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NATIONAL BIOETHICS-COMMITTEES IN EUROPE

Abstract: Many people in central Europe look upon bioethics as an import from the United States. Yet this impression is mistaken in various respects. When Bill Clinton decided to set up a federal-level permanent committee for the field of bioethics, he was actually following a trend already established by Sweden, Denmark, Luxembourg, Italy, Norway, Portugal, Slovenia and Belgium. Indeed, France was the first country to take such an initiative. The advantage of a permanent advisory body over ad hoc committees is that it can deliberate on a wider range of issues, have greater latitude to pursue specific issues independently and be consulted not only by constitutional bodies but also by private persons and organisations. However, the broader range of issues addressed and the greater authority enjoyed by a permanent body makes the task of securing expertise and plurality more demanding. Most European states have therefore endeavoured to lay down solid ground rules, usually through legislation. In the overwhelming majority of cases, their members must be appointed by different constitutional bodies but also by research and educational establishments; others, like Norway or Italy, attempt to ensure plurality by defining the disciplines and philosophical positions to be taken into consideration.

The paper discusses the role of national ethics bodies between ‘academic’ and ‘bureaucratic’ bioethics as well as between philosophical analysis, public debate and participation and political decision-making.

Keywords: National Ethics Councils, Advisory Committees, Legislation, Ethical Expertise, Practical Reason, Pluralism, Independence, Moral Status of Human Beings, Reproductive Medicine

INTRODUCTION

Hardly any other institution is as characteristic of bioethics and the transition from the traditional reflection on the moral appropriateness of medical action to current developments in biomedical ethics as the institution of ethics commissions. The term itself, however, is both ambiguous and multi-faceted. There are at least three distinctive types. First, at a local level, there are commissions whose mandate it is to examine research projects. In Germany, this takes place at university clinics and, if other clinics are concerned, it is the task of the regional medical associations i.e. the chambers of physicians. The examination includes all projects involving research on human beings. As a second type of commission, also on a local level, we find both in Europe and in the United States

of America clinical ethics committees who not only give counsel and advice in research-related, but also in treatment-related decisions. In this context decisions on the choice of therapy as well as the question of the limitation of therapy are of special significance. Last but not least, committees were established on a national level. Their prime task was first to give counsel and advice to government bodies regarding certain questions in the context of legislation. Later, transformed into permanent committees, they were also to provide advice on moral issues in the entire field of biomedicine.¹

THREE TYPES OF ETHICS COMMISSIONS

All three different types of commissions mentioned above have several common characteristics and one of them is the fact that they operate in the field, or at least part of the field of health care and biomedical research, whenever decisions are at stake which involve a moral differentiation of good and evil. Moreover, they were all established as bodies with the task to form judgements on a level which is broader than that of the individual, yet at the same time smaller than that of the entire group of those concerned. The number of members is determined in such a way that a face-to-face debate is possible at all times during the discussions.

A third common feature of all three types of commissions is the fact that though the term 'ethics' or 'ethical' forms part of their titles they do not necessarily count ethicists among their numbers. I will come back to this aspect later on.

There are, though, also significant differences. Strictly speaking all three types of commissions are merely advisory bodies. In the case of the ethics commissions at medical faculties and medical associations, however, the German model professional code requires that they are consulted prior to all clinical trials involving human beings.² This obligation also applies in the case of „research on vital human gametes or living embryonic tissue“ or „research involving person-related data“. The decision gains of course additional weight due to the fact that public funding will only be granted in case of a positive decision.³ As far as research for new drugs is concerned the decision of the commission is of legally binding character for the researchers involved since the European Directive on Good Clinical Practice has been translated into national law.

Clinical ethics committees in hospitals, as we know them today, originated in voluntary initiatives, in most cases on behalf of the hospital management.⁴ It is their task to issue guidelines on certain decisions concerning treatments and create the preconditions for individual case discussions in ad-hoc groups. Their most important function,

1 A similar distinction is also made by the UNESCO: cf. Organisation des Nations unies pour l'éducation, la science et la culture division de l'éthique des sciences et des technologies [UNESCO] (2006), p. 10- p. 15 and Organisation des Nations unies pour l'éducation, la science et la culture division de l'éthique des sciences et des technologies [UNESCO] (2005).

