



Annual Report 2009

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Introduction

At the end of 2009 the German Ethics Council can look back on an active and eventful year. As provided by Section 2(4) of the *Ethikratgesetz* (EthRG – Ethics Council Act) of 16 July 2007, this report documents the activity of the Council from January to December 2009.

In accordance with the Act, the German Ethics Council's brief is to monitor the ethical, social, scientific, medical and legal issues arising in connection with research and development, in particular in the field of the life sciences and their application to man, as well as the likely consequences for the individual and society. Its duties also include informing the public and encouraging discussion in society, preparing Opinions and recommendations for political and legislative action, and cooperation with national ethics councils and comparable institutions in other countries and those of international organizations.

The German Ethics Council is composed of 26 members specializing in scientific, medical, theological, philosophical,

ethical, social, economic and legal disciplines. Its members are appointed by the President of the *Bundestag* (German Federal Parliament) for a four-year term, half of them being nominated by the *Bundestag* and the other half by the Federal Government. Members may be re-appointed once.

The members exercise their office in person and independently. They may not belong either to a legislative body of the Federal Republic or a *Land* or to the Federal Government or a *Land* government. The Chair is the former Federal Minister of Justice, Prof. Dr. Edzard Schmidt-Jortzig, with Prof. Dr. Christiane Woopen and Prof. Dr. Eberhard Schockenhoff as his Deputies.

The costs of the German Ethics Council and its Office are borne by the Federal Government. The sum of 1.695 million euro was allocated in the *Bundestag's* budget to the funding of the Council's work in 2009 (Departmental Budget 02, Title 52603-011).



The members of the German Ethics Council

Procedure

The German Ethics Council works independently and is bound only by the terms of the mandate conferred on it by the Ethics Council Act. In pursuance of Section 6(2) EthRG, the Ethics Council has provided itself with an agenda governing the practical aspects of its procedure.

The Ethics Council decides itself on the issues to be addressed in its Opinions, but may also prepare Opinions at the request of the *Bundestag* or the Federal Government. The German Ethics Council is in addition required to report in writing at the end of each calendar year to the *Bundestag* and the Federal Government on its activities and the current state of the social debate.

Until the elections to the *Bundestag* held in September 2009, the Parliamentary Advisory Council established by the *Bundestag* monitored the work of the German Ethics Council. Nine *Bundestag* deputies served on the Advisory Council.

The members of the Ethics Council come together once a month for a plenary meeting in Berlin,¹ which is as a rule open to the public. To address individual topics or entire fields of related topics, the Council establishes working groups of members (see p. 40) which coordinate the compilation of draft texts for its Opinions and meet as necessary, separately from the routine plenary debates. In addition, the Ethics Council may commission investigations or expert reports and call in experts to assist with its work, in particular in support of the working groups.

The Ethics Council is assisted in the performance of its duties by an Office, established by the President of the *Bundestag* in accordance with Section 8 EthRG and

accommodated at the Berlin-Brandenburg Academy of Sciences. 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 Ethics Council's presence on the World Wide Web, and looking after the Council's international contacts.

The Office had a permanent staff of eight in 2009, supplemented at certain times by a student assistant. The Head of the Office is Dr. Joachim Vetter.

¹ Audio recordings were made of the public meetings held in the period under review and can be accessed on the Ethics Council's website (www.ethikrat.org).

Topics

The German Ethics Council had agreed on the main elements of its 2009 work programme in December 2008. The principal topics addressed by the Ethics Council during the year were accordingly as follows:

- Anonymous relinquishment of infants
- Biobanks
- Research on chimeras
- Allocation of resources in healthcare

Further topics were discussed by the Ethics Council at its public plenary meetings and other public events (see p. 16 ff.).

Anonymous relinquishment of infants

The German Ethics Council published its Opinion “Anonymous relinquishment of infants: tackling the problem” on 26 November. Its main points are summarized below.

Various forms of anonymous relinquishment of infants have been facilitated in Germany since 1999 by denominational and other independent-sector institutions concerned with the welfare of pregnant women, children and young people, and by hospitals. The aim of baby drops, as they are known, is to prevent the killing or abandonment of newborn infants. In addition, provision for anonymous birth in hospitals is intended to allow women who wish to keep the fact of their maternity secret to give birth with medical attendance. However, the various forms of anonymous relinquishment present

serious ethical and legal problems, in particular because they violate the child’s right to a knowledge of his² parentage, which is an important aspect of the right of personality protected by the constitution, as well as his family rights – which, as fundamental rights, also enjoy protection – chief among these being the right to a relationship with his parents. Furthermore, experience so far suggests that it is unlikely that women at risk of killing or abandoning their newborn infants will in fact be reached by these facilities, thus saving the lives of their children. To date there is no record of even a single case in which it can be assumed that a mother would have killed or abandoned her child had the facility for anonymous relinquishment not existed.

In the necessary consideration of the relative merits of the conflicting fundamental rights at issue, the importance attached to the right of personality of the relinquished children, on the one hand, and to the protection of children’s lives that is the intended aim of the facilities, on the other, will substantially depend on the assumed probability that the lives of the relinquished infants would be at risk. Violation of a relinquished child’s right of personality will be acceptable only if it is suitable, necessary and appropriate for the protection of that child’s life. According to one ethical position, however, the impossibility of ruling out the saving of even a single child’s life is of greater moment than the rights of all the other children, mothers and fathers that are violated by the existence of the facilities for anonymous relinquishment of infants.

² For convenience, the masculine form is used where applicable for both sexes throughout this document.

Another significant ethical consideration with regard to the various forms of anonymous relinquishment of infants – baby drops and anonymous birth – is whether anonymous births take place with medical attendance and whether the women concerned can be reached personally and counselled – something that is of course precluded in the case of a baby drop. Furthermore, where an infant is relinquished in a baby drop, it is impossible to be certain whether the person depositing the child was the mother herself or someone else who left the child there against her will.

There are as yet no published studies on the effects of anonymous relinquishment on the relinquishing mother and the child. However, comparative data are available from France (“Generation X”), which, together with the findings of adoption research, can be presumed to apply also to the situation of the children in question. It is considered that the problems familiar from the case of adoption are further exacerbated in that of anonymous relinquishment.

The context of the birth and the circumstances leading to recourse to the anonymous facilities are only a part of the problem. Many mothers who put up their child for adoption feel guilty throughout their lives, as if they had failed by giving up their child, and vow never to do so again. They often spend the whole of the rest of their lives waiting to hear from their child. Again, mothers who relinquish their child anonymously have no prospect of ever finding him again. The possibility of working through the act of separation is also rendered more difficult in the case of a mother who gives up her child anonymously. On the one hand, the psychological constellation of a woman who has relinquished her child

anonymously is more problematic, while, on the other, the opportunity of talking about her decision is minimized, as the giving up of her anonymity represents an additional problem. Experience with the practice of anonymous relinquishment thus suggests that it does not help relinquishing mothers to overcome their situation of distress permanently.

For children, knowing the identity of their biological parents is important, because it will enable them to enquire into the circumstances that led to their relinquishment. This is important because the identity of such children is shaped by the fundamental experience of having been surrendered to the care of other people by their parents or mother. In many cases this gives rise to profound trauma, to lack of self-esteem, to fear of a repetition, and frequently even to guilt feelings in the children. For this reason, the possibility of exploring the reasons for this subjectively enigmatic and extremely burdensome situation at a later stage in their lives is of paramount importance if they are to have any chance of building a stable personal identity. Anonymization of their parentage deprives these children of this possibility once and for all, with severe lifelong adverse consequences.

With regard to the legal aspects, it should be noted that the anonymous relinquishment of infants is inconsistent with current law in many respects. Conflicts arise with family law, the law governing civil status, criminal law and the law of guardianship, as is demonstrated in detail in the Ethics Council’s Opinion. As to the ethical evaluation of the various forms of anonymous relinquishment of infants, questions arise on three different levels. The first and most fundamental level concerns the importance of a knowledge of one’s biological parentage, social incorporation

in the family of origin, and parental responsibility for their child. Secondly, on the level of the relative evaluation of different goods and rights, the issue is whether and, if so, under what circumstances it might be ethically acceptable permanently to deprive children of access to a knowledge of their biological parentage and association with their biological parents, as well as to rob the non-relinquishing parent of the possibility of access to his child. Lastly, on the level of state responsibility, the problem concerns the extent to which, for the purpose of presumed help for the few, the state should adopt provisions applicable to all, with possible adverse effects on society's conception of the family and on the entitlements and duties of third-party family members. Such a posture might in addition foster an ethos in which tragic exceptions take on the appearance of state-tolerated modes of action, especially if the possibility of abuse is taken into account. Another point to be considered is whether the state might in fact have a wider responsibility for averting a mother's exceptional psychosocial distress, which, it appears, can be relieved at most rudimentarily and temporarily by the anonymous relinquishment of her infant.

