

Bioethics in Germany: debates and infrastructure

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Summary. - In Germany the public awareness on ethical problems of the application of medicine and life sciences on human beings is very high. It can be observed that German Society is rather sensitive concerning bioethical issues. Politics supports this attitude. Many articles in professional journals as well as in newspapers cover bioethical issues. Conferences and workshops on a professional and an educational level deal with topics on ethics of life sciences and ethics in general. Moreover, in the case of bioethics many different disciplines contribute with relevant considerations to the process of opinion and judgment formation. This paper summarizes the main ethical and legal debates on bioethical issues in Germany, specifies the focus of leading German centres of bioethics and biolaw, and explains the tasks, services and networking of the German Reference Centre for Ethics in the Life Sciences (DRZE) which was founded by the Federal Government.

Key words: bioethics, networking, public debate, Germany.

Riassunto (*La bioetica in Germania: il dibattito e l'infrastruttura*). - In Germania vi è un'alta consapevolezza delle implicazioni etiche derivanti dall'applicazione della ricerca biomedica all'uomo ed è stato osservato che in generale la società tedesca, compresa la classe politica, è molto attenta a questo tipo di problematiche. Molti articoli di riviste specializzate e di quotidiani riguardano temi di bioetica e spesso si organizzano seminari e conferenze, sia a livello professionale che a livello formativo, su argomenti riguardanti l'etica delle scienze della vita o l'etica in generale. Bisogna considerare, inoltre, come nel caso della bioetica vari settori disciplinari contribuiscano ad alimentare il processo di formazione dell'opinione pubblica. In questo articolo si riassumono le principali tematiche legali ed etiche oggi al centro del dibattito pubblico in Germania; si esaminano le attività dei centri tedeschi più importanti nei campi della bioetica e del biodiritto; si analizzano i compiti e la rete di servizi offerti dal Centro di Riferimento Tedesco per l'Etica delle Scienze della Vita (DRZE), istituito dal governo federale.

Parole chiave: bioetica, reti di comunicazione, dibattito pubblico, Germania.

Introduction

At the beginning of this new century, European society has become more aware than even in recent decades of the urgent need to subject current developments in medicine, science and technology to ethical scrutiny in order to ensure that the new potential emerging in many fields of human activity is used responsibly. This is motivated by the ever more rapid development of modern science that penetrates all spheres of human life and leads to a blurring of the borderline between research and its applications. The complexities of the results and consequences of modern scientific understanding and activity require the formation of ethical judgements, both within the scientific community and within society at large.

In a pluralist society, such as Germany, the ethical and legal debate incited by ongoing developments in the life sciences and their application in medicine and biotechnology is, understandably, rather complex. In Germany the public awareness of ethical problems in the application of medicine and life sciences on human beings is very high. It can be observed that the German society is rather sensitive concerning bioethical issues and politics supports this attitude: many articles in professional journals as well as in newspapers cover bioethical issues. Conferences and workshops on a professional and an educational level deal with topics on ethics of life sciences and ethics in general. Further many different disciplines contribute with relevant considerations to the process of opinion and judgment formation in bioethics. Thus the interdisciplinary

cooperation of researchers from the natural sciences, medicine, law, philosophy, theology, and the social sciences has become indispensable in this field. In addition, the global character of contemporary research, as well as the speed of innovation in the life sciences, necessitate an international dialogue involving, when possible, the pre-emptive consideration of the ethical, legal and social issues at hand. This is the reason why several institutes on science, ethics and law were founded within in the last twenty years, and why the German Reference Centre of Ethics in the Life Sciences (Deutsches Referenzzentrum für Ethik in den Biowissenschaften, DRZE) was established in 1999 to enhance the conditions for the process of moral judgment formation.

The following paragraphs will summarize the main ethical and legal debates on bioethical issues in Germany; specify the focus of leading German centres of bioethics and biolaw; and explain the tasks, services and networking of DRZE.

Recent debates and legislation

Embryonic stem cell research

Embryo Protection Act (1998). - Until 2002 in the Federal Republic of Germany, the Embryo Protection Act (*Embryonenschutzgesetz*, EschG) was the decisive piece of legislation governing the production of human embryonic stem cells. It assumes that a human being exists starting from the completion of cell nuclear fusion, and takes into account the constitutional obligations to protect human dignity and human life. The definition of an embryo protected by this Act also includes a totipotent cell removed from an embryo that is capable of dividing and developing into an individual human being if the necessary conditions prevail. From this follows the prohibition on any use of human embryos that does not directly benefit the subject. The Embryo Protection Act prohibits the production or use of embryos for any purpose other than reproduction. Therefore it prohibits the creation of ES cells in Germany, because the derivation of ES-cells includes the destruction of embryos.

Furthermore, any manipulation of an embryo created outside the body that does not serve its preservation is prohibited. Thus, any embryo research not pertaining to the embryo's preservation is prohibited. In addition, paragraph 6 (1) stipulates that "anyone who causes artificially a human embryo to develop with the same genetic information as another embryo, a fetus, human being, or a deceased person, will be punished with imprisonment up to five years or a fine."

