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Introduction

By virtue of the large number of meetings and other events held, 2010 was a year marked by intense activity on the part of the German Ethics Council; it was also a year that saw many changes. In accordance with Section 2(4) of the *Ethikratgesetz* (Ethics Council Act, see Appendix), the present report documents the work of the Council from January to December 2010.

With a view to informing both the political world and the public at large, the publication of Opinions and the holding of public meetings constitute the Council's principal means of communication. In this connection, the publication of the Ethics Council's second Opinion, "Human biobanks for research", in June 2010 takes pride of place. The Annual Meeting in May and the Bioethics Forum meetings have now also become regular fixtures in the Ethics Council's programme of public information on topics in the field of bioethics. These were complemented by the holding of two public hearings: in Feb-

ruary a hearing involving international experts on human-animal mixed-species entities; and in December a hearing on the regulation of preimplantation genetic diagnosis in Belgium, France and the United Kingdom. As is clear from the numbers attending, both aroused very considerable interest among the public and representatives of the world of politics alike.

Besides these meetings, the Ethics Council for the first time held – in addition to the Annual Meeting – a further whole-day event outside Berlin. The meeting on "Dementia and self-determination" at the Hamburg Chamber of Crafts in November met with an impressive response on the part of the public. This bears out the Ethics Council's belief that it is both important and appropriate not to confine the events it organizes to Berlin, thus enabling interested members of the public in other parts of the Federal Republic to attend the German Ethics Council's public meetings.



Plenary meeting of the German Ethics Council

Until September 2009 the Advisory Council on Ethics had constituted the link between the *Bundestag* (German Federal Parliament), but because that body was not reappointed in the 17th Electoral Term, the Council adopted a new approach to enhancing communication with the Members of the *Bundestag*, in the form of a Parliamentary Evening. The first meeting of this kind was held at the German *Bundestag* on 24 March 2010 and comprised an exchange with the Deputies on the current and future work of the Council and on the ethical issues of the 17th Electoral Term which they regarded as particularly relevant. During the course of this event, the Ethics Council also presented its Opinion on the anonymous relinquishment of infants, published in November 2009, and discussed it with the Deputies. Both sides took an extremely positive view of the evening, and the wish was immediately expressed to hold further such meetings in the future.

At the end of 2010, the Federal Government for the first time made use of the provision in the Ethics Council Act allowing it to give an instruction to the Council. In a joint letter from the Federal Minister of Education and Research, Professor Annette Schavan, and the Federal Minister of Health, Dr. Philipp Rösler, the Ethics Council was charged on behalf of the Federal Government with the preparation of a report on the situation of intersex people in Germany.

Changes in the membership of the German Ethics Council occurred for the first time since the Council's formation. On 1 March 2010, Professor Bettina Schöne-Seifert and Dr. Hermann Barth stood down at their own request. In accordance with the provisions of the Ethics Council Act, Professor Heike Walles and Professor Wolfgang Huber were nominated to

replace them by the Federal Government and were appointed as members of the Council by the President of the German *Bundestag*, Professor Norbert Lammert, on 30 June 2010.

Topics

With a view to the publication of an Opinion, the German Ethics Council considered the following topics in 2010:

- Human biobanks for research
- Allocation of resources in healthcare
- Issues of chimera and hybrid research
- Dementia and self-determination
- Reproductive medicine

These and other topics were addressed by the Ethics Council by means of specific working groups, as well as in public plenary meetings and other public events (see p. 20 ff.).

Human biobanks for research

On 15 June 2010 the German Ethics Council issued its second Opinion, in which it called for clear statutory provisions on research with biobanks. The salient points of the Opinion are set out below.

Human biobanks are collections of human bodily substances, such as tissues,

blood or DNA, linked to personal data and, in particular, to health-related information on their donors. They have a dual character, as collections both of samples and of data. Most current biobanks are research biobanks – that is, institutions that collect samples and data of human origin and either use them for their own research or make them available to third parties for research purposes. They are frequently designed to be used for a variety of research purposes, some of which only arise at a later date.

By virtue of the long-term linkage of medical data of many different kinds, biobanks play a vital part in the investigation of the causes and mechanisms of numerous diseases and their treatment, and constitute an indispensable aid to biomedical research.

Biobanks raise ethical and legal questions which extend from the protection of individual rights to the global regulation of research infrastructures. The *Gendiagnostikgesetz* (Genetic Diagnosis Act) that came into force in February 2010 contains no provisions on these matters. Hence

The Opinions of the German Ethics Council can be accessed online at www.ethikrat.org/publications/opinions



From the left: Joachim Vetter (Head of Office), Regine Kollek and Jochen Taupitz at the launch of the Opinion “Human biobanks for research”

only general legal requirements currently apply to research biobanks in Germany.

Again, developments in this field have been particularly dynamic in the last few years. Not only are new biobanks constantly being established, but they are also coming to be used in new ways and on larger scales.

The new developments include quantitative expansion, greater information content, increasing reidentifiability of donors, more extensive networking, internationalization, privatization and commercialization, as well as expansion of applications and of third-party access. By virtue of these trends, the German Ethics Council felt it necessary to address this subject again, although the former National Ethics Council and the *Bundestag's* Study Commission on Law and Ethics of Modern Medicine had expressed their views on biobanks in earlier Opinions.

Having regard to the growing challenges, the German Ethics Council considers that specific regulatory measures for human biobanks must be adopted.

Early approaches to the protection of donors' interests were substantially based on the notion of informed donor consent. However, in view of the structural particularities of biobanks, individual consent can offer no more than feeble protection, since this consent is inevitably given in the context of limited information. For this reason, the consent aspect should be supplemented by institutional and procedural provisions laying down objective limits to biobank research while also allowing scope for flexibility.

In its Opinion, the German Ethics Council proposes a five-pillar approach to the statutory regulation of biobanks, with the aim of providing an appropriate legal framework for donors' interests and rights of personality, of offering more

legal certainty for biobank research, and at the same time of facilitating research.

The first and most important pillar of this approach is the introduction of biobank secrecy. This is intended to confine the processing and transfer of samples and the associated data to the purposes of scientific research throughout their existence and to guarantee that they remain inaccessible to all third parties external to the field of research. In accordance with the provisions applicable to medical practitioners, biobank secrecy comprises a requirement to observe professional confidentiality and a right to refuse to give evidence on the part of the operators, staff and users of biobanks, as well as a prohibition of access to samples and data for all individuals and institutions external to the field of science, including the state.

The second pillar of the approach concerns the definition of the permissible use of biobank materials and data. As at present, donor consent should constitute the fundamental precondition for the use of samples and data in biobanks. However, donors should also be enabled to make their samples and data available for scientific research without restriction to a given research project or a specific field of research and without limitation of time.

As the third pillar of the approach, the Ethics Council recommends the involvement of ethics commissions, firstly where it is intended to work with personal samples and data or where donors are to be contacted again, and secondly for the periodic appraisal of activities of biobanks not restricted to a particular field and whose duration is unlimited.

The fourth pillar concerns quality assurance. The rights of donors should be protected by appropriate organizational structures and procedures, as well as by evaluation of the systems of all biobanks

not narrowly restricted to specific fields and whose duration is unlimited.

The fifth pillar of the Ethics Council's proposed regulatory approach comprises a number of measures intended to guarantee the objectives and procedures of a biobank. These include, in particular, complete documentation and regular publication of biobank activities and the establishment of a publicly accessible biobank register.

The Ethics Council in addition recommends working towards the introduction of internationally mandatory standards of protection, and in its Opinion proposes a number of measures for the safeguarding of biobank secrecy when samples and data are exchanged with cooperating partners in other countries. These include a contractual obligation on those partners to maintain biobank secrecy and criminal sanctions for violating the prohibition on the provision of information on the basis of foreign access to samples and data in Germany, where such access would have been unlawful in Germany too. In addition, it should not be permissible for the reference lists whereby pseudonymized biobank samples and data can be associated with their donors to be disclosed outside Germany.

In its Opinion, the German Ethics Council applies a broad definition of a human biobank for research, covering any collection that satisfies the following three criteria:

- a) It contains genetic material originating from humans with associated data.
- b) Its samples are electronically linked to personal data and other – in particular, health-related – information.
- c) Its samples and data are collected, stored or used for the purposes of scientific research.

Although, according to such a broad definition, a collection of just a few samples used, for example, for the purposes of a thesis limited to a particular topic and destroyed immediately afterwards would constitute a “biobank”, the Ethics Council decided to adopt it in order to avoid a situation in which the applicability of a statutory system of regulation for biobanks would depend solely on the number of samples collected or on some other arbitrary criterion. This is because the challenges outlined above with regard to donor protection are the same whether they concern, for instance, the international linkage of individual small collections of material or individual large-scale biobanks. Furthermore, subjective elements, such as the planned duration of use, have only limited applicability for the purposes of demarcation, because intentions and plans can change at short notice.

The Ethics Council therefore recommends that the broad definition of “biobanks” given above be used for the entities subject to statutory provisions, but that, as regards the legal consequences, a distinction be made – as proposed in the five-pillar approach – according to the specific challenges presented by different biobanks with differing depths of regulation. The question whether a collection does or does not constitute a biobank for statutory purposes will not then be the criterion for deciding whether specific biobanks remain totally unregulated.

In a supplementary position statement, four members of the Council advocate that collections strictly limited to a specific purpose and duration, for which there are no plans to transfer samples and data for different uses, should not be covered by the proposed system of regulation, because they fear that otherwise such projects would, notwithstanding the

recommended differentiation of regulatory depth, be subject to substantial additional regulatory and administrative complication and expense. They regard the existing provisions on data and donor protection as sufficient when samples are taken for limited collections.

Allocation of resources in healthcare

Audio recordings of the public meetings of the Council held in 2008 can be accessed online (in German) at www.ethikrat.org/sitzungen/2008

At its plenary meeting of 25 September 2008, the German Ethics Council had considered the content and limits of the normative claims of evaluations based on health economics for the first time, on the basis of a paper by Council member Weyma Lübke.

Since 2007 Germany has had an explicit statutory requirement for certain decisions concerning the range of treatments provided by the public healthcare system to be supported by cost-utility analyses. For this purpose, the *Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen* (Institute for Quality and Efficiency in Health Care) has developed methodological proposals that have attracted criticism. In particular, German health economists have complained of departures from the methods of analysis recognized within their discipline.

The controversy implicitly involves value judgements of fundamental importance to the public healthcare system's conception of its own role. With regard to such judgements, the specialism of health economics cannot lay claim to a monopoly of interpretation. The judgements must be rendered transparent, and they call for a broadly based, interdisciplinary and also public debate.

For this reason, the Ethics Council responded to this paper by establishing a

working group which, on the basis of this controversy and the provisions of social welfare law that underlie it, addressed the ethical status of cost-effectiveness analyses. This was done against the more general background of the issue, increasingly also the subject of public discussion in Germany, of acceptable ways of limiting spending on the public healthcare system.

In addition, specifically in the context of the current legislative debate following the adoption of the *Gesetz zur Neuordnung des Arzneimittelmarktes* (Act on the Reform of the Market for Medicinal Products), questions arose in connection with utility analysis – especially early utility analysis – and were taken up by the working group. Since an early benefit analysis is based predominantly on surrogate parameters, so that patient-focused end points are relegated to the background, the result may be the application of therapies which, while deemed effective, in fact present no benefit, or very little additional benefit compared with other therapies, for the relevant patient group.

The working group therefore concentrated on the normative problems of benefit analyses, cost analyses and cost-effectiveness analyses, to help draw the attention of both the political world and the public to the difficult issues of distributive justice based on the example of the ethically disputed analytical methods used in the field of health economics. The Ethics Council had substantially concluded its work on the Opinion by December 2010. Since the Opinion was not published until the end of January 2011, an account of its contents will be held over until the 2011 Annual Report.

Issues of chimera and hybrid research

Mythical and other descriptions of human–animal mixtures have existed since the beginnings of human culture, and are exemplified by the centaurs of Greek antiquity or the Egyptian sphinx. Society today, however, presupposes a clear distinction between human beings and animals. Yet scientists have been experimenting for decades with the mingling of human and animal genes, cells or tissues, for instance in research on the replacement of human tissues or organs by animal material, or in the creation of animals with human genes for the investigation of human diseases and developmental processes.

The German Ethics Council's working group on human–animal mixtures has been deliberating on the ethical aspects of the formation of such mixed entities since 2009. The aim is the preparation of an Opinion intended to contribute to the analysis and evaluation of developments with ethical implications in the production of human–animal mixtures and to answer the question whether, and if so where, action is called for on the part of science, society or the political world. In other countries, after all, the last few years have already seen vigorous public debates on the formation of mixed-species entities – for example, in the United Kingdom on the production of “cytoplasmic hybrids”, or “cybrids”, in which a human nucleus is transplanted into an enucleated animal egg in order to produce embryonic stem cells.

To discuss the situation in Germany in the light of this international experience and to consult ethicists with a particular interest in the subject of human–animal mixed-species entities, the German Ethics Council invited experts from the United

States, the United Kingdom and Austria to take part in a public hearing on 25 February 2010.

The proceedings began with an introduction by Council member Jens Reich on the scientific fundamentals of the formation of mixed-species entities, with an explanation of the various forms of these entities. He said that hybrids were organisms whose cells contained genes of two different species and which arose, for example, from the fusion of eggs and sperm of closely related species such as horses and donkeys. There were also particular forms of hybrids in which only a small number of genes from one species were transferred to the other. These included transgenic animals, produced in Germany as in other countries, that possessed some human genes, as well as the cybrids mentioned earlier, which still contained a few animal genes in their cytoplasm. Chimeras, on the other hand, were composed of cells from different species. Chimeras could be obtained by transplanting cells, tissues or organs into an organism belonging to another species (before or after birth) or by the experimental fusion of embryos of different species. The fusion of human and animal germ cells and embryos and the introduction of animal cells into human embryos were prohibited under Section 7 of the *Embryonenschutzgesetz* (Embryo Protection Act), but not the production of cybrids.