A further issue raised by the Ethics Council in its Opinion, in the context of the current toleration of the existence of facilities for anonymous relinquishment of infants, is how far the state should leave the decision whether the legal order is or is not enforced to anonymous persons who are not called upon to take responsibility for their actions on account of their anonymity.

By means of the following recommendations, the German Ethics Council wishes to help bring about a situation in which the pregnant women and mothers

concerned can receive the best possible assistance in their distress and conflicts without disproportionate violation of the rights of others – in particular, those of their children.

The German Ethics Council recommends:

1. The existing baby drops and arrangements for anonymous birth should be abolished. The ending of the provision for the anonymous relinquishment of infants should as far as possible be implemented jointly by all bodies responsible for policy in the relevant field and the institutions concerned.
2. This measure should be accompanied by an expansion of the availability of public information about the existing legally sanctioned assistance facilities provided by independent-sector institutions and state child and youth welfare bodies, as well as about the aid available to pregnant women and mothers in situations of distress and conflict. In addition, action is necessary to improve trust in the legally sanctioned assistance services so as to increase take-up of this provision. An essential requirement here is cooperation on a basis of trust between the denominational and other independent-sector institutions and the state child and youth welfare bodies. The following objectives and measures are important:
 - More publicity must be given to the fact that a legal entitlement exists to receive anonymous advice on the forms of assistance available in situations of distress and conflict.
 - Easy access to the legally sanctioned facilities for assistance to pregnant women and mothers in situations of distress (such as the confidential arrangement of accommodation in

a mother-and-child hostel or of care for the child) must be guaranteed at any time of the day or night. This includes, for example, the provision of round-the-clock telephone or on-line counselling by persons specially trained to furnish the relevant information and advice. The contact details for these initial ports of call should be posted, for instance, in doctors' surgeries, public transport facilities and other public places such as government offices, as well as on the World Wide Web.

- The counselling and assistance centres should cooperate with each other in such a way that they can promptly point callers to sources of effective help even if they themselves are not formally competent to deal with a woman's specific problem.
- The independent-sector institutions and the state bodies responsible for the welfare of mothers-to-be and for children and youth welfare should, as in the case of the planning of youth welfare (Section 80 of Book VIII of the *Sozialgesetzbuch* [SGB – Social Code]), be required to cooperate at an early stage and to coordinate the services they provide.
- Effective professional advice on the assistance available in situations of distress and psychosocial counselling should also be provided in maternity institutions.
- The fact must be more widely publicized that the assistance available in situations of distress and conflict is confidential, that it offers protection from potential dangers from third parties, and that the birth of a child and the handing over of a child to a care institution or for adoption are subject to the regulations on the

protection of social data and on confidentiality in adoption.

- A parental decision to put a child up for adoption so as to allow him to grow up in a stable family of his own should be respected and deemed a responsible act. The social acceptance of such decisions should be promoted.
3. It is admittedly the case that the law governing emergency situations legitimizes the actions of all who are present and able to assist in an emergency involving immediate physical danger to the life and health of a mother and child for the duration of the emergency. In pursuance of the obligation to render assistance (Section 323c of the *Strafgesetzbuch* [StGB – Criminal Code]), a mother in childbirth cannot be refused medical attention even if she fails to disclose her identity. However, neither the law governing emergency situations nor the obligation to render assistance covers the provision of facilities for the anonymous relinquishment of infants in cases where there is no individual acute emergency, such as the provision of a baby drop or the widespread systematic public availability of anonymous birth. The facilitation of continued anonymity once the emergency is over is also not covered. For this reason, such provision should not be maintained.
 4. As a minimum, the following measures should be mandatory in every situation where a child is relinquished anonymously:
 - a) Immediate notification of the child to the youth welfare office, full information on the circumstances of his relinquishment being supplied.
 - b) Appointment of a neutral guardian for the child, the guardian to be in-

dependent of the institution where the child was anonymously relinquished.

- c) Adoption of children given up anonymously to be arranged only through an adoption agency separate in organization and staffing from the institution at which the child was relinquished.
 - d) The child to be returned to the mother or parents only through the youth welfare office.
5. Pregnant women and/or mothers who consider it necessary to conceal their maternity from their social group, but who prefer to avoid contact with public bodies because they do not trust that their identity will be kept unconditionally secret, should be helped by means of an arrangement which assures them of a reasonable period of maximum possible confidentiality for solving their problems with the aid of counselling and assistance, and which does as little harm as possible to the interests of the child and the father, the arrangement being only temporary and applicable for as short a time as possible. For this reason, statutory provision should be made for “confidential relinquishment of an infant with temporarily anonymous registration”.

The new law to be introduced should include the following core provisions:

- a) A woman in the care of a state-recognized counselling centre before, during or after the birth of a child can request that the data to be furnished in pursuance of Sections 18 to 20 of the *Personenstandsgesetz* (PStG – Law on Civil Status) shall, for a period of one year from the birth of the child, be communicated only to the counselling centre and not to the Registry Office.

- b) For a period of one year from the birth, the counselling centre must not communicate the data concerned to any third party. The woman’s data may and must be communicated to an adoption agency only if she wishes to put up her child for adoption. The adoption agency must not divulge the data to any third party. Neither state nor private bodies may have access to the data held by the counselling centre or adoption agency prior to the expiry of the period of confidentiality. That period shall end if and when the mother no longer wishes the data to remain confidential or if and when she takes the child back.
- c) The counselling centre must, within the specified period, register the birth at the Registry Office as temporarily anonymous.
- d) Upon the expiry of the period of compulsory confidentiality, the counselling centre must communicate the data in its possession relating to the mother and father to the Registry Office, where applicable with a request by the mother for the data to be given blocked-disclosure status.
- e) The counselling centre must furnish comprehensive information to pregnant women and/or mothers about the assistance available to mother and child in situations of distress, such as accommodation in a mother-and-child hostel, taking the child into care, and the possibility of adoption, as well as about the rights and obligations of the father and the child’s right to know his father, and should try to obtain the name of the father. As a part of its advisory obligations, the adoption agency should attempt

to secure the involvement of the father in the adoption procedure.

- f) A decision on adoption cannot be made until after the expiry of the period of compulsory confidentiality or, as the case may be, until after the court has taken cognizance of the mother's or, where applicable, the parents' data.
- g) Over and above the existing provisions of adoption law, the court should be empowered to give consent in place of the father if the woman or the child would be exposed to disproportionate harm as a result of obtaining the father's consent or of the making of contact with the father. However, the father's data should be recorded at least in the adoption documentation, except where the father remains unknown in a given individual case.

In a supplementary position statement, two members of the Council indicated that, although they agreed with the Council's recommendations – in particular, that the facilities for anonymous relinquishment of infants should be abolished – they did not consider the Council's proposed statutory provision for confidential birth to be necessary, because the aim of providing women with a confidential protective space within which to come to terms with their situation of distress could already be achieved by means of the currently existing legally sanctioned easy-access facilities for counselling and assistance.

A group of six members presented a dissenting position statement dissociating themselves from the recommendation that the existing facilities for the anonymous relinquishment of infants should be closed down immediately or gradually, because they felt that, for the small

number of parents and women who could not find their way to the counselling centres, these facilities might be a last resort, providing them with an alternative to abandoning their child without anyone to care for him.

Biobanks

The former National Ethics Council having published its Opinion "Biobanks for research" in 2004, a working group of the German Ethics Council was asked to consider first of all whether the physical and structural evolution of biobanks in the intervening years now called for a fresh ethico-legal evaluation.

Biobanks are defined as collections of samples of human bodily substances (e.g. cells, tissue, blood or DNA) that are or can potentially be associated with personal data and information on their donors. Biobanks thus have a twofold character, as collections of both samples and data. They are an important research resource, in particular for identifying the causation and mechanisms of a large number of monocausal and multicausal disorders and their treatment, and therefore represent an important tool for the development of new drugs and therapies.

Most of the existing biobanks were established for research purposes; that is to say, they are institutions which collect samples and data of human origin and either use them for in-house research or make them available to third parties for their studies. They are designed to facilitate work in a variety of fields of research, some of which may only arise in the future.

A large number of new trends have emerged in recent biobank research, involving both quantitative and qualitative

expansion, privatization and commercialization, links between establishments and internationalization. Science seeks to obtain as much data as possible and to use it without limitation of time, while genome research data can be re-identified with increasing ease because it contains individual genetic patterns; as a result, new data protection requirements have arisen. Additional problems may be presented by the fact that, under current law, state bodies cannot be denied access to databases, while the information available to donors and their ability to keep track of data and samples are constantly decreasing owing to the complexity of the links between biobanks.

The conclusion from the deliberations during the course of the year is that a completely new assessment of the topic is not necessary. Instead, an Opinion based on that of the National Ethics Council is in preparation and is scheduled for completion in the first half of 2010.

