The background of the cover features a large, faint, circular seal of the Berlin-Brandenburg Academy of Science and Humanities. The seal contains an eagle with spread wings and the text 'BERLIN-BRANDENBURGISCHE AKADEMIE DER WISSENSCHAFTEN' around the perimeter. The top half of the cover is a light blue gradient, and the bottom half is a solid dark blue.

Interdisciplinary Study Group „Gene Technology Report“
Berlin-Brandenburg Academy of Science and Humanities (Ed.)

**GENE THERAPY IN GERMANY.
AN INTERDISCIPLINARY SURVEY.**

SUPPLEMENT OF THE GERMAN
GENE TECHNOLOGY REPORT

SUMMARY

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AKADEMIE DER WISSENSCHAFTEN

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Summary

At the present time, gene therapy is not the focal point of public interest. The reasons for this are obvious: The setbacks in the 1990s were followed by a phase of intense research; cell biological and molecular biological bases of ambitious new therapy concepts were not clear and the first therapeutic trials, which were met with euphoria, were obviously not yet fully developed. Since then new developments have taken place, mostly unnoticed by the public, and these are the theme of the study. The book 'Gene Therapy in Germany' attempts to give a comprehensive account of the current state of research and of the potential of gene therapy in Germany as well as an interdisciplinary analysis, taking into account scientific and medical facts, the legal framework, ethical implications and the perception and assessment by the public.

Definition and Differentiation

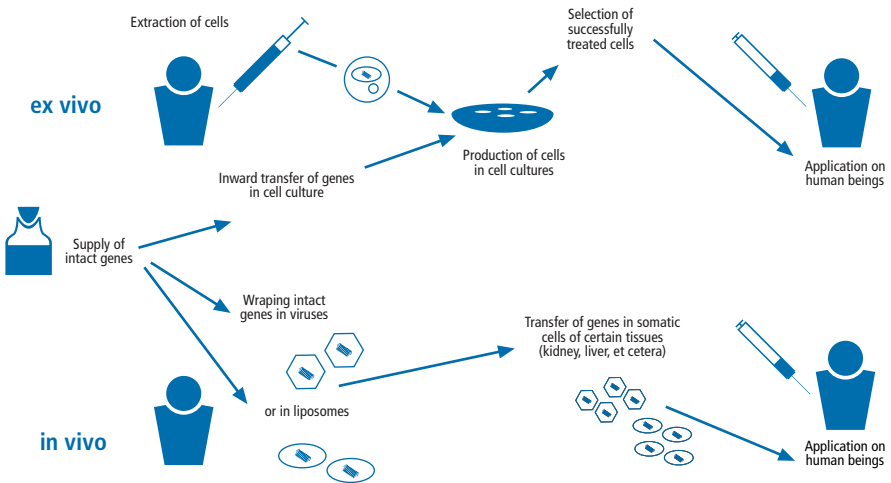
Gene therapy is an attempt to correct defects in the genetic material of a human being. In somatic gene therapy, genetic defects are modified only within the somatic cells. It aims to either eliminate these defects on the molecular level of the DNA by introducing correct genes or gene sequences, or to lessen the effects of genetic defects by introducing genes whose products kill damaged ('sick') cells, e.g. cancer cells.

The genes are transferred by using vectors, i.e. artificially constructed DNA molecules that mostly stem from viruses and carry the desired genetic information (Figure 1). It can be carried out *in vivo* (in the tissue of the patient), or *ex vivo* (in cells that will be subsequently transferred into the human body). Since stem cells can also be used in such cases, it is not possible to make a clear distinction between this procedure and stem cell therapy.

However, there is a distinct line between somatic gene therapy and germline therapy: The former is aimed at the patient's somatic cells, thus affecting only this one person; the latter changes the genome of the ovule or the sperm (or their predecessor cells) and will thus be passed on to the following generations. The authors of this volume – and the global scientific community – reject germline therapy. A special problem arises in so-called human enhancement, in which defects are corrected that are not necessarily pathologically relevant, and instead characteristics irrelevant in terms of illness are genetically altered; this applies to uses of somatic therapy as well as applications of germ line therapy.

