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**EUROPEAN AND LATIN AMERICAN SYSTEMS OF ETHICS
REGULATION OF BIOMEDICAL RESEARCH: COMPARATIVE
ANALYSIS OF THEIR PERTINENCE AND APPLICATION FOR HUMAN
SUBJECTS PROTECTION**

SPECIFIC SUPPORT ACTION

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Introduction

Since many years the Federal Republic of Germany has an extensive system of ethics committees responsible for reviewing research projects on human subjects. The legal context of their work is complex and can only be understood from a perspective that takes into account the federalism enshrined in the German Constitution, with its division of functions between the federal government (*Bund*) and federal states (*Länder*) – a split that also encompasses the healthcare and medical research sector –, as well as the historical development of the committee system.

History

The emergence of ethics committees for the field of medical research dates back to the early 1970s in Germany. The first initiative to set up an ethics committee was launched in 1972 by the German Research Foundation (*Deutsche Forschungsgemeinschaft = DFG*). The DFG required that such a committee be set up to review collaborative research projects (*Sonderforschungsbereich*). The background for this move was the preceding debate that had come out of the USA surrounding the need for regulatory bodies. Taking their lead from the Second Declaration of Helsinki adopted in Tokyo in 1975, numerous medical faculties and the State Chambers of Physicians (*Landesärztekammer*) followed this example and set up an ethics committee. The first ethics committee at a medical faculty was established in 1978 by the University of Münster. In 1979 the German Medical Faculty Association (*Medizinischer Fakultaetentag*) and the Federal Chamber of Physicians (*Bundesärztekammer*) recommended the general introduction of independent ethics committees. The Working Group of Medical Ethics Committees (*Arbeitsgemeinschaft medizinischer Ethikkommissionen*) was set up as early as 1983. Yet it was not until the mid-1990s that a legal framework was put in place on the federal level for the work of the committees. This took the form of the adoption of the Act on Medical Devices (*Medizinproduktegesetz = MPG*) in 1994 and the 5th Amendment of the Act on Pharmaceutical Products (*Arzneimittelgesetz*) in 1995. The legal basis for the work of ethics committees is further determined by specific key court decisions as well as the implementation of the European Directive on Good Clinical Practice in 2001, which was translated into national law by the 12th Amendment of the Act on Pharmaceutical Products.

Legal situation

The legal situation in Germany regarding research ethics committees is quite complex.

There are three different sets of provisions (one regulation and two acts) dealing with the different types of research on human beings and the ethics committees' role in it. Moreover, there is a professional law, issued by the Federal Chamber of Physicians (*Bundesärztekammer, BÄK*) and implemented by the State Chambers of Physicians (*Landesärztekammern*).

The most relevant article for the work of German ethics committees¹ is the Act on Pharmaceutical Products (*Arzneimittelgesetz*, hereinafter referred to as AMG). The AMG deals with pharmaceutical products² and provides rules on the conduct of clinical trials in §§ 40-42 AMG. According to AMG § 40 Sect. 1, 2nd sentence, clinical trials may only commence if there is a prior positive vote by an ethics committee³. If no such vote is given, the trial may only commence if the competent authority the Federal Institute for Drugs and Medical Devices (*Bundesinstitut für Arzneimittel und Medizinprodukte*, hereinafter referred to as BfArM) as indicated in § 77 Sect. 1 AMG) does not gain, within a period of 60 days. § 40 AMG also contains rules on matters such as informed consent, special groups of trial subjects, the qualification of the researcher, pharmacological and toxicological assessment, insurance etc. All these criteria also constitute the parameters of evaluation by the ethics committees. In § 41 the rules for clinical trials on persons who may benefit from the experimental treatment are laid down. In certain cases a clinical trial may be conducted on these persons without their (if not against their) explicitly stated will.