The import of, and research on, stem cell lines derived from embryos abroad were not explicitly prohibited by the Embryo Protection Act. Since ES-cells are not totipotent, they are not embryos according to the legal definition of the embryo in the act.

Furthermore, there was a controversial debate in Germany on the question, whether the Embryo Protection Act needs to be amended in view of the highly significant therapeutic purposes of stem cell research [1, 2].

Statements and recommendations of the German Research Foundation DFG on stem cell research (2001). - In line with its 1999 opinion, the German Research Foundation (Deutsche Forschungsgemeinschaft, DFG), on 3 May 2001 passed new recommendations on human stem cell research and proposed a "step-by-step scheme for standardisation and international co-operation", as well as "research on 'surplus' embryos subject to strict conditions".

First step: it called for the import of and research on stem cell lines derived from surplus embryos abroad, both of which are not currently prohibited by the Embryo Protection Act.

Second step: if necessary, however, institutional international co-operation should be promoted using DFG funds.

Third step: furthermore, if necessary, the DFG proposes to the legislator to allow the production of stem cell lines from "surplus" embryos also in Germany. Research would be monitored by an "independent, pluralistic commission at the Federal level". The DFG rejects the production of embryos exclusively for purposes of research, reproductive and therapeutic cloning as well as germ line manipulation. At the insistence of the German Ministry of Research, the DFG's executive committee on 4 May 2001 postponed the decision regarding the application for approval of a research project using imported stem cells at Bonn University [3-5].

Study Commission "Law and Ethics in Modern Medicine" of the German Bundestag on stem cell research (12 November 2001). - Study commissions are advisory bodies of the German Bundestag. Their task is to gather, process and analyse scientific information on complex issues. They are important interfaces between politics and science: in contrast to the permanent parliamentary committees, independent experts who do not belong to the Bundestag work alongside the members on an equal basis. The purpose of the study commissions' work is to develop recommendations which are presented in a report before the end of the electoral term. This report serves as a basis for the preparation of decisions by the Bundestag.

The Study Commission on “Law and Ethics in Modern Medicine” began its work on 15 May 2000. It consisted of 13 members and their substitutes from the five parliamentary groups represented in the German Bundestag. Thirteen experts - doctors, scientists, lawyers, theologians, philosophers, and social scientists - have also been appointed to the Commission to contribute their specialist knowledge to its work.

On 12 November 2001 the Study Commission stated in its Second Interim Report: “Sub-Report Stem Cell Research” (BT-Drs. 14/7546) that “a legal release for the derivation of stem cell lines from so-called ‘supernumerary’ embryos by amending the protection standard in the Embryo Protection Act cannot be recommended”. The high level of protection afforded by the German Embryo Protection Act was to be retained. In the Commission’s opinion the derivation of stem cells from embryos, which accepts the destruction of human life, could not be justified. The Study Commission formulated two lines of argument concerning the import of human embryonic stem cells. The precondition common to both lines of argument is that the necessary regulations must apply equally to the public and private sectors.

Line of argument A: the use of human embryos for research purposes is not ethically defensible and not sufficiently substantiated scientifically as the necessary fundamental research can also be undertaken using stem cells of a different origin. The Commission’s majority voted against the import of human embryonic stem cells. Everything possible has to be done to avoid imports of this kind (26 of the 37 Commission members voted for A).

Line of argument B: it is doubtful whether a complete ban on the import of human embryonic stem cells can be substantiated on the basis of German constitutional law and European law. Hence, the import is to be tolerated “subject to strict preconditions” and is to be monitored by a “transparent control agency established by law” within the framework of a weighing up of the ethical considerations. These strict preconditions include restricting imports of human embryonic stem cell lines available at present, the “outlining of the suitability, necessity and appropriateness of the research project for which an import application has been submitted” along with evidence of informed consent from the donor couple (12 of the 37 Commission members voted for B, one member voted for both options) [6, 7].

The mandate of the Study Commission finished at the end of the Parliamentary session in 2002. The new German Bundestag decided, in line with a cross-party motion of 18 February 2003 to set up a new Enquete Commission which is now called “Law and Ethics in Modern Medicine”.

German National Ethics Council’s “Opinion on the import of human embryonic stem cells” (20 December 2001). - Following a resolution by the Federal Government of 2 May 2001, the German National Ethics Council was established on 8 June 2001 as the national forum for dialogue on ethical issues in the life sciences. On 20 December 2001 it published an “Opinion on the import of human embryonic stem cells”. Despite the lack of agreement on the question “whether the embryo at the earliest stage is also vested with human dignity and the conclusions to be drawn for its claim to protection of life”, the members of the National Ethics Council, agreed that “human dignity prohibits the use of embryos prior to nidation for arbitrary purposes”. Based on “two systematising outlines” of arguments for and against the derivation of human embryonic stem cells and on arguments for and against their import, four “evaluation options in the import issue” were formulated.

