

GERMAN NATIONAL ETHICS COUNCIL

The Import of Human Embryonic Stem Cells

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Opinion

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1. Function of the National Ethics Council

The function of the National Ethics Council is to express views on the ethical issues that are presented by the development of the life sciences and need to be settled by public debate. In so doing, it must assess the possible consequences of scientific and technical innovations, evaluate them in accordance with universally evident criteria, and reflect on the significance of the changes induced by science and technology both for the living conditions of the individual and for society at large. For this purpose, it must bring together the standpoints of the natural and social sciences, the humanities, medicine, law, theology and philosophy. Finally, its deliberations must take account of the fact that many of the questions to be discussed can be treated only in the context of international commitments.

The Ethics Council is expected to deliver opinions as a basis for political and legislative action. In a democratic society, this process includes a public dialogue. Everyone must be able to form an impression of the prospects and risks of the new technologies, as a basis for arriving at his or her own judgement on the associated ethical issues. To this end, the Ethics Council will seek to facilitate understanding of the presuppositions and consequences of current problems.

For this reason, the National Ethics Council decided at its inaugural meeting that the first subject to which it would turn its attention would be the controversial issue of the import of human embryonic stem cells for research purposes. It had therefore requested the Deutsche Forschungsgemeinschaft, the central public funding organization for academic research in Germany, to postpone its decision on assisting a research project involving imported embryonic stem cells until the beginning of December 2001.

In view of the need for a quick decision, the Ethics Council

considered itself obliged to set aside its concerns about the very short time available for its deliberations and to draw up an Opinion by the end of November.

2. Subject of the opinion

It is the general view of scientists working in the field today that under suitable conditions virtually every type of human tissue can be developed from the human embryonic stem cells with whose import and use this Opinion is concerned, but that these cells do not possess the capacity to develop into a human being. This means that they are pluripotent, but not totipotent. This biological distinction is important because, if they were totipotent, embryonic stem cells would, according to the provisions of the Embryo Protection Law, themselves be deemed embryos and the same ethical problems would arise with regard to research on embryonic stem cells as in the case of research on embryos. An ethical problem would then be presented not only by the destruction of embryos that is associated with the derivation of embryonic stem cells – i.e., the provenance of these cells – but also by the research on these cells itself. However, ethical considerations preclude the possibility of direct verification of the non-totipotency of embryonic stem cells in man, so that recourse must be had to indirect determinations for this purpose. There are indications that, unlike the blastomeres of the embryo in its earliest stages of development, embryonic stem cells are no longer totipotent, but only pluripotent.

A number of research projects are directed towards obtaining a better understanding of the processes of differentiation involved in the development of cells and tissues from embryonic stem cells and how they may be influenced. Underlying these projects is the hope that it may one day be possible to make therapeutic use of this knowledge through the use of replacement tissue to eliminate tissue defects of many different kinds.

The Embryo Protection Law currently in force in Germany forbids the production of human embryonic stem cells. However, there are no legal provisions governing their import and

use. The decision on whether to impose a legal prohibition or a veto based on research-policy considerations, or expressly to allow imports, is primarily an ethical issue. The first relevant aspect is that of the permissibility, as a matter of principle, of using embryos for research projects in which these embryos are destroyed in the first few days of development. For this reason, the National Ethics Council includes these considerations of principle in its deliberations. In addition, the question of imports raises a number of further questions that must be considered in a comparative evaluation of research on imported embryonic stem cells and research on embryonic stem cells derived in the Federal Republic itself. A separate section is devoted to these points.

The present Opinion is thus primarily concerned with the question of the moral and political acceptability of the import of human embryonic stem cells for research purposes. With this in mind, the National Ethics Council has also considered whether research on embryonic stem cells should be permitted in principle, but has not reached a final judgement. That judgement will accrue from further deliberations that will lead to a separate, fuller Opinion to be presented at a later date.

3. The culture of mutual respect

The use of human embryos for research purposes is a matter of political and social controversy. Although our society takes the unanimous view that the protection of human life is a primordial moral and constitutional precept, there is disagreement on the extent of the protection to which human life is entitled during its early embryonic development.

This situation raises highly complex and, in some cases, novel questions. In the view of the National Ethics Council, the first and most important prerequisite for a political solution to the conflict is a culture of mutual respect, in the spirit of which due regard is paid to divergent opinions and all arguments are objectively examined. Each side must be given an opportunity of seriously defending its position. Another element of this respect is the avoidance, in the course of discussion, of language likely to hurt, demean or compromise the other.

4. The normative framework

The National Ethics Council unanimously holds that research on embryonic stem cells touches upon fundamental values of our society and poses questions as to the subject-matter and scope of elementary constitutional principles such as human dignity and the protection of life, as well as of scientific freedom.

The crucial parameters are the inviolability of human dignity and the fundamental significance of the protection of life. Even if views within the National Ethics Council – as also in society and the world of politics – diverge on whether an embryo in its earliest stages is a subject of human dignity and what consequences this may have for its claim to protection of life, all the Council's members agree that considerations of human dignity forbid the use of pre-nidation embryos for arbitrary purposes.

However, the National Ethics Council is also concerned to stress that the freedom of science and research is an object of legal protection to which great importance is attached in the Constitution of the Federal Republic of Germany. Our Constitution provides that the only limitations on the freedom of science and research are those inherent in basic rights. The National Ethics Council sets great store by the search for potential new therapies and improving the prospects of curing disease. The relevant research is directed towards the protection of life and health and may be deemed an ethical obligation. The controversy concerns the particular lines of research with human stem cells that are necessary and ethically acceptable in this search. But the Ethics Council unanimously warns against over-hasty expectations. It stresses the need categorically to pursue the less controversial research approaches that use non-embryonic stem cells.

A consensus also exists on the principle that economic considerations must be disregarded where there are ethical and constitutional objections to research using human embryos.

Finally, the National Ethics Council draws the attention of those in whom political responsibility is vested to the need for a uniform European regulatory framework. Such a framework will also be an important step towards global agreements.

5. Derivation of human embryonic stem cells: for and against

The members of the Council agree on the great and fundamental importance of the objects of legal protection and the ethical principles here at issue, but not on the consequences that ensue for research involving the consumption of early embryos. For the sake of transparency concerning the different positions and the arguments adduced to support them, the Ethics Council has decided to present the main positions adopted in the discussion separately. The two systematizing outlines that follow do not claim to take account of every single argument or to present a complete picture of all the positions for and against embryo research put forward in the debate.

5.1 Arguments in favour of the derivation of embryonic stem cells

Determination of the constitutional and moral status of human embryos is of fundamental importance to the permissibility of stem cell research. For our present purposes, however, the question can be limited to the status of very early embryonic phases of development. After all, stem cells are derived in the first few days after fusion of the ovum and spermatozoon – that is, before the time when, in the case of undisturbed natural development, implantation into the mucous membrane of the uterus (nidation) begins.