2 Cf. Deutsch (1990) as well as Toellner (1990).

3 Cf. Smith (1999).

4 Cf. Gordijn, Steinkamp (2000); Kettner (1999); for the historical background in the USA cf. Sass (1990).

however, seems to be that they increase awareness for moral issues among hospital staff. Currently, the guidelines issued by those committees are of no binding nature. A possible result though could be that - in cases of moral conflict - the individual member of hospital staff is relieved from the sole charge of moral responsibility.

In the case of ethics commissions established by government bodies the motivation was not so much for them to relieve the burden of responsibility in decision-making, but rather to provide improved conditions for pending decisions.⁵ Commissions of that type were first established as ad-hoc groups. Their task was to find out the need for legislation in a certain field. Thus they can be seen as the continuation of other types of political consultancy. As the first institution of this kind the US Congress established the National Commission for the Protection of Biomedical and Behavioural Research in 1974. Unlike later committees this Commission was supplied with an unusually strong legislative mandate, which, as Stephen Toulmin has shown, came very close to delegated legislative power. Until 1978 many of its recommendations concerning criteria for research on human foetuses, on children, prisoners and institutionalised patients with psychic disorders were actually implemented by the Ministry, though be it in most cases not literally.⁶ A factual delegation of legislative power, however, seems impossible in a democratically constituted state. The task of national ethics commissions can, as a consequence, only be of advisory and consultative nature and not the actual decision-making itself.

Other ad-hoc commissions were established mostly in the field of reproductive medicine. From a German point of view, the most important among these were the Warnock Commission in Great Britain and the Benda-Kommission in Germany.

In France it was the newly established Comité Consultatif National d'Éthique pour les Sciences de la Vie et de la Santé that was entrusted with providing ethical advice on questions of artificial insemination and the ensuing problems. As early as 1983, François Mitterand founded the Comité emphasising that he regarded it as an answer to the challenges posed by the modern life sciences. The Comité was to stimulate reflections on the ethics of research. While avoiding both dogmatism and laissez-faire, the aim was not to leave researcher alone with the burden of responsibility, but to approach the issue by way of a broad, pluralistic and thorough discourse. Untouched by changes in the government and presidency, over the past two decades the Comité has shown a remarkable continuity. It is not only the oldest committee of its kind⁷: with its by now 73 opinions and reports – some of which are rather extensive – it is also the most productive one. By establishing this permanent committee France has initiated a development in Europe which can be looked upon as a specifically European contribution to the developments in bioethics.

5 In greater detail cf. Fuchs (2005) and Fuchs (2006). The following is to a large extent based on these two studies.

6 Cf. Toulmin (1987, p. 600).

7 The Slovene National Medical Ethics Committee was already established in late seventies (1977) and is thus even older than the french committee. It started its work as a body responsible for reviewing all medical research protocols in the country. Later it became also a consultative body for the Parliament, the Minister of Health and others (cf. Trontelj (2000)).

When Bill Clinton decided to establish a permanent committee on bioethics at US Federal level, he only followed a development which had already been taking place in Sweden, Denmark, Luxembourg, Italy, Norway, Portugal, Belgium, Slovenia and Finland.

NATIONAL AD-HOC COMMITTEES AND PERMANENT COUNCILS

In comparison with ad-hoc committees permanent advisory bodies have the advantage of being able to deal with a far broader range of topics. They are more at liberty to launch their own thematic initiatives and may not only be consulted by constitutional bodies, but also by private persons and institutions. This broader thematic range and great authority, however, places greater demands on securing both expertise and plurality. Many European states have therefore made great efforts to establish a solid and in most cases legal foundation. In most of the states the authorisation to appoint the committee members is divided up between various constitutional bodies or research and educational institutions. Other countries, such as Norway or Italy, try to secure plurality by clearly defining the disciplines and world views to be represented on the councils. A comprehensive representation of the entire population cannot and is not to be reached in the process. In some cases, however, quotas are defined, as for example in Denmark, concerning gender or in Belgium concerning the various language communities.

