

## APPENDIX

### Section II (3) Opinion

#### 3. Permissibility of balancing objects of legal protection against each other

If the compromise of the Stem Cell Law is accepted as the starting point and foundation of evaluation, it follows that, in the regulation of the import and use of hES cells, on the one hand the embryo protection criteria must not be set below the level provided for in the Stem Cell Law, and, on the other, research must not be subjected to restrictions that would have the effect of completely precluding the use of hES cells. Nor must the interest of the sick in the development of new therapies be disregarded. However, differences of opinion exist as to the consequences of these premises for the detailed provisions.

To begin with, no one disputes that any system intended to be compatible with the compromise of the Stem Cell Law must retain the objective of preventing any German causal contribution to the destruction of embryos in other countries. For this reason, the production of hES cells abroad must not be “instigated” from Germany—that is to say, it must not, by any action in Germany, be carried on, commissioned or facilitated by incentives.

However, opinions differ on whether the compromise represented by the Stem Cell Law is departed from if alternatives to the present cut-off date criterion or threat of penal sanctions are considered. Some hold that these two provisions do not in themselves constitute the objective and purpose of the Stem Cell Law, but are simply means of achieving its objectives and purposes. The cut-off date criterion is intended, as provided in Section 1 No. 2 of the Stem Cell Law, to prevent the derivation of hES cells from being instigated as a result of action in Germany, whereas the criminalization provision has the aim of ensuring that the conditions for approval are observed. In the opinion of others, the cut-off date criterion is one of the essential ends of the Stem Cell Law. In their view, the compromise achieved in the Law would no longer be respected if the cut-off date were to be modified or replaced. [end. p. 15]

This position is no doubt underlain by the assumption that the risk of the production of hES cells being “instigated” by action in Germany would be increased in the event of a departure from the present criterion of a fixed cut-off date. In this connection, however, it is not enough to maintain that concessions on the cut-off date might in effect be perceived as a signal of symbolic support for researchers who produce hES cells in other countries. Symbolic reinforcement of this kind cannot validly be adduced as an instance of the “instigation” of the production of hES cells within the meaning of the Stem Cell Law. Experience has shown that it cannot be assumed that such an incentive would automatically arise if the current cut-off date criterion were dropped because this would create the abstract possibility of using the new cell lines in Germany as well as abroad. The development of new cell lines in other countries is part of a dynamic that proceeds without regard to what is happening in German research. Rather than speculating on a conceivable demand for hES cells in Germany, scientists are in fact pursuing perceived research goals, strategies and opportunities. The fixed cut-off data criterion surely has the sole function of reliably precluding any concrete instigation of the

production of new hES cell lines in other countries. Conversely, with regard to the extent to which new hES cell lines are produced abroad—apart from the conceivable case of such instigation—it is immaterial whether or not the cut-off date criterion is retained in Germany. For this reason, the indispensability or otherwise of the cut-off date criterion depends on the possible existence of regulatory alternatives capable of equally reliably precluding the concrete instigation, by means of action in Germany, of the production of hES cell lines in other countries.

However, the legislative history of the Stem Cell Law suggests that it was actually only the strict cut-off date criterion and the symbolic signal to society of the threat of a severe penalty that persuaded some deputies to vote for the bill. Perhaps these provisions did in this way make some contribution to achieving “peace” in the dispute about the import and use of [end p. 16] embryonic stem cells. It may nevertheless be doubted that the strict cut-off date criterion is an integral component of the compromise defined in the Stem Cell Law. An argument against this idea is that eventually no one in Germany would any longer be able to take part in research with hES cells on the level of international science if the cut-off date really were set in stone (on this point, see Section III.2 below). The Stem Cell Law would then not be a compromise, but simply a deferred complete abandonment of the import and use of hES cells. Such an interpretation can surely not be reconciled with the other declared objective of the Law—that of ensuring the freedom of research. If the compromise character of the Stem Cell Law is taken seriously, the cut-off date criterion cannot be deemed indispensable. This is also implicitly conceded by those who oppose changes to the cut-off date criterion by arguing that science does not in fact need the new cell lines. Anyone who rejects a change in the cut-off date criterion on the grounds that it is not necessary at least does not rule out the possibility of the criterion being modified if this is necessary. [end of section, p. 17]

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