

I. Background to establishment of ethics commissions

Two different sets of preoccupations can be cited to explain the establishment of ethics committees in France. The first concerned the biomedical research community. By the early 1970s medical researchers had come to realize that medicine and biology were undergoing profound transformations which raised fundamental anthropological and ethical questions which required group rather than individual discussion and resolution. Furthermore, some leaders felt that clinical pharmacology based on the experimentation of new therapeutic molecules on human subjects was insufficiently developed in France, partly because the law prohibited experimentation with healthy volunteers. Finally, in the wake of the 1964 Helsinki Declaration, the international scientific community was beginning to require that all research protocols be approved by an independent ethics committee.

The other social group prompting the establishment of ethics committees was the public to whom progress in the life sciences was brought home in 1982 by the birth of a French baby following in vitro fertilization. This event received intense media coverage and stimulated vigorous discussion among various sectors of society, - confessional, juridical, political, social ...,- of a number of fundamental questions for which no single authority had the answers. The establishment of the National Consultative Ethics Committee in 1983 was a response to these publicly aired preoccupations.

The creation in 1974 of an ethics committee at the National Institute for Health and Medical Research, INSERM, composed exclusively of physicians and medical researchers. was the first institutional response to the preoccupations of the

biomedical research community. It was followed by the « spontaneous » creation of several other ethics committees composed primarily of researchers, where they could discuss their professional ethical concerns.

The National Consultative Ethics Committee for Health and Life Sciences (CCNE), was established in 1983 by a decree of the President of the Republic, after an important colloquium on research in 1982. During this meeting various scientists and politicians expressed the opinion that a national committee should be established.

Two alternative models were proposed in the years following 1983. First, in 1988 a State Council study (Rapport Braibant) recommended that two kinds of committees, institutional and non institutional, be established. The first would have official recognition and operate within the teaching hospitals where it would be charged with evaluating medical trials. The second would also be recognized by law as independent committees charged with a mission of reflection and information on ethics. In this proposition the institutional committees were to be independent of the CCNE.

The other model was proposed by the CCNE itself. In several of its Opinions, the CCNE suggested that the country be divided into districts, each having its own committee with legal recognition. Each local committee has to send each year results of works to CCNE.

Neither of these alternative models was taken up by the legislator. Instead, Parliament voted a law in 1988 on medical experimentation with human subjects which established a system of regional committees called Consultative Committees for the Protection of Persons in Biomedical Research (CCPPRB), composed with a view to ensuring a diversity of competences in the biomedical

field and with respect to ethical, social, psychological and legal questions. Their mission is to examine all biomedical research protocols involving the participation of human subjects, and guarantee that these persons are given due protection. They are independent of the CCNE.

The situation since that time is characterized by the coexistence of various types of ethics committees : the national consultative committee for health and life sciences (CCNE) which enjoys a very broad mandate and an official mission defined by law ; the CCPRBs, also established by law (1988) and charged with the protection of subjects of biomedical research ; and several other non institutional committees (local, regional, speciality groups) which are present in health facilities and linked together loosely by a Standing Conference.

N.B. The following observations deal exclusively with the French National Consultative Ethics Committee.

II. Links with existing institutions

The CCNE is an independent consultative body established by a decree in 1983. The decree of May 29 1997 defines its organization and functioning. According to this decree certain officials or institutions can ask the CCNE for its opinion : the presidents of the National Assembly and Senate, a member of the government, as well as by medical teaching or research institutions. The CCNE can also decide to respond to questions asked by other persons or by one or several of its own members.

The Government is free to consult (or not) the CCNE, and to follow (or not) its Opinions. Examples can be found since 1983 of Opinions being followed, contradicted, or ignored by the political authorities since the establishment of the CCNE.

III. Composition

There are three categories of members depending on the authority responsible for naming them. The President and five members drawn from the major philosophical and religious currents are named by the President of the Republic ; nineteen members are designated by various political authorities (such as the Prime Minister, the ministers of Justice, Research, Industry ...) by reason of their competence and interest in ethical questions ; fifteen members belonging to the research community are designated by various research institutions (Academy of Sciences, National Academy of Medicine, College de France, Institut Pasteur, INSERM, CNRS ...). Past Presidents of the Committee can be named Honorary President by the President of the Republic.

The term of office is two years (renewable without limits) for the President and four years for the members (renewable once).

The term Expert is not an entirely appropriate descriptor in the French context. While several of the members, notably those coming from the research field, can be considered experts in their discipline, it must be noted that nineteen members are chosen not only for their competence but also by virtue of their interest in ethical problems. In this category can be found two persons coming from Parliament, one from the National Assembly and one from the Senate.

The notion of social or ideological representativity is not appropriate when observing the composition and mode of designation of the CCNE. Thus none of the members are meant to be an official spokesman of the institution from which they come. However, the presence of five personalities drawn from the major philosophical and religious currents present in France allows for the expression of a plurality of ideological positions.