Option A and *Option B* advocated the import of human embryonic stem cells initially restricted to a period of three years under strictly defined conditions (origin from “supernumerary” embryos, with the informed and remuneration-free consent of the embryo donors etc.) Restricting imports to stem cells which had been derived before a specific deadline was considered to be pointless as the German demand would “not influence” the further production of stem cell lines abroad and research scientists in Germany would otherwise “be denied the possible use of progress made abroad”. These import conditions were to apply equally to state-funded and privately-funded research. Unlike Option B, Option A explicitly assumes that not only the import of human embryonic stem cells but also their derivation from “supernumerary” embryos is “ethically acceptable”.

Option C advocated the “provisional rejection” of imports. The legislator should take a decision once various questions including the potential of the stem cells which do not come from embryos, and the ethical evaluation of the methods used to derive them, had been clarified by him by the end of 2004.

According to *Option D* all imports of human embryonic stem cells were “ethically unacceptable”. Here, it is assumed that the derivation of stem cells from human embryos was to be considered as an “unacceptable instrumentalisation of human life” and, therefore, “the import too” would have to be rejected. “By increasing demand, the import makes a causal contribution to the use of embryos in the “export countries” and would lead “to the level of protection for embryos being lowered in Germany, too”.

Out of the total 25 members of the Ethics Council, 15 were in favour of Option B of which 9, at the same time, of Option A. Ten members voted for Option C including 4 at the same time voting for Option D [8].

Stem Cell Act (2002). - On 30 January 2002 the German Bundestag passed a resolution by a majority vote to regulate the import of human embryonic stem cells by law subject to strict requirements. The motions for an absolute ban on imports and for a more extensive release for the import of human embryonic stem cells were not passed. The Embryo Protection Act will not be amended. On this basis the German Parliament passed a law which only permits the import, for research purposes, of human embryonic stem cells which were produced before a certain deadline abroad. The aim is to prevent the further use of embryos for the derivation of ES-cells abroad for research purposes in Germany. "A transparent control agency, established by law, will ensure compliance with the preconditions outlined; its approval is the prerequisite for their import" (from the motion). The approval has to be given if the prerequisites are fulfilled.

Based on this parliamentary resolution, a multi-faction group of MPs submitted a "bill ensuring protection of embryos in connection with the importation and utilization of human embryonic stem cells (Stem Cell Act - StZG)" to the Bundestag (BT-Drs. 14/8394) on 22 February 2002. Following deliberations in the committees, the German Parliament passed the law on 25 April 2002. It entered into force on 1 July 2002 (Federal Gazette - BGBl. I p. 2277). In the final roll-call vote, 559 votes were cast: 360 in favour, 190 against and 9 abstentions.

According to this law, the import and use of human embryonic stem cells are, in principle, banned. However, under circumstances defined in this law import and use are admissible for research purposes as an exception (Section 4): the stem cells must have been derived "before 1 January 2002" in the country of origin "in accordance with relevant national legislation there". They must be derived from embryos which "have been produced in order to induce pregnancy" but which "were definitely no longer used for this purpose", furthermore, it must be shown that "there is no evidence that this was due to reasons inherent in the embryos themselves" (these conditions limit the import to human embryonic stem cells derived from so-called supernumerary or surplus embryos). For the supply of these embryos for stem cell derivation, "no compensation or other benefit in money's worth has been granted or promised". There must be "scientific reasons" showing that the research work pursues eminent goals, that the questions to be studied, have been "clarified" as far as possible through *in vitro* models using animal cells or through animal experiments, and that the scientific knowledge to be obtained from the research project "cannot be expected to be gained by using cells other than human embryonic stem cells". The meeting of these preconditions is to be verified "by an agency to be

determined by ordinance of the Federal Ministry for Health from its portfolio". This agency will set up and then be advised by an independent, interdisciplinary "Central Ethics Commission on Stem Cell Research". "It shall be composed of nine experts from the disciplines of biology, ethics, medicine and theology" (Section 8) [9].

On 22 June 2002 the Robert Koch Institute (RKI) was chosen by the Federal Cabinet as the competent agency for the approval of applications for the import or use of human embryonic stem cells. The Central Ethics Commission on Stem Cell Research was appointed as the advisory body and to evaluate the applications. It met for the first time in the Robert Koch Institute (RKI) in Berlin on 22 July 2002.

Stem Cell Network NRW. - The first research project using human embryonic stem cells was established in 2002 at the University of Bonn in North Rhine Westphalia. The project is supported by the German Science Foundation. The Federal State Government of North Rhine Westphalia (NRW) created the *Stem Cell Network North Rhine Westphalia* among centres of excellence concerning scientific, legal and ethical issues of stem cell research. With the founding of the Stem Cell Network NRW, the Federal State of North Rhine Westphalia is in a position to coordinate and optimise statewide activities in stem cell research, while funding young researchers and representing NRW in the highly competitive field of international research. Another key objective of the network is the provision of information on biomedical, ethical and legal aspects as a prerequisite for public awareness and discussion on stem cell research. The broadly based dialogue on the chances and risks is seen as an important factor of international competitiveness of biotech research.