Processes that affect gene expression and the splicing process in a regulating way, such as demethylations and processes mediated through small RNA molecules (siRNA) have not been included in the present study. Although considerable therapeutic potential is attributed to the latter, it does not constitute gene therapy in the strict sense.

Figure 1: Gene transfer methods



Source: Winnacker et al., 2002:30

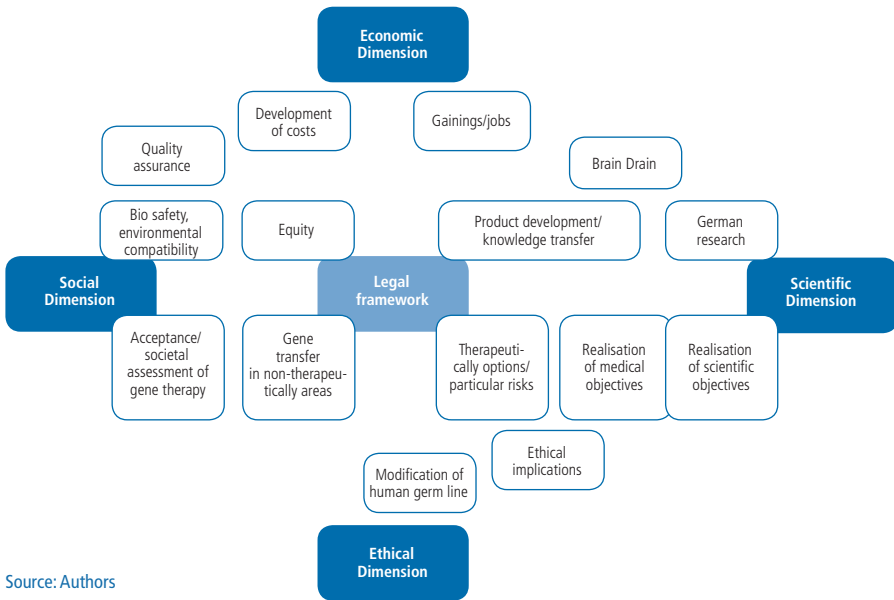
Interdisciplinary Monitoring: Problem area analysis and indicators

The interdisciplinary approach of this volume and of the study group of the Berlin-Brandenburg Academy of Sciences and Humanities is based on indicator analysis. Based on defined 'problem areas', quantifiable descriptions (so-called indicators) were developed which help to evaluate the complex field of gene therapy. The defined 'problem areas' of gene therapy cover the scientific, social, ethical and economic aspects. The legal framework is placed in the centre of figure 2, because the legislature regulates and monitors the entire field of 'gene therapy'.

Numerical data from established sources is being compiled for certain selected indicators regarding these 'problem areas'. The value of such indicators is that they make it possible to gather measuring data on statements about criteria such as 'success' or 'acceptance', which cannot otherwise be quantified. Another advantage of such indicators is that they can show the development of the scientific field by means of time series analysis. This ideal situation is not always manifest, especially in cases where there is insufficient data on individual indicators. However, the indicator tables in the book also list such indicators.

Suitable indicators are, for example: The number of studies on gene therapy (internationally and in Germany, in chronological order), the effort invested in the research, the frequency of patents, licenses and publications, the number of companies active in the field and the number of researchers. Reliable and up-to-date numerical data is available for these indicators. It becomes apparent, for

