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Introduction

The year 2011 was an exceptionally creative one for the German Ethics Council. This is shown not only by the large number of meetings of the plenum and the working groups, but also by the number of Opinions presented and of public events and further initiatives of public discourse.

With regard to providing information to politicians and the public, the Opinions and public events are the cornerstones of the Council's work. In this connection, pride of place goes to the three Opinions which the Ethics Council presented in 2011: "Medical benefits and costs in healthcare: The normative role of their evaluation" (January 2011), "Preimplantation genetic diagnosis" (March 2011) and "Human-animal mixtures in research" (September 2011). In addition to the intensive consultations on the Opinions, the Ethics Council held six public events and introduced a new style of public debate in the form of an online discourse.

In order to encourage direct exchange of opinions between the Ethics Council and the members of the German Bundestag, two Parliamentary Evenings were held, in the course of each of which the Council's latest Opinions were presented and discussed. The Bundestag members find these events extremely interesting, as was shown in particular by the fact that more than forty members attended the Parliamentary Evening on 23 March 2011 on the Bundestag premises. The President of the German Bundestag, Professor Dr. Norbert Lammert, welcomed the Ethics Council members and expressly thanked the Ethics Council for the Opinion on preimplantation genetic diagnosis. He praised this as an extremely important document in which the Bundestag members could find all the relevant information including an objective weighting and evaluation of the arguments. He said that this was the kind of consultation which he hoped to see in the work of the Ethics



Parliamentary Evening of the German Ethics Council at the Paul-Löbe-Haus of the German Bundestag

Council and which all members could use in order to form their own opinion on ethically problematical questions.

The second Parliamentary Evening on 26 October 2011, in which Eduard Oswald, the Vice-President of the German Bundestag, welcomed the Council members, was also well received by the members, who used it to inform themselves on the Opinion on human–animal mixtures and to discuss the topic.

The year 2011 was dominated by the work on the Opinion on intersexuality, which the Federal Government instructed the Ethics Council to prepare in December 2010. The Ethics Council found that the state of scientific data on this topic was insufficient, and therefore it commissioned a survey of persons affected and experts, arranged a public hearing and initiated an online discourse, in which the internet was first used as a forum for public debate.

At the end of October 2011, the Federal Government commissioned the Ethics Council to prepare an Opinion, for the second time since the Council was constituted in April 2008. In a joint letter from Professor Dr. Annette Schavan, the Federal Minister of Education and Research, and Daniel Bahr, the Federal Minister of Health, the Ethics Council was requested in the name of the Federal Government to prepare an Opinion on the topic of “The future of genetic diagnosis from genetic research to clinical practice – social challenges of new methods of genetic diagnosis, taking particular account of predictive and prenatal methods”.

The German Ethics Council is required by law to follow the ethical, social, scientific, medical and legal questions and the expected consequences for the individual and society which arise in connection with research and developments, in particular

in the field of life sciences and their application to humans. Its duties include informing the public and promoting social discourse involving the various social groups, preparing Opinions and recommendations for political and legislative action and working together with national ethics councils and similar institutions of other countries and of international organizations. The present report documents, in compliance with section 2(4) of the *Ethikratgesetz* (Ethics Council Act, see appendix) in what way and to what extent the Council fulfilled this requirement in the time from January to December 2011.

Topics

With a view to the publication of an Opinion, the German Ethics Council considered the following topics in 2011:

- medical benefits and costs in healthcare,
- preimplantation genetic diagnosis,
- human–animal mixtures in research,
- intersexuality,
- dementia and self-determination,
- genetic diagnosis.

These and other topics were addressed by the Ethics Council in specific working groups and also in public plenary meetings and other public events (see p. 24 ff.).

Medical benefits and costs in healthcare

On 27 January 2011, the German Ethics Council published its third Opinion. On the occasion of the legislative debate in the context of the *Gesetz zur Neuordnung des Arzneimittelmarktes* (Act on the Reform of the Market for Medicinal Products) and of the planned *Gesetz zur Verbesserung der Versorgungsstrukturen in der gesetzlichen Krankenversicherung* (Act to Improve the Health Care Structure), the Ethics Council's Opinion was intended to help bring the difficult questions of the equitable allocation of resources to the attention of the public and the political world, using the example of ethically disputed methods of evaluation in health economics.

Germany has one of the most comprehensive healthcare systems in the world. Nevertheless, there are increasing signs

of deterioration of quality arising from relative scarcity of resources in areas of healthcare and of outpatient and inpatient care. Against this background, the Ethics Council regards it as essential to discuss limits that will be placed on solidarity-based (collective) financing of healthcare treatments in the future. If it transpires that it is no longer possible to finance a comprehensive system of healthcare in which every citizen may obtain every medically advisable benefit, there must be a discussion of legitimate entitlements and fair distribution, that is, ultimately of social justice in questions of healthcare. The debate must concern the extent of the entitlements required on moral grounds and of those guaranteed as fundamental rights.

Evaluation of costs and benefits

Attempts are often made to address situations of scarce resources by the instrument of efficiency savings. It is a matter of experience that innovative medicinal products are very expensive. For this reason, a particular aim, internationally as well as in Germany, is to identify potential savings in this field and mechanisms for their achievement. One instrument is the evaluation of the medical benefit and cost-effectiveness of medicinal products. International health economics has developed instruments of cost-effectiveness analysis, which, however, are not uncontroversial. In Germany, the *Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen* (Institute for Quality and Efficiency in Health Care) has since 2007 been required by statute to establish cost-effectiveness analyses on the basis of



German Ethics Council (ed.): Medical benefits and costs in healthcare: The normative role of their evaluation. Berlin, 2011 (ISBN 978-3-941957-20-6)



Eckhard Nagel, spokesperson of the working group, and Christiane Woopen, Vice-Chair of the Ethics Council, during the presentation of the Opinion “Medical benefits and costs in healthcare: The normative role of their evaluation”

“internationally recognized standards”. These analyses are intended to serve as recommendations for the *Gemeinsamer Bundesausschuss* (Federal Joint Committee), which is responsible for determining the extent of treatments provided under the statutory health insurance scheme. However, whether and how such analyses should be conducted and implemented in health policy is not a value-free economic decision, but has significant legal and ethical implications, particularly since the outcome may also entail restrictions on medically necessary treatments. While the analyses are based on economic considerations, their calculations and models are by no means politically or ethically neutral. The implementation raises far-reaching questions of justice which call for careful reflection.

Benefit to the patient

In the determination of benefit to the patient, the measurement of quality of life presents a particular challenge, because this parameter is qualitative and not, as in the case of longevity, purely quantitative. In addition, there is no uniform standard for assessing quality of life. Since analysis

of the medical benefit of a measure is the ultimate criterion for the provision or otherwise of that measure in the statutory health insurance scheme, particular importance attaches to the measurement of quality of life. The Act on the Reform of the Market for Medicinal Products introduced a systematic evaluation of the medical benefits of all medicinal products. Although this is a significant advance, it does not go far enough, owing to the limitation to early evaluation of medical benefits. For the actual benefit of a medicinal product often emerges only years after licensing from evidence-based data accruing from scientific studies. This may result in the application of therapies which, while deemed effective, offer no medical benefits, or only minor benefits in comparison with other therapies, to the patient group concerned. In addition, the patients may thereby be exposed to a high risk of harm, the patient’s trust in his* doctor may be undermined, and lastly there may be a quite considerable waste of resources. In the view of the Ethics Council, reduction of the instrument of benefit assessment to the status of a pricing aid is unacceptable from the point of view of

* In the following, for convenience, the masculine form is used for both sexes.

quality assurance and protection of the patient and incompatible with economically efficient utilization of solidarity-based resources.

Equitable distribution of resources

Establishing criteria for an equitable distribution of healthcare resources is a political task with medical, economic, ethical and legal aspects. In view of the complex issues involved, however, it is impossible to arrive at a consensus between all interested parties. Nevertheless, the German Ethics Council is of the opinion that principles can be formulated against which existing structures and processes must be measured.

The Ethics Council regards it as urgently necessary for prioritization, rationalization and rationing in the health care system to be openly discussed. Every form of “concealed rationing” of medical treatments and benefits must be rejected. Necessary decisions on rationing must not be delegated to an individual medical practitioner or nurse. Acknowledgement of the existence of the problem of how scarce healthcare resources should be distributed does not imply the espousal of an “economization” of decisions. An objective debate in fact calls for the involvement of medical, economic, ethical and legal expertise in a transparent process. Decisions on the extent of solidarity-financed treatments are ultimately ethical decisions, which must be taken on the basis of social discourse and through the political process.

All decisions must proceed from the starting point of the principle of human dignity and fundamental rights, which call for every citizen to have access to appropriate healthcare, this access being guaranteed by rights. These rights must not be subordinated to any considerations

aimed at raising the level of collective medical benefits. Again, the calculated or presumed socioeconomic “value” of individuals or groups must not be the basis of distributional decisions.

Recommendations

On this basis, the German Ethics Council formulates twelve recommendations which should be followed by decision-makers in the healthcare system when they draft statutory provisions, in order to achieve the best possible and at the same time equitable use of the funds for the healthcare system.

If scarce care resources are to be used responsibly, they must be employed for measures that really do yield medical benefits under field conditions. In addition to early evaluation of medical benefits for pricing purposes, it must remain possible for the Federal Joint Committee and the Institute for Quality and Efficiency in Health Care to conduct a comprehensive evaluation of medical benefits at any time irrespective of cost considerations, in particular in relation to the patient-focused end points of mortality, morbidity and quality of life. In the case of important groups of indications, a systematic second stage of evaluation of benefits should follow as a matter of course after an appropriate interval, not only for medicinal products, but also for non-pharmacological treatments. It must always be possible to exclude a given treatment from the range of treatments provided on grounds of lack of medical benefits where necessary for reasons of patient protection.

The Ethics Council recommends that transfer- and care-provision-related research should be expanded, as well as manufacturer-independent subvention of clinical studies in the practical treatment situation after a medicinal product

or medical device has been licensed. This should be linked to the systematic identification of research topics of particular relevance to the provision of medical care, for instance by the Federal Joint Committee. An appropriate statutory framework should be established for this purpose.

An eventual aim should be the compulsory publication of all studies, regardless of their findings, and not only of confirmatory studies conducted for licensing purposes, as well as of post-licensing clinical trials. This is the only way to guarantee access to all data relevant to the assessment of medical benefits.

In the context of the cost-effectiveness analysis of medical treatments, there are important ethical and equity-related reasons not to apply the principle of maximization of medical benefits across patient groups. The legislature should therefore clarify Section 35b of Book V of the *Sozialgesetzbuch* (SGB – Social Code) (evaluation of the cost-effectiveness of medicinal products) accordingly. Yet calculations of cost-effectiveness based on an efficiency frontier approach can also not be deemed ethically “neutral” when applied as a criterion for the appropriateness of decisions on reimbursement for innovations. This is because the cost-effectiveness of the particular established therapy that offers the greatest level of medical benefit in the relevant field of indications – i.e. the status quo – is based on a variety of factors which are not always coordinated with each other. In referring to taking account of the international standards of health economics (section 35b(1) sentence 5 SGB V), the legislature has failed to lay down sufficiently clear requirements.

The effects of the current requirements concerning cost-effectiveness analysis in Germany are at present essentially not harmful, because an insured person’s

entitlement to the provision of all medically necessary care is legally unchanged. These requirements currently serve not as an instrument for the distribution of scarce resources, but for pricing purposes. However, the likely future need of rationing decisions will compel the legislature to clarify the extent to which entitlements to treatments under section 27 and section 12 SGB V may be influenced by a cost-effectiveness analysis, and to spell out the relative roles of this analysis and of the criterion of medical need.

Preimplantation genetic diagnosis

In July 2010, the *Bundesgerichtshof* (Federal Court of Justice) acquitted a doctor who had filed a criminal complaint against himself for conducting genetic tests on embryos, and following this, in August 2010, the German Ethics Council established a working group with the purpose of preparing an Opinion on preimplantation genetic diagnosis (PGD). The Opinion was presented at an early date, on 8 March 2011. In the Opinion, the Council set out the arguments for and against PGD in detail and provided a variety of proposals for legislation on PGD.

Against the background of current scientific, technological and legal developments, which raise a large variety of ethical and social questions with regard to the need for legislation on PGD, the Opinion describes current practice and the new possibilities of genetic diagnosis of embryos, sets out differing positions and arguments on the status and protection of the embryo, and lists the most important socio-ethical aspects, which are subject to considerable controversy in the current debate.



German Ethics Council (ed.): Preimplantation genetic diagnosis. Berlin, [in print] (ISBN 978-3-941957-34-3)

From the left:
Wolfgang Huber,
Christiane Woopen,
Edzard Schmidt-
Jortzig, Wolf-Michael
Catenhusen, Ulrike
Riedel and Jochen Taupitz
during the presentation
of the Opinion
“Preimplantation
genetic diagnosis”



Clinical practice

In order to obtain an impression of the current and probable future clinical practice with regard to PGD and the law governing it, in December 2010 the Ethics Council invited representatives from European countries in which PGD is already practised to attend an exchange of views. In the case of blastomere biopsy, which is the PGD procedure most widely used at present, one to two totipotent cells are removed from the embryo on the third day after fertilization, that is, in approximately the eight-cell stage; this is prohibited in Germany by the *Embryonenschutzgesetz* (Embryo Protection Act). At least with regard to establishing aneuploidy, it has as yet not been shown that this method improves the prospect of a healthy child, among other things because at this stage the embryo's cells often have genetic differences which mean that the number of chromosomes of an examined cell is not very informative.

But currently, improvements in the speed and reliability of the diagnostic testing methods used, in particular in the area of DNA chip technology, are increasing the probability that meaningful tests for

specific genetically based diseases and chromosome abnormalities can be carried out even on older embryos, that is, on the fifth day after fertilization (blastocyst biopsy). At this time, the embryo's cells are no longer totipotent, and therefore even in Germany their examination would not be ruled out at the outset. However, for PGD to be carried out successfully, normally more embryos are needed than the three which, according to prevailing opinion, the Embryo Protection Act permits.

Status of the embryo

The question as to how far the production of such superfluous embryos can be justified depends decisively on how the status of the embryo is assessed. In this connection, the German Ethics Council states clearly that this question cannot be unequivocally answered either legally or ethically. This follows from an analysis of the constitutional framework and of varying positions on the moral status and protection of the embryo. Advocates of one position are of the view that after fertilization is completed a graduated protection of life cannot be justified and also refer to a special responsibility to the embryo

created in vitro. Advocates of the other position, however, argue that parental responsibility only begins to grow when pregnancy is established and continues, and that in the first days of its development the embryo may and can very well be differently assessed and protected than prenatal life in its later stages of development, in particular after the embryo has embedded itself in the uterus.

Socio-ethical aspects

The Opinion also shows contrasting perspectives with regard to socio-ethical questions. There are different assessments here as to whether the permission of PGD might mean fundamental social acceptance of the selection of genetically conspicuous embryos and how far this might lead to discrimination against persons with a disability or put pressure on future parents to have such tests carried out at all or to decide against a life with affected children.

Proceeding from these scientific, legal and ethical considerations, the Council members next develop two opposing arguments for and against the permission of PGD in Germany.

Position statement in favour of restricted permission

A group of thirteen members of the German Ethics Council regard PGD, subject to particular restrictions, as ethically justified, because PGD creates the possibility of avoiding a lawful termination of pregnancy following prenatal diagnosis and on the basis of medical indication, and also offers an opportunity of assistance to couples who for genetic reasons have experienced repeated miscarriages or stillbirths. In both cases, the permission of PGD is supported by good reasons relating to the protection of the woman's health.