The second act with some relevance for research ethics committees is the Act on Medical Devices (*Medizinproduktegesetz*, hereinafter referred to as MPG). Medical devices – broadly speaking – are those instruments and devices used in a medical context, which are not covered by the AMG.⁴ The rules for clinical trials with medical devices are given in §§ 19-24 MPG. Pursuant to § 20 Sect. 7 clinical trials using a medical device may only commence when they have been notified to the competent authority (the authorities being located on the level of the federal Länder) and have been approved by an ethics committee. Again, the trial may also begin if the authority does not issue written disapproval within 60 days. In contrast to the provisions of the AMG, the ethics committees responsible for the evaluation of trials with medical devices must not be registered by the federal Länder but by the BfArM.⁵ § 20 Sect. 8 contains some rules regarding the composition and make up of these committees.⁶ Pursuant to this section they must be independent, interdisciplinary, and must contain at least five members. Some of them must be medical experts, some must be lay members (non-medical professionals). The committee may only be registered by the BfArM if it notifies that institution about its procedures and fees.

¹ 67 % of the research proposals, evaluated by German ethics committee, fall under the framework of the AMG. Q.v. Hanjörg Just “Die öffentlich-rechtlichen medizinischen Ethik-Kommissionen in Deutschland – derzeitige Struktur und Arbeitsweise, so wie Perspektiven der zukünftigen Entwicklung.” http://www.ak-med-ethik-komm.de/struktur_main.html, p. 8.

² Defined as “matters and mixtures of matters” destined to (1) “heal, alleviate, prevent or discern diseases, ailments, suffering or bodily damages”, to (2) “analyse the constitution, the condition und the functions of the human body and mind”, to (3) “substitute agents or bodily fluids produced by the human or animal body”, to (4) “fend off and dispose of etiologic agents, parasites or intruding substances” and to (5) “modify the constitution, the condition und the functions of the human body and mind” in § 1 Sect. 1 AMG.

³ This provision further defines, that the committees have to be established according to the law of the federal Länder. For a complete list q.v. http://www.bfarm.de/de/Arzneimittel/klin_pr/klin_pr_faq/ListeEK_Landesbehoerde.pdf.

⁴ A more exact and comprehensive definition is given in § 3 MPG. But it is far too lengthy and convoluted to be cited in this context.

⁵ For more information also see:

http://www.bfarm.de/de/Medizinprodukte/klin_ethik/index.php.

⁶ For a complete list of those committees see:

http://www.bfarm.de/de/Medizinprodukte/klin_ethik/index.php?more=ethikkom.php.

The last generally binding set of rules is the Regulation on the Protection from Ionising Radiance (*Strahlenschutzverordnung*, hereinafter referred to as StrlSchV). It deals *inter alia* with medical research involving human subjects to be exposed to ionising radiance. The preconditions for the acceptability of such clinical trials are even stricter than those in the AMG and MPG. With regard to the role of ethics committees, the rules are quite similar, nonetheless. Pursuant to § 23 StrlSchV the researcher needs to apply for permission to the Federal Office for Radiation Protection (*Bundesamt für Strahlenschutz*, hereinafter referred to as BfS) before he can conduct medical research of that sort. In contrast to the rules laid down in the AMG and MPG, the trial must be approved explicitly from the start. One of the requirements (§ 24 Sect. 1 No. 2 StrlSchV) for the BfS to comply with the request is that an ethics committee has to issue an opinion (not necessarily positive, according to the StrlSchV) regarding the research plan. According to § 92 StrlSchV, an ethics committee responsible for that kind of research evaluation must be independent, interdisciplinary and registered at the BfS.⁷ To be registered, the committee must be composed of at least five persons, containing medical professionals as well as lay persons, must have issued written rules of procedure and must notify the BfS of their mode of operation. Their opinions must take into account legal, as well as ethical aspects and must be published in written form within three months of the researcher's application.

All three sets of rules detailed above deal with multi-centre trials. In the case of the AMG, the opinion of the ethics committee responsible for the region (federal Land) in which the main-researcher is located, is binding. No further opinions are required.⁸ According to § 20 Sect. 7, 2nd sentence, the vote of just one ethics committee is enough to fulfil the preconditions of the MPG in the case of multi-centre trials. § 92, 3rd sentence StrlSchV delineates, that in the case of multi-centre trials, the vote of one committee is sufficient.