Ethics councils in Europe are not actors in the legislative process. Yet, some of them take an active role by pointing out areas which still need regulation, demanding legislative action, discussing and commenting drafts. In France, for example, the bill concerning a revised bioethical legislation was presented to the French committee for it to issue an opinion, prior to the parliamentary and public debate. In Portugal the council is entitled to present opinions, even when the respective legislation has already been passed and is in force. This is the reason why the Portuguese council sees itself also as a body executing ethical norm control.⁸ Other councils, such as for example the Danish council, have the international reputation of working successfully, even though their influence on political decision is hardly discernible, if at all. In the Danish case, this is attributed to the fact that a considerable group within the council –mainly consisting of members without a biomedical background – have taken a more critical stance towards biomedical developments than the political majority in the Danish parliament, in the Folkething.⁹ Consequently, the influence exerted by the council lies mainly in the field of information and educational activities. Apart from individual reports on ethical problems this task is fulfilled by the annual report. Both types of publication are meant to be widely distributed and free of charge. The information and educational task also becomes clear in the context of creating teaching materials for schools and

⁸ Cf. Presidencia do conselho de Ministros (1999, p. 8).

⁹ Koch, Zahle (2000, p. 133).

other educational institutions. The various activities in the field of publication make up for a considerable part of the council's total budget. Moreover, the council organises conferences and hearings. Through its publishing and educational activities the council succeeded in setting the thematic focuses for the public debate.

Setting the thematic focuses for the public debate and supplying information is also very important with regard to those committees which have been working successfully in exerting their influence on legislative processes. What is true of all them is the fact that they do not come in at the end of a debate, but – on the contrary – initiate the bioethical forum. Thus, the debate itself gains structure by way of systematically examining the individual arguments. What is not, though, aimed at are final answers or even decisions. Measured against the duration of their advisory activities and the expenditures connected with them, all national ethics committees, including the French committee – exerted less influence on the legislative process than the ad-hoc committees mentioned above. It also has to be noted that the tendency to establish permanent committees is by no means irreversible. It may be true that in France, Lucien Sève, expresses a minority opinion, when he states that after the publication of the committee's opinion on the revised bioethics legislation the task of the committee itself is over.¹⁰ In the USA, however, the National Bioethics Advisory Commission, which had only come into existence by way of a Presidential Executive Order, the Bush administration disbanded the committee in October 2001. In its first meeting, though, the new President's Council on Bioethics – created by Presidential Executive Order of 28 November 2001 – took up the topic which its predecessor had dealt with in great detail (17/18 January 2002): reproductive cloning.¹¹ Its last meeting was in March 2009. In Italy, where the Health Ministry did not agree with the mostly restrictive attitude towards the question of embryonic stem cell research, an additional commission, chaired by Nobel Prize winner Dulbecco, was established to examine a number of essential questions.

NATIONAL ETHICS ADVISORY SUPPORT IN GERMANY

In Germany, too, the German Bundestag Study Commission on Law and Ethics in Modern Medicine, which I would place among the ad-hoc committees, was still active when the *Nationaler Ethikrat* (National Ethics Council) was reconstituted. Study Commissions established by the German Bundestag were first introduced in 1969. They present a particular mode of exerting the parliamentary right of inquiry. They are constitutionally legitimised by Article 44 of the German Constitution, i.e. the German Basic Law. In the decision to appoint a committee the subject of investigation has – according to the principle of sufficient precision – to be adequately defined. Study commissions act as Bundestag sub-committees. They are characterised by a balanced number of parliamentarians and external experts. Their goal is to provide

10 Sève (1998, p. 75 seq.)

11 The first report deals with the broader issue of human cloning and dignity (cf. The President's Council on Bioethics (2002)).

a more fundamental and longer-term perspective for legislative and other important factual decisions.