Those in favour of the restricted permission of PGD proceed on the basis of six principles, for which they give detailed reasons in the Opinion:

1. The way should be open for a couple to fulfil their desire for children, even if they know that they may pass on a serious genetic disease to the child.
2. The rights and the claims to protection of the mother must be weighed against those of the embryo; however, those of the mother may not be unilaterally pushed aside.
3. The use of PGD should be restricted.
4. The use of PGD may be restricted.
5. The decision of a couple in this situation does not constitute discrimination against persons with disabilities.
6. The concept of protection of a restricted permission of PGD avoids a conflict with the existing concept of protection of unborn life in our legal system.

Against this background, these Council members devise a number of recommendations for legislation governing a restricted permission of PGD.

According to these, a high degree of medical risk is necessary for genetic tests to be conducted on embryos. This exists

- a) if evidence shows that the parents have a hereditary disposition which if it were passed on to the child would result in a serious illness or disability and if it were established by prenatal diagnosis would constitute a medical indication for termination of pregnancy by reason of an endangerment of the physical or psychological health of the woman in question,
- b) if there is evidence that the parents have a high degree of risk of passing on a chromosome disorder or other

mutation which excludes extrauterine viability of the embryo or

- c) if, after repeated miscarriages or unsuccessful attempts at treatment by assisted reproduction after thorough medical clarification, the parents have a high degree of risk of germ cell maturation disorders, with the result that a large proportion of the embryos created are not viable outside the womb. In these cases, PGD should be carried out only in clinical studies, in order to establish scientifically that it is effective in this area, which has not as yet been shown.

On the other hand, in the opinion of these Council members, PGD is impermissible and must be prohibited by statute

- a) to determine the sex of an embryo, unless this is done in order to prevent the birth of a child with a very serious, sex-linked congenital genetic anomaly,
- b) if it is to be carried out with the objective of selecting an embryo to donate cells, tissues or organs for another person,
- c) if, without any of the indications set out above, it is, for example, to be carried out to prevent a risk of chromosome disorders in the embryo which is assumed solely on the basis of the woman's age, and
- d) in the case of late-onset illnesses.

The supporters of a restricted permission of PGD recommend that the legislature should lay down these criteria but should not create a catalogue of individual illnesses or disabilities in the case of which PGD may be considered.

In addition, they suggest that there should be rules of procedure for conducting PGD, which should be uniform nationwide. After the determination of

the genetic risk and counselling from a human geneticist, after medical advice from a specialist in reproductive medicine and after psychosocial advice by an advice centre recognised under the *Schwangerschaftskonfliktgesetz* (Conflicted Pregnancy Act), the diagnosis should be made jointly by the experts involved in the counselling and a representative of the IVF commission of the State Chamber of Physicians.

In addition, the position in favour contains suggestions on the treatment of superfluous genetic information in the course of PGD, on avoiding superfluous embryos and on the organization and documentation of the conduct of the PGD.

Position statement supporting prohibition

A group of eleven members of the Ethics Council is of the opinion that permission of PGD is ethically indefensible, since it would call into question the protection of embryos created in vitro as a form of human life which deserves respect in itself.

They accept that great weight attaches to the hopes and wishes of couples carrying genetic risks who wish to realize their desire for healthy children with the help of PGD. But they argue that careful ethical examination of PGD and the development it may be expected to take nevertheless leads to the conclusion that the procedure should be expressly prohibited.

The opponents of permission cite the following reasons for this:

1. The embryo created in vitro, because it was artificially created, is subject to a particular and novel responsibility, since there are no comparable possibilities of intervention in the case of natural conception in the first days of

- embryonic development. This particular responsibility forbids creating embryos in vitro in order to discard them in the case of undesired characteristics.
2. PGD is associated with selective consideration which is aimed at selecting some of the embryos created in vitro and discarding the others. This fundamentally differentiates PGD from the situation of termination of pregnancy by reason of medical indication after prenatal diagnosis. For this reason, PGD cannot be justified by a comparison with prenatal diagnosis in which prenatal diagnosis – let it be noted that this is in contradiction to the current statutory provisions – is interpreted as a means to achieve “pregnancy on approval”.
 3. But such a comparison shows that PGD would reintroduce an embryopathic indication, that is, the permission to discard human life by reason of undesired characteristics. But this embryopathic indication was expressly removed from the law on conflicted pregnancy in 1995.
 4. Permitting PGD would result in grave consequences for the protection of embryos. The “rule of three”, which is intended to ensure that human embryos may only be created in vitro for the purpose of human procreation, could not be maintained. Instead, a large number of “superfluous” embryos would be created whose fate would be uncertain.
 5. A restriction to a few groups of cases or to serious diseases could not be adhered to. On the contrary, it can be anticipated that the indications and occasions for the use of PGD will be increased, and this has already happened in other countries which have permitted PGD.
 6. The technological development of chip-assisted diagnosis techniques makes it probable that in the foreseeable future PGD will be used more broadly for the diagnosis at the same time of a large number of genetic deviations or dispositions to illness. For the embryos examined, these techniques will provide results which were not even sought. This “superfluous information” will result in a selection of embryos over and above a selection for “narrowly defined” reasons.
 7. With such developments, the pressure on parents carrying genetic risks who do not wish to undergo PGD, and on persons with disabilities, in particular with genetically caused disabilities, would increase. Such a development would be contrary to the efforts on behalf of integration and inclusion of the disabled.
- In the opinion of the signatories to this position, the anxieties and wishes of couples carrying genetic risks must be taken seriously, But they do not justify the introduction of PGD. Instead, it must be ensured that there is better counselling and support for affected couples or families; it must also be determined whether their genetic problems can be alleviated by means of other procedures.

Dissenting position statement

In a dissenting position statement, one Council member advocates permitting PGD to identify embryos that are capable of development. For those situations in which genetic malfunctions are not compatible with life, it is argued, PGD is capable of forestalling pregnancies which are biologically hopeless and which would only result in a danger to the mother or to the parents. This applies, for example, to

most aneuploidies and many other chromosome abnormalities, but also to some illnesses which are untreatable and which result in death shortly after birth. In order to enable a clear definition of the possibilities of application of PGD under such aspects, however, there must be a binding catalogue of indications.

Human–animal mixtures in research

How do we understand the distinction between humans and animals? What is the significance for humans' self-image of a research development which increasingly calls into question the biological demarcation between humans and animals? Where is there already a need for action by scholarship, society or the political world? The German Ethics Council presented an Opinion on these questions on 27 September 2011.

The self-image of humans is characterized by a strict distinction between humans and animals. Even though from a biological point of view humans are also part of the animal world, ethics and law are based on a strict differentiation, and this also plays a fundamental role in religion and culture. However, despite being conscious of a clear distinction, in their imagination humans do cross the boundary they have created themselves. Thus, for example, mythological tradition is replete with reports and images of mixtures of animals and humans, the Sphinx, Pegasus, the Chimera, centaurs and mermaids.

In biomedical research too, humans have long since begun to cross the boundary between humans and animals. The breeding of mice as “model organisms” for research on human disorders by the

introduction of disease-specific human genes into the mouse genome has been commonplace since as long ago as the 1980s. Researchers are now working on the transfer not only of genes, but also of entire chromosomes. In addition, nerve precursor cells derived for instance from human stem cells have been transferred into the brains of experimental animals, including primates, for the investigation and possible eventual treatment of disorders such as Alzheimer's and Parkinson's disease. The Ethics Council began to concern itself with the topic when the Human Fertilisation and Embryology Act in the United Kingdom expressly legalized the creation of cytoplasmic hybrids (cybrids), formed by the insertion of a human somatic cell into an enucleated animal egg, in order in this way to be able to create embryonic stem cells without resorting to human oocytes. The topic attracted great interest in Germany too, in view of the fact that the Embryo Protection Act does not prohibit the creation of such cybrids in Germany.

Such experiments increasingly call into question the biological species boundary between humans and animals. For this reason, the Ethics Council considers it necessary to identify the ethical challenges that may be presented by the creation of human–animal mixtures and to determine where it may be appropriate to set binding limits. With this in view, the Ethics Council concentrated its attention on the transfer of human material to animals, which it examines on the basis of three examples: cytoplasmic hybrids (cybrids), transgenic animals with human genetic material, and the transfer of human cells into the brains of fetal or adult animals (brain chimeras). The Ethics Council presented recommendations on these examples, which are as follows:



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Joachim Vetter, Head of Office, and the Ethics Council members Jochen Taupitz, Wolf-Michael Catenhusen and Jens Reich during the presentation of the Opinion "Human-animal mixtures in research"

I. General recommendations

I.1 The German Ethics Council is of the opinion that no human-animal mixtures should be permitted to be transferred to a uterus when it is clear in advance that it will not be sufficiently possible to allocate them to animals or humans ("genuine human-animal mixtures"). This applies irrespective of the dispute as to whether it is regarded as permissible to experimentally create such entities or use them in vitro.

I.2 The German Ethics Council endorses the prohibitions laid down in the German Embryo Protection Act (Section 7):

- no transfer of human embryos into an animal,
- no creation of interspecific chimeras or hybrids, that is, of living beings
 - by fertilization using human and animal gametes,
 - by fusion of a human and an animal embryo; or
 - by the joining of a human embryo with an animal cell that is capable of further differentiation with that embryo.

These restrictions should be supplemented by including the following bans:

- a ban on the transfer of animal embryos into humans,
- a ban on the introduction of animal material into the human germline,
- a ban on procedures that could result in the formation of human egg or sperm cells in an animal.

I.3 Under Article 49 of Directive 2010/63/EU, a national committee for the protection of animals used for scientific purposes is to be established in Germany. It is possible that the Animal Welfare Commission under section 16b of the *Tierschutzgesetz* (Animal Welfare Act) is to be entrusted with this committee's duties. This committee should make one of the main emphases of its work the field of research into human-animal mixtures, and in this connection it should have particular regard to the following topics:

- the creation of transgenic animals by the insertion of a considerable proportion of human genetic material and the incorporation of regulatory genes,

- the creation of human–primate brain chimeras,
- projects resulting in drastic changes in the appearance and capabilities of an animal.

The national committee should possess the wide-ranging interdisciplinary competence necessary for the purpose; it should draw up guidelines for the work of the regional animal welfare commissions in this field; it should be involved in relevant decisions of principle in this field; and it should perform its functions with due regard for the status of social discourse.

I.4 More transparency is called for with regard to research involving the creation of human–animal mixtures, for instance by the inclusion of detailed information on “human–animal mixtures” in the Federal Government’s animal welfare reports.

I.5 Experiments involving a high degree of manipulation, in particular the insertion of genes or the injection of cells during embryonic development, should be permissible only if of overriding importance in terms of their scientific objectives, especially as regards the anticipated medical benefits for humanity, and there should be an evaluation of their possible repercussions on the moral status of the mixed entity.

I.6 In biological and interdisciplinary research on the effects of the incorporation of human genes, chromosomes, cells and tissues in an animal organism, more attention must be devoted to ethical issues, including also the effects on behaviour and capabilities, as well as on phenotypic changes. The results of such research should be made public to a greater extent than hitherto.

II. Specific recommendations on the creation of cybrids

A cytoplasmic hybrid, or cybrid, is defined as a living cell formed by the fusion (hybridization) of an enucleated egg (for instance of a cow) with the nucleus of another, somatic cell (in the present case a human somatic cell).

II.1 Irrespective of the question of a possible ban on the creation of human–animal cybrids, the German Ethics Council unanimously recommends prohibition of the implantation of human–animal cybrids into a human or animal uterus. An explicit prohibition to that effect should be incorporated in the Embryo Protection Act.

II.2a The members of the German Ethics Council who consider the creation and use of cybrids to be ethically acceptable take the view that a statutory prohibition is inappropriate.

[Stefanie Dimmeler, Frank Emmrich, Volker Gerhardt, Hildegund Holzheid, Weyma Lübke, Eckhard Nagel, Jens Reich, Edzard Schmidt-Jortzig, Jürgen Schmude, Jochen Taupitz, Kristiane Weber-Hassemmer, Christiane Woopen]

II.2b The members of the German Ethics Council who hold that the creation and use of cybrids is ethically unacceptable call for the incorporation of a statutory prohibition in the Embryo Protection Act.

[Axel W. Bauer, Alfons Bora, Wolf-Michael Catenhusen, Wolfgang Huber, Christoph Kähler, Anton Losinger, Peter Radtke, Ulrike Riedel, Eberhard Schockenhoff, Erwin Teufel, Michael Wunder]

III. Specific recommendations on the creation of transgenic animals with human genetic material

An organism is considered to be transgenic if its genetic material has been modified by technical manipulation involving

the integration of foreign or synthetically derived genetic material into the cell nucleus. The genes are transferred by various methods at a very early stage of individual development. All cells of the transgenic animal always carry the genetic modification, which is also passed on in the germline. However, the expression of the genetic modification may be confined to specific tissues, such as brain or blood cells. An animal is said to be transgenic if genes from other species have been inserted into it.

III.1 The incorporation of human genes into the germline of mammals (other than primates) is ethically acceptable if the objective of the research is of overriding importance in terms of the expected benefit to humanity and provided that the generally applicable ethical requirements of animal welfare are satisfied.

III.2 Owing to our provisional and limited knowledge of the possible effects on appearance, behaviour and capabilities, the insertion of human genetic material (genes or chromosomes) into the germline of primates should be permissible only after an interdisciplinary evaluation process involving the national committee. Such experiments should be carried out only if the expected medical benefit is of overriding importance and there is no alternative. Opinions differ on the definition of overriding importance and the absence of alternatives to be observed with regard to animal experiments in general.

III.3 The creation of transgenic human–animal mixtures involving great apes should be banned.

IV. Specific recommendations on the creation of human–animal brain chimeras

IV.1 The creation of brain chimeras by the transfer of human cells to mammals

other than primates is ethically acceptable if, first, the objective of the research is of overriding importance especially in terms of the expected medical benefit to humanity; second, the generally applicable ethical requirements of animal welfare are satisfied; and, third, chimerization does not take place prior to the development of organ primordia. To ensure that the conditions under which the animal is kept are appropriate to its species, the degree of cell integration and the behaviour of the animal after birth should preferably be monitored.

IV.2 In view of the possible degree of manipulation involved in the implantation of brain-specific human cells into primate brains, of the vital importance of the brain and nervous system for species-specific capabilities, and of our provisional and limited knowledge of the possible effects on physiognomy and cognitive capacity, the insertion of brain-specific human cells into primate brains should be permissible only after an interdisciplinary evaluation process involving the national committee as stated in Recommendation III.2.

IV.3 The insertion of brain-specific human cells into the brains of great apes in particular should be prohibited in accordance with Recommendation III.3.

Council member Regine Kollek explains in a dissenting position statement why she is unable to agree with the version of the Opinion as presented. In her statement she also notes that she considers the creation of human–animal cybrids to be ethically acceptable because there are good reasons for assuming that such entities do not constitute viable human embryos.

Intersexuality

The term intersexuality refers to a large number of different phenomena relating to persons whose gender identity is ambiguous, with varying causes. Data as to how many people are affected diverge widely, depending on which definition is taken as the basis. The terminology used itself implies a variety of definitions and evaluations in each case. Thus, for example, after the 2005 Chicago Consensus Conference the term intersexuality was replaced in medicine by “disorders of sex development”, abbreviated as DSD; this term also includes medical diagnoses which are not part of the concept of intersexuality. Since 2008, the abbreviation DSD – introduced by the *Arbeitsgruppe Ethik im Netzwerk Intersexualität* (Ethics Working Group within the Network Intersexuality) has also been referred to as “differences of sex development”. The expression “differences of sex development” represents a move away from viewing the phenomenon as a deficiency and towards respecting the variety of bodies and sexes. The underlying understanding in each case is particularly important when answering the question as to whether children born intersex may be surgically aligned to the male or female sex.

Socially, intersex persons are in an area regarded as taboo. The public obtain scarcely any information as to how they live or what their experiences and needs are. At most, the public receives a sense of the topic when intersex athletes come to the attention of the media following problematic and hurtful treatment of them by sports associations.