The theologian, scientist and medical specialist Matthias Beck, of the University of Vienna, Austria, who is also the author of a book entitled *Mensch-Tier-Wesen* (Human-Animal Mixed-Species Entities), gave more details of the production of cybrids. Professor Beck considered this research, which was currently undertaken internationally but not in Germany, to

Audio recordings and presentations from the public hearings can be accessed online at www.ethikrat.org/veranstaltungen/anhoeerungen

Beck, Matthias: *Mensch-Tier-Wesen. Zur ethischen Problematik von Hybriden, Chimären, Parthenoten*. Paderborn et al.: Schöningh, 2008.



From the left:
John Harris, Mark
Greene, Matthias Beck
and Robert Streiffer at
a hearing on human-
animal mixtures

be unethical. It was in his view immaterial that research workers doubted that cybrids were capable of development beyond early embryonic stages and that they on no account wished to permit them to mature in the womb. For him, the mere production of a cybrid with a human nucleus was an abomination, as it gave rise to “a human being with an expiry date and with contamination from animal material” – that is, a human embryo that was produced for research purposes only and was damaged by the cloning process and by the residual animal genetic material in the cytoplasm. He stated that the philosophical foundation of the Embryo Protection Act was Immanuel Kant’s categorical imperative, according to which one should “use humanity at all times as an end and never merely as a means”. The creation of cybrids gave rise to “beings” that could never set ends for themselves, and this contradicted the idea of humanity. Professor Beck called for an explicit ban on their production.

Robert Streiffer, a philosopher at the University of Wisconsin-Madison, United States, spoke about the moral status of animals with human cells. Opinions differed on the foundations of moral status. Possible criteria for human dignity might

be, first, specific characteristics, such as, in particular, cognition; second, the mere potential to develop such characteristics; or, third, simple membership of the genus *Homo*. On the basis of these three approaches, different aspects would be assigned more weight in the ethical assessment of mixed-species entities. Advocates of the view that actual or potential cognitive characteristics were particularly relevant would have to opt for a point beyond which mixed-species research made the humanoid formation of such characteristics probable. If, on the other hand, membership of the genus *Homo* was the central consideration, it would be necessary to clarify when this status was attained in a mixed-species entity.

It was always difficult to answer such questions because there were very many possible variations in the quantity and nature of the mixed genes, cells and tissues, as well as in the time of mixing, which was important for the further development of the organism. In the case of the experiments currently in hand, however, it was very unlikely that the moral status of the experimental animals would be altered, regardless of how that status was defined. Yet such alterations were already conceivable both theoretically and

technically. In Professor Streiffer's view, it would not yet be a fundamental problem even if a mixed-species entity were to acquire an altered moral status according to one of the three criteria. Instead, the crucial point was that an animal altered in this way would then have to be treated with more respect, and that could present difficulties in the context of animal experiments.

The philosopher and veterinarian Mark Greene, of the University of Delaware, United States, emphasized that the variation of characteristics whereby the welfare or needs of an animal were changed was also relevant to the ethical appraisal of mixed-species entities. Such variation could present a challenge in terms of animal ethics regardless of considerations of moral status if it led to a situation in which such creatures had no conspecifics with which they could interact normally. As an example, Professor Greene mentioned the hypothetical case of a monkey which, owing to a partially humanized brain, suddenly grinned when it was happy and was then misunderstood by other members of its species, which perceived grinning as a gesture of aggression. Such problems could best be addressed by improved investigation of the normal behaviour of the experimental animals, and this was at the same time an important foundation for the development of better methods of investigating status-related characteristics and behaviours in mixed-species entities. Professor Greene also stressed the need for research to take more account of the risks of the transmission of alien pathogens by mixed-species entities.

John Harris, of the University of Manchester, United Kingdom, began his contribution by predicting that human beings would no longer exist in the future, but said that this did not matter provided that

we were replaced by better organisms. The thesis underlying this statement was that the genetic composition and genesis of a creature were irrelevant as long as the creature was accorded the full dignity appropriate to its specific characteristics. During the course of evolution, man had, firstly, undergone a constant process of gradual change and, secondly, retained many features in common with other species. There was no reason not to remain open to the possibility of future changes, even if these were brought about artificially by human action and involved the abrupt mixing of human and animal genes and cells.

The decisive factor was not the artificiality of a process, but its effects on the subjects concerned, and in this connection it should not be forgotten that failure to act could also have negative consequences. Ultimately, the crucial point for a positive evaluation was whether an artificially produced creature or one modified by mixing with other species was thereby enabled to have a better life, and whether we were prepared, where necessary, to assign a correspondingly modified moral status to a mixed-species entity with correspondingly modified characteristics. A characteristic particularly relevant to status, according to Professor Harris, was the capacity for speech. Where the production of a mixed-species entity was unlikely to modify the moral status of the experimental animal, decisions should in his opinion be made in accordance with the possible medical or social utility of the research.

In the ensuing discussion, the members of the German Ethics Council addressed in particular the various criteria of dignity and possible ways of evaluating relative differences in the depth of intervention in the production of mixed-species entities.

Wolf-Michael Catenhusen, the spokesperson for the human–animal mixtures working group, summed up the proceedings by drawing attention to the need to reflect on the permissibility of inducing qualitative changes in an animal’s characteristics.

Dementia and self-determination

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There are at present approximately a million people living with dementia in Germany, a figure predicted to increase to perhaps as many as 1.7 million by 2030. Dementia presents a challenge not only to sufferers’ families, carers and medicine, but also to society as a whole. This being the case, when discussing its work programme for 2010, the German Ethics Council decided to address the topic of dementia, and commenced its deliberations on the subject on 24 February.

Since the issue of dementia is already the subject of a very broadly based debate on the part of various social actors, the working group concentrates its specifically ethical consideration on the question of self-determination under conditions of dementia. Self-determination is an essential element in man’s understanding of himself * and a central point of reference in any ethical discourse. For a long time, attention was directed solely to the deficiencies associated with dementia, with the result that, after diagnosis, many sufferers felt themselves to be patronized inappropriately. Other people talked about them but seldom to them. However, an ethical approach demands contact with sufferers themselves and respect for their self-determination even if it is restricted. Efforts are now increasingly being made to focus on the capacities

possessed by dementia sufferers. Possible ways are being investigated of more accurately perceiving their wishes, as well as of supporting them and respecting their self-determination and capacity to express themselves. The question thus arises as to how much self-determination is possible under the conditions of dementia, as well as of what is necessary for an improved perception of the capacity of sufferers for self-determination and the forms of care that can best support sufferers in their self-determination.

At a public meeting held on 24 June 2010, Ethics Council member Michael Wunder presented the fundamental considerations on the subject to the full Council in a paper entitled “Self-determination to the last? Suffering from dementia in dignity”.

In the view of Dr. Wunder, our approach to dementia would become one of the greatest future challenges in terms of social and health policy, and would have to be confronted not only by family members, carers and medicine but also by society as a whole. A particular concern was the care of dementia sufferers: should they be cared for in an institution, at home, or, alternatively, in assisted living communities? What was the care objective – curing their disorder or “mere” support compatible with human dignity? Who should be responsible for care – professional carers, family members or civil society volunteers? What limits should be placed on the funding of this care? What quality of care did we owe our fellow human beings – and what quality of life should be guaranteed? At the same time, dementia presented a challenge to our understanding of ourselves as human beings in terms of reason and self-determination, confronting us as it did with our own limitations. The question of whether dementia should

* For convenience, the masculine form is used for both sexes throughout this translation.

be seen as a disease or as a particular form of ageing likewise arose in this connection. Dr. Wunder stated that the principal challenge for the Ethics Council, however, was the issue of self-determination. Self-determination was “the necessary condition for the actualization of human dignity and for a dignified life even under the conditions of dementia”.

This question was not merely theoretical, but had eminently practical implications. For instance, research in the last ten years had shown that the contentment and well-being of dementia sufferers increased in proportion as their activities and living environment provided for self-determination, self-efficacy and self-actualization. More detailed investigation was necessary to determine whether, and if so to what extent, self-determination was still possible as the capacity for decision and consent declined with age and what practical consequences this had in terms of rendering the care of sufferers more difficult or, as the case might be, easier.

The psychologically based conception of self-determination introduced by Dr. Wunder later in his paper was based on three pillars: being capable of acting differently; having reasons; and recognizing one's own autonomy. In order to be able to determine his own actions, an individual must, even under the conditions of dementia, be capable of understanding basic information, assessing that information in the light of his own values, anticipating the result, and defending his own decision to others.

In this situation, however, two fundamental questions immediately arose. Was there a threshold below which the capacities mentioned were so exiguous that competence for self-determination no longer existed, or could competence for self-determination be graduated in

accordance with the individual stages of dementia in the form of a context-related self-determination? How binding were advance directives, as well as advance consent to research: was a decision made at an earlier time on the basis of self-determination always to be assigned greater value than one taken later, when the self-determination of the person concerned was no longer recognized, or should the later decision take precedence?

In pursuing this conception of self-determination and in particular the issue of the practical validity of an earlier expression of a sufferer's wishes, two opposing positions were encountered. For advocates of Position A, wishes set forth in an advance directive had a binding effect for a later stage in the progress of the patient's dementia, even if these were opposed by his present wishes, because the wish expressed in a state of full mental competence was deemed superior to the subsequent preference, which was based only on situational or intuitive factors.

According to Position B, although the wishes expressed in an advance directive had material legal significance, these wishes always had to be balanced, in the practical situation, with the patient's current wishes and determination of his best interests, because wishes expressed in the present took precedence over earlier expressions, particularly where the subject's personality had changed.

Summing up, Dr. Wunder stated that dementia sufferers possessed capacities of understanding, appraisal and autonomous expression of their will at every stage of the development of their condition, albeit on an increasingly constricted and unstable level. Their capacity for self-determination, while decreasing, always had to be respected, and they could express what was important for their quality

of life. The forms in which they expressed their wishes were increasingly difficult to decipher, but could be discerned given sufficient sensitivity and practice. A responsible and accountable system of care, medicine and psychosocial support would take precise account of these expressions at every stage of development and take them as the foundation of best-interests decision-making.

However, according to Dr. Wunder, it was essential, in the consideration of all these factors, to determine whether the reality of care was consistent with these desiderata.

The discussion of Michael Wunder's paper by the full complement of members of the Council focused on his conception of self-determination. Volker Gerhardt commented that Kant's notion of autonomy should be applied to the definition of this concept, not only because Kant was the first to use the concept of self-determination, but also because Kant associated the use of the concepts of autonomy and self-determination with the term "maxim": one needed to "have a conception of the importance of that which, with regard to a situation whose seriousness one has recognized, one actually did on this and all subsequent occasions".

Michael Wunder, however, doubted that the philosophical definition of self-determination was fully applicable to the course of a dementia. He had been more concerned to address the concept of self-determination from a different scientific perspective – namely, "to imbue it with, or place it under the tension of, the psychological approach oriented towards the experiential world", so that it yielded productive questions for the continuation of the debate.

The discussion should, in his view, also address concepts related to self-de-

termination, such as self-actualization, self-efficacy, self-realization, self-organization, self-assertion or autonomous action. Dr. Wunder considered that these points called for further discussion and clarification.

In the course of a whole-day public meeting entitled "Dementia – the end of self-determination?", held in Hamburg on 24 November 2010, the members of the Ethics Council were able to exchange views with sufferers and experts and gain a more detailed understanding of the subject (see p. 28 ff.). The results of the meeting will be incorporated in the Council's continued work on its Opinion.

Reproductive medicine

The Ethics Council had placed the topic of reproductive medicine on its agenda for 2010 as early as in November 2009. The process of deliberation was launched in July 2010 with keynote papers by Council members Jochen Taupitz and Regine Kollek on legal and medical aspects of recent developments in the field of reproductive medicine. A working group with Wolf-Michael Catenhusen as its spokesperson commenced its activity shortly afterwards, in August. In the context of its deliberations on reproductive medicine and having regard to a number of fundamental judgements on the subject in 2010, such as those of the European Court of Human Rights in April, the Rostock Higher Regional Court in May and the Federal Court of Justice in July, the German Ethics Council decided in September 2010 to focus on the aspect of preimplantation genetic diagnosis in an initial Opinion on this topic, and to present this Opinion in the spring of 2011 if possible. To obtain information on the

current practice of preimplantation genetic diagnosis in neighbouring European countries, the Ethics Council held a public hearing in December.

In his keynote paper on 22 July 2010, Council member Jochen Taupitz enquired whether the Embryo Protection Act was still adequate for the current situation. He noted that, notwithstanding numerous innovations in reproductive medicine and developmental biology, the Act had now remained unchanged for twenty years. This was problematic in that the Act included criminal-law prohibitions that needed to be formulated with particular exactitude for constitutional reasons.

Professor Taupitz reviewed the aims of the Embryo Protection Act and drew attention to provisions that had either been restricted by recent case law – such as that of the European Court of Human Rights, the Rostock Higher Regional Court and the Federal Court of Justice, or could in his view be interpreted differently or were disputed by legal authorities. Examples were the prohibition of gamete donation, artificial fertilization with a dead person's sperm, the production and use of embryos for a purpose not directed towards their preservation, surrogate motherhood, and the transfer of more than three embryos to a woman. In Professor Taupitz's view, another relevant question was whether it was justifiable to provide for greater protection of an embryo in vitro in accordance with the Embryo Protection Act than of a growing embryo or fetus under the current law governing abortion. Although few disputed that the Embryo Protection Act needed to be amended, further discussion was necessary on whether it should be supplemented or rendered more precise, or instead be superseded by a wider-ranging reproductive medicine act.

According to Council member Regine Kollek, new developments in the techniques of reproductive medicine, the ethical discourse of the last decade and recent court decisions necessitated a fresh debate. However, it was not clear how far the scientific and technical developments made reform of the Embryo Protection Act indispensable.

