



Workshop:

Ethical aspects of stem cell repositories and stem cell databases
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PANEL 3: A GLANCE AT THE FUTURE

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There are certain limitations in the study of human disorders:

- The availability of tissue samples is scarce and primary cells are very difficult to culture;
- There are severe limitations of immortal cell lines;
- The understanding of polygenic diseases is very limited;
- Not all diseases can be recapitulated in the mouse successfully.

The SCNT (somatic cell nuclear transfer) is like an experimental window in the molecular cell biology of diseases, requiring no a priori knowledge of the underlying genetic cause. The supply of oocytes is one of the defining critical aspects of therapeutic cloning. The derivation of gametes from ES cells (ESDGs) could potentially provide an endless supply of oocytes.

It is important to guarantee the mobility of researchers, cells and materials and data derived from those cells. How to deal with different legal requirements and can a European legal framework be reached?

We should look at the narrative in which the laws are developing. According to the German Embryo Protection Act, it is a criminal offence to separate and use totipotent cells for reproduction, research or diagnosis. Therefore, the artificial splitting to have twins is penalized in Germany, but naturally having twins is fine. As in many other cases, it is the process, not the end result, which defines the crime.

Italy is going to have the referendum on use of embryos for research. There is a traditionally cooperative mode of European research and this is the strength of European research. The concept of national state is completely inadequate to address the tool of embryonic stem cell research.

The morning-after pill entered our society through a discourse on the rights to privacy and within the framework of reproductive liberty and sexual freedom. If we draw a parallel with stem cell research, then the real question becomes: how and why is genome reprogramming for research and therapeutic purposes being framed in a different context, namely as a quintessentially public issue as compared to the private sphere discourse that framed the morning-after pill and other contraceptive methods? This and related

questions highlight how legal settlements in biotechnology are complex social constructions. They reflect the political tools (resources) used to shape them, and they are embedded in the narratives of the society that generates them.

Laurance Lwoff

Stem cell repositories

There are no specific legal instruments on stem cells alone. But the following legal instruments and report includes relevant provisions:

- European convention on human rights and biomedicine (ETS 164, 1997)
- Additional protocol on the prohibition of cloning of human beings (ETS 168, 1998)
- Additional protocol on transplantation of organs and tissues of human origin (ETS 186, 2002)
- Additional protocol on biomedical research CETS 195, 2005)
- Draft recommendation on research on human biological materials
- Report on the protection of the human embryo in vitro (2003)

The Convention on human rights and biomedicine states that human body and its parts as such should not give rise to financial gain. This means that organs and tissues cannot be bought, sold or give rise to financial gain for the person from whom they have been removed or to the third party. However, technical acts, such as sampling, testing or storage can give rise to reasonable remuneration, and compensation is possible for the expenses incurred or the loss of income. It is important to note however, that when these provisions were drafted, patent issues were not addressed. These provisions do not apply to the issue of patentability of biotechnological inventions.

Article 18.2 of the Convention prohibits the creation of embryos for research purposes, but it takes no stand on admissibility of the principle of research on embryo in vitro

The Protocol on the prohibition of cloning of human beings prohibits the creation of a human being genetically identical (with the same nuclear gene set) to another human being, whether living or dead. However, the definition of "human being" for the purpose of the Protocol is left to domestic law. One country has made the following declaration at the time of signature of the Protocol – The Netherlands declared that it interprets the term "human being" as referring exclusively to a human individual, i.e. a human being who has been born.

A Recommendation on research on human biological materials is being elaborated. The removal of human embryonic and foetal biological material is excluded from the scope of recommendation which only covers the removal of biological materials from a person for research storage purposes. It deals with storage of materials, population biobanks and the actual use of human biological materials in research. With regard to storage of biological materials, the draft Recommendation addresses issues of management of collections, security and confidentiality of data; consent and transborder flow. The approval of this Recommendation is foreseen in 2005.

Rudolf Teuwsen

The German national ethics council produced an opinion about biobanks, which is thought to be applicable also to stem cell banks, although it is not dealing with that specifically. Regarding informed consent, the important question is how much information is sufficient to fulfil the requirement that consent is really informed. There are potential abuses that may arise from obtaining consent that is too broad. The issue of secrecy in the research setting was also addressed – if professional secrecy can be required from lawyers or clergymen, then you could protect the donors of biobanks by requiring the researchers to keep the professional secrecy.

There is a strong relationship in the way we think about the issues that are involved in setting biobanks. The setting up of a biobank may depend on the medical system in a given country. For example, when there is a centralised medical system, like in the UK, the issue of setting a biobank is quite different from that in Germany, where medical care is very decentralised. It would be more complicated to set up a stem cell bank in Germany.

We have a moral obligation to support research. But the resources that can be allotted for research are scarce and different areas of medical research, as well as the areas of other research are competing for the same funds. Therefore the researchers must find arguments to support stem cell research rather than other types of research.