the pursuit of medical cure in favor of research (as an end in itself). Believing that creating embryos just for research would seem to be less justifiable than creating them with healing motives, these critics want to avoid the impression that scientists want to experiment on new life just to satisfy their curiosity. (The same argument applies with equal force against the term "experimental cloning.")

Some proponents of "therapeutic" cloning-the use of quotation marks are intended only to indicate that there is dispute over whether this term is apt-also now complain about the term, but not about the adjective. Though they originally coined and used the term, they now want to shed the term "cloning," fearing that the opprobrium of the latter will weigh against the activity itself. Cloning, they insist, should be reserved for the activity that creates live-born cloned babies; it should not apply to the initial act that starts the process, which they would rather call "somatic cell nuclear transfer" or "nuclear transplantation." While not inaccurate, such a substitution is, as the sequel suggests, also problematic.

To escape from the bad connotations of "cloning," and to stay closer to scientific terminology, scientists now seem to prefer the term human "somatic cell nuclear transfer" (SCNT) as the name for the activity they support. But accurate though it may be as a description of the technique that is used to produce the embryonic clone (HOW), it does not touch the nature of the deed itself (WHAT). The WHAT is "the creation of a living-human-zygote (or embryo) that is genetically virtually identical to the donor organism," a fact or meaning not captured in the name for

the HOW, the transfer of a somatic cell nucleus (into an unfertilized egg whose own nucleus has been removed or inactivated). This reduction of act to its mechanism is roughly analogous to describing walking as "sequential alternate leg advancement" (SALA). In fact, it is not even as good as this, for, as a name, SCNT is not a fully accurate description even of the technique itself. Not only does it make no reference to the intended and direct result of the deed of nuclear transfer. It also omits mention of the fact that the recipient of the transferred nucleus is an EGG (rather than another kind of) cell, which then can be made to behave as if it were a zygote produced by fertilization. The further amendments, "somatic cell nuclear transfer for stem cell research" or "nuclear transplantation for regenerative medicine" only compound the difficulty, mixing in the purpose of the activity (WHY) with its technique (HOW), thus further obscuring the immediate meaning (the WHAT) of the act itself, the creation of a living human embryo of a certain type, i.e., cloned.

There is a further difficulty with these expressions. All these descriptions of the activities that the scientists wish to pursue omit all reference not only to cloning but also to embryos (and human embryos). Indeed, some are insisting that the immediate product of somatic cell nuclear transfer is not an "embryo" but rather "an activated cell," and that the subsequent stages of development should not be called embryos but "clumps of cells" or "activated cells."

Once again, we see how the meaning of the act, and hence its proper name and description, falls forward onto the nature of the product. We come then at the question of names from a consideration of the outcome.

The initial product of SCNT is, to be sure, a cell. But it is no ordinary cell. It is a cell that resembles and can be made to act like a fertilized egg, a cell that not only has the full complement of chromosomes but, unlike a somatic cell, is capable of developing into a new organism. In other words, it is a zygote or a zygote-like being. It is, to be sure, not just a cell but an active cell, or, at least, it can be activated, say by electric shocking. But to name it "activated cell" is much too vague to describe the activity of which it is capable. For once stimulated, the activity of this "cell" produced by SCNT is nothing other than human embryological development, initiated and directed by the cell itself. The processes of cellular growth, chromosomal replication, cell division, and (ultimately) differentiation into the tissues and organs of the organism are coordinated processes under the governance of the immanent plan for such development encoded in the cell's genetic material. In other words, the "cell" is an organism in its germinal stage, and its activities are those of an integrated and self-developing whole.

For the same reason, it is inaccurate to describe the next few stages of this developing being as "clumps of cells." Yes, there will be 2, then 4, then 8 cells "clumped" together, and the 100-200 cell spherical stage called the blastocyst may be externally described as a "ball of cells" or a "clump of cells." But this ball

or clump is not just a heap or an aggregate; it is a primordial and unfolding whole that functions as a whole and that is in the process of developing into a mature whole being, if nothing interferes (and if it is implanted). It is, in short, an embryo. That it can be interfered with to prevent it from reaching that maturity does not alter our assessment of what it is, here and now, any more than the eating of a sprouting acorn by a squirrel denies that the acorn is a nascent or embryonic oak tree.

