Human embryos in medical research
Workshop 2
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– Theses –

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I. Current situation

1. While stem cell research is developing at an increasing pace, its legal framework has been essentially frozen for years. On the one hand, this legal situation restricts research (and certain, e.g., therapeutic applications based on it) in a way which raises doubts as to the constitutionality of these restrictions; on the other hand, it opens up new fields of research (and certain applications) which require ethical and legal discussion.

2. The legal framework for stem cell research (and certain applications based on it) must, hence, be readjusted in the light of freedom of research and the state's duty to protect life and health, and in recognition of a normative status of human embryos.

II. Basic considerations

3. From a legal policy perspective, the German legal framework must change in two respects: first, from a culture of prohibition to a culture of permission; second, from a culture of lethargy to a culture of dynamics.

4. With respect to legislative technique, the legislature should pass a Bioethics Act *(Bioethikgesetz)* in order to create a new, coherent and dynamic legal framework. Its first article should amend the current Embryo Protection Act *(Embryonenschutzgesetz, ESchG)*, its second article should introduce an Embryo and Stem Cell Research Act *(Embryonen- und Stammzellforschungsgesetz, ESFoG)* and its third article should amend, or possibly repeal, the current Stem Cell Act *(Stammzellgesetz, StZG)*. A fourth article should prescribe a periodic review of this framework.

III. Definition of the embryo

5. Such a bioethics act should lay down a common definition of the human embryo based on the latest state of science. What should be constitutive for the classification as a human embryo is the relevant entity's belonging to the species *homo sapiens* and its potential, in principle, to develop out of itself into a born human being.

IV. Readjusting the regulation of stem cell research

6. An *ESFoG* should include a section on "human embryonic stem cell procurement". In substantive terms, hESC procurement should be limited to high-priority research or other high-priority (e.g., therapeutic) purposes and to the use of surplus IVF embryos donated gratuitously and after informed consent. In procedural terms, each individual case of hESC procurement should be subject to approval

by the Robert Koch Institute *(Robert Koch-Institut, RKI)* after prior consultation of the Central Ethics Commission on Stem Cell Research *(Zentrale Ethik-Kommission für Stammzellenforschung, ZES)*.

7. An *ESFoG* should include a section on the "use of human pluripotent stem cells" applicable to both hESCs and iPSCs and establishing the requirement of informed consent of cell, tissue, or embryo donors for all uses such cells.

8. The use of hESCs should, in principle, only be permitted for the purposes covered by the procurement licence. As regards such uses, licence holders should not be subject to any further regulatory procedure, whereas third parties should be subject to a procedure of notification to the *RKI* without a waiting period. As regards uses for other purposes as well as all uses of hESCs imported from abroad, a procedure of notification to the *RKI* with a waiting period should be established. The *ZES* should give an advisory opinion on each notification.

9. The derivation of embryoids from iPSCs and their use should only be permitted after notification (without waiting period) to the *RKI*. The notification should include a scientific assessment of the developmental capacity of the embryoids. The use of embryoids to induce pregnancy should be prohibited.

10. The derivation of artificial gametes from hESCs or iPSCs and their use should be permitted for research purposes as well as for purposes of infertility therapy and assisted reproduction to the exclusion of the use of genetically modified artificial gametes. Each individual case of fertility research should be subject to approval by the *RKI* after prior consultation of the *ZES* (if not already covered by the procurement licence, cf. thesis 6).

11. The *ZES* should ethically evaluate the applications and notifications submitted to the *RKI* and provide an annual summary report on its activity. It should also report on the international development of research with brain organoids derived from hESCs or iPSCs.

12. Another possibility would be to amend the *ESchG* and the *StZG* only. In this case, the restriction to research purposes in the *StZG* should be deleted, the scope of application should be extended to iPSCs, the cut-off date as well as the requirements of subsidiarity and lack of alternatives should be deleted, the approval requirement for the use (and import) of hESCs should be replaced by notification requirements as proposed in thesis 8, the derivation and use of embryoids and artificial gametes should be regulated as proposed in theses 9 and 10, and the role of the *ZES* should be redefined as proposed in theses 6, 8, 10 and 11. The *ESchG* would have to be adjusted to a *StZG* as amended accordingly.