Figure 2: Problem areas in the field of gene therapy



Source: Authors

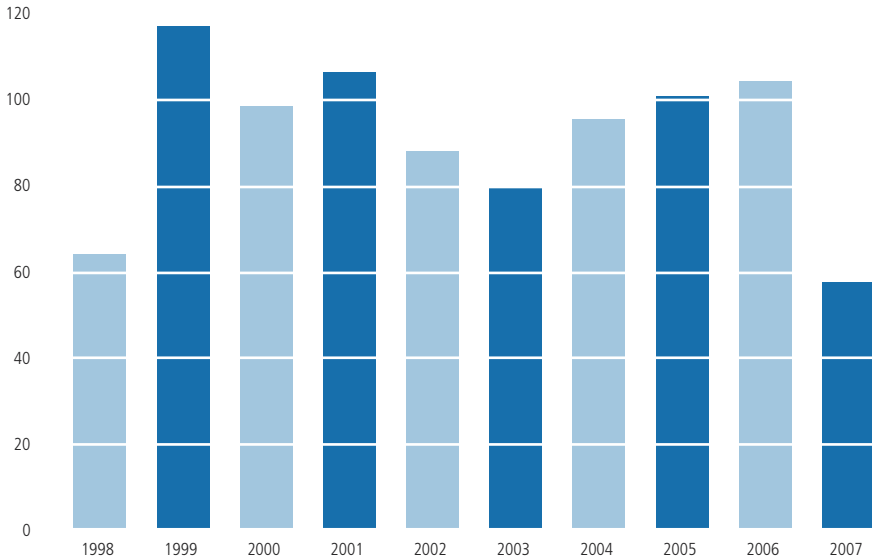
example, that most studies come from the US, that Great Britain is leading the way in Europe, and that currently only a small portion of the studies take place in the clinical phase III, the last stage before the approval procedure.

The current state of research and medical application

Up to now, about 1400 clinical studies on gene therapy have been carried out worldwide, most of them in recent times (Figure 3). However, gene therapy has not yet entered medical practice; the studies were attempts to effect individual healing processes in individual patients using a gene therapeutic intervention. Only after the conclusion of the phase III studies will it be possible to determine whether gene therapy procedures are a dead-end street, whether they can be applied only in single cases or whether they can become generally applicable therapies. Even when this point is reached, it will be a long process before they are developed far enough for application and official admission. The applications of somatic gene therapies mainly pertain to cancer and monogenic diseases (i.e. diseases that are caused by a defect of one specific gene).

A qualified discussion about gene therapy requires knowledge of the procedures and proceedings employed. Therefore, the molecular biological methods will be presented in the book cursorily. Special emphasis will be given to vectors, since they are the predominant tool for introdu-

Figure 3: Number of gene therapy clinical trials (worldwide)



Source: Wiley-Database, Update March 2008

cing genetic material into cells. Vectors derived from viruses have the advantage that they often penetrate cells very efficiently by themselves; however, they also carry considerable risks. Aside from viral methods, there are non-viral methods for introducing genetic material into cells. One common characteristic of them all is that they can, in principle, enter every cell - and thus accidentally enter cells which are not affected by the disease that is to be treated (possibly even cells of the germ line).

For the reasons mentioned, gene therapy research is to a large extent vector research. The main concern is the safety and efficiency of the vectors, since the first gene therapeutic trials at the end of the last century failed because of safety issues. In 1999, a patient died of a severe immune reaction to an adenoviral vector that was used in the gene therapy for treating a lethal metabolic disorder at the University of Pennsylvania. Some time later, complications occurred in Paris after the successful genetic treatment of a severe immune deficiency disease: Several patients developed, usually years after the therapy, leukaemia. The vector used was a modified retrovirus known to cause cancer. In spite of this and other setbacks, these studies in particular provided a proof that gene therapy can work in principle.

The therapy experiments with fatal results and the inefficacy of many other trials did not spell the end for gene therapy experiments, however. The focus of research activity shifted back from clinical application to experimental research. At the present time, efforts are being turned to the development of viral vectors that use certain characteristics of the virus but do not possess

undesired characteristics such as the ability to reproduce. Desired characteristics are, for example, the ability to penetrate the cell membrane, the membrane of the cell nucleus in particular, and to integrate genetic information into the genome of the target cell. An undesired side effect, due to the dangers it poses to the ability to reproduce, is the proliferation in the tissue and the potential immunogenicity. In general retroviruses, including lentiviruses, adenoviruses and adeno-associated viruses are being used in experimental research today. However, as vectors for transfection experiments in humans, it is unlikely that retroviruses will be approved by the authorities because of their cancer-causing side effects.