Besides the three legal codices mentioned above, there is the Stem Cell Act (*Stammzellgesetz*, hereinafter referred to as StZG). Although this law contains rules on the participation of ethical deliberation in administrative procedures, it does not deal with *local* ethics committees. The StZG introduced a central committee that has some part in the decisions on proposals for the import of human embryonic stem cells into Germany (*Zentrale Ethik-Kommission für Stammzellforschung*, ZES).

Another set of rules which have some bearing on the work of ethics committees in Germany is the (Model) Professional Code of Conduct of the German Medical Association (*(Muster-) Berufsordnung für die deutschen Ärztinnen und Ärzte*, hereinafter referred to as MBO-Ä). Although this normative text is in two ways less legally binding than a law or decree, nonetheless its influence on the work of ethics committees is quite important. Firstly, as it originates from professional law, the Code just addresses physicians, being in no way binding for other people (even for other medical professionals). While that lessens the legal force of the code in some way, the practical repercussions of that reservation are quite limited. As physicians are the main conductors of clinical trials, other medical professionals play a secondary role, the code is practically applied to almost all biomedical research. The second restriction of its legal force comes from the fact that it is only a model. The German Medical Association has just given a guideline for the design of codes of conduct for the medical associations of the federal Länder (*Landesärztekammern*). This construction stems from the

⁷ For a complete list of those ethics committees see:

http://www.bfs.de/bfs/dienstleitungen/med_forschung/strlschv/ethikkomm.html.

⁸ Q.v. the BfArM's guidelines for clinical trials online under http://www.bfarm.de/de/-Arzneimittel/klin_pr/klin_pr_faq/index.php#I.

different legal nature of the German Medical Association and the Medical Associations in the federal Länder.⁹ But even this objection does not bear much practical force as the resulting codes only differ very slightly from the model code. For the sake of practicability, we therefore refer to the provisions of the MBO-Ä of the German Medical Association on biomedical research instead of citing the codes of the 16 federal Länder. In § 15 Sect. 1 MPCC physicians are obliged to let themselves be counselled by the ethics committee of the medical associations of the Länder or an ethics committee located within the university's medical department when conducting biomedical research. The definition of biomedical research used in this code also entails research conducted on human gametes and foetal tissue but excludes purely epidemiological studies.¹⁰ The physician does not need to obtain approval from an ethics committee, but is only required to avail himself of advice on legal and ethical matters pertaining to the planned research.

This slight difference in function, compared to the role of ethics committees in the context of AMG and MPG, has led to some legal frictions in the past. As the MPG only requires an ethics committee to be registered (pursuant to the requirements set out in § 20 Sect. 7-8 MPG) to conduct the evaluation of clinical trials, there is no stricture against private ethics committees (opposed to public ones) to operate in this context. However, the MBO-Ä only refers to public ethics committees, which led to claims that the situation constituted an unfair restriction of the private ethics committees' activities. The concerned parties went to court claiming that the legal situation infringed on their freedom of professional activities as no one would obtain a vote by a private ethics committee if that vote only accounts for the requirements of § 20 Sect. 7 MPG but not for those laid down in the code of conduct for the medical associations of the Länder, whereas the vote of a public committee (registered according to § 20 Sect. 7-8 and being competent to carry out consultations according to the conduct code) cover both votes.¹¹ The concerned court decided, that, although the public committees may give votes in both respects, they may not give an opinion that encompasses the counselling being required by professional law and the evaluation required by the MPG in the same act. In particular, they have to issue two different acts. This is grounded in the different natures of professional advice for physicians on the one hand and evaluation of research projects having the nature of legal approval on the other. The first is mainly for the