Preimplantation diagnosis

Opinion of the National Ethics Council "Genetic diagnosis before and during pregnancy". - In the opinion of the National Ethics Council presented on 23 January 2003 a majority of 15 members voted in favour of a "limited authorisation of PGD". A minority of 7 members suggested both to "uphold the ban on PGD as laid down in the current version of the Embryo Protection Act and to render the regulations governing PGD more precisely". Two members basically agreed with the minority vote, pointing out, however, that "in the case of an existential conflict the individual decision of conscience must be free and must not be forced by the power of penal law." All members agreed with the recommendation "to regulate all questions relevant to reproduction medicine in a separate Reproduction Medicine Act".

According to the majority vote, preimplantation genetic diagnosis (PGD) should be authorised in exceptional cases:

- for couples who run a high risk that their child will develop a severe genetic disorder or disability for which there are no effective therapies and who would be thrown into an existential conflict should the child be born;
- for couples who run a high risk of passing on a chromosome disorder which may prevent the embryo from reaching the stage of extra-uterine life [...];
- for infertile couples, if there is scientific evidence that by testing for chromosome disorders the success rate of sterility therapies for certain patient groups (e.g. higher age or after several unsuccessful treatment cycles without known chromosomal disorders) could be raised significantly and that the reduced number of embryo transfers would also reduce the risk of multiple pregnancies.

Moreover "adequate counselling has to be provided covering medical, ethical as well as psychosocial aspects". The diagnosis process itself should be restricted to "a small number of centres under revocable license". It should be regulated by procedural rules which guarantee the "existence of an indication", the "quality of implementation", "scientific appraisal and analysis" as well as "adequate transparency ensuring professional secrecy and data protection". Apart from this "central documentation and monitoring" must be implemented [10].

Study Commission "Law and Ethics in Modern Medicine" of the German Bundestag on preimplantation genetic diagnosis (25 February 2002). - On 25 February 2002 the Study Commission on "Law and Ethics in Modern Medicine" of the German Bundestag concluded its deliberations concerning preimplantation genetic diagnosis. The recommendations are laid down in the Commission's Final Report (Section on PGD) which was handed over to the President of the Bundestag on 14 May 2002. According to the Report a majority of 16 Commission members voted in favour of a ban on PGD in Germany. The Report recommends to amend the German Embryo Protection Act to include PGD explicitly in the existing ban on *in vitro* fertilisation for diagnostic purposes. Three members of the Commission expressed their opinion that PGD should under certain and in exceptional cases be open to couples with a high genetic risk factor only.

Three members of the Study Commission voted in favour of lifting the ban on PDG in exceptional cases for couples with a high genetic risk factor only. A precondition for this would, however, be the establishment of a legal framework designed to preclude a repeat of developments which occurred in

prenatal diagnostics, where a weakening of the original regulations led to a proliferation of its use and an increase in the number of terminations.

Fundamental to such a framework would be a legal requirement to seek counselling which would explore alternatives to PGD. Moreover, access to PGD would be on the condition that the conflict situation of the couple concerned is similar to that of a pregnant woman who is considering an abortion and cannot be forced by law to bear her child. In order to determine such a conflict the dissenting opinion in the Report considers two options:

- first, a catalogue of severe health impairments which could be diagnosed by PGD combined with a precise assessment of the couple's personal conflict. Such a catalogue, could, however, give rise to the misunderstanding that the law implicitly approved of PGD as an agent in eugenic selection. Moreover, the dissenting opinion in the Report stated that the use of this catalogue could also result in the stigmatisation of people suffering from the impairments listed in it;
- as a second option it therefore suggests to avoid such a catalogue and to formulate general stipulations for a counselling and monitoring procedure in a way that excludes any widening of the PGD practice similar to the use of prenatal diagnosis. Thereby PGD should only be performed at centres specially licensed for this purpose. The Federal Minister of Health should establish an appropriate authority for the licensing and monitoring of PGD which would also collect reports from the PGD centres and their ethics commissions [11].

Bioethical publications, research and documentation in Germany

Bioethics is a very intensely discussed issue at the academic centres and institutions. Many academic articles are available in journals (*Zeitschrift für Medizinische Ethik, Ethik in der Medizin, GAIA, Ethik-Magazin, Forum TTN, Gen-ethischer Informationsdienst, TA-Informationen* etc.) yearbooks or monographs. The *Jahrbuch für Wissenschaft und Ethik* is an established publication concerning these topics (ethics of clinical research, energy research, technology, space etc.). The series *Ethik in den Wissenschaften, Graue Reihe, Forum interdisziplinäre Ethik, Bochumer medizinethische Materialien, TTN-Akzente*, etc. cover issues of these debates as well. All materials are collected in the database BELIT: www.drze.de/BELIT.