Neither a right to protection of dignity nor a right to “absolute” protection of life for this early embryonic life can be derived from Article 1(1) and the first sentence of Article 2(2) of the German Basic Law (Constitution). The contrary view not only mixes up the guarantee element of these two provisions, but also,

in particular, disregards the central question of the subject of the relevant rights – that is, the conditions that must be satisfied in order fully to enjoy the right to the protection of life or, as the case may be, of dignity. On closer examination, the postulate of an “absolute” protection of life for early embryos based on considerations of human dignity proves to be an impermissible circular argument that lacks any foundation in the Constitution: the desired result of unrestricted protection of life is achieved only by at the same time postulating unrestrictable protection of dignity for all embryonic life. However, an unequivocal conclusion follows neither from the deliberations of the German Parliamentary Council nor from the constitutional-law literature on the extent of the protection of dignity and of life at this early stage. Nor have any relevant decisions been handed down by the Federal Constitutional Court, as its judgements on the termination of pregnancy are limited to the period after nidation. Again, with regard to the basic right to life, account must be taken of the reservation set out in the third sentence of Article 2(2) of the Basic Law, according to which any restriction of this right must be sanctioned by a law, so that the notion of an “absolute” right to life does not correspond to the constitutional position.

Any attempt to interpret the “perpetuity guarantee” of Article 79(3) of the Basic Law as offering a basis for asserting a right to the protection of dignity and life in respect of early embryonic life is inconsistent with the wording of this provision and therefore irrelevant to the discussion. Apart from the fact that the perpetuity clause does not refer at all to the basic right to life, the fundamental defect of this argument is that Article 79(3) of the Basic Law provides only that the specified articles of the Basic Law cannot be amended, but does not determine their content. The appeal to a “conception of man”, which is vague and susceptible to the vagaries of ideology, also leads nowhere.

Overall, the Basic Law is found to rest on the concept of in-

dividual protection of basic rights, and the general legal order on the concept of a graduated protection of life before birth, consistent with justified ethical convictions and our moral intuitions (Section 5.1.1). This argument is supported by a comparison with the applicable provisions on the termination of pregnancy and how it is evaluated (Section 5.1.2). Other important ethical issues are the consequences of research in which embryos are consumed for humanity and for the moral foundations of society (Section 5.1.3). Finally, a separate consideration of the narrower issue of the derivation of stem cells exclusively from excess embryos is required (Section 5.1.4). Considerations on the state of research and the freedom of research conclude the arguments in favour of the derivation of embryonic stem cells (Section 5.1.5).

5.1.1 Ethico-legal considerations on the status of early embryonic phases of life

The question of whether phases of human development are worthy of protection cannot be answered in straightforward fashion on the basis of specific biological processes, but can ultimately be settled only by a normative value judgement, just as, for example, the transition from cardiac death to brain death was determined by the legislator to be the deciding criterion of the end of life, a view that was accepted by the Federal Constitutional Court. A constitutive element in a corresponding normative determination of the beginning of life would be the fact that both our fundamental ethical convictions and the relevant rules of law are based on gradations of moral valuation and legal protection that correspond to the phases of development of human life. In all advanced legal codes, the killing of a human being who has been born is subject to more severe penalties than that of an unborn child. A seven-month-old foetus benefits from stronger legal protection and greater moral respect than an embryo three

weeks after nidation. From birth on, moral respect becomes unconditional, and the right to life is no longer subject to any balancing of considerations or differentiation.

While the situation at the phase of development prior to the capacity for nidation, with which we are here concerned, is one of species-specific human life, it does not yet involve the individual and personal life of a human being. Any embryo defined in this way can potentially develop into multiple individuals until the formation of the “primitive streak” (12 to 14 days after fertilization). An individual human being – and only an individual human being can be the subject of basic rights – cannot be deemed to have developed at least until this stage.

This view cannot be convincingly countered by the “potentiality argument”, according to which the possibility of growing into a human being that is latent in the early embryonic form suffices for it to enjoy the full protection of the right to life. Although the potentiality argument may suffice to justify the attribution of a “special” status to the embryo, it cannot form the basis of a moral and legal status comparable with that of a foetus or a human being after birth. The ascription of the future legal status or valuation of a being to its preceding phases of development does not correspond to any notion acknowledged in other evaluative contexts or in the legal order.

Another unconvincing argument is that, with the fixing of the genetic program, this early form of embryonic life is already identical, in ethico-legal terms, to the born human being into which it might develop. This thesis ignores the fact that human beings are more than the sum of their genes and that there is more to their identity than the execution of their genetic program: for instance, although monozygotic twins are genetically identical, they do not possess the same personal identity.

It is also argued in the ethical debate that the early embryo, as a likeness of God, is just as worthy of protection as a born hu-

man being. However, this view is based on religious doctrines of Creation and the Will of the Creator which, while deserving of respect, cannot form the basis of a universally binding secular morality and of corresponding laws.

Finally, it is also not evident that the fusion of ovum and sperm constitutes the only non-arbitrary determining point in an otherwise continuous process of genesis of human life. A possible criterion of equal if not greater validity is nidation, as a result of which the embryo first becomes a “fruit of the body” and which is the indispensable prerequisite for its further development. If the caesura for the commencement of the protection of life enshrined in the first sentence of Article 2(2) of the Basic Law is placed here, it is being set most plausibly at the point where a biologically individualizable embryo has arisen out of species-specific human life. However, even if the protection of life pursuant to the Basic Law is deemed to begin at the time of fusion of ovum and sperm, this does not rule out the possibility that the legislator could provide for a graduated protection of life before birth based on the reservation set out in the third sentence of Article 2(2) of the Basic Law, to the effect that the relevant right may be restricted by a law. Both cases involve the making of one of the many gradations that accord with widely accepted moral feelings and ethical judgements and are taken for granted in all legal codes. Such gradations abound in the law of the Federal Republic of Germany, as elsewhere, and are expressed, for example, in the provisions governing the termination of pregnancy (in particular, the three-month period allowed for termination following counselling) and the permissibility of the use of “nidation inhibitors” (intrauterine devices).

5.1.2 Contradictions in legal and ethical value judgements

Conversely, if it is postulated that embryos *in vitro* have the same right to the protection of life and dignity as human beings after birth, far-reaching and unjustifiable contradictions in legal evaluation follow. Under the law currently in force, which is constitutionally not disputed, the use of means of inhibiting nidation, which prevent fertilized ova from being implanted and thus kill embryos, is permitted without restriction. This is the case although nidation inhibitors may perhaps often prevent fertilization from occurring in the first place. The legislator has always presumed that nidation is inhibited, and declared it permissible – as has the Federal Constitutional Court in its relevant decisions.

A termination – that is, the killing of an implanted embryo – is *de facto* permissible without restriction in the first three months of pregnancy; this situation is unaffected either by the requirement of counselling or by the distinction between the concepts of “contrary to law” and “not subject to penal sanctions”, as there are no appreciable legal consequences. In fact, the Federal Constitutional Court has explicitly declared that emergency assistance must not be rendered to the unborn life and that a woman who has a termination is entitled to continued payment of wages or salary and, where necessary, to social security benefit for the cost of the abortion. Furthermore, according to the jurisprudence of the Federal Constitutional Court, not only are contracts covering abortions legally valid, but the abortion activity of doctors falls within the protection of professional freedom as a basic right.