The appointment of external experts takes place via the parties or the parliamentary groups. The fact that it is the parties which decide on the selection and concentration of the various opinions and interests, is widely looked upon as being hardly suited to provide a true picture of the various instances of specific moral dissensus.

The German-speaking countries were late in following the examples of other European countries – all adopting national consultative bodies in 2001. As already mentioned Germany's *Nationaler Ethikrat* (National Ethics Council) was founded before the Study Commission on Law and Ethics in Modern Medicine at the German Bundestag had concluded its work. Since the founding of the Council resulted from an initiative by the Federal Chancellor and a cabinet decision, protests were publicly voiced by Members of the Bundestag who objected to the establishment of a new body. The public and the media also tended to be sceptical, seeing the selection of its members by the Chancellor as an attempt to prejudice the debate and favour a particular position. The Ethics Council brought together a number of eminent scientists, some representatives, including a few high-profile figures, of major groups in society, and some specialists from the field of bioethics. According to the inauguration motion passed by the cabinet, the National Ethics Council not only advises policymakers but also acts as a forum for public debate. In grappling with many different tasks under considerable time pressure, the Council has yet to form a stable sense of its own institutional identity. In its first statement, the Council set out the diverging positions of its members on the question of research on human embryos and presented their respective justifications. At roughly the same time, the Study Commission of the Bundestag presented its report on the subject. The Study Commission's report is far more comprehensive and attempts to identify common ground between the opposing positions. In framing the Stem Cell Act, the Bundestag drew above all on the work of its Study Commission. In 2007 the act on the Establishment of the German Ethics Council (*Deutscher Ethikrat*) created a new council that took over the duties of the National Ethics Council (*Nationaler Ethikrat*).

POLICY ADVICE ON MORAL ISSUES

How far may this kind of counselling and structuring improve the point of departure for a political decision, where moral issues are concerned. What is it that 'improved' means in this context? This question is not usually asked in public. The problematic point in this context is in many cases the question of composition. As the entire population cannot possibly be really represented, this objection cannot be done away with. Why then – if external consultancy is wished for – rather than turning to an individual, consult a group of people and thus risking divergent opinions?

A double answer seems to be adequate here: on the one hand, there is the old conviction that to solve cases of moral conflict, what is needed, is experience. The opinion that such experience can be accumulated, lies behind the establishment of many committees. Moreover, a pluralistic composition of the committee where *Weltanschauung* is

concerned, seems also to lead to an accumulation of moral intuition, which is the first and foremost precondition for the adequate representation of a moral problem. For Aristotle the characteristic that alone distinguishes human beings from other herd animals and human language from animal sign systems is the fact, that humans are capable of discussing in the polis whether actions are just or unjust. On the other hand, ethics commissions are usually not established at the very beginning of a political debate. What is hoped for, though, is that they may help to transform the amorphous course of a public conflict. Such a conflict has the tendency to exacerbate and intensify differences and divergent opinions and not create points of departure for dealing with the problem on a co-operative basis and work towards solutions. Ethics commissions may help to find a form of argumentation oriented toward understanding and agreement.¹² Therefore the number of people assembled around the round table is limited.

ETHICAL EXPERTISE

What distinguishes ethics commissions from other fora oriented towards understanding and agreement, such as the so-called consensus conferences, is that they require a certain degree of expert knowledge. What is conspicuous, though, is the fact that in many cases medical and life science expertise is called in, not though ethical expertise. Among the 40 members of the French committee, for example, 19 were appointed because of their competence and interest in ethical questions. One of them mostly is a philosopher. Among the five members appointed by the French State President representing different types of *Weltanschauung*, one is usually a moral theologian. All members of the committee are said to acquire the competence necessary to analyse ethical problems in the course of their work for the committee.¹³

The fact that professional competence in dealing with ethical problems is needed prior to any advisory activity is reflected in many models of national ethics councils where philosophical-ethical or theological-ethical expertise is called for. The same reason seems to lie behind demanding the co-operation of jurists and social scientists. The question whether the ethicists to be appointed are expected to represent a certain attitude towards values or whether their academic philosophic competence is the reason for their appointment, is not clearly answered in the documents establishing the committees. In the practical work of the committees, too, this is hard to distinguish.