In her paper, Professor Kollek gave an account of the technical possibilities and limits of in vitro fertilization (IVF), intracytoplasmic sperm injection (ICSI), polar body (PB) biopsy, preimplantation genetic diagnosis (PGD) and other techniques used in reproductive medicine. In view of the comparatively low success rate and the relatively high incidence of multiple births with IVF and ICSI, not only blastocyst transfer but also PGD, which was frequently used in countries other than Germany, were now becoming more significant. For diagnostic purposes, PGD was increasingly used to identify pathological predispositions, as well as for the avoidance of disease, for sex selection or for the creation of a "saviour sibling". In addition, PGD was often applied with a view to increasing the pregnancy rate after IVF, although this effect was unproven in practice.

In the course of the debates on amendment of the Embryo Protection Act or, as the case might be, the introduction of a reproductive medicine act, Professor Kollek also considered it necessary to reflect on the possible need to set limits to these new developments. For this purpose, account had to be taken, too, of the possible social and environmental causes of undesired childlessness that made recourse to artificial fertilization more likely.

In the ensuing discussion, the members of the Council initially expressed interest in certain concrete aspects of the topic

– the statistics on IVF, the pregnancy termination rate after IVF and subsequent prenatal diagnosis, and inclusion of these benefits in the statutory health insurance scheme. The discussion then turned to the possible consequences of the incorporation of more specific provisions in the Embryo Protection Act or of a comprehensive regulatory system for the new technologies in the form of a reproductive medicine act, and whether the Ethics Council could assist the legislature in this connection.

In order to learn about the practice of preimplantation genetic diagnosis, on 16 December 2010 the Ethics Council held a public hearing on recent developments in PGD and its regulation and practice in Belgium, France and the United Kingdom.

First of all, Luca Gianaroli, Chair of the European Society of Human Reproduction and Embryology (ESHRE), reported on the state of development of PGD as reflected in the register kept by the ESHRE over a period of more than ten years. Data from 57 of just over 100 centres worldwide were stored and evaluated in the register. Between 1999 and the latest reporting period (treatment year 2007), some 28 000 treatment cycles were conducted and 4047 children were born after examination at the embryo stage. The cells to be tested were taken on the third day in approximately 99.5% of all cases. Because these cells were assumed to have the potential to develop into an independent embryo, this procedure was prohibited in Germany. Overall, however, increasing interest was being shown in the examination of blastocysts – that is, embryos on about the fifth day of their development. By then it was possible to obtain more cells which, moreover, were destined only for the eventual formation of the placenta.

On the practice of PGD in Belgium, Paul Devroey, a specialist in reproductive medicine, explained that the procedure for securing approval for each diagnosis was difficult but transparent. PGD was conducted at seven licensed IVF centres in cooperation with a human genetics centre. Other requirements were the provision of advice to the couple and positive evaluation of the case by a specialist in reproductive medicine, a geneticist, a psychologist and, where necessary, an ethics committee. There was no official list of permitted indications.

The United Kingdom's contribution comprised a report by Emily Jackson, Professor of Law and Deputy Chair of the UK's Human Fertilisation and Embryology Authority (HFEA). The Authority was the competent body in the United Kingdom for the issue of licences required by centres in order to provide PGD. It also decided which genetic and chromosomal disorders constituted permissible grounds for PGD. In the advisory process, the couple's situation was taken into account and the opinions of various experts, such as medical practitioners and patient groups, were obtained. In the case of particularly controversial types of diagnosis – e.g. testing for genes carrying the risk of breast cancer – the public too were increasingly involved in the deliberative process. However, once a test was recognized, any licensed centre could apply it without requiring HFEA approval for each individual case.

Patrick Gaudray, a geneticist and member of the French bioethics committee, the *Comité Consultatif National d'Ethique* (CCNE), described the French model, which set strict limits to PGD that could be changed only by way of amendments to the country's reproductive medicine act. At present, PGD could be carried out



From the left:
Luca Gianaroli,
Paul Devroey, Emily
Jackson and Patrick
Gaudray at a hearing
on preimplantation
diagnosis

only at three licensed centres and only for families already affected by a serious, incurable genetic condition. There was no list of specific pathological dispositions for which PGD was permissible; instead, each individual case was reviewed by a fixed procedure.

Unlike France, Belgium and the United Kingdom also permit testing for chromosomal disorders that are not already present in the parental genome, but arise only during gametogenesis or fertilization. According to the latest ESHRE data set presented by Dr. Gianaroli, from 2007, screening for this purpose is undertaken in just under 64% of cases of PGD, and is therefore much more frequent than diagnoses of specifically inherited pathological dispositions. However, Professor Devroey, Professor Jackson and Dr. Gianaroli pointed out that recent research had shown that, contrary to earlier expectations, the birth rate was not improved by screening. For this reason, this approach could still only be regarded as experimental, even if there were indications that more recent techniques might yield better results in the future.

Following these contributions, members of the Ethics Council and the many members of the German *Bundestag* pre-

sent at the hearing put further questions to the experts. Particular interest was expressed in the number of embryos needed for a PGD. In most cases, this was significantly greater than the maximum of three embryos per IVF cycle considered by most authorities to be permissible to achieve pregnancy. Other questions concerned the details of the procedure for deciding for or against testing for specific genetic pathology. In the view of the experts, given the differing approaches to preimplantation genetic diagnosis and its evaluation, it was important for a democratically legitimized procedure to be applied in order to reach a decision consistent with the society of the relevant country and the differing positions held within it.

The Ethics Council continued its deliberations immediately after the hearing with the aim of bringing them to a conclusion by the beginning of March 2011, so that the Opinion could be delivered to the members of the German *Bundestag* if possible before the commencement of the parliamentary debate.

Public meetings and promotion of social discourse

The German Ethics Council has a mandate to inform the public and to encourage discussion in society, engaging the various social groups.

Proven platforms are the public meetings and other Council events held at intervals throughout the year. In this way, the Ethics Council reaches different parts of the public. For example, at the Annual Meeting, the German Ethics Council engages in a public exchange of views with experts, with academics engaged in research on the life sciences and bioethics, with representatives of organizations and associations, and with interested citizens. The events in the Bioethics Forum series enable an interested, wider and not necessarily expert public to engage in a dialogue with mostly external contributors and the members of the Ethics Council.

During the period under review, five plenary meetings (in February, June, July, October and December) were partially open to the public – that is to say, interested persons could attend the meetings and gain an insight into the work of the Council on the various topics and into its discussion culture. The February programme included a public hearing on the subject of human–animal mixed-species entities. This was followed in June by a paper by Council member Michael Wunder on self-determination and dementia, with an ensuing discussion. In July, the Council learned about the legal, scientific and medical aspects of recent developments in reproductive medicine; while in October Council member Heike Walles gave an introduction to the subject of tissue engineering. For its December meeting, the Ethics Council invited experts from

Belgium, France and the United Kingdom to a hearing in Berlin, to ask them about the regulation and practice of PGD and the latest developments in the genetic testing of embryos.

In addition, the Ethics Council held two whole-day public meetings in Berlin and Hamburg respectively and three public evening meetings in Berlin. Another platform for discourse consisted of information and discussion meetings with students and schoolchildren.

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

Public plenary meetings

The topics addressed at the public plenary meetings were discussed in the previous section if also considered by the Council's internal working groups. The only exception was tissue engineering, which was debated in October, and is discussed below.

Tissue engineering – making tissues in the laboratory

At the public plenary meeting held on 28 October 2010, Heike Walles, a member of the German Ethics Council since July 2010, reported on her research on the artificial production of human tissue.

Professor Walles explained in her introduction that the aims of tissue engineering were, first, to establish the fundamental mechanisms and functions of healthy and diseased tissue and, second, to develop biological replacement tissue

Audio recordings of the public meetings of the Council held in 2010 can be accessed online (in German) at www.ethikrat.org/sitzungen/2010

from the body's own cells to support or replace damaged or failed tissue or organ functions.

Although it would be some time before complex therapeutically usable replacement tissue could be produced synthetically, promising initial results had already been obtained with the transplanting of artificially produced skin, cartilage and tracheas. Again, in the field of research, laboratory-cultured tissues could replace a large number of animal experiments and thereby yield more reliable results, since the material used came from human cells and was more likely to behave like cells and tissues in eventual patients than material from remotely related experimental animals.

The culturing of tissue basically comprised three steps: first, body cells were isolated; then they were grown and propagated in the laboratory; and, lastly, they were made to grow into the desired form and structure with the aid of bioreactors and three-dimensional scaffolds.

To make, say, artificial skin, Professor Walles and her team first grew the type of cells predominant in the deeper layers of the skin, known as fibroblasts, in a collagen gel, adding on the second day a layer of keratinocytes – the cells of which the outermost layer of the skin was composed. After two weeks, the cells had formed a tissue that was similar enough to natural skin to be used in various experiments. These included tests of the skin compatibility and effectiveness of new medicinal products and other substances, wound-healing studies and the investigation of infective processes or skin tumours.

In the production of tissue with a more complex three-dimensional structure, Professor Walles said that a major challenge was the provision of blood vessels. Although natural vascular formation

could be stimulated with growth factors, on the one hand this took a very long time and, on the other, it worked only for very small blood vessels. Even if artificial microvascular networks were used instead and these were then colonized with living endothelial cells, the current upper limit for such vessels was a diameter of only 3 millimetres.



Heike Walles reports on tissue engineering

Even so, Professor Walles was able to report successful results in the culturing of more complex tissues. Using the BioVaSc (biological vascularized scaffold) technique developed by her group, she and her team had produced a liver testing system “of about finger size” with structures similar to those of a functioning bile duct, a trachea test system that simulated conditions within the respiratory system, and a bowel test system allowing investigation of the absorption of active substances via the intestinal mucosa. The artificial tracheas successfully used in patients in initial clinical studies were also produced by the BioVaSc technique.

The scaffold used in this technique was porcine bowel from which all animal cells had been removed. The human cells then grew on this scaffold in the bioreactor with the aid of suitable growth factors.

A further application of tissue engineering mentioned by Professor Walles

was personalized medicine. Methods were currently being developed that would in the future allow the culturing of a patient-specific tumour model from the tissue of a cancer sufferer; the model could then be used for further diagnosis and drug tests in order to optimize therapy for this individual patient.

In the ensuing discussion with the other members of the German Ethics Council, Professor Walles stated that in her view tissue engineering did not raise any ethical problems, and she emphasized its potential to reduce the application of ethically more debatable techniques. This concerned not only the replacement of animal experiments by cultured human tissue, but, in the future, possibly also the field of transplant medicine, should it prove feasible to replace donor organs and tissues by ones grown in the laboratory.

Problems were, however, in her view presented by the current regulatory provisions on research. Tissue engineering fell substantially within the purview of the law relating to medicinal products, which was not optimally suited to work with living cells. “We have to overcome some crazy statutory hurdles in order to demonstrate the substitutive potential of our tissues,” said Professor Walles.

Asked about the longer-term outlook for tissue engineering, Professor Walles stated that it was unlikely that it would ever be possible to create complete organisms with a technique of this kind: “That is too complex. At the moment we can only culture five types of cells together; but in humans there are over 1000 different types of cells, which develop in complex ways over a long period.”

Annual Meeting

On 20 May 2010, more than 300 persons accepted the German Ethics Council’s invitation to attend its second Annual Meeting, on “Migration and health: cultural diversity as a challenge to medical care”.

According to data from the Federal Statistical Office, some 15.6 million people with a background of migration are currently living in Germany. Their biographies, cultures and countries of origin are extremely diverse, so that they can on no account be regarded as a uniform group. Furthermore, a plurality of cultures exists within the individual groups. Since each culture may have a different conception of illness and health, which is likely to influence health-related behaviour and decisions concerning therapy, the doctor-patient relationship, as well as the entire healthcare system, is presented with particular challenges by such patients. In addition to language barriers, heterogeneous culture-specific values must be appropriately allowed for. This means that issues of both medical and social ethics immediately arise. For these reasons, the German Ethics Council wished to use its Annual Meeting to stimulate reflection on the practical form in which these particular challenges could be addressed. The aim of the meeting was to highlight various facets of this wide-ranging topic in terms of their ethical implications and to discuss them with experts from various disciplines and professions, as well as to present these issues, which used to be regarded as falling primarily within the realm of social policy, as having an ethical dimension.

Council member Axel W. Bauer introduced the subject to the meeting. He placed it in a historical and demographic context and drew attention to the many

possible approaches to it, as reflected in a large number of important research projects. He stated that the Annual Meeting could “by no means consider every facet of the complex relationship between migration and health”.

In her initial contribution, Minister of State Maria Böhmer, the Federal Government’s Commissioner for Migration, Refugees and Integration, described health as the aim of integration policy. Germany now saw itself not only as a country of destination for immigrants but also as one characterized by integration; considerable action was required in the field of migration and health. She explicitly thanked the Ethics Council for addressing the issue, particularly as health and care were a particular focus of the Federal Government’s attention in this Electoral Term. She laid particular stress on the need for an intercultural approach by the healthcare system and for the promotion of intercultural competence in the training programmes of the health professions. A vital aspect was culture-aware care of the elderly. However, with a view to prevention, it was equally important to reach mothers, in order to promote child and adolescent health. It was also necessary to facilitate research on the data situa-

tion in health and care reporting, which remained unsatisfactory, “so as to enable us to proceed more directly towards our objective, to identify the exact fields where action is needed, and also to develop solutions”. The Minister of State said that, in a field where many aspects were still at an early stage, advantage should be taken of the opportunity to proceed in the right direction from the start.

The academic introductory address was concerned with the background to migrant health. Oliver Razum, Professor of Epidemiology and International Public Health at the University of Bielefeld and Chair of the *Deutsche Gesellschaft für Epidemiologie* (German Society for Epidemiology), concentrated on three questions: Did the health of migrants differ from that of the majority population? If so, might the differences be predominantly a matter of social class? What other factors might adversely affect the health of migrants? Professor Razum cited studies on infant mortality in Germany and on rehabilitation. According to the data in his first example, although migrants shared in the overall positive trend of infant mortality, mothers who had only recently arrived in Germany had a very much higher risk of losing their child in the first year of its life.