The Akademie für Technikfolgenabschätzung in Baden-Württemberg published research reports, expert reports, citizens' reports, discourse reports, books, and presentations. Some of the publications of the series *Kurzinformationen, Diskursberichte* and *Zeitfragen* included training materials in bioethics and research ethics. They covered ethical issues in special

areas of research (e.g. cloning, gene technology). The Academy has been closed in 2003.

The Institute of Science and Ethics (IWE) at the Universities of Bonn and Essen, which was founded together with the Forschungszentrum Jülich (FZJ) and the Deutsches Zentrum für Luft-und Raumfahrt (DLR), aims to contribute an ethical reflection of current developments in medicine, science and technologies in order to facilitate a responsible use of the new potentials emerging in these fields of human activity. It supports the formation of moral judgements by means of interdisciplinary research. The *Jahrbuch für Wissenschaft und Ethik* is published by the IWE.

The Inter-departmental Centre for Ethics in Science and Humanities (IZEW) at the University of Tübingen tries to establish the process of the formation of moral judgements within the sciences. It has established a Graduierten Kolleg "Bioethik" to promote a cross-departmental research and education. They publish the series *Ethik in den Wissenschaften*.

The Research Center for Biotechnology, Society and the Environment (FSP BIOGUM) at the University of Hamburg has a research group on Technology Assessment of Modern Biotechnology in Plant Breeding and Agriculture and a research group on Technology Assessment of Modern Biotechnology in Medicine/Neuro-Sciences. BIOGUM publishes academic materials and reports on bioethics, research ethics and ethics of technologies (e.g. transgenic plants, preimplantation diagnosis, sustainability etc.).

The European Academy for the Study of Consequences of Scientific and Technological Advance Bad Neuenahr Ahrweiler GmbH has its main focus on the examination of the foreseeable mid- and long-term processes that are especially influenced by natural- and engineering sciences and the medical disciplines. The Academy has established the series *Graue Reihe, Poiesis & Praxis* and *Wissenschaftsethik und Technikfolgenbeurteilung*.

The Institute of Technology-Theology-Natural Sciences (TTN) is a cooperating institution of the University of Munich with representatives of the sciences, the economy, the Lutheran Church of Bavaria and the University to enforce the interdisciplinary dialogue. They produce academic and didactically prepared materials in the Series TTN-Akzente to assess procedures in research.

After the reunion of Germany several centres were established in the eastern part of Germany for example the Ethics Centre of the Friedrich-Schiller-University in Jena, the Interdisciplinary Centre for Ethics at European University Viadrina in Frankfurt (Oder) and the Interdisciplinary Working Ethics and Law at the University of Rostock (EMUR).

Many departments on medical history or medical history and ethics at the medical departments of German Universities (Bochum, Bonn, Erlangen-

Nürnberg, Freiburg, Göttingen, Köln, Leipzig, Jena, Münster, Ulm and others) are involved in the academic discussion on medical ethics and in teaching.

The Akademie für Ethik in der Medizin e. V. (AEM) is an interdisciplinary and interprofessional association in the field of medical ethics. The members are mainly physicians, nurses, philosophers, theologists, lawyers. The aim of the association is a public and scientific dialogue on ethical questions in the area of medicine and health care. The AEM organizes workshops, teaching series and promotes meetings between patients and health care professionals. Also, the Information and Documentation Centre Ethics in Medicine (IDEM) has been established at the AEM in Göttingen.

In Germany some centers on biolaw or law and ethics has been established within the last years. The Institut für Deutsches, Europäisches und Internationales Medizinrecht, Gesundheitsrecht und Bioethik der Universitäten Heidelberg und Mannheim (IMGB) provides a platform for scientific research and theory in the field of medical law, public health law and bioethics. The Institute's objective is to conduct integrant and interdisciplinary research and to discuss the range of medical and public health law problems. The Centre for Ethics and Law in Medicine (ZERM) at the Albert-Ludwig-University Hospital in Freiburg has its focus on "applied ethics". The partners are: Ethics Commission of the Albert-Ludwigs University Freiburg, Institut of Forensic Medicine, and the Max-Planck Institut of Foreign and Institutional Criminal Law. ZERM has its goals in the traditional areas of medicine: research, teaching and patient care. In the research projects, issues in basic ethical and legal principles are dealt with in the socio-cultural context of medicine. The Institute for Health Law and Medical Law (IGMR) was established within the Faculty of Law at the University of Bremen. The Institute concerns itself with legal science, practice and policy issues of national, European and international regulation in the field of health law and medical law. The central concern of the Institute is long-term intradisciplinary and interdisciplinary scientific research into a normative constitution of the medical and health care system. Some law departments at German Universities have long traditions in medical law like in Göttingen or Lüneburg.