A ban on embryo research would thus mean that embryos *in vitro* would enjoy appreciably greater legal protection than embryos *in vivo*. This unequal treatment cannot be convincingly justified by a reference to the unique “special situation” of pregnant

women, their conflictual position and hence the non-comparability of the circumstances. Although the two situations differ in certain respects, the same constellation is present in regard to the decisive point, the existence of embryonic life, and for this reason comparison is both possible and necessary. Differences in both moral and legal assessment of the two cases are surely justified where abortion is medically indicated, because here the life of the pregnant woman must be weighed against that of the embryo or foetus. A conflict of comparable severity does not underlie other types of indication, let alone the time-limit-plus-compulsory-counselling system. Here the law in force *de facto* gives priority to the pregnant woman's right of self-determination, albeit subject to a time limit. After the twelfth week of pregnancy, a pregnant woman is required to carry her child to full term even against her will. This also invalidates the argument that the criminal law does not "reach" a pregnant woman owing to the symbiotic connection of the unborn life with her, and that it is therefore inapplicable. After all, if the law in force provides that criminal-law protection of the unborn life commences only after the third month, there would in principle be no obstacle to corresponding protection before the third month. The only decisive criterion for this normatively determined caesura can be that the right of the unborn child to life has meanwhile increased and therefore enjoys stronger legal protection. All these considerations show once again that our legal order itself is based on the concept of a graduated right to life before birth, which is so to speak enshrined in it.

The foregoing considerations on the consistency of valuation in law are applicable *mutatis mutandis* on the ethical level too. The moral acceptance of nidation inhibitors is inconsistent with the postulation of full protection of life for early embryonic phases of life. The same applies, to an even greater extent, to the moral toleration of the termination of pregnancy in situations where

the pregnant woman's life is not at risk. In contrast to the derivation of stem cells from early embryos *in vitro*, abortion in the first three months affects appreciably more developed organisms, in which organ formation has already progressed and rudimentary human form may be discerned. However, anyone who does not consider an implanted embryo, or indeed one that has developed further *in vivo*, to be absolutely worthy of protection manifestly does not have good reason to take a different view where *in vitro* embryos are concerned. Any difference in the normative treatment of the two cases would be intrinsically contradictory.

This argument does not insist, for example, on the normative force of the de facto situation; that is to say, it does not base the permissibility of embryo research on current abortion practice. Instead, it regards the widespread (not merely pragmatic) moral toleration of the use of the intrauterine device and, frequently also, of abortion in the first three months as constituting a further clear token of the ethical justification of a graduated prenatal protection of life.

Hence, if the differential practice in, and moral justification of, the termination of pregnancy can be explained consistently only if the principles of a graduated protection of life are accepted, then it must be possible, in the case of embryos *in vitro* just as in that of embryos *in vivo*, to balance both the moral and the legal precepts of the protection of life against competing obligations and objects of protection. The objects of legal protection that are to be adduced in relation to embryo research and must be balanced against the protection of life for embryos are by no means of lesser value than those that justify an abortion within a time limit and subject to the requirement of counselling or the use of nidation-inhibiting methods of contraception. Moreover, this is true not only because of the relevance in this connection of the freedom of research, which is granted without reservation by the

first sentence of Article 5(3) of the Basic Law and may only be restricted in favour of high-level objects of constitutional protection. Another important point is that embryo research has promising medical prospects. It is directed towards developing new options for the treatment of diseases, or making these options possible. There is surely no question in ethical terms that there is a moral obligation to relieve human suffering and to help sick people. A corresponding duty of protection on the part of the State follows, in constitutional law, from the basic right to life and health (as enshrined in the first sentence of Article 2(2) of the Basic Law). To satisfy this obligation, it may be justifiable – or indeed imperative – to reduce the right to the protection of life enjoyed by embryos a few days old *in vitro*.

Furthermore, it follows clearly from these considerations that the reservation applicable to the basic right to the protection of life (laid down in the third sentence of Article 2(2) of the Basic Law), whereby this right may be restricted by a law, is certainly not confined to cases such as those of self-defence, shooting to kill with the aim of saving life, or military action. The current law on abortion and contraception admits of other categories of restrictions, applicable specifically to prenatal life, where it is not a matter of one life against another or of defence against an unlawful attack.

5.1.3 Possible social consequences of research in which embryos are “consumed”

Some critics of research in which embryos are consumed predict that, were it to be allowed, serious consequential harm would be done to the public weal, communal ethics and the stability of fundamental ethical standards. It is often also argued that embryo research constitutes an abuse and is uncontrollable. Such predictions, like their invalidation, are of course quite speculative.

The general principle, however, must surely be that those who would prohibit high-level research directed towards curing serious diseases on the basis of negative predictions must justify their views with more than vague presumptions.

Experience so far suggests that the fears expressed are relatively implausible: the graduated conception of the protection of life for embryos, in the form that has not only shaped practical action and law in the Federal Republic in the last few decades but has also been widely accepted in many cultures since ancient times, has not had any manifestly adverse effect on the humanity of the societies concerned. In the Federal Republic, notwithstanding the liberalization introduced by Section 218 of the Penal Code and abortions numbering in excess of 100 000 per year, awareness of issues related to the protection of life has if anything increased, as the present biopolitical debate precisely shows.

Again, predictions of, for instance, an “increasing instrumentalization” of human life, an incipient “morality that allows people to be excluded from society” or the relativization of rights to dignity and protection on the basis of contingent properties, in fact beg the question by assuming in advance that the legal and moral status of an embryo is equivalent to the status of a human being after birth. Since this is not the case, “dam-bursting” predictions of this kind are implausible.

Finally, the fear of the abuse of research results can be appropriately met by a sensible system of legal and institutional safeguards along the same lines as the established and proven regulatory frameworks that govern other fields of research susceptible to abuse. Bans on research, however, cannot be justified.

5.1.4 Limitation of the derivation of stem cells to “excess” embryos

If, lastly, only the question of the permissibility of research on “excess” embryos is considered – this being the main field concerned in practice – other arguments may be adduced in favour of this research, even if the premises of the graduation of the protection of embryonic life outlined above are not shared. After all, these excess embryos, which, contrary to the original intention, cannot be used to satisfy the wish for a child, in effect constitute a special category: they already lack the external prerequisites ever to develop into a human being. Suggestions for pre-implantation adoption or even of a ban on *in vitro* fertilization do not constitute serious legal, ethical or practical alternatives. In view of the hopelessness of these embryos’ position, there is therefore no real possibility of protecting them, as the only alternative to research on excess embryos would be cryogenic storage in perpetuity. In these circumstances, at least the use of excess embryos for medical research seems ethically and constitutionally acceptable, if not positively mandatory. In the view of many, another important ethical consideration is that the production of human life specifically for research purposes is not a prerequisite for the use of these embryos.

This assessment cannot be refuted by the objection that the use of excess embryos would not be the end of the matter, but that demands would immediately be voiced for the deliberate production of embryos for research. For why should these further demands be acceded to? And if the use of excess embryos for medical research is deemed acceptable because they will never have any prospect of further development within a foreseeable time scale and the alternative is simply to let them die, then precisely this use should be allowed.