Presentations from the Annual Meetings as well as audio recordings (in German) can be accessed online at www.ethikrat.org/veranstaltungen/jahrestagungen



Minister of State Maria Böhmer (in the foreground) at the Annual Meeting, next to her the Chair of the Ethics Council, Edzard Schmidt-Jortzig

The second study showed that migrants had an increased need for rehabilitation. At the same time, the take-up of medical rehabilitation was lower than was to be expected and less than that of the German majority population. It was moreover found that the rehabilitation measures were less successful. This suggested that barriers existed in terms of both access and efficacy. In Professor Razum's view, these differences could not be explained solely by sociodemographic factors or, for instance, more physically demanding work. Linguistic and cultural differences also played an important part. Another pertinent factor, however, was the attitude of the institutions concerned. Professor Razum mentioned system-related factors that probably lay in the structure of the rehabilitation centres and which were likewise among the challenges inherent in the relationship between migration and health. For this reason, he recommended not only preventive action on the behavioural level but also structural changes. In order to deal with the heterogeneous group of migrants, it was necessary to develop a capacity which Professor Razum called diversity management.

Ilhan Ilkilic, a medical ethicist at Mainz University's Institute for the History, Theory and Ethics of Medicine, approached the subject from the point of view of medical ethics. He too referred to the heterogeneity of the group of persons with a background of migration and stressed the importance of adopting a definition of culture that took account of this. He began with a description of the possible characteristics of a doctor-patient relationship involving intercultural awareness. This differed from other doctor-patient relationships not in its essence but in its intensity. Dr. Ilkilic then sought to place ethical questions in an intercultural

context, discussing in particular patient autonomy. Since patient autonomy played an important part in the various forms of ethical discourse, Dr. Ilkilic demonstrated the differences discernible in the understanding of this concept and their implications for decisions in the field of medical ethics. He also addressed the issue of the appropriate conception of patient autonomy in a society with a plurality of values. On the basis of various examples, he analysed some specific problems of ethical decision-making and action in an intercultural context. Dr. Ilkilic described his proposal for a culture-sensitive medical ethics as an approach that was both integrative and particularistic, and avoided generalizations and consequent misinterpretations. He helped those present to understand the significance of language barriers, a subject that came up many times during the meeting. Successful communication was necessary not only so that patients could describe their symptoms appropriately, but also in order to permit access to their values and preferences. However, successful communication could often be achieved only with the aid of professional interpreters, who were seldom available. Translation by family members was not always reliable and was furthermore often problematic for reasons of authority within the family. For example, information might be withheld from patients if the family felt that the difficult diagnosis might be detrimental to the patient's prospects of recovery; in addition, certain aspects might be conveyed wrongly because they were not correctly understood. Besides difficulties of this kind, language problems often led to overdiagnosis to compensate for deficiencies of communication.

Theda Borde, Professor of the Medical and Medical-Sociology Foundations of

Social Work and Clinical Social Work at the Alice Salomon University of Applied Sciences in Berlin, concentrated in her paper on migrant women's health in terms of needs, the reality of care and prospects for the future. The Migration Report of the Federal Interior Ministry indicated that nearly half the population with a background of migration was now female and that, as more and more people arrived, this proportion was constantly increasing. Professor Borde addressed four issues in particular: how to reach patients; patient expectations and satisfaction; doctor-patient interaction; and patient education. She considered these with the aid of the data from two comparative studies by Berlin's Charité Hospital on the menopause and hormone therapy. In particular, the results of the patient education survey were alarming: the level of agreement between patient knowledge and medical diagnosis was very low among female migrants, and actually fell even lower in an inpatient situation. Particular problems identified by Professor Borde concerned communication and information, the legal and economic aspects of incorrect, insufficient and excessive care and incorrect, excessive and insufficient take-up of available healthcare benefits – as well as compliance, given that health-related information could be used only if it was understood. Professor Borde considered that the main ethical issues concerned the mandate of the care system, equality, equal treatment, health equity and informed consent. With regard to migrant women's own responsibility, Professor Borde mentioned that whereas previous speakers had claimed that patients were responsible for seeking help, in her view the care system also needed to be proactive. The need was for readily accessible arrangements within the healthcare

institutions for education and information, sensitive to cultural differences, and corresponding staff skills. Another requirement was to raise the level of health competence and self-assertion of migrant women by means of social-work projects.

Alain Di Gallo, senior physician and deputy medical superintendent at Basle University Clinic's Child and Adolescent Psychiatry Unit, reported on experience in his specialty. He complained of the inadequate data situation on the health of children and adolescents with a background of migration in Switzerland. There was, however, no doubt that children and adolescents experienced migration differently from adults. He stressed that migration often resulted in changes in roles and hierarchies within the family. For this reason too, child psychiatry was always also family psychiatry. Children often faced excessive demands and conflicts of loyalty within the family, as he showed with the aid of examples. "Not every child finds it easy to do these cultural splits." Since much of the communication in his discipline in any case took place by way of play and drawings, the language barriers were not quite as difficult to overcome as in other fields. Dr. Di Gallo laid stress on the particular value of intercultural dialogue, from which both sides could learn and profit. Migration called for "a balance between the alien and the familiar, between different emotional, social and cultural needs and demands. The familiar gives us confidence and links us together, but it also ossifies if it is not mixed with the alien and the new."

The doctor-patient relationship addressed at the beginning of the meeting was considered from a specifically legal perspective in the next paper, by Andreas Spickhoff, Professor of Private Law, Medical Law, International Law and

Comparative Law at the University of Göttingen. “German medical law [is actually] sufficiently open that it can apply the necessary flexibility to all the problems mentioned in the previous contributions.” Professor Spickhoff considered in particular the issue of the appropriate provision of information to patients whose mother tongue was not German and who had a non-German cultural background. It was clear from the decisions of the courts that patients had no entitlement to treatment in their mother tongue. Several of the previous contributors had mentioned the need to use professional interpreters. Minister of State Böhmer had even called for the cost to be met as a benefit under the statutory health insurance scheme. In his view, it was debatable whether a constitutional entitlement to the reimbursement of interpreting costs from the statutory health insurance scheme could be established. He himself felt that there were persuasive legal reasons for explicitly including these costs in the list of benefits provided by the statutory health insurance scheme. At present, interpreting costs were not eligible for reimbursement because they were deemed to be external services that were not prescribed by a doctor and for which the doctor could not take responsibility. Only recipients of social welfare benefits could have interpreting costs reimbursed by the social services department.

A subject which also constantly featured prominently in the media was addressed by Bettina Schlemmer, a general practitioner at Munich’s *Malteser Migrant-en Medizin*. She said that this walk-in centre offered not only medical but also social and legal advice to persons who lacked valid residence status or had no health insurance owing to a social emergency situation. “For someone in this life situ-

ation, illness is like a screen on to which the looming insecurity of their position is suddenly projected in glaringly sharp focus.” Advice and treatment were provided free of charge and anonymously. A network of clinics and specialists in private practice offered help for patients in emergencies that could not be dealt with directly at the centre. Dr. Schlemmer graphically described some actual cases, drawing attention to the problems presented by the *Asylbewerberleistungsgesetz* (Asylum Seekers’ Benefits Act) and to the social welfare authorities’ obligation to furnish data to the Aliens Authority, a requirement which was dispensed with only in cases of medical emergency and could lead to deportation and hence to particular psychological stress in a patient. The benefits provided under the Asylum Seekers’ Benefits Act should in fact guarantee the same rights as in the statutory health insurance scheme – but the situation in practice was very different. In the discussion, Dr. Schlemmer remarked: “If you ask what we wish for, the abolition of the Asylum Seekers’ Benefits Act is our dearest wish.” The local health authorities should be expanded, legal lines of demarcation should be changed, and appropriate provisions for meeting the relevant costs should be introduced. There was in addition a need for action with regard to the care of persons without valid residence status in rural regions.

In her paper, Ulrike Kostka, head of the Basic Theological Principles Department of the Catholic relief organization Caritas in Freiburg and *Privatdozentin* at the University of Münster, drew together several of the separate threads of the meeting. On the basis of a multidimensional ethical analysis, Dr. Kostka identified the various actors and levels of reflection. Her aim was to develop an



Panel discussion with Stefanie Vogelsang, Hamit Ince, Eberhard Schockenhoff, Yasemin Yedigargolu and Axel W. Bauer (from the left)

ethical criteriology for the establishment of a healthcare system sensitive to different patient backgrounds and cultures. Taking fundamental considerations on health and illness as her starting point, she emphasized that healthcare as a good called for solidarity, but in addition to this aspect of social ethics had implications on the level of individual ethics, since “health [is] closely bound up with my own view of my body, with my relationship to myself as a subject”. One therefore also had to take responsibility for one’s own self, a responsibility she called “self-care” which could not be delegated. However, the care system had an obligation to be proactive in enabling the individual to undertake self-care. This requirement to be proactive also applied to health professionals, who had to be enabled by means of appropriate training to undertake culture-sensitive care and to practise culture-sensitive medicine. On the level of organizational ethics, benefit and service providers in the healthcare system ought as far as possible to adopt an overall approach in which persons with a background of migration enjoyed the same access as others to services. This called for close collaboration with the various social welfare providers. On the basis of her conception of social

health, which also included higher-level social conditions such as the relationship between health and education, as well as work, poverty and social disadvantage, Dr. Kostka showed that migration and health was a wide-ranging topic that embraced many different perspectives, extending beyond the debate about the healthcare system alone. If the discussion were confined to the aspect of healthcare, the problems that lay concealed behind health difficulties would be medicalized. Dr. Kostka advocated an overarching environmental-prevention approach falling within the fertile area between solidarity and self-care.

The meeting ended with a panel discussion between Stefanie Vogelsang, a member of the German *Bundestag* and of its Health Committee, and former Head of the Department of Health at Berlin-Neukölln; Hamit Ince, senior physician at the Wahrendorff Clinic and Chair of the *Deutsch-Türkische Mediziner-gesellschaft e. V.* (the German-Turkish Society of Medical Practitioners); Yasemin Yedigargolu, a social scientist with a particular interest in the provision of information on consanguineous marriage; and Axel W. Bauer, a member of the German Ethics Council. The panellists discussed and

expanded on the various issues raised at the meeting on the basis of experience in their own fields.

An important conclusion accruing from the Annual Meeting is that the phenomenon of migration must be addressed by a differentiated approach on the various levels discussed, thus making it possible to perceive people in their individuality rather than in terms solely of their history of migration, while at the same time taking account of the particular needs of persons with a background of migration. It was particularly gratifying to note that the contributors consistently responded in concrete terms to the themes raised by the other speakers; this imparted a well-rounded character to the meeting and made it easier for the participants to make connections between the various positions represented in this many-sided issue.

External meeting

Presentations from and audio recordings of external meetings are accessible online (in German) at www.ethikrat.org/veranstaltungen/weitere-veranstaltungen

On 24 November 2010, over 300 members of the public came to the Hamburg Chamber of Crafts to attend the meeting on “Dementia – the end of self-determination?”

The German Ethics Council’s intention in organizing this meeting was to focus on possible ways of improving our perception of the wishes of dementia sufferers and of supporting and respecting their self-determination and capacity for expression even if these were restricted.

In her opening address, Angelika Kempfert, State Councillor in Hamburg’s Social Affairs, Family, Health and Consumer Protection Authority, thanked the Ethics Council for making the subject of dementia one of its principal issues of concern. She thus acknowledged the

valuable contribution of the Council in bringing this severe disorder to the centre of public attention and debate.

The meeting’s moderator, Council member Michael Wunder, also laid stress on the current importance of the subject. In his view, a particular requirement was a change of paradigm whereby the issue of dementia was discussed in terms of potentials rather than deficiencies and it was made clear that sufferers could and should live in the bosom of society.

In her contribution, Ursula Lehr, former Federal Minister and Chair of the *Bundesarbeitsgemeinschaft der Senioren-Organisationen e. V.* (the Federal Association of Senior Citizens’ Organizations), began by describing the context in which issues of dementia arose: “We have increasing longevity – which is gratifying – but at the same time we see this as a challenge to every individual and to society! And let us not close our eyes to the fact that the likelihood of dementia increases with age.” One of the challenges was to safeguard the quality of life even in its final phase – in particular, for dementia sufferers too – while making for a dignified old age. To this end, particular importance attached to reinforcing professional help, care and treatment, as well as to early diagnosis and prevention through physical, mental, intellectual and social activity.

According to Andreas Kruse, Director of Heidelberg University’s Department of Gerontology, three anthropological indicators facilitated a deeper understanding of a person’s quality of life and capacity for self-determination – namely, self-actualization as a means whereby the psyche could express itself in the various qualities of the personality; the exercise of responsibility, in which the person concerned perceived himself as an

autonomous actor; and generativity, defined as the motivation to do something for other people, or to put oneself in someone else's shoes. Even those in the advanced stages of dementia retained a degree of self-determination – albeit limited – and, given appropriate opportunities for communication and a suitable environment, could take responsibility for many aspects of their lives. In Professor Kruse's view, the essential point was to recognize that emotional, social and communicative capabilities and the ability to cope with the practical demands of everyday life were resources to be drawn upon in a dementia sufferer. Every manifestation of autonomous activity and empathy should be exploited and positively reinforced, thus strengthening and making optimum use of the capacities of dementia sufferers. Using studies by the Department of Gerontology at Heidelberg, Professor Kruse gave examples of possible forms of rehabilitation and care with the aim of enhancing quality of life.

In his paper, Rolf-Dieter Hirsch, Medical Director of the Department of Geriatric Psychiatry at the *Rheinische Landeslinik* in Bonn, addressed the issue of research with dementia sufferers. He observed that it was not yet possible

to influence the course of every individual dementia with any degree of permanence, particularly as the causes of and possible treatments for the various dementias were thought to differ very substantially. For this reason, research should be directed to a greater extent towards pathogenesis, treatment, rehabilitation and prevention. Professor Hirsch also advocated an integrated biopsychosocial approach in which the dementias were seen in their diversity, as well as a research policy involving all the relevant academic disciplines. At present, dementias were unfortunately still regarded, researched and treated too much as purely organic disorders. Initial attempts to take more account of the diversity of individual sufferers, in research as elsewhere, were evident in particular in geriatric psychiatry and the nursing sciences. Professor Hirsch emphasized that research involving dementia sufferers must always allow for the fact that some subjects would no longer possess the capacity for consent at a later stage in their illness, and therefore required particular protection. In such cases, he considered that the only acceptable research-related interventions were ones whose results were or could be of direct benefit to the subject's health.

