A Survey of Ethical Questions Concerning Gene Therapy

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Gene therapy, like other biomedical procedures, raises questions of the application of ethical principles or of a balanced ethical judgement about benefits and harms as well as questions about the hermeneutics of ethics. If we see ethics not only within the isolation of the internal problem-solving of law and medicine but in a broader technological, social, and historical context, in gene therapy we will have more questions than we had before and more than we could answer until now. I propose therefore a dual approach, the application approach and the hermeneutical approach, beginning with the first and ending with the second, underlining some questions which cannot be answered in the smaller context of professional ethics.

I will begin with a report about certain positions on ethical questions in gene therapy, a report which is by no means comprehensive, but which functions as an introduction to the second part of my paper, a more systematic description of the discussion about ethical problem-solving. The third part will offer some conclusions related to the hermeneutical problems.

I. Survey of Certain Positions in International and National Committees

1. International Bioethics Committee UNESCO

In August 1994 the Bioethics Committee of the UNESCO received a twenty-eight page report by the Subcommittee on Human Gene Therapy (Professor Edgar and Dr. Tursz). The report underlines UNESCO's "central mission", including "the promotion of science and science education throughout the world", "securing ... fair participation in the benefits that flow from scientific and technical advances." But here participation also means contribution: "The wider the participation, the greater the prospect of discovery. When all may contribute, all should share."
Promoting science, securing fair distribution, and "promoting human rights" are for the committee a question of equilibration: "the benefits for those who suffer, and the principles of free scientific inquiry make appropriate the development of the technology, even as we recognise the risk that national and international social and legal institutions may prove inadequate to control fully its future misuse." This is an application of the medieval scholastic principle "abusus non tollit usum" (misuse is not an ethical reason against use).

Moreover, the report "approves of somatic cell gene therapy to treat diseases, and disapproves germline cell therapy for mere enhancements." It reclaims the "universal consensus that somatic gene therapy should be regulated like other experimental therapies." The presupposition is that "genetically transformed cells ... are used like other drugs." Here the ethical question of enhancement is not differentiated for somatic cell gene therapy and drug therapy, (even if it remains an ethical question).

One question raised in the subcommittee's report is how to weigh the research interest of sooner use against interests of safety. Under the "internationally accepted" ethical principles the report takes the following into account: (5.) the "right to the highest attainable standard of physical and mental health and associated rights of healthcare"; (7.) "the right to enjoy the benefits of scientific progress and its application"; (8.) the "right to freedom for scientific research". Under the eight principles there is no mention of "justice" and no mention of safety.

However, the report later quotes the "International Guidelines for Biomedical Research", following the Declaration of Helsinki: there "justice" is mentioned (1993).

On somatic cell gene therapy the report tries to disarm counterarguments like the high risk of accidents, later consequences for germline cells, and the slippery slope with arguments like the acceptance of other risks (cf. in nuclear power) and the prognosis of only "accidental" alteration of a germline cell, which merely takes part in "constant changes through mutation" resulting from human activities. The report maintains that the slippery slope argument has no "stopping point." But the main point of this report of the Subcommittee on Human Gene Therapy is: "These possible arguments against somatic cell therapy do not respect adequately rights of freedom in scientific research, the duty to protect the vulnerable, and the rights to enjoy the benefits of scientific progress." (p. 18) Thus, the report repeats its own presupposition: that there is an equilibrium between different rights, which all seem to be on the same level. The same presupposition is also made in the preamble to the Bioethics Convention Draft of the Council of Europe.

Nevertheless, the report recommends regulations for an "adequate supervision both of the safety of research practices in the laboratory, and of the decision to initiate human trials..." The benefits must be seen "realistically" and "safety standards" must be maintained against pressure; " the procedures should be