⁹ Whereas the medical associations in the federal Länder are empowered to enact some functions of public law and therefore have the status of public bodies, the German Medical Association acts as an umbrella organisation meant to coordinate the activities and rules of the medical associations in the federal Länder but without public law functions and corresponding public body status. Nevertheless the German Medical Association fulfils vital functions and even provides a central commission concerned with somatic gene-therapy (Kommission Somatische Gentherapie, KSG) and acting as obligatory advisor to local ethics committees involved in such cases according to Sect. 3.1.4 of the German Medical Association's guideline on Gene-transfer into Human Somatic Cells; q.v. <http://www.bundesaerztekammer.de/30/Richtlinien/Richtidx/Gentransferpdf.pdf>.

¹⁰ In that regard the Code of Conduct of the State Medical Chamber of Baden-Württemberg (Landesärztekammer Baden-Württemberg) differs from the model code of the German Medical Association, as it also entails epidemiological studies according to § 15 of the Professional Code of Conduct of the Medical Association of Baden-Württemberg, q.v. <http://www.aerztekammer-bw.de/20/arztrecht/05kammerrecht/bo-neu.pdf>. There are also other instances in which the codes of conduct of the medical associations differ among the federal states from the model code of conduct of the German Medical Association.

¹¹ For a comprehensive description of that case q.v. Taupitz, Jochen, MedR 2003, Heft 2, p. 109–118.

benefit of the medical professional helping and guiding him in his work and decision processes, the second aims at the protection of rights and interests of the research subjects. That said, the private ethics committees are not disadvantaged with regard to the evaluation following § 29 Sect. 7 MPG as even public committees have to issue two different opinions. The court decided further that the exclusion of private ethics committees from the counselling pertaining to the codes of conduct does not infringe on their professional freedom, as it is well within the medical associations of the Länder (*Landesärztekammern*) competence to limit these tasks to institutions of their own choosing.

Besides the different regulatory layers discussed above, another practical level exists in Germany. Even researchers, who do not fall into the above-mentioned norms, (like those conducting psychological research with human beings or just using data) are well advised to have their projects evaluated by the universities' ethics committees. Otherwise, they may face serious problems by trying to publish their results in the acknowledged scientific journals. Also research grants may prove problematic as the German Research Foundation (*Deutsche Forschungsgesellschaft, DFG*) and other institutions are not likely to fund any project that does not comply with the established standards of ethics. In practice, almost all research in German universities is reviewed by ethics committees and most researchers are eager to obtain the advice of their colleagues.

The applicable Act on Pharmaceutical Products and the Act on Medical Devices provide for a competent higher federal authority, the approval of which is required before a clinical trial may commence. These authorities are not required to conduct their own ethical review or share information with the competent ethics committees. The competent higher federal authority for most pharmaceutical products and medical devices is the Federal Institute for Drugs and Medical Devices (*Bundesinstitut für Arzneimittel und Medizinprodukte*) based in Bonn. § 77 of the Act on Pharmaceutical Products specifies that responsibility rests with the Paul-Ehrlich-Institut in the case of serums, vaccines, blood preparations, bone marrow preparations, tissue preparations, allergens, test serums, test antigens, gene transfer drugs, somatic cell therapeutics, xenogenic cell therapeutics and genetically engineered blood plasma products.

The 12th Amendment of the Act on Pharmaceutical Products which became effective on 6th August 2004 brought a number of changes. In accordance with the model of the European Directive, it differentiates between research on children, on the one hand, and research conducted on other persons unable to give informed consent, on the other. Unlike the previous legal situation, there are now legally legitimate forms of research on children for third-party benefit. What is more, the Amendment rescinds the physician's privilege according to which – under the previous law – the conduct of clinical trials had to be led by a physician. The work of ethics committees is now governed by the deadline defined by the European Union, which the competent ethics committees must meet when processing research protocols. In addition, a lead ethics committee must be designated in the case of national multi-centre trials that fall within the competence of several ethics committees. The amended version of the Act on Pharmaceutical Products also confirmed the sole authority of the ethics committees established under public law. Lawmakers have thus not given way to the objections of private committees. On the contrary, the verdict of the competent ethics committee now carries even greater weight than under the previous law. Even the old Act on Pharmaceutical Products required an affirmative opinion by the examining ethics committee, but if an positive opinion was not given it nevertheless allowed the trial to commence, as long as the competent authority did not explicitly ban the trial within a period of 60 days after notification. Under current law the ethics committees acceptance is strictly required.