The informal union of the 52 public German ethics committees in the Working Group of the Medical Ethics Committees (Arbeitskreis Medizinischer Ethik-Kommissionen) created a forum for exchanging ideas as well as for harmonizing procedures and advancing concepts. The working group of the Medical Ethics Committees usually invites national and international experts (especially lawyers) to train members of the German ethics committees and to keep them up to date about the changes in the legal regulations regarding

the activities of ethics committees and ethical issues in medicine in general. They do not provide materials, however the meetings for the working group serve as the training workshops themselves. As mentioned by some groups' members, it is desirable to emphasize the effectiveness of the linkage between different ethics committees. Internet links to all centres can be found at: www.drze.de/links.

**Establishing a bioethics information network:
aims, structure, services and networking
of the German Reference Centre for Ethics
in the Life Sciences**

Tasks and aims of the DRZE

A culture of judgment formation in bioethics can develop only if those involved in it have access to reliable, comprehensive and current information. This being said, the founding of the German Reference Centre for Ethics in the Life Sciences (DRZE) in 1999 can be considered a milestone in fostering bioethical research and debate in Germany. The centre's inception can be dated in 1997 when the Federal Minister for Education, Science, Research and Technology sought means to promote more effectively bioethical reflection in society as a whole as well as in research institutions, upon which the German National Research Foundation (Deutsche Forschungsgemeinschaft, DFG) held a symposium on "Current requirements for bioethics research" and launched an invitation to submit preliminary ideas for a "bioethics reference centre". In 1998 the Federal Government published guidelines for the funding of such a centre. The guidelines stipulated that it should

- maintain a central collection and access point for relevant information;
- be linked to an established research institution in the area of bioethics; and
- cooperate internationally with other database providers.

The conceptual project for what was to become the DRZE, prepared by the Institute for Science and Ethics (IWE) in Bonn in response to the funding guidelines, was oriented on the National Reference Centre for Bioethics Literature in Washington DC, which has been working successfully for more than 25 years. A DFG-sponsored international group of referees supported the concept submitted by the IWE. Subsequently, the University of Bonn and the Institute for Science and Ethics were given the task of setting up the centre: DRZE began its work in January 1999.

The reference Centre's role is the central, comprehensive and current collection, documentation, provision and preparation of relevant national and

international information, documents and literature on ethics in the life sciences, including relevant material regarding legal, social and scientific issues. The Centre aims to facilitate access to such information as well as to highlight the German contribution to the international debate. The services of the DRZE are designed to meet the needs of researchers and teachers in the areas of the life sciences, medicine, ethics, law, as well as representatives from politics, the media and the public at large. In other words, the work of the DRZE assists in enhancing the conditions for the process of judgment formation. However, it is important to note that the Centre neither can nor does attempt to replace that process.

Structure and services

To fulfil its task, the DRZE employs a highly interdisciplinary staff including librarians, computer scientists, philosophers, natural scientists and legal experts. The Centre consists of three departments: a library and documentation centre, an electronic information service department and a research department. The Centre's work is overseen by an accordingly interdisciplinary Board of Directors including philosophers, natural scientists, legal experts, professional librarians, medical doctors, computer specialists. Moreover, international networking is strengthened by the fact that the Centre's work is supported by an international Advisory Council with members from, among others, the United States, Great Britain, Spain and Sweden.

Library and documentation centre. - The library and documentation centre collects and documents relevant nationally and internationally published monographs, collections, reference works, journals, press articles, legal texts, as well as publications from institutions (so-called "grey literature"), e.g. ethics codes and directives, parliamentary publications, conference proceedings, dossiers, statements, discussion papers and expert reports. The collection's main subject areas are bioethics, medical ethics, environmental ethics, animal ethics, philosophical ethics, applied ethics, research ethics and technology ethics. In addition, the holdings encompass relevant literature from the areas of philosophy, biology, genetics, medicine, technology, sociology and law. In January 2003, the collection contained approximately 6500 books, 14 000 documents, and 120 journals in subscription. A unique aspect of the documentation centre is that it also collects and documents articles from 22 German and 31 foreign newspapers and magazines.

In addition to operating the library, the staff of the library and documentation centre also manage the integrated bioethics literature database BELIT (see

below), as well as the Centre's "new books" service and other online documents. All resources of the library and documentation centre are freely accessible to interested members of the public.

Electronic information service department. - The electronic information service department manages the online and in-house information services of the DRZE. Among its projects have been the development of the integrated bioethics literature database BELIT as well as technical support for the Bioethics Communication and Information System (BEKIS), web-server programming and management of the Centre's in-house network. All online services can be accessed from www.drze.de.

Research department. - The research department of the DRZE prepares overviews of the debate and research in bioethics, annotated literature lists, expert reviews and other value-added products. In addition it is responsible for organising and hosting seminars, workshops and conferences designed to inform the scientific community, the media, politicians and the public at large about new developments in bioethics. The department also advises the library and documentation centre and prepares content for the online information services.

Online databases BEKIS and BELIT. - A cornerstone of the centre's freely accessible online resources are the databases BEKIS and BELIT.