Issues of chimera and hybrid research

On the basis of the presentations of Council members Jens Reich and Frank Emmrich on the formation of chimeras and hybrids, the ethical evaluation of chimera and hybrid research was deemed important and was included in the 2009 work programme. At the same time it was decided to establish a working group to structure the topic and to put forward proposals for an Opinion.

In 2009, the working group on human-animal mixed-species entities began by examining the different variants of chimera and hybrid research and considering the associated social, ethical and legal challenges. During the course of these de-

liberations, an exchange of views between members of the working group and the *Bundestag's* Advisory Council on Ethics took place in March, and in August the working group consulted neuroscientists at a hearing, not open to the public, on the transplanting of human cells into animal nervous systems.

In October 2009, the working group presented an interim activity report to a plenary meeting of the German Ethics Council and was charged with the preparation of an Opinion on the subject of human-animal mixed-species entities. The group plans to address the ethical issues on the basis of the following three examples: cybrid production (the transfer of human somatic cell nuclei into enucleated animal eggs); the transplanting of human nerve cells into animals; and the formation of transgenic animals with human genetic material.

All three methods are already in use in international scientific research. In a cybrid, the combination of a purely human cell nucleus with animal cytoplasm gives rise to a mixed entity in which animal genes remain active in the mitochondria, the organelles which supply the cell with energy. Whether an entity of this kind is ethically, legally or scientifically deemed to be a human embryo is disputed. The champions of hybrid research wish to use the cybrids formed in this way for the derivation of embryonic stem cells without destroying human embryos and without obtaining eggs from women as would otherwise be necessary for such experiments, thus avoiding the associated ethical and health concerns.

By transplanting, for instance, nerve cells produced from human stem cells into experimental animals, scientists can study the behaviour and regeneration potential of these cells within the complex of cells

and tissues of the living organism; this is regarded as an important step towards the demonstration in principle of the usability of such cells. In this connection, the Ethics Council is interested mainly in whether the transplanting of human nerve tissue into animals might give rise to the transfer of ethically relevant human characteristics to the animal, thus potentially leading to a changed evaluation of its moral status.

The breeding of transgenic animals with human genes is a common technique of research into the functioning of human genes. Here too the question arises whether the nature and number of human genes transferred in this way to an animal might alter the animal's characteristics so radically as to cast doubt on its moral status.

The working group on human-animal mixed-species entities will present its draft Opinion to the German Ethics Council during the course of 2010. The date of publication has not yet been fixed.

Allocation of resources in healthcare

At its plenary meeting of 25 September 2008, the German Ethics Council had taken a paper presented by Council member Weyma Lübke³ as the starting point for its debate on the purport and limits of the statutory requirement of evaluations based on health economics.

Since 2007, Germany has had an explicit legal provision requiring cost-benefit analyses to be used as the basis for certain decisions on the range of benefits provided by the public healthcare system. The body responsible for the implementation of this requirement, the *Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen* (IQWiG – Institute for Quality

and Efficiency in Health Care), has for this purpose drawn up methodological proposals which have become the subject of critical controversy. In particular, German health economists have complained of departures from the methods of evaluation accepted within their discipline.

This controversy involves implicit value judgements that are of fundamental relevance to the public healthcare system's conception of its role. Where such judgements are concerned, specialists in the field of health economics should not be accorded sole rights of interpretation. The judgements must be rendered transparent, and they call for a wide-ranging interdisciplinary debate also involving the public.

The Ethics Council has set up a working group which will address the ethical status of cost-benefit analyses on the basis of this controversy and the social-law provisions that underlie it. This work is being carried out against the more general background of the issue, which is also increasingly a matter of public discussion in Germany, of finding acceptable ways to limit spending on the public healthcare system. The full membership of the Council will deliberate further on any other aspects of this complex problem, which has already been discussed for more than two decades in international specialist circles, that should additionally be covered by an Ethics Council Opinion on questions of resource allocation.

Council members Bettina Schöne-Seifert and Eckhard Nagel, speaking during the public part of the plenary meeting of 27 August 2009, introduced some concepts relevant to the discourse on the allocation of resources in healthcare.⁴ They noted that, while terms such as “prioritization”, “rationalization”, “rationing”, “medically necessary” and the like often

³ A verbatim record of the public meeting can be downloaded from www.ethikrat.org.

⁴ An audio recording of the public meeting can be accessed at www.ethikrat.org.

had emotional connotations, they lacked unambiguous objective definitions. As a result, these terms were often used for political purposes rather than to inform. For example, whether the formulation “rationalization first and rationing second” was really as reassuring as it was intended to sound depended on the exact underlying definition of rationalization. Even in the case of this concept, not everything it was assumed in the debate to mean was ethically unproblematic. For this reason, more transparency with regard to such “slogans”, as well as a strengthening of the public consciousness of the seriousness and complexity of the underlying problems, was an important concern of the working group in the preparation of its draft text, whose working title was “The statutory status of cost-benefit analyses in healthcare”. As soon as this draft was finished, the Ethics Council would decide whether the subject-matter of the proposed Opinion, in the overall context of the debate about the allocation of resources in healthcare, should be augmented to include the fundamental issues associated with a cost-benefit analysis.

Public meetings and promotion of social discourse

The Ethics Council Act provides that the tasks of the Council shall include informing the public and encouraging discussion in society, while engaging the various social groups. An important aspect of this engagement is that the Council holds regular meetings that are open to the public and organizes at least one public event every year.

During the period under review, four plenary meetings (in January, April, August and December) were completely or at least partially open to the public; that is to say, interested persons could attend and gain an insight into the Council's approach to its topics and its discussion culture.

In addition, the Ethics Council held four public events in a number of different formats. These included the Annual Meeting and three evening meetings in the Bioethics Forum series. Three discussion events with students and schoolchildren respectively represented another platform for social discourse.

The Ethics Council reaches different sections of the public with its programme of events. At the Annual Meeting, the German Ethics Council enters into a public exchange of views with experts, with researchers in the life sciences and bioethics, with representatives of organizations and associations, and with interested citizens. A surprising degree of interest in the Annual Meeting was evident on the part of older secondary school pupils. The Bioethics Forum enables a broad spectrum of the public who are not necessarily in possession of expertise in the relevant subjects to engage in a dialogue with mostly external speakers and the members of the Ethics Council.

To allow hearing-impaired persons to take part in the public meetings and events, real-time transcriptions are prepared; like the audio recordings, these are accessible to the public at large on the Council's website.

Public plenary meetings

The German Ethics Council had selected a wide range of subjects for its four at least partially public plenary meetings. In January and April the Council for the first time addressed the subjects introduced in the following sections of this report – namely, 'Ethical positions on suicide' and 'Synthetic biology'. In August, Council member Bettina Schöne-Seifert defined some of the concepts used in relation to the allocation of resources in healthcare, with a view also to facilitating the discussion within the working group (see p. 14). Finally, the public plenary meeting in December was devoted to the trilateral meeting of the ethics councils of Germany, France and the United Kingdom (see p. 28).

Ethical positions on suicide

At its public plenary meeting on 22 January, the German Ethics Council considered possible ethical positions on suicide on the basis of papers⁵ by Council members Frank Emmrich, Edzard Schmidt-Jortzig, Eberhard Schockenhoff and Michael Wunder, as well as of the ensuing discussion.

Medicine today can significantly prolong life. However, this increases the risk of long-term infirmity and a painful death. Society is thus challenged again and again

⁵ Audio recordings, presentations and papers from this meeting can be accessed at www.ethikrat.org.

to confront the circumstances of dying and to make full use of the possibilities of humane end-of-life and palliative care, as well as not to avoid issues such as suicide, assisted suicide and euthanasia as a last resort for a person in a situation of unbearable suffering.

Although assisted suicide is not a punishable offence in Germany, it conflicts with statutory provisions on the obligation to render assistance and with the associated professional codes. It also raises a plethora of ethical questions, such as that of the helper's responsibility, differentiation from active euthanasia, and the social effect on persons in frail health or seriously ill if assisted suicide were to be accepted by society and practised accordingly.

The speakers agreed unanimously that the boundaries between the various forms of involvement in the death of another individual were not always clear-cut and were also sometimes difficult to define.

In the ensuing discussion, the members of the Ethics Council stated that killing on request should continue to be impermissible. With regard to assisted suicide, on the other hand, a wide range of ethical positions emerged. Some Council members advocated removing the taboo on assisted suicide, while others agreed subject to the proviso that assisted suicide should be placed in the hands of medical practitioners. Some members considered that assisted suicide should in future be made a punishable offence. However, the predominant view expressed was that commercial facilities for assisted suicide were not acceptable.

Synthetic biology

At its public plenary meeting on 23 April 2009, the German Ethics Council discussed ethical issues in relation to recent

developments in the field of synthetic biology.