Following the development of vectors that can potentially be used, and before approving clinical studies, the relevant authorities demand broad-ranging tests on the efficiency and biological safety of a vector for use in gene therapy. Among others, these authorities demand results on:

- ▶ purity and integrity of the gene therapeutic product,
- ▶ Biodistribution, i.e. it must be known which other cells besides the target cells could possibly (and accidentally) assimilate the vector. The specific focus of attention here is on germ line cells. Any risk of transfection must be ruled out or at least minimized.
- ▶ Genotoxicity, i.e. it must be known whether the vector, by implantation "in the wrong place" could cause a tumour to grow or trigger so-called programmed cell death (apoptosis).
- ▶ Immunotoxicity, i.e. it must be ruled out that the vector, the introduced gene, or its product will trigger a severe immune reaction. Like genotoxicity, immunotoxicity can also depend on the context and the dosage.
- ▶ Dosage, i.e. the amount of the gene therapy construct introduced. This is a particularly critical factor, since an insufficient dosage impairs the efficacy and an excessive dosage can give rise to genotoxic and immunotoxic side-effects.
- ▶ Release and mobility of the gene therapeutic agent and its interference with other therapeutic agents - thus far an area that has seen little research.

In principle, all these parameters can be tested in animal experiments or, in part, in cell cultures. But the inability to carry over animal or cell experiment results to human beings can lead to catastrophic misjudgements, as classical pharmaceutical research has repeatedly shown.

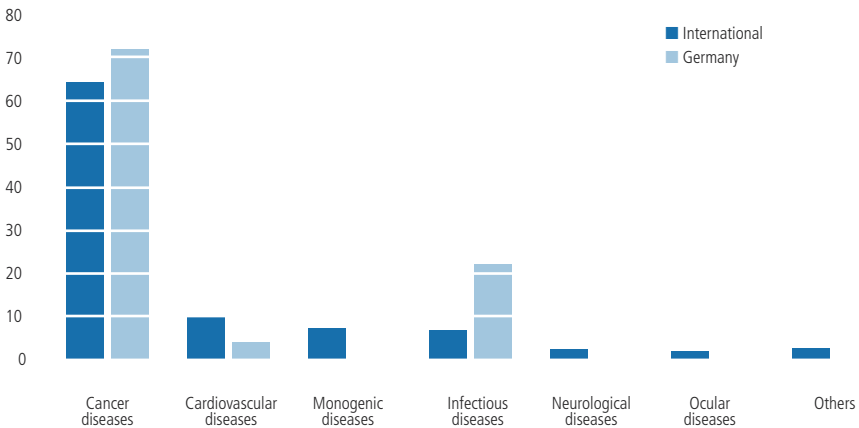
The methods of gene transfer require, beyond actual vector research, the development of supportive, so-called accessory technologies, such as technologies for the isolation and reproduction of cells. A major focal point here is the balance between the efficiency or stability of the gene therapeutic 'tools' and control over their reproduction in the target tissue. Excessive efficiency can cause not only positive therapeutic effects but also undesired side effects. Beyond these closely related cell biological technologies, developments in the fields of endoscopy, catheter technology, microsurgery and image-guided puncture technique are required, especially in cases of an in-vivo gene therapy. Moreover, monitoring procedures for tracking the success and side effects of a therapy are being developed, with the help of which genetically modified tissues and cells can be made visible at high resolutions and sensitivities.

Currently basic research and medical applications are occurring parallel in place and time. As has been common practice in the USA for decades, research groups working scientifically and molecular biologically are more and more often situated in close proximity to clinics. Today, 'molecular medicine' refers to the science that studies the molecular and bio-chemical causes of diseases and thus creates the basis for causal therapies. Three principles of operation are being pursued:

- ▶ the replacement of defective genes by means of gene technology
- ▶ the destruction of 'sick' (i.e. proliferating or pathologically acting) cells and tissues,
- ▶ the introduction of genetically modified cells, e.g. to replace cells that are no longer functional.

The indications for gene therapies are – as mentioned before – mainly monogenic diseases and cancer. Cancer is an indication that accounts for about two thirds of the studies globally, and in Germany as much as three quarters of the studies. Other indications are cardiovascular diseases (9%) and the classical genetically-caused diseases (8%).