The binding effect of the votes taken by a public ethics committee thus varies according to the legal basis on which they were taken. There are three levels of binding force. Votes taken on the basis of the Act on Pharmaceutical Products – and currently these probably account for the lion's share – have the highest level of binding force since a trial may only commence if such a vote is positive. Within the framework of the MPG, similar to the prior situation with the AMG, a positive vote is necessary. But if the committee does not comply, the trial may still commence if the competent authority does not forbid it within 60 days after notification about the negative vote. Finally, there are further opinions on research projects involving human subjects that are delivered by ethics committees in accordance with the professional code of the physicians seeking to conduct human trials or the university regulations by which medical researchers at institutions of higher learning are bound. Irrespective of these different levels of legally binding force, experts report that to date no trial has been performed to which the competent ethics committee objected on account of ethical concerns.

Number and composition of the committees

A total of 21 ethics committees are currently established in Germany under the auspices of the State Chambers of Physicians. The federal states of Bremen and Hamburg have also set up their own ethics committees. There are a further 25 ethics committees at universities and medical schools. The Ethics Committee of the Westphalian State Chamber of Physicians is at the same time the Ethics Committee of the University of Münster. The majority of the members of German ethics committees are physicians and medical researchers. It should, however, be noted that the composition is not determined by the aforementioned laws, but rather by state legislation and the charters of the various committees. Lawyers and nurses very often serve as members of the committees. Some committees also include sociologists, bioethicists or theologians among their ranks. Laypersons are relatively seldom found on the committees as representatives of the general population or patients. In this respect the charter of the Ethics Committee of the Hamburg Chamber of Physicians is to some extent an exception. § 4 of its charter requires that eight of the 15 members should be physicians from various specialisations, together with 1 medical equipment technician, 2 lawyers competent for the office of judge, 1 scholar from the humanities or social sciences, 2 nurses and 1 person as a representative of the general population. The committee is to be chaired by a physician. 7 of the members should be women and 7 should be men, while the 15th member should be a man or woman on a rotating four-year basis.

Bodies on the federal level

The ethics committees set up by the universities and State Chambers of Physicians as well as the committees of the federal states are independent of all bodies on the national level. There is neither an appeal instance nor a coordinating institution. The role of the Ethics Committee at the Federal Chamber of Physicians is limited to an advisory function.¹² This is also true of other central committees set up by the Federal Chamber of Physicians for certain areas of innovative research. Only in gene transfer research and in xenotransplantation the inclusion of an advice by an external specialist by the competent research ethics committee is legally required. For gene transfer research there is a specific central committee that normally gives the required advice.

¹² This committee was the first permanent national-level ethics commission in Germany. It was established on 13 March 1994. Although it does not constitute a high-level body for the local ethics commissions, it was nevertheless in some cases required to express a view on specific projects involving issues of particular importance. Q.v. Fuchs, Michael „National ethics councils“, p. 41.

For research with embryonic stem cells Germany has a specific legal provision. According to the Stem Cell Act (Act ensuring protection of embryos in connection with the importation and utilization of human embryonic stem cells (28 June 2002) an independent, interdisciplinary Central Ethics Commission on Stem Cell Research (*Zentrale Ethik-Kommission für Stammzellforschung*, ZES) was established at the competent agency (*Robert Koch Institut*). It is composed “of nine experts from the disciplines of biology, ethics, medicine and theology” (Sec. 8, 1). The committee shall evaluate if the proposed research project serves eminent research aims, that the scientific knowledge to be obtained cannot be expected to be gained by using cells other than embryonic stem cells and accordingly the research project is ethically acceptable.