5.1.5 State of research and freedom of research

The current debate concerning research on (imported) stem cells is mainly characterized by differing positions on the protection of life, on early embryonic phases of development in general, and on excess embryos in particular. However, many critics base their rejection on two further arguments. First, doubts are occasionally expressed to the effect that embryonic stem cells might perhaps still be “totipotent” and hence by definition themselves still be embryos. Second, the need for research on human embryonic stem cells in addition to the admittedly very interesting and promising other types of stem cells (from the germ layers of aborted embryos, from newborn babies’ umbilical-cord blood and from adult tissue) at the present time is disputed. Both objections clearly contradict the predominant majority view prevailing in the international scientific community.

It is now generally accepted that the initial totipotency of the fertilized human ovum and its first daughter cells persists at most until the eight-cell stage and is thereafter lost. This finding accrued directly from extensive animal experiments, but cannot be confirmed in the case of human embryonic cells. After all, direct verificatory experiments would consist in the trial transfer of single human cells at various stages of development into a maternal uterus, and are of course both legally and ethically out of the question. Nevertheless, a large number of convincing experiments, based for example on the detection of “marker proteins” specific to particular stages of biological development, prove the limited potency of embryonic stem cells in man as well as in animals. According to the latest available information, stem cells, which originate from a specific compartment of the embryo, the inner cell mass, cannot develop into an embryo without a connection to another embryonic compartment, the “trophecto-derm”.

The “need” for the use of embryonic in addition to other stem cells at the present time is, for our purposes, a matter of scientific research strategy that can only be resolved by specialists. There is a wide measure of agreement among the international experts working in the field of stem cell research that comparative research on all types of stem cells is currently the fastest and best way of understanding the processes of cellular differentiation both as such and with a view to possible therapeutic applications. This is because embryonic stem cells have important characteristics that have not so far been found in other types of stem cells.

It is not the function of the Ethics Council – any more than it can be the function of ethics committees or the legislator – to cast doubt on this scientific consensus. It would be wrong to attempt an appreciation of such questions, concerning verification of the credibility of research strategy, from the outside; they are a matter for the scientific community’s own regulatory bodies.

This conclusion is based not only on the ethics of research but also on constitutional considerations. After all, in the debate on the permissibility of stem cell research, the legal and moral status of early embryonic life is not the only relevant consideration; limitation of the freedom of research guaranteed by Article 5(3) of the Basic Law, too, calls for justification derived from the Constitution itself. The prohibition of research on embryonic stem cells would constitute an interference with this basic right, which, according to the established judicial practice of the Federal Constitutional Court, performs a key function both in regard to the self-realization of the individual and for the development of society as a whole. The freedom of research forbids the National Ethics Council – as it would a parliamentary commission of inquiry or the legislator – to dictate to research workers the subject of their investigations; the fixing of a scale of priorities, on the basis of which scientists would have to start with adult

stem cells, would be inconsistent with Article 5(3) of the Basic Law. In addition, in cases of doubt, the general presumption of freedom inherent in the Basic Law and its basic rights argues in favour of research, for it is not the exercise of freedom as a basic right that must be demonstrated and justified, but its limitation by the State.

Since the freedom of research is not covered by the reservation allowing the right concerned to be restricted by a law, even limitations on research call for justification under the Constitution; explicit or implicit bans on research, such as those envisaged in the present case, call for a higher level of justification and must be confined to cases of manifest harm to supreme objects of constitutional protection. In this connection, it is impossible to justify the ban on research by a reference to alternative research possibilities because, as stated above, research on adult stem cells does not constitute an alternative of equal value to research on embryonic stem cells.

5.2 Arguments against the derivation of embryonic stem cells

5.2.1 Ethico-legal considerations on the status of the early embryo

A. Biological approach

Articles 1 and 2 of the Basic Law guarantee the dignity of man and the protection of human life. Individual human life begins with the fusion of an ovum with a spermatozoon. The newly conceived living organism commences its development on completion of fertilization. From this point on, all the essential prerequisites are in place for a human being to be born after im-

plantation in the uterus and when all other phases of development have been completed. Unlike the ovum or spermatozoon, which cannot develop into a new entity in isolation from each other, the zygote contains within itself the potential for its own active development.

The fact that the further development of human life is always dependent on the existence of favourable conditions for the surmounting of critical thresholds does not justify disregarding the qualitative leap that takes place at the beginning of this development with the coming into being of the new human life. Further development admittedly calls for stimuli from the maternal organism if the pre-existing potential for development is to be activated; it is also subject to alternating slow phases of growth and faster surges in development. However, these are neither true caesuras nor precisely definable developmental phases that must be completed. What is in fact involved is a continuous process in which the embryo deploys all the individual potential inherent in it.

The notion of the phases of human development thus overlooks the fact that the embryo, from fertilization on, constitutes individualized human life, which it has the potential to unfold. It does not develop gradually into a human being, but develops from the beginning as a human being, and, moreover, it does so not in a species-specific but in an individual way. The embryo thus exists not only as a human being in a general sense, but also as a particular human being in the phase of commencement of his or her concrete individual existence. During the course of his or her subsequent life history, he or she develops an unmistakable identity of his or her own through the interaction of genetic and biological inheritance and the sociocultural environment. This is rightly expressed in the telling phrase that man is more than the sum of his genes. This does not of course mean that the biological space within which the individual's personal identity

can unfold may be disregarded in determining the point when an individual human life begins.

Since the embryo constitutes a functional unit with effect from the constitution of its individual genome, the qualitative leap represented by the beginning must not be minimized or disregarded by the consideration of subsequent steps in development. The manner in which the embryo comes into existence (whether by natural or artificial fertilization) and its location (in the laboratory or the female body) are irrelevant to this essential appreciation. It is also irrelevant whether twins or a multiple birth might arise out of the embryo, because divisibility is perfectly reconcilable with its individuality at this early stage of development. The contrary view, according to which the embryo is denied the individuality necessary for the full status of a human being until the possibility of twins can be reliably ruled out, is based on an incorrect interpretation of the processes of differentiation possible up to and beyond nidation. These are not in fact destructive divisions in which an end is put to an individual living human organism, but maturational divisions of the same kind as those that can occur naturally, even if only seldom, at this early stage of development. A purely numerical conception of individuality that focuses, in accordance with the etymological derivation *in-divisum*, on the static attribute of mere non-divisibility therefore proves to be inappropriate when applied to the early embryonic phases. Another aspect that is here overlooked is that the genetic individuality of the human zygote is already fixed before the possibility of twins ceases to exist and that it also persists in the numerical sense in by far the majority of cases where a division into twins does not take place. Apart from the theoretical difficulties of interpretation of these processes of development, the fact that an embryo can in certain circumstances give rise to two individuals argues in practice more in favour of greater than of lesser protection for early embryonic stages.