As early as June 2010, in its Bioethics Forum “Intersexuality – life between the sexes”, the German Ethics Council held discussions with intersex individuals

and experts from various disciplines as to how intersex persons live and what responsibility society bears in this connection. Following this, at the end of the year 2010, the Federal Government commissioned the Ethics Council to continue the dialogue and to prepare a report on the situation of intersex persons in Germany. In January 2011 a working group was appointed; it prepared and structured the discussions in the plenary meeting.

In view of the complexity of the topic and with the aim of finding a method of formation of opinions that was as discursive, transparent and participative as possible and which would contribute to freeing the topic of taboos, the Ethics Council conducted a discourse procedure in three stages. At the beginning of May 2011, a written questionnaire which could also be answered online was sent to intersex persons and also to experts and practitioners who are concerned with intersexuality within their specific fields. Following this, on 8 June 2011 there was a public hearing in Berlin of intersex persons, parents, doctors, psychologists and lawyers, in order over and above the written questionnaire to gather expert knowledge to create a solid foundation for the Opinion to be prepared. On the day of the hearing, the Ethics Council started an online discourse as the third stage of the proceedings. In this low-threshold and up-to-date manner it intended to facilitate a debate on a broad social scale, to obtain further important information and to trigger a mutual exchange between intersex persons, experts, practitioners and interested persons.

In this discourse procedure and in particular in the online discourse, the Ethics Council incorporated a new format for social debate in its range of activities. The digital discourse platform was set up in

Online:
www.ethikrat.org/veranstaltungen/forum-bioethik/intersexualitaet-leben-zwischen-den-geschlechtern

particular so that intersex persons who are not organized in networks were given a low-threshold opportunity to enter the debate.

Questionnaire

Questioning intersex persons, experts and practitioners was the first of three steps towards the creation of a solid base for the Opinion on the situation of intersex persons on which the Ethics Council is currently working. The main focus of the questionnaire is on medical intervention, information and consent, quality of life, integration and discrimination, networking between persons affected and the law of civil status.

Questions for experts and practitioners were directed to persons who are concerned with intersexuality in their occupations. They were requested to submit a written expert's report on the questions formulated by the Ethics Council. At the same time the Ethics Council was concerned to reach and question as many intersex persons as possible by way of contact with the organizations and self-help groups of intersex persons. These organizations passed the questionnaire on through their distribution lists and informed users on their websites and at their events of the possibility of taking part in the survey. Persons affected could also fill in the questionnaire online from 2 May to 19 June 2011. The answers received from doctors, therapists, social scientists, philosophers and lawyers can be accessed on the website of the German Ethics Council; the intersex persons were questioned anonymously.

Hearing and dialogue

The second step in the discourse procedure was the public hearing on the situation of intersex persons in Germany on

8 June 2011. The experts invited included doctors, psychologists, lawyers and representatives of parents' initiatives, organizations of intersex persons and self-help groups.

The hearing was conducted in two consecutive parts, in order not only to obtain the varying points of view of the persons heard but also to emphasize a variety of aspects of the topic. The first part deals with the topic "Medical treatment, indication, consent", and the second with "Quality of life, social situation and prospects of intersex persons".

In a first appraisal, the Council members who participated in the hearing stated that the central point in the debate was the right to physical integrity of those involved. In this connection there appears to be a consensus that irreversible medical intervention for the purpose of gender assignment must be deferred for as long as possible. Opinions differed as to whether this should be achieved by statute or by a medical code of practice. However, attention was also drawn to the fact that there may be individual cases in which irreversible intervention is necessary for urgent health reasons at an early date, when the child is not yet capable of consent, and this must then be possible in exceptional cases. All this makes it necessary for the boundaries to be defined as clearly as possible in the Opinion to be prepared. This is difficult and requires careful consideration.

An element seen as important in connection with medical intervention was the fundamental right of parents to decide on medical intervention in the best interests of the child as long as the child itself is incapable of deciding. Since medical intervention for gender assignment affects the core of every person's right of personality, his sexual identity, sexual

sensation and fertility, the parental right finds its limits here. This too suggests that such medical intervention should be carried out as late as possible, in order that the intersex persons affected may make their own decisions. In this connection it was suggested that there should be a moratorium on medical inventions in order to delay a decision on treatment and to allow the parents to get to know their intersex child. There was also a call for the child to be involved as far as possible. The child should be directly involved by way of ongoing information appropriate to age, interdisciplinary consultation and involving the child in all decisions, irrespective of considerations as to its ability to decide for itself.

A further topic which was identified for the Ethics Council's discussions was the law of civil status, although in the course of the hearing some of the intersex persons described it as secondary, albeit not unimportant. There was a call for the law of civil status to be amended to make it possible to defer gender assignment until the person was capable of consent or of full age. Section 47 of the *Personenstandsgesetz* (Civil Status Act) makes it possible to amend an incorrect gender entry; this was not seen as sufficient.

The question as to how to determine ability to consent is a difficult one. For a variety of reasons, puberty, for example, may be a problematic time for an autonomous decision, since this is a period when fundamental processes of finding one's identity are under way. It is also undecided how the question can be answered for those persons who are intersexed and even as adults either cannot or do not wish to be assigned either to the female or the male gender. By reason of the prohibition of discrimination and the right of self-determination, these persons ought

not to be forced to assign themselves to the binary categories male or female.

In the hearing, the persons concerned demanded compensation for suffering resulting from medical intervention. In response, it was pointed out that it is difficult to provide evidence of the culpable violation of medical standards at a date which in most cases was long ago, particularly since at an earlier date there were no medical standards which could be proved to have been violated. But some participants thought that a state fund might be used to provide compensation. Others, however, doubted that a state fund could be implemented, for reasons of law and fiscal policy.

The experts agreed that medical and psychological counselling and treatment of intersex persons must be provided in centres with an interdisciplinary composition and with specially trained specialists.

In addition, the Ethics Council obtained the impression that the areas of standard medical care and appropriate consideration of intersex persons in social insurance are extremely important.

Overall, most of the participants at the hearing requested more information and advice, and state support of the existing assistance, in order to improve the situation of intersex persons in Germany.

Online discourse

The third component of the discourse procedure carried out by the Ethics Council was an internet-based participation platform; in providing this platform, the Ethics Council for the first time used a digital and freely accessible means of transparent and participative communication with a low access threshold in order in particular to extend the debate to persons affected who are not organized in networks.

Online:
diskurs.ethikrat.org

From 8 June to 7 August 2011 intersex persons, experts and practitioners of a variety of disciplines and members of the German Ethics Council had the opportunity to discuss various questions in the context of intersexuality from their respective positions and to come to an agreement among themselves.

In order to conduct a discourse with a wide range of topics and to repeatedly give new stimulus, throughout the duration of the online discourse contributions from named authors were uploaded twice a week; the participants in the discussion could post comments on these. The first contribution was provided by the Council members involved in the hearing, who provided a first assessment. In addition, first impressions from the hearing and short video interviews with the experts at the hearing were made available online. There followed contributions from persons concerned, Council members, experts and practitioners from the fields of law, medicine, psychology, philosophy and gender studies on six different areas:

- medical intervention,
- information and consent,
- quality of life,
- the law of civil status,
- integration and discrimination and
- networking and assistance.

In fifty specialist reports and over 700 comments, the discourse participants discussed a wide range of questions in the context of intersexuality. The great importance which attached to the topic “Medical intervention”, which in the hearing too was determined to be the most important question, is shown by the large number of comments on this topic in the discourse. The greatest disputes arose in questions of the law of civil

status. The comments contain varying and extremely nuanced suggestions for legislation; these were taken into account in the Ethics Council’s deliberations.

The results of the questionnaire, of the public hearing and of the online discourse were included in the deliberations of the Ethics Council and the Opinion and were published separately.

Dementia and self-determination

At present about one million persons with dementia live in Germany and by 2030, according to projections, up to 1.7 million could be affected. Dementia is a challenge not only for family members, carers and the medical profession, but for the whole of society. As early as in February 2010, the Ethics Council established a working group on the topic of dementia; it is the aim of this group to prepare an Opinion.

In connection with the topic of dementia, which is already being widely discussed by a variety of social actors, the working group directs its specifically ethical focus to the question of self-determination in dementia. Self-determination is an essential component of human self-image and is a central point of reference in ethical discourse. For a long time, attention was focused only on the deficiencies associated with dementia, with the result that many persons with dementia felt exposed to disproportionate patronization after diagnosis. Many people talked about them, and few with them. However, it is an ethical imperative to seek communication with the persons concerned themselves and to respect their self-determination even if it is restricted. Thus, for example, for a long period of their illness persons with dementia should be permitted to a

considerable extent to determine their own lifestyle, which gives them a sense of wellbeing which also makes it easier to support and care for them.

There are now increasing attempts to direct attention to considering what capabilities people with dementia have. The possibilities are being investigated of more easily understanding what they want and of supporting them and respecting them in their self-determination and ability to express themselves. In this connection the question arises as to how much self-determination is possible in dementia, as does the question as to what is necessary to obtain a better understanding of the ability of persons with dementia to have self-determination and what forms of care support those concerned in their self-determination.

The introductory presentation of Council member Michael Wunder on the subject of “Self-determined to the end? Dignity in dementia” and the following discussion of the Council of June 2010 laid the foundation for the consultations on the Opinion. A further important step was marked by a one-day public event on 24 November 2010 in Hamburg entitled “Dementia – the end of self-determination?”, in which the members of the Ethics Council were able to have an exchange of views with persons concerned and experts and to give more depth to their reflections on this topic. The results of the conference were incorporated into the deliberations on the Opinion.

Genetic diagnosis

Prof. Dr. Annette Schavan, the Federal Minister of Education and Research, and Daniel Bahr, the Federal Minister of Health, instructed the Ethics Council in

the name of the Federal Government to prepare an Opinion on the topic of “The future of genetic diagnosis from genetic research to clinical practice – social challenges of new methods of genetic diagnosis, taking particular account of predictive and prenatal methods”, if possible before the end of the year 2012.

The context of this assignment is that although the *Gendiagnostik-Kommission* (Genetic Diagnostic Commission) was instructed to evaluate the development of genetic diagnosis, the development of such procedures, with regard to the handling of the results of examination and possible repercussions for society, raises a number of ethically relevant questions which go beyond the statutory mandate of this commission.

The Ethics Council has established a working group, which met for its first session on 14 December 2011. The Opinion is to be completed, if possible, by the end of the year 2012.

Online:
www.ethikrat.org/sitzungen/2010/dokumente/plenarsitzung-24-06-2010

Online:
www.ethikrat.org/veranstaltungen/weitere-veranstaltungen/demenz-ende-der-selbstbestimmung

Public meetings and promotion of social discourse



Online:
www.ethikrat.org/veranstaltungen/jahrestagungen/die-ernaehrung-der-weltbevoelkerung

Informing the public and encouraging discussion in society, involving the various social groups, is part of the range of duties specified by the *Ethikratgesetz* (Ethics Council Act).

In its public meetings – the Annual Meeting, a second day-long meeting, two evening meetings in the Bioethics Forum series and a dialogue of experts held jointly with the TMF (Technology, Methods, and Infrastructure for Networked Medical Research) – the Ethics Council seeks a public exchange of ideas with experts, academics in the life sciences and bioethics research, and with representatives of organizations and associations. These events are designed to enable an interested, wider and not necessarily expert public to engage in dialogue with the speakers, most of whom are external, and the members of the Ethics Council.

In addition to this, in its online discourse on the topic of intersexuality, the Ethics Council for the first time included a new format for social debate in its range of activities.

Another platform for discourse consisted of information and discussion meetings with students and schoolchildren; these were largely organized by the administrative office.

To enable the hearing-impaired to take part in the public meetings and events, real-time transcriptions are made; like the audio recordings, these are made available to a wider public online.

Annual meeting: Feeding the world

On 26 May 2011, over 400 attendees accepted the invitation of the German Ethics Council to attend its third Annual Meeting, which presented courses of action on questions of world food and concentrated in particular on the ethical implications.

In the keynote speech, Hans Rudolf Herren, President of the Millennium Institute in Arlington, Virginia, discussed the question of food security in a world suffering stress. He emphasized that in recent years there have been several crises, in particular with regard to climate, environment, biodiversity, food and finances, which are all interconnected. A holistic approach was therefore needed to solve the problems. He emphasized the importance of a multi-functional and ecological agriculture, with sustained treatment of problems and causes instead of short-term solutions. The three aspects of social questions, the environment and the economy must be brought into harmony and thus determine agriculture. In addition, it was important for agriculture to return to its culture and tradition and to place more weight on the knowledge of farmers. This was also of particular importance because industrialized foodstuff production had led to a gulf between agriculture and the environment and between farmers and consumers, and politicians did not pay enough attention to the consequences of their decisions. Herren emphasized that the amount of food produced was fully adequate to feed the world. Nevertheless, many people had to starve because a large proportion of

agriculture produce was unsuitable for human food and in addition large quantities were lost in the course of processing and as a result of unjust distribution. In order to change this, it was necessary to take new paths in agriculture. These included supporting family operations for sustained agriculture, improved access to production capital and possibilities of paid work, investment in the creation of wealth and an improvement of market access, infrastructures and institutions. In addition, there should be encouragement of responsible governments on global, national and regional levels and of fair trade. In order to solve the problems, therefore, it was necessary to rethink the situation and above all to consider ethical aspects.

Food security as an ethical challenge

In a panel discussion chaired by Christiane Grefe, a journalist for *Die Zeit*, Bernhard Emunds, Professor of Christian Social Ethics and Social Philosophy at Sankt Georgen Graduate School of Philosophy and Theology, Kurt Gerhardt, journalist and co-initiator of the Bonn appeal “A different development policy!” and

Thomas Pogge, Professor of Philosophy and International Affairs at Yale University, discussed the question of food security and food safety from an ethical point of view. Pogge criticized the fact that the situation of the poor had dramatically deteriorated and the number of chronically undernourished persons was at present growing again. He said that a central reason for this development is the process of globalization. In this process, rules are laid down on a supranational level and undemocratically which benefit large enterprises but harm the poor. It is therefore important to make globalization processes more transparent and democratic, and to create better rules to successfully combat poverty and hunger. Bernhard Emunds focused on the human right to food as part of the right to subsistence. In his view, there is an urgent duty to ensure that this human right is realized for everyone. In order to attain this goal, it is of primary importance that the creation of wealth in developing countries increases, as must the share of a broad proportion of the population in this creation of wealth. The duty of people in the north which corresponds to the human right to food is



Panel discussion with Bernhard Emunds, Kurt Gerhardt, Christiane Grefe and Thomas Pogge (from the left)

the duty to ensure that their own governments engage in development cooperation and world trade policy to this end. Kurt Gerhardt emphasized that it is the task of development aid, maintaining the subsidiarity principle, to make people in the developing countries independent of aid, and that it is unethical if development aid creates permanent dependency. In addition, in development aid it is important always to ensure that the recipients remain subjects and are not degraded to objects.

Poverty orientation

In the second part of the Annual Meeting, practical approaches to overcoming the problem of hunger and poverty were presented in the light of the aspects of poverty orientation, the role of women in agriculture and nutrition and sustainability.

First, Cornelia Füllkrug-Weitzel, the director of *Brot für die Welt* (Bread for the World), presented the concept of poverty orientation as an important key in combating hunger. She said that it was necessary to orientate oneself towards the needs, rights and potential of the poor for three reasons: firstly, from the point of view of social science it was crucial to take action against the legal, social and economic marginalization of small farmers and to increase their political involvement. Taking a human rights approach, the starving should be seen as the subjects of rights and not as the recipients of alms. In addition, from an ethical point of view, the dignity of every individual took priority. Humans must remain the subjects of their actions and may not become the objects of pity or of exploitation.