This regulation poses another question which has not yet been decided by German courts: Must a physician who is planning to conduct research on human embryonic stem cells (HESC), apply for counselling according to the code of conduct, separately from his/her proposal to the Central Ethics Committee for Stem-Cell Research? As mentioned above, that issue has not yet been decided by a German court. As far as we know, all of the first four applicants who proposed to import HESC let their research projects be evaluated by the competent research ethics committee. If they should ever go to court in the future, we would expect the decision to follow the legal ideas put forward in the above-mentioned case. The decision of the Central Ethics Committee for Stem-Cell Research to allow the import of stem cells is similar to the vote of a local research ethics committee regarding clinical trials in two important aspects. It has the legal character of admittance (in contrast to counselling) and its central aim is to protect the interests of some third party instead of just giving guidelines and ethical advice to the researcher. The vote of the Central Ethics Committee for Stem-Cell Research differs from the counselling required by the code of conduct in the same manner as the positive vote according to § 20 Sect. 7 MPG differs from it. Therefore, it is to be expected that a court, deciding on that matter in the future, will require the researcher to obtain both votes.

Current debate

The implementation of the European Directive on Good Clinical Practice has attracted relatively little public attention in Germany. This may seem surprising in view of the explosive nature of the topic of research on persons unable to give informed consent. Only a few years earlier in the context of the debate surrounding the Council of Europe's Human Rights Convention on Biomedicine this issue had given rise to a storm of protest, numerous sometimes highly emotional discussions and ultimately – in light of the opposition expected from the broader population and disabled groups – Germany's failure to ratify the Convention. At least as far as children are concerned, the new Act on Pharmaceutical Products provides far greater authority to conduct research for third-party benefit on persons unable to give informed consent than ratification of the document under international law would have entailed. Nor has the amended legal status of the ethics committees attracted significant public attention. The debate surrounding the Amendment of the Act on Pharmaceutical Products and the current state of clinical research in Germany has thus been largely limited to academic circles together with the relevant associations and their representatives. At the heart of this discussion are the two major problems described below.

The first point of criticism is that the ethics committees will not be able to handle their new function since they had hitherto been conceived of as honorary bodies. Now they have been transformed into an institution of an official nature and put under time pressure by the imposition of strict deadlines. From both the technical and organisational perspective, their personnel capacity is also frequently overtaxed. The second area of criticism stems from the transformation of an institution with the status of an honorary body into an institution with the

status of a public agency. This change in status gives rise to liability risks with respect to both the patients and the interests of the sponsors – risks which cannot be borne alone by the ethics committees themselves or the universities / chambers of physicians that support them.

An expert survey conducted by the Life Science Agency NRW revealed that in the opinion of those questioned the amendment of the Act will give rise to greater bureaucracy, although in some areas it will also serve to improve the conditions for research.¹³ In the assessment of Erwin Deutsch, a highly respected scholar of medical law, the amended wording of §§ 40 ff. of the Act on Pharmaceutical Products will also bring about marked overregulation of clinical research in view of the numerous detailed requirements and review duties incumbent on the competent ethics committee.¹⁴ Gödicke and Pestalozza make particular reference to the difficulties associated with the imposition of time limits.¹⁵

The problem of the increased liability risk is reflected in specific requirements relating to the implementation of the 12th Act on Pharmaceutical Products in state law. In its opinion on the draft legislation and in various submissions to the competent government offices, the Berlin Chamber of Physicians had pointed out in 2002 that the Chambers of Physicians would face considerable liability risks as a consequence of the new status assigned to ethics committees. In the subsequent dispute over this issue with the State of Berlin a settlement was reached in Berlin Administrative Court under which the state agreed to take responsibility for any and all liability claims that might ensue. In order to release the Chamber of Physicians from this liability risk the Berlin court took its lead from the State of Bremen, where the state itself had set up an ethics committee responsible for reviewing clinical trials under the Act on Pharmaceutical Products.¹⁶ It should be pointed out that this release from liability was introduced with a special eye to the interests of the research-oriented pharmaceutical industry, since waiting periods entail substantial costs. The German Association of Research-Based Pharmaceutical Companies (*Verband forschender Arzneimittelhersteller e.V.*) nevertheless indicated that availment of the full 60-day time limit by the competent ethics committees would still constitute a significant disadvantage for Germany as a business location in the context of the global market.¹⁷ German industry thus believes that the time limit is still too long.