Figure 4: Indications addressed by gene therapy clinical trials



Source: Wiley-Database, Update March 2008; DeReG-Database, Update May 2005

In China, a genetic technological therapeutic against cancer was approved as early as 2003 and has been used several thousand times (Gendicine™). Thus far, details of the therapy methodology have not been published in international journals however, and therapy records are rarely accessible to Western scientists. Despite these first medical applications it must again be stressed that somatic gene therapy is still far from being applied routinely in medical practice.

For the first time, gene therapy procedures have been tested for the treatment of very rare monogenic immune deficiency diseases (ADA-SCID and SCID-X1) have been tested. Other diseases against which gene therapies have been developed in Germany are chronic granulomatous disease

(CGD) and Wiskott-Aldrich Syndrome (WAS). The use of blood stem cells from bone marrow for genetic correction and transplantation was no coincidence, since bone marrow is very responsive to transfection and transplantation. Adrenoleukodystrophy, which was first treated in 2007 in Paris, also belongs to this group of indications: In this case gene therapeutic treatment has proven effective in easing acute clinical symptoms, however, no long-term prediction on its clinical effectiveness can be made at present since no long-term data is yet available.

There is intense research on the gene therapeutic treatment of other frequent monogenic diseases such as haemophilia, thalassaemia and sickle-cell anemia, though all these gene therapy strategies are still in the early stages of clinical research.

Most clinical gene therapy studies are carried out in the field of oncology. Due to the complexity of cancer, therapeutic approaches do not aim to repair or replace mutated genes but to destroy the tumour cells

- ▶ by using cytotoxically acting genes/gene products,
- ▶ through the expression of gene products which act as an antigen
- ▶ through the activation of factors/signalling pathways which lead to an inhibition of growth or the destruction of the blood vessels that supply the tumour tissue (anti-angiogenesis).

Although most gene therapy projects are being conducted in the USA, Europe is taking on an increasingly important role, particularly in the field of immune therapy. Numerically, Germany is ranked third after the USA and Great Britain. In the Federal Republic of Germany, related research is mainly promoted by the German Research Foundation (DFG) and the Federal Ministry for Education and Research (BMBF); due to the huge potential market in the field of oncology, industrial companies are also involved in these developments. Moreover, gene therapy research is proving to be an attractive proposition for the new generation of academic scientists.

Legal framework in Germany

According to German law, gene therapy is defined as a "medical treatment with gene transfer medicinal products" (section 4, paragraph 9 of the German Medicines Act). The legal admissibility of clinical tests is mainly based on an assessment of risks and benefits. Since every experiment in the field of gene therapy explores unknown scientific ground, the risks and benefits of a gene therapy are hard to predict at present and must be re-evaluated with every scientific development in this field. The following risks are taken into consideration:

- ▶ risks to the life, health and autonomy of the patients involved,
- ▶ direct risks to third parties and to the environment (e.g. risk of release),
- ▶ indirect ethical risks which emerge from the possibility of a germ line transfection (even accidental) and from a 'new eugenics'.

There is general consensus that the optimistic predictions prevalent 10 years ago concerning the expected limited risks can no longer be maintained. On the other hand, the 'Senate Commission on Genetic Research' of the German Research Foundation has expressed cautiously optimistic arguments regarding gene therapy research, at least for diseases that cannot be treated otherwise. However, the Senate envisages possible applications of gene therapy at some point in the distant future.

Bound formally and by law, gene therapy experiments, including clinical studies, are regulated by the Embryo Protection Law, the Gene Technology Law which regulates the pre-clinical field, the German Medicines Act, and the directive on the application of good clinical practice relating to the conduct of clinical trials on medicinal products for human use (GCP directive) and finally the relevant paragraphs in the German Criminal Code.

The German Medicines Act regulates clinical trials on gene transfer medicinal products. It differentiates between different purposes, i.e. whether the objective is to gain scientific knowledge or to attempt to cure an individual patient. Approval for a clinical trial requires two steps to be taken: Firstly, consent must be granted by the ethics commission in charge and then by the Paul-Ehrlich-Institut. In order to reach a decision on gene therapy experiments, the ethics commissions have to consult an expert. Every case has to be decided on an individual basis.