In her introductory paper, Nora Schultz, a research officer at the Council's Office, outlined the state of the art and the ethical aspects of this recent discipline.⁶

Synthetic biology is based on the design of biological elements and systems using standardized building blocks assembled in accordance with engineering principles. In consequence of the progress of genome research and technology since the turn of the millennium and particularly within the last five years, large-scale automated DNA sequencing and synthesis have become affordable, while the precise technical design and production of entire biological systems have become a tangible possibility for the near future.

The principal objectives of synthetic biology extend from the artificial replication and modification of complex biological functional systems and the development of novel biomolecules to the creation of entire synthetic organisms having little in common with their natural models.

The ethical implications of synthetic biology concern in particular the possible consequences of the creation of artificial life for man's attitude to life itself, as well as the risks of unintended interactions between artificial organisms and the natural environment, or of the deliberate misuse of synthetically produced organisms.

Yet as the ensuing discussion also showed, these issues are not fundamentally new, but are characteristic of a trend that commenced in the nineteenth century with the artificial synthesis of natural substances, thus placing man's attitude to and treatment of nature on a new qualitative level. The same questions arise in connection with other biotechnological developments, albeit in a new dimension. However, it is as yet impossible to

⁶ An audio recording, the paper itself and the perspective paper prepared in advance for the Ethics Council can be accessed at www.ethikrat.org.

determine when fundamental practical innovations will be forthcoming in this field. In confronting the prospects held out by synthetic biology, it will be essential to avoid biological reductionism and to consider synthetic biology in the overall context of biotechnology research.

The Ethics Council will continue its attentive monitoring of developments in synthetic biology and will address the subject again in 2010, initially at an evening meeting in the Bioethics Forum series on 24 February.

Annual Meeting

More than 450 people from all walks of life attended the first Annual Meeting⁷ of the German Ethics Council in Berlin on 28 May 2009. The subject was “Are human beings controllable? Insights into the brain and the ways of modifying its functioning”.

New discoveries and applications are constantly being developed by the neurosciences, with implications that are often difficult to predict in spite – or indeed because – of their initial promise.

In her introductory address, Christiane Woopen, Vice-Chair of the Council, noted that this was a burning issue because it not only included questions addressed by ethics, as for example in the case of stem cell research, but also involved the very foundations and presuppositions of ethics itself, since it meant that we had to rethink our relationship with ourselves. Our image of humanity influenced the way in which we posed ethical questions, the specific questions we considered to be particularly important, and the answers we gave to them.

In this connection, could images of the brain help us to understand our thought

and feeling processes? Was it acceptable for healthy persons to seek to enhance their performance by taking drugs developed for the treatment of mental illness, dementia or attention disorders? What might be the eventual outcome if implanted electrodes could be targeted more and more precisely so as to influence brain functions such as motor activity, speech and mood? These were the three central issues addressed by the meeting.

In her introductory paper, the neuropsychiatrist Barbara Wild traced the historical evolution of our present-day conceptions of the brain and our associated image of man, and outlined the current status of brain research.

John-Dylan Haynes, a neurobiologist, gave an account of the still young field of “brain reading”, which investigated how far thoughts can be deduced from a person’s cerebral processes. Although it was not yet possible to interpret any given thought or to transfer ideas from one person to another, a variety of possible applications could already be imagined on the basis of the simpler approaches available today, in particular in forensics and criminology (e.g. lie detectors), or for thought-based control of computers and prostheses.

The psychiatrist Isabella Heuser reported on the rapidly increasing trend for healthy individuals to take drugs in order to improve and enhance their cognitive performance. These were mainly preparations developed for the treatment of attention disorders, narcolepsy and the dementias. Her contribution offered an introduction to the results of research on the effects and side-effects of antidepressants, stimulants and anti-dementia drugs and the associated ethical problems.

In his paper, another psychiatrist, Thomas Schläpfer, described deep brain

⁷ The programme of the Annual Meeting, the presentations, audio recordings and a real-time transcription can be accessed at www.ethikrat.org.



From the left: Tade M. Spranger, Barbara Wild, John-Dylan Haynes, Eberhard Schockenhoff

stimulation as a highly effective technique for the modulation of severely disturbed neuronal activity and the therapy of neurodegenerative and psychiatric disorders that could not be treated by other methods. Professor Schlöpfer emphasized that this procedure, unlike the psychosurgery of the previous century, was minimally invasive, relatively harmless to the patient, and completely reversible. The treatment often enabled patients to lead independent lives again where other approaches had failed.

The legal expert Tade Matthias Spranger pointed out that the ultimate criterion by which these techniques should be judged was human dignity, which was an imponderable. “Thought-reading” by imaging techniques in criminal proceedings was impermissible if carried out against the will of the person concerned, since every individual had the right to informational self-determination. However, other possible applications could improve the legal situation of, for example, disabled persons, who could be helped by technology to communicate their needs better and thereby to regain their legal capacity.

The criminal law specialist Henning Rosenau considered that interventions involving the brain had legal implications if they concerned our image of man and the central core of humanity. However, the question arose whether such interventions had consequences in terms of human dignity and hence did not fall within the legitimate field of disposition of the person concerned. Another aspect to be resolved was whether there were legally valid arguments for restricting neuroenhancement on social grounds.

Addressing the ethical dimension of brain research, the philosopher Ludger Honnefelder concluded that the issue of neuroenhancement was discussed mainly in terms of authenticity, of the preservation of personal identity in the conduct of an individual’s life. It would be legitimate to enhance man’s cognitive capability only if a consensus existed in society as to the intended aims.

The sociologist Wolfgang van den Daele and the theologian Dietmar Mieth took up these ideas in the concluding debate. Professor Van den Daele expressed his conviction that every individual could



From the left: Henning Rosenau, Isabella Heuser, Bettina Schöne-Seifert, Thomas Schläpfer

and should decide for himself whether he could still live an authentic life if he availed himself of neuroenhancement. Any external judgement would be presumptuous.

Professor Mieth, on the other hand, gave notice of a debate in society that would lead to consensual decisions on what we could do, what we should permit, and what we wished to achieve. Although it was ultimately impossible to forbid people to manipulate their own brains, legal limits could be set to the development of harmful products and measures, as well as to experiments and applications of benefit to third parties only.

In three discussion sessions with the audience, a predominantly critical view of neuroenhancement was expressed. In particular, it was feared that, with the increasing availability of such methods, precisely in a performance-

oriented society characterized by intense competition, there would be increasing pressure on the individual to use them.

When the Annual Meeting was evaluated at the plenary session of the German Ethics Council held on 25 June 2009, interest was expressed in pursuing the topic of neuroenhancement in particular. A working group consequently drew up proposals concerning the form in which the German Ethics Council could approach the subject in the future. These were put to a full meeting of the Council's members in September 2009 and considered again in the discussion of the intended work programme for 2010 (see p. 37). The outcome



From the left: Dietmar Mieth, Michael Wunder, Wolfgang van den Daele



The Annual Meeting aroused keen interest on the part of the public.

was that the topic would not be taken up immediately, but would be addressed in the medium term.

Bioethics Forum

The Bioethics Forum is a format for meetings intended to promote dialogue with the public. Controversial subjects of general interest were addressed on three occasions, in February, June and October 2009.

Preventive medicine – legal and ethical aspects

A meeting in the Bioethics Forum series on the subject of preventive medicine was held on 25 February 2009 at the dbb-forum in Berlin and was attended by an audience of 250.⁸ The subject was considered from different points of view in three lectures followed by a discussion. An introduction to the subject from the medical viewpoint was given by Julika Loss, of Bayreuth University's Department of Medical Management and Health Sciences. Harald T. Schmidt, Assistant Direc-

tor of the Nuffield Council on Bioethics, London, spoke about the ethical aspects, while Stefan Huster, a specialist in public and social law from Ruhr University at Bochum, discussed the legal issues associated with the subject.

Julika Loss showed in her contribution that the term "prevention" was used in a wide variety of contexts, such as that of behaviours or lifestyles assumed to have implications for the preservation of health – for instance, healthy nutrition, screening tests, vaccinations, dental care and hygiene, or safe sex. This broad spectrum could be subdivided into two fields: primary prevention (prophylaxis proper), and secondary prevention, which became relevant when the disease was already present but the patient was not yet aware of it. It was hoped that screening would permit more effective treatment. Another area of prevention concerned measures to promote health-aware behaviour. Dr. Loss described this area as prevention policy; it included, for example, the ban on smoking.

Dr. Loss stated that normative issues arose in connection both with the feasibility

⁸ Audio recordings of the meeting and a real-time transcription can be accessed at www.ethikrat.org.

of prevention and with its implementation in such a way that the relevant measures were ethically acceptable. This point was addressed in the contributions of all three speakers.

Harald T. Schmidt considered the preventive measures that existed and possible ways of systematizing them. He introduced the “stewardship model”, based on a report on public health by the Nuffield Council (2007). The issue concerned the level of intervention involved in the various measures and the consequent relationship between state and individual responsibility, as well as the contextual conditions laid down by the state for the unfolding of individual conceptions of a good life. Unlike the “nanny state”, which was characterized by excessive regulation and paternalism, a stewardship state aspired to be a caring welfare state. The aims of the stewardship model were to minimize risks to health, to create environmental conditions favourable to health, to guarantee access to medical care and to seek to overcome social inequalities. At the same time, the stewardship model was subject to certain restrictions. These included the minimization of compulsion and interference, the securing of informed consent, and the development of methods of achieving informed consent.