Martin Bröckelmann-Simon, Managing Director for International Cooperation at Misereor, the German Catholic

Bishops' Organization for Development Cooperation, clarified this concept of poverty orientation by the example of a project in India in which diversified agriculture and self-determined food culture are being encouraged. He emphasized that it is important for the success of development work to focus on people, to recognize their potential and to give them a voice.

The role of women in agriculture and nutrition

The next speaker was Christa Randzio-Plath, the President of the Marie Schlei Association, on the role of women in combating hunger and poverty. She said that globally, women farm the majority of smallholdings, but only rarely do they own their own land. It is therefore crucially important to give women access to land, technical knowledge and resources, in order to achieve agricultural development and food security.

Vandana Shiva, the founder of the organization *Navdanya*, emphasized that a large part of the world's food is produced by women and that women do not regard food as a commodity. She said that this is a decisive aspect, for if food is seen as a commodity, it is irrelevant whether food is used to produce biofuels and to feed animals for meat production or if it is available to feed people. It is also important to preserve food sovereignty; this is endangered by globalization and free trade. Food sovereignty should primarily lie in the hands of women, who should be well informed as to efficient and diversified agriculture.

Sustainability

The third complex dealt with the concept of sustainability in overcoming the problem of hunger and poverty.



Panel discussion with Hans Rudolf Herren, Vandana Shiva, Wolfgang Huber, Robin Roth and Hans-Jürgen Beerfeltz (from the left)

Franz Heidhues, Professor of Agricultural Economics in Developing Countries at the University of Hohenheim, emphasized participation and local knowledge as fundamental elements to make projects sustainable. He said that the central message of sustainability consists in ensuring that decisions made by the present generation do not limit the possibilities of future generations to maintain or improve their conditions of life. With reference to processes of development, he said, there are three dimensions of sustainability: the ecological, the economic and the socio-cultural. In order to realize sustainability in all three dimensions, it is essential to integrate both the local population and local knowledge. This can be achieved by knowledge partnerships which bring together farmers, local institutions, non-governmental organizations, consultancy and research.

Following this, Jörg Heinrich, Desk Officer at *Welthungerhilfe*, explained the concept of sustainability using the example of a project on storing water for times of drought. The aims of this *Welthungerhilfe* project from Kenya are to supply the poor with water, to prepare

the rural population for the regularly recurring periods of drought and the improvement of drinking water hygiene. In emergency relief operations during times of drought, it ensures acute provision of water, but in addition the programme is directed towards a long-term and sustainable safeguarding of water provision. It is particularly important here to involve the local communities in the planning and implementation, in order to achieve sustainability.

Local action

The final stage of the meeting was a panel discussion chaired by Council member Wolfgang Huber between Hans-Jürgen Beerfeltz, State Secretary in the Federal Ministry for Economic Cooperation and Development, Hans Rudolf Herren Robin Roth, Manager of the *Gesellschaft zur Förderung der Partnerschaft mit der Dritten Welt* (GEPA – Society for the Promotion of Partnership with the Third World), and Vandana Shiva. The main emphasis of the discussion was on the challenges presented by the world food situation and how these can be transferred into local action by every individual. The repercussions of

these challenges for responsible political action were discussed.

Hans-Jürgen Beerfeltz conceded that the Europeans, including Germany, have not merely interfered with but actively obstructed development policy with their agricultural export subsidies. These subsidies, he said, must therefore be phased out, and all development policy actions must be based on sustainability and responsibility. Vandana Shiva criticized international trade regulations, in particular those of the World Trade Organization, saying they had a detrimental effect on developing countries and in particular on the production of food by small farmers. She said that the citizens of all countries were called upon to support fair trade conditions and to demand them in the exercise of their democratic rights. Robin Roth also emphasized the importance of international fair trade standards, which must be complied with in order that as much money as possible goes direct to the farmers. Hans Rudolf Herren called on governments to take increased responsibility in the field of agricultural research and not merely to leave the monitoring of this research to the private sector.

One question recurred in all panel discussions: what could the individual and in particular young people do not only to think globally but also to act locally? The unanimous answer was that civic commitment and informed consumer behaviour by every individual can contribute to establishing fair trade partnerships.

The papers and discussion contributions made it clear that poverty and malnutrition cannot easily be overcome by increasing the flow of funds from north to south and thus creating and maintaining dependency. Instead, it is necessary to stimulate local economic development by way of helping people to help themselves,

making the populations of the countries affected by poverty independent of foreign aid. Offers of help should therefore be directed towards giving people access to natural resources, to production capital and to the market, but also to education and research, and in this way enabling them to share in economic growth and thus in the value chain.

Public meeting: Synthetic biology

On 23 November 2011, some three hundred attendees accepted the invitation of the German Ethics Council to join its members in the Great Hall of the University of Mannheim for a whole-day public meeting with German and international experts on the significance of synthetic biology for science and society.

The new research field with the possibilities it promises of engineering forms of life independently of existing forms represents a new stage in the nature and implications of our approach to life. In his opening address, Wolf-Michael Catenhusen described the aim of the meeting as informing the public on the current state of synthetic biology, taking social perception as a theme, putting the ethical challenges in the public view and discussing prospective approaches. With the aim of stimulating further debate in society as a whole, the Ethics Council organized this event in order to enter into discussion with representatives of science, industry and organizations and with the public.

Old wine in new wineskins

Petra Schwille from the Biotechnology Centre of the *Technische Universität Dresden* (Dresden University of Technology) first gave an introduction to synthetic



Online:
www.ethikrat.org/veranstaltungen/
[weiterere-veranstaltungen/](http://www.ethikrat.org/veranstaltungen/weitere-veranstaltungen/)
[werkstatt-leben](http://www.ethikrat.org/veranstaltungen/werkstatt-leben/)

biology, its current development and its potential. She pointed out that the aims of synthetic biology are the same as those of traditional biotechnology, attempting to obtain new active pharmacological substances, materials or natural substances to supply energy. The new element, she said, was that synthetic biology takes a modular engineering approach and thus can model the necessary processes in abstract terms, control them in a targeted manner and thus shape them far more efficiently, and in this way guarantee that the desired products are produced as far as possible on an industrial scale. A central requirement for such efficient production was the construction of a minimal organism. Schwille presented main areas of her work by way of illustrative examples. She said that her aim was to understand a self-organizing dynamic system as the first step in the direction of constructing a self-organizing and self-dividing mini-system. In this connection, Schwille referred to the work of Craig Venter as an enormous technical achievement, but at the same time not the creation of artificial life.

In the following stakeholder discussion, the representatives of various social

interest groups exchanged views. First, Nils-Christian Lübke, a doctoral student at Bielefeld University, reported on the iGEM competition in which he took part in the year 2010. This competition is organized by the Massachusetts Institute of Technology in Cambridge, USA, and is open to students all over the world. It involves carrying out a research project in the field of synthetic biology with the aim of using standardized biological components (BioBricks) to develop models for biological systems. In addition, the project always requires participants to discuss the safety aspects and the ethical considerations. The competitors develop a creative and interdisciplinary approach and engage in active discussion with the public on questions in particular on the possibilities and potential of synthetic biology. This idea was taken up by Rüdiger Stegemann of *Bund für Umwelt und Naturschutz Deutschland* (Union for the Environment and Nature Conservation Germany). He forcefully advocated not deferring social discourse until research had already created a *fait accompli*. The main question in his view related to the responsibility of society and how this should

Stakeholder discussion with Oskar Zelder, Rüdiger Stegemann, Wolf-Michael Catenhusen, Nils-Christian Lübke and Petra Schwille (from the left)



Lehmkuhl, Markus:
Die Repräsentation
der synthetischen
Biologie in der
deutschen Presse.
Abschlussbericht
einer Inhaltsanalyse
von 23 deutschen
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[www.ethikrat.org
/dateien/pdf
/lehmkuhl-studie
-synthetische
-biologie.pdf](http://www.ethikrat.org/dateien/pdf/lehmkuhl-studie-synthetische-biologie.pdf)

be exercised. Who decides on the development and application of new forms of life? Is there an ethically responsibly assessment of the consequences of technology? Stegemann called for transparency in the handling of research findings, an open discussion of the risks, equal treatment in the promotion of alternative technologies and a moratorium on public promotion and implementation of synthetic biology.

Oskar Zelder of BASF's biotechnology research department stated that he was convinced that molecular biotechnology holds great potential. At the same time he warned against equating synthetic biology as it is conducted at present with the creation of synthetic life and thus endangering promising developments. In his opinion, the concept of metabolic engineering already covers everything which falls into synthetic biology in the current state of research.

Presentation in art and the media

New technologies have always exercised a fascination which invites artists to deal with them creatively. In the case of synthetic biology, a number of artists have handled this topic from an epistemological and aesthetic viewpoint. Markus Schmidt, a director of Biofaction and a board member of the *Organisation für Internationalen Dialog und Konfliktmanagement* (Organization for International Dialogue and Conflict Management), introduced presentations of synthetic biology, in particular in art and in the media. Taking examples from the exhibition *synth-ethic* he showed in what different ways artists approach the subject. In this process, synthetic biology – like modern biotechnology in general – is unmasked or embedded in new contexts. In contrast, theatre and film performances, which were among the productions displayed

during the *Bio:Fiction* festival, take a more straightforward approach in the direction of infotainment, which lacks a critical interaction with science.

The interest of the German print media in synthetic biology, as the media analysis prepared by Markus Lehmkuhl on behalf of the Ethics Council showed, appeared relatively small in contrast to reporting on other new technologies. Published opinion, he said, was divided into three parts. Sometimes it conveyed a positivist believe in progress and sometimes sceptical reserve, but it was also open to science's self-promotion.

Between breakthrough and hype

The attraction of new technological developments, according to Armin Grunwald, the head of the Institute for Technology Assessment and Systems Analysis and the Office of Technology Assessment at the German Bundestag, had a tendency to be accorded high to exaggeratedly high expectations. However, this assessment gives way to disillusion at the latest when it transpires that the expectations were inflated or when negative aspects come to attention. This development can also be seen in connection with synthetic biology.

In real life, the time from a scientific breakthrough to application in practice is usually very much longer than at first expected. Against this background, hype results in speculative bubbles without a real basis, and the fascination which proceeds from new technologies in general is used in the positive and the negative sense to influence not only our consciousness, but also the scientific agenda. But hypes do not last long, Grunwald continued, because people soon become tired of them. In contrast, the long path from breakthrough to application has the advantage that one can approach the new

possibilities step by step, evaluate the new technologies in social discourse and if necessary control them.

In the case of synthetic biology, all the criteria necessary for an imminent hype are present. This is manifested in the number of publications, the networks coming into existence, the reports and opinions on the topic both in Germany and internationally, and also the accompanying research. But Grunwald warned against treating the speculations on which the high expectations and fears rest as the yardstick of an ethical assessment.

Life – a question of definition

Since synthetic biology is both a technology and a science that deals with life, the question arises as to the concept of life and how far it is possible to speak of the creation of artificial life in synthetic biology. This topic was discussed by Alfred Pühler from the Centre for Biotechnology of Bielefeld University and Christoph Rehmann-Sutter from the Institute for the History of Medicine and Science Studies of the University of Lübeck. Artificial life cannot be defined before there is agreement as to what it may be compared to,

according to Rehmann-Sutter. Life is not a strictly scientific concept, but a term referring to a phenomenon with its own spontaneity and meaningfulness. But what is more important than the question as to artificial life is the question as to how synthetic cells are used. The potential for endangerment does not result from the new technologies themselves, but from the socialization of these technologies. In this connection, Pühler regarded it as possible to assess the consequences of technology, because to date it has always been possible to find organisms comparable to changed organisms. In his view, synthetic biology as currently practised does not create artificial life. But he did not exclude the possibility that this may need to be assessed differently in future projects.

Creation or plagiarism?

In the following discussion, Joachim Boldt of the Institute for the Ethics and History of Medicine of the Albert Ludwig University of Freiburg and Peter Dabrock of the Department of Theology of the Friedrich-Alexander University of Erlangen-Nuremberg considered the question



Open discussion with Joachim Boldt, Jochen Taupitz and Peter Dabrock (from the left)

as to whether mankind uses synthetic biology to create new forms of life and thus sets himself up as *homo creator*. Boldt compared the current development in synthetic biology with the transition from analytical chemistry to synthetic chemistry. With the help of synthetic chemistry, not only can nature be reproduced, but new materials and classes of materials can be created. It is true that at present synthetic biology does not create life that is really new, but sooner or later it will no longer be a question of analysis and manipulation, but also synthesis and thus creation. Dabrock, in contrast, doubted whether it was desirable to use the theological metaphor of “creation” in this context, since science was only dramatizing itself in this way. Mankind did not create from nothing, but was merely in the position to intervene in the process of preservation of creation. From a theological point of view, therefore, man could not be a *homo creator*, but at best *homo plagiator*. But for Boldt, the concept of “creation” has a less religious connotation. Instead, in this context “creation” must be understood as the summit of the ability of technological production. The

decisive point is that people must become aware of what consequences “creation” would have and what could really be controlled.

The control of new technologies

The future of synthetic biology was the topic of the last session. Pat Roy Mooney of the ETC Group in Canada spoke on the arguments for and against and the necessary control mechanisms in the development and application of new technologies. The crucial issue, he said, was who steered and monitored it and what consequences it had for our everyday life. There must be a public debate on this. Although synthetic biology has great potential, it can nevertheless have detrimental effects on the subsistence of millions of people who have previously produced one of these materials in the natural way. In addition there must be a discussion as to how far patents should be awarded in this area. Mooney said that the control of new technologies must not be permitted to lie in the hands of a few companies. In summary, he said that a moratorium on synthetic biology would not be of much use in solving these problems.



Panel discussion with Bernd Müller-Röber, Klaus Peter Rippe, Wolf-Michael Catenhusen, Pat Roy Mooney and Ralf Wagner (from the left)

The future prospects of synthetic biology were also the subject of the final panel discussion, in which the participants were Pat Roy Mooney, Bernd Müller-Röber of German National Academy of Science and Engineering, Klaus Peter Rippe of the Swiss Federal Ethics Committee on Non-Human Biotechnology and Ralf Wagner, Chief Scientific Officer of GeneArt.

95 per cent of synthetic biology is the continuation of molecular biology, according to Bernd Müller-Röber. Admittedly, its constructive element opens a new viewpoint. One of the recommendations for action of the joint opinion of the National Academy of Science and Engineering, the German Research Foundation and the Germany Academy of Sciences Leopoldina on synthetic biology was to be aware of this constructive element. In addition, Müller-Röber advocated monitoring and interdisciplinary cooperation between chemistry, physics, engineering and bioinformatics. Müller-Röber also said that patents are needed, since they are necessary for the work of industry, but they must be very carefully granted.

Klaus Peter Rippe also advocated this. He said that the ethical questions which arose in the field of synthetic biology were not fundamentally new, but related to all new technologies in the field of the life sciences. One should therefore rather ask what is really new about synthetic biology, and continue the monitoring process which has already been established. In Germany, the *Zentrale Kommission für die Biologische Sicherheit* (Central Commission for Biological Safety) has already been commissioned to carry out such a monitoring process on synthetic biology with the main emphasis on safety questions.

According to Ralf Wagner, the potential of synthetic biology with regard to the development of medicinal products,

biofuels and the reduction of pollutants will only be publicly accepted if the new knowledge also reaches the population. This can only be guaranteed by transparency in research. It is also essential to address the questions of biosafety (the protection of humans and the environment in working with synthetic biology) and biosecurity (measures against abuse) at university level and to establish control mechanisms in companies.

In the course of the day, the public had several opportunities to take part in the various discussions. The centre of general interest was focussed on questions as to the definition of artificial life, the long-term prospects of synthetic biology, social transparency and patenting. In addition, questions were asked on the safety risks, above all on the dangers that might be caused by a deliberate or accidental use of synthetic organisms.