Public meeting
"Dementia – the end of
self-determination?"
at the Hamburg
Chamber of Crafts



The contribution of Margot Lucke, a former consultant at the *Medizinischer Dienst der Krankenversicherung Niedersachsen* (Medical Service for the Health Insurance Funds in Lower Saxony), was devoted to home and inpatient care for dementia sufferers. She laid particular stress on the fact that dementia would lead to the end of self-determination if coordinated measures to satisfy the needs of patients and their carers were not adopted. Family members were often unable to cope with the demands of outpatient care, they had only limited knowledge of respite arrangements, and furthermore often did not know how to access these. In this connection, Dr. Lucke emphasized the vital role of the nursing care insurance funds, which, in addition to their mandate to ensure that care was provided, were also required to provide comprehensive advice on care, including advisory home visits and individual training in the domestic environment.

As for inpatient care, very few centres were capable of fully recognizing the particular needs of dementia sufferers and of adopting an appropriate approach to allow them to exercise self-determination. There was a dearth of suitable staff and family doctors versed in geriatrics

and geriatric psychiatry. Furthermore, the documentation to be compiled under the care regulations in force took up more than 30% of properly trained staff's working time. Dr. Lucke suggested that motivated pensioners should be encouraged to undertake more civil society volunteer work, that family doctors should receive more training in the diagnosis, therapy and care of dementia, and that an element of practical care of the condition should form an integral part of the training of medical practitioners. She pointed out that "perception of the forms of behaviour specific to the disorder, their interpretation and classification, and the appropriate reactions to them must be learned and practised – and this applies to doctors, professional carers and lay carers alike".

Next, people with dementia themselves took the floor. The discussion with Peter Wißmann, head of the dementia support organization *Demenz Support Stuttgart* and Deputy Chair of *Aktion Demenz e. V.*, dementia sufferer Helga Rohra, a former translator, and Christian Zimmermann, formerly a businessman and now suffering from Alzheimer's, was entitled "We speak for ourselves!" Unlike most people diagnosed with dementia, who were reluctant to talk about their condition in



Discussion "We speak for ourselves!" with Volker Gerhardt, Christian Zimmermann, Peter Wißmann and Helga Rohra (from the left)

public, Ms Rohra and Mr. Zimmermann aggressively confronted the public with their situation, because they saw dementia primarily as a social experience. After the shock of diagnosis, they accepted their situation and, by “going public with it”, wished to encourage other sufferers. Mr. Zimmermann thus declared: “There is a life after diagnosis.” Helga Rohra, for her part, said that she wished to “step out of the shadows”. Besides care professionals, family members and civil society volunteers, both wished to see sufferers themselves integrated, as a fourth group of actors, in the process of dealing with the dementias.

The contribution of Otfried Höffe, Head of the Political Philosophy Research Unit at Tübingen University and President of the Swiss National Advisory Commission on Biomedical Ethics, was entitled “Ageing in dignity”. Looking at views of ageing throughout the course of history, he noted that the problem of ageing itself, reflection on ageing and the development of strategies to address the associated challenges were nothing new, but could already be identified in the pre-academic exploration the subject in the ancient world. Pre-academic research on ageing assigned “significant value to the benefits of a consideration that was no longer couched in functional terms”. This was different from the present-day social and political debate, which concentrated on the question of “how to integrate ageing and the elderly as effectively as possible, first in the world of work and society and later in that of old people’s and care homes”. The disquisitions on ageing and old age to be found in Cicero, Voltaire, Jacob Grimm, Ernst Bloch and Hermann Hesse showed, in Professor Höffe’s view, that it was possible and indeed essential to learn how to age. As to the successive

stages of the process of learning “how to grow old in dignity” (Hesse), he proposed the three phases of “resigned ageing”, “reflective and integrative ageing” and “creative ageing”, and noted that the sequence of the phases need not be linear. On the question of self-determination in dementia sufferers, Professor Höffe considered that, on the one hand, the principle of self-determination should not be understood in excessively demanding terms, but preferably on a comparative basis, while, on the other hand, documentation of earlier self-determination – advance directives – should be accepted.

The meeting ended with a panel discussion between Ursula Lehr, Otfried Höffe, Helga Rohra, Peter Wissmann and Johannes Schröder, Head of the Geriatric Psychiatry Section of Heidelberg’s University Clinic. Members of the audience were able to take part in the discussions by channelling questions through appointed spokespersons. Aspects of particular interest raised from the floor were utilization of family members’ expertise; coordination of the relevant medical specialties; training of care professionals; specialist medical care in care homes; continuing training of family doctors; and alternative forms of housing.

An exhibition of photographs by Claudia Thoelen, “Alzheimer’s – another world”, accompanied the meeting. Her photographs display an impressively close approach to dementia sufferers, who may all too readily appear to be living entirely in a world of their own.

The Ethics Council will reflect on all the suggestions made and will take account of them in its forthcoming Opinion on dementia.

Bioethics Forum

The Bioethics Forum is a meeting format intended to promote dialogue with the public. Topics of general interest were vigorously debated on three occasions, in February, June and October 2010.

Synthetic biology – life from a self-assembly kit?

Presentations from and audio recordings of meetings in the Bioethics Forum series (in German) can be accessed online at www.ethikrat.org/veranstaltungen/forum-bioethik

On 24 February 2010, some 350 guests assembled in the Leibniz Room of the Berlin-Brandenburg Academy of Sciences and Humanities for a joint discussion with the contributors and with members of the German Ethics Council for its fifth public evening meeting in the Bioethics Forum series, on issues of synthetic biology.

The still young field of research known as synthetic biology is increasingly associated with headlines such as “living machines”, “bio-building blocks” and “artificial cells”. Using standardized gene modules and applying engineering principles, scientists are attempting to reshape microorganisms and even to create new ones from scratch, the aim being to utilize particularly effective microorganisms for biotechnological purposes. However, the depth of the modifications undertaken to simple life forms also gives rise to ethical and philosophical questions: Does synthetic biology involve the “creation of life”? What is the impact of these new possibilities on our image of humanity? Does genetic engineering present as yet unknown safety risks? What issues of justice arise in a global context?

Bärbel Friedrich, of Berlin’s Humboldt University, introduced the two principal research approaches of synthetic biology. In the first, “building blocks of life” were constructed from inanimate materials with the aim of creating a new living

organism, whereas, in the second, the researchers attempted to remove all non-essential components from natural organisms and to replace them by tailor-made substitutes, in order thereby to create artificial life forms. This implied a change of perspective from manipulation by genetic engineering to the synthetic creation of complex gene modules in the laboratory. The aim of synthetic biology, according to Professor Friedrich, was the making of useful microorganisms which could produce, for instance, pharmaceutical active substances, such as the anti-malaria drug Artemisinin, or biofuels reliably and by clearly defined techniques; examples were tailor-made yeasts, fungi or bacteria that could convert plant waste into biofuel quickly and at low cost.

The synthesis of large-scale fragments of DNA and the production of organisms without any known relationship to nature did not currently impose any additional requirements in terms of biosafety in the laboratory or when released into the natural environment, with regard to unintended interactions between the artificial organisms and that environment. In principle, too, no new risks were discernible on the level of deliberate misuse (biosecurity) as compared with genetic engineering. For this reason, Professor Friedrich for the time being considered there to be no need for specific new legislation or regulations for synthetic biology. The risks were covered by the *Gen-technikgesetz* (Genetic Engineering Act); furthermore, safety switches could be incorporated in the organisms to prevent propagation in the wild and to reduce the risk of known pathogens being synthetically reconstructed or modified. However, since extensive databases of pathogenic organisms and toxins were publicly accessible and genetic building blocks could

Panel discussion with
Bärbel Friedrich, Volker
Gerhardt, Andreas
Brenner, Peter Dabrock,
Eberhard Schockenhoff
and Wolf-Michael
Catenhusen
(from the left)



be purchased online from synthesis firms, precautionary measures were called for.

The ensuing panel discussion concentrated on philosophical and theological aspects of the ethical appraisal of synthetic biology. With Council member Wolf-Michael Catenhusen as moderator, the philosopher Andreas Brenner and the theologian Peter Dabrock, together with Council members Volker Gerhardt and Eberhard Schockenhoff, considered whether, by its aspiration to create completely novel life, synthetic biology might change our attitude to life itself and lead to an understanding of man as *homo creator*.

Andreas Brenner, *Privatdozent* at the University of Basle, Switzerland, stated that the main challenges facing synthetic biology were those of risk assessment and global justice. He said that these were “political issues that had to be taken seriously” and called for much more discussion. Dr. Brenner felt that changes in our conception of “life” were equally important. The claims made by this new branch of science were manifestly quite different from those of traditional biotechnology. If life were to be regarded no longer as something that had come into being or been created, but instead as something manufactured, this had major repercussions for the dignity of

nature, which would become dependent on its maker, man, according to Dr. Brenner. Hence the need for an ethical and a cultural debate in society.

Volker Gerhardt, a philosopher at Humboldt University in Berlin, on the other hand, emphasized that synthetic biology was simply following in the footsteps of other natural sciences, investigating natural processes by analytic, cause-and-effect methods, while also seeking to make the concept of life tangible and comprehensible with causal explanations. Connections could likewise be made with the tradition of philosophy, in which nature was explored by a unified approach based on an interest in its unity. Synthetic biology nevertheless signified a more far-reaching intervention in the self-controlling processes of life. This had the consequence of increased responsibility not only on the part of the individual but also, in particular, on that of society in this case. However, Professor Gerhardt considered that the true challenge presented by the debate about synthetic biology lay not in the new possibilities of interfering with nature, but in the ethical discourse on the concepts of man’s freedom and dignity.

Peter Dabrock, of the University of Marburg, was particularly interested in

the way the theme of “playing God” featured in the public debate on synthetic biology – to a greater extent than with other methods used in contemporary biotechnologies. Many evidently felt that the creation of life was uncanny because it blurred the boundary between life and non-life. On this point, Professor Dabrock considered there to be an urgent need for discussion, both on the part of the sciences on the possibilities and limits of synthetic biology, and on that of the public, on the directions of research it regarded as unacceptable.

In the view of Eberhard Schockenhoff, a Catholic theologian at the University of Freiburg, the metaphor of “playing God” was a manifest dramatization of the debate, because synthetic biology could assume new dimensions only if used as an extension of natural processes – that is, with constructive intent. Whereas theologians considered creation to be accomplished by God “out of nothing”, in the case of synthetic biology man was cast more in the role of an active co-creator. Professor Schockenhoff stressed that the organisms that came into being were “at any rate not what we usually understand by life or find in nature as life, but instead a kind of technical life”. A term commonly used in the English-speaking countries was “living machines”. Should it ever become possible to produce living artefacts as a higher form of life, they would have to be treated with full respect and reverence. In Professor Schockenhoff’s view, “creating life as a mere commodity to serve our needs would impoverish our natural condition.”

When the discussion was thrown open to the floor, the main issues raised were risk research, technology assessment and possible regulatory mechanisms for syn-

thetic biology. Some pointed out that discussion of the notion of human dignity was relevant or appropriate in this context: as long as the debate did not centre on the synthesis of human cells or gametes, it was more correct to use the notion of the dignity of life than that of human dignity. Council member Jochen Taupitz took the view that an ethical debate was called for on the question of our responsibility to future generations in terms of possible consequences of both the use and the non-use of new techniques, with regard not only to the risks, but also to the opportunities, for society.

The moderator, Wolf-Michael Catenhusen, expressed satisfaction with the outcome of the evening’s discussion. He noted in particular that, in the future too, scientific developments should be monitored not only with due sensitivity to ethical issues, but also with the necessary degree of differentiation. Although the discourse was still at an early stage, synthetic biology was an increasingly important field of research, in which questions of social consequences and ethical responsibility arose. In particular, the contributions from the floor, specifically on the definition of life and the safety risks of the new technology, had made it clear that much still remained to be discussed with regard to this subject. The German Ethics Council was interested in taking part in this discourse, and would consider the appropriate steps and formats in the ensuing months.

Intersexuality – life between the sexes

On 23 June 2010, more than 300 guests accepted the Ethics Council’s invitation to join experts from various disciplines and intersex individuals to debate the topic of intersexuality.

A variety of genetic and hormonal changes may give rise to very diverse forms of intersexuality, some of which are immediately evident at birth, while others are recognized only at puberty. As in the past, those concerned undergo genital surgery in early childhood because the medical profession and parents see intersexuality as a developmental disorder calling for surgical and hormonal treatment for the benefit of the child. However, self-help groups of intersexuals increasingly oppose such interventions, invoking the constitutional rights to physical integrity, self-determination and free development of the personality.

Hertha Richter-Appelt, a psychoanalyst at *Universitätsklinikum Hamburg-Eppendorf*, gave an introduction to the medical fundamentals. She drew attention to the fundamental difficulty of drawing an unequivocal distinction between men and women. For instance, individuals with a female chromosome set could nevertheless have an external male genital and vice versa. In the manifestations of intersexuality, it was often impossible to determine an unequivocal biological sex. While this was sometimes due to alterations in the chromosome set, the most common causes were changes in the gonads or hormonal balance. Apart from the variability of physical sexual manifestations, one often also observed a wide range of forms of psychosocial gender, expressed in gender identity, gender role and sexual orientation.

