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The German Stem Cell Law: Contents and Criticism

Development and contents of the Cell Stem Law

On January 30, 2001, the German Parliament decided 339 votes to 266 to essentially forbid research on embryonic stem cells. Only research carried out using imported stem cells under stringent conditions would be permitted. This vote came into action with the enacting of the legislation of May 10, 2002: "Law to guarantee the Embryo Protection Law in relation to the import and use of human embryonic stem cells (Stem cell Law StZG)"[1] . The law entered into force on July 1, 2002. With this legislation, a difficult compromise was worked out after long and intensive discussion. However, this has been criticized by many sides and there have been demands for immediate change.

The law applies according to §2 for the import and use of embryonic stem cells. Such stem cells which are gained from embryonic germ cells, dead fetuses, abortions, adult and animal cells do *not* fall under the jurisdiction of this law. According to the intention of the legislators, a legal norm should be set up which would not be in contradiction to the high protective level of German embryonic laws. At the same time, the fundamental right for freedom of scientific research should be secured, and the interests of sick people in the development of new health procedures should be included in the equation.[2]

It follows from the basic (German) constitutional right to engage in free research and enjoy good **health care** that a total prohibition of such research would be unconstitutional. Therefore, the legislators decided simply to forbid *here in Germany* the production of embryos to gain embryonic stem cells. Likewise the production of embryonic stem cells has also been forbidden. No constitutional rights (like those opposed to the killing of unborn human life) come into question when one relies on the

[1] Bundesrat (German Senate) printed material: 344/o2 from 5/10/2002.

[2] Jochen Taupitz , Import embryonaler Stammzellen. Konsequenzen des Bundestagsbeschlusses von 30.1.2001 in Zeitschrift für Rechtspolitik, no. 3, p. 111 ff (113).

cultures of already existing pluripotent stem cells, especially since existing pluripotent stem cells have no legal protection for their existence or (in a legal sense) human dignity in Germany.[3] However, it is not implied by the aforesaid that the Basic Constitutional Law *in principle* excludes the production of stem cells and that the legislator does not have a relatively broad scope for the organization of research freedom. This can be seen above all in the context of abortions - which under certain conditions are not punished. Furthermore, although the German Constitutional Court has attested to the human dignity of embryos and the protection thereof against destruction, this is clearly "in any case" after the embryo has already installed itself in the womb.[4] Thus, *when* actually legal protection commences before this installation remains unspecified for the moment.

According to the law, Germans are merely allowed to import[5] stem cells that were won before January 1, 2002 and stored in laboratories as cultures. (An embryo cannot develop from such frozen or "cryo-conserved" stem cells.) No commission may be paid for the imported stem cells or cell lines and there must be exact proof of the source. When presenting a research project, the researchers must explain why they wish to use embryonic stem cells rather than adult stem cells from umbilical cord blood or stem cells from animals. In end effect, anyone who deliberately imports or utilizes embryonic stem cells without authorization can be imprisoned to up to three years.

After the stem cell law came into power on July 1, 2002, the Federal Cabinet passed a statutory order to enforce the legal requirements thereof. This statutory order was

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[3] Bundesverfassungsgericht (Federal Constitutional Court) 30, p. 173 (139 f.); Taupitz, ebenda.

[4] An import limitation from countries of the European Union cannot be brought in harmony with Article 28 of the **EGV** because independent of any ethical stipulations, according to Article 23. Ff. of the EGV, the concept of merchandise also includes embryos and embryonic stem cells. Therefore, the trade with them is guaranteed by European Community law stipulating free transport of merchandise, compare EuGH, Rs C-159/90 Slg 1991, I-4685; Schweitzer/Selmayr/Kahlmann/Ahlers, Gesetzgebungskompetenzen der Europäischen Gemeinschaft im Bereich Humangenetik und Fortpflanzungsmedizin. Gutachten im Auftrag der Fraktion der Europäischen Volkspartei und Europäischen Demokraten im Europäischen Parlament, 2001 p. 66 ff; Kopetzki, Rechtliche Aspekte des Embryonenschutzes, in: Embryonenschutz - Hemmschuh für die Biomedizin (ed. Körtner/Kopetzki), 2003, page 51 ff.