Wolf Michael Catenhusen was pleased with the results of the meeting. He summarized the expectations of synthetic biology and the recommendations on how to deal with it which had been expressed in the course of the day: transparent interdisciplinary research, scientific and ethical concomitant research and monitoring by society in order to identify as soon as possible potential dangers to humans, animals and the environment and to recognize where lines have to be drawn in application.

Bioethics Forum: The controversial case of baby drops

The Bioethics Forum is a two-and-a-half hour evening event in Berlin which takes up topics which are currently subject to considerable ethical controversy. On

Online:
www.ethikrat.org/veranstaltungen/forum-bioethik/streitfall-babyklappe

24 February 2011, the German Ethics Council held a discussion with representatives from practice, the media and politics on what developments there have been since the publication of its Opinion on the anonymous relinquishment of infants.



German Ethics Council (ed.): Anonymous relinquishment of infants: tackling the problem. Berlin, 2009 (ISBN 978-3-941957-06-0)

In November 2009, the Ethics Council recommended that the statutory basis should be created for relinquishment of infants on a confidential basis and that the possibilities of anonymous birth and baby drops, which are unlawful but which till now have been tolerated, should be discontinued. Parallel to this, the availability of public information on the existing comprehensive legally sanctioned assistance facilities for pregnant women and mothers in situations of distress or conflict should be expanded.

Christiane Woopen, Vice-Chair of the Ethics Council, introduced the Council's deliberations: She said that although possibilities of relinquishing infants anonymously were established in order to prevent babies from being killed and abandoned, it is improbable that this aim is actually achieved, in the light of statistics and research findings from forensic psychiatry. In addition, the relinquishment of the child does not in itself solve the women's emergency or conflict situation. It is necessary to proceed on the assumption that in many cases the women who have taken advantage of the possibility of anonymous relinquishment without being involved in counselling suffer even more at a later date. The facilities have serious consequences both for the psychological development of the children, who may suffer all their lives from the anonymity of their parentage, and in addition for mothers, and sometimes also for fathers, who are excluded from contact to their biological children for the rest of

their lives. It is therefore not a question of a conflict of values between the right to life and the right to knowledge of one's parentage, but of additional assistance for women who do not make use of the existing help on offer.

Nationwide study

In 2009, the Federal Ministry for Family Affairs, Senior Citizens, Women and Youth commissioned from the *Deutsches Jugendinstitut* (German Youth Institute) the first nationwide study on numbers of cases, facilities and contexts of anonymous child relinquishment. The objective, method and first findings of this study were presented by Joelle Coutinho, the research officer for this project. This study contains a survey of the numbers of cases and of the procedures by means of written questionnaires sent nationwide to 591 youth welfare offices and 343 agencies offering facilities for the anonymous relinquishment of children, and also qualitative interviews, and in addition it examines the psychosocial situation and motivation of women affected. Coutinho reported great differences in the motives and the degree of professionalization of the organizations and in the cooperation and procedures following the anonymous relinquishment of a child.

The position of the suppliers

Maria Elisabeth Thoma, Federal Chair of *Sozialdienst katholischer Frauen* (SkF – Catholic Women's Social Service), reported on the discussion on the Opinion, which she said had been perceived in different ways in the individual SkF organizations. The SkF's federal association had expressly welcomed it. However, the local associations wished to maintain the existing baby drops, at all events as long as there was no good, tried and

tested alternative. The Ethics Council's proposal for a statutory arrangement for confidential birth was welcomed, because this would mean that there was at last a reliable legal framework for confidential facilities.

Media analysis

The science journalist Volker Stollorz presented a media analysis of the press reporting on the Ethics Council's Opinion, co-authored with the communication scientist Markus Lehmkuhl. He stated that in its position the Ethics Council had attempted to remove the empirical basis from an intuitively plausible but only speculatively founded assumption that baby drops could save lives. However, the analysis showed that a balanced discussion in the media had not been achieved. The only subject that had been taken up in substance was the majority recommendation of closing baby drops, in which the Ethics Council had not succeeded in convincing the public. It had not been made clear that this recommendation was made against the background of the conviction that there is no conflict between the right to life and the right to knowledge of one's

own parentage. But the reporting in the media had placed this alleged conflict in the centre.

Discussion

The final item on the programme was a panel discussion with Ingrid Fischbach, the Vice-Chair of the CDU/CSU parliamentary group, Ulrike Herpich-Behrens of the Senate Department for Education, Science and Research of the State of Berlin, Maria Geiss-Wittmann, Chair of *Do-num Vitae* in Bavaria, and Volker Stollorz and Council member Weyma Lübbe.

Ingrid Fischbach reported that all attempts in the last years to make anonymous relinquishment of infants legal had ended without results. Before an initiative for a statutory arrangement for the confidential relinquishment of infants, it had been decided to wait for the German Youth Institute study. It needed to be determined in particular for what reasons women rejected the legal facilities and wished to remain anonymous and how they could best be helped in this situation. It was urgently necessary for there to be a statutory arrangement following this, for the current facilities

Lehmkuhl, Markus: Babyklappen und sonstige Angebote zur anonymen Geburt in der deutschen Presse. Die Stellungnahme des Deutschen Ethikrates und ihre Resonanz in den Massenmedien. Online: www.ethikrat.org/dateien/pdf/lehmkuhl-studie-babyklappen-anonyme-geburt.pdf

Panel discussion with Ulrike Herpich-Behrens, Ingrid Fischbach, Maria Geiss-Wittmann, Christiane Woopen, Weyma Lübbe and Volker Stollorz (from the left)



for anonymous relinquishment of infants were unlawful.

Ulrike Herpich-Behrens stated that the youth welfare offices and the Senate Department had found the opinion very helpful for their work, since it made an discussion of the problems of the facilities possible. She reported particularly problematic cases in Berlin known to her and the difficulties which arise as the result of the lack of statutory provisions.

Maria Geiss-Wittmann emphasized that in order to protect life one must above all reach women. The more successfully this was done, the more successfully the children were protected. Her association agreed with the specific proposals of the Council for a solution; its own model was largely similar to these. The association therefore favoured anonymous birth and anonymous relinquishment of infants. It rejected the baby drop.

Weyma Lübke challenged the much-quoted argument “if only one life is saved, it is worthwhile”. She stated that in its main position, the Ethics Council had not set out clearly enough that in its view baby drops were not justified even if the claim that they protected lives could actually be proved in very rare individual cases. A very small reduction in the risk of children being killed, which baby drops offer at best, could be weighed against other interests and rights such as the right to know one’s own parentage. She said that such a weighing of interests was constantly carried out in other social areas. But the proposal of “confidential relinquishment of infants with temporarily anonymous registration” was presumably unrealistic as an alternative for the same category of persons, since these were persons without sufficient trust in personal contact.

In the discussion with the public, questions on continued toleration of the

unlawful facilities were addressed. Emphasis was also placed on the necessity to continue considering how women in emergency or conflict situations can be reached. A practitioner asked whether it was not necessary to preserve the baby drop as a possibility despite its problems. A confidential birth, such as the Ethics Council proposed, required the mother to act rationally at a time when she was unable to manage this. Doubts were also expressed as to whether legislation was actually necessary. Fischbach emphasized that the legislature had a duty to create clearcut provisions. It was also to be anticipated that children relinquished anonymously would later place the blame for their fate in not knowing their own parentage on the state.

Bioethics Forum: Research on medicines in children

On 21 September 2011, the German Ethics Council held a discussion with experts from the fields of medicine and ethics on how far research on medicines in children is ethically necessary or questionable.

Jochen Taupitz, German Ethics Council member, introduced the controversial subject and summarized the problems involved. On the one hand there is the large percentage of medicinal products which are not approved for paediatric use and therefore are used on children without confirmed knowledge on the effective and safe dose, and the child’s right to appropriate medical care. On the other hand, when children who are not themselves able to give valid legal consent are involved in research, some regard this as the instrumentalization of the defenceless. In order to evaluate the subject objectively, it is necessary to distinguish three

Online:
www.ethikrat.org/veranstaltungen/forum-bioethik/anzneimittelforschung-mit-kindern

areas: standard medical treatment carried out exclusively with the intention of helping a specific patient; therapeutic research using new medicinal products which is directed at the same time to the benefit for the patient and the further development of science; and scientific experiment intended for a specific group, which does not benefit a specific patient, but may in future benefit other patients who have the same illness.

Harm to children

Wolfgang Rascher, Chair of the Commission on Medicinal Products for Children and Young People at the Federal Institute for Drugs and Medical Devices, next reported on the provision of medicinal products to children in Germany and Europe. He emphasized that no other population group is so disadvantaged by untested medicinal products as children. He noted that the new EU Regulation on medicinal products for paediatric use, which entered into force in January 2007 and which requires a detailed paediatric development plan for every medicinal product which must be newly licensed, and the twelfth reenactment of the *Arzneimittelgesetz* (Medicinal Products Act) of the year 2004, which provides that benefit for a group is sufficient, had the effect that in recent years the number of clinical studies in Germany has slightly increased. Although this is not a resounding success, it is a move in the right direction. A large number of clinical studies involving children have currently been deferred, since the data for adults are not yet available. Although studies are always planned to entail minimum risk and minimum stress, Rascher pointed out that there are also undesired events and harm. But a good monitoring system within the studies makes it

possible to intervene in the process in good time.

Off-label use in paediatric oncology

Following this, Angelika Eggert, Director of the West German Tumour Centre at Essen University Hospital, reported on her experience of the clinical treatment of children with cancer. She emphasized that cancer, after accidents, is the second most common cause of death of children in Europe and that the molecular characteristics are very different from those of adult cancers. For this reason, it is urgently necessary for specific medicinal products to be developed. However, she said, it is one of the great success stories of medicine that the cure rate in paediatric oncology has risen from less than 20 per cent in the 1950s to a current figure of 80 per cent. This success is based on the cooperation of paediatric oncologists on a national, European and international level with the aim of carrying out joint clinical studies. A further improvement can be achieved only by further research and better use of medicinal products. Thus, for example, 95 per cent of children with cancer in Europe are treated in what are known as therapy optimization studies, which examine already known medicinal products in both the on-label and off-label areas in order to obtain new findings on possibilities of diagnosis and therapy. The consolidation of the pan-European multicentre data makes it possible to obtain comprehensive findings. In this connection, Eggert emphasized the very high proportion of off-label use in paediatric oncology, which can be as much as 87 per cent. She said that the problem is that on the one hand off-label use results in twice as high a risk of undesired side effects and is often not reimbursed by the health insurance funds; but on the other hand, if we do not rely on

off-label use, we deprive children of medicinal products with proven or potential effectiveness. In addition, Eggert referred to the problem of the lack of incentives for the pharmaceutical industry to invest more effort in the development of medicinal products for children. A further aspect is that the current financing of the therapy optimization studies by way of donations will no longer be possible under the new conditions of the Medicinal Products Act. Eggert therefore recommended that these studies should be treated separately from those of the pharmaceutical industry and that bureaucratic hurdles and additional fees should be dispensed with. She also favoured more incentives for the pharmaceutical industry, public funding and European translational medicine networks at the interface of preclinical and clinical research, and also a paediatric review of the effects of medicinal products, in order that children obtain the best possible supply of medicinal products.

Minimizing risk and burden

Jochen Taupitz next set out the legal situation. He spoke of the capacity to consent and the duty to provide information as the central requirement for research, and of the conditions for the clinical review of medicinal products. In this connection, he discussed a number of protective criteria, such as risk-benefit analysis, procedural safeguarding by means of a review by competent authorities, and the individual right of self-determination of the person affected or of the patient. He explained that clinical research involving healthy children is permitted for diagnostic agents and preventive medication, but not for other products unless there is no alternative method available. On the basis of data from research on adults, a prospective individual benefit or at least

a direct use for the same group of patients must be apparent. In this connection, the associated risks and burdens should be as small as possible. In summary, Taupitz said that there are a number of strict provisions in the Medicinal Products Act and therefore children enjoy a high level of protection in Germany.

Protecting children through research

Georg Marckmann, Director of the Institute of Ethics, History and Theory of Medicine at Munich Ludwig Maximilian University, presented an introduction to the ethical aspects of the subject. In his view, it would be a violation of the ethical principles of not doing harm and of doing good if one were to dispense with studies with children and in this way expose children to increased risks from untested medicinal products, and in this way withhold beneficial therapies from them. Marckmann discussed the protective criteria presented earlier and emphasized the ethical problems of research with children, since their capacity to consent is either limited or non-existent. According to Marckmann, research on medicinal products with children is ethically required and at the same time questionable – a fundamental ethical dilemma which cannot be resolved but only legislated on. He said that it was an ethical challenge on the one hand to protect children with a view to the risk-benefit relationship, informed consent and research which benefits groups or is altruistic, and on the other hand to make ethically responsible paediatric research possible. In this connection, the public sector was called upon to create appropriate regulatory, financial and personal conditions for research and corresponding structures, such as paediatric studies centres.

More information needed on off-label use

Following this, Claudia Wiesemann, Director of the Department of Medical Ethics and History of Medicine at Georg August University Göttingen, presented, exemplified by a number of studies, the point of view of parents who permit their children to take part in research projects. She said that these studies showed that the parents of healthy children were generally more reserved in this respect than the parents of sick children, who often felt that they had no choice, regarded the benefit for their children as greater than the risk, and had a better idea of how important well-tested medicinal products are. Altruistic motives and the consideration that in this way they could have access to free treatment might also be the main reason for the decision to take part in research projects. In addition, the studies had shown that parents are capable of consent and themselves want to give consent even in stressful conditions. Wiesemann showed that when studies are conducted, attention must be given to ensuring that children are not burdened more than is appropriate for their age and

that the study should be associated with positive experiences.

She called for accompanying research on the attitudes of children and young people to research, and appropriate clarification of off-label use, because knowledge that a product might conceivably be used strengthened parents' readiness to allow their child to take part in a study.

Against a prohibition of medicinal product research with children

The event closed with a panel discussion in which the evening's speakers and also Siegfried Throm, Managing Director of the *Verband Forschender Arzneimittelhersteller* (Association of Research-Based Pharmaceutical Companies) and Dietrich Niethammer of the *Stiftung für kranke Kinder Tübingen – Dietrich-Niethammer-Stiftung* (Charitable Foundation for Sick Children) took part.

Throm presented current figures on newly licensed medicinal products for children and their areas of application. He welcomed the goals of the European Regulation on medicinal products for paediatric use of 2006 and provided information on the procedure for the licensing of



Panel discussion with Jochen Taupitz, Dietrich Niethammer, Georg Marckmann, Siegfried Throm, Claudia Wiesemann, Angelika Eggert and Wolfgang Rascher (from the left)

paediatric development plans. In conclusion, Throm said that the question facing pharmaceutical companies is not whether studies with children are permitted, but how they can best be realized.

Niethammer too regarded research into medicinal products with children as necessary. He said that it would be unethical to hinder research with children by means of financial or bureaucratic obstacles, as happens in the case of therapeutic studies. Niethammer referred to the high degree of responsibility of ethics commissions, the right of parents to have a say and the necessity for the children to consent. On the basis of his positive experience, he advocated an ethics commission of specialists, which was to advise not only the doctor but also the parents.

In the course of the discussion, reference was again made to the importance that children should be capable of consenting and possibly have a right of veto. Eggert was of the opinion that the discussion between parents and child and information appropriate to the child's age were of enormous importance.

Taupitz addressed the problems of placebo-controlled studies, in the course of which children in the control group were given a placebo without foreseeable benefit. Rascher replied that such an imbalance could be avoided by very good design of studies. Thus, for example, the children could alternately be given different quantities of the medicinal product at random.

The panel experts agreed that purely altruistic research may not be carried out on children, because it is not ethically defensible. If a study merely benefited a group, this was acceptable, but the main interest must consist in achieving a therapeutic effect for the specific patient.

