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Study Commission of the German Bundestag

Law and Ethics in Modern Medicine

Answers to the questionnaire:

I.

- **The setting up of an Ethics Commission** in Czechoslovakia (as it was then) goes back to small unofficial gatherings, which took place even before the events of 1989, of doctors, psychologists, social workers and carers of various ideological and religious persuasion who were brought together by common interests (e.g. the Raphael ecumenical group, the Catholic periodical *Salus*, secular groups supporting palliative medicine and pain therapy). They were concerned about the total absence of debate on ethics within the standardised nationalised health system and the ideologically based training of doctors and nurses.
- **The first draft** was presented in the spring of 1990 by the newly founded Prague Club of Catholic Doctors to the then Minister of Health, Professor Pavel Klener. Though very favourably disposed towards it, he could not implement it in the short time he was in office.
- There were **no alternative drafts** and the initiative was adopted by Professor Klener's successor, Martin Bojar, in the autumn of the same year. A Central Ethics Commission was set up by ministerial decree within the framework of the Ministry of Health to act as an advisory body to the Minister.

II. Links with existing institutions

- The Central Ethics Commission is a Ministry of Health body; organisationally it is incorporated into the General Directorate for Education and Science. Its status is approved by the Minister of Health. The Medical Union also has an ethics commission (pursuant to an Act of 1992), and there is a bio-ethics commission under the government Science and Research Council (under a minister without portfolio). By legislation, regional ethics commissions have also been set up in medical faculties and research institutes; their primary task is the ethical assessment and approval of research projects and studies on medicines. Interaction between the commissions is not yet coordinated.
- Unfortunately there is as yet **no ethics commission attached to Parliament**. Some Members of Parliament (Senators) have appointed bio-ethic advisers ad hoc.

III Composition

- Members of the Central Ethics Commission were originally recommended by medical faculties, specialist societies and churches and appointed by the Minister of Health. The

chairman was elected by the members. Following a transition period of fundamental problems in the health sector and fluctuations in the post of minister, when the composition of the Commission was not ideal, the Central Commission is to be reorganised from October 2001 and a new system of regional ethics commissions in keeping with the recommendations of the Council of Europe (CADBI) is under preparation.

- **Specialists and laymen** are represented on the commission, but unfortunately no politicians. The same goes for the bio-ethics commission of the Science and Research Council.
- Efforts are being made to achieve a regional and disciplinary balance as well as proportional representation of women and men. Ideologically, a variety of outlooks are represented. Patient organisations have also been represented since October 2001. There are no quotas.

IV Tasks

- The principal task of the Central Ethics Commission hitherto has been the evaluation of draft bills and the preparation of reports on various ethical problems, possibly on specific cases which have model character. The local and regional ethics commissions are responsible for approving research projects.
- The ethics commissions are obliged by law to assess and approve studies of medicines, and the Central Ethics Commission is responsible for projects which cannot be assigned to any other commission. The Central Ethics Commission sets the subjects for debate at its conferences independently, taking into consideration enquiries from the Ministry and political sources.

V. Working Methods

- Various subjects are discussed, the discussion is recorded on tape and documented in writing and the material passed to the Minister of Health. There is no voting and no resolutions are passed. Other commissions have different working methods (e.g. in the Bio-Ethics Commission of the Science and Research Council a summary record with documentation of minority views is prepared for the Government).
- The Central Ethics Commission meets once a month. Working groups are appointed as necessary to prepare reports to fixed deadlines (2-3 weeks).
- Collaboration with other ethics commissions is rare. However, once a year, with the assistance of the Society for Medical Ethics, a meeting of representatives of the regional ethics commissions takes place and seminars are organised on topical issues with the assistance of Mr Daniel Callaghan of the Hastings Centre and representatives of the Council of Europe Steering Committee on Bioethics (CDBI).
- Representatives of the Central Ethics Commission are members of the Czech delegation to the CDBI, they prepare reports on the protocols of the individual working groups and take

part in their work. The Czech Republic ratified the Oviedo Agreement in 2001; the next step is to bring national legislation into line.

- Delegates of the Czech Republic took an active part in drafting the protocol on organ transplantation and a national bill has been prepared accordingly. Representatives of the Czech Republic also contributed to the preparation of the protocol on the ethics of medical research and here too a bill is in preparation.

VI Influence on legislative procedures

- Opinions on draft legislation concerning the health sector are presented to the Minister. The Bioethics Commission of the Council for Science and Research prepares reports for government on draft legislation concerning the health sector and ecology (gene technology, genetically modified foods).
- To date the Central Ethics Commission has had no established powers and can only make recommendations to the competent bodies.

VII Participation

- Members of the ethics commissions give lectures, are interviewed by the media and publish articles on current issues in the specialist press.
- The meetings of the commissions are not open to the public, as individual medical cases are often discussed.
So far conferences have been organised in the framework of specialist medical societies, in a few cases representatives of the ethics commissions have been invited to attend events of the Senate or the Lower House.

VIII Financing

- The ethics commissions do not have any funds of their own and participation in their work is on an honorary basis. Participants have their travel expenses reimbursed by the Ministry, coffee and mineral water are served during meetings, the Ministry makes a meeting room available as well as any necessary technical equipment (projectors etc.). No payment has been made hitherto for written opinions.
- Conferences on medical ethics are subsidised by the Hastings Centre and funded by membership contributions to the Society for Medical Ethics.
- The local and regional ethics commissions also work on an honorary basis, any management costs being met by the institute responsible. Expert reports are not remunerated.