Professor Richter-Appelt took a critical view of earlier criteria for treatment, based in particular on the views of the American psychologist John Money in the 1950s. Money had postulated that sex could be instilled completely by education and that it was therefore possible to assign an unambiguous sex to intersexual

children by genital surgery, the procedure being kept secret from the patient. Professor Richter-Appelt emphasized that therapeutic attempts of this kind, which had often been undertaken without informing the patient and without the patient's consent, were misguided and were no longer appropriate today. In her opinion, the informed consent of those concerned should be sought before a decision was made, instead of "going over their heads in assigning a gender to them and then also requiring them to go through life in a particular role, while experiencing themselves as men or women". There were a multiplicity of identities as well as a multiplicity of genitalia, and not just two. Furthermore, a genital that was not unambiguous need not result in a disturbance of psychosexual development. Repeated genital surgery could have a much greater traumatic effect in this connection. Professor Richter-Appelt mentioned the results of her follow-up study in Hamburg, the main conclusion of which was that the various diagnoses had to be considered in very great detail and treated by a differentiated approach.

Konstanze Plett, an academic lawyer at the University of Bremen, complained that it had not yet been realized in her discipline that not everyone was unequivocally male or female. Although there were instruments such as the *Grundgesetz* (Basic Law) of the Federal Republic of Germany, the Council of Europe's Human Rights Convention and the United Nations Convention on the Rights of the Child, which indicated "that people born intersex also have a right to their own sexual identity", in practice this principle was not followed. Professor Plett considered that legal problems lay in the law of civil status, which required assignment to one sex or the other on entry in the

register of births within one week; in the law of medicine, as regards the issue of whether sex assignment surgery should be regarded as therapy or as physical injury; and with regard to the appropriate criteria for medical intervention.

Professor Plett drew attention to two current legal debates. One concerned the inclusion of the attribute “sex” for the purposes of the Basic Law’s provisions on prohibiting specific groups of persons from being placed at a disadvantage; the other related to the bill proposing that mutilation of the female genitals be made a criminal offence. Both were being debated in the *Bundestag*. Although these drafts also covered intersex individuals, who were even mentioned explicitly in regard to the ban on placing groups of persons at a disadvantage, they were not mentioned in the explanatory memoranda, speeches of introduction and contributions to the debate. Although intersex individuals were already protected by existing laws, there was still a situation of “suppressed visibility” and “continuation of the taboo”, because “intersex individuals are not genuinely perceived, even in the bills intended to benefit them”. To eliminate this undesirable state of affairs, Professor Plett called for more dovetailing of civil and criminal law, increased interdisciplinary cooperation, and assimilation of information that already existed by the political and administrative worlds. She saw that day’s meeting as a step towards the full implementation of human rights for all individuals.

Claudia Kreuzer and Lucie Veith, of the *Verein Intersexuelle Menschen e. V.*, an association of intersex individuals, presented the views of the group concerned. As an example, Claudia Kreuzer described feminizing medical interventions in genotypically male individuals with intersexual

genital status and drew attention to what she saw as the incalculable harm done by such interventions and to the associated risks.

Whereas there was evidence that untreated intersex individuals had few problems with their sexual constitution and gender, medical interventions often resulted in physical disorders and mental problems extending even to traumatization. “The medical interventions deprive those who undergo them of any possibility of individual physical and mental development, as their physical capacity to develop in their own way has been irreversibly destroyed.”

In the manifest absence of studies on the impact and long-term effects of these interventions, they had to be seen as “human experiments”. For this reason, the association called for a ban on surgery that was not necessary for the preservation of life or health.

In the view of Lucie Veith, interventions that were not necessary for medical reasons were contrary to human rights and were experienced by the victims themselves as torture. Although the state had a duty to protect the victims from such interventions, it failed to discharge that duty. The medical interventions, which she described as “normalizing by violent means”, were in her opinion incompatible with the right to physical and mental integrity.

She called on the state to comply with its obligation to protect fundamental rights and not to delegate decisions on such drastic interventions in the life of a child with intersex status to doctors and parents, because this imposed too heavy a burden on them. In addition to calling a halt to such surgery, she proposed that those concerned should be guaranteed compensation and rehabilitation.

The ensuing panel discussion began with an introduction by Claudia Wiesemann, a medical ethicist at the University of Göttingen, to the ethical principles and recommendations of the working group on ethics of the *Netzwerk Intersexualität* (Intersex Network), which was assisted by the Federal Ministry of Education and Research. She stated that the best interests of the child and adult-to-be had to take maximum priority in decisions on therapy. The child's best interests were represented by physical integrity and free development of the personality. The interests of the child and of the adult-to-be could, however, sometimes conflict. Professor Wiesemann recommended that account be taken of the child's right to participation and, depending on the child's age, self-determination, and thus agreed with Professor Richter-Appelt that the children concerned had to be involved in the decision. It was very important to respect and reinforce the parent-child relationship, to support parents in dealing with the situation, and to decide on the medical necessity of surgery on an individual-case basis.

In the course of the panel discussion, the representatives of the *Verein Intersexuelle Menschen e. V.* criticized Professor

Wiesemann's demand for individual-case decisions on surgery. Only a ban on such interventions in the case of minors would effectively protect their interests. The discussion led by Council member Michael Wunder came to focus on possible practical ways of implementing the right of minors to be involved in decisions. Professor Plett pointed out that children would often formulate, or even perceive, the wishes of adult family members as their own. Furthermore, young children frequently lacked the maturity needed for such decisions. The only point on which all participants agreed was that cosmetic interventions resulting from social pressure were totally unacceptable.

When the discussion was thrown open to the floor, contributions were forthcoming from many intersex individuals, and the particular point was made that the individual should not be forced to conform to the expectations of society, but that society must accept people as they were. If society was to be changed, it was necessary, according to Professor Richter-Appelt, to begin with parents and nursery school teachers, as well as with medical training.

One of the criticisms expressed was that the discourse was dominated by the



Panel discussion with Hertha Richter-Appelt, Konstanze Plett, Lucie Veith, Claudia Kreuzer, Michael Wunder and Claudia Wiesemann (from the left)

medical profession, which tended towards the medicalization and hence the pathologization of intersexuality, whereas a much more broadly based debate was demanded by a problem with such wide social implications.

The world of politics was called upon to take cognizance of discrimination against intersex individuals and to adopt urgent measures to end it. In particular, sex assignment surgery on minors should be halted with immediate effect, since it violated the right to the protection of human dignity. At the end of the discussion, Claudia Kreuzer appealed for concrete action: “Lots and lots of people are affected, and lots and lots of children. These children have no time. [...] We need quick decisions, not discussions.”

Opting in or opting out of organ donation: should the state require everyone to choose?

At an evening meeting in its Bioethics Forum series held on 27 October 2010, the German Ethics Council debated the issue of whether the state could require everyone to make a decision about organ donation.

Peter Neuhaus, Director of the Charité Hospital’s General, Visceral and Transplant Surgery Clinic in Berlin, began the proceedings with an introductory report on the development of transplant medicine to date and the outlook for the future. The last few years had shown that organ recipients not only had better prospects of survival, but also enjoyed “immeasurably improved quality of life, physical and mental performance, and joie de vivre”. Another trend was that the age of organ donors was increasing significantly. In the case of liver transplants average donor age had actually doubled in recent years: given that the liver was an

organ capable of self-regeneration, older people too could perfectly well be donors. Yet the proportion of post-mortem organ donation in Germany was low at under 15 per million head of population, putting the country in the bottom third of the league table of European nations. To address this problem and to encourage scientific advances in transplant medicine, Professor Neuhaus recommended that transplants should be concentrated to a greater extent in major centres, and called upon the politicians to help make this a reality.

Thomas Breidenbach, Managing Physician at the *Deutsche Stiftung Organtransplantation, Region Mitte* (German Organ Transplant Foundation, Central Region), offered a more specific view of the situation from the practical perspective of organ donation. According to Dr. Breidenbach, the reasons for the low rate of consent by family members included a concern that doctors might no longer do everything in their power to save the lives of their loved ones, as well as fear of the trade in organs and differing rational and emotional perceptions of brain death. To avoid long-term psychological issues, family members needed to be treated competently and sympathetically, as “an over-hasty yes can be just as wrong as an over-hasty no”.

In her contribution, Weyma Lübke, a member of the German Ethics Council, addressed the ethical implications of mandatory declarations on organ donation. In her personal view, the public debate so far, which included the former National Ethics Council’s Opinion “Increasing the number of organ donations: a pressing issue for transplant medicine in Germany”, represented “a large-scale moral appeal to the public to declare their consent to post-mortem organ donation”. This was not

Opinions issued by the former National Ethics Council can be accessed online in English at www.ethikrat.org/archive/national-ethics-council/opinions

readily reconcilable with the simultaneous assertion that a decision not to donate must also be absolutely respected. The speaker emphasized that a legal obligation to opt either in or out of organ donation could not be imposed without considering what was supposed to happen in the event of failure to declare. She condemned the thesis that a failure to declare, even after state involvement with the issue, automatically implied consent. Invoking the “golden rule” that individuals should themselves be prepared to make sacrifices that they expected or hoped for from others, she commented: “The reciprocity to be guaranteed is mutual respect for an individual’s personal decision, not mutual willingness to donate.”

The ensuing panel discussion, moderated by Council member Eckhard Nagel, was devoted primarily to the issue of how far the individual could be called upon to opt either in or out of organ donation.

As a member of the family of an organ donor and on the basis of her own experience, Marita Donauer favoured a mandatory declaration system. She summed up her conviction in the phrase “I can’t refuse to give an answer”. This meant that family members had a duty to declare one way or the other, even if it was hard for them

to be absolutely certain of the deceased’s presumed wishes.

Annette Widmann-Mauz, a Member of the *Bundestag* and Parliamentary State Secretary to the Federal Minister of Health, took the view that organ donation was an altruistic gift that could not be automatically expected. There must be “no obligation to donate and no obligation to declare”. Instead, other instruments should be deployed to make it easier for people to decide.

Hans Lilie, holder of the Chair of Criminal Law, Law of Criminal Procedure, Comparative Law and Medical Law at the University of Halle-Wittenberg, considered that the matter at any rate needed to be addressed in greater depth, since a compulsion to declare could not be deduced from constitutional law. Professor Lilie was convinced that it was immaterial which model – opt-in or opt-out – was chosen as long as the deficiencies in the organization of transplant medicine had not been overcome.

Jutta Riemer, Chair of the *Verein Lebertransplantierte Deutschland e. V.* (Association of Liver Transplant recipients in Germany), felt that what mattered most for those concerned was to know that the organ donation had been voluntary. Everyone



Panel discussion with Weyma Lübke, Hans Lilie, Annette Widmann-Mauz, Eckhard Nagel, Marita Donauer and Jutta Riemer (from the left)

agreed on the need for full information to be given, and this called for a coordinated approach across the board.

When the debate was then thrown open to the floor, one suggestion was for a formal declaration procedure on a voluntary basis, while others advocated an opt-out system or even a solidarity-based obligation to donate organs. In addition, a wide-ranging public debate that included all positions, however controversial, was considered necessary.

Following this meeting, the Ethics Council decided to establish a working group whose brief would be to draw up recommendations on the possible introduction of a mandatory declaration system.

Debates with schoolchildren and students

During the period under review the German Ethics Council welcomed four student groups from Germany and the United States to its Office.

On 9 April 2010, students from the *Fachhochschule des Bundes für öffentliche Verwaltung* (Federal University of Applied Administrative Sciences) visited the Office of the German Ethics Council. The Head of the Office, Dr. Joachim Vetter, informed them of the activities of the Council.

Students from the *Freie Universität Berlin* (Free University of Berlin), who had come to the Office of the German Ethics Council on 18 June 2010 for a seminar on “Applied Ethics: History and Critique”, were particularly interested in the procedure adopted by the Ethics Council for its work.

As in earlier years, a group of students from the United States visited the Ethics

Council on 3 August 2010 in connection with Bonn University’s summer school on “Life Sciences and Culture”. Council member Jens Reich gave an introduction to the work of the Ethics Council and answered the students’ questions.

Another group of students was received at the Office on 19 November 2010. The Head of the Office introduced the work of the Council to these students from the University of Halle-Wittenberg.

In addition, Dr. Vetter delivered lectures on the work of the German Ethics Council to two schools. He spoke to pupils attending a course on ethics at the *Gabriele-von-Bülow-Oberschule* in Berlin-Tegel on 11 January 2010, and introduced the work of the Ethics Council to an audience at Berlin’s *Hannah-Arendt-Gymnasium* on 21 September 2010. On 7 October 2010, Nora Schultz, a Research Officer at the Office, presented the work of the Council and reported on the latest developments in the fields of reproductive medicine and genetic diagnosis at the *Oberstufenzentrum Lise Meitner* in Berlin to the participants in the EU seminar on “Genetic Engineering in Training and the Laboratory” (GENIAL).

Collaboration with the German Bundestag

The German Ethics Council held its first Parliamentary Evening in Berlin on 25 March 2010. The aim of the meeting was to exchange views with the members of the German *Bundestag* on the current and future work of the Council and on what they saw as the principal ethical issues of the 17th Electoral Term.

In his welcoming address, Edzard Schmidt-Jortzig, the Chair of the Ethics Council, emphasized that it was both the task and the desire of the Council to use its Opinions “in order to approach the constitutional body as directly as possible, to enable that body where appropriate to derive generally valid and legally binding provisions from the recommendations”. The Chair of the Ethics Council took the opportunity to present the Council’s Annual Report for 2009 to the President of the *Bundestag*, Professor Norbert Lammert.

Professor Lammert stated in his opening address that the German *Bundestag* wished the Ethics Council to furnish “advice that should be not only as meticulous but also as regular as possible”. However, as regards the definition and treatment of relevant topics, he personally was less concerned that decisions should where possible be arrived at unanimously. Since a consensus “is almost always decreasingly likely to be forthcoming the more demanding the issues”, he thought it preferable in cases of doubt for the Ethics Council to engage in a vigorous debate and then to present its conclusions “to the *Bundestag* with a position statement to which a greater or lesser majority of members subscribe”.

Later in the evening, the spokespersons for the Council’s internal working groups gave an account of the current

status of their deliberations. Regine Kollek reported on the discussion of the Opinion “Human biobanks for research”, which was approaching its conclusion; Eckhard Nagel mentioned the core issues arising in the discussions of the working group on allocation in healthcare; Michael Wunder gave an introduction to the programme of the working group on dementia, formed at the beginning of the year; and Wolf-Michael Catenhusen gave an interim account of the debate on the topic of human–animal mixed-species entities. The Deputies showed great interest in all these topics and took advantage of the opportunity to discuss them with the members of the Council.