If we look at the significance national ethics councils have gained in the almost 25 years of their existence, it is surprising to find that – in analysing their work and the results of their work - this differentiation has not yet been made clear. One reason for this may be the fact that analysis from without can only be difficult and limited. Ethicists within the committees will – if their background is a theological one – always have to

12 Göran Hermerén mentions “tolerance” as one of the conditions for the proper working of national and international ethics committees (cf. Hermerén (2009, p. 10).

13 Cf. the contribution to the discussion by Jean Michaud in answer to the paper of Göran Hermerén on the role of experts in ethics commissions. (Hermerén 1994) (ibid. p. 48 seq.).

face the difficulty that they are expected to act both as scholars and representatives of their church and thus also of a part of the population.¹⁴ For the philosopher there is no such need for this kind of double justification. He, however, always runs the risk of acting as a moral authority. What has to be emphasised, though, is that the philosophical ethicist differs from the layman in this area not because he knows the difference between good and evil. Neither does he have at his disposal a greater surplus of moral conscience. His special competence consists solely in the fact that he or she has learned how to deal with moral arguments. It is this competence which ought to be integrated into all ethics commissions.

According to the Swedish philosopher and medical ethicist Göran Hermerén¹⁵, whom I will follow in my definition, ethicists or experts in the field of ethics are „persons who by professional training and studies have acquired a particular competence ... that is, are familiar with the basic ethical concepts, the fundamental traditions“ in practical philosophy and „have acquired a certain analytical and critical ability, are familiar with the basic declarations and doctrines.“ The German philosopher Dieter Birnbacher pointed out that – apart from providing this methodological competence - the role of the philosopher in ethics commissions should be that of the medical layman. According to Birnbacher, the moral philosopher’s special sensitivity for moral issues qualifies him particularly for the additional role of the layman.¹⁶ This, though, has to be taken with a pinch of salt: The methodological competence should not be overestimated in its effect. Like everybody else dealing with moral arguments, the ethical expert moves in the field of practical reason, which is neither a technique, nor an art. It describes rather the permanent search for the adequate evaluation of the principles involved and of all moral intuitions relevant to the individual question or decision. It is this delicate balance that each individual on the one hand and the heterogeneous group on the other will have look for and put to the test over and over again. The moral uncertainties that become apparent here, are accompanied and even exacerbated by uncertainties in what we really know and in the necessary prognoses. Moreover, there are ontological and metaphysical uncertainties concerning the appropriate conceptualisation of all aspects to be considered in the judgement.¹⁷ Let me give an example: We have no certain knowledge about the precise development potential of a human cell. Neither do we know what repercussions this potentiality has with regard to the question of identity or continuity of a living organism. Accepting that even in a collective, reason can only be finite, what should surprise us is not the failing judgement, but the successful one. By ‚successful judgement‘, I mean a judgement that not only improves a decision by securing social peace, but also safeguards the moral integrity of those involved and those concerned¹⁸, while at the same time assessing the possible consequences to the best of one’s knowledge and in a morally adequate way.

14 For a detailed discussion of the role of theologians in ethics commission see Müller (2001).

15 Hermerén (1994).

16 Birnbacher (1999, p. 270).

17 For a detailed discussion cf. Fuchs (2006).

18 Cf. Benjamin (1990).

THE DEMAND FOR INDEPENDENCE

All this, however, does not yet cover all of the conditions necessary for success. Apart from the doubts because of the non-representative nature or the composition of the commission, which may not be adequate to the problems to be dealt with, it is first and foremost its independence that can be called into question. Earlier, I already said something about the structural attempts to secure the independence of the committees and their members. Independence, however, also has a psychological side to it. It was Prof. Dieter Simon, president of the Berlin-Brandenburg Academy of Sciences and Humanities and host to the German National Ethics Council, who I think found very wise words to describe this problem: „The Ethics Council will be, whatever it is determined it should be.“¹⁹

Independent consultancy requires comprehensive critique of interest, which does not only apply the rules of rational argumentation, but also the guiding principles of morality.²⁰ The question whether the advice was taken seriously, that is, whether it was provided in the best interest of those receiving advice and not pursuing any own interests, has to be constantly reviewed: in the case of policy advice, that would be the interest of the politicians acting as guardians of the public interest.²¹ Whenever moral arguments cannot be of universal validity, but call for the specific perspective of an *ordo amoris* – for example in the case of national interests – the status of such arguments has to be specified unambiguously.