Following this panel discussion, the public had the opportunity to join in the

discussion. The topics which attracted most general interest were questions as to ethics commissions of this type in hospitals, the criteria for competence to consent, the problems and consequences of patent protection, the risk of being harmed by studies, and the monitoring of studies. Another problem mentioned was that under the Medicinal Products Act only a pharmaceutical enterprise may apply for a medicinal product to be licensed, instead of a doctor who has experience of it and would like to take the initiative in having it reviewed and licensed on this basis. In addition, great lack of understanding was expressed for the fact that the European Union has discontinued further funding of paediatric studies for 2012.

Dialogue of experts: Need for legislation on research with human biobanks?

On 7 April 2011, in a dialogue of experts in Berlin, the German Ethics Council and the TMF (Technology, Methods and Infrastructure for Networked Medical Research) discussed the recommendations of the Ethics Council on putting research using human biobanks on a statutory basis.

Human biobanks are collections of samples of human body substances (for example tissue, blood, DNA) which are electronically linked to personal data and health-related information on the donors. They play a central role in research on the causes and mechanisms of a large number of diseases and their treatment and are an essential resource for biomedical research. New trends in biobank research, including quantitative and qualitative expansion; increased networking and



Online:
www.ethikrat.org/veranstaltungen/weitere-veranstaltungen/regelungsbedarf-fuer-forschung-mit-humanbiobanken

internationalization; and privatization and commercialization, present legal and ethical challenges.

In its Opinion “Human biobanks for research”, published in June 2010, the Ethics Council proposed a concept based on five pillars for legislation on biobanks. The recommendations include the introduction of biobank secrecy; laying down permissible use; involving ethics commissions; quality assurance; and transparency. These recommendations are intended on the one hand to provide a sufficient legal framework for the interests and personality rights of the donors and on the other hand to create more legal certainty for biobank research and at the same time to facilitate research.

In the course of the expert dialogue, scientists, lawyers, data protection specialists and ethicists shed light on the many aspects of research on the basis of human biobanks. They sounded out the consequences of legislative measures governing research practice and discussed with politicians, patients’ representatives and other interested persons whether a biobank statute is necessary.

Stronger protection of donors

The speakers and the participants in the discussion broadly agreed on the central recommendation of the Ethics Council that donors should be protected more strongly than previously against the risks of a misuse of their data and public confidence in the operation of biobanks should be maintained, while at the same time the limitation of the use of samples was relaxed and thus it was made easier to carry out medical research with biobanks. The recommendations on permissible use, on the involvement of ethics commissions, on quality assurance and on transparency were also welcomed. However, there was

dispute as to how far collections whose contents or duration were limited, for example those created in connection with doctoral theses, should be treated in the same way as large biobanks. It was said that some of the recommendations were already customary in practice, and therefore a special statute was not required.

Biobank secrecy

There was intensive discussion on the question as to whether a statutory duty of biobank secrecy was necessary in order to ensure an objective balance between the interests of donors and research.

Biobank secrecy as recommended by the Ethics Council in its Opinion consists of a multi-dimensional duty of confidentiality: Firstly, persons who handle biobank materials may not transmit samples and data to agencies outside science, and secondly, they may not make efforts to identify the donors if they work with pseudonymized samples. Thirdly, the information from biobank research may not be used by external agencies, neither by insurance companies nor by employers. Fourthly, the persons named should be able to rely on a right to refuse to give evidence which is comparable to the professional discretion of doctors. This is intended to guarantee that researchers cannot be forced by state agencies to reveal information which they have obtained in connection with their work with biobank samples. This is an important aspect to strengthen confidence in biobanks. Fifthly, there should be a prohibition of access to individual samples or information by state agencies. In addition, there should be no possibility of matching data as part of electronic profile searching.

In contrast, practitioners in particular expressed reservations in that biobank secrecy would give greater protection to



German Ethics Council (ed.): Human biobanks for research. Berlin, 2010 (ISBN 978-3-941957-10-7)



Panel discussion with Andreas Reimann, Wolfgang Hoffmann, Andreas Edelmann, René Röspe, Volkart Wildermuth, Sabine Riewenherm, Thomas Feist, Markus Nöthen and Jochen Taupitz (from the left)

both donors and scientists, but at the same time it might result in greater administrative expenses for research projects and projects involving international cooperation might pass Germany by. A possible alternative to biobank secrecy would be guidelines which could be given effective sanctions by the refusal or removal of financial promotion.

Lively discussion

In the following discussion, there was no agreement as to whether legislation is necessary or whether self-regulation within the research community on the basis of the existing statutory situation, as supported by the TMF with its data protection ideas and recommendations, is sufficient.

It also remained open whether a uniform federal biobank statute is possible or whether the *Länder* are competent for some of the provisions, which would lead to considerable fragmentation of law.

Online discourse on intersexuality

In its online discourse as the third components of its discourse procedure on the topic of intersexuality, the Ethics Council included a new format for social debate in its range of activities. This digital discourse platform was established during the preparation of the Opinion on intersexuality in order to facilitate a dialogue between intersex persons and parents of intersex children, and also experts and practitioners, and in order to make the complex topic accessible to a broad public. Almost 35 000 page views from Germany and other countries such as Switzerland, Austria, the Netherlands and the USA, fifty articles, and 727 comments in 64 days show that the Ethics Council's invitation to join the discourse was well received (see p. 19 ff.).

Panel discussions with students

In the period covered by this report, the German Ethics Council received two

student groups, from Germany and the USA, in the administrative office.

On 16 June 2010 students of politics from Greifswald University visited the administrative office of the German Ethics Council. Joachim Vetter, the Head of Office, informed the students on the Council's work.

As in the previous years, in 2011 a group of students from the USA who were taking part in Bonn University's Summer School on Life Sciences and Culture again visited the German Ethics Council. Council member Jens Reich presented the work of the Ethics Council and answered the students' questions.

In addition, the Head of Office, presented the work of the Council at the upper secondary level Lise Meitner School of Science in Berlin and held a discussion with the students on the previous Opinions and on fundamental questions of political advice by bodies such as the German Ethics Council.

Collaboration with the German Bundestag

With its first Parliamentary Evening in the year 2010, the German Ethics Council established a practice which it intensified in the year 2011: both the Council members and the members of the Bundestag found the exchange of opinions with the members of the German Bundestag on current Opinions of the Ethics Council very informative and instructive, in particular since it gave the Bundestag members the opportunity to scrutinize the recommendations and to give the Ethics Council suggestions for its future work.

Parliamentary Evening on 23 March 2011

On 23 March 2011, the German Ethics Council held its first Parliamentary Evening in the year 2011 and discussed the Opinion on preimplantation genetic diagnosis with members of the German Bundestag.

In his welcoming address, Professor Dr. Norbert Lammert, the President of the Bundestag, thanked the Ethics Council for its work. With regard to the current Council Opinion on preimplantation genetic diagnosis (PGD), he emphasized that “in case of doubt, I prefer Opinions which relate to matters that are currently on the parliamentary agenda or are likely to be, even if they are not unanimous, to unanimous Opinions which are produced after such an endlessly long process of deliberation and then possibly with their edges so worn down that they no longer have any real operative significance for the parliamentary process”. He emphasized that above all in questions of ethics there is “no single conclusive answer that is plainly free of doubt”, but that it is necessary to evaluate conflicting points of view. He said that credit should be given to the German Ethics Council for having done this in its PGD Opinion. Lammert hoped that some of the Council members would still be available for discussion on the dates when



Wolfgang Huber, Wolf-Michael Catenhusen, Norbert Lammert, Edzard Schmidt-Jortzig and Christiane Woopen (from the left) during the Parliamentary Evening on 23 March 2011

it would be necessary to deal with the matter in more depth in the Bundestag.

Against the background of the ongoing consultations of the German Bundestag on the subject of preimplantation genetic diagnosis, Council members Wolf-Michael Catenhusen, Christiane Woopen and Wolfgang Huber presented the Council's Opinion with its two main positions. Wolf-Michael Catenhusen reported on the general section of the Opinion, which comprises an up-to-date status report on the medical basis, on the constitutional context and on the foundations of the ethical evaluation of PGD. Christiane Woopen presented the principles of those Council members who are in favour of a restricted permission of PGD. Wolfgang Huber then set out the arguments of the Council members who regard the permission of PGD as ethically untenable.

Central issues in the following discussion with the members of the German Bundestag included the possible restriction of the use of PGD, the accuracy of the term "a slippery slope" when applied to the permission of PGD, and the passing on of what is known as superfluous genetic information. The question was also raised as to how far the Ethics Council has taken account of social reality in its deliberations and whether the social climate has changed in countries which permit PGD.

In the course of the evening, Council Chair Edzard Schmidt-Jortzig also presented the 2010 Annual Report to Bundestag President Lammert.

Parliamentary Evening on 26 October 2011

On 26 October 2011 the German Ethics Council issued invitations to its second

Parliamentary Evening of the year in Berlin, in order to present its latest Opinion, "Human-animal mixtures in research" and to discuss with the members of the German Bundestag the subjects currently on the Council's agenda: intersexuality, and dementia and self-determination.

In his welcoming address, Edzard Schmidt-Jortzig, Chair of the German Ethics Council, stated that in this way the German Ethics Council wishes to satisfy the intensely felt need for exchanges and communication between the Council and the Bundestag. He also reminded those attending that the term of office of the first members of the German Ethics Council is ending in April 2012 and new appointments will need to be made.

In his opening address, Eduard Oswald, the Vice-President of the German Bundestag, said that the Ethics Council's independent and sound advice helped the Bundestag members to get to the heart of relevant issues more quickly and hence to make a decision. Quoting the English philosopher and mathematician Bertrand Russell's adage "Even when all the experts agree, they may well be mistaken", Oswald encouraged the Ethics Council to continue its wide-ranging and critical advice to the members of parliament and its expression of divergent views in its Opinions. He expressed thanks in the name of all members of the German Bundestag for the work done by the Ethics Council.

Next, Wolf-Michael Catenhusen, as spokesperson for the Council's internal working group, presented key elements of the Opinion and the Ethics Council's recommendations on approaches to human-animal mixtures and their treatment. The ensuing discussion centred on issues including the actual need for statutory regulation in connection with mixtures and the criteria that should be



Members of the German Ethics Council during the Parliamentary Evening on 26 October 2011

applied in the evaluation of research projects involving human–animal mixtures.

Michael Wunder, the spokesperson for the working group on intersexuality, reported on the current status of the deliberations. With regard to the Federal Government’s request for an Opinion to be prepared and the dialogue with those concerned and their self-help organizations to be continued, he said that the Ethics Council had already done this in that it had carried out a survey of intersex persons and of scientists and practitioners, had held a public hearing and had conducted a highly appreciated online discourse.

In the following panel discussion, the members of the Bundestag were particularly interested in the principle of equal treatment and the prohibition of discrimination, in involving the parents of intersex individuals in the process of dialogue and in the question as to how far the recommendations of the Ethics Council also extended to the field of sport.

Michael Wunder reported in addition on the status of the Council’s deliberations on the issue of dementia and self-determination. A particular aim of the planned

Opinion was to establish the potential capabilities of persons with dementia and to reinforce such self-determination as was still possible even at advanced stages of the disorder. Again, it was appropriate not only to consider dementia as a disease, but also to take account of the psychosocial situation of persons with dementia and their families.

The ensuing questions put by the members of the Bundestag addressed possible points of contact with the statutory provisions on advance directives, the funding of residential care communities and payment for care by family members.

International initiatives and contacts

As in earlier years, the Ethics Council in 2011 again took part in exchanges with national ethics councils and organizations at international level, in accordance with its mandate as laid down in the Ethics Council Act.

Meetings of the national ethics councils of the European Union

On 21 and 22 September 2011 the representatives of the national ethics councils of the EU Member States met for the 17th NEC Forum in Brussels. Kristiane Weber-Hassemer attended the meeting as the representative of the German Ethics Council.

At the beginning of the two-day meeting, there was a joint session with the European Group on Ethics in Science and New Technologies (EGE), in the course of which the ethical implications of information and communications technologies were discussed. On the instructions of the European Commission, the EGE is currently preparing an Opinion on this subject. In an introductory talk, Julian Kinderlerer, the Chair of the EGE, examined the ethical and legal questions. The information and communication technologies include computers, mobile phones and the internet. Kinderlerer emphasized that these technologies were associated with central questions of data protection and of intellectual property. He said that there needed to be a discussion as to how users could be protected and their fundamental rights preserved. It was particularly

difficult to make recommendations in this area, since there were constantly new developments. The EGE's Opinion would deal with the various applications, for example the internet and the use of electronic media in medical care. In a second Opinion, the EGE would deal with the ethical repercussions of security technologies.

Health services on the internet

After a discussion on the challenges presented by the use of information and communication technologies, Hugh Whittall, the Director of the British Nuffield Council on Bioethics, presented the Nuffield Council's report entitled "Medical profiling and online medicine: the ethics of 'personalised healthcare' in a consumer age". The report considers new developments in the fields of personalized healthcare and the health services offered on the internet, and analyses the ethical effects of these developments. The Nuffield Council recommends that the government should provide better monitoring of the services offered and ensure that well-founded and independent information on these services is available. For this reason, doctors in particular should be given special training to enable them to advise patients who look for health information or order medicinal products on the internet.

Next, Christiane Druml, the Chair of the Austrian Bioethics Commission, introduced the report published in May 2010 "Genetic and Genome-Wide Testing on Internet". In this report, the Austrian Bioethics Commission deals with genetic tests offered on the internet for

healthcare and the associated ethical challenges. The tests offered on the internet, she said, circumvent legal standards with regard to data protection, advice and self-determination of the patient. The Austrian Bioethics Commission therefore recommends that before recourse to such a test, patients should have a consultation with a specially trained doctor and should inform themselves of the precise business purpose of the test. If a monogenic disorder is suspected, the Bioethics Commission advises that the patient should consult a medical specialist in order to obtain comprehensive advice.

Responsible research and innovation

The central topic of the following meeting of the European ethics councils was responsible research and innovation. René von Schomberg, from the Directorate General for Research and Innovation, introduced the activities of the European Commission in research and innovation policy. He particularly emphasized the importance of ethical aspects in the development and evaluation of research projects. He said the a project could only be endorsed from an ethical viewpoint if it conformed to the European Charter of Fundamental Rights, in particular to the right to respect for private life and to the protection of personal data.

Building on this, the representatives of the European ethics councils formed smaller groups in which they discussed the role of ethics for responsible research and innovation and exchanged details of their own experience in evaluating research projects. In conclusion, there was a discussion as to what measures should be taken on a national level in order to promote responsible research.

Trilateral meeting of the ethics councils of Germany, France and the United Kingdom

On 1 December 2011 members of the German Ethics Council, the British Nuffield Council on Bioethics and the French *Comité Consultatif National d'Éthique* (National Consultative Ethics Committee) met for a joint meeting in London. The German Ethics Council was represented by Wolf-Michael Catenhusen, Eckhard Nagel, Eberhard Schockenhoff and Kristiane Weber-Hassemer.

At the beginning of the trilateral meeting, the representatives of the three ethics councils exchanged information on their current programmes of work. The agenda of the French ethics council at present contains the topics of neurosciences, biodiversity, drugs and genetic tests, and ethical questions with regard to cord blood banks. The council is also considering the subject of sexuality and disability. The Nuffield Council in Britain is considering mitochondrial disorders, new developments in the fields of biotechnology and neurotechnology, and the subject of genes and education. In future, the topics of research into medicinal products with children, genome databases, data protection and global inequalities in healthcare may be included in the programme. The German Ethics Council is at present preparing Opinions on the issues of intersexuality and “Dementia and self-determination”. In addition, in response to a commission by the Federal Government, it is establishing a working group which will consider the future of genetic diagnosis. Council member Wolf-Michael Catenhusen reported on the Opinion “Human–animal mixtures in research”, which the German Ethics Council published in September.