In the second part of the evening, Christiane Woopen, Vice-Chair of the Ethics Council, presented the Council’s recommendations on the problem of the anonymous relinquishment of infants. She emphasized that full account was not taken of the complexity of the issue by the usual formula that “it was already worthwhile even if only one life could be saved” and by the simplifying judgement, heard even now all too often in public, that the right to life was more important than the right to a knowledge of one’s genetic parentage – which, of course, no one on the Ethics Council disputed. She also considered it unfortunate that the Ethics Council’s recommendations on the provision of help to pregnant women and mothers in distress had not been taken up sufficiently in the public debate. The recommended measures included in particular more effective publicization and a strengthening of trust in the many different kinds of help that were already available.



Prof. Dr. Norbert Lammert (center), President of the *Bundestag*, with Council members Eckhard Nagel, Christiane Woopen, Edzard Schmidt-Jortzig and Eberhard Schockenhoff (from the left)

With a view to possible legislation, the Deputies then discussed with the members of the Ethics Council in particular its recommendation that a law be introduced providing for the confidential relinquishment of children with temporarily anonymous notification.

At the invitation of Ulla Burchardt, the Chair of the *Bundestag*'s Committee on Research, Technology and Technology Assessment, Professor Schmidt-Jortzig attended a meeting of the Committee on 1 December 2010. He informed the Deputies of the projects currently in hand at the Ethics Council and answered questions. The Deputies were manifestly very impressed with the wide range of topics covered, and unanimously emphasized the important role of the Ethics Council in advising Parliament and in the bioethical debate as a whole. They asked a large number of questions about the topics currently being addressed, as well as about the Opinions already published, and also learned about the procedure adopted by the Ethics Council, its funding, and the staffing of the Office. Another particular object of their interest was the interaction between the Ethics Council and the *Bundestag*'s Parliamentary Advisory Council on Ethics in the previous Electoral Term.

This discussion took place in the context of the debate on the appointment of a new Parliamentary Advisory Council on Ethics. With regard to the appointment of a new Advisory Council on Ethics, Professor Schmidt-Jortzig pointed out that, while he was unable to make a recommendation on this point, it was important for the Ethics Council to have an interlocutor in Parliament. The Ethics Council's Opinions had until now already been furnished direct to all Deputies in this way.

Whereas the funding of the Ethics Council was currently adequate, something of an impasse had been reached with regard to the staffing of the Office, especially as regards the work of the Research Officers, owing to the large number of activities involved. For this reason, Professor Schmidt-Jortzig proposed the eventual appointment of a third Research Officer, particularly as this would be possible without any increase in the overall budget. At the end of the meeting, Professor Schmidt-Jortzig announced that the Ethics Council's Opinion on cost-effectiveness analysis in the healthcare system was scheduled for publication in January 2011, to be followed by the Opinion on preimplantation genetic diagnosis by the beginning of March 2011.

International initiatives and contacts

As in earlier years, the Ethics Council in 2010 again took part in exchanges with national ethics councils and organizations at international level, in accordance with its mandate as provided in the Ethics Council Act.

Forum of National Ethics Councils of the European Union

Under the Spanish Presidency of the Council of the European Union, a joint meeting of the Forum of National Ethics Councils of the European Union (NEC Forum) and the European Group on Ethics in Science and New Technologies (EGE) was held in Madrid on 3 and 4 March 2010 to coincide with the 15th NEC Forum.

The subject of the joint meeting of the NEC Forum and the EGE was the institutional role of advisory bodies on ethics, for instance in advising the world of politics. On this point, Michael Fuchs, of the *Institut für Wissenschaft und Ethik* (Institute for Science and Ethics), Bonn, presented an overview of the various ethics committees existing in the European Union. Göran Hermerén, the Chair of the EGE, Paul Schotmans, Chair of the Belgian Advisory Committee on Bioethics, and Kristiane Weber-Hassemmer, a member of the German Ethics Council, then described the structure and working of their respective bodies. Professor Hermerén pointed out that the work of the EGE too had been modified by the Lisbon Treaty, since the fundamental rights enshrined in that treaty now en-

joyed constitutional status in all Member States.

The ensuing NEC Forum centred on the evaluation of clinical trials in an international context; collaboration between the public and private sectors in biomedical research and development; and the regulatory foundations applicable to the ethical evaluation of clinical trials. Introductory papers on the subject were presented by Diego Gracia, of the University of Madrid, John Harris, of Manchester University, and Carlos Alonso, of the Spanish ethics council. Stefan Fühling, of the European Commission, and Daniel Davies, of Georgetown University in the United States, gave an account of the regulatory basis for the ethical appraisal of clinical trials in the European Union and the United States respectively. The question of the approach to be adopted in the composition of Opinions involving both consensus and dissent was vigorously debated at the full meeting. Notwithstanding the differing views expressed, the clear conclusion was that dissenting positions must always remain visible.

Under Belgium's Presidency of the Council of the European Union in the second half of 2010, the 16th NEC Forum was hosted by the *Comité Consultatif de Bioéthique de Belgique* (Belgian Advisory Committee on Bioethics) on 28 and 29 October.

At the beginning of the two-day meeting in Brussels, the representatives of the national ethics councils held a joint session with the EGE to discuss the comparative role of ethics in different European countries. The 16th NEC Forum followed

Further information can be accessed online at ec.europa.eu/European_group_ethics

the joint session with the EGE. Greater provision was made for participation in the Forum, so as to maximize exchanges between the representatives of the various national ethics bodies. For this purpose, the participants could choose between three workshops.

The first workshop, headed by Sigrid Sterckx and Ernst Heinen, addressed the issue of the marketing of the human body. The discussion centred on the extent to which the commercialization of human bodily materials should be permissible. Some participants held that a distinction could be made between the “social body” and the “biological body” and that the donation of materials from the “biological body” was less problematic.

The second workshop, on the subject of assisted dying/euthanasia, was led by Yvon Englert and Gilles Genicot. The participants discussed the permissibility of assisted dying in the various countries and whether public opinion on the subject had changed. Assisted dying was prohibited in most European countries, with a few exceptions such as the Netherlands, Belgium, Luxembourg and Switzerland. Its legalization in these countries had greatly influenced the debate and reflection in Europe. Public opinion now took an increasingly positive view of assisted dying, whereas the majority of doctors tended to reject it.

The third working group, led by Inge Liebaers and Geneviève Schamps, discussed ethical issues of preimplantation genetic diagnosis (PGD), with particular reference to the circumstances and cases in which it should be permissible. The participants expressed differing views on this subject. Whereas some rejected PGD in order to protect the embryo, others emphasized that PGD was less stressful for the mother than prenatal diagnosis

and possible abortion in the event that the embryo was genetically damaged.

The permissibility of using PGD to create a “saviour sibling” as a tissue donor for a seriously ill older brother or sister was another vigorously debated question. Some members of the group considered that this practice should be prohibited, on the grounds that it constituted an instrumentalization of the embryo. Those in favour countered that the value of the embryo was increased by the fact that it was able to save life. Furthermore, there were many reasons why people had children, and these often involved a kind of instrumentalization.

The participants agreed that comprehensive, skilled advice was necessary in all cases and that the technique used should not depend solely on cost.

International Dialogue on Bioethics

Under the Spanish Presidency of the European Council, the second International Dialogue on Bioethics was held on 3 and 4 March 2010, attended not only by participants in the NEC Forum but also by a large number of representatives of national ethics committees throughout the world. This meeting too focused on the role of ethics in international biomedical research. Margaritis Schinas, of the European Commission, noted that the Commission considered exchanges between ethics committees at international level to be very important and would continue to support international dialogue. Again, the EU would assist interested countries in the establishment of competence in the field of bioethics. Javier Arias Díaz, of the Spanish bioethics committee, pointed out that, at the initiative of Spain, a

declaration on the ethics of biomedical research in developing countries was in preparation in the Council of Europe. Professor Sir Michael Marmot, the former head of the working group on the social determinants of health at the World Health Organization (WHO), reported on the group's final report. He stated that life expectancy, both within a country and comparatively as between poor and rich countries, showed a direct correlation with income or the gross domestic product of the country concerned. It was difficult, but not impossible, to change this situation and ultimately to attain a consistent level of healthcare for all at global level too.

Laurence Lwoff (Council of Europe), Dafna Feinholz (UNESCO) and Marie-Charlotte Bouësseau (WHO) reported on the activities of their respective international organizations in the establishment of bioethical competence in developing countries. For instance, UNESCO had embarked on a programme (the "ABC Programme") to facilitate the establishment of national ethics committees. The WHO was assisting the establishment and activities of a global network of bioethics centres.

The members of the bioethics committees of non-EU states reported, with regard to the practice of evaluation of clinical studies with international participation, that all countries had established national bioethics committees that were responsible for the evaluation of such studies and for the development and implementation of guidelines for regional-level ethics committees.

To end the meeting, the participants discussed the possibility of developing a uniform ethical framework for the conduct of biomedical research throughout the world. The consensus was that a har-

monization and eventual standardization of regulations under an international convention would be possible only on the basis of a dialogue on bioethical issues. This could be successfully achieved if it could be agreed that the fundamental universal values could be interpreted differently according to the relevant cultural context.

Global Summit of National Bioethics Advisory Bodies

The eighth Global Summit of National Bioethics Advisory Bodies was held in Singapore on 26 and 27 July 2010 and was attended by Kristiane Weber-Hassemer, a member of the German Ethics Council, and Joachim Vetter, Head of the Office.

The Conference, with delegates from more than 30 bioethics committees and representatives of the WHO, the Council of Europe, the European Commission and UNESCO, is a biennial event and has developed into a permanent fixture for international exchanges between national ethics councils or comparable structures. The secretariat which prepares meetings and deals with exchanges between meetings is accommodated at the WHO in Geneva.

Richard Magnus, the Chairman of the Organizing Committee, and Kandiah Satkunanantham, Director of Medical Services, Ministry of Health, welcomed the delegates at the beginning of the Summit, at which a large number of topics were discussed. These included, for example, ethical issues in the transplantation of organs, tissues and cells; research ethics committees; ethical issues in tuberculosis control; synthetic biology; biobanks; stem cell research and therapy; and bioethical developments in general.

Since the German Ethics Council's Opinion on research with human biobanks had just been published, this topic was particularly interesting for the German participants. For this reason, the English version of the Opinion's recommendations had been circulated to the participants before the conference. Although detailed discussion of the recommendations was not possible, the proposal concerning biobank secrecy met with considerable interest.

The basis of the discussions on synthetic biology, in addition to papers by Amy Gutmann, Chair of the United States Presidential Commission for the Study of Bioethical Issues, and Julian Kinderlerer, of the European Group on Ethics, was a contribution by Dr. Vetter on the course of the public debate on the subject in Germany so far.

At the end of the meeting, the representative of the Tunisian ethics committee invited the delegates to Tunisia for the ninth Global Summit in October 2012.

Following the meeting, the delegates were able to tour a new information and exhibition centre accommodated at the Singapore Science Centre, whose specific purpose is to inform the public about bioethical issues. The intention is to enable visitors to learn about subjects such as stem cell research, genetically modified organisms and plants, or the ethical aspects of organ transplantation, thereby gaining an impression of new developments in the life sciences and their possible consequences for society.

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

In 2010 the German Ethics Council continued its close collaboration with its French and British counterparts, the *Comité Consultatif National d'Ethique* (CCNE) and the Nuffield Council on Bioethics respectively. This year's trilateral meeting of the three ethics councils was held in Paris on 3 December 2010 at the invitation of the CCNE.

The principal topics discussed were medical profiling and global health inequalities. The first was the subject of a paper by Professor Jonathan Wolff, a member of the Nuffield Council. He introduced the Council's consultation paper, published in October 2010, entitled "Medical profiling and online medicine: the ethics of 'personalised healthcare' in a consumer age". In it, the Council recommends improved Government monitoring of the quality of healthcare services recommended on the internet and suggests that doctors should be trained in advising patients looking for health information or purchasing drugs online. The members of the French and German councils associated themselves with these recommendations.

Next, Professor Eckhard Nagel, a member of the German Ethics Council, reported on the allocation of resources in the German healthcare system, with particular reference to the issue of fair distribution in a situation of scarce resources. Professor Nagel also gave an account of the debate within the working group on the allocation of resources, which was preparing the Opinion "Medical benefits and costs in healthcare: the normative role of their evaluation" (the German

version of the Opinion was published in January 2011). The ensuing discussion was devoted predominantly to the issue of social justice in the field of healthcare, at both national and international level.

Following the joint deliberations, the Chair of the Nuffield Council, Professor Albert Weale, invited his French and German colleagues to a trilateral meeting in London in 2011.

Publications

The German Ethics Council uses various regular publications to publicize its Opinions and activities. The print versions of these publications – in German only except where stated – are available free of charge on request from the Office of the Ethics Council and can also be accessed online as PDF files.

Opinions

Opinions are the Ethics Council’s most important publications. They represent the outcome of the in-depth debates conducted both in the Council’s internal working groups and at its Plenary Meetings. Their aim is to draw together the ideas voiced both in society and within the Ethics Council, to develop lines of argument, to indicate possible solutions, and to propose options for action.

On 15 June 2010, the German Ethics Council published the German version of its Opinion “Human biobanks for research” (see p. 7 ff.). Some 3500 copies were printed. The Opinion is also available in English and French translation.

The Infobrief can be accessed online (in German only) at www.ethikrat.org/publikationen/infobrief



Opinion “Human biobanks for research” (German edition)

Proceedings

The papers presented at the Annual Meeting are collated and published in the proceedings (in German only). An issue whose title translates as “Migration and health. Cultural diversity as a challenge to medical care”, of which 2500 copies were printed, was published in December 2010 (see p. 22 ff.).