The Study Commission (*Enquetekommission*) on "Ethics and Law in Modern Medicine", which was set up in the 15th electoral term by the German Federal Parliament, considered clinical trials of drugs and the amendment of the Act on Pharmaceutical Products in the

¹³ Life Science Agency NRW. Expertenfrage der LSA zur 12. Novelle des Arzneimittelgesetzes, <http://www.liscia.de/servlet/PB/menu/1007508>

¹⁴ Deutsch, Erwin. Report for the Association of the Scientific Medical Societies in Germany (AWMF - Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften) <http://www.uni-duesseldorf.de/awmf/pdf/aej05-1.pdf>, p. 19

¹⁵ Gödicke, Patrick. Beschränkung der Staatshaftung für Ethik-Kommissionen im Zuge der 12. Novellierung des Arzneimittelgesetzes?, *MedR* 2004, 481-485; Pestalozza, Christian. Risiken und Nebenwirkungen: Die Klinische Prüfung von Arzneimitteln am Menschen nach der 12. AMG-Novelle, *NJW* 2004, 3374- 3379

¹⁶ Steinberg, Margret. Gesetzgeber zwingt Ärztekammern in existenzielle Risiken, http://aekb.arzt.de/10_Aktuelles/bae/18_BERLINER_AERZTE/BAEthemen/ThemaArtikel2004_09/NovelleAMG.html; Ärztekammer Berlin [Berlin Chamber of Physicians]. Ärztekammer verklagt das Land Berlin, http://www.aerztekammer-berlin.de/10_Aktuelles/10_pressemit/868pak08_2004.html

¹⁷ For the full article see: http://www.vfa.de/de/forschung/txt/neues_amgesetz.html

course of its deliberations. The Study Commission concurred with the view of the Federal Chamber of Physicians and the majority opinion of the medical ethics committees when it concluded that it would be better to retain the physician's privilege for the conduct of clinical trials.¹⁸ A hearing held by the Study Commission gave various interested parties an opportunity to speak, most notably representatives of patients' groups. Of the altogether 15 patients' representatives heard, only the person representing sufferers of Crohn's disease addressed the role of ethics committees in her remarks. Since, in her view, the members of the ethics committees do not always have specialist personal expertise in the clinical picture that forms the subject of a trial, she suggested that – in addition to the vote of the ethics committees – an opinion should be sought from proven experts in the particular clinical picture. She also drew attention to the fact that the independence of the ethics committees could be strengthened through the participation of more scientists who do not work at the same university as the trial leader.¹⁹ At the present time researchers filing an application have the right to present their protocol and discuss it with the committee, although they are excluded from the decision-making process. According to at least the majority opinion on the German ethics committees, rigorous and cooperative vigilance among colleagues remains the most efficient tool for ensuring unbiased and critical votes by the ethics committees.

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¹⁸ Gutachtliche Stellungnahme der Enquete-Kommission Ethik und Recht der modernen Medizin vom 26.01.2004 Kom.-Drs. 15/125; **Korzilius**, 12. Novelle zum AMG: Mehr oder weniger Ethik?, DÄBl. 2004, A-309

¹⁹ **Wortprotokoll der Öffentlichen Anhörung der Enquete-Kommission Ethik und Recht in der modernen Medizin zum Thema „Erfahrungen von Probanden und Patienten als Teilnehmer an klinischen Studien“ vom 25.10.2004 Protokoll 15/26, p. 15**

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