In his discussion of the fundamental normative issues of preventive medicine or public health policy, Stefan Huster favoured an abstract approach. His focus was on the question: “How do we in fact construe the relationship between healthcare and preventive medicine?” He began by describing health as an existential good, considering various aspects of medical care as a public system intended firstly to maximize health and secondly to reach as many people as possible with the level of health thereby achieved. Profes-

sor Huster pointed out that, in terms of health equity, prevention and care were of equal importance and that, if a policy of promoting health and achieving health equity were to be effective, it would have to extend across sectors and be integrative in nature. He stressed the significance of socioeconomic factors in matters of health and disease, and noted that these were just as relevant as individual genetic disposition. He showed that aspects such as education, environmental protection and conditions in the workplace also had to be considered and that an effective health policy could not be based on preventive medicine alone.

Like the other speakers, Professor Huster mentioned the potentially conflicting demands of individual autonomy and public health, and pointed out that the perspective differed according to whether one’s starting point was statistical life or individual life; here a connection could be discerned with Dr. Loss’s comments on the effectiveness of screening. In his view, there was a correlation between individual life and healthcare on the one hand and statistical life and preventive medicine on the other, which he regarded as responsible, among other things, for the fact that healthcare as a rule took precedence over prevention. In normative terms, according to Professor Huster, this made little sense, at least on the macro-level of resource allocation.

Questions of the relationship between curative and preventive measures were raised in the discussion. A particular point of concern was the possible cost saving that could be achieved by preventive measures. Another question was why public health in Germany made a relatively poor showing in international comparisons in terms of science. In addition, certain critical voices claimed that



From the left: Harald T. Schmidt, Julika Loss, Stefan Huster, Bettina Schöne-Seifert

preventive medicine was “overdrawn”, with particular emphasis on the significance of quality of life and the problem of state restrictions on the subjective exercise of individual freedom. Questions were also asked about the ethics of the media approach, in relation to the provision of public information in posters, possible stigmatization, and problematic strategies of deterrence.

**“Medicine takes it personally”:
possibilities and limits of diagnostic
and therapeutic personalization**

Will the medicine of the future provide tailor-made medicines and individualized diagnosis and therapy for all, or is it heading for a biological determinism accompanied by increasingly unequal prospects of obtaining access to the best treatment? This question was addressed by the Ethics Council on 24 June 2009.⁹

The evening began with an introduction to the scientific and medical aspects of personalized medicine by Friedemann Horn, of Leipzig University’s Department of Clinical Immunology and Transfusion Medicine. According to this speaker, the underlying problem was that therapies were not as effective as they could be because many patients received drugs that

were not the most suitable for their condition.

In Professor Horn’s view, there were two reasons for this. On the one hand, a patient’s individual make-up resulted in differences in the metabolization of active substances and their distribution in the body, due for instance to genetically determined variations in liver enzyme efficiency. On the other, disorders that were seemingly identical on the clinical level often proved to have different molecular characteristics. In such cases, patients responded differently to a given drug; this was the case, for instance, with breast cancer, of which there were a number of variant forms. The highly effective drug herceptin, for example, proved suitable for only about a quarter of all patients – those whose tumours exhibited over-expression of the HER2 protein found on the surface of cells.

The aim of personalized medicine was to identify such subtypes of disorders and to predict individual responses to therapies. In this case the usual current approach of searching for genetic markers that could be statistically associated with relevant medical characteristics was unlikely to prove successful on its own, because the treatment outcome for many

⁹ The programme, presentations, audio recordings and a real-time transcription of this meeting can be accessed online at www.ethikrat.org.

disorders did not depend solely on individual genetic differences. More accurate results might be achievable in future by the sequencing of complete genomes, which, however, would then present even greater challenges in terms of interpretability and data protection. Furthermore, it was important to take account of other biological parameters too, such as the activity of certain genes and environmental and lifestyle factors.

These ideas were taken up by Norbert Paul, of Mainz University's Department of the History, Theory and Ethics of Medicine, in his contribution on the ethical and social aspects of personalized medicine. In his view, it was unfortunate that the new possibilities of gaining information led to an emphasis on the individual conditions of health and disease without at the same time significantly increasing patients' scope for action. This raised a number of ethical questions: Did individualization not inevitably involve genetic or biological discrimination? Did it signify increased autonomy or, alternatively, the loss of informational self-determination? Did personalization lead to improved accessibility of healthcare benefits in society, or did it create a new privilege for the few?

With these questions, Professor Paul led the proceedings directly into the ensuing panel discussion, in which not only the two contributors mentioned but also the Cologne journalist and author Sibylle Herbert and Klaus Lindpaintner, of the Roche Molecular Medicine Laboratories in Basle, took part. The debate was moderated by Regine Kollek, a member of the Ethics Council.

Dr. Lindpaintner stressed that the underlying idea of personalized medicine was not new, as doctors had always sought to tailor therapies to individual patients and their medical needs and particularities. While warning of exaggerated expectations, Dr. Lindpaintner also drew attention to the specific risk of premature practical application of as yet incompletely developed diagnoses, the incorrect results of which might lead to inappropriate treatment.

Sibylle Herbert took issue with the fact that, while the phrase "personalized medicine" was heard more and more often, patients in fact found that in a practical situation dominated by bureaucracy and budgetary constraints the system now had very little time for them as individuals.

When the discussion was thrown open to the floor, the main issues raised con-



From the left:
Friedemann Horn, Sibylle
Herbert, Regine Kollek,
Norbert Paul, Klaus
Lindpaintner

cerned new challenges to the doctor-patient relationship, such as how patients could be protected by the provision of wide-ranging and universally comprehensible information and by informed consent. Another matter considered was the potential for misunderstanding of the term personalized or individualized medicine. As Regine Kollek noted in her closing statement, this showed that science also needed to take responsibility for its choice of catchphrases and paradigms in the publicizing of new developments, and that greater reticence was called for in relation to claims of personalization of medicine.

Clones in the cowshed? Animal cloning and meat production

Since the debate on “cloned meat” made headlines in the summer, the cloning of farm animals has been discussed in Germany as in other countries. The German Ethics Council addressed this subject on 21 October 2009.¹⁰

Even if meat from the clones themselves does not find its way on to our plates, but only meat from their offspring, and even if there is as yet no indication that it might be harmful to health, ethical objections remain. Aspects of animal welfare and animal health, as well as fundamental ethical, legal and economic issues, were the main subjects considered at this meeting.

Heiner Niemann, of the Department of Farm Animal Genetics at the Friedrich Loeffler Institute in Neustadt, outlined the present status of research and technology in relation to the cloning of mammals and its potential applications. He explained the method of somatic cell nuclear transfer, which was used in 1997 for the first successful cloning of an adult mammal, Dolly the sheep. A viable embryo was produced by the transfer of a somatic cell

from an adult animal into an enucleated egg whose own genetic material had been removed. Professor Niemann estimated that to date nearly 4000 bovines, 400 sheep, 600 goats and about 800 pigs had been successfully cloned in the world as a whole. However, the efficiency of the cloning process remained low. Professor Niemann was on the whole in favour of the cloning of farm animals.

Eve-Marie Engels, Professor of Ethics in the Life Sciences at Tübingen University, took a different view, rejecting the cloning of mammals on the grounds that it was an unnatural method of reproduction characterized in particular by high mortality, abortions and caesareans, which thus caused additional suffering in highly sentient animals – not only the clones themselves but also the surrogate mothers. In addition to our indirect moral obligation towards animals because they were useful to us, she considered that we also had a direct moral obligation based on the dignity of a creature. All living organisms were entitled to protection for their own sake, and this entitlement increased in proportion to the degree of sentience of the animal concerned. Furthermore, the routine cloning of farm animals could result in a coarsening of our attitude towards animals and even pave the way for the cloning of human beings.

Hille Haker, Professor of Moral Theology and Social Ethics at the University of Frankfurt (Main) and a member of the European Group on Ethics in Science and New Technologies (EGE) established by the European Commission, addressed these economic and consumer-related aspects in particular, giving an account of the European perspective and introducing the EGE’s Opinion on the cloning of farm animals.

¹⁰ The programme and presentations for this meeting, as well as audio recordings and a real-time transcription, can be accessed at www.ethikrat.org.