Proceedings of the Annual Meeting “Migration and health” (in German only)

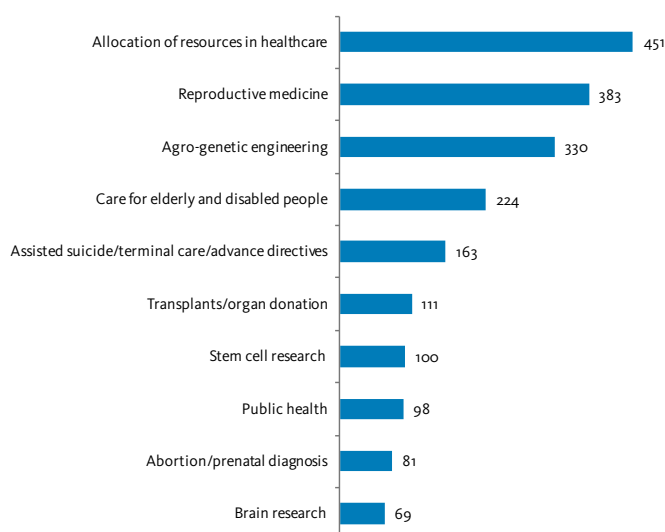
Infobrief

The *Infobrief* (newsletter, available in German only) was introduced to offer a wider interested public not necessarily in possession of the relevant expertise a condensed and readily comprehensible 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 times a year since December 2008, some 3000 copies being printed.

Evolution of the social debate

The Office of the German Ethics Council keeps track of press reports and makes daily compilations of articles on bioethical topics. These compilations are made available to the members of the Council, but can also be accessed by the public on its website via an online calendar. An overall consideration of the monthly and yearly evaluations of these reports thus conveys an impression of the public debate on bioethical issues which, if not complete, is at least evidence-based. In the course of 2010, the following ten topics were represented most frequently in the nationwide German print media (*Financial Times Deutschland, Focus, Frankfurter Allgemeine Sonntagszeitung, Frankfurter Allgemeine Zeitung, Frankfurter Rundschau, Handelsblatt, Rheinischer Merkur, Der Spiegel, Stern, Süddeutsche Zeitung, Der Tagesspiegel, taz, Die Welt, Welt am Sonntag, Die Zeit*):



The *Bundestag* adopted the *Gesetz zur Neuordnung des Arzneimittelmarktes* (Act on the Reform of the Market for Medicinal Products) in November 2010, thus putting a provisional end to a debate on health policy that had dominated press reporting throughout the year. The Federal Minister of Health, Dr. Philipp Rösler, had publicly announced at the beginning of the year his intention to break the pharmaceutical companies' price monopoly. The new act established a regulatory framework that addressed such matters as analysis of the utility and cost-utility ratio of new medicinal products. This was intended to contain increases in spending on drugs and the increasing expenditure of the statutory health insurance funds as a whole. The urgency of the need for savings in the healthcare sector was also stressed by the President of the *Bundesärztekammer* (German Medical Association), Professor

Jörg-Dietrich Hoppe, who on a number of occasions called for a frank debate on prioritization and rationing.

Reproductive medicine was a focus of attention in the first half of the year, at first owing to the fate of a young widow. Eggs had been fertilized in vitro while her husband was still alive and she wanted to have these implanted after his death. She went to court when the clinic refused to release the fertilized eggs. At the

Details of press reports for 2010 can be accessed online (in German) at www.ethikrat.org/presse/pressespiegel/2010

beginning of May, the Higher Regional Court of Rostock ordered the clinic to release them. A spate of reports was then unleashed at the beginning of July by a landmark judgement of the Federal Court of Justice (BGH) on the genetic testing of fertilized eggs for the avoidance of severe genetic disorders. The BGH ruled in its judgement that, in the cases at issue, the *Embryonenschutzgesetz* (Embryo Protection Act) had not been infringed by the conduct of preimplantation genetic diagnosis (PGD). The proceedings leading to this judgement had incidentally been set in train by the head of a Berlin fertility clinic in spontaneously approaching the prosecution authorities with his case, and the ruling immediately gave rise to vigorous political arguments for and against the practice of PGD, since it had implicitly been assumed until the Federal Court of Justice delivered its judgement that PGD was prohibited by the Embryo Protection Act. At the end of 2010, therefore, there were indications that the *Bundestag* would be seeking to place PGD on a statutory foundation in 2011.

Having occupied top position in the league of press reports in 2009, agrogenetic engineering fell back slightly to third place in the following year. A number of events ensured that considerable attention continued to focus on this topic in 2010. For instance, the European Commission approved the commercial cultivation of the genetically modified potato variety “Amflora” at the beginning of March. In early June, the discovery of seed contaminated with genetically modified maize not licensed in Europe caused disquiet in several Federal *Länder*. Then, in November, the Federal Constitutional Court confirmed the strict provisions of the *Gentechnikgesetz* (Genetic Engineering Act) and, in particular, declared the

provision of information to the public on the cultivation of genetically modified plants in a relevant land register to be constitutional.

Reports by the Federal Statistical Office indicated that the increasing ageing of German society would result in a dramatic rise in the need for long-term care. In 2010, this was sufficient reason for both politicians and the public to take a closer look at the future of care for elderly and disabled people. Reform of long-term care insurance, the introduction of a legal entitlement to family care leave, and improvements to the system of care home supervision are aspects of a many-sided topic that gave rise to a particularly large number of press reports throughout the year.

The group of death-related topics – assisted suicide/terminal care/advance directives – came fifth in the press statistics for 2010. It owed this position mainly to an event that took place in June. In a landmark judgement, the Federal Court of Justice ruled that a life-preserving treatment had to be discontinued if that was the patient’s declared wish. The Karlsruhe-based court therefore acquitted a lawyer of the charge of attempted criminal homicide, thus creating with its judgement more legal certainty for medical practitioners and custodians when dealing with comatose patients or those suffering from incurable conditions.

When the Chair of the Social Democratic (SPD) parliamentary party in the *Bundestag*, Dr. Frank-Walter Steinmeier, announced in August that he was withdrawing from politics for several weeks to donate a kidney to his sick wife, this rekindled the debate on the substantial unwillingness of the German population to donate organs and on statutory provisions concerning the harvesting of

organs. Vociferous demands were heard for a change in the *Transplantationsgesetz* (Transplant Act), in particular in favour of the possible introduction of the disputed opt-out system. It was Dr. Steinmeier himself who, having recovered from surgery, advocated a mandatory declaration on organ donation as an alternative model, which the former National Ethics Council had already proposed in an Opinion in 2007.

In addition, stem cell research again excited the media in 2010. This was reflected principally in two events. In October, much attention was aroused by an experimental therapy in the United States with human embryonic stem cells, whose use is controversial in Germany. In that experiment, researchers from the Geron Company aimed to develop a new therapeutic approach by replacing the injured parts of a paraplegic patient's spinal cord. However, the use of adult stem cells, which is not normally regarded as unethical, for "individual therapeutic attempts" not subject to clinical trials also generated negative headlines: the Düsseldorf private clinic *XCell-Center* attracted criticism from the public when it was learned that a young child had died in August after experimental treatment in which stem cells obtained from bone marrow had been injected into the brain.

Outlook

At its meeting of 25 November 2010, the Ethics Council also discussed the continuation of its work programme in 2011.

In view of the vigorous social and political debate on a new statutory system of regulation of preimplantation genetic diagnosis, the Ethics Council decided to prioritize this topic over all others and to complete the relevant Opinion, originally planned for issue in mid-2011, by the end of February. This was intended to ensure that the members of the *Bundestag* were in possession of the Ethics Council's Opinion when the subject was debated in Parliament in the spring. The working group engaged on this Opinion will then continue its work by devoting itself to the wider topic of reproductive medicine as a whole.

Following its Bioethics Forum meeting on the introduction of a mandatory declaration on organ donation, the Ethics Council had already decided, at its plenary meeting in October 2010, to take up the proposals made at this meeting and to ask some of its members to consider the possibility of drafting a short recommendation offering reliable information on organ donation and on a possible mandatory declaration. On account of the work already in hand on the topics of human-animal mixtures and on dementia and self-determination, the Ethics Council did not make any further decisions on addressing new topics.

However, at the end of 2010 the Federal Government for the first time made use of the provision in the Ethics Council Act for instructing the Council to consider a specific topic. In a joint letter from the Federal Minister of Education and

Research, Professor Annette Schavan, and the Federal Minister of Health, Dr. Philipp Rösler, the Ethics Council was charged on behalf of the Federal Government with the preparation of a report on the situation of intersex individuals in Germany. Notwithstanding the work already in progress and the priority assigned by the Ethics Council to the topic of preimplantation genetic diagnosis, the Council will therefore set up a working group by the beginning of 2011 and then immediately commence work on the subject of the Federal Government's instruction, with a view to completing it if possible by the end of 2011.

Decisions were also taken on the topics for the public meetings to be held in 2011. For instance, the Bioethics Forum on 23 February 2011 will be devoted to the Ethics Council's Opinion on the anonymous relinquishment of infants and the resulting activities both in the political world and in society. At its Annual Meeting on 26 May 2011, the Ethics Council will debate the problems of feeding the world's population and discuss these with experts from Germany and abroad at a whole-day meeting. A further whole-day meeting is planned for autumn 2011, to discuss the ethical and legal aspects and the possible social consequences of synthetic biology with representatives of various social groups. In addition, in 2011 the Ethics Council will for the first time hold a joint meeting with another public organization: an expert meeting is planned for 7 April with the *Technologie- und Methodenplattform für die vernetzte medizinische Forschung (TMF) e. V.* (Technology, Methods, and Infrastructure for

Networked Medical Research), an organization dedicated to networked medical research and the associated technology and methods, for a joint discussion of the Ethics Council's Opinion "Human biobanks for research" not only with academics, but also with political actors and other social groups.

The members of the German Ethics Council



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



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



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



Prof. Dr. med. Axel
W. Bauer



Prof. Dr. phil.
Alfons Bora



Wolf-Michael
Catenhusen,
Former State
Secretary



Prof. Dr. rer. nat.
Stefanie Dimmeler



Prof. Dr. med.
Frank Emmrich



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



Hildegund
Holzheid, Former
President of the
Bavarian Consti-
tutional Court and
Munich Higher
Regional Court



Prof. Dr. theol.
Dr. h. c. Wolfgang
Huber, Retired
Bishop (from 30
June 2010)



Prof. Dr. theol.
Christoph Kähler,
Retired Bishop



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. iur. Dres.
h. c. Spiros Simitis



Prof. Dr. iur. Jochen
Taupitz



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



Prof. Dr. rer. nat.
Heike Walles
(from 30 June
2010)



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



Dipl.-Psych. Dr.
phil. Michael
Wunder

The following
ceased to be
Council members
with effect from
1 March 2010:
Dr. theol. Hermann
Barth, Prof. Dr.
med. Bettina
Schöne-Seifert

Appendix

Working groups 2010

The working groups constitute the basis of the Ethics Council's substantive work. The groups mentioned below met more than 50 times in 2010.

Biobanks

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

Research on chimeras and hybrids

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

Dementia

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

Reproductive medicine

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

Allocation of resources in healthcare and social welfare

Spokesperson: Nagel
Members: Bauer, Kollek, Losinger, Lübbe, Riedel, (Schöne-Seifert), Schockenhoff, Taupitz, Woopen, Wunder

Synthetic biology

Spokesperson: Catenhusen
Members: Bora, Reich, Taupitz

Annual Meeting 2011

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

Bioethics Forum on intersexuality

Spokesperson: Wunder
Members: Gerhardt, Riedel, Schockenhoff

Bioethics Forum on organ transplantation

Spokesperson: Nagel
Members: Lübbe, Riedel, Taupitz

Procedure

The German Ethics Council is independent with regard to its activity and is bound only by the terms of the mandate conferred on it by the *Ethikratgesetz* (Ethics Council Act). In pursuance of Section 6(2), the Ethics Council has provided itself with rules of procedure governing the practical aspects of its work.

The Ethics Council decides itself on the issues to be addressed in its Opinions, but may also prepare Opinions on the instructions of the German *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.

The members of the Ethics Council come together once a month for a plenary meeting in Berlin, 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 which coordinate the preparation 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 of the Ethics Council Act and accommodated at the Berlin-Brandenburg Academy of Sciences and Humanities. The general conditions governing the activity of the Office are determined by an agreement between the *Bundestag* Administration and the Academy.

The Office is responsible for locating, preparing and evaluating scientific documents relating to the topics addressed by the Council, for the compilation of material for publication, for the planning and conduct of meetings and public events, and for the publication of Opinions and other documents. The principal duties of the Office also include managing contacts with the media, responding to enquiries from the public, maintaining the Ethics Council's presence on the World Wide Web, and looking after the Council's international contacts. The staff of the Office in 2010 comprised the following persons:

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

Funding

The costs of the German Ethics Council and its Office are borne by the 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 2010 (Departmental Budget 02, Title 52603-011).

Ethics Council Act

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

Section 1 Establishment of the German Ethics Council

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

Section 2 Duties

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

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

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

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

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

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

Section 3

Position

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

Section 4

Members

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

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

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

Section 5

Appointment and term of office of members

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

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

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

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

Section 6

Working methods

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

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

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

Section 7

Public deliberations

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

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

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

Section 8

Administrative office

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

Section 9

Duty of confidentiality

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

Section 10

Costs

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

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

Section 11

Entry into force

This Act shall enter into force on 1 August 2007.

Rules of Procedure

Preamble

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

Section 1

Independence of members. Partiality.

Duty of confidentiality. Suspension of membership

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

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

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

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

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

Section 2

Resolutions

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

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

Section 3

Chair

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

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

Section 4

Work programme

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

Section 5**Meetings**

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

Section 6**Public nature of meetings**

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

Section 7**Minutes**

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

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

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

Section 9**Rapporteurs and working groups**

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

Section 10

Position statements and publications

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

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

Section 11

Cooperation with the German *Bundestag* and the Federal Government

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

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

Section 12

Office and budget

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

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

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

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

Section 13

Amendments to the Rules of Procedure

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