The founding decree, and those that have followed, do not lay down quotas, in particular concerning the sex ratio. In the last years the number of women has increased but has not attained parity with the male members.

As mentioned above, the stipulation that five persons must come from the major philosophical and religious families present in France allows for a wide range of philosophical positions.

IV Tasks

The CCNE's mission is defined by the bioethics law n° 94-654 of July 29, 1994 in the following terms : « give opinions on the ethical problems raised by progress in biology, medicine and health and publish recommendations on these subjects ».

The tasks of the CCNE are as follows : reflect on the fundamental ethical aspects of scientific progress, publish opinions and recommendations, respond to public preoccupations over scientific advances, encourage public debate, participate in the information of the public on these subjects, in particular through the organization each year of Ethics Days. The CCNE does not study medical practice as such.

Apart from responding to those authorized by law to present requests for the CCNE's opinion, the CCNE can also choose topics that it wishes to explore even though they are not related to a specific request. Another method frequently used

consists in extending its reflection on a specific subject to topics of a more general nature that interest society as a whole. In recent years CCNE has elaborated an opinion on socially sensitive questions such as euthanasia and drug abuse.

Working methods

The aim of the discussion is free, unpressured exchange of opinions on the ethical aspects of the question under study, usually after a working group has informed the committee as a whole of the pertinent scientific aspects. Members have observed that in this way they are usually able to reach a consensus on the subject, even though the reasons involved in coming to this conclusion may be different. The usual conclusion is in the form of a consensual opinion, but this is not sought at all costs, and in case of dissension, those in disagreement with the majority's opinion are invited to write up their position which will be published along with the opinion.

The Committee is rarely asked to submit its opinion within a certain time limit. Much more often it takes the time it feels necessary to reach its final statement. The Bureau of the CCNE, called the Section Technique, carries out the initial analysis of a new dossier and entrusts it to a working group that prepares a first draft of the future opinion which is then submitted to the discussion of the CCNE in plenary sessions. Depending on the subject under discussion, the draft can be amended several times, by the Section Technique, the working group or the plenary meeting, before being adopted, usually by consensus, and occasionally by a vote.

The CCNE participates actively in efforts to bring together and stimulate mutual awareness among ethics committees in the world. The Standing

Conference of National Ethics Committees under the auspices of the Council of Europe and the Global Summit on National Bioethics Commissions are two examples of this type of coordination.

Representatives of foreign ethics committees are always invited to the annual Ethics Days organized, usually in Paris, by the CCNE, and CCNE members are often invited to participate in the discussions organized by their foreign counterparts.

There is no explicit mechanism guaranteeing that input will flow from the CCNE to international conventions. However, insofar as members of the CCNE can also participate personally in the drafting of international instruments, for example within the framework of Unesco's International Bioethics Committee or the Council of Europe's Steering Committee on Bioethics, there is probably in fact a certain degree of communication of points of view from one body to the other.

The laws establishing specialist commissions (not necessarily « ethics commissions ») in the area of medicine at the national level often stipulate that the CCNE will designate one of its members to participate officially in their deliberations. Examples are the National Commission on AIDS, the National Commission on Medicine and Biology of Reproduction and Prenatal Diagnosis, and the French Transplant Establishment. The draft law revising the 1994 bioethics laws includes the presence of a representative of the CCNE in a new committee to be established to assist a new Agency of Procreation, Embryology and Human Genetics.

VI. Influence on legislative procedures

The CCNE's reports and opinions are presented to the public via press conferences and the Annual Ethics Days in Paris and the regions. An annual activity report is presented to the President of the Republic and can be purchased by the public.

The results of the committee's work take the form of an Opinion or recommendations. In both cases these can be accompanied by a report that develops the scientific, legal, and ethical aspects of the CCNE's reflection.

As mentioned above, the CCNE's conclusions, whatever their form, do not have binding force for the system of political decision-making.

VII. Participation

The public is informed of the CCNE's work by press reports when an Opinion is made public. Members of the CCNE can be interviewed by the press. The public is invited to attend the Annual Ethics Days and participate in the debates organized on those occasions.

Those persons having access to Internet can consult the CCNE's site and read the Opinions which are put on the site (in French and English) as soon as they are published. They can submit questions by the same media.

Those interested in following the CCNE's work in printed form can subscribe to the CCNE's quarterly journal, *Cahiers du Comité Consultatif National d'Ethique*, which reproduce the Opinions, bibliographies, and individual viewpoints.

The CCNE's deliberations are closed to the public. The working groups are free to consult experts from outside its ranks if the subject under discussion requires this. This is probably what comes closest to the notion of hearings, but there is no obligation.

VIII. Financing and internal structure

The CCNE's funding comes entirely from the public purse via the Ministry of Research.

The CCNE is totally free to organize its funding allocations as it sees fit, even though it must of course respect the conditions established for public spending.