Organ and tissue donation

A report of the Nuffield Council on the donation of bodily material for medicine and research was published in October. In the United Kingdom it is possible for organs to be donated after death if the person concerned was registered in his lifetime in the organ donation register or if the next of kin give their consent. Donations from living donors are also possible if there has been detailed information and the donor has consented. Marilyn Strathern, the Chair of the Nuffield Council working group, presented the core points of the report, which *inter alia* suggests financial incentives for organ donors. Thus, for example, the funeral costs for organ donors could be paid or compensation could be paid to women who donate eggs for research. In April, the French ethics council also published a report on ethical questions of organ donation; this was introduced by Bertrand Weil. In France, everyone is regarded as a potential organ donor unless he has expressly objected to organ donation. The foundation for this is a “presumed consent” of all citizens to organ donation. Donations from living persons are also possible, but in this case the necessary procedure requires express consent of the potential donor given before a judge. Following this, Eckhard Nagel, member of the German Ethics Council, spoke on the current debate on transplantation medicine in Germany. He set out possibilities to reduce the lack of organs and explained the model which is currently under discussion, in which persons have to declare their wishes as to donorship.

Mitochondrial disorders

The Nuffield Council is currently preparing a report on the ethical aspects of a possible treatment of mitochondrial disorders. Mitochondria generate energy in the cell

and whatever the genome they have thirteen genes in the cell nucleus. By reason of the central role of these genes in metabolism, mutations in them can result in diseases affecting virtually every organ and express themselves in a variety of symptoms such as muscle weakness, blindness, liver disease or diabetes. Since mitochondria are only ever inherited through the mother, it would be possible to prevent these diseases being passed on to the children if, in the course of artificial fertilization, the mitochondria were removed from the egg of a carrier and replaced by the mitochondria from the egg of a healthy woman. However, such a procedure would also be an intervention in the germline, since the change would be permanently passed on to the next generation. In addition to an ethical consideration of these treatments, therefore, it is also an aim of the report to encourage public debate as to whether such a procedure is even desired by society.

International cooperation

The participants agreed that the exchange and the discussion with the representatives of other ethics councils were very valuable and helpful, especially in view of the fact that there are a large number of topics of joint interest. International exchange is particularly important in the areas where research touches on ethical and legal questions, as for example in the case of human biobanks for research, where the legislation varies in each country, with the result that there has to be consultation and agreement as to how the different arrangements should be treated. For this reason, the close cooperation of the ethics councils of Germany, France and the United Kingdom should therefore continue in the future. The German Ethics Council invited its British and French counterparts to a trilateral meeting in Berlin in the year 2012.

Publications

Online:
www.ethikrat.org/publikationen

The Ethics Council makes its Opinions and activities known to the public in a number of series of publications. The printed versions of these publications may be ordered free of charge from the office of the Ethics Council and are also accessible on the internet as PDF files.

Opinions

The Opinions are the cornerstones of the Ethics Council's publications. They are the result of intensive discussions in the internal Council working groups and in the plenary meetings. In this way, the Ethics Council pursues the goal of collecting the opinions and convictions held in society and also in the Ethics Council, deriving lines of argument from them and developing options for courses of action.

In the year 2011 the Ethics Council presented three Opinions: on 27 January 2011, it published its opinion "Medical benefits and costs in healthcare: The normative role of their evaluation". On 8 March 2011 there followed the Opinion "Preimplantation genetic diagnosis", and finally on 27 September 2011 the Opinion "Human-animal mixtures in research".

Each of these Opinions was printed in an edition of 3500 copies. English and French translations of these Opinions are either already available or currently in press.

Proceedings

The papers presented at the Annual Meeting, the Synthetic Biology workshop and

the dialogue of experts held jointly with the TMF on the subject of biobanks will be collected in volumes and published. All three collections will shortly be available in print and for download on the Ethics Council's website (in German only).

Infobrief

The *Infobrief* (newsletter, available in German only) was introduced to offer a wider interested public a condensed and readily comprehensible version of the topics discussed by the German Ethics Council. Contributions are prepared in the Ethics Council's office on the basis of the Council's published documents – audio recordings and real-time transcriptions of the public meetings and other events, as well as Opinions. The compilations of news from the Ethics Council have appeared three times a year since December 2008 in a print run of approximately 3000 copies.

Evolution of the social debate

The office of the German Ethics Council keeps track of press reports and prepares daily compilations of reports on bioethics topics. These compilations are made available to the Council members and can also be accessed by the public on its website via an online calendar. A complete set of the monthly or annual evaluations of these reports therefore gives an impression of the public debate on bioethics topics, which is not complete but is at least evidence-based. In the course of 2011, the following ten topics were represented most frequently in the nationwide German print media (*Financial Times Deutschland, Focus, Frankfurter Allgemeine Sonntagszeitung, Frankfurter Allgemeine Zeitung, Frankfurter Rundschau, Handelsblatt, Der Spiegel, Stern, Süddeutsche Zeitung, Der Tagesspiegel, taz, Die Welt, Welt am Sonntag, Die Zeit*).

Care for elderly and disabled people

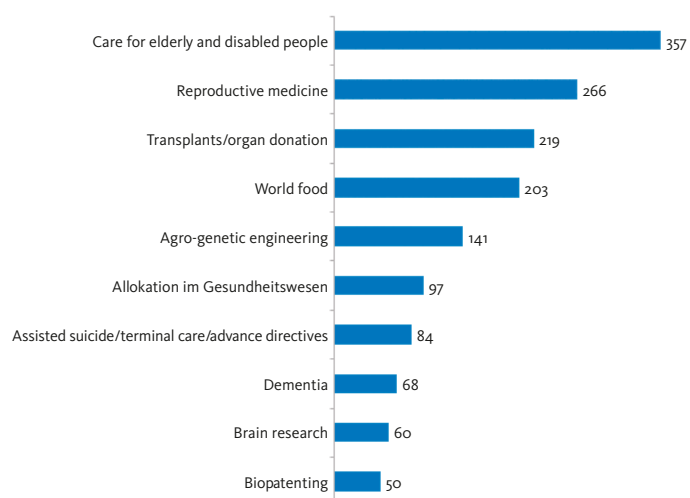
In the year 2010, the topic of care for elderly and disabled people was still in fourth place in press reports, but in 2011 it was the top subject, at least the one most frequently named. The reason for this was probably that 2011 was the “Year of Care”. Improved quality of life and medical progress result in an increase in life expectancy and in connection with this an increasing number of people in Germany who are old and in need of help. In order to cope with the challenges presented by this demographic change, there is need for a coordinated and socially accepted procedure. As part of this process, the Federal Government declared 2011 the Year of Care, and in particular put care reform on the political agenda. After many months

of debates, above all on future financing of long-term care insurance, Daniel Bahr (FDP), the Federal Minister of Health, in November presented the key points of the planned care reform, which had previously been agreed on by the Federal Cabinet: more services for people with dementia and the disabled, support for family member carers, promotion of outpatient forms of accommodation, creation of a private form of supplementary insurance and an increase of contribution rates in long-term care insurance by 0.1 percentage points. A draft bill is to be completed in the first half of 2012.

In October 2011 the Bundestag passed the *Familienpflegezeitgesetz* (Family Long-Term Care Leave Act) initiated by Kristina Schröder (CDU), the Federal Minister of Family Affairs, which is intended to improve the reconciliation of occupation and family care.

In June, the Federal Cabinet resolved on a National Action Plan to implement the United Nations Convention on the Rights of Persons with Disabilities. The

Online:
www.ethikrat.org/presse/pressespiegel



measures presented by Ursula von der Leyen (CDU), the Federal Minister of Labour and Social Affairs, are in particular intended to facilitate occupational and social integration of persons with disabilities. However, disabled persons' associations and social organizations criticized the plans as inadequate.

Reproductive medicine

As in the previous year, in 2011 too the field of reproductive medicine was in second place in the list of frequency of reports. In July 2010, a judgment by the Federal Court of Justice on the permissibility of preimplantation genetic diagnosis triggered proceedings for the reenactment of the Embryo Protection Act; these ended in July 2011 with a resolution of the Bundestag providing a limited permissibility of genetic tests on artificially created embryos. There was a free vote, and a clear majority of the Bundestag members voted for use of preimplantation genetic diagnosis. It is true that it remains prohibited in principle under the Embryo Protection Act, but it is permissible in cases in which one of the parents has a genetic disposition for a serious genetic disease or where a miscarriage or still birth is to be expected. Couples affected may use this method in licensed centres after prior expert advice and the consent of an ethics commission. The decision was preceded by many months of intensive debate among politicians and in society; the German Ethics Council also took part in this debate in its Opinion published in March.

In November the European Court of Human Rights confirmed national prohibitions of egg and sperm donation. Under this judgment, the EU Member States have a duty to legislate on limits to artificial fertilization. At second instance, the

judges dismissed an action from Austria which was directed against the current prohibition of egg and sperm donation. This means that the prohibition of egg donation applicable in Germany does not contravene current EU law either.

Transplants/organ donation

Since Frank-Walter Steinmeier, the leader of the SPD parliamentary group, donated a kidney to his sick wife in August 2010, organ donation has been the subject of intense public discussion. After months of political struggle, in November 2011 all the parliamentary parties in the Bundestag agreed on an initiative to amend the procedure. The plan was that German citizens should in future be regularly asked whether they wish to be donors. The "declaration solution" is to replace the "expanded consent solution" currently laid down in the *Transplantationsgesetz* (Transplantation Act); the latter provides that organs may only be removed if the deceased consented before his death or his next of kin consent to a transplantation. The amended procedure, which had not yet been passed by the Bundestag at the end of the year 2011, is intended to increase the number of organ donors in Germany. According to estimates of the *Deutsche Stiftung Organtransplantation* (German Organ Transplantation Foundation), approximately 1000 people die every year for lack of donor organs.

World food

Last year, a large number of reports on a famine in East Africa drew public attention once again to a global problem with which the German Ethics Council also concerned itself at its Annual Meeting and which in 2011 it included in the focus of its press watching for the first time: feeding the world population and the

associated ethical challenges. Throughout the world, about a billion people are starving, and every day thousands die of the consequences of malnutrition. And yet approximately one-third of all food produced lands on the rubbish dump or is lost in transport, as is shown by a study of the United Nations Food and Agriculture Organization presented in May. The calls for a responsible treatment of food and land resources are becoming louder. But global food security is also threatened by the constantly rising cost of food. In order to ensure more transparency on the international markets and to prevent the manipulation of raw material prices, in June the agriculture ministers of the twenty most important industrialized countries and emerging economies passed an action plan against price fluctuations in agricultural raw materials.

Agro-genetic engineering

In 2011, the debate on the application of procedures of what is known as “green genetic engineering” was also one of the main focal points of public reporting. In this connection, some decisions on European level in particular stood in the foreground. In February, the EU Member States agreed to relax the complete ban on the import of genetically modified plants, which are prohibited in the European Union. The competent agriculture committee in Brussels permitted insignificant residues (0.1 per cent) of genetically modified plants in foodstuff imports, provided there was an application in the European Union for the admission of the plants. In July, the European Parliament adopted a proposal of the EU Commission that in future the Member States themselves were permitted to decide on prohibitions of cultivation for genetically modified plants. However, the Commission remained

responsible for permitting certain species. In November, a judgment of the European Court of Justice caused a stir: In the opinion of the judges in Luxembourg, honey which contains pollen from genetically modified plants may only be marketed if the plants in question are permitted in Europe. Environmentalists and ecologists regarded the judgment, which applies not only to honey but to all foodstuffs with the smallest traces of genetically modified plants, as a great success, which may have far-reaching effects on genetic cultivation throughout Europe.

Allocation in the healthcare system

After the Act on the Reform of the Market for Medicinal Products entered into force at the beginning of 2011, the reports on this topic markedly decreased in number in the course of the year. For the first time in many years it has been possible to reduce expenditure for medicinal products. The statutory health insurance funds profited above all from the Federal Government’s savings package, which reduced the expenditure on medicinal products by approximately six per cent in comparison to the previous year. However, a new initiative of Frank Ulrich Montgomery, the President of the *Bundesärztekammer* (German Medical Association), gave rise to more outrage: in view of the limited financial resources in the healthcare system, he regarded it as necessary to have a list of medical treatments graded by importance. In this, he takes up demands made by his now deceased predecessor, Jörg-Dietrich Hoppe. The Ethics Council too, in its Opinion published in January 2011, “Medical benefits and costs in healthcare: The normative role of their evaluation”, pointed out that “prioritization” in healthcare may be necessary in the future.

Assisted suicide/terminal care/ advance directives

The current legislation on advance directives, which has been in place since September 2009, has calmed the social debate, but the question of euthanasia continues to be controversial in Germany. The call for medical assistance for suicide is also intensively discussed in society. In June, the German Medical Association, at its 114th *Ärztetag* (German Medical Assembly) in Kiel adopted a new version of its professional code, providing that doctors may not render assistance in suicide. Doctors who help patients commit suicide must therefore in future expect to lose their practising certificates.

Dementia

Approximately 1.2 million people with dementia live in Germany. In an aging society, this condition is becoming a widespread disease, which presents family members, carers and the medical profession with great challenges. Consequently, public attention is increasingly directed to interaction with persons with dementia, their care and custodianship, and also their possibilities of self-determination. The German Ethics Council is rising to this challenge and is currently preparing an Opinion.

Brain research

The brain is becoming more and more accessible for medicine and research. Imaging procedures give deeper and deeper understanding of its structures and locate the regions which are active in thinking, feeling and acting. The findings of neurological research may have repercussions for social practice. Reports on the use of brain scans in predicting the success of giving up smoking, recognizing catchy tunes and determining sexual inclinations

appear to confirm this. In the centre of the ethical debate is again and again the question as to humans' free will and whether this can still be seen as really "free" on the basis of scientific findings and not as unavoidably laid down as a result of biophysical conditions.

Biopatenting

In October, the European Court of Justice, in a leading decision, held that procedures which benefit human embryonic stem cells may not be patented. The court held that because fertilized eggs are destroyed in order to obtain such cells, patenting violates the protection of human dignity. In the view of the judges, this is against public policy, since legally fertilized eggs are also embryos. In addition to the patentability of embryonic stem cells, biopatenting also relates to the fundamental question as to the extent to which human genetic sequences should be permitted to be patented at all. While on the one hand researchers fear that research may be blockaded by patents, on the other hand industry points to the significance of patents for safeguarding its claims against third parties and the high costs in connection with developments in the biomedical field.

Outlook

At the end of the year 2011, in contrast to previous years, the German Ethics Council did not lay down the topics of its future Opinions. In view of the fact that the first term of office of twenty-four of the twenty-six Council members ends in April 2012 – Mrs Walles and Mr Huber were appointed on 30 June 2010 – the Council members did not want to make firm decisions on topics in advance for the new Council. By reason of the Federal Government's instructions to prepare an Opinion on the subject of genetic diagnosis, it is merely confirmed that irrespective of the changes in membership of the Ethics Council this subject will be dealt with and the Council is expected to present an Opinion on it at the end of the year 2012.

The Council scheduled only the topic for the Annual Meeting in May, since extensive organization and time planning are necessary to prepare it. The subject of personalized medicine will therefore be the focus of the German Ethics Council's 2012 Annual Meeting. In its Annual Meeting, the German Ethics Council wishes to consider ethical and social questions of personalized medicine, focussing on the patient. Against the background of the present state of research, urgent questions of future medical care will be discussed with doctors, academics in the sciences and the arts, representatives of patients and industry and the public.