A special case is somatic gene therapy in embryos: The Embryo Protection Law prohibits any intervention in embryos created *in vitro* or *in vivo*. Prenatal gene therapeutic treatment of a foetus, i.e. a therapy *in utero* is more feasible, since it is not subject to the embryo protection law or the criminal code. If it is carried out on the basis of a prenatal diagnosis, it is one of the potential options for the future.

Interventions in the cells of the germ line are prohibited by the Embryo Protection Law. At this point in time, they are categorically forbidden on ethical grounds. Indeed, the strongest argument against germ line therapy is being forwarded by the scientific community: In a system as complex as the human genome, the consequences of an intervention that may occur either directly in an individual or in later generations are not only unforeseeable technically but cannot be anticipated in principle. In any case, a germ line therapy would be technically impossible at this point in time. Moreover, there exist no medical indications for its application.

Non-therapeutic interventions into the human genome, so-called genetic enhancements, are currently discussed mainly in the context of gene doping. However the possibility of changing the genetic characteristics of an individual or of the human species has a long history of discussion, at least since the 'Man and His Future' symposium in 1962 (cf. Wolstenholme, 1963). More recently, the subject has re-surfaced as 'new eugenics'. Thus, one could focus on the 'unjust' – since it is unequal – distribution of genetic characteristics and demand its correction in order to achieve equality of opportunities. Aside from such – utopian – ideas, enhancement already occurs these days outside of gene technology, for example in cosmetic surgery and neuropharmacology (nootropics) and is accepted, at least in some parts of society.

Similarly to the distinction between therapeutic and enhancement applications, the line of what is ethically acceptable is drawn between somatic interventions and interventions in the germ line. The latter are in fact interventions into the development and evolution of mankind that have incalculable consequences for an individual and his offspring.

Research-ethical implications of somatic gene therapy

The majority of the population has a generally positive attitude towards somatic gene therapy, although it can be assumed that new techniques will initially meet with fear and rejection. In the case of somatic gene therapy, the ethical postulate is accepted that scientific and medical practice should serve the welfare of mankind. This positive attitude is based on the assumed benefits of gene therapy and on the euphoric promises of healing by scientific means. The ethical discussion – analogous to the legal discussion – distinguishes between somatic and germ line therapy and between therapeutic and enhancing interventions. Somatic gene therapy with the aim of healing is thus considered ethically legitimate for its high moral goals.

Figure 5: Options of gene transfers

intention	therapy / prevention	enhancement
depth of engagement		
somatic cells	somatic gene therapy	gene doping
gametes	germ line therapy	improvement in the genetic fundamentals of offspring

This consensus has to be questioned however, and a risk-benefit assessment has to be taken into consideration: The risks are substantiated by the setbacks in the gene therapy experiments in the 1990s, the benefits by the successful 'proof of principle'. It has to be emphasized, that both arguments are based on a small number of cases for single indications or on treatments and clinical studies with few or single patients. Statistically reliable data is not available in most cases, and furthermore some of the studies were conducted a long time ago and in part undertaken without due regard for the official requirements or under illegal experiment conditions. For clinical studies in the near future and for the application of gene therapy studies on humans, the ethics commissions and the licensing authorities have to rely on limited data and require latitude of judgement at the moment.

Nonetheless, there are some ethical guidelines available: At this point in time, the application of gene therapies is ethically acceptable only in cases of severe or life-threatening diseases that cannot be treated using other methods. The first ethical prerequisite is the informed consent of the patient or, in the case of children and individuals who are unable to give their consent, the consent

of the parents or legal guardian. Whether the patient gives his consent depends predominantly on the opinion and expectations of the attending staff and the information available to them and then passed on to the patient. The individual benefit for the patient must be given priority; but the knowledge gains for future treatments must also be given ethical consideration. A line must be drawn here according to the ethical principle that people are not to be exploited. The result of these considerations is a stalemate that the attending doctor and the ethics commission in charge can only resolve through subjective evaluation. The Federal Medical Association and the German Research Foundation have formulated special procedural requirements and interpretable ethical guidelines. Additionally, the gene therapist can refer to single-case decisions made earlier by the ethics commissions, medical associations and licensing authorities.