BEKIS® (www.drze.de/bekis) is an online database providing access to information about institutions and activities in the area of bioethics research. Users can find information about research institutions, research groups, research projects, and events. Such information, which is otherwise disparate and difficult to locate, is presented in BEKIS through a single access point and in a common format. It is intended to function as a communications tool for researchers as well as politicians, the media and interested members of the public at large. A key aspect of this database is that data entry and maintenance is managed by the participating institutions and groups, thus assuring that the information is up to date.

BELIT® (www.drze.de/belit) is an online bioethics literature database, integrating some 250 000 records from German, American, French, Dutch and Swedish databases on a single platform. This unique bibliographic directory is also an example of the DRZE's international cooperation with other institutions, since it is operated in conjunction with the Kennedy Institute of Ethics / National Reference Center for Bioethics Literature (KIE, Washington, DC), the Centre de documentation en éthique des sciences de la vie et de la santé de l'INSERM (CDEI,

Paris), the Interdepartmental Center for Ethics in the Sciences and Humanities (IZEW, Tübingen) and the Information and Documentation Centre Ethics in Medicine (IDEM, Göttingen).

Other value-added products. - The Centre's research department is primarily involved in preparing various value-added information products, these being print and online media, which go beyond the mere collection and documentation of bioethical literature. To this day the department has published dossiers, reports and concise digests regarding different bioethical topics, such as enhancement, euthanasia, embryonic stem cell research, pre-implantation diagnosis, "therapeutic cloning", and genetically modified food. In preparing these, the department draws its expertise from journals, conferences and workshops, the documentation centre's "new books" service, contacts to experts, current press reviews, and, finally, by relying on the know-how of the Centre's Board of Directors and Advisory Council.

Among the DRZE's printed media, "dossiers" are collections of current international legal texts as well as directives and declarations from institutions and other bodies pertaining to a debate about a particular bioethical issue (PGD, cloning, human ES-cells, genetic testing etc.). The dossiers are available on a CD-ROM as well. In contrast to the dossiers, "scope notes" offer a comprehensive overview on some of the central debates in bioethics and include detailed bibliographies (enhancement etc.). A key feature of the Centre's online services is a collection of concise information regarding certain key bioethical issues called "In Focus". These are summaries of the scientific, legal and moral aspects of the most current issues in bioethics including suggestions for further reading and links to pertinent external sites (euthanasia, genetically modified food, PGD, cloning etc.). A new series *Beiträge zur Ethik in den Biowissenschaften* has been established to publish the proceedings of conferences and workshops.

There are other services provided on an individual basis. For example, in 2001 the DRZE published a sample German school course on bioethics for grades 7-10. The Centre additionally does work on commission and acts as a consultant for governmental bodies and non-governmental organizations. One example of such commissioned work is the conceptual planning and organization of conferences, workshops and seminars. In 2002 the DRZE organized two such events, both of which were commissioned by the German Federal Ministry of Education, Research and Science: an international conference "The impact of genetic knowledge on human life" in Berlin, and a bioethics workshop for representatives from the newly associated states of the European Union in Bonn. In

2003 the DRZE organized an international conference on "Cloning in Biomedical Research and Reproduction" on behalf of the German Federal Ministry of Education, Research and Science.

European cooperation

Responsible research and the responsible application of science and technology in Europe are only possible when both are accompanied by the investigation of ethical implications as well as their legal, social, economic and cultural impact. Such an approach clarifies the relationship between moral considerations and the social consequences of science, developments in technology and their ultimate application. It can ensure that, in view of the rapid progress in the sciences, we do not lose sight of fundamental ethical principles but rather remain in control of the consequences of our actions by means of dialogue, networking, capacity building and early warning. Such an approach involves recognizing the need to create a systematic information resource dealing with ethical issues in science and research and including multi-lingual access to information on legislation, codes of conduct, regulations and topical debates taking place in the different European countries. Such an instrument should facilitate access to the relevant databases in the field of bioethics in Europe and beyond. In order to accomplish this we need a new type of infrastructural facility to serve as an information and documentation tool for both the scientific community as well as the field of politics.

For trans-European cooperation and the development of a functioning infrastructure in the field of bioethics to be a success, it is a key task to recognize and compound the specific abilities of different organizations and national institutions involved, thereby ensuring an efficient exchange of information. For this reason, the DRZE is actively cooperating with many bioethics institutions and database providers on a multinational level. Among them are the leading centres of ethics in the life sciences in Europe like the Sheffield Institute of Biotechnological Law and Ethics at the University of Sheffield (SIBLE), the Centre de documentation en éthique des sciences de la vie et de la santé de l'INSERM (CDEI, Paris), the Centro de Documentación e Información en Bioética y Educación Médica (CENDIBEM, Madrid), the Istituto Superiore di Sanità (ISS, Rome), the Karolinska Institutets Bibliotek (KIB, Stockholm) the University Centre for Bioethics (UCB), Masaryk University, Brno or the Department of Medical History and Ethics at the University of Vilnius.