Legislative decisions on questions of moral dispute are never solely moral decisions. Aspects of power politics and implementation also with regard to the possibilities offered by the legal system will also have to be considered. Basically, it is the task of practical reason to take these conditions into account and offer a choice between realistic possibilities. Yet at the same time a certain reduction of complexities seems to be desirable. In this context, the French Comité leads an interesting way. It emphasises the difference between an ethics committee and the elected bodies of legislation. Even though two of its members are also members of parliament and the membership of other politicians is not ruled out, it has managed – even as a national ethics committee – to keep its distance from political committees. At the same time and right from the beginning, it has been equally determined to distinguish itself from medical professional associations and their efforts to establish professional and ethical self-obligation.

The committee sees itself as an advisory committee on ethical questions – also with regard to the legislative institutions. In many instances it came to the conclusion that an existing law was inadequate and incomplete from an ethical point of view. Already in its second opinion – published in 1984 – on the testing of new drugs on human beings, it pointed out concrete need for regulation which accordingly became the basis of the relevant legislation passed in 1988. In some other cases the decision of the ethics committee and the actual legislation could not be brought into agreement. Down to the

19 Simon (2001, p. 3).

20 Höffe (1985, p. 246). Also cf. Höffe (1993); on the CCNE's Avis 67 cf. Holderegger (2001).

21 Cf. Van den Daele (1998); and also Renn (1999).

present day the CCNE in France has accepted the task of commenting current legislation. It has, however, always attempted not to formulate and present the bills itself, even though it has among its numbers members with the adequate legally-dogmatic and systematic competence. This reserve seems highly recommendable.

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NACIONALNI BIOETIČKI SAVETI U EVROPI

Sažetak: Veliki broj ljudi u centralnoj Evropi doživljava bioetiku kao nešto što je uvezeno iz Sjedinjenih Američkih Država. Ipak, ovaj je utisak višestruko pogrešan. Kada je Bil Klinton odlučio da na federalnom nivou osnuje stalni komitet za polje bioetike, u stvari je pratio trend uspostavljen od strane Švedske, Danske, Luksemburga, Italije, Norveške, Portugalije, Slovenije i Belgije. Zapravo, Francuska je prva država koja je preduzela takav korak. Prednost stalnog savetodavnog tela nad ad hoc komitetima ogleda se u tome što može raspravljati o većem broju pitanja, ima šire mogućnosti za nezavisno istraživanje specifičnih problema i može biti konsultovano ne samo od strane vladajućih struktura, već i privatnih lica i organizacija. Ipak, širi obuhvat istraživanih problema i značajniji autoritet stalnog tela čine zadatak obezbeđenja stručnosti i pluraliteta zahtevnijim. Stoga je većina evropskih država učinila napor ka postavljanju čvrstih temeljnih pravila, najčešće kroz zakonodavstvo. U velikom broju slučajeva, članovi stalnih komiteta moraju biti imenovani od strane različitih vladinih tela, ali isto tako i od istraživačkih i obrazovnih struktura; u drugim slučajevima, poput Norveške ili Italije, pluralitet se nastoji ostvariti putem definisanja disciplina i filozofskih pozicija koje mogu biti uzete u razmatranje.

Rad ispituje ulogu nacionalnih etičkih tela između "akademske" i "birokratske" bioetike, kao i između filozofske analize, javne debate i učešća i političkog odlučivanja.

Ključne reči: nacionalni etički saveti, savetodavni komiteti, zakonodavstvo, etička ekspertiza, praktični razlog, pluralizam, nezavisnost, moralni status ljudskih bića, reproduktivna medicina