The ethical issues concerning genetic technological interventions into the human germ line have already been discussed in relation to legal issues. Germ line therapy is rejected not only nationally but also internationally, for example by the European Society of Gene and Cell Therapy. The authorities do not officially discuss germ line therapy in Germany; they limit themselves to pointing out that it is prohibited. The ethical arguments for its rejection are the unmanageable risks, the slippery slope argument and the principle forbidding the exploitation of people. Its supporters, on the other hand, invoke the commandment to help the severely ill and to serve the welfare of mankind – although regarding this argument it has to be considered that there exist no medical indications for germ line therapy.

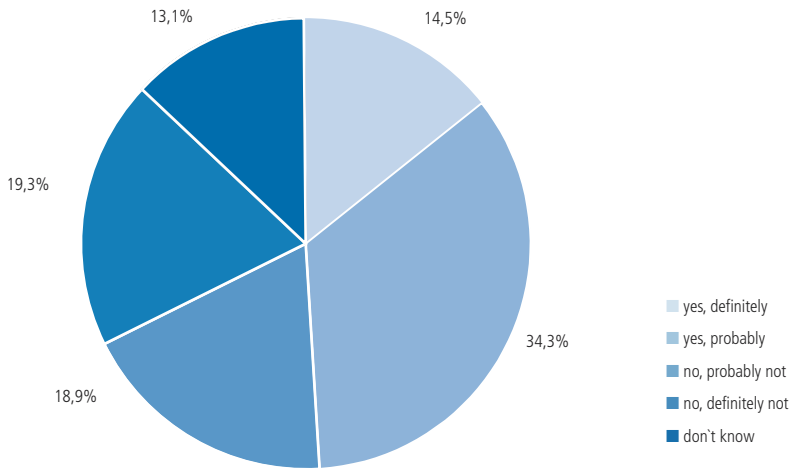
Gene therapy in public perception

Unlike genetic engineering for agriculture and GM food, gene therapy only accounts for a small part of the public debate on gene technology. This may be attributed to the situation described above: Following initial setbacks, unspectacular cell biological basic research has been pursued for about a decade in order to create the prerequisites for successful therapies.

The 2005 Eurobarometer 64.3 survey provides well-founded data. The survey shows that in 2005 less than half of the respondents had heard about gene therapy (45% in Europe as a whole, 41% in Germany). However, acceptance was much higher than for the use of genetic technological procedures in agriculture. The 1997 Biotech Survey, for example, showed 70% acceptance for gene therapeutic procedures; among those who rejected gene technology in food only 9% were opposed to gene therapy (cf. Hampel/Pfennig, 1999). These figures can be explained by the positive expectations towards new medical therapeutic procedures. Since then, between 1997 and 2005, the public has become more sceptical, although its attitude towards gene therapy remains more positive than towards genetic engineering for agriculture and GM food. However, 20% of the respondents in Germany were strictly against gene therapy in 2005, twice the European average (Figure 6).

In further detail, it emerged that few respondents perceived significant benefits, probably due to the fact that no therapeutic applications are yet known. Women responded with more scepticism than men; the perception of benefits increased with higher levels of education. The perception of risks

Figure 6: Support of gene therapy in Germany



Source: Eurobarometer 64.3, 2005

was also significant: 54% of Germans regard gene therapy as risky: this figure is lower among 15- to 24-year-olds (44%), and higher among the over 64-year-olds (62%). It is notable that few Germans feel protected by the regulating authorities in charge. However, the level of trust in the regulating authorities to provide protection rises with education levels. Both groups, supporters and opponents of gene therapy, demand stricter regulation.