From the left: Heiner Niemann, Stefan Etgeton, Eve-Marie Engels, Frank Emmrich, Hille Haker, Dettmar Frese

The EGE had also concluded that the cloning of farm animals was at present unethical, firstly on the grounds of animal ethics mentioned, and secondly because clones were more susceptible to disease than animals produced by conventional breeding owing to their lack of genetic diversity. Furthermore, cloning – at least in the absence of clear labelling – would curtail consumer rights, and there was reason to fear even greater monopolization coupled with patent applications and consequent licensing by commercial cloning interests; these might exacerbate the economic dependence of poor countries in particular, thus potentially further eroding global equity.

In the ensuing panel discussion, moderated by Ethics Council member Frank Emmrich, the issues were debated by the contributors together with Stefan Etgeton, of the German consumer organization *Verbraucherzentrale Bundesverband*, and Dettmar Frese, of the cattle breeding company *Masterrind*, of Verden. Dr. Etgeton shared the scepticism of the two ethicists. He also doubted that the improvements in meat quality anticipated by Professor Niemann from the use of cloning technology would actually be achieved. Dr. Frese, on the other hand, argued that cloning

was justified principally in terms of the safeguarding of resources, if it helped to preserve unusually good breeding stock – something that could never be achieved so precisely by the preservation of siblings or offspring of such animals, even if bred from frozen embryos.

Publications

The German Ethics Council issues a number of regular publications to inform the public of its activity or current trends. The print versions – in German only except where stated – are available free of charge on request and can also be accessed online as PDF files.

Opinions

The Opinions of the Ethics Council represent the main pillar of its publication activity. They reflect the in-depth debates conducted both at plenary meetings of the Council as a whole and within its internal working groups. Their aim is to bring together the ideas voiced on the relevant issues both in society and within the Ethics Council, to develop lines of argument, to indicate possible solutions, and to propose options for action.

On 26 November 2009, the German Ethics Council published the German version of its Opinion “Anonymous relinquishment of infants: tackling the problem” (see p. 7 ff.).



Opinion
“Anonymous
relinquishment of
infants: tackling the
problem” (German
edition)

English and French translations are currently in preparation.

Proceedings

The papers presented at the Annual Meeting are collated and published in the proceedings (in German only). The first issue appeared in December 2009. Its title translates as “Are human beings controllable? Insights into the brain and ways of modifying its functioning” (See p. 18 ff.).



Proceedings
of the Annual
Meeting “Are
human beings
controllable?” (in
German only)

Infobrief

The *Infobrief* (newsletter, available in German only) was introduced to offer the public at large a condensed version of the discourse within the German Ethics Council. Contributions are assembled at 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. These compilations of news from the Ethics Council have been issued three or four times a year since December 2008.

Three editions of the *Infobrief* were published in the period under review.¹¹

¹¹ The various issues of the *Infobrief* can also be accessed online (in German only) at www.ethikrat.org.

International initiatives and contacts

In addition to encouraging discussion in society and preparing Opinions and recommendations for political and legislative action, international cooperation is one of the duties of the German Ethics Council under the Ethics Council Act of 16 July 2007. This includes in particular cooperation with national ethics councils and international organizations. During the period under review, the Ethics Council invited representatives of its counterparts in France and the United Kingdom to a trilateral meeting in Berlin, was represented at two international conferences, and received guests from abroad at its Office.

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

At the invitation of the German Ethics Council, representatives of the ethics councils of Germany, France and the United Kingdom came together in Berlin for a trilateral meeting on 17 December 2009.

Cornelia Quennet-Thielen, State Secretary at the Federal Ministry of Education and Research, together with the British and French ambassadors to Germany, Sir Michael Arthur and Bernard de Montferrand, welcomed the participants at the beginning of this public event. They unanimously emphasized the importance of the ethics councils' work in the bioethical debate in their respective countries and, with a view to arriving at a common European culture of values, at European level too. The joint deliberations focused

on topics with which the three ethics bodies are currently concerned.

Rhona Knight gave an account of the report recently published by the Nuffield Council on Bioethics (United Kingdom) on the ethical aspects of dementia. Jean-Claude Ameisen, of the *Comité Consultatif National d'Ethique* (France) described the bioethics legislation review process, required by law to be carried out every five years. Wolf-Michael Catenhusen, Jochen Taupitz and Michael Wunder, of the German Ethics Council, reported on the amendments to the German legislation on bioethics adopted in the last year or two.

In the subsequent course of the meeting, the members of the three ethics councils exchanged information on their current work programmes. The Nuffield Council is at present preparing reports on new approaches to biofuels and on medical profiling and online medicine. The French ethics council is addressing current issues in embryo research and possible ways of interacting with the public. The agenda of the German Ethics Council includes the topics of biobanks, chimera and hybrid research, and resource allocation in healthcare. In addition, in 2010 the German Ethics Council is to establish new working groups on aspects of dementia and reproductive medicine.

The meeting ended with a discussion by the participants about the current debate in the three countries on the treatment of cell, tissue and organ donations, with particular reference to possible ways of increasing the willingness of the public to donate and of achieving equitable allocation of donated cells, tissue and organs to recipients.



From the left: Eberhard Schockenhoff, Sir Michael Arthur, Albert Weale, Cornelia Quennet-Thielen, Edzard Schmidt-Jortzig, Alain Grimfeld, Bernard de Montferrand

International Dialogue on Bioethics

At the invitation of the European Commission, the first meeting in the context of the International Dialogue on Bioethics, initiated by the European Group on Ethics in Science and New Technologies (EGE), was held on 19 February 2009. Its aim was to promote exchanges of information and an open dialogue on bioethics between European ethics councils and their counterparts in other parts of the world. The meeting was attended by representatives of 15 ethics councils from non-EU states, as well as members of the EGE, and representatives of the 27 ethics councils of the EU Member States and of international organizations such as UNESCO and the WHO. The German Ethics Council was represented by its Chair, Edzard Schmidt-Jortzig. The representatives of the national ethics councils present were unanimous in their view that the meeting was important for the necessary exchanges between their respective bodies, and agreed that future meetings would be held annually, coordinated by the European Commission and assisted by a secretariat accommodated within the Commission.

Forum of National Ethics Councils of the European Union

The 13th meeting of the national ethics councils of the EU Member States (NEC Forum) was held in Prague on 4-5 June 2009, in combination with a meeting of the European Group on Ethics in Science and New Technologies (EGE) established by the European Commission.

The main subject of the exchanges with the EGE was neuroethics, a focus of increasing scientific interest in the last few years. The contributions of Göran Hermerén, the Chair of the EGE, Josef Syka, former Chair of the Czech Bioethical Commission, and Julian Savulescu, Director of the Oxford Centre for Neuroethics, as well as the ensuing discussion, concentrated on issues such as human beings' personal identity and the effects of actions directed towards the modification of brain function on this identity and on our image of a human being.

Whereas procedures such as cochlear implants for the treatment of hearing loss or deep brain stimulation to treat, for example, Parkinson's disease were regarded as acceptable, reservations were expressed in relation to attempts by healthy individuals

to enhance their cognitive performance by means of active substances such as methylphenidate and modafinil, which were actually developed for the treatment of attention disorders and narcolepsy. Contrasting views were advanced in the ensuing vigorous discussion on the permissibility of neuroenhancement and the extent to which the individual might even have a fundamental right to it.

Other topics on the agenda of the NEC Forum were genetic tests and biometric techniques, with contributions by Renata Veselská of the University of Brno (Czech Republic) and Paula Martinho da Silva, Chair of the Portuguese ethics council (CNECV). At present, genetic tests could predict the probability of actually falling ill only in the case of monogenetic disorders. Conversely, for multigenetic diseases, either genetic testing could not readily predict the probability of the actual occurrence of the disorder or else a high degree of uncertainty attached to the result. Many such tests in precisely this field were available on the market, but were of limited value to consumers because the validity of their predictions could not be confirmed. However, European views on whether consumers ought to be protected from such offers, perhaps even by law, were extremely divergent.

Unlike Germany, where clear provisions were laid down in the *Gendiagnostikgesetz* (Genetic Diagnostics Act), most European states lacked statutory regulation in this field. Genetic tests could therefore be marketed on the Internet; and the use of test results by insurers was unregulated. In the United Kingdom, on the other hand, private insurers had observed a voluntary moratorium since 1993 on demanding genetic data from prospective insured parties. As in the case of the German law, however, a limit ap-

plied in the UK too. Any available genetic test results had to be communicated to the insurer if the sum insured exceeded £500 000 sterling.

To conclude the meeting, the participants addressed the subject of biometric techniques and their increasing use in the public sector. Tom Murray, President of the Hastings Center (United States) reported on the situation in his country. The private sphere had always been a particularly well protected space, and could be restricted only in exceptional cases justified by law. This private sphere was increasingly threatened by the holding of personal data by government departments and commercial enterprises (banks, insurance companies, employers, etc.) and by the ever greater monitoring of individuals in the public environment (video recordings in public places, railway stations, airports and the like). In the United States, for example, four million newborn babies underwent screening every year, and the results could later potentially form the basis of a national DNA identification system. In this situation, current notions and regulatory provisions on protection of the private sphere were no longer adequate. For this reason, Dr. Murray proposed the development of a new approach to protection of the private sphere, which he termed “contextual integrity” and which could be used to test whether a measure or procedure encroached impermissibly on that sphere.