However, nidation is often stated to be the step whereby the embryo becomes a “fruit of the body” and thus a living human organism worthy of protection. Yet nidation is not actually the point at which contact is made between the embryo and the female organism. In fact, present-day science has revealed the existence of an interaction of substances, mediated by hormones and signal factors, from the earliest stage of embryonic existence – that is, while the embryo is still passing through the Fallopian tube. In the context of this interaction, or “mother-embryo dialogue”, nidation must be seen as a part of the process whereby the connection between the mother and the embryo is continuously reinforced. Each of these phases is a prerequisite for the further development of the embryo. Hence the reinforcement of a material interaction between the embryo and the female body that exists from the beginning does not constitute a qualitative leap that could justify a normative caesura with such far-reaching implications as the distinction between life that is worthy of protection and life that is not.

b. Anthropological interpretation
in the light of normative principles

Human life is the fundamental object that is protected by our legal order. It is the prerequisite for the realization of all other objects to which a human being may aspire in accordance with his or her personal hierarchy of values. For this reason, effective protection of human life constitutes a primordial function of the authority of the State precisely in a democratic society in which a universally binding consensus on the priorities to be accorded to individual life-aims no longer exists. This protective mission is based directly on the supreme precept of respect enshrined in the legal order. The inviolability of human dignity affords not only an individual right of opposition to encroachments by the

State but also an objective foundation of values for the resolution of conflicts between social groups and between individual interests.

If the discoveries of present-day medical science in the field of human embryonic development are interpreted in the light of these fundamental values as laid down in our Constitution, it follows that human life benefits from the beginning from the protection accorded to human dignity. This requirement follows from respect for the existence of every human being for his or her own sake. Given the essential nature of the corporeality and temporality of human existence, the field of protection of human dignity also embraces every phase of physical development and covers the entire duration of human existence. For this reason, even in the early phases of human embryos, there must be no balancing of objects of protection against each other where criteria other than that of life itself are applied. Since, for an embryo, it is not a matter of a greater or lesser degree of acceptable restrictions, but of existence pure and simple, the conception of a graduated protection of life offers it no protection in cases of doubt. A graduated right to life that cannot be effectively exercised and enforced where life itself is at stake is self-invalidating.

A conception of a graduated right to life that lays down, in addition to life itself, other requirements for the enjoyment of complete protection, such as ego consciousness, reason, sensitivity, self-determination and communication, would, moreover, also have implications for human beings after birth. For if the individuals concerned do not possess these attributes owing to their physical or psychological condition, they might, under these circumstances, no longer be seen as human beings and therefore also no longer be included among those entitled to the protection of dignity and life. Any attempt to fix a time later than that of fertilization as the threshold for the attribution of human dignity would make it possible to define a human existence incon-

sistent with the criteria of human status accepted at any given time in such a way that it does not benefit from the protection accorded by the Basic Law.

On the basis of the Christian traditions, as well as those of the Enlightenment and of humanism, those who drafted the Basic Law, in laying down the protection of dignity and life as a norm, adopted a stable and unequivocal position, in which the concrete embodiment of its provisions was not left to social discourse as based on the trends prevailing at any given time. This view is also borne out by the fact that the inviolability of human dignity and the requirement that all State authority respect and protect it are declared immutable by Article 79(3) of the Basic Law. But the “perpetuity guarantee” laid down in Article 79 of the Basic Law would be eroded if the concepts of human dignity and human life, which, after all, constitute the inalienable foundation of our society, were to be made dependent on trends prevailing at any given point in time. In view of this protective principle, on which the Constitution lays stress, a strict rather than a loose interpretation of law is essential in cases of doubt. Furthermore, on the general level, a heavy onus of demonstration and justification must be imposed on those wishing to amend a legal provision arrived at on the basis of a broad consensus, such as that enshrined in Section 1 of the Embryo Protection Law.

Our Constitution assigns a high value to the autonomy of the individual. However, the boundaries of this autonomy are set at the point where the dignity and rights of others are affected. Our legal order attaches fundamental importance to the protection of every human being’s life that results from his or her inviolable dignity and rights, because the possibility for each autonomous individual to pursue his or her life-aims depends on it. As the basis of their individual autonomy, all human beings are entitled, from their origins on, to dignity and the right to life – not because these have been promised or granted to them, or have not yet

been withdrawn from them, by society, but because they possess them for their own sake.

This has two consequences. First, embryos both inside and outside the female body are entitled to both dignity and protection of life; and, second, the only protection that can exist is that provided for in the Basic Law, and not a protection that is merely graduated or a lesser degree of protection. The opposite view does not grant the embryo in its early stage any protection of dignity and life, but would accord it particular respect and a relatively undefined protection of a different kind. It does not clearly indicate what concrete actions would thereby be prohibited. Some of those who hold this view even consider the production of embryos for the sole purpose of consumption to be consistent with such protection and respect. The extent to which the commercialization of embryos and stem cells would be permissible also remains unclear. This further demonstrates that only the position adopted here leads to unequivocal results. Ending the existence of a living human organism at an early stage of development – for instance, in order to derive stem cells from it – would be tantamount to using it as a means to an end extraneous to itself. Such an instrumentalization would conflict with the Basic Law's provisions that protect dignity.

5.2.2 Limitation of the protection of life in life-threatening conflict situations

According to the third sentence of Article 2(2) of the Basic Law, it is possible on the basis of a law to derogate from the right to life and even, in certain circumstances, for a human being to be killed. This is not prevented by the inviolability of human dignity pursuant to Article 1(1) of the Basic Law. This is because human dignity, for its part, is not an independent basic right, but the primary basic value from which basic rights are derived and on the

basis of which the constitutional permissibility of encroachments on basic rights is assessed. From this point of view, according to the jurisprudence of the Federal Constitutional Court, the concept of human dignity indicates, as a general principle, the direction in which unconstitutional infringements of dignity may be found. The existence or otherwise of such an infringement must therefore be determined in each individual case.

A. Killing in self-defence, termination of pregnancy, and birth control

Our legal code permits the killing of human beings in such cases as self-defence, assistance in emergency and defensive war. Another relevant situation is “shooting to kill”, as defined in the police legislation, in order to ward off a danger to a third party’s life and limb that cannot be eliminated in any other way. Similarly, a person who kills someone else in an emergency affecting both because only one of the two can survive is deemed to have acted unlawfully but not culpably. In these cases a human life is extinguished in order to save another life that faces an acute threat or – in the case of self-defence, if the response is proportionate – to save another object worthy of protection from an attacker.

Human life is destroyed in the termination of pregnancy too. Under the law in force, a termination is either justified by specific medical indications or may be carried out after counselling without penal sanctions although unlawful. The Federal Constitutional Court has deemed the latter situation to be consistent with Articles 1 and 2 of the Basic Law on the grounds that a unique connection exists between the mother and the life growing in her and that the threat of penal sanctions proved ineffective in the past. However, an unconditional obligation to continue a pregnancy to full term is not reconcilable with women’s dignity.