The acceptance of gene therapy does not follow, as with other technologies, the so-called deficit model – which means that deficits in the knowledge of gene therapy do not diminish acceptance. However, greater knowledge leads to greater polarization: the number of those who do not express an opinion decreases. Ultimately, the degree of knowledge about cells, genes and molecules correlates clearly with the acceptance of gene therapy. A similar correlation can be observed in the relation between the benefits expected and a positive attitude.

The complexity of the correlation of parameters such as risk-benefit perception and ethical acceptability render clear statistical statements impossible. The data are summarized, resulting in a typology of supporters, risk-tolerant supporters and opponents of gene therapy; these three types are, according to this analysis, represented in approximately equal proportions. The following results emerged concerning the willingness to participate in the public debate: Neither the majority of the supporters nor the majority of the opponents would participate in demonstrations. But there was a great difference in the respective groups' willingness to participate in discussions or hearings: Almost half of the opponents (43%) and only 22% of the supporters of gene therapy said that they would

not be willing to participate in a public debate on gene technology. Other criteria also showed that the supporters were more prepared to represent their interests.

Overall it can be stated that the general public is animated to a much lesser degree by gene therapy than by genetically modified food products – public opinion is less polarised. However, people are not fully convinced of the benefits of gene therapy and its ethical and practical innocuousness. Nonetheless, a significant majority supports therapeutic applications. While the critics of gene therapy explain their rejection primarily on ethical grounds, its supporters invoke scientific arguments. It is to be expected that this attitude will change as soon as new results reporting successes or failures in gene therapy studies enter public awareness.

Core statements and recommendations

Technology development and application

As a consequence of the human genome project, more than 2000 genes linked to diseases have thus far been identified. In principle, this facilitates a more targeted application of gene therapies. One prerequisite is, nonetheless, to eliminate the existing technical difficulties inherent in gene therapeutic approaches.

Following the setbacks in the 1990s, somatic gene therapy now focuses mainly on the development of more efficient and 'safer' vectors. This stimulates not only medical applications but also molecular and biological basic research. Furthermore, advances in accessory disciplines such as cell therapy, including stem-cell biological basic research, diverse imaging techniques and developments in molecular toxicology, will be important for the future of gene therapy.

Despite promising pre-clinical data none of the gene therapy approaches has proven itself adequate to replace conventional tumour therapies such as surgery, chemotherapy or radiation therapy. Nonetheless, the combination of gene therapy with other experimental or established conventional therapies seems to be a sensible and forward-looking option. Costs, risks and benefits of gene therapy approaches therefore have to be constantly compared to other approaches such as prevention or small molecule therapy. At this point in time it is not foreseeable when (and if at all) somatic gene therapy can be developed from the individual treatment of individual patients to a broader application for severe and common genetically caused diseases. Somatic gene therapy will, for the time being, be confined to monogenic diseases and oncology.

Enhancement applications and germ line therapy

Non-therapeutic interventions into the human genome (somatic interventions as well as interventions into the germ line, so-called genetic enhancement) are currently under consideration, particularly in the context of gene doping.

The problematic differentiation between prevention, rehabilitation and enhancement, or doping in the context of gene therapeutic procedures requires an intensified debate on the ethical issues. Due to the incalculable and currently uncontrollable risks they pose, gene doping and other attempts at enhancement must be prohibited.

Ethically founded moral judgements categorically prohibit all attempts in the direction of germ line therapy at this point in time.

Public and private research funding

Western Europe (Great Britain, the Netherlands, Belgium, France, Italy, Germany and Sweden) has, in certain clinical and pre-clinical areas, currently gained a development advantage over the USA. The national research policy of the German Research Foundation and the Federal Ministry for Education and Research has played an important role in this process, together with the network-building efforts of the EU.

It can be stated that research on somatic gene therapy in Germany is internationally competitive. However, these high standards can only be maintained if the state provides adequate funding. Under these circumstances, public academic research programmes should ideally be extended, Industrial partners' faith in gene therapies could be regained by this means. If the marginal private company activities in gene therapy are reduced further and translational structures fail to receive state funding, Germany could gradually lose the infrastructure necessary for clinical studies and for the development of gene therapeutic products and procedures.

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Supplement of the German Gene Technology Report
Summary

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