Since biometric data are also recorded and stored particularly when national boundaries are crossed, the treatment of such data had to be discussed in an international as well as a national context. The meeting of national ethics councils offered an initial opportunity to do so.

The 14th meeting of the national ethics councils of the EU Member States was

held in Stockholm on 17 and 18 September 2009 and, like the NEC Forum in June 2009, was combined with a meeting of the EGE.

During the joint meeting with the EGE, the participants discussed the subject of synthetic biology, on which the EGE had recently presented an Opinion. An introduction to the field of synthetic biology and the associated ethical issues was given by Ainsley Newson, of Bristol University (UK).

In the field of biomedical research, many health-related applications were expected to accrue from synthetic biology, including the development of new active substances, new diagnostic methods and improved therapeutic procedures. However, a number of ethical questions could also arise – for example: How could synthetic biology be used efficiently and the associated benefits be distributed equitably? What repercussions would the use of such techniques have on the doctor-patient relationship? Was new legislation necessary? Answers to these and other questions would be forthcoming from, for example, the European-Commission-assisted SYBHEL project,¹² which was to undertake an ethical evaluation of synthetic biology and its possible impact on human health. The aim was to prepare recommendations for the regulation and commercialization of synthetic biology and to draw up a strategy for its application. It emerged from the discussion that the existing European and national legal provisions on genetic engineering and medicinal products were also applicable to the techniques of synthetic biology. There was nevertheless a considerable need for supporting ethical research, which ought to receive both national and EU assistance.

Aspects of an equitable system of healthcare and the associated challenges

to national, European and global health policy constituted the principal theme of the NEC Forum, and were addressed in the introductory contributions of Victoria Camps Cervera, of the Spanish Bioethics Committee, and Norman Daniels, of Harvard University. Professor Daniels noted that health was the fundamental prerequisite for equality of opportunity in a society and that an obligation therefore existed to protect health and to guarantee access to healthcare for all. Major challenges to the long-term funding of health systems were in his view demographic change and the question of how medical benefits could in the future be made available to all on an equitable basis notwithstanding constantly increasing costs.

Other speakers and discussants addressed the issue of ways of guaranteeing equitable healthcare in a national, European and global context. Eberhard Schockenhoff, Vice-Chair of the German Ethics Council, introduced the subject of resource allocation in the healthcare system, which was currently being discussed by a Council working group. Denny Vågerö, of the University of Stockholm and a member of the Commission on the Social Determinants of Health of the World Health Organization (WHO), presented the Commission's report of August 2008,¹³ whose brief was to consider how the current unfair distribution of global healthcare could be eliminated within a generation. Dr. Vågerö emphasized that measures in this field could lead to fundamental improvements in the health of many people who had hitherto had practically no access to medical care.

The meeting ended with a report by Thomas Pogge, of Yale University, on how medical innovation could be facilitated and also made available to the population of developing countries. The Health

¹² For further information, see www.sybhel.org.

¹³ The report can be accessed online at whqlibdoc.who.int.

Impact Fund¹⁴ was intended to enable the pharmaceutical industry to continue to develop innovative methods, to translate them into practice, and also to make them available to the medical systems of developing countries on a break-even basis. The participants welcomed this proposal, but were sceptical about the feasibility of the project in view of the annual funding requirement of six billion dollars, which would have to be met by the countries associated with the HIF.

Bioethics debate with young people in secondary education (joint project with the Council of Europe)

On 10-11 December 2009, the German Ethics Council took part in a joint project involving secondary school pupils together with the Council of Europe in Strasbourg. The project was also assisted by the Austrian Bioethics Commission and the French *Comité Consultatif National d’Ethique*. The participants were pupils from schools in Austria (*Öffentliches Gymnasium der Stiftung Theresianische Akademie*, Vienna), France (*Lycée Jean Rostand*, Strasbourg) and Germany (*Lise-Meitner-Schule*, Berlin), and they discussed the ethical implications of genetic testing. The German Ethics Council was represented by Kristiane Weber-Hassemer.

On the first day, the participants worked in moderated small groups, in which they made each other’s acquaintance and exchanged views and information on bioethical issues of current interest and on the relevant legal situation in Germany, France and Austria.

The pupils were welcomed on the second day by Alexander Vladychenko, Director General of Social Cohesion at the

Council of Europe. He drew attention to the importance of a public debate on the subject of bioethics, in which all members of society, and in particular young people, ought to take part. He also emphasized that bioethical issues could not be confined within national boundaries, so that international exchanges on these matters were very important.

The ensuing discussion was moderated by Nathalie Dimarcq, a teacher of life sciences and geosciences in Strasbourg. The pupils had prepared two case studies for the discussion. The first concerned a woman working in a genetics laboratory who decided to have her children undergo genetic testing. Was it appropriate for these tests to be conducted, and should parents be able to decide whether their children should have them? Although opinions differed, the majority view was that genetic tests should be carried out only if preventive or therapeutic prospects existed. Furthermore, the participants considered that online genetic tests should be prohibited, as the element of care provided was inadequate and the risk of abuse was excessive.

The second case study addressed the situation of a 25-year-old woman who, after a placement at a town hall, applied for a permanent position with the local authority concerned and for this purpose had to undergo a medical examination. The examining doctor learned that her father suffered from Huntington’s chorea and asked the woman to undergo a genetic test to establish whether she had inherited the disorder. The woman refused the test and as a result was offered only a short-term contract of employment. The group discussed whether the woman should have consented to the genetic test and whether a test of this kind ought to be a criterion of appointment. Opinions diverged widely.

Some participants expressed understanding for the position of the employer, who, after all, had to think of his organization, while others stressed the employer's social responsibility and rejected genetic testing as a discriminatory measure.

In conclusion, the pupils were able to exchange views with the participating teachers, as well as with the national ethics council representatives, who were impressed by the quality of the debate and the pupils' commitment. The teachers from Germany, Austria and France stressed that the project had been a valuable experience and opportunity for the pupils. The feedback from the Berlin pupils was thoroughly positive.

Meeting with United States students

On 3 August 2009, the German Ethics Council, represented by Council member Jens Reich, welcomed 13 students from the United States in Berlin.

The group was visiting the Ethics Council for a summer school on the subject of "Life sciences and culture", organized by Bonn University for its partner universities, Harvard and Wisconsin-Madison. After a presentation on the work of the German Ethics Council, Professor Reich held a question-and-answer session with the students.

The visitors showed particular interest in the influence of the Council on the world of politics and in how it interacted with the public. Professor Reich welcomed the fact that the German Ethics Council possessed greater democratic legitimation than its predecessor, the National Ethics Council, although it was only when the first Opinions were published that it would be possible to see how they were re-

ceived by the political institutions and the public. Future Opinions might well seek not so much to present concrete proposals for legislation as to place on record the various ethical standpoints represented on the Council and to demonstrate alternative options for action, because some bioethical issues could be more clearly addressed by informed personal decisions than by moral prescriptions enshrined in law. For this reason, an important aim of the German Ethics Council's work was a direct approach to the citizens of the Federal Republic.

Professor Reich added that the members of the Council were often invited to speak at a wide variety of events, and in this way had an opportunity of bringing the work of the Council closer to the public. He emphasized that bioethical debates could be understood perfectly well by the public at large. If fundamental ethical issues and problems were explained in simple language, they would certainly be within the grasp of any interested persons, who could then form a well-founded opinion of their own on the subjects concerned.

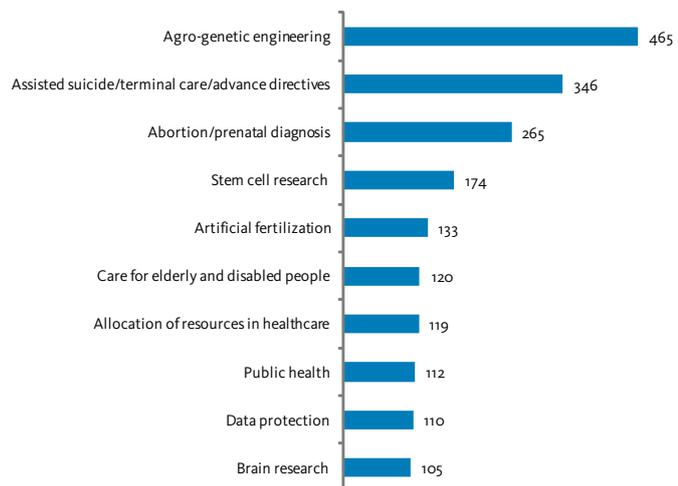
Another matter discussed was the role that ethical issues should play in medical training and education in the life sciences. The students reported that lectures on ethical questions were usually voluntary parts of their courses. One participant remarked that she was confronted with ethical issues particularly when friends and acquaintances asked her what she felt about, for example, working with experimental animals. Professor Reich argued that two central issues should be compulsory in a basic bioethical education for students of biomedicine: first, the nature of human life and when it begins, and, second, the importance to be attached to the right to self-determination in matters of lifestyle, reproduction and the end of life.