The members of the German Ethics Council



Prof. Dr. iur. Edzard Schmidt-Jortzig, former Federal Minister (Chair)



Prof. Dr. med. Christiane Woopen (Vice-Chair)



Prof. Dr. theol. Eberhard Schockenhoff (Vice-Chair)



Prof. Dr. med. Axel W. Bauer



Prof. Dr. phil. Alfons Bora



Wolf-Michael Catenhusen, former State Secretary



Prof. Dr. rer. nat. Stefanie Dimmeler



Prof. Dr. med. Frank Emmrich



Prof. Dr. phil. Dr. h. c. Volker Gerhardt



Hildegund Holzheid, former President of the Bavarian Constitutional Court and Munich Higher Regional Court



Prof. Dr. theol. Dr. h. c. Wolfgang Huber, Bishop (retired)



Prof. Dr. theol. Christoph Käbler, Bishop (retired)



Prof. Dr. rer. nat. Regine Kollek



Auxiliary Bishop Dr. theol. Dr. rer. pol. Anton Losinger



Prof. Dr. phil. Weyma Lübke



Prof. Dr. med. habil.
Dr. phil. Dr. theol.
h. c. Eckhard Nagel



Dr. phil. Peter
Radtke



Prof. Dr. med. Jens
Reich



Ulrike Riedel,
lawyer, former
State Secretary
in the State of
Saxony-Anhalt



Dr. iur. Dr. h. c.
Jürgen Schmude,
former Federal
Minister



Prof. Dr. iur. Dres.
h. c. Spiros Simitis



Prof. Dr. iur. Jochen
Taupitz



Dr. h. c. Erwin
Teufel, former
Prime Minister of
the State of Baden-
Württemberg



Prof. Dr. rer. nat.
Heike Walles



Kristiane Weber-
Hassemer, former
State Secretary in
the State of Hesse



Dipl.-Psych. Dr.
phil. Michael
Wunder

Appendix

Working groups 2011

The working groups of the German Ethics Council form the basis of its substantive work. The groups mentioned below met for more than fifty sessions in the year 2011.

Research on chimeras and hybrids

Spokesperson: Catenhusen
Members: Dimmeler, Emmrich, Kollek, Reich, Schockenhoff, Taupitz, Weber-Hassemer, Woopen

Dementia and self-determination

Spokesperson: Wunder
Members: Gerhardt, Kähler, Radtke, Reich, Riedel, Schmude, Schockenhoff, Teufel, Woopen

Genetic diagnosis

Spokesperson: Kollek
Members: Bora, Catenhusen, Dimmeler, Emmrich, Losinger, Reich, Riedel, Schockenhoff, Schmidt-Jortzig, Taupitz, Weber-Hassemer, Woopen

Intersexuality

Spokesperson: Wunder
Members: Bora, Gerhardt, Kähler, Kollek, Reich, Riedel, Schockenhoff, Taupitz, Weber-Hassemer

Preimplantation genetic diagnosis

Spokesperson: Catenhusen
Members: Bora, Dimmeler, Emmrich, Holzheid, Kollek, Losinger, Reich, Riedel, Schmidt-Jortzig, Schmude, Schockenhoff, Taupitz, Weber-Hassemer, Woopen, Wunder

Synthetic biology

Spokesperson: Catenhusen
Members: Bora, Reich, Taupitz
External experts: Prof. Dr. Peter Dabrock, Prof. Dr. Alfred Pühler

2011 Annual Meeting

Spokesperson: Schockenhoff
Members: Huber, Kollek, Teufel, Weber-Hassemer

Public meeting: Synthetic biology workshop

Spokesperson: Catenhusen
Members: Bora, Reich, Taupitz

Bioethics Forum: The controversial case of baby drops

Spokesperson: Riedel
Members: Gerhardt, Schockenhoff, Schmude, Woopen

Bioethics Forum: Research on medicines in children

Spokesperson: Taupitz
Members: Catenhusen, Dimmeler, Emmrich, Kollek, Walles

Procedure

The German Ethics Council is independent in its work and bound only by the mandate given to it by the *Ethikratgesetz* (Ethics Council Act). Under section 6(2) of the Ethics Council Act, the Ethics Council has adopted rules of procedure governing its procedure in specific terms.

The Ethics Council prepares its Opinions on its own volition, but it may also be instructed to prepare an Opinion by the

German Bundestag or the Federal Government. In addition, the German Ethics Council is required to report in writing to the German Bundestag and the Federal Government at the end of each calendar year on its activities and the current state of the social debate.

The Ethics Council meets once a month in Berlin for a plenary session which is usually open to the public. To address individual topics or entire fields of related topics, the Council establishes working groups of members which coordinate the preparation of draft texts of its Opinions and which meet as necessary separately from the regular plenary debates. In addition, the Ethics Council may arrange for investigations to be carried out and for expert reports to be made and may enlist the services of experts in its work, in particular to assist the working groups.

The German Ethics Council is assisted in the performance of its duties by an office, which was established by the President of the German Bundestag under section 8 of the Ethics Council Act and accommodated at the Berlin-Brandenburg Academy of Sciences and Humanities. The general conditions governing the activity of the office are determined by an agreement between the Bundestag administration and the academy.

The office is responsible for locating, preparing and evaluating scientific documents relating to the topics addressed by the Council, for the compilation of material for publication, for the planning and conduct of meetings and public events and for the publication of Opinions and other documents. The principal duties of the office also include managing contacts with the media, responding to enquiries from the public, maintaining the Council's presence on the internet and looking after the Council's international contacts.

In 2011, the staff of the office comprised the following persons:

- Dr. Joachim Vetter (Head of Office)
- Dr. Katrin Bentele (Research Officer)
- Dr. Nora Schultz (Research Officer)
- Dr. Jana Wolf (Research Officer, parental leave replacement for Dr. Nora Schultz)
- Ulrike Florian (Press and Public Relations Officer)
- Torsten Kulick (Scientific Documentation)
- Carola Böhm (National Affairs and Organisation of Meetings)
- Theresia Sunadi (International Affairs)
- Petra Hohmann (Secretariat)
- Pia Becker (Student Assistant)

Funding

The costs of the German Ethics Council and its office are borne by the Federation. The sum of 1.695 million euro was allocated to the funding of its work in the year 2011 in the Bundestag's budget (Departmental Budget 02, Title 52603-011).

Ethics Council Act

Act on the Establishment of the German Ethics Council
of 16 July 2007 (Federal Law Gazette I p. 1385); entered into force on 1 August 2007

Section 1

Establishment of the German Ethics Council

An independent council of experts shall be formed, bearing the name German Ethics Council.

Section 2

Duties

(1) The German Ethics Council shall pursue the questions of ethics, society, science, medicine and law that arise and the probable consequences for the individual and society that result in connection with research and development, in particular in the field of the life sciences and their application to humanity. Its duties shall include but not be limited to the following:

1. informing the public and encouraging discussion in society, engaging the various social groups;
2. preparing Opinions and recommendations for political and legislative action;
3. cooperation with national ethics councils and comparable institutions of other states and of international organizations.

(2) Every year, the German Ethics Council shall hold at least one public event on questions of ethics, in particular in the field of the life sciences. In addition, it may hold further public events, hearings and public meetings.

(3) The German Ethics Council shall prepare its Opinions on the basis of its own determination, at the request of the German Bundestag or the German Federal Government. It shall forward its Opinions

to the German Bundestag and the Federal Government for their information before publication.

(4) The German Ethics Council shall report in writing to the German Bundestag and the Federal Government at the end of each calendar year on its activities and the current state of the social debate.

Section 3

Position

The German Ethics Council shall be independent in its work and bound only by the mandate given to it by this Act. The members of the German Ethics Council shall exercise their office in person and independently.

Section 4

Members

(1) The German Ethics Council shall be composed of twenty-six members specializing in scientific, medical, theological, philosophical, ethical, social, economic and legal concerns. Its members shall include academics from the above disciplines, and in addition it shall include persons of repute who are particularly familiar with ethical questions of life sciences.

(2) The German Ethics Council shall contain representatives of a variety of ethical approaches and a pluralist spectrum of opinion.

(3) The members of the German Ethics Council may not belong either to a legislative body of the Federal Republic or a Land nor to the Federal Government or a Land government.

Section 5

Appointment and term of office of members

(1) The President of the German Bundestag shall appoint the members of the

German Ethics Council, half on the proposal of the German Bundestag and half on the proposal of the Federal Government.

(2) The members shall be appointed for a four-year term. They may be re-appointed once.

(3) The members may at any time declare their resignation from the German Ethics Council in writing to the President of the German Bundestag. If a member leaves prematurely, a new member shall be appointed for a four-year term. In this case, the appointment of the new member shall be on the proposal of the body that submitted the proposal of the resigning member under paragraph 1.

Section 6

Working methods

(1) The German Ethics Council shall elect a chair and vice-chair or vice-chairs from among its members by secret ballot for a four-year term. They may be re-elected once.

(2) The German Ethics Council shall adopt rules of procedure.

(3) The German Ethics Council may establish working groups and have reports prepared by third parties.

Section 7

Public deliberations

(1) The deliberations of the German Ethics Council are public; it may also meet in closed session and publish the results of such deliberations.

(2) The German Ethics Council shall publish its Opinions, recommendations and reports.

(3) If, in the drafting process, members have a dissenting view, they may express this in the Opinion, the recommendation or the report.

Section 8

Administrative office

The German Ethics Council shall be supported in carrying out its duties by an administrative office. The administrative office shall be established by the President of the German Bundestag. It shall report to the chair of the German Ethics Council.

Section 9

Duty of confidentiality

The members of the German Ethics Council and the members of the administrative office shall observe confidentiality with regard to deliberations in closed session and documents regarded as confidential by the German Ethics Council. The duty of confidentiality shall also apply to information that is given to the German Ethics Council and described as confidential.

Section 10

Costs

(1) The members of the German Ethics Council shall receive a lump-sum expense allowance and reimbursement of their travel costs under the *Bundesreisekostengesetz* (Federal Travel Expenses Act). The expense allowance shall be determined by the President of the German Bundestag.

(2) The costs of the German Ethics Council and its administrative office shall be borne by the Federation.

Section 11

Entry into force

This Act shall enter into force on 1 August 2007.

Rules of Procedure

Preamble

Pursuant to Section 6(2) of the Ethics Council Act (*Ethikratgesetz*), the German Ethics Council adopts the following Rules of Procedure.

Section 1

Independence of members. Partiality.

Duty of confidentiality. Suspension of membership

(1) The members are not bound by instructions. They represent their personal convictions and are bound only by their conscience.

(2) If, in connection with a particular issue, there is concern that there may be a conflict of interest, the member in question shall notify the chair or the vice-chair of this and discuss the matter with the chair or vice-chair. If this discussion does not result in agreement as to whether there is a conflict of interest, the Council shall decide in the absence of the member in question as to whether that member is to take part in the relevant deliberations and voting.

(3) The members have a duty of confidentiality with regard to the deliberations in closed session and the documents described as confidential.

(4) A member may request the chair to permit his or her membership to be suspended. The suspension of membership means that the member will continue to receive all notices from the Office but will no longer attend plenary meetings and meetings of the working groups, and that the absence of the Council member from these meetings shall be deemed to be excused without any further communication. The suspension of membership also means that the Council member will no longer appear in public as a member of the

German Ethics Council. The suspension of membership shall end as soon as the member in question informs the chair that the reasons for suspension no longer apply.

Section 2

Resolutions

(1) The Council shall constitute a quorum if more than half of the members are present. Unless other majorities are prescribed, the Council shall decide by a majority of the members present.

(2) Resolutions may be passed in writing or by electronic means, if the Council so resolves by a majority of the members present.

Section 3

Chair

(1) The chair and the vice-chairs shall be elected by an absolute majority of the members of the Council. If this majority is not attained in a first ballot, there shall be a second ballot, in which the decision shall be by relative majority. In the event of a tie, after a further discussion there shall be a further ballot. If this too results in a tie, there shall be a decision by drawing lots. The Council shall decide by simple majority on the number of deputies.

(2) The chair or a vice-chair shall conduct the meetings and be responsible for preparing the agenda. He or she shall represent the Council. If the chair is prevented, the vice-chairs shall exercise his or her duties in the order determined by the Council. With the consent of the Council, he or she may assign individual duties to the vice-chairs.

Section 4

Work programme

The Council shall adopt a work programme. The programme shall, as a general rule, be updated once a year.

Section 5**Meetings**

- (1) Meetings shall, as a general rule, be held once a month in Berlin.
- (2) The date of each meeting shall be set by the Council a considerable time in advance. An extraordinary meeting shall be held within ten days at the request of a minimum of seven members.
- (3) The agenda of each meeting shall be provisionally decided at the previous meeting. The chair and/or the vice-chairs may add further items to the agenda if a need for this arises subsequently. They shall do this if requested by three members. A final decision on the agenda shall be made by resolution at the beginning of the meeting itself.
- (4) Notices convening meetings, with the agenda and the necessary documentation attached, shall be sent at the latest ten days in advance. In the case of extraordinary meetings, the notice period shall be three days.

Section 6**Public nature of meetings**

- (1) Pursuant to Section 7 of the Ethics Council Act, the plenary meetings of the Council shall, as a general rule, be public. A decision to meet in closed session shall be passed by the votes of the majority of the Council. The meetings of the working groups shall not be public.
- (2) Agenda items that pursuant to paragraph 1 are to be discussed in public shall be so identified on the agenda. This shall be published online.
- (3) Admission to the public meetings shall be subject to availability of seats. In individual cases, the Council may permit sound and image recording.

Section 7**Minutes**

- (1) Resolution minutes of the meetings shall be made. The minutes shall be sent to all members within two weeks of a meeting. Any objections must be made within ten days after forwarding. If objections are not accepted, a decision shall be made on them at the next meeting.
- (2) The minutes or records of the public meetings and events shall be published online. The results of deliberations in closed session may also be published online.

Section 8**Expert reports, experts and guests**

The Council may arrange for investigations to be carried out and expert reports made and may enlist the services of experts for its work. In addition, representatives of the constitutional bodies authorized to instruct the Council, of public authorities and institutions, of organizations and associations, and other guests may be invited to attend deliberations on individual topics.

Section 9**Rapporteurs and working groups**

- (1) The Council may appoint members, with their consent, as rapporteurs on specific topics.
- (2) In addition, the Council may form working groups from among its members to prepare specific topics, as well as to address entire subject areas. The working groups shall appoint their spokesperson and, if necessary, rapporteurs, who shall present the results of their work to the Council.
- (3) Section 8 shall apply mutatis mutandis to the working groups.

Section 10

Position statements and publications

(1) Opinions, recommendations, reports and Annual Reports shall be adopted after an oral discussion of the draft submitted by the rapporteur or spokesperson of the working group. If this cannot be done immediately after the deliberation, the passing of a resolution may be postponed until the next meeting. For this purpose, the members must be provided well in advance with a version of the draft revised by the rapporteur or the spokesperson of the working group on the basis of the results of the deliberation. At the request of dissenting members, the relevant supplementary position statements shall be attached to the resolution.

(2) The Council shall decide in each case on the date and manner of publication of Opinions, recommendations, reports and Annual Reports after they are forwarded to the Federal Government and the Bundestag.

Section 11

Cooperation with the German Bundestag and the Federal Government

(1) The Council shall provide the German Bundestag or a parliamentary body appointed by the German Bundestag and the Federal Government with the agendas of its meetings.

(2) The Council may invite members of the Bundestag and the Federal Government to attend particular deliberations.

Section 12

Office and budget

(1) The Council shall be supported in its work by an administrative office. The staff of the office shall be subject to the instructions of the Council in regard to the relevant subjects and, where matters

of day-to-day business are concerned, of the chair or of the vice-chairs.

(2) The Council shall decide on the basis of relevant submissions of the chair or the vice-chairs on the organization of the office and, where executive-grade posts are concerned, on filling these, and on the appropriation of the total budget funds at its disposal.

(3) The staff of the office shall attend meetings as stipulated in detail by the Council.

Section 13

Amendments to the Rules of Procedure

Amendments to the Rules of Procedure require the consent of a two-thirds majority of the members of the Council.