In this way the current law takes account of the fact that a pregnancy affects a woman's physical and psychological integrity and her right to self-determination in a way not comparable with any other circumstance. Yet the possibility of ending this situation in certain circumstances without liability to punishment can, for reasons of principle, not be equated with the demand for the utilization of embryos by third parties. With regard to the distinction between citizens' rights of opposition based on the body, on the one hand, and demands for utilization, on the other, the toleration of the termination of pregnancy is not inconsistent with the unequivocal provision of the Embryo Protection Law that protects human embryos from the actions of third parties. These considerations imply that measures to prevent the nidation of embryos (for example by means of an intrauterine device), which, according to the second sentence of Section 218(1) of the Penal Code, are not subject to penal sanctions, are not comparable with the use of embryos for research. One consideration here is that intrauterine devices often destroy the sperm before fusion, so that for this reason fertilization does not occur in the first place. Again, these processes belong to the intimate sphere of sexuality and, unlike processes in a laboratory, are therefore as a rule not subject to external control.

b. Protection of life and freedom of research

To justify research in which embryos are consumed, the basic right to freedom of research enshrined in the first sentence of Article 5(3) of the Basic Law could be adduced. In practice it is argued that research in which embryos are consumed is permissible for high-level research objectives at least where "excess" embryos, or even embryos specifically produced for the purpose, are concerned. Since it might thereby be possible to find potential treatments for hitherto incurable diseases, the permissibility of

such actions could also be justified by the provision of the first sentence of Article 2(2) of the Basic Law, which stipulates that everyone has the right to life and to bodily integrity. However, the definition of “high-level research objectives” remains unclear, as well as the degree of concreteness research objectives must have attained in order to be qualify as such. Furthermore, a requirement that the State provide contextual conditions for the development of a given therapy cannot be derived from the right to bodily integrity. The duty of the State to provide public health services and the right to utilize potential prospects for the healing of disease cannot justify the invalidation of human embryos’ right to life. Neither these embryos’ suitability for use for research purposes, nor the hoped-for therapeutic benefits, bear a causal relationship to the danger to life presented to sick people by their illness. The correct formulation of the principle that our legal order does not provide for the unrestricted protection of life is instead as follows: the right of patients to preserve their own life by the testing of new therapeutic methods does not extend to the point that it includes the destruction of another life. Moreover, the withholding of a benefit is less serious than the infliction of harm. This is particularly so where the benefit on one side is potential and lies in the future, whereas the harm on the other is definite and immediate.

Under the Basic Law, freedom of research is a basic freedom which, while it cannot be restricted by the passing of a law, is in fact limited if it affects other constitutionally protected values and, in particular, basic rights. This is the case with research in which embryos are consumed because this research interferes with the basic right to life and thereby, as explained earlier, also touches on human dignity. Another relevant point is that limits to the freedom of research in the field of animal protection have also been derived by the Federal Constitutional Court from the conception of man underlying the Basic Law, according to which

one of the elements of an ethically based system of animal protection is man's partial responsibility for the living organisms entrusted to his care.

5.2.3 The problem of excess embryos and alternative research approaches

The first implication of the foregoing is that research in which embryos are consumed, where these embryos are specifically produced for this research, cannot be permissible. This would involve not only the use of living human organisms at an early stage of their development for extraneous purposes, but also their creation for the exclusive purpose of their instrumentalization. The reification of human life would thereby be particularly pronounced and for that reason alone would conflict glaringly with considerations of human dignity. This point calls for particular emphasis, because it is argued again and again in the current debate that, either now or at a later date, research involving the consumption of such embryos is scientifically indicated and ethically justified. Again, the *in vitro* production of human embryos for research purposes is explicitly prohibited by Article 18(2) of the European Convention on Human Rights and Biomedicine (to which the Federal Republic has not acceded for other reasons).

The question of the permissibility of research on "excess" embryos must not be decided solely on the basis of the pragmatic view that these embryos after all exist and that their death, in the prevailing circumstances, is inevitable. A justifying strategy of this kind, which gives priority to the interests of research where utilization is concerned, would also put the practice of artificial fertilization in a questionable moral position. In such a case, the coming into being of embryos that cannot be transferred to the uterus would, because it cannot be reliably prevented, be not only

accepted but also desired and approved of; it would at least no longer be possible to make a clear distinction between orphaned embryos proper and “excess” embryos desired for other purposes. To avoid such ambiguities and to comply with the intentions of the Embryo Protection Law, one requirement is to find better ways of avoiding the creation of excess embryos, for example by means of techniques for the cryoconservation of unfertilized oocytes. In addition, it is preferable to produce no more embryos than can be used directly for transfer to the uterus, so as to avoid the danger of excess production from the beginning. Another possibility worth considering is the “adoption” of orphaned embryos, to protect them from destruction and instrumentalization.

Fundamental scientific research has not yet unequivocally answered the question whether alternative research approaches present the same long-term prospects as the use of embryonic stem cell lines. From the point of view of the ethics of research, the reprogramming of adult stem cells should initially be thoroughly investigated in the animal kingdom. The experts disagree as to whether enough work has so far been done in this field and indeed whether this is necessary. An initial concrete recommendation is therefore the placing of more emphasis on promoting research on adult stem cells. Provided that there is a moral consensus that research on adult stem cells is permissible, priority must be accorded, in this field too, to the development of appropriate scientific approaches. As a matter of moral principle, ethically neutral lines of research should be preferred to ones that give rise to serious ethical misgivings. If disease-based models are the determining factor for stem cell research, alternatives that are less ethically questionable should be thoroughly investigated and assisted. The more ethically acceptable paradigms and research approaches are directed towards the same objectives, the better the prospects of achieving therapeutic goals.

5.2.4 The symbolic function of the protection of human embryos

Apart from the moral status attaching to embryos as such, their reliable protection has a symbolic function and significance in our culture. Preventing the instrumentalization of embryos for extraneous purposes is a token of the protection of all who are unable to protect themselves and to argue in favour of their own protection. The population's fears about research on embryos must be taken seriously. Furthermore, it is important to consider the consequences of embryo research and use for our conception of man, for the further development of reproductive medicine, for patients and, last but not least, for the people from whom the germ cells or embryos are obtained. It is a fundamental ethical principle that human individuals must not be sacrificed for the benefit of others. The fear that this principle might be departed from in individual cases would jeopardize trust in the legal order.

6. The import of human embryonic stem cells

Following the above considerations of principle for and against the derivation of human stem cells from early embryos, this section discusses whether cell cultures already developed from stem cells in other countries should be imported into Germany for research purposes. This is precisely the question at issue at present, and is therefore central to the present Opinion.

In the predominant view of the international scientific community, embryonic stem cells are pluripotent and not totipotent. This means that their import (and research on them) is not prohibited by the criminal-law provisions of the Embryo Protection Law but is lawful. The point is therefore whether their import is ethically permissible or impermissible, and what implications result for research policy and legislation.

The Ethics Council has decided to confine its Opinion to the import of stem cells produced from “excess” embryos – that is, from embryos that were created to satisfy the wish for a child but can no longer be used for this purpose.