[5] Taupitz, ebenda, p. 314; furthermore it is not certain to what extent the date of the production is still verifiable when stem cells are imported - from which only *later* the stem cell lines are cultivated.

necessary for the execution of the law. This statute determined that the Robert Koch Institute is the responsible authority for the approval of research projects; this regulated at the same time the process under which the "Central Ethics Commission" would be called into being and how this commission should operate. The Federal Cabinet took this opportunity to establish the membership of the commission. Consequently, the Central Ethics Commission for Stem Cell Research met for its constitutive session on June 7, 2002 and discussed its future working procedures. The purpose of this organization is to proof applications for the permission to import or use human embryonic stem cells, (whereby a first application already is being processed).

Criticism of the law and suggestions for amendments

In §1 Section 1 and § 2 of the law, the import and use of embryonic stem cells are defined as an area of application and essentially forbidden. This formulation is unclear in so far as it does not emerge from the text if merely the use of imported stem cells should be forbidden. It could also be meant that generally the import *and* their use is forbidden. This question is relevant to the status of "orphaned" and stored embryos in Germany since according to the Law for the Protection of Embryos, an egg cell that has just been fertilized can be designated as a stem cell. At the same time in §3, Paragraph 4, the definition that "an embryo is already every totipotent cell that under the necessary circumstances can divide and form an individual" only adopts part of the conceptual definition of the Embryo Protection Law. The legislators of the Stem Cell Law renounced the adoption of the partial statement: "Defined as an embryo in the sense of the embryonic protection laws is, from the point of fusion on, the fertilized, potentially developable human egg cell." No reason is given for this omission. However, to avoid uncertainties, the Embryo Protection Law's definition should be utilized.

It is unclear in the German constitution what should be done with so-called "orphaned" embryos. In any case, it would be difficult to find a constitutionally valid reason here to forbid research. Therefore, Taupitz correctly poses the question if the law for limiting import of pluripotent stem cells can be linked to the condition that these cells were

developed before a certain cut off date.[6] He regards that the principle of proportionality requires that the development of stem cells abroad should not be connected to German research projects. Furthermore, the question arises if import of stem cells should only be allowed for research projects. It is correctly indicated here that it should also be possible to utilize embryonic stem cells in the course of medical treatment.[7] This aspect should really not be excluded.

Furthermore, there are a number of unexplained points that will be discussed here quickly. According to §4 Section 2, 1c) there may be no promise or realization of renumeration or other monetary advantage for renunciation of the embryos. What is not explained is how this shall be proved; if a simple written statement is necessary or if even a sworn statement from the donator and/or **bearer** must be submitted? Instead of this, it might be taken into consideration that it suffices when there are no actual indications that the parents have been influenced by financial inducements.[8]

According to Section 3 of these paragraphs, "permission should be withheld if the extraction of the embryonic stem cells is obviously in contradiction to the fundamental principles of the German legal system." This passage is as a whole too imprecise because neither the word "obviously" nor the expression: "fundamental principles of the German legal system "are clear enough to be useful. It is also questionable as to how both can be verified.

This also pertains to the term "high ranking research goals" in §5. It is also not clear what is meant here. The Central Ethics Commission will be responsible for this assessment and this organization will also have to check to see if the potential project is without alternatives. In any case, this ethics commission has the purpose of *only* checking to see if the §5 stated requirements are ethically realized in the research project. It should not be its purpose to investigate the practical implementation of the requirements of §5 as this is what the license authorities are responsible for.

Finally, it should be extremely difficult to prove (as §5 demands) that "the gain in knowledge through the research project can probably only be gained through use of

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[6] Taupitz, ebenda

[7] Taupitz, ebenda

[8] Taupitz, ebenda, p. 315

embryonic stem cells”. It has been pointed out correctly that precisely this kind of result will possibly only become apparent when there has been sufficient research done with both cell types or when it is clear that research with adult stem cells does not suffice. In so far, this is correctly seen as a impermissible limitation of freedom of research in the sense of Article 5, Section 3 of the Basic Constitutional Law. (9)

Conclusion

In all, with the Stem Cell Law one can perceive a compromise which was worked out with difficulty and that will probably exist for a certain period of time. Some aspects of the law itself are unclear and need improvement. Others must be explained point by point in a legal sense, for example the cooperation of German scientists with foreign colleagues where (the Germans) must also be liable for (ethical lapses in) their research abroad. And finally, certain factors are not considered, that for example, the legal restraints that only cell lines may be imported that were set up before January 1, 2002 may cause insurmountable problems. These cell lines may have been infected with animal viruses in the meantime and therefore possibly are unsuitable for the development of new therapies.