Evolution of the social debate

The social debate on bioethical topics is not confined to the world of politics but is also conducted in a large number of meetings and conferences; in addition, it is reflected in a wide range of publications. While the trend of this debate cannot be observed directly, it can be monitored principally through the media reports that make it accessible to society and allow it to be used for individual opinion formation, thus having direct feedback effects on society.

The Office of the German Ethics Council makes daily compilations of reports on bioethical subjects in the nationwide German press and evaluates them statistically. At first these compilations could be supplied only to the members of the Ethics Council, but since the end of November 2009 they have also been made available to the public on the Council's website. Although these compilations can be no more than a limited indicator of the status of the social debate, they do give an indication of the topics that dominated the public discourse in 2009. In the year under review the following ten topics were represented most frequently in the nationwide print media (*Berliner Zeitung, Financial Times Deutschland, Focus, Frankfurter Allgemeine Sonntagszeitung, Frankfurter Allgemeine Zeitung, Frankfurter Rundschau, Handelsblatt, Rheinischer Merkur, Der Spiegel, Stern, Süddeutsche*

Zeitung, Der Tagesspiegel, taz, Die Welt, Welt am Sonntag, Die Zeit):



Bioethical reporting in 2009 was dominated by the debate on the cultivation of genetically modified crops and their use as food or animal feed. It was the subject mentioned most frequently from March to May and in August and September 2009. The debate culminated in the ban imposed in April by Federal Minister of Agriculture Ilse Aigner (Christian Social Union) on the sowing and sale of Monsanto's genetically modified maize MON810. A Round Table on "green genetic engineering" held in May on the initiative of Federal Minister of Research Annette Schavan (Christian Democratic Union) was intended to inject more objectivity into the controversy over the possible dangers of genetically modified plants and to assess the future prospects of agro-genetic engineering. In August the Minister introduced a new logo for GM-free foods. Since then, manufacturers and traders have been free to apply the standard wording "Ohne Gentechnik"

(GM-free) to their packaging to improve consumer transparency. However, critics pointed out that the new label too was subject to exceptions, and called instead for the compulsory labelling of foods containing genetically engineered ingredients. In September, the sector was shaken by a scandal following the discovery of genetically modified linseed by food inspectors in several Federal *Länder*.

With the placing of advance directives on a statutory footing and the amendment of the *Schwangerschaftskonfliktgesetz* (Conflicted Pregnancy Act), two topics that had long been dominant in the public debate moved to the head of the field in terms of media reports.

The debate in the *Bundestag* on advance directives in January and the adoption of the relevant law in June are directly reflected in the numbers of media reports, these subjects featuring most frequently in those months. After years of legal uncertainty, on 18 June 2009 the *Bundestag* passed a law confirming the binding nature of advance directives. It provides that in future doctors must, subject to certain conditions, comply with the wishes, recorded in writing, of a patient who no longer has the capacity for articulation, irrespective of the nature and severity of his illness.

The *Bundestag* had voted by a large majority to amend the Conflicted Pregnancy Act as early as in May 2009. In this case too, the vote had been preceded by several years of debate on the conditions that must be satisfied for a termination to be permissible after prenatal diagnosis. The joint draft presented by a group headed by the deputies Johannes Singhammer (Christian Social Union), Kerstin Griesse (Social Democratic Party of Germany) and Ina Lenke (Free Democratic Party) was ultimately accepted by Parliament.

The rapid pace of progress in stem cell research was also reflected in press reports in 2009. The vigour of this field of research was demonstrated in particular by contributions on the derivation of induced pluripotent stem cells (ipSCs). It will be for future scientific investigation to determine whether the potential of ipSCs is comparable with that of embryonic stem cells. The first approvals by the relevant United States and United Kingdom authorities for clinical tests with embryonic stem cells in human patients were forthcoming in 2009. However, no results have yet been published.

Whereas the next few places were taken up by topics such as artificial fertilization, welfare of the elderly and disabled, resource allocation in healthcare, public health, data protection and brain research, the Genetic Diagnostics Act adopted on 24 April 2009 aroused comparatively little comment in the media.

The field of “baby drops and anonymous birth” was also mentioned hardly at all in media reports up to October 2009, and is therefore not included among the ten most commonly featured subjects. This situation changed overnight with the publication of the Ethics Council’s Opinion on the problem of the anonymous relinquishment of infants: the subject was mentioned in the largest number of reports in November, even though the Opinion was not published until the end of the month (on 26 November). This demonstrates the immediate impact singular events can have on media reports and the public debate. In the case of the Opinion on the anonymous relinquishment of infants, the response in the media was intensified by the instant contentious reactions of politicians, denominational groups and baby drop operators.

Consideration of the topics and the associated actors shows that the issues which are currently being debated by the political institutions or are the subject of legislation unequivocally dominate press reporting. For instance, the three leading topics – green genetic engineering, advance directives and the termination of pregnancy – manifestly owe their positions to the activities of the Federal Government or of the *Bundestag*. The coverage of the other subjects mentioned correlates either with the reporting of new scientific developments, for instance in stem cell research, or with activities of other, non-political, actors.

For the Ethics Council, it will be interesting to see whether the topics of biobanks and chimera research, on which Opinions are expected to be published in 2010, evoke similar reactions to those aroused by the Opinion on the anonymous relinquishment of infants.

Outlook

At its plenary meeting in November 2009, the Ethics Council discussed the continuation of its work programme. Experience in 2009 showed that, with four parallel working groups, the Council has reached the limit of what can reasonably be achieved by its members in terms of the work involved in participating in meetings of the working groups and of the full membership.

Given that the working group on the anonymous relinquishment of infants has completed its mandate with the publication of the relevant Opinion, and that the working group on biobanks will finish its work by the end of June 2010, the German Ethics Council has initially decided to establish new working groups on two topics: one on dementia at the beginning of 2010 and another on reproductive medicine by the middle of the year. A further topic which the Ethics Council plans to address is neuroenhancement.

The second Annual Meeting of the Ethics Council, to be held in Berlin on 20 May 2010, will be devoted to the subject of migration and health. The Council has also decided to hold a further whole-day public event outside Berlin in the second half of 2010. This meeting, on the subject of dementia, will be held in Hamburg.

Another trilateral meeting with the French and British ethics councils is scheduled for the end of the year; an invitation has already been received from the Chair of the French body and the venue will be Paris.

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)



Dr. theol. Hermann
Barth



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 Consti-
tutional Court and
Munich Higher
Regional Court



Prof. Dr. theol.
Christoph Kähler,
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. Dr.
phil. Dr. h. c. theol.
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. med.
Bettina Schöne-
Seifert



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



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



Dipl.-Psych. Dr.
phil. Michael
Wunder

Appendix

Working groups in 2009

Anonymous relinquishment of infants

Spokespersons: Riedel/Schmidt-Jortzig
Members: Gerhardt, Holzheid, Reich, Schockenhoff, Taupitz, Woopen

Biobanks

Spokesperson: Kollek
Members: Bora, Emmrich, Reich, Simitis, Taupitz, Weber-Hassemer

Chimera and hybrid research

Spokesperson: Catenhusen
Members: Barth, Bauer, Dimmeler, Emmrich, Kollek, Reich, Schockenhoff, Schöne-Seifert, Taupitz, Weber-Hassemer, Woopen

Resource allocation in healthcare and social welfare

Spokespersons: Schockenhoff/Nagel
Members: Bauer, Losinger, Lübbe, Riedel, Schöne-Seifert, Taupitz, Wunder

Enquiries from the public

More than 275 written enquiries from the public were received in the period under review. The items requested were Opinions, *Infobrief* newsletters, verbatim records and real-time transcriptions of public meetings and other events held by the Ethics Council, as well as information on a variety of subjects usually connected with topics of current debate or recent meetings and other events. Schoolchildren and students approached the members of the Council and the Office for assistance with the preparation of course

assignments, projects, seminar papers and dissertations. Private individuals sought help in solving their personal problems.

In addition, the Ethics Council received invitations to give lectures and hold panel discussions, in particular at schools.

During the period under review, the Ethics Council acceded to requests to reproduce excerpts from various Opinions of the former National Ethics Council from four publishers (of school textbooks) and the Federal Court of Justice, and supplied extracts from its video recording of the Annual Meeting of 28 May 2009 to a television station for further editing.

Press enquiries

Over 200 enquiries from representatives of the press were received in 2009. Most were requests for interviews and pictures, as well as for background information on topics being addressed by the German Ethics Council at the time or the subject of current public debate – in particular, anonymous relinquishment of infants, biobanks, and the complex of issues comprising advance directives, end-of-life care, euthanasia and medically assisted suicide.