If the derivation of human embryonic stem cells is rejected for the reasons set out in Section 5.2, it would initially seem appropriate also to reject their import and the use of imported cells for research. Conversely, it seems equally appropriate to favour importing stem cells if it is held, for the reasons presented in Section 5.1, that their derivation is acceptable or even imperative. With regard to the specific evaluation of the permissibility of importing these cells, however, further considerations having a different status in the argument are also relevant. These concern matters of general policy, research policy, legal policy, constitutional law and ethics, or relate to views on further developments in research on stem cells and the possible consequences of their import. The arguments that specifically concern imports will be enumerated below, initially without ranking them by value, and

as far as possible compared. This will allow the individual arguments to be considered in various combinations. Concrete conclusions will be drawn only in the next section (Section 7).

6.1 Specific arguments in favour of the import of human embryonic stem cells

1 In so far as they are pluripotent, human embryonic stem cells are not embryos and are therefore worthy of protection not for their own sake but on account of their provenance. A legal ban on the import and use of stem cells would constitute impermissible interference with the freedom of research guaranteed by the Basic Law. It might also be unenforceable under European law.

2 Provided that their import has no causal effect on the production of embryonic stem cells abroad, the use of embryos for the production of stem cell lines cannot be deemed to be the responsibility of the research workers or of the German State authority. The stem cells were produced abroad – that is to say, outside the geographical area of applicability of the Basic Law and the associated basic rights – and the “consumption” of the embryos is already finished and irreversible before they are imported.

3 Since it would no doubt be a long time before the basic permissibility of embryo research was again debated and decided upon by the legislator, a ban on the import of embryonic stem cells would mean that research in Germany would be unable, for the foreseeable future, to contribute to the development of knowledge in fields that might be of great medical importance.

4 It is impossible to forgo imports of embryonic stem cells on the grounds that suitable alternatives are available. In the present state of scientific knowledge, research with embryonic stem cells holds out the promise of important discoveries that might lead to the development of new therapies. There can of course be no guarantee that this research will be successful. However, in view of the high value placed on health as a desirable object, and in the interests of sick people, it is imperative to explore every acceptable research approach that holds out the prospect of new therapeutic options. At any rate, a promising research strategy must not be ruled out because it is presumed or hoped that the goal might be achieved without it.

5 Permitting the import of embryonic stem cells, perhaps for a limited period only, would afford scope for research whereby the potential and prospects of different stem cell research strategies could be identified. At the same time it would be possible to determine whether a further debate on the permissibility in principle of embryo research is necessary. It is conceivable that the discoveries accruing in the interim would suffice for research to continue with other types of stem cells. Research on embryonic stem cells might then become superfluous.

6 The commencement of research on (imported) embryonic stem cells in no way prejudices the legislator's future decision as to whether embryo research should be prohibited in Germany or, as in many other countries, allowed subject to limitations. The legislator must, of course, decide in the light of the results and prospects of the research carried out so far. However, this is true irrespective of whether this research was conducted abroad only or – on imported stem cells – in Germany too.

7 German law allows the import of embryonic stem cells, but not their production. However, this does not mean that it is ethically inconsistent to take advantage of this legal situation. This would be so only if the production of stem cells from embryos were without exception unethical, but that is not the case. The reference to “consistency” is, moreover, problematical. For if the import of embryonic stem cells were to be prohibited on ethical grounds on account of the “consumption” of embryos thereby entailed, “consistency” would also demand the prohibition of possible future therapies developed with the aid of such stem cells (and hence also involving the “consumption” of embryos). But such consistency would not be ethically acceptable, nor, on the basis of experience so far with medicinal products and therapies originating from other countries, is it to be expected.

8 Provided that imports are restricted to embryonic stem cells derived from embryos independently of research projects in Germany and prior to the time when these projects are requested, the existence of an incentive for the “consumption” of embryos can be ruled out, so that the level of protection corresponds to that provided by the German Embryo Protection Law.

9 The fact that the provenance of stem cells may be unverifiable in individual cases cannot justify the comprehensive prohibition of imports.

6.2 Specific arguments against the import of human embryonic stem cells

10 The import of embryonic stem cells should not be allowed, as the underlying action, the killing of embryos so as to derive stem cells from them, is ethically unjustifiable.

- 11 Importation could be seen as moral approval for the production of stem cell lines in Germany.
- 12 A legal ban on imports does not limit the freedom of research at least in the case of an entity whose production in Germany is prohibited by the Constitution.
- 13 Importation will have the effect of weakening the high level of protection for embryos *in vitro* laid down by law.
- 14 Importation will encourage demands for stem cells to be produced in Germany too; it cannot therefore prevent the further destruction of human embryos.
- 15 Imports of stem cells may in addition result in increased consumption of embryos in other countries – particularly if existing stem cell lines prove to be unusable.
- 16 Imports prejudice a future legislative decision on the permissibility of the derivation of embryonic stem cells.
- 17 The import of human embryonic stem cells is ethically unacceptable because the potential of research on, in particular, adult stem cells and stem cells from umbilical-cord blood, while promising, has not yet been fully exploited.
- 18 At present, only speculation is possible about future therapies that might accrue from research on embryonic stem cells. In particular, it is impossible to predict whether embryonic stem cells might serve this purpose better than other stem cells. Uncertain expectations cannot therefore constitute the basis of the decision now to be taken.

19 Allowing imports of stem cells while at the same time prohibiting their derivation is ethically inconsistent even if legally possible, especially as a permanent solution. After all, if a high level of protection is demanded for embryos in Germany, it is inappropriate to resort to research material produced abroad only in violation of this protection.

20 The import of embryonic stem cells should be banned because, in particular where they are imported from countries in which it is legal to produce embryos for research purposes, it is impossible to verify whether the imported cells were really derived from excess embryos.

7. Assessment options for the question of imports

Four conclusions appear possible if the ethical positions of principle on the derivation of stem cells (Section 5) are considered together with the specific considerations concerning imports (Section 6). These four options follow if it is assumed that some of the arguments specifically applicable to imports may be relevant in their own right – that is, independently of the positions of principle – to the decision whether or not to allow imports; for example, the argument that imports of existing stem cell lines do not make a causal contribution to the killing of embryos, or that there are viable alternatives to research on embryonic stem cells.

Option A:

The import of pluripotent human embryonic stem cells for a limited period only is deemed ethically acceptable provided that the conditions set out below are satisfied, because the derivation of such stem cells from excess embryos is held to be ethically permissible. For this reason, the derivation of such stem cells from excess embryos in Germany too would be acceptable. The import conditions enumerated (which are identical to the corresponding conditions in Option B) must apply equally to State-funded research and to research in the private sector.

- A Imports must be exclusively confined to human embryonic stem cells taken from an embryo that was originally produced for the purpose of satisfying a wish for a child by artificial fertilization and that can no longer be used for a transfer.