One recent example of our participation in establishing such infrastructures is the EURETHNET-project (European Information Network Ethics in

Medicine & Biotechnology) founded by the European Commission (2001-2004) with 27 partners from 16 European countries (<http://eurethnet.drze.de/>). Its aim is to develop an internet portal serving as an access point to different databases and including the establishment of documentary standards as well as an integrated core thesaurus as a search tool. The DRZE is the German country representative in EURETHNET's steering committee.

Future plans

The future plans include continuing to expand our cooperation with other European institutions, completing the development of a *Thesaurus Ethics in the Life Sciences*, and introducing a document delivery service for bioethics literature, as well as establishing an online digital library.

Several years ago, in order to facilitate research in BELIT, the DRZE initiated the development of a trilingual *Thesaurus Ethics in the Life Sciences* (German-English-French), jointly developed with our international cooperation partners. The thesaurus consists of a structured, interlingual relational keyword database. This powerful tool is designed to help create associations and combinations between various fields such as the life sciences, ethics, and law. The integration of keyword synonyms will provide the user with a great number and variety of search possibilities and combinations.

The library and documentation centre is also working on introducing a *document delivery service* which would enable users to make online orders for copies of certain documents in BELIT. Work has also commenced on establishing a *digital library* offering online access to downloadable full-text versions of certain documents in BELIT.

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REFERENCES

1. Embryo Protection Act (Embryonenschutzgesetz - ESchG) of 13 December 1990. *Federal Gazette (Bundesgesetzblatt)* 1990 part I, p. 2746-8. Online version: <http://www.jura.uni-sb.de/BGBI/TEIL1/1990/19902746.1.HTML>. Last visited: 2/3/2004.
2. Keller R, Günther HL, Kaiser P. *Embryonenschutzgesetz. Kommentar zum Embryonenschutzgesetz (Embryo protection act. A commentary on the embryo protection act)*. Stuttgart: Kohlhammer; 1992.
3. Deutsche Forschungsgemeinschaft. DFG-Stellungnahme zum Problemkreis "Humane embryonale Stammzellen" (DFG opinion on the issue of human embryonic stem cells). In: Honnefelder L, Streffer C (Ed.). *Jahrbuch für Wissenschaft und Ethik* 4. Berlin: de Gruyter; 1999. pp. 393-399. Online version: http://www.dfg.de/aktuelles_presse

- /reden_stellungnahmen/archiv/humane_embryonale_stammzellen.html. Last visited: 2/3/2004.
4. Deutschen Forschungsgemeinschaft. *Stellungnahme der Deutschen Forschungsgemeinschaft zur Forschung mit menschlichen Stammzellen* 3. Mai 2001, Bonn 2001. Online Version: http://www.dfg.de/aktuelles_presse/reden_stellungnahmen/2001/redstell/forschung_stammzellen.html. Last visited: 2/3/2004.
 5. Winnacker EL. *Statement des DFG Präsidenten Prof. Dr. Ernst-Ludwig Winnacker zur Stellungnahme der Deutschen Forschungsgemeinschaft zur Forschung mit menschlichen Stammzellen* 3. Mai 2001, Bonn 2001. Online version: http://www.dfg.de/aktuelles_presse/reden_stellungnahmen/2001/redstell/forschung_stammzellen.html. Last visited: 2/3/2004.
 6. Study Commission on Law and Ethics in Modern Medicine. *Second Interim Report of the Study Commission on Law and Ethics in Modern Medicine - Subject Report on Stem Cell Research* (12 November 2001). Berlin 2001. Online version: http://www.bundestag.de/gremien/medi/medi_2zwischen.html. Last visited: 2/3/2004.
 7. Study Commission on Law and Ethics in Modern Medicine. *Summary report. Supplement to the interim report on stem cell research focussing on importation problems. Research in imported human embryonic stem cells* (12 November 2001). Online version: http://www.bundestag.de/gremien/medi/medi_2zwischen.html. Last visited: 2/3/2004.
 8. National Ethics Council. *Opinion on the import of human embryonic stem cells* (20 October 2001). Berlin 2001. Online version: http://www.ethikrat.org/_english/publications/stem_cells/stem_cells_index.html. Last visited: 2/3/2004.
 9. Act ensuring protection of embryos in connection with the importation and utilization of human embryonic stem cells – Stem Cell Act - (*Stammzellgesetz - StZG*) (28 June 2002), *Federal Gazette (Bundesgesetzblatt)* 2002 part I, No. 42, p. 2277-80. Online version: http://www.bmbf.de/gesetz_4607.html. Last visited: 2/3/2004.
 10. National Ethics Council. *Opinion "Genetische Diagnostik vor und während der Schwangerschaft"*. Online version (German text only): http://www.ethikrat.org/stellungnahmen/diagnostik/Stellungnahme_Genetische_Diagnostik.pdf. Last visited: 2/3/2004.
 11. Study Commission on Law and Ethics in Modern Medicine. *Study Commission "Law and Ethics in Modern Medicine" of the German Bundestag. Final Report*. Berlin 2002. Online version: <http://www.bundestag.de/gremien/medi/schlussbericht.pdf>. Last visited: 2/3/2004.