The fact of the matter seems to be this: the product of somatic cell nuclear transfer is a living (one-celled) human embryo. The immediate intention of transferring the nucleus is precisely to produce just such a being: one that is alive (rather than non-living), one that is human (rather than non-human or animal), and one that is an embryo, a developing being capable of unfolding into an articulated organismic whole (rather than just a somatic cell capable only of replication into more of the same cell type). This is the intended product of SCNT, whether the motive or purpose is baby-making with the embryo or scientific research to be conducted on the embryo. Also, the blastocyst that develops from this one-celled embryo will be the same being, whether it is then transferred to a woman's uterus to begin a pregnancy or it is used as a source of stem cells for research and possible therapy for others.

The name "SCNT" also omits one further, crucial, and indeed essential aspect of this activity and this product. The human embryo thus produced will be a clone: a genetic copy (rather, a near copy) of the individual that was the source of the transferred nucleus, hence an embryonic clone of the donor. There is, to be sure, much discussion about how close the genetic relation is between donor and embryonic clone, and what that bodes for the phenotypic identity of the clone. The environment in which the donor came to be and lives surely differs from the one in which the cloned embryo may develop (if it does develop). There may be imprinting differences in gene expression early on that may affect the degree of genetic identity. There is also the matter of the mitochondrial genes, some 13 or so genes out of a total of some 30,000, which are inherited from the female source of the egg (the clone would be genetically identical only in those cases in which the same woman donated both egg and somatic cell nucleus, to produce an embryonic clone of herself). Yet the goal in this process is in fact an embryo or child that is genetically virtually identical to the donor; otherwise there would be no reason to create the embryo by SCNT rather than by ordinary IVF.

This analysis leads to the following conclusion regarding the terms most descriptive of the facts of the matter:

WHAT: The term "human cloning" means the asexual production of a new human organism-at whatever stage of development-that is genetically virtually identical to an already existing or previously existing human being.

HOW: It is currently accomplished by introducing the nuclear material of a human

somatic cell into an oocyte whose own nucleus has been removed or inactivated, to produce a living organism that has a human genetic constitution virtually identical to the donor of the somatic cell.

WHY: This same activity may be undertaken for purposes of baby-making or for purposes of scientific and medical investigation and use.

Human "reproductive" cloning and human "therapeutic"/"research" cloning should now be understood to mean the following:

1. "Reproductive" cloning: Creation of a living cloned human embryo, produced for the (proximate) purpose of initiating a pregnancy that will issue in a child who will be a genetic (near-)twin of a previously existing individual, with the ultimate goal of satisfying one or another parental desire to have such a child.

2. "Therapeutic"/"Research" cloning: Creation of a living cloned human embryo, produced for the (proximate) purpose of using it in research or for extracting its stem cells, with the ultimate goals of gaining scientific knowledge of normal and abnormal development and of developing cures for human diseases.

What Does This Mean for the Council's Work?
Where does this linguistic analysis leave us? One possibility is to adopt the dominant terminology ("reproductive" and "therapeutic" or "research"), given that we have little hope of changing the current usage. We could make perfectly clear what these terms mean in our hands, so that there will be no ambiguity. At the same time, our analysis might serve to chasten people regarding the power and pitfalls of the terminology, including the ones we are adopting. The analysis would also alert people to the danger of euphemism and misleading speech.

A second possibility is to attempt a better way of describing these matters, perhaps even coining some new terms. No one should underestimate the difficulty of the task, or exaggerate the chances that our terms, even if better, could gain currency. But the invitation is open to anyone who would like to make a proposal.

1. Though not needed for present purposes, a more careful analysis of the WHAT of this activity would distinguish between the activity itself and the product that results from it. Unlike non-productive activities, for example dancing ("How can we know the dancer from the dance?"), the work (activity) of making and producing issues in separable objects or works (products). Although shoemaking completes itself in the production of a shoe, the shoe as RESULT is distinct from the ACTIVITY of shoemaking. Similarly, though fertilization is an activity that is intelligible only as issuing in a fertilized egg, the now-fertile egg as RESULT or PRODUCT stands apart from the deed of IVF.

2. Although cloning, like fertilization, is responsible for bringing forth a new

organism, the activities are named in very different ways, yet in each case emphasizing the inner intention of the activity. "Fertilization" describes the activity in terms of the capacitation of the egg, as a result of which development begins. "Cloning" describes the activity in terms of the relation between the progenitor and the product. In cloning by somatic cell nuclear transfer, the egg, though it is activated as if it were fertilized, is not cloned; cloned rather is the donor from whom the nucleus was taken; and the resulting organism (at all stages of development) is a clone of the donor. The name of the activity, "cloning," even more than "in vitro fertilization," refers to the *product* of the activity, an identical (or near-identical) thing.