- B** The couple from whose germ cells the embryo was produced must have given their prior consent to its use for the derivation of stem cells. The couple must have been informed about the planned use before giving their consent. Furthermore, they must not receive any inducement, whether financial or of any other kind, for their consent.
- C** The stem cell line must have been derived independently of the research project in Germany and before the project was requested.
- D** Details of the cells to be imported must have been recorded at a central public registration office, with documentary evidence of the satisfaction of conditions (a) – (c) above.
- E** Human embryonic stem cells may be used for research purposes only if the results to be achieved by the research project have a medical aim, cannot be obtained in a comparable way with other human cells, and evidence of the necessary preliminary studies on animal cells has been presented.
- F** The scientific quality of the research project involving imported human embryonic stem cells must be verified by an appropriate expert review on the basis of proven scientific criteria.
- G** The research project must be recommended by an independent interdisciplinary ethics committee. The Federal Government is called upon to establish a central committee.
- H** The results of the research project must be published.
- I** The import of human embryonic stem cells should be permitted for an initial period of three years. A review taking

account of the results of international stem cell research must be carried out before the end of this period.

The advocates of imports consider there to be no point in restricting the stem cells that may be imported to lines produced before a set date. If imports are strictly controlled, the demand from Germany will not be so great as to have significant quantitative effects internationally. Furthermore, such a limitation would have no effect on the production of further stem cell lines in other countries owing to those countries' own research interests, for example in improving culturing conditions by avoiding substances from other species or in the comparability of genetically different embryonic stem cells. This would ultimately make it impossible for research workers in Germany to utilize advances achieved abroad. Indeed, considering the time necessary for preparing a research project, it is clear that the stem cell lines must have come into being appreciably before the end of the period allowed for imports.

Option B:

The provisional import of human embryonic stem cells, for a limited period only and subject to strict conditions, is advocated. All the conditions (which are identical to the import conditions of Option A) apply equally to State-funded research and research in the private sector. All conditions must have been satisfied prior to importation.

- A** Imports must be exclusively confined to human embryonic stem cells taken from an embryo that was originally produced for the purpose of satisfying a wish for a child by artificial fertilization and that can no longer be used for a transfer.

- B** The couple from whose germ cells the embryo was produced must have given their prior consent to its use for the derivation of stem cells. The couple must have been informed about the planned use before giving their consent. Furthermore, they must not receive any inducement, whether financial or of any other kind, for their consent.
- C** The stem cell line must have been derived independently of the research project in Germany and before the project was requested.
- D** Details of the cells to be imported must have been recorded at a central public registration office, with documentary evidence of the satisfaction of conditions (a) – (c) above.
- E** Human embryonic stem cells may be used for research purposes only if the results to be achieved by the research project have a medical aim, cannot be obtained in a comparable way with other human cells, and evidence of the necessary preliminary studies on animal cells has been presented.
- F** The scientific quality of the research project involving imported human embryonic stem cells must be verified by an appropriate expert review on the basis of proven scientific criteria.
- G** The research project must be recommended by an independent interdisciplinary ethics committee. The Federal Government is called upon to establish a central committee.
- H** The results of the research project must be published.

- 1 The import of human embryonic stem cells should be permitted for an initial period of three years. A review taking account of the results of international stem cell research must be carried out before the end of this period.

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Option C:

A provisional ban (moratorium) should be imposed on the import of stem cells. The legislator must take an explicit decision on imports, but must first settle a number of points, as enumerated below. The examination of these points should be completed by the end of 2004.

During the intervening period:

- 1 Specific assistance should be directed to research on adult or somatic stem cells and the testing of their potential to form different types of specialized cells and tissues.

- 2 The scientific and medical objectives to be attained by the research on and use of human stem cells should be specified.
- 3 The following aspects should be investigated by appropriate institutions – for example, those concerned with predicting the scientific consequences of technologies, in cooperation with scientists from other relevant disciplines:
 - A Determination of whether the various research strategies constitute alternative or complementary approaches:
 - Somatic or other stem cells would be deemed an alternative to embryonic stem cells derived from *in vitro* embryos if these cells could be used as a basis for the production of cultures of different kinds of specialized cells or tissues suitable for transplanting.
 - Conversely, an approach would be considered complementary if research showed that the potential of somatic stem cells to form different kinds of specialized, transplantable cell cultures or tissues was insufficient or appreciably less than that of embryonic stem cells according to the published literature.
 - B A comparative ethical review and assessment of techniques required for the derivation of different types of stem cells:
 - Adult stem cells from different tissues of adult human beings.
 - Stem cells from umbilical-cord blood. The study must include a consideration of the possible effect of the extraction of umbilical-cord blood on initial perinatal care of the neonate and his/her personal rights.

- Stem cells from aborted fetuses. The investigation must include a consideration of whether the taking of foetal stem cells influences the decision to terminate pregnancy and the termination methods used.
 - Retroprogramming. In this case the aspects to be considered must include the extent to which human ova or factors derived from them need to be used to obtain these stem cells.
- c A comparative evaluation of different models and institutions for controlling imports of embryonic stem cells:
- Fixing and precise specification of criteria to be met by imported stem cells (for instance, derivation from “excess” embryos, evidence of thoroughly informed consent; production before a specified date, etc.).
 - Imports for research projects: elaboration and specification of criteria for the suitability, necessity and proportionality of the use of human embryonic stem cells for a research project.
 - Ensuring that these criteria can be verified.
 - body to monitor the import of human embryonic stem cells; ensuring the transparency of this body’s work.
- 4 The possible repercussions of research on and the use of “excess” human embryos on the practice of reproductive medicine should be examined, with particular reference to the following:
- the definition of “excess”;
 - the processes whereby “excess” embryos arise;
 - the avoidability of “excess” embryos;

- the possibility of adoption of embryos no longer required for use by the couple from whom the gametes originate;
- the criteria characterizing the voluntary nature of, and informed consent to, the release of embryos for research or adoption;
- the necessary institutional conditions for the granting of informed consent and its verification;
- the development of treatments in the field of reproductive medicine should the use of “excess” embryos for scientific and medical purposes be accepted.

Option D:

The import of stem cells is deemed ethically impermissible. This view is based on considerations of principle concerning the derivation of stem cells from human embryos. Since this is seen as an impermissible instrumentalization of human life (killing), the import of such cells must also be rejected. The imported cells bear the ethical stigma of the conditions of their genesis; through the increase in demand, imports will make a causal contribution to the consumption of embryos in the countries to which they are exported; and imports will lead to a reduction in the level of protection for embryos in Germany too.

Considering that the National Ethics Council is still to express an opinion on the issues of principle raised by stem cell research, and in view of the imminent decisions on the import of embryonic stem cells, fifteen of the Council's members, including nine who have also espoused Option A, favour the import of embryonic stem cells for a limited period and subject to strict conditions (Option B). Ten members consider that stem cell imports should be provisionally banned (Option C); these include four members who also advocate Option D.

Berlin, 20 December 2001

8. Members of the National Ethics Council

Prof. Dr. Dr. h.c. Spiros Simitis (Chair)
Prof. Dr. Regine Kollek (Deputy Chair)
Prof. Dr. Dr. Eckhard Nagel (Deputy Chair)
Prof. Dr. Wolfgang van den Daele
Prof. Dr. Horst Dreier
Prof. Dr. Eve-Marie Engels
Bishop Dr. Gebhard Fürst
Prof. Dr. Detlev Ganten
Prof. Dr. Volker Gerhardt
Bishop Prof. Dr. Wolfgang Huber
Christiane Lohkamp
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